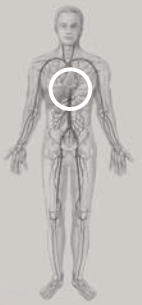


> 2004 ANNUAL REPORT

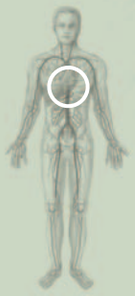
Passion

At Edwards Lifesciences, we are dedicated to fighting advanced cardiovascular disease. We are passionate about turning ideas into clinical realities on behalf of patients around the world. We are privileged to share with you an update of our recent achievements and stories from some extraordinary individuals whose lives have been touched by our work.

Edwards Lifesciences

> UNIQUE
> EXPERIENCED
> INCOMPARABLE

Magna Valve



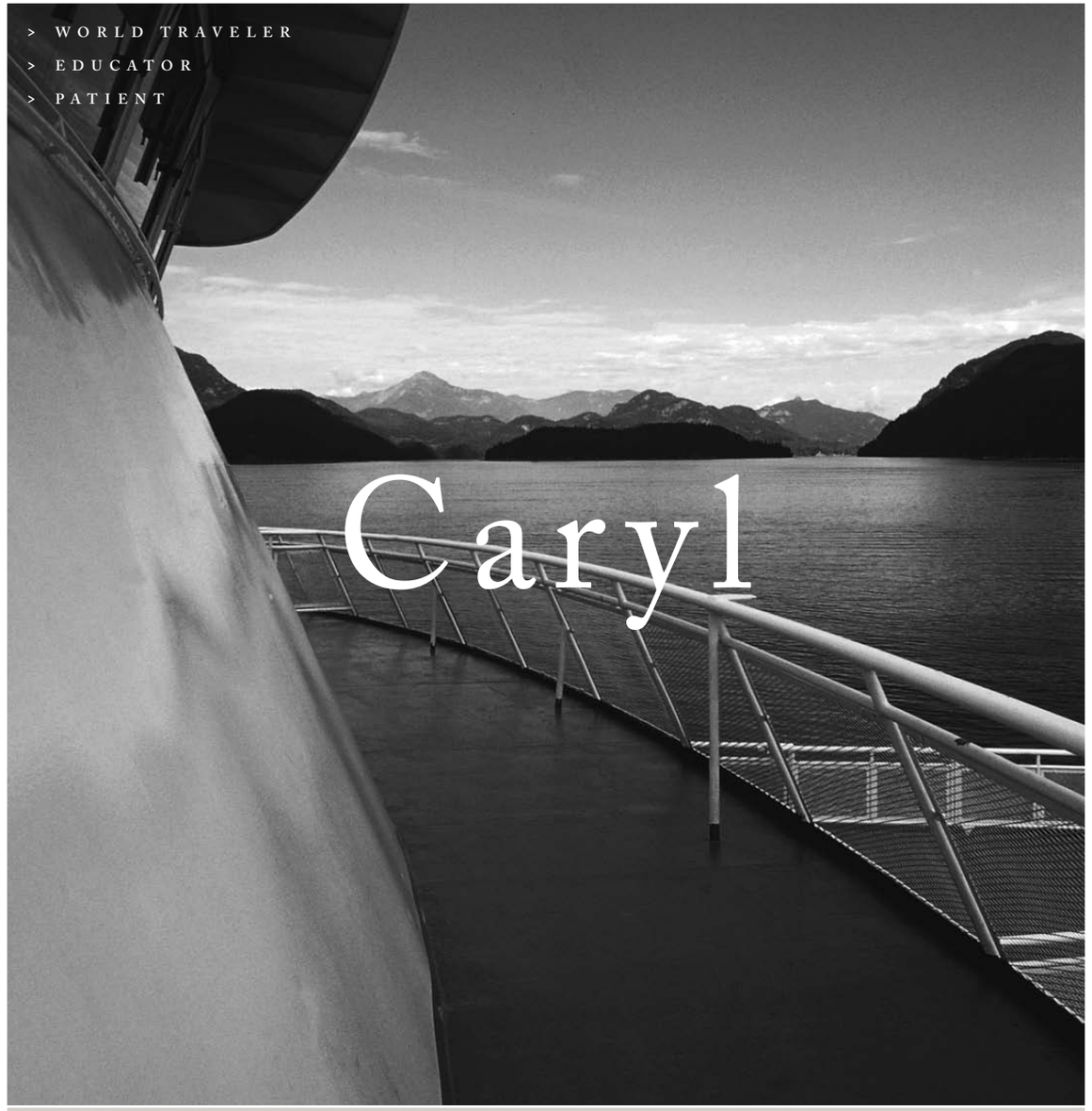
PERICARDIAL TISSUE HEART VALVES

Carpentier-Edwards PERIMOUNT Magna Valve with ThermaFix Process
Edwards is the world's leading heart valve company, and leads the field's investments in heart valve research and development.

The company's PERIMOUNT Magna aortic replacement valve is the only therapy of its kind to combine more than 20 years of clinical experience and innovation with the most advanced tissue engineering technologies and a unique design intended to help maximize patient blood flow.

Although tissue replacement heart valves have demonstrated decades of durability, gradual aggregation of calcium on a valve's leaflets remains the leading cause of tissue valves' degeneration or failure. Edwards' new ThermaFix process is a proprietary advanced tissue treatment developed to mitigate tissue heart valve leaflet calcification. The ThermaFix process has been shown in laboratory studies to significantly reduce leaflet calcification when compared to Edwards' other market-leading tissue treatment.

> WORLD TRAVELER
> EDUCATOR
> PATIENT



Caryl

Edwards' Magna pericardial valve with the ThermaFix process represents the latest example of the company's commitment to heart valve therapy and its focus on continuing innovation to benefit patients around the world.

Caryl
When her heart murmur was first diagnosed during a routine medical examination, Caryl was surprised to learn she had a highly calcified bicuspid aortic valve that would require surgical replacement.

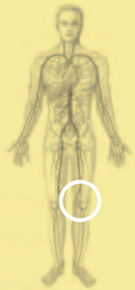
The retired assistant high school principal contacted friends who had experienced previous heart valve surgery and interviewed surgeons to educate herself about her treatment options. As an Edwards shareholder, she also took note of the company's 2003 annual report, which featured the new Magna heart valve, and a newspaper article about Edwards' ThermaFix tissue process.

"Having any operation is scary, so people should gather information and talk with as many patients as possible to take the fear out of it," she says. "They also should ask for the latest technology."

After discussing options with her surgeon, in October 2004 Caryl became one of the first West Coast patients to receive a PERIMOUNT Magna pericardial aortic replacement heart valve with the ThermaFix treatment. She recovered rapidly, and has maintained a regular exercise regimen since her procedure. She and her husband also celebrated her return to health with a three-week South American cruise.

> FLEXIBLE
> STRONG
> THERAPEUTIC

LifeStent System



SELF-EXPANDING
PERIPHERAL STENTS

LifeStent NT
Self-Expanding Stent System

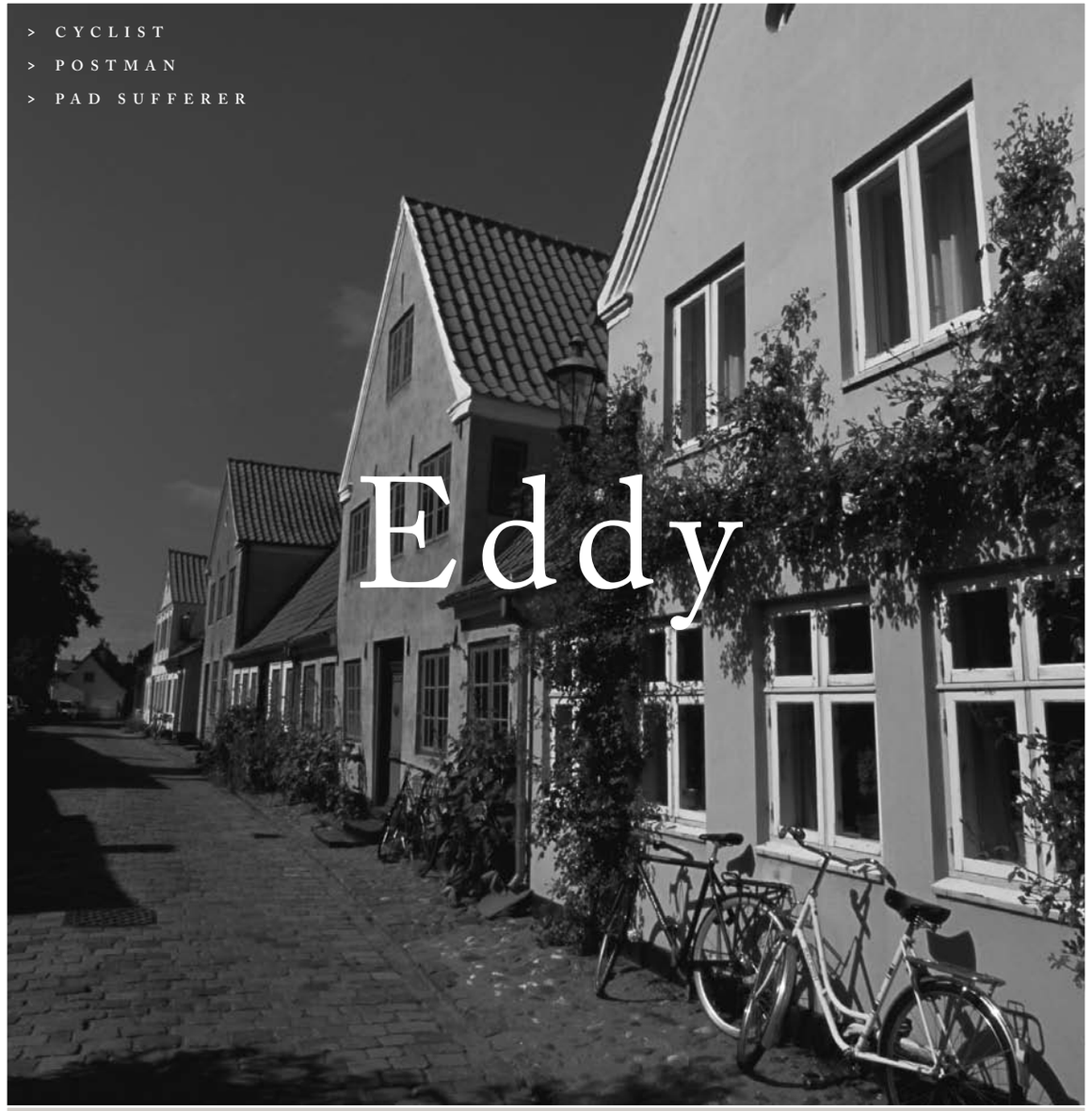
Edwards' LifeStent line of balloon- and self-expanding stents are percutaneously-delivered, flexible mesh tubes intended to restore circulation when deployed inside of diseased vessels. In 2004, Edwards launched its LifeStent NT self-expanding stent system, which has unprecedented flexibility and kink-resistance due to its patented helical design, making it well-suited for repetitive motion and challenging anatomies. The company also offered additional sizes and configurations of its LifeStent balloon-expandable stent to treat iliac, renal and other peripheral vascular disease, and biliary disease to physicians around the world.

Edwards believes its LifeStent technologies have been optimally designed for unique peripheral vascular disease applications, which should ultimately benefit a large and growing patient group.

In 2004, Edwards also initiated the RESILIENT pivotal trial, which is intended to demonstrate the LifeStent NT self-expanding stent's therapeutic superiority over percutaneous transluminal angioplasty (PTA) to treat blockages in the superficial femoral artery (SFA) and proximal popliteal artery, which are key circulatory channels in the leg. PTA's high incidence of restenosis, or reblockage, has led to increasing application of endovascular stents as longer-term and more beneficial alternatives, and RESILIENT is the first-ever prospective randomized trial to evaluate a mesh nitinol stent in the SFA.

> CYCLIST
> POSTMAN
> PAD SUFFERER

Eddy



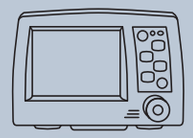
Eddy

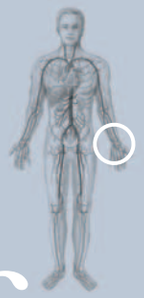
Eddy is a youthful 65-year-old and dedicated postal worker who suffers from peripheral arterial disease (PAD), a progressive medical condition in which the arteries of the legs are filled with circulation-restricting plaque and atherosclerotic material. He particularly enjoyed his postal route, cycling from house to house, until intense leg pain — known clinically as claudication — worsened to the point that he was forced to abandon his bicycle and retire.

Because conventional invasive surgical treatments for PAD can have serious side effects or limited effectiveness, many patients choose to suffer with the pain rather than undergo surgery. Eddy had another alternative; in 2004, he was one of the first patients to receive an Edwards LifeStent NT peripheral stent, an innovative new device designed specifically to treat PAD in the legs.

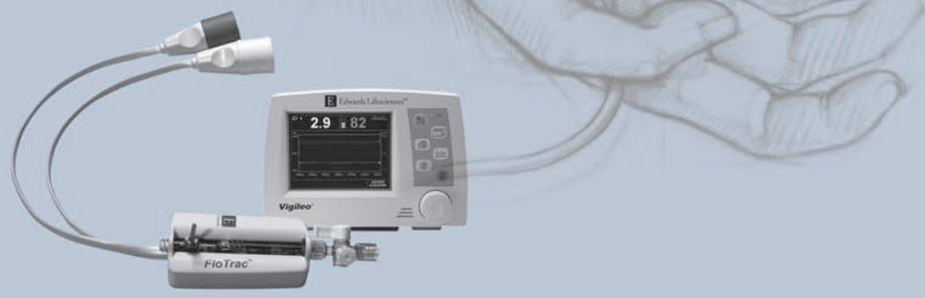
Eddy was home and exercising again just days after his procedure. His health and vitality have returned, and he is again planning bicycle journeys through the beautiful Belgian countryside.

> ADVANCED
> LESS-INVASIVE
> ACCURATE





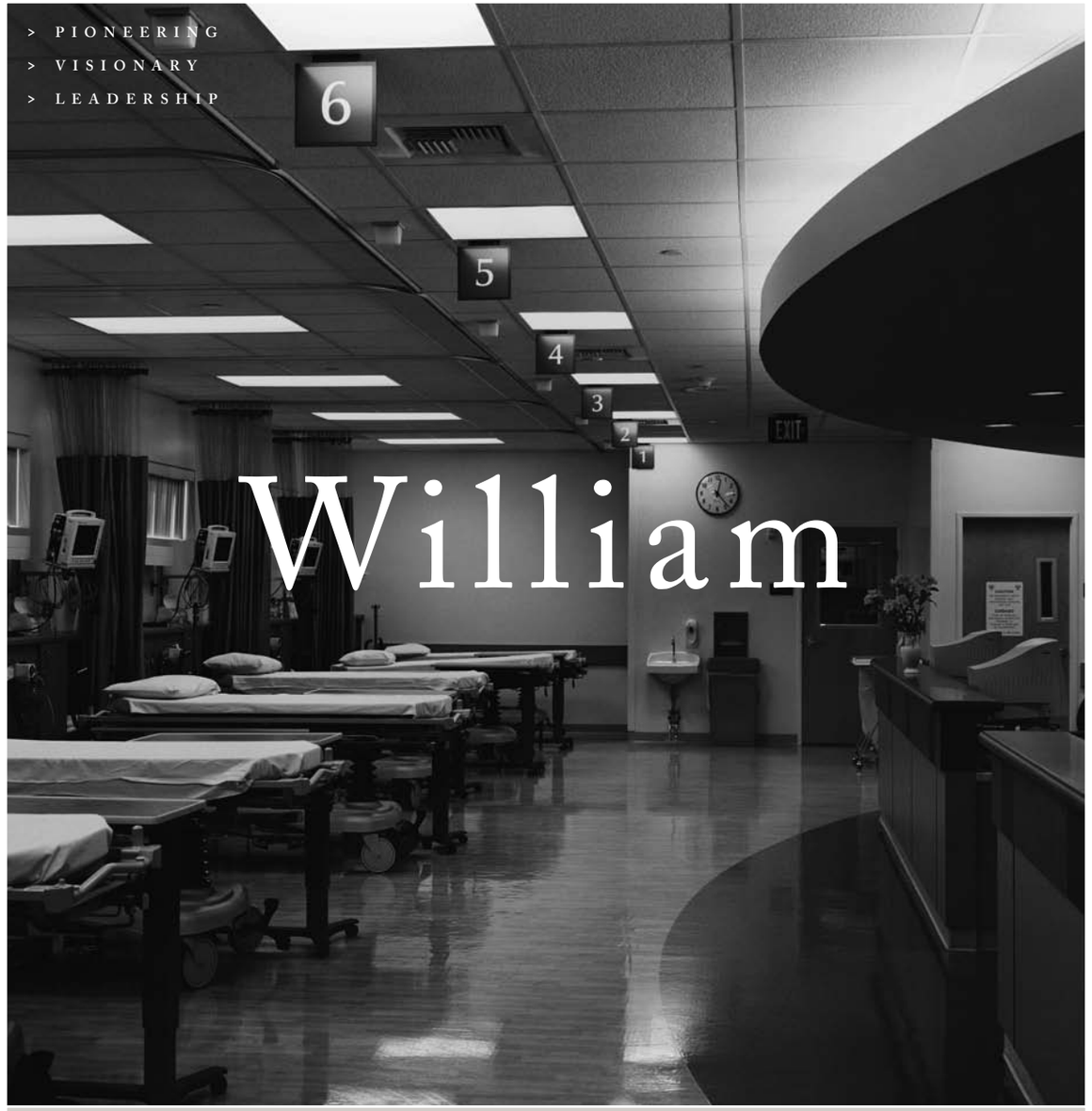
FloTrac Sensor



MINIMALLY INVASIVE CARDIAC MONITORING

For more than three decades, Edwards has pioneered hemodynamic monitoring systems to measure patients' cardiac function in surgical and intensive care settings. These diagnostic technologies allow clinicians to continuously assess and balance critically ill patients' oxygen delivery and consumption and assure their optimal heart function.

> PIONEERING
> VISIONARY
> LEADERSHIP



William

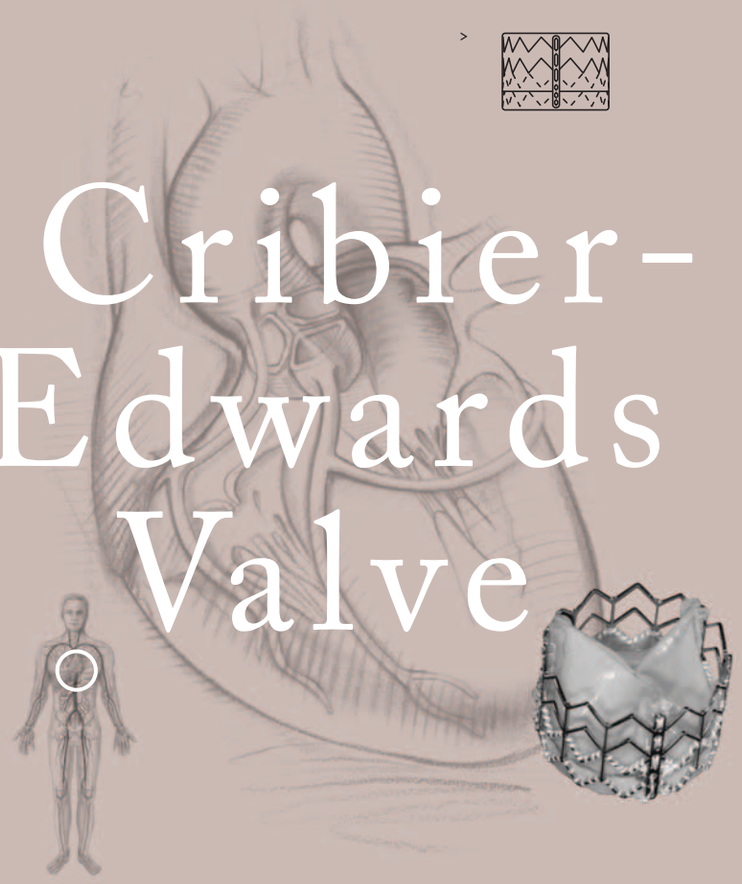
Although failure to appropriately manage patients' hemodynamic needs may lead to organ injury, organ failure or death, conventional technology requires placement of a catheter in the right side of the heart. Thus, while hemodynamic monitoring guides therapy for millions of critically ill patients, its invasiveness essentially disqualifies many more who could benefit from this important diagnostic technology.

In 2004, Edwards developed the new FloTrac sensor, which utilizes a patient's arterial line to less invasively assess important hemodynamic parameters. When used in conjunction with Edwards' new Vigileo monitor, this system can collect such patient data as cardiac output, stroke volume, stroke volume variation and continuous systemic vascular resistance.

Dr. William McGee, Director of ICU Quality Assurance at Baystate Medical Center in Springfield, Mass., led a team of European and American researchers in evaluating the FloTrac sensor's clinical performance, and says, "This technology has accuracy comparable to that of the pulmonary artery catheter for obtaining cardiac output measurements. As an accurate, less-invasive method of measuring cardiac output, the FloTrac sensor may help expand application to patients who currently are not undergoing pulmonary artery monitoring, and compares favorably to Edwards' Swan-Ganz pulmonary artery catheter, which is considered the 'gold standard' of hemodynamic monitoring." The FloTrac sensor is expected to be launched in key global markets in early 2005.

> LESS-INVASIVE
> MARKET-EXPANDING
> REVOLUTIONARY

Cribier-Edwards Valve



CATHETER-BASED
HEART VALVE THERAPIES

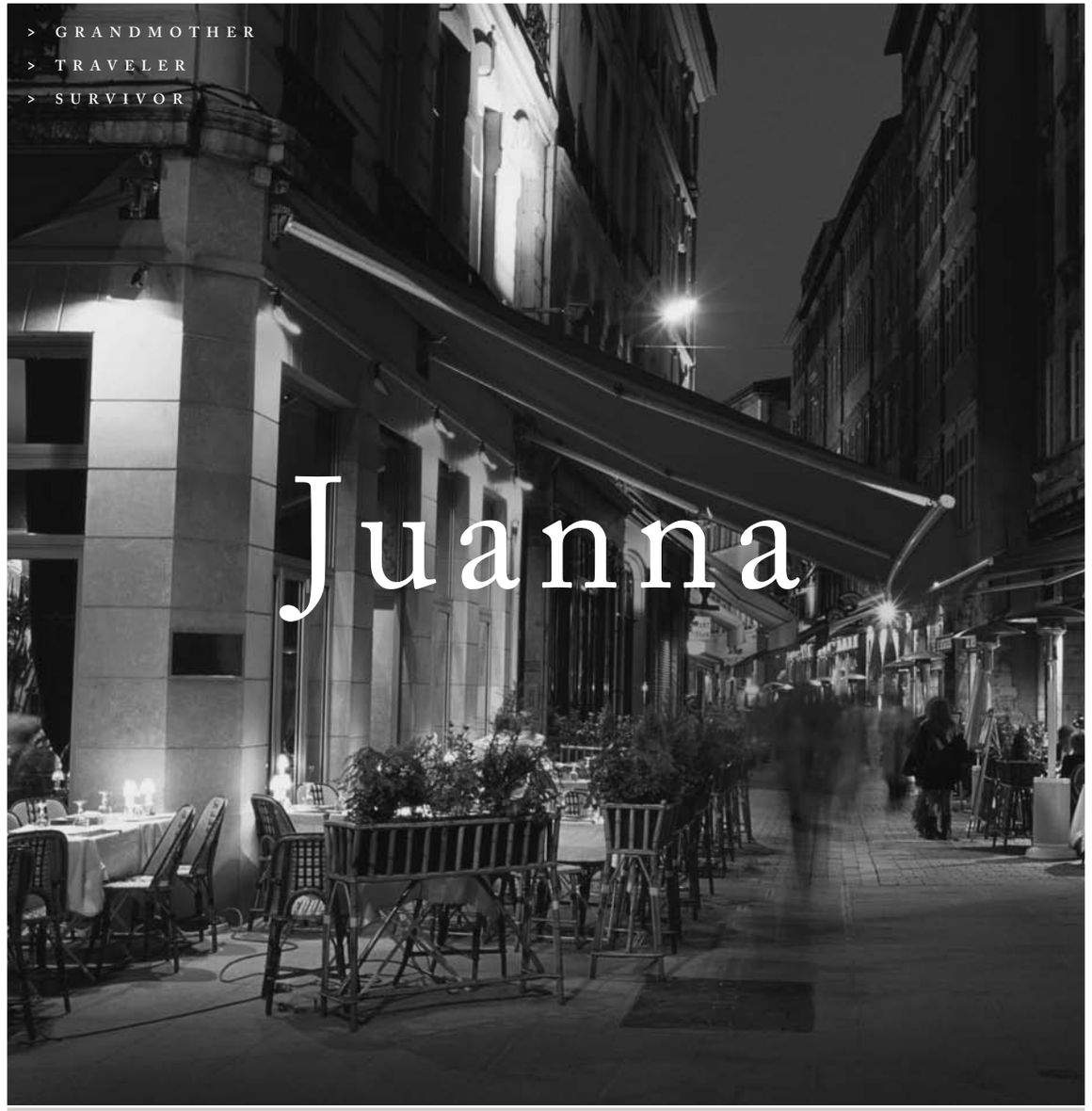
Percutaneous Valve Interventions
Percutaneous, or catheter-based, heart valve replacement and repair represent an important therapeutic opportunity for heart valve patients, and Edwards leads the field with three development programs that capitalize upon the company's decades of expertise in tissue valve technology and catheter development.

In addition to the company's percutaneous aortic valve replacement program and its Cribier-Edwards heart valve, Edwards is pursuing two unique percutaneous approaches to mitral valve repair, to help the potentially millions of patients who suffer from clinically significant mitral valve regurgitation, but for whom surgery is not prescribed.

One approach uses a catheter system to introduce a proprietary stent into a patient's coronary sinus located adjacent to the mitral valve, to reinforce and reshape the mitral valve opening and enable proper blood flow over time. The company's second program employs an edge-to-edge approach, joining the mitral valve's two leaflets together through a proprietary catheter attachment mechanism.

Edwards expects the first patient cases of both percutaneous mitral repair approaches to be performed in 2005.

> GRANDMOTHER
> TRAVELER
> SURVIVOR



Juanna

Juanna
Having successfully overcome breast cancer, a heart attack, and multiple coronary angioplasties and stenting procedures, Juanna, 85, is a survivor.

On New Year's Eve 2003, she was admitted to a private clinic near Paris. Suffering from severe pulmonary edema and cardiogenic shock, she was deemed too ill for needed heart valve replacement surgery. She transferred while still in critical condition to Rouen University Hospital, where she underwent percutaneous aortic valve replacement with the Cribier-Edwards tissue heart valve. The revolutionary technology, in European clinical trials and beginning U.S. clinical feasibility studies in 2005, is especially appealing for patients who are not good candidates for conventional heart valve surgery.

Upon admission, Juanna's survival had been questionable, but normal circulation, blood pressure and breathing parameters were quickly re-established after she received her percutaneous heart valve, and she has maintained excellent clinical outcomes ever since.

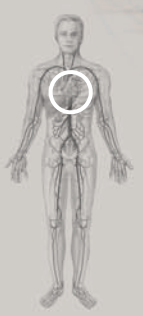
Today, Juanna enjoys meals with friends and attends family celebrations. She and her husband are also eagerly awaiting the arrival of a new grandson, and they even flew to Toulouse to visit family.

"I am so grateful to have a prolonged, active live," Juanna says. "Before my procedure, walking was so difficult. Now, I can go anywhere."

> 2004 ANNUAL REPORT

Progress

Edwards Lifesciences has made great progress in further extending our leadership in key technological and clinical areas. In addition to our strong financial performance in 2004, we are laying the groundwork for 2005 and beyond. Our transformation continues.



Edwards Lifesciences

EDWARDS LIFESCIENCES From our founding by a visionary engineer more than four decades ago, to our emergence as an independent company in 2000, Edwards Lifesciences remains a global leader in advanced cardiovascular technologies. > Because cardiovascular disease claims more lives globally than any other medical condition, Edwards focuses on specific opportunities, including heart valve disease, peripheral vascular disease and critical care technologies. > Because there are patients today whose health is so compromised they have exhausted all current clinical options, Edwards tirelessly drives its research, development and discovery efforts, exploring and cultivating new diagnostic and therapeutic alternatives. > Because helping patients is our life's work, Edwards serves as a trusted partner in the community fighting cardiovascular disease, dedicated to further improving the quality of life around the world.

IN MEMORIAM *Jeremy Swan, M.D., Ph.D. (1922-2005)* We salute the memory of Dr. Swan, a true pioneer in medical technology innovation, whose leadership in developing pulmonary artery catheters helped physicians treat millions of patients around the world. His legacy will serve countless patients and generations of healthcare professionals to come.

> FINANCIAL HIGHLIGHTS

Twelve months ended December 31, *(in millions)*	2004	2003	2002
Net sales	$ 931.5	$ 860.5	$ 704.0
Cost of goods sold	370.2	359.4	299.1
Gross profit	561.3	501.1	404.9
Selling, general and administrative expenses	319.9	289.4	227.9
Research and development expenses	87.0	72.8	65.2
Operating Statistics			
As a percentage of net sales:			
Gross profit	60.3%	58.2%	57.5%
Selling, general and administrative expenses	34.3%	33.7%	32.4%
Research and development expenses	9.3%	8.5%	9.3%
Operating margin[(a)]	16.6%	16.1%	15.9%

(a) Operating margin is calculated by subtracting selling, general and administrative expenses and research and development expenses from gross profit and then dividing by net sales.

The information contained in the table above should be read in conjunction with Edwards Lifesciences' "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Consolidated Financial Statements" found in the accompanying SEC Form 10-K.

This letter to shareholders and selected performance data contain figures that are not prepared in conformity with Generally Accepted Accounting Principles ("GAAP"). Management has determined that inclusion of these non-GAAP figures provides a more meaningful comparison of the company's ongoing operations. For a reconciliation of the difference between the GAAP and non-GAAP figures, see pages R-1 and R-2 in the accompanying SEC Form 10-K and Reconciliations.

A Message to Our Shareholders:

More than 16 million people die each year from cardiovascular disease, which the World Health Organization calls "a true pandemic that respects no borders." And, over the next 20 years that number is expected to grow as the percentage of people over age 60 continues to expand. To the more than 5,000 employees of Edwards Lifesciences, these facts serve as a vivid reminder that the work we do has purpose. Through our focus on key areas within cardiovascular disease, we have been successful in making a positive difference in the lives of people who can benefit from our products today. And our passion to help patients is further fueled by the promise of technologies we are working on for tomorrow.

Another Successful Year in 2004

2004 was a year of outstanding performance for Edwards Lifesciences in several important areas. First, we achieved double-digit underlying growth in our market-leading Heart Valve Therapy product line. The successful launch of the technologically-advanced Carpentier-Edwards PERIMOUNT Magna heart valve, and the combination of a stronger sales force and focused message, enabled us to address the competitive challenges we faced in the U.S. heart valve market in 2003. Sales of the PERIMOUNT Magna valve were more than double our initial expectations. And the introduction of our new Tricentrix mitral valve holder system added to that success, helping Edwards gain share in our largest product line and reinforcing our position as the global leader in heart valve therapies.

Additionally, we substantially lifted our gross profit margin through robust sales of our market leading products, together with the expiration of certain currency hedging contracts and discontinuation of low margin businesses. And while we were improving our profitability, we continued to invest aggressively in future growth drivers including near-term opportunities in peripheral stents and minimally invasive cardiac monitoring.

Lastly, Edwards met or exceeded all of our 2004 financial goals. With total sales of $932 million, we accomplished our $915 to $940 million sales goal. We were able to achieve this goal in spite of a challenging year in our Japan operation, which resulted in flat year over year sales growth in that region. Research and development investment in 2004 was 20 percent higher than last year's level, exceeding our sales growth rate. Net income, when adjusted for acquisitions and special items, achieved our 13 to 15 percent growth target. And, our adjusted free cash flow of $138 million for the year substantially exceeded our goal of $90 to $95 million.

Other 2004 Developments

During 2004, we continued to build the foundation for new growth opportunities, which should contribute more meaningfully to Edwards' success in 2005 and beyond. The introduction of our balloon-expandable and self-expanding LifeStent peripheral stent products, while slower than we originally planned, is beginning to accelerate. We remain optimistic that there is room for our differentiated products in the large and growing peripheral vascular market, and we are encouraged by the positive feedback we continue to receive from clinicians. Additionally, in July we commenced a clinical trial comparing LifeStent products against the current standard of care that, if successful, could further demonstrate the unique characteristics of our product and help Edwards establish a strong market presence.

We also continued to extend our leadership position in our core heart valve therapy product line with the limited introduction in the U.S. of our proprietary ThermaFix tissue treatment process, developed to further mitigate calcification of tissue heart valve leaflets. While initially available only on our newest PERIMOUNT Magna valve, the ThermaFix process is being made more broadly available in 2005. Additionally, we initiated the pivotal clinical trial of the BioPhysio valve, a novel, next-generation heart valve designed to mimic the physiologic function of a natural heart valve. We believe we invest more to advance the treatment of heart valve disease than any other company, and remain committed to providing surgeons with new therapy options for their patients.

During the year, the development of our FloTrac minimally invasive cardiac output technology was so successful that we were able to accelerate our plans for product introduction, which we now expect in the first half of 2005. We continue to believe that the FloTrac system represents a market expanding opportunity to leverage our market-leading position in critical care technologies.

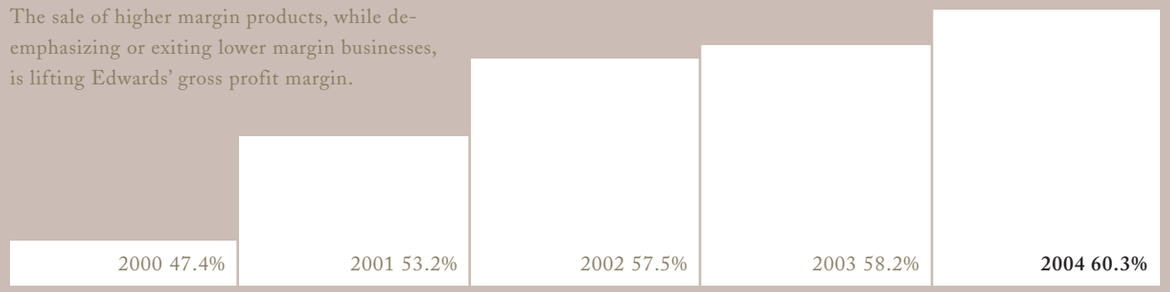
In June, we further enhanced our strong board of directors with the addition of John Cardis, who recently retired as national managing partner – global strategic clients of Deloitte & Touche. Other leadership changes also occurred during the year. Stanton Rowe, the former head of Percutaneous Valve Technologies (PVT), came to Edwards through our acquisition of that company early in the year and now serves as corporate vice president, percutaneous valve interventions. His more than 25 years of medical technology experience, largely in interventional medicine, has greatly enhanced Edwards' work in percutaneous valves, a potentially large and very exciting opportunity. Alex Martin, a 23-year industry veteran, joined Edwards in 2004 as corporate vice president of our North America region. He was followed by Patrick Verguet, with 20 years of experience at Edwards, who was appointed corporate vice president of our European operation. Both regional leaders contributed to the outstanding performance of these two geographies last year.

For a reconciliation of the difference between the GAAP and non-GAAP figures, see pages R-1 and R-2 in the accompanying SEC Form 10-K and Reconciliations.

Gross Profit Margin

(gross profit as a percentage of net sales)

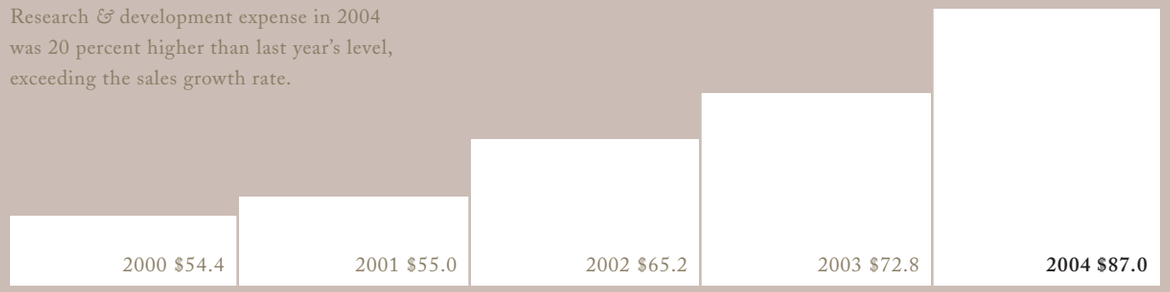
The sale of higher margin products, while de-emphasizing or exiting lower margin businesses, is lifting Edwards' gross profit margin.



R&D Expense

(in millions)

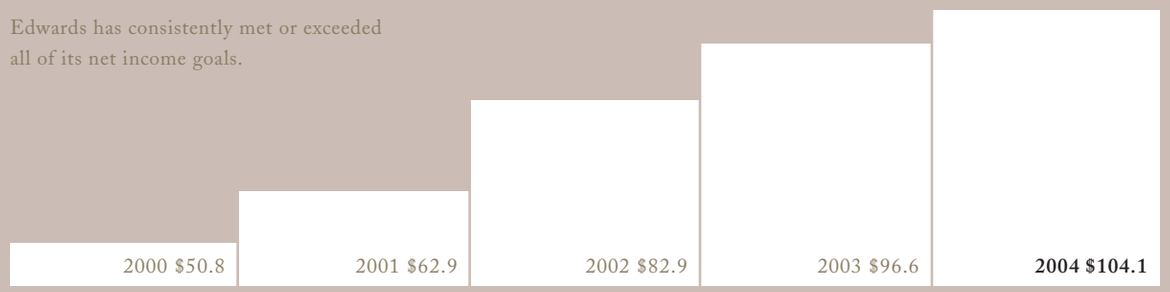
Research & development expense in 2004 was 20 percent higher than last year's level, exceeding the sales growth rate.



Adjusted Net Income

(in millions)

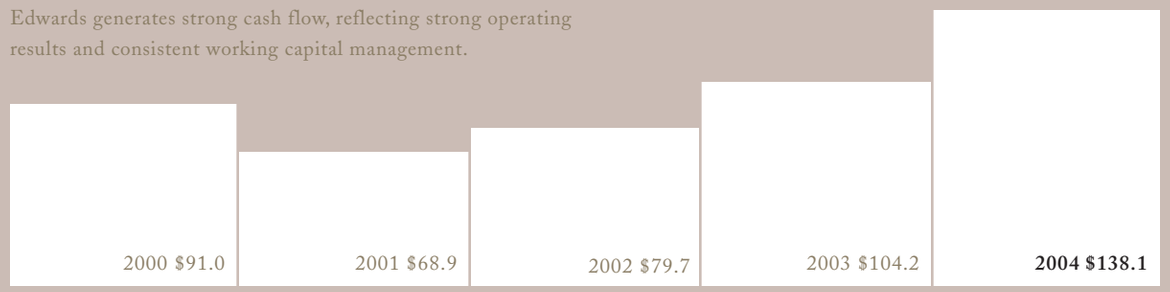
Edwards has consistently met or exceeded all of its net income goals.



Adjusted Free Cash Flow

(in millions)

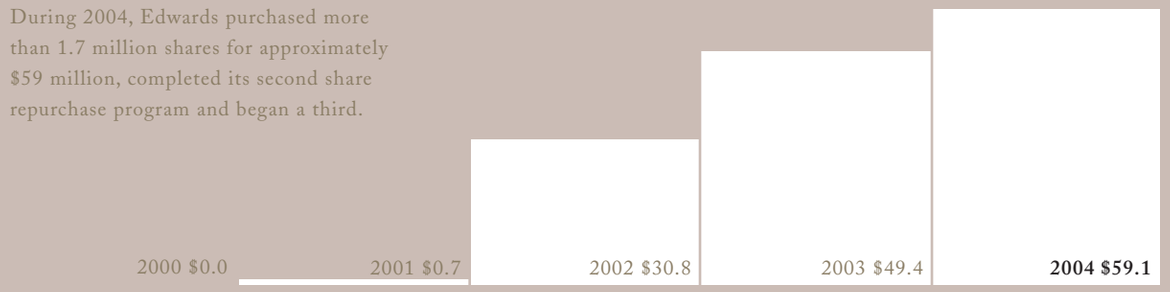
Edwards generates strong cash flow, reflecting strong operating results and consistent working capital management.



Share Repurchase

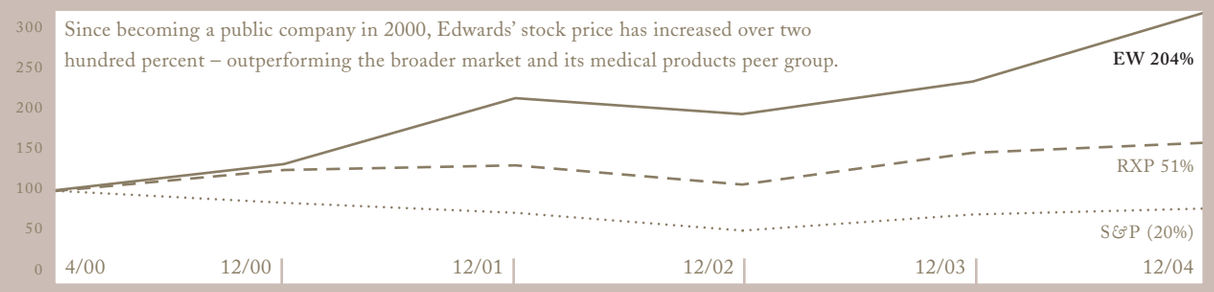
(in millions)

During 2004, Edwards purchased more than 1.7 million shares for approximately $59 million, completed its second share repurchase program and began a third.



Stock Performance vs. Selected Indexes

EW —— RXP[(a)] – – S&P ·····



(a) Morgan Stanley Healthcare Products Index

Laying the Groundwork for Future Growth

In preparation for sustainable future growth, we continued to make significant investments during the year. We are building strong interventional capabilities as part of our peripheral stent product platform. These in-house competencies, including laser cutting of stents, nitinol processing, delivery catheter technology and competitive product performance analysis, are also strategic to our rapidly developing percutaneous valve program.

With our strong balance sheet and ability to generate substantial free cash flow, Edwards was able to fund future growth through acquisitions, including the completion of two transactions to strengthen our position in percutaneous valves — a potentially large and very exciting opportunity. These acquisitions included PVT's aortic valve replacement program at the beginning of the year, and ev3, Inc.'s mitral repair technology in September.

As we continually strive to accelerate our company's growth rate, we are committed to focus resources on our core businesses and areas where Edwards has significant leadership opportunities. To that end, we discontinued our Lifepath AAA graft program following an unsuccessful search for a suitable buyer, and stopped selling certain non-strategic products.

Doing More with Less

For Edwards, helping patients is what we do, and in our drive to do more, we are also looking to do *less*. Less invasive therapies not only offer patients the promise of shorter hospital stays and faster recovery times, they have the potential to treat new groups of patients who may not be good candidates for conventional surgical procedures. In addition to minimally invasive technologies for peripheral vascular disease and cardiac monitoring, Edwards is pioneering the development of several percutaneous or catheter-based therapies to treat heart valve disease.

Our percutaneous aortic valve replacement program, strengthened by our acquisition of PVT, continues to make progress on a number of fronts, including the completion of several product and procedural enhancements. Importantly, several patients who were initially deemed non-operable yet received this less invasive, life-saving treatment, recently celebrated their one-year anniversaries. Significant events like these help reinforce the promise of this innovative technology. In early 2005, we were granted approval to commence an important U.S. clinical trial that will expand the availability of this procedure to less severely ill patients, an important step toward product commercialization.

Edwards is also shaping future treatments in percutaneous mitral valve repair with two unique programs. Our coronary sinus technology demonstrated important pre-clinical success in 2004 and first-in-man procedures began in early 2005. Similarly, we completed successful pre-clinical work in our edge-to-edge program last year and expect to commence clinical use this spring. The market opportunity for percutaneous replacement and repair is very large, and we believe Edwards is ideally positioned to capitalize on these opportunities given our reputation and expertise in valve therapies, our strong intellectual property positions and our valuable clinician relationships.

Outlook for 2005

Our financial goals for 2005 build on our momentum and will drive another year of stronger growth and profitability. We expect to generate total sales for the year in the range of $980 to $1,020 million. The continued high growth rate of our most profitable businesses coupled with our exit of low margin product lines, gives us increased confidence that we will grow our gross profit margin by more than 100 basis points. We also expect to deliver net income growth of 13 to 15 percent (excluding the impact of special items and stock option expensing) and generate free cash flow of $115 to $125 million.

We believe that since becoming an independent public company nearly five years ago, Edwards Lifesciences is now better positioned than it has ever been. We are fortunate to have strong base businesses — namely our heart valve and critical care franchises — on which we are building a number of exciting and market-expanding growth opportunities. In 2004, we laid the groundwork for our peripheral stent and minimally invasive cardiac monitoring platforms to become significant contributors, and we expect to see tangible results from these efforts in 2005 and 2006. We also expect the progress we are making in percutaneous technologies to expand the heart valve market and provide life-saving options for patients who go untreated today.

In sum, we think our growth prospects in the short, medium and long term are brighter than ever, and we are very excited about Edwards Lifesciences' future. Our progress and continued commitment to achieving these goals for growth and profitability are exceeded only by our passion for helping patients suffering from cardiovascular disease. We are honored to share this passion with leading clinicians throughout the world with whom we partner to save lives.

We thank you, our shareholders, for your support in this endeavor.

Michael A. Mussallem Chairman & Chief Executive Officer

Corporate Headquarters
Edwards Lifesciences Corporation
One Edwards Way, Irvine, CA 92614
(949) 250-2500 or (800) 4-A-HEART
www.edwards.com

Annual Meeting
The Annual Meeting of Shareholders will be held on May 12, 2005 at 10:00 a.m. (Pacific) at the offices of Edwards Lifesciences Corporation, One Edwards Way, Irvine, CA 92614.

SEC Form 10-K
A copy of Edwards Lifesciences' annual report to the Securities and Exchange Commission on Form 10-K is available upon request to our Investor Relations department. It is also available on our Web site at www.edwards.com.

Stock Symbol
EW LISTED NYSE Edwards Lifesciences' stock is traded on The New York Stock Exchange (NYSE) under the symbol EW.

Information on the Internet
Edwards Lifesciences' Web site at www.edwards.com provides access to a wide range of information for our customers, patients and shareholders. Persons interested in investing in Edwards Lifesciences are invited to visit the "Investor Relations" section of our Web site to access our press releases, SEC filings and other company information.

Investor Information
Shareholders, securities analysts and investors seeking additional information about Edwards Lifesciences should contact: David K. Erickson
Vice President, Investor Relations
(949) 250-2806 Phone
(949) 250-2248 Fax
investor_relations@edwards.com.

Corporate Public Relations
Members of the news media should call: (949) 250-5070

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Merrill Lynch
Natexis Bleichroeder, Inc.
Oppenheimer & Co. Inc.
Roth Capital Partners, L.L.C.
Stifel, Nicolaus & Co.
Susquehanna Financial Group
U.S. Bancorp Piper Jaffray
William Blair & Company, L.L.C.
ValueLine

Edwards Lifesciences is an affirmative action, equal opportunity employer.

Design & Production : **ramp** creative+design
Printing : ColorGraphics

OUR CREDO At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease. Through our actions, we will become trusted partners with customers, colleagues and patients creating a community unified in its mision to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders. We will celebrate our successes, thrive on discovery and continually expand our boundaries. We will act boldly, decisively and with determination on behalf of people fighting cardiovascular disease. Helping Patients is Our Life's Work, and Life is Now.

Executive Management
(Left to Right)

Patrick B. Verguet
Corporate Vice President, Europe

John ("Alex") Martin
Corporate Vice President, North America

Corinne H. Lyle
Corporate Vice President, Chief Financial Officer & Treasurer

Patricia L. Garvey, Ph.D.
Corporate Vice President, Regulatory, Quality & Clinical Affairs

Stuart L. Foster
Corporate Vice President, Technology & Discovery

Michael A. Mussallem
Chairman & Chief Executive Officer

Robert C. Reindl
Corporate Vice President, Human Resources

Bruce P. Garren
Corporate Vice President, General Counsel

Thomas M. Abate
Corporate Vice President, Financial Control & Operations

John H. Kehl, Jr.
Corporate Vice President, Strategy & Business Development

Huimin Wang, M.D.
Corporate Vice President, Japan & Intercontinental

Randel W. Woodgrift
Corporate Vice President, Manufacturing Operations

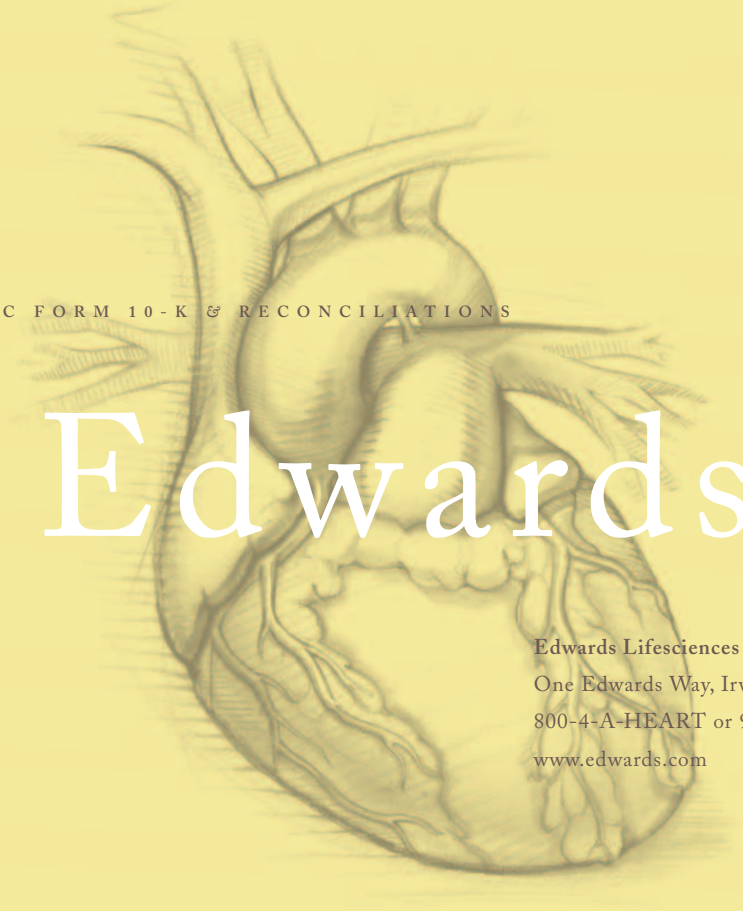
Anita B. Bessler
Corporate Vice President, Global Franchise Management

Keith A. Reisinger
Corporate Vice President, Technology

Stanton J. Rowe
Corporate Vice President, Percutaneous Valve Interventions

On June 9, 2004, Edwards Lifesciences submitted to the New York Stock Exchange a certification signed by its Chief Executive Officer that as of June 8, 2004 he was not aware of any violation by Edwards Lifesciences of the NYSE corporate governance listing standards. In addition, the certifications signed by the Chief Executive Officer and Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act were filed as an exhibit to Edwards' Annual Report on Form 10-K for the year ended December 31, 2004.

> SEC FORM 10-K & RECONCILIATIONS



Edwards

Edwards Lifesciences Corporation
One Edwards Way, Irvine, CA 92614
800-4-A-HEART or 949-250-2500
www.edwards.com

Edwards Lifesciences

RECONCILIATIONS OF GAAP TO NON-GAAP FIGURES

The following tables reconcile GAAP figures to the figures stated in the Letter to Shareholders and Selected Financial Data in the accompanying 2004 Annual Report that are not prepared in conformity with GAAP. These non-GAAP figures are adjusted for the impact of divestitures, purchased in-process research and development expenses, severance charges, reorganizations and/or other items. Management has determined that inclusion of these non-GAAP figures provides a more meaningful comparison of the Company's operating results for the periods presented and better reflects the Company's ongoing operations. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Notes to the Consolidated Financial Statements" in the Company's SEC Form 10-K.

Adjusted Net Income ***(in millions, except per share data)***

	Twelve Months Ended December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
Net income, as reported (GAAP)	$ 1.7	$ 79.0	$ 55.7	$(11.4)	$(271.7)
Reconciling items, net of tax					
Purchased in-process research and development expenses (see Note 4)	91.5	12.4	—	—	—
Asset impairment charges (see Note 5)	5.4	—	54.1	—	—
Discontinued products charges (see Note 6)	6.9	—	—	—	—
Sale of property development rights (see Note 6)	(4.5)	—	—	—	—
Charitable fund (see Note 6)	3.1	—	—	—	—
Severance charge (see Note 6)	—	9.6	—	—	—
Baxter arbitration settlement (see Note 6)	—	4.2	—	—	—
Business divestitures, net (see Note 6)	—	2.8	—	56.3	258.0
Pension curtailment (see Note 6)	—	1.8	—	—	—
Tax benefits of Brazilian reorganization (see Note 16)	—	(13.2)	—	—	—
Tax benefit of perfusion services divestiture (see Note 16)	—	—	(20.1)	—	—
Legal settlement, net (see Note 15)	—	—	(9.1)	—	—
Spin-off charges (see Note 6)	—	—	2.3	—	11.0
Other charges	—	—	—	8.9	—
Asset dispositions and write downs, net	—	—	—	3.9	—
Breaking of interest rate swap agreement	—	—	—	3.7	—
Adoption of SFAS No. 133	—	—	—	1.5	—
Other charges, personnel costs and charges for exit activities	—	—	—	—	62.7
Costs associated with being an independent public company and interest expense associated with the Company's future debt facilities	—	—	—	—	(9.2)
Adjusted net income (non-GAAP)	$104.1	$ 96.6	$ 82.9	$ 62.9	$ 50.8
Adjusted net income above (non-GAAP)	$104.1	$ 96.6	$ 82.9	$ 62.9	$ 50.8
Adjustment for items included in net income related to the contingent convertible debt	4.0	2.6	—	—	—
Adjusted net income including items related to the contingent convertible debt (non-GAAP)	$108.1	$ 99.2	$ 82.9	$ 62.9	$ 50.8
Weighted average common shares outstanding used to calculate diluted earnings per share excluding contingent convertible debt	62.0	61.1	61.3	58.9	59.6
Weighted average shares outstanding for the contingent convertible debt	2.7	1.8	—	—	—
Weighted average common shares outstanding used to calculate diluted earnings per share including the contingent convertible debt	64.7	62.9	61.3	58.9	59.6
Diluted earnings per share including the contingent convertible debt	$ 1.67	$ 1.58	$ 1.35	$ 1.07	$ 0.85

RECONCILIATIONS OF GAAP TO NON-GAAP FIGURES — (Continued)

Adjusted Free Cash Flow ***(in millions)***

	Twelve Months Ended December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
Net cash provided by operating activities, as reported (GAAP)(a)	$180.6	$142.1	$150.5	$106.4	$169.7
Capital expenditures, as reported (GAAP)	(42.5)	(37.9)	(40.7)	(37.5)	(46.0)
Reconciling items					
Implementation of accounts receivable securitization program	—	—	(30.1)	—	(32.7)
Adjusted free cash flow (non-GAAP)	$138.1	$104.2	$ 79.7	$ 68.9	$ 91.0

(a) Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Selected Operating Information ***(in millions)***

	Twelve Months Ended December 31,				
	2004	**2003**	**2002**	**2001**	**2000**
Net sales	$931.5	$860.5	$704.0	$692.1	$803.8
Cost of goods sold	370.2	359.4	299.1	323.7	423.3
Gross profit	561.3	501.1	404.9	368.4	380.5
Selling, general and administrative expenses	319.9	289.4	227.9	203.2	215.6
Research and development expenses	87.0	72.8	65.2	55.0	54.4
Operating Statistics					
As a percentage of net sales:					
Gross profit	60.3%	58.2%	57.5%	53.2%	47.3%
Selling, general and administrative expenses	34.3%	33.7%	32.4%	29.4%	26.8%
Research and development expenses	9.3%	8.5%	9.3%	7.9%	6.8%

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2004

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period From to

Commission File Number 1-15525

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**36-4316614**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

One Edwards Way, Irvine, California 92614

(Address of principal executive offices)(Zip Code)

(949) 250-2500

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:	**Name of each exchange on which registered:**
Common Stock, par value $1.00 per share	New York Stock Exchange
Series A Junior Participating Preferred Purchase Rights (currently traded with common stock)	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2) Yes ☑ No ☐

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2004 (the last trading day of the registrant's most recently completed second quarter): $2,067,621,853 based on a closing price of $34.85 of the registrant's common stock on the New York Stock Exchange. This calculation does not reflect a determination that persons are affiliates for any other purpose.

The number of shares outstanding of the registrant's common stock, $1.00 par value, as of February 25, 2005 was 59,583,131.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2005 Annual Meeting of Stockholders (to be filed on or before April 18, 2005) are incorporated by reference into Part III, as indicated herein.

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report — 2004

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PART I

PART I

Item 1. *Business*

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company intends the forward-looking statements to be covered by the safe harbor provisions for such statements contained in this report. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, any statements of plans, strategies and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, and any statement of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "anticipate," "plan," "continue," "seek," "pro forma," "forecast," or "intend" or other similar words or expressions of the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's future business, financial condition, results of operations, or performance to differ materially from the Company's historical results or those expressed in any forward-looking statements contained in this report.

Overview

Edwards Lifesciences Corporation is a global leader in products and technologies designed to treat advanced cardiovascular disease. The Company focuses on specific cardiovascular opportunities including heart valve disease, peripheral vascular disease and critical care technologies.

Cardiovascular disease is the number-one cause of death in the world, and is among the top three diseases in terms of health care spending in nearly every country. Cardiovascular disease is both progressive and pervasive; progressive, in that it tends to worsen over time, and pervasive because it often affects an individual's entire circulatory system. In its later stages, cardiovascular disease is frequently treated with surgery, including heart valve replacement or repair procedures and coronary artery bypass graft ("CABG") procedures.

The products and technologies provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; Vascular; and Other Distributed Products.

Patients undergoing surgical treatment for cardiovascular disease are likely to be treated using a variety of Edwards Lifesciences' products and technologies. For example, an individual with a heart valve disorder may have a faulty valve reshaped and repaired with an Edwards Lifesciences annuloplasty ring, or a surgeon may elect to remove the valve altogether and replace it with one of Edwards Lifesciences' bioprosthetic tissue heart valves, which are made of bovine pericardial or porcine tissue. Virtually all high-risk patients in the operating room or cardiac care unit are candidates for having their cardiac function monitored by Edwards Lifesciences' critical care products. If a patient undergoes other types of open-heart surgery, such as a CABG procedure, the functions of their heart and lungs may be managed through the use of disposable products and equipment offered in certain international markets by Edwards Lifesciences' perfusion products. If the circulatory problems are in the limbs rather than in the heart, the patient's procedure may involve some of Edwards Lifesciences' vascular products, which include various types of balloon-tipped catheters that are used to remove blood clots, and stents that are used to prop open the diseased blood vessels of patients suffering from atherosclerotic vascular disease. Lastly, Edwards Lifesciences' other distributed products include sales of intra-aortic balloon pumps and other products sold primarily through the Company's distribution network in Japan.

Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999. Unless otherwise indicated or the context otherwise requires, the terms "it," "its," "Company" and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

Edwards Lifesciences' principal executive offices are located at One Edwards Way, Irvine, California 92614. The telephone number at that address is (949) 250-2500. The Company makes available, free of charge on its web site located at www.edwards.com, its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the SEC. The Company's corporate governance guidelines, audit and public policy committee charter, compensation and governance committee charter, and code of business conduct are also posted on the Company's web site and are each available in print to any shareholder upon request by writing to: Edwards Lifesciences Corporation, Investor Relations, One Edwards Way, Irvine, California 92614.

Edwards Lifesciences' Product and Technology Offerings

The following discussion summarizes the five main categories of products and technologies offered by Edwards Lifesciences to treat advanced cardiovascular disease. For more information on net sales from these five main categories, see "Net Sales by Product Line" under Management's Discussion and Analysis of Financial Condition and Results of Operations.

Heart Valve Therapy

Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products, which are used to replace or repair a patient's diseased or defective heart valve. The Company operates manufacturing facilities in Irvine, California, and Horw, Switzerland, producing pericardial and porcine valves from biologically inert animal tissue sewn onto proprietary wireform stents.

The core of Edwards Lifesciences' tissue product line is the *Carpentier-Edwards PERIMOUNT* pericardial valve, including *PERIMOUNT Magna,* the newest generation pericardial valve approved for sale in the United States, Europe and Canada. The *PERIMOUNT* valve is the most widely prescribed tissue heart valve in the world due to its proven durability and performance, and is the only pericardial tissue valve available in the United States. Edwards Lifesciences also sells porcine valves, stentless tissue valves and mechanical valves. In addition to its replacement valves, Edwards Lifesciences pioneered and is the worldwide leader in heart valve repair therapies, including annuloplasty rings and systems.

Edwards Lifesciences is currently developing technologies for the percutaneous (catheter-based) repair and replacement of heart valves, which the Company believes can address a greater number of patients than are currently treated with conventional open-heart surgery.

Critical Care

Edwards Lifesciences is a world leader in hemodynamic monitoring systems that are used to measure a patient's heart function in surgical and intensive care settings. Hemodynamic monitoring enables a clinician to balance the oxygen supply and demand of a critically ill patient and plays an important role in assuring that the heart function of millions of patients who have pre-existing cardiovascular conditions or other critical illnesses is optimized before they undergo a surgical procedure.

Edwards Lifesciences' hemodynamic monitoring technologies are often deployed before, during and after open-heart, major vascular, major abdominal, neurological and orthopedic surgical procedures. Edwards Lifesciences manufactures and markets the *Swan-Ganz* brand line of hemodynamic monitoring products. Edwards Lifesciences' most recent addition to its hemodynamic monitoring product line is the *PreSep* central venous oximetry catheter,

designed to help clinicians identify and manage sepsis, a widespread blood infection. New minimally invasive cardiac monitoring technology, including Edwards' *FloTrac* system, is planned for commercialization in 2005.

Edwards Lifesciences is a global leader in the broader field of disposable pressure monitoring devices and has a line of innovative products enabling closed-loop arterial blood sampling to protect both patients and clinicians from the risk of infection. Central venous catheters are the primary route for fluid and medication delivery to patients undergoing major surgical procedures and/or intensive care. The Company's *Advanced Venous Access* products provide increased convenience, effectiveness and efficiency by integrating the capabilities of an introducer and multi-lumen central venous access catheter into a single device.

The Company also markets a range of products required to perform continuous renal replacement therapies including access catheters, hemofilters, substitution fluids and pumps.

Cardiac Surgery Systems

The Company is a leading manufacturer of select disposable products used during cardiac surgery including cannula to facilitate venous drainage during perfusion, aortic dispersion cannula, and products to facilitate coronary artery bypass surgery when performed on a beating heart. Edwards Lifesciences also produces the *EMBOL-X* system, the only system of its kind designed to capture embolic material, such as blood clots or tissue fragments that might be generated during open-heart surgery procedures.

For customers in regions outside of the United States and Western Europe, Edwards Lifesciences develops, manufactures and distributes a line of disposable perfusion products used during the practice of bypassing the heart and lungs during open-heart surgical procedures. In January 2005, the Company divested its Japanese perfusion products business.

Edwards Lifesciences distributes carbon-dioxide lasers and related disposables for use in transmyocardial revascularization, a procedure for treating severe angina. These products are manufactured by PLC Systems Inc. ("PLC"), and Edwards Lifesciences is responsible for all sales, marketing and distribution of these products in the United States. The Company has also partnered with PLC to commercialize the *Optiwave 980* surgical ablation system, a photonic laser system for treating cardiac arrhythmias.

Vascular

The pervasive nature of cardiovascular disease means that the circulatory conditions that occur inside the heart are often mirrored elsewhere in a patient's body. Atherosclerotic disease is one common condition that involves the thickening of blood-carrying vessels and the formation of circulation-restricting plaque, clots and other substances, and often occurs concurrently in the vascular system as well as in the heart. When the abdomen, arms or legs are impacted, the diagnosis is usually peripheral vascular disease ("PVD"), which occurs in millions of patients worldwide.

Edwards Lifesciences manufactures and sells a variety of products used to treat occlusive PVD, including a line of balloon-tipped, catheter-based products, as well as surgical clips and inserts, angioscopy equipment and artificial implantable grafts. Edwards Lifesciences' *Fogarty* line of embolectomy catheters has been an industry standard for removing blood clots from peripheral blood vessels for more than 40 years.

Edwards Lifesciences also manufactures and sells *LifeStent* balloon-expandable and self-expanding non-coronary stents that are used to prop open the diseased blood vessels of patients suffering from atherosclerotic vascular disease. The Company continued to expand its *LifeStent* product line during the year.

Although Edwards Lifesciences discontinued sales and development of its *Lifepath AAA* endovascular graft system for treating abdominal aortic aneurysms in 2004, the Company continues to distribute third-party abdominal aortic aneurysm graft products in Europe.

Other Distributed Products

Other distributed products primarily include sales of intra-aortic balloon pumps, pacemakers and other products sold though the Company's operations in Japan. During the first quarter of 2005, Edwards exited its pacemaker distribution business.

Competition

The medical devices industry is highly competitive. Edwards Lifesciences competes with many companies, ranging from small start-up enterprises to companies that are larger and more established than Edwards Lifesciences with access to significant financial resources. Furthermore, rapid product development and technological change characterize the market in which Edwards Lifesciences competes. The present or future products of Edwards Lifesciences could be rendered obsolete or uneconomical as a result of technological advances by one or more of Edwards Lifesciences' present or future competitors or by other therapies, including drug therapies. Edwards Lifesciences must continue to develop and acquire new products and technologies to remain competitive in the cardiovascular medical devices industry. Edwards Lifesciences believes that it competes primarily on the basis of product reliability and performance, product features that enhance patient benefit, customer and sales support, and cost-effectiveness.

The cardiovascular segment of the medical device industry is dynamic and currently undergoing significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation and evolving patient needs. The ability to provide cost-effective products and technologies that improve clinical outcomes is becoming increasingly important for medical device manufacturers.

Edwards Lifesciences' products and technologies face substantial competition from a number of companies. In heart valve therapy, the primary competitors include St. Jude Medical, Inc., Medtronic, Inc. and the Sorin Group. In critical care, Edwards Lifesciences' principal competitors include Hospira, Inc. and Arrow International, Inc. In cardiac surgery systems, Edwards Lifesciences competes with the Sorin Group, Medtronic, Inc. and Getinge AB. In vascular, Edwards Lifesciences' primary competitors for the traditional surgical segments of its business include W.L. Gore & Associates, Inc., LeMaitre Vascular Inc. and Applied Medical Resources Corporation. For emerging peripheral vascular disease products, Edwards Lifesciences' competitors are Johnson & Johnson, Boston Scientific Corporation, Guidant Corporation and Medtronic, Inc.

Sales and Marketing

Edwards Lifesciences has a number of broad product lines that require a sales and marketing strategy tailored to its customers in order to deliver high-quality, cost-effective products and technologies to all of its customers worldwide. Edwards Lifesciences' portfolio includes some of the most recognizable product brands in cardiovascular devices today, including *Carpentier-Edwards, Cosgrove-Edwards, Fogarty, Research Medical, Starr-Edwards* and *Swan-Ganz.*

Because of the diverse global needs of the population that Edwards Lifesciences serves, Edwards Lifesciences' distribution system includes a direct sales force and independent distributors. Edwards Lifesciences is not dependent on any single customer and no single customer accounted for more than 10% of Edwards Lifesciences' net sales in 2004.

Sales personnel work closely with the primary decision makers who purchase Edwards Lifesciences' products, which include physicians, material managers, nurses, biomedical staff, hospital administrators and purchasing managers. Also, for certain of its products and where appropriate, Edwards Lifesciences' sales force actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations that negotiate contracts with suppliers of medical products. Edwards Lifesciences has contracts with a number of domestic national buying groups and is working with a growing number of regional buying groups that are emerging in response to cost containment pressures and health care reform in the United States.

United States. In the United States, Edwards Lifesciences sells substantially all of its products through its direct sales force. In 2004, 44.7% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

International. In 2004, 55.3% of Edwards Lifesciences' reported sales were derived internationally through its direct sales force and independent distributors. Edwards Lifesciences sells its products in approximately 100 countries. Major international markets for Edwards Lifesciences' products are: Japan, Germany, France, United Kingdom, Italy, Brazil, Canada, Belgium, Spain, The Netherlands and Australia/New Zealand. The sales and marketing approach in international geographies varies depending on each country's size and state of development. See Note 18 to the "Consolidated Financial Statements" contained herein for additional information.

Raw Materials and Manufacturing

Edwards Lifesciences uses a diverse and broad range of raw and organic materials in the design, development and manufacture of its products. Edwards Lifesciences' non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metal. Most of Edwards Lifesciences' heart valve therapy products are manufactured from natural tissues harvested from animal tissue, as well as man-made materials. Edwards Lifesciences purchases certain materials and components used in manufacturing its products from external suppliers. In addition, Edwards Lifesciences purchases certain supplies from single sources for reasons of quality assurance, sole source availability, cost effectiveness or constraints resulting from regulatory requirements.

Edwards Lifesciences works closely with its suppliers to assure continuity of supply while maintaining high quality and reliability. Alternative supplier options are generally considered and identified, although Edwards Lifesciences does not typically pursue regulatory qualification of alternative sources due to the strength of its existing supplier relationships and the time and expense associated with the regulatory validation process. Although a change in suppliers could require significant effort or investment by Edwards Lifesciences in circumstances where the items supplied are integral to the performance of Edwards Lifesciences' products or incorporate unique technology, management does not believe that the loss of any existing supply contract would have a material adverse effect on the Company.

Edwards Lifesciences follows rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy ("BSE"), commonly known as "mad cow disease." International health and regulatory authorities have given guidance identifying three factors contributing to the control of BSE: source of animals, nature of tissue used and manufacturing process. The Company complies with all current global guidelines regarding risks for products intended to be implanted in humans. The Company obtains bovine tissue used in its pericardial tissue valve products only from sources within the United States and Australia, where strong control measures and surveillance programs exist. In addition, bovine tissue used in the Company's pericardial tissue valve products is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. The Company's manufacturing and sterilization processes render tissue biologically safe from all known infectious agents and viruses, and exceed the worldwide standard for sterile medical products. See "Risk Factors" contained herein.

Quality Assurance

Edwards Lifesciences is committed to providing quality products to its customers. To meet this commitment, Edwards Lifesciences has implemented modern quality systems and concepts throughout the organization. The quality system starts with the initial product specification and continues through the design of the product, component specification processes and the manufacturing, sales and servicing of the product. The quality system is designed to build in quality and to utilize continuous improvement concepts throughout the product lifecycle.

Edwards Lifesciences' operations are certified under applicable international quality systems standards, such as ISO 9001, ISO 9002 and ISO 13485. These standards require, among other items, quality system controls that are

applied to product design, component material, suppliers and manufacturing operations. These ISO certifications can be obtained only after a complete audit of a company's quality system has been conducted by an independent outside auditor. Periodic reexamination by an independent outside auditor is required to maintain these certifications.

Research and Development

Edwards Lifesciences is engaged in ongoing research and development to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety and reliability of its current leading products and to expand the applications of its products as appropriate. Edwards Lifesciences is dedicated to developing novel technologies that will furnish health care providers with a more complete line of products that address opportunities within the specific cardiovascular disease areas on which the Company focuses.

The Company invested $87.0 million on research and development in 2004, $72.8 million in 2003 and $65.2 million in 2002 (9.3%, 8.5% and 9.3% of net sales, respectively). A significant portion of Edwards Lifesciences' research and development investment has been applied to extend and defend its core heart valve, critical care and vascular franchises, including research and development relating to next-generation pericardial tissue valves and enhanced tissue processing technologies.

Edwards Lifesciences is investing in the development of percutaneous heart valve repair and replacement technologies, designed to treat heart valve disease using a catheter-based approach as opposed to direct surgical techniques. In 2004, Edwards Lifesciences acquired Percutaneous Valve Technologies, Inc., a privately held firm with notable clinical experience and intellectual property relating to a percutaneous heart valve replacement system. Also in 2004, the Company acquired all of the technology and intellectual property associated with ev3, Inc.'s percutaneous mitral valve repair program. Both of these acquisitions enhanced the Company's existing percutaneous repair and replacement development efforts.

In its critical care franchise, the Company is also pursuing the development of minimally invasive hemodynamic monitoring systems, which offer the promise of collecting critical data using less invasive methods than current technologies. In its vascular franchise, the Company plans to broaden its *LifeStent* balloon-expandable and self-expanding non-coronary stents. Additionally, the Company is investing in additional growth opportunities, including alternative tissue valve materials, and angiogenesis gene therapy to treat peripheral vascular and coronary artery diseases.

Edwards Lifesciences' research and development activities are carried out primarily in facilities located in the United States. The Company's experienced research and development staff is focused on product design and development, quality, clinical research and regulatory compliance. To pursue primary research efforts, Edwards Lifesciences has developed alliances with several leading research institutions and universities, and also works with leading clinicians around the world in conducting scientific studies on Edwards Lifesciences' existing and developing products. These studies include clinical trials, which provide data for use in regulatory submissions, and post-market approval studies involving applications of Edwards Lifesciences' products.

Proprietary Technology

Patents and other proprietary rights are important to the success of Edwards Lifesciences' business. Edwards Lifesciences also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive position.

Edwards Lifesciences owns approximately 505 issued United States patents, 204 pending United States patent applications, 802 issued foreign patents and 478 pending foreign patent applications, and has licensed numerous United States patents and patent applications that relate to aspects of the technology incorporated in many of Edwards Lifesciences' products.

Most of Edwards Lifesciences' products are protected in some way by issued patents and/or pending patent applications. Although the original *Carpentier-Edwards* pericardial valve patent expired in 2002 in most countries, Edwards Lifesciences has a number of other key patents and pending patent applications in the United States, Europe, Australia, Japan and Canada on improvements to the pericardial valve that enhance and extend the original patent coverage. These improvements are included in the *Carpentier-Edwards PERIMOUNT Magna* pericardial valves and the *Carpentier-Edwards PERIMOUNT Plus* pericardial valves. Because of these design improvements, management does not expect the expiration of the original pericardial patent to have a significant effect on its business.

Edwards Lifesciences has many important United States and foreign patents and pending patent applications related to mitral valve repair and, in particular, patent coverage on the *Cosgrove-Edwards* annuloplasty system and the *Carpentier-Edwards Physio* annuloplasty ring, as well as the *Edwards MC3* tricuspid annuloplasty system and the *IMR ETLogix* annuloplasty ring. Edwards Lifesciences also has a number of significant United States and foreign patents and patent applications in the field of percutaneous heart valve repair and replacement, including the patent rights acquired from Jomed N.V. in February 2003, Percutaneous Valve Technologies, Inc. in January 2004 and ev3, Inc. in September 2004.

Edwards Lifesciences also has a number of key United States and foreign patents and patent applications that cover catheters, systems and methods for hemodynamic monitoring and vascular access products. The issued hemodynamic monitoring and vascular access patents are expected to protect Edwards Lifesciences' intellectual property rights in such technologies for the next 8 to 16 years. Edwards Lifesciences has pending patent applications that relate to aspects of the technology incorporated in the *FloTrac* system, used to measure cardiac output by minimally invasive methods. Edwards Lifesciences also owns a significant number of United States and foreign patents and patent applications relating to intra-aortic embolic management systems, including the *EMBOL-X* system. Edwards Lifesciences has also exclusively licensed and owns several important United States and foreign patents and patent applications relating to peripheral stents, including the *LifeStent* products. In addition, Edwards Lifesciences has exclusively licensed a portfolio of United States and foreign patents and patent applications in the angiogenesis field.

Although some of Edwards Lifesciences' patents are due to expire within the next five years, Edwards Lifesciences' patent strategy is to file improvement patent applications and, in some cases, additional patent applications covering new aspects or modifications of the affected products, or line extensions of these products. As a result, the duration of some of the patents covering Edwards Lifesciences' products can extend up to 20 years from the date of filing of the patent application. There can be no assurance that pending patent applications will result in issued patents. There can also be no assurance that pending improvement applications or additional patent applications covering new aspects or modifications of the affected products, or line extensions of these products, will result in issued patents. Edwards Lifesciences management does not believe that the expiration of any one or more of its patents that are due to expire in the next five years will cause a material adverse effect on the sales of Edwards Lifesciences' products.

Edwards Lifesciences is a party to several license agreements with unrelated third parties pursuant to which it has obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross licensing rights or royalty payments. Edwards Lifesciences has also granted various rights in its own patents to others under license agreements. Competitors may challenge the validity and enforceability of, or circumvent, patents issued to or licensed by Edwards Lifesciences. Such patents may also be found to be insufficiently broad to provide Edwards Lifesciences with a competitive advantage.

Edwards Lifesciences actively monitors the products of its competitors for possible infringement of Edwards Lifesciences' owned and/or licensed patents. Litigation has been necessary to enforce certain patent rights held by Edwards Lifesciences, and the Company plans to continue to defend and prosecute its rights with respect to such patents. However, the Company's efforts in this regard may not be successful. In addition, patent litigation could result in substantial cost and diversion of effort. Edwards Lifesciences also relies upon trade secrets for protection of

its confidential and proprietary information. Others may independently develop substantially equivalent proprietary information and techniques, and third parties may otherwise gain access to Edwards Lifesciences' trade secrets.

The following table identifies some of the primary trademarks of Edwards Lifesciences that are registered in the United States Patent and Trademark Office:

Advanced Venous Access	*Edwards Lifesciences*	*LifeStent*
AnastaFlo	*Edwards MIRA Edwards*	*PERIMOUNT*
AVA 3Xi	*Prima Plus*	*PERIMOUNT Plus*
AVA HF	*Edwards MC3*	*Starr-Edwards*
Carpentier-Edwards	*EMBOL-X*	*Swan-Ganz*
Carpentier-Edwards Physio	*Everclip*	*Vantex*
CCOmbo	*Evergrip*	*Vigilance*
Cosgrove-Edwards	*Fogarty*	

Other key trademarks owned by Edwards Lifesciences include:

BioPhysio	*PERIMOUNT Magna*	*ThermaFix*
Edwards	*Optiwave 980*	*Tricentrix*
FloTrac	*PreSep*	*VisuFlo*
IMR ETLogix	*Research Medical*	*XenoLogiX*

Many of these trademarks have also been registered for use in certain foreign countries where registration is available and Edwards Lifesciences has determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Regulatory Approvals. In the United States, the Food and Drug Administration ("FDA") has responsibility for regulating the introduction of new medical devices. The FDA regulates laboratory and manufacturing practices, labeling and record-keeping for medical devices, and review of required manufacturers' reports of adverse experience to identify potential problems with marketed medical devices. Many of the devices that Edwards Lifesciences develops and markets are in a category for which the FDA has implemented stringent clinical investigation and pre-market approval requirements. The process of obtaining FDA approval to market a product can be resource-intensive, lengthy and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of Edwards Lifesciences' products. Any delay or acceleration experienced by Edwards Lifesciences in obtaining regulatory approvals to conduct clinical trials or in obtaining required market clearances (especially with respect to significant products in the regulatory process that have been discussed in public announcements) may affect Edwards Lifesciences' operations or the market's expectations for the timing of such events and, consequently, the market price for Edwards Lifesciences' common stock. The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, or order the repair, replacement or refund of the costs of such devices. The FDA also may require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may enjoin and restrain certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. Moreover, the FDA administers certain controls over the export of medical devices from the United States and the importation of devices into the United States.

Medical device laws are also in effect in countries outside of the United States where Edwards Lifesciences does business. These range from comprehensive device approval requirements for some or all of Edwards Lifesciences' medical device products to requests for product data or certifications. The number and scope of these requirements are increasing.

Edwards Lifesciences is also governed by federal, state, local and foreign laws of general applicability, such as those regulating employee health and safety. In addition, Edwards Lifesciences is subject to various federal, state, local and foreign environmental protection laws and regulations, including those governing the adverse impact of material on the environment.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, are continuing in many countries where Edwards Lifesciences does business, including the United States and Japan. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. Although Edwards Lifesciences believes it is well positioned to respond to changes resulting from this worldwide trend toward cost containment, proposed legislation and/or changes in the marketplace could have an adverse impact on future operating results.

Diagnostic-related groups' reimbursement schedules regulate the amount the United States government, through the Health and Human Services Centers for Medicare and Medicaid Services, will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. In response to rising Medicare and Medicaid costs, several legislative proposals in the United States have been advanced that would restrict future funding increases for these programs. While Edwards Lifesciences has been unaware of significant domestic price resistance directly as a result of the reimbursement policies of diagnostic-related groups, changes in these reimbursement levels and processes could have an adverse effect on Edwards Lifesciences' domestic pricing flexibility.

In keeping with the increased emphasis on cost-effectiveness in health care delivery, the current trend among domestic hospitals and other customers of medical device manufacturers is to consolidate into larger purchasing groups to enhance purchasing power. The medical device industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex and tend to involve more long-term contracts than in the past. The enhanced purchasing power of these larger customers may also increase the pressure on product pricing, although management is unable to estimate the potential impact at this time.

Employees

As of December 31, 2004, Edwards Lifesciences had approximately 5,200 employees worldwide, the majority of whom were located at the Company's headquarters in Irvine, California, and at its manufacturing facilities in Puerto Rico and the Dominican Republic. Other major concentrations of employees are located in Europe, Japan and Brazil. Edwards Lifesciences emphasizes competitive compensation, benefits, equity participation and work environment practices in its efforts to attract and retain qualified personnel. None of Edwards Lifesciences' North American employees are represented by a labor union. In various countries outside of North America, the Company interacts with trade unions and work councils that represent a limited number of employees.

Risk Factors

An investor should carefully consider the risks described below, as well as other information contained in Edwards Lifesciences' filings with the Securities and Exchange Commission. If any of the events described below occurs, Edwards Lifesciences' business, financial condition or results of operations could be materially harmed. In that case, the value of Edwards Lifesciences' securities could decline and an investor may lose part or all of his or her investment.

If Edwards Lifesciences does not introduce new products in a timely manner, its products may become obsolete, and its operating results may suffer.

The cardiovascular products industry is characterized by rapid technological changes, frequent new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, Edwards Lifesciences' products will likely become technologically obsolete over time, in which case its revenue and operating results would suffer. Even if Edwards Lifesciences is able to develop new technologies, these technologies

may not be accepted quickly because of industry specific factors, such as the need for regulatory clearance, unanticipated restrictions imposed on approved indications, entrenched patterns of clinical practice and uncertainty over third party reimbursement

Moreover, significant technical innovations generally will require a substantial investment before Edwards Lifesciences can determine the commercial viability of these innovations. Edwards Lifesciences may not have the financial resources necessary to fund these technical innovations. In addition, even if Edwards Lifesciences is able to successfully develop enhancements or new generations of its products, these enhancements or new generations of products may not produce revenue in excess of the costs of development, and they may be quickly rendered obsolete by changing customer preferences or the introduction by Edwards Lifesciences' competitors of products embodying new technologies or features.

Edwards Lifesciences may incur product liability losses that could adversely affect its operating results.

Edwards Lifesciences' business exposes it to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. Edwards Lifesciences' products are often used in surgical and intensive care settings with seriously ill patients. In addition, some of the medical devices manufactured and sold by Edwards Lifesciences are designed to be implanted in the human body for long periods of time. Edwards Lifesciences could be the subject of product liability suits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product related risks or product related information could result in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on Edwards Lifesciences' business and reputation and on its ability to attract and retain customers.

Edwards Lifesciences may experience supply interruptions that could harm its ability to manufacture products.

Edwards Lifesciences uses a diverse and broad range of raw and organic materials and other items in the design and manufacture of its products. Edwards Lifesciences' non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metals. Edwards Lifesciences' heart valve therapy products are manufactured from treated natural animal tissue and man-made materials. Edwards Lifesciences purchases certain of the materials and components used in the manufacture of its products from external suppliers. In addition, Edwards Lifesciences purchases certain supplies from single sources for reasons of quality assurance, cost-effectiveness or constraints resulting from regulatory requirements. Edwards Lifesciences works closely with its suppliers to assure continuity of supply while maintaining high quality and reliability. Alternative supplier options are generally considered and identified, although Edwards Lifesciences does not typically pursue regulatory qualification of alternative sources due to the strength of its existing supplier relationships and the time and expense associated with this regulatory process. Although a change in suppliers could require significant effort or investment by Edwards Lifesciences in circumstances where the items supplied are integral to the performance of its products or incorporate unique technology, management does not believe that the loss of any existing supply contract would have a material adverse effect on the Company.

In an effort to reduce potential product liability exposure, in the past certain suppliers have announced that they might limit or terminate sales of certain materials and parts to companies that manufacture implantable medical devices. In some cases, Edwards Lifesciences has been required to indemnify suppliers for product liability expenses in order to continue to receive materials or parts. There can be no assurance that an indemnity from Edwards Lifesciences will be satisfactory to these suppliers in the future. If Edwards Lifesciences is unable to obtain these raw materials or there is a significant increase in the price of materials or components, its business could be harmed.

Edwards Lifesciences may be required to recognize additional charges in connection with the write-down of some of its investments, the disposition of some of its businesses, the termination of its interest rate swap agreements or for other reasons.

Edwards Lifesciences has made investments in the equity instruments of other companies, and may make further such investments in the future. To the extent that the value of any such investment declines, Edwards Lifesciences may be required to recognize charges to write down the value of that investment. See "Asset Impairments" under "Management's Discussion and Analysis of Financial Condition and Results of Operations" included herein.

In the case of some of the companies in which Edwards Lifesciences has invested, the value of its equity securities has declined since the time of its original investment. As a result, Edwards Lifesciences may be required to recognize additional charges, which could be substantial, to write down its investments. At December 31, 2004, Edwards Lifesciences had approximately $20.6 million of investments in equity instruments of other companies and had recorded unrealized losses of $4.5 million on these investments on its balance sheet in "Accumulated Other Comprehensive Income (Loss)," net of tax.

As part of the ongoing evaluation of its various businesses and products, Edwards Lifesciences from time to time identifies businesses or products that are not performing at a level commensurate with the rest of its business. Edwards Lifesciences may from time to time seek to dispose of these under performing businesses or product lines, and may also seek to dispose of businesses or product lines from time to time for strategic or other business reasons. If Edwards Lifesciences is unable to dispose of a business or product line on terms it considers acceptable, Edwards Lifesciences may voluntarily terminate that business or cease providing that product. Any of these events may result in charges, which could be substantial and which could adversely affect its results of operations.

Edwards Lifesciences has entered into interest rate swap agreements in connection with some of its indebtedness, and expects that it will continue to do so from time to time in the future. In the event that Edwards Lifesciences elects to terminate a swap agreement prior to its maturity, it may be required to make cash payments to the counterparty and to recognize a charge in connection with that termination, which could adversely affect its results of operations.

Edwards Lifesciences may not successfully identify and complete acquisitions or strategic alliances on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances, and such acquisitions could result in unforeseen operating difficulties and expenditures, require significant management resources and require significant charges or write-downs.

As part of Edwards Lifesciences' growth strategy, Edwards Lifesciences regularly reviews potential acquisitions of complementary businesses, technologies, services or products, as well as potential strategic alliances. Edwards Lifesciences may be unable to find suitable acquisition candidates or appropriate partners with which to form partnerships or strategic alliances. Even if Edwards Lifesciences identifies appropriate acquisition or alliance candidates, it may be unable to complete such acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service or product into Edwards Lifesciences' existing business and operations may result in unforeseen operating difficulties and expenditures. Integration of an acquired company also may require significant management resources that otherwise would be available for ongoing development of Edwards Lifesciences' business. Moreover, Edwards Lifesciences may not realize the anticipated benefits of any acquisition or strategic alliance, and such transactions may not generate anticipated financial results. In addition, Edwards Lifesciences may be required to take charges or write downs in connection with acquisitions it has made or may make in the future. In particular, acquisitions of businesses engaged in the development of new products may give rise to in-process research and development charges, which could be significant. For example, approximately $81 million was charged to in-process research and development in connection with the Company's 2004 acquisition of Percutaneous Valve Technologies, Inc. Edwards Lifesciences has taken in-process research and development charges in connection with other acquisitions and may take similar charges in connection with

acquisitions the Company makes in the future, which charges could adversely affect its results of operations. Future acquisitions could also require issuances of equity securities, the incurrence of debt, contingent liabilities or amortization expenses related to other intangible assets, any of which could harm Edwards Lifesciences' business.

Edwards Lifesciences' business is subject to economic, political and other risks associated with international sales and operations.

Because Edwards Lifesciences sells its products in a number of foreign countries, its business is subject to risks associated with doing business internationally. Edwards Lifesciences' net sales originating outside of the United States, as a percentage of total net sales, were 55.3% in 2004. Edwards Lifesciences anticipates that sales from international operations will continue to represent a substantial portion of its total sales. In addition, many of Edwards Lifesciences' manufacturing facilities and suppliers are located outside of the United States. Management expects to increase Edwards Lifesciences' international sales, which could expose it to greater risks associated with international sales and operations. Accordingly, Edwards Lifesciences future results could be harmed by a variety of factors, including:

- changes in foreign medical reimbursement policies and programs;
- unexpected changes in foreign regulatory requirements;
- changes in foreign currency exchange rates;
- changes in a specific country's or region's political or economic conditions, particularly in emerging regions;
- trade protection measures and import or export licensing requirements;
- potentially negative consequences from changes in tax laws;
- difficulty in staffing and managing foreign operations;
- changes in the international political situation;
- differing labor regulations; and
- differing protection of intellectual property.

Edwards Lifesciences is subject to risks arising from currency exchange rate fluctuations.

Edwards Lifesciences generated 55.3% of net sales in 2004 outside of the United States. Substantially all of Edwards Lifesciences' sales outside of the United States are denominated in local currencies. Measured in local currency, a substantial portion of Edwards Lifesciences' foreign generated sales was generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of Edwards Lifesciences' foreign generated sales varies with currency exchange rate fluctuations. Significant decreases in the value of the United States dollar to the Euro or the Japanese yen have had the effect of increasing Edwards Lifesciences' earnings even when the volume of foreign sales has remained constant. Significant increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, could have a material adverse effect on Edwards Lifesciences' results of operations. Edwards Lifesciences has a hedging program that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity and cost; however, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations.

Increased interest rates could increase our borrowing costs and make it more difficult for us to access the capital markets.

From time to time Edwards Lifesciences may issue securities to finance acquisitions, capital expenditures, working capital and other general corporate purposes. An increase in interest rates in the general economy could result in an increase in Edwards Lifesciences' borrowing costs for these financings, as well as under any existing

debt that bears interest at a floating rate and for which interest rate swaps are not in place, and could otherwise restrict the ability of Edwards Lifesciences to access the capital markets.

Fluctuations in Edwards Lifesciences' quarterly operating results may cause its stock price to decline.

Edwards Lifesciences' sales and operating results may vary significantly from quarter to quarter. A high proportion of Edwards Lifesciences' costs are fixed, due in part to significant sales, research and development and manufacturing costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter, and the price of Edwards Lifesciences' common stock may fall. Other factors that could affect quarterly operating results include:

- demand for and clinical acceptance of products;
- the timing and execution of customer contracts, particularly large contracts that would materially affect Edwards Lifesciences' operating results in a given quarter;
- the timing of sales of products and of the introduction of new products;
- changes in foreign currency exchange rates;
- unanticipated delays or problems in introducing new products;
- competitors' announcements of new products, services or technological innovations;
- changes in Edwards Lifesciences' pricing policies or the pricing policies of its competitors;
- increased expenses, whether related to sales and marketing, raw materials or supplies, product development or administration;
- adverse changes in the level of economic activity in the United States and other major regions in which Edwards Lifesciences does business;
- costs related to possible acquisitions of technologies or businesses;
- Edwards Lifesciences' ability to expand its operations; and
- the amount and timing of expenditures related to expansion of Edwards Lifesciences' operations.

Edwards Lifesciences' inability to protect its intellectual property could have a material adverse effect on its business.

Edwards Lifesciences' success and competitive position are dependent, in part, upon its proprietary intellectual property. Edwards Lifesciences relies on a combination of patents, trade secrets and nondisclosure agreements to protect its proprietary intellectual property, and will continue to do so. Although Edwards Lifesciences seeks to protect its proprietary rights through a variety of means, Edwards Lifesciences cannot guarantee that the protective steps it has taken are adequate to protect these rights. Patents issued to or licensed by Edwards Lifesciences in the past or in the future may be challenged and held invalid or not infringed by third parties. Competitors may also challenge Edwards Lifesciences' patents. In addition, certain of Edwards Lifesciences' patents are due to expire within the next five years and the Company may be unsuccessful in its efforts to extend these patents through improvement patents, modifications or line extensions. The failure to maintain Edwards Lifesciences' patents could have a material adverse effect on the Company.

Edwards Lifesciences also relies on confidentiality agreements with certain employees, consultants and other parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached and Edwards Lifesciences may not have adequate remedies for any breach. In addition, others may independently develop substantially equivalent proprietary information or gain access to Edwards Lifesciences' trade secrets or proprietary information. Edwards Lifesciences spends significant resources to monitor and enforce its intellectual property rights. However, Edwards Lifesciences may not be able to detect infringement and may lose its

competitive position in the industry. In addition, competitors may design around Edwards Lifesciences' technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture increased market position.

Third parties may claim Edwards Lifesciences is infringing their intellectual property, and Edwards Lifesciences could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, Edwards Lifesciences' competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical device industry generally. From time to time, Edwards Lifesciences may be forced to defend itself against other claims and legal actions alleging infringement of the intellectual property rights of others. Because intellectual property litigation can be costly and time consuming, Edwards Lifesciences' intellectual property litigation expenses could be significant. Adverse determinations in any such litigation could subject Edwards Lifesciences to significant liabilities to third parties, could require Edwards Lifesciences to seek licenses from third parties and could, if such licenses are not available, prevent the Company from manufacturing, selling or using certain of its products, any one of which could have a material adverse effect on the Company.

Third parties could also obtain patents that may require Edwards Lifesciences to either redesign its products or, if possible, negotiate licenses to conduct its business. If Edwards Lifesciences is unable to redesign its products or obtain a license, Edwards Lifesciences may have to exit a particular product offering.

Edwards Lifesciences faces intense competition and consolidation within its industry, and if Edwards Lifesciences does not compete effectively, its business will be harmed.

The cardiovascular medical device industry is highly competitive. Edwards Lifesciences competes with many companies, some of which have longer operating histories, better brand or name recognition and greater access to financial and other resources than Edwards Lifesciences. Furthermore, the industry is characterized by intensive development efforts and rapidly advancing technology. Edwards Lifesciences' present and future products could be rendered obsolete or uneconomical by technological advances made by one or more of its current or future competitors or by alternative therapies, including drug therapies. See "Business — Competition" included herein. Edwards Lifesciences' future success will depend, in large part, on its ability to develop and acquire new products and technologies, anticipate technology advances and keep pace with other developers of cardiovascular therapies and technologies.

The medical device industry has been consolidating and, as a result, transactions with customers are larger, more complex and tend to involve more long-term contracts. The enhanced purchasing power of these larger customers may also increase downward pressure on product pricing. In addition, many existing and potential domestic customers for Edwards Lifesciences' products have combined to form group purchasing organizations, or "GPOs." GPOs negotiate pricing arrangements with medical supply manufacturers and distributors and these negotiated prices are made available to members of GPOs. If Edwards Lifesciences is not one of the providers selected by a GPO, it may be precluded from making sales to members of a GPO. Even if Edwards Lifesciences is one of the selected providers, it may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, Edwards Lifesciences may be required to commit to pricing that has a material adverse effect on its sales and profit margins, business, financial condition and results of operations.

Edwards Lifesciences and its customers are subject to various governmental regulations, and Edwards Lifesciences may incur significant expenses to comply with these regulations and develop its products to be compatible with these regulations.

The medical devices manufactured and marketed by Edwards Lifesciences are subject to rigorous regulation by the U.S. Food and Drug Administration, or "FDA," and numerous other federal, state and foreign governmental

authorities. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products could result in delayed realization of product revenues or in substantial additional costs, which could have material adverse effects on Edwards Lifesciences' business or results of operations. In addition, there can be no assurance that Edwards Lifesciences will be or will continue to be in compliance with applicable FDA and other material regulatory requirements. If the FDA or some other foreign governmental authority were to conclude that Edwards Lifesciences was not in compliance with applicable laws or regulations, the FDA or such other foreign governmental authority, as applicable, could institute proceedings to detain or seize Edwards Lifesciences' products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against Edwards Lifesciences, its officers or its employees and could recommend criminal prosecution to the Department of Justice. Moreover, the FDA or some other foreign governmental authority could proceed to ban, or request recall, repair, replacement or refund of the cost of, any device or product manufactured or distributed by Edwards Lifesciences. Furthermore, both the FDA and foreign government regulators have become increasingly stringent, and Edwards Lifesciences may be subject to more rigorous regulation by governmental authorities in the future.

Unsuccessful clinical trials or developmental procedures relating to products and development could have a material adverse effect on Edwards Lifesciences' prospects.

The development of new products by Edwards Lifesciences requires extensive clinical trials and procedures. There can be no assurance that these trials or procedures will be successful or completed in a timely or cost effective manner. Failure to successfully complete these trials or procedures in a timely and cost effective manner could have a material adverse effect on the Company's prospects. In addition, current results from the Company's clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If current results for a Company product cannot be supported by actual long-term studies or clinical experience, the Company's business could be adversely effected.

Edwards Lifesciences is subject to risks arising from concerns and/or regulatory actions relating to "mad cow disease."

Certain of Edwards Lifesciences' products, including pericardial tissue valve products, are manufactured using bovine tissue. Concerns relating to the potential transmission of bovine spongiform encephalopathy, or "BSE," commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of bovine products. Edwards Lifesciences obtains its bovine tissue only from closely controlled sources within the United States and Australia. In December 2003, one case of a cow infected with BSE was reported in the United States. In response to this situation, the U.S. Department of Agriculture announced new strengthened control and surveillance measures with respect to BSE. To date, there have been no additional reported cases in the United States. The bovine tissue used in Edwards Lifesciences' pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. Edwards Lifesciences has not experienced any significant adverse impact on its sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

If third party payors decline to reimburse Edwards Lifesciences' customers for its products or reduce reimbursement levels, Edwards Lifesciences' ability to profitably sell its products will be harmed.

Edwards Lifesciences sells its products and technologies to hospitals, doctors and other health care providers, all of which receive reimbursement for the health care services provided to its patients from third party payors, such as government programs (both domestic and international), private insurance plans and managed care programs. These third party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third party payors, or was used for an unapproved indication. Third party payors may also decline to reimburse for experimental procedures and devices. Edwards Lifesciences believes that many of its existing and future products are cost-effective because they are

intended to reduce overall health care costs over a long period of time. Edwards Lifesciences cannot be certain whether these third party payors will recognize these cost savings or will merely focus on the lower initial costs associated with competing therapies. If Edwards Lifesciences' products are not considered cost-effective by third party payors, Edwards Lifesciences' customers may not be reimbursed for its products.

In addition, third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for and price levels of Edwards Lifesciences' products. In Japan, customers are reimbursed for Edwards Lifesciences' products under a government-operated insurance system. Under this system, the Japanese government annually reviews the reimbursement levels for products. The Japanese government is also considering other reimbursement regulation. If the Japanese government decides to reduce reimbursement levels for Edwards Lifesciences products, its product pricing may be adversely affected.

Edwards Lifesciences is, or may be, subject to lawsuits related to products or services manufactured or performed by the Company.

Edwards Lifesciences is, or may be, a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products and services currently or formerly manufactured or performed, as applicable, by the Company or other matters. Such cases and claims may raise difficult and complex factual and legal issues and may be subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any pending legal matters or other claims, Edwards Lifesciences may incur charges in excess of presently established reserves. While such a charge could have a material adverse impact on Edwards Lifesciences' net income or net cash flows in the period in which it is recorded or paid, management believes that no such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' consolidated financial position.

Edwards Lifesciences may incur increased costs as a result of recent changes in laws and regulations affecting public companies.

Compliance with recent changes in laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, may result in increased accounting, legal and administrative costs. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 and the rules of the Securities and Exchange Commission and the Public Company Accounting Oversight Board impose new requirements with respect to the evaluation of the effectiveness of the Company's internal controls. The cost of complying with these new requirements could be substantial.

The market price for Edwards Lifesciences' common stock may be volatile.

The market price of Edwards Lifesciences' common stock could fluctuate substantially in the future in response to any of the other risk factors set out above and below as well as a number of factors, including the following:

- quarterly variations in operating results, as discussed above under "— Fluctuations in Edwards Lifesciences' quarterly operating results may cause its stock price to decline;"
- announcements of innovations, new products, strategic developments or business combinations by Edwards Lifesciences or its competitors;
- changes in Edwards Lifesciences expected operating expense levels or income and losses;

- changes in financial estimates and recommendations of securities analysts;
- the operating and securities price performance of other companies that investors may deem comparable to Edwards Lifesciences; and
- changes in general conditions in the economy, the financial markets, the domestic or international political situation or the medical device industry.

In addition, in recent years the stock market has experienced extreme price and volume fluctuations. This volatility has had a significant effect on the market prices of securities issued by many companies for reasons unrelated to their operating performance. These broad market fluctuations may materially adversely affect Edwards Lifesciences' stock price, regardless of its operating results.

Edwards Lifesciences' stockholder rights plan, charter and bylaws, as well as provisions of Delaware law and the change in control provisions of the 3.875% convertible senior debentures issued by Edwards Lifesciences, could make it difficult for a third party to acquire the Company.

Edwards Lifesciences has a stockholder rights plan that may have the effect of discouraging unsolicited takeover proposals. The rights issued under the stockholder rights plan would cause substantial dilution to a person or group that attempts to acquire Edwards Lifesciences on terms not approved in advance by its board of directors. In addition, Delaware corporate law and Edwards Lifesciences' charter and bylaws contain provisions that could delay, deter or prevent a change in control of the Company or its management. These provisions could also discourage proxy contests and make it more difficult for Edwards Lifesciences' stockholders to elect directors and take other corporate actions without the concurrence of its management or board of directors. These provisions:

- authorize Edwards Lifesciences' board of directors to issue "blank check" preferred stock, which is preferred stock that can be created and issued by its board of directors, without stockholder approval, with rights senior to those of common stock;
- provide for a staggered board of directors and three-year terms for directors, so that no more than one-third of Edwards Lifesciences' directors could be replaced at any annual meeting;
- provide that directors may be removed only for cause;
- provide that stockholder action may be taken only at a special or regular meeting and not by written consent;
- provide for super majority voting requirements for some provisions of Edwards Lifesciences' charter; and
- establish advance notice requirements for submitting nominations for election to the board of directors and for proposing matters that can be acted upon by stockholders at a meeting.

Edwards Lifesciences is also subject to anti-takeover provisions under Delaware law, which could also delay or prevent a change of control. Together, these provisions of Edwards Lifesciences' charter and bylaws, Delaware law and its stockholder rights plan may discourage transactions that otherwise could provide for the payment of a premium over prevailing market prices of Edwards Lifesciences' common stock, and also could limit the price that investors are willing to pay in the future for shares of its common stock.

In addition, if Edwards Lifesciences undergoes a change in control (as defined in the indenture relating to Edwards Lifesciences' 3.875% convertible senior debentures) prior to May 15, 2008, the holders of the 3.875% convertible senior debentures have the right, at their option, to require Edwards Lifesciences to purchase all or a portion of the debentures they hold. In addition, certain change in control events relating to the Company may constitute or otherwise result in events of default under the Company's other debt instruments or its receivables facilities, which could result in borrowings outstanding and other amounts due under those debt instruments and receivables facilities becoming immediately due and payable. These features of Edwards

Lifesciences' 3.875% convertible senior debentures and other debt instruments and receivables facilities may also discourage a person or a group from attempting to acquire Edwards Lifesciences.

Edwards Lifesciences' issuance of preferred stock could adversely affect holders of its common stock and discourage a takeover.

Edwards Lifesciences' board of directors is authorized to issue up to 50,000,000 shares of preferred stock without any action on the part of its stockholders. Edwards Lifesciences' board of directors also has the power, without stockholder approval, to set the terms of any series of preferred stock that may be issued, including voting rights, dividend rights, preferences over its common stock with respect to dividends or in the event of a dissolution, liquidation or winding up and other terms. In the event that Edwards Lifesciences issues preferred stock in the future that has preference over its common stock with respect to payment of dividends or upon its liquidation, dissolution or winding up, or if Edwards Lifesciences issues preferred stock with voting rights that dilute the voting power of its common stock, the rights of the holders of its common stock or the market price of its common stock could be adversely affected. In addition, the ability of Edwards Lifesciences' board of directors to issue shares of preferred stock without any action on the part of its stockholders may impede a takeover of Edwards Lifesciences and prevent a transaction favorable to the holders of its common stock.

Future sales of common stock in the public market could adversely affect the trading price of Edwards Lifesciences' common stock and its ability to raise funds in new securities offerings.

Future sales of substantial amounts of the common stock of Edwards Lifesciences in the public market, or the perception that such sales could occur, could adversely affect prevailing trading prices of the common stock of Edwards Lifesciences that it may issue and could impair its ability to raise capital through future offerings of equity or equity-related securities. As of December 31, 2004, Edwards Lifesciences had:

- 59,438,236 shares of common stock outstanding;
- 9,883,077 shares of common stock reserved for issuance upon exercise of options outstanding under Edwards Lifesciences' stock option plans with a weighted average exercise price of $23.90 per share;
- in addition to the shares reserved for issuance upon the exercise of options referred to in the preceding bullet point, 2,872,872 additional shares reserved for future issuance under stock option plans and employee stock purchase plans; and
- 2,744,238 shares of common stock reserved for issuance upon conversion of Edwards Lifesciences' outstanding 3.875% convertible senior debentures.

No prediction can be made as to the effect, if any, that future issuances of shares of common stock or the availability of shares of common stock for future sale, will have on the trading price of our common stock. Issuances of substantial amounts of common stock, or the perception that such issuances could occur, may adversely affect prevailing market prices for our common stock.

Item 2. ***Properties***

The locations and uses of the major properties of Edwards Lifesciences are as follows:

North America		
Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs and Manufacturing
Memphis, Tennessee	(1)	Distribution and Logistics
Midvale, Utah	(1)	Administration, Research and Development and Manufacturing
Haina, The Dominican Republic	(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing
Europe		
Saint Prex, Switzerland	(2)	Administration and Marketing
Horw, Switzerland	(2)	Administration, Distribution and Manufacturing
South America		
São Paulo, Brazil	(1),(2)	Administration, Distribution and Manufacturing
Japan		
Tokyo, Japan	(2)	Japan Headquarters, Distribution
Miyazaki, Japan	(2)	Manufacturing, Distribution

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2006; the Puerto Rico lease expires in 2008; the Horw, Switzerland lease expires in 2007; the Saint Prex, Switzerland lease expires in 2005; the São Paulo, Brazil lease expires in 2009; the Tokyo, Japan lease expires in 2009; and the Miyazaki, Japan lease expires in 2007. The Company's properties have been well maintained, are in good operating condition and are adequate for current needs.

Item 3. ***Legal Proceedings***

On June 29, 2000, Edwards Lifesciences filed a lawsuit against St. Jude Medical, Inc. alleging infringement of several Edwards Lifesciences United States patents. This lawsuit was filed in the United States District Court for the Central District of California, seeking monetary damages and injunctive relief. Pursuant to the terms of a January 7, 2005 settlement agreement, Edwards Lifesciences was paid $5.5 million by St. Jude, Edwards Lifesciences granted St. Jude a paid-up license for certain of its heart valve therapy products and the lawsuit was dismissed. The settlement will not have a material financial impact on the Company.

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc., Medtronic AVE, Cook, Inc. and W.L. Gore & Associates alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. On September 2, 2003, a second patent exclusively licensed to the Company was added to the lawsuit. Each of the defendants has answered and asserted various affirmative defenses and counterclaims. Discovery is proceeding.

In addition, Edwards Lifesciences is or may be a party to, or may be otherwise responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of

each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any pending legal matters, Edwards Lifesciences may incur charges in excess of presently established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or net cash flows in the period in which it is recorded or paid, management does not believe that any such charge would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is also subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2004.

PART II

Item 5. ***Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Unregistered Sales of Equity Securities and Use of Proceeds

Calendar Quarter Ended	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs(a)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs(a)
March 31, 2004	465,000	$31.60	465,000	443,600
June 30, 2004	344,700	$34.12	344,700	2,098,900
September 30, 2004	203,600	$34.45	203,600	1,895,300
December 31, 2004	699,900	$36.69	699,900	1,195,400
Total	1,713,200	$34.53	1,713,200	1,195,400

(a) On May 6, 2003, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 2.0 million shares of the Company's common stock through December 31, 2005. This program was completed in August 2004. On May 12, 2004, the Company announced that the Board of Directors approved an additional stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 2.0 million shares of the Company's common stock through December 31, 2006.

Market Price

The principal market for Edwards Lifesciences' common stock is the New York Stock Exchange (the "NYSE"). The table below sets forth, for the calendar quarters indicated, the high and low sales prices of Edwards Lifesciences' common stock as reported by the NYSE.

	2004		2003	
	High	Low	High	Low
Calendar Quarter Ended:				
March 31	$35.52	$29.61	$27.64	$24.40
June 30	36.58	31.88	33.60	26.95
September 30	36.52	32.77	32.65	25.77
December 31	42.26	32.60	31.56	26.90

Number of Stockholders

On February 25, 2005, there were 35,578 stockholders of record of Edwards Lifesciences' common stock.

Dividends

Edwards Lifesciences has never paid any cash dividends on its capital stock and has no current plans to pay any cash dividends. The current policy of Edwards Lifesciences is to retain any future earnings for use in the business of the Company.

Item 6. ***Selected Financial Data***

The following table sets forth selected financial information with respect to Edwards Lifesciences. The information set forth below should be read in conjunction with Edwards Lifesciences' "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Consolidated Financial Statements" found elsewhere in this Form 10-K. See Note 6 to the "Consolidated Financial Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for discussions of the effect of certain asset divestitures on Edwards Lifesciences' operations.

	As of or for the Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In millions except per share data)				
Operating Results(a)					
Net sales	$ 931.5	$ 860.5	$ 704.0	$692.1	$ 803.8
Gross profit	561.3	501.1	404.9	368.4	380.5
Income (loss) from continuing operations(b)	1.7	79.0	55.7	(11.4)	(271.7)
Balance Sheet Data					
Total assets(c)	$1,112.7	$1,101.4	$1,004.4	$982.9	$1,106.7
Long-term debt and lease obligations	267.1	255.8	245.5	309.8	367.2
Common Stock Information(d)					
Income (loss) from continuing operations per common share:					
Basic	$ 0.03	$ 1.34	$ 0.94	$ (0.19)	—
Diluted	0.03	1.29	0.91	(0.19)	—
Cash dividends declared per common share	—	—	—	—	—

(a) The results prior to April 1, 2000 present Edwards Lifesciences on a divisional basis as it had historically been operated as part of Baxter International Inc. ("Baxter"). From April 1, 2000 (the date following the distribution of the Company's common stock to stockholders of Baxter) to September 30, 2002, Edwards Lifesciences' Japan business is presented on an equity basis. Commencing October 1, 2002, the Company began reporting the results of its Japan business on a fully consolidated basis. See "Joint Venture in Japan" in "Management's Discussion and Analysis of Financial Condition and Results of Operations" for more information.

(b) See Notes 4 to 6 to the "Consolidated Financial Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information regarding charges of $110.5 million, $37.1 million and $70.7 million during 2004, 2003 and 2002, respectively. During 2001, the Company recorded a loss of $68.2 million, related to the sale of Edwards Lifesciences Cardiovascular Resources, Inc. ("ELCR") to Fresenius Medical Care AG and an impairment of the long-lived assets and investments related to certain products that the Company decided to discontinue selling. Additionally, during 2000, the Company recorded charges of $312.2 million related primarily to the sale of its perfusion products in the United States and Western Europe to Jostra AG.

(c) During 2001, the Company wrote down goodwill by $83.0 million in connection with the sale of ELCR. Additionally, during 2000, the Company wrote down goodwill by $282.0 million in connection with the sale of its perfusion products in the United States and Western Europe to Jostra AG.

(d) No per share data for the 2000 year has been presented because Edwards Lifesciences' earnings were part of Baxter's earnings through the close of business on March 31, 2000.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis presents the factors that had a material effect on the results of operations of Edwards Lifesciences during the three years ended December 31, 2004. Also discussed is Edwards Lifesciences' financial position as of December 31, 2004. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K.

Overview

Edwards Lifesciences is a global provider of products and technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address specific cardiovascular opportunities: heart valve disease; peripheral vascular disease; and critical care technologies.

The products and services provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; Vascular and Other Distributed Products.

Edwards Lifesciences' **heart valve therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **critical care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's heart function, in disposable pressure transducers, and in central venous access products for fluid and drug delivery. The Company's **cardiac surgery systems** portfolio comprises a diverse line of products for use during cardiac surgery including oxygenators, blood containers, filters and other disposable products used during cardiopulmonary bypass procedures, as well as cannulae and transmyocardial revascularization ("TMR") technology. Edwards Lifesciences' **vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, angioscopy equipment, artificial implantable grafts, and stents used in the treatment of peripheral vascular disease. Lastly, **other distributed products** include sales of intra-aortic balloon pumps and other products sold primarily though the Company's distribution network in Japan.

The healthcare marketplace continues to be competitive with strong local and global competitors resulting in pressure on maintaining market share. Global demand for healthcare is increasing as the population ages. There is mounting pressure to contain healthcare costs in the face of this increasing demand, which has resulted in pricing pressures. Management expects these trends to continue.

Joint Venture in Japan

Prior to October 1, 2002, the cardiovascular business in Japan was being operated pursuant to a joint venture. A subsidiary of Edwards Lifesciences held a 90% profit interest and (a) recognized its shipments into the joint venture as sales at distributor price at the time the joint venture sold to the end customer and (b) utilized the equity method of accounting to record its 90% profit interest in the operations of the joint venture in Other Income. On October 1, 2002, the Company acquired the cardiovascular business in Japan from Baxter and began reporting the results of the Japan business on a fully consolidated basis. The acquisition did not materially impact the Company's net income as the terms of the joint venture agreement enabled Edwards Lifesciences to record substantially all of the net profit generated by the Japan business.

Results of Operations

Net Sales Trends

The following is a summary of United States and international net sales (dollars in millions):

	Years Ended December 31,			Percent Change	
	2004	2003	2002	2004	2003
United States	$416.5	$384.3	$383.3	8.4%	0.3%
International	515.0	476.2	320.7	8.1%	48.5%
Total net sales	$931.5	$860.5	$704.0	8.3%	22.2%

The increase in net sales in the United States in 2004 was due primarily to increased sales in heart valve therapy products, which was driven by sales of the Company's *Carpentier-Edwards PERIMOUNT and PERIMOUNT Magna* aortic valves and the *PERIMOUNT* valves with *Tricentrix* holder.

The increases in international net sales in 2004 can be explained primarily by:

- foreign currency exchange rate fluctuations which increased net sales by $38.5 million (primarily the strengthening of the Euro and the Japanese yen against the United States dollar);
- heart valve therapy products, which increased net sales by $15.5 million driven primarily by strong *PERIMOUNT* valve sales in Europe;

partially offset by a decrease in net sales of $14.9 million due to the sale of the Company's German and Italian perfusion services businesses and the discontinuation of the *Lifepath AAA* program and a decrease in net sales in Japan resulting primarily from reimbursement changes.

The increase in international net sales in 2003 was due primarily to the following:

- the change in accounting for Japan (see "Joint Venture in Japan") increased net sales by $77.9 million;
- the impact of changes in foreign currency exchange rates increased net sales by $46.7 million (primarily the strengthening of the Euro and Japanese yen against the United States dollar); and
- increased sales of heart valve therapy and vascular products (see below).

The impact of foreign currency exchange rate fluctuations on net sales would not necessarily be indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs, and Edwards Lifesciences' hedging activities. For more information see "Quantitative and Qualitative Disclosure About Market Risk."

Net Sales by Product Line

The following is a summary of net sales by product line (dollars in millions):

	Years Ended December 31,			Percent Change	
	2004	2003	2002	2004	2003
Heart Valve Therapy	$419.2	$366.4	$314.5	14.4%	16.5%
Critical Care	302.3	278.8	230.3	8.4%	21.1%
Cardiac Surgery Systems	107.3	115.0	94.6	(6.7)%	21.6%
Vascular	60.1	55.9	51.3	7.5%	9.0%
Other Distributed Products	42.6	44.4	13.3	(4.1)%	233.8%
Total net sales	$931.5	$860.5	$704.0	8.3%	22.2%

Heart Valve Therapy

The net sales growth of heart valve therapy products in 2004 can be explained primarily by:

- pericardial tissue valves increased net sales by $37.9 million primarily as a result of strong market adoption of the Company's *Carpentier-Edwards PERIMOUNT Magna* valve in the United States and Europe;
- foreign currency exchange rate fluctuations, which increased net sales by $14.3 million (primarily the strengthening of the Euro and Japanese yen against the United States dollar);
- heart valve repair products increased net sales by $5.6 million;

partially offset by decreased sales of porcine tissue valves of $5.1 million.

The net sales growth of heart valve therapy products in 2003 resulted primarily from the following:

- pericardial tissue valves increased net sales by $18.4 million;
- currency exchange rate fluctuations increased net sales by $16.5 million (primarily the strengthening of the Euro and Japanese yen against the United States dollar);
- the change in accounting for Japan increased net sales by $7.9 million; and
- heart valve repair products increased net sales by $6.7 million.

As the Company's *Carpentier-Edwards PERIMOUNT Magna* valve and the other recently introduced products have been well received globally, the Company expects that sales growth of heart valve therapy products in 2005 will exceed 10%. The Company will expand the availability of its *Carpentier-Edwards PERIMOUNT Magna* valve with *ThermaFix,* an anti-calcification process, in 2005 and expects the enhancement to drive further adoption among younger patients.

In Japan, where only one competitor offered a stentless valve, the Company has received both regulatory clearance and reimbursement approval of its *Edwards PrimaPlus* stentless valve. *PrimaPlus* stentless valves expand the Company's product offering into the niche stentless valve market and strengthens the Company's market position in this region.

The Company expects to strengthen its market leadership position in heart valve repair products with the introduction in the second half of 2005 of a new product with an indication-specific design.

Critical Care

The net sales growth of critical care products in 2004 can be explained primarily by:

- foreign currency exchange rate fluctuations, which increased net sales by $13.4 million (primarily the strengthening of the Euro and the Japanese yen against the United States dollar);
- market share gains in pressure monitoring products, which increased net sales by $8.4 million; and
- overall strong sales demand in markets outside of Europe and Japan;

partially offset by decreased sales of base catheter products, which decreased net sales by $6.1 million, and recent reimbursement decreases in Japan.

The net sales growth of critical care products in 2003 resulted primarily from the following:

- the change in accounting for Japan increased net sales by $20.8 million;
- currency exchange rate fluctuations increased net sales by $16.6 million (primarily the strengthening of the Euro and Japanese yen against the United States dollar); and
- strong sales in global pressure monitoring products and overall strong sales demand in emerging global markets.

Critical care products have been, and are expected to be, significant contributors to the Company's total sales. Minimally invasive monitoring systems, featuring the Company's *FloTrac* system, represent a new and potentially market-expanding opportunity for the Company. The Company received 510(k) clearance for the *FloTrac* system in January 2005 and expects to launch this product during the second quarter of 2005.

Cardiac Surgery Systems

The net sales decrease of cardiac surgery systems in 2004 can be explained primarily by:

- the sale of the Company's German and Italian perfusion services businesses in July 2003 and June 2004, respectively, which decreased net sales by $11.4 million;
- perfusion products in Japan, which decreased net sales by $3.8 million; partially offset by
- foreign currency exchange rate fluctuations, which increased net sales by $5.0 million (primarily the strengthening of the Euro and the Japanese yen against the United States dollar); and
- cannula products which increased net sales by $3.3 million.

The net sales growth of cardiac surgery systems for 2003 resulted primarily from the following:

- the change in accounting for Japan increased net sales by $16.6 million;
- currency exchange rate fluctuations increased net sales by $6.4 million (primarily the strengthening of the Euro and Japanese yen against the United States dollar);

partially offset by:

- the reduction of low-margin distributed product sales in North America, which decreased net sales by $3.9 million; and
- the sale of the Company's German perfusion services subsidiary in July 2003, which decreased net sales by $3.2 million.

During the second quarter of 2004, the Company completed the sale of its Italian perfusion services business, which generated approximately $4.3 million of revenue in fiscal year 2003.

In January 2005, the Company sold its Japan perfusion products business and expects to complete the transition of this business to the buyer in 2006. This business generated approximately $26.4 million in sales in 2004. Throughout the transition period, the Company will continue to act as supplier and expects sales of approximately half the level of 2004.

Vascular

The net sales growth of vascular products for 2004 resulted primarily from the following:

- currency exchange rate fluctuations increased net sales by $2.6 million (primarily the strengthening of the Euro and the Japanese yen against the United States dollar);
- sales of interventional products which increased net sales by $2.4 million;

partially offset by the discontinuation of the *Lifepath AAA* program effective June 30, 2004, which decreased net sales by $2.6 million.

The net sales growth of vascular products for 2003 resulted primarily from the following:

- currency exchange rate fluctuations increased net sales by $3.8 million (primarily the strengthening of the Euro and the Japanese yen against the United States dollar);
- the change in accounting for Japan increased net sales by $2.0 million;
- *Lifepath AAA* sales increased net sales by $1.3 million, primarily in Europe;

partially offset by continued declines in base vascular products.

During 2004, the Company continued to introduce *LifeStent* products in the United States and Europe. The Company believes the supply constraints experienced during 2004 have been resolved and sales are expected to increase during 2005. Customer feedback on the *LifeStent* products has been positive, and the Company continues to believe that there is a large opportunity in the peripheral stent market.

Other Distributed Products

The decrease in net sales of other distributed products in 2004 was due primarily to the Company's de-emphasis of certain lower margin distributed cardiology products in Japan. The net sales for 2003 increased primarily due to the impact of the change in accounting for Japan.

The Company discontinued sales in Japan of certain lower margin distributed cardiology products effective September 2004. Additionally, the Company discontinued its distributed, low margin pacemaker business in Japan, in the first quarter of 2005. This product line generated sales of approximately $10.9 million in 2004.

Gross Profit

	Year Ended December 31,			Percentage Point Increase	
	2004	2003	2002	2004	2003
Gross profit as a percentage of net sales	60.3%	58.2%	57.5%	2.1 pts.	0.7 pts.

Gross profit as a percentage of net sales for 2004 increased compared to the prior year due primarily to the impact of foreign currency rate fluctuations, including hedging activities (1.3 percentage points), the elimination of certain lower margin businesses (0.6 percentage points), and increased sales of higher margin products partially offset by reimbursement decreases in Japan.

The increase in gross profit as a percentage of net sales for 2003 resulted primarily from improved manufacturing performance (1.9 percentage points) and the benefit of the consolidation of the Japan business

effective October 1, 2002 (0.7 percentage points), partially offset by increased hedging expenses (2.1 percentage points).

Selling, General and Administrative ("SG&A") Expenses

	Years Ended December 31,			Change	
	2004	2003	2002	2004	2003
SG&A expenses	$319.9	$289.9	$227.9	$30.0	$62.0
SG&A expenses as a percentage of net sales	34.3%	33.7%	32.4%	0.6 pts.	1.3 pts.

The increase in selling, general and administrative expenses in 2004 was due primarily to higher international expenses due to changes in foreign exchange rates ($12.6 million) and higher sales and marketing expenses in the peripheral stent and heart valve therapy product lines in the United States.

The increase in selling, general and administrative expenses in 2003 resulted primarily from the change in accounting for the Japan business effective October 1, 2002 ($34.0 million), the impact of foreign currency rate fluctuations, primarily the strengthening of the Euro and Japanese yen against the United States dollar ($12.8 million), and activities in support of increased sales.

The increase in selling, general and administrative expenses as a percentage of net sales for 2004 was due primarily to the increased investment in United States sales and marketing expenses in the peripheral stent and heart valve therapy product lines, partially offset by the cost reductions made in the third quarter of 2003.

The increase in selling, general and administrative expenses as a percentage of net sales for 2003 resulted primarily from the consolidation of the Japan business effective October 1, 2002 (1.1 percentage point increase) and foreign currency rate fluctuations (0.2 percentage point increase, primarily the strengthening of the Euro and Japanese yen against the United States dollar).

Research and Development Expenses

	Years Ended December 31,			Change	
	2004	2003	2002	2004	2003
Research and development expenses	$87.0	$72.8	$65.2	$14.2	$7.6
Research and development expenses as a percentage of net sales	9.3%	8.5%	9.3%	0.8 pts.	(0.8) pts.

The increase in research and development expenses for 2004 resulted primarily from additional investment in the Company's percutaneous valve programs and the amortization of the Percutaneous Valve Technologies, Inc. ("PVT") intangibles of $14.4 million, partially offset by reduced spending in the *Lifepath AAA* program.

The increases in research and development expenses for 2003 resulted primarily from investments in a broad range of interventional technologies, including market expanding endovascular heart valve repair and replacement therapies, investments in the Company's peripheral vascular disease platform and other growth initiatives.

Research and development expenses as a percentage of net sales for 2004 increased compared to the prior year due primarily to the amortization and additional research and development spending related to PVT.

The decrease in research and development expenses as a percentage of net sales for 2003 resulted primarily from the consolidation of the Japan business effective October 1, 2002.

Purchased in-process Research and Development Expenses

On September 29, 2004, the Company acquired all technology and intellectual property associated with ev3, Inc.'s ("ev3") percutaneous mitral valve repair program for total consideration of $15.0 million. The acquisition is expected to be utilized in the Company's existing percutaneous mitral valve repair research and development efforts. At the time of the purchase, ev3 had been unsuccessful in developing a viable prototype and had discontinued the program. Additional design developments, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of European and United States regulatory approvals. Approximately $12.3 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately $39 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, the Company estimated completion of the mitral valve repair program utilizing the intellectual property acquired from ev3 in 2009, and commencement of net cash inflows in 2010. The remaining fair market value of the assets purchased consisted primarily of patents unrelated to ev3's core mitral valve repair technology, which are being amortized over their estimated economic life of 19 years.

On January 27, 2004, the Company acquired PVT, a development stage company, for $125.0 million in cash, net of cash acquired, plus up to an additional $30.0 million upon the achievement of key milestones through 2007. Included in PVT's technology is a catheter-based (percutaneous) approach for replacing aortic heart valves, comprised of a proprietary percutaneously-delivered balloon-expandable stent technology integrated with a tissue heart valve. Unlike conventional open-heart valve replacement surgery, this less-invasive procedure can be performed under local anesthesia and could potentially be a breakthrough for patients seeking an alternative to open-heart surgery.

At the time of acquisition, the PVT aortic heart valve was being used in compassionate cases in Europe, and these clinical results had generated valuable feasibility data. It had been demonstrated that a heart valve could be successfully deployed and anchored using a catheter-based system. Also at that time, the Company was expecting to obtain a CE mark in Europe by the end of 2005 and to file for a Humanitarian Device Exemption ("HDE") in the United States. Upon approval of the HDE, the Company would be able to offer this device to as many as 4,000 patients per year. Broader commercialization in the United States was expected to begin with the submission of an Investigational Device Exemption ("IDE") by the end of the second quarter of 2004 followed by the commencement of a pivotal trial in 2005 and possible pre-market approval by the end of 2007. The risks and uncertainties associated with completing development within a reasonable period of time included those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies and the timing of European and United States regulatory approvals.

Approximately $81.0 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 25%. The valuation assumed approximately $20.9 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were forecasted to commence in 2007. The remaining fair market value of the net assets acquired consisted primarily of patents of $72.4 million that are being amortized over their estimated economic life of 11 years, and a deferred tax liability related to the patents of $28.1 million.

On December 5, 2003, the Company acquired the stock of Whitland Research Limited ("Whitland") for $3.2 million in cash, although achievement of future milestones through 2006 could increase the total price to $5.6 million. Whitland was focused on the development of critical care monitoring technologies. The $3.2 million purchase price was allocated to acquired in-process research and development ($1.8 million) and patents

($1.4 million) based upon their estimated fair values. The patents are being amortized over their estimated useful life of 10 years.

On February 18, 2003, the Company acquired the percutaneous mitral valve repair program of Jomed N.V. ("Jomed"), a European-based provider of products for minimally invasive cardiovascular intervention, for $20.0 million in cash. The acquisition included all technology and intellectual property associated with the program. At the acquisition date, the program, which was less than 50% complete, was involved in testing proprietary prototypes prior to initiating required pre-clinical studies and human clinicals. Additional design improvements, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to commercially selling the product in Europe and the United States, which at the time of the transaction was expected in 2005 and 2006, respectively. The risks and uncertainties associated with completing development within a reasonable period of time included those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies and the timing of European and United States regulatory approvals. Approximately $11.8 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately $20.0 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, material net cash inflows were forecasted to commence in 2008. The remaining fair market value of the assets acquired consisted primarily of patents that are being amortized over their estimated economic life of 17 years.

Progress continues to be made on all of the purchased research and development programs. As of December 31, 2004 the programs related to the ev3 and Whitland acquisitions remained reasonably on track with the Company's original expectations. Although the PVT program remains reasonably on track with original expectations, the CE Mark is now expected in 2006, a conditional IDE was granted in the United States in January 2005, broad commercialization in the United States is anticipated in three to four years, and the HDE filing has been postponed. In January 2005, the Company commenced human feasibility studies of the product developed under the Jomed program. Commercialization of this product would be expected to occur in several years.

Asset Impairments

In September 2002, the Company recorded a $67.4 million charge related to the impairment of its investment in preferred stock of World Heart Corporation ("WorldHeart"). The investment was written down to $6.2 million, which represented the value of the Company's preferred stock investment had it been converted into common stock at October 15, 2002 (the closing date of September's books). The decision to record the charge was based primarily on WorldHeart's September 2002 decision to refocus its product development efforts by adopting a new design concept for a next generation product that resulted in a significant delay (approximately two years) in its product development timeline (with a revised commercial launch date of 2007) and impaired WorldHeart's competitive position. Accordingly, the Company concluded that sufficient risk existed that WorldHeart may be unable to fully liquidate the Company's investment in WorldHeart's preferred stock. The Company believed that the best objective indicator of the then fair value of its investment in WorldHeart's preferred stock was the market price of WorldHeart's common stock based upon the Company's expectation that the value of its preferred stock investment would be realized through the common stock, as opposed to redemption of the preferred stock. In December, 2004, the Company recorded an additional charge of $4.7 million related to the impairment of its investment in WorldHeart resulting from the decline in its stock price.

Additionally, in 2004, the Company recorded charges totaling $4.3 million related to the other-than-temporary impairment of technology investments in three unconsolidated affiliates. Two of the affiliates had announced they were discontinuing their development efforts and the book value of those investments was reduced to the residual distribution Edwards Lifesciences expects to receive from those companies. The other affiliate

performed a reset financing that reduced the net value per share for all existing investors. This investment is now recorded at the reduced value.

Special Charges, net

Discontinued Products

Due to a re-prioritization of the Company's investment initiatives, the Company decided in March 2004 to discontinue its sales effort of its *Lifepath AAA* endovascular graft program. In the first quarter of 2004, the Company recorded a special charge of $8.4 million related primarily to inventory and contractual clinical obligations. In addition, the Company discontinued certain lower margin cardiology products in Japan resulting in a charge of $2.2 million related primarily to other non-productive assets.

Sale of Property Development Rights

In November 2004, the Company recorded income of $7.4 million for the sale of property development rights in Irvine, California, that had no book value at the time of the sale.

Charitable Fund

In December 2004, the Company recorded a charge of $5.0 million for an irrevocable contribution to a third party to create a charitable fund.

Severance Charge

In July 2003, the Company recorded a charge of $13.0 million associated with a decision to streamline operations. The charge was related primarily to the severance costs associated with reducing the Company's worldwide workforce by 136 employees, primarily in the United States and Europe. As of December 31, 2004, $0.3 million of the charge remained unpaid.

Baxter Arbitration Settlement

In January 2004, the Company concluded a dispute resolution proceeding with Baxter. Each company sought reimbursement from the other for a variety of claims arising from the Company's spin-off from Baxter in April 2000. The resolution resulted in a $5.3 million charge related primarily to the valuation of receivables at the date of spin-off, and a $5.4 million increase to Additional Contributed Capital related to the true-up of the beginning balance of equity.

Loss on Sale of Business

Effective July 4, 2003, the Company sold its German perfusion services subsidiary to WKK GmbH, a German-based provider of hospital services, for a nominal amount. Sales generated by the German perfusion services subsidiary were approximately $3.5 million during the six months ended June 30, 2003 and $6.6 million for the year 2002. In accordance with SFAS No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets,"* and Staff Accounting Bulletin No. 100, *"Restructuring and Impairment Charges,"* the Company recorded a pre-tax impairment charge of $3.3 million in the second quarter of 2003 to reduce the carrying value of the subsidiary's assets to fair value based upon the proceeds from the sale.

Pension Curtailment

On November 4, 2003, the Company suspended its defined benefit pension plan in Puerto Rico ("the Plan"). Effective December 31, 2003, employees ceased earning additional defined benefits for future services. To mitigate the Puerto Rico employees' reduced benefits from the Plan's suspension, effective January 1, 2004, the Company

increased its contributions to the Puerto Rico 1165(e) defined contribution plan. In accordance with SFAS No. 88, *"Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits,"* the Company recorded a curtailment loss of $1.9 million during the fourth quarter 2003. As of December 31, 2004, the Plan's accumulated benefit obligation exceeded the fair value of its assets by $5.2 million.

Spin-Off Expenses

The Company recorded a $3.3 million charge for legal, administrative and regulatory expenses related to the October 2002 acquisition of the cardiovascular business in Japan (see "Joint Venture in Japan").

Equity Earnings in Japan Operations

Equity earnings in Japan operations were $11.0 million in 2002. Equity earnings in Japan operations represent the Company's 90% profit interest in the cardiovascular business in Japan effective from April 1, 2000 through September 30, 2002. For more information, see "Joint Venture in Japan."

Interest Expense, net

Interest expense, net was $14.2 million, $13.2 million and $11.5 million in 2004, 2003 and 2002, respectively. The increase in interest expense, net, for 2004 resulted primarily from a higher average debt balance, due largely to the financing of the PVT acquisition. The increase in interest expense, net for 2003 resulted primarily from the higher interest rate associated with the Company's fixed rate debt.

Other (Income), net

The following is a summary of other (income) expense, net (in millions):

	Years Ended December 31,		
	2004	2003	2002
Foreign exchange gain	$(0.2)	$(10.6)	$ (4.1)
Legal settlements, net	(1.0)	—	(14.7)
Asset dispositions and write-downs	—	3.6	2.3
Accounts receivable securitization costs	1.0	0.8	1.5
Other	(0.2)	1.5	(0.4)
	$(0.4)	$ (4.7)	$(15.4)

Foreign exchange gains and losses relate to global trade and intercompany receivable and payable balances.

Effective April 24, 2002, Edwards Lifesciences and Medtronic, Inc. entered into an agreement related to certain patent infringement claims pursuant to which the Company received a one-time cash payment of $20.0 million (recorded as a gain of $14.7 million, net of legal expenses).

Provision for Income Taxes

The effective income tax rates for 2004, 2003 and 2002 were impacted as follows (in millions):

	Years Ended December 31,		
	2004	2003	2002
Income tax expense at U.S. federal statutory rate	$ 10.5	$ 32.5	$ 19.6
Foreign income tax at different rates	(22.5)	(11.9)	(10.6)
Deemed dividends, net of foreign tax credit	2.5	6.2	—
Tax credits, federal and state	(2.1)	(2.1)	(1.9)
(Benefit) from Brazil reorganization	—	(13.7)	—
State and local taxes, net of federal tax benefit and transactions listed separately	0.8	1.0	(0.1)
(Benefit) on sale of perfusion services business	—	—	(20.1)
Valuation allowance for loss on investments	6.6	—	13.8
Nondeductible in-process research and development expenses	27.8	—	—
Other	4.8	1.8	(0.4)
Income tax expense	$ 28.4	$ 13.8	$ 0.3

Excluding the impact of in-process research and development expenses, asset impairments and special charges, net, noted above, the effective income tax rate was 26% for all years presented. The Company expects its effective income tax rate for recurring operations to be 26% for 2005.

In exchange for the sale of the Novacor mechanical cardiac assist product line to WorldHeart in June 2000, the Company received WorldHeart preferred stock. In 2002, the investment in the WorldHeart preferred stock was deemed to be impaired and written down to its fair market value. A further write-down of the WorldHeart investment occurred in 2004. In addition, three other equity investments were deemed to be impaired and written down to fair market value in 2004. Due to the uncertainty of using any potential tax benefit for the losses, a valuation allowance of $13.8 million was established in 2002 and was increased by $6.6 million in 2004.

Of the $81.0 million charge related to the PVT acquisition discussed above, $1.7 million related to tax deductible payments to exercise certain licensing options pursuant to the stock purchase agreement, and the remaining $79.3 million charge is permanently disallowed for income tax purposes.

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004, which allows companies to repatriate cash into the United States at a special, temporary effective tax rate of 5.25 percent. The Company's evaluation of the amount of foreign earnings to repatriate under the Act, and the financial statement impact, is in process. As such, the Company is not in a position to decide on whether, and to what extent, foreign earnings that have not been remitted to the United States may be repatriated. Based on analysis to date, however, it is reasonably possible that between $150 million and $250 million may be repatriated. The related potential range of the income tax effect of the repatriation cannot be reasonably estimated at this time. The Company expects to be in a position to finalize its assessment by the end of the third quarter 2005.

During 2003, the Company commenced a legal reorganization of its Brazil subsidiary to improve its balance sheet and to enhance its ability to conduct business in Brazil. Since being acquired a number of years ago, this subsidiary has incurred net operating losses due primarily to the devaluation of the local currency and interest expense incurred on inter-company debt. In addition, the reorganization allowed the Company to recognize the accumulated losses and inter-company debt write-off under United States tax law, resulting in federal and state tax benefits of $13.7 million.

During 2003, the Company recapitalized its Japan subsidiary. As a result, a deemed dividend occurred for United States tax purposes resulting in an incremental tax provision of $6.2 million, net of foreign tax credits.

As a result of tax law developments in 2002, the Company recorded a $20.1 million tax benefit during 2002 related to the loss on sale of its United States perfusion services business in June 2001.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities, accounts receivable securitization facilities and cash from operations. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures and other financial commitments. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

On June 28, 2004, the Company replaced its unsecured revolving credit agreement with a new unsecured five-year revolving credit agreement (the "Credit Agreement"), which will expire on June 26, 2009. The Credit Agreement provides up to an aggregate of $500.0 million in one- to six-month borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate ("LIBOR") plus 0.5%, which includes a facility fee and is subject to adjustment in the event of a change in the Company's leverage ratio, as defined by the Credit Agreement. The Company pays this facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.1%. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to the Credit Agreement. As of December 31, 2004, borrowings of $117.1 million were outstanding under the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with as of December 31, 2004.

As further discussed in Note 7 to the consolidated financial statements, the Company has two securitization programs whereby certain subsidiaries in the United States and Japan sell, without recourse, on a continuous basis, an undivided interest in certain eligible pools of accounts receivable. The significant benefits of the securitizations are lower cost of funds and differentiated sources of liquidity. The Company has been able to effectively lower its overall cost of funds as a result of the interest rate spreads it pays on these advances as opposed to borrowings under the current LIBOR based credit facility. Additionally, the Company believes that in diversifying its funding sources, the Company's funding availability in the capital markets is strengthened. As of December 31, 2004, the Company had sold a total of $90.4 million of trade accounts receivable and received funding of $80.4 million. The securitization program in the United States expires on December 19, 2005, and the Japan securitization program expires on December 3, 2005.

On May 6, 2003, the Company's Board of Directors approved a stock repurchase program authorizing the Company to purchase 2.0 million shares of the Company's outstanding common stock through December 31, 2005. In May 2004, the Board of Directors approved a second stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional 2.0 million shares of the Company's common stock through December 31, 2006. Stock repurchased under these programs will be used primarily to offset obligations under the Company's employee stock option programs. During 2004, the Company repurchased 1.7 million shares at an aggregate cost of $59.1 million and also completed the first stock repurchase program.

Net cash provided by **operating activities** in 2004 increased $38.5 million from 2003 due primarily to:

- higher earnings in 2004 adjusted for non-operating and non-cash items;
- increased net cash flows from payables and accrued liabilities from increased taxes payable; and

- increased net cash flows from receivables from improved days sales outstanding offsetting increased sales levels;

partially offset by reduced cash flows from increases in inventories to build new product lines and support increased sales levels.

Cash provided by operating activities in 2003 decreased $8.4 million from 2002 due primarily to:

- reduced cash inflows from accounts receivable securitization; and
- reduced cash inflows from increases in inventories

partially offset by:

- higher earnings in 2003 before non-cash charges and credits;
- decreased net cash outflows from accounts and other receivables; and
- decreased net cash outflows from accounts payable and accrued expenses.

Net cash used in **investing activities** in 2004 consisted primarily of the acquisition of PVT and the purchase of ev3's technology of $137.7 million, and capital expenditures of $42.5 million.

Net cash used in investing activities in 2003 consisted primarily of the acquisition of Jomed, Whitland and Embol-X, Inc. of $33.2 million, and capital expenditures of $37.9 million.

Net cash used in **financing activities** in 2004 consisted primarily of purchases of treasury stock of $59.1 million, partially offset by proceeds from stock plans of $30.5 million and net proceeds from issuance of long-term debt of $7.1 million.

Cash used in financing activities in 2003 consisted primarily of purchases of treasury stock of $49.4 million and net payments on debt of $4.0 million, partially offset by proceeds from stock plans of $36.6 million.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2004 were as follows (in millions):

	Payments Due by Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term debt	$267.1	$ —	$ —	$ —	$267.1
Interest on long-term debt	30.9	11.2	15.4	4.3	—
Operating leases	49.8	13.1	20.4	15.2	1.1
Unconditional purchase obligations(a)	15.1	7.5	7.6	—	—
Contractual development obligations(b)	31.9	4.3	3.6	4.0	20.0
Total contractual cash obligations	$394.8	$36.1	$47.0	$23.5	$288.2

(a) Unconditional purchase obligations consist primarily of minimum purchase commitments of inventory.

(b) Contractual development obligations consist primarily of cash that Edwards Lifesciences is obligated to pay to unconsolidated affiliates upon their achievement of product development milestones.

Critical Accounting Policies and Estimates

The Company's results of operations and financial position are determined based upon the application of the Company's accounting policies, as discussed in the notes to the consolidated financial statements. Certain of the Company's accounting policies represent a selection among acceptable alternatives under Generally Accepted

Accounting Principles in the United States ("GAAP"). In evaluating the Company's transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions. Management has not determined how reported amounts would differ based on the application of different accounting policies. Management has also not determined the likelihood that materially different amounts could be reported under different conditions or using different assumptions.

The application of accounting policies requires the use of judgment and estimates. As it relates to the Company, estimates and forecasts are required to determine sales returns and reserves, rebate reserves, allowances for doubtful accounts, reserves for excess and obsolete inventory, investments in unconsolidated affiliates, workers' compensation liabilities, employee benefit related liabilities, deferred tax asset valuation allowances, any impairments of assets, forecasted transactions to be hedged, litigation reserves and contingencies.

These matters that are subject to judgments and estimation are inherently uncertain, and different amounts could be reported using different assumptions and estimates. Management uses its best estimates and judgments in determining the appropriate amount to reflect in the financial statements, using historical experience and all available information. The Company also uses outside experts where appropriate. The Company applies estimation methodologies consistently from year to year.

The Company believes the following are the critical accounting policies which could have the most significant effect on the Company's reported results and require subjective or complex judgments by management.

Revenue Recognition

The Company recognizes revenue for sales when all of the following have occurred: an agreement of sale exists, product delivery and acceptance has occurred or services have been rendered, and collection is reasonably assured. In the case of certain products where the Company maintains consigned inventory at customer locations, revenue is recognized at the time the Company is notified that the customer has used the inventory. The Company enters into certain arrangements in which it commits to provide multiple elements to its customers. Revenue related to an individual element is deferred unless delivery of the element represents a separate earnings process. Total revenue for these arrangements is allocated among the elements based on the fair value of the individual elements, with the relative fair values determined based on objective evidence (generally based on sales of the individual element to other third parties). Management is required to make judgments about whether or not collectibility is reasonably assured.

When the Company recognizes revenue from the sale of its products, an estimate of various sales returns and allowances is recorded which reduces product sales and accounts receivable. These adjustments include estimates for charge backs, rebates, returns, and other sales allowances. These provisions are estimated based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with wholesale and indirect customers. If the historical data and inventory estimates used to calculate these provisions does not properly reflect future activity, the Company's financial position, results of operations and cash flows could be impacted. The Company's estimates are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations.

Allowance for Doubtful Accounts

The Company records allowances for doubtful accounts based on customer-specific analysis and general matters such as current assessments of past due balances and economic conditions. Additional allowances for doubtful accounts may be required if there is deterioration in past due balances, if economic conditions are less favorable than the Company has anticipated or for customer-specific circumstances, such as financial difficulty. The allowance for doubtful accounts was $4.5 million and $5.1 million at December 31, 2004 and 2003, respectively.

Excess and Obsolete Inventory

The Company records allowances for excess and obsolete inventory based on historical and estimated future demand and market conditions. Additional inventory allowances may be required if future demand or market conditions are less favorable than the Company has estimated. Inventory reserves result from inventory which is obsolete, nearing its expiration date (generally triggered at six months prior to expiration), or damaged or slow moving (defined as quantities in excess of a two year supply). The allowance for excess and obsolete inventory was $15.5 million and $8.5 million at December 31, 2004 and 2003, respectively.

Patent Costs

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes legal costs related to the defense and enforcement of issued patents for which success is deemed probable. The related costs are amortized over the remaining useful lives of the patents using the straight-line method. Such deferred costs are periodically reviewed for impairment and recoverability. To the extent the Company is successful in its defense and enforcement of its patents and receives compensation for past infringement, costs capitalized in connection with the specific defense or enforcement are expensed as an offset against any gain received.

Impairment of Long-Lived Assets

As the Company's operations are comprised of one reporting unit, the Company reviews the recoverability of its goodwill by comparing the Company's fair value to the net book value of its assets. If the book value of the Company's assets exceeds the Company's fair value, the goodwill is written down to its implied fair value.

Additionally, management reviews the carrying amounts of goodwill and other intangibles whenever events and circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are designated as available-for-sale in accordance with the provisions of SFAS No. 115, *"Accounting for Certain Investments in Debt and Equity Securities."* These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as Accumulated Other Comprehensive Income (Loss). Gains or losses on investments sold are based on the specific identification method. The fair values of certain investments are based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. When the fair value of a certain investment declines below cost, management uses the following criteria to determine if such a decline should be considered other than temporary and result in a realized loss:

- the duration and extent to which the market value has been less than cost;
- the financial condition and near term prospects of the investee;
- the reasons for the decline in market value;

- the investee's performance against product development milestones; and
- the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Income Taxes

The Company records a liability for potential tax assessments based on its estimate of the potential exposure. New laws and new interpretations of laws and rulings by tax authorities may affect the liability for potential tax assessments. Due to the subjectivity and complex nature of the underlying issues, actual payments or assessments may differ from estimates. To the extent the Company's estimates differ from actual payments or assessments, income tax expense is adjusted. Additional information regarding income taxes is included in Note 16 of the consolidated financial statements.

The Company accounts for income taxes in accordance with SFAS No. 109, *"Accounting for Income Taxes."* Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. At December 31, 2004, the Company had deferred tax assets of $130.5 million, partially offset by deferred tax liabilities of $60.9 million. The valuation allowance of $26.2 million as of December 31, 2004 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the deferred tax assets established for certain investments and the net operating loss carryforwards of certain non-United States subsidiaries. The Company evaluates annually the realizability of its deferred tax assets by assessing its valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

Employee Stock Option and Stock Purchase Plans

The Company applies the provisions of Accounting Principles Board Opinion No. 25, *"Accounting for Stock Issued to Employees,"* in accounting for its fixed stock option and employee stock purchase plans. In accordance with this intrinsic value method, no compensation expense is recognized for these plans. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *"Accounting for Stock Based Compensation,"* (in millions, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net income, as reported	$ 1.7	$79.0	$55.7
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(15.7)	(16.0)	(15.3)
Pro forma net income (loss)	$(14.0)	$63.0	$40.4
Earnings per basic share:			
Reported net income	$ 0.03	$1.34	$0.94
Pro forma net income (loss)	(0.23)	1.07	0.68
Earnings per diluted share:			
Reported net income	0.03	1.29	0.91
Pro forma net income (loss)	(0.23)	1.03	0.66

The per share weighted-average fair value for options granted during 2004, 2003 and 2002 was $11.96, $10.93, and $11.64, respectively. The fair value of each option was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	2004	2003	2002
Average risk-free interest rate	3.5%	2.5%	4.4%
Expected dividend yield	None	None	None
Expected volatility	41%	42%	44%
Expected life (years)	4	4	5

The pro forma expense for employee stock purchase subscriptions was calculated with the following weighted-average assumptions for grants during the following periods:

	2004	2003	2002
Average risk-free interest rate	2.2%	1.3%	2.1%
Expected dividend yield	None	None	None
Expected volatility	40%	42%	45%
Expected life (years)	1	1	1

The expected volatility assumptions for the stock option and stock purchase plans used in the Black-Scholes option pricing model is estimated on the date of each grant.

Effects of Recent Accounting Pronouncements

In September 2004, the Emerging Issues Task Force ("EITF") issued EITF Abstract Issue No. 04-8 *"The Effect of Contingently Convertible Debt on Diluted Earnings per Share."* The abstract addresses when the dilutive effect of contingently convertible debt investments should be included in diluted earnings per share. This consensus is effective for reporting periods ending after December 15, 2004. Adoption of this consensus did not have an

impact on the Company's consolidated financial statements but may have a minimal impact on the Company's consolidated financial statements in the future.

In November 2004, the FASB issued SFAS No. 151, *"Inventory Costs — an amendment of ARB No. 43, Chapter 4."* This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect adoption of this standard to have a material impact on its consolidated financial statements.

In December 2004, the FASB issued a revision of FASB Statement No. 123, *"Accounting for Stock-Based Compensation."* This Statement supersedes APB Opinion No. 25, *"Accounting for Stock Issued to Employees,"* and its related implementation guidance. This Statement eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. This Statement requires entities to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards (with limited exceptions). This revision is effective for the first interim or annual reporting period that begins after June 15, 2005. The Company is still assessing the impact that adoption of this standard will have on its consolidated financial statements; however, the Company believes that adoption of this standard will result in a charge to reported earnings.

Item 7A. *Quantitative and Qualitative Disclosure About Market Risk*

The Company's business and financial results are affected by fluctuations in world financial markets, including currency exchange rates and interest rates. The Company's hedging policy attempts to manage these risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity and costs.

Edwards Lifesciences maintains an overall risk management strategy that utilizes a variety of interest rate and currency derivative financial instruments to mitigate its exposure to fluctuations in interest rates and currency exchange rates. The derivative instruments used include interest rate swaps, option-based products and forward currency contracts. The Company does not use any of these instruments for trading or speculative purposes. The total notional amounts of the Company's derivative financial instruments at December 31, 2004 and 2003 were $448.3 million and $567.6 million, respectively. The notional amounts of interest rate swap agreements, option-based products, and forward currency contracts do not represent amounts exchanged by the parties and, are not a measure of the Company's exposure through its use of derivatives.

Interest Rate Risk

The Company utilizes interest rate swap agreements in managing its exposure to interest rate fluctuations. Interest rate swap agreements are executed as an integral part of specific debt transactions or on a portfolio basis. The Company's interest rate swap agreements involve agreements to pay a fixed rate and receive a floating rate, at specified intervals, calculated on an agreed-upon notional amount.

As part of its overall risk-management program the Company performs sensitivity analyses to assess potential gains and losses in earnings and changes in fair values to hypothetical movements in interest rates. A 54 basis-point increase in interest rates (approximately 10 percent of the Company's weighted average interest rate) affecting the Company's financial instruments, including debt obligations and related derivatives and investments, would have an immaterial effect on the Company's annual interest expense.

Currency Risk

The Company is primarily exposed to currency exchange-rate risk with respect to its transactions and net assets denominated in Japanese yen and the Euro. Business activities in various currencies expose the Company to

the risk that the eventual net United States dollar cash inflows resulting from transactions with foreign customers and suppliers denominated in foreign currencies may be adversely affected by changes in currency exchange rates. The Company manages these risks utilizing various types of foreign exchange contracts. The Company also enters into foreign exchange contracts to hedge anticipated, but not yet committed, sales expected to be denominated in foreign currencies. In addition, the Company hedges certain of its net investments in international affiliates. Such contracts hedge the United States dollar value of foreign currency denominated net assets from the effects of volatility in currency exchange rates by creating debt denominated in the respective currencies of the underlying net assets. Any changes in the carrying value of these net investments that are a result of fluctuations in currency exchange rates are offset by changes in the carrying value of the foreign currency denominated debt that are a result of the same fluctuations in currency exchange rates.

As part of the strategy to manage risk while minimizing hedging costs, the Company utilizes both foreign currency forward exchange contracts and option-based products in managing its exposure to currency rate fluctuations. Option-based products consist of purchased put options and at times written (sold) call options to create collars. Option-based products are agreements that either grant the Company the right to receive, or require the Company to make payments at, specified currency rate levels.

As part of its risk-management process, the Company uses a value-at-risk ("VAR") methodology in connection with other management tools to assess and manage its foreign currency financial instruments and measure any potential loss in earnings as a result of adverse movements in currency exchange rates. The Company utilizes a Monte Carlo simulation, with a 95 percent confidence level, using spot and three-month implied volatilities as stochastic variables and correlations (as of the measurement date) to estimate this potential loss. The Company's calculated VAR at December 31, 2004 and 2003, with a maturity of up to one year, is $5.0 million and $3.0 million, respectively. This amount excludes the potential effects of any changes in the value of the underlying transactions or balances. The Company's calculated VAR exposure represents an estimate of reasonably possible net losses that would be recognized on its portfolio of financial instruments assuming hypothetical movements in future market rates and is not necessarily indicative of actual results which may occur. It does not represent the maximum possible loss or any expected loss that may occur. Actual future gains or losses may differ from (and could be significantly greater than) these estimates based upon actual fluctuations in market rates, operating exposures and the timing thereof, and changes in the Company's portfolio of derivatives during the measured periods. In addition, the assumption within the VAR model is that changes in currency exchange rates are adverse, which may not be the case. Any loss incurred on the financial instruments is expected to be offset by the effects of currency movements on the hedging of all exposures; there may be currency exchange-rate gains or losses in the future.

Credit Risk

Derivative financial instruments used by the Company involve, to varying degrees, elements of credit risk in the event a counter-party should default and market risk as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counter-party diversification, monitoring of counter-party financial condition and master-netting agreements in place with all derivative counter-parties. Credit exposure of derivative financial instruments is represented by the fair value effects of contracts with a positive fair value at December 31, 2004 reduced by the effects of master netting agreements. Additionally, at December 31, 2004, all derivative financial instruments, based on notional amounts, were with commercial banks and investment banking firms assigned investment grade ratings of "AA" or better by national rating agencies. The Company does not anticipate non-performance by its counter-parties and has no reserves related to non-performance as of December 31, 2004; the Company has not experienced any counterparty default during the four years ended December 31, 2004.

Concentrations of Credit Risk

In the normal course of business, Edwards Lifesciences provides credit to customers in the health care industry, performs credit evaluations of these customers and maintains reserves for potential credit losses which,

when realized, have been within the range of management's allowance for doubtful accounts during all periods presented.

Sales to Baxter, acting in the capacity of the Company's distributor subsequent to the tax-free spin-off of Edwards Lifesciences from Baxter, represented approximately 8% of the Company's total net sales for 2002. Substantially all of these agreements had been terminated as of December 31, 2002. In 2004, the Company had no customers that represent greater than 10% of its total net sales or accounts receivable, net.

Investment Risk

Edwards Lifesciences is exposed to investment risks related to changes in the fair values of its investments. The Company invests in equity instruments of public and private companies. These investments are classified in "Investments in unconsolidated affiliates" on the consolidated balance sheets.

In 2002, the Company recorded a $67.4 million pretax charge related to the impairment of its investment in preferred stock of WorldHeart. The investment was written down to $6.2 million, which represented the value of the Company's preferred stock investment had it been converted into common stock at October 15, 2002. The decision to record the charge was based primarily on delays in WorldHeart's product development timelines, arising from its revised strategy. A further impairment of $4.7 million was charged in 2004 resulting from the decline in WorldHeart's stock price. Should WorldHeart fail to meet certain future development and financing milestones, further impairment charges may be necessary.

In addition to the investment in WorldHeart ($1.5 million at December 31, 2004), Edwards Lifesciences had approximately $19.1 million of investments in equity instruments of other companies. At December 31, 2004, the Company had recorded unrealized losses of $4.5 million on these investments in "Accumulated Other Comprehensive Income," net of tax. Management considers these declines temporary in nature based upon the individual companies' operating results, financial condition and achievement of product development milestones. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the decline in the investments' values may be considered other than temporary and impairment charges may be necessary.

Item 8. ***Financial Statements and Supplementary Data***

Report of Management

The management of Edwards Lifesciences is responsible for the integrity of the financial information presented in this Form 10-K. The consolidated financial statements have been prepared in accordance with generally accepted accounting principles. Where necessary, they reflect estimates based on management's judgment.

Management relies upon established accounting procedures and related systems of internal control for meeting its responsibilities to maintain reliable financial records. These systems are designed to provide reasonable assurance that assets are safeguarded and that transactions are properly recorded and executed in accordance with management's intentions. Internal auditors periodically review the accounting and control systems, and these systems are revised if and when weaknesses or deficiencies are found.

The Audit and Public Policy Committee of the Board of Directors, composed of directors from outside the Company, meets regularly with management, the Company's internal auditors and its independent auditors to discuss audit scope and results, internal control evaluations, and other accounting, reporting and financial matters. The independent registered public accounting firm and internal auditors have access to the Audit and Public Policy Committee without management's presence.

/s/ Michael A. Mussallem

Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

/s/ Corinne H. Lyle

Corinne H. Lyle
Corporate Vice President,
Chief Financial Officer and Treasurer

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE
DECEMBER 31, 2004

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
of Edwards Lifesciences Corporation:

We have completed an integrated audit of Edwards Lifesciences Corporation's (the "Company") 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Edwards Lifesciences Corporation and its subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting

includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP

PricewaterhouseCoopers LLP

Orange County, California
March 4, 2005

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS
(in millions, except share data)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets		
Cash and cash equivalents	$ 48.9	$ 61.1
Accounts receivable, net of allowances of $4.5 and $5.1 at December 31, 2004 and 2003, respectively	104.1	97.5
Other receivables	15.3	21.0
Inventories, net	127.7	120.5
Deferred income taxes	21.1	11.9
Prepaid expenses	42.2	41.8
Other current assets	8.2	6.4
Total current assets	367.5	360.2
Property, plant and equipment, net	201.7	209.9
Goodwill	337.7	338.2
Other intangible assets, net	152.6	81.0
Investments in unconsolidated affiliates	20.6	35.4
Deferred income taxes	22.3	59.3
Other assets	10.3	17.4
Total assets	$1,112.7	$1,101.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 195.4	$ 184.1
Long-term debt	267.1	255.8
Other long-term liabilities	22.1	26.4
Commitments and contingent liabilities (Notes 8, 10 and 17)		
Stockholders' equity		
Preferred stock, $.01 par value, authorized 50,000,000 shares, no shares outstanding	—	—
Common stock, $1.00 par value, 350,000,000 shares authorized, 64,242,836 and 62,572,250 shares issued, 59,438,236 and 59,480,850 shares outstanding at December 31, 2004 and 2003, respectively	64.2	62.6
Additional contributed capital	500.6	463.2
Retained earnings	224.1	222.4
Accumulated other comprehensive income (loss)	(20.8)	(32.2)
Common stock in treasury, at cost, 4,804,600 and 3,091,400 shares at December 31, 2004 and 2003, respectively	(140.0)	(80.9)
Total stockholders' equity	628.1	635.1
Total liabilities and stockholders' equity	$1,112.7	$1,101.4

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2004	2003	2002
Net sales	$931.5	$860.5	$704.0
Cost of goods sold	370.2	359.4	299.1
Gross profit	561.3	501.1	404.9
Selling, general and administrative expenses	319.9	289.9	227.9
Research and development expenses	87.0	72.8	65.2
Purchased in-process research and development expenses (Note 4)	93.3	13.6	—
Asset impairments (Note 5)	9.0	—	67.4
Special charges, net (Note 6)	8.2	23.5	3.3
Equity earnings in Japan operations (Note 1)	—	—	(11.0)
Interest expense, net	14.2	13.2	11.5
Other (income), net (Note 15)	(0.4)	(4.7)	(15.4)
Income before provision for income taxes	30.1	92.8	56.0
Provision for income taxes	28.4	13.8	0.3
Net income	$ 1.7	$ 79.0	$ 55.7
Share information (Note 2):			
Earnings per share:			
Basic	$ 0.03	$ 1.34	$ 0.94
Diluted	$ 0.03	$ 1.29	$ 0.91
Weighted average number of common shares outstanding:			
Basic	59.6	59.1	59.0
Diluted	62.0	61.1	61.3

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)

	Years Ended December 31,		
	2004	2003	2002
Cash flows from operating activities			
Net income	$ 1.7	$ 79.0	$ 55.7
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	55.7	45.6	40.4
Deferred income taxes	0.8	5.3	(13.8)
Purchased in-process research and development	93.3	13.6	—
Special charges, losses and impairments	19.6	7.1	68.9
Other	6.7	5.2	8.7
Changes in operating assets and liabilities:			
Accounts and other receivables	7.1	(11.0)	(32.0)
Accounts receivable securitization	2.5	6.2	29.9
Inventories	(7.1)	4.2	13.3
Accounts payable and accrued liabilities	13.0	(8.4)	(17.6)
Prepaid expenses	(7.2)	3.1	(2.0)
Other	(5.5)	(7.8)	(1.0)
Net cash provided by operating activities	180.6	142.1	150.5
Cash flows from investing activities			
Capital expenditures	(42.5)	(37.9)	(40.7)
Investments in intangible assets	(11.0)	(6.6)	(7.0)
Investments in unconsolidated affiliates	(1.0)	(4.4)	(5.7)
Proceeds from asset dispositions	11.0	6.0	4.1
Acquisitions	(137.7)	(33.2)	(19.0)
Proceeds from sale of business	4.1	—	—
Other	—	(0.8)	—
Net cash used in investing activities	(177.1)	(76.9)	(68.3)
Cash flows from financing activities			
Proceeds from issuance of long-term debt	285.7	333.4	150.9
Payments on long-term debt	(278.6)	(337.4)	(231.9)
Purchases of treasury stock	(59.1)	(49.4)	(30.8)
Proceeds from stock plans	30.5	36.6	13.7
Other	1.0	(4.4)	(1.3)
Net cash used in financing activities	(20.5)	(21.2)	(99.4)
Effect of currency exchange rate changes on cash and cash equivalents	4.8	(17.1)	3.7
Net (decrease) increase in cash and cash equivalents	(12.2)	26.9	(13.5)
Cash and cash equivalents at beginning of year	61.1	34.2	47.7
Cash and cash equivalents at end of year	$ 48.9	$ 61.1	$ 34.2
Supplemental disclosures:			
Cash paid during the year for:			
Interest	$ 12.9	$ 11.9	$ 9.8
Income taxes	$ 11.4	$ 14.1	$ 10.4
Non-cash transactions:			
Purchase of intangible assets in exchange for stock	—	$ 3.0	—

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)
(in millions)

	Years Ended December 31,		
	2004	2003	2002
COMMON STOCK			
Beginning of year	$ 62.6	$ 60.2	$ 59.3
Common stock issued under employee benefit plans	1.6	2.4	0.9
End of year	$ 64.2	$ 62.6	$ 60.2
ADDITIONAL CONTRIBUTED CAPITAL			
Beginning of year	$ 463.2	$412.0	$287.2
Common stock issued under employee benefit plans	28.9	35.1	12.8
Tax benefit from exercise of non-qualified stock options	8.0	10.6	—
Resolution of Baxter arbitration (Note 6)	—	5.4	—
Stock options issued to non-employees	0.5	0.1	1.2
Acquisition of joint venture in Japan (Notes 1 and 3)	—	—	110.8
End of year	$ 500.6	$463.2	$412.0
RETAINED EARNINGS			
Beginning of year	$ 222.4	$143.4	$ 87.7
Net income	1.7	79.0	55.7
End of year	$ 224.1	$222.4	$143.4
ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)			
Beginning of year	$ (32.2)	$ (44.7)	$ 25.2
Other comprehensive income (loss)	11.4	12.5	(69.9)
End of year	$ (20.8)	$ (32.2)	$ (44.7)
TREASURY STOCK			
Beginning of year	$ (80.9)	$ (31.5)	$ (0.7)
Purchases of stock	(59.1)	(49.4)	(30.8)
End of year	$(140.0)	$ (80.9)	$ (31.5)
Total stockholders' equity	$ 628.1	$635.1	$539.4
COMPREHENSIVE INCOME (LOSS)			
Net income	$ 1.7	$ 79.0	$ 55.7
Other comprehensive income (loss):			
Currency translation adjustments, net of tax	16.6	6.5	(8.0)
Currency translation adjustment in connection with the acquisition of joint venture in Japan (Notes 1 and 3)	—	—	(47.8)
Pension adjustments, net of tax	(3.5)	1.2	(1.7)
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	(4.1)	6.3	(1.7)
Net unrealized gain (loss) on cash flow hedges, net of tax	2.4	(1.5)	(10.7)
Other comprehensive income (loss)	11.4	12.5	(69.9)
Total comprehensive income (loss)	$ 13.1	$ 91.5	$ (14.2)

The accompanying notes are an integral part of these consolidated financial statements.

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Edwards Lifesciences is a global provider of products and technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address specific cardiovascular opportunities: heart valve disease; peripheral vascular disease; and critical care technologies.

The products and services provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas: Heart Valve Therapy, Critical Care, Cardiac Surgery Systems, Vascular, and Other Distributed Products.

Edwards Lifesciences Corporation was incorporated under the original name of CVG Controlled Inc. in Delaware on September 10, 1999. Unless the context indicates otherwise, references to the "Company" and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

Joint Venture in Japan

From April 1, 2000 to September 30, 2002, the cardiovascular business in Japan was being operated pursuant to a joint venture under which a subsidiary of Edwards Lifesciences held a 90% profit interest. During that time, Edwards Lifesciences (a) recognized its shipments into the joint venture as sales at distributor price at the time the joint venture sold to the end customer and (b) utilized the equity method of accounting to record its 90% profit interest in the operations of the joint venture in Other Income. On October 1, 2002, the Company acquired from Baxter International Inc. ("Baxter") the cardiovascular business in Japan and began reporting Japan's results on a fully consolidated basis. See Note 3 for more information.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with Generally Accepted Accounting Principles in the United States ("GAAP") which have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. Estimates are used in accounting for, among other items, sales returns and reserves, rebate reserves, allowances for doubtful accounts, excess and obsolete inventory, investments in unconsolidated affiliates, workers compensation, employee benefits, income taxes, asset impairment, forecasted transactions to be hedged, litigation reserves and contingencies.

Foreign Currency Translation

The Company follows the principles of Statement of Financial Accounting Standards ("SFAS") No. 52, *"Foreign Currency Translation."* Accordingly, when the local currency of its foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted average exchange rate prevailing

during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as Accumulated Other Comprehensive Income (Loss). The effects of foreign currency transactions denominated in a currency other than its foreign entities' functional currency are included in Other (Income), net and totaled net income of $0.2 million, $10.6 million and $4.1 million in 2004, 2003 and 2002, respectively.

Revenue Recognition

The Company recognizes revenue for sales when all of the following have occurred: an agreement of sale exists, product delivery and acceptance has occurred or services have been rendered, and collection is reasonably assured. In the case of certain products where the Company maintains consigned inventory at customer locations, revenue is recognized at the time the Company is notified that the customer has used the inventory. The Company enters into certain arrangements in which it commits to provide multiple elements to its customers. Revenue related to an individual element is deferred unless delivery of the element represents a separate earnings process. Total revenue for these arrangements is allocated among the elements based on the fair value of the individual elements, with the relative fair values determined based on objective evidence (generally based on sales of the individual element to other third parties).

When the Company recognizes revenue from the sale of its products, an estimate of various sales returns and allowances is recorded which reduces product sales and accounts receivable. These adjustments include estimates for charge backs, rebates, returns, and other sales allowances. These provisions are estimated based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with wholesale and indirect customers. If the historical data and inventory estimates used to calculate these provisions do not properly reflect future activity, the Company's financial position, results of operations and cash flows could be impacted. The Company's estimates are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations.

Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents. These investments are valued at cost, which approximates fair value.

Accounts Receivable Securitization

The Company accounts for the securitization of accounts receivable in accordance with SFAS No. 140, *"Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities."* When the Company sells accounts receivable in securitizations, a subordinated residual interest in the securitized portfolio is retained by the Company and recorded in Other Current Assets. Gain or loss on sale of the accounts receivable depends in part on the previous carrying amount of the financial assets involved in the transfer, allocated between the assets sold and the residual interests based on their relative fair value at the date of transfer. Because quoted market prices are generally not available to determine the Company's fair value of the residual interest, the Company estimates the fair value of the residual interest by estimating future expected credit losses to determine the future expected cash flows, which generally approximate fair value given the securitized portfolio's short-term weighted average life. At the time the receivables are sold, the balances are removed from the Consolidated Balance Sheets. Costs associated with the sale of receivables, primarily related to the discount and loss on sale, are included in Other (Income), net.

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market value. Market value for raw materials is based on replacement costs, and for other inventory classifications is based on net realizable value.

	December 31,	
	2004	2003
	(in millions)	
Raw materials	$ 22.2	$ 20.4
Work in process	18.9	16.7
Finished products	86.6	83.4
	$127.7	$120.5

Inventory reserves result from inventory which is obsolete, is nearing its expiration date (generally triggered at six months prior to expiration), or is damaged or slow moving (defined as quantities in excess of a two year supply). Reserves for excess and obsolete inventory were approximately $15.5 million and $8.5 million at December 31, 2004 and 2003, respectively. During the years ended December 31, 2004, 2003 and 2002, the Company allocated $9.8 million, $9.8 million and $9.8 million, respectively, of general and administrative costs to inventory. General and administrative costs included in both the December 31, 2004 and 2003 inventory balances were $3.5 million and $3.5 million, respectively.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. Depreciation and amortization are principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 20 to 40 years for buildings and improvements and from 3 to 11 years for machinery and equipment. Leasehold improvements are amortized over the life of the related facility leases or the asset, whichever is shorter. Straight-line and accelerated methods of depreciation are used for income tax purposes.

	December 31,	
	2004	2003
	(in millions)	
Land	$ 17.9	$ 30.1
Buildings and leasehold improvements	78.7	67.4
Machinery and equipment	219.7	204.6
Equipment with customers	108.5	104.8
Construction in progress	13.5	17.2
	438.3	424.1
Accumulated depreciation and amortization	(236.6)	(214.2)
	$ 201.7	$ 209.9

Depreciation and amortization expense for plant and equipment was $36.8 million, $34.6 million and $29.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. Repairs and maintenance expense was $12.6 million, $12.1 million and $9.1 million for the years ended December 31, 2004, 2003 and 2002, respectively.

Impairment of Long-Lived Assets

As the Company's operations are comprised of one reporting unit, the Company reviews the recoverability of its goodwill by comparing the Company's fair value to the net book value of its assets. If the book value of the Company's assets exceeds the Company's fair value, the goodwill is written down to its implied fair value.

Additionally, management reviews the carrying amounts of other intangibles whenever events and circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

Patent Costs

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes legal costs related to the defense and enforcement of issued patents for which success is deemed probable. The related costs are amortized over the remaining useful lives of the patents using the straight-line method. Such deferred costs are periodically reviewed for impairment and recoverability. To the extent the Company is successful in its defense and enforcement of its patents and receives compensation for past infringement, costs capitalized in connection with the specific defense or enforcement are expensed as an offset against any gain received.

Investments in Unconsolidated Affiliates

The Company has made investments in the equity instruments of other companies. These investments in unconsolidated affiliates are designated as available-for-sale in accordance with the provisions of SFAS No. 115, *"Accounting for Certain Investments in Debt and Equity Securities."* These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as Accumulated Other Comprehensive Income (Loss). Gains or losses on investments sold are based on the specific identification method. The fair values of certain investments are based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. When the fair value of a certain investment declines below cost, management uses the following criteria to determine if such a decline should be considered other than temporary and result in a realized loss:

- the duration and extent to which the market value has been less than cost;
- the financial condition and near term prospects of the investee;
- the reasons for the decline in market value;
- the investee's performance against product development milestones; and
- the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

As of December 31, 2004, the Company had a $7.5 million unrealized loss related to a $12.6 million investment in a publicly traded company. Although the trading value of the Company's investment has been less than the Company's original cost for greater than one year, the Company believes that this unrealized loss is temporary in nature due to the investee's successful performance against product development milestones and the historical high volatility of their stock prices. Additionally, the Company has the ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, *"Accounting for Income Taxes."* Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. The Company evaluates annually the realizability of its deferred tax assets by assessing its valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization are the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in the Company's effective tax rate on future earnings.

Research and Development Costs

Research and development costs are charged to expense when incurred.

Earnings per Share

Earnings per share are calculated in accordance with SFAS No. 128, *"Earnings per Share,"* which requires the Company to report both basic earnings per share, based on the weighted-average number of common shares outstanding, and diluted earnings per share, based on the weighted-average number of common shares outstanding adjusted to include the potentially dilutive effect of outstanding stock options.

The Company has adopted Emerging Issues Task Force 04-8. In accordance with this standard, the contingently convertible senior debentures issued by the Company in May 2003 are included in the diluted earnings per share calculations, if dilutive, regardless of whether the contingencies have been met. The adoption of this standard did not have an impact on the Company's diluted earnings per share for either the years ended December 31, 2004 or 2003.

A reconciliation of the shares used in the basic and diluted per share computations is as follows (in millions):

	Years Ended December 31,		
	2004	2003	2002
Basic shares outstanding	59.6	59.1	59.0
Dilutive effect of employee stock options	2.4	2.0	2.3
Diluted shares outstanding	62.0	61.1	61.3

Diluted earnings per share excludes 3.2 million and 2.1 million shares related to options for the years ended December 31, 2003 and 2002, respectively. These options were excluded because the exercise price per share was greater than the average market price, resulting in an anti-dilutive effect on diluted earnings per share. The effect

of approximately 2.7 million common shares relating to the Company's $150.0 million convertible debentures due 2033 has been excluded from the computation of diluted earnings per share for the years ended December 31, 2004 and 2003 because the result is anti-dilutive.

Employee Stock Option and Stock Purchase Plans

The Company applies the provisions of Accounting Principles Board Opinion No. 25, *"Accounting for Stock Issued to Employees,"* in accounting for its fixed stock option and employee stock purchase plans. In accordance with this intrinsic value method, no compensation expense is recognized for these plans. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *"Accounting for Stock Based Compensation"* (in millions, except per share amounts):

	Year Ended December 31,		
	2004	2003	2002
Net income, as reported	$ 1.7	$ 79.0	$ 55.7
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(15.7)	(16.0)	(15.3)
Pro forma net (loss) income	$(14.0)	$ 63.0	$ 40.4
Earnings per basic share:			
Reported net income	$ 0.03	$ 1.34	$ 0.94
Pro forma net income (loss)	(0.23)	1.07	0.68
Earnings per diluted share:			
Reported net income (loss)	0.03	1.29	0.91
Pro forma net income (loss)	(0.23)	1.03	0.66

The per share weighted-average fair value for options granted during 2004, 2003 and 2002 was $11.96, $10.93, and $11.64, respectively. The fair value of each option was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions:

	2004	2003	2002
Average risk-free interest rate	3.5%	2.5%	4.4%
Expected dividend yield	None	None	None
Expected volatility	41%	42%	44%
Expected life (years)	4	4	5

The pro forma expense for employee stock purchase subscriptions was calculated with the following weighted-average assumptions for grants during the following periods:

	2004	2003	2002
Average risk-free interest rate	2.2%	1.3%	2.1%
Expected dividend yield	None	None	None
Expected volatility	40%	42%	45%
Expected life (years)	1	1	1

The expected volatility assumptions for the stock option and stock purchase plans used in the Black-Scholes option pricing model is estimated on the date of each grant.

Derivatives

Edwards Lifesciences maintains an overall risk management strategy that incorporates the use of a variety of interest rate and currency derivative financial instruments to mitigate its exposure to significant unplanned fluctuations in earnings caused by volatility in interest rate and currency exchange rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy include interest rate swaps, option-based products and forward exchange contracts. As of December 31, 2004, all of these derivative instruments are designated as hedges of underlying exposures. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

The Company uses interest rate swaps to convert floating-rate debt to fixed-rate debt. The Company's interest rate swap agreements involve agreements to pay a fixed rate and receive a floating rate, at specified intervals, calculated on an agreed-upon notional amount. The debt and amounts that the Company hedges are determined based on prevailing market conditions and the current shape of the yield curve. Interest rate swap agreements are executed as an integral part of specific debt transactions.

The Company utilizes forward exchange contracts and option contracts to hedge a portion of its exposure to forecasted intercompany and third party foreign currency transactions. These contracts provide for the purchase or sale of foreign currencies at specified future dates at specified exchange rates. These contracts are entered into to reduce the risk that the Company's earnings and cash flows resulting from certain forecasted transactions will be adversely affected by changes in foreign currency exchange rates.

Derivative instruments used by Edwards Lifesciences involve, to varying degrees, elements of credit risk, in the event a counterparty should default, and market risk, as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counterparty diversification, monitoring of counterparty financial condition and International Swap Dealers Association master netting agreements in place with all derivative counterparties. All derivative financial instruments are with commercial banks and investment banking firms assigned investment grade ratings of "AA" or better with national rating agencies.

All derivatives are recognized on the balance sheet at their fair value. On the date that the Company enters into a derivative contract, it designates the derivative as either (a) a hedge of a forecasted transaction or the variability of cash flows that are to be received or paid in connection with a recognized asset or liability (a "cash flow" hedge), or (b) a hedge of an exposure to changes in the fair value of an asset, liability, or an unrecognized firm commitment (a "fair value" hedge). Changes in the fair value of a derivative that is highly effective, and that is designated and qualifies as a cash flow hedge to the extent that the hedge is effective, are recorded in Accumulated Other Comprehensive Income (Loss) until earnings are affected by the variability of cash flows of the hedged transaction (e.g., until periodic settlements of a variable asset or liability are recorded in earnings). Any hedge ineffectiveness (which represents the amount by which the changes in the fair value of the derivative exceed the variability in the cash flows of the forecasted transaction) is recorded in current-period earnings. Changes in the fair value of a derivative that is highly effective, and that is designated and qualifies as a fair value hedge, are recorded in either current-period earnings or Accumulated Other Comprehensive Income (Loss), depending on whether the hedging relationship satisfies the criteria for a fair-value or cash flow hedge.

The Company formally documents all relationships between hedging instruments and hedged items, as well as its risk management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives that are designated as cash flow hedges or specific firm commitments or forecasted transactions. The Company also formally assesses (both at the hedge's inception and on an ongoing basis) whether the derivatives that are used in hedging transactions have been highly effective in offsetting changes in the cash flows of hedged

items and whether those derivatives may be expected to remain highly effective in future periods. All components of each derivative's gain or loss are included in the assessment of hedge effectiveness.

When it is determined that a derivative is not, or has ceased to be, highly effective as a hedge, the Company discontinues hedge accounting prospectively. A derivative ceases to be highly effective when (a) the Company determines that the derivative is no longer effective in offsetting changes in the cash flows of a hedged item such as firm commitments or forecasted transactions, (b) it is no longer probable that the forecasted transaction will occur, (c) the derivative expires or is sold, terminated, or exercised, or (d) management determines that designating the derivative as a hedging instrument is no longer appropriate.

When the Company discontinues hedge accounting because it is no longer probable that the forecasted transaction will occur in the originally expected period, the gain or loss on the derivative remains in Accumulated Other Comprehensive Income (Loss) and is reclassified into earnings when the forecasted transaction affects earnings. However, if it is probable that a forecasted transaction will not occur by the end of the originally specified time period or within an additional two-month period of time thereafter, the gains and losses that were accumulated in Accumulated Other Comprehensive Income (Loss) will be recognized immediately in earnings. In a situation in which hedge accounting is discontinued and the derivative remains outstanding, the Company will carry the derivative at its fair value on the balance sheet, recognizing changes in the fair value in current-period earnings.

Comprehensive Income

Comprehensive income encompasses all changes in equity other than those arising from transactions with stockholders, and consists of net income, currency translation adjustments, pension adjustments, unrealized net gains and losses on cash flow hedges and investments in unconsolidated affiliates classified (or held) as available-for-sale.

Effects of Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *"Inventory Costs — an amendment of ARB No. 43, Chapter 4."* This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect adoption of this standard to have a material impact on its consolidated financial statements.

In December 2004, the FASB issued a revision of FASB Statement No. 123, *"Accounting for Stock-Based Compensation."* This Statement supersedes APB Opinion No. 25, *"Accounting for Stock Issued to Employees,"* and its related implementation guidance. This Statement eliminates the alternative to use Opinion 25's intrinsic value method of accounting that was provided in Statement 123 as originally issued. Under Opinion 25, issuing stock options to employees generally resulted in recognition of no compensation cost. This Statement requires entities to recognize the cost of employee services received in exchange for awards of equity instruments based on the grant-date fair value of those awards (with limited exceptions). This revision is effective for the first interim or annual reporting period that begins after June 15, 2005. The Company is still assessing the impact that adoption of this standard will have on its consolidated financial statements; however, the Company believes that adoption of this standard will result in a charge to reported earnings.

3. Acquisition of Joint Venture in Japan

On October 1, 2002, the Company acquired from Baxter for $19.0 million, net, the cardiovascular business in Japan. The purchase price excluded approximately $30 million of securitized accounts receivable. In the three months ended September 30, 2002, the Company recorded a $3.3 million charge for legal, administrative and regulatory expenses related to the acquisition reflected in special charges on the Statement of Operations for the year ended December 31, 2002. Commencing October 1, 2002, the Company began reporting the results of the Japan business on a fully consolidated basis. The acquisition did not materially impact the Company's net income as the terms of the joint venture agreement enabled Edwards Lifesciences to record substantially all of the net profit generated by the Japan business (see Note 1).

The acquisition of the cardiovascular business in Japan was accounted for using the predecessor basis of accounting, whereby acquired assets and liabilities were recorded at their historical balances.

The following unaudited pro forma consolidated statement of operations for the year ended December 31, 2002 presents the results of Edwards Lifesciences assuming that the acquisition of the cardiovascular business in Japan had been completed as of January 1, 2002 (in millions, except per share information):

		Pro Forma Adjustments		
	Historical	Japan Operating Results(a)	Other(b)	Pro Forma
Net sales	$704.0	$77.2	$ —	$781.2
Cost of goods sold	299.1	31.0	—	330.1
Gross profit	404.9	46.2	—	451.1
Selling, general and administrative expenses	227.9	34.0	—	261.9
Research and development expenses	65.2	2.5	—	67.7
Disposition of assets and other charges, net	67.4	—	—	67.4
Non-recurring spin-off expenses	3.3	—	—	3.3
Equity earnings in Japan operations	(11.0)	11.0	—	—
Interest expense, net	11.5	—	0.8	12.3
Other income, net	(15.4)	(1.5)	—	(16.9)
Income (loss) before provision for income taxes	56.0	0.2	(0.8)	55.4
Provision (benefit) for income taxes	0.3	0.1	(0.2)	0.2
Net income (loss)	$ 55.7	$ 0.1	$(0.6)	$ 55.2
Share information:				
Earnings per basic share	$ 0.94			$ 0.94
Earnings per diluted share	0.91			0.90

Notes:

(a) To reflect Edwards Lifesciences' Japanese business on a consolidated basis for the full year ended December 31, 2002.

(b) To reflect estimated interest expense that would have been incurred by the Company based on incurrence of $19.0 million of debt at an effective interest rate of 5%.

4. Purchased In-Process Research and Development Expense

On September 29, 2004, the Company acquired all technology and intellectual property associated with ev3, Inc.'s ("ev3") percutaneous mitral valve repair program for total consideration of $15.0 million. The acquisition is expected to be utilized in the Company's existing percutaneous mitral valve repair research and development efforts. At the time of the purchase, ev3 had been unsuccessful in developing a viable prototype and had discontinued the program. Additional design developments, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of European and United States regulatory approvals. Approximately $12.3 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately $39 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, the Company estimated completion of the mitral valve repair program utilizing the intellectual property acquired from ev3 in 2009, and commencement of net cash inflows in 2010. The remaining fair market value of the assets purchased consisted primarily of patents unrelated to ev3's core mitral valve repair technology, which are being amortized over their estimated economic life of 19 years.

On January 27, 2004, the Company acquired Percutaneous Valve Technologies, Inc. ("PVT"), a development stage company, for $125.0 million in cash, net of cash acquired, plus up to an additional $30.0 million upon the achievement of key milestones through 2007. Included in PVT's technology is a catheter-based (percutaneous) approach for replacing aortic heart valves, comprised of a proprietary percutaneously-delivered balloon-expandable stent technology integrated with a tissue heart valve. Unlike conventional open-heart valve replacement surgery, this less-invasive procedure can be performed under local anesthesia and could potentially be a breakthrough for patients seeking an alternative to open-heart surgery.

At the time of acquisition, the PVT aortic heart valve was being used in compassionate cases in Europe, and these clinical results had generated valuable feasibility data. It had been demonstrated that a heart valve could be successfully deployed and anchored using a catheter-based system. Also at that time, the Company was expecting to obtain a CE mark in Europe by the end of 2005 and to file for an Humanitarian Device Exemption ("HDE") in the United States. Upon approval of the HDE, the Company would be able to offer this device to as many as 4,000 patients per year. Broader commercialization in the United States was expected to begin with the submission of an Investigational Device Exemption ("IDE") by the end of the second quarter of 2004 followed by the commencement of a pivotal trial in 2005 and possible pre-market approval by the end of 2007. The risks and uncertainties associated with completing development within a reasonable period of time included those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies and the timing of European and United States regulatory approvals.

Approximately $81.0 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 25%. The valuation assumed approximately $20.9 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were forecasted to commence in 2007. The remaining fair market value of the net assets acquired consisted primarily of patents of $72.4 million that are being amortized over their estimated economic life of 11 years, and a deferred tax liability related to the patents of $28.1 million.

On December 5, 2003, the Company acquired the stock of Whitland Research Limited ("Whitland") for $3.2 million in cash, although achievement of future milestones through 2006 could increase the total price to $5.6 million. Whitland was focused on the development of critical care monitoring technologies. The $3.2 million purchase price was allocated to acquired in-process research and development ($1.8 million) and patents ($1.4 million) based upon their estimated fair values. The patents are being amortized over their estimated useful life of 10 years.

On February 18, 2003, the Company acquired the percutaneous mitral valve repair program of Jomed N.V. ("Jomed"), a European-based provider of products for minimally invasive cardiovascular intervention, for $20.0 million in cash. The acquisition included all technology and intellectual property associated with the program. At the acquisition date, the program, which was less than 50% complete, was involved in testing proprietary prototypes prior to initiating required pre-clinical studies and human clinicals. Additional design improvements, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to commercially selling the product in Europe and the United States, which at the time of the transaction was expected in 2005 and 2006, respectively. The risks and uncertainties associated with completing development within a reasonable period of time included those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies and the timing of European and United States regulatory approvals. Approximately $11.8 million of the purchase price was charged to in-process research and development. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately $20.0 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, material net cash inflows were forecasted to commence in 2008. The remaining fair market value of the assets acquired consisted primarily of patents that are being amortized over their estimated economic life of 17 years.

Progress continues to be made on all of the purchased research and development programs. As of December 31, 2004 the programs related to the ev3 and Whitland acquisitions remained reasonably on track with the Company's original expectations. Although the PVT program remains reasonably on track with original expectations, the CE Mark is now expected in 2006, a conditional IDE was granted in the United States in January 2005, broad commercialization in the United States is anticipated in three to four years and the HDE filing has been postponed. In January 2005, the Company commenced human feasibility studies of the product developed under the Jomed program. Commercialization of this product could occur several years after the commencement of a clinical trial.

5. Asset Impairments

In September 2002, the Company recorded a $67.4 million charge related to the impairment of its investment in preferred stock of World Heart Corporation ("WorldHeart"). The investment was written down to $6.2 million, which represented the value of the Company's preferred stock investment had it been converted into common stock at October 15, 2002 (the closing date of September's books). The decision to record the charge was based primarily on WorldHeart's September 2002 decision to refocus its product development efforts by adopting a new design concept for a next generation product that resulted in a significant delay (approximately two years) in its product development timeline (with a revised commercial launch date of 2007) and impaired WorldHeart's competitive position. Accordingly, the Company concluded that sufficient risk existed that WorldHeart may be unable to fully liquidate the Company's investment in WorldHeart's preferred stock. The Company believed that the best objective indicator of the then fair value of its investment in WorldHeart's preferred stock was the market price of WorldHeart's common stock based upon the Company's expectation that the value of its preferred stock investment

would be realized through the common stock, as opposed to redemption of the preferred stock. In December, 2004, the Company recorded an additional charge of $4.7 million related to the impairment of its investment in WorldHeart resulting from the decline in its stock price.

Additionally, in 2004, the Company recorded charges totaling $4.3 million related to the other-than-temporary impairment of technology investments in three unconsolidated affiliates. Two of the affiliates had announced they were discontinuing their development efforts and the book value of those investments was reduced to the residual distribution Edwards Lifesciences expects to receive from those companies. The other affiliate performed a reset financing that reduced the net value per share for all existing investors. This investment is now recorded at the reduced value.

6. Special Charges, Net

During the years ended December 31, 2004, 2003 and 2002, Edwards Lifesciences recorded special charges and credits comprised of the following (in millions):

	2004	2003	2002
Discontinued products	$10.6	$ —	$ —
Sale of property development rights	(7.4)	—	—
Charitable fund	5.0	—	—
Severance charge	—	13.0	—
Resolution of Baxter arbitration	—	5.3	—
Loss on sale of business	—	3.3	—
Pension curtailment	—	1.9	—
Spin-off expenses	—	—	3.3
Total special charges	$ 8.2	$23.5	$3.3

Discontinued Products

Due to a re-prioritization of the Company's investment initiatives, the Company decided in March 2004 to discontinue its sales effort of its *Lifepath AAA* endovascular graft program. In the first quarter of 2004, the Company recorded a special charge of $8.4 million related primarily to inventory and contractual clinical obligations. In addition, the Company discontinued certain lower margin cardiology products in Japan resulting in a charge of $2.2 million related primarily to other non-productive assets.

Sale of Property Development Rights

In November 2004, the Company recorded income of $7.4 million for the sale of property development rights in Irvine, California, that had no book value at the time of the sale.

Charitable Fund

In December 2004, the Company recorded a charge of $5.0 million for an irrevocable contribution to a third party to create a charitable fund.

Severance Charge

In July 2003, the Company recorded a charge of $13.0 million associated with a decision to streamline operations. The charge was related primarily to the severance costs associated with reducing the Company's worldwide workforce by 136 employees, primarily in the United States and Europe. As of December 31, 2004, $0.3 million of the charge remained unpaid.

Baxter Arbitration Settlement

In January 2004, the Company concluded a dispute resolution proceeding with Baxter. Each company sought reimbursement from the other for a variety of claims arising from the Company's spin-off from Baxter in April 2000. The resolution resulted in a $5.3 million charge related primarily to the valuation of receivables at the date of spin-off, and a $5.4 million increase to Additional Contributed Capital related to the true-up of the beginning balance of equity.

Loss on Sale of Business

Effective July 4, 2003, the Company sold its German perfusion services subsidiary to WKK GmbH, a German-based provider of hospital services, for a nominal amount. Sales generated by the German perfusion services subsidiary were approximately $3.5 million during the six months ended June 30, 2003 and $6.6 million for the year 2002. In accordance with SFAS No. 144, *"Accounting for the Impairment or Disposal of Long-Lived Assets,"* and Staff Accounting Bulletin No. 100, *"Restructuring and Impairment Charges,"* the Company recorded a pre-tax impairment charge of $3.3 million in the second quarter of 2003 to reduce the carrying value of the subsidiary's assets to fair value based upon the proceeds from the sale.

Pension Curtailment

On November 4, 2003, the Company suspended its defined benefit pension plan in Puerto Rico (the "Plan"). Effective December 31, 2003, employees ceased earning additional defined benefits for future services. To mitigate the Puerto Rico employees' reduced benefits from the Plan's suspension, effective January 1, 2004, the Company increased its contributions to the Puerto Rico 1165(e) defined contribution plan. In accordance with SFAS No. 88, *"Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits,"* the Company recorded a curtailment loss of $1.9 million during the fourth quarter 2003. As of December 31, 2004, the Plan's accumulated benefit obligation exceeded the fair value of its assets by $5.2 million.

Spin-Off Expenses

The Company recorded a $3.3 million charge for legal, administrative and regulatory expenses related to the October 2002 acquisition of the cardiovascular business in Japan (see "Joint Venture in Japan").

7. Accounts Receivable Securitization

Edwards Lifesciences has two agreements (the "Japan Receivables Facility" and the "U.S. Receivables Facility," or the "Facilities") with financial institutions whereby it securitizes, on a continuous basis, an undivided interest in certain eligible trade account receivables. In December 2002, the Company entered into the Japan Receivables Facility whereby the Company's Japanese subsidiary (Edwards Lifesciences Japan Limited) sells eligible accounts receivable directly to a financial institution. Under the U.S. Receivables Facility, the Company sells eligible accounts receivable to a wholly-owned, qualified, special purpose, bankruptcy-remote subsidiary formed for the purpose of

buying and selling these receivables, which then sells the participating interests in the receivables to a financial institution.

The transactions under both Facilities are accounted for as sales of accounts receivable. The Company retained servicing responsibilities and subordinated residual interests in the accounts receivables. The Company receives annual servicing fees approximating one percent of the outstanding balance and rights to future cash flows arising after the investors in the securitization trust have received their contractual return. No servicing asset or liability has been recorded due to the immateriality of the balances. The investors and the securitization trust have no recourse to the Company's other assets for failure of debtors to pay when due. The Company's residual interests are subordinate to the investors' interests. The U.S. Receivables Facility is renewable for one-year periods at the Company's option and will expire on December 19, 2005. The Japan Receivables Facility will expire on December 3, 2005.

Sales of receivables under these programs result in a reduction of accounts receivable on the Company's Consolidated Balance Sheets. Residual interests of $9.8 million and $14.2 million as of December 31, 2004 and 2003, respectively, are included in Other Current Assets. The interests are carried at their fair value, estimated as the net realizable value, which considers the relatively short liquidation period and includes an estimated provision for credit losses. Pursuant to the terms of the Facilities, the Company had sold $90.4 million and $91.2 million of trade accounts receivable as of December 31, 2004 and 2003, respectively, resulting in a reduction of accounts receivable on the Company's Consolidated Balance Sheets, and received funding of $80.4 million and $76.9 million, respectively. Costs associated with the sale of receivables, primarily related to the discount and loss on sale, were $1.0 million, $0.8 million and $1.5 million in 2004, 2003 and 2002, respectively, and are included in Other (Income), net.

8. Goodwill and Other Intangible Assets

On January 1, 2002, the Company adopted SFAS No. 142, *"Goodwill and Other Intangible Assets,"* whereby goodwill is no longer amortized, but instead is subject to a periodic impairment review, performed by the Company in the fourth quarter of each year. As the Company's operations are comprised of one reporting unit, the Company reviews the recoverability of its goodwill by comparing the Company's fair value to the net book value of its assets. If the book value of the Company's assets exceeds the Company's fair value, the goodwill is written down to its implied fair value. The impairment analyses were completed in the fourth quarters of 2004, 2003 and 2002, and resulted in no impairments.

In April 2003, the Company purchased the technology and intellectual property associated with Embol-X Inc.'s surgically placed, intra-aortic embolic management system. The transaction was accounted for as a purchased business combination. The total consideration for Embol-X Inc. was $13.6 million of which $4.4 million was allocated to goodwill, which was subsequently reduced by $0.5 million in 2004.

If prior to April 16, 2008, the Company's sales of medical devices from the transferred technology are at least $20.0 million in any consecutive 12-month period, the Company will pay an additional $5.0 million to Embol-X Inc. This contingent obligation has not been recorded in the Company's balance sheet as of December 31, 2004. Sales of medical devices from the transferred technology were $1.3 million for 2004.

Other intangible assets subject to amortization consisted of the following (in millions):

December 31, 2004	Patents	Unpatented Technology	Other	Total
Cost	$196.3	$ 36.4	$23.8	$ 256.5
Accumulated amortization	(78.6)	(20.6)	(4.7)	(103.9)
Net carrying value	$117.7	$ 15.8	$19.1	$ 152.6

December 31, 2003	Patents	Unpatented Technology	Other	Total
Cost	$116.9	$ 36.3	$14.3	$167.5
Accumulated amortization	(64.8)	(18.0)	(3.7)	(86.5)
Net carrying value	$ 52.1	$ 18.3	$10.6	$ 81.0

During 2004, the cost of other intangible assets increased $89.0 million primarily due to the acquisitions discussed in Note 4 of $75.4 million and capitalized litigation costs of $4.5 million.

Amortization expense related to other intangible assets for the years ended December 31, 2004, 2003 and 2002 was $17.5 million, $9.5 million and $9.5 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2005	$16.5
2006	18.6
2007	18.7
2008	18.7
2009	17.6

9. Accounts Payable and Accrued Liabilities

	December 31, 2004	December 31, 2003
	(in millions)	
Accounts payable	$ 62.0	$ 67.3
Employee compensation and withholdings	51.3	39.2
Property, payroll and other taxes	35.2	30.5
Derivative liability (Note 11)	10.3	12.4
Other accrued liabilities	36.6	34.7
	$195.4	$184.1

10. Long-Term Debt, Credit Facilities and Lease Obligations

As of December 31, 2004, the Company had one unsecured revolving credit agreement (the "Credit Agreement") providing for up to an aggregate of $500.0 million in one- to six-month borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate plus 0.5%, which includes a facility fee and is subject to adjustment in the event of a change in the Company's leverage ratio, as defined by the

Credit Agreement. The Credit Agreement expires on June 26, 2009. As of December 31, 2004, borrowings of $117.1 million were outstanding under the Credit Agreement. Edwards Lifesciences pays a facility fee, regardless of available or outstanding borrowings, currently at an annual rate of 0.1% for the Credit Agreement. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with at December 31, 2004.

In May 2003, the Company issued $150.0 million of convertible senior debentures, issued at par, bearing an interest rate of 3.875% per annum due May 15, 2033 (the "Notes"). Interest is payable semi-annually in May and November. Issuance costs of approximately $4.4 million are being amortized to interest expense over 5 years. The Notes are convertible into 18.29 shares of the Company's common stock for each $1,000 principal amount of Notes (conversion price of $54.66 per share), subject to adjustment. The Notes may be converted, at the option of the holders, on or prior to the final maturity date under any of the following circumstances:

- during any fiscal quarter, if the closing sale price per share of the Company's common stock exceeds 120% of the conversion price;
- if the Notes have been called for redemption; or
- upon the occurrence of specified corporate events.

Holders of the Notes have the right to require the Company to purchase all or a portion of their Notes at a price equal to 100% of the principal amount of the Notes plus any accrued and unpaid interest on May 15, 2008, 2013, and 2018. The Company will pay cash for all Notes so purchased on May 15, 2008. For any Notes purchased by the Company on May 15, 2013 or 2018, the Company may, at its option, choose to pay the purchase price in cash, in shares of the Company's common stock, or any combination thereof. The Company must pay all accrued and unpaid interest in cash.

The Company may redeem for cash all or part of the Notes at any time on or after May 15, 2008, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus any accrued and unpaid interest.

Beginning with the six-month interest period commencing May 15, 2008, holders of the Notes will receive contingent interest at a rate of 0.25% if the trading price of the Notes equals or exceeds 120% of the principal amounts of the Notes. This contingent interest payment feature represents an embedded derivative. Based on the immaterial value associated with this feature, no value has been assigned to the derivative at issuance or at December 31, 2004.

Edwards Lifesciences utilizes interest rate swap agreements in managing its exposure to interest rate fluctuations. Interest rate swap agreements are executed as an integral part of specific debt transactions. Edwards Lifesciences' interest rate swap agreements involve agreements to receive a floating rate and pay a fixed rate, at specified intervals, calculated on an agreed-upon notional amount. As of December 31, 2004, Edwards Lifesciences had in place three interest rate swaps with a total notional amount of $157.5 million to swap floating rate United States dollar and Yen denominated debt obtained under the Company's revolving credit facilities for fixed rates. The original maturities of the interest rate swap agreements are between three and five years. These interest rate swap agreements in place as of December 31, 2004 are set to expire in May and July of 2005.

The weighted average interest rate under all debt obligations was 5.1% and 5.6% at December 31, 2004 and 2003, respectively, including the effect of interest rate swap agreements. The rates have been calculated using rates in effect at December 31, 2004.

Future minimum lease payments (including interest) under noncancelable operating leases and aggregate debt maturities at December 31, 2004 were as follows (in millions):

	Operating Leases	Aggregate Debt Maturities
2005	$13.1	$ —
2006	11.5	—
2007	8.9	—
2008	8.0	—
2009	7.2	—
Thereafter	1.1	267.1
Total obligations and commitments	$49.8	$267.1

Included in debt at December 31, 2004 and 2003 were unsecured notes denominated in Japanese Yen of ¥7.0 billion (US$67.1 million) and ¥6.0 billion (US$55.8 million), respectively.

Certain facilities and equipment are leased under operating leases expiring at various dates. Most of the operating leases contain renewal options. Total expense for all operating leases was $14.0 million, $12.3 million, and $6.8 million for the years 2004, 2003 and 2002, respectively.

11. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

Fair Values of Financial Instruments

The consolidated financial statements include financial instruments whereby the fair market value of such instruments may differ from amounts reflected on a historical basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities and debt. The fair values of certain investments in unconsolidated affiliates are estimated based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. The carrying amount of the Company's long-term debt approximates fair market value based on prevailing market rates. The Company's other financial instruments generally approximate their fair values based on the short-term nature of these instruments.

Derivative Financial Instruments

The Company utilizes a variety of derivative financial instruments to manage its currency exchange rate and interest rate risk as summarized below. Notional amounts are stated in United States dollar equivalents at spot exchange rates at the respective dates. The Company does not enter into these arrangements for trading or speculation purposes.

	December 31,			
	2004		2003	
	Notional Amount	Fair Value	Notional Amount	Fair Value
	(In millions)			
Interest rate swap agreements	$157.5	$(2.2)	$155.8	$(6.9)
Option-based products	236.6	(2.9)	189.1	(3.0)
Forward currency agreements	54.2	(5.2)	222.7	(2.5)

The fair value of financial instruments was estimated by discounting expected cash flows using quoted market interest rates and foreign exchange rates as of December 31, 2004 and 2003. Considerable judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

At December 31, 2004 and 2003, the fair value of option-based products, forward currency and interest rate swap agreements is recorded in Accrued Liabilities. During the year ended December 31, 2004 and 2003, the Company reclassified from Accumulated Other Comprehensive Income (Loss) a net loss of $8.4 million and $9.3 million, respectively, to Cost of Goods Sold, and a net loss of $5.6 million and $5.7 million, respectively, to Interest Expense, Net. The Company expects that during the next 12 months it will reclassify to earnings a $2.0 million loss currently recorded in Accumulated Other Comprehensive Income (Loss). For the year ended December 31, 2004 and 2003, the Company expensed $1.4 million and $1.1 million, respectively, related to the time value of option-based products.

12. Common Stock

The Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program (the "Program") provides for the grant of incentive and non-qualified stock options, restricted stock and other stock-based incentive awards for eligible employees and contractors of the Company. Under the Program, these grants are generally awarded at a price equal to the fair market value at the date of grant based upon the closing price on the date immediately preceding the grant date. Options to purchase shares of the Company's common stock granted under the Program generally vest over predetermined periods and expire 7 years after the date of grant. An aggregate of 15.5 million shares of the Company's common stock has been reserved for issuance under the Program.

On April 3, 2000, the Company granted two types of stock options to purchase shares of Edwards Lifesciences' common stock under the Program. One type of stock option permitted the purchase of approximately 5.7 million shares at an exercise price of $13.88, the fair market value at the date of grant, and vested 30% on April 3, 2002, and 70% on April 3, 2003. The other type of stock options permitted the purchase of approximately 2.2 million shares at a range of exercise prices from $10.20 to $15.71; these stock options vested as of the end of September 2002.

The Company also maintains the Nonemployee Directors and Consultants Stock Incentive Program (the "Nonemployee Program"). The plan was amended February 2004 and under the amended Nonemployee Program, each non-employee director annually receives 10,000 stock options or 4,000 restricted stock units of the Company's common stock, or a combination thereof. Additionally, each non-employee director may elect to receive all or a portion of the cash retainer to which the director is otherwise entitled through the issuance of stock options, or restricted stock units. A one-time grant of 5,000 shares of restricted stock was made to each of the non-employee directors pursuant to the Nonemployee Program. These grants vest 50% after one year and the balance vests after two years from the date of grant. Under the amended Nonemployee Program, an aggregate of 600,000 shares of the Company's common stock has been authorized for issuance pursuant to the Nonemployee Program. As of December 31, 2004, 282,046 options, restricted shares or restricted stock units have been issued under the Nonemployee Program. Grants of restricted stock to non-employees are charged to unearned compensation in Stockholders' Equity at their intrinsic value and recognized as expense over the vesting period. Compensation expense recognized for such grants was approximately $0.1 million for 2004, 2003 and 2002.

Stock option activity under the Program and the Nonemployee Program was as follows (number of options in thousands):

	2004		2003		2002	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, beginning of year	10,992	$22.65	9,794	$17.97	7,716	$14.79
Options granted	786	33.69	3,884	30.35	2,784	26.03
Options exercised	(1,373)	17.61	(2,085)	14.73	(552)	14.17
Options cancelled	(522)	28.68	(601)	24.89	(154)	18.17
Outstanding, end of year	9,883	23.90	10,992	22.65	9,794	17.97
Exercisable, end of year	6,000	19.82	5,346	14.52	3,251	14.52

The following table summarizes stock options outstanding at December 31, 2004 (number of options in thousands):

	Outstanding			Exercisable	
Range of Exercise Prices	Number of Options	Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$13.88	2,225	5.25	13.88	2,225	13.88
$10.20-$15.71	744	3.45	12.40	744	12.40
$15.44-$36.52	6,914	7.49	28.37	3,031	26.00
	9,883	6.68	23.90	6,000	19.82

Employee Stock Purchase Plan

The Company has two employee stock purchase plans ("ESPP") for eligible employees to purchase shares of the Company's common stock at 85% of the lower of the fair market value of Edwards Lifesciences common stock

on the effective date of subscription or the date of purchase. Under the ESPP, employees can authorize the Company to withhold up to 12% of their compensation for common stock purchases, subject to certain limitations. The ESPP is available to all active employees of the Company paid from the United States payroll and to eligible employees of the Company outside the United States to the extent permitted by local law. The ESPP for United States employees is qualified under Section 423 of the Internal Revenue Code. The Board of Directors authorized an aggregate of 2,150,000 shares of the Company's common stock for issuance under the ESPP. As of December 31, 2004 and 2003, 1,002,718 and 731,606 shares, respectively, have been issued under the plans.

Stockholder Rights Plan

The Company has adopted a Stockholder Rights Plan to protect stockholders' rights in the event of a proposed or actual acquisition of 15% or more of the outstanding shares of the Company's common stock. As part of this plan, each share of the Company's common stock carries a right to purchase one one-hundredth (1/100) of a share of Series A Junior Participating Preferred Stock (the "Rights"), par value $0.01 per share, subject to adjustment, which becomes exercisable only upon the occurrence of certain events. The Rights are subject to redemption at the option of the Board of Directors at a price of $0.01 per right until the occurrence of certain events. The Rights expire on March 31, 2010, unless earlier redeemed or exchanged by the Company.

Treasury Stock

In November 2001, the Company's Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 2.0 million shares of the Company's outstanding common stock. In addition, on May 6, 2003, the Company's Board of Directors approved a second stock repurchase program authorizing the Company to purchase an additional 2.0 million shares of the Company's outstanding common stock through December 31, 2005. In May 2004, the Board of Directors approved a third stock repurchase program authorizing the Company to purchase an additional 2.0 million shares of the Company's outstanding common stock through December 31, 2006. Stock repurchased under these programs will primarily be used to offset obligations under the Company's employee stock option programs. During 2004 and 2003, the Company repurchased 1,713,200 and 1,766,300 shares at an aggregate cost of $59.1 million and $49.4 million, respectively. The timing and size of any future stock repurchases are subject to a variety of factors, including market conditions, stock prices and other cash requirements.

13. Employee Benefit Plans

Defined Benefit Plans

Edwards Lifesciences adopted a defined benefit pension plan in Puerto Rico and in certain European countries. On November 4, 2003, the Company suspended its defined benefit pension plan in Puerto Rico (the "Plan"). Effective December 31, 2003, employees ceased earning additional defined benefits for future services. To mitigate the Puerto Rico employees' reduced benefits from the Plan's suspension, the Company increased its contributions to the Puerto Rico 1165(e) defined contribution plan.

On October 1, 2002, the Company completed its spin-off from Baxter and acquired the cardiovascular business in Japan (see Notes 1 and 3). As part of the transaction, the Company acquired the defined benefit plan that covered the Japan employees and the related pension assets and liabilities.

The Company uses a November 1 measurement date for its plans.

Information regarding the Company's defined benefit pension plans in Puerto Rico, Japan and certain European countries is as follows (in millions):

	Years Ended December 31,	
	2004	2003
Benefit Obligations:		
Beginning of period	$ 45.9	$ 44.7
Service cost	2.6	3.3
Interest cost	1.9	2.2
Participant contributions	0.2	0.4
Actuarial loss	4.8	2.3
Curtailment gains	—	(8.7)
Benefits paid	(1.4)	(2.0)
Currency exchange rate changes and other	1.9	3.7
End of year	$ 55.9	$ 45.9
Fair Value of Plan Assets:		
Beginning of period	$ 29.8	$ 22.9
Actual return on plan assets	1.5	2.7
Employer contributions	3.2	3.6
Participant contributions	0.5	0.6
Benefits paid	(1.4)	(2.0)
Currency exchange rate changes and other	1.0	2.0
End of year	$ 34.6	$ 29.8
Funded Status of Plans:		
Funded status of plans	$(20.9)	$(16.1)
Unrecognized net transition obligation	0.6	0.7
Unrecognized net actuarial losses	12.3	6.6
Unrecognized prior service cost	(0.8)	(0.9)
Net liability on balance sheet	$ (8.8)	$ (9.7)
Net Liability on Balance Sheet Consists of:		
Accrued benefit liability	$(13.1)	$(10.4)
Accumulated other comprehensive loss	3.7	0.4
Deferred tax asset	0.6	0.3
Net liability on balance sheet	$ (8.8)	$ (9.7)

The accumulated benefit obligation for all defined benefit pension plans was $48.0 million and $39.0 million at December 31, 2004 and 2003, respectively. For the years ended December 31, 2004 and 2003, the Company

included $3.3 million and $0.4 million, respectively, in other comprehensive income arising from an increase in the additional minimum pension liability.

The components of net periodic benefit cost are as follows (in millions):

	Years Ended December 31,		
	2004	2003	2002
Service cost	$ 2.6	$ 3.3	$ 1.6
Expected employee contributions	(0.2)	(0.2)	—
Interest cost	1.9	2.2	1.7
Expected return on plan assets	(1.9)	(1.6)	(1.5)
Curtailment loss	—	1.9	—
Amortization of prior service cost and other	0.3	0.8	0.1
Net periodic pension benefits cost	$ 2.7	$ 6.4	$ 1.9

Significant assumptions used in determining benefit obligations and net periodic benefit costs are summarized as follows (in weighted averages):

	Years Ended December 31,	
	2004	2003
Discount Rate	4.07%	4.24%
Expected return on plan assets	4.59%	6.77%
Rate of compensation increase	2.97%	3.05%

Through consultation with investment advisors, expected long-term returns for each of the plans' strategic asset classes were developed. Several factors were considered, including survey of investment managers' expectations, current market data, minimum guaranteed returns in certain insurance contracts and historical market returns over long periods. Using policy target allocation percentages and the asset class expected returns, a weighted-average expected return was calculated.

The actual weighted-average asset allocations at December 31, 2004, and 2003, by asset category are as follows:

	Years Ended December 31,	
	2004	2003
Equity securities	47.9%	47.5%
Debt securities	23.3%	23.3%
Other	28.8%	29.2%
Total	100.0%	100.0%

The Company's investment strategy for plan assets is to seek a competitive rate of return relative to an appropriate level of risk and to earn performance rates of return in accordance with the benchmarks adopted for each asset class. Risk management practices include diversification across asset classes and investment styles, and periodic rebalancing toward asset allocation targets.

The Company's corporate Administrative and Investment Committee decides the target allocation for the Puerto Rico defined benefit plan. The Administrative and Investment Committee decides on the defined benefit plan provider in all other locations and that provider decides the target allocation. The target asset allocation selected reflects a risk/return profile the Company feels is appropriate relative to the plan's liability structure and return goals. In certain plans, asset allocations may be governed by local requirements.

Target weighted-average asset allocations at December 31, 2004, by asset category are as follows:

	2004
Equity securities	46.6%
Debt securities	23.8%
Other	29.6%
Total	100.0%

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2004 are expected to be paid (in millions):

2005	$ 1.1
2006	1.3
2007	1.3
2008	1.4
2009	1.5
2010-2014	11.3

Expected employer contributions, at December 31, 2004 for fiscal 2005 are $2.6 million.

Defined Contribution Plans

The Company's employees in the United States and Puerto Rico are eligible to participate in a qualified 401(k) and 1165(e) plan, respectively. In the United States, participants may contribute up to 25% of their annual compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 3% of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis. Edwards Lifesciences matches the next 2% of the participant's annual eligible compensation to the plan on a 50% basis. In Puerto Rico, participants may contribute up to 10% of their annual compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 6% of the participant's annual eligible compensation contributed to the plan on a 50% basis. Matching contributions relating to Edwards Lifesciences employees were $5.2 million, $4.4 million and $4.4 million in 2004, 2003 and 2002, respectively.

The Company has a nonqualified deferred compensation plan for a select group of management that provides the opportunity to defer a specified percentage of their cash compensation. Participants may elect to defer up to 100% of bonus and 25% of total annual compensation. The Company's obligations under this plan are unfunded. The amount accrued under this plan was $7.7 million and $5.5 million at December 31, 2004 and 2003, respectively.

The Edwards Lifesciences Corporation Executive Option Plan (the "Executive Plan") became effective for participation by eligible employees in 2001. Eligible employees who participate in the Executive Plan may not participate in the Company's nonqualified deferred compensation plan. Under the Executive Plan, executive officers

and certain other key employees may elect to forgo a portion of their annual salary and bonus and instead receive an option to purchase shares of mutual funds or the Company's common stock. The options are granted quarterly with an initial exercise price equal to 25% of the fair market value per share (as defined in the Executive Plan) of the respective security on the grant date. The number of shares subject to each option is determined such that the difference between the aggregate fair market value (as defined in the Executive Plan) and the aggregate exercise price under the option is equal to the amount of forgone compensation attributable to the option. A total of 95,000 shares of the Company's common stock have been registered for issuance under the Executive Plan.

14. Related Party Transactions

In December 2001, the Chief Executive Officer of the Company received a $2.5 million loan pursuant to his employment agreement with the Company as approved by the Board of Directors. The loan was used for the purchase of his primary residence in connection with his relocation. The loan is non-interest bearing and is due in December 2006 or upon resignation or the termination of employment. The loan is collateralized by the Chief Executive Officer's primary residence.

15. Other (Income), Net

	Years Ended December 31,		
	2004	2003	2002
		(in millions)	
Foreign exchange (gain)	$(0.2)	$(10.6)	$ (4.1)
Legal settlements, net	(1.0)	—	(14.7)
Asset dispositions and write downs	—	3.6	2.3
Accounts receivable securitization costs	1.0	0.8	1.5
Other	(0.2)	1.5	(0.4)
	$(0.4)	$ (4.7)	$(15.4)

16. Income Taxes

The Company's income (loss) before provision for income taxes was generated from United States and international operations as follows (in millions):

	Years Ended December 31,		
	2004	2003	2002
United States	$ (74.2)	$ 0.7	$ 3.5
International	104.3	92.1	52.5
	$ 30.1	$92.8	$56.0

The provision (benefit) for income taxes consists of the following (in millions):

	Years Ended December 31,		
	2004	2003	2002
Current			
United States:			
Federal	$11.3	$ —	$ 0.6
State and local	1.3	0.2	0.3
International, including Puerto Rico	12.3	6.3	10.6
Current income tax expense	24.9	6.5	11.5
Deferred			
United States:			
Federal	(1.4)	4.4	(7.4)
State and local	(1.8)	(1.4)	(0.9)
International, including Puerto Rico	6.7	4.3	(2.9)
Deferred income tax expense (benefit)	3.5	7.3	(11.2)
Total income tax expense	$28.4	$13.8	$ 0.3

The components of deferred tax assets and liabilities are as follows (in millions):

	December 31, 2004	December 31, 2003
Deferred tax assets		
Net operating loss carryforwards	$ 25.3	$ 32.0
Investments in unconsolidated affiliates	21.0	19.3
Tax credit carryforwards	16.3	17.5
Compensation and benefits	14.3	8.6
Accrued liabilities	8.0	6.5
Allowance for doubtful accounts	3.7	5.5
Other intangible assets	22.8	5.4
Inventories	2.6	2.1
Other	16.5	11.0
Total deferred tax assets	130.5	107.9
Deferred tax liabilities		
Property, plant and equipment	(10.8)	(14.6)
Other intangible assets	(47.5)	—
Other	(2.6)	(2.6)
Total deferred tax liabilities	(60.9)	(17.2)
Valuation allowance	(26.2)	(19.5)
Net deferred tax assets	$ 43.4	$ 71.2

At December 31, 2004, the Company had deferred tax assets of $130.5 million, partially offset by deferred tax liabilities of $60.9 million. The valuation allowance of $26.2 million as of December 31, 2004 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the deferred tax assets established for impairment losses on certain investments and the net operating loss carryforwards of certain non-United States subsidiaries.

Deferred income taxes have not been provided on the undistributed earnings of the Company's foreign subsidiaries of approximately $191.0 million as of December 31, 2004, since these amounts had been intended to be permanently reinvested in foreign operations. However, in October 2004, the American Jobs Creation Act of 2004 (the "Act") was signed into law, which allows companies to repatriate cash into the United States at a special, temporary effective tax rate of 5.25 percent. The Company's evaluation of the amount of foreign earnings to repatriate under the Act, and the financial statement impact, is in process. As such, the Company is not in a position to decide on whether, and to what extent, foreign earnings that have not been remitted to the U.S. may be repatriated. Based on analysis to date, however, it is reasonably possible that between $150 million and $250 million may be repatriated. The related potential range of the income tax effect of the repatriation cannot be reasonably estimated at this time. The Company expects to be in a position to finalize its assessment by the end of the third quarter 2005.

A reconciliation of the United States federal statutory income tax rate to the Company's effective income tax rate is as follows (in millions):

	Years Ended December 31,		
	2004	2003	2002
Income tax expense at U.S. federal statutory rate	$ 10.5	$ 32.5	$ 19.6
Foreign income tax at different rates	(22.5)	(11.9)	(10.6)
Deemed dividends, net of foreign tax credit	2.5	6.2	—
Tax credits	(2.1)	(2.1)	(1.9)
(Benefit) from Brazil reorganization	—	(13.7)	—
State and local taxes, net of federal tax benefit	0.8	1.0	(0.1)
(Benefit) on sale of perfusion services business	—	—	(20.1)
Valuation allowance for loss on investment	6.6	—	13.8
Nondeductible in-process research and development expenses	27.8	—	—
Other	4.8	1.8	(0.4)
Income tax expense	$ 28.4	$ 13.8	$ 0.3

Excluding the impact of in-process research and development expenses, asset impairments and special charges, net, the effective income tax rate was 26% for all years presented. The Company expects its effective income tax rate for recurring operations to be 26% for 2005.

In exchange for the sale of the Novacor mechanical cardiac assist product line to WorldHeart in June 2000, the Company received WorldHeart preferred stock. In 2002, the investment in the WorldHeart preferred stock was deemed to be impaired and written down to its fair market value. A further write-down of the WorldHeart investment occurred in 2004. In addition, three other equity investments were deemed to be impaired and written down to fair market value in 2004. Due to the uncertainty of using any potential tax benefit for the losses, a valuation allowance of $13.8 million was established in 2002 and was increased by $6.6 million in 2004.

Of the $81.0 million charge related to the PVT acquisition discussed above, $1.7 million related to tax deductible payments to exercise certain licensing options pursuant to the stock purchase agreement, and the remaining $79.3 million charge is permanently disallowed for income tax purposes.

During 2003, the Company commenced a legal reorganization of its Brazil subsidiary to improve its balance sheet and to enhance its ability to conduct business in Brazil. Since being acquired a number of years ago, this subsidiary has incurred net operating losses primarily due to the devaluation of the local currency and interest expense incurred on inter-company debt. In addition, the reorganization allowed the Company to recognize the accumulated losses and inter-company debt write-off under United States tax law, resulting in federal and state tax benefits of $13.7 million.

During 2003, the Company recapitalized its Japan subsidiary. As a result, a deemed dividend occurred for U.S. tax purposes resulting in an incremental tax provision of $6.2 million, net of foreign tax credits.

As a result of tax law developments in 2002, the Company recorded a $20.1 million tax benefit during 2002 related to the loss on sale of its United States perfusion services business in June 2001.

As of December 31, 2004, the Company has approximately $64.6 million of non-United States tax net operating losses and $1.0 million of non-United States, non-expiring tax credits that are available for carryforward. Net operating loss carryforwards, and the related carryforward periods, at December 31, 2004 are summarized as follows (in millions):

	Gross Net Operating Loss	Tax Benefit Amount	Carryforward Period Ends
Non-United States net operating loss	$35.3	$ 9.2	2005–2014
Non-United States net operating loss	29.3	13.9	Indefinite
Total	$64.6	$23.1	

A valuation allowance of $6.8 million has been provided for certain of the above carryforwards. This valuation allowance reduces the deferred tax asset of $23.1 million to an amount that is more likely than not to be realized.

The Company's income tax returns in several locations are being examined by the local taxation authorities. Management believes that adequate amounts of tax and related interest, if any, have been provided for any adjustments that may result from these examinations.

17. Legal Proceedings

On June 29, 2000, Edwards Lifesciences filed a lawsuit against St. Jude Medical, Inc. alleging infringement of several Edwards Lifesciences United States patents. This lawsuit was filed in the United States District Court for the Central District of California, seeking monetary damages and injunctive relief. Pursuant to the terms of a January 7, 2005 settlement agreement, Edwards Lifesciences was paid $5.5 million by St. Jude, Edwards Lifesciences granted St. Jude a paid-up license for certain of its heart valve therapy products and the lawsuit was dismissed. The settlement will not have a material financial impact on the Company.

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc., Medtronic AVE, Cook, Inc. and W.L. Gore & Associates alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. On September 2, 2003, a second patent exclusively licensed to the Company was added to the lawsuit. Each of the defendants has answered and asserted various affirmative defenses and counterclaims. Discovery is proceeding.

In addition, Edwards Lifesciences is or may be a party to, or may be otherwise responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any pending legal matters, Edwards Lifesciences may incur charges in excess of presently established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is also subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of compliance with environmental protection laws,

management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

18. Segment Information

Edwards Lifesciences manages its business on the basis of one reportable segment. Refer to Note 1 for a description of the Company's business. The Company's products and services share similar distribution channels and customers and are sold principally to hospitals and physicians. Management evaluates its various global product portfolios on a revenue basis, which is presented below, and profitability is evaluated on an enterprise-wide basis due to shared infrastructures. Edwards Lifesciences' principal markets are the United States, Europe and Japan.

Geographic area data includes net sales, based on product shipment destination and long-lived tangible assets, based on physical location.

Beginning in January 2004, the Company recategorized its product lines. For comparison purposes, reclassifications have been made to prior years data.

	As of or for the Years Ended December 31,		
	2004	2003	2002
	(in millions)		
Net Sales by Geographic Area			
United States	$416.5	$384.3	$383.3
Europe	221.2	193.5	157.3
Japan	197.2	197.9	94.8
Other countries	96.6	84.8	68.6
	$931.5	$860.5	$704.0
Net Sales by Major Product and Service Area			
Heart Valve Therapy	$419.2	$366.4	$314.5
Critical Care	302.3	278.8	230.3
Cardiac Surgery Systems	107.3	115.0	94.6
Vascular	60.1	55.9	51.3
Other Distributed Products	42.6	44.4	13.3
	$931.5	$860.5	$704.0
Long-Lived Tangible Assets by Geographic Area			
United States	$172.8	$201.9	
Other countries	59.8	60.8	
	$232.6	$262.7	

19. Subsequent Event

On January 26, 2005, the Company announced it had sold its cardiopulmonary products business in Japan for total consideration of between $10.0 million and $20.0 million based upon the achievement of certain milestones. The Company also announced at that time that it was exiting its pacemaker distribution business in Japan and restructuring its Japanese operations. The transactions will result in the transfer or elimination of approximately 60 full-time positions, resulting in a charge in the first quarter of 2005 of between $6 million and $9 million. Sales generated by the cardiopulmonary products and pacemaker distribution businesses in Japan were approximately $37.3 million for the year 2004.

20. Quarterly Financial Results and Market for the Company's Stock (Unaudited)

	Years Ended December 31				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
	(in millions, except per share data)				
2004					
Net sales	$235.0	$234.6	$224.8	$237.1	$931.5
Gross profit	136.3	142.2	136.9	145.9	561.3
Net (loss) income(a)	(62.1)	25.5	12.4	25.9	1.7
(Loss) earnings per common share					
Basic	(1.04)	0.43	0.21	0.44	0.03
Diluted	(1.04)	0.41	0.20	0.42	0.03
Market price					
High	35.52	36.58	36.52	42.26	42.26
Low	29.61	31.88	32.77	32.60	29.61
2003					
Net sales	$212.5	$217.8	$206.1	$224.1	$860.5
Gross profit	123.4	128.2	119.2	130.3	501.1
Net income	14.5	21.1	24.5	18.9	79.0
Earnings per common share					
Basic	0.25	0.36	0.41	0.32	1.34
Diluted	0.24	0.34	0.40	0.31	1.29
Market price					
High	27.64	33.60	32.65	31.56	33.60
Low	24.40	26.95	25.77	26.90	24.40

(a) The first quarter 2004 includes an $81.0 million pretax purchased in-process research and development charge related to the Percutaneous Valve Technologies, Inc. acquisition. The third quarter 2004 includes a $12.3 million pretax purchased in-process research and development charge related to the acquisition of technology and intellectual property from ev3, Inc.

EDWARDS LIFESCIENCES CORPORATION

VALUATION AND QUALIFYING ACCOUNTS

(in millions)

	Balance at Beginning of Period	Additions: Charged to Costs and Expenses	Additions: Charged to Other Accounts	Deductions from Reserves(b)	Balance at End of Period
Year ended December 31, 2004					
Allowance for doubtful accounts and returns	$5.1	$ 6.0	$0.3	$(6.9)	$ 4.5
Inventory reserves	8.5	10.5(a)	0.1	(3.6)	15.5
Litigation reserves	2.0	1.0	—	(1.0)	2.0
Year ended December 31, 2003					
Allowance for doubtful accounts and returns	$5.5	$ 3.9	—	$(4.3)	$ 5.1
Inventory reserves	9.6	3.9(a)	—	(5.0)	8.5
Litigation reserves	4.1	1.1	—	(3.2)	2.0
Year ended December 31, 2002					
Allowance for doubtful accounts and returns	$4.3	$ 5.7	—	$(4.5)	$ 5.5
Inventory reserves	9.4	4.9(a)	1.8	(6.5)	9.6
Litigation reserves	3.4	1.4	—	(0.7)	4.1

(a) Inventory reserves result from inventory which is obsolete, is nearing its expiration date (generally triggered at six months prior to expiration), or is damaged or slow moving (defined as quantities in excess of a two year supply).

(b) The deductions related to allowances for doubtful accounts and returns represent accounts receivable which are written off, and product which is returned from customers. The deductions related to inventory reserves represent inventory that is disposed of or sold as part of a business transaction. The deductions related to litigation reserves represent settlements of litigation and reduced estimates of anticipated settlements.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures — The Company's management, including the Chief Executive Officer and Chief Financial Officer, has established disclosure controls and procedures to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the officers who certify the Company's financial reports and to other members of senior management and the Board of Directors.

Based on their evaluation as of December 31, 2004, the Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) are effective to ensure that the information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Management's Report on Internal Control Over Financial Reporting — The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation under the framework in *Internal Control — Integrated Framework,* the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2004. Management's assessment of the effectiveness of its internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Contol Over Financial Reporting — There have been no changes in the Company's internal controls over financial reporting that were identified during the evaluation that occurred during the Company's fourth fiscal quarter of 2004 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. ***Other Information***

On December 20, 2004, the Company entered into a Sixth Amendment to Receivables Purchase Agreement (the "Sixth Amendment") with Blue Ridge Asset Funding Corporation and Wachovia Bank, National Association. The Sixth Amendment (which is attached hereto as Exhibit 10.19 and incorporated herein by reference) modified certain terms of the Receivables Purchase Agreement dated as of December 21, 2000, as amended.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

This information required by this Item is set forth under the headings "Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Executive Officers of Edwards Lifesciences" in the definitive proxy materials to be filed in connection with its 2005 Annual Meeting of Stockholders (the "Proxy Statement") (which Proxy Statement will be filed with the Securities and Exchange Commission on or before April 18, 2005). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference.

The Company has adopted a code of ethics that applies to its principal executive officer, principal financial and accounting officer and controller. The code of ethics is posted on the Company's website, the address of which is www.edwards.com. The Company intends to include on its website any amendments to, or waivers from, a provision of its code of ethics that applies to the Company's principal executive officer, principal financial officer or controller that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

Item 11. ***Executive Compensation***

Except for information referred to in Item 402(a)(8) of Regulation S-K, the information contained under the headings "Election of Directors" and "Executive Compensation and Other Information" in the Proxy Statement is incorporated herein by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management***

The information contained under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement is incorporated herein by reference.

Item 13. ***Certain Relationships and Related Transactions***

The information contained under the heading "Related Party Transactions" in the Proxy Statement is incorporated herein by reference.

Item 14. ***Principal Accountant Fees and Services***

The information contained under the heading "Fees Paid to Principal Accountants" in the Proxy Statement is incorporated herein by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

Exhibits Filed With Securities and Exchange Commission

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Edwards Lifesciences Corporation (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
3.2	Amended and Restated Bylaws of Edwards Lifesciences Corporation
3.3	Form of Certificate of Designation for Edwards Lifesciences Corporation Series A Junior Participating Preferred Stock (included as Exhibit A to Exhibit 4.4)
4.1	Specimen form of certificate representing Edwards Lifesciences Corporation common stock (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences' Registration Statement on Form 10 (File No. 001-15525))
4.2	Indenture, dated as of May 9, 2003, by and between Edwards Lifesciences Corporation and JPMorgan Chase Bank including the form of 3.875% Convertible Senior Debenture due 2033 (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences' Registration Statement on Form S-3 (File No. 333-107405))
4.3	Form of Debenture (Exhibit A to the Indenture listed above as Exhibit 4.2)
4.4	Rights Agreement, dated as of March 31, 2000 (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
10.1	Form of Tax Sharing Agreement between Edwards Lifesciences Corporation and Baxter International Inc. (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' Registration Statement on Form 10 (File No. 001-15525))
10.2	Supplemental Reorganization Agreement and Amendment to Tax Sharing Agreement, dated as of July 25, 2002, by and between Baxter International Inc. and Edwards Lifesciences Corporation (incorporated by reference to Exhibit 10.34 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2002, under the Securities Exchange Act of 1934)
*10.3	Form of Edwards Lifesciences Corporation Change in Control Severance Agreement (incorporated by reference to Exhibit 10.4 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2000, under the Securities Exchange Act of 1934)
*10.4	Employment Agreement for Michael A. Mussallem (incorporated by reference to Exhibit 10.5 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2000, under the Securities Exchange Act of 1934)
*10.5	Promissory Note Secured by Deed of Trust for Michael A. Mussallem dated December 11, 2001 (incorporated by reference to Exhibit 10.6 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2001, under the Securities Exchange Act of 1934)
*10.6	Form of Employment Agreement (incorporated by reference to Exhibit 10.8 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
10.7	Five Year Credit Agreement dated as of June 28, 2004, among Edwards Lifesciences Corporation, as Borrower; the lenders party thereto; JP Morgan Chase Bank as Administrative Agent; J.P. Morgan Europe Limited as London Agent; Mizuho Corporate Bank, Limited as Tokyo Agent; Bank of America, N.A. as Syndication Agent; and The Bank of Tokyo-Mitsubishi, Ltd., Mizuho Corporate Bank, Limited, Suntrust Bank, Wachovia Bank, N.A., as Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2004, under the Securities Exchange Act of 1934)

Exhibit No.	Description
*10.8	Edwards Lifesciences Corporation Severance Pay Plan (incorporated by reference to Exhibit 10.21 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2000, under the Securities Exchange Act of 1934)
*10.9	Edwards Lifesciences Corporation Executive Option Plan (incorporated by reference to Exhibit 10.6 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.10	Edwards Lifesciences Corporation Executive Deferred Compensation Plan (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K filed on December 27, 2004, under the Securities Exchange Act of 1934)
*10.11	Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-40434))
*10.12	Edwards Lifesciences Corporation 401(k) Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-33056))
10.13	Receivables Purchase Agreement, dated as of December 21, 2000, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, and Wachovia Bank, N.A. (incorporated by reference to Exhibit 10.38 in Edwards Lifesciences' report on Form 10- K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
10.14	Amendment No. 1 to Receivables Purchase Agreement, dated as of February 1, 2001, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, and Wachovia Bank, N.A. (incorporated by reference to Exhibit 10.39 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
10.15	Second Amendment to Receivables Purchase Agreement, dated as of September 20, 2001, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, N.A. (incorporated by reference to Exhibit 10.40 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
10.16	Third Amendment to Receivables Purchase Agreement, dated as of March 8, 2002, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, N.A. (incorporated by reference to Exhibit 10.41 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
10.17	Fourth Amendment to Receivables Purchase Agreement, dated as of December 23, 2002, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, National Association
10.18	Forebearance Agreement and Fifth Amendment to Receivables Purchase Agreement, dated as of March 3, 2004, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, National Association

Exhibit No.	Description
10.19	Sixth Amendment to Receivables Purchase Agreement, dated as of December 20, 2004, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, National Association
10.20	Receivables Purchase Agreement, dated December 4, 2002, by and among Edwards Lifesciences Limited, a Japanese corporation, Apreco, Inc., a Delaware corporation and Citilease Company Limited, a Japanese corporation (incorporated by reference to Exhibit 10.42 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
*10.21	Long-Term Stock Incentive Compensation Program (as amended and restated as of February 20, 2003) (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.22	Nonemployee Directors Stock Incentive Program (amended and restated as of March 4, 2005)
*10.23	Agreement between Edwards Lifesciences Corporation and J. Randall Nelson, dated December 2003 (incorporated by reference to Exhibit 10.22 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2003, under the Securities Exchange Act of 1934)
*10.24	2001 Employee Stock Purchase Plan for United States Employees (amended and restated as of February 20, 2003) (incorporated by reference to Exhibit 10.4 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.25	2001 Employee Stock Purchase Plan for International Employees (amended and restated as of February 20, 2003) (incorporated by reference to Exhibit 10.5 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.26	Edwards Lifesciences Corporation 2005 Incentive Plan
*10.27	Edwards Lifesciences Corporation Officer Perquisite Program Guidelines
21.1	Subsidiaries of Edwards Lifesciences Corporation
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Represents management contract or compensatory plan

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EDWARDS LIFESCIENCES CORPORATION

By: /s/ MICHAEL A. MUSSALLEM
Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

March 4, 2005

We, the undersigned officers and directors of Edwards Lifesciences Corporation, hereby severally constitute and appoint Bruce P. Garren and Jay P. Wertheim, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, all amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable Edwards Lifesciences Corporation to comply with the provisions of the Securities Act of 1934, as amended, and all requirements of the Securities and Exchange Commission. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MICHAEL A. MUSSALLEM Michael A. Mussallem	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 4, 2005
/s/ CORINNE H. LYLE Corinne H. Lyle	Corporate Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 4, 2005
/s/ MIKE R. BOWLIN Mike R. Bowlin	Director	March 4, 2005
/s/ JOHN T. CARDIS John T. Cardis	Director	March 4, 2005
/s/ ROBERT A. INGRAM Robert A. Ingram	Director	March 4, 2005
/s/ VERNON R. LOUCKS JR. Vernon R. Loucks Jr.	Director	March 4, 2005
/s/ PHILIP M. NEAL Philip M. Neal	Director	March 4, 2005
/s/ DAVID E.I. PYOTT David E.I. Pyott	Director	March 4, 2005

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-33054, 333-33056, 333-40434, 333-52332, 333-52334, 333-52346, 333-60670, 333-98219 and 333-105961) and the Registration Statements on Form S-3 (Nos. 333-107405 and 333-116634) of Edwards Lifesciences Corporation of our report dated March 4, 2005 relating to the financial statements, financial statement schedule, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP

PricewaterhouseCoopers LLP

Orange County, California
March 4, 2005

Exhibit 31.1

EDWARDS LIFESCIENCES CORPORATION

CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATION

I, Michael A. Mussallem, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s)and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal controls over financial reporting, or caused such internal controls over financial reporting to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ MICHAEL A. MUSSALLEM

Michael A. Mussallem
Chairman of the Board and
Chief Executive Officer

Date: March 4, 2005

Exhibit 31.2

EDWARDS LIFESCIENCES CORPORATION

CERTIFICATIONS PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATION

I, Corinne H. Lyle, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal controls over financial reporting, or caused such internal controls over financial reporting to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ CORINNE H. LYLE

Corinne H. Lyle
Corporate Vice President,
Chief Financial Officer and Treasurer
(Chief Accounting Officer)

Date: March 4, 2005

Exhibit 32

EDWARDS LIFESCIENCES CORPORATION

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Edwards Lifesciences Corporation (the "Company") on Form 10-K for the year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Michael A. Mussallem, Chairman of the Board and Chief Executive Officer of the Company, and Corinne H. Lyle, Corporate Vice President, Chief Financial Officer and Treasurer, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL A. MUSSALLEM

Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

March 4, 2005

/s/ CORINNE H. LYLE

Corinne H. Lyle
Corporate Vice President, Chief Financial Officer and Treasurer (Chief Accounting Officer)

March 4, 2005