

EDWARDS LIFESCIENCES CORP
Form 10-K
March 01, 2007

[QuickLinks](#) -- Click here to rapidly navigate through this document

**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, 2006

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
(State or other jurisdiction of
incorporation or organization)

36-4316614
(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:

Common Stock, par value \$1.00 per share
Series A Junior Participating Preferred Purchase Rights
(currently traded with common stock)

Name of each exchange on which registered:

**New York Stock Exchange
New York Stock Exchange**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2006 (the last trading day of the registrant's most recently completed second quarter): \$2,637,207,729 based on a closing price of \$45.43 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 27, 2007, was 57,882,620.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2007 Annual Meeting of Stockholders (to be filed on or before April 20, 2007) are incorporated by reference into Part III, as indicated herein.

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report 2006
Table of Contents

PART I

Item 1.	Business	1
Item 1A.	Risk Factors	11
Item 1B.	Unresolved Staff Comments	21
Item 2.	Properties	21
Item 3.	Legal Proceedings	22
Item 4.	Submission of Matters to a Vote of Security Holders	22

PART II

Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	23
Item 6.	Selected Financial Data	24
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	48
Item 8.	Financial Statements and Supplementary Data	51
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	105
Item 9A.	Controls and Procedures	105
Item 9B.	Other Information	106

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	106
Item 11.	Executive Compensation	107
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	107
Item 13.	Certain Relationships and Related Transactions, and Director Independence	107
Item 14.	Principal Accountant Fees and Services	107

PART IV

Item 15.	Exhibits and Financial Statement Schedules	107
	Signatures	112

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 (as defined below in "Corporate Background") 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. See "Risk Factors" below for a further discussion of these risks.

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 progressive and pervasive in that it tends to worsen over time and 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 advanced 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. 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 or re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring. 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, Edwards Lifesciences' Cardiac Surgery Systems disposable products may be used while the patient's heart and lung functions are being bypassed. 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 otherwise required by the context, 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. The contents of the Company's Web site are not incorporated by reference into this report.

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, Horw, Switzerland and Techview, Singapore 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 the *PERIMOUNT Magna* valves, the newest generation pericardial valves for aortic and mitral replacement. The *PERIMOUNT* valve is the most widely prescribed tissue heart valve in the world due to its proven durability and performance. The Company's most recent additions to the *PERIMOUNT* product line include the *Magna* mitral valve, and the *PERIMOUNT Theon* aortic valve. The *Magna* mitral valve, approved in Europe and Canada, is designed specifically to address the mitral valve's unique anatomical structure and rigorous conditions. The durability of Edwards Lifesciences' tissue valves is extended through the use of its proprietary *ThermaFix* and *XenoLogiX* tissue treatment processes. The *ThermaFix* process has now been applied to all pericardial valves sold in the United States with the launch of the *PERIMOUNT Theon* aortic valve. Edwards Lifesciences also sells porcine

valves and stentless tissue 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. The Company has continued to extend its leadership in this field with introduction of disease-specific valve repair products including the *GeoForm* annuloplasty ring, and the newest release, the *Myxo ETlogix* annuloplasty ring.

Edwards Lifesciences is currently developing transcatheter heart valve repair and replacement technologies, designed to treat heart valve disease using catheter-based approaches as opposed to open surgical techniques. For aortic valve replacement, the Company has developed the *Edwards SAPIEN Transcatheter Heart Valve ("THV")*, formerly called the *Cribier-Edwards Percutaneous Heart Valve ("PHV")*, that can be delivered using the *RetroFlex* delivery system for transfemoral approaches, and the *Ascendra* delivery system for transapical approaches. Both are minimal access, beating heart surgery procedures. The Company is leveraging the knowledge and experience from its legacy of tissue heart valve engineering to apply to the transcatheter programs. In the area of transcatheter mitral valve repair, the Company is developing the *MONARC* mitral repair system and *MOBIUS* leaflet repair system. The Company believes that both aortic stenosis and mitral regurgitation in global populations today are under treated and as a result, the market opportunity for these less invasive heart valve therapies is substantial

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 cardiovascular 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, and the *PreSep* venous oximetry catheter for measuring central venous oxygen saturation. Edwards Lifesciences' newest addition to its hemodynamic monitoring product line is a minimally invasive cardiac monitoring technology, the *FloTrac* continuous cardiac output monitoring system, which was launched 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.

Outside of the United States, the Company also markets a range of products required to perform continuous hemofiltration therapies including access catheters, hemofilters, substitution fluids and pumps.

Cardiac Surgery Systems

The Cardiac Surgery Systems product line includes technologies used in conducting cardiac surgery procedures. Edwards Lifesciences is one of the top two global leaders in providing cannula used during cardiac surgery. Edwards' cannulae are used in venous drainage, aortic dispersion, and cardioplegia delivery. New products place particular emphasis on reducing trauma to vessel walls during cannula placement, usage, and removal. The Company's *Embol-X* intra-aortic filtration system is designed to capture emboli released at both application and release of the aortic cross clamp during on-pump cardiac surgery.

In addition, the Company is one of two providers of systems for conducting transmyocardial revascularization procedures. Edwards' proprietary carbon dioxide lasers and the associated disposable handpieces are utilized by cardiac surgeons in treating the no-option patient who presents with intractable anginal pain. The system is available in over 150 cardiac centers across the United States.

In December 2006, as part of a broader initiative to better focus its resources, the Company discontinued its *Optiwave 980* Cardiac Laser Ablation System, used to create lesions in cardiac tissue. During the fourth quarter of 2006, Edwards divested its remaining cardiopulmonary perfusion product line in Brazil. Since 2000, the Company has divested its cardiopulmonary perfusion product lines in the United States, Western Europe and Japan.

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 endoluminal occlusive disease, including self-expanding and balloon expandable stent products, balloon-tipped, catheter-based embolectomy products, as well as surgical clips and clamps. 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. Edwards Lifesciences currently holds FDA 510(k) clearance for the treatment of biliary obstructions, and an expanded European CE Mark that includes the treatment of PVD. These stents are used to prop open the occlusive segments of patients suffering from atherosclerotic vascular disease or malignant strictures in the biliary tree. The Company has continued to expand its *LifeStent* product line with the recent launch of its new *LifeStent FlexStar* self-expanding stent delivery system, which helps to ensure the easy and accurate delivery of its uniquely flexible stent technology. The Company also introduced the *LifeStent FlexStar XL*, a line of longer-length stents specifically designed for longer diseased segments. These longer-length stents help to eliminate the need for multiple stent use and resulting stent overlap.

Other Distributed Products

Other Distributed Products primarily include sales of intra-aortic balloon pumps and other products sold through the Company's operations in Japan.

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, performance, product differentiation and 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 primarily competes with Medtronic, Inc. and Terumo Corporation. 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' primary competitors are Johnson & Johnson, Boston Scientific Corporation, Medtronic, Inc., Abbott Laboratories, Inc. and ev3 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*, *PERIMOUNT*, *Research Medical* 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 2006.

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 have emerged 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 2006, 46% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

International. In 2006, 54% 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, India, 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.

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 mitigate risk and 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 any significant risk exists regarding the loss of any existing supply contract that 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 controls. 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, the Company 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 intended to design in quality and utilizes continuous improvement concepts throughout the product lifecycle.

Edwards Lifesciences' operations are certified under applicable international quality systems standards, such as ISO 9000 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.

Environmental Health and Safety

Edwards Lifesciences is committed to a safe and healthy workplace and the promotion of environmental excellence in its own communities and worldwide. Through its Environmental Health and Safety function, Edwards Lifesciences facilitates and monitors performance against these objectives at all levels of its organization. In order to measure performance, Edwards Lifesciences monitors a number of metrics, which include the generation of both regulated and non-regulated waste, emissions of air toxics, energy usage and lost time incidents in the Company's production activities. Each of the Company's manufacturing sites is evaluated annually with respect to a broad range of Environmental Health and Safety criteria.

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 focuses on opportunities within specific areas of cardiovascular disease and is dedicated to developing novel technologies to better enable clinicians to treat patients who suffer from the disease.

The Company invested \$114 million in research and development in 2006, \$99 million in 2005 and \$87 million in 2004 (11.0%, 9.9% 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 Therapy, Critical Care and Vascular product lines, including research and development relating to next-generation pericardial tissue valves and enhanced tissue processing technologies.

Edwards Lifesciences is investing in the development of transcatheter heart valve replacement and repair technologies, designed to treat heart valve disease using a catheter-based approach as opposed to open surgical techniques. The Company believes the market opportunity for catheter-based heart valve therapies is substantial. In the area of transcatheter aortic valve replacement, the Company is developing the *Edwards SAPIEN THV* aortic valve replacement system. In the area of transcatheter mitral valve repair, the Company is developing the *MONARC* mitral repair system and *MOBIUS* leaflet repair system.

In its Critical Care product line, 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 product line, the Company plans to broaden its *LifeStent* balloon-expandable and self-expanding non-coronary stent product line. Additionally, the Company is investing in additional growth opportunities to treat peripheral vascular disease.

During the fourth quarter of 2006, Sangamo BioSciences acquired Edwards Lifesciences' angiogenesis research and development project in exchange for one million shares of Sangamo common stock. Edwards Lifesciences will also receive royalties on certain products commercialized in the future.

Edwards Lifesciences' research and development activities are conducted primarily in facilities located in the United States and Israel. 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 570 issued United States patents, 270 pending United States patent applications, 1,010 issued foreign patents and 500 pending foreign patent applications, and has licensed numerous United States and foreign 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 respect by issued patents and/or pending patent applications. Edwards Lifesciences has a number of patents and pending patent applications in the United States, Europe, Australia, Japan and Canada on the *Carpentier-Edwards PERIMOUNT Magna* pericardial valves and the *Carpentier-Edwards PERIMOUNT Plus* pericardial valves. Edwards Lifesciences also has issued patents and pending patent applications directed to the

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

ThermaFix tissue treatment process that is used on the *PERIMOUNT*, *PERIMOUNT Plus* and *PERIMOUNT Magna* pericardial valves.

Edwards Lifesciences has many 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 Physioannuloplasty* ring, as well as the *Edwards MC³* tricuspid annuloplasty system, the *IMR ETlogix* annuloplasty ring and the *GeoForm* annuloplasty ring. Edwards Lifesciences also has a number of significant United States and foreign patents and patent applications in the field of transcatheter heart valve repair and replacement.

Edwards Lifesciences owns key United States and foreign patents and patent applications that cover catheters, systems and methods for hemodynamic monitoring and vascular access products. 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* and *EMBOL-X Glide* systems. 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.

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 licensed certain patent rights to others.

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.

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

<i>Advanced Venous Access</i>	<i>Edwards MIRA</i>	<i>Magna</i>
<i>AnastaFlo</i>	<i>Edwards Prima Plus</i>	<i>PERIMOUNT</i>
<i>AVA 3Xi</i>	<i>Edwards MC³</i>	<i>PERIMOUNT Magna</i>
<i>AVA HF</i>	<i>EMBOL-X</i>	<i>PERIMOUNT Plus</i>
<i>Carpentier-Edwards</i>	<i>EverClip</i>	<i>PreSep</i>
<i>Carpentier-Edwards Classic</i>	<i>EverGrip</i>	<i>Swan-Ganz</i>
<i>Carpentier-Edwards Physio</i>	<i>Fogarty</i>	<i>Tricentrix</i>
<i>CCOmbo</i>	<i>GeoForm</i>	<i>Vantex</i>
<i>Cosgrove-Edwards</i>	<i>IMR ETlogix</i>	<i>Vigilance</i>
<i>Edwards Lifesciences</i>	<i>LifeStent</i>	

Other key trademarks owned by Edwards Lifesciences include:

<i>Ascendra</i>	<i>MOBIUS</i>	<i>ThermaFix</i>
<i>Cribier-Edwards</i>	<i>MONARC</i>	<i>Vigileo</i>
<i>Edwards</i>	<i>Myxo ETlogix</i>	<i>VisuFlo</i>
<i>Edwards SAPIEN THV</i>	<i>PERIMOUNT Theon</i>	<i>XenoLogiX</i>
<i>EMBOL-X Glide</i>	<i>Research Medical</i>	
<i>FloTrac</i>	<i>RetroFlex</i>	

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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 Environment. In the United States, the Food and Drug Administration ("FDA") has responsibility for regulating medical devices. The FDA regulates design, development, manufacturing, labeling and record-keeping for medical devices, and reporting of adverse events by manufactures and users 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 is resource-intensive, lengthy and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of Edwards Lifesciences' products.

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.

As previously announced, in February 2007, the Los Angeles District Office of the FDA issued a Warning Letter to the Company resulting from the FDA's inspection of the Company's facility in Irvine, California that concluded in August 2006. The Warning Letter relates specifically to elements of the Company's quality systems, including complaint handling, documentation and quality systems training. The Warning Letter states that until the Company resolves the outstanding issues covered by the Warning Letter, the Company will not receive premarket approvals for devices that are reasonably related to those issues.

Medical device laws are also in effect in most markets around the world including Europe, Japan and many other countries where Edwards Lifesciences does business. Similar to the regulations imposed by the FDA, the regulations in these countries range from comprehensive device approval requirements for some or all of the Company's products to requests for product data, certifications or record-keeping. The process of obtaining approval to market a product and/or complying with product data requests can be resource-intensive, lengthy and costly, and such requirements may or may not be more rigorous than those required by the FDA. Overall, the number and scope of government regulations and requirements are increasing.

Edwards Lifesciences also is 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 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, Europe and Japan. As a result of

these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies.

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 government-funded programs. While Edwards Lifesciences has been unaware of significant domestic price resistance directly as a result of proposed changes to reimbursement policies, 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.

Employees

As of December 31, 2006, Edwards Lifesciences had approximately 5,550 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 Singapore. 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.

Item 1A. Risk Factors

An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10-K or in our other filings with the Securities and Exchange Commission. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. If any of these events or circumstances occurs, Edwards Lifesciences' business, financial condition, results of operations or prospects could be materially harmed. In that case, the value of Edwards Lifesciences' securities could decline and an investor could 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 substantial time and 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 newer 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. 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, or death of, patients. The occurrence of such a problem could result in product liability lawsuits and claims, safety alerts or product recalls in the future, which, 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 incur charges related to such matters in excess of established reserves and which could have a material adverse impact on Edwards Lifesciences' net income or net cash flows.

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' heart valve therapy products are manufactured from treated natural animal tissue and man-made materials. Edwards Lifesciences' non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metals. 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, availability or constraints resulting from regulatory requirements. While Edwards Lifesciences works closely with its suppliers to assure continuity of supply and maintain high quality and reliability, these efforts may not be successful. In addition, due to the rigorous regulations and requirements of the U.S. FDA regarding the manufacture of the Company's products, Edwards Lifesciences may not be able to quickly establish additional or replacement sources for certain components or materials. Although alternative supplier options are considered and identified, 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, certain suppliers have announced in the past that they might limit or terminate sales of certain materials and parts to companies that manufacture implantable medical devices. If Edwards Lifesciences is unable to obtain these raw materials or if there is a significant increase in the price of these materials or components, the Company's business could be harmed.

The manufacture of many of Edwards Lifesciences' products is highly complex and subject to strict quality controls. If the Company or one of its suppliers encounters manufacturing or quality problems, Edwards Lifesciences' business could suffer.

The manufacture of many of Edwards Lifesciences' products is highly complex and subject to strict quality controls, due in part to rigorous regulatory requirements. In addition, quality is extremely important to the Company, its customers and its customers' patients due to the serious and costly consequences of a product failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems or human error. If these problems arise or if the Company fails to meet its quality standards, Edwards Lifesciences' reputation could be damaged, the Company could become subject to a recall, product liability and other costs, and the Company's business could otherwise be adversely affected.

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

At December 31, 2006, Edwards Lifesciences had \$20.2 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.4 million on these investments on its consolidated balance sheet in "Accumulated Other Comprehensive Loss," net of tax.

In addition, Edwards Lifesciences from time to time identifies businesses and products that are not performing at a level commensurate with the rest of its business. The Company may seek to dispose of these under-performing businesses or products, and may also seek to dispose of businesses or products for strategic or other business reasons. If Edwards Lifesciences is unable to dispose of a business or product on terms it considers acceptable, Edwards Lifesciences may voluntarily 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.

Historically, 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.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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.

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 expenditures as well as 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. Edwards Lifesciences has taken in-process research and development charges in connection with past acquisitions and may take similar charges in connection with acquisitions the Company makes in the future, which 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 impact Edwards Lifesciences' results of operations.

External economic and political factors can have a material adverse affect on Edwards Lifesciences' business.

Many external factors can affect Edwards Lifesciences' profitability and financial condition, such as interest rates, tax rates, general economic conditions and the political environment regarding healthcare in general. For example, an increase in interest rates in the general economy could result in an increase in Edwards Lifesciences' borrowing costs and could otherwise restrict the ability of Edwards Lifesciences to access the capital markets. In addition, there have been and may continue to be proposals by legislators, regulators and third-party payors to keep healthcare costs down. Such legislation, regulatory or payor actions may result in limitations on the prices the Company would be able to charge for its products or the amounts that are reimbursable for its products.

Edwards Lifesciences' business is subject to economic, political and other risks associated with international sales and operations, including risks arising from currency exchange rate fluctuations.

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 54% in 2006. Edwards

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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 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;
- an outbreak of any life threatening communicable disease;
- changes in the international political situation;
- differing labor regulations; and
- differing protection of intellectual property.

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' revenues 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' revenues and 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.

The stock market can be volatile and fluctuations in Edwards Lifesciences' quarterly operating results as well as other factors may cause its stock price to decline.

From time to time 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. In addition, the market price of Edwards Lifesciences' common stock could fluctuate substantially in response to any of the other risk factors set out above and below, as well as a number of other factors, including:

- announcements of innovations, new products, strategic developments or business combinations by Edwards Lifesciences or its competitors;

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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.

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;

the timing of regulatory approvals;

changes in foreign currency exchange rates;

delays or problems in introducing new products;

competitors' introductions 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;

changes in the level of economic activity in the United States or other major regions in which Edwards Lifesciences does business;

costs related to 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. 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 its protection

through improvement patents, modifications or line extensions. The failure to maintain or extend 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, resulting, from time to time, in litigation, and intellectual property litigation is complex and can be expensive and time consuming. However, the Company's efforts in this regard may not be successful. 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. Patent litigation can result in substantial cost and diversion of effort. 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. The invalidation of key intellectual property rights or an unsuccessful outcome in lawsuits that may be filed to protect its intellectual property could have a material adverse effect on its financial condition, results of operations or prospects.

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, and 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, or 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. In addition, some licenses may be non-exclusive, which could allow its competitors to have access to the same technologies.

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 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, broader product lines 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.

Consolidation in the healthcare industry could have an adverse effect on Edwards Lifesciences' revenues and results of operations.

The healthcare 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 has increased, and may continue to increase, causing downward pressure on product pricing. As an example, many existing and potential domestic customers for Edwards Lifesciences' products have combined to form group purchasing organizations ("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 revenues and profit margins, business, financial condition and results of operations.

Edwards Lifesciences and its customers are subject to rigorous 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 United States Food and Drug Administration ("FDA") and numerous other federal, state and foreign governmental authorities, including regulations that cover the composition, labeling, testing, clinical study, manufacturing, packaging and distribution of our products. Edwards Lifesciences is required to register with the FDA as a device manufacturer and as a result, is subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation ("QSR") requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require Edwards Lifesciences to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, Edwards Lifesciences is required to maintain certain International Organization for Standardization ("ISO") certifications in order to sell products and the Company undergoes periodic inspections by notified bodies to obtain and maintain these certifications. If the Company or its suppliers fail to adhere to QSR or ISO requirements, this could delay product production and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which could in turn have a material adverse effect on the Company's financial condition and results of operations.

Medical devices must receive FDA clearance or approval before they can be commercially marketed, and the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized, and can prevent or limit further marketing of a product based upon the results of post-marketing programs. Furthermore, most major markets for medical devices outside the United States require clearance, approval or compliance with certain standards before a product can be commercially marketed. 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. At any time after approval of a product, the FDA may conduct periodic inspections to determine compliance with both the FDA's QSR requirements and/or current medical device reporting regulations. Product approvals by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.

In recent years, both the FDA and foreign government regulators have become increasingly rigorous, and Edwards Lifesciences may be subject to more rigorous regulation by governmental authorities in the future. Whenever the FDA or another foreign governmental authority concludes that Edwards Lifesciences is not in compliance with applicable laws or regulations, the FDA or such other foreign governmental authority, as applicable, can impose fines or delays or suspensions of regulatory clearances, 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 can recommend criminal prosecution to the Department of Justice. Moreover, the FDA or some other foreign governmental authority can proceed to ban, or request recall, repair, replacement or refund of the cost of, any device or product manufactured or distributed by Edwards Lifesciences. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on Edwards Lifesciences' financial condition, results of operations and prospects.

As previously announced, in February 2007, the Los Angeles District Office of the FDA issued a Warning Letter to the Company resulting from the FDA's inspection of the Company's facility in Irvine, California that concluded in August 2006. The Warning Letter relates specifically to elements of the Company's quality systems, including complaint handling, documentation and quality systems training. The Warning Letter states that until the Company resolves the outstanding issues covered by the Warning Letter, the Company will not receive premarket approvals for devices that are reasonably related to those issues. The Company is committed to continuously improving its quality systems and to resolving the issues that are the subject of the Warning Letter as promptly as possible. However, there can be no assurance that Edwards Lifesciences is or will continue to be in compliance with applicable FDA and other material regulatory requirements.

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. Such clinical trials are inherently risky and 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, 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 affected.

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 valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of bovine spongiform encephalopathy ("BSE"), commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of bovine products. Certain medical device regulatory agencies have begun to consider whether to continue to permit the sale of medical devices that incorporate bovine material. Edwards Lifesciences obtains its bovine tissue only from closely controlled sources within the United States and Australia. To date, there have been only isolated 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 for the suspected BSE infectious agent. 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. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products.

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. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost-containment pressures by substituting lower cost products or other therapies for Edwards Lifesciences' products.

Initiatives to limit growth of healthcare costs, including price regulation, are underway in several countries around the world. 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.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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.

Edwards Lifesciences is also subject to various federal and state laws pertaining to healthcare pricing and fraud and abuse, including anti-kickback and false claims laws. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in federal and state healthcare programs.

Item 1B. Unresolved Staff Comments

None.

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, Manufacturing
Midvale, Utah	(1)	Administration, Research and Development, Manufacturing
Haina, The Dominican Republic	(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing

Europe

Saint Prex, Switzerland	(2)	Administration, Marketing
Horw, Switzerland	(2)	Administration, Distribution, Manufacturing

Asia

Tokyo, Japan	(2)	Administration, Marketing, Distribution
Miyazaki, Japan	(2)	Distribution
Techview, Singapore	(2)	Manufacturing
Changi, Singapore	(2)	Manufacturing (under construction through June 2007)

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2009; the Puerto Rico lease expires in 2008; the Horw, Switzerland lease expires in 2007 (expected to be renewed through 2011); the Saint Prex, Switzerland

lease expires in 2007 (expected to be renewed for one year); the Tokyo, Japan lease expires in 2009; the Miyazaki, Japan lease expires in 2007; the Techview, Singapore lease expires in 2008; and the Changi, Singapore landlease (a new construction site) expires in 2036. The Company's properties have been well maintained, are in good operating condition and are adequate for current needs.

Item 3. Legal Proceedings

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"), 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. As announced on January 23, 2006, Edwards Lifesciences settled this litigation with Medtronic. In exchange for a cash payment of \$37.5 million from Medtronic to Edwards Lifesciences and Australian-based Endogad Research Pty. Ltd. (the company formed by the clinician-inventors of the patents), Medtronic was granted nonexclusive licenses to the patents involved in the litigation, as well as to certain other related patents. The Company recorded a gain of \$20.2 million in January 2006, which consists of the \$37.5 million cash offset by the settlement paid to Endogad, capitalized patent enforcement costs of \$2.9 million and current legal fees. Edwards Lifesciences remains in litigation with Cook, Inc. and W.L. Gore & Associates, each of which has answered and asserted various affirmative defenses and counterclaims.

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 such legal matters or other claims, Edwards Lifesciences may incur charges in excess of 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 relating to any currently pending lawsuit 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, 2006.

PART II

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

	2006		2005	
	High	Low	High	Low
Calendar Quarter Ended:				
March 31	\$ 47.32	\$ 41.00	\$ 44.28	\$ 39.47
June 30	46.11	42.01	46.76	41.85
September 30	47.50	41.55	46.25	40.65
December 31	48.47	42.29	44.32	39.85

Number of Stockholders

On February 27, 2007, there were 57,882,620 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.

(b) Issuer Purchases of Equity Securities

Calendar Month Ended	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(a)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(a)
October 31, 2006	60,500	\$ 43.94	60,500	3,040,000
November 30, 2006	365,000	43.88	365,000	2,675,000
December 31, 2006				2,675,000
Total	425,500	43.89	425,500	2,675,000

(a)

On May 11, 2006, 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 an additional 4.0 million shares of the Company's common stock.

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 4 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 transactions on Edwards Lifesciences' operations.

		As of or for the years ended December 31,				
		2006	2005	2004	2003	2002
		(in millions except per share data)				
OPERATING RESULTS	Net sales	\$ 1,037.0	\$ 997.9	\$ 931.5	\$ 860.5	\$ 704.0
	Gross profit	663.4	623.3	561.3	501.1	404.9
	Net income (a)	130.5	79.3	1.7	79.0	55.7
BALANCE SHEET DATA	Total assets	\$ 1,246.8	\$ 1,229.1	\$ 1,112.7	\$ 1,101.4	\$ 1,004.4
	Long-term debt and lease obligations	235.9	316.1	267.1	255.8	245.5
COMMON STOCK INFORMATION	Net income per common share (a):					
	Basic	\$ 2.23	\$ 1.33	\$ 0.03	\$ 1.34	\$ 0.94
	Diluted	2.10	1.27	0.03	1.29	0.91
	Cash dividends declared per common share					

(a)

See Notes 3 and 4 to the "Consolidated Financial Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information regarding in-process research and development and other special (gains) charges, net of \$(4.5) million, \$49.4 million and \$110.5 million during 2006, 2005 and 2004, respectively.

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, 2006. Also discussed is Edwards Lifesciences' financial position as of December 31, 2006. 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; critical care technologies; and peripheral vascular disease.

The products and technologies provided by Edwards Lifesciences to treat advanced 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 and in disposable pressure transducers, and also provides 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 cannula, transmyocardial revascularization ("TMR") technology and other disposable products used during cardiopulmonary bypass procedures. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, 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 through the Company's distribution network in Japan.

The healthcare marketplace continues to be competitive with strong global and local competitors. 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 and market share pressures. Management expects these trends to continue.

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,			Change		Percent Change	
	2006	2005	2004	2006	2005	2006	2005
United States	\$ 477.9	\$ 455.9	\$ 416.5	\$ 22.0	\$ 39.4	4.8%	9.5%
Europe	264.6	241.3	221.2	23.3	20.1	9.7%	9.1%
Japan	168.8	186.4	197.2	(17.6)	(10.8)	(9.4)%	(5.5)%
Intercontinental	125.7	114.3	96.6	11.4	17.7	10.0%	18.3%
International	559.1	542.0	515.0	17.1	27.0	3.2%	5.2%
Total net sales	\$ 1,037.0	\$ 997.9	\$ 931.5	\$ 39.1	\$ 66.4	3.9%	7.1%

The \$22.0 million increase in net sales in the United States in 2006 was due primarily to increased sales of Critical Care, Heart Valve Therapy and Vascular products. The net sales increase in Critical Care products of \$10.7 million was primarily driven by sales of the new *FloTrac* minimally invasive monitoring system and advanced hemodynamic products. The net sales increase in Heart Valve Therapy products of \$8.2 million was primarily driven by the continuing penetration of the Company's premium *Carpentier-Edwards PERIMOUNT Magna* and *Magna* with *ThermaFix* valves. The net sales increase in Vascular products of \$4.7 million was primarily driven by sales of *LifeStent* products.

The \$17.1 million increase in international net sales in 2006 was due primarily to increases in Critical Care, Heart Valve Therapy and Vascular products. The net sales increase in Critical Care products of \$15.9 million was primarily driven by sales of the new *FloTrac* minimally invasive monitoring system throughout international locations and advanced hemodynamic products in Europe. The net sales increase in Heart Valve Therapy products of \$14.9 million was primarily driven by increased valve sales in Japan and Europe. The net sales increase in Vascular products of \$4.4 million was primarily driven by sales of *LifeStent* products in Europe. These increases were partially offset by decreases in net sales due primarily from the sale in 2005 of the Company's perfusion products in Japan, which decreased net sales by \$13.8 million, and to foreign currency exchange rate fluctuations (primarily due to the weakening of the Japanese yen against the United States dollar, partially offset by the strengthening of the Brazilian real against the United States dollar), which decreased net sales by \$5.2 million.

The \$39.4 million increase in net sales in the United States in 2005 was due primarily to increased sales in Heart Valve Therapy products driven by the continuing penetration of the Company's *Carpentier-Edwards PERIMOUNT Magna* and *Magna* with *ThermaFix* valves, resulting in market share gains.

The \$27.0 million increase in international net sales in 2005 was due primarily to (1) Heart Valve Therapy products, which increased net sales by \$17.6 million, driven by strong *Carpentier-Edwards PERIMOUNT* valve sales in Europe, (2) Critical Care products, which increased net sales by \$11.4 million, driven by sales of hemofiltration products in Europe and pressure monitoring products in Intercontinental, (3) foreign currency exchange rate fluctuations, which increased net sales by \$6.9 million (primarily the strengthening of the Euro and Brazilian real against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar) and (4) Vascular and Cardiac Surgery products in Europe and Japan, which increased net sales by \$6.3 million. These increases were partially offset by a decrease in net sales of \$22.6 million due to the impact of discontinued products, primarily in Japan.

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 the Company's 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,			Change		Percent Change	
	2006	2005	2004	2006	2005	2006	2005
Heart Valve Therapy	\$ 490.8	\$ 469.3	\$ 419.2	\$ 21.5	\$ 50.1	4.6%	12.0%
Critical Care	349.8	324.1	302.3	25.7	21.8	7.9%	7.2%
Cardiac Surgery Systems	91.0	104.6	107.3	(13.6)	(2.7)	(13.0)%	(2.5)%
Vascular	75.9	66.1	60.1	9.8	6.0	14.8%	10.0%
Other Distributed Products	29.5	33.8	42.6	(4.3)	(8.8)	(12.7)%	(20.7)%
Total net sales	\$ 1,037.0	\$ 997.9	\$ 931.5	\$ 39.1	\$ 66.4	3.9%	7.1%

Heart Valve Therapy

The \$21.5 million increase in net sales of Heart Valve Therapy products in 2006 was due primarily to:

pericardial tissue valves, which increased net sales by \$20.8 million, primarily as a result of the Company's premium *Carpentier-Edwards PERIMOUNT Magna* and *Magna with ThermaFix* valves; and

heart valve repair products, which increased net sales by \$9.0 million, primarily as a result of the continuing adoption of the Company's newest products including the *Edwards MC³*, *IMR ETlogix* and *GeoForm* rings.

These increases in 2006 were partially offset by foreign currency exchange rate fluctuations, which decreased net sales by \$2.6 million (primarily due to the weakening of the Japanese yen against the United States dollar) and the continuing decline in net sales of porcine and mechanical valves. During 2006, the Company's sales growth in Heart Valve Therapy was negatively impacted by the introduction in the United States of a competitor's valve late in 2005. This activity primarily impacted the Company's conversion of competitor mechanical valves to the Company's tissue valves.

The \$50.1 million increase in net sales of Heart Valve Therapy products in 2005 was due primarily to:

pericardial tissue valves, which increased net sales by \$37.0 million, primarily as a result of market share gains globally of the Company's premium *Carpentier-Edwards PERIMOUNT Magna* valve, particularly in the United States;

heart valve repair products, which increased net sales by \$10.1 million, primarily driven by the continuing adoption of the Company's new disease-specific technologies; and

foreign currency exchange rate fluctuations, which increased heart valve therapy net sales by \$1.8 million (primarily the strengthening of the Euro and Brazilian real against the United States dollar, offset by the weakening of the Japanese yen against the United States dollar).

The Company expects that its *PERIMOUNT Magna* and *Magna with ThermaFix* valves will continue to be a strong contributor to 2007 sales growth. In January 2007, the Company launched two new products in the United States. The new *PERIMOUNT Theon* aortic valve offers clinicians the durability and hemodynamics of the *PERIMOUNT* technology with the addition of the *ThermaFix* tissue treatment, and the new *Myxo ETlogix* annuloplasty ring is the first mitral repair product specifically designed to address myxomatous disease. The Company anticipates that both of these products will contribute to growth in Heart Valve Therapy in 2007. In addition, the Company is planning to launch its next generation aortic valve, the *Magna Ease* valve, in Europe in 2007. The Company's new *PERIMOUNT Magna* mitral valve is gaining physician acceptance in Europe and the Company anticipates FDA approval in the United States by the end of 2007. In addition, the Company is planning on launching a new *PERIMOUNT* mitral valve in Japan in 2007.

The Company has decided to exit the mechanical valve market by the end of 2007. Sales of mechanical valves were approximately \$12.0 million in 2006.

Critical Care

The \$25.7 million increase in net sales of Critical Care products in 2006 was due primarily to:

recently launched *FloTrac* systems, which increased net sales by \$11.2 million;

core critical care products, which increased net sales by \$8.6 million, driven primarily by market share gains in advanced technology catheter products and pressure monitoring products; and

hemofiltration products, which increased net sales by \$6.9 million.

Foreign currency exchange rate fluctuations decreased net sales by \$2.2 million in 2006 (primarily due to the weakening of the Japanese yen against the United States dollar).

The \$21.8 million increase in net sales of Critical Care products in 2005 was due primarily to:

core critical care products, which increased net sales by \$12.7 million, driven primarily by market share gains in advanced technology catheter products and pressure monitoring products;

an expanded hemofiltration product line, which increased net sales by \$5.8 million; and

currency exchange rate fluctuations, which increased net sales by \$2.2 million (primarily the strengthening of the Euro and Brazilian real against the United States dollar, offset by the weakening of the Japanese yen against the United States dollar).

The Company launched its *FloTrac* system in Japan in early April 2006 and expects worldwide *FloTrac* system sales to be a significant contributor to Critical Care sales growth in 2007.

Cardiac Surgery Systems

The \$13.6 million decrease in net sales of Cardiac Surgery Systems in 2006 was due primarily to the sale of the Company's perfusion product line in Japan in 2005, which decreased net sales by \$13.8 million, and a decline in TMR sales. These decreases were partially offset by increased sales of specialty cannula products, driven primarily by market share gains.

The \$2.7 million decrease in net sales of Cardiac Surgery Systems in 2005 was due primarily to the sale of the Company's perfusion product line in Japan in January 2005 and the sale of the Company's Italian perfusion services products in June 2004, which together decreased net sales by \$9.6 million. The decreases were partially offset by:

cannula products, which increased net sales by \$2.8 million, driven primarily by market share gains and a shift to specialty products; and

currency exchange rate fluctuations, which increased net sales by \$2.2 million (primarily the strengthening of the Euro and Brazilian real against the United States dollar, offset by the weakening of the Japanese yen against the United States dollar).

In December 2006, the Company announced the discontinuation of the *Optiwave 980* Cardiac Laser Ablation System, which generated approximately \$1 million of sales in 2006, and completed the sale of the Brazil-based international perfusion business (see "*Special (Gains) Charges, net*").

Vascular

The \$9.8 million increase in net sales of Vascular products in 2006 was due primarily to sales of *LifeStent* products. During the third quarter of 2006, the Company made enhancements to its new *FlexStar* delivery system and upgraded the United States field inventory to the new system. In addition, in the third quarter of 2006, the Company introduced a new line of longer-length stents, *FlexStar XL*, in the United States.

The \$6.0 million increase in net sales of Vascular products in 2005 was due primarily to:

LifeStent products, which increased net sales by \$5.7 million; and

currency exchange rate fluctuations, which increased net sales by \$0.8 million (primarily the strengthening of the Euro and Brazilian real against the United States dollar, offset by the weakening of the Japanese yen against the United States dollar).

The 2005 increases were partially offset by the discontinuation of the *Lifepath* AAA program in June 2004.

Other Distributed Products

The \$4.3 million decrease in net sales of Other Distributed Products in 2006 was due primarily to exiting the Japan pacemaker business in the first quarter of 2005 and currency exchange rate fluctuations, which decreased net sales by \$1.2 million (primarily due to the weakening of the Japanese yen against the United States dollar). In May 2006, the Company divested a non-strategic pharmaceutical product representing approximately \$1 million in annual sales.

The \$8.8 million decrease in net sales of Other Distributed Products in 2005 was due primarily to the discontinuation of sales in Japan of certain lower-margin distributed cardiology products in September 2004 and the exit from the Japan pacemaker business during the first quarter of 2005.

Gross Profit

	Year Ended December 31,			Change	
	2006	2005	2004	2006	2005
Gross profit as a percentage of net sales	64.0%	62.5%	60.3%	1.5 pts.	2.2 pts.

The 1.5 percentage point increase in gross profit as a percentage of net sales in 2006 was driven by the Company's international operations. The increase in international gross profit as a percentage of net sales was driven by (1) a 0.8 percentage point increase from the discontinuation of lower margin products and (2) a 0.6 percentage point increase from the favorable impact of foreign currency, including the expiration of currency hedging contracts. These increases were partially offset by a 0.5 percentage point decrease from unfavorable product mix in the international Vascular and Critical Care product lines. The United States gross profit as a percentage of net sales increased 0.5 percentage points due to favorable product mix, primarily in the Heart Valve Therapy product line.

The 2.2 percentage point increase in gross profit as a percentage of net sales in 2005 was due primarily to (1) a 1.3 percentage point increase from the favorable impact of foreign currency,

including the expiration of currency hedging contracts and (2) sales of higher margin heart valve products, primarily in the United States.

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

(in millions)

	Years Ended December 31,			Change	
	2006	2005	2004	2006	2005
SG&A expenses	\$ 376.0	\$ 348.7	\$ 319.9	\$ 27.3	\$ 28.8
SG&A expenses as a percentage of net sales	36.3%	34.9%	34.3%	1.4pts.	0.6 pts.

The \$27.3 million increase in selling, general and administrative expenses in 2006 was due primarily to stock-based compensation expense of \$12.9 million, as a result of adopting Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123R"), and higher sales and marketing expenses primarily related to the Company's Heart Valve Therapy product line and new products in the United States.

The 1.4 percentage point increase in selling, general and administrative expenses as a percentage of sales for 2006 was due primarily to stock-based compensation expense.

The \$28.8 million increase in selling, general and administrative expenses in 2005 resulted primarily from higher sales and marketing expenses of \$19.0 million, primarily related to the Company's United States peripheral stent and heart valve therapy products, higher international expenses of \$2.3 million due to foreign exchange rates, and higher legal and consulting expenses.

The 0.6 percentage point increase in selling, general and administrative expenses as a percentage of net sales for 2005 was due primarily to an increased investment in United States sales and marketing expenses related to peripheral stents.

Research and Development Expenses

(in millions)

	Years Ended December 31,			Change	
	2006	2005	2004	2006	2005
Research and development expenses	\$ 114.2	\$ 99.0	\$ 87.0	\$ 15.2	\$ 12.0
Research and development expenses as a percentage of net sales	11.0%	9.9%	9.3%	1.1pts.	0.6 pts.

The increases in research and development expenses in 2006 and 2005 were due primarily to additional investments in the Company's transcatheter valve programs. In addition, in 2006, research and development expenses increased by \$3.7 million as a result of adopting SFAS 123R.

In the Company's transcatheter aortic valve replacement program, the Company has made clinical and technological progress. In the fourth quarter of 2006, the Company introduced its *Edwards SAPIEN THV*, a transcatheter bovine valve treated with the Company's *ThermaFix* tissue treatment, formerly called *Cribier-Edwards PHV*. The *Edwards SAPIEN THV* valve can be delivered using either the *RetroFlex* delivery system through a transfemoral approach or the *Ascendra* delivery system through

a transapical approach. The Company has completed enrollment in its transfemoral feasibility trial in the United States. In addition, the Company has demonstrated the feasibility of its transapical procedures in its European and Canadian studies. In the fourth quarter of 2006, the Company began enrollment in a transapical feasibility trial in the United States. The Company expects to begin its pivotal trials in the United States in the first quarter of 2007 and expects receipt of a CE mark by the end of 2007.

In the Company's transcatheter mitral valve repair program, the Company has two technologies: the *Edwards MONARC* mitral repair system, a coronary sinus technology, and the *Edwards MOBIUS* leaflet repair system. For the *Edwards MONARC* technology, the Company is continuing its 60-patient EVOLUTION I feasibility trial and anticipates its completion by the first quarter of 2007. If feasibility is established, the Company plans to initiate the EVOLUTION II follow-on trial, which will measure clinical and quality of life endpoints. Data gathered from the EVOLUTION II trial would support a CE Mark and would help to support a pivotal trial in the United States as early as 2008.

For the *Edwards MOBIUS* technology, the Company's feasibility work is continuing in Europe and Canada. The Company implemented several procedural and device enhancements in 2006 to address a broader range of patients and leaflets. Interim feasibility results led to the implementation of additional enhancements to improve repair durability. As a result, the Company expects its feasibility studies to continue into 2007, at which point the Company will assess the performance of the system and develop plans accordingly.

Purchased in-process Research and Development Expenses

The information in "*Purchased in-process Research and Development Expenses*," related to regulatory milestones, describes the Company's expectations with respect to the applicable programs at the time of the respective acquisitions and does not reflect subsequent activities or expectations. Refer to "*Research and Development Expenses*," above, for the current status of these programs and the Company's expectations.

2005

In September 2005, the Company recorded a \$1.2 million pretax charge for in-process research and development related to the acquisition of technology and intellectual property. The acquired assets are expected to be utilized in the Company's existing mitral valve repair research and development efforts. Additional design developments, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to selling any product.

2004

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 acquired assets were 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. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies were required 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 \$39.0 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 (see "*Special (Gains) Charges, net*"). 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 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 in 2004. 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.

Special (Gains) Charges, net

	Years Ended December 31,		
	2006	2005	2004
	(in millions)		
Settlements and litigation (gains) losses, net	\$ (20.2)	\$ 2.9	\$
Gain on sale of assets, net	(13.7)	(14.1)	(7.4)
PVT milestone	10.0		
Realignment expenses, net	9.4	3.9	
Discontinued products	6.8	1.4	10.6
Restructure 3F agreements	2.0	22.8	
Litigation reserve	1.2		
Investment impairments		16.3	9.0
Charitable fund contributions		15.0	5.0
Total special (gains) charges, net	\$ (4.5)	\$ 48.2	\$ 17.2

Settlements and Litigation (Gains) Losses, net

In January 2006, the Company recorded a patent dispute settlement gain of \$20.2 million, which consisted of a net payment of \$23.8 million received from Medtronic, Inc., offset by patent enforcement costs.

In September 2005, the Company recorded a gain of \$2.5 million related to the resolution of intellectual property litigation. In the fourth quarter of 2005, the Company recorded a \$5.4 million charge related to two royalty dispute settlements.

Gain on Sale of Assets, net

In December 2006, the Company sold its assets associated with the Company's angiogenesis research and development project to Sangamo BioSciences Inc. ("Sangamo") in exchange for 1.0 million shares of Sangamo common stock. The Company recorded a \$6.1 million gain, which represents the fair value of the common stock on the closing date, less the book value of the assets sold.

In May 2006, the Company sold a non-strategic pharmaceutical product to Bioniche Teoranta for \$9.0 million. The sale of the related assets resulted in a \$4.5 million gain, consisting of cash proceeds of \$9.0 million, offset by \$4.5 million related primarily to the net book value of intangible assets and inventory that were sold.

In the second quarter of 2006, the Company agreed to sell most of its assets related to its remaining international cardiopulmonary perfusion product line. The Company determined that the carrying values of the underlying assets exceeded their fair values. Consequently, in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), in the second quarter of 2006, the Company recorded an impairment loss of \$2.6 million, which represented the excess of the carrying values of the assets over their fair values, and included direct incremental

costs to transact the sale of \$1.5 million. The sale was completed in December 2006 and no additional gain or loss was recorded.

In November 2005, the Company sold its vascular graft business to Angiotech Pharmaceuticals Inc. for \$14.0 million in cash. Under the agreement, the Company will continue to market and sell its existing *Lifespan* products. The sale of the business resulted in a \$13.1 million net gain, consisting of cash proceeds of \$14.0 million offset by the \$0.9 million net book value of inventory and fixed assets that were sold.

In January 2005, the Company announced that it was realigning its business in Japan as part of the Company's continued efforts to focus on its core cardiovascular businesses. The Company (1) restructured its operations, (2) exited its pacemaker distribution business and (3) sold its perfusion product line in Japan to Terumo Corporation for cash consideration of \$14.9 million, of which \$9.2 million was received in January 2005 and \$5.7 million was received in March 2006 as an earn-out payment. In 2005, the Company recorded a \$1.0 million net gain, consisting of a gain on the sale of the Company's Japan perfusion product line of \$7.7 million, offset by a \$5.7 million charge related to the realignment of its operations, primarily related to severance costs due to headcount reductions, and a \$1.0 million charge related to settlement, curtailment and special termination benefits impacting its defined benefit pension plan. In 2006, the Company recorded a gain of \$5.7 million related to the receipt of the earn-out payment. As of December 31, 2006, payments related to the realignment were complete.

In November 2004, the Company recorded a gain 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.

PVT Milestone

In December 2006, the Company recorded a \$10.0 million charge for the contractual transcatheter clinical milestone obligation to PVT's former shareholders. In the first quarter of 2007, the Company achieved and paid the \$10.0 million to PVT's former shareholders. As all contractual milestone obligation dates have expired, the Company does not expect to make any additional payments to PVT's former shareholders.

Realignment Expenses, net

In December 2006, the Company recorded a \$7.3 million charge related primarily to severance expenses associated with a global reduction in workforce of approximately 70 employees, primarily in the United States and Europe. As of December 31, 2006, the Company paid \$0.4 million of severance with the remaining amount expected to be paid out substantially by the end of 2007.

In the first quarter of 2006, the Company recorded realignment expenses of \$2.1 million related primarily to severance expenses associated with the planned closure of a manufacturing facility in Japan (impacting 92 employees). The Company anticipates payments to be made through the third quarter of 2007. The realignment expenses are net of a \$0.4 million reversal of previously accrued severance costs related to the sale of the Japan perfusion product line to Terumo as discussed in the "*Gain on Sale of Assets, net*" section. As of December 31, 2006, \$1.0 million had been paid related to these actions.

In December 2005, the Company recorded a charge of \$3.9 million related to severance resulting from a resource realignment. The charge was related primarily to the severance costs associated with reducing the Company's workforce by 52 employees, primarily in Puerto Rico, Europe and the United States. As of December 31, 2006, the Company had paid \$3.7 million related to severance with the remaining amount expected to be paid in 2007.

Discontinued Products

In the fourth quarter of 2006, the Company discontinued the *Optiwave 980* Cardiac Laser Ablation System. The Company recorded a \$6.8 million charge resulting primarily from the disposal of fixed assets and the write-off intangible assets. In addition, the Company recorded a \$2.0 million charge to cost of goods sold related to the disposal of inventory.

In the fourth quarter of 2005, the Company recorded a charge of \$1.4 million resulting from the payment of an early termination fee to discontinue certain firm non-cancelable product purchase commitments related to a discontinued product line in Europe.

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

Restructure 3F Agreements

In June 2005, the Company recorded a special charge of \$22.8 million related to the restructuring of development and supply agreements between 3F Therapeutics, Inc. and PVT that were established prior to the Company's acquisition of PVT in early 2004. Under the terms of the new agreements, the Company obtained the rights to self-manufacture all components of its transcatheter heart valves and certain pre-approved technology licenses. In 2006, the Company paid and recorded an additional \$2.0 million for the final payment to 3F Therapeutics for completing certain contractual obligations.

Investment Impairments

In September 2005, the Company recorded an \$8.9 million charge related to the other-than-temporary impairment of its investment in Sangamo. The investment was written down to \$3.7 million, which represented the quoted market price of Sangamo's common stock at September 30, 2005.

The Company considered numerous facts, including those described below, to conclude that any impairment of the Sangamo investment was temporary in nature as of the end of each of the quarters in 2003 and 2004, and the first two quarters of 2005:

Sangamo's key internally established development milestones were progressing and/or remained on track at each quarter-end throughout 2003 and 2004, and the first two quarters of 2005. There were no changes in technology that could impair Sangamo's earnings potential of the investment and the technological progress supported a positive outlook. The Company believed

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

that the number and scope of Sangamo's programs and the range of its third party collaborations and the continued success in the Company's Sangamo-related programs would significantly drive the value of Sangamo. Moreover, the clinical momentum was building at the end of 2004 with the anticipation of three to four Phase I human trials, the likely completion of one or more Phase I trials with positive data and the planned announcements at major medical meetings.

Management of the Company believed that declines in Sangamo's stock price were a result of certain external events and general investor sentiment of the biotechnology sector, and not Sangamo-specific activities. In addition, the Company recognized that, historically, reports of significant positive clinical outcomes had frequently resulted in a significant increase in the stock price of a biotechnology company over a relatively short time period. Management believed this would be the case for Sangamo.

Throughout all periods in which the Company concluded that the impairment of this investment was temporary, Sangamo maintained cash and liquid investment reserves sufficient to continue to fund the ongoing development efforts for the technology for periods well in excess of one year.

Throughout all periods in which the Company concluded that the impairment of this investment was temporary, the Company had the financial ability and intent to retain this investment indefinitely. Sangamo's technology was considered important to the development of certain of the Company's next generation products, and required a long-term horizon for ongoing development of new technology.

Sangamo is a multi-technology (human therapeutics, drug discovery and plant agriculture) biotechnology company and has the ability to attract many different investors. In addition, the diversity of technology applications served to dilute the risk related to any one application failure.

The Company expected the market price of Sangamo's stock to increase not only as a result of announcements of positive clinical trial results, but also other operational events. During the second half of 2005, Sangamo announced five significant key developments regarding collaborative agreements, additional funding and breakthrough technology. The Company expected that this concentration of positive developments could have generated a considerable increase in the stock price, better recognizing the underlying value of Sangamo. Based upon (1) the significant developments in the third quarter of 2005 which, individually and in the aggregate, failed to have a material impact on the quoted market price of Sangamo's stock, (2) the continuing duration and severity of the impairment, and (3) Sangamo's declining cash position, the Company concluded in September 2005 that the impairment on its investment in Sangamo was other-than-temporary and, therefore, recognized an \$8.9 million charge in earnings.

In 2005, the Company recorded additional charges totaling \$7.4 million related to other-than-temporary impairment of technology investments in five other unconsolidated affiliates. Of the total additional charge, \$1.9 million related to declines in the stock prices of two available-for-sale investments. The remaining charges were due to increased potential risk of certain private investees' uncertain future liquidity.

In 2004, the Company recorded charges totaling \$9.0 million related to the other-than-temporary impairment of technology investments in four unconsolidated affiliates. One of the impairments resulted from the decline in the stock price of an affiliate. 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 expected to receive from those companies. The remaining affiliate performed a reset financing that reduced the net value per share for all existing investors. This investment is recorded at the reduced value.

Charitable Fund

In December 2004, the Company made an initial contribution of \$5.0 million to establish the Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular disease charitable causes. In September 2005, the Company completed its funding goal and made an additional \$15.0 million contribution. Both of these contributions were irrevocable contributions to a third party and were recorded as charges at time of payment.

Interest Expense

The \$1.8 million decrease in interest expense for 2006 resulted primarily from lower average interest rates, which resulted from the expiration of the Company's fixed interest rate swap contracts in the third quarter of 2005, combined with a greater portion of debt in low interest rate countries. The \$2.9 million decrease in interest expense for 2005 resulted primarily from lower average interest rates, including the effect of interest rate swaps.

Interest Income

The \$5.2 million increase in interest income for 2006 resulted from higher interest rates and a higher cash and cash equivalent balance. The \$1.6 million increase in interest income for 2005 resulted primarily from a higher cash and cash equivalent balance.

Other Expense (Income), net

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

	Years Ended December 31,		
	2006	2005	2004
Foreign exchange gains	\$ (0.3)	\$ (2.1)	\$ (0.2)
Accounts receivable securitization costs	2.6	1.7	1.0
Other	0.4	0.2	(1.2)
	\$ 2.7	\$ (0.2)	\$ (0.4)

Foreign exchange gains relate to the foreign currency fluctuation on the Company's global trade and intercompany receivable and payable balances. The increases in securitization costs in 2006 and 2005 were due to increases in average interest rates and higher average securitized balances.

Provision for Income Taxes

The effective income tax rates for 2006, 2005, and 2004 were impacted as follows (in millions):

	Years Ended December 31,		
	2006	2005	2004
Income tax expense at U.S. federal statutory rate	\$ 60.3	\$ 40.9	\$ 10.5
Foreign income tax at different rates	(19.8)	(16.4)	(21.5)
Deemed dividends, net of foreign tax credit	4.2	3.6	2.9
Tax credits, federal and state	(2.0)	(2.0)	(1.7)
State and local taxes, net of federal tax benefit	4.7	0.2	0.8
Valuation allowance for loss on investments	(7.0)	(6.2)	6.6
Nondeductible in-process research and development expenses and milestone payment	3.5		27.8
Taxes on repatriation under the American Jobs Creation Act of 2004		15.0	
Nondeductible stock based compensation	2.2		
Reserve for uncertain tax positions for prior years	(5.6)	(0.2)	1.5
Other	1.3	2.5	1.5
	<u>\$ 41.8</u>	<u>\$ 37.4</u>	<u>\$ 28.4</u>
Income tax provision	\$ 41.8	\$ 37.4	\$ 28.4

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004 and allowed companies to repatriate cash during 2004 and 2005 into the United States at a special, temporary effective tax rate of 5.25 percent. On September 13, 2005, the Board of Directors approved a plan for reinvestment and repatriation of specific foreign earnings under the Act. The Company repatriated \$263.1 million in cash in 2005. The Company accrued \$15.0 million for federal, state and foreign taxes attributable to the distribution from its foreign affiliates in 2005.

Beginning in 2002 and through 2006, the Company recorded other-than-temporary impairments and unrealized losses related to certain of its investments in unconsolidated affiliates. The tax benefits that result from reductions in the value of these investments are subject to the Company realizing sufficient capital gains with which to offset these capital losses. Due to the uncertainty of the Company realizing future capital gains, the Company has consistently recorded valuation allowances against these deferred tax assets as they have accumulated. As December 31, 2006, deferred tax assets and corresponding valuation allowances of approximately \$4.4 million had accumulated related to investments.

During 2005, valuation allowances were made in each quarter against investment impairments recognized. The valuation allowance amounts were \$0.2 million in the first quarter, \$2.0 million in the second quarter, \$3.8 million in the third quarter and \$1.1 million in the fourth quarter, for a total for the year of \$7.1 million. Also, during the fourth quarter of 2005, the Company realized a capital gain related to the sale of its vascular graft business and anticipated a capital gain in January 2006 related to the settlement of certain patent litigation against Medtronic (see "*Legal Proceedings*"). As a result, valuation allowances were reversed, reducing income tax provision during the fourth quarter of 2005 by \$13.3 million.

Similarly, in 2006, the Company recognized capital gains in the second quarter from the sale of a non-strategic business and in the fourth quarter, a gain from the sale of the angiogenesis business and a

capital loss on the sale of shares in World Heart Corporation. The capital gains have allowed or will allow the Company to utilize the same amounts of the accumulated losses related to impaired investments. As a result, valuation allowances of \$3.7 million and \$3.3 million were reversed in the second and fourth quarters of 2006, respectively.

Of the \$81.0 million charge for acquired in-process research and development related to the PVT acquisition in 2004, as discussed in "*Purchased in-process Research and Development Expenses*," \$1.7 million is related to tax deductible payments to exercise certain licensing options pursuant to the stock purchase agreement. The remaining \$79.3 million charge is non-deductible for income tax purposes. During the fourth quarter of 2006, the Company recorded a \$10.0 million charge for achieving the contractual transcatheter clinical milestone obligation with PVT. The \$10.0 million payment is not deductible for income tax purposes.

On January 1, 2006 the Company reported results in accordance with SFAS 123R and recognized expense in 2006 related to stock-based compensation. Some of those costs are not deductible in the United States or in foreign countries.

During the fourth quarter ended December 31, 2006, the Company settled several of its ongoing tax examinations in various jurisdictions. The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at anytime. While the Company has accrued for amounts it believes is the expected outcome, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The tax reserves are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related interest, if any, have been provided for any adjustments that may result from these examinations of uncertain tax positions.

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 September 29, 2006, the Company extended its Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), to September 29, 2011. 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 0.45%, 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 a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.8%. 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. Additional issuance costs of \$0.5 million are being amortized to interest expense over 5 years. As of December 31, 2006, borrowings of \$85.9 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 at December 31, 2006.

In addition to the Credit Agreement, as of December 31, 2006, the Company had outstanding \$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, in certain circumstances, into 18.29 shares of the Company's common stock for each \$1,000 principal amount of Notes (at a conversion price of \$54.66 per share), subject to adjustment.

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, 2006, the Company had sold a total of \$85.3 million of trade accounts receivable and received funding of \$75.5 million. In September 2006, the United States securitization program was extended to September 18, 2007. The securitization program in Japan expires on December 3, 2008.

In May 2006, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 4.0 million shares of the Company's common stock through December 31, 2008. Stock repurchased under the new program will be used primarily to offset obligations under the Company's employee stock option programs. In 2006, the Company repurchased 3.3 million shares under the new and the previously approved stock repurchase programs at an aggregate cost of \$145.9 million and has remaining authority under the new program to purchase 2.7 million shares as of December 31, 2006.

On January 23, 2006, the Company settled certain patent litigation against Medtronic. As a result, in January 2006, the Company recorded a gain of \$20.2 million, which consisted of the \$37.5 million cash offset by the settlement paid to Endogad, capitalized patent enforcement costs of \$2.9 million and current legal fees. See Item 3 for additional information.

In 2006, the Company notified its employees of its intent to terminate the defined benefit pension plan in Puerto Rico and expects to distribute benefits in early 2008.

In the first quarter of 2007, the Company paid PVT's former shareholders \$10.0 million for the achievement of a milestone as discussed at "*Special (Gains) Charges, net.*" As all contractual milestone obligation dates have expired, the Company does not expect to make any additional milestone payments to PVT's former shareholders.

Net cash flows provided by **operating activities** of \$230.8 million for 2006 increased \$94.0 million from 2005 primarily due to (1) higher earnings, adjusted for non-operating and non-cash items, (2) cash received in 2006 from the patent litigation settlement with Medtronic of \$23.8 million, (3) a cash payment of \$23.0 million made in 2005 related to the restructuring of development and supply

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

agreements and (4) a charitable contribution payment of \$15.0 million made in 2005. Operating cash flow was negatively impacted versus 2005 by net cash used to fund working capital requirements, which consisted primarily of net cash outflows for accrued liabilities and taxes payable, partially offset by net cash inflows from accounts receivables due to lower days sales outstanding.

Net cash flows provided by operating activities of \$136.8 million for 2005 decreased \$43.8 million from 2004 primarily due to a cash payment of \$23.0 million related to the restructuring of development and supply agreements, and a charitable contribution payment of \$15.0 million, offset by higher earnings, adjusted for non-operating and non-cash items. Operating cash flow was negatively impacted versus 2004 by net cash used to fund working capital requirements, which consisted of decreased net cash inflows from receivables due to higher days sales outstanding in the United States, reduced cash flows from increases in inventories to build new product lines and support increased sales levels, partially offset by lower net cash outflows for accrued liabilities and taxes payable.

Net cash used by **investing activities** of \$35.7 million in 2006 consisted primarily of capital expenditures of \$57.4 million, partially offset by proceeds of (1) \$9.0 million from the sale of a non-strategic pharmaceutical product, (2) \$7.5 million from the sale of assets related to the Company's remaining international cardiopulmonary perfusion product line and (3) \$5.7 million related to an earn-out payment from the 2005 sale of the Company's perfusion product line in Japan.

Net cash used by investing activities of \$27.2 million in 2005 consisted primarily of capital expenditures of \$48.5 million, partially offset by proceeds from the sales of the Company's vascular graft business of \$14.0 million and the Japan perfusion products business of \$9.2 million.

Net cash used in **financing activities** of \$193.6 million in 2006 consisted primarily of purchases of treasury stock of \$145.9 million and net payments on long-term debt of \$85.9 million, partially offset by the proceeds from stock plans of \$33.5 million.

Net cash provided by financing activities of \$29.0 million in 2005 consisted primarily of net proceeds from issuance of long-term debt of \$59.1 million and the proceeds from stock plans of \$26.2 million, partially offset by purchases of treasury stock of \$53.5 million.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2006 were as follows (in millions):

Contractual Obligations	Payments Due By Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term debt	\$ 235.9	\$	\$ 150.0	\$ 85.9	\$
Interest on long-term debt	8.2	5.8	2.4		
Operating leases	34.1	10.9	14.0	7.0	2.2
Contractual development and capital commitment obligations(a)(b)	18.5	12.8	4.0	1.7	
Total contractual cash obligations	\$ 296.7	\$ 29.5	\$ 170.4	\$ 94.6	\$ 2.2

(a) Contractual development obligations consist primarily of cash that Edwards Lifesciences is obligated to pay to unconsolidated affiliates upon their achievement of product development milestones. In the first quarter of 2007, the Company paid PVT's former shareholders

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

\$10.0 million for the achievement of a milestone as discussed at "*Special (Gains) Charges, net*". As all contractual milestone obligation dates have expired, the Company does not expect to make any additional milestone payments to PVT's former shareholders.

(b)

Capital commitment obligations consist primarily of cash that Edwards Lifesciences is obligated to pay to its limited partnership and limited liability corporation investees. These investees make equity investments in various development stage biopharmaceutical and medical device companies, and it is not certain if and/or when these payments will be made.

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, income taxes, 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).

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 approximate 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 \$6.5 million and \$5.4 million at December 31, 2006 and 2005, 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 \$13.2 million and \$12.3 million at December 31, 2006 and 2005, 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. Such legal 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

The Company evaluates the carrying value of goodwill in the fourth quarter of each fiscal year. In evaluating goodwill, the Company completes the two-step goodwill impairment test as required by SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The Company identifies its reporting units and determines the carrying value of each reporting unit by assigning the assets and liabilities, including existing goodwill, to those reporting units. The fair value of the reporting unit is estimated

based on the market capitalization and a market revenue multiple. If the carrying amount of the reporting unit exceeds its fair value, the Company will perform the second step of the impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. Since the adoption of SFAS 142 and SFAS 144, the Company has not performed the second step of the impairment test as the fair value of each reporting unit has exceeded its respective carrying value.

Additionally, in accordance with SFAS 142 and SFAS 144, management reviews the carrying amounts of other intangible and long-lived tangible assets 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 long-term, strategic equity investments in companies that are in various stages of development. Certain of these investments 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 Loss. Gains or losses on investments sold are based on the specific identification method. Other investments in unconsolidated affiliates are accounted for under the cost or the equity method of accounting, as appropriate. The Company accounts for investments in limited partnerships or limited liability corporations, whereby the Company owns a minimum of 3% to 5% of the investee's outstanding voting stock, under the equity method of accounting. These investments are recorded at the amount of the Company's investment and adjusted each period for the Company's share of the investee's income or loss and dividends paid. As investments accounted for under the cost method do not have readily determinable fair value, the Company only estimates fair value if there are identified events or changes in circumstances that could have a significant adverse effect on the investment's fair value.

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 15 of the Consolidated Financial Statements.

The Company accounts for income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes*" ("SFAS 109"). 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, 2006, the Company had deferred tax assets of \$103.3 million, partially offset by deferred tax liabilities of \$47.1 million. The valuation allowance of \$19.9 million as of December 31, 2006, 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 carry forwards of certain United States and non-United States subsidiaries. The Company evaluates quarterly 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.

Stock-based Compensation

On January 1, 2006, the Company adopted SFAS 123R, which requires the measurement and recognition of compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, restricted stock units and employee stock purchase subscriptions. Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period). The valuation provisions of SFAS 123R apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation expense for grants that were outstanding, as of the effective date, will be recognized over the remaining service period using the compensation expense, adjusted for estimated forfeitures, determined in the pro forma disclosures under SFAS No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123"). Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock. The Company elected the modified-prospective method of transition, under which prior periods are not revised for comparative purposes.

Recently Adopted Accounting Standards

In September 2006, the FASB issued SFAS No. 158, "*Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106, and*

132(R)" ("SFAS 158"), which amends SFAS No. 87, "Employers' Accounting for Pension," SFAS No. 88, "Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits," SFAS No. 106, "Employers' Accounting for Postretirement Benefits Other Than Pensions" and SFAS No. 132 (revised 2003), "Employers' Disclosures about Pensions and Other Postretirement Benefits," and other related literature. SFAS 158 results from the initial phase of a comprehensive project to improve an employer's accounting for defined benefit pension and other postretirement plans. SFAS 158 requires employers to recognize the overfunded or underfunded status of a single-employer defined benefit postretirement plan as an asset or liability on its balance sheet and to recognize changes in that funded status in comprehensive income. In addition, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end balance sheet. SFAS 158 does not change the accounting for a multi-employer plan.

SFAS 158 provides different effective dates for the recognition and related disclosure provisions, and for the required change to a fiscal year-end measurement date. In December 2006, the Company applied the requirements to recognize the funded status of its benefit plans and made the required disclosures. As of December 31, 2006, the adoption of SFAS 158 increased the Company's long-term liabilities and accumulated other comprehensive loss, net of taxes by \$4.9 million and \$4.3 million, respectively. The requirement to measure plan assets and benefit obligations as of the date of the employer's fiscal year-end balance sheet shall be effective for the Company for the fiscal year ending December 31, 2008. The Company does not expect the change in fiscal year-end measurement date to have a material impact on its consolidated financial statements.

In September 2006, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" ("SAB 108"). SAB 108 provides guidance on the considerations of the effect of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. In December 2006, the Company adopted SAB 108. The adoption did not have a material impact on the Company's consolidated financial statements.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," ("SFAS 154") a replacement of Accounting Principles Board Opinion No. 20, "Accounting Changes," and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements." SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles required recognition by recording a cumulative effect adjustment within net income in the period of change. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. In January 2006, the Company adopted SFAS 154. The adoption did not have a material impact on the Company's consolidated financial statements.

In December 2004, the FASB issued SFAS 123R. This Statement supersedes APB 25 and its related implementation guidance. SFAS 123R eliminates the alternative to use APB 25's intrinsic value method of accounting that was provided in SFAS 123 as originally issued. Under APB 25, issuing stock options to employees generally resulted in recognition of no compensation cost. SFAS 123R 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). Although SFAS 123R was to be effective for the first interim or annual reporting period that began after June 15,

2005, on April 15, 2005, the SEC extended the date for compliance. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's view regarding interactions between SFAS 123R and certain SEC rules and regulations, and provides interpretations of the valuation of share-based payments for public companies. SAB 107 covers key topics related to the implementation of SFAS 123R which include the valuation models, expected volatility, expected option term, income tax effects of SFAS 123R, classification of stock-based compensation cost, capitalization of compensation cost, and disclosure requirements. In the first quarter of 2006, the Company adopted SFAS 123R.

As a result of adopting SFAS 123R versus continuing to account for stock-based compensation under APB 25, the Company's income before provision for income taxes and net income for the year ended December 31, 2006 were reduced by \$19.3 million and \$13.8 million, respectively. In addition, basic and diluted net income per share for the year ended December 21, 2006 were reduced by \$0.24 and \$0.22, respectively. Prior to the adoption of SFAS 123R, benefits of tax deductions in excess of recognized compensation expense were reported as operating cash flows. SFAS 123R requires that they be recorded as financing cash flows rather than as a reduction of taxes paid. For the year ended December 31, 2006, \$5.2 million of excess tax benefits have been classified as a financing cash inflow.

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 Accounting Research Bulletin No. 43, Chapter 4, "*Inventory Pricing,*" to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). On January 1, 2006, the Company adopted this standard. The adoption did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently assessing the impact, if any, that adopting SFAS 157 will have on its consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*" ("FIN 48"), which is effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainties in income taxes recognized in accordance with SFAS 109 by prescribing guidance for the recognition, de-recognition and measurement in financial statements of income tax positions taken in previously filed tax returns or tax positions expected to be taken in tax returns, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 requires that any liability created for unrecognized tax benefits be disclosed. The application of FIN 48 may also affect the tax bases of assets and liabilities and therefore may change or create deferred tax liabilities or assets. The Company will be required to adopt FIN 48 as of January 1, 2007. If there are changes in the net assets of the Company as a result of the application of FIN 48, the cumulative effects, if any, will be recorded as an adjustment to retained earnings. The Company is currently evaluating the impact of its adoption of FIN 48 and has not yet determined the effect on its earnings and financial position.

In March 2006, the FASB issued SFAS No. 156, "*Accounting for Servicing of Financial Assets*" ("SFAS 156"), which amends SFAS No. 140, "*Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*" ("SFAS 140"). SFAS 156 requires recognition of a servicing asset or liability at fair value each time an obligation is undertaken to service a financial asset by entering into a servicing contract. SFAS 156 also provides guidance on subsequent measurement methods for each class of servicing assets and liabilities and specifies financial statement presentation and disclosure requirements. SFAS 156 is effective for fiscal years beginning after September 15, 2006. The Company does not expect the adoption of SFAS 156 to have a material impact on its consolidated financial statements.

In February 2006, the FASB issued SFAS No. 155, "*Accounting for Certain Hybrid Financial Instruments*" ("SFAS 155"), which amends SFAS No. 133, "*Accounting for Derivative Instruments and Hedging Activities*" ("SFAS 133"), and SFAS No. 140, "*Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*." ("SFAS 140"). SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. The Company does not expect the adoption of SFAS 155 to have a material impact on its consolidated financial statements.

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, 2006 and 2005 were \$295.2 million and \$198.0 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. There were no interest rate swaps in effect as of December 31, 2006.

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 and a 14-day holding period, to estimate this potential loss. The Company's calculated VAR at December 31, 2006 and 2005, with a maturity of up to one year, is \$2.3 million and \$4.3 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, 2006 reduced by the effects of master netting agreements. Additionally, at December 31, 2006, all derivative financial instruments 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, 2006. The Company has not experienced any counterparty default since its inception in April 2000.

Concentrations of Credit Risk

In the normal course of business, Edwards Lifesciences provides credit to customers in the healthcare industry, performs credit evaluations of these customers and maintains allowances for potential credit losses which have historically been adequate compared to actual losses. In 2006, 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.

As of December 31, 2006, Edwards Lifesciences had approximately \$20.2 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.4 million on these investments in "Accumulated Other Comprehensive Income (Loss)," net of tax. 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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2006**

Report of Independent Registered Public Accounting Firm	52
Financial Statements:	
Consolidated Balance Sheets at December 31, 2006 and 2005	54
For the years ended December 31, 2006, 2005 and 2004:	
Consolidated Statements of Operations	55
Consolidated Statements of Cash Flows	56
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)	57
Notes to Consolidated Financial Statements	59
Other schedules are not applicable and have not been submitted	

Report of Independent Registered Public Accounting Firm

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

We have completed integrated audits of Edwards Lifesciences Corporation's consolidated financial statements and of its internal control over financial reporting as of December 31, 2006, 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

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, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation in 2006.

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, 2006 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, 2006, 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
February 28, 2007

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2006	2005
ASSETS		
Current assets		
Cash and cash equivalents	\$ 182.8	\$ 178.6
Accounts receivable, net	111.5	101.1
Other receivables	15.6	17.4
Inventories, net	142.1	131.5
Deferred income taxes	21.8	27.6
Prepaid expenses and other current assets	57.8	58.0
Total current assets	531.6	514.2
Property, plant and equipment, net	213.0	201.9
Goodwill	337.7	337.7
Other intangible assets, net	116.1	137.7
Investments in unconsolidated affiliates	20.2	10.7
Deferred income taxes	14.5	11.5
Other assets	13.7	15.4
Total assets	\$ 1,246.8	\$ 1,229.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 57.2	\$ 60.7
Accrued liabilities	132.0	108.3
Taxes payable	37.0	25.2
Total current liabilities	226.2	194.2
Long-term debt	235.9	316.1
Other long-term liabilities	35.3	28.8
Commitments and contingent liabilities (Notes 9 and 17)		
Stockholders' equity		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 67.0 and 65.6 shares issued, 57.7 and 59.6 shares outstanding at December 31, 2006 and 2005, respectively	67.0	65.6
Additional paid-in capital	603.7	536.7
Retained earnings	433.9	303.4
Accumulated other comprehensive loss	(15.8)	(22.2)
Treasury stock, at cost, 9.3 and 6.0 shares at December 31, 2006 and 2005, respectively	(339.4)	(193.5)
Total stockholders' equity	749.4	690.0

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

December 31,

Total liabilities and stockholders' equity

	December 31,	
	\$ 1,246.8	\$ 1,229.1

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,		
	2006	2005	2004
Net sales	\$ 1,037.0	\$ 997.9	\$ 931.5
Cost of goods sold	373.6	374.6	370.2
Gross profit	663.4	623.3	561.3
Selling, general and administrative expenses	376.0	348.7	319.9
Research and development expenses	114.2	99.0	87.0
Purchased in-process research and development expenses (Note 3)	—	1.2	93.3
Special (gains) charges, net (Note 4)	(4.5)	48.2	17.2
Interest expense	10.5	12.3	15.2
Interest income	(7.8)	(2.6)	(1.0)
Other expense (income), net (Note 15)	2.7	(0.2)	(0.4)
Income before provision for income taxes	172.3	116.7	30.1
Provision for income taxes	41.8	37.4	28.4
Net income	\$ 130.5	\$ 79.3	\$ 1.7

Share information (Note 2):

Earnings per share:			
Basic	\$ 2.23	\$ 1.33	\$ 0.03
Diluted	\$ 2.10	\$ 1.27	\$ 0.03
Weighted average number of common shares outstanding:			
Basic	58.5	59.6	59.6
Diluted	63.9	62.3	62.0

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,		
	2006	2005	2004
Cash flows from operating activities			
Net income	\$ 130.5	\$ 79.3	\$ 1.7
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	56.8	56.2	55.7
Stock-based compensation (Notes 2 and 12)	26.6	3.3	
Deferred income taxes	7.1	(13.8)	0.8
Purchased in-process research and development		1.2	93.3
Special charges (gains), net	19.3	(0.8)	19.6
Other	5.4	15.0	6.7
Changes in operating assets and liabilities:			
Accounts and other receivables	2.5	(12.6)	7.1
Accounts receivable securitization	0.9	(2.6)	2.5
Inventories	(12.8)	(12.9)	(7.1)
Accounts payable and accrued liabilities	(3.9)	25.1	13.0
Prepaid expenses	(1.2)	0.3	(7.2)
Other	(0.4)	(0.9)	(5.5)
Net cash provided by operating activities	230.8	136.8	180.6
Cash flows from investing activities			
Capital expenditures	(57.4)	(48.5)	(42.5)
Investments in intangible assets	(2.0)	(2.5)	(11.0)
Investments in unconsolidated affiliates	(1.8)	(1.5)	(1.0)
Proceeds from sale of assets (Note 4)	22.2	24.6	15.1
Acquisitions			(137.7)
Other	3.3	0.7	
Net cash used in investing activities	(35.7)	(27.2)	(177.1)
Cash flows from financing activities			
Proceeds from issuance of long-term debt	54.8	337.3	285.7
Payments on long-term debt	(140.7)	(278.2)	(278.6)
Purchases of treasury stock	(145.9)	(53.5)	(59.1)
Proceeds from stock plans	33.5	26.2	30.5
Excess tax benefit from stock plans (Notes 2 and 12)	5.2		
Other	(0.5)	(2.8)	1.0
Net cash (used in) provided by financing activities	(193.6)	29.0	(20.5)
Effect of currency exchange rate changes on cash and cash equivalents	2.7	(8.9)	4.8
Net increase (decrease) in cash and cash equivalents	4.2	129.7	(12.2)
Cash and cash equivalents at beginning of year	178.6	48.9	61.1
Cash and cash equivalents at end of year	\$ 182.8	\$ 178.6	\$ 48.9

Years Ended December 31,

Supplemental disclosures:

Cash paid during the year for:

Interest	\$	10.5	\$	12.3	\$	12.9
Income taxes	\$	14.3	\$	37.2	\$	11.4

Non-cash transactions:

Investment received in exchange for assets (Notes 4 and 8)	\$	6.4
--	----	-----

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)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount					
BALANCE AT DECEMBER 31, 2003	62.6	\$ 62.6	3.1	\$ (80.9)	463.2	\$ 222.4	\$ (32.2)	\$ 635.1	
Comprehensive income									
Net income						1.7		1.7	\$ 1.7
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							16.6	16.6	16.6
Unrealized gain on cash flow hedges							2.4	2.4	2.4
Unrealized loss on available-for-sale investments							(8.8)	(8.8)	(8.8)
Reclassification adjustment for other- than-temporary impairments							4.7	4.7	4.7
Minimum pension liability adjustment							(3.5)	(3.5)	(3.5)
Common stock issued under equity plans	1.6	1.6			29.4			30.5	
Tax benefit related to equity plans					8.0			8.0	
Purchase of treasury stock			1.7	(59.1)				(59.1)	
BALANCE AT DECEMBER 31, 2004	64.2	64.2	4.8	(140.0)	500.6	224.1	(20.8)	628.1	\$ 13.1
Comprehensive income									
Net income						79.3		79.3	\$ 79.3
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							(21.0)	(21.0)	(21.0)
Unrealized gains on cash flow hedges							15.3	15.3	15.3
Unrealized loss on available-for-sale investments							(6.9)	(6.9)	(6.9)
Reclassification adjustment for other- than-temporary impairments							10.9	10.9	10.9
Minimum pension liability adjustment							0.3	0.3	0.3
Common stock issued under equity plans	1.4	1.4			24.9			28.6	
Tax benefit related to equity plans					7.9			7.9	
Stock-based compensation expense					3.3			1.0	

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

	Common Stock		Treasury Stock							
Purchase of treasury stock				(53.5)					(53.5)	
BALANCE AT DECEMBER 31, 2005	65.6	65.6	6.0	(193.5)	536.7	303.4	(22.2)	690.0	\$	77.9

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

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount					
BALANCE AT DECEMBER 31, 2005	65.6	65.6	6.0	(193.5)	536.7	303.4	(22.2)	690.0	
Comprehensive income									
Net income						\$ 130.5		\$ 130.5	\$ 130.5
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							11.8	11.8	11.8
Unrealized loss on cash flow hedges							(5.2)	(5.2)	(5.2)
Unrealized gain on available-for-sale investments							2.0	2.0	2.0
Minimum pension liability adjustment							2.1	2.1	2.1
Impact of SFAS 158, net of tax							(4.3)	(4.3)	
Common stock issued under equity plans	1.4	1.4			32.1			33.5	
Tax benefit related to equity plans					8.4			8.4	
Stock-based compensation expense					26.6			26.6	
Purchase of treasury stock			3.3	(145.9)				(145.9)	
BALANCE AT DECEMBER 31, 2006	67.0	\$ 67.0	9.3	\$ (339.4)	603.7	\$ 433.9	(15.8)	\$ 749.4	\$ 141.2

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 Corporation ("Edwards Lifesciences" or the "Company") 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 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.

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. The principles of Financial Accounting Standards Board ("FASB") Interpretation No. 46, "*Consolidation of Variable Interest Entities*," Statements of Financial Accounting Standards ("SFAS") No. 94, "*Consolidation of All Majority-Owned Subsidiaries (an Amendment of ARB No. 51, with Related Amendments of APB Opinion No. 18 and ARB No. 43, Chapter 12)*" and Accounting Research Bulletin No. 51, "*Consolidated Financial Statements*" are considered when determining whether an entity is subject to consolidation.

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, reserves for excess and obsolete inventory, investments in unconsolidated affiliates, workers compensation liabilities, employee benefit related liabilities, income taxes, asset impairments, forecasted transactions to be hedged, litigation reserves and contingencies.

Foreign Currency Translation

The Company follows the principles of 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 loss. The effects of foreign currency transactions denominated in a currency other than an entities' functional currency are included in other expense (income), net.

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 approximate 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. 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, are included in other expense (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.

Inventory reserves result from inventory which is obsolete, is nearing its expiration date (generally triggered at six months prior to expiration), is damaged or slow moving (defined as quantities in excess of a two year supply). Reserves for excess and obsolete inventory were approximately \$13.2 million and \$12.3 million at December 31, 2006 and 2005, respectively.

The Company allocates general and administrative costs to inventory that are related to the production process. These costs include insurance, software, and manufacturing accounting personnel. During the years ended December 31, 2006, 2005 and 2004, the Company allocated \$10.2 million, \$10.0 million and \$9.8 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2006 and 2005 were \$4.2 million and \$3.6 million, respectively.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost. Depreciation is principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 10 to 40 years for buildings and improvements and from 3 to 15 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.

Depreciation expense for plant and equipment was \$39.2 million, \$38.7 million and \$36.8 million for the years ended December 31, 2006, 2005 and 2004, respectively. Repairs and maintenance expense was \$12.8 million, \$12.3 million and \$12.1 million for the years ended December 31, 2006, 2005 and 2004, respectively.

Impairment of Long-Lived Assets

The Company evaluates the carrying value of goodwill in the fourth quarter of each fiscal year. In evaluating goodwill, the Company completes the two-step goodwill impairment test as required by SFAS No. 142, *"Goodwill and Other Intangible Assets"* ("SFAS 142"). The Company identifies its reporting units and determines the carrying value of each reporting unit by assigning the assets and liabilities, including existing goodwill, to those reporting units. The fair value of the reporting unit is estimated based on the market capitalization and a market revenue multiple. If the carrying amount of the reporting unit exceeds its fair value, the Company will perform the second step of the impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test

compares the implied fair value of a reporting unit's goodwill with its carrying value. Since the adoption of SFAS 142, the Company has not performed the second step of the impairment test as the fair value of each reporting unit has exceeded its respective carrying value.

Additionally, in accordance with SFAS 142 and SFAS No.144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*" ("SFAS 144"), management reviews the carrying amounts of other intangible and long-lived tangible assets 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. Such legal 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

Investments in unconsolidated affiliates are long-term, strategic equity investments in companies that are in various stages of development. Certain of these investments 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. Other investments in unconsolidated affiliates are accounted for under the cost or the equity method of accounting, as appropriate. The Company accounts for investments in limited partnerships or limited liability corporations, whereby the Company owns a minimum of 3 to 5% of the investee's outstanding voting stock, under the equity method of accounting. These investments are recorded at the amount of the Company's investment and adjusted each period for the Company's share of the investee's income or loss and dividends paid. As investments accounted for under the cost method do not have readily determinable fair value, the Company only estimates fair value if there are identified events or changes in circumstances that could have a significant adverse effect on the investment's fair value.

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.

The Company accounts for income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes*" ("SFAS 109") 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 quarterly 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

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. SFAS No. 128, "*Earnings per Share*," requires that employee equity share options, nonvested shares and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of the conversion of contingently convertible senior debentures, restricted stock units and in-the-money options. The dilutive impact of the restricted stock units and in-the-money options is

calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount that the employee must pay for exercising stock options, the amount of compensation expense for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital when the award becomes deductible are assumed to be used to repurchase shares. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

The table below presents the computation of basic and diluted earnings per share (in millions, except for per share information):

	Years ended December 31,		
	2006	2005	2004
Basic:			
Net income	\$ 130.5	\$ 79.3	\$ 1.7
Weighted-average shares outstanding	58.5	59.6	59.6
Basic earnings per share	\$ 2.23	\$ 1.33	\$ 0.03
Diluted:			
Net income	\$ 130.5	\$ 79.3	\$ 1.7
Interest expense related to contingently convertible debt, net of tax	4.0		
Net income applicable to diluted shares	\$ 134.5	\$ 79.3	\$ 1.7
Weighted-average shares outstanding	58.5	59.6	59.6
Dilutive effect of contingently convertible debt	2.7		
Dilutive effect of stock plans	2.7	2.7	2.4
Diluted weighted-average shares outstanding	63.9	62.3	62.0
Diluted earnings per share	\$ 2.10	\$ 1.27	\$ 0.03

Stock options and restricted stock units to purchase approximately 2.8 million and 2.7 million shares for the years ended December 31, 2006 and 2005, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive. For the years ended December 31, 2005 and 2004, the effect of approximately 2.7 million potential common share equivalents relating to the Company's \$150.0 million convertible debentures due 2033 has been excluded from the computation of diluted earnings per share because the result would have been anti-dilutive.

Stock-based Compensation

On January 1, 2006, the Company adopted SFAS No. 123 (Revised 2004), "Share-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options,

restricted stock units and employee stock purchase subscriptions. Under the fair value recognition provisions of SFAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period). The valuation provisions of SFAS 123R apply to new grants and to grants that were outstanding as of the effective date and are subsequently modified. Estimated compensation expense for grants that were outstanding, as of the effective date, will be recognized over the remaining service period using the compensation expense, adjusted for estimated forfeitures, determined in the pro forma disclosures under SFAS No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123"). Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock. The Company elected the modified-prospective method of transition, under which prior periods are not revised for comparative purposes.

Upon adoption of SFAS 123R, the Company changed its method of attributing the value of restricted stock unit awards from the graded vesting attribution method to the straight-line attribution method. Compensation expense for all restricted stock unit awards granted prior to adoption of SFAS 123R will continue to be recognized using the graded vesting attribution method, while compensation expense for all restricted stock units granted subsequent to the adoption is recognized using the straight-line attribution method. Stock-based compensation expense related to stock options will continue to be recognized using the straight-line attribution method. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company accounted for forfeitures as they occurred.

Total stock-based compensation expense recognized under SFAS 123R for the year ended December 31, 2006 was \$26.6 million, which was included in (a) cost of goods sold, (b) selling, general and administrative expenses and (c) research and development expenses, in the amounts of \$3.4 million, \$18.4 million, and \$4.8 million, respectively. Prior to the adoption of SFAS 123R, the Company accounted for employee stock-based compensation plans under Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB 25"), and followed the pro forma net income, pro forma income per share, and stock-based compensation plan disclosure requirements set forth in SFAS 123.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

The following table illustrates the effect on net income and earnings per share for the years ended December 31, 2005 and 2004, as if the Company had applied the fair value recognition provision of SFAS 123 to stock-based compensation (in millions, except per share amounts):

	Years Ended December 31,	
	2005	2004
Net income, as reported	\$ 79.3	\$ 1.7
Add: Stock-based employee compensation included in reported net income, net of tax	1.5	
Deduct: Total stock-based compensation expense determined under fair value based method for all awards, net of tax	(15.8)	(15.7)
Pro forma net income (loss)	\$ 65.0	\$ (14.0)
Earnings per basic share:		
Reported net income	\$ 1.33	\$ 0.03
Pro forma net income (loss)	\$ 1.09	\$ (0.23)
Earnings per diluted share:		
Reported net income	\$ 1.27	\$ 0.03
Pro forma net income (loss)	\$ 1.04	\$ (0.23)

For the May 2006 grant, the Company revised the options' and restricted stock units' retirement vesting provisions. Upon retirement, all unvested options are immediately forfeited. In addition, upon retirement, a participant will immediately vest in 25% of restricted stock units for each full year of employment with the Company measured from the grant date. All remaining unvested restricted stock units are immediately forfeited.

For grants made prior to May 2006, upon retirement an employee retains the original vesting schedule for restricted stock units and is entitled to accelerated vesting of stock options, however, the exercisability of the options remains subject to the original exercise schedule. The FASB clarified in SFAS 123R that the fair value of such awards should be expensed based on an accelerated vesting schedule or immediately upon an employee becoming eligible for retirement, rather than ratably over the vesting period stated in the grant. Prior to adoption of SFAS 123R, the Company's pro forma disclosure reflected the expense of options and restricted stock units ratably over the stated vesting period, expensing all unvested shares upon actual retirement.

Upon adoption of SFAS 123R, the Company began applying the accelerated vesting schedule to all grants for employees that meet the retirement eligibility criteria for accelerated vesting upon retirement. Had the Company been accounting for the stock options and restricted stock units, granted prior to adoption of SFAS 123R, using the accelerated vesting schedule for those employees eligible for accelerated vesting upon retirement, the Company would have recognized a \$1.3 million reduction in stock-based compensation expense for the year ended December 31, 2006, a \$2.6 million increase in

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

stock-based compensation expense in the pro forma disclosure for the year ended December 31, 2005, and a \$0.6 million reduction in stock-based compensation expense in the pro forma disclosure for the year ended December 31, 2004.

Derivatives

Edwards Lifesciences maintains an overall risk management strategy that may incorporate the use of a variety of interest rate and currency derivative financial instruments to mitigate its exposure to significant unplanned fluctuations in earnings and cash flow caused by volatility in interest rates 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, 2006, all derivative instruments owned are designated as hedges of underlying exposures. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

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.

The Company uses interest rate swaps to convert floating-rate debt to fixed-rate debt. The Company's interest rate swaps expired in the second quarter of 2005. The Company's interest rate swap agreements involved 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 hedged were determined based on prevailing market conditions and the then current shape of the yield curve. Interest rate swap agreements were executed as an integral part of specific debt transactions.

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 current-period earnings.

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 of 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 or within an additional two-month period of time thereafter, the gain or loss is reclassified into 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.

Recently Adopted Accounting Standards

In September 2006, the FASB issued SFAS No. 158, "*Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106, and 132(R)*" ("SFAS 158"), which amends SFAS No. 87, "*Employers' Accounting for Pension*," SFAS No. 88, "*Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*," SFAS No. 106, "*Employers' Accounting for Postretirement Benefits Other Than*

Pensions" and SFAS No. 132 (revised 2003), *"Employers' Disclosures about Pensions and Other Postretirement Benefits,"* and other related literature. SFAS 158 results from the initial phase of a comprehensive project to improve an employer's accounting for defined benefit pension and other postretirement plans. SFAS 158 requires employers to recognize the overfunded or underfunded status of a single-employer defined benefit postretirement plan as an asset or liability on its balance sheet and to recognize changes in that funded status in comprehensive income. In addition, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end balance sheet. SFAS 158 does not change the accounting for a multi-employer plan.

SFAS 158 provides different effective dates for the recognition and related disclosure provisions, and for the required change to a fiscal year-end measurement date. In December 2006, the Company applied the requirements to recognize the funded status of its benefit plans and made the required disclosures. As of December 31, 2006, the adoption of SFAS 158 increased the Company's long-term liabilities and accumulated other comprehensive loss, net of taxes, by \$4.9 million and \$4.3 million, respectively.

The requirement to measure plan assets and benefit obligations as of the date of the employer's fiscal year-end balance sheet shall be effective for the Company for the fiscal year ending December 31, 2008. In addition, the Company is still assessing the impact that the adoption of SFAS 158 will have on its deferred taxes. The Company does not expect the adoption of SFAS 158 to have a material impact on its consolidated statements of operations and cash flows.

In September 2006, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 108, *"Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements"* ("SAB 108"). SAB 108 provides guidance on the considerations of the effect of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. In December 2006, the Company adopted SAB 108. The adoption did not have a material impact on the Company's consolidated financial statements.

In June 2005, the FASB issued SFAS No. 154, *"Accounting Changes and Error Corrections,"* ("SFAS 154") a replacement of Accounting Principles Board ("APB") Opinion No. 20, *"Accounting Changes,"* and FASB Statement No. 3, *"Reporting Accounting Changes in Interim Financial Statements."* SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. Previously, most voluntary changes in accounting principles required recognition by recording a cumulative effect adjustment within net income in the period of change. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. In January 2006, the Company adopted SFAS 154. The adoption did not have a material impact on the Company's consolidated financial statements.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

In December 2004, the FASB issued SFAS 123R. This Statement supersedes APB 25 and its related implementation guidance. SFAS 123R eliminates the alternative to use APB 25's intrinsic value method of accounting that was provided in SFAS 123 as originally issued. Under APB 25, issuing stock options to employees generally resulted in recognition of no compensation cost. SFAS 123R 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). Although SFAS 123R was to be effective for the first interim or annual reporting period that began after June 15, 2005, on April 15, 2005, the SEC extended the date for compliance. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107"), which provides the Staff's view regarding interactions between SFAS 123R and certain SEC rules and regulations, and provides interpretations of the valuation of share-based payments for public companies. SAB 107 covers key topics related to the implementation of SFAS 123R which include the valuation models, expected volatility, expected option term, income tax effects of SFAS 123R, classification of stock-based compensation cost, capitalization of compensation cost, and disclosure requirements. In the first quarter of 2006, the Company adopted SFAS 123R.

As a result of adopting SFAS 123R versus continuing to account for stock-based compensation under APB 25, the Company's income before provision for income taxes and net income for the year ended December 31, 2006 were reduced by \$19.3 million and \$13.8 million, respectively. In addition, basic and diluted net income per share for the year ended December 21, 2006 were reduced by \$0.24 and \$0.22, respectively. Prior to the adoption of SFAS 123R, benefits of tax deductions in excess of recognized compensation expense were reported as operating cash flows. SFAS 123R requires that they be recorded as financing cash flows rather than as a reduction of taxes paid. For the year ended December 31, 2006, \$5.2 million of excess tax benefits have been classified as a financing cash inflow.

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 Accounting Research Bulletin No. 43, Chapter 4, "*Inventory Pricing,*" to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). On January 1, 2006, the Company adopted this standard. The adoption did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently assessing the impact, if any, that adopting SFAS 157 will have on its consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*" ("FIN 48"), which is effective for fiscal years

beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainties in income taxes recognized in accordance with SFAS 109 by prescribing guidance for the recognition, de-recognition and measurement in financial statements of income tax positions taken in previously filed tax returns or tax positions expected to be taken in tax returns, including a decision whether to file or not to file in a particular jurisdiction. FIN 48 requires that any liability created for unrecognized tax benefits be disclosed. The application of FIN 48 may also affect the tax bases of assets and liabilities and therefore may change or create deferred tax liabilities or assets. The Company will be required to adopt FIN 48 as of January 1, 2007. If there are changes in the net assets of the Company as a result of the application of FIN 48, the cumulative effects, if any, will be recorded as an adjustment to retained earnings. The Company is currently evaluating the impact of its adoption of FIN 48 and has not yet determined the effect on its earnings or financial position.

In March 2006, the FASB issued SFAS No. 156, "*Accounting for Servicing of Financial Assets*" ("SFAS 156"), which amends SFAS No. 140, "*Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*" ("SFAS 140"). SFAS 156 requires recognition of a servicing asset or liability at fair value each time an obligation is undertaken to service a financial asset by entering into a servicing contract. SFAS 156 also provides guidance on subsequent measurement methods for each class of servicing assets and liabilities and specifies financial statement presentation and disclosure requirements. SFAS 156 is effective for fiscal years beginning after September 15, 2006. The Company does not expect the adoption of SFAS 156 to have a material impact on its consolidated financial statements.

In February 2006, the FASB issued SFAS No. 155, "*Accounting for Certain Hybrid Financial Instruments*" ("SFAS 155"), which amends SFAS No. 133, "*Accounting for Derivative Instruments and Hedging Activities*" ("SFAS 133"), and SFAS No. 140, "*Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*." ("SFAS 140"). SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. The Company does not expect the adoption of SFAS 155 to have a material impact on its consolidated financial statements.

3. PURCHASED IN-PROCESS RESEARCH AND DEVELOPMENT EXPENSE

The information herein related to regulatory milestones reflects the Company's expectations at the time of the respective acquisitions and has not been updated to reflect subsequent activities or expectations. Refer to "*Research and Development Expenses*" in Management's Discussion and Analysis for updates to the Company's expectations.

2005

In September 2005, the Company recorded a \$1.2 million pretax charge for in-process research and development related to the acquisition of technology and intellectual property. The acquired assets are expected to be utilized in the Company's existing mitral valve repair research and development efforts. Additional design developments, bench testing, pre-clinical studies and human clinical studies must be successfully completed prior to selling any product.

2004

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 acquired assets from this acquisition were 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. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies were required 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 \$39.0 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 (see Note 4). 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 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.

4. SPECIAL (GAINS) CHARGES, NET

	Years Ended December 31,		
	2006	2005	2004
	(in millions)		
Settlements and litigation (gains) losses, net	\$ (20.2)	\$ 2.9	\$
Gain on sale of assets, net	(13.7)	(14.1)	(7.4)
PVT milestone	10.0		
Realignment expenses, net	9.4	3.9	
Discontinued products	6.8	1.4	10.6
Restructure 3F agreements	2.0	22.8	
Litigation reserve	1.2		
Investment impairments		16.3	9.0
Charitable fund contributions		15.0	5.0
Total special (gains) charges, net	\$ (4.5)	\$ 48.2	\$ 17.2

Settlements and Litigation (Gains) Losses, net

In January 2006, the Company recorded a patent dispute settlement gain of \$20.2 million, which consisted of a net payment of \$23.8 million received from Medtronic, Inc., offset by patent enforcement costs.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

In September 2005, the Company recorded a gain of \$2.5 million related to the resolution of intellectual property litigation. In the fourth quarter of 2005, the Company recorded a \$5.4 million charge related to two royalty dispute settlements.

Gain on Sale of Assets, net

In December 2006, the Company sold its assets associated with the Company's angiogenesis research and development project to Sangamo BioSciences Inc. ("Sangamo") in exchange for 1.0 million shares of Sangamo common stock. The Company recorded a \$6.1 million gain, which represents the fair value of the common stock on the closing date, less the book value of the assets sold.

In May 2006, the Company sold a non-strategic pharmaceutical product to Bioniche Teoranta for \$9.0 million. The sale of the related assets resulted in a \$4.5 million gain, consisting of cash proceeds of \$9.0 million, offset by \$4.5 million related primarily to the net book value of intangible assets and inventory that were sold.

In the second quarter of 2006, the Company agreed to sell most of its assets related to its remaining international cardiopulmonary perfusion product line. The Company determined that the carrying values of the underlying assets exceeded their fair values. Consequently, in accordance with SFAS 144, in the second quarter of 2006, the Company recorded an impairment loss of \$2.6 million, which represented the excess of the carrying values of the assets over their fair values, and included direct incremental costs to transact the sale of \$1.5 million. The sale was completed in December 2006 and no additional gain or loss was recorded.

In November 2005, the Company sold its vascular graft business to Angiotech Pharmaceuticals Inc. for \$14.0 million in cash. Under the agreement, the Company will continue to market and sell its existing *Lifespan* products. The sale of the business resulted in a \$13.1 million net gain, consisting of cash proceeds of \$14.0 million offset by the \$0.9 million net book value of inventory and fixed assets that were sold.

In January 2005, the Company announced that it was realigning its business in Japan as part of the Company's continued efforts to focus on its core cardiovascular businesses. The Company (1) restructured its operations, (2) exited its pacemaker distribution business and (3) sold its perfusion product line in Japan to Terumo Corporation for cash consideration of \$14.9 million, of which \$9.2 million was received in January 2005 and \$5.7 million was received in March 2006 as an earn-out payment. In 2005, the Company recorded a \$1.0 million net gain, consisting of a gain on the sale of the Company's Japan perfusion product line of \$7.7 million, offset by a \$5.7 million charge related to the realignment of its operations, primarily related to severance costs due to headcount reductions, and a \$1.0 million charge related to settlement, curtailment and special termination benefits impacting its defined benefit pension plan. In 2006, the Company recorded a gain of \$5.7 million related to the receipt of the earn-out payment. As of December 31, 2006, payments related to the realignment were complete.

In November 2004, the Company recorded a gain 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.

PVT Milestone

In December 2006, the Company recorded a \$10.0 million charge for the contractual transcatheter clinical milestone obligation to PVT's former shareholders. In the first quarter of 2007, the Company achieved and paid the \$10.0 million to PVT's former shareholders. As all contractual milestone obligation dates have expired, the Company does not expect to make any additional payments to PVT's former shareholders.

Realignment Expenses, net

In December 2006, the Company recorded a \$7.3 million charge related primarily to severance expenses associated with a global reduction in workforce of approximately 70 employees, primarily in the United States and Europe. As of December 31, 2006, the Company paid \$0.4 million of severance with the remaining amount expected to be paid out substantially by the end of 2007.

In the first quarter of 2006, the Company recorded realignment expenses of \$2.1 million related primarily to severance expenses associated with the planned closure of a manufacturing facility in Japan (impacting 92 employees). The Company anticipates payments to be made through the third quarter of 2007. The realignment expenses are net of a \$0.4 million reversal of previously accrued severance costs related to the sale of the Japan perfusion product line to Terumo as discussed in the "Gain on Sale of Assets, net" section. As of December 31, 2006, \$1.0 million had been paid related to these actions.

In December 2005, the Company recorded a charge of \$3.9 million related to severance resulting from a resource realignment. The charge was related primarily to the severance costs associated with reducing the Company's workforce by 52 employees, primarily in Puerto Rico, Europe and the United States. As of December 31, 2006, the Company had paid \$3.7 million related to severance with the remaining amount expected to be paid in 2007.

Discontinued Products

In the fourth quarter of 2006, the Company discontinued the *Optiwave 980* Cardiac Laser Ablation System. The Company recorded a \$6.8 million charge resulting primarily from the disposal of fixed assets and the write-off intangible assets. In addition, the Company recorded a \$2.0 million charge to cost of goods sold related to the disposal of inventory.

In the fourth quarter of 2005, the Company recorded a charge of \$1.4 million resulting from the payment of an early termination fee to discontinue certain firm non-cancelable product purchase commitments related to a discontinued product line in Europe.

In the first quarter of 2004, due to a re-prioritization of the Company's investment initiatives, the Company discontinued its sales effort of its *Lifepath* AAA endovascular graft program. The Company recorded a special charge of \$8.4 million primarily related to inventory and contractual clinical obligations. In addition, the Company decided to discontinue certain lower margin cardiology products

in Japan later that year and recorded a \$2.2 million charge in 2004 primarily related to other non-productive assets.

Restructure 3F Agreements

In June 2005, the Company recorded a special charge of \$22.8 million related to the restructuring of development and supply agreements between 3F Therapeutics, Inc. and PVT that were established prior to the Company's acquisition of PVT in early 2004. Under the terms of the new agreements, the Company obtained the rights to self-manufacture all components of its transcatheter heart valves and certain pre-approved technology licenses. In 2006, the Company paid and recorded an additional \$2.0 million for the final payment to 3F Therapeutics for completing certain contractual obligations.

Investment Impairments

In September 2005, the Company recorded an \$8.9 million charge related to the other-than-temporary impairment of its investment in Sangamo. The investment was written down to \$3.7 million, which represented the quoted market price of Sangamo's common stock at September 30, 2005.

The Company considered numerous facts, including those described below, to conclude that any impairment of the Sangamo investment was temporary in nature as of the end of each of the quarters in 2003 and 2004, and the first two quarters of 2005:

Sangamo's key internally established development milestones were progressing and/or remained on track at each quarter-end throughout 2003 and 2004, and the first two quarters of 2005. There were no changes in technology that could impair Sangamo's earnings potential of the investment and the technological progress supported a positive outlook. The Company believed that the number and scope of Sangamo's programs and the range of its third party collaborations and the continued success in the Company's Sangamo-related programs would significantly drive the value of Sangamo. Moreover, the clinical momentum was building at the end of 2004 with the anticipation of three to four Phase I human trials, the likely completion of one or more Phase I trials with positive data and the planned announcements at major medical meetings.

Management of the Company believed that declines in Sangamo's stock price were a result of certain external events and general investor sentiment of the biotechnology sector, and not Sangamo-specific activities. In addition, the Company recognized that, historically, reports of significant positive clinical outcomes had frequently resulted in a significant increase in the stock price of a biotechnology company over a relatively short time period. Management believed this would be the case for Sangamo.

Throughout all periods in which the Company concluded that the impairment of this investment was temporary, Sangamo maintained cash and liquid investment reserves sufficient to continue to fund the ongoing development efforts for the technology for periods well in excess of one year.

Throughout all periods in which the Company concluded that the impairment of this investment was temporary, the Company had the financial ability and intent to retain this investment indefinitely. Sangamo's technology was considered important to the development of certain of the Company's next generation products, and required a long-term horizon for ongoing development of new technology.

Sangamo is a multi-technology (human therapeutics, drug discovery and plant agriculture) biotechnology company and has the ability to attract many different investors. In addition, the diversity of technology applications served to dilute the risk related to any one application failure.

The Company expected the market price of Sangamo's stock to increase not only as a result of announcements of positive clinical trial results, but also other operational events. During the second half of 2005, Sangamo announced five significant key developments regarding collaborative agreements, additional funding and breakthrough technology. The Company expected that this concentration of positive developments could have generated a considerable increase in the stock price, better recognizing the underlying value of Sangamo. Based upon (1) the significant developments in the third quarter of 2005 which, individually and in the aggregate, failed to have a material impact on the quoted market price of Sangamo's stock, (2) the continuing duration and severity of the impairment, and (3) Sangamo's declining cash position, the Company concluded in September 2005 that the impairment on its investment in Sangamo was other-than-temporary and, therefore, recognized an \$8.9 million charge in earnings.

In 2005, the Company recorded additional charges totaling \$7.4 million related to other-than-temporary impairment of technology investments in five other unconsolidated affiliates. Of the total additional charge, \$1.9 million related to declines in the stock prices of two available-for-sale investments. The remaining charges were due to increased potential risk of certain private investees' uncertain future liquidity.

In 2004, the Company recorded charges totaling \$9.0 million related to the other-than-temporary impairment of technology investments in four unconsolidated affiliates. One of the impairments resulted from the decline in the stock price of an affiliate. 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 expected to receive from those companies. The remaining affiliate performed a reset financing that reduced the net value per share for all existing investors. This investment is recorded at the reduced value.

Charitable Fund

In December 2004, the Company made an initial contribution of \$5.0 million to establish the Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular disease charitable causes. In September 2005, the Company completed its funding goal and made an additional \$15.0 million contribution. Both of these contributions were irrevocable contributions to a third party and were recorded as charges at time of payment.

5. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

Components of selected captions in the consolidated balance sheets at December 31 are as follows:

	December 31,	
	2006	2005
(in millions)		
Accounts receivable, net		
Trade accounts receivable	\$ 118.0	\$ 106.5
Less: allowance for doubtful accounts	(6.5)	(5.4)
	<u>\$ 111.5</u>	<u>\$ 101.1</u>
Inventories, net		
Raw materials	\$ 25.1	\$ 25.6
Work in process	22.4	17.8
Finished products	94.6	88.1
	<u>\$ 142.1</u>	<u>\$ 131.5</u>
Property, plant and equipment, net		
Land	\$ 19.6	\$ 19.6
Buildings and leasehold improvements	88.8	79.4
Machinery and equipment	187.4	183.2
Equipment with customers	85.4	92.8
Software	50.8	42.4
Construction in progress	23.1	19.0
	<u>455.1</u>	<u>436.4</u>
Less: accumulated depreciation	(242.1)	(234.5)
	<u>\$ 213.0</u>	<u>\$ 201.9</u>
Accrued liabilities		
Employee compensation and withholdings	\$ 50.3	\$ 53.0
Property, payroll and other taxes	16.7	14.9
Litigation reserves (Note 17)	10.5	2.7
PVT milestone obligation (Notes 3 and 4)	10.0	
Other accrued liabilities	44.5	37.7
	<u>\$ 132.0</u>	<u>\$ 108.3</u>

6. 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 accounts receivable. Under the Japan Receivables Facility, 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, bankruptcy-remote entity formed for the purpose of buying and selling these receivables, which then sells undivided 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 September 18, 2007. The Japan Receivables Facility will expire on December 3, 2008.

Sales of receivables under these programs result in a reduction of accounts receivable on the Company's consolidated balance sheets. Residual interests of \$9.5 million and \$12.2 million as of December 31, 2006 and 2005, 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 \$85.3 million and \$86.6 million of trade accounts receivable as of December 31, 2006 and 2005, respectively, resulting in a reduction of accounts receivable on the Company's consolidated balance sheets, and received funding of \$75.5 million and \$74.1 million, respectively. Costs associated with the sale of receivables, primarily related to the discount, were \$2.6 million, \$1.7 million and \$1.0 million for the years ended December 31, 2006, 2005 and 2004, respectively, and are included in other expense (income), net.

7. GOODWILL AND OTHER INTANGIBLE ASSETS

In accordance with SFAS 142, goodwill resulting from purchase business combinations is not subject to amortization. Other acquired intangible assets are amortized on a straight-line basis over their expected useful lives, unless determined to have an indefinite life. Goodwill recorded on the Company's balance sheet is largely the result of acquisitions completed prior to the spin-off of the Company from Baxter International, Inc. in 2000.

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 purchase 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, 2006. Sales of medical devices from the transferred technology were \$2.7 million for 2006.

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

December 31, 2006	Patents	Unpatented Technology	Other	Total
Cost	\$ 194.3	\$ 27.9	\$ 17.6	\$ 239.8
Accumulated amortization	(100.1)	(20.4)	(3.2)	(123.7)
Net carrying value	\$ 94.2	\$ 7.5	\$ 14.4	\$ 116.1
December 31, 2005	Patents	Unpatented Technology	Other	Total
Cost	\$ 192.3	\$ 39.8	\$ 22.2	\$ 254.3
Accumulated amortization	(86.7)	(26.5)	(3.4)	(116.6)
Net carrying value	\$ 105.6	\$ 13.3	\$ 18.8	\$ 137.7

Patents includes \$3.2 million and \$2.6 million of capitalized legal costs related to the defense and enforcement of issued patents for which success is deemed probable as of December 31, 2006 and 2005, respectively (see Note 2). In 2006, in connection with the favorable settlement of patent litigation with Medtronic, Inc. (see Notes 4 and 17), the Company wrote-off \$2.9 million of capitalized legal costs as an offset against the gain. In 2005, in connection with the favorable settlement of patent disputes with St. Jude, the Company wrote-off \$5.3 million of capitalized legal costs as an offset against the gain (see Note 17).

In the second quarter of 2006, the Company sold \$3.8 million of net unpatented technology in connection with the sale of a non-strategic product (see Note 4). In addition, in the fourth quarter of 2006, the Company discontinued the *Optiwave 980* Cardiac Laser Ablation System and wrote-off the related \$4.4 million of net patents and other intangibles (see Note 4).

Amortization expense related to other intangible assets for the years ended December 31, 2006, 2005 and 2004 was \$17.6 million, \$17.5 million and \$9.5 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2007	\$ 16.7
2008	16.8
2009	15.6
2010	12.4
2011	11.4

8. INVESTMENTS IN UNCONSOLIDATED AFFILIATES

The Company has entered into a number of strategic alliances with privately and publicly held companies. Investments in unconsolidated affiliates are as follows:

	December 31,	
	2006	2005
	(in millions)	
Available-for-sale investments		
Cost	\$ 13.1	\$ 7.2
Unrealized gains	2.3	
Unrealized losses		(0.6)
	<u>15.4</u>	<u>6.6</u>
Fair value of available-for-sale investments	15.4	6.6
Equity method investments		
Cost	6.1	3.7
Equity in losses	(1.6)	(0.2)
	<u>4.5</u>	<u>3.5</u>
Carrying value of equity method investments	4.5	3.5
Cost method investments		
Carrying value of cost method investments	0.3	0.6
	<u>0.3</u>	<u>0.6</u>
Total investments in unconsolidated affiliates	\$ 20.2	\$ 10.7

In December 2006, the Company sold its assets associated with the Company's angiogenesis research and development project to Sangamo in exchange for 1.0 million shares of Sangamo common stock. At the time of the transaction, the Company recorded the shares as an available-for-sale investment at an estimated fair value of \$6.4 million.

As of December 31, 2005, the Company had \$0.6 million of unrealized losses related to two available-for-sale investments. The trading value of the Company's investments had been less than the Company's original cost for less than six months and the Company had the ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. Accordingly, the Company believed that the unrealized losses were temporary in nature. As of December 31, 2006, these two investments were in an unrealized gain position. See Note 4 for additional information regarding other-than-temporary impairment charges recorded in 2005.

9. LONG-TERM DEBT, CREDIT FACILITIES AND LEASE OBLIGATIONS

On September 29, 2006, the Company extended its Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), to September 29, 2011. 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 0.45%, 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 a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.08%. 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. Additional issuance costs of \$0.5 million are being amortized to interest expense over 5 years. As of December 31, 2006, borrowings of \$85.9 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 at December 31, 2006.

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.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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, 2006.

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. As of December 31, 2006 and 2005, the Company had no outstanding interest rate swap agreements. The last interest rate swap agreements to which the Company was a party expired in May and July of 2005.

The weighted average interest rate under all debt obligations was 3.8% and 3.6% at December 31, 2006 and 2005, respectively, including the effect of the floating-to-fixed interest rate swap agreements which expired in May and June of 2005.

Included in debt at December 31, 2006 and 2005 were unsecured notes denominated in Japanese yen of ¥7.2 billion (US\$60.9 million) and ¥8.8 billion (US\$75.3 million), respectively and in Euro of €19.0 million (US\$25.0 million) and €76.0 million (US\$90.8 million), respectively.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2006 were as follows (in millions):

	Operating Leases	Aggregate Debt Maturities
2007	\$ 10.9	\$
2008	8.2	150.0
2009	5.8	
2010	4.1	
2011	2.9	85.9
Thereafter	2.2	
	\$ 34.1	\$ 235.9

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 \$10.9 million, \$11.6 million and \$14.0 million for the years 2006, 2005 and 2004, respectively.

10. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

Fair Values of Financial Instruments

The consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on an historical cost 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. The Company estimates the fair value of its convertible debenture based on market prices. Carrying amounts of floating rate debt approximate their fair value. For other investments, various methods are used to estimate fair value, including discounted cash flows. The Company's other financial instruments generally approximate their fair values based on the short-term nature of these instruments. As of December 31, 2006 and 2005, the estimated fair value of Company's convertible debenture was \$153.9 million and \$149.2 million, respectively.

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,			
	2006		2005	
	Notional Amount	Fair Value Asset (Liability)	Notional Amount	Fair Value Asset (Liability)
	(in millions)			
Currency option contracts	\$ 233.2	\$ 0.3	\$ 140.1	\$ 2.8
Forward currency agreements	62.0	0.9	57.9	6.0

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, 2006 and 2005. 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, 2006 and 2005, the fair value of currency option contracts and forward currency agreements were recorded in prepaid expenses. These agreements have a maximum duration of one year. During the years ended December 31, 2006 and 2005, the Company reclassified from accumulated other comprehensive loss to cost of goods sold a net gain of \$9.7 million and a net loss of \$0.9 million, respectively. During the years ended December 31, 2006 and 2005, the Company reclassified from accumulated other comprehensive loss to interest expense a net loss of zero and \$1.8 million, respectively. The Company expects that during 2007 it will reclassify to earnings a \$1.5 million gain currently recorded in accumulated other comprehensive loss. For the years ended December 31, 2006, 2005 and 2004, the Company expensed \$3.0 million, \$3.4 million and \$1.4 million, respectively, related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness. The Company recorded to other expense (income) net losses on its fair value hedges of \$0.1 million, zero and \$0.5 million for the years ended December 31, 2006, 2005 and 2004, respectively.

11. EMPLOYEE BENEFIT PLANS

Defined Benefit Plans

Edwards Lifesciences maintains defined benefit pension plans in Japan and in certain European countries. The Company suspended its defined benefit pension plan in Puerto Rico (the "Plan") such that effective December 31, 2003, employees ceased earning additional defined benefits for future

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

services. To mitigate the Puerto Rico employees' reduced benefits from the Plan's suspension, beginning January 1, 2004, the Company increased its contributions to the Puerto Rico 1165(e) defined contribution plan. In 2006, the Company notified its employees of its intent to terminate the Plan and expects to distribute benefits in early 2008.

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,	
	2006	2005
Change in projected benefit obligation:		
Beginning of year	\$ 53.8	\$ 55.9
Service cost	2.5	2.8
Interest cost	2.2	2.2
Participant contributions	0.3	0.2
Actuarial loss	0.3	1.0
Curtailement gain		(0.5)
Special termination benefit cost	0.2	0.7
Settlement gain	(1.5)	(2.9)
Benefits paid	(1.4)	(1.5)
Currency exchange rate changes and other	1.6	(4.1)
	<u> </u>	<u> </u>
End of year	\$ 58.0	\$ 53.8
	<u> </u>	<u> </u>
Change in fair value of plan assets:		
Beginning of year	\$ 35.3	\$ 34.6
Actual return on plan assets	3.9	3.8
Employer contributions	2.4	2.9
Participant contributions	0.3	0.5
Settlement gain	(1.5)	(2.9)
Benefits paid	(1.4)	(1.5)
Currency exchange rate changes and other	1.2	(2.1)
	<u> </u>	<u> </u>
End of year	\$ 40.2	\$ 35.3
	<u> </u>	<u> </u>

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

	December 31,	
	2006	2005
Funded status:		
Projected benefit obligation	\$ (58.0)	\$ (53.8)
Plan assets at fair value	40.2	35.3
Funded status, under funded	\$ (17.8)	\$ (18.5)
Net amounts recognized on the consolidated balance sheet:		
Other long-term liabilities	\$ 17.8	\$ 13.2
Accumulated other comprehensive loss, net of tax:		
Net actuarial loss	\$ (7.8)	\$ (3.8)
Net prior service benefit	0.7	
Net transition asset	(0.3)	
Deferred income tax expense	1.6	0.2
Total	\$ (5.8)	\$ (3.6)

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was \$52.7 million and \$47.4 million as of the December 31, 2006 and 2005, respectively. The projected benefit obligation ("PBO") and ABO was in excess of plan assets for all pension plans as of the December 31, 2006. The PBO was in excess of plan assets for all pension plans as of December 31, 2005. For pension plans with an ABO in excess of plan assets as of December 31, 2005, the ABO was \$39.8 million and the fair value of plan assets was \$27.1 million. For the year ended December 31, 2005, the Company included \$0.3 million in other comprehensive income arising from a decrease in the additional minimum pension liability.

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

	Years Ended December 31,		
	2006	2005	2004
Service cost, net	\$ 2.5	\$ 2.6	\$ 2.4
Interest cost	2.2	2.2	1.9
Expected return on plan assets	(2.2)	(2.0)	(1.9)
Settlement, curtailment and special termination benefits, net	0.3	1.1	
Amortization of prior service cost and other	0.3	0.4	0.3
Net periodic pension benefits cost	\$ 3.1	\$ 4.3	\$ 2.7

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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 weighted average assumptions used to determine the benefit obligations are as follows:

	December 31,	
	2006	2005
Discount Rate	4.2%	4.1%
Rate of compensation increase	2.8%	2.8%
Social securities increase	1.8%	1.6%
Pension increases	1.5%	1.5%

The weighted average assumptions used to determine the net periodic benefit cost are as follows:

	Years Ended December 31,		
	2006	2005	2004
Discount Rate	4.1%	4.1%	4.2%
Expected return on plan assets	6.2%	5.9%	6.2%
Rate of compensation increase	2.8%	3.0%	3.1%
Social securities increase	1.6%	1.7%	1.8%
Pension increases	1.5%	1.5%	1.5%

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 actual weighted-average asset allocations at December 31, 2006 and 2005, by asset category, are as follows:

	December 31,	
	2006	2005
Equity securities	50.3%	48.3%
Debt securities	20.7%	23.3%
Other	29.0%	28.4%
 Total	 100.0%	 100.0%

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

The Company's 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 plans' liability structure and return goals. In certain plans, asset allocations may be governed by local requirements. Target weighted-average asset allocations at December 31, 2006, by asset category, are as follows:

Equity securities	48.0%
Debt securities	22.3%
Other	29.7%
Total	100.0%

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2006, are expected to be paid (in millions):

2007	\$ 1.2
2008	1.3
2009	1.4
2010	1.6
2011	1.8
2012-2016	12.2

As of December 31, 2006, expected employer contributions for fiscal 2007 are \$2.4 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 eligible 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 4% of participant's annual eligible compensation contributed to the plan on a 50% basis. The Company also provides a 2% profit sharing match on eligible earnings for each employee. Matching contributions relating to Edwards Lifesciences employees were \$6.1 million, \$5.4 million and \$5.2 million in 2006, 2005 and 2004, respectively.

The Company has a nonqualified deferred compensation plan for a select group of employees that provides the opportunity to defer a specified percentage of their eligible cash compensation. Participants may elect to defer up to 25% of total eligible compensation. Only employees who were eligible to participate in the Plan during the 2000 Plan Year may defer up to 100% of their bonus. The Company's obligations under this plan are unfunded. The amount accrued under this plan was \$2.9 million and \$2.0 million at December 31, 2006 and 2005, respectively.

In 2001, the Company adopted a nonqualified option plan ("Executive Option Plan") for the benefit of the executive officers and other key employees. The Executive Option Plan permitted participants to receive options to purchase shares of mutual funds or common stock of the Company in lieu of all or a portion of their compensation (base salary and bonus) earned prior to January 1, 2005. The Company discontinued option grants under the Executive Option Plan and has adopted the Executive Deferred Compensation Plan to provide officers and other key employees the opportunity to defer compensation earned after December 31, 2004 to future dates specified by the participant with a return based on investment alternatives selected by the participant. The amounts accrued under these plans were \$11.1 million and \$8.3 million at December 31, 2006 and 2005, respectively, related to the Executive Deferred Compensation Plan and \$5.8 million at December 31, 2004 related to the Executive Option Plan.

12. COMMON STOCK

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 each of the years ended December 31, 2005 and 2004, 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 (for a total of 4.0 million shares). On May 11, 2006, the Board of Directors approved another stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 4.0 million shares of the Company's common stock.

During 2006, 2005 and 2004, the Company repurchased 3.3 million, 1.3 million and 1.7 million shares, respectively, at an aggregate cost of \$145.9 million, \$53.5 million and \$59.1 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.

Employee and Director Stock Plans

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 restricted stock units for eligible employees and contractors of the Company. Under the Program, these grants are 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 of between three to four years and expire seven years after the date of grant. Restricted stock units of the Company's common stock granted under the Program generally vest over predetermined periods ranging from three to five years after the date of grant. On May 11, 2006, an amendment and restatement of the Program was approved by the Company's stockholders. Under the amended Program, the number of shares of common stock available for issuance under the Program was increased by 0.9 million shares from 16.9 million shares to 17.8 million shares. No more than 1.0 million shares reserved for issuance may be granted in the form of restricted stock or restricted stock units.

The Company also maintains the Nonemployee Directors Stock Incentive Compensation Program (the "Nonemployee Directors Program"). Under the Nonemployee Directors Program, each nonemployee director may receive annually up to 10,000 stock options or 4,000 restricted stock units of the Company's common stock, or a combination thereof, provided that in no event may the total value of the combined annual award exceed \$0.2 million. Additionally, each nonemployee director may elect to receive all or a portion of the annual cash retainer to which the director is otherwise entitled through the issuance of stock options or restricted stock units. Each option and restricted stock unit award generally vests in three equal annual installments. Upon a director's initial election to the Board, the director receives an initial grant of 5,000 shares of restricted stock units. These grants vest 50% after one year and the balance vests after two years from the date of grant. The Nonemployee Directors Program was amended on February 17, 2005, to limit to no more than 60,000 the number of shares that will be used for initial awards with two-year vesting, after which the Company will provide initial awards with a minimum three-year vesting. Under the Nonemployee Directors Program, an aggregate of 600,000 shares of the Company's common stock has been authorized for issuance.

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.

The fair value of each option award and employee stock purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. The risk-free interest rate is estimated using the U.S. Treasury yield curve, and is based on the expected term of the option. Prior to adoption of SFAS 123R, the Company based the expected volatility on its historical stock prices. As a result of the adoption of SFAS 123R, the Company changed its methodology of estimating expected volatility to be based on the historical-implied volatility of publicly traded options of its common stock with a term of one year or greater. The expected term of awards granted is estimated from the vesting period of the award, as well as historical exercise behavior, and represents the period of time that awards granted are expected to be outstanding. The Company uses historical data to estimate forfeitures and has estimated an annual forfeiture rate of 4%.

The Black-Scholes option pricing model was used with the following weighted-average assumptions for options granted during the following periods:

	<u>2006</u>	<u>2005</u>	<u>2004</u>
Average risk-free interest rate	5.0%	3.8%	3.5%
Expected dividend yield	None	None	None
Expected volatility	23%	30%	41%
Expected life (years)	4.8	4.0	3.9
Fair value	\$ 13.10	\$ 13.36	\$ 11.96

The Black-Scholes option pricing model was used with the following weighted-average assumptions for employee stock purchase subscriptions granted during the following periods:

	<u>2006</u>	<u>2005</u>	<u>2004</u>
Average risk-free interest rate	4.7%	4.1%	2.2%
Expected dividend yield	None	None	None
Expected volatility	31%	21%	40%
Expected life (years)	0.8	1.0	1.0
Fair value	\$ 10.39	\$ 10.94	\$ 10.66

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

Stock option activity during the year ended December 31, 2006 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2005	10.3	\$ 27.62		
Options granted	1.4	43.96		
Options exercised	(1.2)	20.76		
Options forfeited	(0.3)	38.40		
Outstanding as of December 31, 2006	10.2	34.21	4.4 years	\$ 168.8
Exercisable as of December 31, 2006	6.8	25.19	4.0 years	148.0

The following table summarizes nonvested restricted stock units and activity during the year ended December 31, 2006 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
Nonvested as of December 31, 2005	0.3	\$ 44.21
Granted	0.4	43.97
Vested		
Forfeited		
Nonvested as of December 31, 2006	0.7	44.12

The intrinsic value of stock options exercised and vested restricted stock units during the years ended December 31, 2006, 2005 and 2004 were \$30.3 million, \$25.5 million and \$31.7 million, respectively. The intrinsic value of stock options is calculated as the amount by which the market price of the Company's common stock exceeds the exercise price of the option. During the years ended December 31, 2006, 2005 and 2004, the Company received cash from exercises of stock options of \$25.7 million, \$44.8 million and \$24.2 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$8.4 million, \$7.9 million and \$8.0 million, respectively. The total grant date fair value of stock options vested during the year ended December 31, 2006, 2005 and 2004 were \$14.7 million, \$19.6 million and \$22.0 million, respectively.

As of December 31, 2006, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units and employee stock purchase subscriptions amounted to

\$45.8 million, which will be amortized over the weighted-average remaining requisite service period of 25 months.

13. ACCUMULATED OTHER COMPREHENSIVE LOSS

Presented below is a summary of activity for each component of accumulated other comprehensive loss for the years ended December 31, 2006, 2005 and 2004. Foreign currency translation adjustments are generally not adjusted for income taxes as they relate to indefinite investments in non-United States subsidiaries.

	Foreign Currency Translation Adjustments	Unrealized Gain/(Loss) on Cash Flow Hedges	Unrealized Gain/ (Loss) on Investments in Unconsolidated Affiliates	Minimum Pension Liability	Unrealized Pension Costs	Total Accumulated Other Comprehensive Income (Loss)
December 31, 2003	\$ (19.5)	\$ (11.8)	\$ (0.5)	\$ (0.4)		\$ (32.2)
Pre-tax period change	16.6	4.1	(6.9)	(3.5)		10.3
Deferred income tax benefit (expense)		(1.7)	2.8			1.1
December 31, 2004	(2.9)	(9.4)	(4.6)	(3.9)		(20.8)
Pre-tax period change	(21.0)	25.6	7.1	0.5		12.2
Deferred income tax benefit (expense)		(10.3)	(3.1)	(0.2)		(13.6)
December 31, 2005	(23.9)	5.9	(0.6)	(3.6)		(22.2)
Pre-tax period change	11.8	(8.7)	2.9	1.3		7.3
Impact of SFAS 158				2.5	(7.4)	(4.9)
Deferred income tax benefit (expense)		3.5	(0.9)	(0.2)	1.6	4.0
December 31, 2006	\$ (12.1)	\$ 0.7	\$ 1.4	\$	\$ (5.8)	\$ (15.8)

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 was non-interest bearing and was collateralized by the Chief Executive Officer's primary residence. In December 2006, the loan was fully repaid by the Chief Executive Officer.

15. OTHER EXPENSE (INCOME), NET

	Years Ended December 31,		
	2006	2005	2004
Foreign exchange gain	\$ (0.3)	\$ (2.1)	\$ (0.2)
Accounts receivable securitization costs	2.6	1.7	1.0
Other	0.4	0.2	(1.2)
	<u>\$ 2.7</u>	<u>\$ (0.2)</u>	<u>\$ (0.4)</u>

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,		
	2006	2005	2004
United States	\$ 49.0	\$ (4.2)	\$ (74.2)
International, including Puerto Rico	123.3	120.9	104.3
	<u>\$ 172.3</u>	<u>\$ 116.7</u>	<u>\$ 30.1</u>

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

	Years Ended December 31,		
	2006	2005	2004
Current			
United States:			
Federal	\$ 26.7	\$ 28.3	\$ 11.3
State and local	3.4	3.8	1.3
International, including Puerto Rico	7.0	19.1	12.3
	<u>37.1</u>	<u>51.2</u>	<u>24.9</u>
Current income tax expense			
Deferred			
United States:			
Federal	(2.0)	(14.2)	(1.4)
State and local	(0.2)	(5.7)	(1.8)
International, including Puerto Rico	6.9	6.1	6.7
	<u>4.7</u>	<u>(13.8)</u>	<u>3.5</u>
Deferred income tax expense (benefit)			
Total income tax provision	<u>\$ 41.8</u>	<u>\$ 37.4</u>	<u>\$ 28.4</u>

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

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

	December 31,	
	2006	2005
Deferred tax assets		
Net operating loss carry forwards	\$ 32.8	\$ 27.4
Investments in unconsolidated affiliates	8.3	21.9
Compensation and benefits	19.9	18.6
Other intangible assets	4.6	18.9
Accrued liabilities	20.4	12.6
Tax credit carry forwards	6.9	9.9
Inventories	2.8	3.6
Allowance for doubtful accounts	1.7	2.8
Other	5.9	4.8
Total deferred tax assets	103.3	120.5
Deferred tax liabilities		
Other intangible assets	(36.5)	(41.2)
Property, plant and equipment	(8.4)	(10.2)
Other	(2.2)	(4.8)
Total deferred tax liabilities	(47.1)	(56.2)
Valuation allowance	(19.9)	(25.2)
Net deferred tax assets	\$ 36.3	\$ 39.1

At December 31, 2006, the Company had deferred tax assets of \$103.3 million, partially offset by deferred tax liabilities of \$47.1 million. The valuation allowance of \$19.9 million as of December 31, 2006 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 carry forwards of certain United States and non-United States subsidiaries.

Deferred income taxes have not been provided on the undistributed earnings of the Company's foreign subsidiaries of approximately \$196.6 million as of December 31, 2006, since these amounts are intended to be permanently reinvested in foreign operations. It is not practicable to calculate the deferred taxes associated with these earnings; however, foreign tax credits would likely be available to reduce federal income taxes in the event of distribution.

As of December 31, 2006, the Company has \$7.5 million and \$32.8 million of United States federal and state net operating loss carry forwards, respectively, and \$79.9 million of non-United States net operating losses, some of which will begin to expire in 2007 if not utilized. Net operating loss carry

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

forwards, and the related carry forward periods, at December 31, 2006, are summarized as follows (in millions):

	<u>Net Operating Loss</u>	<u>Tax Benefit Amount</u>	<u>Valuation Allowance</u>	<u>Expected Tax Benefit</u>	<u>Carryforward Period Ends</u>
United States federal and state net operating loss	\$ 40.3	\$ 4.4	\$ (4.4)	\$	2010-2023
Non-United States net operating losses	38.3	15.4	(0.4)	15.0	2007-2015
Non-United States net operating losses	41.6	13.0	(10.7)	2.3	Indefinite
Total	\$ 120.2	\$ 32.8	\$ (15.5)	\$ 17.3	

A valuation allowance of approximately \$15.5 million has been provided for certain of the above carry forwards. This valuation allowance reduces the deferred tax asset related to net operating loss carry forwards of \$32.8 million to an amount that is more likely than not to be realized.

As part of the PVT acquisition in 2004, as discussed in Note 3, the Company acquired \$7.5 million of federal and state net operating losses that the Company established a valuation allowance against. Upon future realization of this net operating loss, \$2.9 million of the deferred tax asset will be credited directly to goodwill.

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

	<u>Years Ended December 31,</u>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>
Income tax expense at U.S. federal statutory rate	\$ 60.3	\$ 40.9	\$ 10.5
Foreign income tax at different rates	(19.8)	(16.4)	(21.5)
Deemed dividends, net of foreign tax credit	4.2	3.6	2.9
Tax credits, federal and state	(2.0)	(2.0)	(1.7)
State and local taxes, net of federal tax benefit	4.7	0.2	0.8
Valuation allowance for loss on investments	(7.0)	(6.2)	6.6
Nondeductible in-process research and development expenses and milestone payment	3.5		27.8
Taxes on repatriation under the American Jobs Creation Act of 2004		15.0	
Nondeductible stock based compensation	2.2		
Reserve for uncertain tax positions for prior years	(5.6)	(0.2)	1.5
Other	1.3	2.5	1.5
Income tax provision	\$ 41.8	\$ 37.4	\$ 28.4

The American Jobs Creation Act of 2004 (the "Act") was signed into law in October 2004, and allowed companies to repatriate cash during 2004 and 2005 into the United States at a special, temporary effective tax rate of 5.25 percent. On September 13, 2005, the Board of Directors approved

a plan for reinvestment and repatriation of specific foreign earnings under the Act. The Company repatriated \$263.1 million in cash in 2005. The Company accrued \$15.0 million for federal, state and foreign taxes attributable to the distribution from its foreign affiliates in 2005.

Beginning in 2002 through 2006, the Company recorded other-than-temporary impairments and unrealized losses related to certain of its investments in unconsolidated affiliates. The tax benefits that result from reductions in the value of these investments are subject to the Company realizing sufficient capital gains with which to offset these capital losses. Due to the uncertainty of the Company realizing future capital gains, the Company has consistently recorded valuation allowances against these deferred tax assets as they have accumulated. As December 31, 2006, deferred tax assets and corresponding valuation allowances of approximately \$4.4 million had accumulated related to investments.

During 2005, valuation allowances were made in each quarter against investment impairments recognized. The valuation allowance amounts were \$0.2 million in the first quarter, \$2.0 million in the second quarter, \$3.8 million in the third quarter and \$1.1 million in the fourth quarter, for a total for the year of \$7.1 million. Also, during the fourth quarter of 2005, the Company realized a capital gain related to the sale of its vascular graft business and anticipated a capital gain in January 2006 related to the settlement of certain patent litigation against Medtronic (see Note 17). As a result, valuation allowances were reversed, reducing income tax provision during the fourth quarter of 2005 by \$13.3 million.

Similarly, in 2006, the Company recognized capital gains in the second quarter from the sale of a non-strategic business and in the fourth quarter, a gain from the sale of the angiogenesis business and a capital loss on the sale of shares in World Heart Corporation. The capital gains have allowed or will allow the Company to utilize the same amounts of the accumulated losses related to impaired investments. As a result, valuation allowances of \$3.7 million and \$3.3 million were reversed in the second and fourth quarters of 2006, respectively.

Of the \$81.0 million charge for acquired in-process research and development related to the PVT acquisition in 2004, as discussed in Note 3, \$1.7 million is related to tax deductible payments to exercise certain licensing options pursuant to the stock purchase agreement. The remaining \$79.3 million charge is non-deductible for income tax purposes. During the fourth quarter of 2006, the Company recorded a \$10.0 million charge for the contractual transcatheter clinical milestone obligation with PVT. The \$10.0 million payment is not deductible for income tax purposes.

On January 1, 2006, the Company reported results in accordance with SFAS 123R and recognized expense in 2006 related to stock-based compensation. Some of those costs are not deductible in the US or in foreign countries.

During the fourth quarter ended December 31, 2006, the Company settled several of its ongoing tax examinations in various jurisdictions. The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at anytime. While the Company has accrued for amounts it believes is the expected outcome, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the financial statements.

Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The tax reserves are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related interest, if any, have been provided for any adjustments that may result from these examinations of uncertain tax positions.

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. This settlement resulted in a net gain of \$0.2 million for the amount of the license payment received from St. Jude net of capitalized patent enforcement costs.

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"), 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. As announced on January 23, 2006, Edwards Lifesciences settled this litigation with Medtronic. In exchange for a cash payment of \$37.5 million from Medtronic to Edwards Lifesciences and Australian-based Endogad Research Pty. Ltd. (the company formed by the clinician-inventors of the patents), Medtronic was granted nonexclusive licenses to the patents involved in the litigation, as well as to certain other related patents. The Company recorded a gain of \$20.2 million in January 2006, which consists of the \$37.5 million cash offset by the settlement paid to Endogad, capitalized patent enforcement costs of \$2.9 million and current legal fees. Edwards Lifesciences remains in litigation with Cook, Inc. and W. L. Gore & Associates, each of which has answered and asserted various affirmative defenses and counterclaims.

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 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 such legal matter or other claims, Edwards Lifesciences may incur charges in excess of 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 relating to any currently pending lawsuit 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 conducts operations worldwide and is managed in four geographical regions: North America, Europe, Japan and Intercontinental. The North America region includes the United States, Canada and Puerto Rico. The Intercontinental region covers primarily Latin America, Asia and the rest of the world (excluding North America, Europe and Japan). All regions sell products that are used to treat advanced cardiovascular disease. In December 2005, based on continuing changes in how certain financial information is used to assess performance and allocated resources, Edwards Lifesciences determined that its four geographic regions are reportable segments as defined by SFAS No. 131, "*Disclosures about Segments of an Enterprise and Related Information*."

The Company evaluates the performance of its segments based on net sales and income before provision for income taxes ("pre-tax income"). The accounting policies of the segments are substantially the same as those described in Note 2, Summary of Significant Accounting Policies. Net sales and pre-tax income of reportable segments are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments, the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include most of the Company's amortization expense, net interest expense, global marketing expenses, corporate research and development expenses, United States manufacturing variances, corporate headquarters costs, special charges (such as in-process research and development and special (gains) charges, net) foreign currency and interest rate hedging activities and certain litigation costs. Although most of the Company's depreciation expense is included in segment pre-tax income, due to the Company's methodology for cost build-up it is impractical to determine the amount of depreciation expense included in each segment. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

The table below presents information about Edwards Lifesciences' reportable segments (in millions):

	Years Ended December 31,		
	2006	2005	2004
Net Sales			
North America	\$ 498.6	\$ 472.9	\$ 430.7
Europe	219.0	199.2	184.2
Japan	178.6	185.4	194.2
Intercontinental	99.0	93.0	75.5
	<u> </u>	<u> </u>	<u> </u>
Total segment net sales	\$ 995.2	\$ 950.5	\$ 884.6
	<u> </u>	<u> </u>	<u> </u>
Pre-Tax Income			
North America	\$ 264.2	\$ 252.4	\$ 214.3
Europe	53.7	45.3	38.7
Japan	67.5	65.4	66.9
Intercontinental	14.2	12.7	9.7
	<u> </u>	<u> </u>	<u> </u>
Total pre-tax income	\$ 399.6	\$ 375.8	\$ 329.6
	<u> </u>	<u> </u>	<u> </u>

The table below presents reconciliations of segment net sales to consolidated net sales and segment pre-tax income to consolidated pre-tax income (in millions):

	Years Ended December 31,		
	2006	2005	2004
Net Sales Reconciliation			
Segment net sales	\$ 995.2	\$ 950.5	\$ 884.6
Foreign currency	41.8	47.4	46.9
	<u> </u>	<u> </u>	<u> </u>
Consolidated net sales	\$ 1,037.0	\$ 997.9	\$ 931.5
	<u> </u>	<u> </u>	<u> </u>
Pre-tax Income Reconciliation			
Segment pre-tax income	\$ 399.6	\$ 375.8	\$ 329.6
Unallocated amounts:			
Corporate items	(249.4)	(220.8)	(180.7)
Special gains (charges), net	4.5	(49.4)	(110.5)
Interest expense, net	(2.7)	(9.7)	(14.2)
Foreign currency	20.3	20.8	5.9
	<u> </u>	<u> </u>	<u> </u>
Consolidated pre-tax income	\$ 172.3	\$ 116.7	\$ 30.1
	<u> </u>	<u> </u>	<u> </u>

Enterprise-Wide Information

Enterprise-wide information is based on foreign exchange rates used in the Company's consolidated financial statements.

	As of or for the years ended December 31,		
	2006	2005	2004
(in millions)			
Net Sales by Geographic Area			
United States	\$ 477.9	\$ 455.9	\$ 416.5
Other countries	559.1	542.0	515.0
	<u>\$ 1,037.0</u>	<u>\$ 997.9</u>	<u>\$ 931.5</u>
Net Sales by Major Product Area			
Heart Valve Therapy	\$ 490.8	\$ 469.3	\$ 419.2
Critical Care	349.8	324.1	302.3
Cardiac Surgery Systems	91.0	104.6	107.3
Vascular	75.9	66.1	60.1
Other Distributed Products	29.5	33.8	42.6
	<u>\$ 1,037.0</u>	<u>\$ 997.9</u>	<u>\$ 931.5</u>
Long-Lived Tangible Assets by Geographic Area			
United States	\$ 186.0	\$ 158.2	\$ 172.8
Other countries	60.9	69.8	59.8
	<u>\$ 246.9</u>	<u>\$ 228.0</u>	<u>\$ 232.6</u>

19. 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)					
2006					
Net sales	\$ 256.7	\$ 267.3	\$ 247.4	\$ 265.6	\$ 1,037.0
Gross profit	163.6	171.6	160.0	168.2	663.4
Net income(a)	45.9	36.1	27.8	20.7	130.5
Earnings per common share(a):					
Basic	0.77	0.61	0.48	0.36	2.23
Diluted	0.73	0.58	0.45	0.34	2.10
Market price:					
High	\$ 47.32	\$ 46.11	\$ 47.50	\$ 48.47	\$ 48.47
Low	41.00	42.01	41.55	42.29	41.00
2005					
Net sales	\$ 249.1	\$ 258.2	\$ 240.9	\$ 249.7	\$ 997.9
Gross profit	152.9	160.3	150.0	160.1	623.3
Net income (loss)(b)	31.2	13.9	(4.4)	38.6	79.3
Earnings (loss) per common share(b):					
Basic	0.52	0.23	(0.07)	0.65	1.33
Diluted	0.50	0.22	(0.07)	0.61	1.27
Market price:					
High	\$ 44.28	\$ 46.76	\$ 46.25	\$ 44.32	\$ 46.76
Low	39.47	41.85	40.65	39.85	39.47

(a)

The first quarter of 2006 includes (1) a gain of \$20.2 million from a patent dispute settlement with Medtronic, Inc., (2) a \$5.7 million gain for the cash received as the final earn-out payment for the sale of the Japan perfusion product line to Terumo Corporation and (3) a \$2.1 million charge for realignment expenses related primarily to severance expenses associated with the planned closure of a manufacturing facility in Japan.

The second quarter of 2006 includes (1) a \$4.5 million gain from the sale of a non-strategic pharmaceutical product to Bioniche Teoranta, (2) a \$2.6 million impairment charge related to the revaluation of the company's international cardiopulmonary perfusion product line, (3) a \$1.2 million charge for litigation reserves, and (4) a \$3.7 million tax benefit related to the reversal of a valuation allowance related to a capital loss.

The third quarter of 2006 includes a \$2.0 million charge for the final contractual obligation to 3F Therapeutics related to the restructuring of development and supply agreements.

The fourth quarter of 2006 includes (1) a \$10.0 million charge for the contractual transcatheter clinical milestone obligation to PVT's former shareholders, (2) a \$7.3 million charge related primarily to severance expenses associated with a global reduction in workforce, (3) a \$8.8 million charge resulting from the discontinuance of the *Optiwave* Laser Ablation System, of which \$2.0 million was recorded in cost of goods sold, and (4) a \$6.1 million gain from the sale of the angiogenesis research and development project to Sangamo.

(b)

The first quarter of 2005 includes a \$2.0 million net gain, consisting of a gain on the sale of the Company's Japan perfusion product line of \$7.7 million, offset by a \$5.7 million charge related to the realignment of its operations, primarily related to severance costs due to headcount reductions.

The second quarter of 2005 includes a \$22.8 million charge related to the restructuring of development and supply agreements with 3F Therapeutics, Inc., and a \$4.8 million charge related to the other-than-temporary impairment of investments in certain unconsolidated affiliates.

The third quarter of 2005 includes (1) a \$15 million charge for the contribution to Edwards Lifesciences charitable fund, (2) an \$8.9 million charge related to the other-than-temporary impairment of the investment in Sangamo, (3) a gain of \$2.5 million related to the resolution of intellectual property litigation, and (4) a \$15.8 million tax expense related to the repatriation of cash.

The fourth quarter of 2005 includes (1) a \$13.1 million gain for the sale of its vascular graft business to Angiotech Pharmaceuticals Inc., (2) a \$5.4 million charge related to two royalty dispute settlements, (3) a \$3.9 million charge related primarily to severance expenses associated with a global reduction in workforce, (4) a \$2.6 million charge related to the other-than-temporary impairment of an investment in a certain unconsolidated affiliate, (5) a \$1.4 million charge resulting from the payment of an early termination fee to discontinue certain firm non-cancelable product purchase commitments related to a discontinued product line in Europe, (6) a \$1.0 million charge related to the settlement, curtailment and special termination benefits impacting the defined benefit pension plan as a direct result of exiting its Japan perfusion product line in the first quarter of 2005, and (7) an \$8.0 million tax benefit related to the reversal of a valuation allowance related to a capital loss.

20. VALUATION AND QUALIFYING ACCOUNTS

	Additions				Balance at end of period
	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions from reserves	
(in millions)					
Year ended December 31, 2006					
Allowance for doubtful accounts(a)	\$ 5.4	\$ 2.3		\$ (1.2)	\$ 6.5
Inventory reserves(b)	12.3	9.0		(7.9)	13.2
Litigation reserves(c)	2.7	11.5		(3.7)	10.5
Year ended December 31, 2005					
Allowance for doubtful accounts(a)	\$ 5.2	\$ 1.6	\$ (0.2)	\$ (1.2)	\$ 5.4
Inventory reserves(b)	15.5	7.1	(0.2)	(10.1)	12.3
Litigation reserves(c)	2.0	2.4		(1.7)	2.7
Year ended December 31, 2004					
Allowance for doubtful accounts(a)	\$ 6.5	\$ 5.0	\$ 0.3	\$ (6.6)	\$ 5.2
Inventory reserves(b)	8.5	10.5	0.1	(3.6)	15.5
Litigation reserves(c)	2.0	1.0		(1.0)	2.0

- (a) The deductions related to allowances for doubtful accounts and returns represent accounts receivable which are written off and product which is returned from customers.
- (b) 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). The deductions related to inventory reserves represent inventory that is disposed of or sold as part of a business transaction.
- (c) 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, performed an evaluation of 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) as of December 31, 2006.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective in providing reasonable assurance 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 the SEC's 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, 2006. Management's assessment of the effectiveness of its internal control over financial reporting as of December 31, 2006, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control 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 2006 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

This information required by this Item is set forth under the headings "Proposal I Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Executive Officers" in the definitive proxy materials to be filed in connection with its 2007 Annual Meeting of Stockholders (the "Proxy Statement") (which Proxy Statement will be filed with the Securities and Exchange Commission on or before April 20, 2007). 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, Edwards' *Global Business Practice Standards*, that applies to its principal executive officer, principal financial and accounting officer and controller. The *Global Business Practice Standards* are posted on the Company's Web site, the address of which is www.edwards.com. The Company intends to include on its Web site any amendments to, or waivers from, a provision of its *Global Business Practice Standards* that applies to the Company's principal executive officer, principal financial officer or controller, and that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

Under the Company's *Corporate Governance Guidelines*, all Board committees, including the Audit and Public Policy Committee and the Compensation and Governance Committee, are comprised solely

of Independent Directors as defined within the listing standards of the New York Stock Exchange ("NYSE"), and have written charters that outline the committee's purpose, goals, membership requirements and responsibilities. These charters are regularly reviewed and updated as necessary by the Company's Board of Directors. The charters and the *Corporate Governance Guidelines* are posted on the Company's Web site located at www.edwards.com. This information is also available in print to any shareholders who request it.

On May 26, 2006, the Company submitted to the NYSE a certification signed by the Chief Executive Officer that he was not aware of any violation by the Company of the NYSE corporate governance listing standards.

Item 11. Executive Compensation

Except for information referred to in Item 402(a)(8) of Regulation S-K, the information contained under the heading "Proposal I Election of Directors" under the subheading "Compensation of Directors" and under the heading "Executive Compensation and Other Information" in the Proxy Statement is incorporated herein by reference. The Report of the Compensation and Governance Committee and the performance graph required by Items 407(e)(5) of Regulation S-K are not incorporated herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

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, and Director Independence

The information contained under the heading "Related Party Transactions" and under the heading "Proposal I Election of Directors" under the subheading "Director Independence" 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 (incorporated by reference to Exhibit 3.2 in Edwards Lifesciences' report on Form 8-K filed on February 21, 2007 under the Securities Exchange Act of 1934)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

- 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 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)
- *10.2 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)
- *10.3 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)
- 10.4 Amended and Restated Five Year Credit Agreement dated as of September 29, 2006, 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 UFI, Ltd., Mizuho Corporate Bank, Limited, Suntrust Bank, and Wachovia Bank, N.A., as Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K, filed September 29, 2006, under the Securities Exchange Act of 1934)
- *10.5 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)
- *10.6 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)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

- *10.7 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)
- 10.8 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))
- 10.9 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))
- 10.10 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)
- 10.11 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)
- 10.12 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)
- 10.13 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)
- 10.14 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 (incorporated by reference to Exhibit 10.17 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

- 10.15 Forbearance 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 (incorporated by reference to Exhibit 10.18 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
- 10.16 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 (incorporated by reference to Exhibit 10.19 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
- 10.17 Seventh Amendment to Receivables Purchase Agreement, dated as of September 17, 2005, 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 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 8-K filed on September 30, 2005 under the Securities Exchange Act of 1934)
- 10.18 Eighth Amendment to Receivables Purchase Agreement, dated as of September 19, 2006, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Variable Funding Capital Company LLC (as assignee of Blue Ridge Asset Funding Corporation) and Wachovia Bank, National Association (incorporated by reference to Edwards Lifesciences' report on Form 8-K, filed September 20, 2006, under the Securities Exchange Act of 1934)
- *10.19 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)
- 10.20 Memorandum, dated December 3, 2005, 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 10.23 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2005, under the Securities Exchange Act of 1934)
- *10.21 Long-Term Stock Incentive Compensation Program (as amended and restated as of February 16, 2006) (incorporated by reference to Exhibit 10 in Edwards Lifesciences' report on Form 8-K, filed May 19, 2006, under the Securities Exchange Act of 1934)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

- 10.22 Nonemployee Directors Stock Incentive Program (amended and restated as of March 4, 2005) (incorporated by reference to Exhibit 10.22 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
 - 10.23 2001 Employee Stock Purchase Plan for United States Employees (as amended and restated on September 13, 2005) (incorporated by reference to Exhibit 10.27 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2005, under the Securities Exchange Act of 1934)
 - 10.24 2001 Employee Stock Purchase Plan for International Employees (as amended and restated on September 13, 2005) (incorporated by reference to Exhibit 10.28 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2005, under the Securities Exchange Act of 1934)
 - *10.25 Edwards Lifesciences Corporation Incentive Plan Guidelines (incorporated by reference to Exhibit 10.26 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
 - *10.26 Edwards Lifesciences Corporation Officer Perquisite Program Guidelines (incorporated by reference to Exhibit 10.27 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
 - 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

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K

/s/ ROBERT A. INGRAM

Director

February 27, 2007

Robert A. Ingram

/s/ VERNON R. LOUCKS JR.

Director

February 27, 2007

Vernon R. Loucks Jr.

/s/ BARBARA J. MCNEIL, M.D., PH.D.

Director

February 27, 2007

Barbara J. McNeil, M.D., Ph.D.

/s/ PHILIP M. NEAL

Director

February 27, 2007

Philip M. Neal

/s/ DAVID E.I. PYOTT

Director

February 27, 2007

David E.I. Pyott

QuickLinks

EDWARDS LIFESCIENCES CORPORATION Form 10-K Annual Report 2006 Table of Contents

PART I

Item 1. Business

Item 1A. Risk Factors

Item 1B. Unresolved Staff Comments

Item 2. Properties

Item 3. Legal Proceedings

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

PART II

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

Item 6. Selected Financial Data

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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2006

Report of Independent Registered Public Accounting Firm

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED BALANCE SHEETS (in millions, except par value)

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS (in millions, except per share information)

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED STATEMENTS OF CASH FLOWS (in millions)

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND

COMPREHENSIVE INCOME (LOSS) (in millions)

EDWARDS LIFESCIENCES CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Item 9A. Controls and Procedures

Item 9B. Other Information

PART III

PART IV

SIGNATURES