

EDWARDS LIFESCIENCES CORP  
Form 10-K  
February 29, 2008

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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, 2007

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

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**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

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.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting  
company)

Smaller reporting company

Indicate by check mark 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 29, 2007 (the last trading day of the registrant's most recently completed second quarter): \$2,753,407,401 based on a closing price of \$49.34 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 January 31, 2008, was 56,689,887.

### Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2008 Annual Meeting of Stockholders (to be filed on or before April 18, 2008) are incorporated by reference into Part III, as indicated herein.

**EDWARDS LIFESCIENCES CORPORATION**  
**Form 10-K Annual Report 2007**  
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**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," "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, critical care technologies, and peripheral vascular disease.

Cardiovascular disease is the number-one cause of death in the world, and is the top disease in terms of health care spending in nearly every country. Cardiovascular disease is progressive 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 by surgical interventions.

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, through 2007, 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, or re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring. Virtually all high-risk patients in the operating room or intensive care unit are candidates for having their cardiac function monitored by Edwards Lifesciences' Critical Care products. If a patient undergoes this type of open-heart surgery, 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, through early 2008, stents that are used to prop open the diseased blood vessels of patients suffering from atherosclerotic vascular disease. Lastly, through 2007, Edwards Lifesciences'

Other Distributed Products included 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," "Edwards" 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 website located at [www.edwards.com](http://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 website 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 website are not incorporated by reference into this report.

### **Edwards Lifesciences' Product and Technology Offerings**

The following discussion summarizes the 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 produces 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, the *PERIMOUNT Theon* aortic valve and the *PERIMOUNT Magna Ease* aortic valve. The durability of Edwards Lifesciences' tissue valves is extended through the use of its proprietary *ThermaFix* and *XenoLogiX* tissue treatment processes. 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 leveraging the knowledge and experience from its legacy of tissue heart valve engineering by 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, which is 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. In the area of transcatheter mitral valve repair, the Company is developing the *MONARC* mitral repair system. During 2007, Edwards discontinued its *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 equipment that is 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* line of hemodynamic monitoring products, and the *PreSep* venous oximetry catheter for measuring central venous oxygen saturation. Edwards' newest addition to its hemodynamic monitoring product line is the *PediaSat* oximetry catheter, the first real-time, continuous venous oxygen saturation monitoring device designed specifically for children. The Company also offers the *FloTrac* continuous cardiac output monitoring system, a minimally invasive cardiac monitoring technology.

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 offers technologies that complement the Company's heart valve therapy product line including products used in conducting cardiac surgery procedures. Edwards Lifesciences is a global leader 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 December 2007, the Company acquired certain assets of the *CardioVations* division of Ethicon, Inc. ("*CardioVations*"). The *CardioVations* product line includes the *PORT-ACCESS* products, such as the proprietary *EndoCPB* and *EndoDirect* systems for minimally invasive heart valve surgery, which comprise soft

tissue retractors, venous and arterial cannulae, vent and coronary sinus catheters, and reusable instruments for performing port-access cardiac valve procedures. The Company provides training to the cardiac surgeons who are performing these minimally invasive procedures using the *CardioVations* product line.

In March 2007, the Company sold its exclusive United States distribution rights and the inventory associated with its transmyocardial revascularization ("TMR") laser product line.

### **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 balloon-tipped, catheter-based embolectomy products, surgical clips and clamps, and through early 2008, the *LifeStent* balloon-expandable and self-expanding non-coronary stents. 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. Stents are used to prop open the occlusive segments of patients suffering from atherosclerotic vascular disease or malignant strictures in the biliary tree. Edwards sold the *LifeStent* product line in January 2008 and will provide transition services, including manufacturing, to the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

### **Other Distributed Products**

Other Distributed Products primarily included sales of intra-aortic balloon pumps and other products sold through the Company's operations in Japan. Edwards terminated its distribution agreement for these products at the end of December 2007.

### **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, new 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 clinical superiority and features that enhance patient benefit, product reliability, performance, 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 products and technologies that demonstrate value and improve clinical outcomes is becoming increasingly important for medical device manufacturers.

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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., the Sorin Group and CoreValve, Inc. In Critical Care, Edwards Lifesciences' principal competitors include Hospira, Inc., Becton, Dickinson and Co., and PULSION Medical Systems AG. 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.

### **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.

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 2007.

Sales personnel work closely with the primary decision makers who purchase Edwards Lifesciences' products, which primarily include physicians, but can also include material managers, nurses, biomedical staff, hospital administrators, purchasing managers, and ministries of health. 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 United States 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 2007, 45% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

**International.** In 2007, 55% 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, and its major international markets include Japan, Germany, France, United Kingdom, Italy, Brazil, Canada, Belgium, Spain, India, the Netherlands and Australia/New Zealand. A substantial portion of the sales and marketing approach in international geographies is direct sales, although it varies depending on each country's size and state of development. The international markets in which the Company chooses to market its products is also influenced by the existence of, or potential for, adequate product reimbursement.

### **Raw Materials and Manufacturing**

Edwards Lifesciences operates manufacturing facilities in various geographies around the world. The Company maintains heart valve manufacturing facilities in Irvine, California, Horw, Switzerland and



Singapore. Critical Care products are manufactured primarily in the Company's facilities located in Puerto Rico and The Dominican Republic. Edwards' Cardiac Surgery Systems and Vascular products are manufactured primarily in Salt Lake City, Utah and Puerto Rico, respectively. The Company has agreed to manufacture the recently divested *LifeStent* product line in Irvine, California until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

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.

Edwards Lifesciences follows rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy ("BSE"). 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. In the countries in which the Company sells its products, it 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 compliance with applicable regulatory requirements and monitors performance against these objectives at all levels of its organization. In order to measure performance, Edwards 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 \$122 million in research and development in 2007, \$114 million in 2006 and \$99 million in 2005 (11.2%, 11.0% and 9.9% 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.

In its Critical Care product line, the Company is also pursuing the development of minimally invasive hemodynamic monitoring equipment and other technologies that collect critical patient information less invasively than current technologies. In its Cardiac Surgery Systems product line, the Company plans to broaden its offering of minimally invasive surgical technologies and other products to complement its core Heart Valve Therapy product line.

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 innovations and licensing opportunities to develop and maintain its competitive position.

Edwards Lifesciences owns more than 1,000 issued United States patents, pending United States patent applications, issued foreign patents, and pending foreign patent applications. The Company also has licensed various United States and foreign patents and patent applications that relate to aspects of the technology incorporated in certain of Edwards Lifesciences' products, including its heart valves, and annuloplasty rings and systems. Edwards Lifesciences also owns or has rights in United States and foreign patents and patent applications in the field of transcatheter heart valve repair and replacement. In addition, Edwards Lifesciences owns or has rights in United States and foreign patents and patent applications that cover catheters, systems and methods for hemodynamic monitoring and vascular access 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 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.

Edwards Lifesciences owns certain United States registered trademarks used in its business. Many Company 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 manufacturers 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 related specifically to elements of the Company's quality systems, including complaint handling, documentation and quality systems training. In April 2007, the FDA formally notified Edwards Lifesciences that the Company's response to the FDA's February 2007 Warning Letter adequately addressed their concerns. The FDA inspected the Company's Irvine facility in January 2008 to follow up on the commitments Edwards made to the FDA following the 2006 inspection. The Company is promptly addressing the issues raised in this inspection.

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.

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 increases the pressure on product pricing.

## Employees

As of December 31, 2007, Edwards Lifesciences had approximately 5,600 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, and employs a very rigorous talent management system. 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 new technological changes, frequent new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, Edwards Lifesciences' products could 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 might not be accepted quickly or at all because of the need for regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third party reimbursement or other factors.

Moreover, significant technical innovations generally 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.

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*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. Product liability claims may be brought by individuals or by groups seeking to represent a class. Edwards Lifesciences may incur charges related to such matters in excess of any established reserves and such charges 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 FDA regarding the manufacture of the Company's products (including the need for approval of any change in supply arrangements), Edwards Lifesciences may be unable to quickly establish additional or replacement sources for certain components or materials if the need arises. 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. 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, and the loss of any existing supply contract could 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.

Regulatory agencies in the United States or other international geographies from time to time limit or ban the use of certain materials that may be used in the manufacture of the Company's products. Typically these actions include transition periods to allow companies to identify and implement alternative materials. If Edwards Lifesciences were unable to identify alternative materials and secure approval for their use, the Company's business could be harmed.

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Edwards Lifesciences' suppliers include international sources. As such, trade embargoes in foreign countries or in the United States could create delays or shortages that could harm the Company's business.

*The manufacturing 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 manufacturing 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. However, 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 otherwise fails to meet its internal quality standards or those of the FDA or other applicable regulatory body, Edwards Lifesciences' reputation could be damaged, the Company could become subject to a recall, product liability and other costs, product approvals could be delayed, and the Company's business could otherwise be adversely affected.

*Edwards Lifesciences may be required to recognize charges in connection with the write-down 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, 2007, Edwards Lifesciences had \$34.3 million of investments in equity instruments of other companies and had recorded unrealized gains of \$7.5 million on these investments on its consolidated balance sheet in "Accumulated Other Comprehensive Income (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, or may also seek to dispose of other 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 could 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 could 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.

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*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 could 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. In the past, Edwards Lifesciences has taken significant in-process research and development charges in connection with 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 the issuance of equity securities, the incurrence of debt, contingent liabilities or amortization of expenses related to other intangible assets, any of which could adversely impact Edwards Lifesciences' financial condition or results of operations.

*External economic and political factors could have a material adverse effect 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 can 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 55% in 2007. Edwards Lifesciences anticipates that sales from international operations will continue to represent a substantial portion of its total sales. In addition, many of Edwards Lifesciences' manufacturing facilities and suppliers are located outside of the



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United States. 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, embargoes 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' reported 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' reported revenues and results of operations. Edwards Lifesciences has a hedging program for certain currencies 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 could cause its stock price to decline.*

From time to time the stock market experiences extreme price and volume fluctuations. This volatility can have 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:

- 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.



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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 could fall. Other factors that could affect quarterly operating results include:

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

changes in Edwards Lifesciences' expected operating expense levels or income and losses;

changes in financial estimates and recommendations of securities analysts;

demand for and clinical acceptance of products;

changes in healthcare reimbursement policies or practices

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.

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*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' customers consider many factors when selecting a product, including product reliability, clinical outcomes, product availability, price and services provided by the manufacturer. 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. Market share can shift as a result of any of these factors. 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. As a result, the Company must devote continued efforts and financial resources to bring new products to market and to maintain the competitiveness of its existing products. See "*Business-Competition*" included herein.

*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' 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, as Edwards Lifesciences' patents expire, 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 such a breach. In addition, others could 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. 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 could 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 can make it easier for competitors to capture increased market position. The invalidation of key intellectual property rights or an unsuccessful outcome in lawsuits filed to protect its intellectual property could have a material adverse effect on the Company's 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 provide the Company's competitors 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 might have to exit a particular product offering.

*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 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 its 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, ISO or similar requirements, this could delay product production and lead to fines, difficulties in obtaining regulatory clearances, recalls or

other consequences, which in turn could have a material adverse effect on the Company's financial condition and results of operations or prospects.

Medical devices must receive FDA clearance or approval before they can be commercially marketed. In addition, 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 may not be granted for future products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products or product improvements could result in delayed realization of product revenues or in substantial additional costs, which could have a material adverse effect on Edwards Lifesciences' business or results of operations or prospects. 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 increased regulation, enforcement and inspections of the medical device industry, and Edwards Lifesciences may be subject to more regulation, enforcement and inspections 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 related specifically to elements of the Company's quality systems, including complaint handling, documentation and quality systems training. In April 2007, the FDA formally notified Edwards Lifesciences that the Company's response to the FDA's February 2007 Warning Letter adequately addressed their concerns. The FDA inspected the Company's Irvine facility in January 2008 to follow up on the commitments Edwards made to the FDA following the 2006 inspection. The Company is promptly addressing the issues raised in this inspection.

*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 considered 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 many countries, customers are reimbursed for Edwards Lifesciences' products under a government-operated insurance system. Under such a system, the government periodically reviews



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the reimbursement levels for products. If a government were to decide to reduce reimbursement levels for Edwards Lifesciences' products, the Company's product pricing may be adversely affected.

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, even though the one-time cost may be significant, 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)	Manufacturing, Administration, Distribution

#### Asia

Tokyo, Japan	(2)	Administration, Marketing, Distribution
Techview, Singapore	(2)	Manufacturing
Changi, Singapore	(2)	Manufacturing, Administration

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2009; one of the Puerto Rico leases expires in 2008 and is expected to be renewed through 2018, and the other expires in 2016; the Horw, Switzerland lease is

renewed annually with appropriate termination notice provisions; the Saint Prex, Switzerland lease is renewed annually with a six month notification requirement; the Tokyo, Japan lease expires in 2009; the Techview, Singapore lease expires in 2008; and the Changi, Singapore landlease 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. ("Cook") 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. Edwards Lifesciences remains in litigation with Cook and W.L. Gore & Associates, each of which has answered and asserted various affirmative defenses and counterclaims.

On May 9, 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. On May 11, 2007, and June 20, 2007, CoreValve filed lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. Edwards Lifesciences recently purchased the Andersen patent family and now has the exclusive right, as owner instead of licensee, to enforce the patents and to conduct the defense in the invalidity proceedings. On February 12, 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the Andersen patents.

On February 1, 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. The Company will vigorously defend the lawsuit.

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, 2007.

## PART II

**Item 5. Market for 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.

	2007		2006	
	High	Low	High	Low
<b>Calendar Quarter Ended:</b>				
March 31	\$ 52.51	\$ 46.06	\$ 47.32	\$ 41.00
June 30	52.95	48.15	46.11	42.01
September 30	50.79	45.55	47.50	41.55
December 31	52.86	45.84	48.47	42.29

*Number of Stockholders*

On January 31, 2008, there were 16,733 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 (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)(a)
October 31, 2007	199,800	\$ 49.79	199,800	\$ 263.8
November 30, 2007	210,200	49.89	210,200	253.2
December 31, 2007	65,000	49.06	65,000	250.0
Total	475,000	\$ 49.73	475,000	\$ 250.0

*(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 4.0 million shares of the Company's common stock. This program was completed in December 2007. On September 18, 2007, the Company announced that the Board of Directors

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approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions, up to an additional \$250 million 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,				
		2007	2006	2005	2004	2003
		(in millions, except per share data)				
<b>OPERATING RESULTS</b>	Net sales	\$ 1,091.1	\$ 1,037.0	\$ 997.9	\$ 931.5	\$ 860.5
	Gross profit	712.9	663.4	623.3	561.3	501.1
	Net income(a)	113.0	130.5	79.3	1.7	79.0
<b>BALANCE SHEET DATA</b>	Total assets	\$ 1,345.1	\$ 1,246.8	\$ 1,229.1	\$ 1,112.7	\$ 1,101.4
	Long-term debt and lease obligations	61.7	235.9	316.1	267.1	255.8
<b>COMMON STOCK INFORMATION</b>	Net income per common share(a):					
	Basic	\$ 1.97	\$ 2.23	\$ 1.33	\$ 0.03	\$ 1.34
	Diluted	1.87	2.10	1.27	0.03	1.29
	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 charges (gains), net, of \$23.3 million, \$(4.5) million and \$49.4 million during 2007, 2006 and 2005, respectively.

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

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, 2007. Also discussed is Edwards Lifesciences' financial position as of December 31, 2007. 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 conditions including 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 equipment used to measure a patient's cardiovascular 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, *EMBOL-X* technologies, transmyocardial revascularization ("TMR") products, and other disposable products used during cardiopulmonary bypass procedures (in March 2007 the Company sold the distribution rights to its TMR products). In December 2007, the Company acquired the *CardioVations* line of products used in minimally invasive heart valve surgery. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, artificial implantable grafts, and stents ("*LifeStent*" products) used in the treatment of peripheral vascular disease (the Company sold the *LifeStent* product line in January 2008). Lastly, **Other Distributed Products** consist primarily of intra-aortic balloon pumps sold through the Company's distribution network in Japan (the Company terminated the distribution agreement effective December 31, 2007).

The healthcare marketplace continues to be competitive with strong global and local competitors. The Company 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 the Company competes. 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. 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. 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	
	2007	2006	2005	2007	2006	2007	2006
United States	\$ 486.6	\$ 477.9	\$ 455.9	\$ 8.7	\$ 22.0	1.8%	4.8%
Europe	309.1	264.6	241.3	44.5	23.3	16.8%	9.7%
Japan	171.4	168.8	186.4	2.6	(17.6)	1.5%	(9.4)%
Intercontinental	124.0	125.7	114.3	(1.7)	11.4	(1.4)%	10.0%
International	604.5	559.1	542.0	45.4	17.1	8.1%	3.2%
Total net sales	\$ 1,091.1	\$ 1,037.0	\$ 997.9	\$ 54.1	\$ 39.1	5.2%	3.9%

The \$8.7 million increase in net sales in the United States in 2007 was due primarily to:

Critical Care products, which increased net sales by \$15.5 million, driven primarily by sales of the *FloTrac* minimally invasive monitoring system, advanced hemodynamic monitoring equipment, and pressure monitoring products;

Vascular products, which increased net sales by \$7.0 million, driven primarily by an increase in *LifeStent* product sales;

partially offset by:

decreased sales of TMR products of \$10.8 million (the Company sold its distribution rights in March 2007);

The \$45.4 million increase in international net sales in 2007 was due primarily to:

Critical Care products, which increased net sales by \$19.6 million, driven primarily by sales of the *FloTrac* minimally invasive monitoring system, pressure monitoring products, and hemofiltration products;

Heart Valve Therapy products, which increased net sales by \$17.7 million, driven primarily by increases in sales of the *Carpentier-Edwards PERIMOUNT Magna* valve, *Magna* with *ThermaFix* valve, and *Magna Ease* valve;

Vascular products, which increased net sales by \$5.1 million, driven primarily by an increase in *LifeStent* product sales;

Foreign currency exchange rate fluctuations, which increased net sales by \$30.2 million, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar;

partially offset by:

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a decrease of \$32.1 million related to (1) the discontinuation of the Brazil-based perfusion product line in December 2006, (2) the Company's exit from the mechanical valve market during 2007, and



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(3) a reduction of distributed sales in Japan of intra-aortic balloon pumps (the Company terminated the distribution agreement effective December 31, 2007).

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 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 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 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 Disclosures 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	
	2007	2006	2005	2007	2006	2007	2006
Heart Valve Therapy	\$ 515.0	\$ 490.8	\$ 469.3	\$ 24.2	\$ 21.5	4.9%	4.6%
Critical Care	397.8	349.8	324.1	48.0	25.7	13.7%	7.9%
Cardiac Surgery Systems	60.9	91.0	104.6	(30.1)	(13.6)	(33.1)%	(13.0)%
Vascular	90.0	75.9	66.1	14.1	9.8	18.6%	14.8%
Other Distributed Products	27.4	29.5	33.8	(2.1)	(4.3)	(7.1)%	(12.7)%
<b>Total net sales</b>	<b>\$ 1,091.1</b>	<b>\$ 1,037.0</b>	<b>\$ 997.9</b>	<b>\$ 54.1</b>	<b>\$ 39.1</b>	<b>5.2%</b>	<b>3.9%</b>

### *Heart Valve Therapy*

The \$24.2 million increase in net sales of Heart Valve Therapy products in 2007 was due primarily to:

pericardial tissue valves, which increased net sales by \$11.6 million, primarily as a result of the premium *Carpentier-Edwards PERIMOUNT Magna* aortic valve and *Magna* with *ThermaFix* valves;

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heart valve repair products, which increased net sales by \$3.6 million, driven primarily by the continuing adoption of the Company's disease-specific products including the *Edwards MC*<sup>3</sup>;

a favorable impact of foreign currency exchange rates of \$14.9 million, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar;

partially offset by:

a decrease in net sales of \$8.1 million due to the Company's exit from the mechanical valve market commencing in the first quarter of 2007 and the continuing decline of mitral valve sales.

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 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 MC*<sup>3</sup>, *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.

The Company expects that its *PERIMOUNT Magna* and *Magna with ThermaFix* valves will continue to be strong contributors to 2008 sales. 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 Company's *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. In May 2007, the Company launched its next generation aortic valve, the *Magna Ease*, in Europe and is expecting to introduce this product into the United States in 2009. The Company's new *PERIMOUNT Magna* mitral valve is gaining physician acceptance in Europe, and the Company looks forward to gaining FDA approval as rapidly as possible in the United States (the Company is currently addressing additional questions from the FDA on the pre-clinical bench testing and anticipates that it will obtain FDA approval by mid-2008). In Japan, the Company received regulatory approval for a new *PERIMOUNT* mitral valve and began sales during the second quarter of 2007. Additionally, the Company anticipates regulatory approval and reimbursement for its *Magna* aortic valve in Japan in the first quarter of 2008. The Company plans to launch the *Carpentier-Edwards Physio II* ring in the third quarter of 2008, which is the next generation repair product for the degenerative segment of mitral repair. *Physio II* represents the first innovation in this area in over a decade.

### ***Critical Care***

The \$48.0 million increase in net sales of Critical Care products in 2007 was due primarily to:

*FloTrac* systems, which increased net sales by \$16.8 million;

core Critical Care products, which increased net sales by \$14.3 million, driven primarily by market share gains in pressure monitoring products, advanced hemodynamic monitoring equipment, and *PreSep*, the Company's central venous oximetry catheter for early detection of sepsis;



hemofiltration products, which increased net sales by \$4.0 million; and

foreign currency exchange rate fluctuations, which increased net sales by \$10.4 million, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar.

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

*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 Company expects worldwide *FloTrac* system sales to be a significant contributor to Critical Care sales growth in 2008. In the fourth quarter of 2007, the Company introduced enhanced *FloTrac* monitoring screens to the United States market, which allow clinicians to more easily trend patient status. In 2008, the Company plans to introduce additional product enhancements that will enable *FloTrac* to address a wider range of patients.

#### ***Cardiac Surgery Systems***

The \$30.1 million decrease in net sales of Cardiac Surgery Systems products in 2007 was due primarily to the impact of the sale of the Company's Brazil-based perfusion product line in December 2006, which resulted in a net sales decrease of \$21.5 million. In addition, the Company's exit from the TMR product line in March 2007 contributed to a decrease in net sales of \$10.8 million. These decreases were partially offset by foreign currency exchange rate fluctuations, which increased net sales by \$1.5 million.

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.

In December 2007, the Company completed its acquisition of certain assets of *CardioVations*. The *CardioVations* product line includes the *PORT-ACCESS* products, such as the proprietary *EndoCPB* and *EndoDirect* systems for minimally invasive heart valve surgery, which comprise soft tissue retractors, venous and arterial cannulae, vent and coronary sinus catheters, and reusable instruments for performing port-access cardiac valve procedures. *CardioVation's* clinical specialists provide training and tools to the cardiac surgeons who are performing these minimally invasive procedures.

#### ***Vascular***

The \$14.1 million increase in net sales of Vascular products in 2007 was due primarily to increased sales of *LifeStent* products. In addition, foreign currency exchange rate fluctuations had a favorable impact on net sales of \$3.0 million, due primarily to the strengthening of the Euro against the United States dollar.

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.

In January 2008, the Company completed the sale of the *LifeStent* product line. This divestiture is part of the Company's ongoing strategy to focus resources on its core heart valve and critical care businesses. The Company has agreed to provide transition services, including manufacturing, to the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer, and will continue to pursue pre-market approval for a superficial femoral artery indication.

#### ***Other Distributed Products***

The \$2.1 million decrease in net sales of Other Distributed Products in 2007 was due primarily to the divestiture in 2006 of a non-strategic pharmaceutical product and a reduction of distributed sales in Japan of intra-aortic balloon pumps. In order to focus on its proprietary products, the Company terminated its distribution of a third party's line of intra-aortic balloon pumps in Japan in December 2007.

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 which represented approximately \$2 million in annual sales.

#### ***Gross Profit***

	Years Ended December 31,			Change	
	2007	2006	2005	2007	2006
Gross profit as a percentage of net sales	65.3%	64.0%	62.5%	1.3 pts.	1.5 pts.

The 1.3 percentage point increase in gross profit as a percentage of net sales in 2007 was driven by:

a 1.5 percentage point increase in international gross profit as a percentage of net sales, which was due to a more profitable product mix, primarily related to higher sales of Heart Valve Therapy products and *FloTrac* systems, combined with the discontinuation of lower margin perfusion products; and

a 0.5 percentage point increase in United States gross profit as a percentage of net sales, which was due to a more profitable product mix, resulting primarily from higher sales of *FloTrac* systems, and the Company's exit from the lower margin TMR product line.

These increases were partially offset by increased investments in quality systems, certain manufacturing costs and the unfavorable impact of foreign currency resulting from the expiration of currency hedging contracts.

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.

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

(dollars in millions)

	Years Ended December 31,			Change	
	2007	2006	2005	2007	2006
SG&A expenses	\$ 418.0	\$ 376.0	\$ 348.7	\$ 42.0	\$ 27.3
SG&A expenses as a percentage of net sales	38.3%	36.3%	34.9%	2.0 pts.	1.4 pts.

The \$42.0 million increase in selling, general and administrative expenses and the 2.0 percentage point increase in selling, general and administrative expenses as a percentage of net sales in 2007 was due primarily to (1) investments for the *Edwards SAPIEN* transcatheter heart valve launch in Europe, (2) higher sales-related spending in the Heart Valve Therapy, Critical Care and Vascular product lines, primarily in the United States, and (3) the impact of foreign currency (primarily the strengthening of the Euro against the United States dollar) in the amount of \$12.4 million.

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 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.

***Research and Development Expenses***

(dollars in millions)

	Years Ended December 31,			Change	
	2007	2006	2005	2007	2006
Research and development expenses	\$ 122.3	\$ 114.2	\$ 99.0	\$ 8.1	\$ 15.2
Research and development expenses as a percentage of net sales	11.2%	11.0%	9.9%	0.2 pts.	1.1 pts.

The increase in research and development expenses in 2007 was due primarily to additional investments in the *Edwards SAPIEN* transcatheter heart valve and Critical Care development programs.

The increase in research and development expenses in 2006 was due primarily to additional investments in the Company's transcatheter valve programs. In addition, 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 (formerly Percutaneous Valve Technologies, Inc.'s ("PVT") percutaneous aortic valve program), the Company received conditional Investigational Device Exemption ("IDE") approval from the FDA in March 2007 to initiate its PARTNER trial, a pivotal clinical trial of the Company's *Edwards SAPIEN* transcatheter heart valve technology. The PARTNER trial, which has two study arms, began enrollment during the second quarter of 2007 and will evaluate the *Edwards SAPIEN* transcatheter heart valve valve in patients who are considered at high risk for conventional open-heart valve surgery. In the first study arm ("Cohort A"), patients will be randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. Cohort A will have

690 patients and is a non-inferiority analysis. In the second study arm ("Cohort B"), patients who are deemed non-operable will be randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. Cohort B will have 350 patients and is a superiority analysis. The Company anticipates it will complete enrollment in Cohort B by the end of 2008 and complete enrollment in Cohort A by the end of the third quarter 2009.

All of the *SAPIEN* valves in the PARTNER trial have been delivered transfemorally using the *RetroFlex* delivery system. During the third quarter of 2007, the Company received approval to begin selling the *SAPIEN* valve in Europe with the *RetroFlex I* and *RetroFlex II* transfemoral delivery systems. Initially, the Company plans to sell the *SAPIEN* valve in Europe with the *RetroFlex I*, and will phase in the *RetroFlex II* during the first half of 2008. The *RetroFlex II*, first used in Canada in the first quarter of 2007, further enhances the ease-of-use benefits of *RetroFlex I* by adding a customized atraumatic tip to enable clinicians to more easily navigate across the native stenotic aortic valve. The Company has received regulatory approval to add *RetroFlex II* to the United States PARTNER trial. Both the *Ascendra* transapical and transfemoral delivery systems are available for sale in Europe.

The Company completed enrollment in its United States feasibility study of the *Ascendra* transapical delivery system in April 2007. In January 2008, the Company obtained FDA approval to add *Ascendra* to the PARTNER trial. Having *Ascendra* in the trial will give cardiac surgeons an opportunity to partner in this technology and it will allow the Company to address more patients.

In the Company's transcatheter mitral valve repair program, the Company had two systems: the *Edwards MONARC* mitral repair system (formerly ev3, Inc.'s ("ev3") percutaneous mitral valve repair program), a coronary sinus technology, and the *Edwards MOBIUS* leaflet repair system. In connection with the *Edwards MONARC* system, the Company completed enrollment of its 60-patient EVOLUTION I feasibility study during the first quarter of 2007 and initiated the EVOLUTION II follow-on trial in Europe and Canada during the second quarter of 2007. The Company is continuing to collect and analyze additional clinical data, and has postponed enrollment of EVOLUTION II until 2008, when that analysis is expected to be completed.

For the *Edwards MOBIUS* system, the Company's feasibility work was completed in Europe and Canada in the first quarter of 2007. After completing the clinical feasibility studies, the Company determined that it would take considerable additional resources and time to affect durable and long-lasting repair results with the *Edwards MOBIUS* device. Therefore, the Company discontinued work on the *MOBIUS* technology and redirected resources into other advanced technology development programs. Although the termination of this program will reduce the Company's future revenue potential, the termination does not materially impact the Company's financial condition since future funding of the Company's operations was not dependent upon the success of this program.

#### ***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, the Company's expectations, and the financial impact from changes in the Company's expectations.

**2005**

In September 2005, the Company recorded a \$1.2 million pre-tax 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's 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 in 2009 of the mitral valve repair program utilizing the intellectual property acquired from ev3, and commencement in 2010 of net cash inflows. The remaining fair market value of the assets purchased consisted primarily of patents unrelated to ev3's core mitral valve repair technology, which are being amortized over their estimated economic life of 19 years.

On January 27, 2004, the Company acquired PVT, a development stage company, for \$125.0 million in cash, net of cash acquired, plus up to an additional \$30.0 million upon the achievement of key milestones through 2007 (see "*Special Charges (Gains), net*"). Included in PVT's technology was 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, PVT 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, PVT 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 Charges (Gains), net*

	Years Ended December 31		
	2007	2006	2005
	(in millions)		
Realignment expenses, net	\$ 13.9	\$ 9.4	\$ 3.9
Pension settlement and adjustment	11.2		
Settlements and litigation (gains) losses, net		(20.2)	2.9
Gain on sale of assets, net	(1.8)	(13.7)	(14.1)
PVT milestone		10.0	
Discontinued products		6.8	1.4
Restructure 3F agreements		2.0	22.8
Litigation reserve		1.2	
Investment impairments			16.3
Charitable fund contribution			15.0
<b>Total special charges (gains), net</b>	<b>\$ 23.3</b>	<b>\$ (4.5)</b>	<b>\$ 48.2</b>

*Realignment Expenses, net*

In December 2007, the Company recorded realignment expenses of \$13.9 million primarily related to (1) severance expenses associated with the sale of the Company's *LifeStent* product line and a global reduction in workforce, primarily in the United States, Europe and Japan (impacting approximately 180 employees), and (2) the termination of the Company's intra-aortic balloon pump distribution agreement in Japan. As of December 31, 2007, remaining payments of approximately \$13.0 million are expected to be paid in 2008.

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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, 2007, all payments related to the realignment were substantially complete.

In January 2006, the Company recorded realignment expenses of \$2.1 million primarily related to severance expenses associated with the planned closure of a manufacturing facility in Japan (impacting 92 employees). 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, 2007, all payments related to the realignment were substantially complete.

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, 2007, all payments related to the realignment were complete.

### *Pension Settlement and Adjustment*

In December 2007, the Puerto Rico pension plan was settled and benefits were distributed to the participants through a combination of lump-sum payments and the purchase of annuities. The Company recorded a charge of \$7.1 million in December 2007 related to the settlement.

In December 2007, the Company applied the provisions of SFAS 87, "*Employers' Accounting for Pensions*" and SFAS 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"), to a defined benefit pension plan in Switzerland, which had previously been accounted for as a defined contribution plan. As a result, the Company recorded a charge of \$4.1 million in December 2007. The Company concluded that the impact on the prior years and current year for the increase in the pension obligation was not material to the consolidated financial statements.

### *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 2007, the Company recorded a gain of \$1.8 million for the sale of real estate development rights in Irvine, California, that had no book value at the time of sale.

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.

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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.

During 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 June 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 (1) a \$5.7 million charge related to the realignment of its operations, primarily related to severance costs due to headcount reductions, and (2) 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.

### *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.

### *Discontinued Products*

During 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 December 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.

*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.

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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.

### *Charitable Fund Contribution*

In September 2005, the Company made a contribution of \$15.0 million to the Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular disease charitable causes. The contribution was an irrevocable contribution to a third party and was recorded as a charge at time of payment.

### *Interest Expense*

The \$1.4 million decrease in interest expense for 2007 resulted primarily from a lower average debt balance as compared to the prior year. 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.

### *Interest Income*

The \$0.1 million decrease in interest income for 2007 resulted from slightly lower average interest rates. The \$5.2 million increase in interest income for 2006 resulted from higher interest rates and a higher cash and cash equivalent balance.

*Other (Income) Expense, net*

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

	Years Ended December 31,		
	2007	2006	2005
Gain on sale of product line	\$ (2.3)	\$	\$
Foreign exchange gain, net	(2.0)	(0.3)	(2.1)
Gain on investments in unconsolidated affiliates	(1.3)		
Accounts receivable securitization costs	3.0	2.6	1.7
Investment valuation reserve	0.7		
Other		0.4	0.2
	<u>\$ (1.9)</u>	<u>\$ 2.7</u>	<u>\$ (0.2)</u>

In March 2007, the Company sold the United States distribution rights and inventory associated with the TMR laser product line to Novadaq Technologies, Inc. for up-front consideration of \$5.4 million, which consisted of \$2.4 million in cash and a \$3.0 million senior secured promissory note, which was collected in full during the third quarter of 2007. This resulted in a gain of \$0.3 million. In connection with the transaction, the Company was entitled to earn-out payments based on Novadaq's TMR sales during 2007. During 2007, the Company earned \$2.0 million, recorded in "*Other (Income) Expense, net.*"

Foreign exchange gains relate to the foreign currency fluctuation on the Company's global trade and intercompany receivable and payable balances. The increase in foreign exchange gains in 2007 was due primarily to the strengthening of various Asia currencies.

The gain on investments in unconsolidated affiliates in 2007 primarily represents the Company's net share of gains and losses in technology investments accounted for under the equity method.

The increases in securitization costs in 2007 and 2006 were due to increases in average interest rates and higher average securitized balances.

The investment valuation reserve of \$0.7 million represents the estimated impairment in the value of the Company's short-term investments. See the "*Liquidity and Capital Resources*" section below for further information.

*Provision for Income Taxes*

The effective income tax rates for 2007, 2006, and 2005 were impacted as follows (in millions):

	Years Ended December 31,		
	2007	2006	2005
Income tax expense at U.S. federal statutory rate	\$ 52.4	\$ 60.3	\$ 40.9
Foreign income tax at different rates	(21.4)	(19.8)	(16.4)
Deemed dividends, net of foreign tax credit	3.2	4.2	3.6
Tax credits, federal and state	(2.8)	(2.0)	(2.0)
State and local taxes, net of federal tax benefit	3.1	4.7	0.2
Valuation allowance for loss on investments	(0.6)	(7.0)	(6.2)
Nondeductible PVT milestone payment		3.5	
Taxes on repatriation under the American Jobs Creation Act of 2004			15.0
Nondeductible stock-based compensation	1.9	2.2	
Reserve for uncertain tax positions for prior years	1.2	(5.6)	(0.2)
Other	(0.2)	1.3	2.5
	<u>          </u>	<u>          </u>	<u>          </u>
Income tax provision	\$ 36.8	\$ 41.8	\$ 37.4
	<u>          </u>	<u>          </u>	<u>          </u>

*Valuation Allowance for Loss on Investments*

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 recorded valuation allowances against these deferred tax assets as they have accumulated. As of December 31, 2007, deferred tax assets and corresponding valuation allowances of approximately \$2.1 million had accumulated related to investments.

During 2007, the Company recognized in the fourth quarter capital gains on the sale of real estate development rights and a capital loss on the sale of investments. As a result, the Company has reversed valuation allowances of \$0.6 million due to adequate capital gains to offset capital losses.

During 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.

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 the Medtronic litigation (see "*Legal Proceedings*"). As a result, valuation allowances were reversed, reducing the income tax provision during the fourth quarter of 2005 by \$13.3 million.

*Nondeductible PVT Milestone Payment*

During the fourth quarter of 2006, the Company recorded a \$10.0 million charge for achieving a contractual transcatheter clinical milestone obligation with PVT. The \$10.0 million payment is not deductible for income tax purposes.

*Taxes on Repatriation Under the American Jobs Creation Act of 2004*

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%. 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.

*Nondeductible Stock-based Compensation*

On January 1, 2006, the Company adopted SFAS 123R and recognized expense in 2006 and 2007 related to stock-based compensation. Some of those costs are not deductible in the United States or in foreign countries.

*Reserve for Uncertain Tax Positions for Prior Years*

During the fourth quarter of 2006, the Company settled several of its ongoing tax examinations in various jurisdictions. As a result, the Company's tax provision benefited from \$5.6 million of favorable audit settlements for prior years. 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 consolidated 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. The Company 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.

During the third quarter of 2007, the Internal Revenue Service initiated an audit of the 2005 and 2006 tax years. This audit is expected to close in late 2008. No significant unexpected adjustments have been proposed to date.

**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, maturing debt obligations 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 the Company on favorable terms, or at all.

The Company has a Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), which matures on 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 0.40%, which includes a facility fee subject to adjustment for leverage ratio changes, as defined in the Credit Agreement. The Company pays a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.075%. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to the Credit Agreement. As of December 31, 2007, borrowings of \$61.7 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, 2007.

In addition to the Credit Agreement, as of December 31, 2007, 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 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. 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 must 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 Notes have been classified as a current liability on the Consolidated Balance Sheet as of December 31, 2007 given their potential redemption for cash by the holders on May 15, 2008.

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, 2007, the Company had sold a total of \$96.7 million of trade accounts receivable and received funding of \$87.6 million. The securitization program in the United States will expire on September 16, 2008 and the securitization program in Japan will expire on December 3, 2008.

In December 2007, the Company completed its acquisition of certain assets of the *CardioVations* Division of Ethicon, Inc., including products and technology used in minimally invasive heart valve surgery. The total purchase price was \$28.1 million, which consisted of \$26.9 million in cash, \$0.2 million in assumed liabilities, and \$1.0 million in transaction costs.

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In December 2007, the Company received notification that the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund in which the Company had invested \$50.1 million as of December 31, 2007, was being closed to new subscriptions or redemptions, resulting in the Company's inability to immediately redeem its investments for cash. The fair value of the Company's investment in this fund as of December 31, 2007 was estimated to be \$49.4 million based on the net asset value of the fund, and has been classified as "Short-Term Investments" on the Company's Consolidated Balance Sheet. As of December 31, 2007, the Company recognized a loss of \$0.7 million, included in "Other (Income) Expense, net," related to the estimated realizable value of this fund. The Company expects to receive cash redemptions for its remaining investment during 2008.

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* peripheral vascular product line. This divestiture is part of the Company's ongoing strategy to focus resources on its core heart valve and critical care businesses. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and will receive up to an additional \$65.0 million in cash upon the achievement of certain milestones, including the receipt of United States regulatory approval of the Company's *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company has agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

In May 2006, 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 4.0 million shares of the Company's common stock through December 31, 2008. In September 2007, 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 \$250.0 million of the Company's common stock. Stock repurchased under these programs will be used primarily to offset obligations under the Company's employee stock option programs. During 2007, the Company repurchased 2.7 million shares at an aggregate cost of \$130.9 million and has remaining authority under the September 2007 program to purchase \$250.0 million of the Company's common stock.

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 its defined benefit pension plan in Puerto Rico (the "Plan") and in December 2007 the Plan was settled and benefits were distributed to the participants through a combination of lump-sum payments and the purchase of annuities. The final distribution was \$30.9 million, which included an \$8.2 million payment to the Plan to ensure that the value of the Plan's assets was sufficient to cover all benefit liabilities. The Company recorded a pre-tax settlement charge of \$7.1 million in December 2007 related to the settlement.

Net cash flows provided by **operating activities** of \$210.2 million for 2007 decreased \$20.6 million from 2006 primarily due to \$23.8 million received in 2006 for the patent litigation settlement with Medtronic and higher tax payments in 2007, partially offset by net cash inflows resulting from an increase in accounts payable and accrued liabilities in 2007.

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) \$23.8 million

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received in 2006 from the patent litigation settlement with Medtronic, (3) a cash payment of \$23.0 million made in 2005 related to the restructuring of development and supply 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 used by **investing activities** of \$144.5 million in 2007 consisted primarily of (1) capital expenditures of \$57.0 million, (2) a \$55.0 million reclassification from cash to short-term investments associated with the closing of the Bank of America Columbia Strategic Cash fund, as explained above, (3) a \$27.2 million payment associated with the acquisition of certain assets of *CardioVations* and (4) a \$9.8 million milestone payment associated with the PVT acquisition in 2004.

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 in **financing activities** of \$108.1 million in 2007 consisted primarily of purchases of treasury stock of \$130.9 million and net payments on long-term debt of \$27.9 million, partially offset by the proceeds from stock plans of \$38.7 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.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2007 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	\$ 211.7	\$ 150.0	\$	\$ 61.7	\$
Interest on long-term debt	5.0	3.1	1.4	0.5	
Operating leases	46.5	13.7	18.3	9.2	5.3
Pension obligation(a)	3.3	3.3			
Contractual development and capital commitment obligations(b)(c)	10.7	4.0	4.2	2.0	0.5
Total contractual cash obligations(d)	\$ 277.2	\$ 174.1	\$ 23.9	\$ 73.4	\$ 5.8

(a) The amount included in "Less Than 1 Year" reflects anticipated contributions to the Company's various pension plans. Anticipated contributions beyond one year are not determinable. The total accrued benefit liability for the Company's pension plans recognized as of December 31, 2007 was \$16.5 million. This amount is impacted by, among other items, pension expense funding levels, changes in plan demographics and assumptions, and investment return on plan assets. Because the accrued liability does not represent expected liquidity needs, we did not include this amount in the contractual

obligations table. See Note 12 of the Notes to Consolidated Financial Statements for further information.

- (b) Contractual development obligations consist primarily of cash that the Company is obligated to pay upon achievement of product development and other milestones.
- (c) Capital commitment obligations consist primarily of cash that the Company 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.
- (d) As of December 31, 2007, the liability for uncertain tax positions including interest was \$39.1 million. Due to the high degree of uncertainty regarding the timing of potential cash flows associated with these liabilities, we are unable to make a reasonably reliable estimate of the amount and period in which these liabilities might be paid.

### **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 consolidated 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 when it is realized or realizable and earned. Revenue is considered realized or realizable and earned upon delivery of the product, provided that an agreement of sale exists, the sales price is fixed or determinable, 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's sales terms are standard terms within the medical device industry, with title and risk of loss transferring upon delivery to the customer, limited right of return, and no unusual provisions or conditions. 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 rebates, returns, and other sales allowances. These provisions are estimated and recorded at the time of sale based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with direct 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 are based on third-party data, as certain third-party information was itself in the form of estimates, and reflect other limitations.

The Company's primary sales adjustment relates to distributor rebates which are given to the Company's United States distributors and represents the difference between the Company's sales price to the distributor (at the Company's distributor "list price") and the negotiated price to be paid by the end-customer. This distributor rebate is recorded by the Company as a reduction to sales and a reduction to the distributor's accounts receivable at the time of sale to a distributor. The Company validates the distributor rebate accrual quarterly through a review of the inventory reports obtained from our largest distributors. This customer inventory information is used to verify the estimated liability for future distributor rebate claims based on historical rebates and contract rates. The Company continually monitors current pricing trends and distributor inventory levels to ensure the liability for future distributor rebates is fairly stated.

The Company also offers volume rebates to certain group purchasing organizations ("GPO") and customers based upon target sales levels. These volume rebates are recorded as a reduction to sales and an obligation to the GPO. The provision for volume rebates is estimated based on our customers' contracted rebate programs and our historical experience of rebates paid. The Company continually monitors its customer rebate programs to ensure that the liability for accrued rebates is fairly stated. Product returns are minimal because returns are not allowed unless the product is damaged at time of receipt. An allowance for return of damaged products is established based on historical experience and recorded as a reduction of sales.

#### *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 \$7.5 million and \$6.5 million at December 31, 2007 and 2006, 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 \$14.9 million and \$13.2 million at December 31, 2007 and 2006, 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 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 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***

Income taxes are determined under guidelines prescribed by 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.

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in evaluating the Company's uncertain tax positions and determining its provision for income taxes. As required by the Financial Accounting Standards Board ("FASB") Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*" ("FIN 48"), the Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based on technical merit if challenged

by the relevant taxing authority and taken by management to the court of last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon settlement with the relevant tax authority. The Company recognizes interest and penalties related to income tax matters in income tax expense.

### ***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, are being 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 July 2006, the FASB issued 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. On January 1, 2007, the Company adopted the provisions of FIN 48. Differences between the amounts reported as a result of adoption have been accounted for as a cumulative effect adjustment recorded to the January 1, 2007 "*Retained Earnings*" balance.

The cumulative effect of adopting FIN 48 was a \$1.7 million decrease in tax reserves and increase in the January 1, 2007 "*Retained Earnings*" balance. As of the adoption date of January 1, 2007, the liability for income taxes associated with uncertain tax positions was \$24.6 million which is included in "*Other Long-Term Liabilities*." This liability can be reduced by \$3.4 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$21.2 million, if recognized, would favorably affect the Company's effective tax rate.



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A reconciliation of the beginning and ending amount of unrecognized tax benefits, excluding interest and penalties, is as follows (in millions):

Unrecognized tax benefits, January 1, 2007	\$ 24.6
Increase prior period tax positions	12.1
Decrease prior period tax positions	(7.9)
Current year tax positions	8.6
Settlements	(0.9)
Lapse of statute of limitations	(0.1)
	<hr/>
Unrecognized tax benefits, December 31, 2007	\$ 36.4

As of December 31, 2007, the liability for income taxes associated with uncertain tax positions was \$36.4 million. This liability can be reduced by \$8.0 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$28.4 million, if recognized, would favorably affect the Company's effective tax rate.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. Upon adoption of FIN 48, the Company had accrued \$1.1 million (net of \$0.2 million tax benefit) of interest related to uncertain tax positions and as of December 31, 2007, the Company had accrued \$3.1 million (net of \$1.1 million tax benefit) of interest related to uncertain tax positions.

The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While the Company has accrued for amounts it believes are the probable outcomes, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the consolidated financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The unrecognized tax positions 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 have been provided for any adjustments that may result from these uncertain tax positions.

During the third quarter of 2007, the Internal Revenue Service ("IRS") initiated an audit of the 2005 and 2006 tax years. This audit is expected to close in late 2008. No significant unexpected adjustments have been proposed to date.

As a result of the IRS and other audits, the total liability for unrecognized tax benefits may change within the next twelve months due to either settlement of audits or expiration of statutes of limitations. Quantification of those potential changes cannot be estimated at this time. At December 31, 2007, the Company has concluded all United States federal income tax matters for years through 2004. All material state, local and foreign income tax matters have been concluded for years through 2002.

### **New Accounting Standards Not Yet Adopted**

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value

measurements. Certain provisions of SFAS 157 are effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company does not expect the adoption of SFAS 157 to have a material impact on its consolidated financial statements.

In September 2006, the FASB issued SFAS 158 which amends SFAS No. 87, "*Employers' Accounting for Pensions*," 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. 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 adoption of the measurement date provisions of SFAS 158 to have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" ("SFAS 159"). SFAS 159 allows reporting entities to choose to measure many financial instruments at fair value and incorporates an amendment to SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," which is applicable to all entities with trading securities or securities that are considered to be available for sale. The provisions within SFAS 159 are effective for fiscal years beginning after November 15, 2007, with early adoption permitted as long as the provisions of SFAS 157 are also early adopted. The Company does not expect the adoption of SFAS 159 to have a material impact on its consolidated financial statements.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*" ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used in future research and development activities be deferred and capitalized until the related service is performed or the goods are delivered. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The Company does not expect the adoption of EITF 07-3 to have a material impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "*Business Combinations*" ("SFAS 141R"). SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business

combination. Among other requirements, SFAS 141R expands the definition of a business combination, requires acquisitions to be accounted for at fair value, and requires transaction costs and restructuring charges to be expensed. SFAS 141R is effective for fiscal years beginning on or after December 15, 2008. SFAS 141R will only impact the Company if it is involved in a business combination.

In December 2007, the FASB issued SFAS No. 160, "*Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51*" ("SFAS 160"). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. The Company does not expect the adoption of SFAS 160 to have a material impact on its consolidated financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF in EITF Issue No. 07-1, "*Accounting for Collaborative Arrangements*" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented is required for all collaborative arrangements existing as of the effective date. The Company does not expect the adoption of EITF 07-1 to have a material impact on its consolidated financial statements.

#### **Item 7A. Quantitative and Qualitative Disclosures 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, 2007 and 2006 were \$336.2 million and \$295.2 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, 2007.

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 39 basis-point increase in interest rates (approximately 10% 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, 2007 and 2006 with a maturity of up to one year, was \$5.1 million and \$2.3 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, 2007 reduced by the effects of master-netting agreements. Additionally, at December 31, 2007, 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, 2007. 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 2007, 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, 2007, Edwards Lifesciences had approximately \$34.3 million of investments in equity instruments of other companies and had recorded unrealized gains of \$7.5 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.

The Company has recorded in "*Short-term Investments*" cash held in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, which was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investments for cash. The fair value of the Company's investment in this fund as of December 31, 2007 was estimated to be \$49.4 million based on the net asset value of the fund. As of December 31, 2007, the Company recognized a loss of \$0.7 million, included in "*Other (Income) Expense, net*," related to the estimated realizable value of this fund. The Company expects to receive cash redemptions for its remaining investment during 2008.

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2007**

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**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss) and cash flows present fairly, in all material respects, the financial position of Edwards Lifesciences Corporation and its subsidiaries at December 31, 2007 and December 31, 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, appearing in Item 9A under "*Management's Report on Internal Control*". Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share-based compensation and uncertain tax provisions in 2006 and 2007, respectively.

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.

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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, 2008



## EDWARDS LIFESCIENCES CORPORATION

## CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2007	2006
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 141.8	\$ 182.8
Short-term investments (Note 2)	49.4	
Accounts receivable, net	115.8	111.5
Other receivables	29.5	15.6
Inventories, net	152.6	142.1
Deferred income taxes	30.2	21.8
Prepaid expenses	25.4	25.7
Other current assets	37.0	32.1
<b>Total current assets</b>	<b>581.7</b>	<b>531.6</b>
Property, plant and equipment, net	228.2	213.0
Goodwill	350.3	337.7
Other intangible assets, net	122.5	116.1
Investments in unconsolidated affiliates	34.3	20.2
Deferred income taxes	13.8	14.5
Other assets	14.3	13.7
<b>Total assets</b>	<b>\$ 1,345.1</b>	<b>\$ 1,246.8</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 63.9	\$ 48.9
Accrued liabilities	161.5	140.3
Taxes payable		37.0
Convertible debt (Note 10)	150.0	
<b>Total current liabilities</b>	<b>375.4</b>	<b>226.2</b>
Long-term debt	61.7	235.9
Other long-term liabilities	73.0	35.3
Commitments and contingencies (Notes 10 and 17)		
<b>Stockholders' equity</b>		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 68.6 and 67.0 shares issued, and 56.6 and 57.7 shares outstanding at December 31, 2007 and 2006, respectively	68.6	67.0
Additional paid-in capital	680.6	603.7
Retained earnings	548.6	433.9
Accumulated other comprehensive income (loss)	7.5	(15.8)

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	<u>December 31,</u>	
Treasury stock, at cost, 12.0 and 9.3 shares at December 31, 2007 and 2006, respectively	(470.3)	(339.4)
Total stockholders' equity	835.0	749.4
Total liabilities and stockholders' equity	\$ 1,345.1	\$ 1,246.8

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,		
	2007	2006	2005
Net sales	\$ 1,091.1	\$ 1,037.0	\$ 997.9
Cost of goods sold	378.2	373.6	374.6
	712.9	663.4	623.3
Gross profit	712.9	663.4	623.3
Selling, general and administrative expenses	418.0	376.0	348.7
Research and development expenses	122.3	114.2	99.0
Purchased in-process research and development expenses			1.2
Special charges (gains), net (Note 4)	23.3	(4.5)	48.2
Interest expense	9.1	10.5	12.3
Interest income	(7.7)	(7.8)	(2.6)
Other (income) expense, net (Note 15)	(1.9)	2.7	(0.2)
	149.8	172.3	116.7
Income before provision for income taxes	149.8	172.3	116.7
Provision for income taxes	36.8	41.8	37.4
	113.0	130.5	79.3
Net income	\$ 113.0	\$ 130.5	\$ 79.3

**Share information** (Note 2):

Earnings per share:			
Basic	\$ 1.97	\$ 2.23	\$ 1.33
Diluted	\$ 1.87	\$ 2.10	\$ 1.27
Weighted-average number of common shares outstanding:			
Basic	57.3	58.5	59.6
Diluted	62.7	63.9	62.3

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

**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in millions)

	Years Ended December 31,		
	2007	2006	2005
<b>Cash flows from operating activities</b>			
Net income	\$ 113.0	\$ 130.5	\$ 79.3
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	54.8	56.8	56.2
Stock-based compensation (Notes 2 and 13)	27.7	26.6	3.3
Deferred income taxes	(5.6)	7.1	(13.8)
Purchased in-process research and development			1.2
Special charges (gains), net	14.9	19.3	(0.8)
Other	1.3	5.4	15.0
Changes in operating assets and liabilities:			
Accounts and other receivables	(6.6)	2.5	(12.6)
Accounts receivable securitization	11.9	0.9	(2.6)
Inventories	(9.0)	(12.8)	(12.9)
Accounts payable and accrued liabilities	14.0	(3.9)	25.1
Prepaid expenses and other current assets	(7.5)	(1.2)	0.3
Other	1.3	(0.4)	(0.9)
	<u>210.2</u>	<u>230.8</u>	<u>136.8</u>
<b>Net cash provided by operating activities</b>			
<b>Cash flows from investing activities</b>			
Capital expenditures	(57.0)	(57.4)	(48.5)
Investments in intangible assets	(5.5)	(2.0)	(2.5)
Investments in unconsolidated affiliates	(2.3)	(1.8)	(1.5)
Transfer to short-term investments (Note 2)	(55.0)		
Proceeds from short-term investments (Note 2)	5.6		
Proceeds from sale of assets (Note 4)	7.2	22.2	24.6
Acquisitions and milestone payment (Notes 4 and 7)	(37.0)		
Other	(0.5)	3.3	0.7
	<u>(144.5)</u>	<u>(35.7)</u>	<u>(27.2)</u>
<b>Net cash used in investing activities</b>			
<b>Cash flows from financing activities</b>			
Proceeds from issuance of long-term debt	57.3	54.8	337.3
Payments on long-term debt	(85.2)	(140.7)	(278.2)
Purchases of treasury stock	(130.9)	(145.9)	(53.5)
Proceeds from stock plans	38.7	33.5	26.2
Excess tax benefit from stock plans (Notes 2 and 13)	8.6	5.2	
Other	3.4	(0.5)	(2.8)
	<u>(108.1)</u>		
<b>Net cash (used in) provided by financing activities</b>			