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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, 2008

OR

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

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 1-15525

**EDWARDS LIFESCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**36-4316614**

(I.R.S. Employer  
Identification No.)

**One Edwards Way, Irvine, California 92614**

(Address of principal executive offices) (ZIP Code)

**(949) 250-2500**

Registrant's telephone number, including area code

**Securities registered pursuant to Section 12(b) of the Act:**

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

**Name of each exchange on which registered:**

New York Stock Exchange  
New York Stock Exchange

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

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

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

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

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

Indicate by check 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 30, 2008 (the last trading day of the registrant's most recently completed second quarter): \$3,416,008,263 based on a closing price of \$62.04 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, 2009, was 55,875,263.

**Documents Incorporated by Reference**

Portions of the registrant's proxy statement for the 2009 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2008) are incorporated by reference into Part III, as indicated herein.

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**EDWARDS LIFESCIENCES CORPORATION**  
**Form 10-K Annual Report—2008**  
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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, plans or expectations with respect to development activities, clinical trials or regulatory approvals, 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 or 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 is focused specifically on technologies that treat structural heart disease and critically ill patients.

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 four main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; and Vascular. Previously, Edwards Lifesciences provided Other Distributed Products, which included sales of intra-aortic balloon pumps and other products sold primarily through the Company’s distribution network in Japan. Edwards terminated its distribution agreement for these products at the end of December 2007.

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 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 from diseased blood vessels.

## Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999. Unless otherwise indicated or otherwise required by the context, the terms “we,” “our,” “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 Securities and Exchange Commission. 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 four 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 global leader in heart valve therapy and 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 line of *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 valve repair products intended to treat specific valve diseases.

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”), 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 procedures. In the area of transcatheter mitral valve repair, the Company is developing the *MONARC* mitral 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' hemodynamic monitoring product line includes 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.

In late 2008, the Company entered into a third party partnership to jointly develop continuous glucose monitoring technologies for intensive care hospital settings. Glycemic control is being advocated in many medical society guidelines as an important therapy for improving clinical outcomes.

## **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.

The Company's minimally invasive surgery ("MIS") product line was acquired from *CardioVations* in December 2007. MIS includes the *PORT-ACCESS* products, such as the proprietary *EndoCPB* system for minimally invasive heart valve surgery, which comprises soft tissue retractors, venous and arterial cannulae, vent and coronary sinus catheters, and reusable instruments for performing port-access cardiac valve procedures. The Company also provides training to the cardiac surgeons who are performing these minimally invasive procedures.

## **Vascular**

The pervasive nature of cardiovascular disease means that the circulatory conditions that occur inside the heart are often mirrored in peripheral blood vessels elsewhere in a patient's body. Atherosclerotic disease is one common condition that involves the thickening of blood vessels and the formation of circulation restricting plaque, clots, and other substances.

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. 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. Through early 2008, Edwards manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents. 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.

## **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 innovative 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.

Edwards Lifesciences' products and technologies face substantial competition from a number of companies including divisions of companies much larger than Edwards Lifesciences and smaller companies that compete in specific product categories or certain geographies. In Heart Valve Therapy, primary competitors include St. Jude Medical, Inc., Medtronic, Inc., Sorin Group, and CoreValve, Inc. In Critical Care, Edwards Lifesciences competes primarily with Hospira, Inc. and a variety of other companies in specific product categories including PULSION Medical Systems AG and Becton, Dickinson and Co. In Cardiac Surgery Systems, Edwards Lifesciences competes primarily with Medtronic, Inc. In Vascular, Edwards Lifesciences competes with a wide variety of mostly smaller companies.

## **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, the Company's 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 the Company's net sales in 2008.

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, the Company's sales force actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations ("GPOs") 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 2008, 44% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

**International.** In 2008, 56% 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 California, 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 Utah and Puerto Rico, respectively. The Company has agreed to manufacture the 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. The Company 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 the Company 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 International Organization for Standardization ("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, the Company facilitates compliance with applicable regulatory requirements and monitors performance against these objectives at all levels of its organization. In order to measure performance, the Company 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 \$139 million in research and development in 2008 (excluding special charges), \$122 million in 2007, and \$114 million in 2006 (11.2%, 11.2%, and 11.0% of net sales, respectively). A significant portion of the Company's research and development investment has been applied to extend and defend its core Heart Valve Therapy and Critical Care product lines, including research and development relating to next-generation pericardial tissue valves and enhanced tissue processing technologies.

Edwards Lifesciences is also 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. In the area of transcatheter aortic valve replacement, the Company is developing next generation versions of its *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 pursuing the development of minimally invasive hemodynamic monitoring equipment, continuous glucose monitoring, 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 the



Company's 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.

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.

## **Seasonality**

Edwards Lifesciences' quarterly net sales are influenced by many factors, including new product introductions, acquisitions, regulatory approvals, patient and physician holiday schedules, and other factors. Net sales in the third quarter are typically lower than other quarters of the year due to the seasonality of the United States and European markets, where summer vacation schedules normally result in fewer procedures.

## **Employees**

As of December 31, 2008, Edwards Lifesciences had approximately 6,200 employees worldwide, the majority of whom were located at the Company's headquarters in Irvine, California, and at its manufacturing facilities in Puerto Rico and the Dominican Republic. Other major concentrations of employees are located in Europe, Japan, and 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 and 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, our business, financial condition, results of operations or prospects could be*

*materially harmed. In that case, the value of our securities could decline and an investor could lose part or all of his or her investment.*

*If we do not introduce new products in a timely manner, our products may become obsolete and our operating results may suffer.*

The cardiovascular products industry is characterized by technological changes, frequent new product introductions, and evolving industry standards. Without the timely introduction of new and improved products, our products could become technologically obsolete and our revenue and operating results would suffer. Even if we are able to develop new products, our ability to market them could be limited by the need for regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third party reimbursement, or other factors.

Technical innovations often require substantial time and investment before we can determine their commercial viability. We may not have the financial resources necessary to fund these projects. In addition, even if we are able to successfully develop new or improved products, they may not produce revenue in excess of the costs of development, and they may be rendered obsolete by changing customer preferences or the introduction by our competitors of products with newer technologies or features.

*We may incur product liability losses that could adversely affect our operating results.*

Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of the medical devices we manufacture and sell 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. 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 our business and reputation and on our ability to attract and retain customers. Product liability claims may be brought from time to time either by individuals or by groups seeking to represent a class. We may incur charges related to such matters in excess of any established reserves and such charges, including the establishment of any such reserves, could have a material adverse impact on our net income or net cash flows.

*We may experience supply interruptions that could harm our ability to manufacture products.*

We use a broad range of raw and organic materials and other items in the design and manufacture of our products. Our Heart Valve Therapy products are manufactured from treated natural animal tissue and man-made materials. Our non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics, and metals. We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we purchase certain supplies from single sources for reasons of quality assurance, cost-effectiveness, availability, or constraints resulting from regulatory requirements. While we work closely with 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 our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources if the need arises. Although alternative supplier options are considered and identified, we typically do not pursue regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with this regulatory process. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us.

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 we are unable to obtain these raw materials, our business could be harmed.

Regulatory agencies in the United States or other international geographies from time to time have limited or banned the use of certain materials used in the manufacture of our products. In these circumstances, transition periods typically provide time to arrange for alternative materials. If we are unable to identify alternative materials and secure approval for their use in a timely manner, our business could be harmed.

Some of our suppliers are located outside the United States. As a result, trade or regulatory embargoes imposed by foreign countries or the United States could result in delays or shortages that could harm our business.

*The manufacturing of many of our products is highly complex and subject to strict quality controls. If we or one of our suppliers encounters manufacturing or quality problems, our business could suffer.*

The manufacture of many of our products is highly complex and subject to strict quality controls, due in part to rigorous regulatory requirements. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to follow protocols and procedures, raw material problems, or human error. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the FDA or other applicable regulatory body, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals could be delayed, and our business could otherwise be adversely affected.

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

We have equity investments in other companies, and we may make similar investments in the future. To the extent that the value of any of these investments declines, we may be required to recognize charges to write down the value of that investment.

At December 31, 2008, we had \$14.7 million of investments in equity instruments of other companies and had recorded unrealized losses of \$5.7 million on these investments on our consolidated balance sheet in "Accumulated Other Comprehensive (Loss) Income," net of tax.

In addition, from time to time we identify businesses and products that are not performing at a level commensurate with the rest of our business. We may seek to dispose of these under performing businesses or products. We may also seek to dispose of other businesses or products for strategic or other business reasons. If we cannot dispose of a business or product on acceptable terms, we may voluntarily cease operations related to that business or product. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

Historically, we have entered into interest rate swap agreements and we expect to continue to do so from time to time in the future. In the event that we elect to terminate a swap agreement prior to its maturity, we could be required to make cash payments to the counterparty and to recognize a charge in connection with that termination, which could adversely affect our results of operations.

*We 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.*

We regularly review potential acquisitions of complementary businesses, technologies, services or products, as well as potential strategic alliances. We may be unable to find suitable acquisition candidates or appropriate partners with which to form alliances. Even if we identify appropriate acquisition or alliance candidates, we may be unable to complete the acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service, or product into our existing operations could result in unforeseen difficulties and expenditures. Integration of an acquired company often requires significant expenditures as well as significant management resources that otherwise would be available for ongoing development of our other businesses. Moreover, we may not realize the anticipated financial or other benefits of an acquisition or alliance.

We may be required to take charges or write-downs in connection with acquisitions. 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, we have taken significant in-process research and development charges in connection with acquisitions and may take similar charges in connection with future acquisitions, which could adversely affect our 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 our financial condition or results of operations. In addition, equity or debt financing required for such acquisitions may not be available.

*General economic and political conditions could have a material adverse effect on our business.*

External factors can affect our profitability and financial condition. Such external factors include general economic conditions, such as interest rates and tax rates, and the political environment regarding healthcare in general. For example, an increase in interest rates could result in an increase in our borrowing costs and could otherwise restrict our ability to access the capital markets. In addition, the recent change in the administration of the United States government could result in significant changes in healthcare policies and regulations. It is likely that there will be proposals for such changes by the administration, legislators, regulators, third party payors, and healthcare providers, including proposals to contain healthcare costs. While we believe our products are appropriately and competitively priced, if enacted, such proposals could affect the prices or reimbursement levels for our products.

*The recent decline in the global economy and turmoil in the credit markets may adversely affect our business, results of operations, and financial condition.*

The current uncertainty arising from domestic and global economic conditions, including the recent disruption in credit markets, poses a risk to the overall economy that could adversely impact our customers, suppliers, creditors, and counterparties to derivative contracts, with a corresponding adverse impact on our business, financial condition, and results of operations. Negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital or other funds and could negatively impact our ability to borrow. These conditions have also resulted in decreased liquidity as well as a decline in value of many investments, and could result in impairments in the carrying value of our investments and adversely affect our results of operations and financial condition. As part of our risk management program, we enter into interest rate swaps and foreign exchange contracts with counterparties in the financial services industry, which industry has come under considerable pressure recently. The financial instability of any of these counterparties could result in losses or impairments to the value of our financial assets. Although sales of our products are not generally sensitive to economic conditions, the current

economic conditions could have an adverse impact on our revenues and profitability. In addition, if our customers experience financial difficulties, the Company could incur increased bad debt expense or write-offs of accounts receivable. Likewise, if our suppliers face challenges in obtaining credit or other financial difficulties they may be unable to provide the materials required to manufacture our products.

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

Because we sell our products in a number of foreign countries, our business is subject to the risks of doing business internationally. Our net sales originating outside of the United States, as a percentage of total net sales, were 56% in 2008. We anticipate that sales from international operations will continue to represent a substantial portion of our total sales. In addition, many of our manufacturing facilities and suppliers are located outside of the United States. Accordingly, our 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, quotas, embargoes, import or export licensing requirements and duties, tariffs, or surcharges;
- potentially negative consequences from changes in tax laws;
- difficulty in staffing and managing foreign operations;
- cultural, exchange rate, or other local factors affecting financial terms with customers;
- an outbreak of any life threatening communicable disease;
- economic and political instability and local economic and political conditions;
- differing labor regulations; and
- differing protection of intellectual property.

Substantially all of our sales outside of the United States are denominated in local currencies. Measured in local currency, a substantial portion of our foreign-generated sales was generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our foreign-generated sales varies with currency exchange rate fluctuations. Decreases in the value of the United States dollar to the Euro or the Japanese yen have the effect of increasing our reported revenues even when the volume of foreign sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect and, if significant, could have a material adverse effect on our reported revenues and results of operations. We have 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 our quarterly operating results as well as other factors could cause our 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 for reasons unrelated to underlying performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results. In addition, the market price of our 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 performance of comparable companies or the medical device industry.

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

- announcements of innovations, new products, strategic developments, or business combinations by us or our competitors;
- changes in financial estimates and recommendations of securities analysts;
- demand for and clinical acceptance of products;
- the timing and execution of customer contracts, particularly large contracts that would materially affect our 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;
- changes in our pricing policies or the pricing policies of our 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 regions in which we do business;
- costs related to acquisitions of technologies or businesses; and
- our ability to expand our operations and the amount and timing of expansion-related expenditures.

*We face intense competition, and if we do not compete effectively our business will be harmed.*

The cardiovascular medical device industry is highly competitive. We compete 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. Our customers consider many factors when selecting a product, including product reliability, clinical outcomes, product availability, price, and services provided by the manufacturer. In addition, our ability to compete will depend in large part on our ability to develop and acquire new products and technologies, anticipate technology advances, and keep pace with other developers of cardiovascular therapies and technologies. Our competitive position can also be adversely affected by product problems, physician advisories, and safety alerts, reflecting the importance of quality in the medical device industry. Market share can shift as a result of any of these factors. See “*Competition*” under “*Business*” included herein.

*Consolidation in the healthcare industry could have an adverse effect on our 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 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 our products have combined to form GPOs. GPOs negotiate pricing arrangements with medical supply manufacturers and distributors and these negotiated prices are made available to members of GPOs. If we are not one of the providers selected by a GPO, we may be

precluded from making sales to members of a GPO. Even if we are one of the selected providers, we 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, we may be required to commit to pricing that has a material adverse effect on our revenues and profit margins, business, financial condition, and results of operations.

*Our inability to protect our intellectual property could have a material adverse effect on our business.*

Our success and competitive position are dependent in part upon our proprietary intellectual property. We rely on a combination of patents and trade secrets to protect our proprietary intellectual property, and we will continue to do so. Although we seek to protect our proprietary rights through a variety of means, we cannot guarantee that the protective steps we have taken are adequate to protect these rights. Patents issued to or licensed by us in the past or in the future may be challenged and held invalid. In addition, as our patents expire, we may be unsuccessful in extending their protection through new patents or patent term extensions. The failure to maintain or extend our patents could have a material adverse effect on us.

We also rely on confidentiality agreements with certain employees, consultants, and other third parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached and we may not have adequate remedies for such a breach. In addition, others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information.

We spend significant resources to enforce our intellectual property rights, sometimes resulting in litigation. Intellectual property litigation is complex and can be expensive and time-consuming. However, our efforts in this regard may not be successful. We may not be able to detect infringement. In addition, competitors may design around our technology or develop competing technologies. Patent litigation can result in substantial cost and diversion of effort. Intellectual property protection may also be unavailable or limited in some foreign countries, enabling our competitors to capture increased market position. The invalidation of key intellectual property rights or an unsuccessful outcome in lawsuits filed to protect our intellectual property could have a material adverse effect on our financial condition, results of operations, or prospects.

*Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products.*

During recent years, our competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical device industry. From time to time, we may be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and such intellectual property litigation could be costly and time-consuming. Adverse determinations in any such litigation could result in significant liabilities to third parties, or could require us to seek licenses from third parties and could, if such licenses are not available on commercially reasonable terms, prevent us from manufacturing, selling, or using certain products, any one of which could have a material adverse effect on us. In addition, some licenses may be non-exclusive, which could provide our competitors access to the same technologies.

Third parties could also obtain patents that may require us to either redesign products or, if possible, negotiate licenses from such third parties. If we are unable to redesign products or obtain a license, we might have to exit a particular product offering.

*We and our customers are subject to rigorous governmental regulations and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations, and financial condition.*

The medical devices we manufacture and market 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, pricing, marketing, and distribution of our products.

We are required to register with the FDA as a device manufacturer. As a result, we are 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. Our compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products, and are subject to periodic inspections by notified bodies to obtain and maintain these certifications. If we or our 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 our 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. In addition, the federal Medical Device Reporting regulations require us 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. 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 our 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 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.

We are also subject to various federal, state, and foreign laws pertaining to healthcare pricing and fraud and abuse, including prohibitions on kickbacks and the submission of false claims laws and restrictions on relationships with physicians and other referral sources. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if they are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment, and exclusion from participation in governmental healthcare programs.

In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections, and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the Foreign Corrupt Practices Act. Despite implementation of robust compliance processes, we may be subject to more regulation, enforcement, inspections, and investigations by governmental authorities in the future. Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and can recommend criminal prosecution to the Department of Justice. Moreover, governmental authorities can ban or request the recall, repair, replacement, or refund of the cost of any device or product we manufacture or distribute. 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 our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition.

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

The development of new products requires extensive clinical trials and procedures. Such clinical trials are inherently uncertain and there can be no assurance that these trials or procedures will be completed in a timely or cost effective manner or result in a commercially viable product. Failure to successfully complete these trials or procedures in a timely and cost effective manner could have a material adverse effect on our prospects. Clinical trials may experience significant setbacks even after earlier trials have shown promising results. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials may be suspended or terminated by us, the FDA, or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

*We are subject to risks arising from concerns and/or regulatory actions relating to “mad cow disease.”*

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of BSE, commonly known as “mad cow disease,” from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our 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. We have not experienced any significant adverse impact on our 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 our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed.*

We sell our products and technologies to hospitals, doctors, and other health care providers, all of which receive reimbursement for the health care services provided to 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 our 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.

Initiatives to limit the growth of healthcare costs, including price regulation, are underway in several countries around the world. In many countries, customers are reimbursed for our products under a

government operated insurance system. Under such a system, the government periodically reviews reimbursement levels. If a government were to decide to reduce reimbursement levels, our 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 deny reimbursement for experimental procedures and devices. We believe that many of our 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. We cannot be certain that these third party payors will recognize these cost savings instead of merely focusing on the lower initial costs associated with competing therapies. If our products are not considered cost-effective by third party payors, our customers may not be reimbursed for them.

*Our operations are subject to environmental, health, and safety regulations that could result in substantial costs.*

Our operations are subject to environmental, health, and safety laws and regulations concerning, among other things, the generation, handling, transportation and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and may incur expenditures in the future in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for new or increased liabilities that could be material.

*The success of many of our products depends upon strong relationships with certain key physicians.*

The development, marketing, and sales of many of our products requires us to maintain working relationships with physicians upon whom we rely to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product consultants, inventors, and as public speakers. If new laws, regulations, or other developments limit our ability to maintain strong relationships with these professionals or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

**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, 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
Changi, Singapore . . . . .	(2)	Manufacturing, Administration

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(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2009; one of the Puerto Rico leases expires in 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; 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

In August 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 ("Gore") 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. In September 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced in January 2006, Edwards Lifesciences settled this litigation with Medtronic. Edwards Lifesciences remains in litigation with Cook and Gore, each of which has answered and asserted various affirmative defenses and counterclaims. In March 2008, the District Court granted summary judgment of non-infringement in favor of Cook and subsequently also in favor of Gore. In September 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals.

In May 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. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007, and June 2007, CoreValve filed separate 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. In January 2009, the United Kingdom Court determined that the Andersen patent was valid but not infringed by CoreValve. The Company is considering an appeal. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. This lawsuit is ongoing.

In February 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. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook has counterclaimed, alleging infringement by Edwards. The trial in Germany on infringement was held on February 19, 2009, and the Company is awaiting the Court's decision.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be 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, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations, or liquidity.

Edwards Lifesciences is 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 continuing 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, 2008.

## PART II

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

#### *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.

	2008		2007	
	High	Low	High	Low
Calendar Quarter Ended:				
March 31 . . . . .	\$47.62	\$41.69	\$52.51	\$46.06
June 30 . . . . .	63.49	44.80	52.95	48.15
September 30 . . . . .	66.99	53.75	50.79	45.55
December 31 . . . . .	58.56	44.76	52.86	45.84

#### *Number of Stockholders*

On January 31, 2009, there were 15,729 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.

#### *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, 2008 . . . . .	395,000	\$53.13	395,000	\$193.5
November 30, 2008 . . . . .	—	—	—	193.5
December 31, 2008 . . . . .	—	—	—	193.5
Total . . . . .	<u>395,000</u>	<u>\$53.13</u>	<u>395,000</u>	<u>\$193.5</u>

- (a) On September 18, 2007, 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 \$250.0 million of the Company's common stock. This program was completed in July 2008. On July 11, 2008, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$250.0 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 3 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,				
		2008	2007	2006	2005	2004
		(in millions, except per share data)				
<b>OPERATING RESULTS</b>	Net sales	\$1,237.7	\$1,091.1	\$1,037.0	\$ 997.9	\$ 931.5
	Gross profit	818.1	712.9	663.4	623.3	561.3
	Net income(a)	128.9	113.0	130.5	79.3	1.7
<b>BALANCE SHEET DATA</b>	Total assets	\$1,400.2	\$1,349.8	\$1,246.8	\$1,229.1	\$1,112.7
	Long-term debt and lease obligations	175.5	61.7	235.9	316.1	267.1
<b>COMMON STOCK INFORMATION</b>						
	Net income per common share(a):					
	Basic	\$ 2.31	\$ 1.97	\$ 2.23	\$ 1.33	\$ 0.03
	Diluted	2.19	1.87	2.10	1.27	0.03
	Cash dividends declared per common share	—	—	—	—	—

(a) See Note 3 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 \$25.1 million, \$23.3 million, and \$(4.5) million during 2008, 2007, and 2006, respectively.

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

The following discussion and analysis presents the factors that had a material effect on the results of operations of Edwards Lifesciences during the three years ended December 31, 2008. Also discussed is Edwards Lifesciences’ financial position as of December 31, 2008. 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 Corporation is a global leader in products and technologies designed to treat advanced cardiovascular disease. The Company is focused specifically on technologies that treat structural heart disease and critically ill patients.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease are categorized into four main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; and Vascular. Previously, Edwards Lifesciences provided Other Distributed Products, which included sales of intra-aortic balloon pumps and other products sold primarily through the Company’s distribution network in Japan. Edwards terminated its distribution agreement for these products at the end of December 2007.

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, and other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also included transmyocardial revascularization (“TMR”) products until March 2007 when the Company sold the distribution rights to its TMR products. In December 2007, the Company acquired the *CardioVations* line of products used in MIS. Edwards Lifesciences’ **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, artificial implantable grafts, and stents (“*LifeStent*” products) for which approval is being sought for use in treatment of peripheral vascular disease. The Company sold the *LifeStent* product line in January 2008, but will continue to manufacture these products for the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

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 technology, cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs are expected to continue to drive change.

## 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	
	2008	2007	2006	2008	2007	2008	2007
United States . . . . .	\$ 543.6	\$ 486.6	\$ 477.9	\$ 57.0	\$ 8.7	11.7%	1.8%
Europe . . . . .	380.3	309.1	264.6	71.2	44.5	23.0%	16.8%
Japan . . . . .	176.5	171.4	168.8	5.1	2.6	3.0%	1.5%
Rest of World . . . . .	137.3	124.0	125.7	13.3	(1.7)	10.7%	(1.4)%
International . . . . .	694.1	604.5	559.1	89.6	45.4	14.8%	8.1%
Total net sales . . . . .	<u>\$1,237.7</u>	<u>\$1,091.1</u>	<u>\$1,037.0</u>	<u>\$146.6</u>	<u>\$54.1</u>	13.4%	5.2%

The \$57.0 million increase in net sales in the United States in 2008 was due primarily to:

- *CardioVations* MIS products, which increased net sales by \$23.7 million. The Company purchased the *CardioVations* MIS product line in December 2007;
- *LifeStent* products (all of which are recorded in the United States in 2008), which increased net sales by \$13.7 million. *LifeStent* sales include end-customer sales recorded prior to the divestiture of *LifeStent* in mid-January 2008, and sales after the divestiture resulting from the on-going manufacturing requirements of the sale agreement, which will continue until the earlier of mid-2010 or the transfer of manufacturing to the buyer;
- Critical Care products, which increased net sales by \$13.8 million, driven primarily by the *FloTrac* minimally invasive monitoring system, hemofiltration products, and pressure monitoring products; and
- Heart Valve Therapy products, which increased net sales by \$7.3 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna* with *ThermaFix* valve and the *Magna* mitral valve, partially offset by a reduction in net sales due to the voluntary retrieval of the Company’s *Myxo* and *IMR ETlogix* repair products pending FDA clearance of its 510(k) submissions.



The \$89.6 million increase in international net sales in 2008 was due primarily to:

- Heart Valve Therapy products, which increased net sales by \$85.1 million, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, and the launch of the *Magna* aortic valve in Japan; and
- Critical Care products, which increased net sales by \$40.2 million, driven primarily by the *FloTrac* minimally invasive monitoring system, pressure monitoring products, and hemofiltration products;

partially offset by:

- a decrease of \$41.3 million related to the discontinuation of distributed sales in Japan of intra-aortic balloon pumps and the divestiture of the *LifeStent* product line.

The benefit of foreign currency exchange rate fluctuations included above increased net sales by \$37.3 million, due primarily to the strengthening of the Euro and Japanese yen against the United States dollar.

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 the *FloTrac* minimally invasive monitoring system, advanced hemodynamic monitoring equipment, and pressure monitoring products; and
- Vascular products, which increased net sales by \$7.0 million, driven primarily by *LifeStent* products;

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:

- Heart Valve Therapy products, which increased net sales by \$33.8 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna* valve, *Magna* with *ThermaFix* valve, and *Magna Ease* valve;
- Critical Care products, which increased net sales by \$32.6 million, driven primarily by the *FloTrac* minimally invasive monitoring system, pressure monitoring products, and hemofiltration products; and
- Vascular products, which increased net sales by \$9.6 million, driven primarily by *LifeStent* products;

partially offset by:

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

The benefit of foreign currency exchange rate fluctuations included above 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.

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	
	2008	2007	2006	2008	2007	2008	2007
Heart Valve Therapy . . . . .	\$ 607.4	\$ 515.0	\$ 490.8	\$ 92.4	\$ 24.2	17.9%	4.9%
Critical Care . . . . .	451.8	397.8	349.8	54.0	48.0	13.6%	13.7%
Cardiac Surgery Systems . . . . .	89.2	60.9	91.0	28.3	(30.1)	46.5%	(33.1)%
Vascular . . . . .	89.3	90.0	75.9	(0.7)	14.1	(0.8)%	18.6%
Other Distributed Products . . . . .	—	27.4	29.5	(27.4)	(2.1)	(100.0)%	(7.1)%
Total net sales . . . . .	<u>\$1,237.7</u>	<u>\$1,091.1</u>	<u>\$1,037.0</u>	<u>\$146.6</u>	<u>\$ 54.1</u>	13.4%	5.2%

#### Heart Valve Therapy

The \$92.4 million increase in net sales of Heart Valve Therapy products in 2008 was due primarily to:

- the launch of the *Edwards SAPIEN* transcatheter heart valve in Europe during the fourth quarter of 2007, which increased net sales by \$50.1 million; and
- pericardial tissue valves, which increased net sales by \$44.9 million, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, the *Magna* with *ThermaFix* aortic valve, and the launch of the *Magna* aortic valve in Japan.

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 \$23.9 million, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna* aortic valve and *Magna* with *ThermaFix* valves; and
- heart valve repair products, which increased net sales by \$6.4 million, driven primarily by the continuing adoption of the Company's disease-specific products, including the *Edwards MC<sup>3</sup>*;

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 Company expects that its *SAPIEN* transcatheter heart valve will continue to be a strong contributor to 2009 sales, and anticipates introducing new products across the aortic, mitral, and valve repair categories. The Company launched the *Magna Ease* valve in Europe in May 2007, and is expecting to introduce this product into the United States in the third quarter of 2009, pending regulatory approval. The Company expects to launch an enhancement to its *Magna Mitral* valve, called the *Magna Mitral Ease*, in the second half of 2009 in the United States and Europe. The *Magna Mitral Ease* is uniquely designed to improve its ease of implantation, which is beneficial for both traditional and minimally invasive surgical procedures. The Company's *PERIMOUNT Magna* mitral valve is gaining physician acceptance in Europe, and the Company launched this product into the United States during September 2008. In Japan, the Company received regulatory and reimbursement approval for its *Magna* aortic valve and introduced this product in Japan during June 2008. The Company expects this product to continue to accelerate its growth rate in Japan. The Company had its first implants of the *Carpentier-Edwards Physio II* ring during the third quarter of 2008 and expects to launch the product in the United States and Europe during the first quarter of 2009. *Physio II* is the next generation repair product for the degenerative segment of mitral repair.

### ***Critical Care***

The \$54.0 million increase in net sales of Critical Care products in 2008 was due primarily to:

- core Critical Care products, which increased net sales by \$26.3 million, driven primarily by market share gains in pressure monitoring products and *PreSep*, the Company's central venous oximetry catheter for early detection of sepsis;
- *FloTrac* systems, which increased net sales by \$19.8 million; and
- hemofiltration products, which increased net sales by \$7.9 million.

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

- core Critical Care products, which increased net sales by \$22.8 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;
- *FloTrac* systems, which increased net sales by \$17.5 million; and
- hemofiltration products, which increased net sales by \$7.7 million.

The Company expects worldwide *FloTrac* system sales to continue to be a significant contributor to Critical Care sales growth in 2009, and that it will continue to expand the market for minimally invasive hemodynamic monitoring. During the second quarter of 2008, the Company introduced an enhancement to the *FloTrac* system that provides additional information in the operating room. At the end of 2008, the Company purchased intellectual property that is expected to be incorporated into a substantial upgrade for *FloTrac*, which is planned for launch in the third quarter of 2009. In addition, the Company anticipates launching a new hardware platform in the third quarter of 2009 that will result in a simpler, more intuitive informational display.

During the fourth quarter of 2008, the Company entered into a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. In 2009, the Company expects to complete clinical studies to support regulatory approval and anticipates introducing a first generation product in Europe by year end.

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

The \$28.3 million increase in net sales of Cardiac Surgery Systems products in 2008 was due primarily to the acquisition of the *CardioVations* MIS product line in December 2007, which increased net sales by \$30.1 million. This increase was partially offset by the discontinuation of the Brazil-based perfusion product line, which resulted in a net sales decrease of \$4.4 million.

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.

### ***Vascular***

The \$0.7 million decrease in net sales of Vascular products in 2008 was due primarily to *LifeStent* products. In January 2008, the Company completed the sale of the *LifeStent* product line. The Company 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 to pursue pre-market approval for a superficial femoral artery indication. *LifeStent* sales include end-customer sales recorded prior to the divestiture of *LifeStent* in mid-January and sales after the divestiture resulting from the on-going manufacturing requirements of the sale agreement.

The \$14.1 million increase in net sales of Vascular products in 2007 was due primarily to *LifeStent* products.

***Other Distributed Products***

The \$27.4 million and \$2.1 million decreases in net sales of Other Distributed Products in 2008 and 2007, respectively, were due primarily to the termination at the end of 2007 of distributed sales in Japan of intra-aortic balloon pumps.

***Gross Profit***

	Years Ended December 31,			Change	
	2008	2007	2006	2008	2007
Gross profit as a percentage of net sales . . . . .	66.1%	65.3%	64.0%	0.8 pts.	1.3 pts.

The 0.8 percentage point increase in gross profit as a percentage of net sales in 2008 was driven by:

- a 2.1 percentage point increase in international gross profit as a percentage of net sales, 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 intra-aortic balloon pumps;

partially offset by:

- a 0.5 percentage point decrease in United States gross profit as a percentage of net sales, due primarily to sales of *LifeStent* products under the on-going manufacturing requirements of the *LifeStent* sale agreement, partially offset by a more profitable product mix, primarily higher sales of *FloTrac* systems; and
- the impact from the expiration of foreign currency hedging contracts.

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 from the expiration of foreign currency hedging contracts.

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

(dollars in millions)

	Years Ended December 31,			Change	
	2008	2007	2006	2008	2007
SG&A expenses . . . . .	\$480.6	\$418.0	\$376.0	\$62.6	\$42.0
SG&A expenses as a percentage of net sales . . . . .	38.8%	38.3%	36.3%	0.5 pts.	2.0 pts.

The \$62.6 million increase in SG&A expenses and the 0.5 percentage point increase in SG&A expenses as a percentage of net sales in 2008 were due primarily to (1) higher sales-related spending, including investments for the *Edwards SAPIEN* transcatheter heart valve launch in Europe, (2) the impact of foreign currency (primarily the strengthening of the Euro and the Japanese yen against the United States dollar) in

the amount of \$16.7 million, and (3) higher compensation expense related to the Company's strong sales performance.

The \$42.0 million increase in SG&A expenses and the 2.0 percentage point increase in SG&A expenses as a percentage of net sales in 2007 were 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.

***Research and Development Expenses***

(dollars in millions)

	Years Ended December 31,			Change	
	2008	2007	2006	2008	2007
Research and development expenses . . . . .	\$139.2	\$122.3	\$114.2	\$16.9	\$8.1
Research and development expenses as a percentage of net sales . . . . .	11.2%	11.2%	11.0%	—	0.2 pts.

The increase in research and development expenses in 2008 was due primarily to additional investments in transcatheter and surgical heart valve programs.

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

The following are the developments related to 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 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 A in August 2009 and in Cohort B by the end of the first quarter of 2009;
- the Company completed enrollment in its United States feasibility study of the *Ascendra* transapical delivery system in April 2007. The Company obtained FDA approval to add *Ascendra* to the PARTNER trial in January 2008, and during the second quarter of 2008 the first patients received the *SAPIEN* valve using *Ascendra*. The Company believes that having *Ascendra* in the trial will give cardiac surgeons an opportunity to partner in this technology and it will allow the Company to address a larger patient population. The *Ascendra* transapical delivery system is available for sale in Europe;
- the Company received regulatory approval to add the *RetroFlex II* delivery system to the PARTNER trial and began selling *RetroFlex II* in Europe during the second quarter of 2008. The *RetroFlex II* 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 recently received CE Mark approval for European commercial sales of its new *RetroFlex III* delivery system, which further simplifies the delivery of its *SAPIEN* valve;

- the Company began its United States feasibility trial of the *SAPIEN* valve in the pulmonic position in April 2008. The goal of this clinical study is to enable physicians to offer a minimally invasive alternative to patients with a failing pulmonic valve, using the Company's transcatheter valve platform and *RetroFlex* delivery system. The Company expects to complete enrollment in April 2009 and then transition to a larger humanitarian device exemption trial; and
- first-in-man cases using the Company's next generation transcatheter heart valve, the *Edwards SAPIEN XT*, were performed during the first quarter of 2008. In December 2008, the first three implants were performed in the CE Mark trial. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, making it available to an even wider group of patients. The Company expects to complete enrollment in its CE Mark trial in the second quarter of 2009, and expects to gain an IDE approval to begin a clinical trial in the United States before the end of 2009.

The following are the developments related to the Company's transcatheter mitral valve program (formerly ev3, Inc.'s ("ev3") percutaneous mitral valve repair program):

- in October 2008, the Company announced the continuation of the EVOLUTION II clinical trial of the *Edwards MONARC* system which is deployed into the coronary sinus. This trial will study patients with moderate to severe mitral regurgitation and heart failure in Europe and Canada. The Company is currently screening patients for this trial, and expects the first implants to be performed in early 2009.

#### ***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.

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*

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(in millions)		
Acquisition of in-process technology and intellectual property . . . . .	\$ 19.5	\$ —	\$ —
DexCom collaboration agreement . . . . .	13.4	—	—
Adjustment to capitalized patent enforcement costs . . . . .	8.2	—	—
Settlements and litigation losses (gains), net . . . . .	0.6	—	(20.2)
Realignment expenses, net . . . . .	(1.7)	13.9	9.4
Gain on sale of assets, net . . . . .	(14.9)	(1.8)	(13.7)
Pension settlement and adjustment . . . . .	—	11.2	—
PVT milestone . . . . .	—	—	10.0
Discontinued products . . . . .	—	—	6.8
Other . . . . .	—	—	3.2
Total special charges (gains), net . . . . .	<u>\$ 25.1</u>	<u>\$23.3</u>	<u>\$ (4.5)</u>

*Acquisition of In-Process Technology and Intellectual Property*

In October 2008, the Company recorded a \$5.0 million charge related to the acquisition of technology and intellectual property. The acquired technology is being developed for use in restoring heart geometry and function and offers a reshaping solution for patients who suffer from debilitating functional mitral regurgitation. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product.

In November 2008, the Company recorded a \$13.2 million charge related to the acquisition of technology and intellectual property, primarily related to a product which is currently under development, and certain tangible assets, including proto-types and equipment used in the development of the product. The

acquired technology is being developed for use in hemodynamic blood pressure monitoring. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product. Under the terms of the purchase agreement, the Company must pay an additional €3.0 million (US\$4.1 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$8.8 million) in any four consecutive quarters in the first five years following market launch in Europe.

In December 2008, the Company recorded a \$1.3 million charge related to the acquisition of technology and intellectual property related to a device for the reduction or elimination of mitral regurgitation and the control of left ventricular dilation. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product.

#### *DexCom Collaboration Agreement*

In November 2008, the Company entered into a collaboration agreement with DexCom to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. The agreement provides Edwards Lifesciences with an exclusive license to all of DexCom's applicable intellectual property. The Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee. Edwards Lifesciences will also pay up to \$24 million over the next three years in product development costs and regulatory approval milestones. In addition, DexCom will receive either a profit-sharing payment of ten percent or a royalty of up to six percent of commercial sales. Edwards Lifesciences will be responsible for global sales and marketing, which is expected to begin in 2010, and DexCom will be responsible for initial manufacturing.

#### *Adjustment to Capitalized Patent Enforcement Costs*

In December 2008, the Company recorded an \$8.2 million charge due primarily to the reversal of capitalized patent enforcement costs for a litigation claim related to patents in a product area where the Company does not currently compete and where the related patent enforcement costs should therefore be expensed as incurred. The Company recorded the correction of this error in the fourth quarter of 2008. Approximately \$5.7 million of the charge related to 2007 and 2006, and \$2.5 million related to the first, second, and third quarters of 2008. The Company concluded that the adjustments were not material to any of the prior years' financial statements, and the impact of the correcting adjustment is not material to the full year 2008 financial statements.

#### *Settlements and Litigation Losses (Gains), net*

In December 2008, the Company recorded a \$1.5 million insurance settlement gain related to a fire that occurred in the third quarter of 2007 which damaged certain inventory held at a third party warehouse in Brazil.

In March 2008, the Company recorded a \$2.1 million charge for the settlement of litigation related to its divested United States perfusion services business. Under the terms of the divestiture, this was the Company's last outstanding case.

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.

#### *Realignment Expenses, net*

In March 2008, the Company recorded a \$1.3 million charge for executive severance associated with the Company's business realignment. As of December 31, 2008, remaining payments of \$0.7 million for the executive severance charge are expected to be paid through the end of 2009.



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. In 2008, the Company reversed \$3.0 million of the December 2007 accrued severance related to the sale of the *LifeStent* product line and global reduction in workforce. As of December 31, 2008, remaining payments of approximately \$2.6 million are expected to be paid in 2009.

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, 2008, all payments related to the realignment were 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 Corporation as discussed in the "Gain on Sale of Assets, net" section. As of December 31, 2008, all payments related to the realignment were complete.

#### *Gain on Sale of Assets, net*

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. This divestiture was part of the Company's ongoing strategy to focus resources on its core Heart Valve and Critical Care product lines. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and is entitled to 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 *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. Because of the Company's continued involvement in the operations of *LifeStent* after its sale, the Company did not report the loss on disposition or the results of *LifeStent's* operations as discontinued operations.

In connection with this transaction, the Company recorded in January 2008 a pre-tax loss of \$8.1 million consisting of the cash proceeds of \$74.0 million, offset by a \$34.6 million write-off of goodwill associated with this product line, \$36.9 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, \$6.9 million of deferred revenue related to the transition services the Company has agreed to provide, and \$3.7 million of transaction and other costs related to the sale.

In December 2008, the Company recorded a gain of \$23.0 million for the receipt of a *LifeStent* milestone payment in connection with the transfer of its pre-market approval ("PMA") to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment upon receipt of the United States regulatory approval, and the remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

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.

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 Statement of Financial Accounting Standards (“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.

The Company sold its perfusion product line in Japan to Terumo Corporation, and in 2006 recorded a \$5.7 million gain related to the receipt of an earn-out payment.

#### *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 No. 87, “*Employers’ Accounting for Pensions*” (“SFAS 87”) and SFAS No. 158, “*Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans—an amendment of FASB Statements No. 87, 88, 106, and 132(R)*” (“SFAS 158”), 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 to correct this error. The Company concluded that the impact for the increase in the pension obligation was not material to the 2007 or prior years’ consolidated financial statements.

#### *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 and subsequently paid \$9.8 million in 2007. 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 of intangible assets. In addition, the Company recorded a \$2.0 million charge to cost of goods sold related to the disposal of inventory.

#### *Interest Expense*

Interest expense was \$7.2 million, \$9.1 million, and \$10.5 million in 2008, 2007, and 2006, respectively. The \$1.9 million decrease in interest expense for 2008 resulted primarily from lower interest rates as compared to the prior year. The \$1.4 million decrease in interest expense for 2007 resulted primarily from a lower average debt balance as compared to the prior year.

#### *Interest Income*

Interest income was \$6.1 million, \$7.7 million, and \$7.8 million in 2008, 2007, and 2006, respectively. The \$1.6 million decrease in interest income for 2008 resulted primarily from lower average interest rates. The \$0.1 million decrease in interest income for 2007 resulted from slightly lower average interest rates.

***Other Expense (Income), net***

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

	Years Ended December 31,		
	2008	2007	2006
Foreign exchange losses (gains), net . . . . .	\$ 7.2	\$(2.0)	\$(0.3)
Investment impairment and realized losses . . . . .	3.0	0.7	—
Accounts receivable securitization costs . . . . .	1.6	3.0	2.6
Gain on sale of property development rights . . . . .	(0.5)	—	—
Gain on investments in unconsolidated affiliates . . . . .	(2.0)	(1.3)	—
Gain on sale of product line . . . . .	—	(2.3)	—
Other . . . . .	(1.6)	—	0.4
	<u>\$ 7.7</u>	<u>\$(1.9)</u>	<u>\$ 2.7</u>

The foreign exchange losses (gains) relate to the foreign currency fluctuations on the Company's global trade and intercompany receivable and payable balances. Foreign exchange resulted in a net loss in 2008 compared to a net gain in 2007 due primarily to fluctuations in the Euro and the Japanese yen.

The investment impairment and realized losses represents the realized losses and estimated impairment in the value of the Company's investment in the Bank of America Columbia Strategic Cash fund. See the "Liquidity and Capital Resources" section for further information.

The decrease in securitization costs in 2008 was due primarily to the Company's termination of its securitization program in the United States in August 2008. The increase in securitization costs in 2007 was due to increases in average interest rates and higher average securitized balances.

The gain on investments in unconsolidated affiliates primarily represents realized gains on the Company's available-for-sale investments and the Company's share of gains and losses in investments accounted for under the equity method.

In March 2007, the Company sold the United States distribution rights and inventory associated with the TMR laser product line to Novadaq Technologies, Inc. ("Novadaq") 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 Expense (Income), net."

### *Provision for Income Taxes*

The effective income tax rates for 2008, 2007, and 2006 were impacted as follows (in millions):

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Income tax expense at U.S. federal statutory rate . . . . .	\$ 57.5	\$ 52.4	\$ 60.3
Foreign income tax at different rates . . . . .	(26.4)	(21.4)	(19.8)
Nondeductible goodwill . . . . .	12.2	—	—
Reserve for uncertain tax positions for prior years . . . . .	(6.2)	1.2	(5.6)
Tax credits, federal and state . . . . .	(3.5)	(2.8)	(2.0)
State and local taxes, net of federal tax benefit . . . . .	2.0	3.1	4.7
Nondeductible stock-based compensation . . . . .	0.9	1.9	2.2
Deemed dividends, net of foreign tax credit . . . . .	0.6	3.2	4.2
Valuation allowance for loss on investments . . . . .	—	(0.6)	(7.0)
Nondeductible PVT milestone payment . . . . .	—	—	3.5
Other . . . . .	(1.6)	(0.2)	1.3
Income tax provision . . . . .	<u>\$ 35.5</u>	<u>\$ 36.8</u>	<u>\$ 41.8</u>

#### *Nondeductible Goodwill*

During 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. A \$34.6 million write-off of goodwill associated with this product line was recorded. This amount is not deductible for tax purposes.

#### *Reserve for Uncertain Tax Positions*

As of December 31, 2008 and 2007, the liability for income taxes associated with uncertain tax positions was \$35.9 million and \$36.4 million, respectively. These liabilities could be reduced by \$2.3 million and \$8.0 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amounts of \$33.6 million and \$28.4 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Unrecognized tax benefits, January 1 . . . . .	\$ 36.4	\$24.6
Increase prior period tax positions . . . . .	12.3	12.1
Decrease prior period tax positions . . . . .	(19.9)	(7.9)
Current year tax positions . . . . .	18.0	8.6
Settlements . . . . .	(10.9)	(0.9)
Lapse of statute of limitations . . . . .	—	(0.1)
Unrecognized tax benefits, December 31 . . . . .	<u>\$ 35.9</u>	<u>\$36.4</u>

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2008, the Company had accrued \$1.9 million (net of \$0.5 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 uncertain 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 penalty and 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 closed during 2008. During 2009, the IRS is expected to initiate an audit of the 2007 tax year.

As a result of the on-going 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, 2008, the Company has concluded all United States federal income tax matters for years through 2006. All material state, local, and foreign income tax matters have been concluded for years through 2003.

#### *Nondeductible Stock-based Compensation*

Some of the costs recognized in accordance with SFAS No. 123 (Revised 2004), “*Share-Based Payment*” (“SFAS 123R”) are not deductible in the United States or in foreign countries.

#### *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 in the appropriate period with which to offset these expected capital losses. Due to the uncertainty of the ready marketability of certain of these impaired investments, the Company has recorded valuation allowances against these deferred tax assets as they have accumulated. As of December 31, 2008, deferred tax assets and corresponding valuation allowances of approximately \$4.3 million had accumulated related to investments. Of the total valuation allowance of \$4.3 million, \$2.2 million was recorded during 2008 as a component of “*Other Comprehensive (Loss) Income.*” The remaining \$2.1 million had previously been recorded as of December 31, 2007 through charges to profit and loss.

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

During 2006, the Company recognized capital gains from the sale of a non-strategic business and 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 \$7.0 million were reversed in 2006.

#### *Nondeductible PVT Milestone Payment*

During 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.

## Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities, and cash from operations. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments. The Company is not currently experiencing any limitation on access to its credit facility as a result of the recent turmoil in global financial markets. 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. As a result of the recent turmoil in the global financial market, as well as other factors, the unfunded portion of the Company's pension obligation has increased significantly from the prior year (See Note 11 to the "*Consolidated Financial Statements*"). As a result, the Company expects that the net periodic benefit cost in future periods will increase. In 2009, the Company is expecting to make a contribution of approximately \$3.3 million.

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 are expected to be refinanced pursuant to the Credit Agreement. As of December 31, 2008, borrowings of \$175.5 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, 2008.

On May 9, 2008, the Company called for redemption its \$150.0 million of convertible senior debentures (the "Notes"). Prior to the redemption date of June 9, 2008, holders of approximately \$147.7 million principal amount of the Notes converted their debentures into approximately 2.7 million shares of Edwards common stock at a conversion price of \$54.66 per share. The remaining outstanding Notes of \$2.3 million were redeemed for cash on the redemption date.

The Company securitizes, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in Japan and, until August 2008, in the United States. The benefits of the securitizations were traditionally 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. In August 2008, the Company terminated its securitization program in the United States, and repurchased \$50.0 million of accounts receivable, as the program no longer offered an attractive financing alternative. As of December 31, 2008, the Company had sold, under its Japan securitization program, a total of \$44.4 million of trade accounts receivable and received funding of \$37.7 million. The securitization program in Japan will expire on February 28, 2009, and the Company does not plan to renew it as the program no longer offers an attractive financing alternative. This will result in a reduction in cash flows from operating activities in the first quarter of 2009 of approximately \$45 million.

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. During the year ended December 31, 2008, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$3.0 million, included in "*Other Expense (Income), net.*" During 2008, the Company received cash redemptions of \$35.5 million. The fair value of the Company's remaining investment in this fund as of December 31, 2008 and 2007 was estimated to be \$10.9 million and \$49.4 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the

timing of the expected redemptions, the Company expects to receive cash redemptions for approximately \$8.1 million during 2009, which has been classified as “*Short-term Investments*” on the Company’s consolidated balance sheet as of December 31, 2008. The remaining \$2.8 million of the investment is expected to be received after December 31, 2009, and has been classified as “*Other Assets*.”

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* peripheral vascular product line. This divestiture was part of the Company’s ongoing strategy to focus resources on its core Heart Valve and Critical Care product lines. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and is entitled to 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 December 2008, the Company recorded a gain of \$23.0 million for the receipt of a *LifeStent* milestone payment in connection with the transfer of its PMA to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment upon receipt of the United States regulatory approval, and the remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

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 \$250.0 million of the Company’s common stock. In July 2008, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 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 and reduce the total shares outstanding. During 2008, the Company repurchased 5.8 million shares at an aggregate cost of \$306.5 million and has remaining authority under the July 2008 program to purchase \$193.5 million of the Company’s common stock.

Net cash flows provided by **operating activities** of \$153.2 million for 2008 decreased \$59.9 million from 2007 primarily due to a \$50.0 million cash payment during 2008 to terminate the Company’s accounts receivable securitization program in the United States. In addition, 2008 operating cash flow was negatively impacted by net cash outflows from the Japan accounts receivable securitization program, partially offset by net cash inflows resulting from an increase in accounts payable and accrued liabilities in 2008.

Net cash flows provided by operating activities of \$213.1 million for 2007 decreased \$19.6 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 provided by **investing activities** of \$58.8 million in 2008 consisted primarily of \$97.0 million of cash received from the sale of the *LifeStent* product line and a related milestone achievement, and \$35.5 million in cash redemptions associated with the Bank of America Columbia Strategic Cash fund, partially offset by capital expenditures of \$50.6 million and a \$27.4 million purchase of intangible assets, primarily due to the acquisition of technology and intellectual property.

Net cash used in investing activities of \$147.4 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 previously, (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 2004 PVT acquisition.

Net cash used in **financing activities** of \$134.1 million in 2008 consisted primarily of purchases of treasury stock of \$306.5 million, partially offset by net proceeds from long-term debt of \$94.2 million and the proceeds from stock plans of \$63.8 million.

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.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2008 were as follows (in millions):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less Than 1 Year</u>	<u>1-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Long-term debt . . . . .	\$175.5	\$ —	\$175.5	\$ —	\$ —
Interest on long-term debt . . . . .	4.7	1.7	3.0	—	—
Operating leases . . . . .	51.2	16.3	19.9	9.1	5.9
Pension obligation(a) . . . . .	3.3	3.3	—	—	—
Contractual development obligations(b) . . . . .	40.0	17.3	17.3	5.4	—
Capital commitment obligations(c) . . . . .	5.5	2.8	2.7	—	—
Total contractual cash obligations(d) . . . . .	<u>\$280.2</u>	<u>\$41.4</u>	<u>\$218.4</u>	<u>\$14.5</u>	<u>\$5.9</u>

- (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, 2008 was \$32.5 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, the Company did not include this amount in the contractual obligations table. See Note 11 to the "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, 2008, the liability for uncertain tax positions including interest was \$38.4 million. Due to the high degree of uncertainty regarding the timing of potential cash flows associated with these liabilities, the Company is 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, the valuation of goodwill and other intangible assets, the allocation of purchase price for acquisitions, 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 the 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 GPOs 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 customers' contracted rebate programs and 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 not significant because returns are generally 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 \$9.9 million and \$7.5 million at December 31, 2008 and 2007, 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), is damaged, or slow moving (defined as quantities in excess of a two year supply). The allowance for excess and obsolete inventory was \$13.2 million and \$14.9 million at December 31, 2008 and 2007, respectively.

### ***Patent Costs***

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes certain legal costs related to the defense and enforcement of issued patents and trademarks. These capitalized legal costs are amortized over the life of the related patent or trademark. Such legal costs are periodically reviewed for impairment and recoverability.

### ***Impairment of Long-Lived Assets***

The Company evaluates the carrying value of goodwill in the fourth quarter of each fiscal year. In evaluating goodwill, the Company completes the two-step goodwill impairment test as required by SFAS No. 142, "*Goodwill and Other Intangible Assets*" ("SFAS 142"). The Company identifies its reporting units and determines the carrying value of each reporting unit by assigning the assets and liabilities, including existing goodwill, to those reporting units. The fair value of the reporting unit is estimated based on the market capitalization and a market revenue multiple. If the carrying amount of the reporting unit exceeds its fair value, the Company will perform the second step of the impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit's goodwill with its carrying value. Since the adoption of SFAS 142, the Company has not performed the second step of the impairment test as the fair value of each reporting unit has exceeded its respective carrying value.

Additionally, in accordance with SFAS 142 and SFAS 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* (“SFAS 115”). These investments are carried at fair market value, with unrealized gains and losses reported in stockholders’ equity as *Accumulated Other Comprehensive (Loss) Income*. 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 an available-for-sale 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 recognized 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 these guidelines, 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 upon its 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*

The Company measures and recognizes 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). Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

### *Fair Value Measurements*

On January 1, 2008, the Company adopted SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"), with respect to its financial assets and liabilities and non-financial assets and liabilities that are measured at fair value on a recurring basis. The Company has deferred the application of the provisions of this statement for its non-financial assets and liabilities in accordance with FASB Staff Position ("FSP") 157-2, "*Effective Date of FASB Statement No. 157*" ("FSP 157-2"). Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In determining fair value, the Company uses various valuation approaches, including market, income and/or cost approaches, and considers the principal or most advantageous market in which it would transact and assumptions that market participants would use when pricing the asset or liability. Upon adoption of SFAS 157, the Company applied the following fair value hierarchy:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3—Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

When possible, the Company looks to active and observable markets to price identical assets or liabilities. When identical assets or liabilities are not traded in active markets, the Company looks to market observable data for similar assets and liabilities. If observable market prices are unavailable or impracticable to obtain, the Company must use alternative valuation techniques to derive a fair value measurement. The Company has procedures to independently verify and test valuations received from third parties.

The financial assets and liabilities that the Company records at fair value include investments in marketable securities, residual interests in securitizations, and derivative instruments.

#### *Investments in Marketable Securities*

- Bank of America Columbia Strategic Cash Fund

The Company holds an investment 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 remaining investment in this fund was estimated based on the net asset value of the fund. As of December 31, 2008, the net asset value of the fund was 82.66% of par.

The fair value of the underlying securities held by the fund was determined based on quoted market prices or broker quotes, when possible. In the absence of observable market quotations, the underlying securities were valued based on alternative valuation techniques using inputs that may not be observable.

In these cases, the fair value was based on available information believed to be reliable, which may be affected by conditions in the financial markets. Different market participants may reach different opinions as to the value of any particular security based on their varying market outlooks, the market information available to them, and the particular circumstances of their portfolios. A decrease in the net asset value of 1%, or 83 basis points, would result in a decrease of approximately \$0.1 million in the investment fair value. The Company's investment in the fund is categorized as Level 3 based on the lowest level input that is significant to the fair value measurement in its entirety.

- Investments Held for the Executive Deferred Compensation Plan

The Company holds investments in trading securities related to its executive deferred compensation plan. The fair values of the securities are based on quoted market prices and are categorized as Level 1.

- Investments in Unconsolidated Affiliates

Certain of the Company's investments in unconsolidated affiliates are designated as available-for-sale in accordance with the provisions of SFAS 115. These investments are carried at fair market value based on quoted market prices and are categorized as Level 1.

#### *Residual Interest in Securitizations*

When the Company sells accounts receivable securitizations, a subordinated residual interest in the securitized portfolio is retained by the Company. The Company estimates the fair value of the residual interest using the net carrying amount of the accounts receivables less the discount paid on the sale of the receivables. This amount is calculated using future expected credit losses and calculated contractual rebates to distributors to determine the future expected cash flows, which generally approximate fair value given the securitized portfolio's short-term weighted-average life. Reserves for credit losses included in the allowance for doubtful accounts are adjusted based on management's assessment of recovery.

The United States securitization program was terminated in August 2008 and all receivables sold under this facility were repurchased by the Company. The residual interest in the Japan securitization program is categorized as Level 3.

#### *Derivative Instruments*

The Company uses forward exchange contracts and option contracts to hedge a portion of its exposure to forecasted intercompany and third party foreign currency transactions. All derivatives are recognized on the balance sheet at their fair value. The fair value for derivatives is determined based on indicative mid-market data levels for spot rate and forward points as of the close of business on December 31, 2008. All values are discounted to present from the expiry date. The values of options are calculated based on the forward implied volatilities to the expiry date. The models used for valuations are based upon well recognized financial principles, and the predominance of market inputs are actively quoted and can be validated through external sources. Although readily observable data is used in the valuations, different valuation methodologies could have an effect on the estimated fair value. The derivative instruments are categorized as Level 2.

### **Recently Adopted Accounting Standards**

In September 2006, the FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FSP 157-2, which delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FSP 157-3, "*Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*" ("FSP 157-3"). FSP 157-3 clarifies the

application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not yet been issued. The Company's adoption of SFAS 157, except as it applies to those non-financial assets and liabilities affected by the one-year delay, did not have a material impact on the Company's consolidated financial statements. The Company does not expect the adoption of SFAS 157 related to its non-financial assets and liabilities to have a material impact on its consolidated financial statements. The adoption of FSP 157-3 did not have an impact on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS 158. 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 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 was effective for the Company for the fiscal year ending December 31, 2008. SFAS 158 provides two approaches for transitioning to a fiscal year-end measurement date. The Company adopted the measurement date provisions using the "one measurement" approach. Under this approach, the Company used the measurement determined as of October 31, 2007 and recognized the net benefit expense for the transition period from November 1 through December 31, 2007 in retained earnings at December 31, 2008. The adoption of the measurement date provisions of SFAS 158 resulted in a \$0.6 million reduction of retained earnings.

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 115, 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. The Company adopted SFAS 159 effective January 1, 2008. The Company has not elected the fair value option for its financial instruments. As required by SFAS 159, the Company has reclassified all cash flows related to its trading securities from operating to investing activities in the consolidated statements of cash flows.

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 adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, "*The Hierarchy of Generally Accepted Accounting Principles*" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 was effective November 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In September 2008, the FASB issued FSP 133-1 and FIN 45-4, "*Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161*" ("FSP 133-1 and FIN 45-4"). FSP 133-1 and FIN 45-4 amends and enhances disclosure requirements for sellers of credit derivatives and financial

guarantees. It also clarifies that the disclosure requirements of SFAS No. 161, “*Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*” (“SFAS 161”), are effective for quarterly periods beginning after November 15, 2008, and fiscal years that include those periods. FSP 133-1 and FIN 45-4 was effective for reporting periods (annual or interim) ending after November 15, 2008. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

In December 2008, the FASB issued FSP 140-4 and FIN 46(R)-8, “*Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities*” (“FSP 140-4 and FIN 46(R)-8”). FSP 140-4 and FIN 46(R)-8 requires additional disclosures about an entity’s involvement with variable interest entities and transfers of financial assets. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

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

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 impact the Company if it is involved in a business combination.

In March 2008, the FASB issued SFAS 161. SFAS 161 requires enhanced disclosures about an entity’s derivative instruments and hedging activities, including (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for, and (c) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect the adoption of SFAS 161 to have a material impact on its consolidated financial statements.

In April 2008, the FASB issued FSP 142-3, “*Determination of the Useful Life of Intangible Assets*” (“FSP 142-3”). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of FSP 142-3 to have a material impact on its consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-6, “*Equity Method Investment Accounting Considerations*” (“EITF 08-6”). EITF 08-6 clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company does not expect the adoption of EITF 08-6 to have a material impact on its consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-7, “*Accounting for Defensive Intangible Assets*” (“EITF 08-7”). EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over a period the asset diminishes in value. EITF 08-7 is effective for fiscal years

beginning after December 15, 2008, with early adoption prohibited. The Company does not expect the adoption of EITF 08-7 to have a material impact on its consolidated financial statements.

In December 2008, the FASB issued FSP 132(R)-1, "*Employers' Disclosures about Postretirement Benefit Plan Assets*" ("FSP 132(R)-1"). FSP 132(R)-1 requires additional disclosures about (a) how investment allocation decisions are made by management, (b) major categories of plan assets, (c) inputs and valuation techniques used to develop fair value measurements, including disclosures similar to that required under SFAS 157, and (d) significant concentrations of risk. FSP 132(R)-1 is effective for fiscal years ending after December 15, 2009. The Company does not expect the adoption of FSP 132(R)-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, 2008 and 2007 were \$225.1 million and \$336.2 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, 2008.

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 14 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, 2008 and 2007 with a maturity of up to one year, was \$5.7 million and \$5.1 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 counterparty should default, and market risk as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counterparty diversification, monitoring of counterparty financial condition and master-netting agreements in place with all derivative counterparties. Credit exposure of derivative financial instruments is represented by the fair value effects of contracts with a positive fair value at December 31, 2008 reduced by the effects of master-netting agreements. Additionally, at December 31, 2008, all derivative financial instruments were with commercial banks and investment banking firms assigned investment grade ratings of “A” or better by national rating agencies. The Company does not anticipate non-performance by its counterparties and has no reserves related to non-performance as of December 31, 2008. 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 2008, 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, 2008, Edwards Lifesciences had approximately \$14.7 million of investments in equity instruments of other companies and had recorded unrealized losses of \$5.7 million on these investments in “*Accumulated Other Comprehensive (Loss) Income*,” 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 holds an investment 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. During the year ended December 31, 2008, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$3.0 million, included in “*Other Expense (Income), net*.” During 2008, the Company received cash redemptions of \$35.5 million. The fair value of the Company’s remaining investment in this fund as of December 31, 2008 was estimated to be \$10.9 million based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions for approximately \$8.1 million through the fourth quarter of 2009, which has been classified as “*Short-term Investments*” on the Company’s consolidated balance sheet as of December 31, 2008. The remaining \$2.8 million of the investment is expected to be received after December 31, 2009, and has been classified as “*Other Assets*.” The markets relating to these investments are subject to ongoing illiquidity and remain uncertain. There may be further decreases in the value of these investments until the fund is fully liquidated.

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

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DECEMBER 31, 2008**

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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, 2008 and December 31, 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 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, 2008, 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 Over Financial Reporting*." 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 uncertain tax positions in 2007.

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

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

PricewaterhouseCoopers LLP  
Orange County, California  
February 27, 2009

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

	December 31,	
	2008	2007
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents . . . . .	\$ 218.7	\$ 141.8
Short-term investments (Note 2) . . . . .	8.1	49.4
Accounts receivable, net (Note 5) . . . . .	186.3	115.8
Other receivables . . . . .	18.4	29.5
Inventories, net . . . . .	151.8	152.6
Deferred income taxes . . . . .	42.4	30.2
Prepaid expenses . . . . .	30.7	25.4
Other current assets . . . . .	35.5	41.7
Total current assets . . . . .	691.9	586.4
Property, plant and equipment, net . . . . .	230.1	228.2
Goodwill (Notes 3 and 7) . . . . .	315.7	350.3
Other intangible assets, net . . . . .	96.9	122.5
Investments in unconsolidated affiliates . . . . .	14.7	34.3
Deferred income taxes . . . . .	37.7	13.8
Other assets . . . . .	13.2	14.3
Total assets . . . . .	\$1,400.2	\$1,349.8
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable . . . . .	\$ 65.6	\$ 63.9
Accrued liabilities . . . . .	186.7	161.5
Taxes payable . . . . .	6.2	4.7
Convertible debt (Note 9) . . . . .	—	150.0
Total current liabilities . . . . .	258.5	380.1
Long-term debt . . . . .	175.5	61.7
Other long-term liabilities . . . . .	87.4	73.0
Commitments and contingencies (Notes 9 and 16)		
<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, 73.7 and 68.6 shares issued, and 55.9 and 56.6 shares outstanding, respectively . . . . .	73.7	68.6
Additional paid-in capital . . . . .	940.4	680.6
Retained earnings . . . . .	676.9	548.6
Accumulated other comprehensive (loss) income . . . . .	(35.4)	7.5
Treasury stock, at cost, 17.8 and 12.0 shares, respectively . . . . .	(776.8)	(470.3)
Total stockholders' equity . . . . .	878.8	835.0
Total liabilities and stockholders' equity . . . . .	\$1,400.2	\$1,349.8

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)

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net sales . . . . .	\$1,237.7	\$1,091.1	\$1,037.0
Cost of goods sold . . . . .	419.6	378.2	373.6
Gross profit . . . . .	818.1	712.9	663.4
Selling, general and administrative expenses . . . . .	480.6	418.0	376.0
Research and development expenses . . . . .	139.2	122.3	114.2
Special charges (gains), net (Note 3) . . . . .	25.1	23.3	(4.5)
Interest expense . . . . .	7.2	9.1	10.5
Interest income . . . . .	(6.1)	(7.7)	(7.8)
Other expense (income), net (Note 14) . . . . .	7.7	(1.9)	2.7
Income before provision for income taxes . . . . .	164.4	149.8	172.3
Provision for income taxes . . . . .	35.5	36.8	41.8
Net income . . . . .	<u>\$ 128.9</u>	<u>\$ 113.0</u>	<u>\$ 130.5</u>
<b>Share information</b> (Note 2):			
Earnings per share:			
Basic . . . . .	\$ 2.31	\$ 1.97	\$ 2.23
Diluted . . . . .	\$ 2.19	\$ 1.87	\$ 2.10
Weighted-average number of common shares outstanding:			
Basic . . . . .	55.8	57.3	58.5
Diluted . . . . .	59.6	62.7	63.9

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

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

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>			
Net income . . . . .	\$ 128.9	\$ 113.0	\$ 130.5
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization . . . . .	55.6	54.8	56.8
Stock-based compensation (Notes 2 and 12) . . . . .	28.7	27.7	26.6
Deferred income taxes . . . . .	(23.5)	(5.6)	7.1
Special charges, net . . . . .	25.4	14.9	19.3
Loss (gain) on trading securities . . . . .	4.9	0.3	(0.8)
Loss on investments . . . . .	3.0	0.7	—
Other . . . . .	(0.3)	1.5	5.4
Changes in operating assets and liabilities:			
Accounts and other receivables, net (Note 5) . . . . .	(61.1)	(6.6)	2.5
Accounts receivable securitization (Note 5) . . . . .	(7.4)	11.9	0.9
Inventories, net . . . . .	(17.8)	(9.0)	(12.8)
Accounts payable and accrued liabilities . . . . .	32.9	14.0	(3.9)
Prepaid expenses and other current assets . . . . .	(3.3)	(5.8)	1.5
Other . . . . .	(12.8)	1.3	(0.4)
Net cash provided by operating activities . . . . .	<u>153.2</u>	<u>213.1</u>	<u>232.7</u>
<b>Cash flows from investing activities</b>			
Capital expenditures . . . . .	(50.6)	(57.0)	(57.4)
Proceeds from sale of assets (Note 3) . . . . .	97.0	7.2	22.2
Investments in intangible assets . . . . .	(27.4)	(5.5)	(2.0)
Proceeds from unconsolidated affiliates . . . . .	5.5	1.4	0.4
Investments in unconsolidated affiliates . . . . .	(1.1)	(3.9)	(1.8)
Investments in trading securities, net . . . . .	(0.2)	(2.0)	(1.9)
Transfer to short-term investments (Note 2) . . . . .	—	(55.0)	—
Proceeds from short-term investments (Note 2) . . . . .	35.5	4.9	—
Acquisitions and milestone payment (Notes 3 and 6) . . . . .	—	(37.0)	—
Other . . . . .	0.1	(0.5)	2.9
Net cash provided by (used in) investing activities . . . . .	<u>58.8</u>	<u>(147.4)</u>	<u>(37.6)</u>
<b>Cash flows from financing activities</b>			
Purchases of treasury stock . . . . .	(306.5)	(130.9)	(145.9)
Proceeds from issuance of long-term debt . . . . .	206.3	57.3	54.8
Payments on long-term debt . . . . .	(112.1)	(85.2)	(140.7)
Proceeds from stock plans . . . . .	63.8	38.7	33.5
Excess tax benefit from stock plans (Notes 2 and 12) . . . . .	14.9	8.6	5.2
Other . . . . .	(0.5)	3.4	(0.5)
Net cash used in financing activities . . . . .	<u>(134.1)</u>	<u>(108.1)</u>	<u>(193.6)</u>
Effect of currency exchange rate changes on cash and cash equivalents . . . . .	(1.0)	1.4	2.7
Net increase (decrease) in cash and cash equivalents . . . . .	76.9	(41.0)	4.2
Cash and cash equivalents at beginning of year . . . . .	141.8	182.8	178.6
Cash and cash equivalents at end of year . . . . .	<u>\$ 218.7</u>	<u>\$ 141.8</u>	<u>\$ 182.8</u>
<b>Supplemental disclosures:</b>			
Cash paid during the year for:			
Interest . . . . .	\$ 7.3	\$ 9.0	\$ 10.5
Income taxes . . . . .	\$ 37.2	\$ 31.0	\$ 14.3
Non-cash transactions:			
Issuance of common shares in redemption of convertible debt (Note 9) . . . . .	\$ 147.7	\$ —	\$ —
Investment received in exchange for assets (Note 3) . . . . .	\$ —	\$ —	\$ 6.4

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

**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND**  
**COMPREHENSIVE INCOME (LOSS)**

(in millions)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount			Comprehensive Income (Loss)		
<b>BALANCE AT DECEMBER 31, 2005</b>	65.6	\$65.6	6.0	\$(193.5)	\$536.7	\$303.4	\$(22.2)	\$ 690.0	
Comprehensive income									
Net income						130.5		130.5	\$130.5
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							11.8	11.8	11.8
Unrealized loss on cash flow hedges							(5.2)	(5.2)	(5.2)
Unrealized gain on available-for-sale investments							2.0	2.0	2.0
Minimum pension liability adjustment							2.1	2.1	2.1
Impact of SFAS 158, net of tax							(4.3)	(4.3)	
Common stock issued under equity plans	1.4	1.4			32.1			33.5	
Tax benefit related to equity plans					8.3			8.3	
Stock-based compensation expense					26.6			26.6	
Purchase of treasury stock			3.3	(145.9)				(145.9)	
<b>BALANCE AT DECEMBER 31, 2006</b>	67.0	67.0	9.3	(339.4)	603.7	433.9	(15.8)	749.4	<u>\$141.2</u>
Comprehensive income									
Net income						113.0		113.0	\$113.0
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							19.1	19.1	19.1
Unrealized loss on cash flow hedges							(6.2)	(6.2)	(6.2)
Unrealized gain on available-for-sale investments							6.1	6.1	6.1
Defined benefit pension plans:									
Net prior service cost							2.5	2.5	2.5
Net gain							1.8	1.8	1.8
Cumulative effect of the adoption of FIN 48						1.7		1.7	
Common stock issued under equity plans	1.6	1.6			37.1			38.7	
Tax benefit related to equity plans					12.1			12.1	
Stock-based compensation expense					27.7			27.7	
Purchase of treasury stock			2.7	(130.9)				(130.9)	
<b>BALANCE AT DECEMBER 31, 2007</b>	68.6	68.6	12.0	(470.3)	680.6	548.6	7.5	835.0	<u>\$136.3</u>

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



**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND**  
**COMPREHENSIVE INCOME (LOSS) (Continued)**

(in millions)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount					
<b>BALANCE AT DECEMBER 31, 2007</b>	68.6	68.6	12.0	(470.3)	680.6	548.6	7.5	835.0	
Comprehensive income									
Net income						128.9		128.9	\$128.9
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							(24.2)	(24.2)	(24.2)
Unrealized gain on cash flow hedges							4.9	4.9	4.9
Unrealized loss on available-for-sale investments							(13.2)	(13.2)	(13.2)
Defined benefit pension plans:									
Net prior service cost (Note 13)							(0.3)	(0.3)	(0.3)
Net loss							(10.1)	(10.1)	(10.1)
Effects of changing the pension plan measurement date pursuant to SFAS 158:									
Service and interest cost, and expected return on plan assets for November 1—December 31, 2007, net of tax (Note 11)						(0.6)		(0.6)	
Common stock issued under equity plans	2.4	2.4			61.4			63.8	
Issuance of shares for convertible debt	2.7	2.7			145.0			147.7	
Tax benefit related to equity plans					20.8			20.8	
Tax benefit due to redemption of convertible debt and other					3.9			3.9	
Stock-based compensation expense					28.7			28.7	
Purchase of treasury stock			5.8	(306.5)				(306.5)	
<b>BALANCE AT DECEMBER 31, 2008</b>	<u>73.7</u>	<u>\$73.7</u>	<u>17.8</u>	<u>\$(776.8)</u>	<u>\$940.4</u>	<u>\$676.9</u>	<u>\$(35.4)</u>	<u>\$ 878.8</u>	<u>\$ 86.0</u>

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS**

Edwards Lifesciences Corporation (“Edwards Lifesciences” or the “Company”) is a global provider of products and technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences is focused specifically on technologies that treat structural heart disease and critically ill patients.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease are categorized into four main areas: Heart Valve Therapy, Critical Care, Cardiac Surgery Systems, and Vascular. Previously, Edwards Lifesciences provided Other Distributed Products, which primarily included sales of intra-aortic balloon pumps. This business was terminated at the end of 2007. The Company’s Heart Valve Therapy products include tissue heart valves and heart valve repair products. The Critical Care products include hemodynamic monitoring equipment used to measure a patient’s cardiovascular function, disposable pressure transducers, and central venous access products for fluid and drug delivery. The Company’s Cardiac Surgery Systems products include a diverse line of products for use during cardiac surgery including cannula, the *Embol-X* intra-aortic filtration system, and certain other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also included transmyocardial revascularization (“TMR”) products until March 2007 when 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. The Vascular products include a line of balloon catheter-based products, surgical clips and inserts, artificial implantable grafts, and stents (“*LifeStent*” products) for which approval is being sought for use in the treatment of peripheral vascular disease. The Company sold the *LifeStent* product line in January 2008, but will continue to manufacture these products for the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The principles of Financial Accounting Standards Board (“FASB”) Interpretation No. 46, “*Consolidation of Variable Interest Entities*,” Statement of Financial Accounting Standards (“SFAS”) No. 94, “*Consolidation of All Majority-Owned Subsidiaries (an Amendment of ARB No. 51, with Related Amendments of APB Opinion No. 18 and ARB No. 43, Chapter 12)*,” and Accounting Research Bulletin No. 51, “*Consolidated Financial Statements*,” are considered when determining whether an entity is subject to consolidation. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

**Use of Estimates**

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with Generally Accepted Accounting Principles in the United States (“GAAP”) which have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. Estimates are used in accounting for, among other items, sales returns and reserves, rebate reserves, allowances for doubtful accounts, reserves for excess and obsolete inventory, investments in unconsolidated affiliates, the valuation of goodwill and other intangible assets, the allocation of purchase price for acquisitions, workers compensation liabilities, employee benefit

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

related liabilities, income taxes, asset impairments, forecasted transactions to be hedged, litigation reserves, and contingencies.

**Foreign Currency Translation**

The Company follows the principles of SFAS No. 52, "*Foreign Currency Translation*." Accordingly, when the local currency of its foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as "*Accumulated Other Comprehensive (Loss) Income*." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "*Other Expense (Income), net*."

**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 its 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 customers' contracted rebate programs and 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 not significant

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

because returns are generally 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.

**Cash Equivalents**

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

**Investments**

The Company holds an investment 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. During the years ended December 31, 2008 and 2007, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$3.0 million and \$0.7 million, respectively, included in "*Other Expense (Income), net.*" During 2008, the Company received cash redemptions of \$35.5 million. The fair value of the Company's remaining investment in this fund as of December 31, 2008 and 2007 was estimated to be \$10.9 million and \$49.4 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions for approximately \$8.1 million through the end of 2009, which has been classified as "*Short-term Investments*" on the accompanying consolidated balance sheet as of December 31, 2008. The remaining \$2.8 million of the investment is expected to be received after December 31, 2009, and has been classified as "*Other Assets.*" The entire investment of \$49.4 million at December 31, 2007 was classified as "*Short-term Investments*" based on the redemption schedule communicated to the Company at that time.

**Accounts Receivable Securitization**

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

**Inventories**

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

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

two year supply). Reserves for excess and obsolete inventory were approximately \$13.2 million and \$14.9 million at December 31, 2008 and 2007, respectively.

The Company allocates general and administrative costs to inventory that are related to the production process. These costs include insurance, manufacturing accounting personnel, human resources, and information technology. During the years ended December 31, 2008, 2007, and 2006, the Company allocated \$21.3 million, \$20.1 million, and \$18.4 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2008 and 2007 were \$8.8 million and \$9.0 million, respectively.

**Property, Plant and Equipment**

Property, plant and equipment are recorded at cost. Depreciation is principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 10 to 40 years for buildings and improvements, from 3 to 15 years for machinery and equipment, and from 3 to 10 years for software. Leasehold improvements are amortized over the life of the related facility leases or the asset, whichever is shorter. Straight-line and accelerated methods of depreciation are used for income tax purposes.

Depreciation expense for property, plant and equipment was \$36.8 million, \$38.0 million, and \$39.2 million for the years ended December 31, 2008, 2007, and 2006, respectively. Repairs and maintenance expense was \$14.6 million, \$14.3 million, and \$14.3 million for the years ended December 31, 2008, 2007, and 2006, respectively.

**Impairment of Long-Lived Assets**

The Company evaluates the carrying value of goodwill in the fourth quarter of each fiscal year. In evaluating goodwill, the Company completes the two-step goodwill impairment test as required by SFAS No. 142, *“Goodwill and Other Intangible Assets”* (“SFAS 142”). The Company identifies its reporting units and determines the carrying value of each reporting unit by assigning the assets and liabilities, including existing goodwill, to those reporting units. The fair value of the reporting unit is estimated based on the market capitalization and a market revenue multiple. If the carrying amount of the reporting unit exceeds its fair value, the Company will perform the second step of the impairment test to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compares the implied fair value of a reporting unit’s goodwill with its carrying value. Since the adoption of SFAS 142, the Company has not performed the second step of the impairment test as the fair value of each reporting unit has exceeded its respective carrying value.

Additionally, in accordance with SFAS 142 and SFAS No. 144, *“Accounting for the Impairment or Disposal of Long-Lived Assets”* (“SFAS 144”), management reviews the carrying amounts of other intangible and long-lived tangible assets whenever events and circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit, and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

**Patent Costs**

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes certain legal costs related to the defense and enforcement of issued patents and trademarks. These capitalized legal costs are amortized over the life of the related patent or trademark. Such legal costs are periodically reviewed for impairment and recoverability.

**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”* (“SFAS 115”). These investments are carried at fair market value, with unrealized gains and losses reported in stockholders’ equity as *“Accumulated Other Comprehensive (Loss) Income.”* 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 an available-for-sale 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 recognized 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 these guidelines, 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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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.

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*" ("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. 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 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 upon its 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.

**Research and Development Costs**

Research and development costs are charged to expense when incurred.

**Earnings per Share**

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Employee equity share options, nonvested shares, and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of the conversion of convertible debt, restricted stock units, and in-the-money options. The dilutive impact of the restricted stock units and in-the-money options is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount that the employee must pay for exercising stock options, the amount of compensation expense for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital when the award becomes deductible are assumed to be used to repurchase shares. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

	Years ended December 31,		
	2008	2007	2006
Basic:			
Net income . . . . .	\$128.9	\$113.0	\$130.5
Weighted-average shares outstanding . . . . .	55.8	57.3	58.5
Basic earnings per share . . . . .	\$ 2.31	\$ 1.97	\$ 2.23
Diluted:			
Net income . . . . .	\$128.9	\$113.0	\$130.5
Interest expense related to convertible debt, net of tax . . . . .	1.7	4.0	4.0
Net income applicable to diluted shares . . . . .	\$130.6	\$117.0	\$134.5
Weighted-average shares outstanding . . . . .	55.8	57.3	58.5
Dilutive effect of convertible debt . . . . .	1.2	2.7	2.7
Dilutive effect of stock plans . . . . .	2.6	2.7	2.7
Diluted weighted-average shares outstanding . . . . .	59.6	62.7	63.9
Diluted earnings per share . . . . .	\$ 2.19	\$ 1.87	\$ 2.10

Stock options and restricted stock units to purchase approximately 1.9 million, 2.7 million, and 2.8 million shares for the years ended December 31, 2008, 2007, and 2006, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive. Diluted shares included the Company's \$150.0 million convertible debentures until they were redeemed on June 9, 2008.

**Stock-based Compensation**

The Company measures and recognizes 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 No. 123 (Revised 2004), "*Share-Based Payment*" ("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). Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

The Company attributes the value of restricted stock unit awards using the straight-line attribution method. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Total stock-based compensation expense recognized under SFAS 123R for the years ended December 31, 2008, 2007, and 2006 was as follows (in millions):

	December 31,		
	2008	2007	2006
Cost of goods sold . . . . .	\$ 2.7	\$ 3.0	\$ 3.4
Selling, general and administrative expenses . . . . .	21.2	19.8	18.4
Research and development expense . . . . .	4.8	4.9	4.8
Total stock-based compensation expense . . . . .	\$28.7	\$27.7	\$26.6

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

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

The Company applies the accelerated vesting schedule to all grants for employees that meet the retirement eligibility criteria for accelerated vesting upon retirement.

**Derivatives**

Edwards Lifesciences maintains an overall risk management strategy that may incorporate the use of a variety of interest rate and currency derivative financial instruments to mitigate its exposure to significant unplanned fluctuations in earnings and cash flow caused by volatility in interest rates and currency exchange rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy include interest rate swaps, option-based products, and forward exchange contracts. As of December 31, 2008, all derivative instruments owned are designated as hedges of underlying exposures. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

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

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

The Company formally documents all relationships between hedging instruments and hedged items, as well as its risk management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives that are designated as cash flow hedges of specific firm commitments or forecasted transactions. The Company also formally assesses (both at the hedge’s inception and on an ongoing basis) whether the derivatives that are used in hedging transactions have been highly effective in offsetting changes in the cash flows of hedged items and whether those derivatives may be expected to remain highly effective in future periods. All components of each derivative’s gain or loss are included in the assessment of hedge effectiveness.

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

When the Company discontinues hedge accounting because it is no longer probable that the forecasted transaction will occur in the originally expected period or within an additional two-month period of time thereafter, the gain or loss is reclassified into earnings. In a situation in which hedge accounting is discontinued and the derivative remains outstanding, the Company will carry the derivative at its fair value on the balance sheet, recognizing changes in the fair value in current-period earnings.

**Recently Adopted Accounting Standards**

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*” (“SFAS 157”), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB Staff Position (“FSP”) 157-2, “*Effective Date of FASB Statement No. 157*” (“FSP 157-2”), which delays the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FSP 157-3, “*Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*” (“FSP 157-3”). FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not yet been issued. The Company's adoption of SFAS 157, except as it applies to those non-financial assets and liabilities affected by the one-year delay, did not have a material impact on the Company's consolidated financial statements. The Company does not expect the adoption of SFAS 157 related to its non-financial assets and liabilities to have a material impact on its consolidated financial statements. The adoption of FSP 157-3 did not have an impact on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS No. 158, "*Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans—An Amendment of FASB Statements No. 87, 88, 106, and 132(R)*" ("SFAS 158"). 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 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 was effective for the Company for the fiscal year ending December 31, 2008. SFAS 158 provides two approaches for transitioning to a fiscal year-end measurement date. The Company adopted the measurement date provisions using the "one measurement" approach. Under this approach, the Company used the measurement determined as of October 31, 2007 and recognized the net benefit expense for the transition period from November 1 through December 31, 2007 in retained earnings at December 31, 2008. The adoption of the measurement date provisions of SFAS 158 resulted in a \$0.6 million reduction of retained earnings.

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 115, 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. The Company adopted SFAS 159 effective January 1, 2008. The Company has not elected the fair value option for its financial instruments. As required by SFAS 159, the Company has reclassified all cash flows related to its trading securities from operating to investing activities in the consolidated statements of cash flows.

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 adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, "*The Hierarchy of Generally Accepted Accounting Principles*" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 was effective November 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

In September 2008, the FASB issued FSP 133-1 and FIN 45-4, “*Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161*” (“FSP 133-1 and FIN 45-4”). FSP 133-1 and FIN 45-4 amends and enhances disclosure requirements for sellers of credit derivatives and financial guarantees. It also clarifies that the disclosure requirements of SFAS No. 161, “*Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB Statement No. 133*” (“SFAS 161”), are effective for quarterly periods beginning after November 15, 2008, and fiscal years that include those periods. FSP 133-1 and FIN 45-4 was effective for reporting periods (annual or interim) ending after November 15, 2008. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

In December 2008, the FASB issued FSP 140-4 and FIN 46(R)-8, “*Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities*” (“FSP 140-4 and FIN 46(R)-8”). FSP 140-4 and FIN 46(R)-8 requires additional disclosures about an entity’s involvement with variable interest entities and transfers of financial assets. The adoption of this standard did not have a material impact on the Company’s consolidated financial statements.

**New Accounting Standards Not Yet Adopted**

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 impact the Company if it is involved in a business combination.

In March 2008, the FASB issued SFAS 161. SFAS 161 requires enhanced disclosures about an entity’s derivative instruments and hedging activities, including (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for, and (c) how derivative instruments and related hedged items affect an entity’s financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect the adoption of SFAS 161 to have a material impact on its consolidated financial statements.

In April 2008, the FASB issued FSP 142-3, “*Determination of the Useful Life of Intangible Assets*” (“FSP 142-3”). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142. FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of FSP 142-3 to have a material impact on its consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-6, “*Equity Method Investment Accounting Considerations*” (“EITF 08-6”). EITF 08-6 clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 is

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company does not expect the adoption of EITF 08-6 to have a material impact on its consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets" ("EITF 08-7"). EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over a period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The Company does not expect the adoption of EITF 08-7 to have a material impact on its consolidated financial statements.

In December 2008, the FASB issued FSP 132(R)-1, "Employers' Disclosures about Postretirement Benefit Plan Assets" ("FSP 132(R)-1"). FSP 132(R)-1 requires additional disclosures about (a) how investment allocation decisions are made by management, (b) major categories of plan assets, (c) inputs and valuation techniques used to develop fair value measurements, including disclosures similar to that required under SFAS 157, and (d) significant concentrations of risk. FSP 132(R)-1 is effective for fiscal years ending after December 15, 2009. The Company does not expect the adoption of FSP 132(R)-1 to have a material impact on its consolidated financial statements.

**3. SPECIAL CHARGES (GAINS), NET**

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(in millions)		
Acquisition of in-process technology and intellectual property . . . . .	\$ 19.5	\$ —	\$ —
DexCom collaboration agreement . . . . .	13.4	—	—
Adjustment to capitalized patent enforcement costs . . . . .	8.2	—	—
Settlements and litigation losses (gains), net . . . . .	0.6	—	(20.2)
Realignment expenses, net . . . . .	(1.7)	13.9	9.4
Gain on sale of assets, net . . . . .	(14.9)	(1.8)	(13.7)
Pension settlement and adjustment . . . . .	—	11.2	—
PVT milestone . . . . .	—	—	10.0
Discontinued products . . . . .	—	—	6.8
Other . . . . .	—	—	3.2
Total special charges (gains), net . . . . .	<u>\$ 25.1</u>	<u>\$ 23.3</u>	<u>\$ (4.5)</u>

*Acquisition of In-Process Technology and Intellectual Property*

In October 2008, the Company recorded a \$5.0 million charge related to the acquisition of technology and intellectual property. The acquired technology is being developed for use in restoring heart geometry and function and offers a reshaping solution for patients who suffer from debilitating functional mitral regurgitation. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product.

In November 2008, the Company recorded a \$13.2 million charge related to the acquisition of technology and intellectual property, primarily related to a product which is currently under development, and

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. SPECIAL CHARGES (GAINS), NET (Continued)**

certain tangible assets, including proto-types and equipment used in the development of the product. The acquired technology is being developed for use in hemodynamic blood pressure monitoring. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product. Under the terms of the purchase agreement, the Company must pay an additional €3.0 million (US\$4.1 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$8.8 million) in any four consecutive quarters in the first five years following market launch in Europe.

In December 2008, the Company recorded a \$1.3 million charge related to the acquisition of technology and intellectual property related to a device for the reduction or elimination of mitral regurgitation and the control of left ventricular dilation. Additional design developments, bench testing, pre-clinical studies, and human clinical studies must be successfully completed prior to selling any product.

*DexCom Collaboration Agreement*

In November 2008, the Company entered into a collaboration agreement with DexCom to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. The agreement provides Edwards Lifesciences with an exclusive license to all of DexCom's applicable intellectual property. The Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee. Edwards Lifesciences will also pay up to \$24 million over the next three years in product development costs and regulatory approval milestones. In addition, DexCom will receive either a profit-sharing payment of ten percent or a royalty of up to six percent of commercial sales. Edwards Lifesciences will be responsible for global sales and marketing, which is expected to begin in 2010, and DexCom will be responsible for initial manufacturing.

*Adjustment to Capitalized Patent Enforcement Costs*

In December 2008, the Company recorded an \$8.2 million charge due primarily to the reversal of capitalized patent enforcement costs for a litigation claim related to patents in a product area where the Company does not currently compete and where the related patent enforcement costs should therefore be expensed as incurred. The Company recorded the correction of this error in the fourth quarter of 2008. Approximately \$5.7 million of the charge related to 2007 and 2006, and \$2.5 million related to the first, second, and third quarters of 2008. The Company concluded that the adjustments were not material to any of the prior years' financial statements, and the impact of the correcting adjustment is not material to the full year 2008 financial statements.

*Settlements and Litigation Losses (Gains), net*

In December 2008, the Company recorded a \$1.5 million insurance settlement gain related to a fire that occurred in the third quarter of 2007 which damaged certain inventory held at a third party warehouse in Brazil.

In March 2008, the Company recorded a \$2.1 million charge for the settlement of litigation related to its divested United States perfusion services business. Under the terms of the divestiture, this was the Company's last outstanding case.

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.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. SPECIAL CHARGES (GAINS), NET (Continued)**

*Realignment Expenses, net*

In March 2008, the Company recorded a \$1.3 million charge for executive severance associated with the Company's business realignment. As of December 31, 2008, remaining payments of \$0.7 million for the executive severance charge are expected to be paid through the end of 2009.

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. In 2008, the Company reversed \$3.0 million of the December 2007 accrued severance related to the sale of the *LifeStent* product line and global reduction in workforce. As of December 31, 2008, remaining payments of approximately \$2.6 million are expected to be paid in 2009.

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, 2008, all payments related to the realignment were 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 Corporation as discussed in the "*Gain on Sale of Assets, net*" section. As of December 31, 2008, all payments related to the realignment were complete.

*Gain on Sale of Assets, net*

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. This divestiture was part of the Company's ongoing strategy to focus resources on its core Heart Valve and Critical Care product lines. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and is entitled to 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 *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. Because of the Company's continued involvement in the operations of *LifeStent* after its sale, the Company did not report the loss on disposition or the results of *LifeStent's* operations as discontinued operations.

In connection with this transaction, the Company recorded in January 2008 a pre-tax loss of \$8.1 million consisting of the cash proceeds of \$74.0 million, offset by a \$34.6 million write-off of goodwill associated with this product line, \$36.9 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, \$6.9 million of deferred revenue related to the transition services the Company has agreed to provide, and \$3.7 million of transaction and other costs related to the sale.

In December 2008, the Company recorded a gain of \$23.0 million for the receipt of a *LifeStent* milestone payment in connection with the transfer of its pre-market approval ("PMA") to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment upon receipt of the United States regulatory approval, and the remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. SPECIAL CHARGES (GAINS), NET (Continued)**

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.

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 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.

The Company sold its perfusion product line in Japan to Terumo Corporation, and in 2006 recorded a \$5.7 million gain related to the receipt of an earn-out payment.

*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 No. 87, "*Employers' Accounting for Pensions*" ("SFAS 87") and 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 to correct this error. The Company concluded that the impact for the increase in the pension obligation was not material to the 2007 or prior years' consolidated financial statements.

*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 and subsequently paid \$9.8 million in 2007. 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 of intangible assets. In addition, the Company recorded a \$2.0 million charge to cost of goods sold related to the disposal of inventory.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(in millions)	
<b>Accounts receivable, net</b>		
Trade accounts receivable (Note 5) . . . . .	\$ 196.2	\$ 123.3
Allowance for doubtful accounts . . . . .	(9.9)	(7.5)
	<u>\$ 186.3</u>	<u>\$ 115.8</u>
<b>Inventories, net</b>		
Raw materials . . . . .	\$ 36.5	\$ 30.5
Work in process . . . . .	19.5	21.8
Finished products . . . . .	95.8	100.3
	<u>\$ 151.8</u>	<u>\$ 152.6</u>
<b>Property, plant and equipment, net</b>		
Land . . . . .	\$ 21.7	\$ 22.1
Buildings and leasehold improvements . . . . .	109.0	93.8
Machinery and equipment . . . . .	192.4	195.0
Equipment with customers . . . . .	49.2	60.6
Software . . . . .	71.9	67.0
Construction in progress . . . . .	27.2	32.0
	471.4	470.5
Accumulated depreciation . . . . .	(241.3)	(242.3)
	<u>\$ 230.1</u>	<u>\$ 228.2</u>
<b>Accrued liabilities</b>		
Employee compensation and withholdings . . . . .	\$ 84.8	\$ 58.3
Property, payroll and other taxes . . . . .	17.1	16.7
Litigation reserves (Note 16) . . . . .	10.7	11.1
Realignment reserves (Note 3) . . . . .	7.0	13.4
Other accrued liabilities . . . . .	67.1	62.0
	<u>\$ 186.7</u>	<u>\$ 161.5</u>

**5. ACCOUNTS RECEIVABLE SECURITIZATION**

The Company securitizes, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in Japan (“Japan Receivables Facility”) and, until August 2008, in the United States (“United States Receivables Facility”). Under the Japan Receivables Facility, the Company sells eligible accounts receivable directly to a financial institution. Under the United States Receivables Facility, the Company previously sold eligible accounts receivable to a wholly-owned, bankruptcy-remote entity formed for the purpose of buying and selling these receivables, which then sold undivided interests in the receivables to a financial institution.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. ACCOUNTS RECEIVABLE SECURITIZATION (Continued)**

The transactions under both Facilities are accounted for as sales of accounts receivable. The Company retains servicing responsibilities and subordinated residual interests in the accounts receivables. The Company receives annual servicing fees approximating one percent of the outstanding balance and rights to future cash flows arising after the investors in the securitization trust have received their contractual return. No servicing asset or liability has been recorded due to the immateriality of the balances. The investors and the securitization trust have no recourse to the Company's other assets for failure of debtors to pay when due. The Company's residual interests are subordinate to the investors' interests. In August 2008, the Company terminated its securitization program in the United States and repurchased \$50.0 million of accounts receivable. The Japan Receivables Facility will expire on February 28, 2009, and the Company does not plan to renew it.

Sales of receivables under the Japan Receivables Facility, and previously under the United States Receivables Facility, result in a reduction of accounts receivable on the Company's consolidated balance sheets. Residual interests of \$6.6 million and \$8.8 million as of December 31, 2008 and 2007, respectively, are included in "Other Current Assets." The interests are carried at their fair value, estimated as the net realizable value, which considers the relatively short liquidation period and includes an estimated provision for credit losses. Pursuant to the terms of the Facilities, the Company had sold \$44.4 million and \$96.7 million of trade accounts receivable as of December 31, 2008 and 2007, respectively, resulting in a reduction of accounts receivable on the Company's consolidated balance sheets, and received funding of \$37.7 million and \$87.6 million, respectively. Costs associated with the sale of receivables, primarily related to the discount, were \$1.6 million, \$3.0 million, and \$2.6 million for the years ended December 31, 2008, 2007, and 2006, respectively, and are included in "Other Expense (Income), net."

**6. ACQUISITIONS**

In December 2007, the Company completed its acquisition of certain assets of the *CardioVations* Division of Ethicon, Inc. ("*CardioVations*"), including products and technology used in minimally invasive heart valve surgery. The acquired technology complements the Company's aortic valve replacement technology for minimally invasive procedures and provides new avenues to optimize patient outcomes in valve replacement and repair. The acquisition was accounted for as a business combination in accordance with SFAS No. 141, "*Business Combinations*." 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. The purchase price was allocated to tangible and intangible assets acquired based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was allocated to goodwill. The following table summarizes the allocation of the purchase price (in millions):

Goodwill . . . . .	\$11.4
Core/developed technology . . . . .	7.1
Customer relationships . . . . .	3.7
Patents . . . . .	3.3
Inventory . . . . .	2.4
Property and equipment, net . . . . .	0.2
	<u>\$28.1</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. ACQUISITIONS (Continued)**

The results of operations for *CardioVations* have been included in the accompanying consolidated financial statements from the date of acquisition. Pro forma results have not been presented as the results of *CardioVations* are not material in relation to the consolidated financial statements of the Company.

**7. GOODWILL AND OTHER INTANGIBLE ASSETS**

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

As explained in Note 3, in January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. In connection with this transaction, the Company recorded a \$34.6 million write-off of goodwill associated with this product line.

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

<u>December 31, 2008</u>	<u>Patents</u>	<u>Unpatented Technology</u>	<u>Other</u>	<u>Total</u>
Cost . . . . .	\$ 204.1	\$ 35.0	\$13.4	\$ 252.5
Accumulated amortization . . . . .	(127.3)	(24.6)	(3.7)	(155.6)
Net carrying value . . . . .	<u>\$ 76.8</u>	<u>\$ 10.4</u>	<u>\$ 9.7</u>	<u>\$ 96.9</u>
 <u>December 31, 2007</u>				
Cost . . . . .	\$ 214.1	\$ 35.0	\$17.4	\$ 266.5
Accumulated amortization . . . . .	(118.7)	(22.2)	(3.1)	(144.0)
Net carrying value . . . . .	<u>\$ 95.4</u>	<u>\$ 12.8</u>	<u>\$14.3</u>	<u>\$ 122.5</u>

Patents include \$7.8 million and \$9.1 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of December 31, 2008 and 2007, respectively (see Note 2). In 2008, the Company reversed \$8.2 million of capitalized patent enforcement costs for a litigation claim related to patents in a product area where the Company does not currently compete (see Note 3).

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line (see Note 3). This transaction resulted in a net reduction in "*Other Intangible Assets, net*" of \$7.8 million.

Amortization expense related to other intangible assets for the years ended December 31, 2008, 2007, and 2006 was \$19.4 million, \$16.9 million, and \$17.6 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2009 . . . . .	\$20.7
2010 . . . . .	19.0
2011 . . . . .	15.1
2012 . . . . .	12.8
2013 . . . . .	12.7

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. INVESTMENTS IN UNCONSOLIDATED AFFILIATES**

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(in millions)	
<b>Available-for-sale investments</b>		
Cost . . . . .	\$10.9	\$12.8
Unrealized (losses) gains . . . . .	(5.8)	12.4
Fair value of available-for-sale investments . . . . .	<u>5.1</u>	<u>25.2</u>
<b>Equity method investments</b>		
Cost . . . . .	9.7	9.4
Equity in losses . . . . .	(1.1)	(1.3)
Carrying value of equity method investments . . . . .	<u>8.6</u>	<u>8.1</u>
<b>Cost method investments</b>		
Carrying value of cost method investments . . . . .	<u>1.0</u>	<u>1.0</u>
<b>Total investments in unconsolidated affiliates</b> . . . . .	<u>\$14.7</u>	<u>\$34.3</u>

Proceeds from sales of available-for-sale investments for the years ended December 31, 2008 and 2007 were \$3.8 million and \$1.4 million, respectively, and the Company realized pre-tax gains of \$1.9 million and \$0.9 million, respectively. There were no material sales of available-for-sale investments during the year ended December 31, 2006.

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

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 are expected to be refinanced pursuant to the Credit Agreement. Additional issuance costs of \$0.5 million are being amortized to interest expense over 5 years. As of December 31, 2008, borrowings of \$175.5 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, 2008.

On May 9, 2008, the Company called for redemption its \$150.0 million of convertible senior debentures (the “Notes”). Prior to the redemption date of June 9, 2008, holders of approximately \$147.7 million principal amount of the Notes converted their debentures into approximately 2.7 million shares of Edwards Lifesciences common stock at a conversion price of \$54.66 per share. The remaining outstanding Notes of \$2.3 million were redeemed for cash on the redemption date.

The weighted-average interest rate under all debt obligations was 1.4% and 3.9% at December 31, 2008 and 2007, respectively.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**9. LONG-TERM DEBT, CREDIT FACILITIES AND LEASE OBLIGATIONS (Continued)**

Included in long-term debt at December 31, 2008 and 2007 were unsecured notes denominated in Japanese yen of ¥7.7 billion (US\$85.5 million) and ¥7.0 billion (US\$61.7 million), respectively.

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2008 were as follows (in millions):

	Operating Leases	Aggregate Debt Maturities
2009 .....	\$16.3	\$ —
2010 .....	13.3	—
2011 .....	6.6	175.5
2012 .....	5.0	—
2013 .....	4.1	—
Thereafter .....	5.9	—
Total obligations and commitments .....	<u>\$51.2</u>	<u>\$175.5</u>

Certain facilities and equipment are leased under operating leases expiring at various dates. Most of the operating leases contain renewal options. Total expense for all operating leases was \$16.7 million, \$15.4 million, and \$14.0 million for the years 2008, 2007, and 2006, respectively.

**10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS**

**Fair Value Measurements**

The consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on an historical cost basis. Financial instruments of the Company consist of cash deposits, short-term investments, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities, and debt.

The Company adopted SFAS 157 as of January 1, 2008. As explained in Note 2, the Company has only adopted the provisions of SFAS 157 with respect to its financial assets and liabilities. The Company has deferred the application of the provisions of this statement to its non-financial assets and liabilities in accordance with FSP 157-2. SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 establishes a fair value hierarchy that prioritizes the inputs used to determine fair values. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

Level 2—Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3—Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)**

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2008 (in millions):

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
<b>Assets</b>				
Investment in the Bank of America Columbia Strategic Cash fund . . . . .	\$ —	\$ —	\$10.9	\$10.9
Investments held for executive deferred compensation plan . . . . .	10.2	—	—	10.2
Investments in unconsolidated affiliates . . . . .	5.1	—	—	5.1
Residual interest in accounts receivable securitizations . . . . .	—	—	6.6	6.6
	<u>\$15.3</u>	<u>\$ —</u>	<u>\$17.5</u>	<u>\$32.8</u>
<b>Liabilities</b>				
Derivatives . . . . .	\$ —	\$1.3	\$ —	\$ 1.3
	<u>\$ —</u>	<u>\$1.3</u>	<u>\$ —</u>	<u>\$ 1.3</u>

The following table summarizes the changes in fair value of the Company's financial assets and liabilities that have been classified as Level 3 for the year ended December 31, 2008 (in millions):

	<u>Investment in the Columbia Strategic Cash Fund</u>	<u>Residual Interest in Accounts Receivable Securitizations</u>	<u>Total</u>
Balance at December 31, 2007 . . . . .	\$ 49.4	\$ 8.8	\$ 58.2
Total losses—realized and unrealized:			
Included in earnings(a) . . . . .	(3.0)	—	(3.0)
Purchases, sales, issuances, and settlements . . . . .	<u>(35.5)</u>	<u>(2.2)</u>	<u>(37.7)</u>
Balance at December 31, 2008 . . . . .	<u>\$ 10.9</u>	<u>\$ 6.6</u>	<u>\$ 17.5</u>

(a) Recorded as a component of "Other Expense (Income), net" in the consolidated statements of operations.

The fair values of certain investments in unconsolidated affiliates and investments held for the executive deferred compensation plan are estimated based on quoted market prices. For other investments, various methods are used to estimate fair value, including discounted cash flows.

The Company's investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investment for cash. The fair value of the Company's remaining investment in this fund was estimated based on the net asset value of the fund. The fair value of the underlying securities held by the fund was determined based on quoted market prices or broker quotes, when possible. In the absence of observable market quotations, the underlying securities were valued based on alternative valuation techniques using inputs that may not be observable. In these cases, the fair value was based on available information believed to be reliable, which may be affected by conditions in the financial markets. Different market participants may reach different opinions as to the value of any particular security based on their varying market outlooks, the market information available to them, and the particular

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)**

circumstances of their portfolios. The Company has procedures to independently verify and test valuations received from third parties.

The Company estimates the fair value of the residual interest in accounts receivable securitizations using the net carrying amount of the accounts receivables less the discount paid on the sale of the receivables. This amount is calculated using future expected credit losses and calculated contractual rebates to distributors to determine the future expected cash flows, which generally approximate fair value given the securitized portfolio's short-term weighted-average life.

On May 9, 2008, the Company called for redemption its \$150.0 million of convertible senior debentures. As of December 31, 2007, the estimated fair value of the Company's convertible debenture was \$151.5 million, estimated based on market prices. Carrying amounts of floating rate debt approximate their fair value.

The Company's other financial instruments generally approximate their fair values based on the short-term nature of these instruments.

**Derivative Financial Instruments**

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

	December 31,			
	2008		2007	
	Notional Amount	Fair Value Asset (Liability)	Notional Amount	Fair Value Asset (Liability)
	(in millions)			
Forward currency agreements . . . . .	\$159.7	\$ 0.2	\$ 82.2	\$(3.4)
Currency option contracts . . . . .	65.4	(1.5)	254.0	(3.1)

The fair value of financial instruments was estimated by discounting expected cash flows using quoted market interest rates and foreign exchange rates as of December 31, 2008 and 2007. Considerable judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

At December 31, 2008 and 2007, the fair value of currency option contracts and forward currency agreements were recorded in "Accrued Liabilities." These agreements have a maximum duration of one year. During the years ended December 31, 2008 and 2007, the Company reclassified from "Accumulated Other Comprehensive (Loss) Income" to "Cost of Goods Sold" a net loss of \$10.7 million and a net gain of \$3.1 million, respectively. The Company expects that during 2009 it will reclassify to earnings a \$1.3 million gain currently recorded in "Accumulated Other Comprehensive (Loss) Income." For the years ended December 31, 2008, 2007, and 2006, the Company expensed \$0.6 million, \$1.7 million, and \$3.0 million, respectively, related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness. The Company recorded to "Other Expense (Income), net" a net gain of \$0.2 million on its fair value hedges for the

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)**

year ended December 31, 2008 and a net loss of \$0.1 million for each of the years ended December 31, 2007 and 2006.

**11. EMPLOYEE BENEFIT PLANS**

**Defined Benefit Plans**

Edwards Lifesciences maintains defined benefit pension plans in Japan and certain European countries. The Company terminated its defined benefit pension plan in Puerto Rico (the "Plan") and in 2007 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 termination.

During the fourth quarter of 2007, the Company applied the provisions of SFAS 87 and 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 during the fourth quarter of 2007 to correct this error. 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.

The Company adopted the measurement date provisions of SFAS 158 during the year ended December 31, 2008 using the "one measurement" approach. Under this approach, the Company used the measurement determined as of October 31, 2007 and recognized the net benefit expense for the transition period from November 1 through December 31, 2007 in retained earnings at December 31, 2008. The adoption of the measurement date provisions of SFAS 158 resulted in a \$0.6 million reduction of retained earnings.



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. EMPLOYEE BENEFIT PLANS (Continued)**

Information regarding the Company's defined benefit pension plans in Japan, certain European countries, and through December 2007, Puerto Rico, is as follows (in millions):

	<u>Years Ended December 31,</u>	
	<u>2008</u>	<u>2007</u>
<b>Change in projected benefit obligation:</b>		
Beginning of year . . . . .	\$ 41.1	\$ 58.0
Service cost . . . . .	4.8	2.7
Interest cost . . . . .	1.6	2.4
Participant contributions . . . . .	1.2	0.4
Actuarial loss . . . . .	10.2	4.5
Plan amendments . . . . .	—	(2.7)
Curtailement gain . . . . .	—	(0.1)
Special termination benefit cost . . . . .	—	0.6
Settlement . . . . .	—	(34.2)
Benefits paid . . . . .	—	(3.1)
Currency exchange rate changes and other . . . . .	3.0	12.6
End of year . . . . .	<u>\$ 61.9</u>	<u>\$ 41.1</u>
<b>Change in fair value of plan assets:</b>		
Beginning of year . . . . .	\$ 24.6	\$ 40.2
Actual return on plan assets . . . . .	(1.6)	2.6
Employer contributions . . . . .	3.7	11.2
Participant contributions . . . . .	1.2	0.4
Settlement . . . . .	—	(34.2)
Benefits paid . . . . .	—	(3.1)
Currency exchange rate changes and other . . . . .	1.5	7.5
End of year . . . . .	<u>\$ 29.4</u>	<u>\$ 24.6</u>
<b>Funded Status</b>		
Projected benefit obligation . . . . .	\$(61.9)	\$(41.1)
Plan assets at fair value . . . . .	29.4	24.6
Funded status, (under funded) . . . . .	<u>\$(32.5)</u>	<u>\$(16.5)</u>
<b>Net amounts recognized on the consolidated balance sheet:</b>		
Other long-term liabilities . . . . .	<u>\$ 32.5</u>	<u>\$ 16.5</u>
Accumulated other comprehensive loss, net of tax:		
Net actuarial loss . . . . .	\$(18.0)	\$ (5.1)
Net prior service benefit . . . . .	3.2	3.5
Net transition asset . . . . .	(0.2)	(0.2)
Deferred income tax expense . . . . .	3.1	0.3
Total . . . . .	<u>\$(11.9)</u>	<u>\$ (1.5)</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. EMPLOYEE BENEFIT PLANS (Continued)**

The accumulated benefit obligation (“ABO”) for all defined benefit pension plans was \$52.8 million and \$36.5 million as of December 31, 2008 and 2007, respectively. The projected benefit obligation (“PBO”) and ABO were in excess of plan assets for all pension plans as of December 31, 2008 and 2007.

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

	Years Ended December 31,		
	2008	2007	2006
Service cost, net . . . . .	\$ 4.1	\$ 2.7	\$ 2.5
Interest cost . . . . .	1.4	2.4	2.2
Expected return on plan assets . . . . .	(0.9)	(2.4)	(2.2)
Settlement, curtailment and special termination benefits, net . . . . .	—	7.7	0.3
Amortization of prior service cost and other . . . . .	0.1	0.2	0.3
Net periodic pension benefits cost . . . . .	<u>\$ 4.7</u>	<u>\$10.6</u>	<u>\$ 3.1</u>

The net actuarial loss and prior service credit that will be amortized from “*Accumulated Other Comprehensive (Loss) Income*” into net periodic benefits cost in 2009 are expected to be \$0.9 million and \$(0.3) million, respectively.

As explained above, the requirement to measure plan assets and benefit obligations as of the date of the employer’s fiscal year-end balance sheet was effective for the Company for the fiscal year ending December 31, 2008. The net benefit expense for the transition period from November 1 through December 31, 2007 recorded to retained earnings at December 31, 2008 was as follows (in millions):

	November 1 through December 31, 2007
Service cost, net . . . . .	\$ 0.7
Interest cost . . . . .	0.2
Expected return on plan assets . . . . .	(0.2)
Deferred income tax . . . . .	(0.1)
Net reduction to retained earnings . . . . .	<u>\$ 0.6</u>

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. EMPLOYEE BENEFIT PLANS (Continued)**

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Discount rate . . . . .	2.8%	3.3%
Rate of compensation increase . . . . .	3.4%	3.3%
Social securities increase . . . . .	1.8%	1.9%
Pension increase . . . . .	2.0%	1.8%

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

	<u>Years ended</u> <u>December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Discount rate . . . . .	3.3%	4.2%	4.1%
Expected return on plan assets . . . . .	3.6%	5.7%	6.2%
Rate of compensation increase . . . . .	3.3%	2.8%	2.8%
Social securities increase . . . . .	1.8%	1.8%	1.6%
Pension increase . . . . .	1.8%	1.5%	1.5%

The Company's investment strategy for plan assets is to seek a competitive rate of return relative to an appropriate level of risk and to earn performance rates of return in accordance with the benchmarks adopted for each asset class. Risk management practices include diversification across asset classes and investment styles, and periodic rebalancing toward asset allocation targets. The actual weighted-average asset allocations at December 31, 2008 and 2007, by asset category, are as follows:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Equity securities . . . . .	10.0%	16.1%
Debt securities . . . . .	8.9%	8.1%
Insurance contracts . . . . .	81.1%	75.8%
Total . . . . .	<u>100.0%</u>	<u>100.0%</u>

The Administrative and Investment Committee decides on the defined benefit plan provider in each location and that provider decides the target allocation for the Company's defined benefit plan at that location. The target asset allocation selected reflects a risk/return profile the Company feels is appropriate relative to the plans' liability structure and return goals. In certain plans, asset allocations may be governed by local requirements. Target weighted-average asset allocations at December 31, 2008, by asset category, are as follows:

Equity securities . . . . .	13.3%
Debt securities . . . . .	7.9%
Insurance contracts . . . . .	78.8%
Total . . . . .	<u>100.0%</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**11. EMPLOYEE BENEFIT PLANS (Continued)**

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2008, are expected to be paid (in millions):

2009 .....	\$ 1.3
2010 .....	1.4
2011 .....	1.5
2012 .....	1.9
2013 .....	2.0
2014-2018 .....	13.9

As of December 31, 2008, expected employer contributions for fiscal 2009 are \$3.3 million.

**Defined Contribution Plans**

The Company's employees in the United States and Puerto Rico are eligible to participate in a qualified 401(k) and 1165(e) plan, respectively. In the United States, participants may contribute up to 25% of their eligible compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 3% of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis. Edwards Lifesciences matches the next 2% of the participant's annual eligible compensation to the plan on a 50% basis. In Puerto Rico, participants may contribute up to 10% of their annual compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 4% of participant's annual eligible compensation contributed to the plan on a 50% basis. The Company also provides a 2% profit sharing contribution calculated on eligible earnings for each employee. Matching contributions relating to Edwards Lifesciences employees were \$7.0 million, \$6.5 million, and \$6.1 million in 2008, 2007, and 2006, respectively.

The Company has a nonqualified deferred compensation plan for a select group of employees that provides the opportunity to defer a specified percentage of their eligible cash compensation. Participants may elect to defer up to 25% of total eligible compensation. The Company's obligations under this plan are unfunded. The amount accrued under this plan was \$3.7 million and \$3.4 million at December 31, 2008 and 2007, respectively.

In 2001, the Company adopted a nonqualified option plan ("Executive Option Plan") for the benefit of the executive officers and other key employees. The Executive Option Plan permitted participants to receive options to purchase shares of mutual funds or common stock of the Company in lieu of all or a portion of their compensation (base salary and bonus) earned prior to January 1, 2005. The Company discontinued option grants under the Executive Option Plan and has adopted the Executive Deferred Compensation Plan to provide officers and other key employees the opportunity to defer compensation earned after December 31, 2004 to future dates specified by the participant with a return based on investment alternatives selected by the participant. The amounts accrued under this plan were \$6.8 million, \$12.3 million, and \$11.1 million at December 31, 2008, 2007, and 2006, respectively.

**12. COMMON STOCK**

**Stockholder Rights Plan**

The Company has adopted a Stockholder Rights Plan to protect stockholders' rights in the event of a proposed or actual acquisition of 15% or more of the outstanding shares of the Company's common stock. As

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMON STOCK (Continued)**

part of this plan, each share of the Company's common stock carries a right to purchase one one-hundredth (1/100) of a share of Series A Junior Participating Preferred Stock (the "Rights"), par value \$0.01 per share, subject to adjustment, which becomes exercisable only upon the occurrence of certain events. The Rights are subject to redemption at the option of the Board of Directors at a price of \$0.01 per right until the occurrence of certain events. The Rights expire on March 31, 2010, unless earlier redeemed or exchanged by the Company.

**Treasury Stock**

For the year ended December 31, 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 of the Company's common stock. In each of the years ended December 31, 2008 and 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 \$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 and reduce the total shares outstanding.

During 2008, 2007, and 2006, the Company repurchased 5.8 million, 2.7 million, and 3.3 million shares, respectively, at an aggregate cost of \$306.5 million, \$130.9 million, and \$145.9 million, respectively. The timing and size of any future stock repurchases are subject to a variety of factors, including market conditions, stock prices, and other cash requirements.

**Employee and Director Stock Plans**

The Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program (the "Program") provides for the grant of incentive and non-qualified stock options, restricted stock, and restricted stock units for eligible employees and contractors of the Company. Under the Program, these grants are awarded at a price equal to the fair market value at the date of grant based upon the closing price on the date immediately preceding the grant date. Options to purchase shares of the Company's common stock granted under the Program generally vest over predetermined periods of between three to four years and expire seven years after the date of grant. Restricted stock units of the Company's common stock granted under the Program generally vest over predetermined periods ranging from three to five years after the date of grant. On May 8, 2008, an amendment and restatement of the Program was approved by the Company's stockholders. Under the amended Program, the number of shares of common stock available for issuance under the Program was increased by 0.9 million shares from 18.8 million shares to 19.7 million shares. No more than 1.2 million shares reserved for issuance may be granted in the form of restricted stock or restricted stock units.

The Company also maintains the Nonemployee Directors Stock Incentive Compensation Program (the "Nonemployee Directors Program"). Under the Nonemployee Directors Program, each nonemployee director may receive annually up to 10,000 stock options or 4,000 restricted stock units of the Company's common stock, or a combination thereof, provided that in no event may the total value of the combined annual award exceed \$0.2 million. Additionally, each nonemployee director may elect to receive all or a portion of the annual cash retainer to which the director is otherwise entitled through the issuance of stock options or restricted stock units. Each option and restricted stock unit award generally vests in three equal annual installments. Upon a director's initial election to the Board, the director receives an initial grant of 5,000 shares of restricted stock units. These grants vest 50% after one year and the balance vests after two years

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMON STOCK (Continued)**

from the date of grant. The Nonemployee Directors Program was amended on February 17, 2005, to limit to no more than 60,000 the number of shares that will be used for initial awards with two-year vesting, after which the Company will provide initial awards with a minimum three-year vesting. Under the Nonemployee Directors Program, an aggregate of 600,000 shares of the Company's common stock has been authorized for issuance.

The Company has two employee stock purchase plans, one in the United States and one for international employees (collectively "ESPP"). Under the ESPP, eligible employees may purchase shares of the Company's common stock at 85% of the lower of the fair market value of Edwards Lifesciences common stock on the effective date of subscription or the date of purchase. Under the ESPP, employees can authorize the Company to withhold up to 12% of their compensation for common stock purchases, subject to certain limitations. The ESPP is available to all active employees of the Company paid from the United States payroll and to eligible employees of the Company outside the United States to the extent permitted by local law. The ESPP for United States employees is qualified under Section 423 of the Internal Revenue Code. On May 10, 2007, an amendment and restatement of the ESPP was approved by the Company's stockholders. Under the amended ESPP, the number of shares of common stock authorized for issuance under the ESPP was increased by 800,000 shares from 2,150,000 shares to 2,950,000 shares.

The fair value of each option award and employee stock purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. The risk-free interest rate is estimated using the U.S. Treasury yield curve and is based on the expected term of the award. Prior to adoption of SFAS 123R, the Company based the expected volatility on its historical stock prices. As a result of the adoption of SFAS 123R, the Company changed its methodology of estimating expected volatility to be based on the historical-implied volatility of publicly traded options of its common stock with a term of one year or greater. The expected term of awards granted is estimated from the vesting period of the award, as well as historical exercise behavior, and represents the period of time that awards granted are expected to be outstanding. The Company uses historical data to estimate forfeitures and has estimated an annual forfeiture rate of 6%.

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

***Option Awards***

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Average risk-free interest rate . . . . .	3.0%	4.6%	5.0%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	23%	19%	23%
Expected life (years) . . . . .	4.7	4.9	4.8
Fair value . . . . .	\$14.36	\$13.08	\$13.10

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMON STOCK (Continued)**

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

**ESPP**

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Average risk-free interest rate . . . . .	2.1%	4.9%	4.7%
Expected dividend yield . . . . .	None	None	None
Expected volatility . . . . .	26%	25%	31%
Expected life (years) . . . . .	0.6	0.6	0.8
Fair value . . . . .	\$14.36	\$11.50	\$10.39

Stock option activity during the year ended December 31, 2008 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
<b>Outstanding as of December 31, 2007</b> . . . . .	9.7	\$33.39		
Options granted . . . . .	1.0	55.40		
Options exercised . . . . .	(2.1)	26.79		
Options forfeited . . . . .	(0.3)	44.76		
<b>Outstanding as of December 31, 2008</b> . . . . .	<u>8.3</u>	37.31	3.5 years	\$146.1
<b>Exercisable as of December 31, 2008</b> . . . . .	5.9	32.19	2.8 years	134.0

The following table summarizes nonvested restricted stock units and activity during the year ended December 31, 2008 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	<u>Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
<b>Nonvested as of December 31, 2007</b> . . . . .	0.9	\$45.89
Granted . . . . .	0.3	54.32
Vested . . . . .	(0.2)	45.37
Forfeited . . . . .	(0.1)	46.73
<b>Nonvested as of December 31, 2008</b> . . . . .	<u>0.9</u>	48.48

The intrinsic value of stock options exercised and vested restricted stock units during the years ended December 31, 2008, 2007, and 2006 were \$68.1 million, \$38.8 million, and \$30.3 million, respectively. The intrinsic value of stock options is calculated as the amount by which the market price of the Company's common stock exceeds the exercise price of the option. During the years ended December 31, 2008, 2007, and 2006, the Company received cash from exercises of stock options of \$54.9 million, \$30.3 million, and \$25.7 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$25.1 million, \$13.2 million, and \$8.4 million, respectively. The total grant date fair value of

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMON STOCK (Continued)**

stock options vested during the year ended December 31, 2008, 2007, and 2006 were \$14.2 million, \$18.4 million, and \$14.7 million, respectively.

As of December 31, 2008, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, and employee stock purchase subscriptions amounted to \$46.6 million, which will be amortized over the weighted-average remaining requisite service period of 29 months.

**13. ACCUMULATED OTHER COMPREHENSIVE (LOSS) INCOME**

Presented below is a summary of activity for each component of “*Accumulated Other Comprehensive (Loss) Income*” for the years ended December 31, 2008, 2007, and 2006. Foreign currency translation adjustments are generally not adjusted for income taxes as they relate to indefinite investments in non-United States subsidiaries.

	Foreign Currency Translation Adjustments	Unrealized Gain/(Loss) on Cash Flow Hedges	Unrealized Gain/ (Loss) on Investments in Unconsolidated Affiliates	Minimum Pension Liability	Unrealized Pension Costs(a)	Total Accumulated Other Comprehensive (Loss) Income
	(in millions)					
December 31, 2005 . . . . .	\$(23.9)	\$ 5.9	\$ (0.6)	\$(3.6)	\$ —	\$(22.2)
Pre-tax period change . . . . .	11.8	(8.7)	2.9	1.3	—	7.3
Impact of SFAS 158 . . . . .	—	—	—	2.5	(7.4)	(4.9)
Deferred income tax benefit (expense) . . . . .	—	3.5	(0.9)	(0.2)	1.6	4.0
December 31, 2006 . . . . .	(12.1)	0.7	1.4	—	(5.8)	(15.8)
Pre-tax period change . . . . .	19.1	(10.2)	10.0	—	5.6	24.5
Deferred income tax benefit (expense) . . . . .	—	4.0	(3.9)	—	(1.3)	(1.2)
December 31, 2007 . . . . .	7.0	(5.5)	7.5	—	(1.5)	7.5
Pre-tax period change . . . . .	(24.2)	8.0	(18.2)	—	(13.2)	(47.6)
Deferred income tax benefit (expense) . . . . .	—	(3.1)	5.0	—	2.8	4.7
December 31, 2008 . . . . .	<u>\$(17.2)</u>	<u>\$ (0.6)</u>	<u>\$ (5.7)</u>	<u>\$ —</u>	<u>\$(11.9)</u>	<u>\$(35.4)</u>

(a) For the years ended December 31, 2008 and 2007, the change in unrealized pension costs consisted of the following (in millions):

<u>2008</u>	<u>Pre-Tax Amount</u>	<u>Tax Expense</u>	<u>Net of Tax Amount</u>
Prior service credit arising during period . . . . .	\$ —	\$ —	\$ —
Amortization of prior service credit . . . . .	(0.3)	—	(0.3)
Net prior service credit arising during period . . . . .	(0.3)	—	(0.3)
Net loss arising during period . . . . .	(12.9)	2.8	(10.1)
Unrealized pension costs, net . . . . .	<u>\$(13.2)</u>	<u>\$2.8</u>	<u>\$(10.4)</u>



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. ACCUMULATED OTHER COMPREHENSIVE (LOSS) INCOME (Continued)**

<u>2007</u>	<u>Pre-Tax Amount</u>	<u>Tax Expense</u>	<u>Net of Tax Amount</u>
Prior service credit arising during period . . . . .	\$2.8	\$(0.3)	\$2.5
Amortization of prior service credit . . . . .	—	—	—
Net prior service credit arising during period . . . . .	2.8	(0.3)	2.5
Net gain arising during period . . . . .	2.8	(1.0)	1.8
Unrealized pension costs, net . . . . .	<u>\$5.6</u>	<u>\$(1.3)</u>	<u>\$4.3</u>

**14. OTHER EXPENSE (INCOME), NET**

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
	(in millions)		
Foreign exchange losses (gains), net . . . . .	\$ 7.2	\$(2.0)	\$(0.3)
Investment impairment and realized losses . . . . .	3.0	0.7	—
Accounts receivable securitization costs . . . . .	1.6	3.0	2.6
Gain on sale of property development rights . . . . .	(0.5)	—	—
Gain on investments in unconsolidated affiliates . . . . .	(2.0)	(1.3)	—
Gain on sale of product line . . . . .	—	(2.3)	—
Other . . . . .	(1.6)	—	0.4
	<u>\$ 7.7</u>	<u>\$(1.9)</u>	<u>\$ 2.7</u>

**15. INCOME TAXES**

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

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
United States . . . . .	\$ (11.9)	\$ 27.0	\$ 49.0
International, including Puerto Rico . . . . .	176.3	122.8	123.3
	<u>\$164.4</u>	<u>\$149.8</u>	<u>\$172.3</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

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

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
<b>Current</b>			
United States:			
Federal . . . . .	\$ 35.9	\$27.5	\$26.7
State and local . . . . .	4.5	3.5	3.4
International, including Puerto Rico . . . . .	16.0	13.5	7.0
Current income tax expense . . . . .	<u>56.4</u>	<u>44.5</u>	<u>37.1</u>
<b>Deferred</b>			
United States:			
Federal . . . . .	(21.3)	(7.6)	(2.0)
State and local . . . . .	(2.7)	(0.9)	(0.2)
International, including Puerto Rico . . . . .	3.1	0.8	6.9
Deferred income tax (benefit) expense . . . . .	<u>(20.9)</u>	<u>(7.7)</u>	<u>4.7</u>
<b>Total income tax provision . . . . .</b>	<u>\$ 35.5</u>	<u>\$36.8</u>	<u>\$41.8</u>

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
<b>Deferred tax assets</b>		
Compensation and benefits . . . . .	\$ 44.5	\$ 34.7
Net operating loss carryforwards . . . . .	25.6	32.1
Accrued liabilities . . . . .	20.1	14.9
Tax credit carryforwards . . . . .	12.4	6.3
Inventories . . . . .	11.9	8.1
Investments in unconsolidated affiliates . . . . .	4.8	5.0
Allowance for doubtful accounts . . . . .	1.2	2.1
Other intangible assets . . . . .	—	1.8
Other . . . . .	5.2	2.9
Total deferred tax assets . . . . .	<u>125.7</u>	<u>107.9</u>
<b>Deferred tax liabilities</b>		
Property, plant and equipment . . . . .	(12.3)	(11.9)
Other intangible assets . . . . .	(9.8)	(28.4)
Other . . . . .	(0.8)	(2.5)
Total deferred tax liabilities . . . . .	<u>(22.9)</u>	<u>(42.8)</u>
<b>Valuation allowance . . . . .</b>	<u>(22.7)</u>	<u>(21.1)</u>
<b>Net deferred tax assets . . . . .</b>	<u>\$ 80.1</u>	<u>\$ 44.0</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

During 2008, net deferred tax assets increased \$36.1 million. Of this amount, \$15.2 million was recorded through stockholders' equity and did not impact the overall tax provision.

The valuation allowance of \$22.7 million as of December 31, 2008 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the deferred tax assets established for impairment losses on certain investments and the net operating loss carryforwards of certain United States and non-United States subsidiaries.

Deferred income taxes have not been provided on the undistributed earnings of the Company's foreign subsidiaries of approximately \$465.3 million as of December 31, 2008, since these amounts are intended to be permanently reinvested in foreign operations. It is not practicable to calculate the deferred taxes associated with these earnings; however, foreign tax credits would likely be available to reduce federal income taxes in the event of distribution.

Net operating loss carryforwards, and the related carryforward periods, at December 31, 2008, are summarized as follows (in millions):

	<u>Net Operating Loss</u>	<u>Tax Benefit Amount</u>	<u>Valuation Allowance</u>	<u>Expected Tax Benefit</u>	<u>Carryforward Period Ends</u>
United States state net operating losses . . .	\$ 48.1	\$ 2.8	\$ (2.8)	\$ —	2009-2015
Non-United States net operating losses . . .	26.4	10.1	(0.2)	9.9	2009-2017
Non-United States net operating losses . . .	38.5	12.5	(11.3)	1.2	Indefinite
Total . . . . .	<u>\$113.0</u>	<u>\$25.4</u>	<u>\$(14.3)</u>	<u>\$11.1</u>	

A valuation allowance of approximately \$14.3 million has been provided for certain of the above carryforwards. This valuation allowance reduces the deferred tax asset related to net operating loss carryforwards of \$25.6 million to an amount that is more likely than not to be realized.

The Company has approximately \$16.1 million of California research expenditure tax credits it expects to use in future periods. The credits may be carried forward indefinitely. Based upon anticipated future taxable income, the Company expects all California research expenditure tax credits to be fully utilized; accordingly, no valuation allowance has been provided.

As part of the PVT acquisition in 2004, the Company acquired \$7.5 million of federal and state net operating losses that the Company established a valuation allowance against. During 2008, it was determined that the acquired federal net operating loss will not be utilized. Therefore, the deferred tax asset was written off and the corresponding valuation allowance was reversed.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

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

	<u>Years Ended December 31,</u>		
	<u>2008</u>	<u>2007</u>	<u>2006</u>
Income tax expense at U.S. federal statutory rate . . . . .	\$ 57.5	\$ 52.4	\$ 60.3
Foreign income tax at different rates . . . . .	(26.4)	(21.4)	(19.8)
Nondeductible goodwill . . . . .	12.2	—	—
Reserve for uncertain tax positions for prior years . . . . .	(6.2)	1.2	(5.6)
Tax credits, federal and state . . . . .	(3.5)	(2.8)	(2.0)
State and local taxes, net of federal tax benefit . . . . .	2.0	3.1	4.7
Nondeductible stock-based compensation . . . . .	0.9	1.9	2.2
Deemed dividends, net of foreign tax credit . . . . .	0.6	3.2	4.2
Valuation allowance for loss on investments . . . . .	—	(0.6)	(7.0)
Nondeductible PVT milestone payment . . . . .	—	—	3.5
Other . . . . .	(1.6)	(0.2)	1.3
Income tax provision . . . . .	<u>\$ 35.5</u>	<u>\$ 36.8</u>	<u>\$ 41.8</u>

*Nondeductible Goodwill*

During 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. A \$34.6 million write-off of goodwill associated with this product line was recorded. This amount is not deductible for tax purposes.

*Reserve for Uncertain Tax Positions*

As of December 31, 2008 and 2007, the liability for income taxes associated with uncertain tax positions was \$35.9 million and \$36.4 million, respectively. These liabilities could be reduced by \$2.3 million and \$8.0 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amounts of \$33.6 million and \$28.4 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Unrecognized tax benefits, January 1 . . . . .	\$ 36.4	\$24.6
Increase prior period tax positions . . . . .	12.3	12.1
Decrease prior period tax positions . . . . .	(19.9)	(7.9)
Current year tax positions . . . . .	18.0	8.6
Settlements . . . . .	(10.9)	(0.9)
Lapse of statute of limitations . . . . .	—	(0.1)
Unrecognized tax benefits, December 31 . . . . .	<u>\$ 35.9</u>	<u>\$36.4</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2008, the Company had accrued \$1.9 million (net of \$0.5 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 uncertain 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 penalty and 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 closed during 2008. During 2009, the IRS is expected to initiate an audit of the 2007 tax year.

As a result of the on-going 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, 2008, the Company has concluded all United States federal income tax matters for years through 2006. All material state, local, and foreign income tax matters have been concluded for years through 2003.

*Nondeductible Stock-based Compensation*

Some of the costs recognized in accordance with SFAS 123R are not deductible in the United States or in foreign countries.

*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 in the appropriate period with which to offset these expected capital losses. Due to the uncertainty of the ready marketability of certain of these impaired investments, the Company has recorded valuation allowances against these deferred tax assets as they have accumulated. As of December 31, 2008, deferred tax assets and corresponding valuation allowances of approximately \$4.3 million had accumulated related to investments. Of the total valuation allowance of \$4.3 million, \$2.2 million was recorded during 2008 as a component of “*Other Comprehensive (Loss) Income.*” The remaining \$2.1 million had previously been recorded as of December 31, 2007 through charges to profit and loss.

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

During 2006, the Company recognized capital gains from the sale of a non-strategic business and 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 \$7.0 million were reversed in 2006.

*Nondeductible PVT Milestone Payment*

During 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.

**16. LEGAL PROCEEDINGS**

In August 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 ("Gore") 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. In September 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced in January 2006, Edwards Lifesciences settled this litigation with Medtronic. Edwards Lifesciences remains in litigation with Cook and Gore, each of which has answered and asserted various affirmative defenses and counterclaims. In March 2008, the District Court granted summary judgment of non-infringement in favor of Cook and subsequently also in favor of Gore. In September 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals.

In May 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. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007, and June 2007, CoreValve filed separate 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. In January 2009, the United Kingdom Court determined that the Andersen patent was valid but not infringed by CoreValve. The Company is considering an appeal. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. This lawsuit is ongoing.

In February 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. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook has counterclaimed, alleging infringement by Edwards. The trial in Germany on infringement was held on February 19, 2009, and the Company is awaiting the Court's decision.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be 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, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. LEGAL PROCEEDINGS (Continued)**

charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations, or liquidity.

Edwards Lifesciences is 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 continuing 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.

**17. SEGMENT INFORMATION**

Edwards Lifesciences conducts operations worldwide and is managed in four geographical regions: United States, Europe, Japan, and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease. The Company has reclassified certain prior period amounts to conform to internal methods of managing and monitoring performance at the segment level during the current period.

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

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

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. SEGMENT INFORMATION (Continued)**

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

	Years Ended December 31,		
	2008	2007	2006
<b>Net Sales</b>			
United States . . . . .	\$ 540.3	\$ 486.6	\$477.9
Europe . . . . .	362.8	234.2	219.0
Japan . . . . .	167.4	182.9	178.6
Rest of World . . . . .	130.8	110.6	118.0
Total segment net sales . . . . .	<u>\$1,201.3</u>	<u>\$1,014.3</u>	<u>\$993.5</u>
<b>Pre-tax Income</b>			
United States . . . . .	\$ 283.9	\$ 255.3	\$251.6
Europe . . . . .	114.8	58.0	53.7
Japan . . . . .	75.2	71.9	67.5
Rest of World . . . . .	34.0	25.4	23.6
Total pre-tax income . . . . .	<u>\$ 507.9</u>	<u>\$ 410.6</u>	<u>\$396.4</u>

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

	Years Ended December 31,		
	2008	2007	2006
<b>Net Sales Reconciliation</b>			
Segment net sales . . . . .	\$1,201.3	\$1,014.3	\$ 993.5
Foreign currency . . . . .	36.4	76.8	43.5
Consolidated net sales . . . . .	<u>\$1,237.7</u>	<u>\$1,091.1</u>	<u>\$1,037.0</u>
<b>Pre-tax Income Reconciliation</b>			
Segment pre-tax income . . . . .	\$ 507.9	\$ 410.6	\$ 396.4
Unallocated amounts:			
Corporate items . . . . .	(307.5)	(261.8)	(246.2)
Special (charges) gains, net . . . . .	(25.1)	(23.3)	4.5
Interest expense, net . . . . .	(1.1)	(1.4)	(2.7)
Foreign currency . . . . .	(9.8)	25.7	20.3
Consolidated pre-tax income . . . . .	<u>\$ 164.4</u>	<u>\$ 149.8</u>	<u>\$ 172.3</u>



**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. SEGMENT INFORMATION (Continued)**

**Enterprise-Wide Information**

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

	As of or for the Years Ended December 31,		
	2008	2007	2006
	(in millions)		
<b>Net Sales by Geographic Area</b>			
United States . . . . .	\$ 543.6	\$ 486.6	\$ 477.9
Other countries . . . . .	694.1	604.5	559.1
	<u>\$1,237.7</u>	<u>\$1,091.1</u>	<u>\$1,037.0</u>
<b>Net Sales by Major Product Area</b>			
Heart Valve Therapy . . . . .	\$ 607.4	\$ 515.0	\$ 490.8
Critical Care . . . . .	451.8	397.8	349.8
Cardiac Surgery Systems . . . . .	89.2	60.9	91.0
Vascular . . . . .	89.3	90.0	75.9
Other Distributed Products . . . . .	—	27.4	29.5
	<u>\$1,237.7</u>	<u>\$1,091.1</u>	<u>\$1,037.0</u>
<b>Long-lived Tangible Assets by Geographic Area</b>			
United States . . . . .	\$ 171.4	\$ 197.9	\$ 186.0
Other countries . . . . .	86.6	78.9	60.9
	<u>\$ 258.0</u>	<u>\$ 276.8</u>	<u>\$ 246.9</u>

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**18. QUARTERLY FINANCIAL RESULTS AND MARKET FOR THE COMPANY'S STOCK (UNAUDITED)**

<u>Years Ended December 31,</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total Year</u>
	(in millions, except per share data)				
<b>2008</b>					
Net sales . . . . .	\$296.8	\$327.6	\$303.6	\$309.7	\$1,237.7
Gross profit . . . . .	193.9	214.6	198.7	210.9	818.1
Net income(a) . . . . .	18.2	39.7	32.9	38.1	128.9
Earnings per common share(a):					
Basic . . . . .	0.32	0.72	0.59	0.68	2.31
Diluted . . . . .	0.31	0.67	0.56	0.66	2.19
Market price:					
High . . . . .	\$47.62	\$63.49	\$66.99	\$58.56	\$ 66.99
Low . . . . .	41.69	44.80	53.75	44.76	41.69
<b>2007</b>					
Net sales . . . . .	\$264.1	\$272.6	\$261.4	\$293.0	\$1,091.1
Gross profit . . . . .	170.9	177.9	170.7	193.4	712.9
Net income(b) . . . . .	33.2	34.9	29.1	15.8	113.0
Earnings per common share(b):					
Basic . . . . .	0.57	0.61	0.51	0.28	1.97
Diluted . . . . .	0.54	0.57	0.48	0.27	1.87
Market price:					
High . . . . .	\$52.51	\$52.95	\$50.79	\$52.86	\$ 52.95
Low . . . . .	46.06	48.15	45.55	45.84	45.55

(a) The first quarter of 2008 includes an \$8.1 million charge related to the sale of the *LifeStent* product line.

The fourth quarter of 2008 includes (1) a \$23.0 million gain for achieving a milestone related to the divested *LifeStent* product line, (2) a \$19.5 million charge related to the acquisition of technology and intellectual property, (3) a \$13.4 million charge related to upfront licensing and collaboration fees required under the Company's agreement with DexCom, Inc., (4) a \$8.2 million charge primarily for the reversal of capitalized patent enforcement costs related to patents not currently marketed by the Company, (5) a \$5.2 million reduction in gross profit for the voluntary retrieval of *Myxo* and *IMR ETlogix* repair products, and (6) a \$10.1 million tax benefit resulting from audit settlements.

(b) The fourth quarter of 2007 includes (1) a \$13.9 million charge related to a worldwide realignment of resources, including a global reduction in workforce, the sale of the *LifeStent* product line, and the termination of the Company's intra-aortic balloon pump distribution agreement in Japan and (2) a \$11.2 million charge related to the termination of the Puerto Rico pension plan and an adjustment to the Switzerland pension plan, as described in Note 11.

**EDWARDS LIFESCIENCES CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. VALUATION AND QUALIFYING ACCOUNTS**

	Balance at Beginning of Period	Additions		Deductions From Reserves	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts (in millions)		
Year ended December 31, 2008					
Allowance for doubtful accounts(a) . . . . .	\$ 7.5	\$ 3.6	\$ —	\$(1.2)	\$ 9.9
Inventory reserves(b) . . . . .	14.9	4.2	—	(5.9)	13.2
Tax valuation allowance(c) . . . . .	21.1	5.4	2.2	(6.0)	22.7
Litigation reserves(d) . . . . .	11.1	3.2	—	(3.6)	10.7
Year ended December 31, 2007					
Allowance for doubtful accounts(a) . . . . .	\$ 6.5	\$ 2.7	\$ —	\$(1.7)	\$ 7.5
Inventory reserves(b) . . . . .	13.2	7.1	0.5	(5.9)	14.9
Tax valuation allowance(c) . . . . .	19.9	1.2	1.8	(1.8)	21.1
Litigation reserves(d) . . . . .	10.5	6.0	—	(5.4)	11.1
Year ended December 31, 2006					
Allowance for doubtful accounts(a) . . . . .	\$ 5.4	\$ 2.3	\$ —	\$(1.2)	\$ 6.5
Inventory reserves(b) . . . . .	12.3	8.8	—	(7.9)	13.2
Tax valuation allowance(c) . . . . .	23.2	(4.6)	1.0	0.3	19.9
Litigation reserves(d) . . . . .	2.7	11.5	—	(3.7)	10.5

- (a) The deductions related to allowances for doubtful accounts and returns represent accounts receivable which are written off and product which is returned from customers.
- (b) Inventory reserves result from inventory which is obsolete, is nearing its expiration date (generally triggered at six months prior to expiration), is damaged, or slow moving (defined as quantities in excess of a two year supply). The deductions related to inventory reserves represent inventory that is disposed of or sold as part of a business transaction.
- (c) The tax valuation allowances are provided for other-than-temporary impairments and unrealized losses related to certain unconsolidated affiliates that may not be recognized due to insufficient capital gains, and net operating loss carryforwards that may not be recognized due to insufficient taxable income.
- (d) The deductions related to litigation reserves represent settlements of litigation and reduced estimates of anticipated settlements.

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

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures.** The Company's management, including the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2008.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control Over Financial Reporting.** The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation under the framework in *Internal Control—Integrated Framework*, the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2008. The effectiveness of the Company's internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**Changes in Internal Control Over Financial Reporting.** There have been no changes in the Company's internal controls over financial reporting that were identified during the evaluation that occurred during the Company's fourth fiscal quarter of 2008 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

None.

### **PART III**

#### **Item 10. Directors, Executive Officers and Corporate Governance**

Certain information required by this Item is set forth under the headings "Corporate Governance," "Executive Compensation and Other Information—Executive Officers," and "Other Matters and Business—Additional Information" and "—Section 16(a) Beneficial Ownership Reporting Compliance" in the definitive proxy materials to be filed in connection with its 2009 Annual Meeting of Stockholders (the "Proxy Statement") (which Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of December 31, 2008). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference. The Company has adopted Governance Guidelines that apply to all employees, including the Company's principal executive officer, principal financial officer, and controller. The Governance Guidelines are posted on the Company's website, which is found at [www.edwards.com](http://www.edwards.com) under "Investor Relations." The Company intends to include on its website any amendments to, or waivers from, any provision of its Governance Guidelines that applies to the Company's principal executive officer, principal financial officer, or controller and that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

#### **Item 11. Executive Compensation**

The information contained under the heading "Executive Compensation and Other Information" in the Proxy Statement is incorporated herein by reference.

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

The information contained under the headings “Security Ownership of Certain Beneficial Owners and Management” and “The Long-Term Stock Incentive Compensation Program—Equity Compensation Plan Information” in the Proxy Statement is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information contained under the heading “Other Matters and Business—Related Party Transactions” and under the heading “Corporate Governance—Director Independence” in the Proxy Statement is incorporated herein by reference.

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

The information contained under the heading “Audit Matters—Fees Paid to Principal Accountants” in the Proxy Statement is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

#### EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

<u>Exhibit No.</u>	<u>Description</u>
3.1	Restated Certificate of Incorporation of Edwards Lifesciences Corporation (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
3.2	Amended and Restated Bylaws of Edwards Lifesciences Corporation, as amended and restated on February 12, 2009 (incorporated by reference to Exhibit 3.2 in Edwards Lifesciences' report on Form 8-K filed on February 18, 2009, under the Securities Exchange Act of 1934)
3.3	Form of Certificate of Designation for Edwards Lifesciences Corporation Series A Junior Participating Preferred Stock (included in Exhibit A to Exhibit 4.2)
4.1	Specimen form of certificate representing Edwards Lifesciences Corporation common stock (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences' Registration Statement on Form 10 (File No. 001-15525))
4.2	Rights Agreement, dated as of March 31, 2000 (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.1	Form of Employment Agreement (incorporated by reference to Exhibit 10.8 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.2	Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem dated November 13, 2008
*10.3	Edwards Lifesciences Corporation Chief Executive Officer Change-in-Control Severance Agreement, as Amended and Restated November 13, 2008
10.4	Amended and Restated Five Year Credit Agreement dated as of September 29, 2006, among Edwards Lifesciences Corporation, as Borrower; the lenders party thereto; JP Morgan Chase Bank as Administrative Agent; J.P. Morgan Europe Limited as London Agent; Mizuho Corporate Bank, Limited as Tokyo Agent; Bank of America, N.A. as Syndication Agent; and The Bank of Tokyo-Mitsubishi UFI, Ltd., Mizuho Corporate Bank, Limited, Suntrust Bank, and Wachovia Bank, N.A., as Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K, filed September 29, 2006, under the Securities Exchange Act of 1934)
*10.5	Edwards Lifesciences Corporation Severance Pay Plan (incorporated by reference to Exhibit 10.21 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2000, under the Securities Exchange Act of 1934)
*10.6	Edwards Lifesciences Corporation Executive Option Plan (incorporated by reference to Exhibit 10.6 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.7	Edwards Lifesciences Corporation Executive Deferred Compensation Plan (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K filed on December 27, 2004, under the Securities Exchange Act of 1934)

Exhibit No.	Description
10.8	Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-40434))
*10.9	Edwards Lifesciences Corporation 401(k) Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-33056))
10.10	Receivables Purchase Agreement, dated December 4, 2002, by and among Edwards Lifesciences Limited, a Japanese corporation, Apreco, Inc., a Delaware corporation, and Citilease Company Limited, a Japanese corporation (incorporated by reference to Exhibit 10.42 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2002, under the Securities Exchange Act of 1934)
10.11	Memorandum, dated December 3, 2005, by and among Edwards Lifesciences Limited, a Japanese corporation, Apreco, Inc., a Delaware corporation, and Citilease Company Limited, a Japanese corporation (incorporated by reference to Exhibit 10.23 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2005, under the Securities Exchange Act of 1934)
*10.12	Long-Term Stock Incentive Compensation Program (as amended and restated as of February 14, 2008) (incorporated by reference to Appendix A to Edwards Lifesciences' Definitive Proxy Statement filed March 28, 2008, under the Securities Exchange Act of 1934)
*10.13	Nonemployee Directors Stock Incentive Program (amended and restated as of May 10, 2007) (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 8-K, filed May 16, 2007, under the Securities Exchange Act of 1934)
*10.14	2001 Employee Stock Purchase Plan for United States Employees (as amended and restated as of February 15, 2007) (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 8-K, filed May 16, 2007, under the Securities Exchange Act of 1934)
*10.15	2001 Employee Stock Purchase Plan for International Employees (as amended and restated on September 13, 2005) (incorporated by reference to Exhibit 10.28 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2005, under the Securities Exchange Act of 1934)
*10.16	Edwards Lifesciences Corporation Incentive Plan Guidelines (incorporated by reference to Exhibit 10.26 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2004, under the Securities Exchange Act of 1934)
*10.17	Edwards Lifesciences' Officer Perquisite Program Guidelines, as of January 2008 (incorporated by reference to Exhibit 10.27 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2007, under the Securities and Exchange Act of 1934)
*10.18	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement, as Amended and Restated effective November 13, 2008
*10.19	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement effective July 10, 2008, as amended
10.20	Asset Purchase Agreement, dated as of December 6, 2007, among Edwards Lifesciences LLC, a Delaware limited liability company, Edwards Lifesciences A.G., a Swiss corporation, C. R. Bard, Inc., a New Jersey corporation, and Angiomed GMGH & Co., Medizintechnik KG, a German limited partnership (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K, filed January 11, 2008, under the Securities Exchange Act of 1934)
21.1	Subsidiaries of Edwards Lifesciences Corporation

<u>Exhibit No.</u>	<u>Description</u>
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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\* Represents management contract or compensatory plan





<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ BARBARA J. MCNEIL, M.D., PH.D.</u> Barbara J. McNeil, M.D., Ph.D.	Director	February 27, 2009
<u>/s/ DAVID E.I. PYOTT</u> David E.I. Pyott	Director	February 27, 2009

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-33054, 333-33056, 333-40434, 333-52332, 333-52334, 333-52346, 333-60670, 333-98219, 333-105961, 333-127260, 333-150810 and 333-154242) and the Registration Statement on Form S-3 (Nos. 333-155744) of Edwards Lifesciences Corporation of our report dated February 27, 2009 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP

PricewaterhouseCoopers LLP  
Orange County, California  
February 27, 2009

**EDWARDS LIFESCIENCES CORPORATION  
CERTIFICATIONS PURSUANT TO  
SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002  
CERTIFICATION**

I, Michael A. Mussallem, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: \_\_\_\_\_ /s/ MICHAEL A. MUSSALLEM

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

February 27, 2009

**EDWARDS LIFESCIENCES CORPORATION  
CERTIFICATIONS PURSUANT TO  
SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002  
CERTIFICATION**

I, Thomas M. Abate, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: \_\_\_\_\_ /s/ THOMAS M. ABATE

Thomas M. Abate  
Corporate Vice President,  
*Chief Financial Officer and Treasurer*  
*(Chief Accounting Officer)*

February 27, 2009

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

In connection with the Annual Report of Edwards Lifesciences Corporation (the "Company") on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Michael A. Mussallem, Chairman of the Board and Chief Executive Officer of the Company, and Thomas M. Abate, Corporate Vice President, Chief Financial Officer and Treasurer, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL A. MUSSALLEM

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Michael A. Mussallem

*Chairman of the Board and Chief Executive Officer*

February 27, 2009

/s/ THOMAS M. ABATE

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Thomas M. Abate

*Corporate Vice President,*

*Chief Financial Officer and Treasurer*

*(Chief Accounting Officer)*

February 27, 2009