

Edwards Lifesciences Corp  
Form 10-K  
February 26, 2010

Table of Contents

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

---

**FORM 10-K**

(Mark One)

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

For the Fiscal Year Ended December 31, 2009

OR

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

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 1-15525

---

**EDWARDS LIFESCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**36-4316614**  
(I.R.S. Employer  
Identification No.)

**One Edwards Way, Irvine, California 92614**  
(Address of principal executive offices) (ZIP Code)

**(949) 250-2500**

Registrant's telephone number, including area code

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

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

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

New York Stock Exchange  
New York Stock Exchange

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

---

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

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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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  Smaller Reporting Company   
(Do not check if a 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, 2009 (the last trading day of the registrant's most recently completed second quarter): \$3,767,534,054 based on a closing price of \$68.03 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, 2010, was 56,558,931.

### Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2010 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2009) are incorporated by reference into Part III, as indicated herein.

---

# Edgar Filing: Edwards Lifesciences Corp - Form 10-K

## Table of Contents

### EDWARDS LIFESCIENCES CORPORATION Form 10-K Annual Report 2009 Table of Contents

#### **PART I**

<u>Item 1.</u>	<u>Business</u>	<u>1</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>2</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>17</u>
<u>Item 2.</u>	<u>Properties</u>	<u>18</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>18</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	<u>19</u>

#### **PART II**

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>20</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>20</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>43</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>46</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>97</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>97</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>97</u>

#### **PART III**

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>98</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>98</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>98</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>98</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>98</u>

#### **PART IV**

<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>99</u>
	<u>Signatures</u>	<u>102</u>

---

Table of Contents

**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," "goal," "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 or implied in any forward-looking statements contained in this report. See "Risk Factors" below for a further discussion of these risks, as well as the Company's subsequent reports on Forms 10-Q and 8-K. These forward-looking statements speak only as of the date on which they are made and the Company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If the Company does update or correct one or more of these statements, investors and others should not conclude that the Company will make additional updates or corrections.*

**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.

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 clinician may elect to remove the valve and replace it with one of Edwards Lifesciences' bioprosthetic surgical tissue heart valves, surgically re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring, or deploy an Edwards Lifesciences transcatheter valve via a minimally invasive catheter-based system. 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.

Table of Contents

**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 ("SEC"). The Company's corporate governance guidelines, audit and public policy committee charter, compensation and governance committee charter, and code of business conduct are also posted on the Company's website at [www.edwards.com](http://www.edwards.com) under "Investor Relations." 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' surgical tissue heart valve 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 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 the recent introduction of the next generation *Carpentier-Edwards Physio II* mitral valve repair ring.

Edwards Lifesciences is leveraging the knowledge and experience from its legacy of tissue heart valve engineering by developing transcatheter heart valve replacement and repair 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 3* delivery system for transfemoral approaches, and the *Ascendra* delivery system for transapical approaches. Both are minimal access, beating heart procedures. A number of Edwards Lifesciences' products are pending regulatory approval to begin commercial sales, including the *Edwards SAPIEN THV* in the United States, and the *Edwards SAPIEN XT THV*, the *NovaFlex* delivery system and *Ascendra 2* delivery system in Europe. 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.

Table of Contents

**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. Prior to September 2009, the Company marketed outside of the United States a line 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 automated, real-time 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. In late 2009, the Company received European regulatory approval to begin commercialization of the product and market evaluations were begun in a limited number of clinical sites.

**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 cannulae, which are used during cardiac surgery 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 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.

**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

Table of Contents

Lifesciences' *Fogarty* line of embolectomy catheters has been an industry standard for removing blood clots from peripheral blood vessels for more than 40 years. Edwards manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents until the sale of this product line in January 2008. The Company continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred 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 markets 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 subject to 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. and Sorin Group. In Critical Care, Edwards Lifesciences competes primarily with ICU Medical, Inc. and a variety of other companies in specific product categories including PULSION Medical Systems AG, LiDCO Group PLC 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 consists of a direct sales force as well as 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 2009.

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. Additionally, Edwards Lifesciences has contracts with a number of United States national and regional buying groups.

# Edgar Filing: Edwards Lifesciences Corp - Form 10-K

## Table of Contents

**United States.** In the United States, Edwards Lifesciences sells substantially all of its products through its direct sales force. In 2009, 42% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

**International.** In 2009, 58% 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 Australia, Belgium, Canada, France, Germany, Italy, Japan, the Netherlands, Spain and United Kingdom. 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 are 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.

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.



Table of Contents

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 routinely 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 \$175 million in research and development in 2009, \$139 million in 2008 (excluding special charges) and \$122 million in 2007 (13.3%, 11.2% and 11.2% 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 investing substantially 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, automated 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

Table of Contents

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.

A number of Edwards Lifesciences' products are pending regulatory approval to begin commercial sales including the *Edwards SAPIEN* THV in the United States, and the *Edwards SAPIEN XT* THV, the *NovaFlex* delivery system and *Ascendra 2* delivery system in Europe.

# Edgar Filing: Edwards Lifesciences Corp - Form 10-K

## Table of Contents

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, and reporting of adverse events by manufacturers and users to identify potential problems with marketed medical devices. 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. Several legislative proposals in the United States have been advanced that would restrict future funding increases for government-funded programs, including Medicare and Medicaid.

Over the years, health care cost containment efforts have prompted domestic hospitals and other customers of medical device manufacturers to consolidate into larger purchasing groups to enhance purchasing power, and this trend is expected to continue. 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.

**Health Care Reform.** Government initiatives to slow the rising costs associated with health care and expand access to uninsured residents of the United States are being considered by Congress. Some proposals would fund a portion of the cost of expanded health care access through a tax or fee levied on medical device manufacturers, although it is unlikely that such a tax or fee will be effective in 2010. Any such initiatives could ultimately put pressure on the product pricing and profitability of medical device companies, including Edwards Lifesciences.

## **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, 2009, Edwards Lifesciences had approximately 6,400 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

Table of Contents

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. The global recession and general economic conditions could adversely affect the financial

Table of Contents

viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their financial viability and 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 and foreign regulatory authorities 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, 2009, we had \$22.3 million of investments in equity instruments of other companies and had recorded unrealized losses of \$1.0 million on these investments on our consolidated balance sheet in "Accumulated Other Comprehensive Loss," 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 underperforming 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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

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, health care reform initiatives currently being considered by the United States Congress could result in additional taxes or fees levied on the medical device industry in connection with expanding access to, and containing costs associated with, health care uninsured residents of the United States. Although it is unlikely that such taxes or fees will be effective in 2010, such initiatives could ultimately affect reimbursement levels or otherwise put pressure on the Company's product pricing and profitability.

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

The uncertainty arising from domestic and global economic conditions, including disruption in the credit markets and the impact on the overall economy 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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

ability to borrow. These conditions have 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 may enter into interest rate swaps and foreign exchange contracts with counterparties in the financial services industry, which industry has come under considerable pressure. 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 uncertain economic conditions and pressure on government and hospital budgets 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, including risks associated with United States government oversight and enforcement of the Foreign Corrupt Practices Act. Our net sales originating outside of the United States, as a percentage of total net sales, were 58% in 2009. 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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.



## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

*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.*

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

*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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

*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, 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

Table of Contents

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. Further, preliminary results from clinical trials may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or 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

Table of Contents

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. In addition, current United States government initiatives to reform health care policies could adversely affect reimbursement levels for our products, or otherwise adversely affect our product pricing and profitability.

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 and may limit patient access. If a government were to decide to reduce reimbursement levels, our product pricing could 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 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 sale 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.

Table of Contents**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
Draper, Utah	(2) Administration, Research and Development, Manufacturing
Haina, Dominican Republic	(2) Manufacturing
Añasco, Puerto Rico	(2) Manufacturing

**Europe**

Horw, Switzerland	(2) Manufacturing, Administration, Distribution
Nyon, Switzerland	(1) Administration, Marketing

**Asia**

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

(1) Owned property.

(2) Leased property.

The Draper, Utah lease expires in 2025; the Dominican Republic lease expires in 2015; the Puerto Rico property has one lease that expires in 2018, and another that expires in 2016; the Horw, Switzerland lease is renewed annually with appropriate termination notice provisions; the Tokyo, Japan lease expires in 2012; 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 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 appealed this decision and in February 2010 a German Appeals Court affirmed. In May 2007 and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, 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 parties have filed cross-appeals on the validity and infringement decisions. In January 2010, a German Court determined that the Andersen patent was valid. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. Trial is scheduled for March 2010.

In February 2008, Cook, Inc. ("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 counterclaimed, alleging infringement by Edwards. In March 2009, the German Court ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court

Table of Contents

also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. Cook is appealing the judgments in Germany and the United Kingdom. The German Court decision on validity of the Cook patent is expected in April 2010.

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, 2009.



Table of Contents**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.

Calendar Quarter Ended:	2009		2008	
	High	Low	High	Low
March 31	\$ 63.50	\$ 52.86	\$ 47.62	\$ 41.69
June 30	68.23	55.82	63.49	44.80
September 30	70.44	60.90	66.99	53.75
December 31	88.25	67.65	58.56	44.76

*Number of Stockholders*

On January 31, 2010, there were 15,078 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, 2009	102,500	\$ 70.69	102,500	\$ 106.7
November 30, 2009	50,000	79.81	50,000	102.7
December 31, 2009	55,000	84.69	55,000	98.0
Total	207,500	76.60	207,500	

(a)

On July 11, 2008, 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. On February 11, 2010, the Company approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$500.0 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*

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

*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,				
		2009	2008	2007	2006	2005
		(in millions, except per share data)				
<b>OPERATING RESULTS</b>	Net sales	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1	\$ 1,037.0	\$ 997.9
	Gross profit	922.3	818.1	712.9	663.4	623.3
	Net income(a)	229.1	128.9	113.0	130.5	79.3
<b>BALANCE SHEET DATA</b>	Total assets	\$ 1,615.5	\$ 1,400.2	\$ 1,349.8	\$ 1,246.8	\$ 1,229.1
	Long-term debt and lease obligations	90.3	175.5	61.7	235.9	316.1
<b>COMMON STOCK INFORMATION</b>	Net income per common share(a):					
	Basic	\$ 4.07	\$ 2.31	\$ 1.97	\$ 2.23	\$ 1.33
	Diluted	3.90	2.19	1.87	2.10	1.27
	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 (gains) charges, net, of \$(63.8) million, \$25.1 million and \$23.3 million during 2009, 2008 and 2007, 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, 2009. Also discussed is Edwards Lifesciences' financial position as of December 31, 2009. 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 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. Prior to September 2009, Edwards Lifesciences provided central venous access products for fluid and drug delivery ("hemofiltration product line"). The Company sold the hemofiltration

Table of Contents

product line effective September 1, 2009. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannulae, *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, and artificial implantable grafts. Edwards Lifesciences manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents until the sale of this product line in January 2008. The Company continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred 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	
	2009	2008	2007	2009	2008	2009	2008
United States	\$ 556.1	\$ 543.6	\$ 486.6	\$ 12.5	\$ 57.0	2.3%	11.7%
Europe	404.6	380.3	309.1	24.3	71.2	6.4%	23.0%
Japan	214.1	176.5	171.4	37.6	5.1	21.3%	3.0%
Rest of World	146.6	137.3	124.0	9.3	13.3	6.8%	10.7%
<b>International</b>	<b>765.3</b>	<b>694.1</b>	<b>604.5</b>	<b>71.2</b>	<b>89.6</b>	<b>10.3%</b>	<b>14.8%</b>
Total net sales	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1	\$ 83.7	\$ 146.6	6.8%	13.4%

The \$12.5 million **increase in net sales in the United States in 2009** was due primarily to:

Heart Valve Therapy products, which increased sales by \$33.6 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Ease* and *Magna* with *ThermaFix* valves, and the *Carpentier-Edwards Physio II* ring, which was launched in the first quarter of 2009;

partially offset by:

the divestiture of the *LifeStent* product line in mid-January 2008, which decreased net sales by \$23.2 million. *LifeStent* sales after the divestiture resulted from the on-going manufacturing requirements of the sale agreement, which continued until the transfer of manufacturing to the buyer in September 2009.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

The \$71.2 million **increase in international net sales in 2009** was due primarily to:

Heart Valve Therapy products, which increased net sales by \$80.0 million, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve and the *Magna* aortic valve in Japan; and

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

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$15.2 million, due primarily to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar; and

hemofiltration products, which decreased net sales by \$10.6 million. The Company sold its hemofiltration product line effective September 1, 2009. For more information see "*Special (Gains) Charges, net.*"

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 were 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 continued until the transfer of manufacturing to the buyer in September 2009;

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 \$70.7 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;

Critical Care products, which increased net sales by \$22.9 million, driven primarily by the *FloTrac* minimally invasive

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

monitoring system, pressure monitoring products and hemofiltration products;

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

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 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.*"

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

#### *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	
	2009	2008	2007	2009	2008	2009	2008
Heart Valve Therapy	\$ 714.9	\$ 607.4	\$ 515.0	\$ 107.5	\$ 92.4	17.7%	17.9%
Critical Care	452.5	451.8	397.8	0.7	54.0	0.2%	13.6%
Cardiac Surgery							
Systems	92.8	89.2	60.9	3.6	28.3	4.0%	46.5%
Vascular	61.2	89.3	90.0	(28.1)	(0.7)	(31.5)%	(0.8)%
Other Distributed Products			27.4		(27.4)	%	(100.0)%
Total net sales	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1	\$ 83.7	\$ 146.6	6.8%	13.4%

#### *Heart Valve Therapy*

The \$107.5 million increase in net sales of Heart Valve Therapy products in 2009 was due primarily to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$59.5 million;

pericardial tissue valves, which increased net sales by \$41.7 million, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, the *Magna with ThermaFix* mitral valve and the *Magna* aortic valve in Japan; and

the launch of the *Carpentier-Edwards Physio II* ring in the first quarter of 2009, which increased net sales by \$12.0 million;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$8.6 million, due primarily to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar.

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 \$47.7 million;

pericardial tissue valves, which increased net sales by \$32.4 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; and

foreign currency exchange rate fluctuations, which increased net sales by \$17.4 million, due primarily to the strengthening of the Euro and Japanese yen against the United States dollar.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

The Company expects that its *SAPIEN* transcatheter heart valve will continue to be a strong contributor to 2010 sales. The Company also expects that the launches of its newly approved *Magna* valves will enable the Company to continue its surgical heart valve sales momentum in 2010. The Company received FDA approval for its *Magna Ease* aortic valve in May 2009. The *Magna Ease* valve is designed for easier implantation and has the potential for leadership in the largest segment of surgical valve replacement. In July 2009, the Company received United States regulatory approval for its *Magna* mitral valve, called the *Magna Mitral Ease*. The *Magna Mitral Ease* will extend the *Magna* platform by providing improved MIS capabilities and ease of implantation. The Company initiated a limited launch during the fourth quarter of 2009 and plans a broader introduction of *Magna Mitral Ease* in the United States and Europe during the third quarter of 2010. In January 2010, the Company completed first-in-man procedures and initiated a small clinical feasibility study in Europe, called TRITON, for a novel minimally invasive aortic valve surgery system, called



Table of Contents

Project Odyssey. The Project Odyssey system leverages the design of the *Carpentier-Edwards PERIMOUNT Magna Ease* tissue heart valve to create a new valve platform with an innovative delivery and attachment system. It is designed to enable a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision. The Company launched the *Carpentier-Edwards Physio II* ring in the United States and Europe during the first quarter of 2009, and in Japan during the first quarter of 2010. The Company expects this product to contribute to its growth in the repair segment. *Physio II* is the next generation repair product for the degenerative segment of mitral repair. In Japan, the Company received regulatory approval for its *IMR ETlogix* ring during the first quarter of 2009, and launched this product in Japan during the third quarter of 2009.

***Critical Care***

The \$0.7 million increase in net sales of Critical Care products in 2009 was due primarily to:

*FloTrac* systems, which increased net sales by \$14.2 million; and

core Critical Care products, which increased net sales by \$4.3 million, driven primarily by pressure monitoring products;

partially offset by:

hemofiltration products, which decreased net sales by \$13.6 million. The Company sold its hemofiltration product line effective September 1, 2009. For more information see "*Special (Gains) Charges, net*"; and

foreign currency exchange rate fluctuations, which decreased net sales by \$4.1 million, due primarily to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar.

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

*FloTrac* systems, which increased net sales by \$17.5 million;

core Critical Care products, which increased net sales by \$12.0 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;

hemofiltration products, which increased net sales by \$7.3 million; and

foreign currency exchange rate fluctuations, which increased net sales by \$15.5 million, due primarily to the strengthening of the Euro and Japanese yen against the United States dollar.

The Company expects worldwide *FloTrac* systems sales will continue to be a significant contributor to 2010 Critical Care sales growth, and that it will continue to expand the market for minimally invasive hemodynamic monitoring. During the first quarter of 2009, the Company launched a third generation algorithm enhancement for the *FloTrac* system that enhances its accuracy when used in patients with sepsis and other critical illnesses. In the second quarter of 2010, the Company expects to launch a substantial upgrade designed to strengthen the *FloTrac* system's applicability in the medical intensive care unit. Also in the second quarter of 2010, the Company expects to launch a new hardware platform with a simpler, more intuitive informational display, and expects to ultimately consolidate all parameters into one new hardware platform.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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. During the third quarter of 2009, the first of two clinical studies to validate performance and support regulatory approval was completed. During the fourth quarter of 2009, the Company received CE Mark and began clinical evaluation of its first generation product in a limited number of European sites. In 2010, the Company plans to continue conducting post-CE Mark trials in Europe and implement system enhancements. In the United States, the Company anticipates filing for regulatory approval in the middle of 2010.

Table of Contents

**Cardiac Surgery Systems**

The \$3.6 million increase in net sales of Cardiac Surgery Systems products in 2009 was due primarily to MIS products, which increased net sales by \$2.8 million.

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.

**Vascular**

The \$28.1 million decrease in net sales of Vascular products in 2009 was due primarily to reduced sales of the *LifeStent* product line which was divested in January 2008. Sales after the divestiture resulted from the on-going manufacturing requirements of the sale agreement, which continued until the transfer of manufacturing to the buyer in September 2009.

The \$0.7 million decrease in net sales of Vascular products in 2008 was due primarily to the divestiture of the *LifeStent* product line.

**Other Distributed Products**

The \$27.4 million decrease in net sales of Other Distributed Products in 2008 was due primarily to the termination at the end of 2007 of intra-aortic balloon pump distributed sales in Japan.

**Gross Profit**

	Years Ended December 31,			Change	
	2009	2008	2007	2009	2008
Gross profit as a percentage of net sales	69.8%	66.1%	65.3%	3.7 pts.	0.8 pts.

The 3.7 percentage point increase in gross profit as a percentage of net sales in 2009 was driven by:

a 1.5 percentage point increase in the United States due primarily to a more profitable product mix, primarily from reduced sales of *LifeStent* products under the manufacturing requirements of the *LifeStent* sale agreement and higher sales of Heart Valve Therapy products;

a 1.4 percentage point increase in international markets due to a more profitable product mix, primarily higher sales of Heart Valve Therapy products and *FloTrac* systems; and

the impact from the expiration of foreign currency hedging contracts.

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 markets 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 the United States 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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

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

(dollars in millions)

	Years Ended December 31,			Change	
	2009	2008	2007	2009	2008
SG&A expenses	\$ 508.8	\$ 480.6	\$ 418.0	\$ 28.2	\$ 62.6
SG&A expenses as a percentage of net sales	38.5%	38.8%	38.3%	(0.3) pts.	0.5 pts.

The \$28.2 million increase in SG&A expenses in 2009 was due primarily to (1) investments for the *Edwards SAPIEN* transcatheter heart valve program in Europe and (2) higher sales-related spending in the Heart Valve Therapy product line. The increase was partially offset by the favorable impact of foreign currency (primarily the weakening of the Euro against the United States dollar) in the amount of \$5.4 million.

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.

#### ***Research and Development Expenses***

(dollars in millions)

	Years Ended December 31,			Change	
	2009	2008	2007	2009	2008
Research and development expenses	\$ 175.5	\$ 139.2	\$ 122.3	\$ 36.3	\$ 16.9
Research and development expenses as a percentage of net sales	13.3%	11.2%	11.2%	2.1pts.	

The increase in research and development expenses in 2009 was due primarily to additional investments in transcatheter heart valve and glucose programs.

The increase in research and development expenses in 2008 was due primarily to additional investments in transcatheter and surgical heart valve 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 is evaluating 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 are randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. Enrollment of 690 patients in Cohort A, which is a non-inferiority analysis, was completed in the third quarter of 2009. In the second study arm ("Cohort B"), patients who are deemed non-operable are randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. Enrollment of 350 patients in Cohort B, which is a superiority analysis, was completed in the first quarter of 2009. In addition, the Company received FDA approval for non-randomized continued access for all of its existing PARTNER sites. The Company anticipates submitting Cohort B to the FDA for approval during the fourth quarter of 2010, and Cohort A in mid-2011. A favorable data comparison and an expected one-year approval process would result in United States approval of the *Edwards SAPIEN* transcatheter heart valve for medically managed patients in 2011;

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

the Company received CE Mark in the fourth quarter of 2008 for European commercial sales of its *RetroFlex 3* transfemoral delivery system, which simplifies the delivery of its *SAPIEN* valve. In addition, in the first quarter of 2009, the Company received IDE approval to use its *RetroFlex 3* delivery system in its United States PARTNER trial;

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. Upon completion of enrollment, the Company intends to transition to a larger humanitarian device exemption trial;

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. In the second quarter of 2009, the first implants were performed with *SAPIEN XT* and *NovaFlex*, the Company's next generation transfemoral delivery system. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, enabling it to better address the requirements of transfemoral delivery. The Company anticipates European approval and limited launch of *SAPIEN XT* with *NovaFlex* in the first quarter of 2010. The first-in-man cases in the PREVAIL TA study, which uses the *SAPIEN XT* with the lower-profile *Ascendra 2* transapical delivery system, were performed in the third quarter of 2009. The Company anticipates a limited European launch of *SAPIEN XT* with *Ascendra 2* in the second quarter of 2010;

in the United States, the Company submitted an IDE for *SAPIEN XT* in October 2009. This clinical trial, called PARTNER 2, will evaluate the *SAPIEN XT* with both the *NovaFlex* and *Ascendra 2* delivery systems and will target the same high risk patients studied in the PARTNER trial. The Company received questions from the FDA and is working closely with them to further the approval process. Based on the current rigorous regulatory environment, trial approval may be delayed into the second quarter of 2010; and

in Japan, the Company completed its first compassionate use cases with the *SAPIEN* valve using both the transapical and transfemoral delivery systems in October 2009. The Company intends to start a clinical trial with its *SAPIEN XT* valve during the second quarter of 2010. Successful trial completion could result in an approval as early as 2013.

The following are the activities 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. The Company has expanded the trial to include specialty heart failure centers in order to increase the pace of enrollment.

#### ***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 product prototype and had discontinued the program. Completion of successful design developments, bench testing,



Table of Contents

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 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 \$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. At the time of the valuation, the Company's assumptions included 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. 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.



Table of Contents*Special (Gains) Charges, net*

	Years Ended December 31,		
	2009	2008	2007
	(in millions)		
Gain on sale of assets, net	\$ (86.9)	\$ (14.9)	\$ (1.8)
Charitable fund contribution	15.0		
Settlements and litigation, net	3.8	0.6	
Adjustment to capitalized patent enforcement costs	3.7	8.2	
Investment impairment	1.6		
Reserve reversal	(1.0)		
Acquisition of in-process technology and intellectual property		19.5	
DexCom collaboration agreement		13.4	
Realignment expenses, net		(1.7)	13.9
Pension settlement and adjustment			11.2
<b>Total special (gains) charges, net</b>	<b>\$ (63.8)</b>	<b>\$ 25.1</b>	<b>\$ 23.3</b>

*Gain on Sale of Assets, net*

Effective September 1, 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years, of which \$2.1 million was earned in 2009 and recorded in "Other (Income) Expense, net." The sale resulted in a pre-tax gain of \$43.6 million consisting of the cash proceeds of \$55.9 million, offset by \$8.5 million related to the net book value of inventory, fixed assets and intangible assets that were sold, a \$0.6 million satisfaction of a receivable, a \$0.5 million write-off of goodwill associated with this product line and \$2.7 million of transaction and other costs related to the sale. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance related to the pending sale. The Company will provide transition services to the buyer. This transaction allows the Company to better focus on its global strategic priorities.

In March 2009, the Company recorded a \$2.8 million gain related to the sale of its distribution rights in Europe for a specialty vascular graft.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of *LifeStent* device manufacturing to the buyer.

In connection with the *LifeStent* 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 agreed to provide and \$3.7 million of transaction and other costs related to the sale.

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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

#### *Charitable Fund Contribution*

In September 2009, the Company contributed \$15.0 million to The Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular and community related charitable causes. The contribution was an irrevocable contribution to a third party, and was recorded as an expense at the time of payment.

#### *Settlements and Litigation, net*

In September 2009, the Company recorded a \$3.8 million charge for litigation related to a royalty dispute in connection with a product in the Company's Cardiac Surgery Systems product line.

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.

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

In December 2009, the Company recorded a \$3.7 million charge for the write-off of capitalized patent enforcement costs related to litigation in Europe for which success was no longer deemed probable.

In December 2008, the Company recorded an \$8.2 million charge due primarily to the reversal of capitalized patent enforcement costs for a litigated claim related to patents in a product area where the Company did not then, and does not currently, compete and where the related patent enforcement costs, therefore, should 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 out-of-period amounts 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.

#### *Investment Impairment*

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its technology investment in an unconsolidated affiliate. The Company concluded that the impairment of its investment was other-than-temporary based upon (a) the continuing duration and severity of the impairment and (b) positive clinical trial developments in the third quarter of 2009 which failed to raise the quoted market price of the affiliate's stock to the Company's carrying value.

#### *Reserve Reversal*

In 2004, the Company discontinued its *Lifepath* AAA endovascular graft program. In March 2009, upon completion of its remaining clinical obligations related to this program, the Company reversed its remaining \$1.0 million clinical reserve.

#### *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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

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 prototypes 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\$4.3 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$9.1 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 \$24.0 million over the next three years in product development costs and regulatory approval milestones. In addition, DexCom will receive either a profit-sharing payment or a royalty based upon 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.

#### *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, 2009, payments related to the executive severance charge were substantially complete.

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, 2009, payments related to the realignment were substantially complete.

#### *Pension Settlement and Adjustment*

In December 2007, the Company's 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 the Financial Accounting Standards Board Accounting Standards Codification ("ASC") Topic 715 to a defined benefit pension plan in Switzerland, which had previously been accounted for as a defined contribution plan. The Company recorded a charge of \$4.1 million in December 2007 to correct this error. The Company concluded that the impact of the increase in the pension obligation was not material to the 2007 or prior years' consolidated financial statements.

Table of Contents**Interest Expense**

Interest expense was \$2.7 million, \$7.2 million and \$9.1 million in 2009, 2008 and 2007, respectively. The \$4.5 million decrease in interest expense for 2009 resulted primarily from lower interest rates and a lower average debt balance as compared to the prior year. The \$1.9 million decrease in interest expense for 2008 resulted primarily from lower interest rates as compared to the prior year.

**Interest Income**

Interest income was \$1.6 million, \$6.1 million and \$7.7 million in 2009, 2008 and 2007, respectively. The \$4.5 million and \$1.6 million decreases in interest income for 2009 and 2008, respectively, resulted primarily from lower average interest rates.

**Other (Income) Expense, net**

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

	Years Ended December 31,		
	2009	2008	2007
Foreign exchange (gains) losses, net	\$ (2.3)	\$ 7.2	\$ (2.0)
Earn-out payments	(2.1)		(2.3)
Gain on investments in unconsolidated affiliates	(1.2)	(2.0)	(1.3)
Investment realized (gains) losses and impairment	(0.5)	3.0	0.7
Accounts receivable securitization costs		1.6	3.0
Other	2.4	(2.1)	
	\$ (3.7)	\$ 7.7	\$ (1.9)

The foreign exchange (gains) losses relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances. Foreign exchange resulted in a net gain in 2009 compared to a net loss in 2008 due primarily to fluctuations in the Euro.

In September 2009, the Company sold its hemofiltration product line. In connection with the transaction, the Company is entitled to earn-out payments up to \$9.0 million based on certain revenue objectives to be achieved by the buyer over the next two years. During 2009, the Company earned \$2.1 million.

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.

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

The investment realized (gains) losses and impairment represents the realized gains and 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 decreases in accounts receivable securitization costs in 2009 and 2008 were due primarily to the Company's termination of its securitization programs in the United States (August 2008) and Japan (February 2009).

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

#### *Provision for Income Taxes*

The effective income tax rates for 2009, 2008 and 2007 were impacted as follows (in millions):

	Years Ended December 31,		
	2009	2008	2007
Income tax expense at U.S. federal statutory rate	\$ 106.5	\$ 57.5	\$ 52.4
Foreign income tax at different rates	(27.9)	(26.4)	(21.4)
Tax credits, federal and state	(5.5)	(3.5)	(2.8)
State and local taxes, net of federal tax benefit	4.9	2.0	3.1
Reserve for uncertain tax positions for prior years	(3.8)	(6.2)	1.2
Nondeductible stock-based compensation	1.4	0.9	1.9
Deemed dividends, net of foreign tax credit	1.0	0.6	3.2
Valuation allowance for loss on investments	0.6		(0.6)
Nondeductible goodwill		12.2	
Other	(1.9)	(1.6)	(0.2)
<b>Income tax provision</b>	<b>\$ 75.3</b>	<b>\$ 35.5</b>	<b>\$ 36.8</b>

#### *Reserve for Uncertain Tax Positions*

As of December 31, 2009 and 2008, the liability for income taxes associated with uncertain tax positions was \$47.1 million and \$35.9 million, respectively. These liabilities could be reduced by \$3.2 million and \$2.3 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 \$44.0 million and \$33.6 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):

	December 31,		
	2009	2008	2007
Unrecognized tax benefits, January 1	\$ 35.9	\$ 36.4	\$ 24.6
Increase prior period tax positions	8.9	12.3	12.1
Decrease prior period tax positions	(9.4)	(19.9)	(7.9)
Current year tax positions	15.7	18.0	8.6
Settlements	(3.6)	(10.9)	(0.9)
Lapse of statute of limitations	(0.4)		(0.1)
<b>Unrecognized tax benefits, December 31</b>	<b>\$ 47.1</b>	<b>\$ 35.9</b>	<b>\$ 36.4</b>

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2009, the Company had accrued \$2.7 million (net of \$0.5 million tax benefit) of interest related to uncertain tax positions, and 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.

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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management

Table of Contents

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.

As a result of on-going negotiations of Advanced Pricing Agreements between Switzerland and Japan, and Japan and the United States, the expiration of statutes of limitations, and the possible settlement of on-going audits in several jurisdictions for multiple years throughout the world, the total liability for unrecognized tax benefits may change within the next 12 months. The range of such change could vary, but the amount of such change could result in a reduction of as much as \$26 million. At December 31, 2009, 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. The Company is currently under examination by the Internal Revenue Service for the 2007 and 2008 tax years.

In February 2009, California enacted tax legislation which will be effective beginning 2011. The impact of the new legislation has been considered in determining the Company's tax provision for 2009, including the realizability of its California research and development credit carryforward.

*Nondeductible Stock-based Compensation*

Some of the Company's stock-based compensation costs 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 contingent on 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, 2009, deferred tax assets and corresponding valuation allowances of approximately \$3.2 million had accumulated related to investments. Of the total valuation allowance of \$3.2 million, \$0.5 million was recorded as a component of "Accumulated Other Comprehensive Loss," while \$0.6 million was recorded in 2009 through a charge to profit and loss. The remaining \$2.1 million had previously been recorded as of December 31, 2008 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.

*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.

The Company has received tax incentives in Puerto Rico, Dominican Republic, Singapore and Switzerland. The tax reductions as compared to the local statutory rates favorably impacted earnings per diluted share for the years ended December 31, 2009, 2008 and 2007 by \$0.66, \$0.59 and \$0.50, respectively. The Puerto Rico, Dominican Republic, Singapore and Switzerland grants provide the Company's manufacturing operations partial or full exemption from local taxes until the years 2013, 2017, 2019 and indefinitely, respectively.

**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

Table of Contents

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 conditions 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 Edwards Lifesciences on favorable terms, or at all.

The Company has a Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement") which matures on September 29, 2011. The Credit Agreement provides up to an aggregate of \$500.0 million in one- to six-month borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate ("LIBOR") plus 0.40%, which includes a facility fee subject to adjustment for leverage ratio changes, as defined in the Credit Agreement. The Company pays a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.075%. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings are expected to be refinanced pursuant to the Credit Agreement. As of December 31, 2009, borrowings of \$90.3 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, 2009.

The Company previously securitized, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in the United States and Japan. In August 2008, the Company terminated its securitization program in the United States, and repurchased \$50.0 million of accounts receivable. In February 2009, the Company terminated its securitization program in Japan and paid \$39.0 million for the outstanding accounts receivable and February collections. The securitization programs no longer offered an attractive financing alternative.

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. As of December 31, 2009, the Company's investment in this fund had been fully liquidated.

In September 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. 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 to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. The remaining \$15.0 million milestone was earned and recorded in September 2009 upon the transfer of *LifeStent* device manufacturing to the buyer.

In July 2008, 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. During 2009, the Company repurchased 1.5 million shares at an aggregate cost of \$95.5 million and as of December 31, 2009 had remaining authority under the July 2008 program to purchase \$98.0 million of common stock. In February 2010, the Company approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$500.0 million of the Company's common stock. Stock repurchased under these programs has been used primarily to offset obligations under the Company's employee stock option programs and reduce the total shares outstanding.



## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

Net cash flows provided by **operating activities** of \$165.3 million for 2009 increased \$12.1 million from 2008 primarily due to a \$50.0 million cash payment during 2008 to terminate the Company's accounts receivable securitization program in the United States, compared to a \$39.0 million cash payment during 2009 to terminate the Company's accounts receivable securitization program in Japan. In addition, 2009 operating cash flow was positively impacted by higher operating profits and lower tax payments, offset by net cash outflows resulting from a decrease in accounts payable and accrued liabilities in 2009.

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 higher operating profits and an increase in accounts payable and accrued liabilities in 2008.

Net cash provided by **investing activities** of \$40.1 million in 2009 consisted primarily of \$55.9 million of cash received from the sale of the hemofiltration product line, \$42.0 million of cash received for milestone achievements associated with the *LifeStent* pre-market approval, and \$11.4 million in cash redemptions associated with the Bank of America Columbia Strategic Cash fund, partially offset by capital expenditures of \$64.0 million.

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 **financing activities** of \$91.8 million in 2009 consisted primarily of purchases of treasury stock of \$95.5 million and net payments on long-term debt of \$84.6 million, partially offset by the proceeds from stock plans of \$66.7 million.

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.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2009 were as follows (in millions):

Contractual Obligations	Total	Payments Due by Period			
		Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Long-term debt	\$ 90.3	\$ 90.3	\$ 90.3	\$	\$
Interest on long-term debt	1.0	0.6	0.4		
Operating leases	74.7	16.1	21.2	12.4	25.0
Pension obligation(a)	4.7	4.7			
Contractual development obligations(b)	31.9	9.6	17.5	4.8	
Capital commitment obligations(c)	3.5	2.0	1.5		
<b>Total contractual cash obligations(d)</b>	<b>\$ 206.1</b>	<b>\$ 33.0</b>	<b>\$ 130.9</b>	<b>\$ 17.2</b>	<b>\$ 25.0</b>

(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, 2009 was \$25.7 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. Therefore, the Company is unable

Table of Contents

to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and 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, 2009, the liability for uncertain tax positions including interest was \$50.3 million. As a result of on-going negotiations of Advanced Pricing Agreements between Switzerland and Japan, and Japan and the United States, the expiration of statutes of limitations, and the possible settlement of on-going audits in several jurisdictions for multiple years throughout the world, the total liability for unrecognized tax benefits may change within the next 12 months. The range of such change could vary, but the amount of such change could result in a reduction of as much as \$26 million.

**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.

Table of Contents

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 periodically 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 periodically 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 \$12.4 million and \$9.9 million at December 31, 2009 and 2008, 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. A write-down for excess or inactive inventory is recorded for 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 \$16.0 million and \$13.2 million at December 31, 2009 and 2008, 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

Table of Contents

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 Goodwill and 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 a two-step goodwill impairment test. 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. In 2009, 2008 and 2007, the Company did not perform the second step of the impairment test as the fair value of each reporting unit exceeded its respective carrying value.

Additionally, 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. These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as "*Accumulated Other Comprehensive Loss*." Gains or losses on investments sold are based on the specific identification method. Other investments in unconsolidated affiliates are accounted for under the cost or the equity method of accounting, as appropriate. The Company accounts for investments in limited partnerships or limited liability corporations, whereby the Company owns a minimum of 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.

Table of Contents

***Income Taxes***

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. 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. 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. The Black-Scholes model requires various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. Stock-based compensation expense is recorded net of estimated forfeitures. Judgment is required in estimating the stock awards that will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and the Company's results of operations could be impacted.

***Fair Value Measurements***

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. The Company prioritizes the inputs used to determine fair value 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.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

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*

##### **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. These investments are carried at fair market value based on quoted market prices and are categorized as Level 1.

#### *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, 2009. 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.

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

In June 2009, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIEs"). This accounting guidance eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a VIE based on whether the entity (a) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (b) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. The guidance requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. The guidance is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In October 2009, the FASB issued an amendment to ASC Topic 605, "*Revenue Recognition*," to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. ASC Topic 605 was also amended to eliminate the requirement that all undelivered elements

Table of Contents

must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an amendment to ASC Topic 820, "*Fair Value Measurements and Disclosures*," to require companies to (a) disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for such transfers and (b) present separately in the Level 3 reconciliation information about purchases, sales, issuances and settlements. The amendment also clarifies existing guidance on the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation, which is effective for fiscal years beginning after December 15, 2010, and for interim periods within those years. The Company does not expect the adoption of this guidance will 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 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, 2009 and 2008 were \$343.1 million and \$225.1 million, respectively. The notional amounts of 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**

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 15 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

Table of Contents

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, 2009 and 2008 with a maturity of up to one year, was \$4.5 million and \$5.7 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, 2009 reduced by the effects of master-netting agreements. Additionally, at December 31, 2009, 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, 2009. 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 2009, the Company had no customers that represent greater than 10% of its total net sales or accounts receivable, net.



Table of Contents

**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, 2009, Edwards Lifesciences had \$22.3 million of investments in equity instruments of other companies and had recorded unrealized losses of \$1.0 million on these investments in "*Accumulated Other Comprehensive Loss*," net of tax. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the decline in the investments' values may be considered other than temporary and impairment charges may be necessary.

Table of Contents

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2009**

<u>Report of Independent Registered Public Accounting Firm</u>	<u>47</u>
Financial Statements:	
<u>Consolidated Balance Sheets at December 31, 2009 and 2008</u>	<u>48</u>
For the Years Ended December 31, 2009, 2008 and 2007:	
<u>Consolidated Statements of Operations</u>	<u>49</u>
<u>Consolidated Statements of Cash Flows</u>	<u>50</u>
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)</u>	<u>51</u>
<u>Notes to Consolidated Financial Statements</u>	<u>53</u>
Other schedules are not applicable and have not been submitted	

Table of Contents

**Report of Independent Registered Public Accounting Firm**

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Edwards Lifesciences Corporation and its subsidiaries at December 31, 2009 and December 31, 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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, included 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.

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

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

/s/ PricewaterhouseCoopers LLP  
Orange County, California  
February 26, 2010

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****CONSOLIDATED BALANCE SHEETS**

(in millions, except par value)

	December 31,	
	2009	2008
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 334.1	\$ 218.7
Short-term investments (Note 2)		8.1
Accounts receivable, net (Note 5)	249.4	186.3
Other receivables	22.7	18.4
Inventories, net	165.9	151.8
Deferred income taxes	48.3	42.4
Prepaid expenses	33.7	30.7
Other current assets	35.1	35.5
<b>Total current assets</b>	<b>889.2</b>	<b>691.9</b>
Property, plant and equipment, net	252.0	230.1
Goodwill (Notes 3 and 7)	315.2	315.7
Other intangible assets, net	86.7	96.9
Investments in unconsolidated affiliates	22.3	14.7
Deferred income taxes	37.1	37.7
Other assets	13.0	13.2
<b>Total assets</b>	<b>\$ 1,615.5</b>	<b>\$ 1,400.2</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 51.1	\$ 65.6
Accrued liabilities	203.5	186.7
Taxes payable	35.9	6.2
<b>Total current liabilities</b>	<b>290.5</b>	<b>258.5</b>
Long-term debt (Note 9)	90.3	175.5
Other long-term liabilities	76.8	87.4
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, 76.1 and 73.7 shares issued, and 56.8 and 55.9 shares outstanding, respectively	76.1	73.7
Additional paid-in capital	1,056.0	940.4
Retained earnings	906.0	676.9
Accumulated other comprehensive loss	(7.9)	(35.4)
Treasury stock, at cost, 19.3 and 17.8 shares, respectively	(872.3)	(776.8)
<b>Total stockholders' equity</b>	<b>1,157.9</b>	<b>878.8</b>

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Total liabilities and stockholders' equity           \$ 1,615.5   \$ 1,400.2

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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(in millions, except per share information)

	Years Ended December 31,		
	2009	2008	2007
Net sales	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1
Cost of goods sold	399.1	419.6	378.2
<b>Gross profit</b>	<b>922.3</b>	<b>818.1</b>	<b>712.9</b>
Selling, general and administrative expenses	508.8	480.6	418.0
Research and development expenses	175.5	139.2	122.3
Special (gains) charges, net (Note 3)	(63.8)	25.1	23.3
Interest expense	2.7	7.2	9.1
Interest income	(1.6)	(6.1)	(7.7)
Other (income) expense, net (Note 14)	(3.7)	7.7	(1.9)
<b>Income before provision for income taxes</b>	<b>304.4</b>	<b>164.4</b>	<b>149.8</b>
Provision for income taxes	75.3	35.5	36.8
<b>Net income</b>	<b>\$ 229.1</b>	<b>\$ 128.9</b>	<b>\$ 113.0</b>

**Share information**

(Note 2):

Earnings per share:			
Basic	\$ 4.07	\$ 2.31	\$ 1.97
Diluted	\$ 3.90	\$ 2.19	\$ 1.87
Weighted-average number of common shares outstanding:			
Basic	56.3	55.8	57.3
Diluted	58.7	59.6	62.7

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

Table of Contents

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

(in millions)

	Years Ended December 31,		
	2009	2008	2007
<b>Cash flows from operating activities</b>			
Net income	\$ 229.1	\$ 128.9	\$ 113.0
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	58.7	55.6	54.8
Stock-based compensation (Notes 2 and 12)	28.3	28.7	27.7
Deferred income taxes	(4.0)	(23.5)	(5.6)
Special (gains) charges, net (Note 3)	(75.5)	25.4	14.9
(Gain) loss on trading securities	(3.3)	4.9	0.3
(Gain) loss on investments	(0.5)	3.0	0.7
Other	0.8	(0.3)	1.5
Changes in operating assets and liabilities:			
Accounts and other receivables, net (Note 5)	(58.9)	(61.1)	(6.6)
Accounts receivable securitization (Note 5)	7.3	(7.4)	11.9
Inventories, net	(13.1)	(17.8)	(9.0)
Accounts payable and accrued liabilities	(23.9)	32.9	14.0
Prepaid expenses and other current assets	7.6	(3.3)	(5.8)
Other	12.7	(12.8)	1.3
Net cash provided by operating activities	165.3	153.2	213.1
<b>Cash flows from investing activities</b>			
Capital expenditures	(64.0)	(50.6)	(57.0)
Proceeds from sale of assets (Note 3)	97.9	97.0	7.2
Proceeds from short-term investments (Note 2)	11.4	35.5	4.9
Investments in unconsolidated affiliates	(5.8)	(1.1)	(3.9)
Proceeds from unconsolidated affiliates	2.3	5.5	1.4
Investments in trading securities, net	(1.6)	(0.2)	(2.0)
Transfer to short-term investments (Note 2)			(55.0)
Investments in intangible assets		(27.4)	(5.5)
Acquisitions and milestone payment (Notes 3 and 6)			(37.0)
Other	(0.1)	0.1	(0.5)
Net cash provided by (used in) investing activities	40.1	58.8	(147.4)
<b>Cash flows from financing activities</b>			
Payments on long-term debt	(213.9)	(112.1)	(85.2)
Proceeds from issuance of long-term debt	129.3	206.3	57.3
Purchases of treasury stock	(95.5)	(306.5)	(130.9)
Proceeds from stock plans	66.7	63.8	38.7
Excess tax benefit from stock plans (Notes 2 and 12)	20.6	14.9	8.6
Other	1.0	(0.5)	3.4
Net cash used in financing activities	(91.8)	(134.1)	(108.1)
Effect of currency exchange rate changes on cash and cash equivalents	1.8	(1.0)	1.4
Net increase (decrease) in cash and cash equivalents	115.4	76.9	(41.0)
Cash and cash equivalents at beginning of year	218.7	141.8	182.8
Cash and cash equivalents at end of year	\$ 334.1	\$ 218.7	\$ 141.8

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Supplemental disclosures:

Cash paid during the year for:

Interest	\$	2.7	\$	7.3	\$	9.0
Income taxes	\$	34.2	\$	37.2	\$	31.0

Non-cash transaction:

Issuance of common shares in redemption of convertible debt (Note 9)	\$		\$	147.7	\$	
---	----	--	----	-------	----	--

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



Table of Contents

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

(in millions)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive (Loss)		Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount			Income	Total	
<b>BALANCE AT DECEMBER 31, 2006</b>	67.0	\$ 67.0	9.3	\$ (339.4)	\$ 603.7	\$ 433.9	\$ (15.8)	\$ 749.4	
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 new accounting guidance on uncertain tax positions						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	\$ 136.3
Comprehensive income									
Net income						128.9		128.9	\$ 128.9
Other comprehensive income (loss), net of tax:									
							(24.2)	(24.2)	(24.2)

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Foreign currency translation adjustments										
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						(0.3)	(0.3)	(0.3)		
Net loss						(10.1)	(10.1)	(10.1)		
Effects of changing the pension plan measurement date:										
Service and interest cost, and expected return on plan assets for November 1 December 31, 2007, net of tax						(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>	73.7	73.7	17.8	(776.8)	940.4	676.9	(35.4)	878.8	\$	86.0

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

Table of Contents

**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 (Loss) Income		Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount			Total		
<b>BALANCE AT DECEMBER 31, 2008</b>	73.7	73.7	17.8	(776.8)	940.4	676.9	(35.4)	878.8	
Comprehensive income									
Net income						229.1		229.1	\$ 229.1
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							17.3	17.3	17.3
Unrealized loss on cash flow hedges							(3.5)	(3.5)	(3.5)
Unrealized gain on available-for-sale investments							4.7	4.7	4.7
Defined benefit pension plans:									
Net gain (Note 13)							9.0	9.0	9.0
Common stock issued under equity plans	2.4	2.4			64.3			66.7	
Tax benefit related to equity plans					22.8			22.8	
Tax benefit due to redemption of convertible debt					0.2			0.2	
Stock-based compensation expense					28.3			28.3	
Purchase of treasury stock			1.5	(95.5)				(95.5)	
<b>BALANCE AT DECEMBER 31, 2009</b>	76.1	\$ 76.1	19.3	\$ (872.3)	\$ 1,056.0	\$ 906.0	\$ (7.9)	\$ 1,157.9	\$ 256.6

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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS**

Edwards Lifesciences Corporation ("Edwards Lifesciences" or the "Company") 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 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, and disposable pressure transducers. Prior to September 2009, Edwards Lifesciences provided central venous access products for fluid and drug delivery ("hemofiltration product line"). The Company sold the hemofiltration product line effective September 1, 2009. The Company's Cardiac Surgery Systems products include a diverse line of products for use during cardiac surgery including cannulae, 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, and artificial implantable grafts. Edwards Lifesciences manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents until the sale of this product line in January 2008. The Company continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred 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.

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

**Foreign Currency Translation**

When the local currency of the Company's 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.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as "*Accumulated Other Comprehensive Loss*." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "*Other (Income) Expense, 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 periodically 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 ("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 periodically 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.

**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.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**Investments**

The Company held 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. As of December 31, 2009, the Company's investment in this fund had been fully liquidated. The fair value of the Company's 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. As of December 31, 2008, \$8.1 million of the investment was classified as "*Short-term Investments*" and \$2.8 million was classified as "*Other Assets*" based on the redemption schedule communicated to the Company at that time. During the years ended December 31, 2009 and 2008, the Company recognized realized gains of \$0.5 million, and realized losses and unrealized losses considered other-than-temporary of \$3.0 million, respectively, included in "*Other (Income) Expense, 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.

A write-down for excess or inactive inventory is recorded for 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 \$16.0 million and \$13.2 million at December 31, 2009 and 2008, 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, 2009, 2008 and 2007, the Company allocated \$20.9 million, \$21.3 million and \$20.1 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2009 and 2008 were \$10.3 million and \$8.8 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 \$38.0 million, \$36.8 million and \$38.0 million for the years ended December 31, 2009, 2008 and 2007, respectively. Repairs and maintenance expense was \$15.4 million, \$14.6 million and \$14.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

**Impairment of Goodwill and 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 a two-step goodwill impairment test. The Company identifies

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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. In 2009, 2008 and 2007, the Company did not perform the second step of the impairment test as the fair value of each reporting unit exceeded its respective carrying value.

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

**Patent Costs**

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes 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. These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as "*Accumulated Other Comprehensive Loss*." Gains or losses on investments sold are based on the specific identification method. Other investments in unconsolidated affiliates are accounted for under the cost or the equity method of accounting, as appropriate. The Company accounts for investments in limited partnerships or limited liability corporations, whereby the Company owns a minimum of 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;

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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**

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. 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.

**Collaborative Agreement**

In November 2008, the Company entered into a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for automated, real-time monitoring of 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. At the inception of the agreement, the Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee (see Note 3). The Company will also pay up to \$24.0 million over the next three years in product development costs and regulatory approval milestones. The product development costs are expensed to "*Research and Development Expenses*" as incurred, and the regulatory approval milestones are recorded as "*Other Intangible Assets, net*" and amortized over the useful life of the product. In addition, DexCom will receive either a profit-sharing payment or a royalty based upon 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. During 2009, the Company recorded \$5.5 million of product development costs, and as of December 31, 2009 had capitalized \$0.9 million of regulatory milestone payments.



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)****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.

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

	Years ended December 31,		
	2009	2008	2007
<b>Basic:</b>			
Net income	\$ 229.1	\$ 128.9	\$ 113.0
Weighted-average shares outstanding	56.3	55.8	57.3
Basic earnings per share	\$ 4.07	\$ 2.31	\$ 1.97
<b>Diluted:</b>			
Net income	\$ 229.1	\$ 128.9	\$ 113.0
Interest expense related to convertible debt, net of tax		1.7	4.0
Net income applicable to diluted shares	\$ 229.1	\$ 130.6	\$ 117.0
Weighted-average shares outstanding	56.3	55.8	57.3
Dilutive effect of convertible debt		1.2	2.7
Dilutive effect of stock plans	2.4	2.6	2.7
Dilutive weighted-average shares outstanding	58.7	59.6	62.7
Diluted earnings per share	\$ 3.90	\$ 2.19	\$ 1.87

Stock options and restricted stock units to purchase approximately 1.0 million, 1.9 million and 2.7 million shares for the years ended December 31, 2009, 2008 and 2007, 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 shares issuable pursuant to 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. Stock-based compensation cost is measured at the grant date based on the fair value



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Total stock-based compensation expense for the years ended December 31, 2009, 2008 and 2007 was as follows (in millions):

	December 31,		
	2009	2008	2007
Cost of goods sold	\$ 2.4	\$ 2.7	\$ 3.0
Selling, general and administrative expenses	21.4	21.2	19.8
Research and development expense	4.5	4.8	4.9
 Total stock-based compensation expense	 \$ 28.3	 \$ 28.7	 \$ 27.7

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.

**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 option-based products and forward exchange contracts. As of December 31, 2009, 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. These agreements have a maximum duration of one year.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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. The master-netting agreements reduce the Company's counterparty payment settlement risk on any given maturity date to the net amount of any receipts or payments due between the Company and the counterparty financial institution. Although these protections do not eliminate concentrations of credit, the Company does not consider the risk of counterparty default to be significant. All derivative financial instruments are with a diversified group of major financial institutions assigned investment grade ratings with national rating agencies. None of the Company's outstanding derivative instruments contain credit-risk related contingent features that may require the Company to post or permit the Company to call collateral from any counterparty.

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*" 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.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

**Recently Adopted Accounting Standards**

In September 2006, the Financial Accounting Standards Board ("FASB") issued accounting guidance on fair value measurements. This guidance defined fair value, established a framework for measuring fair value, and expanded disclosures about fair value measurements. In February 2008, the FASB delayed the effective date of this guidance 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. The Company's adoption of this guidance, 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. See Note 10 for further information.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") on accounting for collaborative arrangements. This accounting guidance defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The guidance also established the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. The guidance was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented was required for all collaborative arrangements existing as of the effective date. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. See "*Collaborative Agreement*" above for further information.

In December 2007, the FASB issued accounting guidance on business combinations which established 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. This guidance also established principles and requirements for recognizing and measuring goodwill acquired in the business combination and determined 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, the guidance expanded the definition of a business combination, required acquisitions to be accounted for at fair value, and required transaction costs and restructuring charges to be expensed. The guidance was effective for fiscal years beginning on or after December 15, 2008 and will impact the Company's consolidated financial statements if it is involved in business combinations in the future.

In March 2008, the FASB issued accounting guidance on disclosures about derivative instruments and hedging activities. The guidance required 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. The guidance was effective for fiscal years and interim periods beginning after November 15, 2008. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. See Note 10 for further information.

In April 2008, the FASB issued accounting guidance that amended the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The guidance applied to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions and required expanded disclosure related to the determination of intangible asset useful lives. The guidance was effective for fiscal years beginning after

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

December 15, 2008. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF which clarified the accounting for certain transactions and impairment considerations involving equity method investments. This accounting guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF which clarified 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. The guidance required 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. The guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2008, the FASB issued accounting guidance on disclosures about postretirement benefit plan assets. The guidance required 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 and (d) significant concentrations of risk. The guidance was effective for fiscal years ending after December 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. See Note 11 for further information.

In April 2009, the FASB issued accounting guidance which required that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably determined. If the fair value cannot be reasonably determined, then the assets and liabilities should be recognized at the amount that would be recognized in accordance with the FASB Accounting Standards Codification ("ASC") Topic 450, "Contingencies." The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued accounting guidance on estimating fair value when the volume and level of activity for the asset or liability have significantly decreased, and identifying circumstances that indicate a transaction is not orderly. The guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued accounting guidance that amended the other-than-temporary impairment guidance related to debt securities and expanded and increased the frequency of existing disclosures about debt and equity securities and other-than-temporary impairments for debt and equity securities. The guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued accounting guidance which required disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. The guidance was effective for interim reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

In May 2009, the FASB issued accounting guidance that established general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The guidance required the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. The guidance was effective for interim or annual financial periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In June 2009, the FASB issued an accounting standard establishing the ASC as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The accounting standard was effective for financial statements issued for interim and annual periods ending after September 15, 2009. The ASC does not change GAAP and did not have a material impact on the Company's consolidated financial statements.

In August 2009, the FASB issued an amendment to ASC Topic 820, "*Fair Value Measurements and Disclosures*," to clarify how an entity should measure the fair value of liabilities when a quoted price in an active market for the identical liability is not available. The guidance was effective for the first reporting period beginning after its issuance. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In February 2010, the FASB issued an amendment to ASC Topic 855 "*Subsequent Events*," to remove the requirement for SEC filers to disclose the date through which an entity has evaluated subsequent events. This change alleviates potential conflicts with current SEC guidance. The guidance was effective upon its issuance. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

**New Accounting Standards Not Yet Adopted**

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIEs"). This accounting guidance eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a VIE based on whether the entity (a) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (b) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. The guidance requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. The guidance is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In October 2009, the FASB issued an amendment to ASC Topic 605, "*Revenue Recognition*," to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. ASC Topic 605 was also amended to eliminate the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an amendment to ASC Topic 820, "*Fair Value Measurements and Disclosures*," to require companies to (a) disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for such transfers and (b) present separately in the Level 3 reconciliation information about purchases, sales, issuances and settlements. The amendment also clarifies existing guidance on the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance is effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation, which is effective for fiscal years beginning after December 15, 2010, and for interim periods within those years. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

## 3. SPECIAL (GAINS) CHARGES, NET

	Years Ended December 31,		
	2009	2008	2007
	(in millions)		
Gain on sale of assets, net	\$ (86.9)	\$ (14.9)	\$ (1.8)
Charitable fund contribution	15.0		
Settlements and litigation, net	3.8	0.6	
Adjustment to capitalized patent enforcement costs	3.7	8.2	
Investment impairment	1.6		
Reserve reversal	(1.0)		
Acquisition of in-process technology and intellectual property		19.5	
DexCom collaboration agreement		13.4	
Realignment expenses, net		(1.7)	13.9
Pension settlement and adjustment			11.2
<b>Total special (gains) charges, net</b>	<b>\$ (63.8)</b>	<b>\$ 25.1</b>	<b>\$ 23.3</b>

*Gain on Sale of Assets, net*

Effective September 1, 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years, of which \$2.1 million was earned in 2009 and recorded in "*Other (Income) Expense, net*." The sale resulted in a pre-tax gain of \$43.6 million consisting of the cash proceeds of \$55.9 million, offset by \$8.5 million related to the net book value of inventory, fixed assets and intangible assets that were sold, a \$0.6 million satisfaction of a receivable, a \$0.5 million write-off of goodwill associated with this product line and \$2.7 million of transaction and other costs related to the sale. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance related to the pending sale. The Company will provide transition services to the buyer.



Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

In March 2009, the Company recorded a \$2.8 million gain related to the sale of its distribution rights in Europe for a specialty vascular graft.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of *LifeStent* device manufacturing to the buyer.

In connection with the *LifeStent* 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 agreed to provide and \$3.7 million of transaction and other costs related to the sale.

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.

*Charitable Fund Contribution*

In September 2009, the Company contributed \$15.0 million to The Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular and community related charitable causes. The contribution was an irrevocable contribution to a third party, and was recorded as an expense at the time of payment.

*Settlements and Litigation, net*

In September 2009, the Company recorded a \$3.8 million charge for litigation related to a royalty dispute in connection with a product in the Company's Cardiac Surgery Systems product line.

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.

*Adjustment to Capitalized Patent Enforcement Costs*

In December 2009, the Company recorded a \$3.7 million charge for the write-off of capitalized patent enforcement costs related to litigation in Europe for which success was no longer deemed probable.

In December 2008, the Company recorded an \$8.2 million charge due primarily to the reversal of capitalized patent enforcement costs for a litigated claim related to patents in a product area where the Company did not then, and does not currently, compete and where the related patent enforcement costs,

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

therefore, should 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 out-of-period amounts 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.

*Investment Impairment*

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its technology investment in an unconsolidated affiliate. The Company concluded that the impairment of its investment was other-than-temporary based upon (a) the continuing duration and severity of the impairment and (b) positive clinical trial developments in the third quarter of 2009 which failed to raise the quoted market price of the affiliate's stock to the Company's carrying value.

*Reserve Reversal*

In 2004, the Company discontinued its *Lifepath* AAA endovascular graft program. In March 2009, upon completion of its remaining clinical obligations related to this program, the Company reversed its remaining \$1.0 million clinical reserve.

*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 prototypes 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\$4.3 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$9.1 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 automated, real-time monitoring of 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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

applicable intellectual property. The Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee. See Note 2 for further information.

*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, 2009, payments related to the executive severance charge were substantially complete.

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, 2009, payments related to the realignment were substantially complete.

*Pension Settlement and Adjustment*

In December 2007, the Company's 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 ASC Topic 715 to a defined benefit pension plan in Switzerland, which had previously been accounted for as a defined contribution plan. The Company recorded a charge of \$4.1 million in December 2007 to correct this error. The Company concluded that the impact of the increase in the pension obligation was not material to the 2007 or prior years' consolidated financial statements.

Table of Contents

## 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:

	December 31,	
	2009	2008
	(in millions)	
<b>Accounts receivable, net</b>		
Trade accounts receivable (Note 5)	\$ 261.8	\$ 196.2
Allowance for doubtful accounts	(12.4)	(9.9)
	\$ 249.4	\$ 186.3
<b>Inventories, net</b>		
Raw materials	\$ 32.8	\$ 36.5
Work in process	30.4	19.5
Finished products	102.7	95.8
	\$ 165.9	\$ 151.8
<b>Property, plant and equipment, net</b>		
Land	\$ 21.8	\$ 21.7
Buildings and leasehold improvements	137.2	109.0
Machinery and equipment	210.0	192.4
Equipment with customers	41.1	49.2
Software	79.6	71.9
Construction in progress	15.7	27.2
	505.4	471.4
Accumulated depreciation	(253.4)	(241.3)
	\$ 252.0	\$ 230.1
<b>Accrued liabilities</b>		
Employee compensation and withholdings	\$ 88.7	\$ 84.8
Property, payroll and other taxes	16.7	17.1
Litigation reserves (Note 16)	25.7	10.7
Other accrued liabilities	72.4	74.1
	\$ 203.5	\$ 186.7

**5. ACCOUNTS RECEIVABLE SECURITIZATION**

The Company previously securitized, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in Japan ("Japan Receivables Facility") until February 2009, and in the United States ("United States Receivables Facility") until August 2008. Under the Japan Receivables Facility, the Company sold eligible accounts receivable directly to a financial institution. Under the United States Receivables Facility, the Company 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.

The transactions under both Facilities were accounted for as sales of accounts receivable. The Company retained servicing responsibilities and subordinated residual interests in the accounts receivables. The



Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 5. ACCOUNTS RECEIVABLE SECURITIZATION (Continued)

Company received annual servicing fees approximating one percent of the outstanding balance and rights to future cash flows arising after the investors in the securitization trust received their contractual return. In August 2008, the Company terminated its securitization program in the United States and repurchased \$50.0 million of accounts receivable. The Company terminated the Japan Receivables Facility in February 2009 and upon termination paid the financial institution \$39.0 million for the outstanding accounts receivable and February collections.

Residual interests of \$6.6 million as of December 31, 2008 were included in "Other Current Assets." The interests were 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 of trade accounts receivable as of December 31, 2008, resulting in a reduction of accounts receivable on the Company's consolidated balance sheet, and received funding of \$37.7 million. Costs associated with the sale of receivables, primarily related to the discount, were \$1.6 million and \$3.0 million for the years ended December 31, 2008 and 2007, respectively, and were included in "Other (Income) Expense, net." As a result of the termination of both the United States and Japan Receivables Facilities, the Company had not sold any trade accounts receivable as of December 31, 2009, and there were no costs associated with the sale of receivables during the year ended December 31, 2009.

## 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 the applicable accounting guidance on 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
	\$ 28.1

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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. GOODWILL AND OTHER INTANGIBLE ASSETS**

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. 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.

The changes in the carrying amount of goodwill for the years ended December 31, 2009 and 2008 were as follows:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in millions)</b>	
<b>Balance as of January 1</b>		
Goodwill	\$ 315.7	\$ 350.3
Accumulated impairment losses		
	315.7	350.3
Goodwill related to sale of product line	(0.5)	(34.6)
<b>Balance as of December 31</b>		
Goodwill	315.2	315.7
Accumulated impairment losses		
	\$ 315.2	\$ 315.7

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. Effective September 1, 2009, the Company sold its hemofiltration product line. In connection with this transaction, the Company recorded a \$0.5 million write-off of goodwill associated with this product line.

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

	<b>Patents</b>	<b>Unpatented Technology</b>	<b>Other</b>	<b>Total</b>
<b>December 31, 2009</b>				
Cost	\$ 212.0	\$ 35.0	\$ 12.6	\$ 259.6
Accumulated amortization	(141.3)	(27.1)	(4.5)	(172.9)
Net carrying value	\$ 70.7	\$ 7.9	\$ 8.1	\$ 86.7
<b>December 31, 2008</b>				
Cost	\$ 204.1	\$ 35.0	\$ 13.4	\$ 252.5
Accumulated amortization	(127.3)	(24.6)	(3.7)	(155.6)
Net carrying value	\$ 76.8	\$ 10.4	\$ 9.7	\$ 96.9

Patents include \$13.2 million and \$7.8 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, 2009 and 2008, respectively (see Note 2). In 2009, the Company wrote off \$3.7 million of capitalized patent enforcement costs related to litigation in Europe for which success was no longer deemed probable (see Note 3).





Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)**

Amortization expense related to other intangible assets for the years ended December 31, 2009, 2008 and 2007 was \$20.6 million, \$19.4 million and \$16.9 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2010	\$ 18.0
2011	16.1
2012	14.3
2013	14.2
2014	12.8

**8. INVESTMENTS IN UNCONSOLIDATED AFFILIATES**

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

	December 31,	
	2009	2008
	(in millions)	
<b>Available-for-sale investments</b>		
Cost	\$ 8.5	\$ 10.9
Unrealized losses	(0.9)	(5.8)
Fair value of available-for-sale investments	7.6	5.1
<b>Equity method investments</b>		
Cost	10.7	9.7
Equity in losses	(0.8)	(1.1)
Carrying value of equity method investments	9.9	8.6
<b>Cost method investments</b>		
Carrying value of cost method investments	4.8	1.0
<b>Total investments in unconsolidated affiliates</b>	<b>\$ 22.3</b>	<b>\$ 14.7</b>

Proceeds from sales of available-for-sale investments for the years ended December 31, 2009, 2008 and 2007 were \$1.4 million, \$3.8 million and \$1.4 million, respectively, and the Company realized pre-tax gains of \$0.5 million, \$1.9 million and \$0.9 million, respectively. In September 2009, the Company recorded an other-than-temporary impairment charge of \$1.6 million related to one of its available-for-sale investments. See Note 3 for additional information.

**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



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. LONG-TERM DEBT, CREDIT FACILITIES AND LEASE OBLIGATIONS (Continued)**

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, 2009, borrowings of \$90.3 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, 2009.

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 1.5% and 1.4% at December 31, 2009 and 2008, respectively.

Included in long-term debt at December 31, 2009 were unsecured notes denominated in Japanese yen of ¥4.0 billion (US\$43.9 million) and in Euro of €8.0 million (US\$11.4 million). Included in long-term debt at December 31, 2008 were unsecured notes denominated in Japanese yen of ¥7.7 billion (US\$85.5 million).

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2009 were as follows (in millions):

	<b>Operating Leases</b>	<b>Aggregate Debt Maturities</b>
2010	\$ 16.1	\$
2011	13.7	90.3
2012	7.5	
2013	6.3	
2014	6.1	
Thereafter	25.0	
<b>Total obligations and commitments</b>	<b>\$ 74.7</b>	<b>\$ 90.3</b>

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 \$18.2 million, \$16.7 million and \$15.4 million for the years 2009, 2008 and 2007, 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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)**

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. The Company prioritizes the inputs used to determine fair values 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.

*Assets and Liabilities Measured at Fair Value on a Recurring Basis*

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2009 and 2008 (in millions):

<b>December 31, 2009</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Investments held for executive deferred compensation plan	\$ 15.1	\$	\$	\$ 15.1
Investments in unconsolidated affiliates	7.6			7.6
	\$ 22.7	\$	\$	\$ 22.7
<b>Liabilities</b>				
Derivatives	\$	\$ 3.0	\$	\$ 3.0
	\$	\$ 3.0	\$	\$ 3.0

<b>December 31, 2008</b>				
<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
	\$ 15.3	\$	\$ 17.5	\$ 32.8
<b>Liabilities</b>				
Derivatives	\$	\$ 1.3	\$	\$ 1.3
	\$	\$ 1.3	\$	\$ 1.3

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 years ended December 31, 2009 and 2008 (in millions):

	Investment in the Columbia Strategic Cash Fund	Residual Interest in Accounts Receivable Securitizations	Total
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	(35.5)	(2.2)	(37.7)
Balance at December 31, 2008	10.9	6.6	17.5
Total gains realized and unrealized:			
Included in earnings(a)	0.5		0.5
Purchases, sales, issuances and settlements	(11.4)	(6.6)	(18.0)
Balance at December 31, 2009	\$	\$	\$

(a) Recorded as a component of "Other (Income) Expense, 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 circumstances of their portfolios. The Company has procedures to independently verify and test valuations received from third parties.

The Company estimated 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. The Company terminated its securitization programs in the United States (August 2008) and Japan (February 2009).

Carrying amounts of floating rate debt approximate their fair value.



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)***Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis*

The Company has assets that are subject to measurement at fair value on a non-recurring basis, including assets acquired in a business combination, such as goodwill and intangible assets, and other long-lived assets. The Company reviews the carrying value of these assets whenever events and circumstances indicate that the carrying amounts of the assets may not be recoverable. If it is determined that the assets are impaired, the carrying value would be reduced to estimated fair market value. During the year ended December 31, 2009, the Company had no impairments related to these assets.

**Derivative Financial Instruments**

The Company uses a variety of derivative financial instruments to manage its currency exchange 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,			
	2009		2008	
	Notional Amount	Fair Value Asset (Liability)	Notional Amount	Fair Value Asset (Liability)
	(in millions)			
Forward currency agreements	\$ 130.5	\$ (1.7)	\$ 159.7	\$ 0.2
Currency option contracts	212.6	(1.3)	65.4	(1.5)

The fair value of financial instruments was estimated by discounting expected cash flows using quoted market interest rates and foreign exchange rates as of December 31, 2009 and 2008. 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.

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated balance sheet as of December 31, 2009 and 2008 (in millions):

	Liability Derivatives			
	December 31, 2009		December 31, 2008	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<b>Derivatives designated as hedging instruments</b>				
Foreign exchange contracts	Accrued liabilities	\$ 3.0	Accrued liabilities	\$ 1.3

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

The following tables present the effect of derivative instruments on the consolidated statements of operations for the years ended December 31, 2009, 2008 and 2007 (in millions):

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2009	2008	2007
<b>Derivatives in fair value hedging relationships</b>				
Foreign exchange contracts	Other (income) expense, net	\$ (2.7)	\$ 0.2	\$ (0.1)

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	2009	2008		2009	2008
<b>Derivatives in cash flow hedging relationships</b>					
Foreign exchange contracts	\$ (0.8)	\$ (2.7)	Cost of goods sold	\$ 5.0	\$ (10.7)

The Company expects that during 2010 it will reclassify to earnings a \$3.6 million loss currently recorded in "Accumulated Other Comprehensive Loss." For the years ended December 31, 2009, 2008 and 2007, the Company expensed \$0.8 million, \$0.6 million and \$1.7 million, respectively, related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness.

## 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 ASC Topic 715 to a defined benefit pension plan in Switzerland, which had previously been accounted for as a defined contribution plan. 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 of the increase in the pension obligation was not material to the 2007 or prior years' consolidated financial statements.

During the year ended December 31, 2008, the Company adopted new accounting guidance on retirement benefits that required defined benefit plan assets and obligations to be measured as of the Company's fiscal year end date. The Company adopted the measurement date provisions of this new accounting guidance 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



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. EMPLOYEE BENEFIT PLANS (Continued)**

adoption of the measurement date provisions resulted in a \$0.6 million reduction of retained earnings, as follows (in millions):

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

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. EMPLOYEE BENEFIT PLANS (Continued)

Information regarding the Company's defined benefit pension plans is as follows (in millions):

	Years Ended December 31,	
	2009	2008
<b>Change in projected benefit obligation:</b>		
Beginning of year	\$ 61.9	\$ 41.1
Service cost	5.6	4.8
Interest cost	1.8	1.6
Participant contributions	1.2	1.2
Actuarial (gain) loss	(10.1)	10.2
Benefits paid	(3.4)	
Currency exchange rate changes and other	3.1	3.0
End of year	\$ 60.1	\$ 61.9

<b>Change in fair value of plan assets:</b>		
Beginning of year	\$ 29.4	\$ 24.6
Actual return on plan assets	0.9	(1.6)
Employer contributions	4.2	3.7
Participant contributions	1.2	1.2
Benefits paid	(3.3)	
Currency exchange rate changes and other	2.0	1.5
End of year	\$ 34.4	\$ 29.4

<b>Funded Status</b>		
Projected benefit obligation	\$ (60.1)	\$ (61.9)
Plan assets at fair value	34.4	29.4
Funded status, (under funded)	\$ (25.7)	\$ (32.5)

<b>Net amounts recognized on the consolidated balance sheet:</b>		
Other long-term liabilities	\$ 25.7	\$ 32.5

Accumulated other comprehensive loss, net of tax:

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Net actuarial loss	\$	(7.8)	\$	(18.0)
Net prior service benefit		3.2		3.2
Net transition asset		(0.2)		(0.2)
Deferred income tax expense		1.9		3.1
Total	\$	(2.9)	\$	(11.9)

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was \$54.2 million and \$52.8 million as of December 31, 2009 and 2008, respectively. The projected benefit obligation ("PBO") and ABO were in excess of plan assets for all pension plans as of December 31, 2009 and 2008.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. EMPLOYEE BENEFIT PLANS (Continued)**

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

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Service cost, net	\$ 5.6	\$ 4.1	\$ 2.7
Interest cost	1.8	1.4	2.4
Expected return on plan assets	(0.9)	(0.9)	(2.4)
Settlement, curtailment and special termination benefits, net			7.7
Amortization of actuarial loss	0.9	0.3	0.2
Amortization of prior service credit	(0.3)	(0.3)	
Amortization of transition obligation		0.1	
Net periodic pension benefits cost	\$ 7.1	\$ 4.7	\$ 10.6

The net actuarial loss and prior service credit that will be amortized from "Accumulated Other Comprehensive Loss" into net periodic benefits cost in 2010 are expected to be \$0.4 million and \$(0.3) million, respectively.

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.

To select the discount rates for the defined benefit pension plans, the Company uses a modeling process that involves matching the expected duration of its benefit plans to a yield curve constructed from a portfolio of AA-rated fixed-income debt instruments, or their equivalent. For each country, the Company uses the implied yield of this hypothetical portfolio at the appropriate duration as a discount rate benchmark.

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Discount rate	3.2%	2.8%
Rate of compensation increase	3.2%	3.4%
Social securities increase	1.8%	1.8%
Pension increase	2.0%	2.0%

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. EMPLOYEE BENEFIT PLANS (Continued)

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

	Years ended December 31,		
	2009	2008	2007
Discount rate	2.8%	3.3%	4.2%
Expected return on plan assets	2.8%	3.6%	5.7%
Rate of compensation increase	3.4%	3.3%	2.8%
Social securities increase	1.8%	1.8%	1.8%
Pension increase	2.0%	1.8%	1.5%

**Plan Assets**

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 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, 2009, by asset category, are as follows:

Equity securities	10.8%
Debt securities	9.2%
Insurance contracts	80.0%
Total	100.0%

The fair values of the Company's defined benefit plan assets at December 31, 2009, by asset category, are as follows (in millions):

Asset Category	Level 1	Level 2	Level 3	Total
Cash	\$ 0.3	\$	\$	\$ 0.3
Equity securities:				
United States equities	0.7			0.7
International equities	3.0			3.0
Debt securities:				
United States government bonds	0.3			0.3
International government bonds	2.9			2.9
Insurance contracts			27.2	27.2
	\$ 7.2	\$	\$ 27.2	\$ 34.4

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. EMPLOYEE BENEFIT PLANS (Continued)**

The following table summarizes the changes in fair value of the Company's defined benefit plan assets that have been classified as Level 3 for the year ended December 31, 2009 (in millions):

	<b>Insurance Contracts</b>
Balance at December 31, 2008	\$ 23.6
Actual return on plan assets:	
Relating to assets still held at December 31, 2009	0.6
Relating to assets sold during 2009	
Purchases, sales and settlements	1.0
Currency exchange rate impact	2.0
Balance at December 31, 2009	\$ 27.2

Equity and debt securities are valued at fair value based on quoted market prices reported on the active markets on which the individual securities are traded. The insurance contracts are valued at the cash surrender value of the contracts, which is deemed to approximate its fair value.

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2009, are expected to be paid (in millions):

2010	\$ 3.0
2011	3.3
2012	3.6
2013	3.7
2014	3.7
2015-2019	25.6

As of December 31, 2009, expected employer contributions for fiscal 2010 are \$4.7 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 25% 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 \$8.1 million, \$7.0 million and \$6.5 million in 2009, 2008 and 2007, 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 \$4.4 million and \$3.7 million at December 31, 2009 and 2008, respectively.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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 \$12.0 million, \$6.8 million and \$12.3 million at December 31, 2009, 2008 and 2007, 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 part of this plan, each share of the Company's common stock carries a right to purchase one one-hundredth (1/100) of a share of Series A Junior Participating Preferred Stock (the "Rights"), par value \$0.01 per share, subject to adjustment, which becomes exercisable only upon the occurrence of certain events. The Rights are subject to redemption at the option of the Board of Directors at a price of \$0.01 per right until the occurrence of certain events. The Rights expire on March 31, 2010, unless earlier redeemed or exchanged by the Company.

**Treasury Stock**

In each of the years ended December 31, 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. In February 2010, the Company approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$500.0 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 2009, 2008 and 2007, the Company repurchased 1.5 million, 5.8 million and 2.7 million shares, respectively, at an aggregate cost of \$95.5 million, \$306.5 million and \$130.9 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.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMON STOCK (Continued)**

On May 7, 2009, 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 1.0 million shares from 19.7 million shares to 20.7 million shares. No more than 1.3 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 restricted stock units. Prior to May 2007, the initial grant was 5,000 shares. In May 2007, the initial grant was revised to a fair market value on grant date of \$0.2 million, not to exceed 5,000 shares. These grants vest 50% after one year and the balance vests after two years from the date of grant. The Nonemployee Directors Program was amended on February 17, 2005, to limit to no more than 60,000 the number of shares that will be used for initial awards with two-year vesting, after which the Company will provide initial awards with a minimum three-year vesting. Under the Nonemployee Directors Program, an aggregate of 600,000 shares of the Company's common stock has been authorized for issuance.

The Company has two employee stock purchase plans, 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 January 1, 2006, the Company based the expected volatility on its historical stock prices. As a result of the adoption of new accounting guidance on share-based payments, 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 7%.



Table of Contents

## 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 options granted during the following periods:

*Option Awards*

	2009	2008	2007
Average risk-free interest rate	1.9%	3.0%	4.6%
Expected dividend yield	None	None	None
Expected volatility	28%	23%	19%
Expected life (years)	4.6	4.7	4.9
Fair value	\$ 17.19	\$ 14.36	\$ 13.08

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*

	2009	2008	2007
Average risk-free interest rate	0.4%	2.1%	4.9%
Expected dividend yield	None	None	None
Expected volatility	36%	26%	25%
Expected life (years)	0.6	0.6	0.6
Fair value	\$ 17.43	\$ 14.36	\$ 11.50

Stock option activity during the year ended December 31, 2009 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Outstanding as of December 31, 2008</b>	8.3	\$ 37.31		
Options granted	0.9	63.43		
Options exercised	(1.9)	28.63		
Options forfeited	(0.1)	47.38		
<b>Outstanding as of December 31, 2009</b>	7.2	42.95	3.3 years	\$ 320.2
<b>Exercisable as of December 31, 2009</b>	5.1	37.56	2.4 years	255.5
<b>Vested and expected to vest as of December 31, 2009</b>	6.8	42.27	3.2 years	307.7

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**12. COMMON STOCK (Continued)**

The following table summarizes nonvested restricted stock units and activity during the year ended December 31, 2009 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
<b>Nonvested as of December 31, 2008</b>	0.9	\$ 48.48
Granted	0.2	63.80
Vested	(0.2)	45.11
Forfeited		
<b>Nonvested as of December 31, 2009</b>	0.9	53.64

The intrinsic value of stock options exercised and vested restricted stock units during the years ended December 31, 2009, 2008 and 2007 were \$92.3 million, \$68.1 million and \$38.8 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, 2009, 2008 and 2007, the Company received cash from exercises of stock options of \$56.4 million, \$54.9 million and \$30.3 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$31.2 million, \$25.1 million and \$13.2 million, respectively. The total grant-date fair value of stock options vested during the year ended December 31, 2009, 2008 and 2007 were \$15.6 million, \$14.2 million and \$18.4 million, respectively.

As of December 31, 2009, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units and employee stock purchase subscriptions amounted to \$44.5 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, 2009, 2008 and 2007. Foreign currency translation adjustments are

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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	Unrealized Pension Costs(a)	Total Accumulated Other Comprehensive (Loss) Income
(in millions)					
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	(17.2)	(0.6)	(5.7)	(11.9)	(35.4)
Pre-tax period change	17.3	(5.8)	4.9	10.2	26.6
Deferred income tax benefit (expense)		2.3	(0.2)	(1.2)	0.9
December 31, 2009	\$ 0.1	\$ (4.1)	\$ (1.0)	\$ (2.9)	\$ (7.9)

(a) For the years ended December 31, 2009, 2008 and 2007, the change in unrealized pension costs consisted of the following (in millions):

	Pre-Tax Amount	Tax Expense	Net of Tax Amount
<b>2009</b>			
Prior service credit arising during period	\$ 0.3	\$	\$
Amortization of prior service credit	(0.3)		
Net prior service credit arising during period			
Net gain arising during period	10.2	(1.2)	9.0
Unrealized pension costs, net	\$ 10.2	\$ (1.2)	\$ 9.0
<b>2008</b>			
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)

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Net loss arising during period (12.9) 2.8 (10.1)

Unrealized pension costs, net \$ (13.2) \$ 2.8 \$ (10.4)

**2007**

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 \$ 5.6 \$ (1.3) \$ 4.3

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31,		
	2009	2008	2007
	(in millions)		
Foreign exchange (gains) losses, net	\$ (2.3)	\$ 7.2	\$ (2.0)
Earn-out payments	(2.1)		(2.3)
Gain on investments in unconsolidated affiliates	(1.2)	(2.0)	(1.3)
Investment realized (gains) losses and impairment	(0.5)	3.0	0.7
Accounts receivable securitization costs		1.6	3.0
Other	2.4	(2.1)	
	\$ (3.7)	\$ 7.7	\$ (1.9)

**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):

	Years Ended December 31,		
	2009	2008	2007
United States	\$ 93.3	\$ (11.9)	\$ 27.0
International, including Puerto Rico	211.1	176.3	122.8
	\$ 304.4	\$ 164.4	\$ 149.8

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

	Years Ended December 31,		
	2009	2008	2007
<b>Current</b>			
United States:			
Federal	\$ 46.3	\$ 35.9	\$ 27.5
State and local	5.8	4.5	3.5
International, including Puerto Rico	25.2	16.0	13.5
Current income tax expense	77.3	56.4	44.5
<b>Deferred</b>			
United States:			
Federal	(7.7)	(21.3)	(7.6)
State and local	(1.0)	(2.7)	(0.9)
International, including Puerto Rico	6.7	3.1	0.8
Deferred income tax benefit	(2.0)	(20.9)	(7.7)
<b>Total income tax provision</b>	\$ 75.3	\$ 35.5	\$ 36.8



Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 15. INCOME TAXES (Continued)

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

	December 31,	
	2009	2008
<b>Deferred tax assets</b>		
Compensation and benefits	\$ 53.0	\$ 44.5
Net operating loss carryforwards	21.3	25.6
Accrued liabilities	18.2	20.1
Net tax credit carryforwards	12.6	12.4
Inventories	18.0	11.9
Investments in unconsolidated affiliates	3.2	4.8
Allowance for doubtful accounts	1.9	1.2
Charitable contribution carryforward	3.5	
Other	6.1	5.2
<b>Total deferred tax assets</b>	<b>137.8</b>	<b>125.7</b>
<b>Deferred tax liabilities</b>		
Property, plant and equipment	(9.0)	(12.3)
Other intangible assets	(18.8)	(9.8)
Other	(0.3)	(0.8)
<b>Total deferred tax liabilities</b>	<b>(28.1)</b>	<b>(22.9)</b>
<b>Valuation allowance</b>	<b>(24.3)</b>	<b>(22.7)</b>
<b>Net deferred tax assets</b>	<b>\$ 85.4</b>	<b>\$ 80.1</b>

During 2009, net deferred tax assets increased \$5.3 million. Of this amount, \$3.3 million was recorded through stockholders' equity and did not impact the overall tax provision.

The valuation allowance of \$24.3 million as of December 31, 2009 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the net operating loss carryforwards of certain United States and non-United States subsidiaries and the deferred tax assets established for impairment losses on certain investments.

Deferred income taxes have not been provided on the undistributed earnings of the Company's foreign subsidiaries of approximately \$575.5 million as of December 31, 2009, 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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****15. INCOME TAXES (Continued)**

Net operating loss carryforwards, and the related carryforward periods, at December 31, 2009, are summarized as follows (in millions):

	Net Operating Loss	Tax Benefit Amount	Valuation Allowance	Expected Tax Benefit	Carryforward Period Ends
United States state net operating losses	\$ 55.6	\$ 3.2	\$ (3.2)	\$	2010-2016
Non-United States net operating losses	5.1	1.6		1.6	2010-2020
Non-United States net operating losses	54.2	16.5	(16.3)	0.2	Indefinite
Total	\$ 114.9	\$ 21.3	\$ (19.5)	\$ 1.8	

A valuation allowance of \$19.5 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 \$21.3 million to an amount that is more likely than not to be realized.

The Company has approximately \$15.1 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.

The Company has received tax incentives in Puerto Rico, Dominican Republic, Singapore and Switzerland. The tax reductions as compared to the local statutory rates favorably impacted earnings per diluted share for the years ended December 31, 2009, 2008 and 2007 by \$0.66, \$0.59 and \$0.50, respectively. The Puerto Rico, Dominican Republic, Singapore and Switzerland grants provide the Company's manufacturing operations partial or full exemption from local taxes until the years 2013, 2017, 2019 and indefinitely, respectively.

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

	Years Ended December 31,		
	2009	2008	2007
Income tax expense at U.S. federal statutory rate	\$ 106.5	\$ 57.5	\$ 52.4
Foreign income tax at different rates	(27.9)	(26.4)	(21.4)
Tax credits, federal and state	(5.5)	(3.5)	(2.8)
State and local taxes, net of federal tax benefit	4.9	2.0	3.1
Reserve for uncertain tax positions for prior years	(3.8)	(6.2)	1.2
Nondeductible stock-based compensation	1.4	0.9	1.9
Deemed dividends, net of foreign tax credit	1.0	0.6	3.2
Valuation allowance for loss on investments	0.6		(0.6)



Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Nondeductible goodwill		12.2		
Other	(1.9)	(1.6)	(0.2)	
Income tax provision	\$ 75.3	\$ 35.5	\$ 36.8	

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****15. INCOME TAXES (Continued)***Reserve for Uncertain Tax Positions*

As of December 31, 2009 and 2008, the liability for income taxes associated with uncertain tax positions was \$47.1 million and \$35.9 million, respectively. These liabilities could be reduced by \$3.2 million and \$2.3 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 \$44.0 million and \$33.6 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):

	December 31,		
	2009	2008	2007
Unrecognized tax benefits, January 1	\$ 35.9	\$ 36.4	\$ 24.6
Increase prior period tax positions	8.9	12.3	12.1
Decrease prior period tax positions	(9.4)	(19.9)	(7.9)
Current year tax positions	15.7	18.0	8.6
Settlements	(3.6)	(10.9)	(0.9)
Lapse of statute of limitations	(0.4)		(0.1)
Unrecognized tax benefits, December 31	\$ 47.1	\$ 35.9	\$ 36.4

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2009, the Company had accrued \$2.7 million (net of \$0.5 million tax benefit) of interest related to uncertain tax positions, and 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.

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.

As a result of on-going negotiations of Advanced Pricing Agreements between Switzerland and Japan, and Japan and the United States, the expiration of statutes of limitations, and the possible settlement of on-going audits in several jurisdictions for multiple years throughout the world, the total liability for unrecognized tax benefits may change within the next 12 months. The range of such change could vary, but the amount of such change could result in a reduction of as much as \$26 million. At December 31, 2009, 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. The Company is currently under examination by the Internal Revenue Service for the 2007 and 2008 tax years.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. INCOME TAXES (Continued)**

*Nondeductible Stock-based Compensation*

Some of the Company's stock-based compensation costs 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 contingent on 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, 2009, deferred tax assets and corresponding valuation allowances of approximately \$3.2 million had accumulated related to investments. Of the total valuation allowance of \$3.2 million, \$0.5 million was recorded as a component of "Accumulated Other Comprehensive Loss," while \$0.6 million was recorded in 2009 through a charge to profit and loss. The remaining \$2.1 million had previously been recorded as of December 31, 2008 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.

*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.

**16. LEGAL PROCEEDINGS**

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 appealed this decision and in February 2010 a German Appeals Court affirmed. In May 2007 and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, 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 parties have filed cross-appeals on the validity and infringement decisions. In January 2010, a German Court determined that the Andersen patent was valid. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. Trial is scheduled for March 2010.

In February 2008, Cook, Inc. ("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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. LEGAL PROCEEDINGS (Continued)**

Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Court ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. Cook is appealing the judgments in Germany and the United Kingdom. The German Court decision on validity of the Cook patent is expected in April 2010.

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.

**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 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, and therefore a portion is maintained at the corporate level. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

Table of Contents

## 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,		
	2009	2008	2007
<b>Segment Net Sales</b>			
United States	\$ 556.1	\$ 540.3	\$ 486.6
Europe	392.3	362.8	234.2
Japan	181.7	167.4	182.9
Rest of World	150.8	130.8	110.6
Total segment net sales	\$ 1,280.9	\$ 1,201.3	\$ 1,014.3
<b>Segment Pre-tax Income</b>			
United States	\$ 303.8	\$ 283.9	\$ 255.3
Europe	133.3	114.8	58.0
Japan	84.6	75.2	71.9
Rest of World	44.3	34.0	25.4
Total segment pre-tax income	\$ 566.0	\$ 507.9	\$ 410.6

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,		
	2009	2008	2007
<b>Net Sales Reconciliation</b>			
Segment net sales	\$ 1,280.9	\$ 1,201.3	\$ 1,014.3
Foreign currency	40.5	36.4	76.8
Consolidated net sales	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1
<b>Pre-tax Income Reconciliation</b>			
Segment pre-tax income	\$ 566.0	\$ 507.9	\$ 410.6
Unallocated amounts:			
Corporate items	(346.0)	(307.5)	(261.8)
Special gains (charges), net	63.8	(25.1)	(23.3)
Interest expense, net	(1.1)	(1.1)	(1.4)
Foreign currency	21.7	(9.8)	25.7
Consolidated pre-tax income	\$ 304.4	\$ 164.4	\$ 149.8

Table of Contents**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,		
	2009	2008	2007
	(in millions)		
<b>Net Sales by Geographic Area</b>			
United States	\$ 556.1	\$ 543.6	\$ 486.6
Other countries	765.3	694.1	604.5
	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1

<b>Net Sales by Major Product Area</b>			
Heart Valve Therapy	\$ 714.9	\$ 607.4	\$ 515.0
Critical Care	452.5	451.8	397.8
Cardiac Surgery Systems	92.8	89.2	60.9
Vascular	61.2	89.3	90.0
Other Distributed Products			27.4
	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1

<b>Long-lived Tangible Assets by Geographic Area</b>			
United States	\$ 185.3	\$ 171.4	\$ 197.9
Other countries	102.0	86.6	78.9
	\$ 287.3	\$ 258.0	\$ 276.8

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Years Ended December 31,	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
(in millions, except per share data)					
<b>2009</b>					
Net sales	\$ 313.5	\$ 335.5	\$ 325.7	\$ 346.7	\$ 1,321.4
Gross profit	216.5	233.6	227.2	245.0	922.3
Net income(a)	60.5	47.5	73.5	47.6	229.1
Earnings per common share(a):					
Basic	1.08	0.85	1.30	0.84	4.07
Diluted	1.03	0.81	1.25	0.80	3.90
Market price:					
High	\$ 63.50	\$ 68.23	\$ 70.44	\$ 88.25	\$ 88.25
Low	52.86	55.82	60.90	67.65	52.86
<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(b)	18.2	39.7	32.9	38.1	128.9
Earnings per common share(b):					
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

(a)

The first quarter of 2009 includes (1) a \$27.0 million gain for achieving milestones related to the divested *LifeStent* product line, (2) a \$2.8 million gain related to the sale of the Company's distribution rights in Europe for a specialty vascular graft and (3) a \$1.0 million gain resulting from the reversal of clinical reserves upon completion of the *Lifepath* AAA clinical obligations.

The second quarter of 2009 includes a \$1.5 million charge for transaction costs and employee severance related to the sale of the hemofiltration product line.

The third quarter of 2009 includes (1) a \$43.6 million gain related to the sale of the hemofiltration product line, (2) a \$15.0 million gain for achieving a milestone related to the divested *LifeStent* product line, (3) a \$15.0 million charge related to the Company's contribution to The Edwards Lifesciences Fund, (4) a \$3.8 million charge for litigation related to a royalty dispute and (5) a \$1.6 million charge for the impairment of an investment in an unconsolidated affiliate.

The fourth quarter of 2009 includes a \$3.7 million charge for the write-off of capitalized patent enforcement costs related to litigation for which success was no longer deemed probable.

(b)

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

upfront licensing and collaboration fees required under the Company's agreement with DexCom, Inc., (4) a \$8.2 million charge primarily for the



Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

## 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)					
<b>Year ended December 31, 2009</b>					
Allowance for doubtful accounts(a)	\$ 9.9	\$ 3.6	\$	\$ (1.1)	\$ 12.4
Inventory reserves(b)	13.2	7.9		(5.1)	16.0
Tax valuation allowance(c)	22.7	1.0	4.3	(3.7)	24.3
<b>Year ended December 31, 2008</b>					
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
<b>Year ended December 31, 2007</b>					
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

- (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 the uncertainty of the ready marketability of certain impaired investments, and net operating loss carryforwards that may not be recognized due to insufficient taxable income.

Table of Contents

**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, 2009.

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, 2009. The effectiveness of the Company's internal control over financial reporting as of December 31, 2009 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 2009 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.

Table of Contents

**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 2010 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, 2009). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference. The Company has adopted a code of ethics that applies to all employees, including the Company's principal executive officer, principal financial officer and controller. The code of ethics is 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 code of ethics that apply 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 "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.

Table of Contents

**PART IV**

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

**EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION**

<b>Exhibit No.</b>	<b>Description</b>
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	Form of Edwards Lifesciences Corporation, Amended and Restated Employment Agreement for Michael A. Mussallem dated March 30, 2009 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009, under the Securities Exchange Act of 1934)
*10.3	Form of Edwards Lifesciences Corporation Chief Executive Officer Change-in-Control Severance Agreement, as Amended and Restated March 30, 2009 (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009, under the Securities Exchange Act of 1934)
10.4	Amended and Restated Five Year Credit Agreement dated as of September 29, 2006, among Edwards Lifesciences Corporation, as Borrower; the lenders party thereto; JP Morgan Chase Bank as Administrative Agent; J.P. Morgan Europe Limited as London Agent; Mizuho Corporate Bank, Limited as Tokyo Agent; Bank of America, N.A. as Syndication Agent; and The Bank of Tokyo-Mitsubishi UFI, Ltd., Mizuho Corporate Bank, Limited, Suntrust Bank, and Wachovia Bank, N.A., as Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K, filed September 29, 2006, under the Securities Exchange Act of 1934)
*10.5	Edwards Lifesciences Corporation Severance Pay Plan (incorporated by reference to Exhibit 10.21 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2000, under the Securities Exchange Act of 1934)
*10.6	Edwards Lifesciences Corporation Executive Option Plan (incorporated by reference to Exhibit 10.6 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)

## Edgar Filing: Edwards Lifesciences Corp - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
*10.7	Edwards Lifesciences Corporation Executive Deferred Compensation Plan (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K filed on December 27, 2004, under the Securities Exchange Act of 1934)
10.8	Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-40434))
*10.9	Edwards Lifesciences Corporation 401(k) Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-33056))
*10.12	Long-Term Stock Incentive Compensation Program (as amended and restated as of March 20, 2009) (incorporated by reference to Appendix A to Edwards Lifesciences' Definitive Proxy Statement filed March 31, 2009, 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 November 10, 2009)
*10.15	2001 Employee Stock Purchase Plan for International Employees (as amended and restated November 10, 2009)
*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 (incorporated by reference to Exhibit 10.18 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009, under the Securities and Exchange Act of 1934)
*10.19	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement (incorporated by reference to Exhibit 10.19 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009, under the Securities and Exchange Act of 1934)
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
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

# Edgar Filing: Edwards Lifesciences Corp - Form 10-K

## Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

---

\*  
Represents management contract or compensatory plan



Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Signature	Title	Date
<hr/> /s/ WILLIAM J. LINK, PH.D.	Director	February 26, 2010
William J. Link, Ph.D. <hr/> /s/ BARBARA J. MCNEIL, M.D., PH.D.	Director	February 26, 2010
Barbara J. McNeil, M.D., Ph.D. <hr/> /s/ DAVID E.I. PYOTT	Director	February 26, 2010
David E.I. Pyott <hr/> /s/ WESLEY W. VON SCHACK	Director	February 26, 2010
Wesley W. von Schack		