

Edwards Lifesciences Corp
Form 10-K
February 28, 2011

**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, 2010

OR

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

**For the Transition Period From _____ to
Commission File Number 1-15525**

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

(949) 250-2500

Registrant's telephone number, including area code

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

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

Name of each exchange on which registered:

New York Stock Exchange
New York Stock Exchange

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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, 2010 (the last trading day of the registrant's most recently completed second quarter): \$6,278,651,239 based on a closing price of \$56.02 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, 2011, was 114,850,737.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2011 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2010) 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 2010** **Table of Contents**

PART I

<u>Item 1.</u>	<u>Business</u>	<u>1</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>10</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>19</u>
<u>Item 2.</u>	<u>Properties</u>	<u>19</u>
<u>Item 3.</u>	<u>Legal Proceedings</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>21</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>21</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>22</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>42</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>44</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>91</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>91</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>91</u>

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>92</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>92</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>92</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>92</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>92</u>

PART IV

<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>93</u>
	<u>Signatures</u>	<u>95</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 contained in this report to be covered by the safe harbor provisions of such Acts. 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 statements 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," "should," "anticipate," "plan," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or 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 results or 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 may 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 products may be used while the patient's heart and lung functions are being bypassed, or used during minimally invasive valve surgery. 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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, 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 (business practice standards) are also posted on the Company's website at 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 *PERIMOUNT Magna Ease* aortic and mitral valves. 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. Sales of the Company's surgical tissue heart valve products represented approximately 44%, 46% and 45% of the Company's net sales in 2010, 2009 and 2008, respectively.

Edwards Lifesciences has leveraged the knowledge and experience from its tissue heart valve portfolio to develop transcatheter heart valve replacement technologies, designed to treat heart valve disease using catheter-based approaches as opposed to open surgical techniques. For aortic valve replacement, the Company has developed the *Edwards SAPIEN* transcatheter heart valve, 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. The *Edwards SAPIEN* valve is currently sold in Europe and other international markets, and commercial sales in the United States are pending regulatory approval. The Company has also developed the *Edwards SAPIEN XT* transcatheter heart valve, which is delivered using the lower profile *NovaFlex* delivery system for transfemoral approaches, and the *Ascendra2* delivery system for transapical approaches. The *Edwards SAPIEN XT* valve is available for sale in Europe and other international markets, is currently in clinical study in Japan, and clinical study of the valve is expected to commence in the

Table of Contents

United States in 2011. The Company discontinued development of its *MONARC* transcatheter mitral repair system in 2010. Sales of the Company's transcatheter heart valves represented approximately 14%, 9% and 4% of the Company's net sales in 2010, 2009 and 2008, respectively.

Critical Care

Edwards Lifesciences is a world leader in hemodynamic monitoring systems 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 tissue and organ perfusion, and ultimately patient survival.

Edwards Lifesciences' hemodynamic monitoring technologies are utilized 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 pulmonary artery catheters, and the *PreSep* continuous venous oximetry catheter for measuring central venous oxygen saturation. Edwards' hemodynamic monitoring product line also 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 for goal-directed fluid optimization. Edwards Lifesciences is the global leader in disposable pressure monitoring devices and innovative closed-loop blood sampling systems to protect both patients and clinicians from the risk of infection. Sales of the Company's disposable pressure monitoring devices represented approximately 11% of the Company's net sales in both 2010 and 2009, and 12% of the Company's net sales in 2008.

In late 2010, Edwards Lifesciences introduced its *VolumeView* sensor-catheter set and *EV1000* clinical monitoring platform in Europe, which expand the Company's product offering in the medical intensive care setting. The *VolumeView* set measures a critically ill patient's volumetric hemodynamic parameters, while the *EV1000* touch-screen monitor displays a patient's physiologic status and integrates many of the Company's sensors and catheters into one intuitive system.

Pursuant to a partnership arrangement with a third party, the Company is jointly developing 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.

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 perfusion, venting and cardioplegia delivery. 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, aortic occlusion, venting 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Edwards Lifesciences manufactures and sells a variety of products used to treat endoluminal occlusive disease, including balloon-tipped, catheter-based embolectomy products, surgical clips and clamps. Edwards Lifesciences' *Fogarty* line of embolectomy catheters has been an industry standard for removing blood clots from peripheral blood vessels for more than 40 years.

Competition

The medical device 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 device 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 believes that it is one of the leading competitors, in terms of global market share, in each of its major product lines. The Company's 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, the Company's 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 and LiDCO Group PLC. 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 2010.

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 2010, 39% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

International. In 2010, 61% of Edwards Lifesciences' reported sales were derived internationally through its direct sales force and independent distributors. Of the total international sales, 32% were in Europe, 17% were in Japan, and 12% were in Rest of World. 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 majority of the sales and marketing approach outside the United States 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 at the country level.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

of the product, component specification processes, and the manufacturing, sales and servicing of the product. The quality system is intended to incorporate quality into products 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 regularly 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 \$204.4 million in research and development in 2010, \$175.5 million in 2009, and \$139.2 million in 2008 (14.1%, 13.3% 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. Additionally, the Company dedicates a sizable portion of its research and development investment to developing advanced technologies designed to address unmet clinical needs within the area of structural heart disease.

Edwards Lifesciences is investing substantially in the development of transcatheter heart valve 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* transcatheter heart valve system. Other development programs within its Heart Valve Therapy product line include the *INTUITY Valve System*, a minimally invasive aortic heart valve system designed to enable a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision. The *INTUITY Valve System* is currently in clinical study in Europe.

In its Critical Care product line, the Company is pursuing the development of minimally invasive hemodynamic monitoring systems, 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

research efforts, Edwards Lifesciences has developed alliances with several leading research institutions and universities, and also works with leading clinicians around the world in conducting scientific studies on the Company's existing and developing products. These studies include clinical trials, which provide data for use in regulatory submissions, and post-market approval studies involving applications of Edwards Lifesciences' products.

Proprietary Technology

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

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

Edwards Lifesciences is a party to several license agreements with unrelated third parties pursuant to which it has obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross licensing rights or royalty payments. Edwards Lifesciences has also licensed certain patent rights to others.

Edwards Lifesciences monitors the products of its competitors for possible infringement of Edwards Lifesciences' owned and/or licensed patents. Litigation has been necessary to enforce certain patent rights held by Edwards Lifesciences, and the Company plans to continue to defend and prosecute its rights with respect to such patents.

Edwards Lifesciences owns certain United States registered trademarks used in its business. Many Company trademarks have also been registered for use in certain foreign countries where registration is available and Edwards Lifesciences has determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Regulatory Environment. The Company's products and technologies are subject to regulation by numerous domestic and foreign government agencies, including the United States Food and Drug Administration ("FDA"), and various laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of the Company's products and technologies. The Company is also governed by federal, state, local and international laws of general applicability, such as those regulating employee health and safety and the protection of the environment. Overall, the amount and scope of domestic and foreign laws and regulations applicable to the Company's business is increasing.

In the United States, the FDA has responsibility for regulating medical devices. The FDA regulates design, development, testing, clinical studies, manufacturing, labeling, promotion and record-keeping for medical devices, and reporting of adverse events, recalls, or other field actions 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 clearance or approval requirements. The process of obtaining FDA clearance or 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. A number of the Company's products are pending regulatory clearance or approval to begin commercial sales in various markets, including

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

the *Edwards SAPIEN* transcatheter valve in the United States. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other standards for clearance. Additionally, even if a product is cleared or approved, the FDA may require testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement or refund of the costs of such devices, or preclude the importation of devices that are or appear violative. The FDA also conducts inspections to determine compliance with the quality system regulations concerning the manufacturing and design of devices and current medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays or suspensions of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. The Company's compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other United States agencies administer controls over the export of medical devices from the United States and the importation of devices into the United States, which could also subject the Company to sanctions for noncompliance.

Medical device laws are also in effect in most markets around the world including Europe, Japan and many other countries. Similar to the United States laws, foreign regulations include import/export regulation, inspection requirements, comprehensive device approval requirements, 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). In addition, the process of obtaining foreign approval to market a product 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 in the United States. Foreign regulations can also subject the Company to penalties for noncompliance, criminal sanctions and the revocation of its license to conduct business in a foreign jurisdiction.

The Company is also subject to additional laws and regulations that govern its business operations, products and technologies, including:

federal, state and foreign anti-kickback laws and regulations, which generally prohibit payments to physicians or other purchasers of medical products as an inducement to purchase a product;

the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider;

federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996;

the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payor; and

the United States Foreign Corrupt Practices Act, which can be used to prosecute companies in the United States for arrangements with foreign government officials or other parties outside the United States.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity and substantial costs and expenses associated with investigation and enforcement

Table of Contents

activities. To assist in the Company's compliance efforts, the Company adheres to many codes of ethics and conduct regarding its sales and marketing activities in the United States and other countries in which it operates. In addition, the Company has in place and works to improve its internal business compliance programs and policies.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness therapies, technology assessments and managed-care arrangements, 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. For example, government programs, private health care insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for procedures or treatments, and some third-party payors require their pre-approval before new or innovative devices or therapies are utilized by patients. These various initiatives have created increased price sensitivity over medical products generally and may impact demand for the Company's products and technologies.

The delivery of the Company's products is subject to regulation by the Health and Human Services Centers for Medicare and Medicaid Services and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services. Reimbursement schedules regulate the amount the United States government 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. Changes in current reimbursement levels could have an adverse effect on market demand and the Company's pricing flexibility.

Health care cost containment efforts have also 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. In 2010, significant reforms to the health care system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. The new law or any future legislation could reduce medical procedure volumes, lower reimbursement for the Company's products, and impact the demand for the Company's products or the prices at which the Company sells its products.

Puerto Rico Excise Tax. On October 25, 2010, the Puerto Rican government enacted a new tax law effective for transactions occurring after December 31, 2010. The law, Act 154, modifies Puerto Rican tax law by imposing a temporary excise tax on intercompany purchases made through 2016 and by adopting a new sourcing rule. The Company projects that the excise tax impact for 2011 of approximately \$6.0 million will be offset by credits available under the implementing excise tax regulations. The financial impact of the new sourcing rule is not expected to be material.

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.

Table of Contents

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, 2010, Edwards Lifesciences had approximately 7,000 employees worldwide, the majority of whom were located at the Company's headquarters in Irvine, California, and at its manufacturing facilities in Puerto Rico and the Dominican Republic. Other major concentrations of employees are located in Europe, Japan and Singapore. Edwards Lifesciences emphasizes competitive compensation, benefits, equity participation and work environment practices in its efforts to attract and retain qualified personnel, and employs a 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 and net cash flows.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 general economic conditions could adversely affect the financial 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 on a timely basis or at all 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 the regulatory validation 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

At December 31, 2010, we had \$25.0 million of investments in equity instruments of other companies and had recorded unrealized gains of \$2.2 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 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 may 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, cash flow and financial condition.

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 explore 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 assets. To the extent that the value of these assets declines, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired in-process research and development. Either of these situations could result in substantial charges, 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 domestic and global 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. Negative conditions in the credit and capital markets could also impair our ability to access the financial markets for working capital or other funds, and could negatively impact our ability to borrow. Such conditions could result in decreased liquidity, and could result in impairments in the carrying value of our investments and adversely affect our results of operations and financial condition. In 2010, significant reforms to the healthcare system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. The new law or any future legislation could reduce medical procedure volumes, lower reimbursement for the Company's products, and impact the demand for the Company's products or the prices at which the Company sells its 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 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 as well as with the United Kingdom's Bribery Act and similar laws in other jurisdictions. Our net sales originating outside of the United States, as a percentage of total net sales, were 61% in 2010. 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 local 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 global 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 international sales was generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our international 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 international 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

currencies that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity and cost; however, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations.

The stock market can be volatile and fluctuations in our quarterly operating results as well as other factors could cause our stock price to decline.

From time to time the stock market experiences extreme price and volume fluctuations. This volatility can have a significant effect on the market prices of securities for reasons unrelated to underlying performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results. In addition, the market price of our common stock could fluctuate substantially in

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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;

changes in governmental reimbursement rates for our products;

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.

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

Table of Contents

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, we and 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. Such licenses may materially increase our expenses. If we are unable to redesign products or obtain a license, we might have to exit a particular product offering.

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

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities, including regulations that cover the composition, labeling, testing, clinical study, design, manufacturing, packaging, marketing, advertising, promotion and distribution of our products.

Table of Contents

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, design, quality control and documentation procedures. The FDA may also inspect our compliance with requirements related to adverse event reporting, recalls or corrections (field actions), the conduct of clinical studies, and other requirements. In the European Union, we are required to maintain certain CE Mark and 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/or 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 the United States. 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, would be likely to cause or contribute to a death or serious injury. Federal regulations also require us to report certain recalls or corrective actions to the FDA. 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 clearances or approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time-consuming, and clearances or 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, clearances or 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, or other regulatory requirements. Noncompliance with applicable requirements may subject the Company or responsible individuals to sanctions including civil money penalties, product seizure, injunction, or criminal prosecution. Additionally, 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 United States and international 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, including misbranding investigations, and enforcement of the Foreign Corrupt Practices Act. In addition, the recently enacted United Kingdom Bribery Act as well as similar laws in other jurisdictions could give rise to increased enforcement of prohibitions against bribery and other illegal payments or for the failure to have procedures in place that prevent such payments. Despite implementation of robust compliance processes, we may be subject, from time to time, to increased regulation, as well as inspections, investigations and other enforcement actions by governmental authorities. Whenever the United States or another foreign governmental authority concludes that we are not in compliance with applicable laws or regulations, such governmental authority can impose fines, delay, or suspend, or revoke regulatory clearances or approvals, institute proceedings to detain or seize our products, issue a recall, impose marketing

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

or 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.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater governmental regulation in the future.

Our medical devices and our business activities are subject to rigorous regulation, including by the FDA and numerous other federal, state and foreign governmental authorities. These authorities and members of Congress have been increasing their scrutiny of our industry. In addition, certain states have recently passed or are considering legislation restricting our interactions with health care providers and requiring disclosure of certain payments to them. Also, while recent case law has clarified that the FDA's authority over certain medical devices preempts state tort laws, legislation has been introduced at the federal level to allow state intervention. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities may increase compliance costs, exposure to litigation and other adverse effects to our operations.

Unsuccessful clinical trials or developmental procedures relating to products under 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

If third-party payors decline to reimburse our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed.

We sell our products and technologies to hospitals, doctors and other health care providers, all of which receive reimbursement for the health care services provided to patients from third-party payors, such as government programs (both domestic and international), private insurance plans and managed care programs. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation or reimbursement policies of third-party payors will not otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care 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, recently enacted legislation in the United States 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 health care 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, resulting in lower sales of our products.

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 trainers and 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

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

North America

Irvine, California	(1), (2)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, 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
Nyon, Switzerland	(1)	Administration, Marketing

Asia

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

(1) Owned property.

(2) Leased property.

The Irvine, California lease expires in 2021; the Draper, Utah lease expires in 2025; the Dominican Republic property has one lease that expires in 2012 and one that expires in 2016; the Puerto Rico property has one lease that expires in 2018 and one 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 February 2008, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve") in the United States District Court for the District of Delaware alleging that its ReValving System infringes three of the Company's U.S. Andersen patents, later narrowed to one patent ("the '552 patent"). CoreValve was acquired by Medtronic, Inc. ("Medtronic") in April 2009. In April 2010, a federal jury found that patent to be valid and found that CoreValve willfully infringes it. The jury also awarded Edwards \$73.9 million in damages. In February 2011, the District Court reaffirmed the jury decision and ruled that Edwards is entitled to recover additional damages due to CoreValve's continued infringing sales from the trial through the life of the patent, plus interest. In the same ruling, the court denied Edwards' motions for a permanent injunction and increased damages relating to CoreValve's willful infringement. CoreValve has appealed and Edwards plans to file a cross-appeal. A second lawsuit is pending in the same court against CoreValve and Medtronic alleging infringement of three U.S. Andersen patents. In September 2010, the United States Patent and Trademark Office granted Medtronic's third request to reexamine the validity of the claim of the '552 patent and later issued an initial Office Action rejecting the claim of the '552 patent. The reexamination process is ongoing.

Earlier, in May 2007, the Company filed a lawsuit against CoreValve alleging infringement of the Company's European Andersen patent. The lawsuit was filed in the District Patent Court in Dusseldorf,

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Germany, seeking injunctive and declaratory relief. In October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. 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 the patent to be 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 is valid but not infringed by CoreValve. In May 2010, a United Kingdom Appeals Court affirmed the lower court. In January 2010, the German Courts also determined that the Andersen patent is valid. In December 2010, these lawsuits were resolved pursuant to a confidential settlement between the parties.

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 were invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Courts 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. In June 2010, a United Kingdom Appeals Court affirmed. In April 2010, the German Courts also determined that the Cook patent is invalid.

In March and September 2010, the Company received grand jury subpoenas for documents from the United States Attorney's Office in the Central District of California in connection with an investigation by the FDA. The subpoenas to the Company seek records relating to the Vigilance I Monitor model with software release 5.3 that was the subject of a voluntary field recall by the Company in June 2006. The Company is cooperating fully with the investigation.

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.

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, as adjusted for the two-for-one stock split paid on May 27, 2010 to shareholders of record on May 14, 2010, of Edwards Lifesciences' common stock, as reported by the NYSE.

Calendar Quarter Ended:	2010		2009	
	High	Low	High	Low
March 31	\$ 50.99	\$ 42.31	\$ 31.75	\$ 26.43
June 30	56.44	46.58	34.12	27.91
September 30	69.29	53.10	35.22	30.45
December 31	85.47	63.23	44.13	33.83

Number of Stockholders

On January 31, 2011 there were 13,918 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

On February 11, 2010, 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 \$500.0 million of the Company's common stock. The Company did not purchase any of its common stock during the fourth quarter of 2010 and, as of December 31, 2010, had remaining authority to purchase \$398.0 million of 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,				
		2010	2009	2008	2007	2006
		(in millions, except per share data)				
OPERATING RESULTS	Net sales	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7	\$ 1,091.1	\$ 1,037.0
	Gross profit	1,038.7	922.3	818.1	712.9	663.4
	Net income(a)	218.0	229.1	128.9	113.0	130.5
BALANCE SHEET DATA	Total assets	\$ 1,767.2	\$ 1,615.5	\$ 1,400.2	\$ 1,349.8	\$ 1,246.8
	Long-term debt and lease obligations(b)		90.3	175.5	61.7	235.9
COMMON STOCK INFORMATION	Net income per common share(a):					
	Basic	\$ 1.92	\$ 2.04	\$ 1.15	\$ 0.99	\$ 1.12
	Diluted	1.83	1.95	1.10	0.93	1.05
	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 special charges (gains), net, of \$22.7 million, \$(63.8) million and \$25.1 million during 2010, 2009 and 2008, respectively.

(b)

The Company's Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement") matures on September 29, 2011. At December 31, 2010, all amounts outstanding under the Credit Agreement have been classified as short-term obligations as these obligations are due within one year. The Company anticipates that it will extend or replace the Credit Agreement upon maturity.

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, 2010. Also discussed is Edwards Lifesciences' financial position as of December 31, 2010. 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.

Edwards Lifesciences' **Heart Valve Therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **Critical Care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function, and in disposable pressure transducers. Prior to September 2009, Edwards Lifesciences provided products for continuous renal replacement therapy ("hemofiltration product line"). The Company sold the hemofiltration

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

product line in September 2009. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery, including cannulae, embolic protection devices and other products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also includes the Company's minimally invasive surgery ("MIS") product line. 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.

In March 2010, significant reforms to the healthcare system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. The new law or any future legislation could reduce medical procedure volumes, lower reimbursement for the Company's products, and impact the demand for the Company's products or the prices at which the Company sells its products.

On April 12, 2010, the Company's Board of Directors declared a two-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, paid on May 27, 2010 to shareholders of record on May 14, 2010. The Company distributed its treasury shares in addition to newly issued shares to effect the stock split. All applicable share and per-share amounts in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" have been retroactively adjusted to give effect to this stock split.

Results of Operations

Net Sales by Major Regions

(dollars in millions)

	Years Ended December 31,			Change		Percent Change	
	2010	2009	2008	2010	2009	2010	2009
United States	\$ 567.6	\$ 556.1	\$ 543.6	\$ 11.5	\$ 12.5	2.1%	2.3%
Europe	457.0	404.6	380.3	52.4	24.3	13.0%	6.4%
Japan	247.8	214.1	176.5	33.7	37.6	15.7%	21.3%
Rest of World	174.6	146.6	137.3	28.0	9.3	19.1%	6.8%
International	879.4	765.3	694.1	114.1	71.2	14.9%	10.3%
Total net sales	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7	\$ 125.6	\$ 83.7	9.5%	6.8%

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

The \$11.5 million **increase in net sales in the United States in 2010** was due primarily to:

Heart Valve Therapy products, which increased net sales by \$9.7 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve (launched in the second quarter of 2009), *Magna Mitral Ease* valve (launched in the third quarter of 2010), *Physio II* ring (launched in the first quarter of 2009), and sales of the *Edwards SAPIEN* transcatheter heart valve for clinical trials;

Critical Care products, which increased net sales by \$5.7 million, driven primarily by the *FloTrac* minimally invasive monitoring system; and

Cardiac Surgery Systems products, which increased net sales by \$2.7 million, driven primarily by the MIS product line;

partially offset by:

the discontinuance of manufacturing in September 2009 of the divested *LifeStent* product line, which decreased net sales by \$8.2 million.

The \$114.1 million **increase in international net sales in 2010** was due primarily to:

Heart Valve Therapy products, which increased net sales by \$112.6 million, driven primarily by the *Edwards SAPIEN XT* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve and the new *Carpentier-Edwards Physio II* ring, which was launched in Europe in the first quarter of 2009 and in Japan in the first quarter of 2010;

Critical Care products, which increased net sales by \$18.1 million, driven primarily by the *FloTrac* minimally invasive monitoring system and pressure monitoring products;

Cardiac Surgery Systems products, which increased net sales by \$4.1 million, driven primarily by specialty cannula products; and

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

partially offset by:

hemofiltration products, which decreased net sales by \$32.0 million. The Company sold its hemofiltration product line in September 2009. For more information see "*Special Charges (Gains), net.*"

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

Heart Valve Therapy products, which increased net sales by \$33.6 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, *Magna* with *ThermaFix* valve, and the *Physio II* ring;

partially offset by:

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 in September 2009.

The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs and the Company's hedging activities. For more information see "*Quantitative and Qualitative Disclosures About Market Risk.*"

Net Sales by Product Line

(dollars in millions)

	Years Ended December 31,			Change		Percent Change	
	2010	2009	2008	2010	2009	2010	2009
Heart Valve Therapy	\$ 838.3	\$ 714.9	\$ 607.4	\$ 123.4	\$ 107.5	17.3%	17.7%
Critical Care	454.1	452.5	451.8	1.6	0.7	0.4%	0.2%
Cardiac Surgery							
Systems	100.2	92.8	89.2	7.4	3.6	8.0%	4.0%
Vascular	54.4	61.2	89.3	(6.8)	(28.1)	(11.1)%	(31.5)%
Total net sales	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7	\$ 125.6	\$ 83.7	9.5%	6.8%

Heart Valve Therapy

The \$123.4 million increase in net sales of Heart Valve Therapy products in 2010 was due primarily to:

the *Edwards SAPIEN XT* transcatheter heart valve, which increased net sales by \$99.0 million; and

pericardial tissue valves, which increased net sales by \$26.2 million, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve.

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 TheraFix* mitral valve and the *Magna* aortic valve in Japan; and

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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 Company expects that its *SAPIEN* and *SAPIEN XT* transcatheter heart valves will continue to be strong contributors to 2011 sales. The Company also expects that sales of its other new products will

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

continue to drive surgical heart valve growth in 2011. The Company launched its *Magna Mitral Ease* valve in the United States and Europe during the third quarter of 2010, and expects to obtain approval in Japan during the fourth quarter of 2011. The *Magna Mitral Ease* extends the *Magna* platform and is intended to provide improved MIS capabilities and ease of implantation.

In January 2010, the Company completed first-in-human procedures and initiated a clinical feasibility study in Europe, called TRITON, for a novel minimally invasive aortic valve surgery system, called *INTUITY* (formerly Project Odyssey). The *INTUITY Valve 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. In April 2010, the Company expanded the study into a CE Mark trial. The Company completed enrollment in TRITON during the third quarter of 2010, and anticipates receiving CE Mark in mid-2011. In the United States, the Company expects to obtain Investigational Device Exemption ("IDE") approval for the clinical trial of the *INTUITY Valve System* during 2011.

During the second quarter of 2011, the Company expects to launch the *Carpentier-Edwards Physio Tricuspid* annuloplasty ring in the United States and Europe. This new ring expands the Company's market-leading repair portfolio and is designed to provide a more physiologic repair for a patient's tricuspid valve.

Critical Care

The \$1.6 million increase in net sales of Critical Care products in 2010 was due primarily to:

premium products, led by *FloTrac* systems, which increased net sales by \$14.2 million, and *PreSep*, the Company's continuous central venous oximetry catheter for early detection of sepsis, which increased net sales by \$3.3 million;

pressure monitoring products, which increased net sales by \$8.5 million; and

foreign currency exchange rate fluctuations, which increased net sales by \$8.7 million, due primarily to the strengthening of the Japanese yen against the United States dollar;

partially offset by:

hemofiltration products, which decreased net sales by \$32.3 million. The Company sold its hemofiltration product line in September 2009.

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 in September 2009; and

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.

During the fourth quarter of 2010, the Company launched, outside of the United States, a substantial upgrade designed to strengthen the *FloTrac* system's applicability in the medical intensive care unit and a new hardware platform with a simpler, more intuitive informational display. The Company expects to obtain approval for these products in the United States in the third quarter of 2011.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

In September 2010, the Company entered into a collaboration, license, and supply agreement related to its Central Venous Access product line ("Access Products"). Under the terms of the agreement, the Company granted the buyer an exclusive, perpetual, royalty-free license to manufacture, distribute, market and sell the Access Products in the United States. The Company agreed to manufacture and exclusively supply the Access Products to the buyer through March 2013.

The Company has a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. In Europe, the Company received CE Mark in the fourth quarter of 2009 and has made progress on the development of a second generation product designed to enhance ease of use. The Company anticipates obtaining CE Mark on the second generation product by the end of 2011 and plans to begin commercial sales in 2012.

Cardiac Surgery Systems

The \$7.4 million increase in net sales of Cardiac Surgery Systems products in 2010 was due primarily to MIS products, which increased net sales by \$3.7 million, and specialty cannula products, which increased net sales by \$3.1 million.

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.

Vascular

The \$6.8 million and \$28.1 million decreases in net sales of Vascular products in 2010 and 2009, respectively, were due primarily to the discontinuance of manufacturing in September 2009 of the divested *LifeStent* product line.

Gross Profit

	Years Ended December 31,			Change	
	2010	2009	2008	2010	2009
Gross profit as a percentage of net sales	71.8%	69.8%	66.1%	2.0 pts.	3.7 pts.

The 2.0 percentage point increase in gross profit as a percentage of net sales in 2010 was driven by:

a 1.5 percentage point increase due to a more profitable international product mix, primarily higher sales of transcatheter heart valves and the divestiture of the hemofiltration product line, and the favorable impact of manufacturing performance; and

a 0.5 percentage point increase primarily due to the favorable impact of manufacturing performance in the United States.

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 due primarily to a more profitable product mix in the United States, 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 due to a more profitable international product mix, primarily higher sales of Heart Valve Therapy products and *FloTrac* systems; and

the impact from the outcome 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	
	2010	2009	2008	2010	2009
SG&A expenses	\$ 550.0	\$ 508.8	\$ 480.6	\$ 41.2	\$ 28.2
SG&A expenses as a percentage of net sales	38.0%	38.5%	38.8%	(0.5) pts.	(0.3) pts.

The \$41.2 million increase in SG&A expenses in 2010 was primarily in Europe due to the following: (1) higher sales and marketing expenses, primarily to support the transcatheter heart valve program and (2) higher sales-related spending in the Critical Care and Surgical Heart Valve Therapy product lines. Foreign currency had an unfavorable impact of \$2.7 million, primarily due to the strengthening of various currencies against the United States dollar, primarily the Japanese yen, partially offset by the weakening of the Euro against the United States dollar.

The \$28.2 million increase in SG&A expenses in 2009 was primarily in Europe due to the following: (1) investments for the *Edwards SAPIEN* transcatheter heart valve program in Europe and (2) higher sales-related spending in the Surgical 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.

Research and Development Expenses

(dollars in millions)

	Years Ended December 31,			Change	
	2010	2009	2008	2010	2009
Research and development expenses	\$ 204.4	\$ 175.5	\$ 139.2	\$ 28.9	\$ 36.3
Research and development expenses as a percentage of net sales	14.1%	13.3%	11.2%	0.8 pts.	2.1 pts.

The increase in research and development expenses in 2010 was due to additional investments in all major product lines, primarily the transcatheter heart valve program.

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

The following are the developments related to the Company's transcatheter heart valve program:

the Company received conditional 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, 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 were randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. In the second study arm ("Cohort B"), patients who were deemed non-operable were randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. In addition, the Company received FDA approval for non-randomized continued access for all of its existing PARTNER sites. During the third quarter of 2010, positive one-year data from Cohort B was published and the Company completed the submission of its pre-market approval to the FDA during the fourth quarter of 2010. The Company anticipates launching its *SAPIEN* transcatheter valve in the United States during the fourth quarter of 2011. The Company anticipates submitting its pre-market approval for Cohort A to the FDA during the second quarter of 2011;

the Company announced it received CE Mark in March 2010 for its next generation transcatheter heart valve, the *Edwards SAPIEN XT* valve, as well as its *NovaFlex* transfemoral and *Ascendra2*

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

transapical delivery systems. 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 began disciplined European launches of *SAPIEN XT* with *NovaFlex* at the end of the first quarter of 2010, and *SAPIEN XT* with *Ascendra2* at the end of the second quarter of 2010;

in the United States, the Company submitted an IDE for *SAPIEN XT* in October 2009. The PARTNER II trial will evaluate *SAPIEN XT* with both the *NovaFlex* and *Ascendra2* delivery systems and will target high risk patients similar to those studied in the PARTNER trial. The first cohort of the PARTNER II trial ("PARTNER II Cohort B") will study up to 500 inoperable patients with severe, symptomatic aortic stenosis using a 1:1 randomization of *SAPIEN XT* with the *NovaFlex* transfemoral delivery system versus *SAPIEN* with the *RetroFlex 3* delivery system. In February 2011, the Company received conditional IDE approval from the FDA for PARTNER II Cohort B. The Company expects to complete enrollment in this cohort by the end of 2011. The second planned patient cohort ("PARTNER II Cohort A") will compare traditional open-heart surgery with *SAPIEN XT* delivered either transfemorally or transapically in high-risk surgical patients. The Company anticipates that IDE approval for PARTNER II Cohort A could be received in the first quarter of 2011;

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 began enrolling patients in a clinical trial with its *SAPIEN XT* valve, called PREVAIL JAPAN, during the second quarter of 2010. The PREVAIL JAPAN clinical trial will evaluate *SAPIEN XT* with both the transfemoral and transapical delivery systems. The Company believes that successful trial completion could result in an approval as early as 2013; and

during the second quarter of 2010, the Company decided to discontinue its *MONARC* transcatheter mitral valve program due to slow enrollment in the EVOLUTION II trial. Also, in early analysis of the data, *MONARC* did not demonstrate a significant efficacy advantage.

Special Charges (Gains), net

	Years Ended December 31,		
	2010	2009	2008
	(in millions)		
<i>MONARC</i> program discontinuation	\$ 8.3	\$	\$
Realignment expenses, net	7.2		(1.7)
Investment impairment	7.2	1.6	
Gain on sale of assets, net		(86.9)	(14.9)
Charitable fund contribution		15.0	
Settlements and litigation, net		3.8	0.6
Adjustment to capitalized patent enforcement costs		3.7	8.2
Reserve reversal		(1.0)	
Acquisition of in-process technology and intellectual property			19.5
DexCom collaboration agreement			13.4
Total special charges (gains), net	\$ 22.7	\$ (63.8)	\$ 25.1

MONARC Program Discontinuation

During the second quarter of 2010, the Company decided to discontinue its *MONARC* transcatheter mitral valve program due to slow enrollment in the EVOLUTION II trial. As a result, the Company recorded an \$8.3 million charge consisting of a \$7.6 million impairment of intangible assets associated with the program and \$0.7 million of clinical trial costs that will continue to be incurred under a contractual obligation that existed prior to the discontinuation date.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Realignment Expenses, net

In December 2010, the Company recorded a \$7.2 million charge related primarily to severance expenses associated with a global workforce realignment impacting 84 employees. As of December 31, 2010, remaining payments of \$5.7 million related to the realignment are expected to be paid in 2011.

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, 2010, payments related to the executive severance charge were complete.

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.

Investment Impairment

In September and December 2010, the Company recorded a \$3.9 million charge and a \$3.3 million charge, respectively, related to the other-than-temporary impairment of certain of its investments in unconsolidated affiliates. The Company concluded that the impairment of these investments was other-than-temporary based upon the continuing duration and severity of the impairment.

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its 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.

Gain on Sale of Assets, net

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 would receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the two years following the sale, of which \$6.0 million and \$2.1 million was earned in 2010 and 2009, respectively, 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.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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.

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 was not material to the full year 2008 financial statements.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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\$3.9 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$8.4 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 DexCom's applicable intellectual property. The Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee.

Interest Expense

Interest expense was \$2.4 million, \$2.7 million and \$7.2 million in 2010, 2009 and 2008, respectively. The \$0.3 million decrease in interest expense for 2010 resulted primarily from prior year interest expense related to a sales and use tax audit settlement, partially offset by a higher average debt balance as compared to the prior year. 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.

Interest Income

Interest income was \$0.9 million, \$1.6 million and \$6.1 million in 2010, 2009 and 2008, respectively. The \$0.7 million decrease in interest income for 2010 resulted primarily from lower average interest rates, partially offset by higher cash and short-term investment balances. The \$4.5 million decrease in interest income for 2009 resulted primarily from lower average interest rates.

Other (Income) Expense, net

	Years Ended December 31,		
	2010	2009	2008
	(in millions)		
Earn-out payments	\$ (6.0)	\$ (2.1)	\$
Gain on investments in unconsolidated affiliates	(0.8)	(1.2)	(2.0)
Foreign exchange (gains) losses, net	(0.2)	(2.3)	7.2
Investment realized (gains) losses and impairment		(0.5)	3.0
Accounts receivable securitization costs			1.6
Other	(1.1)	2.4	(2.1)
Total other (income) expense, net	\$ (8.1)	\$ (3.7)	\$ 7.7

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 two years following the sale.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 foreign exchange (gains) losses relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances. Foreign exchange fluctuations (primarily the Euro and the Japanese yen) resulted in a net gain in 2010.

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.

The decrease in accounts receivable securitization costs was due to the Company's termination of its securitization programs in the United States (August 2008) and Japan (February 2009).

Provision for Income Taxes

The Company's effective income tax rates for 2010, 2009 and 2008 were impacted as follows (in millions):

	Years Ended December 31,		
	2010	2009	2008
Income tax expense at U.S. federal statutory rate	\$ 93.9	\$ 106.5	\$ 57.5
Foreign income tax at different rates	(28.1)	(27.9)	(26.4)
Release of reserve for uncertain tax positions for prior years	(13.4)	(3.8)	(6.2)
Tax credits, federal and state	(7.8)	(5.5)	(3.5)
State and local taxes, net of federal tax benefit	4.1	4.9	2.0
U.S. tax on foreign earnings, net of credits	2.2	1.0	0.6
Nondeductible stock-based compensation	1.9	1.4	0.9
Nondeductible goodwill			12.2
Other	(2.6)	(1.3)	(1.6)
Income tax provision	\$ 50.2	\$ 75.3	\$ 35.5

Reserve for Uncertain Tax Positions

As of December 31, 2010 and 2009, the liability for income taxes associated with uncertain tax positions was \$55.1 million and \$47.1 million, respectively. These liabilities could be reduced by \$4.7 million and \$3.2 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 \$50.4 million and \$44.0 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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

	December 31,		
	2010	2009	2008
Unrecognized tax benefits, January 1	\$ 47.1	\$ 35.9	\$ 36.4
Increase prior period tax positions	8.6	8.9	12.3
Decrease prior period tax positions	(20.1)	(9.4)	(19.9)
Current year tax positions	20.8	15.7	18.0
Settlements	(0.1)	(3.6)	(10.9)
Lapse of statute of limitations	(1.2)	(0.4)	
Unrecognized tax benefits, December 31	\$ 55.1	\$ 47.1	\$ 35.9

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2010, the Company had accrued \$1.7 million (net of \$1.4 million tax benefit) of interest related to uncertain tax positions, and 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.

The federal research credit was reinstated as of December 31, 2010. The effective income tax rate for the year ended December 31, 2010 has been calculated with the benefit for the federal research credit. The federal research credit favorably impacted the effective tax rate by 1.6 percentage points.

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 in income tax expense 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 the United States and between 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 is not expected to be material. At December 31, 2010, all material state, local and foreign income tax matters have been concluded for years through 2005. The Internal Revenue Service has completed its examination of the Company's 2007 and 2008 tax years for all matters except for certain transfer pricing issues. The Company has entered the appeals process for those transfer pricing issues.

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 2010, 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.

Table of Contents

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, 2010, deferred tax assets and corresponding valuation allowances of approximately \$3.1 million had accumulated related to investments. Of the total valuation allowance of \$3.1 million, \$0.4 million was recorded in 2010 through a charge to profit and loss. The remaining \$2.7 million had previously been recorded as of December 31, 2009 through charges to profit and loss.

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.

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, 2010, 2009 and 2008 by \$0.34, \$0.31 and \$0.28, 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 fund the current requirements of working capital, capital expenditures and other financial commitments. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

As of December 31, 2010, cash and cash equivalents held outside the United States was approximately \$367.0 million, and has historically been used to fund international operations. The Company believes that cash and cash equivalents held in the United States, in addition to amounts available under credit facilities and cash from operations, is sufficient to fund its United States operating requirements. Cash and cash equivalents held outside the United States can be repatriated back to the United States, if needed. Cash repatriations are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes.

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 short-term obligations as these obligations are due within one year. The Company anticipates that it will extend or replace the Credit Agreement upon maturity. However, no assurances can be given that the Credit Agreement will be extended or replaced on comparable terms as those currently in place. As of December 31, 2010, borrowings of \$41.8 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, 2010.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 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 would receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the two years following the sale, \$6.6 million of which had been received as of December 31, 2010.

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 received in 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. In February 2010, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$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 incentive programs and reduce the total shares outstanding. During 2010, the Company repurchased 4.1 million shares (as adjusted to reflect the May 2010 two-for-one stock split) at an aggregate cost of \$200.0 million and has remaining authority under the February 2010 program to purchase \$398.0 million of the Company's common stock.

Net cash flows provided by **operating activities** of \$251.4 million for 2010 increased \$86.1 million from 2009 primarily due to (1) a \$39.0 million cash payment during 2009 to terminate the Company's accounts receivable securitization program in Japan, (2) lower supplier payments in 2010 compared to 2009 and (3) higher operating profits. These increases were partially offset by higher inventory purchases in 2010, primarily related to the transcatheter heart valve product line, and the negative impact from increased excess tax benefits from stock plans due to the appreciation in the Company's stock price and increased exercises (which is offset in financing activities).

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 used in **investing activities** of \$61.5 million in 2010 consisted primarily of capital expenditures of \$61.8 million.

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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Net cash used in **financing activities** of \$103.9 million in 2010 consisted primarily of purchases of treasury stock of \$200.0 million and net payments on debt of \$48.4 million, partially offset by the proceeds from stock plans of \$92.1 million and the excess tax benefit from stock plans of \$55.1 million, which increased compared to the prior year due to the appreciation in the Company's stock price and increased exercises.

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 debt of \$84.6 million, partially offset by the proceeds from stock plans of \$66.7 million and the excess tax benefit from stock plans of \$20.6 million.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2010 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
Debt	\$ 41.8	\$ 41.8	\$	\$	\$
Interest on debt	0.3	0.3			
Operating leases	77.3	15.9	20.4	12.1	28.9
Pension obligation(a)	5.7	5.7			
Contractual development obligations(b)	13.2	8.0	1.3	3.9	
Capital commitment obligations(c)	4.6	3.8	0.6	0.2	
Total contractual cash obligations(d)	\$ 142.9	\$ 75.5	\$ 22.3	\$ 16.2	\$ 28.9

- (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, 2010 was \$33.4 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 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 10 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, 2010, the liability for uncertain tax positions including interest was \$58.2 million. As a result of on-going negotiations of Advanced Pricing Agreements between Switzerland and the United States and between 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 is not expected to be material.

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

Table of Contents

Accepted Accounting Principles in the United States of America ("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.

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, impairments of assets, forecasted transactions to be hedged, litigation reserves and contingencies.

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

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

Revenue Recognition

The Company recognizes revenue when it is realized or realizable and earned. Revenue is considered realized or realizable and earned upon delivery of the product, provided that an agreement of sale exists, the sales price is fixed or determinable and collection is reasonably assured. In the case of certain products where the Company maintains consigned inventory at customer locations, revenue is recognized at the time the Company is notified that the customer has used the inventory.

The Company's sales terms are standard terms within the medical device industry, with title and risk of loss transferring upon delivery to the customer, limited right of return and no unusual provisions or conditions. When the Company recognizes revenue from the sale of its products, an estimate of various sales returns and allowances is recorded which reduces product sales and accounts receivable. These adjustments include estimates for rebates, returns and other sales allowances. These provisions are estimated and recorded at the time of sale based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. Product returns are not significant because returns are generally not allowed unless the product is damaged at time of receipt. 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 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 either a review of the inventory reports obtained from its distributors or an estimate of its distributor's inventory. This distributor 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. For volume rebates offered to GPOs, the rebates are recorded as a reduction to sales and an obligation to the GPO. For volume rebates offered to customers, the rebates are recorded as a reduction to sales and

Table of Contents

accounts receivable. 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 allowance and liability for accrued rebates is fairly stated.

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 \$11.6 million and \$12.4 million at December 31, 2010 and 2009, 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 \$11.2 million and \$10.9 million at December 31, 2010 and 2009, respectively.

Patent Costs

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

Impairment of 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 Company's 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 2010, 2009 and 2008, 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.

Table of Contents

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are long-term 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.

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 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

Table of Contents

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 in income tax expense for any adjustments that may result from these uncertain tax positions.

As a result of on-going negotiations of various Advanced Pricing Agreements, 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 is not expected to be material.

The Company has significant 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.

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.

New Accounting Standards Not Yet Adopted

In October 2009, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on 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. The guidance 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 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 the accounting guidance on fair value 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 guidance also clarifies the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance was 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 adopted this guidance as of January 1, 2010, other than those provisions related to the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation.

In April 2010, the FASB issued an amendment to the accounting guidance on revenue recognition to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Consideration that is contingent upon achievement of a milestone in its entirety may be recognized as revenue in the period in which the

Table of Contents

milestone is achieved only if the milestone meets all criteria to be considered substantive. The guidance is effective for milestones achieved in fiscal years, and interim periods within those 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.

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 changes in currency exchange rates and interest rates. The Company manages these risks through a combination of normal operating and financing activities and derivative financial instruments. The Company uses forward currency exchange contracts and option-based products to mitigate its exposure to fluctuations in foreign currency rates. Historically, the Company has used interest rate swap contracts to manage its exposure to interest rate changes. The Company does not use derivative financial instruments for trading or speculative purposes.

Interest Rate Risk

In addition to available cash and cash from operations, the Company uses short- and long-term debt to finance business activities. The Company is exposed to interest rate risk on its debt obligations. The Company is not currently using derivative financial instruments to manage interest rate risk since the risk is not considered significant. A hypothetical 10% increase in the Company's weighted-average interest rate would have an immaterial effect on the Company's financial condition and results of operations.

For more information related to outstanding debt obligations, see Note 8 to the "*Consolidated Financial Statements*."

Currency Risk

The Company is exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances and results of the Company's non-United States subsidiaries into United States dollars, gains and losses related to intercompany and third-party transactions denominated in currencies other than a location's functional currency, and currency gains and losses associated with intercompany loans. The Company's principal currency exposures relate to the Japanese yen and the Euro. The Company's objective is to minimize the volatility of its exposure to these risks through a combination of normal operating and financing activities and the use of derivative financial instruments in the form of foreign currency forward exchange contracts and foreign currency options. The Company does not hedge its exposure related to its net investments in its non-United States subsidiaries. The total notional amounts of the Company's derivative financial instruments entered into for foreign currency management purposes at December 31, 2010 and 2009 were \$539.2 million and \$343.1 million, respectively. A hypothetical 10% increase/decrease in the value of the United States dollar against all hedged currencies would increase/decrease the fair value of these derivative contracts by \$44.4 million and \$49.5 million, respectively. Any gains or losses on the fair value of derivative contracts would be offset by gains and losses on the underlying transactions and would not be significant to the Company's financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Notes 2 and 9 to the "*Consolidated Financial Statements*."

Credit Risk

Derivative financial instruments involve credit risk in the event the financial institution counterparty should default. It is the Company's policy to execute such instruments with major financial institutions that the Company believes to be creditworthy. At December 31, 2010, all derivative financial instruments were with banks assigned investment grade ratings of "A" or better by national rating agencies. The Company

Table of Contents

further diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company also uses International Swap Dealers Association master-netting agreements with all derivative counterparties. The master-netting agreements reduce the Company's counterparty settlement risk to the net amount of any receipts or payments due between the Company and the counterparty financial institutions. The Company has not experienced a counterparty default and does not anticipate any non-performance by the Company's current derivative counterparties.

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 2010, the Company had no customers that represent greater than 10% of its total net sales or accounts receivable, net.

Investment Risk

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

As of December 31, 2010, Edwards Lifesciences had \$25.0 million of investments in equity instruments of other companies and had recorded unrealized gains of \$2.2 million on these investments in "*Accumulated Other Comprehensive Loss*," net of tax. In 2010, the Company reclassified to earnings a \$4.0 million loss, before tax, recorded in "*Accumulated Other Comprehensive Loss*." The amount reclassified related primarily to the other-than-temporary impairment of two non-strategic investments in unconsolidated affiliates. 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, 2010**

<u>Report of Independent Registered Public Accounting Firm</u>	<u>45</u>
Financial Statements:	
<u>Consolidated Balance Sheets at December 31, 2010 and 2009</u>	<u>46</u>
For the Years Ended December 31, 2010, 2009 and 2008:	
<u>Consolidated Statements of Operations</u>	<u>47</u>
<u>Consolidated Statements of Cash Flows</u>	<u>48</u>
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)</u>	<u>49</u>
<u>Notes to Consolidated Financial Statements</u>	<u>51</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 on page 44 present fairly, in all material respects, the financial position of Edwards Lifesciences Corporation and its subsidiaries at December 31, 2010 and December 31, 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, 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 28, 2011

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

(in millions, except par value)

	December 31,	
	2010	2009
ASSETS		
Current assets		
Cash and cash equivalents	\$ 396.1	\$ 334.1
Accounts receivable, net (Note 5)	277.3	249.4
Other receivables	25.2	22.7
Inventories, net	203.6	165.9
Deferred income taxes	51.9	48.3
Prepaid expenses	35.4	33.7
Other current assets	43.1	35.1
Total current assets	1,032.6	889.2
Property, plant and equipment, net	269.8	252.0
Goodwill	315.2	315.2
Other intangible assets, net	67.1	86.7
Investments in unconsolidated affiliates	25.0	22.3
Deferred income taxes	44.5	37.1
Other assets	13.0	13.0
Total assets	\$ 1,767.2	\$ 1,615.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 47.6	\$ 51.1
Accrued liabilities	226.1	203.5
Taxes payable	22.3	35.9
Short-term debt (Note 8)	41.8	
Total current liabilities	337.8	290.5
Long-term debt (Note 8)		90.3
Other long-term liabilities	121.2	76.8
Commitments and contingencies (Notes 8 and 15)		
Stockholders' equity (Note 2)		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 117.0 and 76.1 shares issued, and 115.0 and 56.8 shares outstanding, respectively	117.0	76.1
Additional paid-in capital	211.3	1,056.0
Retained earnings	1,124.0	906.0
Accumulated other comprehensive loss	(42.1)	(7.9)
Treasury stock, at cost, 2.0 and 19.3 shares, respectively	(102.0)	(872.3)
Total stockholders' equity	1,308.2	1,157.9

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Total liabilities and stockholders' equity	\$	1,767.2	\$	1,615.5
--	----	---------	----	---------

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,		
	2010	2009	2008
Net sales	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7
Cost of goods sold	408.3	399.1	419.6
Gross profit	1,038.7	922.3	818.1
Selling, general and administrative expenses	550.0	508.8	480.6
Research and development expenses	204.4	175.5	139.2
Special charges (gains), net (Note 3)	22.7	(63.8)	25.1
Interest expense	2.4	2.7	7.2
Interest income	(0.9)	(1.6)	(6.1)
Other (income) expense, net (Note 13)	(8.1)	(3.7)	7.7
Income before provision for income taxes	268.2	304.4	164.4
Provision for income taxes	50.2	75.3	35.5
Net income	\$ 218.0	\$ 229.1	\$ 128.9

Share information

(Note 2):

Earnings per share:			
Basic	\$ 1.92	\$ 2.04	\$ 1.15
Diluted	\$ 1.83	\$ 1.95	\$ 1.10
Weighted-average number of common shares outstanding:			
Basic	113.7	112.5	111.7
Diluted	119.2	117.5	119.2

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,		
	2010	2009	2008
Cash flows from operating activities			
Net income	\$ 218.0	\$ 229.1	\$ 128.9
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	56.5	58.7	55.6
Stock-based compensation (Notes 2 and 11)	29.3	28.3	28.7
Excess tax benefit from stock plans (Notes 2 and 11)	(55.1)	(20.6)	(14.9)
Deferred income taxes	(11.2)	(10.0)	(27.8)
Special charges (gains), net (Note 3)	22.7	(75.5)	25.4
(Gain) loss on trading securities	(2.7)	(3.3)	4.9
Other	(5.0)	0.3	2.7
Changes in operating assets and liabilities:			
Accounts and other receivables, net (Note 5)	(34.2)	(58.9)	(61.1)
Accounts receivable securitization (Note 5)		7.3	(7.4)
Inventories, net	(36.8)	(13.1)	(17.8)
Accounts payable and accrued liabilities	63.6	2.7	52.1
Prepaid expenses and other current assets	(2.5)	7.6	(3.3)
Other	8.8	12.7	(12.8)
Net cash provided by operating activities	251.4	165.3	153.2
Cash flows from investing activities			
Capital expenditures	(61.8)	(64.0)	(50.6)
Proceeds from sale of assets (Note 3)	6.6	97.9	97.0
Investments in unconsolidated affiliates	(6.9)	(5.8)	(1.1)
Proceeds from unconsolidated affiliates	2.2	2.3	5.5
Investments in intangible assets	(1.2)		(27.4)
Investments in trading securities, net	(0.4)	(1.7)	(0.1)
Proceeds from investments (Note 2)		11.4	35.5
Net cash (used in) provided by investing activities	(61.5)	40.1	58.8
Cash flows from financing activities			
Payments on debt	(302.8)	(213.9)	(112.1)
Proceeds from issuance of debt	254.4	129.3	206.3
Purchases of treasury stock	(200.0)	(95.5)	(306.5)
Proceeds from stock plans	92.1	66.7	63.8
Excess tax benefit from stock plans (Notes 2 and 11)	55.1	20.6	14.9
Other	(2.7)	1.0	(0.5)
Net cash used in financing activities	(103.9)	(91.8)	(134.1)
Effect of currency exchange rate changes on cash and cash equivalents	(24.0)	1.8	(1.0)
Net increase in cash and cash equivalents	62.0	115.4	76.9
Cash and cash equivalents at beginning of year	334.1	218.7	141.8

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Cash and cash equivalents at end of year	\$	396.1	\$	334.1	\$	218.7
--	----	-------	----	-------	----	-------

Supplemental disclosures:

Cash paid during the year for:

Interest	\$	2.4	\$	2.7	\$	7.3
Income taxes	\$	14.7	\$	34.2	\$	37.2

Non-cash transaction:

Distribution of treasury shares to effect stock split (Note 2)	\$	970.3	\$		\$	
Issuance of common shares in redemption of convertible debt (Note 8)	\$		\$		\$	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	Retained	Accumulated Other Comprehensive Income (Loss)	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount	Paid-In Capital	Earnings			
BALANCE AT DECEMBER 31, 2007	68.6	\$ 68.6	12.0	\$ (470.3)	\$ 680.6	\$ 548.6	\$ 7.5	\$ 835.0	
Comprehensive income									
Net income						128.9		128.9	\$ 128.9
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							(24.2)	(24.2)	(24.2)
Unrealized gain on cash flow hedges							4.9	4.9	4.9
Unrealized loss on available-for-sale investments							(11.5)	(11.5)	(11.5)
Reclassification of net realized investment gain to earnings							(1.7)	(1.7)	(1.7)
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, including tax benefits and other	2.4	2.4			82.2			84.6	
Issuance of shares for convertible debt	2.7	2.7			145.0			147.7	
Tax benefit due to redemption of convertible debt and other					3.9			3.9	
Stock-based compensation expense					28.7			28.7	

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Purchase of treasury stock			5.8	(306.5)				(306.5)		
BALANCE AT DECEMBER 31, 2008	73.7	73.7	17.8	(776.8)	940.4	676.9	(35.4)	878.8	\$	86.0
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							4.1	4.1		4.1
Reclassification of net realized investment loss to earnings							0.6	0.6		0.6
Defined benefit pension plans:										
Net gain							9.0	9.0		9.0
Common stock issued under equity plans, including tax benefits and other	2.4	2.4			87.1			89.5		
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)		
BALANCE AT DECEMBER 31, 2009	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

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND (Continued)

COMPREHENSIVE INCOME (LOSS)

(in millions)

	Common Stock		Treasury Stock		Additional	Retained	Accumulated Other Comprehensive Income (Loss)	Total	Comprehensive Income (Loss)
	Shares	Par Value	Shares	Amount	Paid-In Capital	Earnings	(Loss)		(Loss)
BALANCE AT DECEMBER 31, 2009	76.1	\$ 76.1	19.3	\$ (872.3)	\$ 1,056.0	\$ 906.0	\$ (7.9)	\$ 1,157.9	
Comprehensive income									
Net income						218.0		218.0	\$ 218.0
Other comprehensive income (loss), net of tax:									
Foreign currency translation adjustments							(24.9)	(24.9)	(24.9)
Unrealized loss on cash flow hedges							(6.8)	(6.8)	(6.8)
Unrealized loss on available-for-sale investments							(0.8)	(0.8)	(0.8)
Reclassification of net realized investment loss to earnings							4.0	4.0	4.0
Defined benefit pension plans:									
Net loss (Note 12)							(5.7)	(5.7)	(5.7)
Common stock issued under equity plans, including tax benefits and other	4.3	4.3			132.9			137.2	
Stock-based compensation expense					29.3			29.3	
Purchase of treasury stock			3.1	(200.0)				(200.0)	
Stock issued to effect stock split	36.6	36.6	(20.4)	970.3	(1,006.9)				
BALANCE AT DECEMBER 31, 2010	117.0	\$ 117.0	2.0	\$ (102.0)	\$ 211.3	\$ 1,124.0	\$ (42.1)	\$ 1,308.2	\$ 183.8

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") conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan and Rest of World. Edwards Lifesciences 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 the following main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; and Vascular. The Company's Heart Valve Therapy products include tissue heart valves and heart valve repair products. The Critical Care products include hemodynamic monitoring systems used to measure a patient's cardiovascular function, and disposable pressure transducers. Prior to September 2009, Edwards Lifesciences provided products for continuous renal replacement therapy ("hemofiltration product line"). The Company sold the hemofiltration product line in September 2009. The Company's Cardiac Surgery Systems products include a diverse line of products for use during cardiac surgery, including cannulae, embolic protection devices and other products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also includes the Company's minimally invasive surgery product line. 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.

Stock Split

On April 12, 2010, the Company's Board of Directors declared a two-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, paid on May 27, 2010 to shareholders of record on May 14, 2010. The Company distributed its treasury shares in addition to newly issued shares to effect the stock split. All applicable share and per-share amounts in the notes to consolidated financial statements and the consolidated statements of operations have been retroactively adjusted to reflect this stock split. The consolidated balance sheet as of December 31, 2009 and the consolidated statements of stockholders' equity and comprehensive income (loss) for the years ended December 31, 2009 and 2008 have not been retroactively adjusted to reflect the stock split.

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with Generally Accepted Accounting Principles in the United States of America ("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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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. 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. Product returns are not significant because returns are generally not allowed unless the product is damaged at time of receipt. 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 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 either a review of the inventory reports obtained from its distributors or an estimate of its distributor's inventory. This distributor 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. For volume rebates offered to GPOs, the rebates are recorded as a reduction to sales and an obligation to the GPO. For volume rebates offered to customers, the rebates are

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

recorded as a reduction to sales and accounts receivable. 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 allowance and liability for accrued rebates is fairly stated.

Cash Equivalents

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

Investments

The Company 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. During the fourth quarter of 2009, the Company received cash redemptions fully redeeming its remaining investment in this fund. 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 \$11.2 million and \$10.9 million at December 31, 2010 and 2009, 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, 2010, 2009 and 2008, the Company allocated \$23.4 million, \$20.9 million and \$21.3 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2010 and 2009 were \$12.0 million and \$10.3 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 \$40.0 million, \$38.0 million and \$36.8 million for the years ended December 31, 2010, 2009 and 2008, respectively. Repairs and maintenance

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

expense was \$16.1 million, \$15.4 million and \$14.6 million for the years ended December 31, 2010, 2009 and 2008, 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 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 Company's 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 2010, 2009 and 2008, 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 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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

value, the Company only estimates fair value if there are identified events or changes in circumstances that could have a significant adverse effect on the investment's fair value.

When the fair value of an available-for-sale investment declines below cost, management uses the following criteria to determine if such a decline should be considered other-than-temporary and result in a recognized loss:

the duration and extent to which the market value has been less than cost;

the financial condition and near term prospects of the investee;

the reasons for the decline in market value;

the investee's performance against product development milestones; and

the Company's ability and intent to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Income Taxes

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

The Company has 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

to DexCom's applicable intellectual property. Product development costs under this agreement are expensed to "*Research and Development Expenses*" as incurred. Edwards Lifesciences is responsible for global sales and marketing, and DexCom is

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

responsible for initial manufacturing. DexCom will receive either a profit-sharing payment or a royalty based upon commercial sales. For the years ended December 31, 2010 and 2009, the Company recorded \$4.2 million and \$5.5 million of product development costs, respectively.

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,		
	2010	2009	2008
Basic:			
Net income	\$ 218.0	\$ 229.1	\$ 128.9
Weighted-average shares outstanding	113.7	112.5	111.7
Basic earnings per share	\$ 1.92	\$ 2.04	\$ 1.15
Diluted:			
Net income	\$ 218.0	\$ 229.1	\$ 128.9
Interest expense related to convertible debt, net of tax			1.7
Net income applicable to diluted shares	\$ 218.0	\$ 229.1	\$ 130.6
Weighted-average shares outstanding	113.7	112.5	111.7
Dilutive effect of convertible debt			2.3
Dilutive effect of stock plans	5.5	5.0	5.2
Dilutive weighted-average shares outstanding	119.2	117.5	119.2
Diluted earnings per share	\$ 1.83	\$ 1.95	\$ 1.10

Stock options and restricted stock units to purchase approximately 0.9 million, 1.9 million and 3.8 million shares for the years ended December 31, 2010, 2009 and 2008, 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 convertible debentures until they were redeemed on June 9, 2008.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)****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 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, 2010, 2009 and 2008 was as follows (in millions):

	December 31,		
	2010	2009	2008
Cost of goods sold	\$ 2.7	\$ 2.4	\$ 2.7
Selling, general and administrative expenses	22.0	21.4	21.2
Research and development expenses	4.6	4.5	4.8
Total stock-based compensation expense	\$ 29.3	\$ 28.3	\$ 28.7

Upon retirement, all unvested stock 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

The Company uses derivative financial instruments to manage foreign currency risks. The Company uses foreign currency forward exchange contracts and foreign currency option contracts to offset the changes due to currency rate movements in the amount of future cash flows associated with intercompany transactions expected to occur within the next thirteen months. These foreign exchange contracts are designated as cash flow hedges. Certain of the Company's locations have assets and liabilities denominated in currencies other than their functional currencies resulting from intercompany and third-parties transactions. The Company uses forward currency exchange contracts that are not designated as hedging instruments to offset the transaction gains and losses associated with certain of these assets and liabilities. All foreign currency forward contracts and foreign currency option contracts are denominated in currencies of major industrial countries, principally the Euro and the Japanese yen. It is the Company's policy not to enter into derivative financial instruments for speculative purposes.

All derivative financial instruments are recognized at fair value in the consolidated balance sheets. The Company reports in "Other Comprehensive Loss" the effective portion of the gain or loss on derivative financial instruments that are designated and that qualify as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same period in which the underlying hedged transactions affect earnings. All cash flow hedges during 2010, 2009 and 2008 were highly effective. The gains and losses on derivative financial instruments for which the Company does not elect hedge accounting treatment are recognized in the

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

consolidated statements of operations in each period, based upon the change in the fair value of the derivative financial instrument. Cash flows from derivative financial instruments are reported as operating activities in the consolidated statements of cash flows.

Derivative financial instruments involve credit risk in the event the counterparty should default. It is the Company's policy to execute such instruments with global financial institutions that the Company believes to be creditworthy. The Company diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company also uses International Swap Dealers Association master-netting agreements. The master-netting agreements reduce the Company's counterparty settlement risk to the net amount of any receipts or payments due between the Company and the counterparty financial institution.

Recently Adopted Accounting Standards

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 was 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 performed an evaluation and determined that there were no relationships with affiliates that represent variable interests requiring consolidation under this guidance.

New Accounting Standards Not Yet Adopted

In October 2009, the FASB issued an amendment to the accounting guidance on 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. The guidance 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 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.

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

In January 2010, the FASB issued an amendment to the accounting guidance on fair value 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 guidance also clarifies the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance was 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 adopted this guidance as of January 1, 2010, other than those provisions related to the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation.

In April 2010, the FASB issued an amendment to the accounting guidance on revenue recognition to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Consideration that is contingent upon achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The guidance is effective for milestones achieved in fiscal years, and interim periods within those 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.

3. SPECIAL CHARGES (GAINS), NET

	Years Ended December 31,		
	2010	2009	2008
	(in millions)		
MONARC program discontinuation	\$ 8.3	\$	\$
Realignment expenses, net	7.2		(1.7)
Investment impairment	7.2	1.6	
Gain on sale of assets, net		(86.9)	(14.9)
Charitable fund contribution		15.0	
Settlements and litigation, net		3.8	0.6
Adjustment to capitalized patent enforcement costs		3.7	8.2
Reserve reversal		(1.0)	
Acquisition of in-process technology and intellectual property			19.5
DexCom collaboration agreement			13.4
Total special charges (gains), net	\$ 22.7	\$ (63.8)	\$ 25.1

MONARC Program Discontinuation

During the second quarter of 2010, the Company decided to discontinue its *MONARC* transcatheter mitral valve program due to slow enrollment in the EVOLUTION II trial. As a result, the Company recorded an \$8.3 million charge consisting of a \$7.6 million impairment of intangible assets associated with the program and \$0.7 million of clinical trial costs that will continue to be incurred under a contractual obligation that existed prior to the discontinuation date.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Realignment Expenses, net

In December 2010, the Company recorded a \$7.2 million charge related primarily to severance expenses associated with a global workforce realignment impacting 84 employees. As of December 31, 2010, remaining payments of \$5.7 million related to the realignment are expected to be paid in 2011.

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, 2010, payments related to the executive severance charge were complete.

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.

Investment Impairment

In September and December 2010, the Company recorded a \$3.9 million charge and a \$3.3 million charge, respectively, related to the other-than-temporary impairment of certain of its investments in unconsolidated affiliates. The Company concluded that the impairment of these investments was other-than-temporary based upon the continuing duration and severity of the impairment.

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its 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.

Gain on Sale of Assets, net

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 would receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the two years following the sale, of which \$6.0 million and \$2.1 million was earned in 2010 and 2009, respectively, 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.

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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.

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 was not material to the full year 2008 financial statements.

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.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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\$3.9 million) milestone payment should the Company achieve net sales of the product in Europe of €6.4 million (US\$8.4 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 DexCom's applicable intellectual property. The Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee.

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,	
	2010	2009
	(in millions)	
Accounts receivable, net		
Trade accounts receivable (Note 5)	\$ 288.9	\$ 261.8
Allowance for doubtful accounts	(11.6)	(12.4)
	\$ 277.3	\$ 249.4

Inventories, net		
Raw materials	\$ 38.2	\$ 32.8
Work in process	39.0	30.4
Finished products	126.4	102.7
	\$ 203.6	\$ 165.9

Property, plant and equipment, net		
Land	\$ 21.6	\$ 21.8
Buildings and leasehold improvements	147.4	137.2
Machinery and equipment	224.8	210.0
Equipment with customers	39.2	41.1
Software	81.2	79.6
Construction in progress	28.2	15.7
	542.4	505.4
Accumulated depreciation	(272.6)	(253.4)
	\$ 269.8	\$ 252.0

Accrued liabilities		
Employee compensation and withholdings	\$ 98.9	\$ 88.7
Property, payroll and other taxes	21.5	16.7
Fair value of derivatives	14.7	3.0
Clinical trial accruals	14.0	8.5
Litigation reserves (Note 15)	5.8	25.7
Other accrued liabilities	71.2	60.9
	\$ 226.1	\$ 203.5

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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. ACCOUNTS RECEIVABLE SECURITIZATION (Continued)**

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 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.

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, 2010 and 2009, and there were no costs associated with the sale of receivables during the years ended December 31, 2010 and 2009. The cost associated with the sale of receivables, primarily related to the discount, was \$1.6 million for the year ended December 31, 2008 and was included in "*Other (Income) Expense, net.*"

6. 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, 2010 and 2009 were as follows:

	December 31,	
	2010	2009
	(in millions)	
Balance as of January 1		
Goodwill	\$ 315.2	\$ 315.7
Accumulated impairment losses		
	315.2	315.7
Goodwill related to sale of product line		(0.5)
Balance as of December 31		
Goodwill	315.2	315.2
Accumulated impairment losses		
	\$ 315.2	\$ 315.2

In September 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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)**

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

December 31, 2010	Patents	Unpatented Technology	Other	Total
Cost	\$ 203.0	\$ 35.0	\$ 12.4	\$ 250.4
Accumulated amortization	(147.8)	(29.6)	(5.9)	(183.3)
Net carrying value	\$ 55.2	\$ 5.4	\$ 6.5	\$ 67.1

December 31, 2009				
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

During the second quarter of 2010, the Company recorded a \$7.6 million impairment of patents related to its *MONARC* transcatheter mitral valve program, which was discontinued due to slow enrollment in the EVOLUTION II trial (see Note 3).

The net carrying value of patents includes \$16.0 million and \$13.2 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, 2010 and 2009, 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).

Amortization expense related to other intangible assets for the years ended December 31, 2010, 2009 and 2008 was \$16.6 million, \$20.6 million and \$19.4 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2011	\$ 14.9
2012	13.4
2013	13.4
2014	12.0
2015	10.1

The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. INVESTMENTS IN UNCONSOLIDATED AFFILIATES**

The Company has a number of equity investments in privately and publicly held companies. Investments in these unconsolidated affiliates are as follows:

	December 31,	
	2010	2009
	(in millions)	
Available-for-sale investments		
Cost	\$ 4.1	\$ 8.5
Unrealized gains (losses)	3.6	(0.9)
Fair value of available-for-sale investments	7.7	7.6
Equity method investments		
Cost	11.5	10.7
Equity in losses	(1.5)	(0.8)
Carrying value of equity method investments	10.0	9.9
Cost method investments		
Carrying value of cost method investments	7.3	4.8
Total investments in unconsolidated affiliates	\$ 25.0	\$ 22.3

Proceeds from sales of available-for-sale investments for the years ended December 31, 2010, 2009 and 2008 were \$0.3 million, \$1.4 million and \$3.8 million, respectively, and the Company realized pre-tax gains of \$0.2 million, \$0.5 million and \$1.9 million, respectively. In 2010 and 2009, the Company recorded other-than-temporary impairment charges of \$4.2 million and \$1.6 million, respectively, related to certain available-for-sale investments. In 2010, the Company also recorded an other-than-temporary impairment charge of \$3.0 million related to one of its cost method investments. See Note 3 for additional information.

8. 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 short-term obligations as these obligations are due within one year. The Company anticipates that it will extend or replace the Credit Agreement upon maturity. However, no assurances can be given that the Credit Agreement will be extended or replaced on comparable terms as those currently in place. Additional issuance costs of \$0.5 million are being amortized to interest expense over 5 years. As of December 31, 2010, borrowings of \$41.8 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, 2010.

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 5.4 million shares of Edwards

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. DEBT, CREDIT FACILITIES AND LEASE OBLIGATIONS (Continued)**

Lifesciences common stock at a conversion price of \$27.33 per share. The remaining outstanding Notes of \$2.3 million were redeemed for cash on the redemption date.

Included in short-term debt at December 31, 2010 were unsecured notes denominated in Japanese yen of ¥1.3 billion (US\$15.5 million) and in Euro of €20.0 million (US\$26.3 million). 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).

The weighted-average interest rate under all debt obligations was 2.7% and 1.5% at December 31, 2010 and 2009, respectively.

Certain facilities and equipment are leased under operating leases expiring at various dates. Most of the operating leases contain renewal options. Total expense for all operating leases was \$19.6 million, \$18.2 million and \$16.7 million for the years 2010, 2009 and 2008, respectively.

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2010 were as follows (in millions):

	Operating Leases	Aggregate Debt Maturities
2011	\$ 15.9	\$ 41.8
2012	11.9	
2013	8.5	
2014	6.4	
2015	5.7	
Thereafter	28.9	
Total obligations and commitments	\$ 77.3	\$ 41.8

9. 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 a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities and borrowings under a revolving credit agreement. The carrying value of these financial instruments generally approximates fair value due to their short-term nature.

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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)**

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, 2010 and 2009 (in millions):

December 31, 2010	Level 1	Level 2	Level 3	Total
Assets				
Investments held for executive deferred compensation plan	\$ 18.3	\$	\$	\$ 18.3
Investments in unconsolidated affiliates	7.7			7.7
	\$ 26.0	\$	\$	\$ 26.0
Liabilities				
Derivatives	\$	\$ 14.7	\$	\$ 14.7
	\$	\$ 14.7	\$	\$ 14.7

December 31, 2009				
Assets				
Investments held for executive deferred compensation plan	\$ 15.1	\$	\$	\$ 15.1
Investments in unconsolidated affiliates	7.6			7.6
	\$ 22.7	\$	\$	\$ 22.7
Liabilities				
Derivatives	\$	\$ 3.0	\$	\$ 3.0
	\$	\$ 3.0	\$	\$ 3.0

Investments Held for the Executive Deferred Compensation Plan

The Company holds investments in trading securities related to its executive deferred compensation plan ("EDCP"). The amounts deferred under the EDCP are invested in a variety of stock and bond mutual funds. The fair values of these investments are based on quoted market prices and are categorized as Level 1.

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are long-term equity investments in companies that are in various stages of development. 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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)***Derivative Instruments*

The Company uses derivative financial instruments in the form of foreign currency forward exchange contracts and foreign currency option contracts to manage foreign currency exposures. All derivatives contracts are recognized on the balance sheet at their fair value. The fair value for derivatives is determined based on quoted market data and recognized financial principles. Although readily observable data is used in the valuations, different valuation methods could have an effect on the estimated fair value. The derivative instruments are categorized as Level 2.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

The Company has assets that are subject to measurement at fair value on a nonrecurring 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 intangible and other long-lived 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, 2010, the Company recorded an \$8.5 million impairment of intangible assets, primarily related to the Company's *MONARC* transcatheter mitral valve program, which was discontinued due to slow enrollment in the EVOLUTION II trial (see Note 3). During the year ended December 31, 2009, the Company had no impairments related to assets subject to measurement at fair value on a nonrecurring basis.

Derivative Financial Instruments

The Company uses 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,			
	2010		2009	
	Notional Amount	Fair Value Asset (Liability)	Notional Amount	Fair Value Asset (Liability)
	(in millions)			
Forward currency agreements	\$ 486.0	\$ (12.5)	\$ 130.5	\$ (1.7)
Currency option contracts	53.2	(2.2)	212.6	(1.3)

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, 2010 and 2009. 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.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS (Continued)

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated balance sheets (in millions):

Derivatives designated as hedging instruments	Balance Sheet Location	Fair Value	
		December 31, 2010	December 31, 2009
Liabilities			
Foreign exchange contracts	Accrued liabilities	\$ 14.7	\$ 3.0

The following tables present the effect of derivative instruments on the consolidated statements of operations (in millions):

	Amount of Gain or (Loss) Recognized in Other Comprehensive Income ("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	
	2010	2009		2010	2009
	Derivatives in cash flow hedging relationships				
Foreign exchange contracts	\$ (9.4)	\$ (0.8)	Cost of goods sold	\$ 1.8	\$ 5.0

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2010	2009	2008
Derivatives not designated as hedging instruments				
Foreign exchange contracts	Other (income) expense, net	\$ (5.0)	\$ (2.7)	\$ 0.2

The Company expects that during 2011 it will reclassify to earnings a \$3.2 million loss currently recorded in "Accumulated Other Comprehensive Loss." For the years ended December 31, 2010, 2009 and 2008, the Company expensed \$0.1 million, \$0.8 million and \$0.6 million, respectively, related to the premium costs of option-based products and did not record any gains or losses due to hedge ineffectiveness.

[Table of Contents](#)**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. EMPLOYEE BENEFIT PLANS****Defined Benefit Plans**

Edwards Lifesciences maintains defined benefit pension plans in Japan and certain European countries. Information regarding the Company's defined benefit pension plans is as follows (in millions):

	Years Ended December 31,	
	2010	2009
Change in projected benefit obligation:		
Beginning of year	\$ 60.1	\$ 61.9
Service cost	4.7	5.6
Interest cost	1.9	1.8
Participant contributions	1.4	1.2
Actuarial loss (gain)	6.0	(10.1)
Benefits paid	(0.2)	(3.4)
Currency exchange rate changes and other	4.8	3.1
End of year	\$ 78.7	\$ 60.1

Change in fair value of plan assets:

Beginning of year	\$ 34.4	\$ 29.4
Actual return on plan assets	1.1	0.9
Employer contributions	5.3	4.2
Participant contributions	1.4	1.2
Benefits paid		(3.3)
Currency exchange rate changes and other	3.1	2.0
End of year	\$ 45.3	\$ 34.4

Funded Status

Projected benefit obligation	\$ (78.7)	\$ (60.1)
Plan assets at fair value	45.3	34.4
Funded status, (under funded)	\$ (33.4)	\$ (25.7)

Net amounts recognized on the consolidated balance sheet:

Other long-term liabilities	\$ 33.4	\$ 25.7
-----------------------------	---------	---------

Accumulated other comprehensive loss, net

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

of tax:

Net actuarial loss	\$ (14.7)	\$ (7.8)
Net prior service benefit	3.2	3.2
Net transition obligation	(0.2)	(0.2)
Deferred income tax benefit	3.1	1.9
Total	\$ (8.6)	\$ (2.9)

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was \$70.0 million and \$54.2 million as of December 31, 2010 and 2009, respectively. The projected benefit obligation ("PBO") and ABO were in excess of plan assets for all pension plans as of December 31, 2010 and 2009.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. EMPLOYEE BENEFIT PLANS (Continued)**

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

	Years Ended December 31,		
	2010	2009	2008
Service cost, net	\$ 4.7	\$ 5.6	\$ 4.1
Interest cost	1.9	1.8	1.4
Expected return on plan assets	(1.2)	(0.9)	(0.9)
Amortization of actuarial loss	0.4	0.9	0.3
Amortization of prior service credit	(0.3)	(0.3)	(0.3)
Amortization of transition obligation			0.1
Net periodic pension benefits cost	\$ 5.5	\$ 7.1	\$ 4.7

The net actuarial loss and prior service credit that will be amortized from "Accumulated Other Comprehensive Loss" into net periodic benefits cost in 2011 are expected to be \$0.6 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:

	December 31,	
	2010	2009
Discount rate	2.7%	3.2%
Rate of compensation increase	3.1%	3.2%
Social securities increase	1.8%	1.8%
Pension increase	2.0%	2.0%

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

	Years ended December 31,		
	2010	2009	2008
Discount rate	3.2%	2.8%	3.3%
Expected return on plan assets	3.4%	2.8%	3.6%
Rate of compensation increase	3.2%	3.4%	3.3%
Social securities increase	1.8%	1.8%	1.8%
Pension increase	2.0%	2.0%	1.8%

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. EMPLOYEE BENEFIT PLANS (Continued)***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, 2010, by asset category, are as follows:

Equity securities	10.6%
Debt securities	8.6%
Insurance contracts	80.8%
Total	100.0%

The fair values of the Company's defined benefit plan assets at December 31, 2010 and 2009, by asset category, are as follows (in millions):

December 31, 2010	Level 1	Level 2	Level 3	Total
Asset Category				
Cash	\$ 0.3	\$	\$	\$ 0.3
Equity securities:				
United States equities	1.0			1.0
International equities	4.0			4.0
Debt securities:				
United States government bonds	0.4			0.4
International government bonds	3.1			3.1
Insurance contracts			36.5	36.5
	\$ 8.8	\$	\$ 36.5	\$ 45.3
December 31, 2009				
Asset Category				
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)****10. 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 years ended December 31, 2010 and 2009 (in millions):

	Insurance Contracts
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
Actual return on plan assets:	
Relating to assets still held at December 31, 2010	1.0
Relating to assets sold during 2010	
Purchases, sales and settlements	5.7
Currency exchange rate impact	2.6
Balance at December 31, 2010	\$ 36.5

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, 2010, are expected to be paid (in millions):

2011	\$ 3.6
2012	3.9
2013	4.0
2014	4.0
2015	4.1
2016-2020	29.9

As of December 31, 2010, expected employer contributions for fiscal 2011 are \$5.7 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 \$8.9 million, \$8.1 million and \$7.0 million in 2010, 2009 and 2008, respectively.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. EMPLOYEE BENEFIT PLANS (Continued)

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 \$6.2 million and \$4.4 million at December 31, 2010 and 2009, respectively.

In 2001, the Company adopted a nonqualified option plan ("Executive Option Plan") for the benefit of the executive officers and other key employees. The Executive Option Plan permitted participants to receive options to purchase shares of mutual funds or common stock of the Company in lieu of all or a portion of their compensation (base salary and bonus) earned prior to January 1, 2005. The Company discontinued option grants under the Executive Option Plan and has adopted the Executive Deferred Compensation Plan to provide officers and other key employees the opportunity to defer compensation earned after December 31, 2004 to future dates specified by the participant with a return based on investment alternatives selected by the participant. The amount accrued under this plan was \$13.1 million and \$12.0 million at December 31, 2010 and 2009, respectively.

11. COMMON STOCK

Stockholder Rights Plan

The Company had 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. On March 31, 2010, the Stockholder Rights Plan expired pursuant to its terms.

Treasury Stock

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. In February 2010, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$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.

In May 2010, the Company used 20.4 million treasury shares, in addition to newly issued shares, to effect a two-for-one stock split of its outstanding shares of common stock. See Note 2 for further information.

During 2010, 2009 and 2008, the Company repurchased, on a post-split basis, 4.1 million, 3.0 million and 11.6 million shares, respectively, at an aggregate cost of \$200.0 million, \$95.5 million and \$306.5 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 that

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. COMMON STOCK (Continued)

date. Options to purchase shares of the Company's common stock granted under the Program generally vest over predetermined periods of between three to four years and expire seven years after the date of grant. Restricted stock units of the Company's common stock granted under the Program generally vest over predetermined periods ranging from three to five years after the date of grant. On May 13, 2010, 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 3.0 million shares from 41.4 million shares to 44.4 million shares. No more than 3.0 million shares reserved for issuance may be granted in the form of restricted stock or restricted stock units.

The Company also maintains the Nonemployee Directors Stock Incentive Compensation Program (the "Nonemployee Directors Program"). Under the Nonemployee Directors Program, each nonemployee director may receive annually up to 20,000 stock options or 8,000 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 equal to a fair market value on grant date of \$0.2 million, not to exceed 10,000 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 120,000 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. On February 11, 2010, the Nonemployee Directors Program was amended to increase the aggregate number of shares authorized for issuance by 0.2 million shares from 1.2 million shares to 1.4 million shares.

The Company has an employee stock purchase plan for United States employees and a plan 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 1.6 million shares from 4.3 million shares to 5.9 million 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. Expected volatility is estimated 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 7.5%.

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

	2010	2009	2008
Average risk-free interest rate	2.0%	1.9%	3.0%
Expected dividend yield	None	None	None
Expected volatility	26%	28%	23%
Expected life (years)	4.6	4.6	4.7
Fair value	\$ 13.08	\$ 8.60	\$ 7.18

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

ESPP

	2010	2009	2008
Average risk-free interest rate	0.3%	0.4%	2.1%
Expected dividend yield	None	None	None
Expected volatility	28%	36%	26%
Expected life (years)	0.6	0.6	0.6
Fair value	\$ 12.09	\$ 8.72	\$ 7.18

Stock option activity during the year ended December 31, 2010 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2009	14.4	\$ 21.47		
Options granted	1.7	51.51		
Options exercised	(4.6)	17.28		
Options forfeited	(0.3)	31.30		
Outstanding as of December 31, 2010	11.2	27.62	3.5 years	\$ 598.5
Exercisable as of December 31, 2010	7.7	22.34	2.6 years	451.5
Vested and expected to vest as of December 31, 2010	10.6	27.01	3.4 years	568.7

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. COMMON STOCK (Continued)**

The following table summarizes nonvested restricted stock units and activity during the year ended December 31, 2010 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
Nonvested as of December 31, 2009	1.8	\$ 26.82
Granted	0.3	51.22
Vested	(0.6)	23.68
Forfeited	(0.1)	28.19
Nonvested as of December 31, 2010	1.4	32.73

The intrinsic value of stock options exercised and vested restricted stock units during the years ended December 31, 2010, 2009 and 2008 were \$190.9 million, \$92.3 million and \$68.1 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, 2010, 2009 and 2008, the Company received cash from exercises of stock options of \$78.8 million, \$56.4 million and \$54.9 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$64.7 million, \$31.2 million and \$25.1 million, respectively. The total grant-date fair value of stock options vested during the year ended December 31, 2010, 2009 and 2008 were \$15.8 million, \$15.6 million and \$14.2 million, respectively.

As of December 31, 2010, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units and employee stock purchase subscriptions amounted to \$46.8 million, which will be amortized over the weighted-average remaining requisite service period of 29 months.

12. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

Presented below is a summary of activity for each component of "Accumulated Other Comprehensive Income (Loss)" for the years ended December 31, 2010, 2009 and 2008. Foreign currency translation

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) (Continued)**

adjustments are generally not adjusted for income taxes as they relate to indefinite investments in non-United States subsidiaries.

	Foreign Currency Translation Adjustments	Unrealized (Loss) Gain on Cash Flow Hedges	Unrealized Gain (Loss) on Investments in Unconsolidated Affiliates	Unrealized Pension Costs(a)	Total Accumulated Other Comprehensive Income (Loss)
(in millions)					
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 (expense) benefit		(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)
Pre-tax period change	(24.9)	(11.2)	4.5	(6.9)	(38.5)
Deferred income tax benefit (expense)		4.4	(1.3)	1.2	4.3
December 31, 2010	\$ (24.8)	\$ (10.9)	\$ 2.2	\$ (8.6)	\$ (42.1)

(a)

For the years ended December 31, 2010, 2009 and 2008, the change in unrealized pension costs consisted of the following (in millions):

	Pre-Tax Amount	Tax Benefit (Expense)	Net of Tax Amount
2010			
Prior service credit arising during period	\$ 0.3	\$	\$ 0.3
Amortization of prior service credit	(0.3)		(0.3)
Net prior service credit arising during period			
Net actuarial loss arising during period	(6.9)	1.2	(5.7)
Unrealized pension costs, net	\$ (6.9)	\$ 1.2	\$ (5.7)

2009			
Prior service credit arising during period	\$ 0.3	\$	\$ 0.3
Amortization of prior service credit	(0.3)		(0.3)
Net prior service credit arising during period			

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Net actuarial gain arising during period	10.2	(1.2)	9.0
--	------	-------	-----

Unrealized pension costs, net	\$ 10.2	\$ (1.2)	\$ 9.0
-------------------------------	---------	----------	--------

2008

Prior service credit arising during period	\$	\$	\$
--	----	----	----

Amortization of prior service credit	(0.3)		(0.3)
--------------------------------------	-------	--	-------

Net prior service credit arising during period	(0.3)		(0.3)
--	-------	--	-------

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

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

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****13. OTHER (INCOME) EXPENSE, NET**

	Years Ended December 31,		
	2010	2009	2008
	(in millions)		
Earn-out payments	\$ (6.0)	\$ (2.1)	\$
Gain on investments in unconsolidated affiliates	(0.8)	(1.2)	(2.0)
Foreign exchange (gains) losses, net	(0.2)	(2.3)	7.2
Investment realized (gains) losses and impairment		(0.5)	3.0
Accounts receivable securitization costs			1.6
Other	(1.1)	2.4	(2.1)
	\$ (8.1)	\$ (3.7)	\$ 7.7

14. 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,		
	2010	2009	2008
United States	\$ 71.4	\$ 93.3	\$ (11.9)
International, including Puerto Rico	196.8	211.1	176.3
	\$ 268.2	\$ 304.4	\$ 164.4

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

	Years Ended December 31,		
	2010	2009	2008
Current			
United States:			
Federal	\$ 25.7	\$ 46.3	\$ 35.9
State and local	3.2	5.8	4.5
International, including Puerto Rico	27.2	25.2	16.0
Current income tax expense	56.1	77.3	56.4
Deferred			
United States:			
Federal	(1.8)	(7.7)	(21.3)
State and local	(0.2)	(1.0)	(2.7)
International, including Puerto Rico	(3.9)	6.7	3.1
Deferred income tax benefit	(5.9)	(2.0)	(20.9)
Total income tax provision	\$ 50.2	\$ 75.3	\$ 35.5

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****14. INCOME TAXES (Continued)**

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

	December 31,	
	2010	2009
Deferred tax assets		
Compensation and benefits	\$ 52.8	\$ 53.0
Net operating loss carryforwards	24.9	21.3
Inventories	21.5	18.0
Net tax credit carryforwards	19.6	12.6
Accrued liabilities	18.1	19.6
Investments in unconsolidated affiliates	4.8	3.2
Allowance for doubtful accounts	1.1	1.9
Charitable contribution carryforward	3.5	3.5
Cash flow hedges	5.8	1.3
Other	2.3	3.4
 Total deferred tax assets	 154.4	 137.8
Deferred tax liabilities		
Property, plant and equipment	(5.7)	(9.0)
Other intangible assets	(21.9)	(18.8)
Other	(0.1)	(0.3)
 Total deferred tax liabilities	 (27.7)	 (28.1)
 Valuation allowance	 (30.3)	 (24.3)
 Net deferred tax assets	 \$ 96.4	 \$ 85.4

During 2010, net deferred tax assets increased \$11.0 million. Of this amount, \$5.1 million was recorded through stockholders' equity and did not impact the overall tax provision.

The valuation allowance of \$30.3 million as of December 31, 2010 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 and for certain non-United States credit carryforwards.

Deferred income taxes have not been provided on the undistributed earnings of certain of the Company's foreign subsidiaries of approximately \$675.0 million as of December 31, 2010, 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. Additionally, in 2010, the Company entered into a plan to repatriate all of the accumulated earnings from certain of its European subsidiaries that were previously considered to be indefinitely reinvested by the Company. An estimated tax benefit of \$1.3 million resulted from the planned repatriation of the earnings. In addition, the Company does not expect future earnings in these European subsidiaries to be indefinitely reinvested and will record the tax impact prospectively.

[Table of Contents](#)

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. INCOME TAXES (Continued)

Net operating loss carryforwards, and the related carryforward periods, at December 31, 2010, 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	\$ 97.8	\$ 6.3	\$ (2.4)	\$ 3.9	2011-2020
Non-United States net operating losses	7.2	1.1	(0.7)	0.4	2011-2020
Non-United States net operating losses	61.1	18.0	(17.8)	0.2	Indefinite
Total	\$ 166.1	\$ 25.4	\$ (20.9)	\$ 4.5	

A valuation allowance of \$20.9 million has been provided for certain of the above carryforwards. This valuation allowance reduces the deferred tax asset related to net operating loss carryforwards of \$25.4 million to an amount that is more likely than not to be realized.

The United States state net operating loss carryforwards include \$11.9 million of losses attributable to windfall stock option deductions. A benefit of \$0.5 million will be recorded to *"Additional Paid-In Capital"* when realized as a reduction to income taxes payable.

The Company has approximately \$22.2 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 federal research credit was reinstated as of December 31, 2010. The effective income tax rate for the year ended December 31, 2010 has been calculated with the benefit for the federal research credit. The federal research credit favorably impacted the effective tax rate by 1.6 percentage points.

Approximately \$9.2 million of United States federal and state tax credit carryforwards are attributable to windfall stock option deductions and will be recorded as a benefit to *"Additional Paid-In Capital"* when realized as a reduction to income taxes payable.

The Company has received tax incentives in Puerto Rico, Dominican Republic, Singapore and Switzerland. 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.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****14. INCOME TAXES (Continued)**

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

	Years Ended December 31,		
	2010	2009	2008
Income tax expense at U.S. federal statutory rate	\$ 93.9	\$ 106.5	\$ 57.5
Foreign income tax at different rates	(28.1)	(27.9)	(26.4)
Release of reserve for uncertain tax positions for prior years	(13.4)	(3.8)	(6.2)
Tax credits, federal and state	(7.8)	(5.5)	(3.5)
State and local taxes, net of federal tax benefit	4.1	4.9	2.0
U.S. tax on foreign earnings, net of credits	2.2	1.0	0.6
Nondeductible stock-based compensation	1.9	1.4	0.9
Nondeductible goodwill			12.2
Other	(2.6)	(1.3)	(1.6)
Income tax provision	\$ 50.2	\$ 75.3	\$ 35.5

Reserve for Uncertain Tax Positions

As of December 31, 2010 and 2009, the liability for income taxes associated with uncertain tax positions was \$55.1 million and \$47.1 million, respectively. These liabilities could be reduced by \$4.7 million and \$3.2 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 \$50.4 million and \$44.0 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, penalties and foreign exchange, is as follows (in millions):

	December 31,		
	2010	2009	2008
Unrecognized tax benefits, January 1	\$ 47.1	\$ 35.9	\$ 36.4
Increase prior period tax positions	8.6	8.9	12.3
Decrease prior period tax positions	(20.1)	(9.4)	(19.9)
Current year tax positions	20.8	15.7	18.0
Settlements	(0.1)	(3.6)	(10.9)
Lapse of statute of limitations	(1.2)	(0.4)	
Unrecognized tax benefits, December 31	\$ 55.1	\$ 47.1	\$ 35.9

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2010, the Company had accrued \$1.7 million (net of \$1.4 million tax benefit) of interest related to uncertain tax positions, and 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. INCOME TAXES (Continued)

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 in income tax expense 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 the United States and between 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 is not expected to be material. At December 31, 2010, all material state, local and foreign income tax matters have been concluded for years through 2005. The Internal Revenue Service has completed its examination of the Company's 2007 and 2008 tax years for all matters except for certain transfer pricing issues. The Company has entered the appeals process for those transfer pricing issues.

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, 2010, deferred tax assets and corresponding valuation allowances of approximately \$3.1 million had accumulated related to investments. Of the total valuation allowance of \$3.1 million, \$0.4 million was recorded in 2010 through a charge to profit and loss. The remaining \$2.7 million had previously been recorded as of December 31, 2009 through charges to profit and loss.

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.

15. LEGAL PROCEEDINGS

In February 2008, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve") in the United States District Court for the District of Delaware alleging that its ReValving System infringes three of the Company's U.S. Andersen patents, later narrowed to one patent ("the '552 patent"). CoreValve was acquired by Medtronic, Inc. ("Medtronic") in April 2009. In April 2010, a federal jury found that patent to be valid and found that CoreValve willfully infringes it. The jury also awarded Edwards \$73.9 million in

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. LEGAL PROCEEDINGS (Continued)

damages. In February 2011, the District Court reaffirmed the jury decision and ruled that Edwards is entitled to recover additional damages due to CoreValve's continued infringing sales from the trial through the life of the patent, plus interest. In the same ruling, the court denied Edwards' motions for a permanent injunction and increased damages relating to CoreValve's willful infringement. CoreValve has appealed and Edwards plans to file a cross-appeal. A second lawsuit is pending in the same court against CoreValve and Medtronic alleging infringement of three U.S. Andersen patents. In September 2010, the United States Patent and Trademark Office granted Medtronic's third request to reexamine the validity of the claim of the '552 patent and later issued an initial Office Action rejecting the claim of the '552 patent. The reexamination process is ongoing.

Earlier, in May 2007, the Company filed a lawsuit against CoreValve alleging infringement of the Company's European Andersen patent. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. In October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. 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 the patent to be 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 is valid but not infringed by CoreValve. In May 2010, a United Kingdom Appeals Court affirmed the lower court. In January 2010, the German Courts also determined that the Andersen patent is valid. In December 2010, these lawsuits were resolved pursuant to a confidential settlement between the parties.

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 were invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Courts 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. In June 2010, a United Kingdom Appeals Court affirmed. In April 2010, the German Courts also determined that the Cook patent is invalid.

In March and September 2010, the Company received grand jury subpoenas for documents from the United States Attorney's Office in the Central District of California in connection with an investigation by the FDA. The subpoenas to the Company seek records relating to the Vigilance I Monitor model with software release 5.3 that was the subject of a voluntary field recall by the Company in June 2006. The Company is cooperating fully with the investigation.

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. LEGAL PROCEEDINGS (Continued)

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.

16. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease.

The Company's geographic segments are reported based on the financial information provided to the Chief Operating Decision Maker (the Chief Executive Officer). Individual members of the Executive Leadership Team report to the Chief Operating Decision Maker and are responsible for the geographic regions of the Company. The Company evaluates the performance of its geographic 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)****16. SEGMENT INFORMATION (Continued)**

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

	Years Ended December 31,		
	2010	2009	2008
Segment Net Sales			
United States	\$ 567.6	\$ 556.1	\$ 540.3
Europe	460.1	392.3	362.8
Japan	217.7	181.7	167.4
Rest of World	167.2	150.8	130.8
 Total segment net sales	 \$ 1,412.6	 \$ 1,280.9	 \$ 1,201.3
Segment Pre-tax Income			
United States	\$ 311.0	\$ 303.8	\$ 283.9
Europe	178.9	133.3	114.8
Japan	101.2	84.6	75.2
Rest of World	49.5	44.3	34.0
 Total segment pre-tax income	 \$ 640.6	 \$ 566.0	 \$ 507.9

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,		
	2010	2009	2008
Net Sales Reconciliation			
Segment net sales	\$ 1,412.6	\$ 1,280.9	\$ 1,201.3
Foreign currency	34.4	40.5	36.4
 Consolidated net sales	 \$ 1,447.0	 \$ 1,321.4	 \$ 1,237.7
Pre-tax Income Reconciliation			
Segment pre-tax income	\$ 640.6	\$ 566.0	\$ 507.9
Unallocated amounts:			
Corporate items	(366.0)	(346.0)	(307.5)
Special (charges) gains, net	(22.7)	63.8	(25.1)
Interest expense, net	(1.5)	(1.1)	(1.1)
Foreign currency	17.8	21.7	(9.8)
 Consolidated pre-tax income	 \$ 268.2	 \$ 304.4	 \$ 164.4

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. 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,		
	2010	2009	2008
	(in millions)		
Net Sales by Geographic Area			
United States	\$ 567.6	\$ 556.1	\$ 543.6
International	879.4	765.3	694.1
	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7

Net Sales by Major Product Area			
Heart Valve Therapy	\$ 838.3	\$ 714.9	\$ 607.4
Critical Care	454.1	452.5	451.8
Cardiac Surgery Systems	100.2	92.8	89.2
Vascular	54.4	61.2	89.3
	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7

Long-lived Tangible Assets by Geographic Area			
United States	\$ 180.5	\$ 163.0	\$ 156.7
International	102.3	102.0	86.6
	\$ 282.8	\$ 265.0	\$ 243.3

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. 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)					
2010					
Net sales	\$ 340.5	\$ 365.2	\$ 348.9	\$ 392.4	\$ 1,447.0
Gross profit	241.9	264.8	253.1	278.9	1,038.7
Net income(a)	47.7	57.5	48.0	64.8	218.0
Earnings per common share(a):					
Basic	0.42	0.51	0.42	0.57	1.92
Diluted	0.40	0.48	0.40	0.54	1.83
Market price:					
High	\$ 50.99	\$ 56.44	\$ 69.29	\$ 85.47	\$ 85.47
Low	42.31	46.58	53.10	63.23	42.31
2009					
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(b)	60.5	47.5	73.5	47.6	229.1
Earnings per common share(b):					
Basic	0.54	0.42	0.65	0.42	2.04
Diluted	0.52	0.41	0.63	0.40	1.95
Market price:					
High	\$ 31.75	\$ 34.12	\$ 35.22	\$ 44.13	\$ 44.13
Low	26.43	27.91	30.45	33.83	26.43

(a)

The second quarter of 2010 includes an \$8.3 million charge for the impairment of intangible assets and clinical trial costs associated with the discontinued *MONARC* transcatheter mitral valve program.

The third quarter of 2010 includes a \$3.9 million charge for the impairment of certain investments in unconsolidated affiliates.

The fourth quarter of 2010 includes a \$7.2 million charge for realignment expenses related primarily to severance associated with a global workforce realignment and a \$3.3 million charge for the impairment of certain investments in unconsolidated affiliates.

(b)

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

[Table of Contents](#)**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****17. QUARTERLY FINANCIAL RESULTS AND MARKET FOR THE COMPANY'S STOCK (UNAUDITED) (Continued)**

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.

18. VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions		Deductions From Reserves	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
(in millions)					
Year ended December 31, 2010					
Allowance for doubtful accounts(a)	\$ 12.4	\$ 3.3	\$	\$ (4.1)	\$ 11.6
Inventory reserves(b)	10.9	7.1		(6.8)	11.2
Tax valuation allowance(c)	24.3	1.9	5.5	(1.4)	30.3
Year ended December 31, 2009					
Allowance for doubtful accounts(a)	\$ 9.9	\$ 3.6	\$	\$ (1.1)	\$ 12.4
Inventory reserves(b)	9.1	7.2		(5.4)	10.9
Tax valuation allowance(c)	22.7	1.0	4.3	(3.7)	24.3
Year ended December 31, 2008					
Allowance for doubtful accounts(a)	\$ 7.5	\$ 3.6	\$	\$ (1.2)	\$ 9.9
Inventory reserves(b)	9.6	4.3		(4.8)	9.1
Tax valuation allowance(c)	21.1	5.4	2.2	(6.0)	22.7

(a) The deductions related to allowances for doubtful accounts 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 and credit 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, 2010.

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, 2010. The effectiveness of the Company's internal control over financial reporting as of December 31, 2010 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 2010 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 2011 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, 2010). 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 (business practice standards) is posted on the Company's website, which is found at 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Edwards Lifesciences Corporation (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
3.2	Amended and Restated Bylaws of Edwards Lifesciences Corporation, 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)
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))
*10.1	Form of Employment Agreement (incorporated by reference to Exhibit 10.8 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003, under the Securities Exchange Act of 1934)
*10.2	Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem dated 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	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)
*10.7	Edwards Lifesciences Corporation Executive Deferred Compensation Plan (as amended and restated effective January 1, 2009)
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))

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Exhibit No.	Description
*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 February 11, 2010 and amended further on March 23, 2010) (incorporated by reference to Appendix A to Edwards Lifesciences' Definitive Proxy Statement filed March 31, 2010, under the Securities Exchange Act of 1934)
*10.13	Nonemployee Directors Stock Incentive Program (as amended and restated as of February 11, 2010 and amended further on March 23, 2010) (incorporated by reference to Appendix B to Edwards Lifesciences' Definitive Proxy Statement filed March 31, 2010, 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) (incorporated by reference to Exhibit 10.14 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2009, under the Securities Exchange Act of 1934)
*10.15	2001 Employee Stock Purchase Plan for International Employees (as amended and restated November 10, 2009) (incorporated by reference to Exhibit 10.15 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2009, under the Securities Exchange Act of 1934)
*10.16	Edwards Lifesciences Corporation 2010 Edwards Incentive Plan (incorporated by reference to Appendix C in Edwards Lifesciences' Definitive Proxy Statement filed March 31, 2010, 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 original Change-in-Control Severance Agreement and form of subsequent amendments thereto
*10.19	Edwards Lifesciences Corporation Form of current Change-in-Control Severance Agreement
21.1	Subsidiaries of Edwards Lifesciences Corporation
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101**	The following financial statements from Edwards Lifesciences' Annual Report on Form 10-K for the year ended December 31, 2010, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) and (v) Notes to Consolidated Financial Statements.

*
Represents management contract or compensatory plan

**
XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities and Exchange Act of 1933, is deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

SIGNATURES

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

EDWARDS LIFESCIENCES CORPORATION

February 28, 2011

By: /s/ MICHAEL A. MUSSALLEM

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

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

Signature	Title	Date
<u>/s/ MICHAEL A. MUSSALLEM</u> Michael A. Mussallem	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 28, 2011
<u>/s/ THOMAS M. ABATE</u> Thomas M. Abate	Corporate Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 28, 2011
<u>/s/ MIKE R. BOWLIN</u> Mike R. Bowlin	Director	February 28, 2011
<u>/s/ JOHN T. CARDIS</u> John T. Cardis	Director	February 28, 2011
<u>/s/ ROBERT A. INGRAM</u> Robert A. Ingram	Director	February 28, 2011

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Signature	Title	Date
/s/ WILLIAM J. LINK, PH.D.	Director	February 28, 2011
William J. Link, Ph.D. /s/ BARBARA J. MCNEIL, M.D., PH.D.	Director	February 28, 2011
Barbara J. McNeil, M.D., Ph.D. /s/ DAVID E.I. PYOTT	Director	February 28, 2011
David E.I. Pyott /s/ WESLEY W. VON SCHACK	Director	February 28, 2011
Wesley W. von Schack		