

Edwards Lifesciences Corp
Form 10-K
February 27, 2012

Use these links to rapidly review the document

[EDWARDS LIFESCIENCES CORPORATION Form 10-K Annual Report 2011 Table of Contents](#)
[Item 8. Financial Statements and Supplementary Data](#)

[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2011

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

Name of each exchange on which registered:
New York Stock Exchange

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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

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

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

Indicate by check mark 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, 2011 (the last trading day of the registrant's most recently completed second quarter): \$9,923,942,894 based on a closing price of \$87.18 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, 2012, was 114,980,530.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2012 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2011) are incorporated by reference into Part III, as indicated herein.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report 2011
Table of Contents

PART I

| | | |
|-----------------|----------------------------------|-----------|
| <u>Item 1.</u> | <u>Business</u> | <u>1</u> |
| <u>Item 1A.</u> | <u>Risk Factors</u> | <u>11</u> |
| <u>Item 1B.</u> | <u>Unresolved Staff Comments</u> | <u>21</u> |
| <u>Item 2.</u> | <u>Properties</u> | <u>21</u> |
| <u>Item 3.</u> | <u>Legal Proceedings</u> | <u>21</u> |
| <u>Item 4.</u> | <u>Mine Safety Disclosures</u> | <u>22</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>23</u> |
| <u>Item 6.</u> | <u>Selected Financial Data</u> | <u>23</u> |
| <u>Item 7.</u> | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | <u>24</u> |
| <u>Item 7A.</u> | <u>Quantitative and Qualitative Disclosures About Market Risk</u> | <u>41</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>93</u> |
| <u>Item 9A.</u> | <u>Controls and Procedures</u> | <u>93</u> |
| <u>Item 9B.</u> | <u>Other Information</u> | <u>94</u> |

PART III

| | | |
|-----------------|---|-----------|
| <u>Item 10.</u> | <u>Directors, Executive Officers and Corporate Governance</u> | <u>95</u> |
| <u>Item 11.</u> | <u>Executive Compensation</u> | <u>95</u> |
| <u>Item 12.</u> | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | <u>95</u> |
| <u>Item 13.</u> | <u>Certain Relationships and Related Transactions, and Director Independence</u> | <u>95</u> |
| <u>Item 14.</u> | <u>Principal Accounting Fees and Services</u> | <u>95</u> |

PART IV

| | | |
|-----------------|--|-----------|
| <u>Item 15.</u> | <u>Exhibits, Financial Statement Schedules</u> | <u>96</u> |
| | <u>Signatures</u> | <u>98</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 experiences 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 the science of heart valves and hemodynamic monitoring. Driven by a passion to help patients, the Company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring that enable them to save and enhance lives.

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 or less invasive therapies.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease or critically ill patients 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. With their proven durability and performance, *PERIMOUNT* valves are the most widely prescribed tissue heart valves in the world. 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 its surgical tissue heart valve product line with the recent introduction of the *PERIMOUNT Magna Ease* valve and the next generation *Carpentier-Edwards Physio II* mitral valve repair ring. Sales of the Company's surgical heart valve products represented approximately 40%, 44% and 46% of the Company's net sales in 2011, 2010 and 2009, respectively.

Edwards Lifesciences has leveraged the knowledge and experience from its surgical 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. In late 2011, the *Edwards SAPIEN* valve with the *RetroFlex 3* delivery system was approved for use in certain inoperable patients in the United States. 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, and is currently in clinical study in the United States and Japan. Sales of the Company's

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

transcatheter heart valves represented approximately 20%, 14% and 9% of the Company's net sales in 2011, 2010 and 2009, 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. The Company's *VolumeView* sensor-catheter set measures a critically ill patient's volumetric hemodynamic parameters, while the *EVI000* touch-screen clinical monitoring platform displays a patient's physiologic status and integrates many of the Company's sensors and catheters into one intuitive system. During 2011, the availability of the *EVI000* platform was expanded to include the United States. Edwards Lifesciences is also 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 hemodynamic monitoring devices represented approximately 29% of the Company's net sales in 2011 and 2010, and 30% of the Company's net sales in 2009.

Together with a third party, the Company is developing automated glucose monitoring technologies for intensive care hospital settings. Glycemic control has been advocated in many medical society guidelines as an important therapy for improving clinical outcomes.

Cardiac Surgery Systems

Cardiac surgeons and their patients increasingly are seeking less invasive approaches to aortic or mitral valve surgery, which offer a number of benefits, including smaller incisions, less blood loss, quick recoveries and less scarring. Edwards Lifesciences' Cardiac Surgery Systems product line includes the *ThruPort* minimal incision valve surgery ("MIVS") platform that enables surgeons to perform intricate procedures through small incisions and tailor procedures based on their preferred surgical approach. The *ThruPort* systems portfolio includes soft tissue retractors, aortic occlusion devices, venting, coronary sinus catheters and reusable instrumentation. To support the adoption of MIVS techniques, the Company offers comprehensive team training, onsite clinical operating room support and extensive educational platforms. Edwards Lifesciences is also a global leader in protection cannulae, which are used during cardiac surgery in venous drainage, aortic perfusion, venting and cardioplegia delivery.

Vascular

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

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

Table of Contents

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 a variety of companies in specific product categories including ICU Medical, Inc., 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. To help broaden awareness of the Company's products and technologies, Edwards Lifesciences conducts educational symposia and provides training to its customers.

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 2011.

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.

United States. In the United States, Edwards Lifesciences sells substantially all of its products through its direct sales force. In 2011, 36% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

International. In 2011, 64% of Edwards Lifesciences' reported sales were derived internationally through its direct sales force and independent distributors. Of the total international sales, 54% were in

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Europe, 26% were in Japan, and 20% were in Rest of World. Edwards Lifesciences sells its products in approximately 100 countries, and its major international markets include Australia, Belgium, Canada, China, 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 are designed to render tissue biologically safe from all known infectious agents and viruses, and exceed the worldwide standard for sterile medical products. See "*Risk Factors*" contained herein.

Quality Assurance

Edwards Lifesciences is committed to providing quality products to its customers. To meet this commitment, the Company has implemented modern quality systems and concepts throughout the organization. The quality system starts with the initial product specification and continues through the design of the product, component specification processes, and the manufacturing, sales and servicing of the product. The quality system is intended to incorporate quality into products and utilizes continuous improvement concepts throughout the product lifecycle.

Table of Contents

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 requirements 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 critical care monitoring, and is dedicated to developing novel technologies to better enable clinicians to treat patients who suffer from the disease.

The Company invested \$246.3 million in research and development in 2011, \$204.4 million in 2010, and \$175.5 million in 2009 (14.7%, 14.1% and 13.3% of net sales, respectively). A significant portion of the Company's research and development investment has been applied to extend and defend its leadership position in transcatheter heart valve replacement technologies, surgical tissue heart valves, heart valve repair therapies, and hemodynamic monitoring products. 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 a repositionable, self-expanding transcatheter heart valve system, the *Edwards CENTERA* valve, in addition to its next generation balloon-expandable valve, the *Edwards SAPIEN 3*. Surgical heart valve therapy development programs include the *EDWARDS 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.

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 surgical heart valve therapy products.

Edwards Lifesciences' research and development activities are conducted primarily in facilities located in the United States and Israel. The Company's experienced research and development staff is focused on product design and development, quality, clinical research and regulatory compliance. To pursue primary research efforts, Edwards Lifesciences has developed alliances with several leading research institutions and universities, and also works with leading clinicians around the world in conducting scientific studies on the Company's existing and developing products. These studies include clinical trials, which provide data for use in regulatory submissions, and post-market approval studies involving applications of Edwards Lifesciences' products.

Table of Contents

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

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.

United States Regulation. 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. 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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.

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 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.

International Regulation. Internationally, the regulation of medical devices is complex. In Europe, the Company's products are subject to extensive regulatory requirements. The regulatory regime in the European Union for medical devices became mandatory in June 1998. It requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained and used in accordance with their intended purpose. National laws conforming to the European Union's legislation regulate the Company's products under the medical devices regulatory system. Although the more variable national requirements under which medical devices were formerly regulated have been substantially replaced by the European Union Medical Devices Directive, individual nations can still impose unique requirements that may require supplemental submissions. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE Mark. Manufacturers' quality systems for products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In Japan, pre-market approval and clinical studies are required as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent "Good Clinical Practices" standard. Approval time frames from the Japanese Ministry of Health, Labour and Welfare vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation into Japan of medical devices is subject to the "Good Import Practices" regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

In many of the other foreign countries in which the Company markets its products, the Company may be subject to regulations affecting, among other things:

product standards and specifications;

packaging requirements;

labeling requirements;

quality system requirements;

import restrictions;

tariffs;

duties; and

tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In some regions, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require the Company's products to be qualified before they can be marketed and considered eligible for reimbursement.

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 ("CMS") 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. CMS may also review whether and/or under what circumstances a procedure or technology is reimbursable. 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.

Table of Contents

Hospital reimbursement in the United States for transcatheter aortic valve replacement ("TAVR") procedures is currently aligned with surgical aortic valve replacement codes. In September 2011, CMS initiated a national coverage analysis for TAVR, which was expected to lead to a national coverage determination ("NCD"). In February 2012, CMS issued a draft NCD, and a final NCD is expected by mid-year 2012. The Company believes a well-written NCD that ensures adequate patient access would be positive for patients and physicians. The Company cannot predict the outcome of this process, and a negative determination, such as one that restricts the use of its products, could have an adverse effect on the Company's business, results of operations and financial condition.

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. These larger customers, due to their enhanced purchasing power, may attempt to increase the pressure on product pricing.

Health Care Reform. 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 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. Because many parts of the 2010 healthcare law remain subject to implementation, the long-term impact on the Company is uncertain. 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 \$6.1 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. 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, 2011, Edwards Lifesciences had approximately 7,800 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.

Table of Contents

Item 1A. Risk Factors

Our business and assets are subject to varying degrees of risk and uncertainty. 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. In addition, forward-looking statements within the meaning of the federal securities laws that are contained in this Annual Report on Form 10-K or in our other filings or statements may be subject to the risks described below as well as other risks and uncertainties. Please read the cautionary notice regarding forward-looking statements in Item 7 below.

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 or more susceptible to competition and our revenue and operating results would suffer. Even if we are able to develop new or improved 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. We devote significant financial and other resources to our research and development activities; however, the research and development process is prolonged and entails considerable uncertainty. Accordingly, products we are currently developing may not complete the development process or obtain the regulatory or other approvals required to market such products in a timely manner or at all.

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 or less competitive by changing customer preferences or the introduction by our competitors of products with newer technologies or features or other factors.

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.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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. 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.

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 manufacture 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, which include detailed record-keeping requirements, 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, from time to time, to recognize charges in connection with the write-down of our investments, asset or business dispositions, the termination of interest rate swap agreements, or for other reasons.

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

At December 31, 2011, we had \$21.8 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.1 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 involve 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, tax rates and factors affecting global economic stability, and the political environment regarding healthcare in general. While the economic environment has shown some signs of improvement, the strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown may negatively impact our business. 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 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 impairments in the carrying value of our investments, and could adversely affect our results of operations and financial condition. These and other conditions could also adversely affect our customers, and may impact their ability or decision to purchase our products or make payments on a timely basis.

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 increased taxes. Specifically, the law requires

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 our operating expenses. Because many parts of the 2010 healthcare law remain subject to implementation, the long-term impact on us is uncertain. 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. The Budget Control Act of 2011, which provided an increase to the United States debt limit, imposed significant cuts in federal spending over the next decade. Subsequently, as a result of the inability of a bipartisan Congressional committee to agree on further deficit reduction, certain additional mandatory spending cuts will take effect in the future unless Congress and the President agree otherwise. In addition, alternative deficit reduction proposals could adversely affect our results of operations, financial condition, and prospects if they were to include cuts to, or a restructuring of, entitlement programs such as Medicare and Medicaid programs.

We do business with foreign governments outside the United States. A number of these countries, including certain European countries, have experienced a deterioration in credit and economic conditions. These conditions have resulted in, and may continue to result in, a reduction in the number of procedures that use our products and an increase in the average length of time that it takes to collect accounts receivable outstanding in these countries. In addition, we have been and may continue to be impacted by declines in sovereign credit ratings or sovereign defaults in these countries.

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 anti-corruption laws in other jurisdictions. Our net sales originating outside of the United States, as a percentage of total net sales, were 64% in 2011. 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;

changes in foreign regulatory requirements;

changes in a specific country's or region's political or economic conditions, such as the current financial uncertainties in Europe and changing circumstances in emerging regions;

trade protection measures, quotas, embargoes, import or export licensing requirements and duties, tariffs or surcharges;

potentially negative impact of tax laws, including tax costs associated with the repatriation of cash;

difficulty in staffing and managing global operations;

cultural, exchange rate or other local factors affecting financial terms with customers;

local economic and financial conditions affecting the collectability of receivables, including receivables from sovereign entities;

an outbreak of any life threatening communicable disease;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

economic and political instability and local economic and political conditions;

differing labor regulations; and

differing protection of intellectual property.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 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 United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and similar laws in other jurisdictions contain prohibitions against bribery and other illegal payments or for the failure to have procedures in place that prevent such payments. Recent years have seen an increasing number of investigations and other enforcement activities under these laws. Although we have compliance programs in place with respect to these laws, no assurance can be given that a violation will not be found, and if found, the resulting penalties could adversely affect us and our business.

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

From time to time the stock market experiences extreme price and volume fluctuations. This volatility can have a significant effect on the market prices of securities for reasons unrelated to underlying performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results. In addition, the market price of our common stock could fluctuate substantially in response to any of the other risk factors set out above and below, as well as a number of other factors, including the performance of comparable companies or the medical device industry.

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

announcements of innovations, new products, strategic developments or business combinations by us or our competitors;

changes in financial estimates and recommendations of securities analysts;

demand for and clinical acceptance of products;

the timing and execution of customer contracts, particularly large contracts that would materially affect our operating results in a given quarter;

the timing of sales of products and of the introduction of new products;

the timing of marketing, training, and other expenses related to the introduction of new products;

the timing of regulatory approvals;

changes in foreign currency exchange rates;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

delays or problems in introducing new products;

changes in our pricing policies or the pricing policies of our competitors;

the timing of approvals of governmental reimbursement rates or changes in reimbursement rates for our products;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

increased expenses, whether related to sales and marketing, raw materials or supplies, product development or administration;

changes in the level of economic activity in the United States or other regions in which we do business;

costs related to acquisitions of technologies or businesses; and

our ability to expand our operations and the amount and timing of expansion-related expenditures.

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

The cardiovascular medical device industry is highly competitive. We compete with many companies, some of which have longer operating histories, better brand or name recognition, broader product lines and greater access to financial and other resources. Our customers consider many factors when selecting a product, including product reliability, breadth of product line, clinical outcomes, product availability, price, availability and rate of reimbursement, 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 organizations such as GPOs, independent delivery networks, and large single accounts such as the United States Veterans Administration, continue to consolidate purchasing decisions for many of our healthcare provider customers. 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. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenues and profit margins, business, financial condition and results of operations. We expect that market demand, governmental regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances, which may exert further downward pressure on the prices of our products and could adversely impact our 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 expect to 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 patent term extensions. The expiration of, or 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 have been and may in the future be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and such intellectual property litigation is typically costly and time-consuming. Adverse determinations in any such litigation could result in significant liabilities to third parties or injunctions, or could require us to seek licenses from third parties and, 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.

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, CE Mark, ISO or similar requirements, this could delay or interrupt product production or sales 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

Table of Contents

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 products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, clearances or approvals for 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 for commercial sale, the FDA may conduct periodic inspections to determine compliance with 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 we are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions against the Company and our officers and employees, including substantial fines, imprisonment and exclusion from participation in governmental healthcare programs.

Despite our implementation of robust compliance processes, we may be subject, from time to time, to inspections, investigations and other enforcement actions by governmental authorities. If we are found not to be in compliance with applicable laws or regulations, the applicable governmental authority can impose fines, delay, suspend, or revoke regulatory clearances or approvals, institute proceedings to detain or seize our products, issue a recall, impose marketing or operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and institute criminal prosecution. 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.

In recent years, the medical device industry has been subject to increased regulatory scrutiny, including by the FDA, numerous other federal, state and foreign governmental authorities, as well as members of Congress. This has included increased regulation, enforcement, inspections, and governmental investigations of the medical device industry and disclosure of financial relationships with health care professionals. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities, both foreign and domestic, may increase compliance costs, exposure to litigation and other adverse effects to our operations.

Table of Contents

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

The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures. Unfavorable or inconsistent clinical data from current or future clinical trials conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials are inherently uncertain and there can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product. Failure to successfully complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

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

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of BSE, commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility for the suspected BSE infectious agent. We have not experienced any significant adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

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

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

Hospital reimbursement in the United States for TAVR procedures is currently aligned with surgical aortic valve replacement codes. In September 2011, CMS initiated a national coverage analysis for TAVR, which was expected to lead to a NCD. In February 2012, CMS issued a draft NCD, and a final NCD is expected by mid-year 2012. We believe a well-written NCD that ensures adequate patient access would be positive for patients and physicians. We cannot predict the outcome of this process, and a negative determination, such as one that restricts the use of our products, could have an adverse effect on our business, results of operations and financial condition.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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, the 2010 United States healthcare law 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.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing approval from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific indications. We are prohibited by law from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training we provide to physicians and other healthcare professionals is limited to approved uses, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved.

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

Table of Contents**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 2019; the Puerto Rico property has one lease that expires in 2018 and one that expires in 2016; the Horw, Switzerland lease expires in 2013; 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, as well as its motion for increased damages relating to CoreValve's willful infringement. Both Edwards and CoreValve have appealed. 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 ("USPTO") granted Medtronic's third request to reexamine the validity of the claim of the '552 patent and in July 2011 confirmed the validity of that patent.

In June 2011, Medtronic filed a lawsuit in the U.S. District Court for the District of Minnesota alleging that certain surgical valve holders and a surgical embolic filter device infringe its patents. Edwards counterclaimed against Medtronic, alleging that the Medtronic Contour 3D annuloplasty ring infringes an Edwards ring patent. By the Order of a Magistrate Judge in January 2012, the lawsuit has been stayed pending the outcome of future reexamination findings by the USPTO.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

In June 2011, Medtronic also filed another lawsuit in the U.S. District Court for the Central District of California alleging that the *Edwards SAPIEN* transcatheter heart valve infringes a Medtronic patent. Edwards counterclaimed against Medtronic, alleging that the Medtronic CoreValve heart valve infringes Edwards' U.S. Letac-Cribier transcatheter heart valve patent. Edwards' counterclaim was subsequently transferred to the U.S. District Court for the District of Delaware.

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. The Company is not able to estimate the amount or range of any loss for legal contingencies for which there is no reserve or additional loss for matters already reserved. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***Market Price*

The principal market for Edwards Lifesciences' common stock is the New York Stock Exchange (the "NYSE"). The table below sets forth, for the calendar quarters indicated, the high and low sales prices of Edwards Lifesciences' common stock as reported by the NYSE.

| Calendar Quarter Ended: | 2011 | | 2010 | |
|-------------------------|----------|----------|----------|----------|
| | High | Low | High | Low |
| March 31 | \$ 91.82 | \$ 77.26 | \$ 50.99 | \$ 42.31 |
| June 30 | 90.38 | 80.44 | 56.44 | 46.58 |
| September 30 | 91.50 | 61.63 | 69.29 | 53.10 |
| December 31 | 77.40 | 61.59 | 85.47 | 63.23 |

Number of Stockholders

On January 31, 2012 there were 18,026 stockholders of record of Edwards Lifesciences' common stock.

Dividends

Edwards Lifesciences has never paid any cash dividends on its capital stock and has no current plans to pay any cash dividends. The current policy of Edwards Lifesciences is to retain any future earnings for use in the business of the Company.

Issuer Purchases of Equity Securities

| Calendar Month Ended | Total Number of Shares (or Units) Purchased | Average Price Paid per Share (or Unit) | Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)(a) |
|----------------------|---|--|---|---|
| October 31, 2011 | 295,000 | \$ 71.18 | 295,000 | \$ 616.9 |
| November 30, 2011 | 263,000 | 72.21 | 263,000 | 597.9 |
| December 31, 2011 | | | | 597.9 |
| Total | 558,000 | 71.66 | 558,000 | |

(a)

On February 11, 2010, the Company approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$500.0 million of the Company's common stock. On September 13, 2011, the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$500.0 million of the Company's common stock.

Item 6. Selected Financial Data

The following table sets forth selected financial information with respect to Edwards Lifesciences. The information set forth below should be read in conjunction with Edwards Lifesciences' "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Consolidated Financial Statements" found elsewhere in this Form 10-K. See Note 3 to the "Consolidated Financial Statements" and "Management's

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Discussion and Analysis of Financial Condition and Results of Operations" for discussions of the effect of certain transactions on Edwards Lifesciences' operations.

| | | As of or for the Years Ended December 31, | | | | |
|---------------------------------|--|---|------------|------------|------------|------------|
| | | 2011 | 2010 | 2009 | 2008 | 2007 |
| | | (in millions, except per share data) | | | | |
| OPERATING RESULTS | Net sales | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 | \$ 1,237.7 | \$ 1,091.1 |
| | Gross profit | 1,188.8 | 1,038.7 | 922.3 | 818.1 | 712.9 |
| | Net income(a) | 236.7 | 218.0 | 229.1 | 128.9 | 113.0 |
| BALANCE SHEET DATA | Total assets | \$ 1,980.5 | \$ 1,767.2 | \$ 1,615.5 | \$ 1,400.2 | \$ 1,349.8 |
| | Long-term debt and lease obligations(b) | 150.4 | | 90.3 | 175.5 | 61.7 |
| COMMON STOCK INFORMATION | Net income per common share(a): | | | | | |
| | Basic | \$ 2.07 | \$ 1.92 | \$ 2.04 | \$ 1.15 | \$ 0.99 |
| | Diluted | 1.98 | 1.83 | 1.95 | 1.10 | 0.93 |
| | 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 \$21.6 million, \$22.7 million and \$(63.8) million during 2011, 2010 and 2009, respectively.

(b) The Company's Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement") matured on September 29, 2011. At December 31, 2010, all amounts outstanding under the Credit Agreement were classified as short-term obligations as these obligations were due within one year. In July 2011, the Company entered into a new Four-Year Credit Agreement ("the Credit Facility"). All amounts outstanding under the new Credit Facility have been classified as long-term as the obligations are expected to be refinanced on a long-term basis under the Credit Facility.

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, 2011. Also discussed is Edwards Lifesciences' financial position as of December 31, 2011. 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 the science of heart valves and hemodynamic monitoring. Driven by a passion to help patients, the Company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring that enable them to save and enhance lives.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function. 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** portfolio comprises a diverse line of products for use during cardiac surgery including cannulae, embolic protection devices and other products used during cardiopulmonary bypass and minimally invasive surgical procedures. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts. 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 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. Because many parts of the 2010 healthcare law remain subject to implementation, the long-term impact on the Company is uncertain. 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.

Results of Operations

Net Sales by Major Regions

(dollars in millions)

| | Years Ended December 31, | | | Change | | Percent Change | |
|-----------------|--------------------------|------------|------------|----------|----------|----------------|-------|
| | 2011 | 2010 | 2009 | 2011 | 2010 | 2011 | 2010 |
| United States | \$ 605.6 | \$ 567.6 | \$ 556.1 | \$ 38.0 | \$ 11.5 | 6.7% | 2.1% |
| Europe | 574.0 | 457.0 | 404.6 | 117.0 | 52.4 | 25.6% | 13.0% |
| Japan | 283.7 | 247.8 | 214.1 | 35.9 | 33.7 | 14.5% | 15.7% |
| Rest of World | 215.3 | 174.6 | 146.6 | 40.7 | 28.0 | 23.3% | 19.1% |
| International | 1,073.0 | 879.4 | 765.3 | 193.6 | 114.1 | 22.0% | 14.9% |
| Total net sales | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 | \$ 231.6 | \$ 125.6 | 16.0% | 9.5% |

The \$38.0 million **increase in net sales in the United States in 2011** was due primarily to:

Heart Valve Therapy products, which increased net sales by \$28.5 million, driven primarily by (1) sales of the *Edwards SAPIEN* and *SAPIEN XT* transcatheter heart valves for clinical trials and commercial sales resulting from the United States launch in the fourth quarter of 2011, and (2) the

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

Carpentier-Edwards PERIMOUNT Magna Aortic Ease and *Magna Mitral Ease* valves (launched in the third quarter of 2010); and

Critical Care products, which increased net sales by \$11.2 million, driven primarily by the *FloTrac* minimally invasive monitoring system and pressure monitoring products.

The \$193.6 million **increase in international net sales in 2011** was due primarily to:

Heart Valve Therapy products, which increased net sales by \$104.3 million, driven primarily by commercial sales of the *Edwards SAPIEN XT* transcatheter heart valve and the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve;

Critical Care products, which increased net sales by \$20.9 million, driven primarily by pressure monitoring products and the *FloTrac* minimally invasive monitoring system; and

foreign currency exchange rate fluctuations, which increased net sales by \$58.0 million, due to the strengthening of various currencies against the United States dollar, primarily the Euro and the Japanese yen.

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 minimally invasive surgery ("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;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.*"

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 | |
|------------------------|--------------------------|-------------------|-------------------|-----------------|-----------------|----------------|-------------|
| | 2011 | 2010 | 2009 | 2011 | 2010 | 2011 | 2010 |
| Heart Valve Therapy | \$ 1,010.7 | \$ 838.3 | \$ 714.9 | \$ 172.4 | \$ 123.4 | 20.6% | 17.3% |
| Critical Care | 508.3 | 454.1 | 452.5 | 54.2 | 1.6 | 11.9% | 0.4% |
| Cardiac Surgery | | | | | | | |
| Systems | 107.5 | 100.2 | 92.8 | 7.3 | 7.4 | 7.3% | 8.0% |
| Vascular | 52.1 | 54.4 | 61.2 | (2.3) | (6.8) | (4.4)% | (11.1)% |
| Total net sales | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 | \$ 231.6 | \$ 125.6 | 16.0% | 9.5% |

Heart Valve Therapy

The \$172.4 million increase in net sales of Heart Valve Therapy products in 2011 was due primarily to:

transcatheter heart valves, which increased net sales by \$111.7 million primarily as a result of the *Edwards SAPIEN XT* transcatheter heart valve;

surgical heart valves, which increased net sales by \$21.1 million, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* valves; and

foreign currency exchange rate fluctuations, which increased net sales by \$33.6 million due primarily to the strengthening of the Euro and the Japanese yen against the United States dollar.

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.

In November 2011, the Company received approval from the FDA for the transfemoral delivery of the *Edwards SAPIEN* transcatheter heart valve for treatment of certain inoperable patients with severe symptomatic aortic stenosis. During the second quarter of 2011, the Company received regulatory approval and initiated its launch of the *Carpentier-Edwards Physio Tricuspid* annuloplasty ring in the United States and Europe. In Japan, the Company obtained approval of its *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve in July 2011, and introduced this product in the third quarter of 2011. In Europe, the Company received CE Mark in February 2012 for *EDWARDS INTUITY*, its minimally invasive aortic valve surgery system.

Critical Care

The \$54.2 million increase in net sales of Critical Care products in 2011 was due primarily to:

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

pressure monitoring products, which increased net sales by \$15.4 million;

advanced monitoring products, led by *FloTrac* systems, which increased net sales by \$13.1 million, and the *EV1000 Clinical Platform*, which increased net sales by \$5.7 million; and

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

foreign currency exchange rate fluctuations, which increased net sales by \$19.4 million, due primarily to the strengthening of the Euro and Japanese yen against the United States dollar.

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

advanced monitoring 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.

Cardiac Surgery Systems

The \$7.3 million increase in net sales of Cardiac Surgery Systems products in 2011 was due primarily to specialty cannula products, which increased net sales by \$3.1 million, and foreign currency exchange rate fluctuations, which increased net sales by \$2.8 million due primarily to the strengthening of the Euro and the Japanese yen against the United States dollar.

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.

During the fourth quarter of 2011, the Company obtained CE Mark and 510(k) clearance for its *IntraClude* aortic occlusion device. IntraClude is the first of several new products that the Company expects to introduce in its MIS portfolio.

Vascular

The \$2.3 million decrease in net sales of Vascular products in 2011 was due primarily to the Company's discontinued distribution of artificial implantable grafts during the first quarter of 2011.

The \$6.8 million decrease in net sales of Vascular products in 2010 was due primarily to the discontinuance of manufacturing in September 2009 of the divested *LifeStent* product line.

Gross Profit

| | Years Ended December 31, | | | Change | |
|---|--------------------------|-------|-------|------------|---------|
| | 2011 | 2010 | 2009 | 2011 | 2010 |
| Gross profit as a percentage of net sales | 70.8% | 71.8% | 69.8% | (1.0) pts. | 2.0pts. |

The 1.0 percentage point decrease in gross profit as a percentage of net sales in 2011 was driven by:

a 1.3 percentage point decrease due to the impact of foreign currency exchange rate fluctuations, including the outcome of foreign currency hedging contracts; and

investments in the expansion of the Company's international manufacturing capacity in preparation for its transcatheter heart valve launch in the United States;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

partially offset by:

a 0.5 percentage point increase in international markets due to a more profitable international product mix, primarily higher sales of transcatheter heart valves; and

a 0.3 percentage point increase in the United States due to a more profitable product mix, primarily higher sales of Heart Valve Therapy products, including transcatheter heart valves, and Critical Care products.

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.

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

(dollars in millions)

| | Years Ended December 31, | | | Change | |
|--|--------------------------|----------|----------|----------|-----------|
| | 2011 | 2010 | 2009 | 2011 | 2010 |
| SG&A expenses | \$ 642.4 | \$ 550.0 | \$ 508.8 | \$ 92.4 | \$ 41.2 |
| SG&A expenses as a percentage of net sales | 38.3% | 38.0% | 38.5% | 0.3 pts. | (0.5)pts. |

The \$92.4 million increase in SG&A expenses in 2011 was due primarily to higher sales and marketing expenses in the United States and Europe, mainly to support the transcatheter heart valve program, including the launch in the United States. Foreign currency rate fluctuations increased SG&A expenses by \$21.3 million due to the strengthening of various currencies against the United States dollar, primarily the Euro and the Japanese yen.

The \$41.2 million increase in SG&A expenses in 2010 was primarily in Europe due to (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.

Research and Development Expenses

(dollars in millions)

| | Years Ended December 31, | | | Change | |
|--|--------------------------|----------|----------|---------|---------|
| | 2011 | 2010 | 2009 | 2011 | 2010 |
| Research and development expenses | \$ 246.3 | \$ 204.4 | \$ 175.5 | \$ 41.9 | \$ 28.9 |
| Research and development expenses as a percentage of net sales | 14.7% | 14.1% | 13.3% | 0.6pts. | 0.8pts. |

The increase in research and development expenses in 2011 was due primarily to additional investments in clinical studies and new product development efforts in the transcatheter heart valve program.

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.

Table of Contents

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 The PARTNER Trial, a pivotal clinical trial of the Company's *Edwards SAPIEN* transcatheter heart valve technology. The PARTNER Trial, which has two study arms, evaluated 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 2010, positive one-year data from Cohort B was published and the Company completed the submission of its pre-market approval application ("PMA") to the FDA. In November 2011, the Company received approval from the FDA for the transfemoral delivery of the *Edwards SAPIEN* transcatheter heart valve for treatment of certain inoperable patients with severe symptomatic aortic stenosis. During the second quarter of 2011, the Company announced that one-year Cohort A trial data met all its primary endpoints and submitted its PMA for Cohort A to the FDA;

in the United States, the Company submitted an IDE for the *Edwards SAPIEN XT* transcatheter heart valve in October 2009. The PARTNER II trial will evaluate the *Edwards SAPIEN XT* with both the *NovaFlex* and *Ascendra2* delivery systems. In February 2011, the Company received conditional IDE approval from the FDA for the first pivotal cohort of the PARTNER II trial ("PARTNER II Cohort B"). PARTNER II Cohort B is a study of up to 600 inoperable patients with severe, symptomatic aortic stenosis using a 1:1 randomization of the *Edwards SAPIEN XT* with the *NovaFlex* transfemoral delivery system versus the *Edwards SAPIEN* with the *RetroFlex 3* delivery system. In January 2012, the Company completed enrollment in this cohort of inoperable patients. In November 2011, the Company received conditional IDE approval from the FDA for the second planned cohort ("PARTNER II Cohort A"). PARTNER II Cohort A is a non-inferiority study of up to 2,000 patients with severe, symptomatic aortic valve stenosis who have an elevated risk for traditional open-heart surgery. Patients will be evenly randomized to receive the *Edwards SAPIEN XT* valve or surgery. Those undergoing transcatheter valve replacement will be treated either transfemorally or transapically;

in Japan, the Company began enrolling patients in a clinical trial with its *SAPIEN XT* valve, called PREVAIL JAPAN, during 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

in Europe, the Company expects to commence clinical trials in 2012 for *SAPIEN 3*, its next generation balloon-expandable valve that includes a unique feature to further reduce paravalvular leak, and *CENTERA*, its repositionable, self-expanding valve featuring a motorized delivery system designed for stable deployment and single operator use.

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

(in millions)

| | Years Ended December 31, | | |
|--|--------------------------|---------|-----------|
| | 2011 | 2010 | 2009 |
| European receivables | \$ 12.8 | \$ | \$ |
| Realignment expenses | 5.5 | 7.2 | |
| Settlements and litigation | 3.3 | | 3.8 |
| MONARC program discontinuation | | 8.3 | |
| Investment impairment | | 7.2 | 1.6 |
| Gain on sale of assets, net | | | (86.9) |
| Charitable fund contribution | | | 15.0 |
| Adjustment to capitalized patent enforcement costs | | | 3.7 |
| Reserve reversal | | | (1.0) |
| Total special charges (gains), net | \$ 21.6 | \$ 22.7 | \$ (63.8) |

European Receivables

During 2011, the Company recorded a \$12.8 million charge to reflect the increased risk associated with its southern European receivables, primarily Greece.

Realignment Expenses

In December 2011, the Company recorded a \$5.5 million charge related primarily to severance expenses associated with a global workforce realignment impacting 49 employees. As of December 31, 2011, the Company's remaining severance obligations of \$5.2 million are expected to be substantially paid by March 2013.

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, 2011, the Company's remaining severance obligations of \$1.2 million are expected to be substantially paid by June 2012.

Settlements and Litigation

In December 2011, the Company recorded a \$3.3 million charge related to a litigation settlement.

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.

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.

Investment Impairment

During 2010, the Company recorded a \$7.2 million charge 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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 was 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. As of March 31, 2011, all earn-out payments had been earned. 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, satisfaction of a \$0.6 million 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. During 2009, under the terms of the sale agreement, the Company received \$42.0 million in milestone payments.

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.

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.

Reserve Reversal

During 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.

Interest Expense

Interest expense was \$3.1 million, \$2.4 million and \$2.7 million in 2011, 2010 and 2009, respectively. The \$0.7 million increase in interest expense for 2011 resulted primarily from a higher average debt balance as compared to the prior year. 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.

Interest Income

Interest income was \$3.4 million, \$0.9 million and \$1.6 million in 2011, 2010 and 2009, respectively. The \$2.5 million increase in interest income for 2011 resulted primarily from higher investment returns. The

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

\$0.7 million decrease in interest income for 2010 resulted primarily from lower average interest rates, partially offset by higher balances of cash and cash equivalents.

Other Income, net

(in millions)

| | Years Ended December 31, | | |
|---|--------------------------|-----------------|-----------------|
| | 2011 | 2010 | 2009 |
| Gains on investments in unconsolidated affiliates | \$ (5.4) | \$ (0.8) | \$ (1.2) |
| Foreign exchange losses (gains), net | 1.9 | (0.2) | (2.3) |
| Earn-out payments | (1.0) | (6.0) | (2.1) |
| Other | (0.3) | (1.1) | 1.9 |
| Total other income, net | \$ (4.8) | \$ (8.1) | \$ (3.7) |

The gains on investments in unconsolidated affiliates primarily represents the Company's net 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 and cost method investments.

The foreign exchange losses (gains) relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances. Foreign exchange fluctuations (primarily related to United States dollar payables in non-United States dollar functional currency locations) resulted in a net loss in 2011.

In September 2009, the Company sold its hemofiltration product line. In connection with the transaction, the Company was 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. As of March 31, 2011, all earn-out payments had been earned.

Provision for Income Taxes

The Company's effective income tax rates for 2011, 2010 and 2009 were impacted as follows (in millions):

| | Years Ended December 31, | | |
|--|--------------------------|----------------|----------------|
| | 2011 | 2010 | 2009 |
| Income tax expense at U.S. federal statutory rate | \$ 99.2 | \$ 93.9 | \$ 106.5 |
| Foreign income tax at different rates | (57.4) | (28.1) | (27.9) |
| U.S. tax on foreign earnings, net of credits | 11.8 | 2.2 | 1.0 |
| Tax credits, federal and state | (10.4) | (7.8) | (5.5) |
| State and local taxes, net of federal tax benefit | 4.6 | 4.1 | 4.9 |
| Release of reserve for uncertain tax positions for prior years | (4.1) | (13.4) | (3.8) |
| Nondeductible stock-based compensation | 1.9 | 1.9 | 1.4 |
| Other | 1.3 | (2.6) | (1.3) |
| Income tax provision | \$ 46.9 | \$ 50.2 | \$ 75.3 |

Reserve for Uncertain Tax Positions

As of December 31, 2011 and 2010, the liability for income taxes associated with uncertain tax positions was \$78.0 million and \$55.1 million, respectively. The Company estimates that these liabilities would be reduced by \$6.8 million and \$4.7 million, respectively, from offsetting tax benefits associated with the

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amounts of \$71.2 million and \$50.4 million, respectively, if not required, 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, | | |
|---|---------------------|----------------|----------------|
| | 2011 | 2010 | 2009 |
| Unrecognized tax benefits, January 1 | \$ 55.1 | \$ 47.1 | \$ 35.9 |
| Current year tax positions | 26.0 | 20.8 | 15.7 |
| Increase prior period tax positions | 5.9 | 8.6 | 8.9 |
| Decrease prior period tax positions | (5.5) | (20.1) | (9.4) |
| Settlements | (0.1) | (0.1) | (3.6) |
| Lapse of statutes of limitations | (3.4) | (1.2) | (0.4) |
| Unrecognized tax benefits, December 31 | \$ 78.0 | \$ 55.1 | \$ 47.1 |

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2011, the Company had accrued \$2.0 million (net of \$1.2 million tax benefit) of interest related to uncertain tax positions, and 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.

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 matters it believes are more likely than not to require settlement, 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.

At December 31, 2011, all material state, local and foreign income tax matters have been concluded for years through 2006. 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 appeals process for those transfer pricing issues is on-going. The Internal Revenue Service began its examination of the 2009 and 2010 tax years during the second quarter of 2011. As a result of on-going negotiations of an Advanced Pricing Agreement between Switzerland 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.

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

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, 2011, 2010 and 2009 by \$0.40, \$0.34 and \$0.31, 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, 2024 and 2015, respectively. The Company is engaged in negotiations with the Puerto Rican government for an

Table of Contents

extension of the Puerto Rico grant. The Singapore grant was extended during 2011 for an additional five years and will now terminate in 2024.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, short-term investments (bank time deposits with original maturities over three months but less than one year), 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 the Company on favorable terms, or at all.

As of December 31, 2011, cash and cash equivalents and short-term investments held outside the United States were approximately \$409.2 million, and have historically been used to fund international operations. The Company believes that cash held in the United States, in addition to amounts available under credit facilities and cash from operations, are sufficient to fund its United States operating requirements. The majority of cash and cash equivalents and short-term investments held outside the United States relate to undistributed earnings of certain of the Company's foreign subsidiaries which are considered to be indefinitely reinvested by the Company. Repatriations of cash and cash equivalents and short-term investments held outside the United States are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes. The potential tax liability related to any repatriation would be dependent on the facts and circumstances that would exist at the time such repatriation is made and the complexities of the tax laws of the United States and the respective foreign jurisdictions.

In July 2011, Edwards Lifesciences entered into a Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015. The proceeds of the Credit Facility were used to refinance the Company's previous Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"). The Credit Facility provides up to an aggregate of \$500.0 million in borrowings in multiple currencies. Borrowings generally bear interest at the London interbank offering rate ("LIBOR") plus 0.875%, subject to adjustment for leverage ratio changes as defined in the Credit Facility. The Company also pays a facility fee of 0.125% on the entire \$500.0 million facility whether or not drawn. The facility fee is also subject to adjustment for leverage ratio changes. As of December 31, 2011, borrowings of \$150.4 million were outstanding under the Credit Facility and have been classified as long-term obligations as these borrowings are expected to be refinanced pursuant to the Credit Facility. The Credit Facility is unsecured and contains various financial and other covenants, including a maximum leverage ratio and a minimum interest coverage ratio, as defined in the Credit Facility. As of December 31, 2011, the Company was in violation of certain covenants as a result of the Company's restatement of its 2011 interim consolidated condensed financial statements. See Note 20 to the *"Consolidated Financial Statements"* for further information. Subsequent to the balance sheet date, the Company obtained a waiver for this noncompliance from the lenders.

In March 2011, the Company acquired all the outstanding shares of Embrella Cardiovascular, Inc. ("Embrella"), including shares already owned by the Company, for an aggregate purchase price of \$42.6 million. The purchase price was funded with cash on hand and borrowings under the Credit Agreement. Embrella was a start-up medical device company developing a device for cerebral embolic protection during cardiovascular procedures.

In February 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. In September 2011, 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

reduce the total shares outstanding. During 2011, the Company repurchased 3.8 million shares at an aggregate cost of \$300.1 million and had remaining authority to purchase \$597.9 million of the Company's common stock. In addition to shares repurchased under the stock repurchase program, the Company also acquired shares to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees.

Net cash flows provided by **operating activities** of \$314.5 million for 2011 increased \$63.1 million from 2010 due primarily to higher operating profits and a \$49.1 million positive impact from decreased excess tax benefits from stock plans due to credit carryforwards and net operating losses in the United States in 2011 resulting in excess tax benefits that were not realized. This increase was partially offset by higher working capital needs (primarily inventory and accounts receivables).

Net cash flows provided by operating activities of \$251.4 million for 2010 increased \$86.1 million from 2009 due primarily 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 used in **investing activities** of \$412.8 million in 2011 consisted primarily of net purchases of short-term investments of \$293.4 million, a \$42.6 million payment associated with the acquisition of Embrella, and capital expenditures of \$82.9 million.

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

Net cash used in **financing activities** of \$135.2 million in 2011 consisted primarily of net purchases of treasury stock of \$303.4 million, partially offset by net proceeds from debt of \$104.4 million and proceeds from stock plans of \$59.5 million.

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.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2011 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 | \$ 150.4 | \$ | \$ | \$ 150.4 | \$ |
| Interest on debt | 10.4 | 2.9 | 5.8 | 1.7 | |
| Operating leases | 81.4 | 14.2 | 22.1 | 14.5 | 30.6 |
| Pension obligations(a) | 6.5 | 6.5 | | | |
| Contractual development obligations(b) | 5.2 | 0.5 | 4.4 | 0.3 | |
| Capital commitment obligations(c) | 2.3 | 0.6 | 1.7 | | |
| Total contractual cash obligations(d) | \$ 256.2 | \$ 24.7 | \$ 34.0 | \$ 166.9 | \$ 30.6 |

(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, 2011 was \$41.8 million. This

Table of Contents

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 11 to the "Consolidated Financial Statements" for further information.

- (b) Contractual development obligations consist primarily of cash that the Company is obligated to pay upon achievement of product development and other milestones.
- (c) Capital commitment obligations consist primarily of cash that the Company is obligated to pay to its limited partnership and limited liability corporation investees. These investees make equity investments in various development stage biopharmaceutical and medical device companies, and it is not certain if and/or when these payments will be made.
- (d) As of December 31, 2011, the liability for uncertain tax positions including interest was \$81.2 million. As a result of on-going negotiations of an Advanced Pricing Agreement between Switzerland 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 Accepted Accounting Principles in the United States ("GAAP"). In evaluating the Company's transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions.

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.

Table of Contents

The Company's sales terms are standard terms within the medical device industry, with title and risk of loss transferring upon delivery to the customer, limited right of return and no unusual provisions or conditions. When the Company recognizes revenue from the sale of its products, an estimate of various sales returns and allowances is recorded which reduces product sales and accounts receivable. These adjustments include estimates for rebates, returns and other sales allowances. These provisions are estimated and recorded at the time of sale based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. 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 credit 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 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. The credit and economic conditions within Italy, Spain, Portugal and Greece, among other members of the European Union, have deteriorated as these countries have experienced slower economic growth and higher debt levels. When evaluating its allowances for doubtful accounts related to these European receivables, the Company's analysis considers a number of factors including evidence of the customer's ability to comply with credit terms, economic conditions and procedures implemented by the Company to collect the historical receivables. 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 \$19.0 million and \$11.6 million at December 31, 2011 and 2010, 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 \$12.9 million and \$11.2 million at December 31, 2011 and 2010, respectively.

Table of Contents

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 2011, 2010 and 2009, the Company did not perform the second step of the impairment test as the fair value of each reporting unit exceeded its respective carrying value.

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

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are long-term 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;

Table of Contents

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 adjusting the amount, if necessary. The factors used to assess the likelihood of realization are both historical experience and 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 matters it believes are more likely than not to require settlement, 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 an Advanced Pricing Agreement, 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 approximately \$29.5 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 over an extended number of years, 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

Table of Contents

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 May 2011, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on fair value measurements to ensure that United States GAAP and International Financial Reporting Standards have common requirements for fair value measurement and disclosures, including a consistent definition of fair value. The guidance is effective for interim and annual periods beginning on or after December 15, 2011. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2011, the FASB issued an amendment to the accounting guidance on the presentation of comprehensive income. The guidance eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity, and instead requires that all nonowner changes in stockholders' equity be presented in either a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011.

In September 2011, the FASB issued an amendment to the accounting guidance on goodwill to permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In December 2011, the FASB issued an amendment to the accounting guidance on disclosures about offsetting assets and liabilities. The guidance requires an entity to disclose both gross and net information about financial instruments and derivative instruments that are eligible for offset in the consolidated balance sheet or subject to an enforceable master netting arrangement or similar agreement. The guidance is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. 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 foreign currency forward exchange contracts and option-based products to mitigate its exposure to fluctuations in foreign currency rates. 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 manages this risk through normal financing and investing activities and is not currently using derivative financial instruments to manage interest rate risk. 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.

Table of Contents

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, currency 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 contracts. 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, 2011 and 2010 were \$759.5 million and \$539.2 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 \$50.4 million and \$51.7 million, respectively. Any gains or losses on the fair value of derivative contracts would generally 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 10 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, 2011, all derivative financial instruments were with bank counterparties assigned investment grade ratings of "A" or better by national rating agencies. The Company further diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company has not experienced a counterparty default and does not anticipate any non-performance by the Company's current derivative counterparties.

Concentrations of Risk

The Company invests excess cash in bank time deposits and diversifies the concentration of cash amongst different financial institutions.

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 2011, the Company had no customers that represent greater than 10% of its total net sales or accounts receivable, net.

The Company continues to do business with foreign governments in certain European countries that have experienced a deterioration in credit and economic conditions. These conditions have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect accounts receivable outstanding in these countries. In addition, the Company may also be impacted by declines in sovereign credit ratings or sovereign defaults in these countries.

During 2011, the Company recorded a \$12.8 million charge to reflect the increased risk associated with its Southern European receivables, primarily Greece. A significant further decline in sovereign credit ratings or a debt default in Greece, or in other European countries, may decrease the likelihood that the Company

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

will collect these accounts receivable, which could result in a negative impact to the Company's operating results. As of December 31, 2011, the Company's accounts receivables, net of the allowance for doubtful accounts, from customers in Italy, Spain, Portugal and Greece were \$113.7 million.

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, 2011, Edwards Lifesciences had \$21.8 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.1 million on these investments in "*Accumulated Other Comprehensive Loss*," net of tax. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the decline in the investments' values may be considered other than temporary and impairment charges may be necessary.

Table of Contents

Item 8. Financial Statements and Supplementary Data

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2011**

| | |
|--|-----------|
| <u>Report of Independent Registered Public Accounting Firm</u> | <u>45</u> |
| Financial Statements: | |
| <u>Consolidated Balance Sheets at December 31, 2011 and 2010</u> | <u>47</u> |
| For the Years Ended December 31, 2011, 2010 and 2009: | |
| <u>Consolidated Statements of Operations</u> | <u>48</u> |
| <u>Consolidated Statements of Cash Flows</u> | <u>49</u> |
| <u>Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)</u> | <u>50</u> |
| <u>Notes to Consolidated Financial Statements</u> | <u>52</u> |
| Other schedules are not applicable and have not been submitted | |

Table of Contents

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Edwards Lifesciences Corporation and its subsidiaries at December 31, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) because a material weakness in internal control over financial reporting related to the effective controls not being in place with respect to communication to appropriate financial reporting personnel from other departments of changes to information impacting classification and disclosures in the financial statements existed as of that date. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2011 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements. 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 management's report referred to above. 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

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
Irvine, California
February 27, 2012

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

(in millions, except par value)

| | December 31, | |
|--|---------------------|-------------------|
| | 2011 | 2010 |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 171.2 | \$ 396.1 |
| Short-term investments (Notes 2 and 20) | 279.3 | |
| Accounts receivable, net (Note 4) | 283.8 | 277.3 |
| Other receivables | 36.9 | 25.2 |
| Inventories, net (Note 4) | 261.3 | 203.6 |
| Deferred income taxes | 43.9 | 32.3 |
| Prepaid expenses | 35.0 | 35.4 |
| Other current assets | 57.1 | 62.7 |
| Total current assets | 1,168.5 | 1,032.6 |
| Long-term accounts receivable, net (Note 4) | 24.6 | |
| Property, plant and equipment, net (Note 4) | 304.3 | 269.8 |
| Goodwill (Note 6) | 349.8 | 315.2 |
| Other intangible assets, net (Note 6) | 66.9 | 67.1 |
| Investments in unconsolidated affiliates (Note 7) | 21.8 | 25.0 |
| Deferred income taxes | 20.0 | 44.5 |
| Other assets | 24.6 | 13.0 |
| Total assets | \$ 1,980.5 | \$ 1,767.2 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 85.0 | \$ 47.6 |
| Accrued liabilities (Note 4) | 234.8 | 226.1 |
| Taxes payable | 15.4 | 22.3 |
| Short-term debt (Note 8) | | 41.8 |
| Total current liabilities | 335.2 | 337.8 |
| Long-term debt (Note 8) | 150.4 | |
| Other long-term liabilities | 157.0 | 121.2 |
| Commitments and contingencies (Notes 8 and 16) | | |
| Stockholders' equity (Note 11) | | |
| Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding | | |
| Common stock, \$1.00 par value, 350.0 shares authorized, 120.0 and 117.0 shares issued, and 114.1 and 115.0 shares outstanding, respectively | 120.0 | 117.0 |
| Additional paid-in capital | 300.5 | 211.3 |
| Retained earnings | 1,360.7 | 1,124.0 |
| Accumulated other comprehensive loss | (37.5) | (42.1) |
| Treasury stock, at cost, 5.9 and 2.0 shares, respectively | (405.8) | (102.0) |
| Total stockholders' equity | 1,337.9 | 1,308.2 |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

| | | |
|--|------------|------------|
| Total liabilities and stockholders' equity | \$ 1,980.5 | \$ 1,767.2 |
|--|------------|------------|

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

| | Years Ended December 31, | | |
|---|--------------------------|----------------|--------------|
| | 2011 | 2010 | 2009 |
| Net sales | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 |
| Cost of goods sold | 489.8 | 408.3 | 399.1 |
| Gross profit | 1,188.8 | 1,038.7 | 922.3 |
| Selling, general and administrative expenses | 642.4 | 550.0 | 508.8 |
| Research and development expenses | 246.3 | 204.4 | 175.5 |
| Special charges (gains), net (Note 3) | 21.6 | 22.7 | (63.8) |
| Interest expense | 3.1 | 2.4 | 2.7 |
| Interest income | (3.4) | (0.9) | (1.6) |
| Other income, net (Note 14) | (4.8) | (8.1) | (3.7) |
| | | | |
| Income before provision for income taxes | 283.6 | 268.2 | 304.4 |
| Provision for income taxes (Note 15) | 46.9 | 50.2 | 75.3 |
| | | | |
| Net income | \$ 236.7 | \$ 218.0 | \$ 229.1 |
| | | | |
| Share information (Note 2): | | | |
| Earnings per share: | | | |
| Basic | \$ 2.07 | \$ 1.92 | \$ 2.04 |
| Diluted | \$ 1.98 | \$ 1.83 | \$ 1.95 |
| Weighted-average number of common shares outstanding: | | | |
| Basic | 114.6 | 113.7 | 112.5 |
| Diluted | 119.4 | 119.2 | 117.5 |

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, | | |
|---|--------------------------|----------|----------|
| | 2011 | 2010 | 2009 |
| Cash flows from operating activities | | | |
| Net income | \$ 236.7 | \$ 218.0 | \$ 229.1 |
| Adjustments to reconcile net income to cash provided by operating activities: | | | |
| Depreciation and amortization | 58.0 | 56.5 | 58.7 |
| Stock-based compensation (Notes 2 and 12) | 35.0 | 29.3 | 28.3 |
| Excess tax benefit from stock plans (Notes 2 and 12) | (6.0) | (55.1) | (20.6) |
| Deferred income taxes | (0.6) | (11.2) | (10.0) |
| Special charges (gains), net (Note 3) | 21.2 | 22.7 | (75.5) |
| Loss (gain) on trading securities | 1.0 | (2.7) | (3.3) |
| Other | (1.1) | (5.0) | 0.3 |
| Changes in operating assets and liabilities: | | | |
| Accounts and other receivables, net | (53.7) | (34.2) | (58.9) |
| Accounts receivable securitization | | | 7.3 |
| Inventories, net | (57.0) | (36.8) | (13.1) |
| Accounts payable and accrued liabilities | 61.7 | 63.6 | 2.7 |
| Prepaid expenses and other current assets | 20.6 | (2.5) | 7.6 |
| Other | (1.3) | 8.8 | 12.7 |
| Net cash provided by operating activities | 314.5 | 251.4 | 165.3 |
| Cash flows from investing activities | | | |
| Capital expenditures | (82.9) | (61.8) | (64.0) |
| Purchases of short-term investments (Note 2 and 20) | (643.3) | | |
| Proceeds from short-term investments (Note 2 and 20) | 349.9 | | 11.4 |
| Acquisition (Note 5) | (42.6) | | |
| Proceeds from sale of assets (Note 3) | 3.9 | 6.6 | 97.9 |
| Investments in unconsolidated affiliates | (2.3) | (6.9) | (5.8) |
| Proceeds from unconsolidated affiliates | 9.1 | 2.2 | 2.3 |
| Investments in intangible assets | (7.7) | (1.2) | |
| Proceeds from (investments in) trading securities, net | 3.1 | (0.4) | (1.7) |
| Net cash (used in) provided by investing activities | (412.8) | (61.5) | 40.1 |
| Cash flows from financing activities | | | |
| Payments on debt | (421.7) | (302.8) | (213.9) |
| Proceeds from issuance of debt | 526.1 | 254.4 | 129.3 |
| Purchases of treasury stock | (303.4) | (200.0) | (95.5) |
| Proceeds from stock plans | 59.5 | 92.1 | 66.7 |
| Excess tax benefit from stock plans (Notes 2 and 12) | 6.0 | 55.1 | 20.6 |
| Other | (1.7) | (2.7) | 1.0 |
| Net cash used in financing activities | (135.2) | (103.9) | (91.8) |
| Effect of currency exchange rate changes on cash and cash equivalents | 8.6 | (24.0) | 1.8 |
| Net (decrease) increase in cash and cash equivalents | (224.9) | 62.0 | 115.4 |
| Cash and cash equivalents at beginning of year | 396.1 | 334.1 | 218.7 |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

| | | | |
|--|----------|----------|----------|
| Cash and cash equivalents at end of year | \$ 171.2 | \$ 396.1 | \$ 334.1 |
|--|----------|----------|----------|

Supplemental disclosures:

Cash paid during the year for:

| | | | |
|----------|--------|--------|--------|
| Interest | \$ 3.2 | \$ 2.4 | \$ 2.7 |
|----------|--------|--------|--------|

| | | | |
|--------------|---------|---------|---------|
| Income taxes | \$ 15.4 | \$ 14.7 | \$ 34.2 |
|--------------|---------|---------|---------|

Non-cash investing and financing transactions:

| | | | |
|---|----|----------|----|
| Distribution of treasury shares to effect stock split | \$ | \$ 970.3 | \$ |
|---|----|----------|----|

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 | Total | Comprehensive |
|--|--------------|--------------|----------------|---------|--------------------|----------|---------------------------------------|-------------------------|------------------|
| | Shares | Par Value | Shares | Amount | Paid-In Capital | Earnings | Income (Loss) | Stockholders' Equity | Income (Loss) |
| BALANCE AT DECEMBER 31, 2008 | 73.7 | 73.7 | 17.8 | (776.8) | 940.4 | 676.9 | (35.4) | 878.8 | |
| Comprehensive income | | | | | | | | | |
| Net income | | | | | | 229.1 | | 229.1 | \$ 229.1 |
| Other comprehensive income (loss), net of tax: | | | | | | | | | |
| Foreign currency translation adjustments | | | | | | | 17.3 | 17.3 | 17.3 |
| Unrealized loss on cash flow hedges | | | | | | | (3.5) | (3.5) | (3.5) |
| Unrealized gain on available-for-sale investments | | | | | | | 4.1 | 4.1 | 4.1 |
| Reclassification of net realized investment loss to earnings | | | | | | | 0.6 | 0.6 | 0.6 |
| Defined benefit pension plans net actuarial 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 |
| 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 actuarial loss | | | | | | | (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
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND
COMPREHENSIVE INCOME (LOSS) (Continued)

(in millions)

| | Common Stock | | Treasury Stock | | Additional Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity | Comprehensive Income (Loss) |
|--|--------------|--------------|----------------|------------|----------------------------------|----------------------|---|----------------------------------|-----------------------------------|
| | Shares | Par Value | Shares | Amount | | | | | |
| BALANCE AT DECEMBER 31, 2010 | 117.0 | \$ 117.0 | 2.0 | \$ (102.0) | \$ 211.3 | \$ 1,124.0 | \$ (42.1) | \$ 1,308.2 | |
| Comprehensive income | | | | | | | | | |
| Net income | | | | | | 236.7 | | 236.7 | \$ 236.7 |
| Other comprehensive income (loss), net of tax: | | | | | | | | | |
| Foreign currency translation adjustments | | | | | | | (5.2) | (5.2) | (5.2) |
| Unrealized gain on cash flow hedges | | | | | | | 16.8 | 16.8 | 16.8 |
| Unrealized loss on available-for-sale investments | | | | | | | (0.1) | (0.1) | (0.1) |
| Reclassification of net realized investment gain to earnings | | | | | | | (1.0) | (1.0) | (1.0) |
| Defined benefit pension plans net actuarial loss and other (Note 13) | | | | | | | (5.9) | (5.9) | (5.9) |
| Common stock issued under equity plans, including tax benefits and other | 3.0 | 3.0 | | | 54.2 | | | 57.2 | |
| Stock-based compensation expense | | | | | 35.0 | | | 35.0 | |
| Purchase of treasury stock | | | 3.9 | (303.8) | | | | (303.8) | |
| BALANCE AT DECEMBER 31, 2011 | 120.0 | \$ 120.0 | 5.9 | \$ (405.8) | \$ 300.5 | \$ 1,360.7 | \$ (37.5) | \$ 1,337.9 | \$ 241.3 |

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 the science of heart valves and hemodynamic monitoring. The Company develops innovative technologies in the areas of structural heart disease and critical care monitoring.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease or critically ill patients 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, until the first quarter of 2011, artificial implantable grafts. Edwards Lifesciences manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents until the sale of this product line in January 2008. The Company continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred to the buyer.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 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 credit 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 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.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company's premises to the customer's premises, are included in "*Selling, General and Administrative Expenses*." Handling costs, which are costs incurred to store, move and prepare products for shipment, are included in "*Cost of Goods Sold*." For the

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

years ended December 31, 2011, 2010 and 2009, shipping costs of \$51.0 million, \$43.6 million and \$41.4 million, respectively, were included in "Selling, General and Administrative Expenses."

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.

Short-term Investments

The Company invests in bank time deposits. Bank time deposits with original maturities of three months or less are classified as cash equivalents, and bank time deposits with original maturities over three months are classified as short-term investments. Investments in bank time deposits are classified as held-to-maturity, as management has both the intent and ability to hold these investments to maturity, and are reported at cost, which approximates fair value. Income relating to these bank time deposits is reported as interest income.

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 year ended December 31, 2009, the Company recognized realized gains of \$0.5 million, included in "Other Income, net."

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. The credit and economic conditions within Italy, Spain, Portugal and Greece, among other members of the European Union, have deteriorated as these countries have experienced slower economic growth and higher debt levels. When evaluating its allowances for doubtful accounts related to these European receivables, the Company's analysis considers a number of factors including evidence of the customer's ability to comply with credit terms, economic conditions and procedures implemented by the Company to collect the historical receivables. 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 \$19.0 million and \$11.6 million at December 31, 2011 and 2010, respectively.

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 \$12.9 million and \$11.2 million at December 31, 2011 and 2010, respectively.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company allocates to inventory general and administrative costs 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, 2011, 2010 and 2009, the Company allocated \$25.3 million, \$23.4 million and \$20.9 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2011 and 2010 were \$15.9 million and \$12.0 million, respectively.

Property, Plant and Equipment

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

Depreciation expense for property, plant and equipment was \$44.0 million, \$40.0 million and \$38.0 million for the years ended December 31, 2011, 2010 and 2009, respectively. Repairs and maintenance expense was \$18.1 million, \$16.1 million and \$15.4 million for the years ended December 31, 2011, 2010 and 2009, 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 2011, 2010 and 2009, 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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 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 adjusting the amount, if necessary. The factors used to assess the likelihood of realization are both historical experience and 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

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

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

Research and Development Costs

Research and development costs are charged to expense when incurred.

Earnings per Share

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Employee equity share options, nonvested shares and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of 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, | | |
|--|--------------------------|----------|----------|
| | 2011 | 2010 | 2009 |
| Basic: | | | |
| Net income | \$ 236.7 | \$ 218.0 | \$ 229.1 |
| Weighted-average shares outstanding | 114.6 | 113.7 | 112.5 |
| Basic earnings per share | \$ 2.07 | \$ 1.92 | \$ 2.04 |
| Diluted: | | | |
| Net income | \$ 236.7 | \$ 218.0 | \$ 229.1 |
| Weighted-average shares outstanding | 114.6 | 113.7 | 112.5 |
| Dilutive effect of stock plans | 4.8 | 5.5 | 5.0 |
| Dilutive weighted-average shares outstanding | 119.4 | 119.2 | 117.5 |
| Diluted earnings per share | \$ 1.98 | \$ 1.83 | \$ 1.95 |

Stock options and restricted stock units to purchase approximately 1.0 million, 0.9 million and 1.9 million shares for the years ended December 31, 2011, 2010 and 2009, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

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, 2011, 2010 and 2009 was as follows (in millions):

| | December 31, | | |
|--|---------------------|-------------|-------------|
| | 2011 | 2010 | 2009 |
| Cost of goods sold | \$ 4.0 | \$ 2.7 | \$ 2.4 |
| Selling, general and administrative expenses | 25.4 | 22.0 | 21.4 |
| Research and development expenses | 5.6 | 4.6 | 4.5 |
| Total stock-based compensation expense | \$ 35.0 | \$ 29.3 | \$ 28.3 |

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 currency forward exchange contracts and foreign currency option 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-party transactions. The Company uses foreign currency forward 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 exchange 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 Income" ("OCI") 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. Any hedge ineffectiveness (which represents the amount by which the changes in fair value of the derivative exceed the variability in the cash flows of the forecasted transaction) is recorded in

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

current period earnings. All cash flow hedges during 2011, 2010 and 2009 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 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 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 was effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

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 was effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2010, the FASB issued an amendment to the accounting guidance on business combinations to clarify the acquisition date that should be used for reporting pro forma financial information disclosures when comparative financial statements are presented. An entity is required to disclose pro forma revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The guidance also expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The guidance was effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)****New Accounting Standards Not Yet Adopted**

In May 2011, the FASB issued an amendment to the accounting guidance on fair value measurements to ensure that United States GAAP and International Financial Reporting Standards have common requirements for fair value measurement and disclosures, including a consistent definition of fair value. The guidance is effective for interim and annual periods beginning on or after December 15, 2011. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2011, the FASB issued an amendment to the accounting guidance on the presentation of comprehensive income. The guidance eliminates the option to present components of OCI as part of the statement of changes in stockholders' equity, and instead requires that all nonowner changes in stockholders' equity be presented in either a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011.

In September 2011, the FASB issued an amendment to the accounting guidance on goodwill to permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, with early adoption permitted. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In December 2011, the FASB issued an amendment to the accounting guidance on disclosures about offsetting assets and liabilities. The guidance requires an entity to disclose both gross and net information about financial instruments and derivative instruments that are eligible for offset in the consolidated balance sheet or subject to an enforceable master netting arrangement or similar agreement. The guidance is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. 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, | | |
|--|--------------------------|---------|-----------|
| | 2011 | 2010 | 2009 |
| | (in millions) | | |
| European receivables | \$ 12.8 | \$ | \$ |
| Realignment expenses | 5.5 | 7.2 | |
| Settlements and litigation | 3.3 | | 3.8 |
| MONARC program discontinuation | | 8.3 | |
| Investment impairment | | 7.2 | 1.6 |
| Gain on sale of assets, net | | | (86.9) |
| Charitable fund contribution | | | 15.0 |
| Adjustment to capitalized patent enforcement costs | | | 3.7 |
| Reserve reversal | | | (1.0) |
| Total special charges (gains), net | \$ 21.6 | \$ 22.7 | \$ (63.8) |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

European Receivables

During 2011, the Company recorded a \$12.8 million charge to reflect the increased risk associated with its southern European receivables, primarily Greece.

Realignment Expenses

In December 2011, the Company recorded a \$5.5 million charge related primarily to severance expenses associated with a global workforce realignment impacting 49 employees. As of December 31, 2011, the Company's remaining severance obligations of \$5.2 million are expected to be substantially paid by March 2013.

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, 2011, the Company's remaining severance obligations of \$1.2 million are expected to be substantially paid by June 2012.

Settlements and Litigation

In December 2011, the Company recorded a \$3.3 million charge related to a litigation settlement.

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.

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.

Investment Impairment

During 2010, the Company recorded a \$7.2 million charge 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 was 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. As of March 31, 2011, all earn-out payments had been earned. The sale resulted in a pre-tax gain of

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

\$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, satisfaction of a \$0.6 million 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. During 2009, under the terms of the sale agreement, the Company received \$42.0 million in milestone payments.

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.

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.

Reserve Reversal

During 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)

4. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

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

| | December 31, | |
|--|---------------|----------|
| | 2011 | 2010 |
| | (in millions) | |
| Accounts receivable, net(a) | | |
| Trade accounts receivable | \$ 298.6 | \$ 288.9 |
| Allowance for doubtful accounts | (14.8) | (11.6) |
| | \$ 283.8 | \$ 277.3 |
| Inventories, net | | |
| Raw materials | \$ 51.7 | \$ 38.2 |
| Work in process | 66.6 | 39.0 |
| Finished products | 143.0 | 126.4 |
| | \$ 261.3 | \$ 203.6 |
| Property, plant and equipment, net | | |
| Land | \$ 21.6 | \$ 21.6 |
| Buildings and leasehold improvements | 172.8 | 147.4 |
| Machinery and equipment | 248.8 | 224.8 |
| Equipment with customers | 37.9 | 39.2 |
| Software | 94.0 | 81.2 |
| Construction in progress | 29.0 | 28.2 |
| | 604.1 | 542.4 |
| Accumulated depreciation | (299.8) | (272.6) |
| | \$ 304.3 | \$ 269.8 |
| Long-term accounts receivable, net(a) | | |
| Long-term trade accounts receivable | \$ 28.8 | \$ |
| Allowance for doubtful accounts | (4.2) | |
| | \$ 24.6 | \$ |
| Accrued liabilities | | |
| Employee compensation and withholdings | \$ 106.6 | \$ 98.9 |
| Property, payroll and other taxes | 22.1 | 21.5 |
| Accrued rebates | 13.4 | 10.0 |
| Clinical trial accruals | 12.7 | 14.0 |
| Deferred income taxes | 8.6 | |
| Litigation reserves (Note 16) | 6.6 | 5.8 |
| Fair value of derivatives | | 14.7 |
| Other accrued liabilities | 64.8 | 61.2 |
| | \$ 234.8 | \$ 226.1 |

(a)

The credit and economic conditions within certain European countries have deteriorated. As of December 31, 2011, the Company's accounts receivables, net of the allowance for doubtful accounts, from customers in Italy, Spain, Portugal and Greece were \$113.7 million. Balances from customers located in these countries that are expected to be collected beyond one year have been discounted to present value based on the estimated collection date and have been classified as "*Long-term Accounts Receivable, net*" on the accompanying consolidated balance sheets.

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

On March 11, 2011, the Company acquired all the outstanding shares of Embrella Cardiovascular, Inc. ("Embrella"), including shares already owned by the Company, for an aggregate cash purchase price of \$42.6 million. In connection with the acquisition, the Company placed \$4.5 million of the purchase price into escrow to satisfy any claims for indemnification made in accordance with the terms of the merger agreement. Any remaining funds will be disbursed to Embrella's former shareholders one year after the acquisition date. Acquisition-related costs of \$0.9 million were recorded in "*Other Income, net.*"

Embrella was a start-up medical device company developing a device for cerebral embolic protection during cardiovascular procedures. The acquisition provides the Company with full rights to develop and commercialize Embrella's embolic deflector system, designed to be used as a protective shield during transcatheter heart valve procedures. The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was allocated to goodwill. The following table summarizes the fair value of the assets acquired (in millions):

| | |
|---|---------|
| Goodwill | \$ 34.6 |
| In-process research and development ("IPR&D") | 6.3 |
| Unpatented technology | 5.8 |
| Deferred income taxes | (4.1) |
| | \$ 42.6 |

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Europe segment and is partially deductible for tax purposes. IPR&D has been capitalized at fair value as an intangible asset with an indefinite life and will be assessed for impairment in subsequent periods. The fair value of the IPR&D was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Upon completion of development, the underlying research and development intangible asset will be amortized over its estimated useful life. Developed technology assets are being amortized over a weighted-average useful life of 8 years.

Prior to the acquisition date, the Company owned approximately 9% of the fully-diluted outstanding shares of Embrella. As a result of the acquisition, the Company remeasured at fair value its previously held ownership in Embrella, which had a carrying value of \$1.3 million at the date of acquisition, and, accordingly, recognized a gain of \$3.1 million. The gain was recorded in "*Other Income, net*" during the quarter ended March 31, 2011, and the cash received was recorded in "*Proceeds from Unconsolidated Affiliates*" on the consolidated statements of cash flows. The fair value of the Company's previous ownership interest in Embrella was determined using a market approach considering the amounts paid to acquire the remaining outstanding shares of Embrella.

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

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. during 2000. Goodwill and IPR&D resulting

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

from purchase business combinations are 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, by segment, during the years ended December 31, 2011 and 2010 were as follows:

| | United States | Europe | Total |
|-----------------------------------|------------------|---------|----------|
| | (in millions) | | |
| Goodwill at December 31, 2009 | \$ 304.2 | \$ 11.0 | \$ 315.2 |
| Accumulated impairment losses | | | |
| Goodwill at December 31, 2010 | 304.2 | 11.0 | 315.2 |
| Goodwill acquired during the year | 4.1 | 30.5 | 34.6 |
| Accumulated impairment losses | | | |
| Goodwill at December 31, 2011 | \$ 308.3 | \$ 41.5 | \$ 349.8 |

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

| | 2011 | | | December 31, 2010 | | |
|--|----------|-----------------------------|--------------------------|----------------------|-----------------------------|--------------------------|
| | Cost | Accumulated Amortization | Net Carrying Value | Cost | Accumulated Amortization | Net Carrying Value |
| Amortizable intangible assets | | | | | | |
| Patents | \$ 205.9 | \$ (158.4) | \$ 47.5 | \$ 203.0 | \$ (147.8) | \$ 55.2 |
| Unpatented technology | 39.3 | (31.3) | 8.0 | 35.0 | (29.6) | 5.4 |
| Other | 12.0 | (6.9) | 5.1 | 12.4 | (5.9) | 6.5 |
| | 257.2 | (196.6) | 60.6 | 250.4 | (183.3) | 67.1 |
| Unamortizable intangible assets | | | | | | |
| IPR&D | 6.3 | | 6.3 | | | |
| | \$ 263.5 | \$ (196.6) | \$ 66.9 | \$ 250.4 | \$ (183.3) | \$ 67.1 |

In March 2011, the Company completed its acquisition of Embrella (see Note 5). This transaction resulted in a net increase to goodwill of \$34.6 million, unpatented technology of \$5.8 million and IPR&D of \$6.3 million.

The net carrying value of patents includes \$16.1 million and \$16.0 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, 2011 and 2010, respectively (see Note 2).

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

Amortization expense related to other intangible assets for the years ended December 31, 2011, 2010 and 2009 was \$14.1 million, \$16.6 million and \$20.6 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

| | |
|------|---------|
| 2012 | \$ 13.1 |
| 2013 | 13.0 |
| 2014 | 11.3 |
| 2015 | 10.1 |
| 2016 | 10.0 |

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

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, | |
|---|----------------|----------------|
| | 2011 | 2010 |
| | (in millions) | |
| Available-for-sale investments | | |
| Cost | \$ 2.0 | \$ 4.1 |
| Unrealized gains | 1.3 | 3.6 |
| Fair value of available-for-sale investments | 3.3 | 7.7 |
| Equity method investments | | |
| Cost | 12.6 | 11.5 |
| Equity in losses | (0.7) | (1.5) |
| Carrying value of equity method investments | 11.9 | 10.0 |
| Cost method investments | | |
| Carrying value of cost method investments | 6.6 | 7.3 |
| Total investments in unconsolidated affiliates | \$ 21.8 | \$ 25.0 |

Proceeds from sales of available-for-sale investments for the years ended December 31, 2011, 2010 and 2009 were \$3.6 million, \$0.3 million and \$1.4 million, respectively, and the Company realized pre-tax gains of \$1.4 million, \$0.2 million and \$0.5 million, respectively. During 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. During 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

In July 2011, Edwards Lifesciences entered into a Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015. The proceeds of the Credit Facility were used to refinance the Company's previous Five-Year Unsecured Revolving Credit Agreement. The Credit Facility provides up to an aggregate of \$500.0 million in borrowings in multiple currencies. Borrowings generally bear interest at the London

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

interbank offering rate ("LIBOR") plus 0.875%, subject to adjustment for leverage ratio changes as defined in the Credit Facility. The Company also pays a facility fee of 0.125% on the entire \$500.0 million facility whether or not drawn. The facility fee is also subject to adjustment for leverage ratio changes. All amounts outstanding under the Credit Facility have been classified as long-term obligations as these borrowings are expected to be refinanced pursuant to the Credit Facility. Issuance costs of \$1.8 million are being amortized to interest expense over 4 years. As of December 31, 2011, borrowings of \$150.4 million were outstanding under the Credit Facility. The Credit Facility is unsecured and contains various financial and other covenants, including a maximum leverage ratio and a minimum interest coverage ratio, as defined in the Credit Facility. As of December 31, 2011, the Company was in violation of certain covenants as a result of the Company's restatement of its 2011 interim consolidated condensed financial statements (see Note 20). Subsequent to the balance sheet date, the Company obtained a waiver for this noncompliance from the lenders.

Included in long-term debt at December 31, 2011 were unsecured notes under the Credit Facility denominated in Japanese yen of ¥1.2 billion (US\$15.4 million). 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).

The weighted-average interest rate under all debt obligations was 1.8% and 2.7% at December 31, 2011 and 2010, 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 \$21.5 million, \$19.6 million and \$18.2 million for the years 2011, 2010 and 2009, respectively.

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2011 were as follows (in millions):

| | Operating Leases | Aggregate Debt Maturities |
|--|---------------------|---------------------------------|
| 2012 | \$ 14.2 | \$ |
| 2013 | 13.0 | |
| 2014 | 9.1 | |
| 2015 | 7.6 | 150.4 |
| 2016 | 6.9 | |
| Thereafter | 30.6 | |
| Total obligations and commitments | \$ 81.4 | \$ 150.4 |

9. 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, bank time 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.

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

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Company prioritizes the inputs used to determine fair values in one of the following three categories:

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

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

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

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

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2011 and 2010 (in millions):

| December 31, 2011 | Level 1 | Level 2 | Level 3 | Total |
|---|----------------|----------------|----------------|--------------|
| Assets | | | | |
| Investments held for executive deferred compensation plan | \$ 11.5 | \$ | \$ | \$ 11.5 |
| Investments in unconsolidated affiliates | 3.3 | | | 3.3 |
| Derivatives | | 12.7 | | 12.7 |
| | \$ 14.8 | \$ 12.7 | \$ | \$ 27.5 |
| Liabilities | | | | |
| Executive deferred compensation plan | \$ 9.9 | \$ | \$ | \$ 9.9 |
| | \$ 9.9 | \$ | \$ | \$ 9.9 |
| December 31, 2010 | | | | |
| 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 |
| Executive deferred compensation plan | 13.1 | | | 13.1 |
| | \$ 13.1 | \$ 14.7 | \$ | \$ 27.8 |

Executive Deferred Compensation Plan

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. FAIR VALUE MEASUREMENTS (Continued)

The fair values of these investments and the corresponding liabilities 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.

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 spot and foreign currency exchange rates discounted to present as appropriate. The fair value of options also takes into account forward implied volatility. The valuation procedures are based upon well 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, 2011, the Company acquired Embrella. This transaction resulted in an increase to "Goodwill" and "Other Intangible Assets" of \$34.6 million and \$12.1 million, respectively. See Note 5 for additional information. During the year ended December 31, 2011, the Company had no impairments related to assets subject to measurement at fair value on a nonrecurring basis. 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).

10. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

the respective dates. The Company does not enter into these arrangements for trading or speculation purposes.

| | December 31, | | | |
|---|--------------------|------------------------------------|--------------------|------------------------------------|
| | 2011 | | 2010 | |
| | Notional Amount | Fair Value Asset (Liability) | Notional Amount | Fair Value Asset (Liability) |
| | (in millions) | | | |
| Foreign currency forward exchange contracts | \$ 759.5 | \$ 12.7 | \$ 486.0 | \$ (12.5) |
| Foreign currency option contracts | | | 53.2 | (2.2) |

The fair value of derivative financial instruments was estimated by discounting expected cash flows using quoted market interest rates and foreign exchange rates as of December 31, 2011 and 2010. Considerable judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

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

| | Balance Sheet Location | Fair Value | |
|--|------------------------|----------------------|----------------------|
| | | December 31, 2011 | December 31, 2010 |
| Derivatives designated as hedging instruments | | | |
| <u>Assets</u> | | | |
| Foreign currency contracts | Prepaid expenses | \$ 12.7 | \$ |
| <u>Liabilities</u> | | | |
| Foreign currency contracts | Accrued liabilities | \$ | \$ 14.7 |

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

| | Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion) | | Location of Gain or (Loss) Reclassified from Accumulated OCI into Income | Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income | |
|---|--|----------|---|--|--------|
| | 2011 | 2010 | | 2011 | 2010 |
| Derivatives in cash flow hedging relationships | | | | | |
| Foreign currency contracts | \$ (1.6) | \$ (9.4) | Cost of goods sold | \$ (29.0) | \$ 1.8 |

| | Location of Gain or (Loss) Recognized in Income on Derivative | Amount of Gain or (Loss) Recognized in Income on Derivative | | |
|--|---|---|----------|----------|
| | | 2011 | 2010 | 2009 |
| Derivatives not designated as hedging instruments | | | | |
| Foreign currency contracts | Other income, net | \$ (6.0) | \$ (5.0) | \$ (2.7) |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

The Company expects that during 2012 it will reclassify to earnings a \$3.8 million loss currently recorded in "Accumulated Other Comprehensive Loss." For the years ended December 31, 2011, 2010 and 2009, the Company did not record any gains or losses due to hedge ineffectiveness. For the years ended December 31, 2010 and 2009, the Company expensed \$0.1 million and \$0.8 million, respectively, related to the premium costs of option-based products.

11. 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, | |
|--|-----------------------------|-----------|
| | 2011 | 2010 |
| Change in projected benefit obligation: | | |
| Beginning of year | \$ 78.7 | \$ 60.1 |
| Service cost | 6.6 | 4.7 |
| Interest cost | 2.2 | 1.9 |
| Participant contributions | 1.9 | 1.4 |
| Actuarial loss | 5.7 | 6.0 |
| Benefits paid | (2.3) | (0.2) |
| Currency exchange rate changes and other | 2.8 | 4.8 |
| End of year | \$ 95.6 | \$ 78.7 |
| Change in fair value of plan assets: | | |
| Beginning of year | \$ 45.3 | \$ 34.4 |
| Actual return on plan assets | 0.7 | 1.1 |
| Employer contributions | 6.3 | 5.3 |
| Participant contributions | 1.9 | 1.4 |
| Benefits paid | (2.1) | |
| Currency exchange rate changes and other | 1.7 | 3.1 |
| End of year | \$ 53.8 | \$ 45.3 |
| Funded Status | | |
| Projected benefit obligation | \$ (95.6) | \$ (78.7) |
| Plan assets at fair value | 53.8 | 45.3 |
| Funded status, (under funded) | \$ (41.8) | \$ (33.4) |
| Net amounts recognized on the consolidated balance sheet: | | |
| Other long-term liabilities | \$ 41.8 | \$ 33.4 |
| Accumulated other comprehensive loss, net of tax: | | |
| Net actuarial loss | \$ (21.1) | \$ (14.7) |
| Net prior service benefit | 2.9 | 3.2 |
| Net transition obligation | (0.1) | (0.2) |
| Deferred income tax benefit | 3.8 | 3.1 |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

| | | |
|-------|-----------|----------|
| Total | \$ (14.5) | \$ (8.6) |
|-------|-----------|----------|

71

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

The accumulated benefit obligation ("ABO") for all defined benefit pension plans was \$84.0 million and \$70.0 million as of December 31, 2011 and 2010, respectively. The projected benefit obligation ("PBO") and ABO were in excess of plan assets for all pension plans as of December 31, 2011 and 2010.

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

| | Years Ended December 31, | | |
|---------------------------------------|--------------------------|--------|--------|
| | 2011 | 2010 | 2009 |
| Service cost, net | \$ 6.6 | \$ 4.7 | \$ 5.6 |
| Interest cost | 2.2 | 1.9 | 1.8 |
| Expected return on plan assets | (1.4) | (1.2) | (0.9) |
| Amortization of actuarial loss | 0.6 | 0.4 | 0.9 |
| Amortization of prior service credit | (0.4) | (0.3) | (0.3) |
| Amortization of transition obligation | 0.1 | | |
| Net periodic pension benefits cost | \$ 7.7 | \$ 5.5 | \$ 7.1 |

The net actuarial loss and prior service credit that will be amortized from "*Accumulated Other Comprehensive Loss*" into net periodic benefits cost in 2012 are expected to be \$1.0 million and \$(0.3) million, respectively.

Expected long-term returns for each of the plans' strategic asset classes were developed through consultation with investment advisors. 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, | |
|-------------------------------|--------------|------|
| | 2011 | 2010 |
| Discount rate | 2.5% | 2.7% |
| Rate of compensation increase | 3.0% | 3.1% |
| Social securities increase | 1.8% | 1.8% |
| Pension increase | 2.0% | 2.0% |

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

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

| | Years ended December 31, | | |
|--------------------------------|--------------------------|------|------|
| | 2011 | 2010 | 2009 |
| Discount rate | 2.4% | 3.2% | 2.8% |
| Expected return on plan assets | 2.7% | 3.4% | 2.8% |
| Rate of compensation increase | 2.9% | 3.2% | 3.4% |
| Social securities increase | 1.8% | 1.8% | 1.8% |
| Pension increase | 2.0% | 2.0% | 2.0% |

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, 2011, by asset category, are as follows:

| | |
|---------------------|--------|
| Insurance contracts | 80.8% |
| Equity securities | 10.5% |
| Debt securities | 8.7% |
| Total | 100.0% |

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

The fair values of the Company's defined benefit plan assets at December 31, 2011 and 2010, by asset category, are as follows (in millions):

| December 31, 2011 | Level 1 | Level 2 | Level 3 | Total |
|--------------------------------|----------------|----------------|----------------|--------------|
| Asset Category | | | | |
| Cash | \$ 0.3 | \$ | \$ | \$ 0.3 |
| Equity securities: | | | | |
| United States equities | 1.4 | | | 1.4 |
| International equities | 4.4 | | | 4.4 |
| Debt securities: | | | | |
| United States government bonds | 0.4 | | | 0.4 |
| International government bonds | 3.8 | | | 3.8 |
| Insurance contracts | | | 43.5 | 43.5 |
| | \$ 10.3 | \$ | \$ 43.5 | \$ 53.8 |

| December 31, 2010 | | | | |
|--------------------------------|--------|----|---------|---------|
| 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 |

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

The following table summarizes the changes in fair value of the Company's defined benefit plan assets that have been classified as Level 3 for the years ended December 31, 2011 and 2010 (in millions):

| | Insurance Contracts |
|--|--------------------------------|
| 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 |
| Actual return on plan assets: | |
| Relating to assets still held at December 31, 2011 | 1.2 |
| Relating to assets sold during 2011 | |
| Purchases, sales and settlements | 4.6 |
| Currency exchange rate impact | 1.2 |
| Balance at December 31, 2011 | \$ 43.5 |

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, 2011, are expected to be paid (in millions):

| | |
|-----------|--------|
| 2012 | \$ 4.0 |
| 2013 | 4.8 |
| 2014 | 4.7 |
| 2015 | 4.8 |
| 2016 | 5.6 |
| 2017-2021 | 34.4 |

As of December 31, 2011, expected employer contributions for fiscal 2012 are \$6.5 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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. EMPLOYEE BENEFIT PLANS (Continued)

contribution calculated on eligible earnings for each employee. Matching contributions relating to Edwards Lifesciences employees were \$9.9 million, \$8.9 million and \$8.1 million in 2011, 2010 and 2009, respectively.

The Company has a nonqualified deferred compensation plan for a select group of employees that provides the opportunity to defer a specified percentage of their eligible cash compensation. Participants may elect to defer up to 25% of total eligible compensation. The Company's obligations under this plan are unfunded. The amount accrued under this plan was \$7.3 million and \$6.2 million at December 31, 2011 and 2010, respectively.

During 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 \$9.9 million and \$13.1 million at December 31, 2011 and 2010, respectively.

12. COMMON STOCK

Treasury Stock

In February 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. In September 2011, 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 addition to shares repurchased under the stock repurchase program, the Company also acquired shares to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees.

During 2011, 2010 and 2009, the Company repurchased 3.9 million, 4.1 million and 3.0 million shares, respectively, at an aggregate cost of \$303.4 million, \$200.0 million and \$95.5 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 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 12, 2011, an

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. COMMON STOCK (Continued)

amendment and restatement of the Program was approved by the Company's stockholders. Under the amended Program, the number of shares of common stock available for issuance under the Program was increased by 1.5 million shares from 44.4 million shares to 45.9 million shares. No more than 3.6 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 33¹/₃% per year over three years from the date of grant. Under the Nonemployee Directors Program, an aggregate of 1.4 million shares of the Company's common stock has been authorized for issuance.

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. The number of shares of common stock authorized for issuance under the ESPP was 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 7.6%.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****12. COMMON STOCK (Continued)**

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

Option Awards

| | 2011 | 2010 | 2009 |
|---------------------------------|----------|----------|---------|
| Average risk-free interest rate | 1.7% | 2.0% | 1.9% |
| Expected dividend yield | None | None | None |
| Expected volatility | 27% | 26% | 28% |
| Expected life (years) | 4.5 | 4.6 | 4.6 |
| Fair value | \$ 22.78 | \$ 13.08 | \$ 8.60 |

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

ESPP

| | 2011 | 2010 | 2009 |
|---------------------------------|----------|----------|---------|
| Average risk-free interest rate | 0.2% | 0.3% | 0.4% |
| Expected dividend yield | None | None | None |
| Expected volatility | 28% | 28% | 36% |
| Expected life (years) | 0.6 | 0.6 | 0.6 |
| Fair value | \$ 20.02 | \$ 12.09 | \$ 8.72 |

Stock option activity during the year ended December 31, 2011 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, 2010 | 11.2 | \$ 27.62 | | |
| Options granted | 1.1 | 88.55 | | |
| Options exercised | (2.3) | 18.54 | | |
| Options forfeited | | | | |
| Outstanding as of December 31, 2011 | 10.0 | 36.50 | 3.3 years | \$ 362.4 |
| Exercisable as of December 31, 2011 | 7.1 | 27.55 | 2.5 years | 308.6 |
| Vested and expected to vest as of December 31, 2011 | 9.5 | 35.44 | 3.2 years | 353.8 |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. COMMON STOCK (Continued)

The following table summarizes nonvested restricted stock units and activity during the year ended December 31, 2011 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, 2010 | 1.4 | \$ 32.73 |
| Granted | 0.2 | 86.99 |
| Vested | (0.4) | 26.62 |
| Forfeited | (0.1) | 37.51 |
| Nonvested as of December 31, 2011 | 1.1 | 44.30 |

The intrinsic value of stock options exercised and vested restricted stock units during the years ended December 31, 2011, 2010 and 2009 were \$180.7 million, \$190.9 million and \$92.3 million, respectively. The intrinsic value of stock options is calculated as the amount by which the market price of the Company's common stock exceeds the exercise price of the option. During the years ended December 31, 2011, 2010 and 2009, the Company received cash from exercises of stock options of \$42.4 million, \$78.8 million and \$56.4 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$60.7 million, \$64.7 million and \$31.2 million, respectively. The total grant-date fair value of stock options vested during the year ended December 31, 2011, 2010 and 2009 were \$16.9 million, \$15.8 million and \$15.6 million, respectively.

As of December 31, 2011, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units and employee stock purchase subscriptions amounted to \$55.9 million, which will be amortized over the weighted-average remaining requisite service period of 30 months.

13. ACCUMULATED OTHER COMPREHENSIVE LOSS

Presented below is a summary of activity for each component of "Accumulated Other Comprehensive Loss" for the years ended December 31, 2011, 2010 and 2009. Foreign currency translation adjustments are

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)

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, 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) |
| Pre-tax period change | (5.2) | 27.4 | (2.3) | (6.6) | 13.3 |
| Deferred income tax (expense) benefit | | (10.6) | 1.2 | 0.7 | (8.7) |
| December 31, 2011 | \$ (30.0) | \$ 5.9 | \$ 1.1 | \$ (14.5) | \$ (37.5) |

- (a) For the years ended December 31, 2011, 2010 and 2009, the change in unrealized pension costs consisted of the following (in millions):

| | Pre-Tax Amount | Tax Benefit (Expense) | Net of Tax Amount |
|--|-------------------|--------------------------|----------------------|
| 2011 | | | |
| Prior service credit arising during period | \$ 0.1 | \$ | \$ 0.1 |
| Amortization of prior service credit | (0.4) | 0.1 | (0.3) |
| Net prior service cost arising during period | (0.3) | 0.1 | (0.2) |
| Net transition asset amortized during period | 0.1 | | 0.1 |
| Net actuarial loss arising during period | (6.4) | 0.6 | (5.8) |
| Unrealized pension costs, net | \$ (6.6) | \$ 0.7 | \$ (5.9) |
| 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 | | | |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

| | | | |
|--|----------|--------|----------|
| Net actuarial loss arising during period | (6.9) | 1.2 | (5.7) |
| Unrealized pension costs, net | \$ (6.9) | \$ 1.2 | \$ (5.7) |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)

| | Pre-Tax Amount | Tax Benefit (Expense) | Net of Tax Amount |
|--|-------------------|--------------------------|----------------------|
| 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 | | | |
| Net actuarial gain arising during period | 10.2 | (1.2) | 9.0 |
| Unrealized pension costs, net | | | |
| | \$ 10.2 | \$ (1.2) | \$ 9.0 |

14. OTHER INCOME, NET

| | Years Ended December 31, | | |
|---|--------------------------|----------|----------|
| | 2011 | 2010 | 2009 |
| | (in millions) | | |
| Gains on investments in unconsolidated affiliates | \$ (5.4) | \$ (0.8) | \$ (1.2) |
| Foreign exchange losses (gains), net | 1.9 | (0.2) | (2.3) |
| Earn-out payments | (1.0) | (6.0) | (2.1) |
| Other | (0.3) | (1.1) | 1.9 |
| | \$ (4.8) | \$ (8.1) | \$ (3.7) |

15. INCOME TAXES

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

| | Years Ended December 31, | | |
|--------------------------------------|--------------------------|----------|----------|
| | 2011 | 2010 | 2009 |
| United States | \$ 23.6 | \$ 71.4 | \$ 93.3 |
| International, including Puerto Rico | 260.0 | 196.8 | 211.1 |
| | \$ 283.6 | \$ 268.2 | \$ 304.4 |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. INCOME TAXES (Continued)

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

| | Years Ended December 31, | | |
|--------------------------------------|--------------------------|----------------|----------------|
| | 2011 | 2010 | 2009 |
| Current | | | |
| United States: | | | |
| Federal | \$ 29.1 | \$ 25.7 | \$ 46.3 |
| State and local | 3.0 | 3.2 | 5.8 |
| International, including Puerto Rico | 25.0 | 27.2 | 25.2 |
| Current income tax expense | 57.1 | 56.1 | 77.3 |
| Deferred | | | |
| United States: | | | |
| Federal | (6.4) | (1.8) | (7.7) |
| State and local | 1.2 | (0.2) | (1.0) |
| International, including Puerto Rico | (5.0) | (3.9) | 6.7 |
| Deferred income tax benefit | (10.2) | (5.9) | (2.0) |
| Total income tax provision | \$ 46.9 | \$ 50.2 | \$ 75.3 |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. INCOME TAXES (Continued)

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

| | December 31, | |
|--|--------------|-------------|
| | 2011 | 2010 |
| Deferred tax assets | | |
| Compensation and benefits | \$ 51.0 | \$ 52.8 |
| Net operating loss carryforwards | 21.8 | 24.9 |
| Net tax credit carryforwards | 15.4 | 19.6 |
| Accrued liabilities | 11.8 | 18.1 |
| Benefits from uncertain tax positions | 10.3 | 4.5 |
| Investments in unconsolidated affiliates | 3.3 | 4.8 |
| Inventories | 1.8 | 1.9 |
| Cash flow hedges | | 5.8 |
| Charitable contribution carryforward | | 3.5 |
| Other | 2.4 | (1.1) |
| Total deferred tax assets | 117.8 | 134.8 |
| Deferred tax liabilities | | |
| Property, plant and equipment | (22.2) | (21.9) |
| Cash flow hedges | (4.8) | |
| Other intangible assets | (3.3) | (5.7) |
| Other | (0.3) | (0.1) |
| Total deferred tax liabilities | (30.6) | (27.7) |
| Valuation allowance | (32.4) | (30.3) |
| Net deferred tax assets | \$ 54.8 | \$ 76.8 |

During 2011, net deferred tax assets decreased \$22.0 million, including items that were recorded as a reduction to stockholders' equity and did not impact the Company's income tax provision.

The valuation allowance of \$32.4 million as of December 31, 2011 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.

Net operating loss carryforwards, and the related carryforward periods, at December 31, 2011, 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 | \$ 166.6 | \$ 10.9 | \$ (2.4) | \$ 8.5 | 2012-2021 |
| Non-United States net operating losses | 5.6 | 1.3 | (1.1) | 0.2 | 2012-2021 |
| Non-United States net operating losses | 61.3 | 18.2 | (18.0) | 0.2 | Indefinite |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

| | | | | | | | | |
|-------|----|-------|----|------|----|--------|----|-----|
| Total | \$ | 233.5 | \$ | 30.4 | \$ | (21.5) | \$ | 8.9 |
|-------|----|-------|----|------|----|--------|----|-----|

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. INCOME TAXES (Continued)

The Company has approximately \$29.5 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 United States state net operating loss carryforwards include \$128.9 million of losses attributable to windfall stock option deductions. A net benefit of \$5.5 million will be recorded to "*Additional Paid-In Capital*" when realized as a reduction to income taxes payable.

Approximately \$56.4 million of United States federal and state tax credit and charitable contribution 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.

Deferred income taxes have not been provided on the undistributed earnings of certain of the Company's foreign subsidiaries of approximately \$873.7 million as of December 31, 2011 since these amounts are intended to be indefinitely 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. In evaluating this assertion, the Company evaluates, among other factors, the profitability of its United States and foreign operations and the need for cash within and outside the United States, including cash requirements for capital improvement, acquisitions, market expansion and stock repurchase programs. Additionally, during 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. A tax benefit of \$1.3 million resulted from the planned repatriation of the earnings in 2010. The Company does not expect earnings in these European subsidiaries to be indefinitely reinvested and records the tax impact in net income currently.

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, 2011, 2010 and 2009 by \$0.40, \$0.34 and \$0.31, 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, 2024 and 2015, respectively. The Company is engaged in negotiations with the Puerto Rican government for an extension of the Puerto Rico grant. The Singapore grant was extended during 2011 for an additional five years and will now terminate in 2024.

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

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

| | Years Ended December 31, | | |
|---|--------------------------|----------------|----------------|
| | 2011 | 2010 | 2009 |
| Income tax expense at U.S. federal statutory rate | \$ 99.2 | \$ 93.9 | \$ 106.5 |
| Foreign income tax at different rates | (57.4) | (28.1) | (27.9) |
| U.S. tax on foreign earnings, net of credits | 11.8 | 2.2 | 1.0 |
| Tax credits, federal and state | (10.4) | (7.8) | (5.5) |
| State and local taxes, net of federal tax benefit | 4.6 | 4.1 | 4.9 |
| Release of reserve for uncertain tax positions related to prior years | (4.1) | (13.4) | (3.8) |
| Nondeductible stock-based compensation | 1.9 | 1.9 | 1.4 |
| Other | 1.3 | (2.6) | (1.3) |
| Income tax provision | \$ 46.9 | \$ 50.2 | \$ 75.3 |

Reserve for Uncertain Tax Positions

As of December 31, 2011 and 2010, the liability for income taxes associated with uncertain tax positions was \$78.0 million and \$55.1 million, respectively. The Company estimates that these liabilities would be reduced by \$6.8 million and \$4.7 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 \$71.2 million and \$50.4 million, respectively, if not required, 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, | | |
|---|----------------|----------------|----------------|
| | 2011 | 2010 | 2009 |
| Unrecognized tax benefits, January 1 | \$ 55.1 | \$ 47.1 | \$ 35.9 |
| Current year tax positions | 26.0 | 20.8 | 15.7 |
| Increase prior period tax positions | 5.9 | 8.6 | 8.9 |
| Decrease prior period tax positions | (5.5) | (20.1) | (9.4) |
| Settlements | (0.1) | (0.1) | (3.6) |
| Lapse of statute of limitations | (3.4) | (1.2) | (0.4) |
| Unrecognized tax benefits, December 31 | \$ 78.0 | \$ 55.1 | \$ 47.1 |

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2011, the Company had accrued \$2.0 million (net of \$1.2 million tax benefit) of interest related to uncertain tax positions, and 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.

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 matters it believes are more likely than not to require settlement, 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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. INCOME TAXES (Continued)

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.

At December 31, 2011, all material state, local and foreign income tax matters have been concluded for years through 2006. 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 appeals process for those transfer pricing issues is on-going. The Internal Revenue Service began its examination of the 2009 and 2010 tax years during the second quarter of 2011. As a result of on-going negotiations of an Advanced Pricing Agreement between Switzerland 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.

16. 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, as well as its motion for increased damages relating to CoreValve's willful infringement. Both Edwards and CoreValve have appealed. 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 ("USPTO") granted Medtronic's third request to reexamine the validity of the claim of the '552 patent and in July 2011 confirmed the validity of that patent.

In June 2011, Medtronic filed a lawsuit in the U.S. District Court for the District of Minnesota alleging that certain surgical valve holders and a surgical embolic filter device infringe its patents. Edwards counterclaimed against Medtronic, alleging that the Medtronic Contour 3D annuloplasty ring infringes an Edwards ring patent. By the Order of a Magistrate Judge in January 2012, the lawsuit has been stayed pending the outcome of future reexamination findings by the USPTO.

In June 2011, Medtronic also filed another lawsuit in the U.S. District Court for the Central District of California alleging that the *Edwards SAPIEN* transcatheter heart valve infringes a Medtronic patent. Edwards counterclaimed against Medtronic, alleging that the Medtronic CoreValve heart valve infringes Edwards' U.S. Letac-Cribrier transcatheter heart valve patent. Edwards' counterclaim was subsequently transferred to the U.S. District Court for the District of Delaware.

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 Food and Drug Administration. 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.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. LEGAL PROCEEDINGS (Continued)

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. The Company is not able to estimate the amount or range of any loss for legal contingencies for which there is no reserve or additional loss for matters already reserved. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

17. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in 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). 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. Net sales by geographic area are based on the location of the customer.

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, manufacturing variances, corporate headquarters costs, special gains and charges, stock-based compensation, foreign currency hedging activities, certain litigation costs and most of the Company's amortization expense. Although most of the Company's depreciation expense is included in segment pre-tax income, due to the Company's methodology for cost build-up, it is impractical to determine the amount of depreciation expense included in each segment, and therefore a portion is maintained at the corporate level. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****17. SEGMENT INFORMATION (Continued)**

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

| | Years Ended December 31, | | |
|-------------------------------|--------------------------|------------|------------|
| | 2011 | 2010 | 2009 |
| Segment Net Sales | | | |
| United States | \$ 605.6 | \$ 567.6 | \$ 556.1 |
| Europe | 549.4 | 460.1 | 392.3 |
| Japan | 226.8 | 217.7 | 181.7 |
| Rest of world | 200.8 | 167.2 | 150.8 |
| | | | |
| Total segment net sales | \$ 1,582.6 | \$ 1,412.6 | \$ 1,280.9 |
| | | | |
| Segment Pre-tax Income | | | |
| United States | \$ 314.9 | \$ 311.0 | \$ 303.8 |
| Europe | 237.9 | 178.9 | 133.3 |
| Japan | 107.6 | 101.2 | 84.6 |
| Rest of world | 60.3 | 49.5 | 44.3 |
| | | | |
| Total segment pre-tax income | \$ 720.7 | \$ 640.6 | \$ 566.0 |

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, | | |
|--------------------------------------|--------------------------|------------|------------|
| | 2011 | 2010 | 2009 |
| Net Sales Reconciliation | | | |
| Segment net sales | \$ 1,582.6 | \$ 1,412.6 | \$ 1,280.9 |
| Foreign currency | 96.0 | 34.4 | 40.5 |
| | | | |
| Consolidated net sales | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 |
| | | | |
| Pre-tax Income Reconciliation | | | |
| Segment pre-tax income | \$ 720.7 | \$ 640.6 | \$ 566.0 |
| Unallocated amounts: | | | |
| Corporate items | (436.3) | (366.0) | (346.0) |
| Special (charges) gains, net | (21.6) | (22.7) | 63.8 |
| Interest income (expense), net | 0.3 | (1.5) | (1.1) |
| Foreign currency | 20.5 | 17.8 | 21.7 |
| | | | |
| Consolidated pre-tax income | \$ 283.6 | \$ 268.2 | \$ 304.4 |

Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****17. SEGMENT INFORMATION (Continued)****Enterprise-Wide Information**

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

| | As of or for the Years Ended December 31, | | |
|--|--|------------|------------|
| | 2011 | 2010 | 2009 |
| | (in millions) | | |
| Net Sales by Geographic Area | | | |
| United States | \$ 605.6 | \$ 567.6 | \$ 556.1 |
| Europe | 574.0 | 457.0 | 404.6 |
| Japan | 283.7 | 247.8 | 214.1 |
| Rest of World | 215.3 | 174.6 | 146.6 |
| | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 |
| Net Sales by Major Product Area | | | |
| Heart Valve Therapy | \$ 1,010.7 | \$ 838.3 | \$ 714.9 |
| Critical Care | 508.3 | 454.1 | 452.5 |
| Cardiac Surgery Systems | 107.5 | 100.2 | 92.8 |
| Vascular | 52.1 | 54.4 | 61.2 |
| | \$ 1,678.6 | \$ 1,447.0 | \$ 1,321.4 |
| Long-lived Tangible Assets by Geographic Area | | | |
| United States | \$ 223.0 | \$ 180.5 | \$ 163.0 |
| International | 130.5 | 102.3 | 102.0 |
| | \$ 353.5 | \$ 282.8 | \$ 265.0 |

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

| Years Ended December 31, | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Total Year |
|--------------------------------------|------------------|-------------------|------------------|-------------------|---------------|
| (in millions, except per share data) | | | | | |
| 2011 | | | | | |
| Net sales | \$ 404.5 | \$ 431.2 | \$ 412.7 | \$ 430.2 | \$ 1,678.6 |
| Gross profit | 287.7 | 303.4 | 287.1 | 310.6 | 1,188.8 |
| Net income(a) | 63.9 | 58.1 | 51.6 | 63.1 | 236.7 |
| Earnings per common share(a): | | | | | |
| Basic | 0.56 | 0.51 | 0.45 | 0.55 | 2.07 |
| Diluted | 0.53 | 0.48 | 0.43 | 0.53 | 1.98 |
| Market price: | | | | | |
| High | \$ 91.82 | \$ 90.38 | \$ 91.50 | \$ 77.40 | \$ 91.82 |
| Low | 77.26 | 80.44 | 61.63 | 61.59 | 61.59 |
| 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(b) | 47.7 | 57.5 | 48.0 | 64.8 | 218.0 |
| Earnings per common share(b): | | | | | |
| 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 |

(a) The second quarter of 2011 includes a \$4.0 million charge to reflect the increased collection risk associated with the Company's receivables in Greece.

The fourth quarter of 2011 includes (1) an \$8.8 million charge to reflect the increased risk associated with its southern European receivables, (2) a \$5.5 million charge related primarily to severance associated with a global workforce realignment, and (3) a \$3.3 million charge related to a litigation settlement.

(b) 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.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. VALUATION AND QUALIFYING ACCOUNTS

| | Balance at Beginning of Period | Charged to Costs and Expenses | Additions Charged to Other Accounts (in millions) | Deductions From Reserves | Balance at End of Period |
|------------------------------------|--------------------------------------|-------------------------------------|---|--------------------------------|--------------------------------|
| Year ended December 31, 2011 | | | | | |
| Allowance for doubtful accounts(a) | \$ 11.6 | \$ 9.0 | \$ 0.3 | \$ (1.9) | \$ 19.0 |
| Inventory reserves(b) | 11.2 | 15.3 | | (13.6) | 12.9 |
| Tax valuation allowance(c) | 30.3 | 3.1 | 0.4 | (1.4) | 32.4 |
| 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 |

- (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.

20. RESTATEMENT OF UNAUDITED INTERIM CONSOLIDATED CONDENSED FINANCIAL STATEMENTS

During the fourth quarter of 2011, the Company determined that its previously issued consolidated condensed balance sheets and consolidated condensed statements of cash flows for the quarters ended March 31, June 30, and September 30, 2011 contained errors related to (1) its cash equivalents and short-term investments and (2) the excess tax benefit from stock plans. Neither of these errors had an impact on the consolidated condensed statements of operations.

First, during 2011, the Company purchased bank time deposits with original maturities over three months but less than one year. The Company determined that these bank time deposits had been incorrectly

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

20. RESTATEMENT OF UNAUDITED INTERIM CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (Continued)

classified as cash equivalents for the above mentioned periods and, accordingly, the Company has restated the presentation as reflected below. The classification error had no impact on the Company's current assets.

| Balance Sheets | As of March 31, 2011 | | As of June 30, 2011 | | As of September 30, 2011 | |
|---------------------------|----------------------|-----------------|---------------------|-----------------|--------------------------|-----------------|
| | As Reported | As Restated | As Reported | As Restated | As Reported | As Restated |
| | (in millions) | | | | | |
| Cash and cash equivalents | \$ 433.8 | \$ 325.2 | \$ 468.2 | \$ 175.6 | \$ 451.1 | \$ 244.0 |
| Short-term investments | | 108.6 | | 292.6 | | 207.1 |
| Total | \$ 433.8 | \$ 433.8 | \$ 468.2 | \$ 468.2 | \$ 451.1 | \$ 451.1 |

| Statements of Cash Flows | Three Months Ended March 31, 2011 | | Six Months Ended June 30, 2011 | | Nine Months Ended September 30, 2011 | |
|---|-----------------------------------|-------------|--------------------------------|-------------|--------------------------------------|-------------|
| | As Reported | As Restated | As Reported | As Restated | As Reported | As Restated |
| | (in millions) | | | | | |
| Cash flows from investing activities | | | | | | |
| Purchases of short-term investments | | \$ (105.6) | | \$ (304.3) | | \$ (454.0) |
| Proceeds from short-term investments | | | | 14.6 | | 237.2 |
| Net cash used in investing activities | | (52.5) | (158.1) | (63.8) | (353.5) | (298.2) |
| Effect of currency exchange rate changes on cash and cash equivalents | | 15.8 | 12.8 | 20.9 | 18.0 | 3.2 |
| Net increase (decrease) in cash and cash equivalents | | 37.7 | (70.9) | 72.1 | (220.5) | 55.0 |
| Cash and cash equivalents at end of period | | 433.8 | 325.2 | 468.2 | 175.6 | 451.1 |

Second, the amounts presented in the consolidated condensed statements of cash flows as "*Excess Tax Benefits from Stock Plans*" for the periods ended June 30 and September 30, 2011 were not reduced to reflect the absence of cash flows from the generation of credit carryforwards and net operating losses in the United States in 2011 primarily due to significant tax deductions from stock option exercises and, accordingly, the Company has restated the presentation as reflected below.

| Statements of Cash Flows | Six Months Ended June 30, 2011 | | Nine Months Ended September 30, 2011 | |
|---|--------------------------------|-------------|--------------------------------------|-------------|
| | As Reported | As Restated | As Reported | As Restated |
| | (in millions) | | | |
| Cash flows from operating activities | | | | |
| Excess tax benefit from stock plans | \$ (36.4) | \$ (11.2) | \$ (47.0) | \$ (3.6) |
| Net cash provided by operating activities | 74.2 | 99.4 | 171.4 | 214.8 |
| Cash flows from financing activities | | | | |
| Excess tax benefit from stock plans | 36.4 | 11.2 | 47.0 | 3.6 |
| Net cash provided by (used in) financing activities | 40.8 | 15.6 | (38.2) | (81.6) |

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

None.

Item 9A. Controls and Procedures

Background. As previously reported in the Company's fourth quarter earnings press release, which was included in its Current Report on Form 8-K filed on February 2, 2012, the Company determined that certain short-term investments were incorrectly shown as cash and cash equivalents in the consolidated condensed balance sheets and cash flow statements contained in its interim reports for the periods ended March 31, June 30, and September 30, 2011. Since that time, the Company also identified certain errors related to the presentation of the excess tax benefit from stock plans in its consolidated condensed statements of cash flows for the interim periods ended June 30 and September 30, 2011.

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 amended) as of December 31, 2011. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as a result of the material weakness in internal control over financial reporting that is described below in Management's Report on Internal Control Over Financial Reporting, the Company's disclosure controls and procedures were not effective as of December 31, 2011.

Notwithstanding the material weakness identified in the evaluation, based upon additional analysis, the Company concluded that the consolidated financial statements included in this Annual Report on Form 10-K fairly present in all material respects the Company's financial position, results of operations and cash flows as of and for the year ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

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 Rule 13a-15(f). 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. Management, under the supervision and with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of December 31, 2011 of the effectiveness of its internal control over financial reporting based upon the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement to the annual or interim financial statements will not be prevented or detected on a timely basis. Management identified the following material weakness in internal control over financial reporting.

The Company did not maintain effective controls over the completeness and timeliness of information impacting classification and disclosures related to financial reporting. Specifically, effective controls were not in place with respect to communication to appropriate financial reporting personnel from other departments of changes to information impacting classification and disclosures in the financial statements. This control deficiency resulted in a restatement to the Company's unaudited consolidated condensed balance sheets as of March 31, June 30, and September 30, 2011 to correct the misclassification of short-term investments incorrectly classified as cash equivalents, and the restatement of the Company's unaudited consolidated condensed statements of cash flows for the periods ended March 31, June 30, and September 30, 2011 to appropriately present the activity related to short-term investments resulting from the aforementioned

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

classification error and to correct the amount presented as excess tax benefit from stock plans as a component of cash flows from operating and financing activities. Additionally, this control deficiency could result in other classification and disclosure misstatements related to financial reporting that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, the Company's management has determined that this control deficiency constitutes a material weakness.

Because of this material weakness, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2011, based on criteria in *Internal Control - Integrated Framework* as issued by COSO.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting. Since December 31, 2011, the Company has begun the implementation of the remedial actions described below. There were no changes in the Company's internal control over financial reporting that occurred during the Company's fourth fiscal quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Plan for Remediation of Material Weakness. Beginning in February 2012, with the oversight of the Audit and Public Policy Committee, the Company's management began to design and implement certain remediation measures to address the material weakness discussed above and to improve its internal control over financial reporting. Specifically, the Company is enhancing its controls to improve the communication to appropriate financial reporting personnel from other departments of changes to information impacting classification and disclosures in the financial statements.

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 2012 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, 2011). 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.

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 | Four Year Credit Agreement dated as of July 29, 2011, among Edwards Lifesciences Corporation and certain of its subsidiaries, as Borrower; the lenders signatory thereto, Bank of America, N.A., as Administrative Agent; JPMorgan Chase Bank, N.A. and Wells Fargo Bank, National Association, as Co-Syndication Agents, and U.S. Bank, National Association, The Bank of Tokyo-Mitsubishi UFJ, Ltd., Deutsche Bank AG New York Branch and Mizuho Corporate Bank, Ltd., as Co-Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 8-K, filed August 4, 2011, 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 November 9, 2011) |
| 10.8 | Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-40434)) |
| *10.9 | Edwards Lifesciences Corporation 401(k) Savings and Investment Plan (incorporated by reference to Exhibit 4.3 in Edwards Lifesciences' Registration Statement on Form S-8 (File No. 333-33056)) |

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

| Exhibit No. | Description |
|--------------------|---|
| *10.12 | Long-Term Stock Incentive Compensation Program (as amended and restated as of May 12, 2011) |
| *10.13 | Nonemployee Directors Stock Incentive Program (as amended and restated as of November 9, 2011) |
| *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 (incorporated by reference to Exhibit 10.18 in Edward Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2010, under the Securities Exchange Act of 1934) |
| *10.19 | Edwards Lifesciences Corporation Form of current Change-in-Control Severance Agreement (incorporated by reference to Exhibit 10.19 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2010, under the Securities and Exchange Act of 1934) |
| *10.20 | Edwards Lifesciences Corporation Form of Indemnification 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, 2011, 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

| Signature | Title | Date |
|--|--------------|-------------------|
| <hr/> <i>/s/ WILLIAM J. LINK, PH.D.</i> <hr/> William J. Link, Ph.D. | Director | February 27, 2012 |
| <hr/> <i>/s/ BARBARA J. MCNEIL, M.D., PH.D.</i> <hr/> Barbara J. McNeil, M.D., Ph.D. | Director | February 27, 2012 |
| <hr/> <i>/s/ DAVID E.I. PYOTT</i> <hr/> David E.I. Pyott | Director | February 27, 2012 |
| <hr/> <i>/s/ WESLEY W. VON SCHACK</i> <hr/> Wesley W. von Schack | Director | February 27, 2012 |