

Edwards Lifesciences Corp  
Form 10-K  
February 28, 2013

Use these links to rapidly review the document

[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, 2012

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 29, 2012 (the last trading day of the registrant's most recently completed second quarter): \$11,803,285,983 based on a closing price of \$103.30 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, 2013, was 114,100,658.

### Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2013 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2012) are incorporated by reference into Part III, as indicated herein.

---

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**  
**Form 10-K Annual Report 2012**  
**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>21</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>22</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>23</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>39</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>42</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>91</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>91</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>91</u>

**PART III**

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

**PART IV**

<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>93</u>
	<u>Signatures</u>	<u>96</u>

---

Table of Contents

**PART I**

**Item 1. Business**

*This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company (as defined below in "Corporate Background") intends the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials or regulatory approvals, any statements of plans, strategies and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, and any statements of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's results or future business, financial condition, results of operations or performance to differ materially from the Company's historical results or experiences 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 focused on technologies that treat structural heart disease and critically ill patients. 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. The Company is also a global leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

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.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease or critically ill patients are categorized into three main areas: Surgical Heart Valve Therapy, which combines surgical heart valves and Cardiac Surgery Systems; Transcatheter Heart Valves; and Critical Care, which includes 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. 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. 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 the circulatory problems are in the limbs rather than in the heart, the patient's procedure may involve some of

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

## Table of Contents

Edwards Lifesciences' Vascular products, which include various types of balloon-tipped catheters that are used to remove blood clots from diseased blood vessels.

### **Corporate Background**

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999. Unless otherwise indicated or otherwise required by the context, the terms "we," "our," "it," "its," "Company," "Edwards" and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

Edwards Lifesciences' principal executive offices are located at One Edwards Way, Irvine, California 92614. The telephone number at that address is (949) 250-2500. The Company makes available, free of charge on its website located at [www.edwards.com](http://www.edwards.com), its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission ("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](http://www.edwards.com) under "Investors." 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 areas of products and technologies offered by Edwards Lifesciences to treat advanced cardiovascular disease. For more information on net sales from these three main areas, see "*Net Sales by Product Line*" under "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

#### **Surgical 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 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 Ease* 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. In addition to its replacement valves, Edwards Lifesciences pioneered and is the worldwide leader in heart valve repair therapies, including annuloplasty rings and systems.

Cardiac surgeons and their patients increasingly are seeking less invasive approaches to aortic or mitral valve surgery, which offer a number of potential benefits, including smaller incisions, less blood loss, quicker recoveries and less scarring. Edwards Lifesciences' *ThruPort* systems enable minimal incision valve surgery ("MIVS") where surgeons perform intricate procedures through small incisions, and allow surgeons to 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 educational programs. 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.

Sales of the Company's surgical tissue heart valve products represented approximately 36%, 40% and 44% of the Company's net sales in 2012, 2011 and 2010, respectively.

Table of Contents

**Transcatheter Heart Valves**

Edwards Lifesciences has leveraged the knowledge and experience from its Surgical Heart Valve portfolio to optimize transcatheter heart valve replacement technology, designed to treat heart valve disease using catheter-based approaches. The Company received approval in the United States in 2011 for the transfemoral delivery of the *Edwards SAPIEN* transcatheter aortic heart valve for treatment of certain inoperable patients, and in 2012 for the transfemoral and transapical delivery of the *Edwards SAPIEN* transcatheter aortic heart valve for treatment of certain patients deemed at high risk for traditional open-heart surgery. The *Edwards SAPIEN* transcatheter aortic heart valve is delivered using the *RetroFlex 3* delivery system for transfemoral approach, and the *Ascendra* delivery system for transapical approach. Both are percutaneous beating heart procedures. The Company has also developed the *Edwards SAPIEN XT* transcatheter heart valve, which is delivered using the lower profile *NovaFlex+* delivery system for transfemoral approach, and the *Ascendra+* delivery system for other approaches. The *Edwards SAPIEN XT* valve is available for sale in Europe and certain other international markets, and is currently in clinical study in the United States. In Japan, the clinical study of the *Edwards SAPIEN XT* valve has been completed and the regulatory approval process is underway. Sales of the Company's Transcatheter Heart Valves represented approximately 29%, 20% and 14% of the Company's net sales in 2012, 2011 and 2010, 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, as well as for acutely ill patients with conditions such as sepsis, acute respiratory distress syndrome and multi-organ failure. 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. The Edwards hemodynamic monitoring product line also includes the *FloTrac* continuous cardiac output monitoring system, a minimally invasive cardiac monitoring technology for goal-directed hemodynamic optimization. The Company's *VolumeView* sensor-catheter set measures a critically ill patient's volumetric hemodynamic parameters, while the *EV1000* clinical monitoring platform displays a patient's physiologic status and integrates many of the Company's sensors and catheters into one intuitive platform.

In 2012, Edwards Lifesciences extended its Critical Care product offering with the acquisition of a non-invasive hemodynamic monitoring product line, which the Company plans to further develop and integrate into its *EV1000* clinical platform.

Edwards Lifesciences is also the global leader in disposable pressure monitoring devices and innovative closed blood sampling systems to help protect both patients and clinicians from the risk of infection. Sales of the Company's hemodynamic monitoring devices represented approximately 26% of the Company's net sales in 2012 and 29% of the Company's net sales in 2011 and 2010.

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 with broader product offerings than Edwards Lifesciences. Furthermore, new product development and technological change characterize the areas 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 globally one of the leading competitors 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 lines or certain geographies. In Surgical and Transcatheter Heart Valve therapies, 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 lines including ICU Medical, Inc., PULSION Medical Systems AG and LiDCO Group PLC.

**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 10% or more of the Company's net sales in 2012.

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 2012, 43% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States.

**International.** In 2012, 57% of Edwards Lifesciences' reported sales were derived internationally through its direct sales force and independent distributors. Of the total international sales, 51% were in Europe, 27% were in Japan, and 22% were in Rest of World. Edwards Lifesciences sells its products in approximately 100 countries, and its major international markets include Australia, Canada, China, France,

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

## Table of Contents

Germany, Italy, Japan, the Netherlands, Spain and the 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's Surgical Heart Valve Therapy and Transcatheter Heart Valve products are manufactured in California, Switzerland, Utah and Singapore. Critical Care products are manufactured primarily in the Company's facilities located in Puerto Rico and the Dominican Republic.

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' Surgical Heart Valve Therapy and Transcatheter Heart Valve 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 uncompromised 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.

Edwards Lifesciences' operations are certified under applicable international quality systems standards, such as International Organization for Standardization ("ISO") 13485. These standards require, among other items, quality system controls that are applied to product design, component material, suppliers and



Table of Contents

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 structural heart 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 \$291.3 million in research and development in 2012, \$246.3 million in 2011, and \$204.4 million in 2010 (15.3%, 14.7% and 14.1% 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 catheter-based approaches. In the area of transcatheter aortic valve replacement, the Company is developing a repositionable, self-expanding transcatheter heart valve system, the *Edwards CENTERA* transcatheter valve system, in addition to its next generation balloon-expandable valve, the *Edwards SAPIEN 3* transcatheter valve system. Surgical heart valve therapy development programs include the *EDWARDS INTUITY Elite Valve System*, a minimally invasive aortic heart valve system designed to enable a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision. The Company also plans to broaden its offering of minimally invasive surgical technologies and other products to complement its surgical heart valve therapy products.

In its Critical Care product line, the Company is pursuing the development of non-invasive and minimally invasive hemodynamic monitoring systems, including continuous hemodynamic monitoring, automated glucose monitoring and other technologies that collect critical patient information to help clinicians make more informed treatment decisions, for larger patient populations.

Edwards Lifesciences' research and development activities are conducted primarily in facilities located in the United States, Israel and the Netherlands. 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 2,500 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 Physician Payments Sunshine Act, which requires public disclosure of the financial relationships of United States physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical and biologics companies;

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 a dedicated team 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

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

### Table of Contents

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 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

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

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

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

### Table of Contents

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.

Hospital reimbursement in the United States for transcatheter aortic valve replacement ("TAVR") procedures is currently aligned with surgical aortic valve replacement codes. On May 1, 2012, CMS issued a National Coverage Determination ("NCD") that provided nationwide coverage of TAVR for patients who either fall within FDA-approved criteria or are part of an approved clinical study. The Company has always believed a well-written NCD that ensures adequate patient access is a positive for patients and physicians.

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 health care system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. Because many other parts of the 2010 health care 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 2012 of \$5.9 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.

The Puerto Rican government recently announced plans effective in 2013 to increase the excise tax rate to four percent and to maintain that level through 2017. The Company projects that the excise tax impact for 2013 of approximately \$5.3 million will be fully offset by credits.

### **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 medical procedures.

### **Employees**

As of December 31, 2012, Edwards Lifesciences had approximately 8,200 employees worldwide, the majority of whom were located in the United States, the Dominican Republic, and Singapore. Other major concentrations of employees are located in Europe and Japan. 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

Table of Contents

American employees are represented by a labor union. In various countries outside of North America, the Company interacts with trade unions and work councils that represent a limited number of employees.

**Item 1A. Risk Factors**

*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, Management's Discussion and Analysis of Financial Condition and Results of Operations, 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 all of 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.

Table of Contents

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

We use a broad range of raw and organic materials and other items in the design and manufacture of our products. Our Surgical and Transcatheter Heart Valve Therapy products are manufactured from treated natural animal tissue and man-made materials. Our non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metals. We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we purchase certain supplies from single sources for reasons of quality assurance, cost-effectiveness, availability or constraints resulting from regulatory requirements. 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. In addition, the SEC recently enacted disclosure rules regarding products that may contain certain minerals that originate from conflict areas in and around the Democratic Republic of Congo. If our suppliers cannot certify that their components do not originate from these conflict areas, we may need to source components from alternative suppliers. If we are unable to identify alternative materials or suppliers 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.



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

### Table of Contents

*We may be required, from time to time, to recognize charges in connection with the write-down of our investments, asset or business dispositions, 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, 2012, we had \$21.1 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.4 million on these investments on our consolidated balance sheet in "Accumulated Other Comprehensive Loss," net of tax.

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

*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 health care 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, negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital or other funds, and could negatively impact our

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

### Table of Contents

ability to borrow. 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. 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 health care system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase our operating expenses. Because many other parts of the 2010 health care 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. For example, 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. This measure and other such deficit reduction legislation could adversely affect our results of operations, financial condition, and prospects if they were to result in cuts to, or a restructuring of, entitlement programs such as Medicare and Medicaid.

We do business with 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 57% in 2012. 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;

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

### Table of Contents

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

an outbreak of any life threatening communicable disease;

economic and political instability and local economic and political conditions;

differing labor regulations; and

differing protection of intellectual property.

Substantially all of our sales outside of the United States are denominated in local currencies. Measured in local currency, a substantial portion of our international sales was generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our international sales varies with currency exchange rate fluctuations. Decreases in the value of the United States dollar to the Euro or the Japanese yen have the effect of increasing our reported revenues even when the volume of international sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect and, if significant, could have a material adverse effect on our reported revenues and results of operations. We have a hedging program for certain 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, or changes in financial estimates and recommendations of securities analysts.

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;

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;

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

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;

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

### Table of Contents

the timing of regulatory approvals;

changes in foreign currency exchange rates;

delays or problems in introducing new products, such as slower than anticipated adoption of transcatheter heart valves;

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;

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, and broader product offerings. 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 sales, technical and other key personnel play an integral role in the development, marketing and selling of new and existing products. If we are unable to recruit, hire, develop and retain a talented, competitive work force, our ability to compete may be adversely affected. 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. Our position can shift as a result of any of these factors. See "*Competition*" under "*Business*" included herein.

*Consolidation in the health care industry could have an adverse effect on our revenues and results of operations.*

The health care 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 health care 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 health care 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.

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

### Table of Contents

*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.

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, sourcing, 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

### Table of Contents

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 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 health care 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 health care 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.

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

### Table of Contents

*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.

*Unsuccessful clinical trials or 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, including early clinical experiences and regulatory studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures 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 and procedures 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 or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures 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 or procedures 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.



Table of Contents

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation or reimbursement policies of third-party payors will not otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost-containment pressures by substituting lower cost products or other therapies. In addition, the 2010 United States health care 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 health care professionals is limited to approved uses or for clinical trials, 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

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

## Table of Contents

relationships with these professionals or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

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

#### **North America**

Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing
Irvine, California	(2)	Administration
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
Singapore	(2)	Manufacturing, Marketing, Distribution, 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 2016 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 2014; the Tokyo, Japan lease expires in 2015; and Singapore has one landlease that expires in 2036 and one that expires in 2041. The Company believes its properties have been well maintained, are in good operating condition and are adequate for current needs.

### **Item 3. Legal Proceedings**

For a description of our material pending legal proceedings, please see Note 16 to the "*Consolidated Financial Statements*" of this Annual Report on Form 10-K, which is incorporated by reference.

### **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:	2012		2011	
	High	Low	High	Low
March 31	\$ 83.96	\$ 67.95	\$ 91.82	\$ 77.26
June 30	104.25	67.86	90.38	80.44
September 30	109.88	96.36	91.50	61.63
December 31	110.79	81.29	77.40	61.59

*Number of Stockholders*

On January 31, 2013 there were 17,086 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) (b)
October 31, 2012	700,000	\$ 86.70	700,000	\$ 373.9
November 30, 2012	1,358,164	86.23	1,358,164	247.6
December 31, 2012				247.6
Total	2,058,164	86.39	2,058,164	

(a) 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 \$500.0 million of the Company's common stock.

(b) In November 2012, the Company paid \$100.0 million under its November accelerated share repurchase ("ASR") agreement and received an initial delivery of 1.1 million shares of the Company's common stock at \$85.73 per share, representing approximately 90 percent of the total contract value. In February 2013, the November ASR concluded, and the Company received an additional 0.1 million shares. Shares purchased pursuant to the ASR agreement are presented in the above table in the periods in which they are received. The amount that may yet be purchased under the stock repurchase program, as presented in the above table, was reduced by the \$100.0 million payment.



Table of Contents**Item 6. Selected Financial Data**

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

		As of or for the Years Ended December 31,				
		2012	2011	2010	2009	2008
		(in millions, except per share data)				
<b>OPERATING RESULTS</b>	Net sales	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0	\$ 1,321.4	\$ 1,237.7
	Gross profit	1,405.0	1,188.8	1,038.7	922.3	818.1
	Net income(a)	293.2	236.7	218.0	229.1	128.9
<b>BALANCE SHEET DATA</b>	Total assets	\$ 2,221.5	\$ 1,980.5	\$ 1,767.2	\$ 1,615.5	\$ 1,400.2
	Long-term debt(b)	189.3	150.4		90.3	175.5
<b>COMMON STOCK INFORMATION</b>	Net income per common share(a):					
	Basic	\$ 2.55	\$ 2.07	\$ 1.92	\$ 2.04	\$ 1.15
	Diluted	2.48	1.98	1.83	1.95	1.10
	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 of \$16.0 million, \$21.6 million and \$22.7 million during 2012, 2011 and 2010, 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, 2012. Also discussed is Edwards Lifesciences' financial position as of December 31, 2012. 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 focused on technologies that treat structural heart disease and critically ill patients. 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. The Company is also a global leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

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

### Table of Contents

During the first quarter of 2012, the Company began reporting its products and technologies in three new product groups: Surgical Heart Valve Therapy, which combines surgical heart valves and Cardiac Surgery Systems; Transcatheter Heart Valves; and Critical Care, which includes Vascular. Sales amounts for the prior year periods have been recast to conform with the new product classifications.

Edwards Lifesciences' **Surgical Heart Valve Therapy** portfolio is comprised primarily of tissue heart valves and heart valve repair products for the surgical replacement or repair of a patient's heart valve. The portfolio also includes a diverse line of products used during minimally invasive surgical procedures, and cannulae, embolic protection devices and other products used during cardiopulmonary bypass. The Company's **Transcatheter Heart Valves** portfolio includes technologies designed to treat heart valve disease using catheter-based approaches as opposed to open surgical techniques. In the **Critical Care** portfolio, Edwards Lifesciences' products include pulmonary artery catheters, disposable pressure transducers and advanced monitoring systems. The portfolio also includes a line of balloon catheter-based vascular products, surgical clips and inserts.

The health care 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 with broader product offerings than Edwards Lifesciences. Furthermore, rapid product development and technological change characterize the market in which the Company competes. Global demand for health care is increasing as the population ages. There is mounting pressure to contain health care 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 health care system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. Because many other parts of the 2010 health care 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	
	2012	2011	2010	2012	2011	2012	2011
United States	\$ 812.1	\$ 605.6	\$ 567.6	\$ 206.5	\$ 38.0	34.1%	6.7%
Europe	559.7	574.0	457.0	(14.3)	117.0	(2.5)%	25.6%
Japan	294.1	283.7	247.8	10.4	35.9	3.7%	14.5%
Rest of World	233.7	215.3	174.6	18.4	40.7	8.5%	23.3%
International	1,087.5	1,073.0	879.4	14.5	193.6	1.3%	22.0%
Total net sales	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0	\$ 221.0	\$ 231.6	13.2%	16.0%

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

### Table of Contents

The \$206.5 million **increase in net sales in the United States in 2012** was due primarily to:

Transcatheter Heart Valves, which increased net sales by \$203.5 million, driven primarily by sales of the *Edwards SAPIEN* transcatheter heart valve which was launched in the fourth quarter of 2011.

The \$14.5 million **increase in international net sales in 2012** was due primarily to:

Transcatheter Heart Valves, which increased net sales by \$35.9 million, driven primarily by sales of the *Edwards SAPIEN XT* transcatheter heart valve; and

Surgical Heart Valve Therapy products, which increased net sales by \$19.5 million, driven primarily by sales of the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$42.4 million, due primarily to the weakening of the Euro against the United States dollar.

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

Transcatheter Heart Valves, which increased net sales by \$23.5 million, driven primarily by sales of the *Edwards SAPIEN* and *SAPIEN XT* transcatheter heart valves for clinical trials and commercial sales resulting from the launch in the fourth quarter of 2011;

Critical Care products, which increased net sales by \$9.3 million, driven primarily by the *FloTrac* minimally invasive monitoring system and pressure monitoring products.

Surgical Heart Valve Therapy products, which increased net sales by \$5.1 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* valves (launched in the third quarter of 2010).

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

Transcatheter Heart Valves, which increased net sales by \$88.2 million, driven primarily by sales of the *Edwards SAPIEN XT* transcatheter heart valve;

Surgical Heart Valve Therapy products, which increased net sales by \$20.2 million, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve;

Critical Care products, which increased net sales by \$18.6 million, driven primarily by pressure monitoring products and the *FloTrac* minimally invasive monitoring system; and

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

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 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.*"



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

### Table of Contents

#### ***Net Sales by Product Line***

(dollars in millions)

	Years Ended December 31,			Change		Percent Change	
	2012	2011	2010	2012	2011	2012	2011
Surgical Heart Valve Therapy	\$ 787.5	\$ 784.4	\$ 732.1	\$ 3.1	\$ 52.3	0.4%	7.1%
Transcatheter Heart Valves	552.1	333.8	206.4	218.3	127.4	65.4%	61.7%
Critical Care	560.0	560.4	508.5	(0.4)	51.9	(0.1)%	10.2%
Total net sales	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0	\$ 221.0	\$ 231.6	13.2%	16.0%

#### ***Surgical Heart Valve Therapy***

The \$3.1 million increase in net sales of Surgical Heart Valve Therapy products in 2012 was primarily due to:

surgical heart valve products, which increased net sales by \$12.5 million, driven by sales of the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve; and

cardiac surgery systems, which increased net sales by \$6.0 million, driven by specialty cannula products and minimally invasive surgical products;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$15.3 million, primarily due to the weakening of the Euro against the United States dollar.

The \$52.3 million increase in net sales of Surgical Heart Valve Therapy products in 2011 was primarily due to:

surgical heart valve products, which increased net sales by \$21.1 million, driven by sales of the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* valves; and

foreign currency exchange rate fluctuations, which increased net sales by \$25.4 million, primarily due to the strengthening of the Euro and the Japanese yen against the United States dollar.

In Europe, the Company received CE Mark in February 2012 for *EDWARDS INTUITY*, its minimally invasive aortic valve surgery system. During the second quarter of 2012, the Company received conditional Investigational Device Exemption ("IDE") approval from the United States Food and Drug Administration ("FDA") to initiate the TRANSFORM Trial, which will evaluate the *EDWARDS INTUITY* valve system, and began enrollment in the third quarter of 2012. Also, during the second quarter of 2012, the Company received IDE approval to initiate a clinical trial, called COMMENCE, to study its *GLX* next-generation tissue treatment platform applied to the *Magna Ease* aortic surgical valve, and in the fourth quarter of 2012 received approval to include the *Magna Mitral Ease* valve in the study.

During the second quarter of 2012, the Company received regulatory approval in the United States and Europe for its *ProPlege* retrograde cardioplegia device, designed to protect the heart during aortic and mitral valve procedures. The Company initiated a limited launch of *ProPlege* in Europe in June 2012 and in the United States in July 2012.

#### ***Transcatheter Heart Valves***

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

The \$218.3 million increase in net sales of Transcatheter Heart Valves in 2012 was primarily due to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$176.7 million, primarily due to the launch in the United States in the fourth quarter of 2011; and

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

### Table of Contents

the *Edwards SAPIEN XT* transcatheter heart valve, which increased net sales by \$63.8 million, primarily due to an increase in international sales;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$16.7 million, primarily due to the weakening of the Euro against the United States dollar.

The \$127.4 million increase in net sales of Transcatheter Heart Valves in 2011 was primarily due to:

the *Edwards SAPIEN XT* transcatheter heart valve, which increased net sales by \$185.6 million, primarily due to an increase in international sales; and

foreign currency exchange rate fluctuations, which increased net sales by \$11.0 million, primarily due to the strengthening of the Euro and the Japanese yen against the United States dollar;

partially offset by:

decreased international sales of the *Edwards SAPIEN* transcatheter heart valve due to the adoption of the *SAPIEN XT* valve.

The Company expects that sales of its transcatheter heart valves will continue to grow during 2013. 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 (Cohort B of The PARTNER Trial). In October 2012, the Company received approval from the FDA for the transfemoral and transapical delivery of the *Edwards SAPIEN* transcatheter heart valve for treatment of patients with severe, symptomatic aortic stenosis deemed at high risk for traditional open-heart surgery (Cohort A of The PARTNER Trial). The Company is continuing to conduct the PARTNER II Trial, which is evaluating the *Edwards SAPIEN XT* transcatheter heart valve for the United States market. In September 2012, the Company received FDA approval to add to the trial its larger 29 millimeter *SAPIEN XT* valve with the *NovaFlex+* delivery system and the *Ascendra+* delivery system for both the transapical and new transaortic approach. In early 2013, the Company began enrollment in the CE Mark trial for its *SAPIEN 3* valve, designed to reduce paravalvular leak.

### ***Critical Care***

The \$0.4 million decrease in net sales of Critical Care products in 2012 was primarily due to:

foreign currency exchange rate fluctuations, which decreased net sales by \$10.4 million, primarily due to the weakening of the Euro against the United States dollar; and

the discontinuation of distributed sales of certain oximetry products and reduced sales of the Company's Central Venous Access products, which decreased net sales by \$6.7 million;

partially offset by:

advanced monitoring products, which increased net sales by \$16.7 million, driven by *FloTrac* systems.

The \$51.9 million increase in net sales of Critical Care products in 2011 was primarily due 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

foreign currency exchange rate fluctuations, which increased net sales by \$21.6 million, primarily due to the strengthening of the Euro and Japanese yen against the United States dollar.

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

### Table of Contents

#### *Gross Profit*

	Years Ended December 31,			Change	
	2012	2011	2010	2012	2011
Gross profit as a percentage of net sales	74.0%	70.8%	71.8%	3.2pts.	(1.0pts.)

The 3.2 percentage point increase in gross profit as a percentage of net sales in 2012 was driven by:

a 2.3 percentage point increase due to the impact of foreign currency exchange rate fluctuations, including the settlement of foreign currency hedging contracts; and

a 2.3 percentage point increase in the United States due to a more profitable product mix, primarily higher sales of Transcatheter Heart Valves;

partially offset by:

the voluntary recalls in the second quarter of 2012 of certain of the Company's heart valves and Critical Care catheters, and manufacturing inefficiencies.

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 settlement 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;

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 across all product lines.

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

(dollars in millions)

	Years Ended December 31,			Change	
	2012	2011	2010	2012	2011
SG&A expenses	\$ 705.3	\$ 642.4	\$ 550.0	\$ 62.9	\$ 92.4
SG&A expenses as a percentage of net sales	37.1%	38.3%	38.0%	(1.2) pts.	0.3pts.

The \$62.9 million increase in SG&A expenses in 2012 was due primarily to higher sales and marketing expenses in the United States, mainly to support the launch of the Transcatheter Heart Valve program. The decrease in SG&A expenses as a percentage of net sales in 2012 was primarily due to the impact of foreign currency and lower sales and marketing expenses in Europe as a percentage of net sales. The impact of foreign currency reduced SG&A expenses by \$17.0 million due primarily to the weakening of the Euro against the United States dollar.

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

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 launch of the Transcatheter Heart Valve program. The impact of foreign currency 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.

In 2010, significant reforms to the health care system were adopted as law in the United States. The law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on

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

### Table of Contents

United States sales of most medical devices beginning in 2013, which will increase the Company's SG&A expenses.

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

(dollars in millions)

	Years Ended December 31,			Change	
	2012	2011	2010	2012	2011
Research and development expenses	\$ 291.3	\$ 246.3	\$ 204.4	\$ 45.0	\$ 41.9
Research and development expenses as a percentage of net sales	15.3%	14.7%	14.1%	0.6pts.	0.6pts.

The increase in research and development expenses in 2012 and 2011 was primarily due to additional investments in clinical studies and new product development efforts in the Transcatheter Heart Valve program.

#### ***Special Charges***

(in millions)

	Years Ended December 31,		
	2012	2011	2010
Realignment expenses	\$ 9.0	\$ 5.5	\$ 7.2
Licensing of intellectual property	7.0		
European receivables reserve		12.8	
Settlements and litigation		3.3	
MONARC program discontinuation			8.3
Investment impairment			7.2
<b>Total special charges</b>	<b>\$ 16.0</b>	<b>\$ 21.6</b>	<b>\$ 22.7</b>

#### ***Realignment Expenses***

In December 2012, the Company recorded a \$9.0 million charge related primarily to severance expenses associated with a global workforce realignment impacting 92 employees. As of December 31, 2012, the Company's remaining severance obligations of \$8.5 million are expected to be substantially paid by the end of 2013.

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, 2012, payments related to the realignment were substantially complete.

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, 2012, payments related to the realignment were complete.

#### ***Licensing of Intellectual Property***

In April 2012, the Company obtained an exclusive license to a suturing device for minimally invasive surgery applications. The intellectual property is under development and there is uncertainty as to whether the product will ultimately be approved. The Company recorded a charge of \$2.0 million related to the upfront licensing and royalty fees.

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

### Table of Contents

In June 2012, the Company obtained a co-exclusive sublicense to intellectual property related to processing tissue and implanting cardiovascular valves. The intellectual property is under development and there is uncertainty as to whether the product will ultimately be approved. The Company recorded a charge of \$5.0 million related to the upfront licensing fee.

#### *European Receivables Reserve*

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

#### *Settlements and Litigation*

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

#### *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 primarily related to the impairment of intangible assets associated with the program.

#### *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.

#### *Interest Expense*

Interest expense was \$4.4 million, \$3.1 million and \$2.4 million in 2012, 2011 and 2010, respectively. The \$1.3 million increase in interest expense for 2012 resulted primarily from higher average interest rates and a higher average debt balance as compared to the prior year. The \$0.7 million increase in interest expense for 2011 resulted primarily from a higher average debt balance as compared to the prior year.

#### *Interest Income*

Interest income was \$4.8 million, \$3.4 million and \$0.9 million in 2012, 2011 and 2010, respectively. The \$1.4 million increase in interest income for 2012 resulted primarily from the recognition of interest income on discounted accounts receivables in southern Europe, partially offset by lower average interest rates. The \$2.5 million increase in interest income for 2011 resulted primarily from higher investment returns.

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

(in millions)

	<b>Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Foreign exchange losses (gains), net	\$ 1.2	\$ 1.9	\$ (0.2)
Losses (gains) on investments in unconsolidated affiliates	0.7	(5.4)	(0.8)
Earn-out payments		(1.0)	(6.0)
Other	(0.2)	(0.3)	(1.1)
<b>Total other expense (income), net</b>	<b>\$ 1.7</b>	<b>\$ (4.8)</b>	<b>\$ (8.1)</b>



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

### Table of Contents

The foreign exchange losses (gains) relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances, offset by the gains and losses on derivative instruments intended as an economic hedge of those exposures. Foreign exchange fluctuations (primarily related to United States dollar payables in non-United States dollar functional currency locations) resulted in a net loss in 2012.

The losses (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.

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 2012, 2011 and 2010 were impacted as follows (in millions):

	<b>Years Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Income tax expense at U.S. federal statutory rate	\$ 136.9	\$ 99.2	\$ 93.9
Foreign income tax at different rates	(39.8)	(57.4)	(28.1)
Tax credits, federal and state	(4.9)	(10.4)	(7.8)
State and local taxes, net of federal tax benefit	3.9	4.6	4.1
Nondeductible stock-based compensation	1.9	1.9	1.9
U.S. tax on foreign earnings, net of credits	(1.0)	11.8	2.2
Release of reserve for uncertain tax positions for prior years	(0.8)	(4.1)	(13.4)
Other	1.7	1.3	(2.6)
<b>Income tax provision</b>	<b>\$ 97.9</b>	<b>\$ 46.9</b>	<b>\$ 50.2</b>

### *Reserve for Uncertain Tax Positions*

As of December 31, 2012 and 2011, the liability for income taxes associated with uncertain tax positions was \$113.6 million and \$78.0 million, respectively. The Company estimates that these liabilities would be reduced by \$26.1 million and \$6.8 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 \$87.5 million and \$71.2 million, respectively, if not required, would favorably affect the Company's effective tax rate.

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

### Table of Contents

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

	December 31,		
	2012	2011	2010
Unrecognized tax benefits, January 1	\$ 78.0	\$ 55.1	\$ 47.1
Current year tax positions	41.7	26.0	20.8
Increase prior period tax positions	2.6	5.9	8.6
Decrease prior period tax positions	(4.3)	(5.5)	(20.1)
Settlements	(4.3)	(0.1)	(0.1)
Lapse of statutes of limitations	(0.1)	(3.4)	(1.2)
<b>Unrecognized tax benefits, December 31</b>	<b>\$ 113.6</b>	<b>\$ 78.0</b>	<b>\$ 55.1</b>

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2012, the Company had accrued \$3.1 million (net of \$2.1 million tax benefit) of interest related to uncertain tax positions, and 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. During 2012, 2011 and 2010, the Company recognized interest expense, net of tax benefit, of \$1.0 million, \$0.4 million and (\$0.9) million, respectively, in "*Provision for Income Taxes*" on the consolidated statements of operations.

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, 2012, all material state, local and foreign income tax matters have been concluded for years through 2006. The Internal Revenue Service ("IRS") has completed its examination of the Company's 2007 and 2008 tax years, including certain transfer pricing issues that were under appeal. The appeals process for those transfer pricing issues was finalized during the third quarter of 2012. The IRS 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 throughout the world for multiple years, 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 November 2012, California voters approved a ballot measure which implements mandatory single sales factor apportionment for years beginning on or after January 1, 2013. The impact of the new legislation has been considered in determining the Company's tax provision for 2012, including the realizability of its California research and development credit carryforward.

The federal research credit expired on December 31, 2011 and was retroactively reinstated on January 2, 2013. As a result, the effective income tax rate for the year ended December 31, 2012 has been calculated without a benefit for the federal research credit. It is expected that the Company will record an \$8.4 million tax benefit in the first quarter of 2013 representing the benefit earned retroactively from January 1 through

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

### Table of Contents

December 31, 2012. Had the federal research credit been recorded in 2012, it would have favorably impacted the effective tax rate by 2.0 percentage points.

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, 2012, 2011 and 2010 by \$0.39, \$0.40 and \$0.34, 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 2028, 2017, 2024 and 2015, respectively. In 2012, the Company negotiated a new Puerto Rico grant with the Puerto Rican government with an extended term until 2028.

### **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.

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. As of December 31, 2012, cash and cash equivalents and short-term investments held outside the United States were \$473.3 million, and have historically been used to fund international operations and acquire businesses outside of the United States. 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.

The Company has a Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015. 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. 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. As of December 31, 2012, borrowings of \$189.3 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. The Company was in compliance with all covenants at December 31, 2012.

In October 2012, the Company acquired all the outstanding shares of BMEYE, B.V. ("BMEYE") for an aggregate cash purchase price of €28.4 million (\$36.9 million). In addition, the Company paid €3.9 million (\$5.1 million) to BMEYE as an intercompany loan for payment of certain liabilities that were assumed as part of the acquisition. The purchase price and intercompany loan were funded with cash on hand. BMEYE was a medical device company that specialized in the development of non-invasive technology for advanced hemodynamic monitoring. The acquisition provided the Company with full rights to develop BMEYE's existing technology platform to create a new, integrated hemodynamic monitoring system that has a disposable sensor unit worn by the patient.

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

### Table of Contents

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 Facility. 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 reduce the total shares outstanding. Under these stock repurchase authorizations, in February 2012, May 2012 and November 2012, the Company entered into ASR agreements to repurchase \$54 million, \$50 million, and \$100 million, respectively, of the Company's common stock. As of December 31, 2012, the Company had received a total of 2.3 million shares under these agreements. The February 2012 and May 2012 agreements concluded in May 2012 and August 2012, respectively. In February 2013, the November agreement concluded, and the Company received an additional 0.1 million shares. Also, under these stock repurchase authorizations, the Company entered into Rule 10b5-1 repurchase plans. In August 2012, the Company entered into a Rule 10b5-1 plan to repurchase up to \$100.0 million of the Company's common stock in accordance with certain pre-defined price parameters. The Rule 10b5-1 plan had a termination date of December 31, 2012, and as of that date, the Company had repurchased \$100.0 million under that plan. In November 2012, the Company entered into a new Rule 10b5-1 plan to repurchase, during 2013, up to \$245.0 million of the Company's common stock in accordance with certain pre-defined price parameters. During 2012, the Company repurchased a total of 4.0 million shares at an aggregate cost of \$350.3 million and had remaining authority to purchase \$247.6 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 \$373.8 million for 2012 increased \$59.3 million from 2011 due primarily to (1) improved operating performance, (2) a decrease in inventory builds in comparison to the prior year and (3) increased collection of accounts receivable, particularly a \$26.3 million non-recurring collection in Spain and the sale of the Company's Greek bonds. These increases were partially offset by (1) a \$50.5 million impact from increased excess tax benefits from stock plans, primarily the realization of excess tax benefits that had been previously unrealized due to credit carryforwards and net operating losses in the United States, and (2) the timing of supplier payments.

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 used in **investing activities** of \$90.5 million in 2012 consisted primarily of capital expenditures of \$120.7 million and a \$36.6 million payment associated with the acquisition of BMEYE, partially offset by net proceeds from short-term investments of \$69.7 million.

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.

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

### Table of Contents

Net cash used in **financing activities** of \$155.6 million in 2012 consisted primarily of net purchases of treasury stock of \$353.2 million, partially offset by proceeds from stock plans of \$100.1 million, the excess tax benefit from stock plans of \$56.5 million (including the realization of previously unrealized excess tax benefits), and net proceeds from debt of \$39.5 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.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2012 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	\$ 189.3	\$ 189.3	\$ 189.3	\$	\$
Operating leases	101.2	23.1	31.6	15.0	31.5
Interest on debt	8.2	3.2	5.0		
Pension obligations(a)	6.8	6.8			
Contractual development obligations(b)	4.7	0.5	3.9	0.3	
Capital commitment obligations(c)	3.2	2.0	1.2		
Purchase and other commitments	14.7	11.8	1.2	0.6	1.1
<b>Total contractual cash obligations(d)</b>	<b>\$ 328.1</b>	<b>\$ 47.4</b>	<b>\$ 232.2</b>	<b>\$ 15.9</b>	<b>\$ 32.6</b>

- (a) The amount included in "Less Than 1 Year" reflects anticipated contributions to the Company's various pension plans. Anticipated contributions beyond one year are not determinable. The total accrued benefit liability for the Company's pension plans recognized as of December 31, 2012 was \$50.8 million. This amount is impacted by, among other items, pension expense funding levels, changes in plan demographics and assumptions, and investment return on plan assets. Therefore, the Company is unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table. See Note 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, 2012, the liability for uncertain tax positions including interest was \$118.8 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. 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.

Table of Contents

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

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

***Revenue Recognition***

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

The Company's sales terms are standard terms within the medical device industry, with title and risk of loss transferring upon delivery to the customer, limited right of return and no unusual provisions or conditions. When the Company recognizes revenue from the sale of its products, an estimate of various sales returns and allowances is recorded which reduces product sales and accounts receivable. These adjustments include estimates for rebates, returns and other sales allowances. These provisions are estimated and recorded at the time of sale based upon historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. Product returns are not significant because returns are generally not allowed unless the product is damaged at time of receipt. If the historical data and inventory estimates used to calculate these provisions do not approximate future activity, the Company's financial position, results of operations and cash flows could be impacted.

The Company's primary sales adjustment relates to distributor rebates which are given to the Company's United States distributors and represents the difference between the Company's sales price to the distributor (at the Company's distributor "list price") and the negotiated price to be paid by the end-customer. This distributor rebate is recorded by the Company as a reduction to sales and a reduction to the distributor's accounts receivable at the time of sale to a distributor. The Company validates the distributor rebate accrual quarterly through either a review of the inventory reports obtained from its distributors or an estimate of its distributor's inventory. This distributor inventory information is used to verify the estimated liability for future distributor rebate claims based on historical rebates and contract rates. The Company periodically monitors current pricing trends and distributor inventory levels to ensure the 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, as the Company expects to pay in cash. For volume rebates offered to customers, the rebates are recorded as a reduction to sales and accounts receivable, as the Company expects a net payment from the

Table of Contents

customer. 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 \$12.0 million and \$19.0 million at December 31, 2012 and 2011, 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 (generally defined as quantities in excess of a two year supply). The allowance for excess and obsolete inventory was \$16.3 million and \$12.9 million at December 31, 2012 and 2011, respectively.

***Patent Costs***

The Company expenses legal costs incurred for patent preparation and applications. The Company capitalizes certain legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable. 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.

***Goodwill, Intangible Assets and Long-Lived Assets***

The Company acquires intangible assets in connection with business combinations and asset purchases. The acquired intangible assets are recorded at fair value, which is determined based on a discounted cash flow analysis. The determination of fair value requires significant estimates, including, but not limited to, the amount and timing of projected future cash flows, the discount rate used to discount those cash flows, the assessment of the asset's life cycle, including the timing and expected costs to complete in-process projects, and the consideration of legal, technical, regulatory, economic, and competitive risks.

Goodwill and indefinite-lived intangible assets, which relate to in-process research and development acquired in business combinations, are reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. Additionally, management reviews the carrying amounts of other intangible and long-lived assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. The impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates.

Table of Contents

***Income Taxes***

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. The Company evaluates quarterly the realizability of its deferred tax assets by assessing its valuation allowance and 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.

When assessing whether a windfall tax benefit relating to stock-based compensation has been realized, the Company follows the with and without approach, under which the windfall benefit is recognized only if an incremental benefit is provided after considering all other tax attributes presently available to the Company. Consideration is given only to the direct impacts of stock awards when calculating the amount of windfalls and shortfalls.

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 \$38.4 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 that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the far distant future. 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, market-based 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



Table of Contents

valuation model. The fair value of market-based restricted stock units is determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The Black-Scholes and Monte Carlo models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. Stock-based compensation expense is recorded net of estimated forfeitures. Judgment is required in estimating the stock awards that will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and the Company's results of operations could be impacted.

**New Accounting Standards Not Yet Adopted**

In December 2011, the Financial Accounting Standards Board ("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. In January 2013, the FASB clarified that this guidance applies only to derivatives, repurchase agreements and reverse purchase agreements, and securities borrowing and securities lending transactions that are either offset in accordance with specific criteria contained in the accounting guidance or subject to a 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 will provide the information required by this guidance in 2013.

In July 2012, the FASB issued an amendment to the accounting guidance on intangible assets to permit an entity to first assess qualitative factors to determine whether it is more likely than not that the indefinite-lived asset is impaired as a basis for determining whether it is necessary to calculate the fair value of the indefinite-lived asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. The guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In February 2013, the FASB issued an amendment to the accounting guidance on reporting amounts reclassified out of accumulated other comprehensive income. The guidance requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under United States GAAP to be reclassified in its entirety to net income. For other amounts that are not required under United States GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. The guidance is effective prospectively for reporting periods beginning after December 15, 2012, and interim periods within those annual periods. The Company will provide the information required by this guidance in 2013.

**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 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 using derivative financial instruments to

Table of Contents

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.

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 Euro and the Japanese yen. 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, 2012 and 2011 were \$779.0 million and \$759.5 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 \$55.0 million and \$58.9 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, 2012, 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 health care industry, performs credit evaluations of these customers and maintains allowances for potential credit losses which have historically been adequate compared to actual losses. In 2012, the Company had no customers that represent 10% or more 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, a reduction in value and 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.

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

### Table of Contents

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 will collect these accounts receivable, which could result in a negative impact to the Company's operating results. As of December 31, 2012, the Company's accounts receivables, net of the allowance for doubtful accounts, from customers in Italy, Spain, Portugal and Greece were \$104.7 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, 2012, Edwards Lifesciences had \$21.1 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.4 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, 2012**

<u>Report of Independent Registered Public Accounting Firm</u>	<u>43</u>
Financial Statements:	
<u>Consolidated Balance Sheets at December 31, 2012 and 2011</u>	<u>44</u>
For the Years Ended December 31, 2012, 2011 and 2010:	
<u>Consolidated Statements of Operations</u>	<u>45</u>
<u>Consolidated Statements of Comprehensive Income</u>	<u>46</u>
<u>Consolidated Statements of Cash Flows</u>	<u>47</u>
<u>Consolidated Statements of Stockholders' Equity</u>	<u>48</u>
<u>Notes to Consolidated Financial Statements</u>	<u>49</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, 2012 and December 31, 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ PricewaterhouseCoopers LLP  
Irvine, California  
February 28, 2013

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

(in millions, except par value)

	December 31,	
	2012	2011
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 310.9	\$ 171.2
Short-term investments (Note 2)	210.5	279.3
Accounts receivable, net (Note 4)	321.1	283.8
Other receivables	26.4	36.9
Inventories, net (Note 4)	281.0	261.3
Deferred income taxes	43.4	43.9
Prepaid expenses	41.6	35.0
Other current assets	57.0	57.1
<b>Total current assets</b>	<b>1,291.9</b>	<b>1,168.5</b>
Long-term accounts receivable, net (Note 4)	9.9	24.6
Property, plant and equipment, net (Note 4)	373.3	304.3
Goodwill (Note 6)	384.7	349.8
Other intangible assets, net (Note 6)	67.0	66.9
Investments in unconsolidated affiliates (Note 7)	21.1	21.8
Deferred income taxes	47.3	20.0
Other assets	26.3	24.6
<b>Total assets</b>	<b>\$ 2,221.5</b>	<b>\$ 1,980.5</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 74.7	\$ 85.0
Accrued liabilities (Note 4)	263.2	234.8
Taxes payable	9.5	15.4
<b>Total current liabilities</b>	<b>347.4</b>	<b>335.2</b>
Long-term debt (Note 8)	189.3	150.4
<b>Other long-term liabilities</b>	<b>205.5</b>	<b>157.0</b>
Commitments and contingencies (Notes 8 and 16)		
<b>Stockholders' equity</b> (Note 12)		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 124.2 and 120.0 shares issued, and 114.3 and 114.1 shares outstanding, respectively	124.2	120.0
Additional paid-in capital	489.0	300.5
Retained earnings	1,653.9	1,360.7
Accumulated other comprehensive loss	(37.9)	(37.5)
Treasury stock, at cost, 9.9 and 5.9 shares, respectively	(749.9)	(405.8)
<b>Total stockholders' equity</b>	<b>1,479.3</b>	<b>1,337.9</b>

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Total liabilities and stockholders' equity	\$ 2,221.5	\$ 1,980.5
--	------------	------------

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

Table of Contents

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

(in millions, except per share information)

	Years Ended December 31,		
	2012	2011	2010
Net sales	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0
Cost of goods sold	494.6	489.8	408.3
<b>Gross profit</b>	<b>1,405.0</b>	<b>1,188.8</b>	<b>1,038.7</b>
Selling, general and administrative expenses	705.3	642.4	550.0
Research and development expenses	291.3	246.3	204.4
Special charges (Note 3)	16.0	21.6	22.7
Interest expense	4.4	3.1	2.4
Interest income	(4.8)	(3.4)	(0.9)
Other expense (income), net (Note 14)	1.7	(4.8)	(8.1)
Income before provision for income taxes	391.1	283.6	268.2
Provision for income taxes (Note 15)	97.9	46.9	50.2
Net income	\$ 293.2	\$ 236.7	\$ 218.0
<b>Share information</b> (Note 2):			
Earnings per share:			
Basic	\$ 2.55	\$ 2.07	\$ 1.92
Diluted	\$ 2.48	\$ 1.98	\$ 1.83
Weighted-average number of common shares outstanding:			
Basic	114.9	114.6	113.7
Diluted	118.3	119.4	119.2

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



Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(in millions)

	Years Ended December 31,		
	2012	2011	2010
Net income	\$ 293.2	\$ 236.7	\$ 218.0
Other comprehensive (loss) income, net of tax (Note 13):			
Foreign currency translation adjustments	4.2	(5.2)	(24.9)
Unrealized gain (loss) on cash flow hedges	1.1	16.8	(6.8)
Unrealized loss on available-for-sale investments for the period		(0.1)	(0.8)
Reclassification of net realized investment loss (gain) to earnings	0.3	(1.0)	4.0
Defined benefit pension plans net actuarial loss and other	(6.0)	(5.9)	(5.7)
Other comprehensive (loss) income, net of tax	(0.4)	4.6	(34.2)
Comprehensive income	\$ 292.8	\$ 241.3	\$ 183.8

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,		
	2012	2011	2010
<b>Cash flows from operating activities</b>			
Net income	\$ 293.2	\$ 236.7	\$ 218.0
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	57.3	58.0	56.5
Stock-based compensation (Notes 2 and 12)	42.1	35.0	29.3
Excess tax benefit from stock plans (Notes 2 and 12)	(56.5)	(6.0)	(55.1)
Deferred income taxes	8.1	(0.6)	(11.2)
Special charges (Note 3)	14.9	21.2	22.7
(Gain) loss on trading securities	(0.7)	1.0	(2.7)
Other	3.9	(1.1)	(5.0)
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(26.5)	(53.7)	(34.2)
Inventories, net	(21.7)	(57.0)	(36.8)
Accounts payable and accrued liabilities	41.9	61.7	63.6
Prepaid expenses and other current assets	12.8	20.6	(2.5)
Other	5.0	(1.3)	8.8
Net cash provided by operating activities	373.8	314.5	251.4
<b>Cash flows from investing activities</b>			
Capital expenditures	(120.7)	(82.9)	(61.8)
Proceeds from short-term investments (Note 2)	662.3	349.9	
Purchases of short-term investments (Note 2)	(592.6)	(643.3)	
Acquisitions (Note 5)	(36.6)	(42.6)	
Investments in intangible assets	(7.0)	(7.7)	(1.2)
Proceeds from sale of assets	3.0	3.9	6.6
Proceeds from unconsolidated affiliates	2.8	9.1	2.2
Investments in unconsolidated affiliates	(2.0)	(2.3)	(6.9)
(Investments in) proceeds from trading securities, net	(0.6)	3.1	(0.4)
Other	0.9		
Net cash used in investing activities	(90.5)	(412.8)	(61.5)
<b>Cash flows from financing activities</b>			
Proceeds from issuance of debt	407.0	526.1	254.4
Payments on debt	(367.5)	(421.7)	(302.8)
Purchases of treasury stock	(344.1)	(303.4)	(200.0)
Equity forward contract related to accelerated share repurchase agreement (Note 12)	(9.1)		
Proceeds from stock plans	100.1	59.5	92.1
Excess tax benefit from stock plans (Notes 2 and 12)	56.5	6.0	55.1
Other	1.5	(1.7)	(2.7)
Net cash used in financing activities	(155.6)	(135.2)	(103.9)
Effect of currency exchange rate changes on cash and cash equivalents	12.0	8.6	(24.0)
Net increase (decrease) in cash and cash equivalents	139.7	(224.9)	62.0
Cash and cash equivalents at beginning of year	171.2	396.1	334.1

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

Cash and cash equivalents at end of year	\$ 310.9	\$ 171.2	\$ 396.1
--	----------	----------	----------

### Supplemental disclosures:

Cash paid during the year for:

Interest	\$ 4.4	\$ 3.2	\$ 2.4
----------	--------	--------	--------

Income taxes	\$ 38.0	\$ 15.4	\$ 14.7
--------------	---------	---------	---------

Non-cash investing and financing transactions:

Capital expenditures accruals	\$ 2.4	\$ 4.3	\$ 3.0
-------------------------------	--------	--------	--------

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**

(in millions)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Par Value	Shares	Amount				
<b>BALANCE AT DECEMBER 31, 2009</b>	76.1	76.1	19.3	(872.3)	1,056.0	906.0	(7.9)	1,157.9
Net income						218.0		218.0
Other comprehensive loss, net of tax							(34.2)	(34.2)
Common stock issued under equity plans, including tax benefits	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)			
<b>BALANCE AT DECEMBER 31, 2010</b>	117.0	117.0	2.0	(102.0)	211.3	1,124.0	(42.1)	1,308.2
Net income						236.7		236.7
Other comprehensive income, net of tax							4.6	4.6
Common stock issued under equity plans, including tax benefits	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)
<b>BALANCE AT DECEMBER 31, 2011</b>	120.0	120.0	5.9	(405.8)	300.5	1,360.7	(37.5)	1,337.9
Net income						293.2		293.2
Other comprehensive loss, net of tax							(0.4)	(0.4)
Common stock issued under equity plans, including tax benefits	4.2	4.2			155.5			159.7
Stock-based compensation expense					42.1			42.1
Purchase of treasury stock			4.0	(344.1)	(9.1)			(353.2)
<b>BALANCE AT DECEMBER 31, 2012</b>	124.2	\$ 124.2	9.9	\$ (749.9)	\$ 489.0	\$ 1,653.9	\$ (37.9)	\$ 1,479.3

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 focused on technologies that treat structural heart disease and critically ill patients. 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. The Company is also a global leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease or critically ill patients are categorized into the following main areas: Surgical Heart Valve Therapy; Transcatheter Heart Valves; and Critical Care. The Company's Surgical Heart Valve Therapy portfolio includes tissue heart valves and heart valve repair products for the surgical replacement or repair of a patient's heart valve. The portfolio also includes a diverse line of products used during minimally invasive surgical procedures, and cannulae, embolic protection devices and other products used during cardiopulmonary bypass procedures. The Company's Transcatheter Heart Valves portfolio includes technologies designed to treat heart valve disease using catheter-based approaches as opposed to open surgical techniques. In the Critical Care portfolio, Edwards Lifesciences' products include pulmonary artery catheters, disposable pressure transducers and advanced monitoring systems. The portfolio also includes a line of balloon catheter-based vascular products, surgical clips and inserts.

**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 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.

**Foreign Currency Translation**

When the local currency of the Company's foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as a component of "*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 Expense (Income), net*."

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

**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, as the Company expects to pay in cash. For volume rebates offered to customers, the rebates are recorded as a reduction to sales and accounts receivable, as the Company expects a net payment from the customer. 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 years ended December 31, 2012, 2011 and 2010, shipping costs of \$54.9 million, \$51.0 million and \$43.6 million, respectively, were included in "*Selling, General and Administrative Expenses*."

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

**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 between three months and one year 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.*"

**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 \$12.0 million and \$19.0 million at December 31, 2012 and 2011, 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 (generally defined as quantities in excess of a two year supply). The allowance for excess and obsolete inventory was \$16.3 million and \$12.9 million at December 31, 2012 and 2011, respectively.

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 personnel and information technology. During the years ended December 31, 2012, 2011 and 2010, the Company allocated \$26.2 million, \$25.3 million and \$23.4 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2012 and 2011 were \$15.1 million and \$15.9 million, respectively.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

**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, \$44.0 million and \$40.0 million for the years ended December 31, 2012, 2011 and 2010, respectively. Repairs and maintenance expense was \$20.6 million, \$18.1 million and \$16.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

**Impairment of Goodwill and Long-Lived Assets**

Goodwill is reviewed for impairment annually in the fourth quarter of each fiscal year or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. 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 value of the reporting unit exceeds its estimated fair value, then the Company measures the amount of the impairment loss by comparing the implied fair value of goodwill to its carrying value. In 2012, 2011 and 2010, the Company did not record any impairment loss as the fair value of each reporting unit significantly exceeded its respective carrying value.

Indefinite-lived intangible assets, which relate to in-process research and development ("IPR&D") acquired in business combinations, is reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value.

Additionally, management reviews the carrying amounts of other finite-lived intangible assets and long-lived tangible assets whenever events or 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.

**In-process Research and Development**

The estimated fair values of IPR&D projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets subject to impairment testing until completion or abandonment of the projects. Upon successful completion of the



Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

project, the capitalized amount is amortized over its estimated useful life. If the project is abandoned, all remaining capitalized amounts are written off immediately. IPR&D projects acquired in an asset acquisition are expensed unless the project has an alternative future use.

**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 for which success is deemed probable. 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 a component of "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 values, 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



Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

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.

When assessing whether a windfall tax benefit relating to stock-based compensation has been realized, the Company follows the with and without approach, under which the windfall benefit is recognized only if an incremental benefit is provided after considering all other tax attributes presently available to the Company. Consideration is given only to the direct impacts of stock awards when calculating the amount of windfalls and shortfalls.

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in evaluating the Company's uncertain tax positions and determining its provision for income taxes. The Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based upon its technical merit if challenged by the relevant taxing authority and taken by management to the court of last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon settlement with the relevant tax authority. The Company recognizes interest and penalties related to income tax matters in income tax expense.

**Research and Development Costs**

Research and development costs are charged to expense when incurred.

**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, market-based restricted stock units and in-the-money options. The dilutive impact of the restricted stock units, market-based 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.

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

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

	Years ended December 31,		
	2012	2011	2010
<b>Basic:</b>			
Net income	\$ 293.2	\$ 236.7	\$ 218.0
Weighted-average shares outstanding	114.9	114.6	113.7
Basic earnings per share	\$ 2.55	\$ 2.07	\$ 1.92
<b>Diluted:</b>			
Net income	\$ 293.2	\$ 236.7	\$ 218.0
Weighted-average shares outstanding	114.9	114.6	113.7
Dilutive effect of stock plans	3.4	4.8	5.5
Dilutive weighted-average shares outstanding	118.3	119.4	119.2
Diluted earnings per share	\$ 2.48	\$ 1.98	\$ 1.83

Stock options, restricted stock units and market-based restricted stock units to purchase approximately 1.7 million, 1.0 million and 0.9 million shares for the years ended December 31, 2012, 2011 and 2010, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive. Additionally, 0.1 million shares that would have been received if the accelerated share repurchase ("ASR") agreement discussed in Note 12 was settled as of December 31, 2012, were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

**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, market-based 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) on a straight-line basis. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Upon exercise of stock options or vesting of restricted stock units and market-based restricted stock units, the Company issues common stock.

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

Total stock-based compensation expense for the years ended December 31, 2012, 2011 and 2010 was as follows (in millions):

	December 31,		
	2012	2011	2010
Cost of goods sold	\$ 5.0	\$ 4.0	\$ 2.7
Selling, general and administrative expenses	31.2	25.4	22.0
Research and development expenses	5.9	5.6	4.6
Total stock-based compensation expense	\$ 42.1	\$ 35.0	\$ 29.3

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. For market-based restricted stock units, upon retirement and in certain other specified cases, a participant will receive a pro-rated portion of the shares that would ultimately be issued based on attainment of the performance goals as determined on the vesting date. The pro-rated portion is based on the participant's whole months of service with the Company during the performance period prior to the date of termination.

**Derivatives**

The Company uses derivative financial instruments to manage foreign currency risks. It is the Company's policy not to enter into derivative financial instruments for speculative purposes. The Company uses foreign currency forward exchange contracts to offset the changes due to currency rate movements in the amount of future cash flows associated with intercompany transactions and certain third-party expenses expected to occur within the next 13 months. These foreign currency forward exchange contracts are designated as cash flow hedges. Certain of the Company's locations have assets and liabilities denominated in currencies other than their functional currencies resulting from intercompany and third-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 are denominated in currencies of major industrial countries, principally the Euro and the Japanese yen.

All derivative financial instruments are recognized at fair value in the consolidated balance sheets. The Company reports in "*Accumulated Other Comprehensive Loss*" the effective portion of the gain or loss on derivative financial instruments that are designated, and that qualify, as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same period in which the underlying hedged transactions affect earnings. 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) are recorded in current period earnings. During 2012, 2011 and 2010, the Company did not record any gains or losses due to hedge ineffectiveness. 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.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

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. Under the master-netting agreements, the Company's counterparty settlement risk is the net amount of any receipts or payments due between the Company and the counterparty financial institution.

**Recently Adopted Accounting Standards**

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 was effective for interim and annual periods beginning on or after December 15, 2011. The adoption of this guidance did not have a material impact on the Company's 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 ("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 was effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company elected to present two separate but consecutive statements.

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 was effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

**New Accounting Standards Not Yet Adopted**

In 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. In January 2013, the FASB clarified that this guidance applies only to derivatives, repurchase agreements and reverse purchase agreements, and securities borrowing and securities lending transactions that are either offset in accordance with specific criteria contained in the accounting guidance or subject to a 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 will provide the information required by this guidance in 2013.

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

In July 2012, the FASB issued an amendment to the accounting guidance on intangible assets to permit an entity to first assess qualitative factors to determine whether it is more likely than not that the indefinite-lived asset is impaired as a basis for determining whether it is necessary to calculate the fair value of the indefinite-lived asset and perform the quantitative impairment test by comparing the fair value with the carrying amount. The guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In February 2013, the FASB issued an amendment to the accounting guidance on reporting amounts reclassified out of accumulated other comprehensive income. The guidance requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under United States GAAP to be reclassified in its entirety to net income. For other amounts that are not required under United States GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under United States GAAP that provide additional detail about those amounts. The guidance is effective prospectively for reporting periods beginning after December 15, 2012, and interim periods within those annual periods. The Company will provide the information required by this guidance in 2013.

**3. SPECIAL CHARGES**

	Years Ended December 31,		
	2012	2011	2010
	(in millions)		
Realignment expenses	\$ 9.0	\$ 5.5	\$ 7.2
Licensing of intellectual property	7.0		
European receivables reserve		12.8	
Settlements and litigation		3.3	
MONARC program discontinuation			8.3
Investment impairment			7.2
<b>Total special charges</b>	<b>\$ 16.0</b>	<b>\$ 21.6</b>	<b>\$ 22.7</b>

*Realignment Expenses*

In December 2012, the Company recorded a \$9.0 million charge related primarily to severance expenses associated with a global workforce realignment impacting 92 employees. As of December 31, 2012, the Company's remaining severance obligations of \$8.5 million are expected to be substantially paid by the end of 2013.

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, 2012, payments related to the realignment were substantially complete.

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, 2012, payments related to the realignment were complete.

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

**3. SPECIAL CHARGES (Continued)**

*Licensing of Intellectual Property*

In April 2012, the Company obtained an exclusive license to a suturing device for minimally invasive surgery applications. The intellectual property is under development and there is uncertainty as to whether the product will ultimately be approved. The Company recorded a charge of \$2.0 million related to the upfront licensing and royalty fees.

In June 2012, the Company obtained a co-exclusive sublicense to intellectual property related to processing tissue and implanting cardiovascular valves. The intellectual property is under development and there is uncertainty as to whether the product will ultimately be approved. The Company recorded a charge of \$5.0 million related to the upfront licensing fee.

*European Receivables Reserve*

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

*Settlements and Litigation*

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

*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 primarily related to the impairment of intangible assets associated with the program.

*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.



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,	
	2012	2011
	(in millions)	
<b>Accounts receivable, net(a)</b>		
Trade accounts receivable	\$ 326.7	\$ 298.6
Allowance for doubtful accounts	(5.6)	(14.8)
	\$ 321.1	\$ 283.8
<b>Inventories, net(b)</b>		
Raw materials	\$ 49.5	\$ 51.7
Work in process	58.8	66.6
Finished products	172.7	143.0
	\$ 281.0	\$ 261.3
<b>Property, plant and equipment, net</b>		
Land	\$ 21.5	\$ 21.6
Buildings and leasehold improvements	183.7	172.8
Machinery and equipment	278.9	248.8
Equipment with customers	40.2	37.9
Software	102.1	94.0
Construction in progress	68.1	29.0
	694.5	604.1
Accumulated depreciation	(321.2)	(299.8)
	\$ 373.3	\$ 304.3
<b>Long-term accounts receivable, net(a)</b>		
Long-term trade accounts receivable	\$ 16.3	\$ 28.8
Allowance for doubtful accounts	(6.4)	(4.2)
	\$ 9.9	\$ 24.6
<b>Accrued liabilities</b>		
Employee compensation and withholdings	\$ 102.7	\$ 106.6
Property, payroll and other taxes	31.0	22.1
Clinical trial accruals	23.1	12.7
Accrued rebates	14.2	13.4
Realignment reserves	8.7	6.4
Deferred income taxes	8.7	8.6
Litigation reserves (Note 16)	3.1	6.6
Other accrued liabilities	71.7	58.4
	\$ 263.2	\$ 234.8

(a)

The credit and economic conditions within certain European countries have deteriorated. As of December 31, 2012 and 2011, the Company's accounts receivables, net of the allowance for doubtful accounts, from customers in Italy, Spain, Portugal and Greece were \$104.7 million and \$113.7 million, respectively. Balances from customers located in these countries that are expected to be collected beyond

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS (Continued)

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.

(b)

The Company recorded an \$8.1 million charge to gross profit during the second quarter of 2012 due to the voluntary recalls of certain of the Company's heart valves and Critical Care catheters. The majority of the affected products were still part of inventory at the time of the recalls. As of December 31, 2012, there were \$0.4 million of reserves for the recall remaining in inventory.

## 5. ACQUISITIONS

**BMEYE, B.V.**

On October 9, 2012, the Company acquired all the outstanding shares of BMEYE, B.V. ("BMEYE") for an aggregate cash purchase price of €28.4 million (\$36.9 million). In addition, the Company paid €3.9 million (\$5.1 million) to BMEYE as an intercompany loan for payment of certain liabilities that were assumed as part of the acquisition. In connection with the acquisition, the Company placed €4.3 million of the purchase price into escrow to satisfy any claims for indemnification made in accordance with the merger agreement. Any funds remaining 18 months after the acquisition date will be disbursed to BMEYE's former shareholders. Acquisition-related costs of \$0.5 million were recorded in "*Selling, General and Administrative Expenses*" during the year ended December 31, 2012.

BMEYE was a medical device company that specialized in the development of non-invasive technology for advanced hemodynamic monitoring. The acquisition provides the Company with full rights to develop BMEYE's existing technology platform to create a new, integrated hemodynamic monitoring system that has a disposable sensor unit worn by the patient. 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 recorded to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed (in millions):

Cash	\$ 0.3
Other current assets	0.9
Property and equipment, net	1.3
Goodwill	34.9
IPR&D	5.2
Developed technology	1.2
Current liabilities assumed	(4.5)
Long-term liabilities assumed	(2.4)
<b>Total purchase price</b>	<b>36.9</b>
Less: cash acquired	(0.3)
<b>Total purchase price, net of cash acquired</b>	<b>\$ 36.6</b>

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Company's Europe segment and is not 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. Completion of successful design developments, bench testing, pre-clinical

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

studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed approximately \$8.4 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were forecasted to commence in 2014. 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 6 years.

The results of operations for BMEYE 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 BMEYE are not material in relation to the consolidated financial statements of the Company.

**Embrella Cardiovascular, Inc.**

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. All remaining funds were disbursed to Embrella's former shareholders one year after the acquisition date. Acquisition-related costs of \$0.9 million were recorded in "*Other Expense (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 recorded to goodwill. The following table summarizes the fair value of the assets acquired (in millions):

Goodwill	\$ 34.6
IPR&D	6.3
Developed 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 Company's 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. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. At the time of the valuation, it was assumed that

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

approximately \$4.4 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in late 2013. Due to unanticipated efforts required to redesign the product, the Company is currently projecting that approximately \$7.9 million of research and development expenditures will be incurred prior to the date of product introduction and that net cash inflows will commence in 2015. 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 Expense (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**

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2012 and 2011 were as follows:

	United States	Europe	Total
	(in millions)		
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
Goodwill acquired during the year		34.9	34.9
Accumulated impairment losses			
Goodwill at December 31, 2012	\$ 308.3	\$ 76.4	\$ 384.7

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 6. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

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

	December 31,					
	2012			2011		
	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
<b>Amortizable intangible assets</b>						
Patents	\$ 211.2	\$ (167.3)	\$ 43.9	\$ 205.9	\$ (158.4)	\$ 47.5
Developed technology	41.3	(33.0)	8.3	39.3	(31.3)	8.0
Other	10.6	(6.8)	3.8	12.0	(6.9)	5.1
	263.1	(207.1)	56.0	257.2	(196.6)	60.6
<b>Unamortizable intangible assets</b>						
IPR&D	11.0		11.0	6.3		6.3
	\$ 274.1	\$ (207.1)	\$ 67.0	\$ 263.5	\$ (196.6)	\$ 66.9

Goodwill and IPR&D resulting from purchase business combinations are not subject to amortization. Other acquired intangible assets with definite lives are amortized on a straight-line basis over their expected useful lives. The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

In October 2012, the Company completed its acquisition of BMEYE (see Note 5). This transaction resulted in an increase to goodwill of \$34.9 million, developed technology of \$1.2 million and IPR&D of \$5.2 million. In March 2011, the Company completed its acquisition of Embrella (see Note 5). This transaction resulted in an increase to goodwill of \$34.6 million, developed technology of \$5.8 million and IPR&D of \$6.3 million.

The net carrying value of patents includes \$19.2 million and \$16.1 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of December 31, 2012 and 2011, respectively (see Note 2).

Amortization expense related to other intangible assets for the years ended December 31, 2012, 2011 and 2010 was \$13.3 million, \$14.1 million and \$16.6 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2013	\$ 14.7
2014	13.2
2015	12.0
2016	11.6
2017	2.9

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**7. INVESTMENTS IN UNCONSOLIDATED AFFILIATES**

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

	December 31,	
	2012	2011
	(in millions)	
<b>Available-for-sale investments</b>		
Cost	\$ 0.4	\$ 2.0
Unrealized gains	1.6	1.3
Fair value of available-for-sale investments	2.0	3.3
<b>Equity method investments</b>		
Cost	13.3	12.6
Equity in losses	(1.8)	(0.7)
Carrying value of equity method investments	11.5	11.9
<b>Cost method investments</b>		
Carrying value of cost method investments	7.6	6.6
<b>Total investments in unconsolidated affiliates</b>	<b>\$ 21.1</b>	<b>\$ 21.8</b>

Proceeds from sales of available-for-sale investments for the years ended December 31, 2012, 2011 and 2010 were \$2.1 million, \$3.6 million and \$0.3 million, respectively, and the Company realized pre-tax gains of \$0.4 million, \$1.4 million and \$0.2 million, respectively. During 2010, the Company recorded an other-than-temporary impairment charge of \$4.2 million 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**

The Company has a Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015. 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. 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, 2012, borrowings of \$189.3 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. The Company was in compliance with all covenants at December 31, 2012.

Included in the Credit Facility at December 31, 2012 and 2011 were unsecured notes denominated in Japanese yen of ¥1.2 billion (US\$14.3 million) and ¥1.2 billion (US\$15.4 million), respectively.

The weighted-average interest rate under all debt obligations was 1.7% and 1.8% at December 31, 2012 and 2011, respectively.

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

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 \$23.9 million, \$21.5 million and \$19.6 million for the years 2012, 2011 and 2010, respectively.

Future minimum lease payments (including interest) under non-cancelable operating leases and aggregate debt maturities at December 31, 2012 were as follows (in millions):

	Operating Leases	Aggregate Debt Maturities
2013	\$ 23.1	\$
2014	19.9	
2015	11.7	189.3
2016	8.8	
2017	6.2	
Thereafter	31.5	
<b>Total obligations and commitments</b>	<b>\$ 101.2</b>	<b>\$ 189.3</b>

**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.

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.



Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. FAIR VALUE MEASUREMENTS (Continued)***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, 2012 and 2011 (in millions):

<b>December 31, 2012</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Investments held for executive deferred compensation plan	\$ 12.7	\$	\$	\$ 12.7
Investments in unconsolidated affiliates	2.0			2.0
Derivatives		5.7		5.7
	\$ 14.7	\$ 5.7	\$	\$ 20.4

**Liabilities**

Executive deferred compensation plan	\$ 12.4	\$	\$	\$ 12.4
--------------------------------------	---------	----	----	---------

**December 31, 2011**

<b>Assets</b>				
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
--------------------------------------	--------	----	----	--------

*Executive Deferred Compensation Plan*

The Company holds investments in trading securities related to its executive deferred compensation plan. The investments are in a variety of stock and bond mutual funds. 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 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 foreign currency exchange rates discounted to present as appropriate. 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.



Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	December 31,			
	2012		2011	
	Notional Amount	Fair Value Asset	Notional Amount	Fair Value Asset
	(in millions)			
Foreign currency forward exchange contracts	\$ 779.0	\$ 5.7	\$ 759.5	\$ 12.7

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, 2012 and 2011. 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, 2012	December 31, 2011
<b>Derivatives designated as hedging instruments</b>			
Assets			
Foreign currency contracts	Prepaid expenses	\$ 5.7	\$ 12.7

The following tables present the effect of derivative instruments on the consolidated statements of operations and consolidated statements of comprehensive income (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	
	2012	2011		2012	2011
	<b>Derivatives in cash flow hedging relationships</b>				
Foreign currency contracts	\$ 13.7	\$ (1.6)	Cost of goods sold	\$ 12.2	\$ (29.0)

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2012	2011	2010
		<b>Derivatives not designated as hedging instruments</b>		
Foreign currency contracts	Other expense (income), net	\$ 4.4	\$ (6.0)	\$ (5.0)

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**10. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)**

The Company expects that during 2013 it will reclassify to earnings a \$5.3 million gain currently recorded in "Accumulated Other Comprehensive Loss." For the years ended December 31, 2012, 2011 and 2010, the Company did not record any gains or losses due to hedge ineffectiveness.

**11. EMPLOYEE BENEFIT PLANS****Defined Benefit Plans**

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

	Years Ended December 31,	
	2012	2011
<b>Change in projected benefit obligation:</b>		
Beginning of year	\$ 95.6	\$ 78.7
Service cost	7.2	6.6
Interest cost	2.3	2.2
Participant contributions	2.0	1.9
Actuarial loss	10.2	5.7
Benefits paid	(6.5)	(2.3)
Curtailement gain	(2.0)	
Currency exchange rate changes and other	(0.8)	2.8
End of year	\$ 108.0	\$ 95.6
<b>Change in fair value of plan assets:</b>		
Beginning of year	\$ 53.8	\$ 45.3
Actual return on plan assets	1.7	0.7
Employer contributions	6.5	6.3
Participant contributions	2.0	1.9
Benefits paid	(6.3)	(2.1)
Currency exchange rate changes and other	(0.5)	1.7
End of year	\$ 57.2	\$ 53.8
<b>Funded Status</b>		
Projected benefit obligation	\$ (108.0)	\$ (95.6)
Plan assets at fair value	57.2	53.8
Funded status, (under funded)	\$ (50.8)	\$ (41.8)
<b>Net amounts recognized on the consolidated balance sheet:</b>		
Other long-term liabilities	\$ 50.8	\$ 41.8
<b>Accumulated other comprehensive loss, net of tax:</b>		
Net actuarial loss	\$ (27.9)	\$ (21.1)
Net prior service credit	2.4	2.9
Net transition obligation		(0.1)
Deferred income tax benefit	5.0	3.8

Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Total \$ (20.5) \$ (14.5)

69

---

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 \$93.3 million and \$84.0 million as of December 31, 2012 and 2011, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2012 and 2011.

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

	Years Ended December 31,		
	2012	2011	2010
Service cost, net	\$ 7.2	\$ 6.6	\$ 4.7
Interest cost	2.3	2.2	1.9
Expected return on plan assets	(1.4)	(1.4)	(1.2)
Curtailment gain	(0.2)		
Amortization of actuarial loss	0.8	0.6	0.4
Amortization of prior service credit	(0.3)	(0.4)	(0.3)
Amortization of transition obligation	0.1	0.1	
Net periodic pension benefits cost	\$ 8.5	\$ 7.7	\$ 5.5

The net actuarial loss and prior service credit that will be amortized from "Accumulated Other Comprehensive Loss" into net periodic benefits cost in 2013 are expected to be \$1.3 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,	
	2012	2011
Discount rate	1.9%	2.5%
Rate of compensation increase	3.1%	3.0%
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,		
	2012	2011	2010
Discount rate	2.5%	2.4%	3.2%
Expected return on plan assets	2.6%	2.7%	3.4%
Rate of compensation increase	3.1%	2.9%	3.2%
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, 2012, by asset category, are as follows:

Insurance contracts	80.3%
Equity securities	10.6%
Debt securities	9.1%
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, 2012 and 2011, by asset category, are as follows (in millions):

<b>December 31, 2012</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Asset Category</b>				
Cash	\$ 0.8	\$	\$	\$ 0.8
Equity securities:				
United States equities	1.6			1.6
International equities	4.5			4.5
Debt securities:				
United States government bonds	0.6			0.6
International government bonds	4.0			4.0
Insurance contracts			45.7	45.7
	\$ 11.5	\$	\$ 45.7	\$ 57.2

<b>December 31, 2011</b>				
<b>Asset Category</b>				
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



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, 2012 and 2011 (in millions):

	<b>Insurance Contracts</b>
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
Actual return on plan assets:	
Relating to assets still held at December 31, 2012	1.2
Relating to assets sold during 2012	0.1
Purchases, sales and settlements	0.4
Currency exchange rate impact	0.5
Balance at December 31, 2012	\$ 45.7

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, 2012, are expected to be paid (in millions):

2013	\$ 4.0
2014	4.1
2015	4.1
2016	5.0
2017	5.9
2018-2022	29.7

As of December 31, 2012, expected employer contributions for 2013 are \$6.8 million.

**Defined Contribution Plans**

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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

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

Lifesciences employees were \$10.8 million, \$9.9 million and \$8.9 million in 2012, 2011 and 2010, 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 \$8.2 million and \$7.3 million at December 31, 2012 and 2011, 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 \$12.4 million and \$9.9 million at December 31, 2012 and 2011, 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.

During 2012, 2011 and 2010, the Company repurchased 4.0 million, 3.9 million and 4.1 million shares, respectively, at an aggregate cost of \$353.2 million, \$303.4 million and \$200.0 million, respectively, including shares purchased under the ASR agreements described below and shares acquired to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees. 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.

*Accelerated Share Repurchase*

In February 2012, the Company entered into an ASR agreement with an investment bank to repurchase \$54.0 million of the Company's common stock. The February ASR agreement provided for the repurchase of the Company's common stock based on the volume-weighted average price ("VWAP") of the Company's common stock during the term of the agreement, less a discount, and was subject to collar provisions that established minimum and maximum number of shares to be repurchased. In March 2012, the Company paid the \$54.0 million purchase price and received an initial delivery of 0.6 million shares, representing the minimum number of shares to be repurchased under the agreement. The initial shares were valued at \$72.40 per share based on the VWAP of the Company's common stock on March 1, 2012, which was the date the major terms of the ASR agreement were finalized, and represented approximately 80 percent of the total

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

**12. COMMON STOCK (Continued)**

contract value. The February ASR agreement concluded in May 2012, and upon final settlement, the Company had received a total of 0.7 million shares at an average price per share of \$75.12 based on the VWAP of the Company's common stock during the term of the agreement.

In May 2012, the Company entered into another ASR agreement with the same investment bank to repurchase \$50.0 million of the Company's common stock. The May ASR agreement provided for the repurchase of the Company's common stock based on the VWAP of the Company's common stock during the term of the agreement, less a discount, and was subject to collar provisions that established minimum and maximum number of shares to be repurchased. In June 2012, the Company paid the \$50.0 million purchase price and received an initial delivery of 0.5 million shares, representing the minimum number of shares to be repurchased under the agreement. The initial shares were valued at \$84.81 per share based on the VWAP of the Company's common stock on June 1, 2012, which was the date the major terms of the May ASR agreement were finalized, and represented approximately 80 percent of the total contract value. The May ASR agreement concluded in August 2012, and upon final settlement, the Company had received a total of 0.5 million shares at an average price per share of \$97.50 based on the VWAP of the Company's common stock during the term of the agreement.

In November 2012, the Company entered into another ASR agreement with a different investment bank to repurchase \$100.0 million of the Company's common stock. The November ASR agreement provides for the repurchase of the Company's common stock based on the VWAP of the Company's common stock during the term of the agreement, less a discount, and is subject to collar provisions that established minimum and maximum number of shares to be repurchased. In November 2012, the Company paid the \$100.0 million purchase price and received an initial delivery of 1.1 million shares, representing the minimum number of shares to be repurchased under the agreement. The initial shares were valued at \$85.73 per share based on the VWAP of the Company's common stock on November 19, 2012, which was the date the major terms of the November ASR agreement were finalized, and represented approximately 90 percent of the total contract value. The November ASR agreement concluded in February 2013, and upon final settlement, the Company had received a total of 1.2 million shares at an average price of \$88.93 based on the VWAP of the Company's common stock during the term of the agreement.

The ASR agreements were accounted for as two separate transactions: (a) the value of the initial delivery of shares was recorded as shares of common stock acquired in a treasury stock transaction on the acquisition date and (b) the remaining amount of the purchase price paid was recorded as a forward contract indexed to the Company's own common stock and was recorded in "*Additional Paid-in Capital*" on the consolidated balance sheets. The initial delivery of shares resulted in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted earnings per share. The Company determined that the forward contract indexed to the Company's common stock met all the applicable criteria for equity classification and, therefore, was not accounted for as a derivative instrument.

**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

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

**12. COMMON STOCK (Continued)**

predetermined periods ranging from three to five years after the date of grant. Market-based restricted stock units of the Company's common stock granted under the Program vest based on a combination of certain service and market conditions. The actual number of shares issued will be determined based on the Company's total shareholder return relative to a selected industry peer group over a three-year performance period, and may range from 0 percent to 175 percent of the targeted number of shares granted. On May 10, 2012, an amendment and restatement of the Program was approved by the Company's stockholders. Under the amended Program, the number of shares of common stock available for issuance under the Program was increased by 1.5 million shares to a total available for issuance of 47.4 million shares. No more than 2.0 million shares reserved for issuance may be granted in the form of stock options. 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 granted in 2011 or prior generally vests in three equal annual installments. Each option and restricted stock unit award granted after 2011 generally vests after one year. 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 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 tables. 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 6.4%.

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*

	2012	2011	2010
Average risk-free interest rate	0.7%	1.7%	2.0%
Expected dividend yield	None	None	None
Expected volatility	31%	27%	26%
Expected life (years)	4.6	4.5	4.6
Fair value, per share	\$ 23.93	\$ 22.78	\$ 13.08

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

*ESPP*

	2012	2011	2010
Average risk-free interest rate	0.1%	0.2%	0.3%
Expected dividend yield	None	None	None
Expected volatility	33%	28%	28%
Expected life (years)	0.6	0.6	0.6
Fair value, per share	\$ 21.30	\$ 20.02	\$ 12.09

The fair value of market-based restricted stock units was determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The weighted-average assumptions used to determine the fair value of the market-based restricted stock units included a 0.3 percent risk-free interest rate and a 30.4 percent expected volatility rate.

Stock option activity during the year ended December 31, 2012 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
<b>Outstanding as of December 31, 2011</b>	10.0	\$ 36.50		
Options granted	1.1	86.70		
Options exercised	(3.5)	23.08		
Options forfeited	(0.1)	60.11		
<b>Outstanding as of December 31, 2012</b>	7.5	49.92	3.7 years	\$ 304.3
<b>Exercisable as of December 31, 2012</b>	5.0	38.02	2.9 years	262.1
<b>Vested and expected to vest as of December 31, 2012</b>	7.2	48.68	3.7 years	298.1

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 12. COMMON STOCK (Continued)

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2012 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
<b>Nonvested as of December 31, 2011</b>	1.1	\$ 44.30
Granted(a)	0.3	89.88
Vested	(0.5)	30.48
Forfeited	(0.1)	53.87
<b>Nonvested as of December 31, 2012</b>	0.8	67.92

(a)

Includes 47,275 shares of market-based restricted stock units granted during 2012, which represents the targeted number of shares to be issued. As described above, the actual number of shares ultimately issued will be determined based on the Company's total shareholder return relative to a selected industry peer group.

The intrinsic value of stock options exercised and restricted stock units vested during the years ended December 31, 2012, 2011 and 2010 were \$252.8 million, \$180.7 million and \$190.9 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, 2012, 2011 and 2010, the Company received cash from exercises of stock options of \$80.5 million, \$42.4 million and \$78.8 million, respectively, and realized tax benefits from exercises of stock options and vesting of restricted stock units of \$82.6 million, \$60.7 million and \$64.7 million, respectively. The total grant-date fair value of stock options vested during the years ended December 31, 2012, 2011 and 2010 were \$19.5 million, \$16.9 million and \$15.8 million, respectively.

As of December 31, 2012, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, market-based restricted stock units and employee stock purchase subscriptions amounted to \$70.7 million, which will be amortized over the weighted-average remaining requisite service period of 30 months.

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 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, 2012, 2011 and 2010. Foreign currency translation adjustments are generally not adjusted for income taxes as they relate to indefinite investments in non-United States subsidiaries.

	Foreign Currency Translation Adjustments	Unrealized Gain (Loss) on Cash Flow Hedges	Unrealized Gain (Loss) on Available-for-Sale Investments	Unrealized Pension Costs(a)	Total Accumulated Other Comprehensive Loss
(in millions)					
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 benefit (expense)		(10.6)	1.2	0.7	(8.7)
December 31, 2011	(30.0)	5.9	1.1	(14.5)	(37.5)
Pre-tax period change	4.2	1.5	0.4	(7.2)	(1.1)
Deferred income tax (expense) benefit		(0.4)	(0.1)	1.2	0.7
December 31, 2012	\$ (25.8)	\$ 7.0	\$ 1.4	\$ (20.5)	\$ (37.9)

(a) For the years ended December 31, 2012, 2011 and 2010, the change in unrealized pension costs consisted of the following (in millions):

	Pre-Tax Amount	Tax Benefit (Expense)	Net of Tax Amount
<b>2012</b>			
Prior service cost arising during period	\$ (0.2)	\$	\$ (0.2)
Amortization of prior service credit	(0.3)		(0.3)
Net prior service cost arising during period	(0.5)		(0.5)
Net transition obligation amortized during period	0.1		0.1
Net actuarial loss arising during period	(6.8)	1.2	(5.6)
Unrealized pension costs, net	\$ (7.2)	\$ 1.2	\$ (6.0)
<b>2011</b>			
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)





Table of Contents**EDWARDS LIFESCIENCES CORPORATION****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****14. OTHER EXPENSE (INCOME), NET**

	Years Ended December 31,		
	2012	2011	2010
	(in millions)		
Foreign exchange losses (gains), net	\$ 1.2	\$ 1.9	\$ (0.2)
Losses (gains) on investments in unconsolidated affiliates	0.7	(5.4)	(0.8)
Earn-out payments		(1.0)	(6.0)
Other	(0.2)	(0.3)	(1.1)
<b>Total other expense (income), net</b>	<b>\$ 1.7</b>	<b>\$ (4.8)</b>	<b>\$ (8.1)</b>

**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,		
	2012	2011	2010
United States	\$ 143.7	\$ 23.6	\$ 71.4
International, including Puerto Rico	247.4	260.0	196.8
	<b>\$ 391.1</b>	<b>\$ 283.6</b>	<b>\$ 268.2</b>

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

	Years Ended December 31,		
	2012	2011	2010
<b>Current</b>			
United States:			
Federal	\$ 87.2	\$ 29.1	\$ 25.7
State and local	5.9	3.0	3.2
International, including Puerto Rico	31.6	25.0	27.2
Current income tax expense	124.7	57.1	56.1
<b>Deferred</b>			
United States:			
Federal	(23.8)	(6.4)	(1.8)
State and local	(2.0)	1.2	(0.2)
International, including Puerto Rico	(1.0)	(5.0)	(3.9)
Deferred income tax benefit	(26.8)	(10.2)	(5.9)
<b>Total income tax provision</b>	<b>\$ 97.9</b>	<b>\$ 46.9</b>	<b>\$ 50.2</b>

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,	
	2012	2011
<b>Deferred tax assets</b>		
Compensation and benefits	\$ 53.5	\$ 51.0
Benefits from uncertain tax positions	28.1	10.3
Net operating loss carryforwards	27.6	21.8
Net tax credit carryforwards	20.8	15.4
Accrued liabilities	13.0	11.8
Investments in unconsolidated affiliates	2.8	3.3
Inventories	0.4	1.8
Other	0.5	2.4
Total deferred tax assets	146.7	117.8
<b>Deferred tax liabilities</b>		
Property, plant and equipment	(20.8)	(22.2)
Cash flow hedges	(2.0)	(4.8)
Other intangible assets	(1.8)	(3.3)
Other	(3.3)	(0.3)
Total deferred tax liabilities	(27.9)	(30.6)
<b>Valuation allowance</b>	(38.6)	(32.4)
<b>Net deferred tax assets</b>	\$ 80.2	\$ 54.8

During 2012, net deferred tax assets increased \$25.4 million, including items that were recorded to stockholders' equity and which did not impact the Company's income tax provision.

The valuation allowance of \$38.6 million as of December 31, 2012 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 to the deferred tax assets established for impairment losses on certain investments and for certain non-United States credit carryforwards.

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 15. INCOME TAXES (Continued)

Net operating loss, charitable contribution and tax credit carryforwards, and the related carryforward periods, at December 31, 2012, are summarized as follows (in millions):

	Carryforward Amount	Tax Benefit Amount	Valuation Allowance	Net Tax Benefit	Carryforward Period Ends
United States state net operating losses	\$ 143.0	\$ 9.3	\$ (1.9)	\$ 7.4	2013-2032
United States federal net operating losses	16.8	5.9		5.9	2032
Non-United States net operating losses	32.1	8.1	(6.5)	1.6	2013-2021
Non-United States net operating losses	52.1	17.6	(16.4)	1.2	Indefinite
United States federal charitable contributions	9.2	3.4		3.4	2014-2017
United States federal tax credits	54.2	54.2		54.2	2021-2032
California research expenditure tax credits	38.4	38.4		38.4	Indefinite
Puerto Rico purchases credit	11.0	11.0	(11.0)		Indefinite
<b>Total</b>	<b>\$ 356.8</b>	<b>\$ 147.9</b>	<b>\$ (35.8)</b>	<b>\$ 112.1</b>	

A valuation allowance of \$2.8 million has been provided for other-than-temporary impairments and unrealized losses related to certain investments in unconsolidated affiliates that may not be recognized due to the uncertainty of the ready marketability of certain impaired investments.

The Company has \$38.4 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 that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the far distant future. Accordingly, no valuation allowance has been provided.

The United States state net operating loss carryforwards include \$143.0 million of losses attributable to windfall stock option deductions. A net benefit of \$4.8 million will be recorded to "Additional Paid-in Capital" when realized as a reduction to income taxes payable.

The United States federal net operating loss carryforward of \$16.8 million is attributable to windfall stock option deductions. A net benefit of \$5.9 million will be recorded to "Additional Paid-in Capital" when realized as a reduction to income taxes payable.

Approximately \$64.6 million of the total \$96.0 million 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 \$1,135.9 million as of December 31, 2012 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 because of the variability of multiple factors that would need to be assessed at the time of any assumed repatriation; however, foreign tax credits would likely be available to reduce federal income taxes in the event of distribution. In making 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, in 2010, the Company entered into a plan to repatriate all of the accumulated earnings from certain of its European subsidiaries. The Company does not expect earnings in these European subsidiaries to be indefinitely reinvested and records the tax impact in net income currently.

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 15. INCOME TAXES (Continued)

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, 2012, 2011 and 2010 by \$0.39, \$0.40 and \$0.34, 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 2028, 2017, 2024 and 2015, respectively. In 2012, the Company negotiated a new Puerto Rico grant with the Puerto Rican government with an extended term until 2028.

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,		
	2012	2011	2010
Income tax expense at U.S. federal statutory rate	\$ 136.9	\$ 99.2	\$ 93.9
Foreign income tax at different rates	(39.8)	(57.4)	(28.1)
Tax credits, federal and state	(4.9)	(10.4)	(7.8)
State and local taxes, net of federal tax benefit	3.9	4.6	4.1
Nondeductible stock-based compensation	1.9	1.9	1.9
U.S. tax on foreign earnings, net of credits	(1.0)	11.8	2.2
Release of reserve for uncertain tax positions related to prior years	(0.8)	(4.1)	(13.4)
Other	1.7	1.3	(2.6)
<b>Income tax provision</b>	<b>\$ 97.9</b>	<b>\$ 46.9</b>	<b>\$ 50.2</b>

The federal research credit expired on December 31, 2011 and was not reinstated until January 2, 2013. As a result, the effective income tax rate for the year ended December 31, 2012 has been calculated without a benefit for the federal research credit. Had the federal research credit been recorded in 2012, it would have favorably impacted the effective tax rate by 2.0 percentage points, or \$8.4 million.

*Reserve for Uncertain Tax Positions*

As of December 31, 2012 and 2011, the liability for income taxes associated with uncertain tax positions was \$113.6 million and \$78.0 million, respectively, the majority of which was included in "Other Long-term Liabilities." The Company estimates that these liabilities would be reduced by \$26.1 million and \$6.8 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 \$87.5 million and \$71.2 million, respectively, if not required, would favorably affect the Company's effective tax rate.

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

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,		
	2012	2011	2010
Unrecognized tax benefits, January 1	\$ 78.0	\$ 55.1	\$ 47.1
Current year tax positions	41.7	26.0	20.8
Increase prior period tax positions	2.6	5.9	8.6
Decrease prior period tax positions	(4.3)	(5.5)	(20.1)
Settlements	(4.3)	(0.1)	(0.1)
Lapse of statute of limitations	(0.1)	(3.4)	(1.2)
Unrecognized tax benefits, December 31	\$ 113.6	\$ 78.0	\$ 55.1

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2012, the Company had accrued \$3.1 million (net of \$2.1 million tax benefit) of interest related to uncertain tax positions, and 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. During 2012, 2011 and 2010, the Company recognized interest expense, net of tax benefit, of \$1.0 million, \$0.4 million and (\$0.9) million, respectively, in "*Provision for Income Taxes*" on the consolidated statements of operations.

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.

At December 31, 2012, 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, including certain transfer pricing issues that were under appeal. The appeals process for those transfer pricing issues was finalized during the third quarter of 2012. 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. in the U.S. District Court for the District of Delaware alleging that its ReValving System infringes three of Edwards' U.S. Andersen patents, later narrowed to one patent ("the '552 patent"). Medtronic, Inc. ("Medtronic") acquired

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

**16. LEGAL PROCEEDINGS (Continued)**

CoreValve, Inc. ("Medtronic CoreValve") in April 2009. In April 2010, a federal jury found the '552 patent to be valid and found that Medtronic 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 Medtronic 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 Medtronic CoreValve's willful infringement. In November 2012, the U.S. Court of Appeals for the Federal Circuit affirmed the April 2010 federal jury decision that Medtronic CoreValve is willfully infringing the '552 patent and ordered the trial court to reconsider Edwards' request for a permanent injunction that would prohibit the manufacture or sale of the CoreValve System in the United States. The Court of Appeals also affirmed the validity of the '552 patent and the federal jury's verdict awarding an initial payment of \$73.9 million in damages to Edwards, which covers infringement through early 2010. In February 2013, the Court of Appeals issued a mandate affirming the judgment of the District Court and directing it to reconsider its prior denial of Edwards' request for a permanent injunction. The mandate renders enforceable the initial jury damages award, and restores jurisdiction to the District Court to assess additional damages for the period after the date of the jury award.

A second lawsuit is pending in the same trial court against Medtronic CoreValve and Medtronic alleging infringement of three of Edwards' U.S. Andersen patents.

In May 2012, the United States Patent and Trademark Office ("USPTO") granted Medtronic's fourth request to reexamine the validity of the claim of the '552 patent and in February 2013 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. Edwards subsequently added two more patents to its counterclaim. In February and March 2012, the USPTO granted Edwards' requests to reexamine the validity of three of the four Medtronic patents involved in this lawsuit.

In June 2011, Medtronic CoreValve 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 CoreValve patent. Edwards counterclaimed against Medtronic CoreValve and 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, where proceedings continue. In April 2012, the USPTO granted Edwards' request to reexamine the validity of the Medtronic CoreValve patent. In November 2012, the California court ruled that the Medtronic CoreValve patent is invalid and dismissed the lawsuit in favor of Edwards. Medtronic has filed an appeal.

In March 2012, Medtronic filed another lawsuit in the U.S. District Court for the Central District of California alleging that the methods of implanting the *Edwards SAPIEN* transcatheter heart valve in the United States infringes two Medtronic patents relating to methods of pacing the heart.

In August 2012, Edwards filed a lawsuit against Medtronic in the German District Court of Mannheim alleging that Medtronic's CoreValve and Evolut valves infringe two of Edwards' transcatheter valve patents. These patents were issued by the European Patent Office and were validated as national patents in various

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

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

**16. LEGAL PROCEEDINGS (Continued)**

European countries, including Germany. The matter is scheduled for trial in April 2013. Related oppositions on the validity of these patents are ongoing at the European Patent Office.

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,		
	2012	2011	2010
<b>Segment Net Sales</b>			
United States	\$ 812.1	\$ 605.6	\$ 567.6
Europe	577.0	549.4	460.1
Japan	293.4	226.8	217.7
Rest of world	236.0	200.8	167.2
Total segment net sales	\$ 1,918.5	\$ 1,582.6	\$ 1,412.6
<b>Segment Pre-tax Income</b>			
United States	\$ 465.0	\$ 314.9	\$ 311.0
Europe	250.9	237.9	178.9
Japan	153.1	107.6	101.2
Rest of world	68.8	60.3	49.5
Total segment pre-tax income	\$ 937.8	\$ 720.7	\$ 640.6

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

	Years Ended December 31,		
	2012	2011	2010
<b>Net Sales Reconciliation</b>			
Segment net sales	\$ 1,918.5	\$ 1,582.6	\$ 1,412.6
Foreign currency	(18.9)	96.0	34.4
Consolidated net sales	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0
<b>Pre-tax Income Reconciliation</b>			
Segment pre-tax income	\$ 937.8	\$ 720.7	\$ 640.6
Unallocated amounts:			
Corporate items	(536.2)	(436.3)	(366.0)
Special charges	(16.0)	(21.6)	(22.7)
Interest income (expense), net	0.4	0.3	(1.5)
Foreign currency	5.1	20.5	17.8
Consolidated pre-tax income	\$ 391.1	\$ 283.6	\$ 268.2



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 actual foreign exchange rates used in the Company's consolidated financial statements.

	As of or for the Years Ended December 31,		
	2012	2011	2010
	(in millions)		
<b>Net Sales by Geographic Area</b>			
United States	\$ 812.1	\$ 605.6	\$ 567.6
Europe	559.7	574.0	457.0
Japan	294.1	283.7	247.8
Rest of World	233.7	215.3	174.6
	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0
<b>Net Sales by Major Product Area</b>			
Surgical Heart Valve Therapy	\$ 787.5	\$ 784.4	\$ 732.1
Transcatheter Heart Valves	552.1	333.8	206.4
Critical Care	560.0	560.4	508.5
	\$ 1,899.6	\$ 1,678.6	\$ 1,447.0
<b>Long-lived Tangible Assets by Geographic Area</b>			
United States	\$ 263.4	\$ 223.0	\$ 180.5
International	136.2	105.9	102.3
	\$ 399.6	\$ 328.9	\$ 282.8

Table of Contents

## EDWARDS LIFESCIENCES CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

Years Ended December 31,	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total Year
(in millions, except per share data)					
<b>2012</b>					
Net sales	\$ 459.2	\$ 482.0	\$ 447.9	\$ 510.5	\$ 1,899.6
Gross profit	331.9	352.2	336.2	384.7	1,405.0
Net income(a)	65.1	67.8	69.2	91.1	293.2
Earnings per common share(a):					
Basic	0.57	0.59	0.60	0.79	2.55
Diluted	0.55	0.57	0.58	0.77	2.48
Market price:					
High	\$ 83.96	\$ 104.25	\$ 109.88	\$ 110.79	\$ 110.79
Low	67.95	67.86	96.36	81.29	67.86
<b>2011</b>					
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(b)	63.9	58.1	51.6	63.1	236.7
Earnings per common share(b):					
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

(a) The second quarter of 2012 includes an \$8.1 million charge due to the voluntary recalls of certain of the Company's heart valves and Critical Care catheters and a \$7.0 million charge for the licensing of intellectual property.

The fourth quarter of 2012 includes a \$9.0 million charge related primarily to severance associated with a global workforce realignment.

(b) 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.

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
<b>Year ended December 31, 2012</b>					
Allowance for doubtful accounts(a)	\$ 19.0	\$ 3.0	\$ 0.4	\$ (10.4)	\$ 12.0
Inventory reserves(b)	12.9	21.8		(18.4)	16.3
Tax valuation allowance(c)	32.4	3.1	5.2	(2.1)	38.6
<b>Year ended December 31, 2011</b>					
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
<b>Year ended December 31, 2010</b>					
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

- (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, nearing its expiration date, damaged or slow moving. The deductions related to inventory reserves represent inventory that has been disposed.
- (c) The tax valuation allowances are provided for other-than-temporary impairments and unrealized losses related to certain unconsolidated affiliates that may not be recognized due to the uncertainty of the ready marketability of certain impaired investments, and net operating loss and credit carryforwards that may not be recognized due to insufficient taxable income.

Table of Contents

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

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures.** The Company's management, including the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation 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, 2012.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded as of December 31, 2012 that the Company's disclosure controls and procedures are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control Over Financial Reporting.** The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2012. The effectiveness of the Company's internal control over financial reporting as of December 31, 2012 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.** There have been no changes in the Company's internal controls over financial reporting that occurred during the Company's fourth fiscal quarter of 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information**

None.

Table of Contents

**PART III**

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

Certain information required by this Item is set forth under the headings "Corporate Governance," "Executive Compensation and Other Information Executive Officers," and "Other Matters and Business Additional Information" and " Section 16(a) Beneficial Ownership Reporting Compliance" in the definitive proxy materials to be filed in connection with its 2013 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, 2012). 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](http://www.edwards.com) under "Investors." The Company intends to include on its website any amendments to, or waivers from, any provision of its code of ethics that apply to the Company's principal executive officer, principal financial officer or controller and that relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K.

**Item 11. Executive Compensation**

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

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

The information contained under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in the Proxy Statement is incorporated herein by reference.

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

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

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

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

Table of Contents

**PART IV**

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

**EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of Edwards Lifesciences Corporation (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003)
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)
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	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)
10.2	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)
*10.3	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)
*10.4	Edwards Lifesciences Corporation Amended and Restated Chief Executive Officer Change-in-Control Severance Agreement, dated October 9, 2012 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.5	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.6	Long-Term Stock Incentive Compensation Program, as amended and restated as of February 16, 2012 (incorporated by reference to Appendix A in Edwards Lifesciences' Definitive Proxy Statement filed on March 30, 2012)
*10.7	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Long-Term Stock Incentive Compensation Program Global Nonqualified Stock Option Award Agreement (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.8	Edwards Lifesciences Corporation Form of Participant Restricted Stock Unit Statement and related Long-Term Stock Incentive Compensation Program Global Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
*10.9	Edwards Lifesciences Corporation Form of Performance-Based Restricted Stock Unit Statement and related Long-Term Stock Incentive Compensation Program Global Performance-Based Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2012)
*10.10	Nonemployee Directors Stock Incentive Program, as amended and restated as of November 9, 2011(incorporated by reference to Exhibit 10.13 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
*10.11	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Nonemployee Directors Stock Incentive Program Nonqualified Stock Option Award Agreement (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.12	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Units Agreement (incorporated by reference to Exhibit 10.4 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.13	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Agreement (incorporated by reference to Exhibit 10.5 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.14	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)
*10.15	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)
*10.16	Edwards Lifesciences Corporation Executive Deferred Compensation Plan, as amended and restated effective November 9, 2011 (incorporated by reference to Exhibit 10.7 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
*10.17	Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan, as amended and restated January 1, 2011
*10.18	Edwards Lifesciences Corporation 401(k) Savings and Investment Plan, as amended and restated January 1, 2009
*10.19	Amendment #1 to the Edwards Lifesciences Corporation 401(k) Savings and Investment Plan, dated April 1, 2011
*10.20	Amendment #2 to the Edwards Lifesciences Corporation 401(k) Savings and Investment Plan, dated September 13, 2011
*10.21	Amendment #3 to the Edwards Lifesciences Corporation 401(k) Savings and Investment Plan, dated October 21, 2011
*10.22	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)
*10.23	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)

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
*10.24	Edwards Lifesciences Corporation 2010 Edwards Incentive Plan (incorporated by reference to Appendix C in Edwards Lifesciences' Definitive Proxy Statement filed March 31, 2010)
*10.25	Edwards Lifesciences' Officer Perquisite Program Guidelines, as of February 20, 2013
*10.26	Edwards Lifesciences Corporation Form of Indemnification Agreement (incorporated by reference to Exhibit 10.20 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
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, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Income, (iv) the Consolidated Statements of Cash Flows, (v) the Consolidated Statements of Stockholders' Equity and (v) Notes to Consolidated Financial Statements.

---

\*  
Represents management contract or compensatory plan





Edgar Filing: Edwards Lifesciences Corp - Form 10-K

Table of Contents

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<hr/> <i>/s/ WILLIAM J. LINK, PH.D.</i> <hr/> William J. Link, Ph.D.	Director	February 28, 2013
<hr/> <i>/s/ BARBARA J. MCNEIL, M.D., PH.D.</i> <hr/> Barbara J. McNeil, M.D., Ph.D.	Director	February 28, 2013
<hr/> <i>/s/ DAVID E.I. PYOTT</i> <hr/> David E.I. Pyott	Director	February 28, 2013
<hr/> <i>/s/ WESLEY W. VON SCHACK</i> <hr/> Wesley W. von Schack	Director	February 28, 2013