

EDWARDS LIFESCIENCES CORP
Form 10-K/A
October 30, 2003

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

FORM 10-K/A

AMENDMENT NO. 1

(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, 2002

OR

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

For the Transition Period From to

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.)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

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

(949) 250-2500
Registrant's telephone number, including area code

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

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

Name of each exchange on which registered:

New York Stock Exchange
New York Stock Exchange

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

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

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

Indicate by check whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2) Yes No

The aggregate market value of the registrant's common stock held by non-affiliates as of June 28, 2002 (the last trading day of the fiscal quarter): \$1,380,185,562 based on a closing price of \$23.20 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 February 28, 2003 was 60,225,224.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2003 Annual Meeting of Stockholders (to be filed on or before April 30, 2003) are incorporated by reference into Part III, as indicated herein.

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report 2002
Table of Contents

PART I

<u>Item 1.</u>	<u>Business</u>
<u>Item 2.</u>	<u>Properties</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>

PART II

<u>Item 5.</u>	<u>Market for the Registrant's Common Equity and Related Stockholder Matters</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>

PART III

<u>Item 10.</u>	<u>Directors and Executive Officers of the Registrant</u>
<u>Item 11.</u>	<u>Executive Compensation</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions</u>
<u>Item 14.</u>	<u>Controls and Procedures</u>

PART IV

<u>Item 15.</u>	<u>Financial Statements and Schedule, Exhibits and Reports on Form 8-K</u> <u>Signatures</u>
-----------------	---

EXPLANATORY NOTE

We are filing this Amendment No. 1 on Form 10-K/A in response to comments received by us from the Staff of the Securities and Exchange Commission in connection with their review of our Registration Statement on Form S-3 filed on July 28, 2003. We have not been requested to, and we are not, restating our financial results. While only certain portions of this Annual Report have been amended, for convenience and ease of reference we are filing this Annual Report in its entirety. Unless otherwise stated, all information contained in this amendment is as of March 14, 2003, the filing date of our Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

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. These statements include, among other things, statements concerning our future operations, financial condition and prospects, and business strategies. The words may, believe, will, expect, project, estimate, anticipate, plan, continue, and similar expressions generally identify forward-looking statements. 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 our future business, financial condition, results of operations, or performance to differ materially from our historical results or those expressed in any forward-looking statements contained in this report. Investors should carefully review the information contained under the caption Certain Business Risks beginning on page 11, and elsewhere in, or incorporated by reference into, this report.

Overview

Edwards Lifesciences Corporation is a global leader in products and technologies designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address four main cardiovascular disease states:

heart valve disease;

coronary artery disease;

peripheral vascular disease; and

congestive heart failure.

Cardiovascular disease is the number-one cause of death in the world, and is among the top three diseases in terms of health care spending in nearly every country. Cardiovascular disease is both progressive and pervasive; progressive, in that it tends to worsen over time, and pervasive because it often affects an individual's entire circulatory system. In its later stages, cardiovascular disease is frequently treated with surgery, including coronary artery bypass graft (CABG) procedures and heart valve replacement or repair procedures.

The products and technologies provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas:

Cardiac Surgery;

Critical Care;

Vascular;

Perfusion; and

Other Distributed Products.

Patients undergoing surgical treatment for cardiovascular disease are likely to encounter a variety of Edwards Lifesciences products and technologies. For example, an individual with a heart valve disorder may have a faulty valve re-shaped and repaired with an Edwards Lifesciences annuloplasty ring, or the surgeon may elect to remove the valve altogether and replace it with one of Edwards Lifesciences bioprosthetic tissue heart valves, which can be made of bovine or porcine tissue. If a patient undergoes other types of open-heart surgery, such as a CABG procedure, the functions of their heart and lungs may be managed through the use of disposable products and equipment offered outside the United States and Western Europe by Edwards Lifesciences perfusion product line. If the circulatory problems are in the limbs rather than in the heart, the patient's procedure may involve some of Edwards Lifesciences vascular products, which include various types of balloon-tipped

catheters that are used to remove blood clots. Virtually all high-risk patients in the operating room or cardiac care unit are candidates for having their cardiac function monitored by Edwards Lifesciences' critical care products. Lastly, Edwards Lifesciences' other distributed products include sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through the Company's distribution network in Japan, and miscellaneous pharmaceutical products sold in the United States.

Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999 as a wholly owned subsidiary of Baxter International Inc. (Baxter) to assume the business and operations of Baxter's CardioVascular Group. Effective March 31, 2000, the business, assets and liabilities of Baxter's CardioVascular Group were transferred to Edwards Lifesciences and its subsidiaries and 100% of the common stock of Edwards Lifesciences was distributed to the stockholders of Baxter in a tax-free spin-off (the Distribution). Since that time, Edwards Lifesciences has operated as an independent company. Unless the context indicates otherwise, references to the Company and Edwards Lifesciences refer to Baxter's CardioVascular Group for periods prior to April 1, 2000 and to Edwards Lifesciences Corporation and its subsidiaries for the periods on or after such date.

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 web site located at www.edwards.com, its annual report on Form 10-K, quarterly reports of 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 SEC.

Edwards Lifesciences' Product and Technology Offerings

The following discussion summarizes the five main categories of products and technologies offered by Edwards Lifesciences to treat advanced cardiovascular disease. For more information on net sales from these five main categories, see Net Sales by Product Line under Management's Discussion and Analysis of Financial Condition and Results of Operations.

Cardiac Surgery

Heart Valve Therapy. Edwards Lifesciences' heart valve and valve repair products are used to replace or repair a patient's diseased or defective heart valve. Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products. Edwards Lifesciences operates manufacturing facilities in Irvine, California, and Horw, Switzerland, producing pericardial and porcine valves from biologically inert animal tissue sewn onto proprietary wireform stents.

The core of Edwards Lifesciences' tissue product line is the *Carpentier-Edwards PERIMOUNT* pericardial valve, including *PERIMOUNT Magna*, the newest generation pericardial valve recently launched in Europe. The *PERIMOUNT* valve is the most widely prescribed tissue heart valve in the world due to its proven durability and performance, and is the only pericardial valve available in the United States. Edwards Lifesciences' *Carpentier-Edwards* porcine valves, *Edwards Prima Plus* stentless tissue valve, *Edwards MIRA* bi-leaflet mechanical valve and the

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Starr-Edwards silastic ball valve complement its line of heart tissue valves.

In addition to its replacement valves, Edwards Lifesciences is the worldwide leader in heart valve repair therapies with products including its *Carpentier-Edwards* annuloplasty rings, *Cosgrove-Edwards* annuloplasty system and *Edwards MC³ Tricuspid* annuloplasty system.

Cannula. The Company is a leading manufacturer of cannula products used during cardiac surgery including cannula to facilitate vacuum-assisted venous drainage during perfusion, and aortic dispersion cannula. Edwards Lifesciences also has a number of products to facilitate coronary artery

bypass surgery when performed on a beating heart, including the *AnastaFlo* coronary shunt used to redirect blood away from the suturing site and the *VisuFlo* humidifying blower to keep the surgical site dry and optimize the surgeon's visual field during a cardiothoracic surgical procedure.

Angina Therapy. Edwards Lifesciences distributes carbon-dioxide lasers and related disposables for use in transmyocardial revascularization, a procedure for treating severe angina. These products are manufactured by PLC Medical Systems Inc. and Edwards Lifesciences is responsible for all sales, marketing and distribution of these products in the United States.

Cardiac Tissue Ablation. The Company's cardiac surgery products also include the *Optimize* surgical ablation system, a photonic laser system for cardiac tissue ablation. This system is expected to be available for commercial sale in the United States in the third quarter of 2003 and in Europe by the end of 2003.

Critical Care

Edwards Lifesciences is a world leader in hemodynamic monitoring systems that are used to measure a patient's heart function in surgical and intensive care settings. Hemodynamic monitoring enables a clinician to balance the oxygen supply and demand of a critically ill patient and plays an important role in assuring that the heart function of millions of patients who have pre-existing cardiovascular conditions or other critical illnesses is optimized before they undergo a surgical procedure.

Edwards Lifesciences' hemodynamic monitoring technologies are often deployed before, during and after open heart, major vascular, major abdominal, neurological and orthopedic surgical procedures. Edwards Lifesciences manufactures and markets the *Swan-Ganz* brand line of hemodynamic monitoring products, originally launched in the 1970s. The latest evolution in the *Swan-Ganz* product line is the *CCOmbo V* catheter. The *CCOmbo V* catheter adds a proprietary continuous volume measurement to the series of continuous parameters already integrated into the device, most notably cardiac output and venous oxygen saturation. Edwards Lifesciences most recent addition to its hemodynamic monitoring product line is the *PreSep* central venous oximetry catheter.

Edwards Lifesciences is also a global leader in the broader field of disposable pressure monitoring devices and has a line of innovative products enabling closed-loop arterial blood sampling to protect both patients and clinicians from the risk of infection. Central venous catheters are the primary route for fluid and medication delivery to patients undergoing major surgical procedures and/or intensive care. The Company's *Advanced Venous Access* products, marketed under the *AVA HF* and *AVA 3Xi* brand names, provide increased convenience, effectiveness and efficiency by integrating the capabilities of an introducer and multi-lumen central venous access into a single device. Edwards Lifesciences *Vantex* central venous catheter, which is manufactured from a patented, antimicrobial material, addresses the potentially life-threatening and costly problems of bloodstream infections.

The Company also markets a range of products required to perform hemofiltration, including access catheters, filters and solutions.

Vascular

The pervasive nature of cardiovascular disease means that the circulatory conditions that occur inside the heart are often mirrored elsewhere in a patient's body. Atherosclerotic disease is one common circulatory condition, which involves the thickening of blood-carrying vessels and the formation of circulation-restricting plaque, clots and other substances, and often occurs concurrently in the vascular system as well as in the heart. When the abdomen, arms or legs are impacted, the diagnosis is usually peripheral vascular disease (PVD), which occurs in millions of patients worldwide.

Edwards Lifesciences manufactures and sells a variety of products used to treat occlusive PVD, including a line of balloon-tipped, catheter-based products, as well as surgical clips and inserts, angioscopy equipment and artificial implantable grafts. 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.

A significant area of interest and investment for Edwards Lifesciences has been the development of endovascular grafts. Edwards Lifesciences has developed the *Lifepath AAA* endovascular graft system to less invasively treat potentially life-threatening abdominal aortic aneurysms. An aneurysm can form in the aorta, the body's main circulatory channel, when a portion of the aortic wall becomes weakened and bulges outward. Often, the aneurysm grows until it poses a life threatening risk of rupturing. The *Lifepath AAA* system treats abdominal aortic aneurysms by introducing an implantable graft that relines the wall of the aorta in the damaged area. By utilizing an endovascular approach, accessing and repairing the aneurysm from within the aorta, rather than making a major incision that exposes most of the body's internal organs, this procedure is less traumatic and less invasive than standard aortic repair surgery. The *Lifepath AAA* system is available for commercial sale in Europe and is undergoing clinical trials in the United States. The Company expects the *Lifepath AAA* system will be available for commercial sale in the United States in late 2004.

In November 2001, Edwards Lifesciences announced an exclusive licensing agreement with Orbus Medical Technologies, Inc. to develop balloon- and self-expanding peripheral stents. Stents are small tubular structures used to prop open the diseased blood vessels of patients suffering from atherosclerotic vascular disease. To accelerate this initiative, the Company has partnered with Syntheon LLC to provide near-term engineering services and limited manufacturing support. Edwards Lifesciences expects to have a broad peripheral stent product offering ready for global release in mid-2003.

Perfusion

Edwards Lifesciences develops, manufactures and distributes a line of disposable perfusion products for customers in regions outside of the United States and Western Europe. These products include the Edwards *Vital* oxygenator and various blood containers, filters and related devices used during the practice of bypassing the heart and lungs during open-heart surgical procedures. Edwards Lifesciences operates an oxygenator manufacturing facility in Brazil.

Edwards Lifesciences also maintains a small perfusion services operation in Europe.

Other Distributed Products

Other distributed products include sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through the Company's distribution network in Japan, and miscellaneous pharmaceutical products sold in the United States.

Competition

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

The medical devices industry is highly competitive. Edwards Lifesciences competes with many companies, ranging from small start-up enterprises to companies that are larger and more established than Edwards Lifesciences with access to significant financial resources. Furthermore, rapid product development and technological change characterize the market in which Edwards Lifesciences competes. The present or future products of Edwards Lifesciences could be rendered obsolete or uneconomical by technological advances by one or more of Edwards Lifesciences' present or future competitors or by other therapies, including drug therapies. Edwards Lifesciences must continue to develop and acquire new products and technologies to remain competitive in the cardiovascular medical devices industry. Edwards Lifesciences believes that it competes primarily on the basis of product

reliability and performance, product features that enhance patient benefit, customer and sales support, and cost-effectiveness.

The cardiovascular segment of the medical device industry is dynamic and currently undergoing significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation and evolving patient needs. The ability to provide cost-effective products and technologies that improve clinical outcomes is becoming increasingly important for medical device manufacturers.

Edwards Lifesciences' products and technologies face substantial competition from a number of companies. In cardiac surgery, the primary competitors include St. Jude Medical, Inc., Medtronic, Inc. and SNIA S.p.A. In critical care, Edwards Lifesciences' principal competitors include Abbott Laboratories and Arrow International, Inc. In vascular, Edwards Lifesciences' primary competitors for the traditional surgical segments of its business include W.L. Gore & Associates, Inc. and Applied Medical Resources Corporation. For the *Lifepath* AAA system and the emerging peripheral vascular disease products, Edwards Lifesciences' competitors are, or are expected to be, Medtronic, Inc., Guidant Corporation, Johnson & Johnson and Boston Scientific Corporation. In perfusion, Edwards Lifesciences competes with SNIA S.p.A., Medtronic, Inc. and Jostra AG.

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, including *Carpentier-Edwards*, *Cosgrove-Edwards*, *Duraflo*, *Fogarty*, *Research Medical*, *Starr-Edwards* and *Swan-Ganz*.

Because of the diverse global needs of the population that Edwards Lifesciences serves, Edwards Lifesciences' distribution system includes a direct sales force and independent distributors. During the year ended December 31, 2002, approximately 8% of Edwards Lifesciences' net sales were from sales to Baxter, the majority of which resulted from sales to Baxter in Japan. In addition, Baxter served as a distributor of Edwards Lifesciences' products or provided distribution services in various other countries outside the United States. As of December 31, 2002, substantially all of these service agreements and relationships had been terminated. The distribution agreement with Baxter for sales in Japan was terminated when Edwards Lifesciences acquired the Japan business effective October 1, 2002. (See *Japan Joint Venture* in Management's Discussion and Analysis of Financial Condition and Results of Operations.) Edwards Lifesciences is not dependent on any single customer and no single customer accounted for more than 10% of Edwards Lifesciences' net sales in 2002.

Sales personnel work closely with the primary decision makers who purchase Edwards Lifesciences' products, which include physicians, material managers, nurses, biomedical staff, hospital administrators and purchasing managers. Also, where appropriate, Edwards Lifesciences' sales force actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations that negotiate contracts with suppliers of medical products. Edwards Lifesciences has contracts with a number of domestic national buying groups and is working with a growing number of regional buying groups that are emerging in response to cost containment pressures and health care reform in the United States.

United States. In the United States, Edwards Lifesciences sells substantially all of its products through its direct sales force. Substantially all of its direct sales force consists of employees of Edwards Lifesciences. In 2002, 54.4% of Edwards Lifesciences' reported sales were derived from sales to customers in the United States. Adjusting for the

impact of the Company's acquisition of the cardiovascular business in Japan, foreign exchange and changes in distribution arrangements, 47.8% of Edwards Lifesciences' sales were derived from the United States.

International. In 2002, 45.6% of Edwards Lifesciences' reported sales were derived internationally through its direct sales force and independent distributors. Adjusting for the impact of the Company's acquisition of the cardiovascular business in Japan, foreign exchange and changes in distribution arrangements, 52.2% of Edwards Lifesciences' sales were derived from international sales. Edwards Lifesciences sells its products in approximately 100 countries. Major international markets for Edwards Lifesciences' products are: Japan, Germany, France, United Kingdom, Italy, Brazil, Canada, Belgium, Spain and The Netherlands. The sales and marketing approach in international geographies varies depending on each country's size and state of development. See Note 16 to the Consolidated Financial Statements contained herein for additional information.

Raw Materials and Manufacturing

Edwards Lifesciences uses a diverse and broad range of raw and organic materials in the design, development and manufacture of its products. Edwards Lifesciences' non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metal. Most of Edwards Lifesciences' heart valve therapy products are manufactured from natural tissues harvested from animal tissue, as well as man-made materials. Edwards Lifesciences 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 assure continuity of supply while maintaining high quality and reliability. Alternative supplier options are generally considered and identified, although Edwards Lifesciences 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. Although a change in suppliers could require significant effort or investment by Edwards Lifesciences in circumstances where the items supplied are integral to the performance of Edwards Lifesciences' products or incorporate unique technology, management does not believe that the loss of any existing supply contract would have a material adverse effect on the Company.

Edwards Lifesciences follows rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy (BSE), commonly known as mad cow disease. 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. The Company 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, where strong control measures and surveillance programs exist and where no BSE cases have been reported. In addition, bovine tissue used in the Company's pericardial tissue valve products are from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. The Company's manufacturing and sterilization processes render tissue biologically safe from all known infectious agents and viruses, and exceed the worldwide standard for sterile medical products.

In 1998, Congress enacted the Biomaterials Access Assurance Act to help ensure a continued supply of raw materials and component parts essential to the manufacture of medical devices by allowing for rapid dismissal of claims against suppliers in some product liability lawsuits if certain facts and circumstances exist. This law has not yet had a material impact, and it is not possible to assess the long-term impact it will have, on the continued availability of raw materials. The inability to develop satisfactory alternatives, if required, or a reduction or interruption in supply or a significant increase in the price of materials or components could have a material adverse effect on Edwards Lifesciences' business.

Quality Assurance

Edwards Lifesciences is committed to providing quality products to its customers. To meet this commitment, Edwards Lifesciences 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 designed to build in quality and to utilize continuous improvement concepts throughout the product lifecycle.

Edwards Lifesciences' operations are certified under applicable international quality systems standards, such as ISO 9001, ISO 9002 and ISO 13485. These standards require, among other items, quality system controls that are applied to product design, component material, suppliers and manufacturing operations. These ISO certifications can be obtained only after a complete audit of a company's quality system has been conducted by an independent outside auditor. Periodic reexamination by an independent outside auditor is required to maintain these certifications.

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 is dedicated to developing novel technologies that will furnish health care providers with a more complete line of products to treat heart valve disease, coronary artery disease, peripheral vascular disease and congestive heart failure.

The Company spent \$65.2 million on research and development in 2002, \$55.0 million in 2001 and \$54.4 million in 2000 (9.3%, 7.9% and 6.8% of net sales, respectively). A majority of Edwards Lifesciences' research and development investment has been applied to extend and defend its core cardiac surgery, critical care and vascular franchises, including research and development relating to next-generation pericardial tissue valves and enhanced tissue processing technologies. Additionally, the Company is investing in activities designed to create new growth platforms including endovascular graft systems, peripheral stents, endovascular heart valve repair and replacement, tissue engineered heart valves, laser-based photonic ablation to treat cardiac arrhythmia, and angiogenesis gene therapy treatment for coronary artery and peripheral vascular diseases.

Edwards Lifesciences' research and development activities are carried out primarily in facilities located in the United States. 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 Edwards Lifesciences' existing and developing products. These studies include clinical trials, which provide data for use in regulatory submissions and post-market approval studies involving applications of Edwards Lifesciences' products.

Proprietary Technology

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Patents and other proprietary rights are important to the success of Edwards Lifesciences' business. Edwards Lifesciences also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain its competitive position. All employees and consultants who have access to confidential and proprietary information, or who are employed to perform duties or services that are likely to result in inventions, are required to sign either the Company's standard employment agreement or the Company's standard consulting agreement. All third parties who are given access to confidential and proprietary information are required to sign the Company's standard outgoing confidentiality agreement. Edwards Lifesciences also reviews third-party

patents and patent applications in an effort to develop an effective patent strategy, identify licensing opportunities and monitor the patent claims of others.

Edwards Lifesciences owns approximately 320 issued United States patents, 130 pending United States patent applications, 575 issued foreign patents and 445 pending foreign patent applications, and has licensed numerous United States patents and patent applications that relate to aspects of the technology incorporated in many of Edwards Lifesciences' products. This proprietary protection often affords Edwards Lifesciences the opportunity to enhance its position in the marketplace by precluding its competitors from using or otherwise exploiting Edwards Lifesciences' technology.

Most of Edwards Lifesciences' products are protected in some way by issued patents and/or pending patent applications. Although the original *Carpentier-Edwards* pericardial valve patent expired in 2002 in most countries, Edwards Lifesciences has several other key patents and pending patent applications in the United States, Europe, Australia, Japan and Canada on improvements to the pericardial valve that enhance and extend the original patent coverage. Because of these design improvements, management does not expect the expiration of the original pericardial patent to have a significant effect on its business. Edwards Lifesciences also has many important United States and foreign patents and pending patent applications related to mitral valve repair and, in particular, patent coverage on the *Cosgrove-Edwards* annuloplasty system and the *Carpentier-Edwards Physio* annuloplasty ring. The *Lifepath AAA* system for endovascular repair of abdominal aortic aneurysms is an important technology that is protected by at least 17 issued United States patents and numerous issued patents and foreign patent applications pending in Europe, Canada, Japan and Australia. Edwards Lifesciences also has a number of key United States and foreign patents and patent applications that cover catheters, systems and methods for measuring and monitoring continuous cardiac output (CCO) and vascular access products, including combinations of introducers and central venous catheters. Many of the CCO and vascular access patents were issued only recently and are expected to protect Edwards Lifesciences' intellectual property rights in such technologies for the next 10 to 15 years. In addition, Edwards Lifesciences has purchased and licensed extensive United States and foreign patents and patent applications in the angiogenesis field.

Although some of Edwards Lifesciences' patents are due to expire within the next six years, Edwards Lifesciences' patent strategy is to file improvement patent applications and, in some cases, additional patent applications covering new aspects or modifications of the affected products, or line extensions of these products. As a result, the duration of some of the patents covering Edwards Lifesciences' products can extend up to 20 years from the date of filing of the patent application. Edwards Lifesciences management does not believe that the expiration of any one or more of its patents that are due to expire in the next six years will cause a material adverse effect on the sales of Edwards Lifesciences' products. In addition, 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 granted various rights in its own patents to others under license agreements. There can be no assurance that pending patent applications will result in issued patents. Competitors may challenge the validity and enforceability of, or circumvent, these patents issued to or licensed by Edwards Lifesciences. Such patents may also be found to be insufficiently broad to provide Edwards Lifesciences with a competitive advantage.

Edwards Lifesciences actively monitors the products of its competitors for possible infringement of Edwards Lifesciences' owned and/or licensed patents. Historically, litigation has been necessary to enforce certain patent rights held by Edwards Lifesciences and Edwards Lifesciences plans to continue to defend and prosecute its rights with respect to such patents. However, the Company's efforts in this regard may not be successful. In addition, patent litigation could result in substantial cost and diversion of effort. Edwards Lifesciences also relies upon trade secrets for protection of its confidential and proprietary information. Others may independently develop substantially equivalent proprietary

information and techniques, and third parties may otherwise gain access to Edwards Lifesciences' trade secrets.

Following are some of the primary trademarks of Edwards Lifesciences that are registered in the United States Patent and Trademark Office:

<i>Advanced Venous Access</i>	<i>Duraflo</i>	<i>PERIMOUNT Plus</i>
<i>AnastaFlo</i>	<i>Edwards MIRA</i>	<i>Starr-Edwards</i>
<i>AVA 3Xi</i>	<i>Edwards Prima Plus</i>	<i>Swan-Ganz</i>
<i>Carpentier-Edwards</i>	<i>Evergrip</i>	<i>Vantex</i>
<i>Carpentier-Edwards Physio</i>	<i>Fogarty</i>	<i>Vigilance</i>
<i>CCOmbo</i>	<i>Lifepath AAA</i>	
<i>Cosgrove-Edwards</i>	<i>PERIMOUNT</i>	

Other key trademarks owned by Edwards Lifesciences:

<i>AVA HF V</i>	<i>Edwards MC³</i>	<i>PreSep</i>
<i>CCOmbo</i>	<i>Everclip</i>	<i>Research Medical</i>
<i>BioPhysio</i>	<i>LifeStent</i>	<i>Thrombex PMT</i>
<i>Edwards</i>	<i>Optimize</i>	<i>VisuFlo</i>
<i>Edwards Lifesciences</i>	<i>PERIMOUNT Magna</i>	<i>XenoLogiX</i>

Many of these trademarks have also been registered for use in certain foreign countries where registration is available and Edwards Lifesciences has determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Regulatory Approvals. In the United States, the Food and Drug Administration (FDA) has responsibility for regulating the introduction of new medical devices. The FDA regulates laboratory and manufacturing practices, labeling and record-keeping for medical devices, and review of required manufacturers' reports of adverse experience to identify potential problems with marketed medical devices. Many of the devices that Edwards Lifesciences develops and markets are in a category for which the FDA has implemented stringent clinical investigation and pre-market approval requirements. The process of obtaining FDA approval to market a product can be resource-intensive, lengthy and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of Edwards Lifesciences' products. Any delay or acceleration experienced by Edwards Lifesciences in obtaining regulatory approvals to conduct clinical trials or in obtaining required market clearances (especially with respect to significant products in the regulatory process that have been discussed in public announcements) may affect Edwards Lifesciences' operations or the market's expectations for the timing of such events and, consequently, the market price for Edwards Lifesciences' common stock. The FDA has the authority to halt the distribution of certain medical

devices, detain or seize adulterated or misbranded medical devices, or order the repair, replacement or refund of the costs of such devices. The FDA also may require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may enjoin and restrain certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. Moreover, the FDA administers certain controls over the export of medical devices from the United States and the importation of devices into the United States.

Medical device laws are also in effect in countries outside of the United States where Edwards Lifesciences does business. These range from comprehensive device approval requirements for some or all of Edwards Lifesciences' medical device products to requests for product data or certifications. The number and scope of these requirements are increasing.

Edwards Lifesciences is also governed by federal, state, local and foreign laws of general applicability, such as those regulating employee health and safety. In addition, Edwards Lifesciences is subject to various federal, state, local and foreign environmental protection laws and regulations, including those governing the adverse impact of material on the environment.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, are continuing in many countries where Edwards Lifesciences does business, including the United States and Japan. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. Although Edwards Lifesciences believes it is well positioned to respond to changes resulting from this worldwide trend toward cost containment, proposed legislation and/or changes in the marketplace could have an adverse impact on future operating results.

Diagnostic-related groups reimbursement schedules regulate the amount the United States government, through the Health and Human Services Centers for Medicare and Medicaid Services, will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. In response to rising Medicare and Medicaid costs, several legislative proposals in the United States have been advanced that would restrict future funding increases for these programs. While Edwards Lifesciences has been unaware of significant domestic price resistance directly as a result of the reimbursement policies of diagnostic-related groups, changes in these reimbursement levels and processes could have an adverse effect on Edwards Lifesciences domestic pricing flexibility.

In keeping with the increased emphasis on cost-effectiveness in health care delivery, the current trend among domestic hospitals and other customers of medical device manufacturers is to consolidate into larger purchasing groups to enhance purchasing power. The medical device industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex and tend to involve more long-term contracts than in the past. The enhanced purchasing power of these larger customers may also increase the pressure on product pricing, although management is unable to estimate the potential impact at this time.

Employees

As of December 31, 2002, Edwards Lifesciences had approximately 5,000 employees worldwide, the majority of whom were located at the Company's headquarters in Irvine, California, and at its manufacturing facility in Puerto Rico. Other major concentrations of employees are located in The Dominican Republic, Europe and Japan. Edwards Lifesciences emphasizes competitive compensation, benefits, equity participation and work environment practices in its efforts to attract and retain qualified personnel. None of Edwards Lifesciences North American employees are represented by a labor union. In various countries outside of North America, the Company interacts with trade unions and work councils that represent a limited number of employees. Edwards Lifesciences has a very engaged workforce as measured by the Gallup Employee Engagement Survey.

Certain Business Risks

This report, including Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements and other prospective information relating to future events. These forward-looking statements and other information are subject to risks and uncertainties that could cause Edwards Lifesciences' actual results to differ materially from historical results or currently anticipated results, including, without limitation, the following:

If Edwards Lifesciences does not introduce new products in a timely manner, its products may become obsolete, and its operating results may suffer.

The cardiovascular products industry is characterized by rapid technological changes, frequent new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, Edwards Lifesciences' products will likely become technologically obsolete over time, in which case Edwards Lifesciences' revenue and operating results would suffer. Even if Edwards Lifesciences is able to develop new technologies, these technologies may not be accepted quickly because of industry-specific factors, such as the need for regulatory clearance, unanticipated restrictions imposed on approved indications, entrenched patterns of clinical practice and uncertainty over third-party reimbursement.

Moreover, significant technical innovations generally will require a substantial investment before Edwards Lifesciences can determine the commercial viability of these innovations. Edwards Lifesciences may not have the financial resources necessary to fund these technical innovations. In addition, even if Edwards Lifesciences is able to successfully develop enhancements or new generations of its products, these enhancements or new generations of products may not produce revenue in excess of the costs of development, and they may be quickly rendered obsolete by changing customer preferences or the introduction by Edwards Lifesciences' competitors of products embodying new technologies or features.

Edwards Lifesciences may incur product liability losses that could adversely affect its operating results.

Edwards Lifesciences' business exposes it to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. Edwards Lifesciences' products are often used in surgical and intensive care settings with seriously ill patients. In addition, some of the medical devices manufactured and sold by Edwards Lifesciences are designed to be implanted in the human body for long periods of time. Edwards Lifesciences could be the subject of product liability suits alleging that 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 patients. Product liability lawsuits and claims, safety alerts or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on Edwards Lifesciences' business and reputation and on its ability to attract and retain customers.

Edwards Lifesciences may experience supply interruptions that could harm its ability to manufacture products.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Edwards Lifesciences uses a diverse and broad range of raw and organic materials and other items in the design and manufacture of its products. Edwards Lifesciences' non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics and metals. Edwards Lifesciences' heart valve therapy products are manufactured from treated natural animal tissue and man-made materials. Edwards Lifesciences purchases certain of the materials and components used in the manufacture of its products from external suppliers. In addition, Edwards Lifesciences purchases certain supplies from single sources for reasons of quality assurance, cost-effectiveness or constraints resulting from regulatory requirements. Edwards Lifesciences works closely with its suppliers to assure continuity of supply while maintaining high quality and reliability. Alternative supplier options are generally considered and identified, although Edwards Lifesciences 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 this regulatory process. Although a change in suppliers could require significant effort or investment by Edwards Lifesciences in circumstances where the items supplied are integral to the performance of Edwards Lifesciences' products or incorporate unique technology, management does not believe that the loss of any existing supply contract would have a material adverse effect on the Company.

In an effort to reduce potential product liability exposure, in the past certain suppliers have announced that they might limit or terminate sales of certain materials and parts to companies that manufacture implantable medical devices. In some cases Edwards Lifesciences has been required to indemnify suppliers for product liability expenses in order to continue to receive materials or parts. There can be no assurance that an indemnity from Edwards Lifesciences will be satisfactory to these suppliers in the future. If Edwards Lifesciences is unable to obtain these raw materials or there is a significant increase in the price of materials or components, its business could be harmed.

Edwards Lifesciences may not successfully identify and complete acquisitions or strategic alliances on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances.

As part of its growth strategy, Edwards Lifesciences regularly reviews potential acquisitions of complementary businesses, technologies, services or products and potential strategic alliances. Edwards Lifesciences may be unable to find suitable acquisition candidates or appropriate partners with which to form partnerships or strategic alliances. Even if Edwards Lifesciences identifies appropriate acquisition or alliance candidates, Edwards Lifesciences may be unable to complete such acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service or product into Edwards Lifesciences' existing business and operations may result in unforeseen operating difficulties and expenditures. Integration of an acquired company also may require significant management resources that otherwise would be available for ongoing development of Edwards Lifesciences' business. Moreover, Edwards Lifesciences may not realize the anticipated benefits of any acquisition or strategic alliance, and such transactions may not generate anticipated financial results. Future acquisitions could also require issuances of equity securities, the incurrence of debt, contingent liabilities or amortization expenses related to other intangible assets, any of which could harm Edwards Lifesciences' business.

Edwards Lifesciences' business is subject to economic, political and other risks associated with international sales and operations.

Because Edwards Lifesciences sells its products in a number of foreign countries, its business is subject to risks associated with doing business internationally. Sales of Edwards Lifesciences originating outside of the United States, as a percentage of total sales, were 45.6% in 2002. Edwards Lifesciences anticipates that sales from international operations will continue to represent a substantial portion of its total sales. In addition, many of Edwards Lifesciences' manufacturing facilities and suppliers are located outside of the United States. Edwards Lifesciences management expects to increase its sales efforts internationally, which could expose it to greater risks associated with international sales and operations. Accordingly, Edwards Lifesciences' future results could be harmed by a variety of factors, including:

changes in foreign medical reimbursement policies and programs;

unexpected changes in foreign regulatory requirements;

changes in foreign currency exchange rates;

changes in a specific country's or region's political or economic conditions, particularly in emerging regions;

trade protection measures and import or export licensing requirements;

potentially negative consequences from changes in tax laws;

difficulty in staffing and managing foreign operations;

differing labor regulations; and

differing protection of intellectual property.

Edwards Lifesciences is subject to risks arising from currency exchange rate fluctuations.

Edwards Lifesciences generated 45.6% of its 2002 sales outside of the United States. Measured in local currency, a substantial portion of Edwards Lifesciences' foreign generated sales were generated in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of Edwards Lifesciences' foreign-generated sales varies with currency exchange rate fluctuations. Significant increases in the value of the United States dollar relative to the Euro or the Japanese Yen, as well as other currencies, could have a material adverse effect on Edwards Lifesciences' results of operations. Edwards Lifesciences has a hedging policy 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 policy may not completely eliminate the effects of currency exchange rate fluctuations.

Fluctuations in Edwards Lifesciences' quarterly operating results may cause Edwards Lifesciences' stock price to decline.

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

demand for and clinical acceptance of products;

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

the timing of sales of products;

changes in foreign currency exchange rates;

unanticipated delays or problems in introducing new products;

competitors' announcements of new products, services or technological innovations;

changes in Edwards Lifesciences' pricing policies or the pricing policies of its competitors;

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

adverse changes in the level of economic activity in the United States and other major regions in which Edwards Lifesciences does business;

costs related to possible acquisitions of technologies or businesses;

Edwards Lifesciences' ability to expand its operations; and

the amount and timing of expenditures related to expansion of Edwards Lifesciences' operations.

Edwards Lifesciences' inability to protect its intellectual property could have a material adverse effect on its business.

Edwards Lifesciences' success and competitive position are dependent, in part, upon its proprietary intellectual property. Edwards Lifesciences relies on a combination of patents, trade secrets and nondisclosure agreements to protect its proprietary intellectual property, and will continue to do so. Although Edwards Lifesciences seeks to protect its proprietary rights through a variety of means, the

Company cannot guarantee that the protective steps it has taken are adequate to protect these rights. Patents issued to or licensed by Edwards Lifesciences in the past or in the future may be challenged and held invalid or not infringed by third parties. Competitors may also challenge Edwards Lifesciences' patents.

Edwards Lifesciences also relies on confidentiality agreements with certain employees, consultants and other parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached and Edwards Lifesciences may not have adequate remedies for any breach. In addition, others may independently develop substantially equivalent proprietary information or gain access to Edwards Lifesciences' trade secrets or proprietary information. Edwards Lifesciences spends significant resources to monitor and enforce its intellectual property rights. However, Edwards Lifesciences may not be able to detect infringement and may lose its competitive position in the industry. In addition, competitors may design around Edwards Lifesciences' technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture increased market position.

Third parties may claim Edwards Lifesciences is infringing their intellectual property, and Edwards Lifesciences could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, Edwards Lifesciences' competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical device industry generally. In the future, Edwards Lifesciences may be forced to defend itself against other claims and legal actions alleging infringement of the intellectual property rights of others. Because intellectual property litigation can be costly and time consuming, Edwards Lifesciences' intellectual property litigation expenses could be significant. Adverse determinations in any such litigation could subject Edwards Lifesciences to significant liabilities to third parties, could require Edwards Lifesciences to seek licenses from third parties and could, if such licenses are not available, prevent Edwards Lifesciences from manufacturing, selling or using certain of its products, any one of which could have a material adverse effect on Edwards Lifesciences.

Third parties could also obtain patents that may require Edwards Lifesciences to either redesign its products or, if possible, negotiate licenses to conduct its business. If Edwards Lifesciences is unable to redesign its products or obtain a license, the Company may have to exit a particular product offering.

Edwards Lifesciences faces intense competition and consolidation within its industry, and if Edwards Lifesciences does not compete effectively, its business will be harmed.

The cardiovascular medical products industry is highly competitive. Edwards Lifesciences competes with many companies, some of which have longer operating histories, better brand or name recognition and greater access to financial and other resources than Edwards Lifesciences. Furthermore, the industry is characterized by intensive development efforts and rapidly advancing technology. Edwards Lifesciences' present and future products could be rendered obsolete or uneconomical by technological advances by one or more of Edwards Lifesciences' current or future competitors or by alternative therapies, including drug therapies. The future success of Edwards Lifesciences will depend, in large part, on its ability to anticipate technology advances and keep pace with other developers of cardiovascular therapies and technologies.

The medical device industry has been consolidating and as a result, transactions with customers are larger, more complex and tend to involve more long-term contracts. The enhanced purchasing power of these larger customers may also increase downward pressure on product pricing. In addition, many existing and potential domestic customers for Edwards Lifesciences' products have combined to form Group Purchasing

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Organizations (GPOs). GPOs negotiate pricing arrangements with medical supply manufacturers and distributors and these negotiated prices are made available to members of GPOs. If Edwards Lifesciences is not one of the providers selected by a GPO, Edwards Lifesciences may be

precluded from making sales to members of a GPO for several years. Even if Edwards Lifesciences is one of the selected providers, the Company 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, Edwards Lifesciences may be required to commit to pricing that has a material adverse effect on sales and profit margins, the business, financial condition and results of operations of Edwards Lifesciences.

Edwards Lifesciences and its customers are subject to various governmental regulations, and Edwards Lifesciences may incur significant expenses to comply with these regulations and develop its products to be compatible with these regulations.

The medical devices manufactured and marketed by Edwards Lifesciences are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. Delays in receipt of, or failure to obtain, approvals for future products could result in delayed realization of product revenues or in substantial additional costs, which could have material adverse effects on Edwards Lifesciences' business or results of operations. In addition, there can be no assurance that Edwards Lifesciences will be or will continue to be in compliance with applicable FDA and other material regulatory requirements. If the FDA were to conclude that Edwards Lifesciences was not in compliance with applicable laws or regulations, it could institute proceedings to detain or seize Edwards Lifesciences' products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against Edwards Lifesciences, its officers or its employees and could recommend criminal prosecution to the Department of Justice. Moreover, the FDA could proceed to ban, or request recall, repair, replacement or refund of the cost of, any device or product manufactured or distributed by Edwards Lifesciences. Furthermore, both the FDA and foreign government regulators have become increasingly stringent, and Edwards Lifesciences may be subject to more rigorous regulation by governmental authorities in the future.

Edwards Lifesciences is subject to risks arising from concerns and/or regulatory actions relating to BSE.

Certain of Edwards Lifesciences products, including pericardial tissue valve products, are manufactured using bovine tissue. Concerns relating to the potential transmission of BSE from cows to humans may result in reduced acceptance in certain geographies of bovine products. In addition, various governmental bodies are considering stricter regulation of such products. The Company obtains its bovine tissue only from sources within the United States, where strong control measures and surveillance programs exist and where no BSE cases have been reported. In addition, the bovine tissue used in the Company's pericardial tissue valve products are from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. The Company has not experienced any adverse impact on its 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 Edwards Lifesciences customers for Edwards Lifesciences products or reduce reimbursement levels, Edwards Lifesciences' ability to profitably sell its products will be harmed.

Edwards Lifesciences sells its products and technologies to hospitals, doctors and other health care providers, all of which receive reimbursement for the health care services provided to their patients from third-party payors, such as government programs (both domestic and international), private insurance plans and managed care programs. These 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 payor, or was used for an unapproved indication. Third-party payors may also decline to reimburse for experimental procedures and devices. Many of Edwards Lifesciences' existing and future products are cost-effective because they are intended to reduce overall

health care costs over a long period of time. Edwards Lifesciences cannot be certain whether these third-party payors will recognize these cost savings or will merely focus on the lower initial costs associated with competing therapies. If Edwards Lifesciences' products are not considered cost-effective by third-party payors, Edwards Lifesciences' customers may not be reimbursed for the Company's products.

In addition, 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 Edwards Lifesciences' products. In Japan, customers are reimbursed for Edwards Lifesciences products under a government-operated insurance system. Under this system, the Japanese government annually reviews the reimbursement levels for products. The Japanese government is also considering other reimbursement regulation. If the Japanese government decides to reduce reimbursement levels for Edwards Lifesciences' products, Edwards Lifesciences' product pricing may be adversely affected.

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 and Manufacturing
Memphis, Tennessee	(1)	Distribution and Logistics
Midvale, Utah	(1)	Administration, Research and Development and Manufacturing
Haina, The Dominican Republic	(2)	Manufacturing
Anasco, Puerto Rico	(2)	Manufacturing

Europe

Horw, Switzerland	(2)	Administration, Distribution and Manufacturing
Saint Prex, Switzerland	(2)	European Headquarters

South America

São Paulo, Brazil	(1),(2)	Administration, Distribution and Manufacturing
-------------------	---------	--

Japan

Tokyo, Japan	(2)	Japan Headquarters, Distribution
Miyazaki, Japan	(2)	Manufacturing, Distribution

(1) Owned property.

(2) Leased property.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

The Dominican Republic lease expires in 2006; the Puerto Rico lease expires in 2008; the Horw, Switzerland lease expires in 2003; the Saint Prex, Switzerland lease expires in 2005; and the São Paulo, Brazil lease expires in 2003. The Company's properties have been well maintained, are in good operating condition and are adequate for current needs.

Item 3 Legal Proceedings

On June 29, 2000, Edwards Lifesciences filed a lawsuit for patent infringement against Medtronic, Inc., which, as amended, alleged infringement of three Edwards Lifesciences United States patents. On September 18, 2001, Edwards Lifesciences filed a separate complaint against Medtronic

alleging infringement of a fourth Edwards Lifesciences United States patent. These lawsuits were filed in the United States District Court for the District of Delaware. Effective April 24, 2002, Edwards Lifesciences entered into an agreement with Medtronic resolving these patent infringement claims and dismissing the two lawsuits. Under the terms of the settlement, Edwards Lifesciences received a one-time cash payment of \$20.0 million (recorded as a gain of \$14.7 million, net of legal expenses, in Other (Income) Expense, net) and granted Medtronic a royalty-bearing license on two of the Edwards Lifesciences patents. In addition, on July 2, 2002, Edwards Lifesciences and Medtronic submitted to binding arbitration on another of the patents in dispute. Medtronic prevailed in this arbitration and will not require an additional license.

On June 29, 2000, Edwards Lifesciences also filed a lawsuit against St. Jude Medical, Inc. alleging infringement of three Edwards Lifesciences United States patents. This lawsuit was filed in the United States District Court for the Central District of California, seeking monetary damages and injunctive relief. St. Jude has answered and asserted various affirmative defenses and counterclaims with respect to the lawsuits. On April 9, 2002, a fourth Edwards Lifesciences United States patent was added to the lawsuit. Discovery is proceeding.

In addition, Edwards Lifesciences is, or may be, a party to, or may be otherwise 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 and complexities, 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 pending legal matters, Edwards Lifesciences may incur charges in excess of presently established reserves. While such a charge could have a material adverse impact on Edwards Lifesciences net income or net cash flows in the period in which it is recorded or paid, management believes that no such charge would have a material adverse effect on Edwards Lifesciences consolidated financial position.

Edwards Lifesciences is also 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 compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences financial position, results of operations or liquidity.

Item 4 Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2002.

PART II

Item 5 Market for the Registrant's Common Equity and Related Stockholder Matters*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:	2002		2001	
	High	Low	High	Low
March 31	\$ 29.60	\$ 25.00	\$ 22.75	\$ 16.75
June 30	28.05	22.18	26.45	17.80
September 30	25.75	18.40	28.00	20.40
December 31	27.50	23.81	29.15	22.60

Number of Stockholders

On February 28, 2003, there were 38,593 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.

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. No per share data for the years 2000 and prior have been presented because Edwards Lifesciences' earnings were part of Baxter's earnings through the close of business on March 31, 2000. See Note 4 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 asset divestitures on Edwards Lifesciences' operations.

		As of or for the years ended December 31				
		2002	2001	2000	1999	1998
		(in millions except per share data)				
OPERATING RESULTS(a)						
	Net sales	\$ 704.0	\$ 692.1	\$ 803.8	\$ 905.0	\$ 865.0
	Gross profit	404.9	368.4	380.5	439.0	399.0
	Income (loss) from continuing operations(b)	55.7	(11.4)	(271.7)	82.0	62.0
BALANCE SHEET DATA						
	Total assets(c)	\$ 1,008.2	\$ 982.9	\$ 1,106.7	\$ 1,437.0	\$ 1,483.0
	Long-term debt and lease obligations	245.5	309.8	367.2		
COMMON STOCK INFORMATION						
	Income (loss) from continuing operations per common share:					
	Basic	\$ 0.94	\$ (0.19)			
	Diluted	0.91	(0.19)			
	Cash dividends declared per common share					

(a) The results prior to April 1, 2000 present Edwards Lifesciences on a divisional basis as it had historically been operated as part of Baxter. From April 1, 2000 (the date following the distribution of the Company's common stock to stockholders of Baxter) to September 30, 2002, Edwards Lifesciences Japan business is presented on an equity basis as opposed to the consolidation method reflected in the historical results. Commencing October 1, 2002, the Company began reporting the results of its Japan business on a fully consolidated basis. See "Joint Venture in Japan" in Management's Discussion and Analysis of Financial Condition and Results of Operations for more information.

(b) See Note 4 to the Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations for additional information regarding charges of \$67.4 million, \$83.0 million and \$312.2 million during 2002, 2001 and 2000, respectively.

(c) See Note 4 to the Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations for additional information regarding the write down of goodwill of \$80.7 million and \$282.0 million during 2001 and 2000, respectively.

Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis present the factors that had a material effect on the results of operations of Edwards Lifesciences during the three years ended December 31, 2002. Also discussed is Edwards Lifesciences' financial position as of December 31, 2002. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K.

Certain disclosures prepared in accordance with Generally Accepted Accounting Principles (GAAP) contained in this discussion are not prepared in conformity with GAAP. These non-GAAP disclosures, and the basis for reflecting them, are set forth below:

Foreign Exchange

Fluctuation in exchange rates impacts the comparative results and growth rates of the Company's underlying business. By excluding the impact of foreign exchange rate fluctuations, management explains changes in the fundamental business operations.

Japan Operations

Prior to the spin-off from Baxter, the operations of the Japanese business were consolidated with the Company's operations. Subsequent to the spin-off, the Company had a 90% interest in the operations of the Japanese business. However, participating rights granted to Baxter at the time of spin-off precluded the Company from consolidating these results under GAAP. Also at the time of spin-off, the Company was granted an option to acquire 100% of the operations (see Joint Venture in Japan). Due to the significance of the Japanese business on the Company's results, the Company's influence on the Japan operations and the Company's plans to ultimately exercise its option, the Company has presented information as if the Japan business had always been consolidated. As the Company acquired the Japanese business in October 2002, these comparisons to prior years are more informative to both management and readers of the financial statements.

Non-strategic Businesses

Subsequent to the spin-off from Baxter, the Company made the decision to exit certain non-strategic businesses, which had significant contributions to sales and, due to the losses upon divestiture, had a significant impact on the profitability of the Company in the year of disposition. In order to illustrate the impact, if any, these divestitures have on the Company's ongoing business operations, the results of these divestitures were excluded from the Company's GAAP results (see Disposition of Assets and Other Charges, net).

Management has determined that inclusion of these non-GAAP disclosures provides (1) a more meaningful, consistent comparison of the Company's operating results for the periods presented, on a basis consistent with management's means of evaluating operating performance, and (2) additional information for investors to assess changes between periods that better reflect the Company's ongoing operations.

Overview

Edwards Lifesciences is a global provider of products and technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address four main cardiovascular disease states:

heart valve disease;

coronary artery disease;

peripheral vascular disease; and

congestive heart failure.

The products and services provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas:

Cardiac Surgery;

Critical Care;

Vascular;

Perfusion; and

Other Distributed Products.

Edwards Lifesciences' cardiac surgery portfolio is comprised primarily of products relating to heart valve therapy, transmyocardial revascularization, and cannula products used during open-heart surgery. Edwards Lifesciences is the world's leader in, and has been a pioneer in the development and commercialization of, tissue valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the critical care area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's heart

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

function, and also provides central venous access products for fluid and drug delivery. Edwards Lifesciences' vascular portfolio includes a line of balloon catheter-based products, surgical clips and inserts, angioscopy equipment, artificial implantable grafts, and an endovascular system used to treat life-threatening abdominal aortic aneurysms less invasively. In the perfusion category, Edwards Lifesciences develops, manufactures and markets, in regions outside

the United States and Western Europe, a diverse line of disposable products used during cardiopulmonary bypass procedures, including oxygenators, blood containers, filters and related devices. Effective June 30, 2001, the Company sold its perfusion services business in the United States to an affiliate of Fresenius Medical Care AG (see Disposition of Assets and Other Charges, net). The Company continues to maintain a small perfusion services business in Europe. Lastly, other distributed products include sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through the Company's distribution network in Japan, and miscellaneous pharmaceutical products sold in the United States.

The health care marketplace continues to be competitive. There has been consolidation in Edwards Lifesciences' customer base and among its competitors, which has resulted in pricing and market share pressures. Edwards Lifesciences has experienced increases in its labor and material costs, which are primarily influenced by general inflationary trends. Management expects these trends to continue.

Joint Venture in Japan

The Japanese business is included in the Consolidated Statements of Operations for the three months ended March 31, 2000, consistent with the historical treatment of the Company's operations while a part of Baxter. Subsequent to the distribution of the Company's common stock to stockholders of Baxter on March 31, 2000 (referred to as the Distribution), the cardiovascular business in Japan was being operated pursuant to a joint venture under which a Japanese subsidiary of Baxter retained ownership of the Japanese business assets, but a subsidiary of Edwards Lifesciences held a 90% profit interest. Edwards Lifesciences was given an option to purchase the Japanese business assets that was exercisable no earlier than August 1, 2002 and no later than March 31, 2005. From April 1, 2000 to September 30, 2002, Edwards Lifesciences (a) recognized its shipments into the joint venture as sales at distributor price at the time the joint venture sold to the end customer, and (b) utilized the equity method of accounting to record its 90% profit interest in the operations of the joint venture in Other Operating Income.

On October 1, 2002, the Company acquired from Baxter for \$19.0 million, net, the cardiovascular business in Japan. The purchase price excluded approximately \$30 million of securitized accounts receivable. In the three months ended September 30, 2002, the Company recorded a \$3.3 million charge for legal, administrative and regulatory expenses related to the acquisition. Commencing October 1, 2002 the Company began reporting the results of the Japan business on a fully consolidated basis. The acquisition did not materially impact the Company's net income as the terms of the joint venture agreement enabled Edwards Lifesciences to record substantially all of the net profit generated by the Japan business.

Results of Operations

Net Sales Trends

The following table is a summary of domestic and international net sales (dollars in millions):

Years Ended December 31,			Percent Change	
2002	2001	2000	2002	2001

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

United States	\$	383.3	\$	420.8	\$	481.8	(8.9)%	(12.7)%
International		320.7		271.3		322.0	18.2%	(15.7)%
Total net sales	\$	704.0	\$	692.1	\$	803.8	1.7%	(13.9)%

The net sales decreases in the United States during 2002 and 2001 were due primarily to the sale of the Company's perfusion services business in the United States effective June 30, 2001, partially

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

offset by an increase in sales of cardiac surgery products. The 2001 decrease was also impacted by the sale of the Company's perfusion products line effective August 31, 2000 (see Disposition of Assets and Other Charges, net for more information regarding the sales of the perfusion services and products lines).

The increase in international net sales in 2002 and the decrease in 2001 resulted primarily from the change in accounting for sales in Japan (see Joint Venture in Japan). Assuming the Japan business was consolidated for all periods presented, international net sales for the years 2002 and 2001 would have increased 4.5% and decreased 7.2%, respectively. Additionally, excluding the impact of changes in foreign currency exchange rates (primarily the movement of the United States dollar against the Euro and the Japanese Yen), international net sales for the years 2002 and 2001 would have increased 5.5% and 1.3%, respectively. These adjusted fluctuations were due primarily to an increase in sales of cardiac surgery products, offset in 2001 by the partial sale of the Company's perfusion products line effective August 31, 2000.

The impact of foreign currency exchange rate fluctuations on net sales would not necessarily be indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs, and Edwards Lifesciences' hedging activities. For more information, see Quantitative and Qualitative Disclosure About Market Risk.

Net Sales by Product Line

The following table is a summary of net sales by product line (dollars in millions):

	Years Ended December 31,			Percent Change	
	2002	2001	2000	2002	2001
Cardiac Surgery	\$ 365.9	\$ 329.0	\$ 311.2	11.2%	5.7%
Critical Care	230.3	209.9	217.3	9.7%	(3.4)%
Vascular	51.3	49.3	54.8	4.1%	(10.0)%
Perfusion	43.2	102.1	206.7	(57.7)%	(50.6)%
Other Distributed Products	13.3	1.8	13.8	638.9%	(87.0)%
Total net sales	\$ 704.0	\$ 692.1	\$ 803.8	1.7%	(13.9)%

Commencing October 1, 2002 the Company began reporting the results of its Japan business on a fully consolidated basis. Assuming the Japan business was consolidated for all periods presented, net sales by product line would have been as follows (dollars in millions):

	Years Ended December 31,			Percent Change	
	2002	2001	2000	2002	2001
Cardiac Surgery	\$ 375.0	\$ 338.6	\$ 317.9	10.8%	6.5%
Critical Care	251.1	245.2	247.7	2.4%	(1.0)%
Vascular	53.3	52.3	57.3	1.9%	(8.7)%
Perfusion	58.6	122.6	221.3	(52.2)%	(44.6)%

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Other Distributed Products	43.2	42.5	47.2	1.6%	(10.0)%
Total net sales	\$ 781.2	\$ 801.2	891.4	(2.5)%	(10.1)%

Assuming the Japan business was consolidated for all periods presented, excluding the impact of foreign currency exchange rate fluctuations and assuming the sales of (a) the mechanical cardiac assist product line, (b) the perfusion product line and (c) the perfusion services business had occurred as of

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

January 1, 2000 (see Disposition of Assets and Other Charges, net), net sales by product line (Adjusted Net Sales) would have changed as follows (dollars in millions):

	Years Ended December 31,			Percent Change	
	2002	2001	2000	2002	2001
Cardiac Surgery	\$ 376.4	\$ 338.6	308.7	11.2%	9.7%
Critical Care	258.6	250.6	240.5	3.2%	4.2%
Vascular	53.6	52.5	55.6	2.1%	(5.6)%
Perfusion	63.4	66.2	70.1	(4.2)%	(5.6)%
Other Distributed Products	49.0	46.4	46.2	5.6%	0.4%
Total net sales	\$ 801.0	\$ 754.3	\$ 721.1	6.2%	4.6%

Cardiac Surgery

The Adjusted Net Sales growth in 2002 and 2001 in cardiac surgery products resulted primarily from strong sales growth of pericardial tissue valves and heart valve repair products in the United States and Japan. Management expects that its heart-valve therapy products will continue to serve as a key driver of Edwards Lifesciences sales growth.

Critical Care

The Adjusted Net Sales growth in 2002 and 2001 in critical care products was due primarily to strong sales of advanced technology catheter products and access and hemofiltration products, partially offset by the decline in base hemodynamic catheters. Critical care products have been, and are expected to continue to be, significant contributors to Edwards Lifesciences total sales.

Vascular

The Adjusted Net Sales growth for vascular products for 2002 was primarily the result of initial sales of the *Lifepath AAA* endovascular graft system, which offset declining sales of the Company's base vascular products due to the ongoing shift to less invasive therapies and non-surgical options. The decline in Adjusted Net Sales for vascular products for 2001 resulted primarily from declines in base vascular products, and the wind-down of a distribution contract in France during 2001.

Management continues to see opportunities in less invasive peripheral vascular disease treatments and intends to build on the Company's strong base franchise by developing and marketing products such as (a) its *Lifepath AAA* endovascular graft system, which is currently being marketed in Europe and undergoing clinical studies in the United States, and (b) a broad peripheral stent offering, which is scheduled for launch in mid-2003.

Perfusion

The Adjusted Net Sales decrease for perfusion for 2002 and 2001 was due primarily to an ongoing reduction of sales to Jostra AG, the purchaser during 2000 of the Company's line of perfusion products in Western Europe and the United States. Additionally, in 2001 there was a decline in perfusion services in Western Europe due to a continually increasing number of beating heart coronary artery bypass surgeries. The Company anticipates that sales of distributed perfusion products in certain regions and its sales to Jostra will continue to decline.

Other Distributed Products

Other distributed products includes sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through the Company's distribution network in Japan, and

miscellaneous pharmaceutical products sold in the United States. The increase in Adjusted Net Sales in 2002 is spread across several product categories.

Gross Profit

	Years Ended December 31,			Percentage Point Increase	
	2002	2001	2000	2002	2001
Gross profit as a percentage of net sales	57.5%	53.2%	47.3%	4.3pts.	5.9pts.

Reflecting the Japanese business on a consolidated basis for all periods presented, and assuming the sales of the mechanical cardiac assist product line, the perfusion products line and the perfusion services business (see Disposition of Assets and Other Charges, net) had occurred on January 1, 2000, gross profit as a percentage of net sales (Adjusted Percentage) would have been 57.7% in 2002, 57.1% in 2001 and 55.2% in 2000.

The increase in the Adjusted Percentage for 2002 and 2001 was due primarily to increased sales of higher-margin cardiac surgery products, offset in 2002 by the impact of foreign exchange.

Selling, General and Administrative (SG&A) Expenses

	Years Ended December 31,			Percentage Point Increase	
	2002	2001	2000	2002	2001
SG&A expenses as a percentage of net sales	32.4%	29.4%	26.8%	3.0pts.	2.6pts.

Reflecting the Japanese business on a consolidated basis for all periods presented, and assuming the sales of the mechanical cardiac assist product line, the perfusion products line and the perfusion services business (see Disposition of Assets and Other Charges, net) had occurred on January 1, 2000, SG&A expenses as a percentage of net sales (Adjusted Percentage) would have been 33.5% in 2002, 32.8% in 2001 and 31.0% in 2000.

The increase in the Adjusted Percentage for 2002 was due primarily to increased spending on heart valve growth opportunities and the impact of foreign exchange. The Adjusted Percentage increase in 2001 was due primarily to additional personnel costs and expenses associated with the Company's operation as an independent company commencing April 1, 2000.

Research and Development Expenses

	Years Ended December			Percentage Point	
	2002	31, 2001	2000	2002	2001
Research and development expenses as a percentage of net sales	9.3%	7.9%	6.8%	1.4pts.	1.1pts.

Reflecting the Japanese business on a consolidated basis for all periods presented, and assuming the sales of the mechanical cardiac assist product line, the perfusion products line and the perfusion services business (see Disposition of Assets and Other Charges, net) had occurred on January 1, 2000, research and development expenses as a percentage of net sales (Adjusted Percentage) would have been 8.7% in 2002, 7.8% in 2001 and 6.7% in 2000.

The Adjusted Percentage increases in research and development expenses relate primarily to investments in the Company's peripheral vascular disease platform and other growth initiatives. These increases reflect Edwards Lifesciences' commitment to ongoing research and development to deliver

advanced new products, to enhance the effectiveness, ease of use, safety and reliability of its current products and to expand the applications of its products as appropriate.

Goodwill Amortization

The elimination of goodwill amortization for the year 2002 resulted from the adoption of Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets (see New Accounting and Disclosure Standards Issued). Effective January 1, 2002, the accounting for goodwill changed from an amortization method to an impairment-only approach.

The reduction in goodwill amortization for the year 2001 resulted primarily from (a) the sale of the perfusion services business in the United States and the disposition of the related goodwill effective June 30, 2001, and (b) the write-down of goodwill related to the sale of the Company s line of perfusion products in the United States and Western Europe effective June 30, 2000 (see Disposition of Assets and Other Charges, net).

Disposition of Assets and Other Charges, net

2002

In September 2002, the Company recorded a \$67.4 million pretax charge related to the impairment of its investment in preferred stock of World Heart Corporation (WorldHeart).The investment was written down to \$6.2 million, which represented the value of the Company s preferred stock investment had it been converted into common stock at October 15, 2002 (the closing date of September s books). The decision to record the charge was based primarily on WorldHeart s September 2002 decision to refocus its product development efforts by adopting a new design concept for a next generation product that resulted in a significant delay (approximately two years) in its product development timeline (with a revised commercial launch date of 2007) and impaired WorldHeart s competitive position. Accordingly, the Company concluded that sufficient risk existed that WorldHeart may be unable to fully liquidate the Company s investment in WorldHeart s preferred stock. The Company believed that the best objective indicator of the then fair value of its investment in WorldHeart s preferred stock was the market price of WorldHeart s common stock based upon the Company s expectation that the value of its preferred stock investment would be realized through the common stock, as opposed to redemption of the preferred stock.

2001

Loss on Sale of Assets (\$68.2 million)

Effective June 30, 2001, the Company sold the stock of Edwards Lifesciences Cardiovascular Resources, Inc. (ELCR) to Fresenius Medical Care AG (Fresenius) for cash proceeds of \$45.0 million (the ELCR Sale), resulting in a pre-tax loss of \$68.2 million. ELCR provided and managed perfusionists, monitoring systems, capital equipment and disposable material on a contract service basis to hospitals in the United

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

States and Puerto Rico.

The following unaudited pro forma consolidated condensed statement of operations gives effect to the ELCR Sale as if it had occurred on January 1, 2001 and excludes the \$68.2 million loss on the sale. The unaudited pro forma consolidated condensed statement of operations does not purport to be indicative of either the results of future operations or the results of operations that would have occurred had the ELCR Sale been consummated on January 1, 2001. The following amounts are in millions, except per share amounts:

	Year Ended December 31, 2001
Net sales	\$ 631.1
Net income	45.9
Net loss per share:	
Basic	0.78
Diluted	0.75

Other Charges (\$14.8 million)

Based upon the non-strategic nature and declining profitability of certain products in the Company's portfolio (including certain distributed products), the Company decided during the quarter ended June 30, 2001 to discontinue its sales effort of these products. The long-lived assets and the investments related to these products were evaluated to determine whether any impairment in their recoverability existed at the determination date. As a result, Edwards Lifesciences assessed whether the estimated cash flows of the products or investments over the estimated lives of the related assets were sufficient to recover their costs. Where such cash flows were insufficient, the Company utilized a discounted cash flow model to estimate the fair value of assets or investments and recorded an impairment charge to adjust the carrying values to estimated fair values. As a result of this evaluation, Edwards Lifesciences recorded a non-cash charge of \$14.8 million primarily related to the impairment of intangibles (\$8.3 million), the impairment of an investment (\$5.5 million) and the write-down of non-productive assets (\$1.0 million).

2000*Loss on Sale and Abandonment of Assets (\$302.0 million)*

During 2000, the Company sold the majority of its United States and Western European assets and rights related to its perfusion products to Jostra AG (the Jostra Sale). In accordance with SFAS No.121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of, and Staff Accounting Bulletin No. 100, Restructuring and Impairment Charges, the Company recorded a pre-tax impairment charge of \$290.5 million in 2000 to reduce the carrying value of these assets to fair value based upon the estimated net proceeds from the Jostra Sale. Assets subject to this impairment charge consisted primarily of goodwill (\$245.0 million) and special-use manufacturing and support assets. The goodwill impairment charge was calculated based upon a pro rata allocation of the goodwill using the relative fair values of the affected long-lived assets and identifiable intangibles acquired at the inception date of the goodwill. On August 31, 2000, Edwards Lifesciences completed the Jostra Sale for \$24.0 million (consisting of \$10.0 million in cash and a \$14.0 million note receivable, payable in six equal quarterly installments through March 1, 2002, plus interest at an annual effective rate of 8%). All payments under the note have been made.

In conjunction with the Jostra Sale, during 2000 the Company recorded charges to establish a \$9.7 million reserve for personnel costs and a \$1.8 million reserve for exit activities. The personnel costs consisted primarily of severance, medical plan continuation and outplacement services for the approximately 225 employees impacted by the Jostra Sale. The impacted employees were located in Europe, the United States and Puerto Rico, and primarily worked in a manufacturing capacity. The exit activities consisted primarily of information systems costs, contract termination costs and shutdown expenses.

The following table summarizes the utilization of these reserves through December 31, 2001 (in millions):

	Initial Reserve	Utilized in 2000	Balance at December 31, 2000	Utilized in 2001	Balance at December 31, 2001
Personnel costs	\$ 9.7	\$ (1.8)	\$ 7.9	\$ (7.9)	\$
Exit activities	1.8	(1.4)	0.4	(0.4)	

\$ 11.5 \$ (3.2) \$ 8.3 \$ (8.3) \$

Gain on Sale of Assets (\$35.0 million)

On June 30, 2000, Edwards Lifesciences transferred the rights, intellectual property and United States assets related to the Novacor mechanical cardiac assist product line to WorldHeart. In return, the Company received (a) preferred stock of a subsidiary of WorldHeart which, at Edwards option, can be exchanged for approximately five million shares of WorldHeart's common stock commencing July 2003, bears a cumulative dividend and matures in June 2015, and (b) exclusive worldwide distribution rights to the Novacor left ventricular assist system and any ventricular assist technologies developed by WorldHeart. Edwards Lifesciences also will provide components and technical support to WorldHeart for ventricular assist products at agreed upon prices. The Company recorded a pre-tax gain of \$35.0 million during 2000 in connection with this transaction.

As part of the transaction with WorldHeart, the Company invested \$20.0 million in WorldHeart convertible preferred stock. The preferred stock bears a cumulative dividend, matures in June 2007, is callable at any time by WorldHeart and is convertible by Edwards Lifesciences into WorldHeart common stock commencing July 2006. Edwards Lifesciences reports its investments in WorldHeart as available-for-sale securities.

The following unaudited pro forma consolidated condensed statement of operations gives effect to the sales to Jostra AG and WorldHeart by Edwards Lifesciences as if the sales had occurred on January 1, 2000 and exclude the \$302.0 million loss on sale to Jostra AG and the \$35.0 million gain on sale to WorldHeart. The unaudited pro forma consolidated condensed statement of operations does not purport to be indicative of either the results of future operations or the results of operations that would have occurred had the sales been consummated on January 1, 2000. The following amounts are in millions, except per share amounts:

	Year Ended December 31, 2000
Net sales	\$ 771.9
Net income	8.2
Net income per share:	
Basic	0.14
Diluted	0.13

Other Charges (\$45.2 million)

As a result of Edwards Lifesciences' continuing efforts to focus the Company's product portfolio and effect the Company's business strategy following the spin-off from Baxter, during 2000 the Company decided to discontinue certain products in its portfolio that did not meet the objectives of its business strategy. The long-lived assets or the investments in these products were evaluated to determine whether any impairment in their recoverability existed at the determination date. As a result, Edwards Lifesciences assessed whether the estimated cash flows of the products over the estimated lives of the related assets were sufficient to recover their costs. Where such cash flows were insufficient, the Company utilized a discounted cash flow model to estimate the fair value of assets or investments and recorded an impairment charge to adjust the carrying values to estimated fair values. As a result of this evaluation, Edwards Lifesciences recorded a non-cash charge of \$45.2 million during 2000 primarily related to the impairment of goodwill unrelated to perfusion products (\$37.0 million), impairment of other intangibles (\$5.1 million) and the write-down of non-productive assets (\$3.1 million).

Non-recurring Spin-off Expenses

During the quarter ended September 30, 2002, the Company recorded a \$3.3 million charge for legal, administrative and regulatory expenses related to the acquisition of the cardiovascular business in Japan (see [Joint Venture in Japan](#)).

In connection with the spin-off of Edwards Lifesciences from Baxter, Edwards Lifesciences incurred certain one-time costs totaling \$18.4 million during 2000. These costs primarily related to the coordination and implementation of the transaction and the recruitment of personnel to perform new corporate administrative functions.

Other Operating Income

Other operating income was \$11.0 million and \$16.4 million in 2002 and 2001, respectively. Other operating income represents the Company's 90% profit interest in the cardiovascular business in Japan effective from April 1, 2000 through September 30, 2002. For more information, see [Joint Venture in Japan](#).

Interest Expense, net

Interest expense, net was \$11.5 million and \$22.9 million in 2002 and 2001, respectively. The decrease in interest expense, net for 2002 resulted primarily from (a) the Company's reduction of debt, (b) lower interest rates on its floating rate debt, and (c) a \$6.2 million charge during the three months ended June 30, 2001 related to a payment to unwind an interest rate swap agreement that had locked in a fixed interest rate on \$75.0 million of floating rate debt. The decision to unwind the interest rate swap agreement resulted from the Company's pay-down of underlying floating rate debt not anticipated to be necessary in funding future requirements of working capital, capital expenditures and other financial commitments.

The increase in interest expense, net for 2001 resulted primarily from the \$6.2 million charge to unwind the interest rate swap agreement, described above, partially offset by the impact of the Company's reduction of debt and lower interest rates on its floating rate debt.

Other (Income) Expense, net

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

Years Ended December 31,		
2002	2001	2000

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Legal settlement, net	\$	(14.7)	\$	\$
Foreign exchange (gain) loss		(4.1)		2.3
Asset dispositions and write-downs, net		2.3		6.5
Investment write-offs		1.4		
Other		(0.3)		(0.9)
	\$	(15.4)	\$	10.6
			\$	3.8

Effective April 24, 2002, Edwards Lifesciences and Medtronic, Inc. entered into an agreement related to certain patent infringement claims pursuant to which the Company received a one-time cash payment of \$20.0 million (recorded as a gain of \$14.7 million, net of legal expenses).

Foreign exchange gains and losses relate to global trade and intercompany receivable balances.

Provision for Income Taxes

The effective income tax rates for 2002, 2001 and 2000 were impacted by several items as follows (in millions):

	Years Ended December 31,		
	2002	2001	2000
Provision for income taxes on recurring operations	\$ 29.1	\$ 24.5	\$ 18.4
Tax benefit from sale of perfusion services subsidiary in 2001	(20.1)	(11.9)	
Tax benefit from impairment charge on WorldHeart investment	(13.3)		
Impact of legal settlement	5.6		
Other	(1.0)	(11.1)	(5.1)
Provision (benefit) for income taxes, as reported	\$ 0.3	\$ 1.5	\$ 13.3

As a result of recent tax law developments and the filing of the Company's 2001 tax return, the Company recorded a \$20.1 million tax benefit during 2002 related to the loss on sale of its United States perfusion services business in June 2001.

Excluding the impact of non-recurring items, the effective income tax rate was 26.0%, 28.0% and 26.6% for 2002, 2001 and 2000. The decrease in the effective income tax rate for 2002 was due primarily to the elimination of all non-deductible goodwill amortization upon the adoption of SFAS No. 142 effective January 1, 2002. For more information see *New Accounting and Disclosure Standards Adopted*. The increase in the effective income tax rate for 2001 was due primarily to higher taxable income from products manufactured and sold in the United States, one of the Company's highest tax jurisdictions.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash and cash equivalents on hand, cash from operations, amounts available under credit facilities and other external sources of funds. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures and other financial commitments. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

The Company has two unsecured revolving credit agreements (the *Credit Facilities*) providing for up to an aggregate of \$530.0 million in borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate (LIBOR) plus 0.78%, which includes a facility fee. One of the credit agreements provides for long-term borrowings up to an aggregate of \$430.0 million and expires on March 30, 2005. The other credit agreement provides for short-term borrowings up to an aggregate of \$100.0 million through March 27, 2003. The Company anticipates that it will replace the \$100.0 million credit agreement with a similar credit agreement through March 2004. As of December 31, 2002, approximately \$245.5 million was outstanding under the \$430.0 million credit agreement. Edwards Lifesciences pays a facility fee, regardless of available or outstanding borrowings, currently at an annual rate of 0.15% for the \$430 million credit agreement and, 0.125% for the \$100 million credit agreement. The Credit Facilities contain various financial and other covenants of Edwards Lifesciences, including a maximum leverage ratio and a minimum interest coverage ratio. All amounts outstanding under the \$430 million credit agreement

have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to this credit agreement.

As further discussed in Note 5 to the consolidated financial statements, the Company has also entered into two securitization agreements whereby it sells without recourse, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable. The significant benefits of the securitizations are lower cost of funds and differentiated sources of liquidity. As of December 31, 2002 the Company had sold a total of \$82.7 million of trade accounts receivable and received funding of \$67.1 million under both agreements. These proceeds are generally used to reduce revolving lines of credit. The Company has been able to effectively lower its overall cost of funds as a result of the interest rate spreads it pays on these advances as opposed to borrowings under the current LIBOR based credit facility. Additionally, the Company believes that in diversifying its funding sources, the Company's funding availability in the capital markets is strengthened. The securitization agreements expire each December and are renewable for one-year periods at the Company's option. Management believes that the expiration or termination of the securitization agreements will not have an adverse material impact on the Company's financial position, results of operations or liquidity.

In November 2001, the Company's Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to two million shares of the Company's outstanding common stock. Stock repurchased under the program will primarily be used to offset obligations under the Company's employee stock option programs. Through December 31, 2002 the Company had repurchased approximately 1.3 million shares at an aggregate cost of \$31.5 million. For the period January 1, 2003, through March 12, 2003, the Company repurchased approximately an additional 0.3 million shares at an aggregate cost of \$8.2 million.

On February 18, 2003, the Company announced that it had acquired the endovascular mitral valve repair program of Jomed N.V., a European-based provider of products for minimally invasive vascular intervention, for approximately \$20.0 million in cash. The acquisition includes all technology and intellectual property associated with the program. The Company expects to take an in-process research and development charge related to this transaction in the first quarter of 2003.

A summary of all of the Company's contractual obligations and commercial commitments as of December 31, 2002 were as follows (in millions):

Contractual Obligations	Total	Payments Due By Period			
		Less Than 1 Year	1 3 Years	4 5 Years	After 5 Years
Long-term debt	\$ 245.5	\$	\$ 245.5	\$	\$
Operating leases	18.5	5.8	8.7	4.0	
Unconditional purchase obligations	23.2	5.8	11.6	5.8	
Contractual development obligations (a)	58.0	13.7	2.3	4.0	38.0
Total contractual cash obligations	\$ 345.2	\$ 25.3	\$ 268.1	\$ 13.8	\$ 38.0

(a) Contractual development obligations consist primarily of cash that Edwards Lifesciences is obligated to pay to unconsolidated affiliates upon their achievement of product development milestones.

Cash flows provided by operating activities for the year 2002 increased \$19.4 million from the year 2001 due primarily to higher earnings (before non-cash items), which included a \$20.0 million legal settlement (see Other (income) expense, net), and decreased inventory levels. These increases in operating cash flows were partially offset by higher net cash outflows from accounts receivable, accounts payable and

accrued liabilities.

Cash flows provided by operating activities for the year 2001 decreased \$36.5 million from the year 2000 due primarily to a \$6.2 million payment to unwind an interest rate swap (see Interest Expense,

net), \$5.1 million of incremental personnel and exit costs associated with the Company's sale of its perfusion product line to Jostra AG (see Disposition of Assets and Other Charges, net), increased corporate costs associated with the Company's operation as an independent company commencing April 1, 2000 and increased inventory levels.

Uses of cash for investing activities during the year 2002 included \$19.0 million spent to acquire the Japan business (see Joint Venture in Japan) and \$12.7 million of investments in various unconsolidated affiliates, investments in patent technology related to the Company's peripheral stent program and other patent-related investments.

Uses of cash for investing activities during the year 2001 included \$10.6 million of investments in various unconsolidated affiliates, an investment in peripheral stent patent technology and other patent related investments. Cash flows provided by investing activities included \$45.0 million received from the sale of the Company's stock of ELCR and \$9.7 million of installment payments received against a note receivable from Jostra AG (see Disposition of Assets and Other Charges, net).

Capital expenditures increased \$3.2 million to \$40.7 million in 2002 from \$37.5 million in 2001. Capital expenditures during 2002 related primarily to support for manufacturing facilities, information systems and monitoring equipment placed at customers. The increase in 2002 resulted primarily from capital investments in information systems in the Company's Japanese business acquired on October 1, 2002. In 2003, the Company expects capital expenditures to be less than \$45 million.

Capital expenditures decreased \$8.5 million to \$37.5 million in 2001, from \$46.0 million in 2000. The reduction in 2001 resulted primarily from the completion during 2000 of the expansion and renovation of the Company's corporate headquarters and the sale of the perfusion product line and the perfusion services business.

Critical Accounting Policies and Estimates

The Company's results of operations and financial position are determined based upon the application of the Company's accounting policies, as discussed in the notes to the consolidated financial statements. Certain of the Company's accounting policies represent a selection among acceptable alternatives under Generally Accepted Accounting Principles in the United States (GAAP). In evaluating the Company's transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions. Management has not determined how reported amounts would differ based on the application of different accounting policies. Management has also not determined the likelihood that materially different amounts could be reported under different conditions or using different assumptions.

The application of accounting policies requires the use of judgment and estimates. As it relates to the Company, estimates and forecasts are required to determine sales returns and reserves, rebate reserves, allowances for doubtful accounts, reserves for excess and obsolete inventory, investments in unconsolidated affiliates, workers' compensation liabilities, employee benefit related liabilities, deferred tax asset valuation allowances, any impairments of assets, anticipated transactions to be hedged, reserves and contingencies.

These matters that are subject to judgments and estimation are inherently uncertain, and different amounts could be reported using different assumptions and estimates. Management uses its best estimates and judgments in determining the appropriate amount to reflect in the financial

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

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

Sales are generally recorded when all of the following have occurred: an agreement of sale exists, product delivery and acceptance has occurred or services have been rendered, and collection is reasonably assured. Management is required to make judgments about whether or not collectibility is reasonably assured. For certain products, the Company maintains consigned inventory at customer locations. For these products, revenue is recognized at the time the Company is notified that the customer has used the inventory. The Company reduces revenue with reserves for estimated price concessions and sales returns. Allowances, which are recorded at the time revenue is recognized, in accordance with SFAS No. 48, Revenue Recognition When Right of Return Exists, are based upon historical price concessions and sales returns.

Allowance for Doubtful Accounts

The Company records allowances for doubtful accounts based on customer-specific analysis and general matters such as current assessments of past due balances and economic conditions. Additional allowances for doubtful accounts may be required if there is deterioration in past due balances, if economic conditions are less favorable than the Company has anticipated or for customer-specific circumstances, such as financial difficulty. The allowance for doubtful accounts was \$5.5 million and \$4.3 million at December 31, 2002 and 2001, 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. The allowance for excess and obsolete inventory was \$9.6 million and \$9.4 million at December 31, 2002 and 2001, respectively.

Impairment of Long-Lived Assets

On January 1, 2002, the Company adopted SFAS No. 142, Goodwill and Other Intangible Assets, whereby goodwill is no longer amortized, but instead is subject to a periodic impairment review. As the Company's operations are comprised of one reporting unit, the Company reviews the recoverability of its goodwill by comparing the Company's fair value to the net book value of its assets. If the book value of the Company's assets exceeds the Company's fair value, the goodwill is written down to its implied fair value.

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

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are accounted for under the cost method and have been designated as available-for-sale in accordance with the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as Accumulated Other Comprehensive Income. Gains or losses on investments sold are based on the specific identification method. The fair values of certain investments are based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. When the fair value of a certain 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 realized 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; 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

The Company records a liability for potential tax assessments based on its estimate of the potential exposure. New laws and new interpretations of laws and rulings by tax authorities may affect the liability for potential tax assessments. Due to the subjectivity and complex nature of the underlying issues, actual payments or assessments may differ from estimates. To the extent the Company's estimates differ from actual payments or assessments, income tax expense is adjusted. During 2002, the Company resolved certain matters from 2001 resulting in a \$20.1 million reduction of its provision for income taxes. Additional information regarding income taxes is included in Note 14 of the consolidated financial statements.

The Company has recorded a valuation allowance of \$19.9 million at December 31, 2002 for the majority of its deferred tax assets related to net operating loss carry-forwards and capital loss carry-forwards. The valuation allowance is based on an evaluation of the uncertainty of the amounts of net operating loss carry-forwards and capital loss carry-forwards that are expected to be realized. An increase to income would result if the Company determines it could utilize more net operating loss carry-forwards and capital loss carry-forwards than originally expected.

At the end of each interim reporting period, the Company estimates the effective tax rate expected to be applicable for the full fiscal year. The estimated effective tax rate contemplates the expected jurisdiction where income is earned (e.g., United States compared to non-United States) as well as tax planning strategies. If the actual results are different from the Company's estimates, adjustments to the effective tax rate may be required in the period such determination is made.

Employee Stock Options

The Company applies the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, in accounting for its fixed stock option and employee stock purchase plans. In accordance with this intrinsic value method, no compensation expense is recognized for these plans. The Company has adopted the disclosure requirements for SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, if compensation expense for the Company's stock option and employee stock purchase plans had been recognized, based upon the fair value of awards granted, the Company's net income and earnings per

share would have been reduced to the following pro forma amounts (in millions, except per share amounts):

	2002		2001		2000	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net Income	\$ 55.7	\$ 40.4	\$ (11.4)	\$ (22.2)	\$ (271.7)	\$ (280.2)
Basic earnings per share	0.94	0.68	(0.19)	(0.38)		
Diluted earnings per share	0.91	0.66	(0.19)	(0.38)		

The per share weighted-average fair value for options granted during 2002, 2001 and 2000 was \$11.64, \$7.00 and \$6.39, respectively. The fair value of each option was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	2002	2001	2000
Average risk-free interest rate	4.35%	5.8%	5.8%
Expected dividend yield	None	None	None
Expected volatility	44%	45%	45%
Expected live (years)	5	5	5

New Accounting and Disclosure Standards Adopted

In June 2001, the FASB issued SFAS No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142, which changes the accounting for goodwill from an amortization method to an impairment-only approach, is effective for fiscal years beginning after December 15, 2001. No transition adjustment was recorded upon adoption of this standard on January 1, 2002. However, adoption of this standard resulted in the elimination of goodwill amortization commencing January 1, 2002. See Note 6 of the consolidated financial statements for more information.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets*. SFAS No. 144, which changes the accounting and reporting for the impairment of long-lived assets, is effective for fiscal years beginning after December 15, 2001. Adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 *Consolidation of Variable Interest Entities* an interpretation of ARB No. 51. This interpretation addresses consolidation by business enterprises of variable interest entities. Certain provisions of this interpretation were effective immediately. While the Company has a qualified special purpose entity, this interpretation does not have a material impact on the Company's consolidated financial statements as qualified special purpose entities are specifically excluded from the interpretation's requirements.

New Accounting and Disclosure Standards Issued

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143, which changes the accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated retirement costs, will be effective for fiscal years beginning after June 15, 2002. The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

In July 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 changes the accounting and reporting for costs associated with exit or disposal activities, termination benefits and other costs to exit an activity, including certain costs incurred in a restructuring. The provisions of this statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not

expect that the adoption of this standard will have a material impact on its consolidated financial statements.

Item 7A Quantitative and Qualitative Disclosure About Market Risk

The Company's business and financial results are affected by fluctuations in world financial markets, including currency exchange rates and interest rates. The Company's hedging policy attempts to manage these risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity and costs.

Edwards Lifesciences maintains an overall risk management strategy that utilizes a variety of interest rate and currency derivative financial instruments to mitigate its exposure to fluctuations in interest rates and currency exchange rates. The derivative instruments used include interest rate swaps, option-based products and forward currency contracts. The Company does not use any of these instruments for trading or speculative purposes. The total notional amounts of the Company's derivative financial instruments at December 31, 2002 and 2001 were \$588.2 million and \$324.8 million, respectively. The notional amounts of interest rate swap agreements, option-based products, and forward currency contracts do not represent amounts exchanged by the parties and, are not a measure of the Company's exposure through its use of derivatives.

Interest Rate Risk

The Company utilizes interest rate swap agreements in managing its exposure to interest rate fluctuations. Interest rate swap agreements are executed as an integral part of specific debt transactions or on a portfolio basis. The Company's interest rate swap agreements involve agreements to pay a fixed rate and receive a floating rate, at specified intervals, calculated on an agreed-upon notional amount.

As part of its overall risk-management program the Company performs sensitivity analyses to assess potential gains and losses in earnings and changes in fair values to hypothetical movements in interest rates. A 46 basis-point increase in interest rates (approximately 10 percent of the Company's weighted average interest rate), affecting the Company's financial instruments, including debt obligations and related derivatives and investments, would increase the Company's annual interest expense, net by approximately \$0.3 million.

Currency Risk

The Company is primarily exposed to currency exchange-rate risk with respect to its transactions and net assets denominated in Japanese Yen and the Euro. Business activities in various currencies expose the Company to the risk that the eventual net United States dollar cash inflows resulting from transactions with foreign customers and suppliers denominated in foreign currencies may be adversely affected by changes in currency exchange rates. The Company manages these risks utilizing various types of foreign exchange contracts. The Company also enters into foreign exchange contracts to hedge anticipated, but not yet committed, sales expected to be denominated in foreign currencies. In addition, the Company hedges certain of its net investments in international affiliates. Such contracts hedge the United States dollar value of foreign currency denominated net assets from the effects of volatility in currency exchange rates by creating debt denominated in the respective currencies of the underlying net assets. Any changes in the carrying value of these net investments that are a result of fluctuations in currency exchange rates are offset by changes in the carrying value of the foreign currency denominated debt that are a result of the same fluctuations in currency exchange rates.

As part of the strategy to manage risk while minimizing hedging costs, the Company utilizes both foreign currency forward exchange contracts and option-based products in managing its exposure to currency rate fluctuations. Option-based products consist primarily of purchased put options in conjunction with written (sold) call options to create collars. Option-based products are agreements

that either grant the Company the right to receive, or require the Company to make payments at, specified currency rate levels.

As part of its risk-management process, the Company uses a value-at-risk (VAR) methodology in connection with other management tools to assess and manage its foreign currency financial instruments and measure any potential loss in earnings as a result of adverse movements in currency exchange rates. The Company utilizes a Monte Carlo simulation, with a 95 percent confidence level, using spot and three-month implied volatilities as stochastic variables and correlations (as of the measurement date) to estimate this potential loss. The Company's calculated VAR at December 31, 2002, with a maturity of up to one year, is \$4.3 million. This amount excludes the potential effects of any changes in the value of the underlying transactions or balances. The Company's calculated VAR exposure represents an estimate of reasonably possible net losses that would be recognized on its portfolio of financial instruments assuming hypothetical movements in future market rates and is not necessarily indicative of actual results which may occur. It does not represent the maximum possible loss or any expected loss that may occur. Actual future gains or losses may differ from (and could be significantly greater than) these estimates based upon actual fluctuations in market rates, operating exposures and the timing thereof, and changes in the Company's portfolio of derivatives during the measured periods. In addition, the assumption within the VAR model is that changes in currency exchange rates are adverse, which may not be the case. Any loss incurred on the financial instruments is expected to be offset by the effects of currency movements on the hedging of all exposures; there may be currency exchange-rate gains or losses in the future.

Credit Risk

Derivative financial instruments used by the Company involve, to varying degrees, elements of credit risk in the event a counter-party should default and market risk as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counter-party diversification, monitoring of counter-party financial condition and master-netting agreements in place with all derivative counter-parties. Credit exposure of derivative financial instruments is represented by the fair value effects of contracts with a positive fair value at December 31, 2002 reduced by the effects of master netting agreements. Additionally, at December 31, 2002, all derivative financial instruments, based on notional amounts, were with commercial banks and investment banking firms assigned investment grade ratings of AA or better by national rating agencies. The Company does not anticipate non-performance by its counter-parties and has no reserves related to non-performance as of December 31, 2002; the Company has not experienced any counterparty default during the three years ended December 31, 2002.

Concentrations of Credit Risk

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 reserves for potential credit losses which, when realized, have been within the range of management's allowance for doubtful accounts during all periods presented.

Sales to Baxter, acting in the capacity of the Company's distributor subsequent to the Distribution, represented approximately 8%, 11% and 12% of the Company's total net sales for 2002, 2001 and 2000, respectively. Substantially all of these agreements had been terminated as of December 31, 2002.

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.

In 2002, the Company recorded a \$67.4 million pretax charge related to the impairment of its investment in preferred stock of WorldHeart. The investment was written down to \$6.2 million, which represented the value of the Company's preferred stock investment had it been converted into common stock at October 15, 2002. The decision to record the charge was based primarily on delays in WorldHeart's product development timelines, arising from its revised strategy. Should WorldHeart fail to meet certain future development and financing milestones, further impairment charges may be necessary.

In addition to the investment in WorldHeart (\$6.1 million at December 31, 2002), Edwards Lifesciences had approximately \$17.4 million of investments in equity instruments of other companies. At December 31, 2002, the Company had recorded unrealized losses on these investments of \$6.8 million in Accumulated Other Comprehensive Income, net of tax. Management considers these declines temporary in nature based upon the individual companies' operating results, financial condition and achievement of product development milestones. 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.

Item 8 Financial Statements and Supplementary Data

Report of Management

The management of Edwards Lifesciences is responsible for the integrity of the financial information presented in this Form 10-K. The consolidated financial statements have been prepared in accordance with generally accepted accounting principles. Where necessary, they reflect estimates based on management's judgment.

Management relies upon established accounting procedures and related systems of internal control for meeting its responsibilities to maintain reliable financial records. These systems are designed to provide reasonable assurance that assets are safeguarded and that transactions are properly recorded and executed in accordance with management's intentions. Internal auditors periodically review the accounting and control systems, and these systems are revised if and when weaknesses or deficiencies are found.

The Audit and Public Policy Committee of the Board of Directors, composed of directors from outside the Company, meets regularly with management, the Company's internal auditors and its independent accountants to discuss audit scope and results, internal control evaluations, and other accounting, reporting and financial matters. The independent accountants and internal auditors have access to the Audit and Public Policy Committee without management's presence.

/s/ MICHAEL A. MUSSALLEM
Michael A. Mussallem

Chairman of the Board and Chief Executive Officer

/s/ BRUCE J. BENTCOVER

Bruce J. Bentcover
*Corporate Vice President,
Chief Financial Officer
and Treasurer*

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE
DECEMBER 31, 2002**

Report of Independent Accountants

Financial Statements:

Consolidated Balance Sheets at December 31, 2002 and 2001

For the years ended December 31, 2002, 2001 and 2000:

Consolidated Statements of Operations

Consolidated Statements of Cash Flows

Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)

Notes to Consolidated Financial Statements

Financial statement schedule for the years ended December 31, 2002, 2001 and 2000:

Valuation and Qualifying Accounts

Other schedules are not applicable and have not been submitted

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Shareholders

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, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 6 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets on January 1, 2002 and as a result changed its method of accounting for goodwill.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Orange County, California
February 3, 2003

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except share data)

	December 31,	
	2002	2001
ASSETS		
Current assets		
Cash and cash equivalents	\$ 34.2	\$ 47.7
Accounts receivable, net of allowances of \$5.5 and \$4.3	88.3	85.3
Other receivables	20.1	15.3
Inventories, net	111.8	86.6
Deferred income taxes	27.6	18.2
Prepaid expenses	21.0	18.9
Other current assets	23.4	20.0
Total current assets	326.4	292.0
Property, plant and equipment, net	209.4	187.8
Goodwill	333.8	333.8
Other intangible assets, net	61.9	68.6
Investments in unconsolidated affiliates	23.5	92.9
Deferred income taxes	38.8	
Other assets	14.4	7.8
Total assets	\$ 1,008.2	\$ 982.9
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 197.9	\$ 183.5
Short-term debt		1.1
Total current liabilities	197.9	184.6
Long-term debt	245.5	309.8
Other liabilities	25.4	29.8
Commitments and contingent liabilities		
Stockholders' equity		

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Preferred stock, \$.01 par value, authorized 50,000,000 shares, no shares outstanding				
Common stock, \$1.00 par value, authorized 350,000,000 shares, 60,177,275 and 59,327,872 shares outstanding		60.2		59.3
Additional contributed capital		412.0		287.2
Retained earnings		143.4		87.7
Accumulated other comprehensive income		(44.7)		25.2
Common stock in treasury, at cost		(31.5)		(0.7)
Total stockholders equity		539.4		458.7
Total liabilities and stockholders equity	\$	1,008.2	\$	982.9

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2002	2001	2000
Net sales	\$ 704.0	\$ 692.1	\$ 803.8
Cost of goods sold	299.1	323.7	423.3
Gross profit	404.9	368.4	380.5
Selling, general and administrative expenses	227.9	203.2	215.6
Research and development expenses	65.2	55.0	54.4
Goodwill amortization		18.5	28.5
Disposition of assets and other charges, net	67.4	83.0	312.2
Non-recurring spin-off expenses	3.3		18.4
Other operating income	(11.0)	(16.4)	(14.0)
Operating income (loss)	52.1	25.1	(234.6)
Interest expense, net	11.5	22.9	20.0
Other (income) expense, net	(15.4)	10.6	3.8
Income (loss) before provision for income taxes	56.0	(8.4)	(258.4)
Provision for income taxes	0.3	1.5	13.3
Income (loss) before cumulative effect of change in accounting principle	55.7	(9.9)	(271.7)
Cumulative effect of change in accounting principle, net of tax (Note 2)		1.5	
Net income (loss)	\$ 55.7	\$ (11.4)	\$ (271.7)
Share information (Note 2):			
Earnings (loss) per basic share			
Income (loss) before cumulative effect of change in accounting principle	\$ 0.94	\$ (0.17)	
Cumulative effect of change in accounting principle (Note 2)	\$	\$ (0.02)	
Net income (loss)	\$ 0.94	\$ (0.19)	
Earnings (loss) per diluted share			
Income (loss) before cumulative effect of change in accounting principle	\$ 0.91	\$ (0.17)	

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Cumulative effect of change in accounting principle (Note 2)	\$		\$	(0.02)
Net income (loss)	\$	0.91	\$	(0.19)
Weighted average number of common shares outstanding				
Basic		59.0		58.9
Diluted		61.3		58.9

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Years Ended December 31,		
	2002	2001	2000
Cash flows provided by operating activities			
Net income (loss)	\$ 55.7	\$ (11.4)	\$ (271.7)
Income charges (credits) not affecting cash:			
Dispositions and write-downs of assets and other charges, net	68.9	89.4	333.4
Depreciation and amortization	40.4	57.4	74.1
Deferred income taxes	(13.8)	(29.7)	(1.0)
Other	5.7	(7.4)	4.6
Changes in operating assets and liabilities, net of effect from ownership change of Japan business (Notes 1 and 3):			
Accounts and other receivables	(32.0)	(4.7)	(8.1)
Inventories	13.3	(7.7)	0.3
Accounts payable and accrued liabilities	(17.6)	7.0	12.0
Other		8.3	(5.9)
Net cash provided by operating activities	120.6	101.2	137.7
Cash flows from investing activities			
Capital expenditures	(40.7)	(37.5)	(46.0)
Acquisition of joint venture in Japan	(19.0)		
Proceeds from sale of business		45.0	
Purchase of convertible debentures			(13.0)
Investments in unconsolidated affiliates	(5.7)	(10.6)	(28.0)
Proceeds from asset dispositions	4.1	9.7	12.3
Investments in intangible assets	(7.0)	(8.0)	(1.0)
Other		(2.5)	
Net cash used in investing activities	(68.3)	(3.9)	(75.7)
Cash flows from financing activities			
Proceeds from issuance of short-term debt	0.4	26.1	219.9
Payments on short-term debt	(1.5)	(86.3)	(68.6)
Proceeds from issuance of long-term debt	150.9	180.0	448.6
Payments on long-term debt	(231.9)	(211.2)	(158.6)
Proceeds from accounts receivable securitization, net	29.9	5.2	32.0

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Purchases of treasury stock	(30.8)	(0.7)	
Payments to Baxter International Inc., net			(511.0)
Proceeds from stock plans	13.7	8.9	4.1
Other	(0.2)	(0.6)	(3.0)
Net cash used in financing activities	(69.5)	(78.6)	(36.6)
Effect of currency exchange rate changes on cash and cash equivalents	3.7	0.9	2.7
Net (decrease) increase in cash and cash equivalents	(13.5)	19.6	28.1
Cash and cash equivalents at beginning of year	47.7	28.1	
Cash and cash equivalents at end of year	\$ 34.2	\$ 47.7	\$ 28.1
Supplemental disclosures:			
Cash paid during the year for:			
Interest	\$ 9.8	\$ 19.2	\$ 17.0
Income taxes	10.4	10.2	6.0
Non-cash transactions:			
De-consolidation of Japan business (Notes 1 and 3)	\$	\$	\$ 43.0
Sale of inventory in exchange for note receivable (Note 4)			14.0
Net assets sold in consideration for convertible preferred stock (Note 4)			13.0

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND
COMPREHENSIVE INCOME (LOSS)

(in millions)

	Years Ended December 31,		
	2002	2001	2000
COMMON STOCK			
Beginning of year	\$ 59.3	\$ 58.7	\$
Common stock issued in connection with the Distribution			58.1
Common stock issued under employee benefit plans	0.9	0.6	0.6
End of year	\$ 60.2	\$ 59.3	\$ 58.7
ADDITIONAL CONTRIBUTED CAPITAL			
Beginning of year	\$ 287.2	\$ 277.4	\$
Common stock issued in connection with the Distribution			269.5
Acquisition of joint venture in Japan (Notes 1 and 3)	110.8		
Stock options issued to non-employees	1.2	1.6	1.7
Common stock issued under employee benefit plans	12.8	8.2	6.2
End of year	\$ 412.0	\$ 287.2	\$ 277.4
RETAINED EARNINGS			
Beginning of year	\$ 87.7	\$ 102.9	\$ 417.5
Net income (loss)	55.7	(11.4)	(271.7)
De-consolidation of Japan			(42.9)
Elimination of reporting lag for certain international operations (Note 2)		(3.8)	
End of year	\$ 143.4	\$ 87.7	\$ 102.9
ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)			
Beginning of year	\$ 25.2	\$ 0.6	\$ (26.5)
Other comprehensive (loss) income	(69.9)	24.6	27.1
End of year	(44.7)	\$ 25.2	\$ 0.6
TREASURY STOCK			
Beginning of year	\$ (0.7)	\$	\$

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Purchases of stock		(30.8)		(0.7)	
End of year	\$	(31.5)	\$	(0.7)	\$
INVESTMENT BY BAXTER INTERNATIONAL INC., NET					
Beginning of year	\$		\$		\$ 833.5
Investments by and advances from (payments to) Baxter International Inc., net					(833.5)
End of year	\$		\$		\$
Total stockholders equity	\$	539.4	\$	458.7	\$ 439.6

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

	Years Ended December 31,		
	2002	2001	2000
COMPREHENSIVE INCOME (LOSS)			
Currency translation adjustments, net of tax	\$ (8.0)	\$ 29.9	\$ (2.6)
Currency translation adjustment in connection with the Japan business (Notes 1 and 3)	(47.8)		
Currency translation adjustment in connection with the Distribution			27.4
Pension adjustments, net of tax	(1.7)		
Unrealized net (loss) gain on investments in unconsolidated affiliates, net of tax	(1.7)	(5.8)	2.3
Net unrealized (loss) gain on cash flow hedges, net of tax	(10.7)	0.5	
Other comprehensive income (loss)	(69.9)	24.6	27.1
Net income (loss)	55.7	(11.4)	(271.7)
Total comprehensive income (loss)	\$ (14.2)	\$ 13.2	\$ (244.6)

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

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Edwards Lifesciences Corporation is a global provider of products and technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences' sales are categorized in five main product areas: cardiac surgery, critical care, vascular, perfusion and other distributed products. Edwards Lifesciences' cardiac surgery portfolio is comprised primarily of products relating to heart valve therapy, transmyocardial revascularization, and cannula products used during open-heart surgery. Edwards Lifesciences is the world's leader in, and has been a pioneer in the development and commercialization of, tissue valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the critical care area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's heart function, and also provides central venous access products for fluid and drug delivery. Edwards Lifesciences' vascular portfolio includes a line of balloon catheter-based products, surgical clips and inserts, angiography equipment, artificial implantable grafts, and an endovascular system used to treat life-threatening abdominal aortic aneurysms less invasively. In the perfusion category, Edwards Lifesciences develops, manufactures and markets, in regions outside the United States and Western Europe, a diverse line of disposable products used during cardiopulmonary bypass procedures, including oxygenators, blood containers, filters and related devices (see Note 4). Effective June 30, 2001, the Company sold its perfusion services business in the United States to an affiliate of Fresenius Medical Care AG (see Note 4). The Company continues to maintain a small perfusion services business in Europe. Lastly, other distributed products include sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through the Company's distribution network in Japan, and miscellaneous pharmaceutical products sold in the United States.

Edwards Lifesciences Corporation was incorporated under the original name of CVG Controlled Inc. in Delaware on September 10, 1999, as a subsidiary of Baxter International Inc. (Baxter). On March 31, 2000 (the Distribution Date), Baxter transferred its cardiovascular business (the Edwards Lifesciences Business) to Edwards Lifesciences in connection with a tax-free spin-off by Baxter of the Edwards Lifesciences Business. The spin-off was effected on the Distribution Date through a distribution of 58.1 million shares of Edwards Lifesciences' common stock (the Distribution) to Baxter stockholders of record on March 29, 2000, resulting in Edwards Lifesciences operating as an independent entity commencing April 1, 2000 with publicly traded common stock. Unless the context indicates otherwise, references to the Company and Edwards Lifesciences refer to Baxter's cardiovascular business for periods prior to April 1, 2000 and to Edwards Lifesciences Corporation and its subsidiaries for the periods on or after such date. No annual earnings per share data are presented for 1999 and 2000 as the Edwards Lifesciences earnings were part of Baxter's earnings through the close of business on March 31, 2000.

Baxter performed certain services for Edwards Lifesciences pursuant to various agreements that are outlined in Note 12. However, unless released by third parties, Baxter may remain liable for certain lease and other obligations and liabilities that were transferred to and assumed by Edwards Lifesciences. Edwards Lifesciences is obligated to indemnify Baxter for liabilities related to those transferred obligations and liabilities.

Joint Venture in Japan

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

The Japan business is included in the Consolidated Statements of Operations for the three months ended March 31, 2000, consistent with the historical treatment of the Company's operations while a part of Baxter. Subsequent to the Distribution, the cardiovascular business in Japan was being operated pursuant to a joint venture under which a Japanese subsidiary of Baxter retained ownership of the

Japanese business assets, but a subsidiary of Edwards Lifesciences held a 90% profit interest. Edwards Lifesciences was given an option to purchase the Japanese business assets that was exercisable no earlier than August 1, 2002 and no later than March 31, 2005. From April 1, 2000 to September 30, 2002, Edwards Lifesciences (a) recognized its shipments into the joint venture as sales at distributor price at the time the joint venture sold to the end customer, and (b) utilized the equity method of accounting to record its 90% profit interest in the operations of the joint venture in Other Operating Income. Commencing October 1, 2002, the Company acquired from Baxter the cardiovascular business in Japan and began reporting Japan's results on a fully consolidated basis. See Note 3 for more information.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with Generally Accepted Accounting Principles in the United States (GAAP) and have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. Estimates are used in accounting for, among other items, sales returns and reserves, rebate reserves, allowances for doubtful accounts, excess and obsolete inventory, investments in unconsolidated affiliates, workers compensation, employee benefits, income taxes, asset impairment, anticipated transactions to be hedged, reserves and contingencies.

Basis of presentation

The consolidated financial statements have been prepared using Baxter's historical bases in the assets and liabilities and the historical results of operations of the Edwards Lifesciences Business prior to the Distribution, operated primarily as a division of Baxter, and continuing as a separate legal entity, Edwards Lifesciences Corporation and its subsidiaries, subsequent to the Distribution. All material intercompany balances have been eliminated. Prior to the Distribution, the combined financial statements included allocations of certain Baxter corporate assets, liabilities and expenses to the Edwards Lifesciences Business, which were allocated on the basis that was considered by Baxter management to reflect most fairly or reasonably the utilization of the services provided to or the benefit obtained by the Edwards Lifesciences Business (see Note 12). Typical measures and activity indicators used for allocation purposes included headcount, sales, payroll expense, or the specific level of activity related to the allocated item. Management believes the methods used to allocate amounts were reasonable. However, the financial information included herein does not necessarily reflect what the financial position, results of operations and cash flows of the Company would have been had it operated as a stand-alone public entity during the periods prior to the Distribution, and may not be indicative of future operations, cash flows or financial position. The consolidated financial statements do not include an allocation of Baxter's consolidated debt and interest expense prior to the Distribution. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Fiscal year of international operations

Prior to 2001, certain operations outside the United States had been included in the consolidated financial statements on the basis of fiscal years ending November 30 in order to facilitate timely consolidation. This one-month lag was eliminated as of the beginning of 2001 for these international operations as it was no longer required to achieve a timely consolidation. The December 2000 net loss from operations of \$3.8 million for these entities was recorded as an adjustment to retained earnings on January 1, 2001.

Foreign currency translation

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

Revenue recognition

Sales are generally recorded when all of the following have occurred: an agreement of sale exists, product delivery and acceptance has occurred or services have been rendered, and collection is reasonably assured. Management is required to make judgments about whether or not collectibility is reasonably assured. For certain products, the Company maintains consigned inventory at customer locations. For these products, revenue is recognized at the time the Company is notified that the customer has used the inventory. The Company reduces revenue with reserves for estimated price concessions and sales returns. Allowances which are recorded at the time revenue is recognized, in accordance with SFAS No. 48, Revenue Recognition When Right of Return Exists, are based upon historical price concessions and sales returns.

Cash equivalents

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

Accounts receivable securitization

The Company accounts for the securitization of accounts receivable in accordance with SFAS No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. When the Company sells accounts receivable in securitizations, a subordinated residual interest in the securitized portfolio is retained by the Company (recorded in Other Current Assets). Gain or loss on sale of the accounts

receivable depends in part on the previous carrying amount of the

financial assets involved in the transfer, allocated between the assets sold and the residual interests based on their relative fair value at the date of transfer. Because quoted market prices are generally not available to determine the Company's fair value of the residual interest, the Company estimates the fair value of the residual interest by estimating future expected credit losses to determine the future expected cash flows, which generally approximate fair value given the securitized portfolio's short-term weighted average life. At the time the receivables are sold, the balances are removed from the Consolidated Balance Sheets. Costs associated with the sale of receivables, primarily related to the discount and loss on sale, are included in Other (Income) Expense, net.

Inventories

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

	December 31,	
	2002	2001
	(in millions)	
Raw materials	\$ 17.4	\$ 21.8
Work in process	14.7	23.6
Finished products	79.7	41.2
	\$ 111.8	\$ 86.6

Reserves for excess and obsolete inventory were approximately \$9.6 million and \$9.4 million at December 31, 2002 and 2001, respectively. During the years ended December 31, 2002, 2001 and 2000, the Company allocated \$9.8 million, \$8.4 million and \$5.0 million, respectively, of general and administrative costs to inventory. General and administrative costs included in both the December 31, 2002 and 2001 inventory balances were \$2.8 and \$2.4 million, respectively.

Property, plant and equipment

Property, plant and equipment are recorded at cost. Depreciation and amortization are principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 20 to 50 years for buildings and improvements and from three to 15 years for machinery and equipment. 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.

	December 31,	
	2002	2001
	(in millions)	
Land	\$ 32.6	\$ 34.3
Buildings and leasehold improvements	70.0	65.5
Machinery and equipment	192.8	179.7
Equipment with customers (Note 3)	101.5	46.0
Construction in progress	8.5	6.4
	405.4	331.9
Accumulated depreciation and amortization	(196.0)	(144.1)
	\$ 209.4	\$ 187.8

Depreciation expense was \$29.6 million, \$27.0 million and \$34.2 million for the years ended December 31, 2002, 2001 and 2000, respectively. Repairs and maintenance expense was \$9.1 million, \$11.1 million and \$10.2 million for the years ended December 31, 2002, 2001 and 2000, respectively.

Investments in unconsolidated affiliates

Investments in unconsolidated affiliates are accounted for under the cost method and have been designated as available-for-sale in accordance with the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. These investments are carried at fair market value, with unrealized gains and losses reported in stockholders' equity as Accumulated Other Comprehensive Income. Gains or losses on investments sold are based on the specific identification method. The fair values of certain investments are based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. When the fair value of a certain 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 realized 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; 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

The Company accounts for income taxes in accordance with SFAS No. 109, Accounting for Income Taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases.

Edwards Lifesciences' operations were included in Baxter's consolidated United States federal and state income tax returns and in the tax returns of certain Baxter foreign subsidiaries prior to the Distribution. The provision for income taxes prior to the Distribution has been determined as if Edwards Lifesciences had filed separate tax returns under its existing structure for the periods presented. Prior to the Distribution, all income taxes were settled with Baxter on a current basis through the Investment by Baxter International Inc., net account.

Investment by Baxter International Inc., net

Investment by Baxter International Inc., net includes common stock, additional paid-in capital and net intercompany balances with Edwards Lifesciences that were contributed at the time of the spin-off. Baxter did not manage the activity in this account on the basis of separate legal entities. There is no distinction in this account between net investments in and net advances to Edwards Lifesciences as there was no term associated with the cash infusions and no intent or expectation that the infusions would be remitted to Baxter.

Research and development costs

Research and development costs are charged to expense when incurred.

Earnings per share

Earnings per share are calculated in accordance with SFAS No. 128, Earnings per Share, which requires the Company to report both basic earnings per share, based on the weighted-average number of common shares outstanding, and diluted earnings per share, based on the weighted-average number of common shares outstanding adjusted to include the potentially dilutive effect of outstanding stock options. No earnings per share data is presented in the Consolidated Statements of Operations for 2000 as the Edwards Lifesciences earnings were part of Baxter's earnings through the close of business on March 31, 2000.

A reconciliation of the shares used in the basic and diluted per share computations is as follows:

	2002	Years Ended December 31, 2001
	(in millions)	
Basic shares outstanding	59.0	58.9
Dilutive effect of employee stock options	2.3	
Diluted shares outstanding	61.3	58.9

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Anti-dilutive shares of 2.1 million, comprised of dilutive employee stock options, were excluded from the calculation of diluted shares outstanding in 2001.

Derivatives

Edwards Lifesciences maintains an overall risk management strategy that incorporates the use of a variety of interest rate and currency derivative financial instruments to mitigate its exposure to significant unplanned fluctuations in earnings caused by volatility in interest rate and currency exchange

rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy include interest rate swaps, option-based products and forward exchange contracts. These instruments are designated as cash flow hedges. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

The Company uses interest rate swaps to convert floating-rate debt to fixed-rate debt. The Company's interest rate swap agreements involve agreements to pay a fixed rate and receive a floating rate, at specified intervals, calculated on an agreed-upon notional amount. The debt and amounts that the Company hedges are determined based on prevailing market conditions and the current shape of the yield curve. Interest rate swap agreements are executed as an integral part of specific debt transactions.

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

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

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

The Company formally documents all relationships between hedging instruments and hedged items, as well as its risk management objective and strategy for undertaking various hedge transactions. This process includes linking all derivatives that are designated as cash flow hedges or specific firm commitments or forecasted transactions. The Company also formally assesses (both at the hedge's inception and on an ongoing basis) whether the derivatives that are used in hedging transactions have been highly effective in offsetting changes in the cash flows of hedged items and whether those

derivatives may be expected to remain highly effective in future periods. All components of each derivative's gain or loss are included in the assessment of hedge effectiveness.

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

When the Company discontinues hedge accounting because it is no longer probable that the forecasted transaction will occur in the originally expected period, the gain or loss on the derivative remains in Accumulated Other Comprehensive Income and is reclassified into earnings when the forecasted transaction affects earnings. However, if it is probable that a forecasted transaction will not occur by the end of the originally specified time period or within an additional two-month period of time thereafter, the gains and losses that were accumulated in Accumulated Other Comprehensive Income will be recognized immediately in earnings. In a situation in which hedge accounting is discontinued and the derivative remains outstanding, the Company will carry the derivative at its fair value on the balance sheet, recognizing changes in the fair value in current-period earnings.

Comprehensive income

Comprehensive income encompasses all changes in equity other than those arising from transactions with stockholders, and consists of net income, currency translation adjustments, pension adjustments and unrealized net gains and losses on cash flow hedges and investments in unconsolidated affiliates.

New accounting and disclosure standards adopted

Effective January 1, 2001, Edwards Lifesciences adopted the provisions of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended. SFAS No. 133 requires companies to record derivatives on the balance sheet as assets and liabilities, measured at fair value. Accounting for the gain or loss due to changes in fair value of the derivative instrument depends on whether the derivative qualifies as a hedge. If the derivative instrument does not qualify as a hedge, the gains or losses are reported in earnings when they occur. If the derivative instrument qualifies as a hedge, the accounting varies based upon the type of risk being hedged. Adopting the provisions of SFAS No. 133 on January 1, 2001 resulted in a one-time cumulative after-tax increase in net loss of

\$1.5 million. In addition, the Company recorded the following one-time cumulative after-tax adjustments in Accumulated Other Comprehensive Income:

	Unrealized Gain (Loss)
	(in millions)
Related to previously designated cash flow hedging relationships:	
Fair value of hedging instruments	\$ (6.9)
Previously deferred hedging gains and losses	1.5
Total cumulative effect of adoption on Other Comprehensive Income, net of tax	\$ (5.4)

Effective January 1, 2001, Edwards Lifesciences adopted the provisions of SFAS No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. This statement replaces SFAS No. 125 and revises the standards for accounting for securitizations and other transfers of financial assets and collateral. SFAS No. 140 is effective for transfers and servicing of financial assets and extinguishments of liabilities occurring after March 31, 2001. This statement was effective for recognition and reclassification of collateral and for disclosures relating to securitization transactions and collateral for fiscal years ending after December 15, 2000. Adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2001, the FASB issued SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 was effective for fiscal years beginning after December 15, 2001 and requires that goodwill no longer be amortized, but instead be subject to a periodic impairment review. See Note 6 for further information.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long Lived Assets. SFAS No. 144, which changes the accounting and reporting for the impairment of long-lived assets, is effective for fiscal years beginning after December 15, 2001. Adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 Consolidation of Variable Interest Entities an interpretation of ARB No. 51. This interpretation addresses consolidation by business enterprises of variable interest entities. Certain provisions of this interpretation were effective immediately. While the Company has a special purpose entity, this interpretation does not have a material impact on the Company's consolidated financial statements as qualified special purpose entities are specifically excluded from the interpretation's requirements.

New accounting and disclosure standards issued

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143, which changes the accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated retirement costs, will be effective for fiscal years beginning after June 15, 2002. The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 changes the accounting and reporting for costs associated with exit or disposal activities, termination benefits and other costs to exit an activity, including certain costs incurred in a restructuring. The provisions of this statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company does not expect that the adoption of this standard will have a material impact on its consolidated financial statements.

3. ACQUISITION OF JOINT VENTURE IN JAPAN

On October 1, 2002, the Company acquired from Baxter for \$19.0 million, net, the cardiovascular business in Japan. The purchase price excluded approximately \$30 million of securitized accounts receivable. In the three months ended September 30, 2002, the Company recorded a \$3.3 million charge for legal, administrative and regulatory expenses related to the acquisition. Commencing October 1, 2002 the Company began reporting the results of the Japan business on a fully consolidated basis. The acquisition did not materially impact the Company's net income as the terms of the joint venture agreement enabled Edwards Lifesciences to record substantially all of the net profit generated by the Japan business (see Note 1).

The acquisition of the cardiovascular business in Japan was accounted for using the predecessor basis of accounting, whereby acquired assets and liabilities are recorded at their historical balances. The impact to the Company's balance sheet on October 1, 2002 from the acquisition was as follows (in millions):

	Net Assets Acquired	Other	Net Impact
Current assets			
Accounts and other receivables, net	\$ 18.8	\$ (14.8)(b)	\$ 4.0
Inventories, net	36.0		36.0
Prepaid expenses and other current assets	1.6		1.6
Total current assets	56.4	(14.8)	41.6
Property, plant and equipment, net	15.3		15.3
Deferred income taxes	42.7(a)		42.7
Other assets	3.1		3.1
	\$ 117.5	\$ (14.8)	\$ 102.7
Accounts payable and accrued liabilities	\$ 29.6	\$ (14.8)(b)	\$ 14.8
Long-term debt		19.0(c)	19.0
Other liabilities	5.9		5.9
Stockholders' equity			
Additional contributed capital	129.8	(19.0)	110.8
Accumulated other comprehensive income	(47.8)		(47.8)
Total stockholders' equity	82.0	(19.0)	63.0
	\$ 117.5	\$ (14.8)	\$ 102.7

Notes

- (a) Deferred tax asset relates to a tax basis step up in connection with the acquisition.

- (b) To reflect the elimination of receivables and payables between Edwards Lifesciences and the joint venture in Japan which are considered intercompany balances after the acquisition.

- (c) To reflect the incurrence of \$19.0 million of long-term debt to effect the transaction.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

The following unaudited pro forma consolidated statement of operations for the year ended December 31, 2002 presents the results of Edwards Lifesciences assuming that the acquisition of the cardiovascular business in Japan had been completed as of January 1, 2002 (in millions, except per share information):

	Historical	Pro Forma Adjustments		Pro Forma
		Japan Operating Results (a)	Other (b)	
Net sales	\$ 704.0	\$ 77.2	\$	\$ 781.2
Cost of goods sold	299.1	31.0		330.1
Gross profit	404.9	46.2		451.1
Selling, general and administrative expenses	227.9	34.0		261.9
Research and development expenses	65.2	2.5		67.7
Disposition of assets and other charges, net	67.4			67.4
Non-recurring spin-off expenses	3.3			3.3
Other operating income	(11.0)	11.0		
Operating income (loss)	52.1	(1.3)		50.8
Interest expense, net	11.5		0.8	12.3
Other (income) expense, net	(15.4)	(1.5)		(16.9)
Income (loss) before provision for income taxes	56.0	0.2	(0.8)	55.4
Provision (benefit) for income taxes	0.3	0.1	(0.2)	0.2
Net income (loss)	\$ 55.7	\$ 0.1	\$ (0.6)	\$ 55.2
Share information:				
Earnings per basic share	\$ 0.94			\$ 0.94
Earnings per diluted share	\$ 0.91			\$ 0.90

Notes

(a) To reflect Edwards Lifesciences Japanese business on a consolidated basis for the full year ended December 31, 2002.

(b) To reflect estimated interest expense that would have been incurred by the Company based on incurrence of \$19.0 million of debt at an effective interest rate of approximately 5%.

On a pro forma basis, assuming that the acquisition of the cardiovascular business in Japan had been completed as of January 1, 2001, the following unaudited amounts would have been recorded for the year ended December 31, 2001 (in millions, except per share information):

Net sales	\$	801.2
Loss before cumulative effect of change in accounting principle		10.0
Net loss		11.5
Basic and diluted loss per share:		
Loss before cumulative effect of change in accounting principle	\$	0.17
Cumulative effect of change in accounting		0.02
Net loss		0.20

4. DISPOSITION OF ASSETS AND OTHER CHARGES, NET

During 2002, 2001 and 2000, Edwards Lifesciences recorded charges comprised of the following:

2002

In September 2002, the Company recorded a \$67.4 million pretax charge related to the impairment of its investment in preferred stock of World Heart Corporation (WorldHeart). The investment was written down to \$6.2 million, which represented the value of the Company's preferred stock investment had it been converted into common stock at October 15, 2002 (the closing date of September's books). The decision to record the charge was based primarily on WorldHeart's September 2002 decision to refocus its product development efforts by adopting a new design concept for a next generation product that resulted in a significant delay (approximately two years) in its product development timeline (with a revised commercial launch date of 2007) and impaired WorldHeart's competitive position. Accordingly, the Company concluded that sufficient risk existed that WorldHeart may be unable to fully liquidate the Company's investment in WorldHeart's preferred stock. The Company believed that the best objective indicator of the then fair value of its investment in WorldHeart's preferred stock was the market price of WorldHeart's common stock based upon the Company's expectation that the value of its preferred stock investment would be realized through the common stock, as opposed to redemption of the preferred stock.

2001*Loss on Sale of Assets (\$68.2 million)*

Effective June 30, 2001, the Company sold the stock of Edwards Lifesciences Cardiovascular Resources, Inc. (ELCR) to Fresenius Medical Care AG (Fresenius) for cash proceeds of \$45.0 million (the ELCR Sale), resulting in a pre-tax loss of \$68.2 million. ELCR provided and managed perfusionists, monitoring systems, capital equipment and disposable material on a contract service basis to hospitals in the United States and Puerto Rico.

The following unaudited pro forma consolidated condensed statement of operations gives effect to the ELCR Sale as if it had occurred on January 1, 2001 and excludes the \$68.2 million loss on the sale. The unaudited pro forma consolidated condensed statement of operations does not purport to be indicative of either the results of future operations or the results of operations that would have occurred had the ELCR Sale been consummated on January 1, 2001. The following amounts are in millions, except per share amounts:

	Year Ended December 31, 2001
Net sales	\$ 631.1
Net income	45.9
Net income per share:	
Basic	0.78
Diluted	0.75

Other Charges (\$14.8 million)

Based upon the non-strategic nature and declining profitability of certain products in the Company's portfolio (including certain distributed products), the Company decided during the quarter ended June 30, 2001 to discontinue its sales effort of these products. The long-lived assets and the investments related to these products were evaluated to determine whether any impairment in their recoverability existed at the determination date. As a result, Edwards Lifesciences assessed whether the estimated cash flows of the products or investments over the estimated lives of the related assets were sufficient to recover their costs. Where such cash flows were insufficient, the Company utilized a discounted cash flow model to estimate the fair value of assets or investments and recorded an impairment charge to adjust the carrying values to estimated fair values. As a result of this evaluation, Edwards Lifesciences recorded a non-cash charge of \$14.8 million primarily related to the impairment of intangibles (\$8.3 million), the impairment of an investment (\$5.5 million) and the write-down of non-productive assets (\$1.0 million).

2000*Loss on Sale and Abandonment of Assets (\$302.0 million)*

During 2000, the Company sold the majority of its United States and Western European assets and rights related to its perfusion products to Jostra AG (the Jostra Sale). In accordance with SFAS No.121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of, and Staff Accounting Bulletin No. 100, Restructuring and Impairment Charges, the Company recorded a pre-tax impairment charge of \$290.5 million in 2000 to reduce the carrying value of these assets to fair value based upon the estimated net proceeds from the Jostra Sale. Assets subject to this impairment charge consisted primarily of goodwill (\$245.0 million) and special-use manufacturing and support assets. The goodwill impairment charge was calculated based upon a pro rata allocation of the goodwill using the relative fair values of the affected long-lived assets and identifiable intangibles acquired at the inception date of the goodwill. On August 31, 2000, Edwards Lifesciences completed the Jostra Sale for \$24.0 million (consisting of \$10.0 million in cash and a \$14.0 million note receivable, payable in six equal quarterly installments through March 1, 2002, plus interest at an annual effective rate of 8%). All payments under the note have been made.

In conjunction with the Jostra Sale, during 2000 the Company recorded charges to establish a \$9.7 million reserve for personnel costs and a \$1.8 million reserve for exit activities. The personnel costs consisted primarily of severance, medical plan continuation and outplacement services for the approximately 225 employees impacted by the Jostra Sale. The impacted employees were located in Europe, the United States and Puerto Rico, and primarily worked in a manufacturing capacity. The exit activities consisted primarily of information systems costs, contract termination costs and shutdown expenses.

The following table summarizes the utilization of these reserves through December 31, 2001 (in millions):

	Initial Reserve	Utilized in 2000	Balance at December 31, 2000	Utilized in 2001	Balance at December 31, 2001
Personnel costs	\$ 9.7	\$ (1.8)	\$ 7.9	\$ (7.9)	\$
Exit activities	1.8	(1.4)	0.4	(0.4)	
	\$ 11.5	\$ (3.2)	\$ 8.3	\$ (8.3)	\$

Gain on Sale of Assets (\$35.0 million)

On June 30, 2000, Edwards Lifesciences transferred the rights, intellectual property and United States assets related to the Novacor mechanical cardiac assist product line to WorldHeart. In return, the Company received (a) preferred stock of a subsidiary of WorldHeart which, at Edwards option, can be exchanged for approximately five million shares of WorldHeart's common stock commencing July 2003, bears a cumulative dividend and matures in June 2015 and (b) exclusive worldwide distribution rights to the Novacor left ventricular assist system and any ventricular assist technologies developed by WorldHeart. Edwards Lifesciences also will provide components and technical support to WorldHeart for ventricular assist products at agreed upon prices. The Company recorded a pre-tax gain of \$35.0 million during 2000 in connection with this transaction.

As part of the transaction with WorldHeart, the Company invested \$20.0 million in WorldHeart convertible preferred stock. The preferred stock bears a cumulative dividend, matures in June 2007, is callable at any time by WorldHeart and is convertible by Edwards Lifesciences into WorldHeart common stock commencing July 2006. Edwards Lifesciences reports its investments in WorldHeart as available-for-sale securities.

The following unaudited pro forma consolidated condensed statement of operations gives effect to the sales to Jostra AG and WorldHeart by Edwards Lifesciences as if the sales had occurred on January 1, 2000 and exclude the \$302.0 million loss on sale to Jostra AG and the \$35.0 million gain on sale to WorldHeart. The unaudited pro forma consolidated condensed statement of operations does not purport to be indicative of either the results of future operations or the results of operations that would have occurred had the sales been consummated on January 1, 2000. The following amounts are in millions, except per share amounts:

	Year Ended December 31, 2000
Net sales	\$ 771.9
Net income	8.2
Net income per share:	
Basic	0.14
Diluted	0.13

Other Charges (\$45.2 million)

As a result of Edwards Lifesciences' continuing efforts to focus the Company's product portfolio and effect the Company's business strategy following the spin-off from Baxter, during 2000 the Company decided to discontinue certain products in its portfolio that did not meet the objectives of its business strategy. The long-lived assets or the investments in these products were evaluated to determine whether any impairment in their recoverability existed at the determination date. As a result, Edwards Lifesciences assessed whether the estimated cash flows of the products over the estimated lives of the related assets were sufficient to recover their costs. Where such cash flows were insufficient, the Company utilized a discounted cash flow model to estimate the fair value of assets or investments and recorded an impairment charge to adjust the carrying values to estimated fair values. As a result of this evaluation, Edwards Lifesciences recorded a non-cash charge of \$45.2 million during 2000 primarily related to the impairment of goodwill unrelated to perfusion products (\$37.0 million), impairment of other intangibles (\$5.1 million) and the write-down of non-productive assets (\$3.1 million).

5. ACCOUNTS RECEIVABLE SECURITIZATION

Edwards Lifesciences has two agreements (the Japan Receivables Facility and the U.S. Receivables Facility, or the Facilities) with financial institutions whereby it securitizes, on a continuous basis, an undivided interest in certain eligible trade account receivables. In December 2002 the Company entered into the Japan Receivables Facility whereby the Company's Japanese subsidiary (Edwards Lifesciences Japan Limited) sells eligible accounts receivable directly to a financial institution. Under the U.S. Receivables Facility, the Company sells eligible accounts receivable to a wholly owned, special purpose, bankruptcy-remote subsidiary formed for the purpose of buying and selling these receivables, which then sells the participating interests in the receivables to a financial institution.

The transactions under both Facilities are accounted for as sales of accounts receivable. The Company retained servicing responsibilities and subordinated residual interests in the accounts receivables. No servicing asset or liability has been recorded as the Company's compensation for servicing the assets is just adequate to cover the cost of its servicing responsibilities. The Company receives annual servicing fees approximating one percent of the outstanding balance and rights to future cash flows arising after the investors in the securitization trust have received their contractual return. The investors and the securitization trust have no recourse to the Company's other assets for failure of debtors to pay when due. The Company's residual interests are subordinate to the investors' interests. The Facilities expire in December 2003 and are renewable for one-year periods at the Company's option.

Sales of receivables under these programs result in a reduction of accounts receivable on the Company's Consolidated Balance Sheets. Residual interests are carried at their fair value estimated as the net realizable value, which considers the relatively short liquidation period and includes an estimated provision for credit losses, and are included in Other Current Assets. Pursuant to the terms of the Facilities, the Company had sold approximately \$82.7 million and \$42.1 million of trade accounts receivable as of December 31, 2002 and 2001, respectively, resulting in a reduction of trade accounts receivable on the Company's Consolidated Balance Sheets, and received funding of approximately \$67.1 million and \$37.2 million. In 2002, proceeds from new sales totaled \$474.1 million and cash collections totaled \$455.2 million. In 2001, proceeds from new sales totaled \$411.6 million and cash collections totaled \$406.4 million. Costs associated with the sale of receivables, primarily related to the discount and loss on sale, were \$1.6 million, \$1.4 million and \$0.4 million in 2002, 2001 and 2000, respectively, and are included in Other (Income) Expense, net.

6. GOODWILL AND OTHER INTANGIBLE ASSETS

On January 1, 2002, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets, whereby goodwill is no longer amortized, but instead is subject to a periodic impairment review, performed by the Company in the fourth quarter of each year. As the Company's operations are comprised of one reporting unit, the Company reviews the recoverability of its goodwill by comparing the Company's fair value to the net book value of its assets. If the book value of the Company's assets exceeds the Company's fair value, the goodwill is written down to its implied fair value. The initial impairment analysis was completed in the fourth quarter of 2002 and resulted in no impairment.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

Pursuant to SFAS No. 142, the results for periods prior to adoption are not to be restated. If SFAS No. 142 had been effective January 1, 2000, net loss and earnings per basic and diluted share would have been as follows (in millions, except per share information):

	Years Ended December 31,	
	2001	2000
Reported net income (loss)	\$ (11.4)	\$ (271.7)
Goodwill amortization, net of tax	17.7	28.3
Adjusted net income (loss)	\$ 6.3	\$ (243.4)
Earnings per basic share:		
Reported net loss	\$ (0.19)	
Adjusted net income	\$ 0.11	
Earnings per diluted share:		
Reported net loss	\$ (0.19)	
Adjusted net income	\$ 0.10	

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

December 31, 2002	Patents	Unpatented Technology	Other	Total
Cost	\$ 96.8	\$ 36.3	\$ 5.8	\$ 138.9
Accumulated amortization	(58.2)	(15.5)	(3.3)	(77.0)
Net carrying value	\$ 38.6	\$ 20.8	\$ 2.5	\$ 61.9
December 31, 2001	Patents	Unpatented Technology	Other	Total
Cost	\$ 128.8	\$ 39.8	\$ 5.1	\$ 173.7
Accumulated amortization	(84.9)	(16.4)	(3.8)	(105.1)
Net carrying value	\$ 43.9	\$ 23.4	\$ 1.3	\$ 68.6

Amortization expense related to other intangible assets for the years ended December 31, 2002 and 2001 was \$9.5 million and \$9.9 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2003	\$ 8.7
2004	8.7
2005	8.7
2006	8.5
2007	8.5

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	December 31,	
	2002	2001
	(in millions)	
Accounts payable	\$ 69.5	\$ 53.1
Employee compensation and withholdings	38.4	33.5
Property, payroll and other taxes	33.7	31.5
Other accrued liabilities	56.3	65.4
	\$ 197.9	\$ 183.5

8. LONG-TERM DEBT, CREDIT FACILITIES AND LEASE OBLIGATIONS

Edwards Lifesciences entered into two unsecured revolving credit agreements (the Credit Facilities) as of the Distribution, providing for up to an aggregate of \$530.0 million in borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate (LIBOR) plus 0.78%, which includes a facility fee. One of the credit agreements provides for long-term borrowings up to an aggregate of \$430.0 million and expires on March 30, 2005. The other credit agreement provides for short-term borrowings up to an aggregate of \$100.0 million and expires on March 27, 2003. The Company anticipates that it will replace the \$100.0 million credit agreement with a similar credit agreement through March 2004. As of December 31, 2002, approximately \$245.5 million was outstanding under the \$430.0 million credit agreement. Edwards Lifesciences pays a facility fee, regardless of available or outstanding borrowings, currently at an annual rate of 0.15% for the \$430 million credit agreement and 0.125% for the \$100.0 million credit agreement. The Credit Facilities contain various financial and other covenants of Edwards Lifesciences, including a maximum leverage ratio and a minimum interest coverage ratio. All amounts outstanding under the \$430.0 million credit agreement have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to this credit agreement.

Edwards Lifesciences utilizes interest rate swap agreements in managing its exposure to interest rate fluctuations. Interest rate swap agreements are executed as an integral part of specific debt transactions. Edwards Lifesciences' interest rate swap agreements involve agreements to receive a floating rate and pay a fixed rate, at specified intervals, calculated on an agreed-upon notional amount. As of December 31, 2002, Edwards Lifesciences had in place four interest rate swaps with a total notional amount of \$199.4 million to swap floating rate United States dollar and Yen denominated debt obtained under the Company's revolving credit facilities for fixed rates. The original maturities of the interest rate swap agreements are between three and five years.

The weighted average interest rate under the Credit Facilities was 4.79% at December 31, 2002, including the effect of interest rate swap agreements. The rates have been calculated using rates in effect at December 31, 2002, some of which are floating rates that reset periodically.

Future minimum lease payments (including interest) under noncancelable operating leases and aggregate debt maturities at December 31, 2002 were as follows:

	Operating Leases	Aggregate Debt Maturities	
	(in millions)		
2003	\$ 5.8	\$	
2004	5.4		
2005	3.3		245.5
2006	3.0		
2007	1.0		
Thereafter			
Total obligations and commitments	\$ 18.5	\$	245.5

Included in debt at December 31, 2002 were unsecured notes denominated in various foreign currencies as follows (in millions):

Japanese Yen	13,700.0
Euro	15.0
Swiss Franc	5.0

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 \$6.8 million, \$6.1 million and \$5.3 million for the years 2002, 2001 and 2000, respectively.

9. FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

Fair values of financial instruments

The consolidated financial statements include financial instruments whereby the fair market value of such instruments may differ from amounts reflected on a historical basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities and debt. The fair values of certain investments in unconsolidated affiliates are estimated based on quoted market prices. For other investments, various methods are used to estimate fair value, including external valuations and discounted cash flows. The carrying amount of the Company's long-term debt approximates fair market value based on prevailing market rates. The Company's other financial instruments generally approximate their fair values based on the short-term nature of these instruments.

Derivative financial instruments

The Company utilizes a variety of derivative financial instruments to manage its currency exchange rate and interest rate risk as summarized below. The Company does not enter into these arrangements for trading or speculation purposes.

	2002		December 31,		2001	
	Notional Amount	Fair Value	Notional Amount	Fair Value	Notional Amount	Fair Value
(in millions)						
Interest rate swap agreements	\$ 199.4	\$ (11.0)	\$ 168.4	\$ (10.3)		
Option-based products	162.7	(2.7)	94.4	0.7		
Forward currency agreements	226.1	(2.6)	62.0	8.5		

The fair value of financial instruments was estimated by discounting expected cash flows using quoted market interest rates and foreign exchange rates as of December 31, 2002 and 2001. Notional amounts are stated in the United States dollar equivalents at spot exchange rates at the respective dates. Considerable judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

At December 31, 2002, the fair value of option-based products, forward currency and interest rate swap agreements is recorded in Accrued Liabilities. During the year ended December 31, 2002 and 2001, the Company reclassified from Accumulated Other Comprehensive Income a net gain of \$5.9 million and \$8.2 million, respectively, to Cost of Goods Sold, and a net loss of \$5.0 million and \$3.8 million, respectively, to Interest Expense, Net. The Company expects that during the next 12 months it will reclassify to earnings an \$11.2 million loss currently recorded in Accumulated Other Comprehensive Income. For the year ended December 31, 2002 and 2001, the Company expensed \$1.3 million and \$2.0 million, respectively, related to the time value of option-based products.

10. COMMON STOCK

The Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program (the Program), which became effective April 1, 2000, provides for the grant of incentive and non-qualified stock options, restricted stock and other stock-based incentive awards for eligible employees and contractors of the Company. Under the Program, these grants are generally awarded at a price equal to the fair market value at the date of grant based upon the closing price on the date immediately preceding the grant date. Options to purchase shares of the Company's common stock granted under the Program generally vest over predetermined periods and expire 10 years after the date of grant. An aggregate of 12.5 million shares of the Company's common stock has been reserved for issuance under the Program.

On April 3, 2000, the Company granted options to purchase shares of Edwards Lifesciences' common stock under the Program. The grants include two types of stock options: Founders Options and Conversion Options. The Founders Options were awarded to all salaried employees of the Company, and permit the purchase of approximately 5.7 million shares at an exercise price of \$13.88, the fair market value at the date of

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

grant. The Founders Options vested 30% on April 3, 2002, and the balance will vest on April 3, 2003. The Founders Options included approximately 634,000 options

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

granted to non-employees of the Company in Japan (employees of Baxter dedicated to the joint venture as described in Notes 1 and 3). In accordance with SFAS No. 123, Accounting for Stock-Based Compensation, the \$4.0 million value of these options is being amortized over the three-year vesting period on a straight-line basis. The Conversion Options permitted the purchase of approximately 2.2 million shares at an exercise price based upon an equitable conversion of the exercise price under the Baxter stock option plan, with reference to the when-issued price of the Company's stock and the closing price of Baxter's common stock on March 31, 2000. The Conversion Options retained the vesting periods under the Baxter stock option plan, resulting in various vesting periods. All of the Conversion Options were vested as of the end of September 2002.

The Company also maintains the Nonemployee Directors and Consultants Stock Incentive Program (the Nonemployee Program), which became effective April 1, 2000, and has subsequently been amended. Under the Nonemployee Program, each non-employee director annually receives 10,000 stock options. Additionally, each non-employee director may elect to receive all or a portion of the cash retainer to which the director is otherwise entitled through the issuance of stock options. As of December 31, 2002, 172,962 options were issued under the Nonemployee Program.

Stock option activity under the Program and the Nonemployee Program was as follows (options in thousands):

	2002		2001		2000	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding, beginning of year	7,716	\$ 14.79	7,686	\$ 13.59		\$
Options issued with the Distribution					7,852	13.37
Options granted during period	2,784	26.03	1,123	22.01	424	16.87
Options exercised	(552)	14.17	(481)	12.14		
Options cancelled	(154)	18.17	(612)	14.33	(590)	13.14
Outstanding, end of year	9,794	17.97	7,716	14.79	7,686	13.59
Exercisable, end of year	3,251	14.52	1,857	13.46	523	10.20

The following table summarizes stock options outstanding at December 31, 2002 (options in thousands):

Range of Exercise Prices	Number of Options	Outstanding Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Options	Exercisable Weighted Average Exercise Price
\$13.88 (Founders Options)	4,353	7.3	\$ 13.88	1,132	\$ 13.88
\$10.20-\$15.71 (Conversion options)	1,438	5.4	12.13	1,438	12.13
\$15.44-\$28.85 (Other options)	4,003	9.0	24.52	681	20.63
	9,794	7.7	17.97	3,251	13.46

The Company applies the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, in accounting for its fixed stock option and employee stock purchase plans. In accordance with this intrinsic value method, no compensation expense is recognized for these plans. The Company has adopted the disclosure requirements for SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, if compensation expense for the Company's stock option and employee stock purchase plans had been recognized, based upon the fair value of awards granted, the Company's net income and earnings per share would have been reduced to the following pro forma amounts (in millions, except per share amounts):

	2002		2001		2000	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net Income	\$ 55.7	\$ 40.4	\$ (11.4)	\$ (22.2)	\$ (271.7)	\$ (280.2)
Basic earnings per share	0.94	0.68	(0.19)	(0.38)		
Diluted earnings per share	0.91	0.66	(0.19)	(0.38)		

The per share weighted-average fair value for options granted during 2002, 2001 and 2000 was \$11.64, \$7.00 and \$6.39, respectively. The fair value of each option was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	2002	2001	2000
Average risk-free interest rate	4.4%	5.8%	5.8%
Expected dividend yield	None	None	None
Expected volatility	44%	45%	45%
Expected life (years)	5	5	5

Restricted Stock

A one-time grant of 5,000 shares of restricted stock was made to each of the non-employee directors pursuant to the Nonemployee Program. These grants vest 50% after one year and the balance vests after two years from the date of grant. An aggregate of 300,000 shares of the Company's common stock has been authorized for issuance pursuant to the Nonemployee Program. Grants of restricted stock to non-employees are charged to unearned compensation in Stockholders' Equity at their intrinsic value and recognized as expense over the vesting period. Compensation expense recognized for such grants was approximately \$0.1 million for 2002 and \$0.2 million for both 2001 and 2000.

Employee Stock Purchase Plan

The Company has two employee stock purchase plans (ESPP) for eligible employees to 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 Board of Directors authorized an aggregate of 2,150,000 shares of the Company's common stock for issuance under the ESPP. As of December 31, 2002, 290,385 shares have been issued under the plans.

Special Ownership Stock Option Plan

Prior to the Distribution, certain employees of Edwards Lifesciences participated in stock-based compensation plans sponsored by Baxter. Such plans principally included fixed stock option plans and employee stock purchase plans. Baxter applied APB Opinion No. 25, and related interpretations in accounting for such plans. Accordingly, no compensation cost was recognized for the fixed stock option plans and the employee stock purchase plans. These plans remain the sole responsibility of Baxter.

Employees who transferred to Edwards Lifesciences were required to exercise any vested options within 90 days from the spin-off date from Baxter unless an employee qualified for certain retirement, disability or other special provisions, and all unvested Baxter options were cancelled by Baxter on June 30, 2000.

Stockholder Rights Plan

In connection with the Distribution, the Company adopted a Stockholder Rights Plan to protect stockholders' rights in the event of a proposed or actual acquisition of 15% or more of the outstanding shares of the Company's common stock. As part of this plan, each share of the Company's common stock carries a right to purchase one one-hundredth (1/100) of a share of Series A Junior Participating Preferred Stock (the Rights), par value \$0.01 per share, subject to adjustment, which becomes exercisable only upon the occurrence of certain events. The Rights are subject to redemption at the option of the Board of Directors at a price of \$0.01 per right until the occurrence of certain events. The Rights expire on March 31, 2010, unless earlier redeemed or exchanged by the Company.

Other

During 2000, Edwards Lifesciences issued to certain hourly employees approximately 125,000 shares of the Company's common stock valued at \$1.7 million.

Treasury Stock

In November 2001, the Company's Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to two million shares of the Company's outstanding common stock. Stock repurchased under the program will primarily be used to offset dilution resulting from shares issued under the Company's employee stock option programs. During 2002 and 2001, the Company repurchased 1,298,300 and 26,800 shares at an aggregate cost of \$30.8 million and \$686,000, respectively. The timing and size of any future stock repurchases are subject to a variety of factors, including market conditions, stock prices and other cash

requirements.

11. EMPLOYEE BENEFIT PLANS

Defined Benefit Plans

Prior to the Distribution, Edwards Lifesciences employees participated in Baxter-sponsored defined benefit pension plans covering substantially all employees in the United States and Puerto Rico and employees in certain European countries. The benefits were based on years of service and the employees' compensation during five of the last 10 years of employment as defined by the plans. Effective as of the Distribution, Edwards Lifesciences' employees ceased to be eligible to accrue any additional benefits under the Baxter plan for United States employees. Edwards Lifesciences did not adopt a pension plan for United States employees to replace the Baxter plan in the United States. The pension liability related to Edwards Lifesciences' United States employees' service prior to the Distribution remains with Baxter. With respect to the Puerto Rico and certain European plans, Baxter transferred the assets and liabilities relating to Edwards Lifesciences' employees to Edwards Lifesciences as of the Distribution. Edwards Lifesciences has adopted a defined benefit pension plan in Puerto Rico and in certain European countries.

Pension expense for the Baxter-sponsored plans relating to Edwards Lifesciences' employees was \$0.4 million for the three months ended March 31, 2000.

On October 1, 2002, the Company completed its spin-off from Baxter and acquired the cardiovascular business in Japan (See Notes 1 and 3). As part of the transaction, the Company acquired the defined benefit plan that covered the Japan employees and the related pension assets and liabilities.

In addition to pension benefits, Edwards Lifesciences participated in Baxter-sponsored contributory health care and life insurance benefits for substantially all domestic retired employees through the Distribution. Baxter and Edwards Lifesciences froze benefits under these plans as of the Distribution for Edwards Lifesciences employees. Edwards Lifesciences has not established new health care and life insurance plans for employees retiring subsequent to the Distribution. Expense associated with these benefits relating to Edwards Lifesciences employees was less than \$1.0 million in 2000.

Edwards Lifesciences sponsors defined benefit pension plans in Puerto Rico, Japan and in certain European countries. A reconciliation of these plans' benefit obligations, assets, funded status and net liability are as follows (in millions):

	Years Ended December 31,	
	2002	2001
Benefit Obligations:		
Beginning of period	\$ 28.1	\$ 23.0
Service cost	1.6	1.5
Interest cost	1.7	1.7
Participant contributions	0.2	0.2
Actuarial loss	4.1	2.6
Addition of Japan plan	8.6	
Curtailement gains	(0.2)	(1.6)
Benefits paid	(0.3)	
Currency exchange rate changes and other	0.9	0.7
End of year	\$ 44.7	\$ 28.1
Fair value of plan assets:		
Beginning of period	\$ 20.3	\$ 17.6
Actual return on plan assets	(0.7)	(0.4)
Employer contributions	1.6	2.1
Participant contributions	0.2	0.2
Addition of Japan plan	1.1	
Benefits paid	(0.3)	
Currency exchange rate changes and other	0.7	0.8
End of year	\$ 22.9	\$ 20.3
Funded status of plans:		
Funded status of plans	\$ (21.8)	\$ (7.7)
Unrecognized net transition obligation	0.6	
Unrecognized net losses	13.5	4.6
Unrecognized prior service cost	1.6	2.6
Net liability on balance sheet	\$ (6.1)	\$ (0.5)
Net liability on balance sheet consists of:		
Prepaid benefit cost	\$ 0.1	\$ 0.9
Accrued benefit liability	(11.8)	(1.4)
Other assets	3.1	
Accumulated other comprehensive loss	1.6	
Deferred tax asset	0.9	
Net liability on balance sheet	\$ (6.1)	\$ (0.5)

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

	Years Ended December 31,					
	2002		2001		2000	
Service cost	\$	1.6	\$	1.5	\$	1.1
Interest cost		1.7		1.7		1.1
Expected return on plan assets		(1.5)		(1.5)		(1.0)
Amortization of prior service cost and other		0.1		0.3		0.2
Net periodic pension benefits cost	\$	1.9	\$	2.0	\$	1.4

Significant assumptions used in determining benefit obligations and net periodic benefit cost are summarized as follows (in weighted averages):

	Years Ended December 31,	
	2002	2001
Discount Rate	4.96%	6.31%
Expected return on plan assets	6.77%	7.74%
Rate of compensation increase	3.66%	3.83%

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. Participants may contribute up to 15% of their annual compensation (subject to tax code limitation) to the plans. Edwards Lifesciences matches the first 3 percent of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis. Edwards Lifesciences matches the next 2 percent of the participant's annual eligible compensation to the plan on a 50% basis. Matching contributions relating to Edwards Lifesciences employees were \$4.4 million and \$3.9 million, \$3.2 million 2002, 2001 and 2000, respectively.

The Company has a nonqualified deferred compensation plan for a select group of management that provides the opportunity to defer a specified percentage of their cash compensation. Participants may elect to defer up to 100% of bonus and 15% of total annual compensation. The Company's obligations under this plan are unfunded. The amount accrued under this plan was \$3.3 million at December 31, 2002 and \$2.2 million at December 31, 2001.

The Edwards Lifesciences Corporation Executive Option Plan (the Executive Plan) became effective for participation by eligible employees in 2001. Eligible employees who participate in the Executive Plan may not participate in the Company's nonqualified deferred compensation plan. Under the Executive Plan, executive officers and certain other key employees may elect to forgo a portion of their annual salary and bonus for an option to purchase shares of mutual funds or the Company's common stock. The options are granted quarterly with an initial exercise price equal to 25% of the fair market value per share (as defined in the Executive Plan) of the respective security on the grant date. The number of shares subject to each option is determined such that the difference between the aggregate fair market value (as defined in the Executive Plan) and the aggregate exercise price under

the option is equal to the amount of forgone compensation attributable to the option. A total of 95,000 shares of the Company's common stock have been registered for issuance under the Executive Plan.

12. RELATED PARTY TRANSACTIONS

Prior to the Distribution, Baxter provided to the Edwards Lifesciences Business certain legal, treasury, employee benefit, insurance and administrative services. Charges for these services were based on actual costs incurred by Baxter. The amounts charged to Edwards Lifesciences varied depending on the nature of the service, but generally were determined using headcount, sales, payroll, square footage or other appropriate data, or were determined on actual utilization of services. Management believes that the allocation of service charges is reasonable. However, the terms of these transactions may differ from those that would result from transactions with unrelated third parties or had Edwards Lifesciences performed these functions on its own.

Prior to the Distribution, Edwards Lifesciences participated in a centralized cash management program administered by Baxter. Short-term advances from Baxter or excess cash sent to Baxter have been treated as an adjustment to the Investment by Baxter International Inc., net account as of and through March 31, 2000. No interest was allocated to Edwards Lifesciences on this balance.

The following table summarizes the charges from Baxter for the above-mentioned services, as recorded in Edwards Lifesciences' Consolidated Statements of Operations for the year ended December 31, 2000 (in millions):

Cost of goods sold	\$ 1.6
Selling, general and administrative expenses	10.5
Research and development expenses	0.7

Effective on the Distribution, Baxter and Edwards Lifesciences entered into a series of administrative services agreements pursuant to which Baxter and Edwards Lifesciences continued to provide, for a specified period of time, certain administrative services (primarily information systems support, payroll, accounting and warehousing and logistics support) that each entity historically provided to the other. These agreements required the parties to pay each other a fee that approximated the actual costs of these services. Additionally, subsequent to March 31, 2000, Edwards Lifesciences had continuing relationships with Baxter as a customer and supplier for certain products, and used Baxter as a distributor of the Company's products in certain regions of the world. Substantially all of these service agreements and relationships had been terminated as of December 31, 2002.

Sales to Baxter, acting in the capacity of the Company's distributor subsequent to the Distribution, represented approximately 8%, 11% and 12% of the Company's total net sales for 2002, 2001 and 2000, respectively.

In December 2001, the Chief Executive Officer of the Company received a \$2.5 million loan pursuant to his employment agreement with the Company as approved by the Board of Directors. The loan was used for the purchase of his primary residence in connection with his relocation. The loan is non-interest bearing and is due in December 2006 or upon resignation or the termination of employment. The loan is collateralized by the Chief Executive Officer's primary residence.

13. OTHER (INCOME) EXPENSE, NET

	Years Ended December 31,		
	2002	2001	2000
	(in millions)		
Legal settlement, net	\$ (14.7)	\$	\$
Foreign exchange (gain) loss	(4.1)	5.0	2.3
Asset dispositions and write downs, net	2.3	6.5	0.5
Investment write-offs	1.4		
Other	(0.3)	(0.9)	1.0
	\$ (15.4)	\$ 10.6	\$ 3.8

14. INCOME TAXES

Edwards Lifesciences operations prior to the Distribution were included in the consolidated income tax returns of Baxter. The income tax information for periods prior to the Distribution was calculated as if Edwards Lifesciences were a stand-alone affiliated group for those periods.

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

	Years Ended December 31,		
	2002	2001	2000
	(in millions)		
United States	\$ 3.5	\$ (66.7)	\$ (320.8)
International	52.5	58.3	62.4
	\$ 56.0	\$ (8.4)	\$ (258.4)

The provision for income taxes consists of the following:

	Years Ended December 31,		
	2002	2001	2000
	(in millions)		
Current			
United States			
Federal	\$ 0.6	\$	\$
State and local	0.3	0.7	1.0
International including Puerto Rico	10.6	30.9	13.2
Current income tax expense	11.5	31.6	14.2
Deferred			
United States			
Federal	(7.4)	(15.3)	
State and local	(0.9)	(5.1)	(0.9)
International including Puerto Rico	(2.9)	(9.7)	
Deferred income tax benefit	(11.2)	(30.1)	(0.9)
Total income tax expense	\$ 0.3	\$ 1.5	\$ 13.3

The components of deferred tax assets and liabilities are as follows:

	2002	December 31, (in millions)	2001
Deferred tax assets			
Investments in unconsolidated affiliates	\$ 29.7		\$
Net operating loss carryforwards	19.0		13.2
Accrued liabilities	12.0		4.9
Other intangible assets	10.5		
Allowance for doubtful accounts	7.9		5.5
Tax credit carryforwards	6.4		3.1
Compensation and benefits	5.6		6.7
Inventories	2.4		3.0
Other	9.9		4.7
Total deferred tax assets	103.4		41.1
Deferred tax liabilities			
Property, plant and equipment	(15.8)		(12.9)
Deferred gain on sale of assets			(13.9)
Other intangible assets			(10.0)
Other	(1.3)		(1.1)
Total deferred tax liabilities	(17.1)		(37.9)
Valuation allowance	(19.9)		(4.2)
Net deferred tax assets (liabilities)	\$ 66.4		\$ (1.0)

Deferred income taxes have not been provided on the undistributed earnings of the Company's foreign subsidiaries of approximately \$80.1 million as of December 31, 2002 since these amounts are intended to be permanently reinvested in foreign operations. It is not practicable to calculate the deferred taxes associated with these earnings; however, foreign tax credits would likely be available to reduce federal income taxes in the event of distribution.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

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

	Years Ended December 31,		
	2002	2001	2000
	(in millions)		
Income tax expense (benefit) at U.S. federal statutory rate	\$ 19.6	\$ (2.9)	\$ (90.4)
(Benefit) loss on sale of perfusion services business	(20.1)	11.0	
Valuation allowance for loss on investment	13.8		
Foreign income tax at different rates	(10.6)	(6.8)	(8.4)
Tax credits	(1.9)	(1.6)	(0.7)
State and local taxes, net of federal tax benefit	(0.1)	(3.0)	
Nondeductible charges (Note 4)			99.9
Nondeductible goodwill		6.0	9.8
Other	(0.4)	(1.2)	3.1
Income tax expense	\$ 0.3	\$ 1.5	\$ 13.3

The Company has manufacturing operations outside the United States, primarily in Puerto Rico, Switzerland and The Dominican Republic, which benefit from reductions in local tax rates under various tax incentives.

As a result of recent tax law developments and the filing of the Company's 2001 tax return, the Company recorded a \$20.1 million tax benefit during 2002 related to the loss on sale of its United States perfusion services business in June 2001.

In exchange for the sale of the Novacor mechanical cardiac assist product line to WorldHeart in June 2000, the Company received WorldHeart preferred stock (see Note 4). In 2002, the investment in the WorldHeart preferred stock was deemed to be impaired and written down to its fair market value. Due to the uncertainty of using any potential tax benefit for the loss, a valuation allowance of \$13.8 million has been established.

As of December 31, 2002, the Company has approximately \$19.0 million of U.S. federal and state tax net operating losses and \$5.5 million of tax credits available for carry-forward that will begin to expire in 2012 if not utilized. The Company also has approximately \$38.2 million of foreign tax net operating losses available for carry-forward that will begin to expire in 2005 if not utilized and approximately \$0.9 million of non-expiring tax credits that are available for carry-over. A valuation allowance of \$6.1 million has been provided on certain foreign net operating losses.

15. LEGAL PROCEEDINGS

On June 29, 2000, Edwards Lifesciences filed a lawsuit for patent infringement against Medtronic, Inc., which, as amended, alleged infringement of three Edwards Lifesciences United States patents. On September 18, 2001, Edwards Lifesciences filed a separate complaint

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

against Medtronic alleging infringement of a fourth Edwards Lifesciences United States patent. These lawsuits were filed in the United States District Court for the District of Delaware. Effective April 24, 2002, Edwards Lifesciences entered into an agreement with Medtronic resolving these patent infringement claims and dismissing the two lawsuits. Under the terms of the settlement, Edwards Lifesciences received a

one-time cash payment of \$20.0 million (recorded as a gain of \$14.7 million, net of legal expenses, in Other (Income) Expense, net) and granted Medtronic a royalty-bearing license on two of the Edwards Lifesciences patents. In addition, on July 2, 2002, Edwards Lifesciences and Medtronic submitted to binding arbitration on another of the patents in dispute. Medtronic prevailed in this arbitration and will not require an additional license.

On June 29, 2000, Edwards Lifesciences also filed a lawsuit against St. Jude Medical, Inc. alleging infringement of three Edwards Lifesciences United States patents. This lawsuit was filed in the United States District Court for the Central District of California, seeking monetary damages and injunctive relief. St. Jude has answered and asserted various affirmative defenses and counterclaims with respect to the lawsuits. On April 9, 2002, a fourth Edwards Lifesciences United States patent was added to the lawsuit. Discovery is proceeding.

Edwards Lifesciences is, or may be, a party to, or may be otherwise 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 and complexities, 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 pending legal matters, Edwards Lifesciences may incur charges in excess of presently established reserves. While such a charge could have a material adverse impact on Edwards Lifesciences net income or net cash flows in the period in which it is recorded or paid, management believes that no such charge would have a material adverse effect on Edwards Lifesciences consolidated financial position.

Edwards Lifesciences also 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 compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences financial position, results of operations or liquidity.

16. SEGMENT INFORMATION

Edwards Lifesciences manages its business on the basis of one reportable segment. Refer to Note 1 for a description of the Company's business. The Company's products and services share similar distribution channels and customers and are sold principally to hospitals and physicians. Management evaluates its various global product portfolios on a revenue basis, which is presented below, and profitability is evaluated on an enterprise-wide basis due to shared infrastructures. Edwards Lifesciences principal markets are the United States, Europe and Japan.

Geographic area data includes net sales based on product shipment destination and long-lived asset data is presented based on physical location.

	As of or for the years ended December 31,		
	2002	2001	2000
	(in millions)		
Net Sales by Geographic Area			
United States	\$ 383.3	\$ 420.8	\$ 481.8
Europe	157.3	145.4	160.2
Japan	94.8	62.0	93.9
Other countries	68.6	63.9	67.9
	\$ 704.0	\$ 692.1	\$ 803.8
Net Sales by Major Product and Service Area			
Cardiac Surgery	\$ 365.9	\$ 329.0	\$ 311.2
Critical Care	230.3	209.9	217.3
Vascular	51.3	49.3	54.8
Perfusion	43.2	102.1	206.7
Other Distributed Products	13.3	1.8	13.8
	\$ 704.0	\$ 692.1	\$ 803.8
Long-Lived Assets by Geographic Area			
United States	\$ 572.2	\$ 657.5	\$ 772.7
Other countries	70.8	33.4	32.8
	\$ 643.0	\$ 690.9	\$ 805.5

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

	Years ended December 31					Total year
	First quarter	Second quarter	Third quarter	Fourth quarter		
(in millions, except per share data)						
2002						
Net sales	\$ 162.3	\$ 172.8	\$ 165.8	\$ 203.1	\$	704.0
Gross profit	93.2	98.4	95.9	117.4		404.9
Net income (loss)(a)	20.8	30.6	(17.4)	21.7		55.7
Earnings (loss) per common share						
Basic	0.35	0.52	(0.30)	0.37		0.94
Diluted	0.34	0.50	(0.30)	0.36		0.91
Market price						
High	29.60	28.05	25.75	27.50		29.60
Low	25.00	22.18	18.40	23.81		18.40
2001						
Net sales	\$ 191.9	\$ 192.4	\$ 147.8	\$ 160.0	\$	692.1
Gross profit	95.7	97.2	83.4	92.1		368.4
Net income (loss)(b)	12.7	(55.7)	14.5	17.1		(11.4)
Earnings (loss) per common share						
Basic	0.22	(0.95)	0.25	0.29		(0.19)
Diluted	0.21	(0.95)	0.24	0.28		(0.19)
Market price						
High	22.75	26.45	28.00	29.15		29.15
Low	16.75	17.80	20.40	22.60		16.75

n/a not applicable

(a) The third quarter includes (1) a \$67.4 million pretax charge related to the impairment of the Company's investment in WorldHeart preferred stock, (2) a \$20.1 million tax benefit related to the loss on sale of its United States perfusion services business in June 2001 resulting from tax law developments and the filing of the Company's 2001 tax return, and (3) a \$3.3 million charge for legal, administrative and regulatory expense related to the acquisition of the cardiovascular business in Japan.

(b) The second quarter includes (1) a \$68.2 million pretax loss on the sale of the Company's perfusion services business to Fresenius, and (2) a \$14.8 million pretax charge consisting of the write-down of selected goodwill, intangible assets and other assets.

EDWARDS LIFESCIENCES CORPORATION

VALUATION AND QUALIFYING ACCOUNTS (in millions)

	Balance at beginning of period	Charged to costs and expenses	Additions Charged to other accounts	Deductions from reserves	Balance at end of period
Year ended December 31, 2002					
Allowance for doubtful accounts and returns	\$ 4.3	\$ 5.7		\$ (4.5)	\$ 5.5
Inventory reserves	9.4	4.9	1.8	(6.5)	9.6
Litigation reserves	3.4	1.4		(0.7)	4.1
Year ended December 31, 2001					
Allowance for doubtful accounts and returns	4.5	3.6		(3.8)	4.3
Inventory reserves	8.3	9.1		(8.0)	9.4
Litigation reserves	5.4	1.5		(3.5)	3.4
Year ended December 31, 2000					
Allowance for doubtful accounts and returns	8.1	2.8		(6.4)	4.5
Inventory reserves	12.2	21.2		(25.1)	8.3
Litigation reserves	2.1	5.4		(2.1)	5.4

Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

PART III

Item 10 Directors and Executive Officers of the Registrant

This information required by this Item is set forth under the headings Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Executive Officers of Edwards Lifesciences in the definitive proxy materials to be filed in connection with its 2003 Annual Meeting of Stockholders (the Proxy Statement) (which Proxy Statement will be filed with the Securities and Exchange Commission on or before April 30, 2003). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference.

Item 11 Executive Compensation

Except for information referred to in Item 402(a)(8) of Regulation S-K, the information contained under the headings Election of Directors and 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 are incorporated herein by reference.

Item 13 Certain Relationships and Related Transactions

The information contained under the heading Related Party Transactions in the Proxy Statement is incorporated herein by reference.

Item 14 Controls and Procedures

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

The Company's management, including the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the Company's disclosure controls and procedures as of a date within 90 days of the filing of this report on Form 10-K. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer have determined that such controls and procedures are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to them, particularly during the period in which this Form 10-K was being prepared. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls subsequent to the date of their evaluation.

PART IV

Item 15 Exhibits, Financial Statement Schedules, and Reports on Form 8-K

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of Edwards Lifesciences Corporation (l)
3.2	Amended and Restated Bylaws of Edwards Lifesciences Corporation (a)
3.3	Form of Certificate of Designation for Edwards Lifesciences Corporation Series A Junior Participating Preferred Stock (included as Exhibit A to Exhibit 10.9) (a)
4.1	Specimen form of certificate representing Edwards Lifesciences Corporation common stock (a)
10.1	Form of Agreement and Plan of Reorganization, to be entered into between Edwards Lifesciences Corporation and Baxter International Inc. (a)
10.2	Form of Tax Sharing Agreement, to be entered into between Edwards Lifesciences Corporation and Baxter International Inc. (a)
*10.3	Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program (a)
*10.4	Form of Edwards Lifesciences Corporation Change in Control Severance Agreement (i)
*10.5	Employment Agreement for Michael A. Mussallem (i)
*10.6	Promissory Note Secured by Deed of Trust for Michael A. Mussallem dated December 11, 2001 (l)
10.9	Form of Rights Agreement between Edwards Lifesciences Corporation and EquiServe Trust Company, N.A, as Rights Agent, dated as of March 31, 2000 (a)
10.10	Services and Distribution Agreement between Edwards Lifesciences LLC, as successor in interest to Baxter Healthcare Corporation, and Allegiance Healthcare Corporation, dated as of October 1, 1996. CONFIDENTIAL INFORMATION APPEARING IN THIS DOCUMENT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION IN ACCORDANCE WITH SECTION 24(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND RULE 24b-2 PROMULGATED THEREUNDER. OMITTED INFORMATION HAS BEEN REPLACED WITH ASTERISKS (a)
*10.11	Form of Employment Agreement (a)
10.12	Form of Consulting Agreement (a)
10.13	Form of Outgoing Confidentiality Agreement (a)
*10.14	Edwards Lifesciences Corporation Nonemployee Directors and Consultants Stock Incentive Program (a)
10.16	Form of Tokumei Kumiai Agreement by and between Baxter Limited and Edwards Lifesciences Finance Limited, dated as of April 1, 2000 (a)
10.17	Form of Option Agreement by and between Baxter Limited and Edwards Lifesciences Limited, dated as of April 1, 2000 (a)
10.18	Form of Japan Distribution Agreement by and between Baxter Limited and Edwards Lifesciences LLC, dated as of April 1, 2000 (a)
10.19	Five Year Credit Agreement dated as of March 31, 2000, among Edwards Lifesciences Corporation, a Delaware corporation; the Swiss Borrowers; the Japanese Borrowers; the Lenders from time to time party hereto; The Chase Manhattan Bank, as Administrative Agent; Chase Manhattan International Limited, as London Agent; The Fuji Bank, Limited, as the Tokyo Agent; Bank One, N.A., as Syndication Agent; and Credit Suisse First Boston, as Documentation Agent (b)

- 10.20 364-Day Credit Agreement dated as of March 30, 2000, among Edwards Lifesciences Corporation, a Delaware corporation; the Lenders from time to time party hereto; The Chase Manhattan Bank, as Administrative Agent; Bank One, N.A., as Syndication Agent; and Credit Suisse First Boston, as Documentation Agent (b)
- *10.21 Edwards Lifesciences Corporation Severance Pay Plan (b)
- 10.22 Contribution Agreement by and among Edwards Lifesciences LLC, Edwards Novacor LLC, WorldHeart Corporation and Valentine Acquisition Corp. dated as of May 24, 2000 (c)
- 10.23 Amendment No. 1, dated as of June 30, 2000, to the Five Year Credit Agreement dated as of March 30, 2000, among Edwards Lifesciences Corporation, a Delaware corporation; the Swiss Borrowers; the Japanese Borrowers; the Lenders from time to time party thereto; The Chase Manhattan Bank, as Administrative Agent; Chase Manhattan International Limited, as London Agent; The Fuji Bank, Limited, as the Tokyo Agent; Bank One, N.A., as Syndication Agent; and Credit Suisse First Boston, as Documentation Agent, and to the 364 Day Credit Agreement dated as of March 30, 2000, among Edwards Lifesciences Corporation, the Lenders from time to time party thereto, The Chase Manhattan Bank, as Administrative Agent, Bank One, N.A., as Syndication Agent and Credit Suisse First Boston, as Documentation Agent (c)
- *10.24 Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program (as amended and restated July 12, 2000) (d)
- *10.25 Edwards Lifesciences Corporation Nonemployee Directors and Consultants Stock Incentive Program (as amended and restated March 2001) (h)
- *10.26 Edwards Lifesciences Corporation Executive Option Plan (e)
- *10.27 Amendment Edwards Lifesciences Corporation of Puerto Rico Savings and Investment Plan (f)
- *10.28 Edwards Lifesciences Corporation 401(k) Savings and Investment Plan (g)
- *10.29 Edwards Lifesciences Corporation 2002 Incentive Plan. CONFIDENTIAL INFORMATION APPEARING IN THIS DOCUMENT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION IN ACCORDANCE WITH SECTION 24(b) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED AND RULE 24b-2 PROMULGATED THEREUNDER. OMITTED INFORMATION HAS BEEN REPLACED WITH ASTERISKS (m)
- 10.30 Amendment No. 2, dated as of March 29, 2001, to the Five Year Credit Agreement dated as of March 30, 2000 among Edwards Lifesciences Corporation, a Delaware corporation; the Swiss Borrowers; the Japanese Borrowers; the Lenders from time to time party thereto; The Chase Manhattan Bank, as Administrative Agent; Chase Manhattan International Limited, as London Agent; The Fuji Bank, Limited, as the Tokyo Agent; Bank One, N.A., as Syndication Agent; and Credit Suisse First Boston, as Documentation Agent (j)
- 10.31 Amended and Restated 364-Day Credit Agreement dated as of March 29, 2001 among Edwards Lifesciences Corporation, as Borrower, the lenders Party hereto; The Chase Manhattan Bank, as Administrative Agent; Credit Suisse First Boston, as Syndication Agent; and the Bank of Nova Scotia, as Documentation Agent; JP Morgan, a division of Chase Securities Inc., as Advisor, Lead Arranger and Bookrunner (j)
- 10.32 Agreement between Edwards Lifesciences Corporation and Richard L. Miller, dated May 3, 2001 (k)

- 10.33 Amendment and Restatement Agreement (to the 364-Day Credit Agreement dated as of March 30, 2000 and the Amended and Restated 364-Day Credit Agreement dated as of March 29, 2001) dated as of March 28, 2002 among Edwards Lifesciences Corporation, as Borrower, the lenders Party hereto; JPMorgan Chase Bank, as Administrative Agent; Credit Suisse First Boston, Cayman Islands Branch and Wachovia Bank, N.A. as Co-Syndication Agents; and the Bank of Nova Scotia and Bank of America, N.A. as Co-Documentation Agents; JPMorgan Securities Inc., as Lead Arranger and Bookrunner (m)
- 10.34 Supplemental Reorganization Agreement and Amendment to Tax Sharing Agreement, dated as of July 25, 2002, by and between Baxter International Inc. and Edwards Lifesciences Corporation (n)
- 10.35 Kaisha Bunkatsu & Stock purchase Agreement, dated as of July 25, 2002, entered into by and among Baxter Limited; Baxter Holdings Limited; Edwards Lifesciences Limited; and Edwards Lifesciences AG (n)
- 10.36 Amendment No. 3, dated as of October 21, 2002, to the Five Year Credit Agreement dated as of March 30, 2000 among Edwards Lifesciences Corporation, a Delaware corporation; the Swiss Borrowers; The Japanese Borrowers; the Lenders from time to time party thereto; JPMorgan Chase Bank, as Administrative Agent; J. P. Morgan Europe Limited, as London Agent; Mizuho Corporate Bank, LTD., as the Tokyo Agent; Bank One, N.A., as Syndication Agent; and Credit Suisse First Boston, as Documentation Agent (n)
- 10.37 Amendment No. 1, dated as of October 21, 2002, to the 364-Day Amended And Restated Credit Agreement dated as of March 28, 2002 among Edwards Lifesciences Corporation, a Delaware corporation; the Lenders from time to time party thereto, JPMorgan Chase Bank, as Administrative Agent; Credit Suisse First Boston, Cayman Islands Branch and Wachovia Bank, N.A., as Co-Syndication Agents and The Bank Of Nova Scotia And Bank Of America, N.A., as Co-Documentation Agents (n)
- 10.38 Receivables Purchase Agreement, dated as of December 21, 2000, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, and Wachovia Bank, N.A.
- 10.39 Amendment No. 1 to Receivables Purchase Agreement, dated as of February 1, 2001, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, and Wachovia Bank, N.A.
- 10.40 Second Amendment to Receivables Purchase Agreement, dated as of September 20, 2001, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, N.A.
- 10.41 Third Amendment to Receivables Purchase Agreement, dated as of March 8, 2002, by and among Edwards Lifesciences Financing LLC, a Delaware limited liability company, Edwards Lifesciences LLC, a Delaware limited liability company, Blue Ridge Asset Funding Corporation, a Delaware corporation, the Liquidity Banks and Wachovia Bank, N.A.
- 10.42 Receivables Purchase Agreement, dated December 4, 2002, by and among Edwards Lifesciences Limited, a Japanese corporation, Apreco, Inc., a Delaware corporation and Citilease Company Limited, a Japanese corporation
- *10.43 Long-Term Stock Incentive Compensation Program (as amended and restated May 8, 2002)
- *10.44 Nonemployee Directors and Consultants Stock Incentive Program (as amended and restated November 13, 2002)
- 21.1 Subsidiaries of Edwards Lifesciences Corporation

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-K/A

23	Consent of Independent Accountants
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

-
- (a) Incorporated by reference to the cited exhibit in Edwards Lifesciences Registration Statement on Form 10 (File No. 001-15525).
- (b) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended March 31, 2000, under the Securities Exchange Act of 1934.
- (c) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended June 30, 2000, under the Securities Exchange Act of 1934.
- (d) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended September 30, 2000, under the Securities Exchange Act of 1934.
- (e) Incorporated by reference to Exhibit 4.4 in Edwards Lifesciences Registration Statement on Form S-8 (File No. 333-52332).
- (f) Incorporated by reference to Exhibit 4.3 in Edwards Lifesciences Registration Statement on Form S-8 (File No. 333-40434).
- (g) Incorporated by reference to Exhibit 4.3 in Edwards Lifesciences Registration Statement on Form S-8 (File No. 333-33056).
- (h) Incorporated by reference to Exhibit 4.6 in Edwards Lifesciences Registration Statement on Form S-8 (File No. 333-60670).
- (i) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-K for the fiscal year ended December 31, 2000, under the Securities Exchange Act of 1934.
- (j) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended March 31, 2001, under the Securities Exchange Act of 1934.
- (k) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended June 30, 2001, under the Securities Exchange Act of 1934.
- (l) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-K for the fiscal year ended December 31, 2001, under the Securities Exchange Act of 1934.
- (m) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended March 31, 2002, under the Securities Exchange Act of 1934.
- (n) Incorporated by reference to the cited exhibit in Edwards Lifesciences report on Form 10-Q for the quarterly period ended September 30, 2002, under the Securities Exchange Act of 1934.

* Represents management contract or compensatory plan

SIGNATURES

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

EDWARDS LIFESCIENCES CORPORATION

October 29, 2003

By: /s/ MICHAEL A. MUSSALLEM
 Michael A. Mussallem
*Chairman of the Board and
 Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MICHAEL A. MUSSALLEM Michael A. Mussallem	Chairman of the Board and Chief Executive Officer	October 29, 2003
/s/ CORINNE H. LYLE Corinne H. Lyle	Corporate Vice President, Chief Financial Officer and Treasurer (Chief Accounting Officer)	October 29, 2003
/s/ BRUCE P. GARREN Bruce P. Garren	Corporate Vice President, General Counsel and Secretary	October 29, 2003
/s/ MIKE R. BOWLIN* Mike R. Bowlin	Director	October 29, 2003
/s/ ROBERT A. INGRAM* Robert A. Ingram	Director	October 29, 2003
/s/ VERNON R. LOUCKS JR.* Vernon R. Loucks Jr.	Director	October 29, 2003
/s/ PHILIP M. NEAL* Philip M. Neal	Director	October 29, 2003
/s/ DAVID E.I. PYOTT* David E.I. Pyott	Director	October 29, 2003

*By /s/ BRUCE P. GARREN
Bruce P. Garren
Attorney-in-fact