

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

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q/A

AMENDMENT NO. 1

(Mark One)

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

For the Quarterly Period Ended March 31, 2003

or

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

For the transition period from to

Commission file number 1-15525

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

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Delaware

(State or other jurisdiction of
incorporation or organization)

36-4316614

(I.R.S. Employer Identification No.)

One Edwards Way, Irvine, California

(Address of principal executive offices)

92614

(Zip Code)

(949) 250-2500

(Registrant's telephone number, including area code)

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

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

The number of shares outstanding of the registrant's common stock, \$1.00 par value, as of April 30, 2003, was 60,943,358.

**EDWARDS LIFESCIENCES CORPORATION
FORM 10-Q**

For the quarterly period ended March 31, 2003

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Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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EXPLANATORY NOTE

We are filing this Amendment No. 1 on Form 10-Q/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 Quarterly Report have been amended, for convenience and ease of reference we are filing this Quarterly Report in its entirety. Unless otherwise stated, all information contained in this amendment is as of May 15, 2003, the filing date of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.

Part I. Financial Information

Item 1. Financial Statements

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED BALANCE SHEETS

(unaudited) (in millions, except share data)

| | March 31, 2003 | December 31, 2002 |
|---|-------------------|----------------------|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 29.8 | \$ 34.2 |
| Accounts and other receivables, net | 124.9 | 108.4 |
| Inventories, net | 116.3 | 111.8 |
| Deferred income taxes | 29.2 | 27.6 |
| Prepaid expenses and other current assets | 50.9 | 44.4 |
| Total current assets | 351.1 | 326.4 |
| Property, plant and equipment, net | 205.1 | 209.4 |
| Goodwill | 333.8 | 333.8 |
| Other intangible assets, net | 69.5 | 61.9 |
| Investments in unconsolidated affiliates | 23.2 | 23.5 |
| Deferred income taxes | 39.0 | 38.8 |
| Other assets | 14.2 | 14.4 |
| | \$ 1,035.9 | \$ 1,008.2 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 189.6 | \$ 197.9 |
| Long-term debt | 276.9 | 245.5 |
| Other liabilities | 26.4 | 25.4 |

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Commitments and contingent liabilities

Stockholders equity

| | | |
|---|--------------|--------------|
| Common stock, \$1.00 par value, 350,000,000 shares authorized, 60,396,796 and 60,177,275 shares outstanding | 60.4 | 60.2 |
| Additional contributed capital | 416.0 | 412.0 |
| Retained earnings | 157.9 | 143.4 |
| Accumulated other comprehensive income | (51.6) | (44.7) |
| Common stock in treasury, at cost | (39.7) | (31.5) |
| Total stockholders equity | 543.0 | 539.4 |
| | \$ 1,035.9 | \$ 1,008.2 |

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(unaudited) (in millions, except per share information)

| | Three Months Ended March 31, | |
|---|---------------------------------|----------|
| | 2003 | 2002 |
| Net sales | \$ 212.5 | \$ 162.3 |
| Cost of goods sold | 89.1 | 69.1 |
| Gross profit | 123.4 | 93.2 |
| Selling, general and administrative expenses | 71.4 | 50.7 |
| Research and development expenses | 19.0 | 15.4 |
| Purchased in-process research and development expenses | 11.8 | |
| Other operating income | | (3.8) |
| Operating income | 21.2 | 30.9 |
| Interest expense, net | 2.7 | 2.8 |
| Other income, net | (3.6) | |
| Income before provision for income taxes | 22.1 | 28.1 |
| Provision for income taxes | 7.6 | 7.3 |
| Net income | \$ 14.5 | \$ 20.8 |
| Share information: | | |
| Earnings per basic share | \$ 0.25 | \$ 0.35 |
| Earnings per diluted share | \$ 0.24 | \$ 0.34 |
| Weighted average number of common shares outstanding | | |
| Basic | 58.8 | 59.3 |
| Diluted | 60.9 | 61.8 |

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(unaudited) (in millions)

| | Three Months Ended March 31, | |
|---|---------------------------------|---------|
| | 2003 | 2002 |
| Cash flows from operating activities | | |
| Net income | \$ 14.5 | \$ 20.8 |
| Income charges (credits) not affecting cash: | | |
| Depreciation and amortization | 10.8 | 9.7 |
| Other | | (0.6) |
| Changes in operating assets and liabilities: | | |
| Accounts and other receivables | (14.4) | (12.4) |
| Inventories | (1.8) | (0.3) |
| Accounts payable and accrued liabilities | (11.7) | (15.1) |
| Other | (6.0) | (3.0) |
| Net cash used in operating activities | (8.6) | (0.9) |
| Cash flows from investing activities | | |
| Capital expenditures | (7.8) | (7.6) |
| Investments in intangible assets | (9.5) | (1.7) |
| Proceeds from asset dispositions | 5.6 | 2.3 |
| Investments in unconsolidated affiliates | (0.7) | (0.5) |
| Net cash used in investing activities | (12.4) | (7.5) |
| Cash flows from financing activities | | |
| Proceeds from issuance of short-term debt | | 0.4 |
| Proceeds from issuance of long-term debt | 69.1 | 20.0 |
| Payments on long-term debt | (39.5) | (31.1) |
| Purchases of treasury stock | (8.2) | (1.8) |
| Proceeds from stock plans | 3.6 | 3.3 |
| Proceeds from accounts receivable securitization, net | 2.5 | (1.0) |
| Other | (0.3) | (0.3) |
| Net cash provided by (used in) financing activities | 27.2 | (10.5) |
| Effect of currency exchange rate changes on cash and cash equivalents | (10.6) | (0.8) |

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| | | |
|--|---------|---------|
| Net decrease in cash and cash equivalents | (4.4) | (19.7) |
| Cash and cash equivalents at beginning of period | 34.2 | 47.7 |
| Cash and cash equivalents at end of period | \$ 29.8 | \$ 28.0 |

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

Edwards Lifesciences Corporation

Notes to Consolidated Condensed Financial Statements

March 31, 2003

(unaudited)

1. BASIS OF PRESENTATION AND ACCOUNTING POLICIES

These interim consolidated condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission and should be read in conjunction with the consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2002. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted.

In the opinion of management of Edwards Lifesciences Corporation (the Company or Edwards Lifesciences), the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair presentation of the interim periods. All such adjustments are of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, which amends SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 148 provides alternative methods of transition for companies that voluntarily change to the fair value-based method of accounting for stock-based employee compensation, and also requires expanded disclosures in both interim and annual financial statements. During the quarter ended March 31, 2003, the Company adopted the provisions of this statement related to expanded disclosures.

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 following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB No. 123 (in millions, except per share amounts):

| Three Months Ended March 31, | |
|---|-------------|
| 2003 | 2002 |

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| | | | | |
|--|----|-------|----|-------|
| Net income, as reported | \$ | 14.5 | \$ | 20.8 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of tax | | (4.3) | | (4.2) |
| Pro forma net income | \$ | 10.2 | \$ | 16.6 |
| Earnings per basic share: | | | | |
| Reported net income | \$ | 0.25 | \$ | 0.35 |
| Pro forma net income | \$ | 0.17 | \$ | 0.28 |
| Earnings per diluted share: | | | | |
| Reported net income | \$ | 0.24 | \$ | 0.34 |
| Pro forma net income | \$ | 0.17 | \$ | 0.27 |

Joint Venture in Japan

Subsequent to the distribution of the Company's common stock to stockholders of Baxter International Inc. (Baxter) on March 31, 2000, 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. 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 the cardiovascular business in Japan and 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 Japanese cardiovascular business.

2. ACQUISITION OF ASSETS

On February 18, 2003, as disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2002, the Company acquired the endovascular mitral valve repair program of Jomed N.V., a European-based provider of products for minimally invasive vascular intervention, for \$20.0 million in cash. The acquisition included all technology and intellectual property associated with the program. The fair market value of the assets acquired consists primarily of patents which are being amortized over their estimated economic life of 17 years. During the quarter ended March 31, 2003, the Company recorded an \$11.8 million pretax charge for in-process research and development expenses related to this transaction. The value of the in-process research and development was calculated using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately \$20 million of additional research and development expenditures would be incurred prior to the date of product introduction. Material net cash inflows were forecasted in the valuation to commence in 2008.

3. INVENTORIES

Inventories consisted of the following (in millions):

| | March 31, 2003 | | December 31, 2002 |
|-------------------|-------------------|----|----------------------|
| Raw materials | \$ 20.5 | \$ | 17.4 |
| Work in process | 20.9 | | 14.7 |
| Finished products | 74.9 | | 79.7 |
| | \$ 116.3 | \$ | 111.8 |

4. OTHER INTANGIBLE ASSETS

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

| | Patents | Unpatented Technology | Other | Total |
|--------------------------|----------|--------------------------|--------|----------|
| <u>March 31, 2003</u> | | | | |
| Cost | \$ 106.6 | \$ 36.3 | \$ 5.8 | \$ 148.7 |
| Accumulated amortization | (59.7) | (16.1) | (3.4) | (79.2) |
| Net carrying value | \$ 46.9 | \$ 20.2 | \$ 2.4 | \$ 69.5 |
| <u>December 31, 2002</u> | | | | |
| 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 |

Amortization expense related to other intangible assets for the quarters ended March 31, 2003 and 2002 was \$2.2 million and \$2.4 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

| | |
|------|--------|
| 2003 | \$ 8.8 |
| 2004 | 8.8 |
| 2005 | 8.7 |
| 2006 | 8.6 |
| 2007 | 8.6 |

5. CONVERTIBLE SENIOR DEBT

On May 9, 2003, the Company issued \$125.0 million of convertible senior debentures, bearing an interest rate of 3.875% per annum due May 15, 2033. Interest is payable semi-annually in May and November. Beginning on May 15, 2008, the Company may be required to pay additional interest contingent upon certain events and conditions. Issuance costs of approximately \$3.6 million will be amortized to interest expense over 5 years. Holders of the convertible debentures may upon certain conditions convert their debentures into shares of the Company's common stock at an initial conversion price of \$54.66.

Holders of the debentures have the right to require the Company to purchase all or a portion of their debentures at a price equal to 100% of the principal amount of the debentures plus any accrued interest on May 15, 2008, May 15, 2013, and May 15, 2018. The Company will pay cash for all debentures so purchased on May 15, 2008. For any debentures purchased by the Company on May 15, 2013, or May 15, 2018, the Company may at its option pay the purchase price for any such debentures in cash or in shares of the Company's common stock or any combination thereof. The Company must pay all accrued interest in cash.

The Company may redeem for cash all or part of the debentures, at any time and from time to time, on or after May 15, 2008, at a redemption price equal to 100% of the principal amount of the debentures to be redeemed plus any accrued interest.

If the Company undergoes a change in control prior to May 15, 2008, holders of the debentures have the right to require the Company to purchase all or any portion of their debentures at a purchase price equal to 100% of the principal amount of the debentures being purchased plus any accrued interest. The Company may at its option pay the purchase price for any debentures that holders require to be purchased upon a change in control in cash or in shares of the Company's common stock or any combination thereof. The Company must pay accrued interest in cash.

6. COMMITMENTS AND CONTINGENCIES

On June 29, 2000, Edwards Lifesciences 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 and pretrial hearings are proceeding.

Edwards Lifesciences is or may be, a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences or other matters. Such cases and claims may raise difficult and complex factual and legal issues and may be 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 or other claims, Edwards Lifesciences may incur a charge or charges in excess of presently established reserves. While any such 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 relating to any currently pending lawsuit or other claim 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' net income, cash flows or financial position.

7. COMPREHENSIVE INCOME

Reconciliation of net income to comprehensive income is as follows (in millions):

| | Three Months Ended March 31, | |
|--|---|-------------|
| | 2003 | 2002 |
| Net income | \$ 14.5 | \$ 20.8 |
| Other comprehensive income: | | |
| Currency translation adjustments, net of tax | (4.1) | 4.8 |
| Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax | (0.4) | 0.7 |
| Unrealized net loss on cash flow hedges, net of tax | (2.4) | (0.5) |
| Comprehensive income | \$ 7.6 | \$ 25.8 |

8. EARNINGS PER SHARE

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

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2003 | 2002 |
| Basic shares outstanding | 58.8 | 59.3 |
| Dilutive effect of employee stock options | 2.1 | 2.5 |
| Diluted shares outstanding | 60.9 | 61.8 |

Anti-dilutive stock options to purchase 2.6 million and 0.2 million shares of common stock were excluded from the computation of diluted shares outstanding for the quarters ended March 31, 2003 and 2002, respectively.

9. SEGMENT INFORMATION

Edwards Lifesciences manages its business on the basis of one reportable segment. The Company's products and technologies 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 generally 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, based upon physical location.

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2003 | 2002 |
| (in millions) | | |
| Net Sales by Geographic Area | | |
| United States | \$ 97.0 | \$ 94.8 |
| Japan (Note 1) | 49.1 | 16.2 |
| Europe | 47.2 | 36.5 |
| Other countries | 19.2 | 14.8 |
| | \$ 212.5 | \$ 162.3 |
| Net Sales by Major Product and Service Lines | | |
| Cardiac Surgery | \$ 107.4 | \$ 87.7 |
| Critical Care | 66.4 | 52.6 |
| Vascular | 13.8 | 11.8 |
| Perfusion | 13.7 | 9.5 |
| Other Distributed Products | 11.2 | 0.7 |
| | \$ 212.5 | \$ 162.3 |

| | March 31, 2003 | December 31, 2002 |
|---|---------------------------|------------------------------|
| | (in millions) | |
| Long-Lived Assets by Geographic Area | | |
| United States | \$ 569.4 | \$ 572.2 |
| Other countries | 76.4 | 70.8 |
| | \$ 645.8 | \$ 643.0 |

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company intends the forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in these sections. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are forward-looking statements for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, any statements of the plans, strategies and objectives of management for future operations, any statements concerning proposed new products, any statements regarding future economic conditions, any statements concerning our future operations, financial conditions and prospects, and any statement of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as may, believe, will, expect, project, estimate, and plan, continue, seek, pro forma, or intend or similar words or expressions of the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's future business, financial condition, results of operations, or performance to differ materially from the Company's historical results or those expressed in any forward-looking statements contained in this report. Investors should carefully review the information contained in the Company's Current Report on Form 8-K dated May 13, 2003, and elsewhere in, or incorporated by reference into, the Company's Annual Report on Form 10-K for the year ended December 31, 2002, or this report.

The following discussion and analysis presents the factors that had a material effect on the results of operations of Edwards Lifesciences during the three months ended March 31, 2003. Also discussed is Edwards Lifesciences' financial position as of March 31, 2003. You should read this discussion in conjunction with Company's Annual Report on Form 10-K for the year ended December 31, 2002 and the historical consolidated condensed financial statements and related notes included elsewhere in this Form 10-Q.

Certain disclosures prepared in accordance with generally accepted accounting principles (GAAP) contained in this discussion are accompanied by disclosures that are not prepared in conformity with GAAP. These non-GAAP disclosures exclude the impacts of fluctuations in foreign currency exchange rates and reflect our cardiovascular business in Japan (which prior to October 1, 2002, was operated through a joint venture) as if it had been our wholly-owned subsidiary for the first quarter of 2002 (see Joint Venture in Japan). The Company has included this non-GAAP information because the Company's management believes that it provides a more meaningful comparison of the Company's operating results for the periods presented in this discussion and of 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 cannulation used during open-heart surgery. Edwards Lifesciences is the world's leading manufacturer in, and has been a pioneer in the development and commercialization of, tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **critical care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's 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 than conventional surgical procedures. 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. Lastly, **other distributed products** include sales of intra-aortic balloon pumps, pacemakers, angioplasty systems and other products sold through our distribution network in Japan, and miscellaneous pharmaceutical products sold in the United States.

Joint Venture in Japan

Subsequent to the distribution of the Company's common stock to stockholders of Baxter International Inc. (Baxter) on March 31, 2000, 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. 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 the cardiovascular business in Japan and 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 is a summary of United States and international net sales (dollars in millions):

| | Three Months Ended March 31, | | Percent Change |
|-----------------|---------------------------------|----------|-------------------|
| | 2003 | 2002 | |
| United States | \$ 97.0 | \$ 94.8 | 2.3% |
| International | 115.5 | 67.5 | 71.1% |
| Total net sales | \$ 212.5 | \$ 162.3 | 30.9% |

The net sales increase in the United States for the three months ended March 31, 2003 was due primarily to increased sales of cardiac surgery products. The increase in international net sales was due primarily to the change in accounting for sales in Japan (see Joint Venture in Japan). Assuming the Japan business was consolidated for the three months ended March 31, 2002, international net sales for the quarter ended March 31, 2003 would have increased 28.0%. 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 quarter ended March 31, 2003 would have increased 14.4%. This adjusted international increase was due primarily to (a) an increase in sales of cardiac surgery and critical care products and (b) the assumption of direct sales responsibility and the associated buy-back of inventory in several small countries during the quarter ended March 31, 2002.

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.

Net Sales by Product Line

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

| | Three Months Ended March 31, | | Percent Change |
|-----------------|---------------------------------|---------|-------------------|
| | 2003 | 2002 | |
| Cardiac Surgery | \$ 107.4 | \$ 87.7 | 22.5% |
| Critical Care | 66.4 | 52.6 | 26.2% |
| Vascular | 13.8 | 11.8 | 16.9% |
| Perfusion | 13.7 | 9.5 | 44.2% |

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| | | | |
|----------------------------|----------|----------|-------|
| Other Distributed Products | 11.2 | 0.7 | NM |
| Total net sales | \$ 212.5 | \$ 162.3 | 30.9% |

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 the quarter ended March 31, 2002, net sales by product line would have been as follows (dollars in millions):

| | Three Months Ended March 31, | | Percent Change |
|----------------------------|---------------------------------|-----------------|-------------------|
| | 2003 | 2002 | |
| Cardiac Surgery | \$ 107.4 | \$ 89.9 | 19.5% |
| Critical Care | 66.4 | 57.9 | 14.7% |
| Vascular | 13.8 | 12.4 | 11.3% |
| Perfusion | 13.7 | 14.0 | (2.1)% |
| Other Distributed Products | 11.2 | 10.8 | 3.7% |
| Total net sales | \$ 212.5 | \$ 185.0 | 14.9% |

Assuming the Japan business was consolidated for the quarter ended March 31, 2002, and excluding the impact of foreign currency exchange rate fluctuations, net sales by product line (Adjusted Net Sales) would have changed as follows (dollars in millions):

| | Three Months Ended March 31, | | Percent Change |
|----------------------------|---------------------------------|-----------------|-------------------|
| | 2003 | 2002 | |
| Cardiac Surgery | \$ 107.4 | \$ 94.1 | 14.1% |
| Critical Care | 66.4 | 61.8 | 7.4% |
| Vascular | 13.8 | 13.3 | 3.8% |
| Perfusion | 13.7 | 14.7 | (6.8)% |
| Other Distributed Products | 11.2 | 11.9 | (5.9)% |
| Total net sales | \$ 212.5 | \$ 195.8 | 8.5% |

Cardiac Surgery

The Adjusted Net Sales growth in cardiac surgery products resulted primarily from strong sales growth of pericardial tissue valves and valve repair products in Japan and other international markets. Several new products launched in 2002 also contributed to the Adjusted Net Sales growth for the quarter ended March 31, 2003.

During the quarter ended March 31, 2003, the Company acquired the endovascular mitral valve repair program of Jomed N.V., a European-based provider of products for minimally invasive vascular intervention (see Purchased in-process research and development expenses). Management considers endovascular valve repair to be an important opportunity in the field of heart valve therapy and the Jomed program complements the Company's existing programs in this field.

Critical Care

The Adjusted Net Sales growth in critical care products was due primarily to physicians' continuing conversion to more advanced technology catheter products. Additionally, the Company had significant growth in emerging markets and Japan, as well as strong hemofiltration sales in Europe. Adjusted Net Sales growth was 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 2003 was due primarily to sales of the *Lifepath* AAA endovascular graft system in Europe and strong sales of base vascular products in developing markets.

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) peripheral stents, which are anticipated to be introduced in mid-2003.

Perfusion

The Adjusted Net Sales decrease for perfusion was due primarily to the planned reduction of distributed product sales.

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. The decrease in Adjusted Net Sales is due to particularly strong sales in Japan during the quarter ended March 31, 2002.

Gross Profit

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2003 | 2002 |
| Gross profit as a percentage of net sales | 58.1% | 57.4% |

Reflecting the Japanese business on a consolidated basis for the quarter ended March 31, 2002, gross profit as a percentage of net sales (Adjusted Percentage) would have been 58.0%. The increase in the Adjusted Percentage resulted primarily from increased sales of higher-margin cardiac surgery products, partially offset by the impact of foreign currency exchange rates.

Selling, General and Administrative (SG&A) Expenses

| | Three Months Ended March 31, | |
|--|---|-------------|
| | 2003 | 2002 |
| SG&A expenses as a percentage of net sales | 33.6% | 31.2% |

Reflecting the Japanese business on a consolidated basis for the quarter ended March 31, 2002, SG&A expenses as a percentage of net sales (Adjusted Percentage) would have been 32.7%. The increase in the Adjusted Percentage was due primarily to the impact of foreign currency exchange rates and greater spending for growth initiatives.

Research and Development Expenses

| | Three Months Ended March 31, | |
|--|---|-------------|
| | 2003 | 2002 |
| Research and development expenses as a percentage of net sales | 8.9% | 9.5% |

Reflecting the Japanese business on a consolidated basis for the quarter ended March 31, 2002, research and development expenses as a percentage of net sales (Adjusted Percentage) would have been 8.7%. The increase in the Adjusted Percentage was due primarily to investments in experienced talent related to new platforms in the cardiac surgery and vascular product lines.

Purchased in-process research and development expenses

During the three months ended March 31, 2003, the Company recorded an \$11.8 million pretax charge for in-process research and development expenses associated with the \$20.0 million acquisition of intellectual property and assets related to Jomed's endovascular mitral valve repair program. The value of the in-process research and development was calculated with the assistance of a third party appraiser using cash flow projections discounted for the risk inherent in such projects. The discount rate used was 30%. The valuation assumed approximately \$20 million of additional research and development expenditures would be incurred prior to the date of product introduction. Material net cash inflows were forecasted in the valuation to commence in 2008.

Other Operating Income

Other operating income for the three months ended March 31, 2002 represented the Company's 90% profit interest in the cardiovascular business in Japan, which was recorded utilizing the equity method of accounting through September 30, 2002. As a result of the acquisition of the Japanese business on October 1, 2002, there was no other operating income during the three months ended March 31, 2003. For more information, see Joint Venture in Japan.

Interest Expense, net

Interest expense, net was \$2.7 million and \$2.8 million during the three months ended March 31, 2003 and 2002, respectively. The decrease in interest expense, net resulted primarily from the Company's reduction of debt.

Other Income, net

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

| | Three Months Ended March 31, | |
|---|---|-------------|
| | 2003 | 2002 |
| Foreign exchange gains | \$ (5.6) | \$ 0.0 |
| Sale of property development rights | | (1.8) |
| Asset dispositions and write-downs, net | 0.8 | 1.1 |

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| | | |
|--|----------|--------|
| Accounts receivable securitization discount fees | 0.4 | 0.5 |
| Other | 0.8 | 0.2 |
| | \$ (3.6) | \$ 0.0 |

Foreign exchange gains relate primarily to the favorable impact of Euro and Japanese Yen exchange rates related to the structure of the Company's acquisition of the cardiovascular business in Japan effective October 1, 2002 (the cardiovascular business in Japan is owned by one of the Company's European subsidiaries). The Company has mitigated this exposure and does not expect similar significant foreign exchange gains or losses in future periods resulting from this transaction.

Provision for Income Taxes

The effective income tax rate was 34.4% and 26.0% for the three months ended March 31, 2003 and 2002, respectively. The increase in the effective income tax rate for the quarter ended March 31, 2003, was due to the in-process research and development charge being incurred in a low tax jurisdiction (see Purchased in-process research and development expenses). Excluding the impact of the in-process research and development charge, the effective income tax rate would have been 26.0% for the quarter ended March 31, 2003.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash and cash equivalents, cash from operations, proceeds from a convertible debt offering, amounts available under credit facilities, accounts receivables securitization 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.

As of March 31, 2003, the Company had two unsecured revolving credit agreements providing for up to an aggregate of \$530.0 million in borrowings in multiple currencies. 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 Five Year Credit Facility). The other credit agreement provides for borrowings up to an aggregate of \$100.0 million through March 25, 2004 (the 364 Day Facility). In March 2003, the Company extended the expiration date of the 364 Day Facility to March 25, 2004. As of March 31, 2003, borrowings of \$276.9 million were outstanding under the Five Year Credit Facility and no borrowings were outstanding under the 364 Day Facility. All amounts outstanding under the Five Year Credit Facility have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to this credit facility. The credit facilities contain various financial and other covenants, all of which the Company was in compliance with at March 31, 2003.

The Company also has two securitization programs whereby certain of our subsidiaries sell, without recourse, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable. As of March 31, 2003, the Company had sold a total of \$85.6 million of trade accounts receivable and received funding of \$69.6 million under both programs. One of the securitization programs expires December 3, 2005, and the other expires in December 2003 and is expected to be renewed.

On May 9, 2003, the Company issued \$125.0 million of senior convertible debentures bearing an interest rate of 3.875% per annum due May 15, 2033. A portion of the net proceeds from the senior debentures were used to repurchase approximately 915,000 shares of the Company's common stock for a total price of approximately \$26.3 million. The remaining net proceeds will be used for general corporate purposes, which may include the purchase of additional shares of our common stock and the repayment of indebtedness. Pending use of the remaining net proceeds, Edwards Lifesciences intends to invest those funds in short-term investments or to use those funds to temporarily reduce borrowings under revolving credit facilities. Interest on the debentures is payable semi-annually in May and November. Issuance costs of approximately \$3.6 million will be amortized to interest expense over the term of the senior debentures. For more information see Note 5 to the consolidated condensed financial statements.

At March 31, 2003, there have been no material changes in the Company's significant contractual obligations and commercial commitments as disclosed in its Annual Report on Form 10-K for the year ended December 31, 2002.

Cash flows used in operating activities for the three months ended March 31, 2003, increased \$7.7 million from the same period a year ago due primarily to reduced earnings (before non-cash items), which resulted primarily from the purchased in-process research and development charge (see Purchased in-process research and development expenses).

Cash used in investing activities for the three months ended March 31, 2003, consisted primarily of \$7.8 million of capital expenditures and \$9.5 million in patent related investments, primarily the acquisition of Jomed's intellectual property (see Purchased in-process research and development expenses). Offsetting these uses of cash were \$5.6 million of proceeds from the sale of an idle manufacturing facility and other machinery and equipment.

Cash provided by financing activities for the three months ended March 31, 2003, consisted primarily of \$29.6 million of net proceeds from long-term debt borrowings. During the three months ended March 31, 2003, the Company repurchased approximately 314,000 shares of its common stock, for an aggregate of \$8.2 million, bringing the total shares repurchased through March 31, 2003, to approximately 1.6 million (out of 2.0 million shares initially authorized to be repurchased).

The Company's Board of Directors approved a second stock repurchase program, effective as of May 6, 2003, authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional 2.0 million shares of the Company's outstanding common stock through December 31, 2005.

For the period April 1, 2003, through May 9, 2003, the Company repurchased no shares under the initial stock repurchase program and approximately 915,000 shares at an aggregate cost of \$26.3 million under the new stock repurchase program.

Critical Accounting Policies

The condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States which require the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and revenues and expenses during the periods reported. Actual results could differ from those estimates. Information with respect to the Company's critical accounting policies which the Company believes could have the most significant effect on the Company's reported results and require subjective or complex judgments by management is contained on pages 31-34 in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of the Company's Annual Report on Form 10-K for the year ended December 31, 2002. Management believes that at March 31, 2003, there has been no material change to this information.

New Accounting and Disclosure Standards Issued

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS No. 149 amends and clarifies financial accounting and reporting for hedging activities and derivative instruments including certain derivative instruments embedded in other contracts. SFAS No. 149 is effective for contracts entered into or modified after June 30, 2003 and is not expected to have a material impact on the Company's consolidated condensed financial statements.

New Accounting and Disclosure Standards Adopted

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. Adoption of this standard

in the quarter ended March 31, 2003, did not have a material impact on the Company's consolidated condensed 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. Adoption of this standard in the quarter ended March 31, 2003, did not have a material impact on the Company's consolidated condensed financial statements.

In December 2002, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*, which amends SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 148 provides alternative methods of transition for companies that voluntarily change to the fair value-based method of accounting for stock-based employee compensation, and also requires expanded disclosures in both interim and annual financial statements. During the quarter ended March 31, 2003, the Company adopted the provisions of this statement related to expanded disclosures (see Note 1 to the consolidated condensed financial statements).

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

For a discussion of the Company's exposure to interest rate risk, refer to Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* on pages 35-37 of the Company's Annual Report on Form 10-K for the year ended December 31, 2002. There have been no significant changes from the information discussed therein.

Currency Risk

For a discussion of the Company's exposure to foreign currency risk, refer to Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* on pages 35-37 of the Company's Annual Report on Form 10-K for the year ended December 31, 2002. There have been no significant changes from the information discussed therein.

Credit Risk

For a discussion of the Company's exposure to credit risk, refer to Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* on pages 35-37 of the Company's Annual Report on Form 10-K for the year ended December 31, 2002. There have been no significant changes from the information discussed therein.

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 probable credit losses, which have been adequate, based upon historical experience.

Investment Risk

Edwards Lifesciences is exposed to risks related to changes in the fair values of its investments in unconsolidated affiliates. The Company invests in equity securities of public and private companies. These investments are classified in Investments in unconsolidated affiliates on the consolidated balance sheets.

At March 31, 2003, the Company had approximately \$23.2 million of investments in equity securities and had recorded unrealized losses on these investments of \$7.3 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 4. Controls and Procedures

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-Q. 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-Q 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 the evaluation.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On June 29, 2000, Edwards Lifesciences 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 and pretrial hearings are proceeding.

Edwards Lifesciences is or may be, a party to, or may be otherwise responsible for, pending or threatened lawsuits or other claims related to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences or other matters. Such cases and claims may raise difficult and complex factual and legal issues and may be 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 or other claims, Edwards Lifesciences may incur a charge or charges in excess of presently established reserves. While any such 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 relating to any currently pending lawsuit or other claim 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' net income, cash flows or financial position.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits

Exhibits required by Item 601 of Regulation S-K are listed in the Exhibit Index hereto and include the following:

- | | |
|-------|--|
| 3.1 | Restated Certificate of Incorporation |
| 4.1 | Form of Debenture (Exhibit A to the Indenture listed below as Exhibit 4.2) |
| 4.2 | Indenture, dated as of May 9, 2003, between Edwards Lifesciences Corporation and JPMorgan Chase Bank, as Trustee |
| 4.3 | Rights Agreement, dated as of March 31, 2000 |
| 10.1 | Registration Rights Agreement, dated as of May 9, 2003 |
| 10.2 | Second Amendment and Restatement, dated March 27, 2003, to the 364-day Credit Agreement |
| *10.3 | Long-Term Stock Incentive Compensation Program (amended and restated as of February 20, 2003) |
| *10.4 | 2001 Employee Stock Purchase Plan for United States Employees (amended and restated as of February 20, 2003) |
| *10.5 | 2001 Employee Stock Purchase Plan for International Employees (amended and restated as of February 20, 2003) |
| *10.6 | Executive Option Plan (as amended and restated May 14, 2003) |
| *10.7 | Edwards Lifesciences Corporation 2003 Incentive Plan |
| *10.8 | Form of Employment Agreement |
| 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 |

(b) Reports on Form 8-K

None

* Represents management contract or compensatory plan.

SIGNATURE

Pursuant to the requirements 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

(Registrant)

Date: October 29, 2003

By:

/s/ CORINNE H. LYLE

Corinne H. Lyle

Corporate Vice President, Chief

Financial Officer and Treasurer

(Chief Accounting Officer)