

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 June 30, 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)

**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 July 31, 2003, was 61,925,231.



**EDWARDS LIFESCIENCES CORPORATION  
FORM 10-Q**

**For the quarterly period ended June 30, 2003**

**TABLE OF CONTENTS**

	<b>Page Number</b>
<b><u>Part I. FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	<u>Financial Statements (Unaudited)</u> 1
	<u>Consolidated Condensed Balance Sheets</u> 1
	<u>Consolidated Condensed Statements of Operations</u> 2
	<u>Consolidated Condensed Statements of Cash Flows</u> 3
	<u>Notes to Consolidated Condensed Financial Statements</u> 4
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 11
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 19
<u>Item 4.</u>	<u>Controls and Procedures</u> 20
<b><u>Part II. OTHER INFORMATION</u></b>	
<u>Item 1.</u>	<u>Legal Proceedings</u> 21
<u>Item 2.</u>	<u>Changes in Securities and Use of Proceeds</u> 21
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u> 22
<u>Item 6.</u>	<u>Exhibits and Reports on Form 8-K</u> 22
Signature	24
Exhibits	25

---

**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 August 13, 2003, the filing date of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.**

---

## Part I. Financial Information

## Item 1. Financial Statements

**EDWARDS LIFESCIENCES CORPORATION**  
**CONSOLIDATED CONDENSED BALANCE SHEETS**

(unaudited) (in millions, except share data)

	June 30, 2003	December 31, 2002
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 50.7	\$ 34.2
Accounts and other receivables, net	124.4	108.4
Inventories, net	125.6	111.8
Deferred income taxes	28.4	27.6
Prepaid expenses and other current assets	59.1	44.4
<b>Total current assets</b>	<b>388.2</b>	<b>326.4</b>
Property, plant and equipment, net	205.8	209.4
Goodwill	338.2	333.8
Other intangible assets, net	80.5	65.0
Investments in unconsolidated affiliates	21.5	23.5
Deferred income taxes	31.4	38.8
Other assets	14.1	11.3
	\$ 1,079.7	\$ 1,008.2
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 186.1	\$ 197.9
Long-term debt	307.3	245.5
Other liabilities	27.3	25.4
Commitments and contingent liabilities		
<b>Stockholders' equity</b>		
Common stock, \$1.00 par value, 350,000,000 shares authorized, 61,796,008 and 61,502,375 shares issued, 59,172,508 and 60,177,275 shares outstanding at June 30, 2003 and December 31, 2002, respectively	61.8	60.2
Additional contributed capital	434.8	412.0
Retained earnings	179.0	143.4

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

Accumulated other comprehensive income	(48.5)	(44.7)
Common stock in treasury, at cost, 2,623,500 and 1,325,100 shares at June 30, 2003 and December 31, 2002, respectively	(68.1)	(31.5)
Total stockholders' equity	559.0	539.4
	\$ 1,079.7	\$ 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 June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net sales	\$ 217.8	\$ 172.8	\$ 430.3	\$ 335.1
Cost of goods sold	89.6	74.4	178.7	143.5
Gross profit	128.2	98.4	251.6	191.6
Selling, general and administrative expenses	75.8	54.3	147.2	105.0
Research and development expenses	18.0	16.6	37.0	32.0
Purchased in-process research and development expenses			11.8	
Loss on sale of business	3.3		3.3	
Other operating income		(3.6)		(7.4)
Operating income	31.1	31.1	52.3	62.0
Interest expense, net	3.5	3.0	6.2	5.8
Other income, net	(1.4)	(15.7)	(5.0)	(15.7)
Income before provision for income taxes	29.0	43.8	51.1	71.9
Provision for income taxes	7.9	13.2	15.5	20.5
Net income	\$ 21.1	\$ 30.6	\$ 35.6	\$ 51.4
<b>Share information:</b>				
Earnings per share				
Basic	\$ 0.36	\$ 0.52	\$ 0.60	\$ 0.87
Diluted	\$ 0.34	\$ 0.50	\$ 0.58	\$ 0.83
Weighted average number of common shares outstanding				
Basic	59.0	59.3	58.9	59.3
Diluted	61.4	61.5	61.1	61.7

*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)

	Six Months Ended June 30,	
	2003	2002
<b>Cash flows from operating activities</b>		
Net income	\$ 35.6	\$ 51.4
Income charges (credits) not affecting cash:		
Depreciation and amortization	22.1	19.3
Deferred income taxes	8.3	(1.1)
Loss on sale of business	3.3	
Other	5.5	3.6
Changes in operating assets and liabilities:		
Accounts and other receivables	(10.6)	(15.7)
Inventories	(6.9)	(1.6)
Accounts payable and accrued liabilities	(12.3)	(4.6)
Prepaid expenses	(11.3)	(9.3)
Other	(6.2)	0.7
Net cash provided by operating activities	27.5	42.7
<b>Cash flows from investing activities</b>		
Capital expenditures	(18.0)	(16.4)
Investments in intangible assets	(17.4)	(2.9)
Proceeds from asset dispositions	5.6	2.9
Investments in unconsolidated affiliates	(0.9)	(1.8)
Net cash used in investing activities	(30.6)	(18.2)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of short-term debt		0.4
Proceeds from issuance of long-term debt	242.1	46.9
Payments on short-term debt		(0.8)
Payments on long-term debt	(187.6)	(71.9)
Purchases of treasury stock	(36.6)	(20.3)
Proceeds from stock plans	23.5	7.4
Proceeds from accounts receivable securitization, net	(0.2)	
Other	(4.4)	(0.3)
Net cash provided by (used in) financing activities	36.8	(38.6)
Effect of currency exchange rate changes on cash and cash equivalents	(17.2)	1.9



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

Net increase (decrease) in cash and cash equivalents	16.5	(12.2)
Cash and cash equivalents at beginning of period	34.2	47.7
Cash and cash equivalents at end of period	\$ 50.7	\$ 35.5

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

## Edwards Lifesciences Corporation

## Notes to Consolidated Condensed Financial Statements

June 30, 2003

(unaudited)

## 1. BASIS OF PRESENTATION

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. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current period.

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.

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 Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock Based Compensation*, (in millions, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net income, as reported	\$ 21.1	\$ 30.6	\$ 35.6	\$ 51.4
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(3.8)	(3.5)	(8.1)	(7.7)
Pro forma net income	\$ 17.3	\$ 27.1	\$ 27.5	\$ 43.7
Earnings per basic share:				
Reported net income	\$ 0.36	\$ 0.52	\$ 0.60	\$ 0.87
Pro forma net income	\$ 0.29	\$ 0.46	\$ 0.47	\$ 0.74
Earnings per diluted share:				
Reported net income	\$ 0.34	\$ 0.50	\$ 0.58	\$ 0.83
Pro forma net income	\$ 0.28	\$ 0.44	\$ 0.45	\$ 0.71

*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.

## **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 and are being amortized over their estimated economic life of 17 years. Approximately \$11.8 million of the purchase price has been charged to in-process research and development. 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. LOSS ON SALE OF BUSINESS**

Effective July 4, 2003, the Company sold its German perfusion services subsidiary to WKK GmbH, a German-based provider of hospital services, for a nominal amount. Sales generated by the German perfusion services subsidiary were approximately \$3.5 million during each of the six months ended June 30, 2003 and 2002. 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 \$3.3 million in the second quarter of 2003 to reduce the carrying value of the subsidiary's assets to fair value based upon the proceeds from the sale.

**4. INVENTORIES**

Inventories consisted of the following (in millions):

	June 30, 2003		December 31, 2002	
Raw materials	\$	21.5	\$	17.4
Work in process		18.8		14.7
Finished products		85.3		79.7
	\$	125.6	\$	111.8

**5. GOODWILL AND OTHER INTANGIBLE ASSETS**

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

June 30, 2003	Patents	Unpatented Technology	Other	Total
Cost	\$ 110.2	\$ 36.3	\$ 15.6	\$ 162.1
Accumulated amortization	(61.4)	(16.7)	(3.5)	(81.6)
Net carrying value	\$ 48.8	\$ 19.6	\$ 12.1	\$ 80.5
<b>December 31, 2002</b>				
Cost	\$ 96.8	\$ 36.3	\$ 8.9	\$ 142.0
Accumulated amortization	(58.2)	(15.5)	(3.3)	(77.0)
Net carrying value	\$ 38.6	\$ 20.8	\$ 5.6	\$ 65.0

Amortization expense related to other intangible assets was \$2.4 million for the quarters ended June 30, 2003 and June 30, 2002, and \$4.6 million and \$4.4 million for the six months ended June 30, 2003 and June 30, 2002, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2003	\$ 9.6
2004	10.0
2005	10.2
2006	10.2
2007	10.2

During the quarter ended June 30, 2003, the Company made an immaterial acquisition of a business resulting in \$4.4 million of goodwill.

**6. CONVERTIBLE SENIOR DEBT**

On May 9, 2003, the Company issued \$125.0 million of convertible senior debentures, issued at par, bearing an interest rate of 3.875% per annum due May 15, 2033 (the "Notes"). Interest is payable semi-annually in May and November. Issuance costs of approximately \$3.6 million will be amortized to



interest expense over 5 years. The Notes are convertible into 18.29 shares of the Company's common stock for each \$1,000 principal amount of Notes (conversion price of \$54.66 per share), subject to adjustment. The Notes may be converted, at the option of the holders, on or prior to the final maturity date under any of the following circumstances:

during any fiscal quarter commencing with the quarter ending September 30, 2003 if the closing sale price per share of the Company's common stock exceeds 120% of the conversion price;

if the Notes have been called for redemption; or

upon the occurrence of specified corporate events.

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

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

Beginning with the six month interest period commencing May 15, 2008, holders of the Notes will receive contingent interest if the trading price of the Notes equals or exceeds 120% of the principal amounts of the Notes. This contingent interest payment feature represents an embedded derivative. Based on the de minimis value associated with this feature, however, no value has been assigned to the derivative at issuance or at June 30, 2003.

On May 20, 2003, the Company issued an additional \$25.0 million aggregate principal amount of convertible senior debentures due 2033. The issuance of the additional \$25.0 million aggregate principal amount of debentures was pursuant to the exercise of an over-allotment option granted by the Company. These debentures have the same terms as the Notes issued on May 9, 2003.

## **7. 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 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 or other claims, Edwards Lifesciences may incur charges in excess of currently 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 relating to any currently pending lawsuit 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.

## 8. COMPREHENSIVE INCOME

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net income	\$ 21.1	\$ 30.6	\$ 35.6	\$ 51.4
Other comprehensive income:				
Currency translation adjustments, net of tax	1.5	(11.2)	(2.6)	(6.4)
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	0.7	(2.4)	0.2	(1.7)
Unrealized net gain (loss) on cash flow hedges, net of tax	1.0	(9.8)	(1.4)	(10.3)
Comprehensive income	\$ 24.3	\$ 7.2	\$ 31.8	\$ 33.0

## 9. 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 June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Basic shares outstanding	59.0	59.3	58.9	59.3
Dilutive effect of employee stock options	2.4	2.1	2.2	2.4
Dilutive effect of employee stock purchase plans		0.1		
Diluted shares outstanding	61.4	61.5	61.1	61.7

Diluted earnings per share excludes 1.7 million and 1.9 million shares related to options for the three months ended June 30, 2003 and 2002, respectively, and 4.3 million and 2.1 million shares related to options for the six months ended June 30, 2003 and 2002, respectively. These options were excluded because the exercise price per share was greater than the average market price, resulting in an anti-dilutive effect on diluted earnings per share. The effect of approximately 2.7 million common shares related to the assumed conversion of the \$150.0 million convertible debentures due 2033 has been excluded from the computation of diluted earnings per share for the three and six months ended June 30, 2003 because none of the conditions that would permit conversion had been satisfied.

#### **10. 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 June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
(in millions)				
<b>Net Sales by Geographic Area</b>				
United States	\$ 97.5	\$ 98.4	\$ 194.5	\$ 193.2
Japan (Note 1)	48.8	15.5	97.9	31.7
Europe	50.6	39.2	97.7	75.7
Other countries	20.9	19.7	40.2	34.5
	\$ 217.8	\$ 172.8	\$ 430.3	\$ 335.1
<b>Net Sales by Major Product Lines</b>				
Cardiac Surgery	\$ 108.5	\$ 92.8	\$ 215.9	\$ 180.5
Critical Care	68.8	55.2	135.1	107.8
Vascular	14.0	13.0	27.8	24.8
Perfusion	15.1	11.1	28.8	20.6
Other Distributed Products	11.4	0.7	22.7	1.4
	\$ 217.8	\$ 172.8	\$ 430.3	\$ 335.1

	June 30, 2003		December 31, 2002	
	(in millions)			
<b>Long-Lived Assets by Geographic Area</b>				
United States	\$ 578.4	\$ 572.2		
Other countries	81.0	70.8		
	\$ 659.4	\$ 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 the 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 plans, strategies and objectives of management for future operations, any statements concerning the Company's 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, anticipate, plan, continue, seek, pro forma, forecast, or intend or other similar words or expressions, and 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 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 and six months ended June 30, 2003. Also discussed is Edwards Lifesciences' financial position as of June 30, 2003. You should read this discussion in conjunction with the 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 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.

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**

## Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q/A

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. See "Loss on Sale of Business" regarding the sale of the Company's German perfusion services business. 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 June 30,			Percent	Six Months Ended June 30,			Percent
	2003	2002	Change	2003	2002	Change		
United States	\$ 97.5	\$ 98.4	(0.9)%	\$ 194.5	\$ 193.2	0.7%		
International	120.3	74.4	61.7%	235.8	141.9	66.2%		
Total net sales	\$ 217.8	\$ 172.8	26.0%	\$ 430.3	\$ 335.1	28.4%		



The changes in net sales in the United States for the three and six months ended June 30, 2003 were due primarily to decreased sales in perfusion and vascular products, offset by increased sales of cardiac surgery and critical care products.

The increases in international net sales were due primarily to the change in accounting for sales in Japan (see Joint Venture in Japan ) and the impact of changes in foreign currency exchange rates (primarily the movement of the United States dollar against the Euro and the Japanese Yen). Assuming the Japan business was consolidated for the three and six months ended June 30, 2002, international net sales for the three and six months ended June 30, 2003 would have increased 19.1% and 23.3%, respectively. Additionally, excluding the impact of changes in foreign currency exchange rates, international net sales for the three and six months ended June 30, 2003 would have increased 5.9% and 8.5%, respectively. These increases are due primarily to increased international sales of cardiac surgery and vascular products.

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 June 30,			Percent Change	Six Months Ended June 30,			Percent Change		
	2003		2002		2003		2002			
Cardiac Surgery	\$	108.5	\$	92.8	16.9%	\$	215.9	\$	180.5	19.6%
Critical Care		68.8		55.2	24.6%		135.1		107.8	25.3%
Vascular		14.0		13.0	7.7%		27.8		24.8	12.1%
Perfusion		15.1		11.1	36.0%		28.8		20.6	39.8%
Other Distributed Products		11.4		0.7	NM		22.7		1.4	NM
Total net sales	\$	217.8	\$	172.8	26.0%	\$	430.3	\$	335.1	28.4%

NM=Not Meaningful

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):

	Three Months Ended June 30,			Percent Change	Six Months Ended June 30,			Percent Change
	2003		2002		2003		2002	
Cardiac Surgery	\$	108.5						