

EDWARDS LIFESCIENCES CORP

Form 10-Q

November 09, 2007

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2007

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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

Indicate by check mark whether the registrant is a shell company (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 October 31, 2007 was 56,705,179.

EDWARDS LIFESCIENCES CORPORATION

FORM 10-Q

For the Quarterly Period Ended September 30, 2007

TABLE OF CONTENTS

	Page Number
Part I.	<u>FINANCIAL INFORMATION</u>
Item 1.	<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
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 15
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 27
Item 4.	<u>Controls and Procedures</u> 28
Part II.	<u>OTHER INFORMATION</u>
Item 1.	<u>Legal Proceedings</u> 29
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 29
Item 6.	<u>Exhibits</u> 29
<u>Signature</u>	30
<u>Exhibits</u>	31

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED BALANCE SHEETS

(in millions, except par value; unaudited)

Part I. Financial Information

Item 1. Financial Statements

	September 30, 2007	December 31, 2006
ASSETS		
Current assets		
Cash and cash equivalents	\$ 175.7	\$ 182.8
Accounts and other receivables, net of allowances of \$7.2 and \$6.5, respectively	136.7	127.1
Inventories, net	158.3	142.1
Deferred income taxes	25.9	21.8
Prepaid expenses and other current assets	68.2	57.8
Total current assets	564.8	531.6
Property, plant and equipment, net	228.0	213.0
Goodwill	337.7	337.7
Other intangible assets, net	107.0	116.1
Investments in unconsolidated affiliates	36.8	20.2
Deferred income taxes	7.7	14.5
Other assets	17.7	13.7
	\$ 1,299.7	\$ 1,246.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 198.8	\$ 226.2
Convertible debt (Note 5)	150.0	
Total current liabilities	348.8	226.2
Long-term debt (Note 5)	61.2	235.9
Other long-term liabilities (Note 1)	65.9	35.3
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 68.4 and 67.0 shares issued, and 56.9 and 57.7 shares outstanding at September 30, 2007 and December 31, 2006	68.4	67.0
Additional contributed capital	666.3	603.7
Retained earnings (Note 1)	532.8	433.9
Accumulated other comprehensive income (loss)	2.9	(15.8)

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

	September 30, 2007	December 31, 2006
Treasury stock, at cost, 11.5 and 9.3 shares at September 30, 2007 and December 31, 2006, respectively	(446.6)	(339.4)
Total stockholders' equity	823.8	749.4
	\$ 1,299.7	\$ 1,246.8

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(in millions, except per share information; unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net sales	\$ 261.4	\$ 247.4	\$ 798.1	\$ 771.4
Cost of goods sold	90.7	87.4	278.6	276.2
Gross profit	170.7	160.0	519.5	495.2
Selling, general and administrative expenses	103.2	91.7	303.5	280.9
Research and development expenses	30.9	28.1	88.8	84.2
Special (gains) charges, net (Note 2)	(2.5)	2.0	(2.5)	(22.5)
Interest expense, net	0.4	0.8	1.0	2.3
Other (income) expense, net	(0.1)	0.7	(1.5)	1.7
Income before provision for income taxes	38.8	36.7	130.2	148.6
Provision for income taxes	9.7	8.9	33.0	38.8
Net income	\$ 29.1	\$ 27.8	\$ 97.2	\$ 109.8

Share information (Note 10)

Earnings per share:				
Basic	\$ 0.51	\$ 0.48	\$ 1.69	\$ 1.87
Diluted	\$ 0.48	\$ 0.45	\$ 1.59	\$ 1.76
Weighted average number of common shares outstanding:				
Basic	57.1	58.2	57.5	58.8
Diluted	62.4	63.6	63.0	64.1

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(in millions; unaudited)

	Nine Months Ended September 30,	
	2007	2006
Cash flows from operating activities		
Net income	\$ 97.2	\$ 109.8
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	41.1	42.2
Stock-based compensation (Note 7)	20.9	19.8
Deferred income taxes	1.0	(3.7)
Special (gains) charges, net	(2.5)	1.3
Other	1.2	1.5
Changes in operating assets and liabilities:		
Accounts and other receivables, net	0.8	(3.5)
Inventories	(12.2)	(14.9)
Accounts payable and accrued liabilities	(7.5)	13.3
Prepaid expenses	(10.1)	(5.9)
Other	3.4	0.9
Net cash provided by operating activities	133.3	160.8
Cash flows from investing activities		
Capital expenditures	(43.1)	(40.0)
Investments in intangible assets	(1.0)	(2.0)
Investments in unconsolidated affiliates	(3.0)	(1.5)
Proceeds from sale of assets (Notes 2 and 4)	5.4	14.7
Acquisition milestone payment	(9.6)	
Other	(0.5)	0.5
Net cash used in investing activities	(51.8)	(28.3)
Cash flows from financing activities		
Proceeds from issuance of long-term debt	44.2	42.0
Payments on long-term debt	(71.4)	(110.2)
Purchases of treasury stock	(107.2)	(127.2)
Proceeds from stock plans	32.6	26.2
Excess tax benefit from stock plans	7.4	3.9
Other	4.6	4.0
Net cash used in financing activities	(89.8)	(161.3)
Effect of currency exchange rate changes on cash and cash equivalents	1.2	1.5
Net decrease in cash and cash equivalents	(7.1)	(27.3)
Cash and cash equivalents at beginning of period	182.8	178.6
Cash and cash equivalents at end of period	\$ 175.7	\$ 151.3

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

1. BASIS OF PRESENTATION

The accompanying interim consolidated condensed financial statements and related disclosures 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, 2006. 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 statement 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.

Recently Adopted Accounting Standards

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). Differences between the amounts reported as a result of adoption have been accounted for as a cumulative effect adjustment to the January 1, 2007 "Retained Earnings" balance.

The cumulative effect of adopting FIN 48 was a \$1.7 million decrease in tax reserves and increase in the January 1, 2007 "Retained Earnings" balance. As of the adoption date of January 1, 2007, the liability for income taxes associated with uncertain tax positions was \$24.6 million which is included in "Other Long-Term Liabilities." This liability can be reduced by \$3.4 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$21.2 million, if recognized, would favorably affect the Company's effective tax rate.

As of September 30, 2007, the liability for income taxes associated with uncertain tax positions was \$35.8 million. This liability can be reduced by \$9.0 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$26.8 million, if recognized, would favorably affect the Company's effective tax rate.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. At adoption, the Company had accrued \$1.1 million (net of tax benefits) of interest related to uncertain tax positions and as of September 30, 2007, the Company had accrued \$2.8 million (net of tax benefits) of interest related to uncertain tax positions.

During the fourth quarter ended December 31, 2006, the Company settled several of its ongoing tax examinations in various jurisdictions. The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While the Company has accrued for amounts it believes are the probable outcomes, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The unrecognized tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related interest have been provided for any adjustments that may result from these uncertain tax positions.

The total liability for unrecognized tax benefits may change within the next twelve months due to either settlement of audits or expiration of statutes of limitations. Quantification of those potential changes cannot be estimated at this time. At September 30, 2007, the Company has concluded all United States federal income tax matters for years through 2004. All material state and local, and foreign income tax matters have been concluded for years through 2002.

New Accounting Standards Not Yet Adopted

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurement" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company does not expect the adoption of SFAS 157 to have a material impact on its consolidated financial statements.

In September 2006, the FASB issued SFAS No. 158, "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106, and 132(R)" ("SFAS 158"), which amends SFAS No. 87, "Employers' Accounting for Pension," SFAS No. 88, "Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits," SFAS No. 106, "Employers' Accounting for Postretirement Benefits Other Than Pensions" and SFAS No. 132 (revised 2003), "Employers' Disclosures about Pensions and Other Postretirement Benefits," and other related literature. SFAS 158 results from the initial phase of a comprehensive project to improve an employer's accounting for defined benefit pension and other postretirement plans. SFAS 158 requires employers to recognize the overfunded or underfunded status of a single-employer defined benefit postretirement plan as an asset or liability on its balance sheet and to recognize changes in that funded status in comprehensive income. In addition, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end balance sheet. SFAS 158 does not change the accounting for a multi-employer plan.

SFAS 158 provides different effective dates for the recognition and related disclosure provisions, and for the required change to a fiscal year-end measurement date. In December 2006, the Company applied the requirements to recognize the funded status of its benefit plans and made the required disclosures. The requirement to measure plan assets and benefit obligations as of the date of the employer's fiscal year-end balance sheet shall be effective for the Company for the fiscal year ending December 31, 2008. The Company does not expect the adoption of the measurement date provisions of SFAS 158 to have a material impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 allows reporting entities to choose to measure many financial instruments at fair value and incorporates an amendment to SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," which is applicable to all entities with trading securities or securities that are considered to be available for sale. The provisions within SFAS 159 are effective for fiscal years beginning after November 15, 2007, with early adoption permitted as long as the provisions of SFAS No. 157 are also early adopted. The Company does not expect the adoption of SFAS 159 to have a material impact on its consolidated financial statements.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used in future research and development activities be deferred and capitalized until the related service is performed or the goods are delivered. EITF 07-3 is effective for fiscal years beginning after December 15, 2007.

The Company does not expect the adoption of EITF 07-3 to have a material impact on its consolidated financial statements.

2. SPECIAL (GAINS) CHARGES, NET

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
(in millions)				
Gain on estimated insurance settlement	\$ (2.5)	\$	\$ (2.5)	\$
Gain on patent settlement				(20.2)
Gain on sale of product lines				(10.2)
Impairment of assets held for sale				2.6
Realignment expenses, net				2.1
Restructure 3F agreements		2.0		2.0
Litigation reserve				1.2
Special (gains) charges, net	\$ (2.5)	\$ 2.0	\$ (2.5)	\$ (22.5)

Gain on Estimated Insurance Settlement

During the third quarter of 2007, the Company experienced a fire that damaged certain inventory held at a third party warehouse in Brazil. The total amount of the loss related to the inventory was \$1.8 million, which is expected to be reimbursed by insurance. In addition, the Company held business interruption insurance to cover the lost profit of \$2.5 million due to the property damage. As of September 30, 2007, the Company had recorded a receivable from the insurance company of \$4.3 million and a gain of \$2.5 million for the estimated insurance settlement.

Gain on Patent Settlement

In January 2006, the Company recorded a patent dispute settlement gain of \$20.2 million, which consisted of a net payment of \$23.8 million received from Medtronic, Inc., offset by patent enforcement costs. See Note 8 for additional information.

Gain on Sale of Product Lines

In May 2006, the Company sold a non-strategic pharmaceutical product line to Bioniche Teoranta for \$9.0 million. The sale of the assets resulted in a \$4.5 million gain, consisting of cash proceeds of \$9.0 million, offset by \$4.5 million primarily related to the net book value of intangible assets and inventory that were sold.

During the first quarter of 2005, the Company sold its perfusion product line in Japan to Terumo Corporation for cash consideration of \$14.9 million, of which \$9.2 million was received in January 2005 and \$5.7 million was received in March 2006 as an earn-out payment. In the first quarter of 2006, the Company recorded a gain of \$5.7 million related to the receipt of the earn-out payment.

Impairment of Assets Held for Sale

In the second quarter of 2006, the Company agreed to sell most of its assets related to its remaining international cardiopulmonary perfusion product line. The Company determined that the carrying values of the underlying assets exceeded their fair values. Consequently, in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," in the second quarter of 2006, the Company recorded an impairment loss of \$2.6 million, which represented the

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

excess of the carrying values of the assets over their fair values, and included direct incremental costs to transact the sale of \$1.5 million. The sale was completed in December 2006 and no additional gain or loss was recorded.

Realignment Expenses, net

In December 2006, the Company recorded a \$7.3 million charge primarily related to severance expenses associated with a global reduction in workforce of approximately 70 employees, primarily in the United States and Europe. As of September 30, 2007, the Company had paid \$5.4 million of severance with the remaining amount expected to be substantially paid by the end of 2007.

During the first quarter of 2006, the Company recorded realignment expense of \$2.1 million primarily related to severance expenses associated with the planned closure of a manufacturing facility in Japan (impacting 92 employees). As of September 30, 2007, remaining payments of approximately \$0.4 million are expected to be paid during the fourth quarter of 2007.

In December 2005, the Company recorded a charge of \$3.9 million related to severance resulting from a resource realignment. The charge was primarily related to the severance costs associated with reducing the Company's workforce by 52 employees, primarily in Puerto Rico, Europe and the United States. As of September 30, 2007, the payments related to the realignment were substantially complete.

Restructure 3F Agreements

In June 2005, the Company recorded a special charge of \$22.8 million related to the restructuring of development and supply agreements between 3F Therapeutics, Inc. and Percutaneous Valve Technologies ("PVT") that were established prior to the Company's acquisition of PVT in early 2004. Under the terms of the new agreements, the Company obtained the rights to self-manufacture all components of its transcatheter heart valves and certain pre-approved technology licenses. During the third quarter of 2006, the Company paid and recorded an additional \$2.0 million charge for the final payment to 3F Therapeutics for completing certain contractual obligations.

3. INVENTORIES

Inventories consisted of the following (in millions):

	September 30, 2007	December 31, 2006
Raw materials	\$ 30.6	\$ 25.1
Work in process	21.4	22.4
Finished products	106.3	94.6
	<u>\$ 158.3</u>	<u>\$ 142.1</u>

4. OTHER INTANGIBLE ASSETS

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

September 30, 2007	Patents	Unpatented Technology	Other	Total
Cost	\$ 205.0	\$ 27.9	\$ 13.5	\$ 246.4
Accumulated amortization	(115.0)	(21.7)	(2.7)	(139.4)
Net carrying value	\$ 90.0	\$ 6.2	\$ 10.8	\$ 107.0
December 31, 2006				
Cost	\$ 194.3	\$ 27.9	\$ 17.6	\$ 239.8
Accumulated amortization	(100.1)	(20.4)	(3.2)	(123.7)
Net carrying value	\$ 94.2	\$ 7.5	\$ 14.4	\$ 116.1

Patents includes \$6.8 million of capitalized legal costs related to the defense and enforcement of issued patents for which success is deemed probable as of September 30, 2007.

In March 2007, the Company sold the United States distribution rights and inventory associated with its transmyocardial revascularization ("TMR") laser product line to Novadaq Technologies, Inc. for upfront consideration of \$5.4 million, which consists of \$2.4 million in cash and a \$3.0 million senior secured promissory note, which was collected in full during the third quarter of 2007. This transaction resulted in a net reduction in other intangibles of \$3.8 million. In connection with the transaction, the Company is entitled to earn-out payments based on Novadaq's TMR sales for the remainder of 2007. For the three and nine months ended September 30, 2007, the Company earned \$0.4 million and \$1.6 million, respectively, recorded in "Other (Income) Expense, Net."

Amortization expense related to other intangible assets was \$4.2 million and \$4.5 million for the three months ended September 30, 2007 and 2006, respectively, and \$12.6 million and \$13.2 million for the nine months ended September 30, 2007 and 2006, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2007	\$ 17.1
2008	17.1
2009	15.9
2010	12.7
2011	11.7

5. CONVERTIBLE DEBT

In May 2003, the Company issued \$150.0 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 \$4.4 million are being 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. 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, in shares of the Company's common stock, or any combination thereof. The Notes have been reclassified as a current liability from long-term debt on the Consolidated Condensed Balance Sheet as of September 30, 2007 given their potential redemption for cash by the holders on May 15, 2008.

6. DEFINED BENEFIT PLANS

The components of net periodic benefit costs for the three and nine months ended September 30, 2007 and 2006 were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Service cost	\$ 0.7	\$ 0.6	\$ 2.0	\$ 2.0
Employee contributions		(0.1)		(0.2)
Interest cost	0.6	0.5	1.8	1.6
Expected return on plan assets	(0.6)	(0.5)	(1.8)	(1.6)
Amortization of prior service cost and other		0.1	0.1	0.2
Net periodic pension benefit cost	\$ 0.7	\$ 0.6	\$ 2.1	\$ 2.0

7. STOCK-BASED COMPENSATION

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three and nine months ended September 30, 2007 and 2006 was as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Cost of goods sold	\$ 0.8	\$ 0.9	\$ 2.3	\$ 2.6
Selling, general and administrative expenses	5.4	4.9	14.9	13.7
Research and development expense	1.3	1.3	3.7	3.5
Total stock-based compensation expense	\$ 7.5	\$ 7.1	\$ 20.9	\$ 19.8

At September 30, 2007, the total remaining compensation cost related to unvested stock options, restricted stock units and employee stock purchase subscription awards amounted to \$54.9 million and will be amortized on a straight-line basis over a weighted average vesting period of approximately 32 months.

During the nine months ended September 30, 2007, the Company granted 1.1 million stock options at a weighted average exercise price of \$49.05 and 0.3 million shares of restricted stock units at a weighted average grant-date fair value of \$49.28.

Fair Value Disclosures

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

Option Awards

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
Risk-free interest rate	4.8%	5.1%	4.6%	5.0%
Expected dividend yield	None	None	None	None
Expected volatility	18.5%	22.6%	18.7%	22.6%
Expected term (years)	4.9	4.8	4.9	4.8
Fair value, per share	\$ 13.36	\$ 13.54	\$ 13.09	\$ 13.12

9

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

The Black-Scholes option pricing model was used with the following weighted average assumptions for employee stock purchase plan ("ESPP") subscriptions granted during the following periods:

ESPP

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Risk-free interest rate	4.9%	5.2%	4.9%	4.7%
Expected dividend yield	None	None	None	None
Expected volatility	23.8%	30.8%	24.6%	30.6%
Expected term (years)	0.6	0.6	0.6	0.8
Fair value, per share	\$ 11.53	\$ 11.56	\$ 11.51	\$ 10.39

8. COMMITMENTS AND CONTINGENCIES

On May 9, 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent exclusively licensed to the Company. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. On May 11, 2007, and June 20, 2007, CoreValve filed lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid.

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"), Cook, Inc. and W.L. Gore & Associates alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. On September 2, 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced on January 23, 2006, Edwards Lifesciences settled this litigation with Medtronic. In exchange for a cash payment of \$37.5 million from Medtronic to Edwards Lifesciences and Australian-based Endogad Research Pty., Ltd. (the company formed by the clinician-inventors of the patents), Medtronic was granted nonexclusive licenses to the patents involved in the litigation, as well as to certain other related patents. The Company recorded a gain of \$20.2 million in January 2006, which consists of the \$37.5 million cash, offset by the settlement paid to Endogad, capitalized patent enforcement costs of \$2.9 million and current legal fees. Edwards Lifesciences remains in litigation with Cook, Inc. and W.L. Gore & Associates, each of which has answered and asserted various affirmative defenses and counterclaims.

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 such legal matter or other claims, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is 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.

9. COMPREHENSIVE INCOME

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net income	\$ 29.1	\$ 27.8	\$ 97.2	\$ 109.8
Other comprehensive income:				
Currency translation adjustments	10.1	1.3	15.5	5.6
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	6.5	(1.8)	8.1	2.3
Unrealized net (loss) gain on cash flow hedges, net of tax	(4.8)	1.7	(4.9)	(4.9)
Comprehensive income	\$ 40.9	\$ 29.0	\$ 115.9	\$ 112.8

10. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income by the weighted average common shares outstanding during a period. SFAS No. 128, "Earnings per Share," requires that employee equity share options, nonvested shares and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of the conversion of contingently convertible senior debentures, restricted stock units and in-the-money options. The dilutive impact of the restricted stock units and in-the-money options is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount that the employee must pay for exercising stock options, the amount of compensation expense for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital when the award becomes deductible are assumed to be used to repurchase shares. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Basic:				
Net income	\$ 29.1	\$ 27.8	\$ 97.2	\$ 109.8
Weighted average shares outstanding	57.1	58.2	57.5	58.8
Basic earnings per share	\$ 0.51	\$ 0.48	\$ 1.69	\$ 1.87
Assuming dilution:				
Net income	\$ 29.1	\$ 27.8	\$ 97.2	\$ 109.8
Interest expense related to contingently convertible debt, net of tax	1.0	1.0	3.0	3.0
Net income applicable to diluted shares	\$ 30.1	\$ 28.8	\$ 100.2	\$ 112.8
Weighted average shares outstanding	57.1	58.2	57.5	58.8
Dilutive effect of contingently convertible debt	2.7	2.7	2.7	2.7
Dilutive effect of stock plans	2.6	2.7	2.8	2.6
Dilutive weighted average shares outstanding	62.4	63.6	63.0	64.1
Diluted earnings per share	\$ 0.48	\$ 0.45	\$ 1.59	\$ 1.76

Stock options and restricted stock units to purchase approximately 3.5 million and 2.8 million shares for the three months ended September 30, 2007 and 2006, respectively, and 2.8 million and 2.4 million for the nine months ended September 30, 2007 and 2006, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

11. INCOME TAXES

Beginning in 2002 through 2005, the Company recorded other-than-temporary impairments and unrealized losses related to certain of its investments in unconsolidated affiliates. The tax benefits that result from reductions in the value of these investments are subject to the Company realizing sufficient capital gains with which to offset these capital losses. Due to the uncertainty of the Company realizing future capital gains, the Company has consistently recorded valuation allowances against these deferred tax assets as they have accumulated. During the second quarter of 2006, the Company realized a capital gain related to a sale of a non-strategic pharmaceutical product line (see Note 2). This capital gain allowed the Company to utilize a portion of the accumulated losses related to the reduced values of certain investments in unconsolidated affiliates. As a result, valuation allowances of \$3.7 million were reversed, reducing income tax expense during the second quarter of 2006.

12. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in four geographical regions: North America, Europe, Japan and Intercontinental. The North America region includes the United States, Canada and Puerto Rico. The Intercontinental region covers primarily Latin America, Asia and the rest of the world (excluding North America, Europe and Japan). All regions sell products that are used to treat advanced cardiovascular disease.

The Company evaluates the performance of its segments based on net sales and income before provision for income taxes ("pre-tax income"). The accounting policies of the segments are substantially the same as those described in Note 2, Summary of Significant Accounting Policies, in the Company's Annual Report on Form 10-K for the year ended December 31, 2006. Net sales and pre-tax income of reportable segments are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments, the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include most of the Company's amortization expense, net interest expense, global marketing expenses, corporate research and development expenses, United States manufacturing variances, corporate headquarters costs, in-process research and development, special charges (gains), stock-based compensation, foreign currency and interest rate hedging activities and certain litigation costs. Although most of the Company's depreciation expense is included in segment pre-tax income, due to the Company's methodology for cost build-up it is impractical to determine the amount of depreciation expense included in each segment. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net Sales				
North America	\$ 123.7	\$ 119.8	\$ 378.9	\$ 373.9
Europe	53.9	49.7	172.4	162.5
Japan	43.3	42.4	131.3	131.3
Intercontinental	22.7	25.2	65.2	74.2
Total segment net sales	\$ 243.6	\$ 237.1	\$ 747.8	\$ 741.9
Pre-Tax Income				
North America	\$ 63.1	\$ 61.9	\$ 200.5	\$ 199.0
Europe	11.1	9.9	42.7	38.5
Japan	17.0	15.7	50.0	49.4
Intercontinental	4.3	4.1	11.0	10.3
Total segment pre-tax income	\$ 95.5	\$ 91.6	\$ 304.2	\$ 297.2

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Net Sales Reconciliation				
Segment net sales	\$ 243.6	\$ 237.1	\$ 747.8	\$ 741.9
Foreign currency	17.8	10.3	50.3	29.5
Consolidated net sales	\$ 261.4	\$ 247.4	\$ 798.1	\$ 771.4
Pre-Tax Income Reconciliation				
Segment pre-tax income	\$ 95.5	\$ 91.6	\$ 304.2	\$ 297.2
Unallocated amounts:				
Corporate items	(66.0)	(55.9)	(193.9)	(186.4)
Special gains (charges), net	2.5	(2.0)	2.5	22.5
Interest expense, net	(0.4)	(0.8)	(1.0)	(2.3)
Foreign currency	7.2	3.8	18.4	17.6
Consolidated pre-tax income	\$ 38.8	\$ 36.7	\$ 130.2	\$ 148.6

Enterprise-Wide Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
(in millions)				
Net Sales by Geographic Area				
United States	\$ 118.1	\$ 114.9	\$ 362.7	\$ 358.6
Other countries	143.3	132.5	435.4	412.8
	\$ 261.4	\$ 247.4	\$ 798.1	\$ 771.4
Net Sales by Major Product and Service Area				
Heart Valve Therapy	\$ 122.8	\$ 117.3	\$ 383.6	\$ 370.2
Critical Care	96.5	84.9	284.8	255.6
Cardiac Surgery Systems	13.8	21.5	45.8	69.1
Vascular	22.4	17.6	64.9	54.9
Other Distributed Products	5.9	6.1	19.0	21.6
	\$ 261.4	\$ 247.4	\$ 798.1	\$ 771.4

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

	September 30, 2007	December 31, 2006
	<hr/>	<hr/>
	(in millions)	
Long-Lived Tangible Assets by Geographic Area		
United States	\$ 205.6	\$ 186.0
Other countries	76.9	60.9
	<hr/>	<hr/>
	\$ 282.5	\$ 246.9

13. SUBSEQUENT EVENT

On November 1, 2007, the Company entered into a definitive agreement to acquire certain assets of the CardioVations Division of Ethicon, Inc., including products and technology used in minimally invasive heart valve surgery, for approximately \$27 million. The transaction is expected to be completed by the end of 2007, subject to customary closing conditions.

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 contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, any statements of plans, strategies and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, any statements regarding the timing of regulatory approvals or related matters, 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," "should," "anticipate," "plan," "continue," "seek," "pro forma," "forecast," or "intend" or other 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, or incorporated by reference into, the Company's annual report on Form 10-K for the year ended December 31, 2006 for a description of certain of these risks and uncertainties.

Overview

Edwards Lifesciences is a global provider of technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address specific cardiovascular conditions including heart valve disease, critical care technologies and peripheral vascular disease.

The products and technologies provided by Edwards Lifesciences to treat cardiovascular disease are categorized into five main areas: Heart Valve Therapy, Critical Care, Cardiac Surgery Systems, Vascular and Other Distributed Products.

Edwards Lifesciences' **Heart Valve Therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **Critical Care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring systems used to measure a patient's heart function and in disposable pressure transducers, and also provides central venous access products

for fluid and drug delivery. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannula, *EMBOL-X* technologies and other disposable products used during cardiopulmonary bypass procedures (in March 2007 the Company sold the distribution rights to its transmyocardial revascularization ("TMR") products). Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, artificial implantable grafts, and stents used in the treatment of peripheral vascular disease. Lastly, **Other Distributed Products** include sales of intra-aortic balloon pumps sold primarily through the Company's distribution network in Japan (in October 2007 the Company announced its intention to terminate the distribution agreement effective December 31, 2007).

The healthcare marketplace continues to be competitive with strong global and local competitors. The Company competes with many companies, ranging from small start-up enterprises to companies that are larger and more established than Edwards Lifesciences with access to significant financial resources. Furthermore, rapid product development and technological change characterize the market in which the Company competes. Global demand for healthcare is increasing as the population ages. There is mounting pressure to contain healthcare costs in the face of this increasing demand, which has resulted in pricing and market share pressures. The cardiovascular segment of the medical device industry is dynamic and currently undergoing significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation and evolving patient needs. Management expects these trends to continue.

As previously discussed in the Company's annual report on Form 10-K, in February 2007 the Company received a Warning Letter resulting from a United States Food and Drug Administration (the "FDA") inspection of the Irvine facility that concluded in August of 2006. The Warning Letter related specifically to elements of the Company's quality systems, including complaint handling, documentation and quality systems training. The Company submitted a written response to the FDA in March 2007. As announced on April 23, 2007, the FDA has notified the Company that its response to the Warning Letter has adequately addressed the FDA's concerns. As a result, the FDA will not defer approval of pending pre-market submissions or export certificates for products manufactured at the Company's Irvine, California, facility.

Recently Adopted Accounting Standards

On January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). Differences between the amounts reported as a result of adoption have been accounted for as a cumulative effect adjustment to the January 1, 2007 "Retained Earnings" balance.

The cumulative effect of adopting FIN 48 was a \$1.7 million decrease in tax reserves and increase in the January 1, 2007 "Retained Earnings" balance. As of the adoption date of January 1, 2007, the liability for income taxes associated with uncertain tax positions was \$24.6 million which is included in "Other Long-Term Liabilities." This liability can be reduced by \$3.4 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$21.2 million, if recognized, would favorably affect the Company's effective tax rate.

As of September 30, 2007, the liability for income taxes associated with uncertain tax positions was \$35.8 million. This liability can be reduced by \$9.0 million of offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$26.8 million, if recognized, would favorably affect the Company's effective tax rate.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. At adoption, the Company had accrued \$1.1 million (net of tax benefits) of

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

interest related to uncertain tax positions and as of September 30, 2007, the Company had accrued \$2.8 million (net of tax benefits) of interest related to uncertain tax positions.

The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While the Company has accrued for amounts it believes are the probable outcomes, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The unrecognized tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related interest have been provided for any adjustments that may result from these uncertain tax positions.

The total liability for unrecognized tax benefits may change within the next twelve months due to either settlement of audits or expiration of statutes of limitations. Quantification of those potential changes cannot be estimated at this time. At September 30, 2007, the Company has concluded all United States federal income tax matters for years through 2004. All material state and local, and foreign income tax matters have been concluded for years through 2002.

Results of Operations

Net Sales Trends

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2007	2006	Change	Percent Change	2007	2006	Change	Percent Change
United States	\$ 118.1	\$ 114.9	\$ 3.2	2.8%	\$ 362.7	\$ 358.6	\$ 4.1	1.1%
International	143.3	132.5	10.8	8.2%	435.4	412.8	22.6	5.5%
Total net sales	\$ 261.4	\$ 247.4	\$ 14.0	5.7%	\$ 798.1	\$ 771.4	\$ 26.7	3.5%

In the United States, the \$3.2 million increase in net sales for the three months ended September 30, 2007 was due primarily to:

Critical Care products, which increased net sales by \$2.6 million, driven primarily by sales of the *FloTrac* minimally invasive monitoring system and pressure monitoring products;

Vascular products, which increased net sales by \$2.6 million, driven primarily by an increase in *LifeStent* product sales;

Heart Valve Therapy products, which increased net sales by \$0.6 million, driven primarily by an increase in the *Carpentier-Edwards PERIMOUNT Magna and Magna with TheraFix* valves;

partially offset by:

decreased sales of TMR products of \$2.4 million (the Company sold its distributions rights in March 2007).

The \$4.1 million increase in net sales in the United States for the nine months ended September 30, 2007 was due primarily to increased sales of Critical Care and Vascular products of \$9.3 million and \$5.3 million, respectively, partially offset by decreased sales of TMR products of \$8.2 million and Heart Valve Therapy products of \$1.5 million.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

International net sales increased \$10.8 million and \$22.6 million for the three and nine months ended September 30, 2007, respectively, due primarily to:

Critical Care products, which increased net sales by \$6.4 million and \$12.9 million, respectively, driven primarily by increases in net sales of the *FloTrac* minimally invasive monitoring system, pressure monitoring products, and hemofiltration products;

Heart Valve Therapy products, which increased net sales by \$3.6 million and \$10.1 million, respectively, driven primarily by increases in sales of the Company's *Carpentier-Edwards PERIMOUNT Magna* valve, *Magna* with *ThermaFix* valve and *Magna Ease* valve;

Vascular products, which increased net sales by \$1.8 million and \$3.7 million, respectively, driven primarily by an increase in *LifeStent* product sales;

foreign currency exchange rate fluctuations, which increased net sales by \$5.6 million and \$16.8 million, respectively, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar;

partially offset by:

decreases of \$8.0 million and \$23.1 million for the three and nine months ended September 30, 2007, respectively, related to (1) the discontinuation of the Brazil-based perfusion product line, (2) the Company's decision to exit the mechanical valve market during 2007, and (3) a reduction of distributed sales in Japan of intra-aortic balloon pumps.

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 the Company's 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):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2007	2006	Change	Percent Change	2007	2006	Change	Percent Change
Heart Valve Therapy	\$ 122.8	\$ 117.3	\$ 5.5	4.7%	\$ 383.6	\$ 370.2	\$ 13.4	3.6%
Critical Care	96.5	84.9	11.6	13.7%	284.8	255.6	29.2	11.4%
Cardiac Surgery Systems	13.8	21.5	(7.7)	(35.8)%	45.8	69.1	(23.3)	(33.7)%
Vascular	22.4	17.6	4.8	27.3%	64.9	54.9	10.0	18.2%
Other Distributed Products	5.9	6.1	(0.2)	(3.3)%	19.0	21.6	(2.6)	(12.0)%
Total net sales	\$ 261.4	\$ 247.4	\$ 14.0	5.7%	\$ 798.1	\$ 771.4	\$ 26.7	3.5%

Heart Valve Therapy

The \$5.5 million and \$13.4 million increases in net sales of Heart Valve Therapy products for the three and nine months ended September 30, 2007, respectively, were due primarily to:

pericardial tissue valves, which increased net sales by \$2.8 million and \$7.3 million, respectively, primarily as a result of the Company's premium *Carpentier-Edwards PERIMOUNT Magna* aortic valve and *Magna* with *ThermaFix* valves;

heart valve repair products, which increased net sales by \$1.0 million and \$3.1 million, respectively, driven primarily by the continuing adoption of the Company's disease-specific products including the *Edwards MC3*;

a favorable impact of foreign currency exchange rates of \$2.7 million and \$8.5 million, respectively, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar;

partially offset by:

decreases in net sales of \$2.1 million and \$6.0 million for the three and nine months ended September 30, 2007, respectively, due to the Company's exit from the mechanical valve market commencing in the first quarter of 2007 and the continuing decline of porcine valve sales.

The Company expects that its *PERIMOUNT Magna* and *Magna* with *ThermaFix* valves will continue to be strong contributors to 2007 sales. In January 2007, the Company launched two new products in the United States. The new *PERIMOUNT Theon* aortic valve offers clinicians the durability and hemodynamics of the Company's *PERIMOUNT* technology with the addition of the *ThermaFix* tissue treatment, and the new *Myxo ETlogix* annuloplasty ring is the first mitral repair product specifically designed to address myxomatous disease. In May 2007, the Company launched its next generation aortic valve, the *Magna Ease*, in Europe and is expecting to introduce this product into the United States by the end of 2008. The Company's new *PERIMOUNT Magna* mitral valve is gaining physician acceptance in Europe and the Company believes that this is also an important valve for United States patients. While the Company looks forward to gaining FDA approval as rapidly as possible, the Company is currently addressing additional questions from the FDA on the pre-clinical bench testing and, therefore, no longer anticipates that it will obtain FDA approval in the United States by the end of 2007. In Japan, the Company received regulatory approval for a new *PERIMOUNT* mitral valve and began sales during the second quarter of 2007.

Critical Care

The \$11.6 million and \$29.2 million increases in net sales of Critical Care products for the three and nine months ended September 30, 2007, respectively, were due primarily to:

FloTrac systems, which increased net sales by \$3.8 million and \$11.5 million, respectively;

core Critical Care products, which increased net sales by \$3.4 million and \$7.4 million, respectively, driven primarily by market share gains in pressure monitoring products and advanced hemodynamic monitoring systems;

hemofiltration products, which increased net sales by \$1.8 million and \$3.2 million, respectively; and

foreign currency exchange rate fluctuations, which increased net sales by \$2.0 million and \$5.6 million, respectively, due primarily to the strengthening of the Euro against the United States dollar, partially offset by the weakening of the Japanese yen against the United States dollar.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

The Company continues to expect worldwide *FloTrac* system sales to be a significant contributor to Critical Care sales growth in 2007. In August 2007, the Company introduced its *PediaSat* oximetry catheter, the first real-time, continuous central venous oxygen saturation monitoring device designed specifically for children.

Cardiac Surgery Systems

The \$7.7 million and \$23.3 million decreases in net sales of Cardiac Surgery Systems products for the three and nine months ended September 30, 2007, respectively, were due primarily to the impact of the sale of the Company's Brazil-based perfusion product line in December 2006, which resulted in net sales decreases of \$5.4 million and \$15.5 million for the three and nine months ended September 30, 2007, respectively. In addition, the Company's exit from the TMR product line in March 2007 contributed to a decrease in net sales of \$2.4 million and \$8.2 million, respectively. Cardiac Surgery Systems now consists of the Company's core Research Medical cannula and *EMBOL-X* technologies.

Vascular

The \$4.8 million and \$10.0 million increases in net sales of Vascular products for the three and nine months ended September 30, 2007, respectively, were due primarily to increased sales of *LifeStent* products. In addition, foreign currency exchange rate fluctuations had a favorable impact on net sales of \$0.5 million and \$1.9 million, respectively, due primarily to the strengthening of the Euro against the United States dollar.

During the second quarter, the Company launched its *FlexStar* system in Europe and submitted its six-month data set from its *RESILIENT* trial to the FDA as part of its pre-market approval for a superficial femoral artery indication. The Company is currently addressing questions from the FDA on the pre-clinical testing which will require additional bench testing and, therefore, no longer expects to obtain approval by the end of 2007.

Other Distributed Products

The \$0.2 million and \$2.6 million decreases in net sales of Other Distributed Products for the three and nine months ended September 30, 2007, respectively, were due primarily to the divestiture in 2006 of a non-strategic pharmaceutical product and a reduction of distributed sales in Japan of intra-aortic balloon pumps. In order to focus on its proprietary products, the Company has decided to terminate its distribution of a third party's line of intra-aortic balloon pumps in Japan. The distribution agreement is expected to terminate on December 31, 2007.

Gross Profit

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
Gross profit as a percentage of net sales	65.3%	64.7%	0.6 pts.	65.1%	64.2%	0.9 pts.

For the three months ended September 30, 2007, the United States gross profit as a percentage of net sales increased 0.4 percentage points due to a more profitable product mix, resulting primarily from higher sales of *FloTrac* systems and the Company's exit from the TMR product line. The international gross profit as a percentage of net sales increased 1.3 percentage points due to a more profitable product mix, primarily related to higher sales of Heart Valve Therapy products and *FloTrac* systems, combined with the discontinuation of lower margin perfusion products. Gross profit as a percentage of net sales increased 0.9 percentage points from the favorable impact of foreign currency, including the

expiration of currency hedging contracts. These increases were partially offset by manufacturing costs specific to the quarter.

For the nine months ended September 30, 2007, the United States gross profit as a percentage of net sales increased 0.4 percentage points due to a more profitable product mix, resulting primarily from higher sales of *FloTrac* systems and the Company's exit from the TMR product line. The international gross profit as a percentage of net sales increased 1.4 percentage points due to a more profitable product mix, primarily related to higher sales of Heart Valve Therapy products and *FloTrac* systems, combined with the discontinuation of lower margin perfusion products. These increases were partially offset by increased investments in quality systems and manufacturing costs specific to the period.

Selling, General and Administrative (SG&A) Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
(dollars in millions)						
SG&A expenses	\$ 103.2	\$ 91.7	\$ 11.5	\$ 303.5	\$ 280.9	\$ 22.6
SG&A expenses as a percentage of net sales	39.5%	37.1%	2.4 pts.	38.0%	36.4%	1.6 pts.

The \$11.5 million and \$22.6 million increases in selling, general and administrative expenses and the 2.4 and 1.6 percentage point increases in selling, general and administrative expenses as a percentage of net sales for the three and nine months ended September 30, 2007, respectively, were due primarily to (1) investments for the *Edwards SAPIEN Transcatheter Heart Valve ("THV")* launch in Europe, (2) higher sales-related spending in the Heart Valve Therapy, Critical Care and Vascular product lines, primarily in the United States, and (3) the impact of foreign currency (primarily the strengthening of the Euro against the United States dollar) in the amounts of \$2.2 million and \$6.4 million, respectively.

Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
(dollars in millions)						
Research and development expenses	\$ 30.9	\$ 28.1	\$ 2.8	\$ 88.8	\$ 84.2	\$ 4.6
Research and development expenses as a percentage of net sales	11.8%	11.4%	0.4 pts.	11.1%	10.9%	0.2 pts.

The increases in research and development expenses for the three and nine months ended September 30, 2007 were due primarily to additional investments in the Company's transcatheter valve and Critical Care development programs.

In the Company's transcatheter aortic valve replacement program, the Company received conditional Investigational Device Exemption ("IDE") approval from the FDA in March 2007 to initiate its PARTNER trial, a pivotal clinical trial of the Company's *Edwards SAPIEN THV* technology. The PARTNER trial began enrollment during the second quarter of 2007 and will evaluate the *Edwards SAPIEN THV* valve in patients who are considered at high risk for conventional open-heart valve surgery. The Company anticipates it will complete enrollment by the end of 2008.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

All of the *SAPIEN* valves in the PARTNER trial have been delivered transfemorally using the *RetroFlex* delivery system. During the third quarter of 2007, the Company received approval to begin selling the *SAPIEN* valve in Europe with the *RetroFlex I* and *RetroFlex II* transfemoral delivery systems. Initially, the Company plans to sell the *SAPIEN* valve in Europe with the *RetroFlex I*, and will phase in the *RetroFlex II* during the first quarter of 2008. The *RetroFlex II*, first used in Canada in the first quarter of 2007, further enhances the ease-of-use benefits of *RetroFlex I* by adding a customized atraumatic tip to enable clinicians to more easily navigate across the native stenotic aortic valve. The Company is currently awaiting regulatory approval to add *RetroFlex II* to the United States PARTNER trial.

The Company completed enrollment in its United States feasibility study of the *Ascendra* transapical delivery system in April 2007. The Company is working to gain IDE FDA approval to add *Ascendra* to the PARTNER trial.

In the Company's transcatheter mitral valve repair program, the Company had two programs: the *Edwards MONARC* mitral repair system, a coronary sinus technology, and the *Edwards MOBIUS* leaflet repair system. In connection with the *Edwards MONARC* system, the Company completed enrollment of its 60-patient EVOLUTION I feasibility study during the first quarter of 2007 and initiated the EVOLUTION II follow-on trial in Europe and Canada during the second quarter of 2007. The Company is continuing to collect and analyze additional clinical data, and has postponed enrollment of EVOLUTION II until 2008, when that analysis is expected to be completed.

For the *Edwards MOBIUS* technology, the Company's feasibility work was completed in Europe and Canada in the first quarter of 2007. After completing the clinical feasibility studies, the Company determined that it would take considerable additional resources and time to affect durable and long-lasting repair results with the *Edwards MOBIUS* device. Therefore, the Company has discontinued work on the *MOBIUS* technology and redirected resources into other advance technology development programs.

Special (Gains) Charges, net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
	(in millions)			
Gain on estimated insurance settlement	\$ (2.5)	\$	\$ (2.5)	\$
Gain on patent settlement				(20.2)
Gain on sale of product lines				(10.2)
Impairment of assets held for sale				2.6
Realignment expenses, net				2.1
Restructure 3F agreements		2.0		2.0
Litigation reserve				1.2
Special (gains) charges, net	\$ (2.5)	\$ 2.0	\$ (2.5)	\$ (22.5)

Gain on Estimated Insurance Settlement

During the third quarter of 2007, the Company experienced a fire that damaged certain inventory held at a third party warehouse in Brazil. The total amount of the loss related to the inventory was \$1.8 million, which is expected to be reimbursed by insurance. In addition, the Company held business interruption insurance to cover the lost profit of \$2.5 million due to the property damage. As of September 30, 2007, the Company had recorded a receivable from the insurance company of \$4.3 million and a gain of \$2.5 million for the estimated insurance settlement.

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

Gain on Patent Settlement

In January 2006, the Company recorded a patent dispute settlement gain of \$20.2 million, which consisted of a net payment of \$23.8 million received from Medtronic, Inc., offset by patent enforcement costs.

Gain on Sale of Product Lines

In May 2006, the Company sold a non-strategic pharmaceutical product line to Bioniche Teoranta for \$9.0 million. The sale of the assets resulted in a \$4.5 million gain, consisting of cash proceeds of \$9.0 million, offset by \$4.5 million primarily related to the net book value of intangible assets and inventory that were sold.

During the first quarter of 2005, the Company sold its perfusion product line in Japan to Terumo Corporation for cash consideration of \$14.9 million, of which \$9.2 million was received in January 2005 and \$5.7 million was received in March 2006 as an earn-out payment. In the first quarter of 2006, the Company recorded a gain of \$5.7 million related to the receipt of the earn-out payment.

Impairment of Assets Held for Sale

In the second quarter of 2006, the Company agreed to sell most of its assets related to its remaining international cardiopulmonary perfusion product line. The Company determined that the carrying values of the underlying assets exceeded their fair values. Consequently, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," in the second quarter of 2006, the Company recorded an impairment loss of \$2.6 million, which represented the excess of the carrying values of the assets over their fair values, and included direct incremental costs to transact the sale of \$1.5 million. The sale was completed in December 2006 and no additional gain or loss was recorded.

Realignment Expenses, net

In December 2006, the Company recorded a \$7.3 million charge primarily related to severance expenses associated with a global reduction in workforce of approximately 70 employees, primarily in the United States and Europe. As of September 30, 2007, the Company had paid \$5.4 million of severance with the remaining amount expected to be substantially paid by the end of 2007.

During the first quarter of 2006, the Company recorded realignment expense of \$2.1 million primarily related to severance expenses associated with the planned closure of a manufacturing facility in Japan (impacting 92 employees). As of September 30, 2007, remaining payments of approximately \$0.4 million are expected to be paid during the fourth quarter of 2007.

In December 2005, the Company recorded a charge of \$3.9 million related to severance resulting from a resource realignment. The charge was primarily related to the severance costs associated with reducing the Company's workforce by 52 employees, primarily in Puerto Rico, Europe and the United States. As of September 30, 2007, the payments related to the realignment were substantially complete.

Restructure 3F Agreements

In June 2005, the Company recorded a special charge of \$22.8 million related to the restructuring of development and supply agreements between 3F Therapeutics, Inc. and Percutaneous Valve Technologies ("PVT") that were established prior to the Company's acquisition of PVT in early 2004. Under the terms of the new agreements, the Company obtained the rights to self-manufacture all components of its transcatheter heart valves and certain pre-approved technology licenses. During the third quarter of 2006, the Company paid and recorded an additional \$2.0 million charge for the final payment to 3F Therapeutics for completing certain contractual obligations.

Interest Expense, net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2007	2006	Change	2007	2006	Change
	(in millions)					
Interest expense	\$ 2.2	\$ 2.6	\$ (0.4)	\$ 6.8	\$ 8.1	\$ (1.3)
Interest income	(1.8)	(1.8)		(5.8)	(5.8)	
Interest expense, net	\$ 0.4	\$ 0.8	\$ (0.4)	\$ 1.0	\$ 2.3	\$ (1.3)

The decreases in interest expense for the three and nine months ended September 30, 2007 resulted primarily from a lower average debt balance as compared to the prior year periods.

Other (Income) Expense, net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Foreign exchange gain, net	\$ (0.8)	\$ (0.2)	\$ (1.9)	\$ (0.6)
Investment gain	(0.1)		(0.4)	
Gain on sale of product line	(0.4)		(1.9)	
Accounts receivable securitization costs	0.9	0.7	2.4	1.9
Other	0.3	0.2	0.3	0.4
Other (income) expense, net	\$ (0.1)	\$ 0.7	\$ (1.5)	\$ 1.7

The net foreign exchange gains for the three and nine months ended September 30, 2007 and 2006 relate primarily to foreign currency fluctuations on the Company's global trade and intercompany receivable and payable balances. The increase in foreign exchange gains in 2007 was due primarily to the strengthening of various Asia currencies.

The investment gains for the three and nine months ended September 30, 2007 primarily represent the Company's share of gains and losses in technology investments accounted for under the equity method.

In March 2007, the Company sold the United States distribution rights and inventory associated with the TMR laser product line to Novadaq Technologies, Inc. for up-front consideration of \$5.4 million, which consisted of \$2.4 million in cash and a \$3.0 million senior secured promissory note, which was collected in full during the third quarter of 2007. This resulted in a gain of \$0.3 million. In connection with the transaction, the Company is entitled to earn-out payments based on Novadaq's TMR sales for the remainder of 2007. For the three and nine months ended September 30, 2007, the Company earned \$0.4 million and \$1.6 million, respectively, recorded in "Other (Income) Expense, Net."

Provision for Income Taxes

The provision for income taxes consists of provisions for federal, state and foreign income taxes. The Company operates in an international environment with significant operations in various locations outside the United States, which have statutory tax rates lower than the United States tax rate. Accordingly, the consolidated income tax rate is a composite rate reflecting the earnings in the various locations and the applicable rates. The effective income tax rates were 25.0% and 25.3% for the three

Edgar Filing: EDWARDS LIFESCIENCES CORP - Form 10-Q

and nine months ended September 30, 2007, respectively, and 24.3% and 26.1% for the three and nine months ended September 30, 2006, respectively. The 2006 income tax rates were impacted by the favorable resolution of a patent dispute in the first quarter of 2006, which was tax effected at the Company's blended United States federal and state statutory tax rate of 39.4%, and a \$3.7 million release of valuation allowances against deferred tax assets in the second quarter of 2006. The valuation allowances were no longer necessary because of the recognition of a taxable gain from the May 2006 sale of a non-strategic product line.

The Company adopted the provisions of FIN 48 on January 1, 2007 (see "Recently Adopted Accounting Standards").

Liquidity and Capital Resources

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

The Company has a Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), which matures on September 29, 2011. The Credit Agreement provides up to an aggregate of \$500.0 million in one-to-six month borrowings in multiple currencies. Borrowings currently bear interest at LIBOR plus 0.40%, which includes a facility fee subject to adjustment for leverage ratio changes as defined in the Credit Agreement. The Company pays a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.075%. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings will continue to be refinanced pursuant to the Credit Agreement. As of September 30, 2007, borrowings of \$61.2 million were outstanding under the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with at September 30, 2007.

In addition to the Credit Agreement, as of September 30, 2007, the Company had outstanding \$150.0 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 \$4.4 million are being amortized to interest expense over 5 years. The Notes are convertible, as defined per the agreement, 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. 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, in shares of the Company's common stock, or any combination thereof. The Notes have been reclassified as a current liability from long-term debt on the Consolidated Condensed Balance Sheet as of September 30, 2007 given their potential redemption for cash by the holders on May 15, 2008.

The Company has two securitization programs whereby certain subsidiaries in the United States and Japan sell, without recourse, on a continuous basis, an undivided interest in certain eligible pools of accounts receivable. As of September 30, 2007, the Company had sold a total of \$91.4 million of trade accounts receivable and received funding of \$80.3 million. The securitization program in the United States will expire on September 16, 2008 and the securitization program in Japan will expire on December 3, 2008.

In May 2006, the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to 4.0 million shares of the Company's common stock through December 31, 2008. During the nine months ended September 30, 2007, the Company repurchased 2.2 million shares under the stock repurchase program at an aggregate cost of \$107.2 million and as of September 30, 2007 had remaining authority under the program to purchase 0.5 million shares. In September 2007, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$250.0 million of the Company's common stock. The Company has not yet repurchased any shares under the new stock repurchase plan.

In 2006, the Company notified its employees of its intent to terminate its defined benefit pension plan in Puerto Rico (the "Plan") and expects to distribute benefits in the fourth quarter of 2007. The Company estimates that the final distribution will be approximately \$32 million, which includes an approximate \$9 million payment to the Plan to ensure that the value of the Plan's assets is sufficient to cover all benefit liabilities. The Company also estimates that upon final termination, it will record a pre-tax settlement charge of approximately \$7 million.

At September 30, 2007, there had 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, 2006, except for the presentation of our liability for unrecognized tax benefits due to the adoption of FIN 48. As of September 30, 2007, we had a liability of \$35.8 million for unrecognized tax benefits. We are unable to determine when cash settlement with taxing authorities will occur.

On November 1, 2007, the Company entered into a definitive agreement to acquire certain assets of the CardioVations Division of Ethicon, Inc., including products and technology used in minimally invasive heart valve surgery, for approximately \$27 million. The transaction is expected to be completed by the end of 2007, subject to customary closing conditions.

Net cash flows provided by **operating activities** of \$133.3 million for the nine months ended September 30, 2007 decreased \$27.5 million from the same period a year ago. This decrease was due primarily to cash received during the first quarter of 2006 for the patent litigation settlement of \$23.8 million and higher tax payments in 2007, partially offset by an increase in accounts receivables in 2007.

Net cash used by **investing activities** of \$51.8 million in the nine months ended September 30, 2007 consisted primarily of capital expenditures of \$43.1 million and a \$9.6 million milestone payment associated with the Percutaneous Valve Technologies, Inc. acquisition in 2004.

Net cash used by investing activities of \$28.3 million in the nine months ended September 30, 2006 consisted primarily of capital expenditures of \$40.0 million and investments in intangible assets of \$2.0 million, partially offset by proceeds of \$14.7 million from the sale of certain product lines.

Net cash used in **financing activities** of \$89.8 million for the nine months ended September 30, 2007 consisted primarily of purchases of treasury stock of \$107.2 million and net payments on long-term debt of \$27.2 million, partially offset by the proceeds from stock plans of \$32.6 million.

Net cash used in financing activities of \$161.3 million in the nine months ended September 30, 2006 consisted primarily of purchases of treasury stock of \$127.2 million and net payments on long term debt of \$68.2 million, partially offset by the proceeds from stock plans of \$26.2 million.

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 42-45 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, 2006. Management believes that at September 30, 2007 there had been no material changes to this information.

On January 1, 2007, the Company adopted FIN 48 which establishes a single model to address accounting for uncertain tax positions. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. See "Recently Adopted Accounting Standards."

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

For a complete discussion of the Company's exposure to interest rate risk, refer to Item 7A "Quantitative and Qualitative Disclosures About Market Risk" on pages 48-50 of the Company's Annual Report on Form 10-K for the year ended December 31, 2006. There have been no significant changes from the information discussed therein.

Currency Risk

For a complete discussion of the Company's exposure to foreign currency risk, refer to Item 7A "Quantitative and Qualitative Disclosures About Market Risk" on pages 48-50 of the Company's Annual Report on Form 10-K for the year ended December 31, 2006. There have been no significant changes from the information discussed therein.

Credit Risk

For a complete discussion of the Company's exposure to credit risk, refer to Item 7A "Quantitative and Qualitative Disclosures About Market Risk" on pages 48-50 of the Company's Annual Report on Form 10-K for the year ended December 31, 2006. 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 healthcare industry, performs credit evaluations of these customers and maintains allowances for potential credit losses which have historically been adequate compared to actual losses.

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 condensed balance sheets.

As of September 30, 2007, Edwards Lifesciences had approximately \$36.8 million of investments in equity instruments of other companies and had recorded unrealized gains of \$9.5 million on these investments in "Accumulated Other Comprehensive Income (Loss)," net of tax. Should these companies

experience a decline in financial condition or fail to meet certain development milestones, the investments' values may decline and be considered other than temporary. As a result, impairment charges may be necessary.

Item 4. Controls and Procedures

The Company's management, including the Chief Executive Officer and the Chief Financial Officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures as of September 30, 2007. Based on this evaluation, the Chief Executive Officer and the Chief Financial Officer have determined that such controls and procedures are effective to provide reasonable assurance that information relating to the Company, including its consolidated subsidiaries, required to be disclosed in reports that it files or submits under the Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding disclosure.

During the quarter ended September 30, 2007, the Company implemented the sales and distribution module of its Enterprise Resource Planning system which has enabled greater efficiencies in financial reporting and has provided enhanced controls and analytical capabilities. There have been no other changes in the Company's internal controls over financial reporting that were identified during this evaluation that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II. Other Information**Item 1. Legal Proceedings**

On May 9, 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent exclusively licensed to the Company. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. On May 11, 2007, and June 20, 2007, CoreValve filed lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid.

For additional information on the Company's legal proceedings, refer to Item 3 "Legal Proceedings" in Part I on page 22 of the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)(a)
July 1, 2007 through July 31, 2007	179,700	\$ 49.49	179,700	\$ 59.5
August 1, 2007 through August 31, 2007	692,200	46.84	692,200	29.1
September 1, 2007 through September 30, 2007	128,100	47.76	128,100	273.4
Total	1,000,000	\$ 47.43	1,000,000	\$ 273.4

(a)

On May 11, 2006, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions, up to 4.0 million shares of the Company's common stock. As of September 30, 2007, 475,000 shares may yet be purchased under this program. On September 18, 2007, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions, up to an additional \$250 million of the Company's common stock.

Item 6. Exhibits

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

- 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

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: November 8, 2007

By: /s/ THOMAS M. ABATE

Thomas M. Abate
Corporate Vice President,
Chief Financial Officer and Treasurer
(Chief Accounting Officer)

30

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit No.	Description
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