

Edwards Lifesciences Corp
Form 10-Q
November 08, 2010

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[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, 2010

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 ☐

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller Reporting
☒	☐	☐ (Do not check if a smaller reporting company)	Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock, \$1.00 par value, as of October 31, 2010 was 114,178,665.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

FORM 10-Q

For the quarterly period ended September 30, 2010

TABLE OF CONTENTS

	Page Number
<u>Part I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (Unaudited)</u>	
<u>Consolidated Condensed Balance Sheets</u>	<u>1</u>
<u>Consolidated Condensed Statements of Operations</u>	<u>1</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>2</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>3</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>4</u>
<u>Item 2.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>20</u>
<u>Item 3.</u>	
<u>Controls and Procedures</u>	<u>31</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>32</u>
<u>Part II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>33</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>34</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>34</u>
<u>Signature</u>	<u>35</u>
<u>Exhibits</u>	<u>36</u>

Table of Contents**Part I. Financial Information****Item 1. Financial Statements**

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED BALANCE SHEETS

(in millions, except par value; unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	\$ 361.0	\$ 334.1
Accounts and other receivables, net of allowances of \$11.4 and \$12.4, respectively	303.4	272.1
Inventories, net	212.2	165.9
Deferred income taxes	44.2	48.3
Prepaid expenses	45.0	33.7
Other current assets	26.6	35.1
Total current assets	992.4	889.2
Property, plant and equipment, net	260.3	252.0
Goodwill	315.2	315.2
Other intangible assets, net	71.7	86.7
Investments in unconsolidated affiliates (Note 6)	22.3	22.3
Deferred income taxes	51.4	37.1
Other assets	12.1	13.0
	\$ 1,725.4	\$ 1,615.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 281.6	\$ 290.5
Short-term debt	100.6	
Total current liabilities	382.2	290.5
Long-term debt		90.3
Other long-term liabilities	109.7	76.8
Commitments and contingencies (Note 11)		
Stockholders' equity (Note 1)		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding	116.1	76.1

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Common stock, \$1.00 par value, 350.0 shares authorized, 116.1 and 76.1 shares issued, and 114.1 and 56.8 shares outstanding, respectively		
Additional paid-in capital	184.4	1,056.0
Retained earnings	1,059.2	906.0
Accumulated other comprehensive loss	(24.2)	(7.9)
Treasury stock, at cost, 2.0 and 19.3 shares, respectively	(102.0)	(872.3)
 Total stockholders' equity	 1,233.5	 1,157.9
	\$ 1,725.4	\$ 1,615.5

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

Table of Contents**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,	
	2010	2009	2010	2009
Net sales	\$ 348.9	\$ 325.7	\$ 1,054.6	\$ 974.7
Cost of goods sold	95.8	98.5	294.8	297.4
Gross profit	253.1	227.2	759.8	677.3
Selling, general and administrative expenses	133.0	126.1	407.6	376.5
Research and development expenses	52.7	44.7	148.5	127.2
Special charges (gains), net (Note 2)	3.9	(38.2)	12.2	(67.5)
Interest expense, net	0.4	0.6	1.1	0.9
Other income, net	(3.1)	(0.2)	(7.7)	(1.8)
Income before provision for income taxes	66.2	94.2	198.1	242.0
Provision for income taxes	18.2	20.7	44.9	60.5
Net income	\$ 48.0	\$ 73.5	\$ 153.2	\$ 181.5

Share information

(Notes 1 and 13)

Earnings per share:				
Basic	\$ 0.42	\$ 0.65	\$ 1.35	\$ 1.62
Diluted	\$ 0.40	\$ 0.63	\$ 1.29	\$ 1.55
Weighted-average number of common shares outstanding:				
Basic	113.6	112.7	113.4	112.3
Diluted	118.9	117.5	118.9	117.1

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(in millions; unaudited)

	Nine Months Ended September 30,	
	2010	2009
Cash flows from operating activities		
Net income	\$ 153.2	\$ 181.5
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	41.1	44.5
Stock-based compensation (Note 10)	22.4	20.5
Excess tax benefit from stock plans	(42.0)	(12.9)
Deferred income taxes	(6.8)	(4.3)
Special charges (gains), net (Note 2)	12.2	(79.2)
Gain on trading securities	(1.5)	(2.6)
Gain on investments	(0.2)	(0.1)
Other	(3.6)	3.1
Changes in operating assets and liabilities:		
Accounts and other receivables, net (Note 3)	(31.8)	(52.1)
Inventories, net	(43.5)	(13.9)
Accounts payable and accrued liabilities	65.2	6.4
Prepaid expenses and other current assets	(11.7)	(4.0)
Other	4.4	12.5
Net cash provided by operating activities	157.4	99.4
Cash flows from investing activities		
Capital expenditures	(40.1)	(40.3)
Proceeds from sale of assets	5.1	92.4
Investments in unconsolidated affiliates, net	(1.9)	(4.0)
Investments in intangible assets	(1.2)	
Investments in trading securities, net	(0.3)	(1.1)
Proceeds from investments		9.0
Net cash (used in) provided by investing activities	(38.4)	56.0
Cash flows from financing activities		
Proceeds from issuance of debt	216.8	129.3
Payments on debt	(207.6)	(202.2)
Purchases of treasury stock	(200.0)	(79.6)
Proceeds from stock plans	73.8	43.9
Excess tax benefit from stock plans	42.0	12.9
Other	(2.3)	
Net cash used in financing activities	(77.3)	(95.7)
Effect of currency exchange rate changes on cash and cash equivalents	(14.8)	9.2
Net increase in cash and cash equivalents	26.9	68.9
Cash and cash equivalents at beginning of period	334.1	218.7

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Cash and cash equivalents at end of period	\$	361.0	\$	287.6
--	----	-------	----	-------

Supplemental disclosures:

Non-cash transaction:

Distribution of treasury shares to effect stock split (Note 1)	\$	970.3
--	----	-------

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

Table of Contents

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 ("SEC") and should be read in conjunction with the consolidated financial statements and notes included in Edwards Lifesciences Corporation's Annual Report on Form 10-K for the year ended December 31, 2009. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles ("GAAP") 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. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Stock Split

On April 12, 2010, the Company's Board of Directors declared a two-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, paid on May 27, 2010 to shareholders of record on May 14, 2010. The Company distributed treasury shares in addition to newly issued shares to effect the stock split. All applicable share and per-share amounts in the notes to consolidated condensed financial statements and the consolidated condensed statements of operations have been retroactively adjusted to reflect this stock split. The consolidated condensed balance sheet as of December 31, 2009 has not been retroactively adjusted to reflect the stock split.

Recently Adopted Accounting Standards

In June 2009, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIEs"). This accounting guidance eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a VIE based on whether the entity (a) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (b) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. The guidance requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. The guidance was effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company performed an evaluation and determined that there were no relationships with affiliates that represent variable interests requiring consolidation under this guidance.

New Accounting Standards Not Yet Adopted

In October 2009, the FASB issued an amendment to the accounting guidance on revenue recognition to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. The guidance was also amended to eliminate the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or

Table of Contents

materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an amendment to the accounting guidance on fair value disclosures to require companies to (a) disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for such transfers and (b) present separately in the Level 3 reconciliation information about purchases, sales, issuances and settlements. The guidance also clarifies the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance was effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation, which is effective for fiscal years beginning after December 15, 2010, and for interim periods within those years. The Company adopted this guidance as of January 1, 2010, other than those provisions related to the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation.

In April 2010, the FASB issued an amendment to the accounting guidance on revenue recognition to provide guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research and development transactions. Consideration that is contingent upon achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The guidance is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

2. SPECIAL CHARGES (GAINS), NET

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in millions)			
Investment impairment	\$ 3.9	\$ 1.6	\$ 3.9	\$ 1.6
MONARC program discontinuation			8.3	
Gain on sale of product lines		(58.6)		(84.1)
Charitable fund contribution		15.0		15.0
Litigation		3.8		3.8
Sale of distribution rights				(2.8)
Reserve reversal				(1.0)
Special charges (gains), net	\$ 3.9	\$ (38.2)	\$ 12.2	\$ (67.5)

Investment Impairment

In September 2010, the Company recorded a \$3.9 million charge related to the other-than-temporary impairment of two non-strategic investments in unconsolidated affiliates. The Company concluded that the impairment of these investments was other-than-temporary based upon the continuing duration and severity of the impairment.

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its investment in an unconsolidated affiliate. The Company concluded that the impairment of its investment was other-than-temporary based upon (a) the continuing duration and severity of the impairment and (b) positive clinical trial developments in the third quarter of 2009 which failed to raise the quoted market price of the affiliate's stock to the Company's carrying value.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

MONARC Program Discontinuation

During the second quarter of 2010, the Company decided to discontinue its *MONARC* transcatheter mitral valve program due to slow enrollment in the EVOLUTION II trial. As a result, the Company recorded an \$8.3 million charge consisting of a \$7.6 million impairment of intangible assets associated with the program and \$0.7 million of clinical trial costs that will continue to be incurred under a contractual obligation that existed prior to the discontinuation date.

Gain on Sale of Product Lines

Effective September 1, 2009, the Company sold its hemofiltration product line, which resulted in a pre-tax gain of \$43.6 million. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. In February 2009, under the terms of the sale agreement, the Company received a \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of *LifeStent* device manufacturing to the buyer. The Company received \$8.9 million of this milestone in September 2009 and \$6.1 million in October 2009.

Charitable Fund Contribution

In September 2009, the Company contributed \$15.0 million to The Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular and community related charitable causes. The contribution was an irrevocable contribution to a third party, and was recorded as an expense at the time of payment.

Litigation

In September 2009, the Company recorded a \$3.8 million charge for litigation related to a royalty dispute in connection with a product in the Company's Cardiac Surgery Systems product line.

Sale of Distribution Rights

In March 2009, the Company recorded a \$2.8 million gain related to the sale of its distribution rights in Europe for a specialty vascular graft.

Reserve Reversal

In 2004, the Company discontinued its *Lifepath* AAA endovascular graft program. In March 2009, upon completion of its remaining clinical obligations related to this program, the Company reversed its remaining \$1.0 million clinical reserve.

3. ACCOUNTS RECEIVABLE SECURITIZATION

The Company terminated its securitization program in Japan in February 2009. Previously, under the Japan Receivables Facility, the Company sold eligible accounts receivable directly to a financial institution, and the transactions were accounted for as sales of accounts receivable. Upon termination of the program, the Company paid the financial institution \$39.0 million for the outstanding accounts receivable and February collections.

Table of Contents**4. INVENTORIES**

Inventories consisted of the following (in millions):

	September 30, 2010	December 31, 2009
Raw materials	\$ 40.0	\$ 32.8
Work in process	39.9	30.4
Finished products	132.3	102.7
	\$ 212.2	\$ 165.9

5. OTHER INTANGIBLE ASSETS

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

September 30, 2010	Patents	Unpatented Technology	Other	Total
Cost	\$ 203.6	\$ 35.0	\$ 12.5	\$ 251.1
Accumulated amortization	(144.8)	(29.0)	(5.6)	(179.4)
Net carrying value	\$ 58.8	\$ 6.0	\$ 6.9	\$ 71.7

December 31, 2009	Patents	Unpatented Technology	Other	Total
Cost	\$ 212.0	\$ 35.0	\$ 12.6	\$ 259.6
Accumulated amortization	(141.3)	(27.1)	(4.5)	(172.9)
Net carrying value	\$ 70.7	\$ 7.9	\$ 8.1	\$ 86.7

During the second quarter of 2010, the Company recorded a \$7.6 million impairment of patents related to its *MONARC* transcatheter mitral valve program, which was discontinued due to slow enrollment in the EVOLUTION II trial (see Note 2).

The net carrying value of patents includes \$16.6 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of September 30, 2010.

Amortization expense related to other intangible assets was \$4.2 million and \$5.4 million for the three months ended September 30, 2010 and 2009, respectively, and \$12.4 million and \$16.1 million for the nine months ended September 30, 2010 and 2009, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2010	\$ 17.2
2011	14.7
2012	13.3
2013	13.3
2014	11.9

The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

Table of Contents**6. INVESTMENTS IN UNCONSOLIDATED AFFILIATES**

The Company has a number of equity investments in privately and publicly held companies, as follows:

	September 30, 2010	December 31, 2009
	(in millions)	
Available-for-sale investments		
Cost	\$ 4.5	\$ 8.5
Unrealized losses		(0.9)
Fair value of available-for-sale investments	4.5	7.6
Equity method investments		
Cost	11.2	10.7
Equity in losses	(1.2)	(0.8)
Carrying value of equity method investments	10.0	9.9
Cost method investments		
Carrying value of cost method investments	7.8	4.8
Total investments in unconsolidated affiliates	\$ 22.3	\$ 22.3

Proceeds from sales of available-for-sale investments were \$0.3 million for the three and nine months ended September 30, 2010. The Company realized pre-tax gains from these sales of \$0.2 million for the three and nine months ended September 30, 2010. There were no sales of available-for-sale investments during the nine months ended September 30, 2009. In September 2010 and 2009, the Company recorded other-than-temporary impairment charges of \$3.9 million and \$1.6 million, respectively, related to certain available-for-sale investments. See Note 2 for additional information.

7. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS

The consolidated condensed financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities and borrowings under a revolving credit agreement. The carrying value of these financial instruments generally approximates fair value due to their short-term nature.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Company prioritizes the inputs used to determine fair values in one of the following three categories:

- Level 1 Quoted market prices in active markets for identical assets or liabilities.
- Level 2 Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.
- Level 3 Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis (in millions):

September 30, 2010	Level 1	Level 2	Level 3	Total
Assets				
Investments held for executive deferred compensation plan	\$ 16.9	\$	\$	\$ 16.9
Investments in unconsolidated affiliates	4.5			4.5
	\$ 21.4	\$	\$	\$ 21.4
Liabilities				
Derivatives	\$	\$ 15.7	\$	\$ 15.7
	\$	\$ 15.7	\$	\$ 15.7
December 31, 2009				
Assets				
Investments held for executive deferred compensation plan	\$ 15.1	\$	\$	\$ 15.1
Investments in unconsolidated affiliates	7.6			7.6
	\$ 22.7	\$	\$	\$ 22.7
Liabilities				
Derivatives	\$	\$ 3.0	\$	\$ 3.0
	\$	\$ 3.0	\$	\$ 3.0

Investments Held for the Executive Deferred Compensation Plan

The Company holds investments in trading securities related to its executive deferred compensation plan ("EDCP"). The amounts deferred under the EDCP are invested in a variety of stock and bond mutual funds. The fair values of these investments are based on quoted market prices and are categorized as Level 1.

Investments in Unconsolidated Affiliates

Investments in unconsolidated affiliates are long-term equity investments in companies that are in various stages of development. Certain of the Company's investments in unconsolidated affiliates are designated as available-for-sale. These investments are carried at fair market value based on quoted market prices and are categorized as Level 1.

Derivative Instruments

The Company uses forward exchange contracts and option contracts to hedge a portion of its exposure to forecasted intercompany and third-party foreign currency transactions. All derivatives are recognized on the balance sheet at their fair value. The fair value for derivatives is determined based on indicative mid-market data levels for spot rate and forward points. All values are discounted to present from the expiry date. The values of options are calculated based on the forward implied volatilities to the expiry date. The models used for valuations are based upon well recognized financial principles, and the predominance of market inputs are actively quoted and can be validated through external sources. Although readily observable data is used in the valuations, different valuation methodologies could have an effect on the estimated fair value. The derivative instruments are categorized as Level 2.

Table of Contents***Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis***

The Company has assets that are subject to measurement at fair value on a non-recurring basis, including assets acquired in a business combination, such as goodwill and intangible assets, and other long-lived assets. The Company reviews the carrying value of intangible and other long-lived assets whenever events and circumstances indicate that the carrying amounts of the assets may not be recoverable. If it is determined that the assets are impaired, the carrying value would be reduced to estimated fair market value. During the nine months ended September 30, 2010, the Company recorded a \$7.6 million impairment of intangible assets related to the Company's *MONARC* transcatheter mitral valve program, which was discontinued due to slow enrollment in the EVOLUTION II trial (see Note 2). During the nine months ended September 30, 2009, the Company had no impairments related to assets subject to measurement at fair value on a non-recurring basis.

8. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

Edwards Lifesciences maintains an overall risk management strategy that may incorporate the use of a variety of derivative financial instruments, as summarized below, to mitigate its exposure to significant unplanned fluctuations in earnings and cash flow caused by volatility in interest rates and currency exchange rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy include option-based products and forward exchange contracts. As of September 30, 2010, all derivative instruments owned were designated as hedges of underlying exposures. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

	September 30, 2010		December 31, 2009	
	Notional	Fair Value	Notional	Fair Value
	Amount	Asset (Liability)	Amount	Asset (Liability)
	(in millions)			
Forward currency agreements	\$ 376.8	\$ (13.8)	\$ 130.5	\$ (1.7)
Currency option contracts	53.2	(1.9)	212.6	(1.3)

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

Derivative instruments used by Edwards Lifesciences involve, to varying degrees, elements of credit risk, in the event a counterparty should default, and market risk, as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counterparty diversification, monitoring of counterparty financial condition, and International Swap Dealers Association master-netting agreements in place with all derivative counterparties. The master-netting agreements reduce the Company's counterparty payment settlement risk on any given maturity date to the net amount of any receipts or payments due between the Company and the counterparty financial institution. Although these protections do not eliminate concentrations of credit, the Company does not consider the risk of counterparty default to be significant. All derivative financial instruments are with a diversified group of major financial institutions assigned investment grade ratings with national rating agencies. None of the Company's outstanding derivative instruments contain credit-risk related contingent features that may require the Company to post or permit the Company to call collateral from any counterparty.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated condensed balance sheets (in millions):

	Balance Sheet Location	Fair Value September 30, 2010	December 31, 2009
Derivatives designated as hedging instruments			
Liabilities			
Foreign exchange contracts	Accrued liabilities	\$ 15.7	\$ 3.0

The following tables present the effect of derivative instruments on the consolidated condensed statements of operations (in millions):

		Amount of Gain or (Loss) Recognized in Income on Derivative	
	Location of Gain or (Loss) Recognized in Income on Derivative	Three Months Ended September 30,	
		2010	2009
Derivatives in fair value hedging relationships			
Foreign exchange contracts	Other income, net	\$ (3.0)	\$ (2.1)

		Amount of Gain or (Loss) Recognized in Income on Derivative	
	Location of Gain or (Loss) Recognized in Income on Derivative	Nine Months Ended September 30,	
		2010	2009
Derivatives in fair value hedging relationships			
Foreign exchange contracts	Other income, net	\$ (4.4)	\$ (2.5)

Table of Contents

	Amount of Gain or (Loss) Recognized in Other Comprehensive Income ("OCI") on Derivative (Effective Portion)			Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income					
	Three Months Ended September 30,		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Three Months Ended September 30,					
	2010	2009		2010	2009				
Derivatives in cash flow hedging relationships									
Foreign exchange contracts	\$	(24.9)	\$	(10.6)	Cost of goods sold	\$	4.0	\$	2.7

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)			Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	Nine Months Ended September 30,		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Nine Months Ended September 30,	
	2010	2009		2010	2009
Derivatives in cash flow hedging relationships					
Foreign exchange contracts	\$ (7.1)	\$ (5.6)	Cost of goods sold	\$ (1.0)	\$ 8.8

The Company expects that during the next twelve months it will reclassify to earnings a \$2.8 million gain currently recorded in "Accumulated Other Comprehensive Loss." For the three and nine months ended September 30, 2010, the Company expensed \$0.1 million related to the premium costs of option-based products and did not record any gains or losses due to hedge ineffectiveness. For the three and nine months ended September 30, 2009, the Company expensed \$0.3 million and \$0.8 million, respectively, related to the premium costs of option-based products and did not record any gains or losses due to hedge ineffectiveness.

9. DEFINED BENEFIT PLANS

The components of net periodic benefit costs for the three and nine months ended September 30, 2010 and 2009 were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Service cost	\$ 1.2	\$ 1.4	\$ 3.5	\$ 4.1
Employee contributions				
Interest cost	0.5	0.4	1.4	1.3
Expected return on plan assets	(0.3)	(0.3)	(0.9)	(0.7)
Amortization of prior service cost and other		0.2	0.1	0.5
Net periodic pension benefit cost	\$ 1.4	\$ 1.7	\$ 4.1	\$ 5.2

Table of Contents
10. 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, 2010 and 2009 was as follows (in millions):

	Three Months Ended September 30		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of goods sold	\$ 0.9	\$ 0.6	\$ 2.1	\$ 1.7
Selling, general and administrative expenses	6.4	6.0	16.8	15.5
Research and development expenses	1.3	1.3	3.5	3.3
Total stock-based compensation expense	\$ 8.6	\$ 7.9	\$ 22.4	\$ 20.5

At September 30, 2010, the total remaining compensation cost related to nonvested stock options, restricted stock units and employee stock purchase subscription awards amounted to \$53.2 million, which will be amortized on a straight-line basis over the weighted-average remaining requisite service period of 30 months.

During the nine months ended September 30, 2010, the Company granted 1.7 million stock options at a weighted-average exercise price of \$51.14 and 0.3 million shares of restricted stock units at a weighted-average grant-date fair value of \$50.31.

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,	
	2010	2009	2010	2009
Risk-free interest rate	1.7%	2.3%	2.0%	1.9%
Expected dividend yield	None	None	None	None
Expected volatility	25.7%	28.1%	25.9%	28.1%
Expected term (years)	4.8	4.9	4.6	4.6
Fair value, per share	\$ 14.25	\$ 9.57	\$ 12.98	\$ 8.54

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,	
	2010	2009	2010	2009
Risk-free interest rate	0.3%	0.4%	0.3%	0.4%
Expected dividend yield	None	None	None	None
Expected volatility	24.0%	36.6%	27.5%	36.3%
Expected term (years)	0.6	0.6	0.6	0.6
Fair value, per share	\$ 12.61	\$ 8.96	\$ 12.09	\$ 8.71

Table of Contents

11. COMMITMENTS AND CONTINGENCIES

In February 2008, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve") in the United States District Court for the District of Delaware alleging that its ReValving System infringes three of the Company's U.S. Andersen patents, later narrowed to one patent ("the '552 patent"). CoreValve was acquired by Medtronic, Inc. ("Medtronic") in April 2009. In April 2010, a federal jury found that patent to be valid and found that CoreValve willfully infringes it. The jury also awarded Edwards \$73.9 million in damages, which may be increased by the judge by up to three times that amount because of the willfulness finding. The Company is seeking a permanent injunction against CoreValve's manufacture or sale of the infringing device in the United States. A second lawsuit is pending in the same court against CoreValve and Medtronic alleging infringement of three U.S. Andersen patents. In September 2010, the United States Patent and Trademark Office granted Medtronic's third request to reexamine the validity of the '552 patent, and this process is ongoing.

Earlier, in May 2007, the Company filed a lawsuit against CoreValve alleging infringement of the Company's European Andersen patent. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. In October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. In February 2010, a German Appeals Court affirmed. In May 2007 and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, alleging the patent to be invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. In January 2009, the United Kingdom Court determined that the Andersen patent is valid but not infringed by CoreValve. In May 2010, a United Kingdom Appeals Court affirmed the lower court. In January 2010, the German Courts also determined that the Andersen patent is valid.

In February 2008, Cook, Inc. ("Cook") filed a lawsuit in the District Patent Court in Dusseldorf, Germany, against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents were invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Courts ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. In June 2010, a United Kingdom Appeals Court affirmed. In April 2010, the German Courts also determined that the Cook patent is invalid.

In March and September 2010, the Company received grand jury subpoenas for documents from the United States Attorney's Office in the Central District of California in connection with an investigation by the federal Food and Drug Administration. The subpoenas to the Company seek records relating to the Vigilance I Monitor model with software release 5.3 that was the subject of a voluntary field recall by the Company in June 2006. The Company is cooperating fully with the investigation.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur charges in excess of established reserves. 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.

Table of Contents

Edwards Lifesciences is subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

12. COMPREHENSIVE INCOME

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net income	\$ 48.0	\$ 73.5	\$ 153.2	\$ 181.5
Other comprehensive income:				
Currency translation adjustments	42.7	20.0	(13.6)	29.0
Unrealized net (loss) gain on investments in unconsolidated affiliates, net of tax	(0.1)	3.7	(2.7)	7.0
Reclassification of net realized investment loss in earnings	3.7	1.6	3.7	1.6
Unrealized net loss on cash flow hedges, net of tax	(17.5)	(8.1)	(3.7)	(8.7)
Comprehensive income	\$ 76.8	\$ 90.7	\$ 136.9	\$ 210.4

13. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Employee equity share options, nonvested shares and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of restricted stock units 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

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Basic:				
Net income	\$ 48.0	\$ 73.5	\$ 153.2	\$ 181.5
Weighted-average shares outstanding	113.6	112.7	113.4	112.3
Basic earnings per share	\$ 0.42	\$ 0.65	\$ 1.35	\$ 1.62
Diluted:				
Net income	\$ 48.0	\$ 73.5	\$ 153.2	\$ 181.5
Weighted-average shares outstanding	113.6	112.7	113.4	112.3
Dilutive effect of stock plans	5.3	4.8	5.5	4.8
Dilutive weighted-average shares outstanding	118.9	117.5	118.9	117.1
Diluted earnings per share	\$ 0.40	\$ 0.63	\$ 1.29	\$ 1.55

Stock options and restricted stock units to purchase 1.7 million and 2.0 million shares for the three months ended September 30, 2010 and 2009, respectively, and 1.2 million and 2.5 million for the nine months ended September 30, 2010 and 2009, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

14. INCOME TAXES

The Company's effective income tax rates were 27.5% and 22.7% for the three and nine months ended September 30, 2010, respectively, and 22.0% and 25.0% for the three and nine months ended September 30, 2009, respectively. The income tax rate for the nine months ended September 30, 2010 included a \$9.8 million tax benefit resulting from a partial settlement of a prior year tax audit. The income tax rate for the nine months ended September 30, 2009 included the tax detriment on the *LifeStent* milestone receipt and the sale of the hemofiltration product line. See Note 2 for further information.

The federal research credit expired on December 31, 2009 and has not been reinstated as of September 30, 2010. The effective income tax rate for the three and nine months ended September 30, 2010 has been calculated without a benefit for the federal research credit. In 2009, the federal research credit favorably impacted the effective tax rate by approximately 1.5%.

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 consolidated condensed financial statements. Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related penalty and interest have been provided for any adjustments that may result from these uncertain tax positions.

Table of Contents

As of September 30, 2010 and December 31, 2009, the liability for income taxes associated with uncertain tax positions was \$51.1 million and \$47.1 million, respectively. These liabilities could be reduced by \$3.4 million and \$3.2 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amounts of \$47.7 million and \$44.0 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

All material state, local and foreign income tax matters have been concluded for years through 2003. The Internal Revenue Service has completed its examination of the 2007 and 2008 tax years for all matters except for certain transfer pricing issues. The Company has entered the appeals process for those transfer pricing issues.

15. COLLABORATIVE AGREEMENT

The Company has a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for automated, real-time monitoring of blood glucose levels in patients hospitalized for a variety of conditions. The agreement provides Edwards Lifesciences with an exclusive license to all of DexCom's applicable intellectual property. Product development costs under this agreement are expensed to "*Research and Development Expenses*" as incurred, and regulatory approval milestones are recorded as "*Other Intangible Assets*" and amortized over the useful life of the product. The Company recorded \$1.3 million and \$3.3 million of product development costs for the three and nine months ended September 30, 2010, respectively, and \$1.3 million and \$4.5 million for the three and nine months ended September 30, 2009, respectively. At both September 30, 2010 and December 31, 2009, the Company had \$0.9 million of capitalized regulatory milestone payments.

16. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in four geographical regions: United States, Europe, Japan and Rest of World. 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, 2009. 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 net interest expense, global marketing expenses, corporate research and development expenses, United States manufacturing variances, corporate headquarters costs, in-process research and development, special gains and charges, stock-based compensation, foreign currency hedging activities, certain litigation costs and most of the Company's amortization expense. Although most of the Company's depreciation expense is included in segment pre-tax income, due to the Company's methodology for cost build-up, it is impractical to determine the amount of depreciation expense included in each segment, and therefore a portion is maintained at the corporate level. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Segment Net Sales				
United States	\$ 140.1	\$ 137.0	\$ 423.1	\$ 415.4
Europe	109.2	92.2	333.2	295.3
Japan	53.8	45.3	160.0	132.6
Rest of world	41.9	39.0	121.9	112.5

Total segment net sales	\$ 345.0	\$ 313.5	\$ 1,038.2	\$ 955.8
-------------------------	----------	----------	------------	----------

Segment Pre-Tax Income				
United States	\$ 75.6	\$ 73.4	\$ 232.8	\$ 223.5
Europe	40.7	29.3	125.6	97.8
Japan	25.3	21.2	73.9	62.2
Rest of world	13.1	12.8	35.4	32.1

Total segment pre-tax income	\$ 154.7	\$ 136.7	\$ 467.7	\$ 415.6
------------------------------	----------	----------	----------	----------

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net Sales Reconciliation				
Segment net sales	\$ 345.0	\$ 313.5	\$ 1,038.2	\$ 955.8
Foreign currency	3.9	12.2	16.4	18.9

Consolidated net sales	\$ 348.9	\$ 325.7	\$ 1,054.6	\$ 974.7
------------------------	----------	----------	------------	----------

Pre-Tax Income Reconciliation				
Segment pre-tax income	\$ 154.7	\$ 136.7	\$ 467.7	\$ 415.6
Unallocated amounts:				
Corporate items	(92.7)	(85.8)	(269.0)	(259.1)
Special (charges) gains, net	(3.9)	38.2	(12.2)	67.5
Interest expense, net	(0.4)	(0.6)	(1.1)	(0.9)
Foreign currency	8.5	5.7	12.7	18.9

Consolidated pre-tax income	\$ 66.2	\$ 94.2	\$ 198.1	\$ 242.0
-----------------------------	---------	---------	----------	----------

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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,	
	2010	2009	2010	2009
(in millions)				
Net Sales by Geographic Area				
United States	\$ 140.1	\$ 137.0	\$ 423.1	\$ 415.4
Other countries	208.8	188.7	631.5	559.3
	\$ 348.9	\$ 325.7	\$ 1,054.6	\$ 974.7

Net Sales by Major Product and Service Area				
Heart Valve Therapy	\$ 200.6	\$ 174.1	\$ 612.1	\$ 526.6
Critical Care	111.0	114.2	326.6	331.7
Cardiac Surgery Systems	23.7	22.3	75.0	68.9
Vascular	13.6	15.1	40.9	47.5
	\$ 348.9	\$ 325.7	\$ 1,054.6	\$ 974.7

	September 30, 2010	December 31, 2009
(in millions)		
Long-Lived Tangible Assets by Geographic Area		
United States	\$ 171.5	\$ 163.0
Other countries	100.9	102.0
	\$ 272.4	\$ 265.0

Table of Contents

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 (as defined below in "Overview") intends the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials or regulatory approvals, any statements of plans, strategies and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, and any 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," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's future business, financial condition, results of operations or performance to differ materially from the Company's historical results or those expressed or implied 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, 2009 and subsequent filings on Form 10-Q for a description of certain of these risks and uncertainties. These forward-looking statements speak only as of the date on which they are made and the Company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If the Company does update or correct one or more of these statements, investors and others should not conclude that the Company will make additional updates or corrections.

Overview

Edwards Lifesciences Corporation ("Edwards Lifesciences" or the "Company") is a global leader in products and technologies designed to treat advanced cardiovascular disease. The Company is focused specifically on technologies that treat structural heart disease and critically ill patients.

The products and technologies provided by Edwards Lifesciences are categorized into four main areas: Heart Valve Therapy; Critical Care; Cardiac Surgery Systems; and Vascular.

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 equipment used to measure a patient's cardiovascular function, and in disposable pressure transducers. Prior to September 2009, Edwards Lifesciences provided products for continuous renal replacement therapy ("hemofiltration product line"). The Company sold the hemofiltration product line effective September 1, 2009. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannulae, **EMBOL-X** technologies and other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also includes the Company's minimally invasive surgery ("MIS") product line. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, and artificial implantable grafts. Edwards Lifesciences manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents until the sale of this product line in January 2008. The Company continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred to the buyer.

Table of Contents

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 technology, cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs are expected to continue to drive change.

In March 2010, significant reforms to the healthcare system were adopted as law in the United States. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. The excise tax will increase the Company's operating expenses. The new law or any future legislation could reduce medical procedure volumes, lower reimbursement for the Company's products, and impact the demand for the Company's products or the prices at which the Company sells its products.

On April 12, 2010, the Company's Board of Directors declared a two-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, paid on May 27, 2010 to shareholders of record on May 14, 2010. The Company distributed treasury shares in addition to newly issued shares to effect the stock split. All applicable share and per-share amounts in this *"Management's Discussion and Analysis of Financial Condition and Results of Operations"* have been retroactively adjusted to give effect to this stock split.

New Accounting Standards Not Yet Adopted

In October 2009, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on revenue recognition to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. The guidance was also amended to eliminate the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an amendment to the accounting guidance on fair value disclosures to require companies to (a) disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for such transfers and (b) present separately in the Level 3 reconciliation information about purchases, sales, issuances and settlements. The guidance also clarifies the level of disaggregation to present and disclosures about inputs and valuation techniques. The guidance was effective for interim and annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation, which is effective for fiscal years beginning after December 15, 2010, and for interim periods within those years. The Company adopted this guidance as of January 1, 2010, other than those provisions related to the disclosures about purchases, sales, issuances and settlements in the Level 3 reconciliation.

In April 2010, the FASB issued an amendment to the accounting guidance on revenue recognition to provide guidance on defining a milestone and determining when it may be appropriate to apply the

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

milestone method of revenue recognition for research and development transactions. Consideration that is contingent upon achievement of a milestone in its entirety may be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. The guidance is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

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,			
	2010	2009	Change	Percent Change	2010	2009	Change	Percent Change
United States	\$ 140.1	\$ 137.0	\$ 3.1	2.3%	\$ 423.1	\$ 415.4	\$ 7.7	1.9%
International	208.8	188.7	20.1	10.7%	631.5	559.3	72.2	12.9%
Total net sales	\$ 348.9	\$ 325.7	\$ 23.2	7.1%	\$ 1,054.6	\$ 974.7	\$ 79.9	8.2%

In the United States, the \$3.1 million and \$7.7 million increases in net sales for the three and nine months ended September 30, 2010, respectively, were due primarily to:

Heart Valve Therapy products, which increased net sales by \$1.7 million and \$6.2 million, respectively, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* valves, which were launched in the second quarter of 2009 and the third quarter of 2010, respectively, and the *Carpentier-Edwards Physio II* ring, which was launched in the first quarter of 2009, partially offset by \$4.1 million of sales recognized in the second quarter of 2009 due to the return of the Company's *IMR* and *dETlogix* repair products to its customers;

Critical Care products, which increased net sales by \$1.9 million and \$5.9 million, respectively, driven primarily by the *FloTrac* minimally invasive monitoring system; and

Cardiac Surgery Systems products, which increased net sales by \$0.9 million and \$2.3 million, respectively, driven primarily by the MIS product line;

partially offset by:

the discontinuance of manufacturing in September 2009 of the divested *LifeStent* product line, which decreased net sales by \$1.9 million and \$7.8 million, respectively.

International net sales increased \$20.1 million and \$72.2 million for the three and nine months ended September 30, 2010, respectively, due primarily to:

Heart Valve Therapy products, which increased net sales by \$29.1 million and \$77.1 million, respectively, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, and the new *Carpentier-Edwards Physio II* ring, which was launched in Europe in the first quarter of 2009 and in Japan in the first quarter of 2010;

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Critical Care products, which increased net sales by \$3.9 million and \$13.6 million, respectively, driven primarily by *FloTrac* systems and pressure monitoring products; and

Cardiac Surgery Systems products, which increased net sales by \$0.7 million and \$3.0 million, respectively, driven primarily by specialty cannula products;

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$3.7 million for the three month period due primarily to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar. For the nine month period, foreign currency exchange rate fluctuations increased net sales by \$8.8 million due primarily to the strengthening of the Japanese yen, Australian dollar and the Canadian dollar against the United States dollar, partially offset by the weakening of the Euro against the United States dollar; and

hemofiltration products, which decreased net sales by \$10.2 million and \$32.0 million for the three and nine months ended September 30, 2010, respectively. The Company sold its hemofiltration product line effective September 1, 2009.

The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs and the Company's hedging activities. For more information see Item 3, "*Quantitative and Qualitative Disclosures 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,		Change	Percent Change	Nine Months Ended September 30,		Change	Percent Change
	2010	2009			2010	2009		
Heart Valve Therapy	\$ 200.6	\$ 174.1	\$ 26.5	15.2%	\$ 612.1	\$ 526.6	\$ 85.5	16.2%
Critical Care	111.0	114.2	(3.2)	(2.8)%	326.6	331.7	(5.1)	(1.5)%
Cardiac Surgery Systems	23.7	22.3	1.4	6.3%	75.0	68.9	6.1	8.9%
Vascular	13.6	15.1	(1.5)	(9.9)%	40.9	47.5	(6.6)	(13.9)%
Total net sales	\$ 348.9	\$ 325.7	\$ 23.2	7.1%	\$ 1,054.6	\$ 974.7	\$ 79.9	8.2%

Heart Valve Therapy

Net sales of Heart Valve Therapy products for the three and nine months ended September 30, 2010 increased by \$26.5 million and \$85.5 million, respectively, due primarily to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$25.9 million and \$67.1 million, respectively; and

pericardial tissue valves, which increased net sales by \$5.5 million and \$20.1 million, respectively, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$4.4 million for the three month period due primarily to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar. The impact to sales for the nine month period was relatively flat, as the weakening of the Euro against the United States dollar was offset by the strengthening of the Japanese yen, Australian dollar and Canadian dollar against the United States dollar.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

The Company expects that its *SAPIEN* transcatheter heart valve will continue to be a strong contributor to 2010 sales. The Company also expects that sales of its new products, such as the *Magna Ease* valve and the *Carpentier-Edwards Physio II* ring, will continue to drive growth for the remainder of

Table of Contents

2010. The Company launched its *Magna Mitral Ease* valve in the United States and Europe during the third quarter of 2010. The *Magna Mitral Ease* will extend the *Magna* platform by providing improved MIS capabilities and ease of implantation. In January 2010, the Company completed first-in-man procedures and initiated a clinical feasibility study in Europe, called TRITON, for a novel minimally invasive aortic valve surgery system, called Project Odyssey. The Project Odyssey system leverages the design of the *Carpentier-Edwards PERIMOUNT Magna Ease* tissue heart valve to create a new valve platform with an innovative delivery and attachment system. It is designed to enable a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision. In April 2010, the Company expanded the study into a CE Mark trial. The Company completed enrollment in TRITON during the third quarter of 2010, and anticipates receiving CE Mark in 2011.

Critical Care

Net sales of Critical Care products for the three and nine months ended September 30, 2010 decreased by \$3.2 million and \$5.1 million, respectively, due primarily to:

hemofiltration products, which decreased net sales by \$10.2 million and \$32.3 million, respectively. The Company sold its hemofiltration product line effective September 1, 2009;

partially offset by:

premium products, led by *FloTrac* systems, which increased net sales by \$3.3 million and \$10.7 million, respectively, and *PreSep*, the Company's central venous oximetry catheter for early detection of sepsis, which increased net sales by \$1.0 million and \$2.6 million, respectively;

pressure monitoring products, which increased net sales by \$1.5 million and \$6.7 million, respectively; and

foreign currency exchange rate fluctuations, which increased net sales by \$1.2 million and \$6.7 million, respectively, due primarily to the strengthening of the Japanese yen against the United States dollar, partially offset by the weakening of the Euro against the United States dollar.

The Company expects worldwide sales of *FloTrac* systems will continue to be a significant contributor to 2010 Critical Care sales, and that it will continue to expand the market for minimally invasive hemodynamic monitoring. The Company conducted a clinical study of a substantial upgrade designed to strengthen the *FloTrac* system's applicability in the medical intensive care unit and a new hardware platform with a simpler, more intuitive informational display, and received CE Mark in the fourth quarter of 2010.

In September 2010, the Company entered into a collaboration, license, and supply agreement related to its Central Venous Access product line ("Access Products"). Under the terms of the agreement, the Company granted the buyer an exclusive, perpetual, royalty-free license to manufacture, distribute, market and sell the Access Products in the United States. The Company agreed to manufacture and exclusively supply the Access Products to the buyer through March 2013.

The Company has a collaboration agreement with DexCom, Inc. to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. In the United States, the Company filed for regulatory approval of its first generation product in the second quarter of 2010. In Europe, the Company is continuing its post-CE Mark trials to evaluate its continuous glucose monitor, and has made great progress to enhance its ease of use in the second generation product, which it expects to be commercially available in Europe in late 2011.

Table of Contents

Cardiac Surgery Systems

Net sales of Cardiac Surgery Systems products for the three and nine months ended September 30, 2010 increased by \$1.4 million and \$6.1 million, respectively, due to MIS products, which increased net sales by \$1.0 million and \$3.0, respectively, and specialty cannula products, which increased net sales by \$0.5 million and \$2.3 million, respectively.

Vascular

Net sales of Vascular products for the three and nine months ended September 30, 2010 decreased by \$1.5 million and \$6.6 million, respectively, due primarily to the discontinuance of manufacturing in September 2009 of the divested *LifeStent* product line.

Gross Profit

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
Gross profit as a percentage of net sales	72.5%	69.8%	2.7 pts.	72.0%	69.5%	2.5 pts.

The 2.7 and 2.5 percentage point increases in gross profit as a percentage of net sales for the three and nine months ended September 30, 2010, respectively, were driven by:

a 1.8 percentage point increase in international markets for both the three and nine month period due to a more profitable product mix, primarily higher sales of transcatheter heart valves and the divestiture of the hemofiltration product line; and

a 0.3 percentage point and a 0.8 percentage point increase in the United States due to a more profitable product mix, primarily from reduced sales of *LifeStent* products under the manufacturing requirements of the *LifeStent* sale agreement, and the favorable impact of manufacturing performance.

Gross profit as a percentage of net sales for the three months ended September 30, 2010 was also favorably impacted by foreign currency, including the outcome of foreign currency hedging contracts.

Selling, General and Administrative (SG&A) Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
	(dollars in millions)					
SG&A expenses	\$ 133.0	\$ 126.1	\$ 6.9	\$ 407.6	\$ 376.5	\$ 31.1
SG&A expenses as a percentage of net sales	38.1%	38.7%	(0.6) pts.	38.6%	38.6%	

The \$6.9 million and \$31.1 million increases in SG&A expenses for the three and nine months ended September 30, 2010, respectively, were due primarily to higher sales and marketing expenses, primarily to support the transcatheter heart valve program. Foreign currency had an unfavorable impact of \$2.2 million for the three month period, primarily due to the weakening of the Euro against the United States dollar, partially offset by the strengthening of the Japanese yen against the United States dollar. Foreign currency had a favorable impact of \$3.1 million for the nine month period, primarily due to the strengthening of the Japanese yen and the Australian dollar against the United States dollar, partially offset by the weakening of the Euro against the United States dollar.

Table of Contents**Research and Development Expenses**

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
	(dollars in millions)					
Research and development expenses	\$ 52.7	\$ 44.7	\$ 8.0	\$ 148.5	\$ 127.2	\$ 21.3
Research and development expenses as a percentage of net sales	15.1%	13.7%	1.4 pts.	14.1%	13.1%	1.0 pts.

The increases in research and development expenses for the three and nine months ended September 30, 2010 were due to additional investments in all major product lines, primarily the transcatheter heart valve program.

The following are the developments related to the Company's transcatheter aortic valve replacement program (formerly Percutaneous Valve Technologies, Inc.'s percutaneous aortic valve program):

the Company received conditional Investigational Device Exemption ("IDE") approval from the Food and Drug Administration ("FDA") in March 2007 to initiate its PARTNER trial, a pivotal clinical trial of the Company's *Edwards SAPIEN* transcatheter heart valve technology. The PARTNER trial, which has two study arms, is evaluating the *Edwards SAPIEN* transcatheter heart valve in patients who are considered at high risk for conventional open-heart valve surgery. In the first study arm ("Cohort A"), patients are randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. In the second study arm ("Cohort B"), patients who are deemed non-operable are randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. In addition, the Company received FDA approval for non-randomized continued access for all of its existing PARTNER sites. During the third quarter of 2010, positive one-year data from Cohort B was published and the Company completed the submission of its pre-market approval to the FDA during the fourth quarter of 2010. The Company anticipates submitting Cohort A to the FDA for approval in mid-2011;

the Company announced it received CE Mark in March 2010 for its next generation transcatheter heart valve, the *Edwards SAPIEN XT* valve, as well as its *NovaFlex* transfemoral and *Ascendra2* transapical delivery systems. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, enabling it to better address the requirements of transfemoral delivery. The Company began disciplined European launches of *SAPIEN XT* with *NovaFlex* at the end of the first quarter of 2010, and *SAPIEN XT* with *Ascendra2* at the end of the second quarter of 2010;

in the United States, the Company submitted an IDE for *SAPIEN XT* in October 2009. During the third quarter of 2010, the Company received conditional approval from the FDA for the first of two planned cohorts of the PARTNER II clinical trial. The PARTNER II trial will evaluate *SAPIEN XT* with both the *NovaFlex* and *Ascendra2* delivery systems and will target high risk patients similar to those studied in the PARTNER trial. The first cohort of the PARTNER II trial will study up to 450 inoperable patients with severe, symptomatic aortic stenosis using a 2:1 randomization. The Company expects to begin enrollment in this cohort during the fourth quarter of 2010. The second planned patient cohort will compare traditional open-heart surgery with *SAPIEN XT* delivered either transfemorally or transapically in high-risk surgical patients. The Company anticipates that IDE approval for this second cohort could be received by the end of 2010; and

in Japan, the Company completed its first compassionate use cases with the *SAPIEN* valve using both the transapical and transfemoral delivery systems in October 2009. The Company began

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

enrolling patients in a clinical trial with its *SAPIEN XT* valve, called PREVAIL JAPAN, during the second quarter of 2010. The PREVAIL JAPAN clinical trial will evaluate *SAPIEN XT* with both the transfemoral and transapical delivery systems. Successful trial completion could result in an approval as early as 2013.

Special Charges (Gains), net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in millions)			
Investment impairment	\$ 3.9	\$ 1.6	\$ 3.9	\$ 1.6
MONARC program discontinuation			8.3	
Gain on sale of product lines		(58.6)		(84.1)
Charitable fund contribution		15.0		15.0
Litigation		3.8		3.8
Sale of distribution rights				(2.8)
Reserve reversal				(1.0)
Special charges (gains), net	\$ 3.9	\$ (38.2)	\$ 12.2	\$ (67.5)

Investment Impairment

In September 2010, the Company recorded a \$3.9 million charge related to the other-than-temporary impairment of two non-strategic investments in unconsolidated affiliates. The Company concluded that the impairment of these investments was other-than-temporary based upon the continuing duration and severity of the impairment.

In September 2009, the Company recorded a \$1.6 million charge related to the other-than-temporary impairment of its investment in an unconsolidated affiliate. The Company concluded that the impairment of its investment was other-than-temporary based upon (a) the continuing duration and severity of the impairment and (b) positive clinical trial developments in the third quarter of 2009 which failed to raise the quoted market price of the affiliate's stock to the Company's carrying value.

MONARC Program Discontinuation

During the second quarter of 2010, the Company decided to discontinue its *MONARC* transcatheter mitral valve program due to slow enrollment in the EVOLUTION II trial. As a result, the Company recorded an \$8.3 million charge consisting of a \$7.6 million impairment of intangible assets associated with the program and \$0.7 million of clinical trial costs that will continue to be incurred under a contractual obligation that existed prior to the discontinuation date.

Gain on Sale of Product Lines

Effective September 1, 2009, the Company sold its hemofiltration product line, which resulted in a pre-tax gain of \$43.6 million. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. In February 2009, under the terms of the sale agreement, the Company received a \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

LifeStent device manufacturing to the buyer. The Company received \$8.9 million of this milestone in September 2009 and \$6.1 million in October 2009.

Charitable Fund Contribution

In September 2009, the Company contributed \$15.0 million to The Edwards Lifesciences Fund, a donor-advised fund intended to provide philanthropic support to cardiovascular and community related charitable causes. The contribution was an irrevocable contribution to a third party, and was recorded as an expense at the time of payment.

Litigation

In September 2009, the Company recorded a \$3.8 million charge for litigation related to a royalty dispute in connection with a product in the Company's Cardiac Surgery Systems product line.

Sale of Distribution Rights

In March 2009, the Company recorded a \$2.8 million gain related to the sale of its distribution rights in Europe for a specialty vascular graft.

Reserve Reversal

In 2004, the Company discontinued its *Lifepath* AAA endovascular graft program. In March 2009, upon completion of its remaining clinical obligations related to this program, the Company reversed its remaining \$1.0 million clinical reserve.

Interest Expense, net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
	(in millions)					
Interest expense	\$ 0.7	\$ 0.9	\$ (0.2)	\$ 1.9	\$ 2.2	\$ (0.3)
Interest income	(0.3)	(0.3)		(0.8)	(1.3)	0.5
Interest expense, net	\$ 0.4	\$ 0.6	\$ (0.2)	\$ 1.1	\$ 0.9	\$ 0.2

The decrease in interest expense for the three and nine months ended September 30, 2010 resulted primarily from prior year interest expense related to a sales and use tax audit settlement, partially offset by a higher average debt balance as compared to the prior year period. The decrease in interest income for the nine months ended September 30, 2010 resulted primarily from lower average interest rates, partially offset by higher cash and short-term investment balances as compared to the prior year period.

Table of Contents***Other Income, net***

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Foreign exchange (gains) losses, net	\$ (1.7)	\$ 0.1	\$ (1.7)	\$ (2.4)
Earn-out payments	(1.5)	(0.6)	(4.5)	(0.6)
Loss (gain) on investments in unconsolidated affiliates	0.2	0.1	(1.1)	1.1
Other	(0.1)	0.2	(0.4)	0.1
Other income, net	\$ (3.1)	\$ (0.2)	\$ (7.7)	\$ (1.8)

The foreign exchange (gains) losses for the three and nine months ended September 30, 2010 relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances. Foreign exchange gains increased \$1.8 million and decreased \$0.7 million for the three and nine months ended September 30, 2010, respectively. The increase in the three month period was due primarily to fluctuations in the Euro. The decrease in the nine month period was due primarily to fluctuations in the Japanese yen and the Euro.

In September 2009, the Company sold its hemofiltration product line. In connection with the transaction, the Company is entitled to earn-out payments up to \$9.0 million based on certain revenue objectives to be achieved by the buyer over the two years following the sale. During the three and nine months ended September 30, 2010, the Company earned \$1.5 million and \$4.5 million, respectively. During September 2009, the Company earned \$0.6 million.

The loss (gain) on investments in unconsolidated affiliates primarily represents the Company's share of gains and losses in investments accounted for under the equity method, and realized gains and losses on the Company's available-for-sale investments.

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 Company's effective income tax rates were 27.5% and 22.7% for the three and nine months ended September 30, 2010, respectively, and 22.0% and 25.0% for the three and nine months ended September 30, 2009, respectively. The income tax rate for the nine months ended September 30, 2010 included a \$9.8 million tax benefit resulting from a partial settlement of a prior year tax audit. The income tax rate for the nine months ended September 30, 2009 included the tax detriment on the *LifeStent* milestone receipt and the sale of the hemofiltration product line. See the "*Special Charges (Gains), net*" section for further information.

The federal research credit expired on December 31, 2009 and has not been reinstated as of September 30, 2010. The effective income tax rate for the three and nine months ended September 30, 2010 has been calculated without a benefit for the federal research credit. In 2009, the federal research credit favorably impacted the effective tax rate by approximately 1.5%.

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 consolidated condensed financial statements.

Table of Contents

Furthermore, the Company may later decide to challenge any assessments, if made, and may exercise its right to appeal. The uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues and issuance of new legislation, regulations or case law. Management believes that adequate amounts of tax and related penalty and interest have been provided for any adjustments that may result from these uncertain tax positions.

As of September 30, 2010 and December 31, 2009, the liability for income taxes associated with uncertain tax positions was \$51.1 million and \$47.1 million, respectively. These liabilities could be reduced by \$3.4 million and \$3.2 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amounts of \$47.7 million and \$44.0 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities and cash from operations. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures and other financial commitments. The Company is not currently experiencing any limitation on access to its credit facility as a result of the conditions in global financial markets. 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 the London interbank offering rate ("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 short-term obligations as these obligations are due within one year. The Company anticipates that it will extend or replace the Credit Agreement upon maturity. However, no assurances can be given that the Credit Agreement will be extended or replaced on comparable terms as those currently in place. As of September 30, 2010, borrowings of \$100.6 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, 2010.

In July 2008, 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 \$250.0 million of the Company's common stock. In February 2010, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$500.0 million of the Company's common stock. During the nine months ended September 30, 2010, the Company repurchased 4.1 million shares (as adjusted to reflect the May 2010 two-for-one stock split) at an aggregate cost of \$200.0 million and has remaining authority under the February 2010 program to purchase \$398.0 million of the Company's common stock.

At September 30, 2010, 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, 2009.

Table of Contents

Net cash flows provided by **operating activities** of \$157.4 million for the nine months ended September 30, 2010 increased \$58.0 million over the same period a year ago. This increase was due primarily to (1) a \$39.0 million cash payment during the first quarter of 2009 to terminate the Company's accounts receivable securitization program in Japan, (2) lower supplier payments in the first nine months of 2010 compared to the first nine months of 2009 and (3) improved operating performance. These increases were partially offset by higher inventory purchases in the first nine months of 2010, primarily related to the transcatheter heart valve product line, decreased cash inflows from receivables due to higher days sales outstanding, and the negative impact from increased excess tax benefits from stock plans due to the appreciation in the Company's stock price and increased exercises.

Net cash used in **investing activities** of \$38.4 million for the nine months ended September 30, 2010 consisted primarily of capital expenditures of \$40.1 million.

Net cash provided by investing activities of \$56.0 million for the nine months ended September 30, 2009 consisted primarily of \$35.9 million of cash received for milestone achievements associated with the *LifeStent* pre-market approval and \$55.9 million of cash received from the sale of the hemofiltration product line, partially offset by capital expenditures of \$40.3 million.

Net cash used in **financing activities** of \$77.3 million for the nine months ended September 30, 2010 consisted primarily of purchases of treasury stock of \$200.0 million, partially offset by net proceeds from debt of \$9.2 million, proceeds from stock plans of \$73.8 million, and the excess tax benefit from stock plans of \$42.0 million, which increased compared to the prior year due to the appreciation in the Company's stock price and increased exercises.

Net cash used in financing activities of \$95.7 million for the nine months ended September 30, 2009 consisted primarily of net payments on debt of \$72.9 million and purchases of treasury stock of \$79.6 million, partially offset by the proceeds from stock plans of \$43.9 million and the excess tax benefit from stock plans of \$12.9 million.

Critical Accounting Policies

The consolidated condensed 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 38-42 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, 2009. Management believes that at September 30, 2010, there had been no material changes to this information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate, Foreign Currency and Credit Risk

For a complete discussion of the Company's exposure to interest rate, foreign currency and credit risk, refer to Item 7A "*Quantitative and Qualitative Disclosures About Market Risk*" on pages 43-45 of the Company's Annual Report on Form 10-K for the year ended December 31, 2009. There have been no significant changes from the information discussed therein.

Table of Contents

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, 2010, Edwards Lifesciences had \$22.3 million of investments in equity instruments of other companies. In September 2010, the Company reclassified to earnings a \$3.7 million net loss, before tax, recorded in "*Accumulated Other Comprehensive Loss*." The amount reclassified related primarily to the other-than-temporary impairment of two non-strategic investments in unconsolidated affiliates. As of September 30, 2010, there were no unrealized gains or losses remaining in "*Accumulated Other Comprehensive Loss*" related to these investments. Should these companies experience a further decline in financial condition or fail to meet certain development milestones, additional 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, 2010. Based on their evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that such controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. There have been no changes in the Company's internal controls over financial reporting during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

Part II. Other Information

Item 1. Legal Proceedings

In February 2008, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve") in the United States District Court for the District of Delaware alleging that its ReValving System infringes three of the Company's U.S. Andersen patents, later narrowed to one patent ("the '552 patent"). CoreValve was acquired by Medtronic, Inc. ("Medtronic") in April 2009. In April 2010, a federal jury found that patent to be valid and found that CoreValve willfully infringes it. The jury also awarded Edwards \$73.9 million in damages, which may be increased by the judge by up to three times that amount because of the willfulness finding. The Company is seeking a permanent injunction against CoreValve's manufacture or sale of the infringing device in the United States. A second lawsuit is pending in the same court against CoreValve and Medtronic alleging infringement of three U.S. Andersen patents. In September 2010, the United States Patent and Trademark Office granted Medtronic's third request to reexamine the validity of the '552 patent, and this process is ongoing.

Earlier, in May 2007, the Company filed a lawsuit against CoreValve alleging infringement of the Company's European Andersen patent. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. In October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. In February 2010, a German Appeals Court affirmed. In May 2007 and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, alleging the patent to be invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. In January 2009, the United Kingdom Court determined that the Andersen patent is valid but not infringed by CoreValve. In May 2010, a United Kingdom Appeals Court affirmed the lower court. In January 2010, the German Courts also determined that the Andersen patent is valid.

In February 2008, Cook, Inc. ("Cook") filed a lawsuit in the District Patent Court in Dusseldorf, Germany, against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents were invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Courts ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. In June 2010, a United Kingdom Appeals Court affirmed. In April 2010, the German Courts also determined that the Cook patent is invalid.

In March and September 2010, the Company received grand jury subpoenas for documents from the United States Attorney's Office in the Central District of California in connection with an investigation by the FDA. The subpoenas to the Company seek records relating to the Vigilance I Monitor model with software release 5.3 that was the subject of a voluntary field recall by the Company in June 2006. The Company is cooperating fully with the investigation.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur charges in excess of established reserves. 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Edwards Lifesciences is subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on Edwards Lifesciences' financial position, results of operations or liquidity.

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, 2010 through July 31, 2010	13,264	\$ 53.90	13,264	\$ 398.0
August 1, 2010 through August 31, 2010				398.0
September 1, 2010 through September 30, 2010				398.0
Total	13,264	53.90	13,264	

- (a) On February 11, 2010, the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$500.0 million of the Company's common stock.

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
- 101 * The following financial statements from Edwards Lifesciences' Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Condensed Balance Sheets, (ii) the Consolidated Condensed Statements of Operations, (iii) the Consolidated Condensed Statements of Cash Flows, and (iv) Notes to Consolidated Condensed Financial Statements.

* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities and Exchange Act of 1933, is deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Table of Contents

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, 2010

By: /s/ THOMAS M. ABATE

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

Table of Contents

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
101*	The following financial statements from Edwards Lifesciences' Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Condensed Balance Sheets, (ii) the Consolidated Condensed Statements of Operations, (iii) the Consolidated Condensed Statements of Cash Flows, and (iv) Notes to Consolidated Condensed Financial Statements.

*

XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities and Exchange Act of 1933, is deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, and otherwise is not subject to liability under these sections.