

Edwards Lifesciences Corp  
Form 10-Q  
August 08, 2011

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 June 30, 2011

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)

---

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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

Indicate by check mark whether the registrant 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
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Company
		(Do not check if a smaller reporting company)	<input type="checkbox"/>

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 July 31, 2011 was 114,955,113.

---

Table of Contents

**EDWARDS LIFESCIENCES CORPORATION**

**FORM 10-Q**

**For the quarterly period ended June 30, 2011**

**TABLE OF CONTENTS**

	<b>Page Number</b>
<b><u>Part I.</u></b>	
<b><u>FINANCIAL INFORMATION</u></b>	
<u>Item 1.</u>	
<u>Financial Statements (Unaudited)</u>	
	<u>1</u>
<u>Consolidated Condensed Balance Sheets</u>	<u>1</u>
<u>Consolidated Condensed Statements of Operations</u>	<u>2</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>3</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>4</u>
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>20</u>
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>29</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>29</u>
<b><u>Part II.</u></b>	
<b><u>OTHER INFORMATION</u></b>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>31</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>32</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>32</u>
<u>Signature</u>	<u>33</u>
<u>Exhibits</u>	<u>34</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)

	June 30, 2011	December 31, 2010
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 468.2	\$ 396.1
Accounts and other receivables, net of allowances of \$17.3 and \$11.6, respectively	364.1	302.5
Inventories, net (Note 3)	229.4	203.6
Deferred income taxes	57.8	51.9
Prepaid expenses	44.0	35.4
Other current assets	53.3	43.1
<b>Total current assets</b>	<b>1,216.8</b>	<b>1,032.6</b>
Property, plant and equipment, net	281.0	269.8
Goodwill (Note 4)	349.9	315.2
Other intangible assets, net (Note 5)	72.9	67.1
Investments in unconsolidated affiliates (Note 6)	24.8	25.0
Deferred income taxes	45.1	44.5
Other assets	11.9	13.0
	<b>\$ 2,002.4</b>	<b>\$ 1,767.2</b>

<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 313.3	\$ 296.0
Short-term debt		41.8
<b>Total current liabilities</b>	<b>313.3</b>	<b>337.8</b>
Long-term debt	174.8	
Other long-term liabilities	129.1	121.2

Commitments and contingencies  
(Note 11)

**Stockholders' equity**  
Preferred stock, \$.01 par value,  
authorized 50.0 shares, no shares  
outstanding

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Common stock, \$1.00 par value, 350.0 shares authorized, 118.8 and 117.0 shares issued, and 114.9 and 115.0 shares outstanding, respectively	118.8	117.0
Additional paid-in capital	291.4	211.3
Retained earnings	1,246.0	1,124.0
Accumulated other comprehensive loss	(9.5)	(42.1)
Treasury stock, at cost, 3.9 and 2.0 shares, respectively	(261.5)	(102.0)
 Total stockholders' equity	 1,385.2	 1,308.2
	\$ 2,002.4	\$ 1,767.2

*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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net sales	\$ 431.2	\$ 365.2	\$ 835.7	\$ 705.7
Cost of goods sold	127.8	100.4	244.6	199.0
Gross profit	303.4	264.8	591.1	506.7
Selling, general and administrative expenses	163.2	140.6	313.5	274.6
Research and development expenses	64.9	50.6	123.9	95.8
Special charges, net (Note 2)	4.0	8.3	4.0	8.3
Interest (income) expense, net	(0.3)	0.5	(0.3)	0.7
Other income, net	(1.2)	(1.6)	(7.4)	(4.6)
Income before provision for income taxes	72.8	66.4	157.4	131.9
Provision for income taxes	14.7	8.9	35.4	26.7
Net income	\$ 58.1	\$ 57.5	\$ 122.0	\$ 105.2

**Share information**

(Note 13)

Earnings per share:				
Basic	\$ 0.51	\$ 0.51	\$ 1.06	\$ 0.93
Diluted	\$ 0.48	\$ 0.48	\$ 1.01	\$ 0.88
Weighted-average number of common shares outstanding:				
Basic	114.8	113.4	114.9	113.3
Diluted	120.0	118.8	120.2	118.9

*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)

	Six Months Ended June 30,	
	2011	2010
<b>Cash flows from operating activities</b>		
Net income	\$ 122.0	\$ 105.2
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	29.3	27.7
Stock-based compensation (Note 10)	15.5	13.8
Excess tax benefit from stock plans	(36.4)	(31.5)
Deferred income taxes	1.8	(4.2)
Special charges, net (Note 2)	4.0	8.3
Other	(2.2)	(3.2)
Changes in operating assets and liabilities:		
Accounts and other receivables, net	(48.3)	(41.1)
Inventories, net	(14.8)	(27.6)
Accounts payable and accrued liabilities	13.9	26.7
Prepaid expenses and other current assets	(6.5)	(10.6)
Other	(4.1)	(2.5)
Net cash provided by operating activities	74.2	61.0
<b>Cash flows from investing activities</b>		
Capital expenditures	(31.1)	(23.7)
Acquisition (Note 4)	(42.6)	
Proceeds from (investments in) unconsolidated affiliates, net	4.9	(1.2)
Proceeds from sale of assets	3.9	3.6
Proceeds from (investments in) trading securities, net	3.3	(0.7)
Investments in intangible assets	(2.3)	(1.2)
Other	0.1	
Net cash used in investing activities	(63.8)	(23.2)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of debt	200.5	188.2
Payments on debt	(71.3)	(99.4)
Purchases of treasury stock	(159.0)	(199.3)
Proceeds from stock plans	33.4	53.4
Excess tax benefit from stock plans	36.4	31.5
Other	0.8	4.9
Net cash provided by (used in) financing activities	40.8	(20.7)
Effect of currency exchange rate changes on cash and cash equivalents	20.9	(30.9)
Net increase (decrease) in cash and cash equivalents	72.1	(13.8)
Cash and cash equivalents at beginning of period	396.1	334.1

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Cash and cash equivalents at end of period	\$	468.2	\$	320.3
--	----	-------	----	-------

**Supplemental disclosures:**

Non-cash transaction:

Distribution of treasury shares to effect stock split	\$	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, 2010. 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 ("Edwards Lifesciences" or the "Company"), the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair statement of the interim periods. All such adjustments are of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year.

**Recently Adopted Accounting Standards**

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 was effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

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 was effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The adoption of this guidance did not have an impact on the Company's consolidated financial statements.

In December 2010, the FASB issued an amendment to the accounting guidance on business combinations to clarify the acquisition date that should be used for reporting pro forma financial information disclosures when comparative financial statements are presented. An entity is required to disclose pro forma revenue and earnings of the combined entity as though the business combination that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. The guidance also expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. The guidance was effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. The adoption of this guidance did not have an impact on the Company's consolidated financial statements.

**New Accounting Standards Not Yet Adopted**

In May 2011, the FASB issued an amendment to the accounting guidance on fair value measurements to ensure that United States GAAP and International Financial Reporting Standards

Table of Contents

have common requirements for fair value measurement and disclosures, including a consistent definition of fair value. The guidance is effective for interim and annual periods beginning on or after December 15, 2011. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2011, the FASB issued an amendment to the accounting guidance on the presentation of comprehensive income. The guidance eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity, and instead requires that all nonowner changes in stockholders' equity be presented in either a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011.

**2. SPECIAL CHARGES, NET**

*Greece Receivables Reserve*

In June 2011, the Company recorded a \$4.0 million charge to reflect the increased collection risk associated with its receivables in Greece.

*Realignment Expenses, net*

In December 2010, the Company recorded a \$7.2 million charge related primarily to severance expenses associated with a global workforce realignment impacting 84 employees. As of June 30, 2011, the Company's remaining severance obligations of \$1.9 million are expected to be substantially paid by December 2011.

*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.

**3. INVENTORIES, NET**

Inventories, net of reserves, consisted of the following (in millions):

	June 30, 2011	December 31, 2010
Raw materials	\$ 44.8	\$ 38.2
Work in process	59.9	39.0
Finished products	124.7	126.4
	\$ 229.4	\$ 203.6

**4. ACQUISITION**

On March 11, 2011, the Company acquired all the outstanding shares of Embrella Cardiovascular, Inc. ("Embrella"), including shares already owned by the Company, for an aggregate cash purchase price of \$42.6 million. In connection with the acquisition, the Company placed \$4.5 million of the purchase price into escrow to satisfy any claims for indemnification made in accordance with the terms of the merger agreement. Any remaining funds will be disbursed to Embrella's former shareholders one year after the acquisition date. As of June 30, 2011, no claims for

Table of Contents

indemnification had been made. Acquisition-related costs of \$0.9 million were recorded in "*Other Income, net*" during the quarter ended March 31, 2011.

Embrella is a start-up medical device company developing a device for cerebral embolic protection during cardiovascular procedures. The acquisition provides the Company with full rights to develop and commercialize Embrella's embolic deflector system, designed to be used as a protective shield during transcatheter heart valve procedures. The acquisition was accounted for as a business combination. The purchase price was allocated to tangible and intangible assets acquired based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was allocated to goodwill. The Company is in the process of finalizing its purchase price allocation; therefore the amounts reflected below are subject to change. The following table summarizes the preliminary allocation of the purchase price (in millions):

Goodwill	\$ 34.7
In-process research and development ("IPR&D")	6.3
Developed technology	5.8
Deferred income taxes	(4.2)
	\$ 42.6

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. IPR&D has been capitalized at fair value as an intangible asset with an indefinite life and will be assessed for impairment in subsequent periods. The fair value of the IPR&D was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Upon completion of development, the underlying research and development intangible asset will be amortized over its estimated useful life. Developed technology assets are being amortized over a weighted-average useful life of 8 years.

Prior to the acquisition date, the Company owned approximately 9% of the fully-diluted outstanding shares of Embrella. As a result of the acquisition, the Company remeasured its previously held ownership in Embrella, which had a carrying value of \$1.3 million at the date of acquisition, at fair value and, accordingly, recognized a gain of \$3.1 million. The gain was recorded in "*Other Income, net*" during the quarter ended March 31, 2011, and the cash received was recorded in "*Proceeds from (Investments in) Unconsolidated Affiliates, net*" on the consolidated condensed statements of cash flows. The fair value of the Company's previous ownership interest in Embrella was determined using a market approach considering the amounts paid to acquire the remaining outstanding shares of Embrella.

The results of operations for Embrella have been included in the accompanying consolidated condensed financial statements from the date of acquisition. Pro forma results have not been presented as the results of Embrella are not material in relation to the consolidated financial statements of the Company.

Table of Contents**5. OTHER INTANGIBLE ASSETS**

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

	June 30, 2011			December 31, 2010		
	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
<b>Amortizable intangible assets</b>						
Patents	\$ 205.1	\$ (154.7)	\$ 50.4	\$ 203.0	\$ (147.8)	\$ 55.2
Unpatented technology	41.0	(30.8)	10.2	35.0	(29.6)	5.4
Other	12.8	(6.8)	6.0	12.4	(5.9)	6.5
	258.9	(192.3)	66.6	250.4	(183.3)	67.1
<b>Unamortizable intangible assets</b>						
IPR&D	6.3		6.3			
	\$ 265.2	\$ (192.3)	\$ 72.9	\$ 250.4	\$ (183.3)	\$ 67.1

In March 2011, the Company completed its acquisition of Embrella (see Note 4). This transaction resulted in a net increase to unpatented technology of \$5.8 million and IPR&D of \$6.3 million.

The net carrying value of patents includes \$15.9 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of June 30, 2011.

Amortization expense related to other intangible assets was \$4.2 million and \$4.1 million for the three months ended June 30, 2011 and 2010, respectively, and \$8.4 million and \$8.2 million for the six months ended June 30, 2011 and 2010, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2011	\$ 15.7
2012	14.5
2013	14.4
2014	12.5
2015	10.5

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. Investments in these unconsolidated affiliates are as follows:

	June 30, 2011	December 31, 2010
	(in millions)	
<b>Available-for-sale investments</b>		
Cost	\$ 4.1	\$ 4.1
Unrealized gains	3.1	3.6
Fair value of available-for-sale investments	7.2	7.7
<b>Equity method investments</b>		
Cost	12.2	11.5
Equity in losses	(0.6)	(1.5)
Carrying value of equity method investments	11.6	10.0
<b>Cost method investments</b>		
Carrying value of cost method investments	6.0	7.3
<b>Total investments in unconsolidated affiliates</b>	<b>\$ 24.8</b>	<b>\$ 25.0</b>

There were no sales of available-for-sale investments during the six months ended June 30, 2011 and 2010. In March 2011, the Company acquired all of the outstanding shares of Embrella, which was accounted for as a cost method investment prior to the acquisition. As a result, the Company has consolidated Embrella as of the acquisition date. See Note 4 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):

<b>June 30, 2011</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Investments held for executive deferred compensation plan	\$ 12.1	\$	\$	\$ 12.1
Investments in unconsolidated affiliates	7.2			7.2
	\$ 19.3	\$	\$	\$ 19.3
<b>Liabilities</b>				
Derivatives	\$	\$ 23.2	\$	\$ 23.2
Executive deferred compensation plan	10.1			10.1
	\$ 10.1	\$ 23.2	\$	\$ 33.3
<b>December 31, 2010</b>				
<b>Assets</b>				
Investments held for executive deferred compensation plan	\$ 18.3	\$	\$	\$ 18.3
Investments in unconsolidated affiliates	7.7			7.7
	\$ 26.0	\$	\$	\$ 26.0
<b>Liabilities</b>				
Derivatives	\$	\$ 14.7	\$	\$ 14.7
Executive deferred compensation plan	13.1			13.1
	\$ 13.1	\$ 14.7	\$	\$ 27.8

#### *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 and the corresponding liabilities 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 derivative financial instruments in the form of foreign currency forward exchange contracts and foreign currency option contracts to manage foreign currency exposures. All derivatives contracts are recognized on the balance sheet at their fair value. The fair value for derivatives is determined based on quoted spot and foreign currency exchange rates discounted to present as appropriate. The fair value of options also takes into account forward implied volatility. The valuation procedures are based upon well recognized financial principles. Although readily observable data is used in the valuations, different valuation methods 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 six months ended June 30, 2011, the Company had no impairments related to assets subject to measurement at fair value on a non-recurring basis. In March 2011, the Company acquired Embrella. This transaction resulted in an increase to "Goodwill" and "Other Intangible Assets, net" of \$34.7 million and \$12.1 million, respectively. See Note 4 for additional information. During the six months ended June 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).

**8. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES**

The Company uses derivative financial instruments to manage its currency exchange rate risk as summarized below. Notional amounts are stated in United States dollar equivalents at spot exchange rates at the respective dates.

	June 30, 2011		December 31, 2010	
	Notional	Fair Value	Notional	Fair Value
	Amount	Asset (Liability)	Amount	Asset (Liability)
	(in millions)			
Foreign currency forward exchange contracts	\$ 684.8	\$ (23.2)	\$ 486.0	\$ (12.5)
Foreign currency option contracts			53.2	(2.2)

The Company uses foreign currency forward exchange contracts and foreign currency option contracts to offset the changes due to currency rate movements in the amount of future cash flows associated with intercompany transactions expected to occur within the next thirteen months. These foreign currency forward exchange contracts and foreign currency option contracts are designated as cash flow hedges. Certain of the Company's locations have assets and liabilities denominated in currencies other than their functional currencies resulting from intercompany and third-parties transactions. The Company uses foreign currency forward exchange contracts that are not designated as hedging instruments to offset the transaction gains and losses associated with certain of these assets and liabilities. All foreign currency forward exchange contracts and foreign currency option contracts are denominated in currencies of major industrial countries, principally the Euro and the Japanese yen. It is the Company's policy not to enter into derivative financial instruments for speculative purposes.

All derivative financial instruments are recognized at fair value in the consolidated condensed balance sheets. The Company reports in "Other Comprehensive Income" the effective portion of the gain or loss on derivative financial instruments that are designated and that qualify as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same period in which the underlying hedged transactions affect 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. The gains and losses on derivative financial instruments for which the Company does not elect hedge accounting treatment are recognized in the consolidated condensed statements of operations in each period, based upon the change in the fair value of the derivative financial instrument. Cash flows from derivative financial instruments are reported as operating activities in the consolidated condensed statements of cash flows.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Derivative financial instruments involve credit risk in the event the counterparty should default. It is the Company's policy to execute such instruments with global financial institutions that the Company believes to be creditworthy. The Company diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities.

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

Derivatives designated as hedging instruments	Balance Sheet Location	Fair Value	
		June 30, 2011	December 31, 2010
<b>Liabilities</b>			
Foreign currency contracts	Accrued liabilities	\$ 23.2	\$ 14.7

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

Derivatives in cash flow hedging relationships	Amount of Gain or (Loss) Recognized in Other Comprehensive Income ("OCI") on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	Three Months Ended June 30,			Three Months Ended June 30,	
	2011	2010		2011	2010
Foreign currency contracts	\$ (11.7)	\$ 10.3	Cost of goods sold	\$ (6.7)	\$ (1.4)

Derivatives in cash flow hedging relationships	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	Six Months Ended June 30,			Six Months Ended June 30,	
	2011	2010		2011	2010
Foreign currency contracts	\$ (26.8)	\$ 17.8	Cost of goods sold	\$ (9.9)	\$ (5.0)

Derivatives not designated as hedging instruments	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative	
		Three Months Ended June 30,	
		2011	2010
Foreign currency contracts	Other income, net	\$ (0.7)	\$ (2.2)

Derivatives not designated as hedging instruments	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative	
		Six Months Ended June 30,	
		2011	2010
Foreign currency contracts	Other income, net	\$ (4.3)	\$ (1.4)

The Company expects that during the next twelve months it will reclassify to earnings an \$11.6 million loss currently recorded in "Accumulated Other Comprehensive Loss." For the six months ended June 30, 2011 and 2010, the Company did not record any expense related to the premium costs of option-based products and did not record any gains or losses due to hedge ineffectiveness.





Table of Contents**9. DEFINED BENEFIT PLANS**

The components of net periodic benefit costs for the three and six months ended June 30, 2011 and 2010 were as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Service cost	\$ 1.6	\$ 1.1	\$ 3.1	\$ 2.3
Employee contributions				
Interest cost	0.5	0.4	1.0	0.9
Expected return on plan assets	(0.4)	(0.3)	(0.7)	(0.6)
Amortization of actuarial loss, prior service credit and other	0.1	0.1	0.2	0.1
Net periodic pension benefit cost	\$ 1.8	\$ 1.3	\$ 3.6	\$ 2.7

**10. STOCK-BASED COMPENSATION**

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three and six months ended June 30, 2011 and 2010 was as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Cost of goods sold	\$ 0.9	\$ 0.6	\$ 1.7	\$ 1.2
Selling, general and administrative expenses	5.6	4.7	11.2	10.4
Research and development expenses	1.3	1.0	2.6	2.2
Total stock-based compensation expense	\$ 7.8	\$ 6.3	\$ 15.5	\$ 13.8

At June 30, 2011, the total remaining compensation cost related to nonvested stock options, restricted stock units and employee stock purchase subscription awards amounted to \$65.6 million, which will be amortized on a straight-line basis over the weighted-average remaining requisite service period of 33 months.

During the six months ended June 30, 2011, the Company granted 1.1 million stock options at a weighted-average exercise price of \$89.07 and 0.2 million shares of restricted stock units at a weighted-average grant-date fair value of \$88.76.

Table of Contents**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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Risk-free interest rate	1.6%	2.0%	1.7%	2.0%
Expected dividend yield	None	None	None	None
Expected volatility	27.6%	25.8%	27.4%	25.9%
Expected term (years)	4.4	4.5	4.5	4.5
Fair value, per share	\$ 22.80	\$ 12.91	\$ 22.87	\$ 12.90

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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Risk-free interest rate	0.3%	0.3%	0.2%	0.3%
Expected dividend yield	None	None	None	None
Expected volatility	29.8%	24.0%	25.3%	32.6%
Expected term (years)	0.7	0.6	0.7	0.6
Fair value, per share	\$ 21.30	\$ 11.07	\$ 18.91	\$ 11.31

**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. In February 2011, the District Court reaffirmed the jury decision and ruled that Edwards is entitled to recover additional damages due to CoreValve's continued infringing sales from the trial through the life of the patent, plus interest. In the same ruling, the court denied Edwards' motions for a permanent injunction and increased damages relating to CoreValve's willful infringement. Both Edwards and CoreValve have appealed. 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 claim of the '552 patent and in July 2011 confirmed the validity of that patent.

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

Table of Contents

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 May 2011, the Company and Cook resolved these disputes and, as a result, all of the proceedings have been withdrawn.

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 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 June 2011, Medtronic filed a lawsuit in the United States District Court for the District of Minnesota alleging that certain surgical valve holders and a surgical embolic filter device infringe its patents. Medtronic also filed another lawsuit in the United States District Court for the Central District of California alleging that the *Edwards SAPIEN* transcatheter heart valve infringes a Medtronic patent. The Company plans to vigorously defend against these claims.

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. The Company is not able to estimate the amount or range of any loss for certain of the legal contingencies for which there is no reserve or additional loss for matters already reserved. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is 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.

Table of Contents**12. COMPREHENSIVE INCOME**

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Net income	\$ 58.1	\$ 57.5	\$ 122.0	\$ 105.2
Other comprehensive income:				
Currency translation adjustments	10.8	(33.0)	43.1	(56.3)
Unrealized net loss on investments in unconsolidated affiliates, net of tax	(1.7)	(2.1)	(0.3)	(2.6)
Unrealized net (loss) gain on cash flow hedges, net of tax	(3.1)	7.0	(10.2)	13.8
Comprehensive income	\$ 64.1	\$ 29.4	\$ 154.6	\$ 60.1

The tax effect on the unrealized net loss on investments in unconsolidated affiliates was \$1.2 million and \$0.2 million for the three and six months ended June 30, 2011, respectively. There was no tax effect for the three and six months ended June 30, 2010. The tax effect on the unrealized net (loss) gain on cash flow hedges was \$1.9 million and \$6.7 million for the three and six months ended June 30, 2011, respectively, and \$(4.7) million and \$(9.0) million for the three and six months ended June 30, 2010, respectively.

**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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Basic:</b>				
Net income	\$ 58.1	\$ 57.5	\$ 122.0	\$ 105.2
Weighted-average shares outstanding	114.8	113.4	114.9	113.3
Basic earnings per share	\$ 0.51	\$ 0.51	\$ 1.06	\$ 0.93
<b>Diluted:</b>				
Net income	\$ 58.1	\$ 57.5	\$ 122.0	\$ 105.2
Weighted-average shares outstanding	114.8	113.4	114.9	113.3
Dilutive effect of stock plans	5.2	5.4	5.3	5.6
Dilutive weighted-average shares outstanding	120.0	118.8	120.2	118.9
Diluted earnings per share	\$ 0.48	\$ 0.48	\$ 1.01	\$ 0.88

Stock options and restricted stock units to purchase 1.2 million and 1.8 million shares for the three months ended June 30, 2011 and 2010, respectively, and 0.7 million and 1.0 million for the six months ended June 30, 2011 and 2010, 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 20.2% and 22.5% for the three and six months ended June 30, 2011, respectively, and 13.4% and 20.2% for the three and six months ended June 30, 2010, respectively. The effective income tax rates for the three and six months ended June 30, 2011 included a \$2.5 million tax benefit resulting from the partial settlement of a prior year European tax audit. The effective income tax rates for the three and six months ended June 30, 2010 were calculated without the benefit of the federal research credit as it was not reinstated until after June 30, 2010. In addition, the income tax rates for the three and six months ended June 30, 2010 included a \$9.8 million tax benefit resulting from a partial settlement of a prior year tax audit.

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 more likely than not 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.

As of June 30, 2011 and December 31, 2010, the liability for income taxes associated with uncertain tax positions was \$66.2 million and \$55.1 million, respectively. These liabilities could be reduced by \$8.0 million and \$4.7 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 \$58.2 million and \$50.4 million, respectively, if recognized, would favorably affect the Company's effective tax rate.

Table of Contents

All material state, local and foreign income tax matters have been concluded for years through 2005. The Internal Revenue Service ("IRS") 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. The Company had its opening conference with the IRS related to the examination of its 2009 and 2010 tax years during the second quarter of 2011.

**15. SEGMENT INFORMATION**

Edwards Lifesciences conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease. Net sales by geographic area are based on the location of the customer.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Segment Net Sales</b>				
United States	\$ 151.3	\$ 144.7	\$ 300.4	\$ 283.0
Europe	142.3	119.9	280.1	224.0
Japan	57.2	55.6	114.6	106.2
Rest of world	53.5	42.8	97.8	80.0
Total segment net sales	\$ 404.3	\$ 363.0	\$ 792.9	\$ 693.2
<b>Segment Pre-Tax Income</b>				
United States	\$ 79.6	\$ 80.1	\$ 160.9	\$ 157.2
Europe	62.4	45.6	124.8	84.9
Japan	28.0	25.8	55.3	48.6
Rest of world	17.1	12.7	29.4	22.3
Total segment pre-tax income	\$ 187.1	\$ 164.2	\$ 370.4	\$ 313.0

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Net Sales Reconciliation</b>				
Segment net sales	\$ 404.3	\$ 363.0	\$ 792.9	\$ 693.2
Foreign currency	26.9	2.2	42.8	12.5
Consolidated net sales	\$ 431.2	\$ 365.2	\$ 835.7	\$ 705.7
<b>Pre-Tax Income Reconciliation</b>				
Segment pre-tax income	\$ 187.1	\$ 164.2	\$ 370.4	\$ 313.0
Unallocated amounts:				
Corporate items	(116.6)	(91.9)	(220.4)	(176.3)
Special charges, net	(4.0)	(8.3)	(4.0)	(8.3)
Interest income (expense), net	0.3	(0.5)	0.3	(0.7)
Foreign currency	6.0	2.9	11.1	4.2
Consolidated pre-tax income	\$ 72.8	\$ 66.4	\$ 157.4	\$ 131.9

### *Enterprise-Wide Information*

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
(in millions)				
<b>Net Sales by Geographic Area</b>				
United States	\$ 151.3	\$ 144.7	\$ 300.4	\$ 283.0
International	279.9	220.5	535.3	422.7
	\$ 431.2	\$ 365.2	\$ 835.7	\$ 705.7
<b>Net Sales by Major Product and Service Area</b>				
Heart Valve Therapy	\$ 263.1	\$ 214.8	\$ 508.0	\$ 411.5
Critical Care	127.7	110.5	248.3	215.6
Cardiac Surgery Systems	27.3	26.5	53.4	51.3
Vascular	13.1	13.4	26.0	27.3
	\$ 431.2	\$ 365.2	\$ 835.7	\$ 705.7

	June 30, 2011	December 31, 2010
(in millions)		
<b>Long-Lived Tangible Assets by Geographic Area</b>		
United States	\$ 187.2	\$ 180.5
International	105.7	102.3
	\$ 292.9	\$ 282.8





Table of Contents

**16. SUBSEQUENT EVENT**

In July 2011, Edwards Lifesciences entered into a Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015. The proceeds of the Credit Facility will be used to refinance the Company's existing Five-Year Unsecured Revolving Credit Agreement ("Credit Agreement") and for general corporate purposes. As of June 30, 2011, the \$174.8 million outstanding under the Credit Agreement has been classified as long-term obligations as these obligations are expected to be refinanced on a long-term basis under the Credit Facility. The Credit Facility provides up to an aggregate of \$500.0 million in borrowings in multiple currencies. Borrowings generally bear interest at the London interbank offering rate ("LIBOR") plus 0.875%, subject to adjustment for leverage ratio changes as defined in the Credit Facility. The Company also pays a facility fee of 0.125% on the entire \$500.0 million facility whether or not drawn. The facility fee is also subject to adjustment for leverage ratio changes. The Credit Facility is unsecured and contains various financial and other covenants, including a maximum leverage ratio and a minimum interest coverage ratio, as defined in the Credit Facility.

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 statements 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 results or 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, 2010 and subsequent reports on Forms 10-Q and 8-K 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 systems used to measure a patient's cardiovascular function, and in disposable pressure transducers. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannulae, embolic protection devices and other products used during cardiopulmonary bypass and minimally invasive surgical procedures. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts.

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

Table of Contents

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.

**New Accounting Standards Not Yet Adopted**

In May 2011, the Financial Accounting Standards Board ("FASB") issued an amendment to the accounting guidance on fair value measurements to ensure that United States generally accepted accounting principles and International Financial Reporting Standards have common requirements for fair value measurement and disclosures, including a consistent definition of fair value. The guidance is effective for interim and annual periods beginning on or after December 15, 2011. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In June 2011, the FASB issued an amendment to the accounting guidance on the presentation of comprehensive income. The guidance eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity, and instead requires that all nonowner changes in stockholders' equity be presented in either a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011.

**Results of Operations***Net Sales Trends*

(dollars in millions)

	Three Months Ended June 30,			Percent Change	Six Months Ended June 30,			Percent Change
	2011	2010	Change		2011	2010	Change	
United States	\$ 151.3	\$ 144.7	\$ 6.6	4.6%	\$ 300.4	\$ 283.0	\$ 17.4	6.1%
International	279.9	220.5	59.4	26.9%	535.3	422.7	112.6	26.6%
<b>Total net sales</b>	<b>\$ 431.2</b>	<b>\$ 365.2</b>	<b>\$ 66.0</b>	<b>18.1%</b>	<b>\$ 835.7</b>	<b>\$ 705.7</b>	<b>\$ 130.0</b>	<b>18.4%</b>

In the United States, the \$6.6 million and \$17.4 million increases in net sales for the three and six months ended June 30, 2011 was due primarily to:

Heart Valve Therapy products, which increased net sales by \$4.2 million and \$12.7 million, respectively, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* (launched in the third quarter of 2010) valves, and sales of the *Edwards SAPIEN* and *SAPIEN XT* transcatheter heart valves for clinical trials; and

Critical Care products, which increased net sales by \$4.4 million and \$7.6 million, respectively, driven primarily by the *FloTrac* minimally invasive monitoring system and pressure monitoring products.

International net sales increased \$59.4 million and \$112.6 million for the three and six months ended June 30, 2011 due primarily to:

Heart Valve Therapy products, which increased net sales by \$27.6 million and \$64.8 million, respectively, driven primarily by the *Edwards SAPIEN XT* transcatheter heart valve and the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve;

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

Critical Care products, which increased net sales by \$5.2 million and \$13.9 million, respectively, driven primarily by pressure monitoring products and the *FloTrac* minimally invasive monitoring system; and

foreign currency exchange rate fluctuations, which increased net sales by \$22.8 million and \$27.8 million, respectively, due to the strengthening of various currencies against the United States dollar, primarily the Euro and the Japanese yen.

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* (dollars in millions)

	Three Months Ended June 30,				Six Months Ended June 30,			
	2011	2010	Change	Percent Change	2011	2010	Change	Percent Change
Heart Valve Therapy	\$ 263.1	\$ 214.8	\$ 48.3	22.5%	\$ 508.0	\$ 411.5	\$ 96.5	23.5%
Critical Care	127.7	110.5	17.2	15.6%	248.3	215.6	32.7	15.2%
Cardiac Surgery Systems	27.3	26.5	0.8	3.0%	53.4	51.3	2.1	4.1%
Vascular	13.1	13.4	(0.3)	(2.2)%	26.0	27.3	(1.3)	(5.2)%
<b>Total net sales</b>	<b>\$ 431.2</b>	<b>\$ 365.2</b>	<b>\$ 66.0</b>	<b>18.1%</b>	<b>\$ 835.7</b>	<b>\$ 705.7</b>	<b>\$ 130.0</b>	<b>18.4%</b>

### *Heart Valve Therapy*

Net sales of Heart Valve Therapy products for the three and six months ended June 30, 2011 increased by \$48.3 million and \$96.5 million, respectively, due primarily to:

transcatheter heart valves, which increased net sales by \$25.1 million and \$58.8 million, respectively, primarily as a result of the *Edwards SAPIEN XT* transcatheter heart valve;

surgical tissue valves, which increased net sales by \$5.4 million and \$16.3 million, respectively, driven by the *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* and *Magna Mitral Ease* valves; and

foreign currency exchange rate fluctuations, which increased net sales by \$13.9 million and \$15.6 million, respectively, due primarily to the strengthening of the Euro and the Japanese yen against the United States dollar.

The Company expects that its transcatheter heart valves will continue to be a strong contributor to 2011 sales. In July 2011, a United States Food and Drug Administration ("FDA") advisory panel reviewed and recommended approval of the Company's *SAPIEN* transcatheter heart valve for treatment of certain inoperable patients. The Company anticipates launching its *SAPIEN* transcatheter valve in the United States in 2011. During the second quarter of 2011, the Company received regulatory approval and initiated its launch of the *Carpentier-Edwards Physio Tricuspid* annuloplasty ring in the United States and Europe. In Japan, the Company obtained approval of its *Carpentier-Edwards PERIMOUNT Magna Aortic Ease* valve in July 2011, and plans to introduce this product in the third quarter of 2011. In Europe, the Company expects to receive CE Mark in the fourth quarter of 2011 of *EDWARDS INTUITY*, its minimally invasive aortic valve surgery system. In the United States, the



## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

Company expects to obtain Investigational Device Exemption ("IDE") approval for the clinical trial of *EDWARDS INTUITY* during 2011.

#### ***Critical Care***

Net sales of Critical Care products for the three and six months ended June 30, 2011 increased by \$17.2 million and \$32.7 million, respectively, due primarily to:

pressure monitoring products, which increased net sales by \$4.0 million and \$8.8 million, respectively;

premium products, led by *FloTrac* systems, which increased net sales by \$3.1 million and \$6.9 million, respectively, and *PreSep*, the Company's continuous central venous oximetry catheter for early detection of sepsis, which increased net sales by \$0.7 million and \$1.5 million, respectively; and

foreign currency exchange rate fluctuations, which increased net sales by \$6.7 million and \$9.6 million, respectively, due primarily to the strengthening of the Euro and the Japanese yen against the United States dollar.

During the fourth quarter of 2010, the Company launched, outside of the United States, the *VolumeView System*, which broadens the Company's product offering in the medical intensive care unit. At the same time, the Company launched the *EV1000 Clinical Platform*, a new hardware platform with a simpler, more intuitive informational display. The Company obtained regulatory clearance for these products in the United States in the second quarter of 2011.

The Company has a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. The Company has continued to make progress on the development of a second generation product designed to enhance ease of use. The Company anticipates obtaining CE Mark on the second generation product by the end of 2011 and plans to begin commercial sales in Europe in 2012.

#### ***Cardiac Surgery Systems***

Net sales of Cardiac Surgery Systems products for the three and six months ended June 30, 2011 increased by \$0.8 million and \$2.1 million, respectively, due primarily to foreign currency exchange rate fluctuations, which increased net sales by \$1.3 million and \$1.5 million, and specialty cannula products, which increased net sales by \$0.6 million and \$1.8 million, respectively. These increases were partially offset by minimally invasive surgery products, which decreased net sales by \$1.2 million and \$1.4 million, respectively.

#### ***Vascular***

Net sales of Vascular products for the three and six months ended June 30, 2011 decreased by \$0.3 million and \$1.3 million, respectively, due primarily to the Company's discontinued distribution of artificial implantable grafts during the first quarter of 2011.

#### ***Gross Profit***

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Gross profit as a percentage of net sales	70.4%	72.5%	(2.1) pts.	70.7%	71.8%	(1.1) pts.

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

The 2.1 and 1.1 percentage point decreases in gross profit as a percentage of net sales for the three and six months ended June 30, 2011, respectively, were driven primarily by international operations as follows:

a 1.8 percentage point and 0.9 percentage point decrease due to the impact of foreign currency exchange rate fluctuations, including the outcome of foreign currency hedging contracts; and

investments in the expansion of the Company's manufacturing capacity in preparation for its transcatheter heart valve launch in the United States;

partially offset by:

a more profitable international product mix, primarily higher sales of transcatheter heart valves.

#### ***Selling, General and Administrative (SG&A) Expenses***

(dollars in millions)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
SG&A expenses	\$ 163.2	\$ 140.6	\$ 22.6	\$ 313.5	\$ 274.6	\$ 38.9
SG&A expenses as a percentage of net sales	37.8%	38.5%	(0.7) pts.	37.5%	38.9%	(1.4) pts.

The increase in SG&A expenses for the three and six months ended June 30, 2011 was due primarily to higher sales and marketing expenses in the United States and Europe, mainly to support the transcatheter heart valve program, including the anticipated launch in the United States. Foreign currency had an unfavorable impact of \$8.4 million and \$9.9 million, respectively, due to the strengthening of various currencies against the United States dollar, primarily the Euro and the Japanese yen.

#### ***Research and Development Expenses***

(dollars in millions)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Research and development expenses	\$ 64.9	\$ 50.6	\$ 14.3	\$ 123.9	\$ 95.8	\$ 28.1
Research and development expenses as a percentage of net sales	15.1%	13.9%	1.2 pts.	14.8%	13.6%	1.2 pts.

The increase in research and development expenses for the three and six months ended June 30, 2011 was due primarily to additional investments in clinical studies and development efforts in the transcatheter heart valve program.

The following are the developments related to the Company's transcatheter heart valve program:

the Company received conditional IDE approval from the 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, evaluated 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 were randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. In the second



Table of Contents

study arm ("Cohort B"), patients who were deemed non-operable were 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 2010, positive one-year data from Cohort B was published and the Company completed the submission of its pre-market approval to the FDA. In July 2011, an FDA advisory panel reviewed and recommended approval of the Company's *SAPIEN* transcatheter heart valve for treatment of certain inoperable patients. The Company anticipates launching its *SAPIEN* transcatheter valve in the United States in 2011. During the second quarter of 2011, the Company announced that one-year Cohort A trial data met all its primary endpoints and submitted its pre-market approval for Cohort A to the FDA;

in the United States, the Company submitted an IDE for *SAPIEN XT* in October 2009. 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 ("PARTNER II Cohort B") will study up to 500 inoperable patients with severe, symptomatic aortic stenosis using a 1:1 randomization of *SAPIEN XT* with the *NovaFlex* transfemoral delivery system versus *SAPIEN* with the *RetroFlex 3* delivery system. In February 2011, the Company received conditional IDE approval from the FDA for PARTNER II Cohort B. The Company expects to complete enrollment in this cohort by the end of 2011. The second planned patient cohort ("PARTNER II Cohort A") will compare traditional open-heart surgery with *SAPIEN XT* delivered either transfemorally or transapically in surgical patients. The Company is working with the FDA to finalize the optimal trial design for PARTNER II Cohort A and anticipates that IDE approval could be received in the third quarter of 2011; and

in Japan, the Company began enrolling patients in a clinical trial with its *SAPIEN XT* valve, called PREVAIL JAPAN, during 2010. The PREVAIL JAPAN clinical trial will evaluate *SAPIEN XT* with both the transfemoral and transapical delivery systems. The Company believes that successful trial completion could result in an approval as early as 2013.

***Special Charges, net***

*Greece Receivables Reserve*

In June 2011, the Company recorded a \$4.0 million charge to reflect the increased collection risk associated with its receivables in Greece.

*Realignment Expenses, net*

In December 2010, the Company recorded a \$7.2 million charge related primarily to severance expenses associated with a global workforce realignment impacting 84 employees. As of June 30, 2011, the Company's remaining severance obligations of \$1.9 million are expected to be substantially paid by December 2011.

*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.

Table of Contents**Interest (Income) Expense, net**  
(in millions)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Interest expense	\$ 0.7	\$ 0.7	\$	\$ 1.2	\$ 1.2	\$
Interest income	(1.0)	(0.2)	(0.8)	(1.5)	(0.5)	(1.0)
Interest (income) expense, net	\$ (0.3)	\$ 0.5	\$ (0.8)	\$ (0.3)	\$ 0.7	\$ (1.0)

The increase in interest income for the three and six months ended June 30, 2011 resulted primarily from higher average interest rates and higher cash and short-term investment balances.

**Other Income, net**  
(in millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Foreign exchange (gains) losses, net	\$ (0.5)	\$ 0.2	\$ (1.4)	\$
(Gain) loss on investments in unconsolidated affiliates	(0.3)	0.1	(4.6)	(1.3)
Earn-out payments		(1.5)	(1.0)	(3.0)
Other	(0.4)	(0.4)	(0.4)	(0.3)
Other income, net	\$ (1.2)	\$ (1.6)	\$ (7.4)	\$ (4.6)

The foreign exchange (gains) losses relate to the foreign currency fluctuations in the Company's global trade and intercompany receivable and payable balances. Foreign exchange fluctuations (primarily the Euro) resulted in a net gain in 2011.

The gain on investments in unconsolidated affiliates primarily represents the Company's net 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 and cost method investments.

In September 2009, the Company sold its hemofiltration product line. In connection with the transaction, the Company was 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. As of March 31, 2011, all \$9.0 million of earn-out payments had been earned.

**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 20.2% and 22.5% for the three and six months ended June 30, 2011, respectively, and 13.4% and 20.2% for the three and six months ended June 30, 2010, respectively. The effective income tax rates for the three and six months ended June 30, 2011 included a \$2.5 million tax benefit resulting from the partial settlement of a prior year European tax audit. The effective income tax rates for the three and six months ended June 30, 2010 were calculated without the benefit of the federal research credit as it was not reinstated until

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

after June 30, 2010. In addition, the income tax rates for the three and six months ended June 30, 2010 included a \$9.8 million tax benefit resulting from a partial settlement of a prior year tax audit.

The Company anticipates realizing an additional tax benefit from the final settlement of a prior year European tax audit. The Company estimates the additional tax benefit will be approximately \$7 million to \$8 million and expects to record it in the three months ending September 30, 2011.

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 more likely than not 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 in income tax expense for any adjustments that may result from these uncertain tax positions.

As of June 30, 2011 and December 31, 2010, the liability for income taxes associated with uncertain tax positions was \$66.2 million and \$55.1 million, respectively. These liabilities could be reduced by \$8.0 million and \$4.7 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 \$58.2 million and \$50.4 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 further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

As of June 30, 2011, cash and cash equivalents held outside the United States was approximately \$445.5 million, and has historically been used to fund international operations. The Company believes that cash and cash equivalents held in the United States, in addition to amounts available under credit facilities and cash from operations, is sufficient to fund its United States operating requirements. The majority of cash and cash equivalents held outside the United States relates to undistributed earnings of certain of the Company's foreign subsidiaries which is considered to be indefinitely reinvested by the Company. Repatriations of cash and cash equivalents held outside the United States are subject to restrictions in certain jurisdictions and may be subject to withholding and other taxes. The potential tax liability related to any repatriation would be dependent on the facts and circumstances that would exist at the time such repatriation is made and the complexities of the tax laws of the United States and the respective foreign jurisdictions.

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 0.325%. The Company also pays a facility fee on the full \$500.0 million available under the Credit Agreement, currently at an annual rate of 0.075%. The borrowing rates and facility fee are subject to adjustment for leverage ratio changes, as defined in the Credit Agreement. As of June 30, 2011, borrowings of \$174.8 million were outstanding

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

under the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with at June 30, 2011.

In July 2011, Edwards Lifesciences entered into a new Four-Year Credit Agreement ("the Credit Facility") which matures on July 29, 2015 and replaces the Credit Agreement. As a result, all amounts outstanding under the Credit Agreement have been classified as long-term obligations as these obligations are expected to be refinanced on a long-term basis under the Credit Facility. The Credit Facility will provide up to an aggregate of \$500.0 million in borrowings in multiple currencies. Borrowings will generally bear interest at LIBOR plus 0.875%, subject to adjustment for leverage ratio changes as defined in the Credit Facility. The Company will also pay a facility fee of 0.125% on the entire \$500.0 million facility whether or not drawn. The facility fee will also be subject to adjustment for leverage ratio changes. The Credit Facility is unsecured and contains various financial and other covenants, including a maximum leverage ratio and a minimum interest coverage ratio, as defined in the Credit Facility.

In March 2011, the Company acquired all the outstanding shares of Embrella Cardiovascular, Inc. ("Embrella"), including shares already owned by the Company, for an aggregate purchase price of \$42.6 million. The purchase price was funded with cash on hand and borrowings under the Credit Agreement. Embrella is a start-up medical device company developing a device for cerebral embolic protection during cardiovascular procedures.

In February 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. During the six months ended June 30, 2011, the Company repurchased 1.8 million shares at an aggregate cost of \$156.3 million and has remaining authority to purchase \$241.7 million of the Company's common stock.

At June 30, 2011, 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, 2010.

Net cash flows provided by **operating activities** of \$74.2 million for the six months ended June 30, 2011 increased \$13.2 million over the same period a year ago due primarily to improved operating performance and lower inventory purchases, partially offset by higher supplier payments.

Net cash used in **investing activities** of \$63.8 million for the six months ended June 30, 2011 consisted primarily of a \$42.6 million payment associated with the acquisition of Embrella, and capital expenditures of \$31.1 million.

Net cash used in investing activities of \$23.2 million for the six months ended June 30, 2010 consisted primarily of capital expenditures of \$23.7 million.

Net cash provided by **financing activities** of \$40.8 million for the six months ended June 30, 2011 consisted primarily of net proceeds from debt of \$129.2 million, proceeds from stock plans of \$33.4 million, and the excess tax benefit from stock plans of \$36.4 million, partially offset by purchases of treasury stock of \$159.0 million.

Net cash used in financing activities of \$20.7 million for the six months ended June 30, 2010 consisted primarily of purchases of treasury stock of \$199.3 million, partially offset by net proceeds from long-term debt of \$88.8 million, proceeds from stock plans of \$53.4 million, and the excess tax benefit from stock plans of \$31.5 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

Table of Contents

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 37-41 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, 2010. Management believes that at June 30, 2011, 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 42-43 of the Company's Annual Report on Form 10-K for the year ended December 31, 2010. There have been no significant changes from the information discussed therein.

*Concentrations of Credit Risk*

In the normal course of business, Edwards Lifesciences provides credit to customers in the healthcare industry, performs credit evaluations of these customers and maintains allowances for potential credit losses which have historically been adequate compared to actual losses. The Company continues to do business with foreign governments in certain European countries that have experienced a deterioration in credit and economic conditions. These conditions have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect accounts receivable outstanding in these countries. In addition, the Company may also be impacted by declines in sovereign credit ratings or sovereign defaults in these countries.

In June 2011, the Company recorded a \$4.0 million charge to reflect the increased collection risk associated with its receivables in Greece. A significant further decline in sovereign credit ratings or a default in Greece, or in other countries, may decrease the likelihood that the Company will collect these accounts receivable, which could result in a negative impact to the Company's operating results.

*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 June 30, 2011, Edwards Lifesciences had \$24.8 million of investments in equity instruments of other companies and had recorded unrealized gains of \$1.9 million on these investments in "Accumulated Other Comprehensive Loss," net of tax. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the decline in the investments' value may be considered other-than-temporary and impairment charges may be necessary.

**Item 4. Controls and Procedures**

The Company's management, including the Chief Executive Officer and the Chief Financial Officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures as of June 30, 2011. 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

## Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

### Table of Contents

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 June 30, 2011 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. In February 2011, the District Court reaffirmed the jury decision and ruled that Edwards is entitled to recover additional damages due to CoreValve's continued infringing sales from the trial through the life of the patent, plus interest. In the same ruling, the court denied Edwards' motions for a permanent injunction and increased damages relating to CoreValve's willful infringement. Both Edwards and CoreValve have appealed. 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 claim of the '552 patent and in July 2011 confirmed the validity of that patent.

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 May 2011, the Company and Cook resolved these disputes and, as a result, all of the proceedings have been withdrawn.

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 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 June 2011, Medtronic filed a lawsuit in the United States District Court for the District of Minnesota alleging that certain surgical valve holders and a surgical embolic filter device infringe its patents. Medtronic also filed another lawsuit in the United States District Court for the Central District of California alleging that the *Edwards SAPIEN* transcatheter heart valve infringes a Medtronic patent. The Company plans to vigorously defend against these claims.

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. The Company is not able to estimate the amount or range of any loss for certain of the legal contingencies for which there is no reserve or additional loss for matters already reserved. 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

Table of Contents

lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

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(a)	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)(b)
April 1, 2011 through April 30, 2011	297,301	\$ 84.23	296,282	\$ 297.2
May 1, 2011 through May 31, 2011	342,643	87.49	312,000	269.9
June 1, 2011 through June 30, 2011	329,159	85.60	329,000	241.7
Total	969,103	85.85	937,282	

(a) The difference between the total number of shares (or units) purchased and the total number of shares (or units) purchased as part of publicly announced plans or programs is due to shares surrendered to the Company to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees.

(b) 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 June 30, 2011, 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: August 8, 2011

By:            /s/ THOMAS M. ABATE

\_\_\_\_\_  
Thomas M. Abate  
*Corporate Vice President,  
Chief Financial Officer  
(Chief Accounting Officer)*

Table of Contents

**EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION**

<b>Exhibit No.</b>	<b>Description</b>
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 June 30, 2011, 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.