

Edwards Lifesciences Corp
Form 10-Q
August 07, 2009

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, 2009

or

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

**For the transition period from _____ to
Commission file number 1-15525**

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

36-4316614

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

One Edwards Way, Irvine, California

(Address of principal executive offices)

92614

(Zip Code)

(949) 250-2500

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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 <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller Reporting Company <input type="checkbox"/>
---	---	---	---

(Do not check if a
smaller reporting
company)

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

The number of shares outstanding of the registrant's common stock, \$1.00 par value, as of July 31, 2009 was 56,418,947.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

FORM 10-Q

For the quarterly period ended June 30, 2009

TABLE OF CONTENTS

	Page Number
<u>Part I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (Unaudited)</u>	
<u>Consolidated Condensed Balance Sheets</u>	<u>1</u>
<u>Consolidated Condensed Statements of Operations</u>	<u>1</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>2</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>3</u>
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>4</u>
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>22</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>35</u>
<u>Part II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>36</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>37</u>
<u>Item 4.</u>	
<u>Submission of Matters to a Vote of Security Holders</u>	<u>38</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>38</u>
<u>Signature</u>	<u>39</u>
<u>Exhibits</u>	<u>40</u>
	<u>41</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, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	\$ 183.1	\$ 218.7
Short-term investments (Note 3)	5.2	8.1
Accounts and other receivables, net of allowances of \$11.5 and \$9.9, respectively (Note 4)	274.5	204.7
Inventories, net	160.9	151.8
Deferred income taxes	38.3	42.4
Prepaid expenses	44.8	30.7
Other current assets	38.8	35.5
Total current assets	745.6	691.9
Property, plant and equipment, net	239.1	230.1
Goodwill	315.7	315.7
Other intangible assets, net	91.3	96.9
Investments in unconsolidated affiliates (Note 7)	20.3	14.7
Deferred income taxes	36.4	37.7
Other assets	16.7	13.2
	\$1,465.1	\$ 1,400.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 245.1	\$ 258.5
Long-term debt	113.9	175.5
Other long-term liabilities	103.0	87.4
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 75.1 and 73.7 shares issued, and 56.4 and 55.9 shares outstanding, respectively	75.1	73.7
Additional paid-in capital	998.1	940.4
Retained earnings	784.9	676.9
Accumulated other comprehensive loss	(23.7)	(35.4)
Treasury stock, at cost, 18.7 and 17.8 shares, respectively	(831.3)	(776.8)
Total stockholders' equity	1,003.1	878.8
	\$1,465.1	\$ 1,400.2

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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,	
	2009	2008	2009	2008
Net sales	\$335.5	\$327.6	\$649.0	\$624.4
Cost of goods sold	101.9	113.0	198.9	215.9
Gross profit	233.6	214.6	450.1	408.5
Selling, general and administrative expenses	128.5	126.5	250.4	241.1
Research and development expenses	42.6	35.4	82.5	68.3
Special charges (gains), net (Note 2)	1.5	(0.8)	(29.3)	9.3
Interest expense, net	0.2	0.4	0.3	0.8
Other (income) expense, net	(2.0)	1.0	(1.6)	2.2
Income before provision for income taxes	62.8	52.1	147.8	86.8
Provision for income taxes	15.3	12.4	39.8	28.9
Net income	\$ 47.5	\$ 39.7	\$ 108.0	\$ 57.9
Share information (Note 14)				
Earnings per share:				
Basic	\$ 0.85	\$ 0.72	\$ 1.93	\$ 1.04
Diluted	\$ 0.81	\$ 0.67	\$ 1.85	\$ 0.98
Weighted-average number of common shares outstanding:				
Basic	56.2	55.4	56.1	55.8
Diluted	58.5	60.2	58.5	60.7

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

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(in millions; unaudited)

	Six Months Ended June 30,	
	2009	2008
Cash flows from operating activities		
Net income	\$ 108.0	\$ 57.9
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	29.1	27.5
Stock-based compensation (Note 11)	12.6	12.8
Deferred income taxes	4.8	1.0
Special (gains) charges, net (Note 2)	(25.9)	8.4
(Gain) loss on trading securities	(1.0)	1.2
Loss on investments		0.8
Other	3.2	(1.0)
Changes in operating assets and liabilities:		
Accounts and other receivables, net (Note 4)	(62.1)	(19.6)
Inventories, net	(8.0)	0.1
Accounts payable and accrued liabilities	(27.9)	(19.2)
Prepaid expenses and other current assets	(11.5)	(19.1)
Other	6.6	8.1
Net cash provided by operating activities	27.9	58.9
Cash flows from investing activities		
Capital expenditures	(28.2)	(20.7)
Investments in intangible assets		(0.4)
(Investments in) proceeds from unconsolidated affiliates, net	(3.5)	1.9
Investments in trading securities, net	(0.3)	(0.4)
Proceeds from investments (Note 3)	4.2	23.4
Proceeds from sale of assets (Note 2)	30.5	74.0
Net cash provided by investing activities	2.7	77.8
Cash flows from financing activities		
Proceeds from issuance of long-term debt	99.3	97.0
Payments on long-term debt	(157.7)	(22.5)
Purchases of treasury stock	(54.5)	(214.8)
Proceeds from stock plans	33.2	35.3
Excess tax benefit from stock plans	10.3	8.0
Other		1.3
Net cash used in financing activities	(69.4)	(95.7)
Effect of currency exchange rate changes on cash and cash equivalents	3.2	5.4
Net (decrease) increase in cash and cash equivalents	(35.6)	46.4
Cash and cash equivalents at beginning of period	218.7	141.8
Cash and cash equivalents at end of period	\$ 183.1	\$ 188.2

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, 2008. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted.

In the opinion of management of Edwards Lifesciences Corporation (the "Company" or "Edwards Lifesciences"), the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair statement of the interim periods. All such adjustments are of a normal, recurring nature. In connection with the preparation of the consolidated condensed financial statements, the Company has evaluated subsequent events through August 7, 2009, which is the date the financial statements were issued. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defined fair value, established a framework for measuring fair value, and expanded disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position ("FSP") No. 157-2, "*Effective Date of FASB Statement No. 157*" ("FSP 157-2"), which delayed the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. The Company's adoption of SFAS 157, as it applies to those non-financial assets and liabilities affected by the one-year delay, did not have a material impact on the Company's consolidated financial statements. See Note 8 for further information.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-1, "*Accounting for Collaborative Arrangements*" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented is required for all collaborative arrangements existing as of the effective date. The Company's adoption of EITF 07-1 did not have a material impact on its consolidated financial statements. See Note 16 for further information.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "*Business Combinations*" ("SFAS 141R"). SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Among other requirements, SFAS 141R expands the definition of a business combination, requires acquisitions to be accounted for at fair value, and requires transaction

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

costs and restructuring charges to be expensed. SFAS 141R was effective for fiscal years beginning on or after December 15, 2008. SFAS 141R will impact the Company if it is involved in a business combination.

In March 2008, the FASB issued SFAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133*" ("SFAS 161"). SFAS 161 requires enhanced disclosures about an entity's derivative instruments and hedging activities, including (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 was effective for fiscal years and interim periods beginning after November 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements. See Note 9 for further information.

In April 2008, the FASB issued FSP No. FAS 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "*Goodwill and Other Intangible Assets*." FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 was effective for fiscal years beginning after December 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-6, "*Equity Method Investment Accounting Considerations*" ("EITF 08-6"). EITF 08-6 clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-7, "*Accounting for Defensive Intangible Assets*" ("EITF 08-7"). EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over a period the asset diminishes in value. EITF 08-7 was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 141 (R)-1, "*Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*" ("FSP 141R-1"). FSP 141R-1 amends the guidance in SFAS 141R to require that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably determined. If the fair value cannot be reasonably determined, then the assets and liabilities should be recognized at the amount that would be recognized in accordance with SFAS No. 5, "*Accounting for Contingencies*," and FASB Interpretation No. 14, "*Reasonable Estimation of the Amount of a Loss*." The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 157-4, "*Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*" ("FSP 157-4"). FSP 157-4 provides additional guidance for estimating fair value in

Table of Contents

accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. FSP 157-4 also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 115-2 and FAS 124-2, "*Recognition and Presentation of Other-Than-Temporary Impairments*" ("FSP 115-2 and 124-2"). FSP 115-2 and 124-2 amends the other-than-temporary impairment guidance related to debt securities and expands and increases the frequency of existing disclosures about other-than-temporary impairments for debt and equity securities. In addition, FSP 115-2 and 124-2 requires that the annual disclosures in SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," and FSP No. FAS 115-1 and FAS 124-1, "*The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*," be made for interim periods. FSP 115-2 and 124-2 was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the SEC issued Staff Accounting Bulletin ("SAB") No. 111, "*Other Than Temporary Impairment of Certain Investments in Debt and Equity Securities*" ("SAB 111"). SAB 111 amends SAB Topic 5M to reflect the guidance in FSP 115-2 and 124-2. SAB 111 maintains the prior staff views related to equity securities but amends SAB Topic 5M to exclude debt securities from its scope. The adoption of SAB 111 did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 107-1 and APB 28-1, "*Interim Disclosures about Fair Value of Financial Instruments*" ("FSP 107-1 and 28-1"). FSP 107-1 and 28-1 requires disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP 107-1 and 28-1 was effective for interim reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, "*Subsequent Events*" ("SFAS 165"). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 requires the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 was effective for interim or annual financial periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2009, the SEC issued SAB No. 112, "*Update of Codification of Staff Accounting Bulletins*" ("SAB 112"). SAB 112 amends or rescinds portions of the SEC staff's interpretive guidance included in the Staff Accounting Bulletin Series in order to make the relevant interpretive guidance consistent with SFAS 141R and SFAS No. 160, "*Noncontrolling Interests in Consolidated Financial Statements*." The adoption of SAB 112 did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In June 2009, the FASB issued SFAS No. 167, "*Amendments to FASB Interpretation No. 46(R)*" ("SFAS 167"). SFAS 167 eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a variable interest entity ("VIE") based on whether the entity (1) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (2) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. SFAS 167

Table of Contents

requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. SFAS 167 is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of SFAS 167 will have a material impact on its consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, "*The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*" ("SFAS 168"). SFAS 168 establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles ("GAAP"). Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS 168 replaces SFAS No. 162, "*The Hierarchy of Generally Accepted Accounting Principles*." SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of SFAS 168 will have a material impact on its consolidated financial statements.

2. SPECIAL CHARGES (GAINS), NET

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(in millions)			
Loss (gain) on sale of product lines	\$ 1.5	\$	\$ (25.5)	\$ 8.1
Sale of distribution rights			(2.8)	
Reserve reversal			(1.0)	
Litigation settlement				2.1
Realignment expenses, net		(0.8)		(0.9)
Special charges (gains), net	\$ 1.5	\$ (0.8)	\$ (29.3)	\$ 9.3

Loss (Gain) on Sale of Product Lines

In June 2009, the Company entered into a definitive agreement to sell certain assets related to its hemofiltration product line. Under the terms of the agreement, the Company will receive a cash payment of approximately \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years. The Company will provide transition services to the buyer. This transaction allows the Company to better focus on its global strategic priorities. The Company expects this transaction to close in the third quarter of 2009, pending regulatory approvals. In June 2009, the Company recorded a \$1.5 million charge for transaction costs and employee severance related to the pending sale.

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market

Table of Contents

approval. The remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

In connection with the *LifeStent* transaction, the Company recorded in January 2008 a pre-tax loss of \$8.1 million consisting of the cash proceeds of \$74.0 million, offset by a \$34.6 million write-off of goodwill associated with this product line, \$36.9 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, \$6.9 million of deferred revenue related to the transition services the Company has agreed to provide, and \$3.7 million of transaction and other costs related to the sale.

Sale of Distribution Rights

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

Reserve Reversal

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

Litigation Settlement

In March 2008, the Company recorded a \$2.1 million charge for the settlement of litigation related to its divested United States perfusion services business. Under the terms of the divestiture, this was the Company's last outstanding case.

Realignment Expenses, net

In June 2008, the Company recorded a \$0.8 million reversal of previously accrued severance costs from the fourth quarter of 2007 related to the global reduction in workforce.

In March 2008, the Company recorded a \$1.3 million charge for executive severance associated with the Company's business realignment, offset by a \$1.4 million reversal of the December 2007 accrued severance related to the sale of the *LifeStent* product line. As of June 30, 2009, all payments related to the executive severance charge were substantially complete.

In December 2007, the Company recorded realignment expenses of \$13.9 million primarily related to (1) severance expenses associated with the sale of the Company's *LifeStent* product line and a global reduction in workforce, primarily in the United States, Europe, and Japan (impacting approximately 180 employees), and (2) the termination of the Company's intra-aortic balloon pump distribution agreement in Japan. As of June 30, 2009, remaining payments of approximately \$1.7 million are expected to be paid through the end of 2009.

3. INVESTMENTS

The Company holds an investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, which was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investments for cash. During the three and six months ended June 30, 2009, the Company recognized unrealized gains of \$0.3 million and \$0.4 million, respectively, included in "*Accumulated Other Comprehensive Loss*." During the three and six months ended June 30, 2008, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$0.2 million and 0.8 million, respectively, included in "*Other (Income) Expense, net*." Additionally, during the three months ended June 30, 2008, the Company recognized an unrealized gain of \$0.2 million, included in "*Accumulated Other Comprehensive*

Table of Contents

Loss," related to an increase in the net asset value of the fund since March 31, 2008. Since December 31, 2007, the Company has received cash redemptions of \$39.7 million. The fair value of the Company's remaining investment in this fund as of June 30, 2009 and December 31, 2008 was estimated to be \$7.1 million and \$10.9 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$5.2 million through the second quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of June 30, 2009. The remaining \$1.9 million of the investment is expected to be received after the second quarter of 2010, and has been classified as "*Other Assets*." As of December 31, 2008, \$8.1 million of the investment was classified as "*Short-term Investments*" and \$2.8 million was classified as "*Other Assets*" based on the redemption schedule communicated to the Company at that time.

4. ACCOUNTS RECEIVABLE SECURITIZATION

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

5. INVENTORIES

Inventories consisted of the following (in millions):

	June 30, 2009	December 31, 2008
Raw materials	\$ 35.3	\$ 36.5
Work in process	28.4	19.5
Finished products	97.2	95.8
	\$ 160.9	\$ 151.8

6. OTHER INTANGIBLE ASSETS

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

June 30, 2009	Unpatented			Total
	Patents	Technology	Other	
Cost	\$ 209.3	\$ 35.0	\$ 13.5	\$ 257.8
Accumulated amortization	(136.1)	(25.9)	(4.5)	(166.5)
Net carrying value	\$ 73.2	\$ 9.1	\$ 9.0	\$ 91.3
December 31, 2008	Unpatented			Total
	Patents	Technology	Other	
Cost	\$ 204.1	\$ 35.0	\$ 13.4	\$ 252.5
Accumulated amortization	(127.3)	(24.6)	(3.7)	(155.6)
Net carrying value	\$ 76.8	\$ 10.4	\$ 9.7	\$ 96.9

Patents include \$11.1 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, 2009.

Table of Contents

Amortization expense related to other intangible assets was \$5.4 million and \$4.6 million for the three months ended June 30, 2009 and 2008, respectively, and \$10.7 million and \$9.2 million for the six months ended June 30, 2009 and 2008, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2009	\$20.8
2010	20.6
2011	18.1
2012	14.7
2013	14.5

The Company expenses costs incurred to renew or extend the term of acquired intangible assets. No such costs were incurred during the three months ended June 30, 2009.

7. INVESTMENTS IN UNCONSOLIDATED AFFILIATES

The Company has entered into a number of strategic alliances with privately and publicly held companies. Investments in these unconsolidated affiliates are as follows:

	June 30, 2009	December 31, 2008
(in millions)		
Available-for-sale investments		
Cost	\$ 10.9	\$ 10.9
Unrealized losses	(2.6)	(5.8)
Fair value of available-for-sale investments	8.3	5.1
Equity method investments		
Cost	10.4	9.7
Equity in losses	(1.7)	(1.1)
Carrying value of equity method investments	8.7	8.6
Cost method investments		
Carrying value of cost method investments	3.3	1.0
Total investments in unconsolidated affiliates	\$ 20.3	\$ 14.7

There were no sales of available-for-sale investments during the six months ended June 30, 2009. Proceeds from sales of available-for-sale investments were \$1.1 million and \$2.3 million for the three and six months ended June 30, 2008, respectively. The Company realized pre-tax gains from these sales of \$0.6 million and \$1.3 million for the three and six months ended June 30, 2008, respectively.

8. 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 an historical cost basis. Financial instruments of the Company consist of cash deposits, short-term investments, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities, and debt.

The Company adopted SFAS 157 as of January 1, 2008 with respect to its financial assets and liabilities, and as of January 1, 2009 with respect to its non-financial assets and liabilities. SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 establishes a fair value hierarchy that prioritizes the inputs used to

Table of Contents

determine fair values. Financial assets and liabilities carried at fair value are classified and disclosed 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.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

June 30, 2009	Level 1	Level 2	Level 3	Total
Assets				
Investment in the Bank of America Columbia Strategic Cash fund	\$	\$	\$ 7.1	\$ 7.1
Investments held for executive deferred compensation plan	11.7			11.7
Investments in unconsolidated affiliates	8.3			8.3
	\$ 20.0	\$	\$ 7.1	\$27.1
Liabilities				
Derivatives	\$	\$ 4.3	\$	\$ 4.3
	\$	\$ 4.3	\$	\$ 4.3
December 31, 2008				
Assets				
Investment in the Bank of America Columbia Strategic Cash fund	\$	\$	\$ 10.9	\$ 10.9
Investments held for executive deferred compensation plan	10.2			10.2
Investments in unconsolidated affiliates	5.1			5.1
Residual interest in accounts receivable securitizations			6.6	6.6
	\$ 15.3	\$	\$ 17.5	\$32.8
Liabilities				
Derivatives	\$	\$ 1.3	\$	\$ 1.3
	\$	\$ 1.3	\$	\$ 1.3

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

The following table summarizes the changes in fair value of the Company's financial assets and liabilities that have been classified as Level 3 (in millions):

	Six Months Ended June 30, 2009		
	Investment in the Columbia Strategic Cash Fund	Residual Interest in Accounts Receivable Securitized	Total
Balance at December 31, 2008	\$ 10.9	\$ 6.6	\$ 17.5
Total gains realized and unrealized:			
Included in other comprehensive loss	0.4		0.4
Purchases, sales, issuances, and settlements	(4.2)	(6.6)	(10.8)
Balance at June 30, 2009	\$ 7.1	\$	\$ 7.1

	Six Months Ended June 30, 2008		
	Investment in the Columbia Strategic Cash Fund	Residual Interest in Accounts Receivable Securitized	Total
Balance at December 31, 2007	\$ 49.4	\$ 8.8	\$ 58.2
Total losses realized and unrealized:			
Included in earnings (a)	(0.8)		(0.8)
Included in other comprehensive loss	0.2		0.2
Purchases, sales, issuances, and settlements	(23.4)	1.6	(21.8)
Balance at June 30, 2008	\$ 25.4	\$ 10.4	\$ 35.8

(a)

Recorded as a component of "*Other (Income) Expense, net*" in the consolidated condensed statement of operations.

The Company's investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investment for cash. The fair value of the Company's remaining investment in this fund was estimated based on the net asset value of the fund. The fair value of the underlying securities held by the fund was determined based on quoted market prices or broker quotes, when possible. In the absence of observable market quotations, the underlying securities were valued based on alternative valuation techniques using inputs that may not be observable. In these cases, the fair value was based on available information believed to be reliable, which may be affected by conditions in the financial markets. Different market participants may reach different opinions as to the value of any particular security based on their varying market outlooks, the market information available to them, and the particular circumstances of their portfolios. The Company has procedures to independently verify and test valuations received from third parties.

The Company estimates the fair value of the residual interest in accounts receivable securitizations using the net carrying amount of the accounts receivables less the discount paid on the sale of the receivables. This amount is calculated using future expected credit losses and calculated contractual rebates to distributors to determine the future expected cash flows, which generally approximate fair value given the securitized portfolio's short-term weighted-average life. The Company terminated its securitization program in the United States in August 2008 and in Japan in February 2009.

The Company's other financial instruments generally approximate their fair values based on the short-term nature of these instruments.

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 these 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, 2009, the Company had no impairments related to these assets.

9. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

Edwards Lifesciences maintains an overall risk management strategy that may incorporate the use of a variety of derivative financial instruments, as summarized below, to mitigate its exposure to significant unplanned fluctuations in earnings and cash flow caused by volatility in interest rates and currency exchange rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy can include interest rate swaps, option-based products, and forward exchange contracts. As of June 30, 2009, all derivative instruments owned were designated as hedges of underlying exposures. Edwards Lifesciences does not use any of these instruments for trading or speculative purposes.

	June 30, 2009	
	Fair Value	
	Notional	Asset
	Amount	(Liability)
	(in millions)	
Forward currency agreements	\$222.4	\$ (3.9)
Currency option contracts	141.7	(0.4)

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

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

All derivatives are recognized on the balance sheet at their fair value. On the date that the Company enters into a derivative contract, it designates the derivative as either (a) a hedge of a forecasted transaction or the variability of cash flows that are to be received or paid in connection with a recognized asset or liability (a "cash flow" hedge), or (b) a hedge of an exposure to changes in the

Table of Contents

fair value of an asset, liability, or an unrecognized firm commitment (a "fair value" hedge). Changes in the fair value of a derivative that is highly effective, and that is designated and qualifies as a cash flow hedge to the extent that the hedge is effective, are recorded in "Accumulated Other Comprehensive Loss" until earnings are affected by the variability of cash flows of the hedged transaction (e.g., until periodic settlements of a variable asset or liability are recorded in earnings). Any hedge ineffectiveness (which represents the amount by which the changes in the fair value of the derivative exceed the variability in the cash flows of the forecasted transaction) is recorded in current-period earnings. Changes in the fair value of a derivative that is highly effective, and that is designated and qualifies as a fair value hedge, are recorded in current-period earnings.

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated condensed balance sheet as of June 30, 2009 (in millions):

	June 30, 2009			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments under SFAS 133				
	Prepaid		Accrued	
Foreign exchange contracts	expenses	\$	liabilities	\$ 4.3

The following tables present the effect of derivative instruments on the consolidated statement of operations for the three and six months ended June 30, 2009 (in millions):

	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, 2009	Six Months Ended June 30, 2009
		Derivatives in SFAS 133 fair value hedging relationships	
Foreign exchange contracts	Other (income) expense, net	\$ (1.2)	\$ (0.4)

	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	
	Three Months Ended June 30, 2009	Six Months Ended June 30, 2009		Three Months Ended June 30, 2009	Six Months Ended June 30, 2009
	Derivatives in SFAS 133 cash flow hedging relationships				
Foreign exchange contracts	\$ (7.1)	\$ 5.0	Cost of goods sold	\$ 4.8	\$ 6.1

The Company expects that during the next twelve months it will reclassify to earnings a \$2.8 million gain currently recorded in "Accumulated Other Comprehensive Loss." For both the three and six months ended June 30, 2009, the Company expensed \$0.5 million related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness.

Table of Contents**10. DEFINED BENEFIT PLANS**

The components of net periodic benefit costs for the three and six months ended June 30, 2009 and 2008 were as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Service cost	\$ 1.3	\$ 0.9	\$ 2.7	\$ 1.9
Employee contributions				
Interest cost	0.5	0.4	0.9	0.7
Expected return on plan assets	(0.2)	(0.2)	(0.4)	(0.4)
Amortization of prior service cost and other	0.2		0.3	
Net periodic pension benefit cost	\$ 1.8	\$ 1.1	\$ 3.5	\$ 2.2

11. 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, 2009 and 2008 was as follows (in millions):

	Three Months Ended June 30		Six Months Ended June 30,	
	2009	2008	2009	2008
Cost of goods sold	\$ 0.5	\$ 0.6	\$ 1.1	\$ 1.2
Selling, general and administrative expenses	4.3	4.6	9.5	9.2
Research and development expenses	0.9	1.0	2.0	2.4
Total stock-based compensation expense	\$ 5.7	\$ 6.2	\$ 12.6	\$ 12.8

At June 30, 2009, the total remaining compensation cost related to unvested stock options, restricted stock units, and employee stock purchase subscription awards amounted to \$55.7 million and will be amortized on a straight-line basis over a weighted-average vesting period of approximately 32 months.

During the six months ended June 30, 2009, the Company granted 0.9 million stock options at a weighted-average exercise price of \$62.93 and 0.2 million shares of restricted stock units at a weighted-average grant-date fair value of \$62.59.

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,	
	2009	2008	2009	2008
Risk-free interest rate	1.9%	3.0%	1.9%	3.0%
Expected dividend yield	None	None	None	None
Expected volatility	28.2%	23.5%	28.1%	23.3%
Expected term (years)	4.6	4.4	4.6	4.4
Fair value, per share	\$17.00	\$14.43	\$16.98	\$14.31

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,	
	2009	2008	2009	2008
Risk-free interest rate	0.5%	1.5%	0.4%	3.3%
Expected dividend yield	None	None	None	None
Expected volatility	37.3%	25.6%	36.7%	23.8%
Expected term (years)	0.7	0.6	0.7	0.6
Fair value, per share	\$16.56	\$10.22	\$16.36	\$10.58

12. COMMITMENTS AND CONTINGENCIES

In August 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"); Cook, Inc. ("Cook"); and W.L. Gore & Associates ("Gore") alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. In September 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced in January 2006, Edwards Lifesciences settled this litigation with Medtronic. Edwards Lifesciences remains in litigation with Cook and Gore. In March 2008, the District Court granted summary judgment of non-infringement in favor of Cook and subsequently in favor of Gore. In 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals; the appeal was heard in July 2009.

In May 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007, and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. In January 2009, the United Kingdom Court determined that the Andersen patent was valid but not infringed by

Table of Contents

CoreValve. The parties have filed cross-appeals on the validity and infringement decisions. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. This lawsuit is ongoing.

In February 2008, 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 in each country are invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. As announced, the German Court ruled in March 2009 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. Cook is appealing the judgments in Germany and the United Kingdom.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations, or liquidity.

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.

13. COMPREHENSIVE INCOME

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net income	\$47.5	\$39.7	\$108.0	\$57.9
Other comprehensive income:				
Currency translation adjustments	15.1	(0.8)	9.0	17.2
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	2.2	(0.4)	3.3	(4.1)
Unrealized net (loss) gain on cash flow hedges, net of tax	(7.2)	3.1	(0.6)	(1.5)
Comprehensive income	\$49.1	\$41.6	\$119.7	\$69.5

14. 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

Table of Contents

equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of the conversion of convertible debt, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Basic:				
Net income	\$47.5	\$39.7	\$108.0	\$57.9
Weighted-average shares outstanding	56.2	55.4	56.1	55.8
Basic earnings per share	\$0.85	\$0.72	\$ 1.93	\$1.04
Diluted:				
Net income	\$47.5	\$39.7	\$108.0	\$57.9
Interest expense related to convertible debt, net of tax		0.7		1.7
Net income applicable to diluted shares	\$47.5	\$40.4	\$108.0	\$59.6
Weighted-average shares outstanding	56.2	55.4	56.1	55.8
Dilutive effect of convertible debt		2.0		2.4
Dilutive effect of stock plans	2.3	2.8	2.4	2.5
Dilutive weighted-average shares outstanding	58.5	60.2	58.5	60.7
Diluted earnings per share	\$0.81	\$0.67	\$ 1.85	\$0.98

Stock options and restricted stock units to purchase 1.8 million and 1.4 million shares for the three months ended June 30, 2009 and 2008, respectively, and 1.4 million and 2.4 million for the six months ended June 30, 2009 and 2008, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive. Diluted shares included shares issuable pursuant to the Company's \$150 million convertible debentures until they were redeemed on June 9, 2008.

15. INCOME TAXES

The effective income tax rates were 24.4% and 26.9% for the three and six months ended June 30, 2009, respectively, and 23.8% and 33.3% for the three and six months ended June 30, 2008, respectively. The income tax rate for the six months ended June 30, 2009 included the tax effect on a *LifeStent* milestone receipt. The income tax rate for the six months ended June 30, 2008 included the tax effect on the sale of the *LifeStent* product line. See Note 2 for further information.

As of June 30, 2009, March 31, 2009, and December 31, 2008, the liability for income taxes associated with uncertain tax positions was \$43.0 million, \$38.0 million, and \$35.9 million, respectively. These liabilities could be reduced by \$3.8 million, \$1.9 million, and \$2.3 million, respectively, from

Table of Contents

offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amounts of \$39.2 million, \$36.1 million, and \$33.6 million, respectively, if recognized, would favorably affect the Company's effective tax rate. Changes to potential interest expense upon settlement during the period were immaterial.

As a result of on-going audits, the total liability for unrecognized tax benefits may change within the next 12 months due to either settlements of audits or expiration of statutes of limitations. Quantification of those potential changes cannot be estimated at this time. At June 30, 2009, the Company has concluded all United States federal income tax matters for years through 2006. All material state, local, and foreign income tax matters have been concluded for years through 2003.

In February 2009, California enacted tax legislation which will be effective beginning 2011. The impact of the new legislation has been considered in determining the Company's tax provision for the three and six months ended June 30, 2009, including the realizability of its California research and development credit carryforward.

16. COLLABORATIVE AGREEMENT

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 agreement provides Edwards Lifesciences with an exclusive license to all of DexCom's applicable intellectual property. In December 2008, at the inception of the agreement, the Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee. The Company will also pay up to \$24 million over the next three years in product development costs and regulatory approval milestones. The product development costs are expensed to "*Research and Development Expenses*" as incurred, and the regulatory approval milestones are recorded as "*Other Intangible Assets*" and amortized over the useful life of the product. In addition, DexCom will receive either a profit-sharing payment or a royalty based upon commercial sales. Edwards Lifesciences will be responsible for global sales and marketing, which is expected to begin in 2010, and DexCom will be responsible for initial manufacturing. The Company recorded \$1.1 million and \$3.2 million of product development costs for the three and six months ended June 30, 2009.

17. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in four geographical regions: United States, Europe, Japan, and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease.

The Company evaluates the performance of its segments based on net sales and income before provision for income taxes ("pre-tax income"). The accounting policies of the segments are substantially the same as those described in Note 2, "*Summary of Significant Accounting Policies*," in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. Net sales and pre-tax income of reportable segments are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments, the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include net interest expense, global marketing expenses, corporate research and development expenses, United States manufacturing variances, corporate headquarters costs, in-process research and development, special gains and charges, stock-based compensation, foreign currency hedging activities, certain litigation costs, and most of the Company's amortization expense. Although most of the Company's depreciation expense is included in segment pre-tax income, due to the Company's methodology for cost build-up, it is impractical to determine the amount of depreciation

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

expense included in each segment. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net Sales				
United States	\$ 143.5	\$ 138.1	\$ 278.4	\$ 273.6
Europe	102.2	95.3	203.1	180.6
Japan	46.0	42.3	87.3	79.7
Rest of world	39.5	33.2	73.5	63.5
 Total segment net sales	 \$ 331.2	 \$ 308.9	 \$ 642.3	 \$ 597.4
Pre-Tax Income				
United States	\$ 77.7	\$ 71.3	\$ 150.1	\$ 142.3
Europe	33.9	31.2	68.5	57.1
Japan	21.6	18.5	41.0	34.2
Rest of world	11.3	9.3	19.3	16.5
 Total segment pre-tax income	 \$ 144.5	 \$ 130.3	 \$ 278.9	 \$ 250.1

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,	
	2009	2008	2009	2008
Net Sales Reconciliation				
Segment net sales	\$ 331.2	\$ 308.9	\$ 642.3	\$ 597.4
Foreign currency	4.3	18.7	6.7	27.0
 Consolidated net sales	 \$ 335.5	 \$ 327.6	 \$ 649.0	 \$ 624.4
Pre-Tax Income Reconciliation				
Segment pre-tax income	\$ 144.5	\$ 130.3	\$ 278.9	\$ 250.1
Unallocated amounts:				
Corporate items	(88.0)	(77.7)	(173.3)	(148.0)
Special (charges) gains, net	(1.5)	0.8	29.3	(9.3)
Interest expense, net	(0.2)	(0.4)	(0.3)	(0.8)
Foreign currency	8.0	(0.9)	13.2	(5.2)
 Consolidated pre-tax income	 \$ 62.8	 \$ 52.1	 \$ 147.8	 \$ 86.8

Table of Contents**Enterprise-Wide Information**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(in millions)			
Net Sales by Geographic Area				
United States	\$ 143.5	\$ 139.7	\$ 278.4	\$ 275.2
Other countries	192.0	187.9	370.6	349.2
	\$ 335.5	\$ 327.6	\$ 649.0	\$ 624.4
Net Sales by Major Product and Service Area				
Heart Valve Therapy	\$ 182.1	\$ 162.6	\$ 352.5	\$ 309.3
Critical Care	113.0	116.6	217.5	223.3
Cardiac Surgery Systems	24.1	23.5	46.6	44.9
Vascular	16.3	24.9	32.4	46.9
	\$ 335.5	\$ 327.6	\$ 649.0	\$ 624.4

	June 30, 2009	December 31, 2008
	(in millions)	
Long-Lived Tangible Assets by Geographic Area		
United States	\$ 176.5	\$ 171.4
Other countries	99.6	86.6
	\$ 276.1	\$ 258.0

Table of Contents

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

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company intends the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials, or regulatory approvals, any statements of plans, strategies, and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, and any statement of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "forecast," "intend" or other similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's future business, financial condition, results of operations, or performance to differ materially from the Company's historical results or those expressed 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, 2008 for a description of certain of these risks and uncertainties.

Overview

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

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

Edwards Lifesciences' **Heart Valve Therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **Critical Care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring equipment used to measure a patient's cardiovascular function and in disposable pressure transducers, and also provides central venous access products for fluid and drug delivery. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannula, *EMBOL-X* technologies, and other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also includes the Company's minimally invasive surgery ("MIS") product line. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, and artificial implantable grafts. Through early 2008, Edwards manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents. The Company sold the *LifeStent* product line in January 2008, but will continue to manufacture these products for the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

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.

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defined fair value, established a framework for measuring fair value, and expanded disclosures about fair value measurements. In February 2008, the FASB issued FASB Staff Position ("FSP") No. 157-2, "*Effective Date of FASB Statement No. 157*" ("FSP 157-2"), which delayed the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. The Company's adoption of SFAS 157, as it applies to those non-financial assets and liabilities affected by the one-year delay, did not have a material impact on the Company's consolidated financial statements.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-1, "*Accounting for Collaborative Arrangements*" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented is required for all collaborative arrangements existing as of the effective date. The Company's adoption of EITF 07-1 did not have a material impact on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "*Business Combinations*" ("SFAS 141R"). SFAS 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Among other requirements, SFAS 141R expands the definition of a business combination, requires acquisitions to be accounted for at fair value, and requires transaction costs and restructuring charges to be expensed. SFAS 141R was effective for fiscal years beginning on or after December 15, 2008. SFAS 141R will impact the Company if it is involved in a business combination.

In March 2008, the FASB issued SFAS No. 161, "*Disclosures about Derivative Instruments and Hedging Activities - an amendment of FASB Statement No. 133*" ("SFAS 161"). SFAS 161 requires enhanced disclosures about an entity's derivative instruments and hedging activities, including (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 was effective for fiscal years and interim periods beginning after November 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2008, the FASB issued FSP No. FAS 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS

Table of Contents

No. 142, "Goodwill and Other Intangible Assets." FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 was effective for fiscal years beginning after December 15, 2008. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-6, "Equity Method Investment Accounting Considerations" ("EITF 08-6"). EITF 08-6 clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2008, the FASB ratified the consensus reached by the EITF in EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets" ("EITF 08-7"). EITF 08-7 clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over a period the asset diminishes in value. EITF 08-7 was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 141 (R)-1, "Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies" ("FSP 141R-1"). FSP 141R-1 amends the guidance in SFAS 141R to require that assets acquired and liabilities assumed in a business combination that arise from contingencies be recognized at fair value if fair value can be reasonably determined. If the fair value cannot be reasonably determined, then the assets and liabilities should be recognized at the amount that would be recognized in accordance with SFAS No. 5, "Accounting for Contingencies," and FASB Interpretation No. 14, "Reasonable Estimation of the Amount of a Loss." The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 157-4, "Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly" ("FSP 157-4"). FSP 157-4 provides additional guidance for estimating fair value in accordance with SFAS 157 when the volume and level of activity for the asset or liability have significantly decreased. FSP 157-4 also includes guidance on identifying circumstances that indicate a transaction is not orderly. FSP 157-4 was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 115-2 and FAS 124-2, "Recognition and Presentation of Other-Than-Temporary Impairments" ("FSP 115-2 and 124-2"). FSP 115-2 and 124-2 amends the other-than-temporary impairment guidance related to debt securities and expands and increases the frequency of existing disclosures about other-than-temporary impairments for debt and equity securities. In addition, FSP 115-2 and 124-2 requires that the annual disclosures in SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities," and FSP No. FAS 115-1 and FAS 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," be made for interim periods. FSP 115-2 and 124-2 was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

In April 2009, the SEC issued Staff Accounting Bulletin ("SAB") No. 111, *"Other Than Temporary Impairment of Certain Investments in Debt and Equity Securities"* ("SAB 111"). SAB 111 amends SAB Topic 5M to reflect the guidance in FSP 115-2 and 124-2. SAB 111 maintains the prior staff views related to equity securities but amends SAB Topic 5M to exclude debt securities from its scope. The adoption of SAB 111 did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued FSP No. FAS 107-1 and APB 28-1, *"Interim Disclosures about Fair Value of Financial Instruments"* ("FSP 107-1 and 28-1"). FSP 107-1 and 28-1 requires disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP 107-1 and 28-1 was effective for interim reporting periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2009, the FASB issued SFAS No. 165, *"Subsequent Events"* ("SFAS 165"). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 requires the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 was effective for interim or annual financial periods ending after June 15, 2009. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2009, the SEC issued SAB No. 112, *"Update of Codification of Staff Accounting Bulletins"* ("SAB 112"). SAB 112 amends or rescinds portions of the SEC staff's interpretive guidance included in the Staff Accounting Bulletin Series in order to make the relevant interpretive guidance consistent with SFAS 141R and SFAS No. 160, *"Noncontrolling Interests in Consolidated Financial Statements."* The adoption of SAB 112 did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In June 2009, the FASB issued SFAS No. 167, *"Amendments to FASB Interpretation No. 46(R)"* ("SFAS 167"). SFAS 167 eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a variable interest entity ("VIE") based on whether the entity (1) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (2) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. SFAS 167 requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. SFAS 167 is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of SFAS 167 will have a material impact on its consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *"The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles"* ("SFAS 168"). SFAS 168 establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles ("GAAP"). Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. SFAS 168 replaces SFAS No. 162, *"The Hierarchy of Generally Accepted Accounting Principles."* SFAS 168 is effective for financial statements issued for interim and

Table of Contents

annual periods ending after September 15, 2009. The Company does not expect the adoption of SFAS 168 will have a material impact on its consolidated financial statements.

Results of Operations*Net Sales Trends*

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	Change	Percent Change	2009	2008	Change	Percent Change
United States	\$ 143.5	\$ 139.7	\$ 3.8	2.7%	\$ 278.4	\$ 275.2	\$ 3.2	1.2%
International	192.0	187.9	4.1	2.2%	370.6	349.2	21.4	6.1%
Total net sales	\$ 335.5	\$ 327.6	\$ 7.9	2.4%	\$ 649.0	\$ 624.4	\$ 24.6	3.9%

In the United States, the \$3.8 million and \$3.2 million increases in net sales for the three and six months ended June 30, 2009, respectively, were due primarily to:

Heart Valve Therapy products, which increased net sales by \$10.2 million and \$13.4 million, respectively, driven primarily by the *Magna* mitral valve and the *Carpentier-Edwards PERIMOUNT Magna with ThermaFix* valve;

partially offset by:

Vascular products, which decreased net sales by \$6.3 million and \$10.4 million, respectively, primarily due to the divestiture of the *LifeStent* product line in mid-January 2008. Sales after the divestiture result from the on-going manufacturing requirements of the sale agreement, which will continue until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

International net sales increased \$4.1 million and \$21.4 million for the three and six months ended June 30, 2009, respectively, due primarily to:

Heart Valve Therapy products, which increased net sales by \$9.4 million and \$29.9 million, respectively. The increase was driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, and the *Magna* aortic valve in Japan, offset by foreign exchange fluctuations of \$10.2 million and \$15.3 million, respectively;

partially offset by:

Critical Care products, which decreased net sales by \$2.7 million and \$3.9 million, respectively, due primarily to foreign exchange fluctuations of \$6.2 million and \$9.5 million, respectively, offset by increased sales of *FloTrac* systems of \$2.4 million and \$4.7 million, respectively; and

Vascular products, which decreased net sales by \$2.3 million and \$4.0 million, respectively, due primarily to the divestiture of the *LifeStent* product line and the termination of distributed sales in Europe of a specialty vascular graft.

Foreign currency exchange rate fluctuations are due primarily to the weakening of the Euro against the United States dollar. The impact of foreign currency exchange rate fluctuations on net sales would not necessarily be indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs and the Company's hedging activities. For more information see Item 3, "*Quantitative and Qualitative Disclosures About Market Risk*."

Table of Contents***Net Sales by Product Line***

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2009	2008	Change	Percent Change	2009	2008	Change	Percent Change
Heart Valve Therapy	\$ 182.1	\$ 162.6	\$ 19.5	12.0%	\$ 352.5	\$ 309.3	\$ 43.2	14.0%
Critical Care	113.0	116.6	(3.6)	(3.1)%	217.5	223.3	(5.8)	(2.6)%
Cardiac Surgery Systems	24.1	23.5	0.6	2.6%	46.6	44.9	1.7	3.8%
Vascular	16.3	24.9	(8.6)	(34.5)%	32.4	46.9	(14.5)	(30.9)%
Total net sales	\$ 335.5	\$ 327.6	\$ 7.9	2.4%	\$ 649.0	\$ 624.4	\$ 24.6	3.9%

Heart Valve Therapy

Net sales of Heart Valve Therapy products for the three and six months ended June 30, 2009 increased by \$19.5 million and \$43.2 million, respectively, including the negative impact from foreign currency exchange of \$10.2 million and \$15.3 million, respectively. The increases were due primarily to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$12.8 million and \$29.3 million, respectively; and

pericardial tissue valves, which increased net sales by \$3.9 million and \$12.6 million, respectively, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, the *Magna* with *ThermaFix* aortic and mitral valves, and the launch of the *Magna* aortic valve in Japan in the second quarter of 2008.

The Company expects that its *SAPIEN* transcatheter heart valve will continue to be a strong contributor to 2009 sales, and anticipates introducing new products across the aortic, mitral, and valve repair categories. The Company received Food and Drug Administration ("FDA") approval for its *Magna Ease* aortic valve in May 2009. The *Magna Ease* valve is designed for easier implantation and has the potential for leadership in the largest segment of surgical valve replacement. In July 2009, the Company received United States regulatory approval for its newest *Magna Mitral* valve, called the *Magna Mitral Ease*, and expects a limited launch of the product in the fourth quarter of 2009. The *Magna Mitral Ease* will extend the *Magna* platform by providing improved MIS capabilities and ease of implantation. The Company launched the *Carpentier-Edwards Physio II* ring in the United States and Europe during the first quarter of 2009, and expects this product to lift its growth in the repair segment. *Physio II* is the next generation repair product for the degenerative segment of mitral repair. In Japan, the Company received regulatory approval for its *IMR ETlogix* ring during the first quarter of 2009, and expects to launch this product in Japan pending reimbursement approval.

Critical Care

The \$3.6 million and \$5.8 million decreases in net sales of Critical Care products for the three and six months ended June 30, 2009, respectively, were due primarily to:

foreign exchange fluctuations, which decreased net sales by \$6.2 million and \$9.5 million, respectively; and

decreased sales of advanced hemodynamic monitoring products;

partially offset by:

FloTrac systems, which increased net sales by \$3.0 million and \$6.0 million, respectively.

Table of Contents

The Company expects worldwide *FloTrac* system sales to continue to be a significant contributor to Critical Care sales growth in 2009, and that it will continue to expand the market for minimally invasive hemodynamic monitoring. During the first quarter of 2009, the Company launched a third generation algorithm enhancement for the *FloTrac* system that enhances its accuracy when used in patients with sepsis and other critical illnesses. At the end of the third quarter of 2009, the Company expects to launch a substantial upgrade that will strengthen the *FloTrac* system's applicability in the medical intensive care unit. In addition, the Company anticipates launching a new hardware platform in the third quarter of 2009 with a simpler, more intuitive informational display, and expects to ultimately consolidate all parameters into one platform.

During the fourth quarter of 2008, the Company entered into a collaboration agreement with DexCom, Inc. to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. During 2009, the Company expects to complete clinical studies to support regulatory approval and, if the clinical studies are successful, anticipates introducing a first generation product in Europe by year end.

During the second quarter of 2009, the Company entered into a definitive agreement to sell certain assets related to its hemofiltration product line. The Company expects this transaction to close in the third quarter of 2009, pending regulatory approvals. For more information see "*Special Charges (Gains), net.*"

Cardiac Surgery Systems

The \$0.6 million and \$1.7 million increases in net sales of Cardiac Surgery Systems products for the three and six months ended June 30, 2009, respectively, were due primarily to MIS products, which increased net sales by \$1.5 million and \$2.7 million, respectively.

Vascular

The \$8.6 million and \$14.5 million decreases in net sales of Vascular products for the three and six months ended June 30, 2009, respectively, were due primarily to the reduced sales of the *LifeStent* product line which was divested in January 2008. The Company agreed to provide transition services, including manufacturing, to the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer. *LifeStent* sales after the divestiture result from the on-going manufacturing requirements of the sale agreement.

Gross Profit

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	Change	2009	2008	Change
Gross profit as a percentage of net sales	69.6%	65.5%	4.1 pts.	69.4%	65.4%	4.0 pts.

The 4.1 and 4.0 percentage point increases in gross profit as a percentage of net sales for the three and six months ended June 30, 2009, respectively, were driven by:

the impact from the expiration of foreign currency hedging contracts;

a 1.6 percentage point and a 1.4 percentage point increase in the United States gross profit as a percentage of net sales for the three and six months ended June 30, 2009, respectively, due primarily to a more profitable product mix, primarily from reduced sales of *LifeStent* products under the on-going manufacturing requirements of the *LifeStent* sale agreement; and

Table of Contents

a 0.8 percentage point and a 1.3 percentage point increase in international gross profit as a percentage of net sales for the three and six months ended June 30, 2009, respectively, due to a more profitable product mix, primarily higher sales of Heart Valve Therapy products and *FloTrac* systems;

partially offset by:

the unfavorable impact of Critical Care manufacturing variations.

Selling, General and Administrative (SG&A) Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	Change	2009	2008	Change
	(dollars in millions)					
SG&A expenses	\$ 128.5	\$ 126.5	\$ 2.0	\$ 250.4	\$ 241.1	\$ 9.3
SG&A expenses as a percentage of net sales	38.3%	38.6%	(0.3) pts.	38.6%	38.6%	

The \$2.0 million and \$9.3 million increases in SG&A expenses for the three and six months ended June 30, 2009, respectively, were due primarily to (1) investments for the transcatheter heart valve program in Europe and (2) higher sales-related spending in the Heart Valve Therapy product line. The increases were partially offset by the favorable impact of foreign currency (primarily the weakening of the Euro against the United States dollar) in the amounts of \$7.0 million and 10.9 million, respectively.

Research and Development Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	Change	2009	2008	Change
	(dollars in millions)					
Research and development expenses	\$ 42.6	\$ 35.4	\$ 7.2	\$ 82.5	\$ 68.3	\$ 14.2
Research and development expenses as a percentage of net sales	12.7%	10.8%	1.9 pts.	12.7%	10.9%	1.8 pts.

The increases in research and development expenses for the three and six months ended June 30, 2009 were due primarily to additional investments in the transcatheter heart valve, *FloTrac*, and glucose programs.

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

the Company received conditional Investigational Device Exemption ("IDE") approval from the 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, began enrollment during the second quarter of 2007 and will evaluate the *Edwards SAPIEN* transcatheter heart valve in patients who are considered at high risk for conventional open-heart valve surgery. In the first study arm ("Cohort A"), patients are randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. Cohort A will have 690 patients (enrollment completion is anticipated by the end of August 2009) and is a non-inferiority analysis. In the second study arm ("Cohort B"), patients who are deemed non-operable are randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. Enrollment of 350 patients in Cohort B, which is a superiority analysis, was completed in the first quarter of 2009. In addition, the Company received FDA approval for

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

continued access to Cohort B for all of its existing PARTNER sites, and is working with the FDA to achieve continued access to Cohort A once enrollment is complete to ensure this technology remains available for patients;

the Company received CE Mark approval in the fourth quarter of 2008 for European commercial sales of its *RetroFlex III* transfemoral delivery system, which simplifies the delivery of its *SAPIEN* valve. In addition, in the first quarter of 2009, the Company received IDE approval to use its *RetroFlex III* delivery system in its United States PARTNER trial;

the Company began its United States feasibility trial of the *SAPIEN* valve in the pulmonic position in April 2008. The goal of this clinical study is to enable physicians to offer a minimally invasive alternative to patients with a failing pulmonic valve, using the Company's transcatheter valve platform and *RetroFlex* delivery system. The Company expects to complete enrollment by the end of the third quarter of 2009 and then transition to a larger humanitarian device exemption trial; and

first-in-man cases using the Company's next generation transcatheter heart valve, the *Edwards SAPIEN XT*, were performed during the first quarter of 2008. In December 2008, the first three implants were performed in the CE Mark trial. In the second quarter of 2009, the first implants were performed with *SAPIEN XT* and *NovaFlex*, the Company's next generation valve and transfemoral delivery system. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, enabling it to better address the requirements of transfemoral delivery. In Europe, the Company believes the patients enrolled in its CE Mark PREVAIL trial will fulfill the requirements for a CE mark approval and support a European launch in the first quarter of 2010. In the United States, the Company anticipates submitting an IDE in the third quarter of 2009, which could result in approval for a clinical trial before the end of 2009.

The following are the developments related to the Company's transcatheter mitral valve program (formerly ev3, Inc.'s percutaneous mitral valve repair program):

in October 2008, the Company announced the continuation of the EVOLUTION II clinical trial of the *Edwards MONARC* system which is deployed into the coronary sinus. The Company has expanded the trial to include specialty heart failure centers in order to increase the pace of enrollment.

Special Charges (Gains), net

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
	(in millions)			
Loss (gain) on sale of product lines	\$ 1.5	\$	\$(25.5)	\$ 8.1
Sale of distribution rights			(2.8)	
Reserve reversal			(1.0)	
Litigation settlement				2.1
Realignment expenses, net		(0.8)		(0.9)
Special charges (gains), net	\$ 1.5	\$(0.8)	\$(29.3)	\$ 9.3

Loss (Gain) on Sale of Product Lines

In June 2009, the Company entered into a definitive agreement to sell certain assets related to its hemofiltration product line. Under the terms of the agreement, the Company will receive a cash

Table of Contents

payment of approximately \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years. The Company will provide transition services to the buyer. This transaction allows the Company to better focus on its global strategic priorities. The Company expects this transaction to close in the third quarter of 2009, pending regulatory approvals. In June 2009, the Company recorded a \$1.5 million charge for transaction costs and employee severance related to the pending sale.

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. The remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

In connection with the *LifeStent* transaction, the Company recorded in January 2008 a pre-tax loss of \$8.1 million consisting of the cash proceeds of \$74.0 million, offset by a \$34.6 million write-off of goodwill associated with this product line, \$36.9 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, \$6.9 million of deferred revenue related to the transition services the Company has agreed to provide, and \$3.7 million of transaction and other costs related to the sale.

Sale of Distribution Rights

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

Reserve Reversal

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

Litigation Settlement

In March 2008, the Company recorded a \$2.1 million charge for the settlement of litigation related to its divested United States perfusion services business. Under the terms of the divestiture, this was the Company's last outstanding case.

Realignment Expenses, net

In June 2008, the Company recorded a \$0.8 million reversal of previously accrued severance costs from the fourth quarter of 2007 related to the global reduction in workforce.

In March 2008, the Company recorded a \$1.3 million charge for executive severance associated with the Company's business realignment, offset by a \$1.4 million reversal of the December 2007 accrued severance related to the sale of the *LifeStent* product line. As of June 30, 2009, all payments related to the executive severance charge were substantially complete.

In December 2007, the Company recorded realignment expenses of \$13.9 million primarily related to (1) severance expenses associated with the sale of the Company's *LifeStent* product line and a global reduction in workforce, primarily in the United States, Europe, and Japan (impacting approximately

Table of Contents

180 employees), and (2) the termination of the Company's intra-aortic balloon pump distribution agreement in Japan. As of June 30, 2009, remaining payments of approximately \$1.7 million are expected to be paid through the end of 2009.

Interest Expense, net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2009	2008	Change	2009	2008	Change
	(in millions)					
Interest expense	\$ 0.5	\$ 1.9	\$ (1.4)	\$ 1.3	\$ 4.0	\$ (2.7)
Interest income	(0.3)	(1.5)	1.2	(1.0)	(3.2)	2.2
Interest expense, net	\$ 0.2	\$ 0.4	\$ (0.2)	\$ 0.3	\$ 0.8	\$ (0.5)

The decrease in interest expense for the three and six months ended June 30, 2009 resulted primarily from lower interest rates and a lower average debt balance as compared to the prior year period. The decrease in interest income resulted primarily from lower average interest rates and lower cash and short-term investment balances as compared to the prior year period.

Other (Income) Expense, net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Foreign exchange (gains) losses, net	\$ (2.0)	\$ 1.2	\$ (2.5)	\$ 2.3
Accounts receivable securitization costs		0.5		1.1
Investment impairment and realized losses		0.2		0.8
Loss (gain) on investments in unconsolidated affiliates	0.1	(0.6)	1.0	(1.3)
Other	(0.1)	(0.3)	(0.1)	(0.7)
Other (income) expense, net	\$ (2.0)	\$ 1.0	\$ (1.6)	\$ 2.2

The foreign exchange (gains) losses for the three and six months ended June 30, 2009 relate to the foreign currency fluctuations on the Company's global trade and intercompany receivable and payable balances. Foreign exchange resulted in a net gain in 2009 compared to a net loss in 2008 due primarily to fluctuations in the Euro.

The decrease in securitization costs in 2009 was due to the Company's termination of its securitization programs in the United States in August 2008 and in Japan in February 2009.

The investment impairment and realized losses represent the realized losses and estimated impairment in the value of the Company's investment in the Bank of America Columbia Strategic Cash fund. See the "Liquidity and Capital Resources" section for further information.

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

Provision for Income Taxes

The provision for income taxes consists of provisions for federal, state, and foreign income taxes. The Company operates in an international environment with significant operations in various locations

Table of Contents

outside the United States, which have statutory tax rates lower than the United States tax rate. Accordingly, the consolidated income tax rate is a composite rate reflecting the earnings in the various locations and the applicable rates. The effective income tax rates were 24.4% and 26.9% for the three and six months ended June 30, 2009, respectively, and 23.8% and 33.3% for the three and six months ended June 30, 2008, respectively. The income tax rate for the six months ended June 30, 2009 included the tax effect on a *LifeStent* milestone receipt (see the "*Special Charges (Gains), net*" section for further information). The income tax rate for the six months ended June 30, 2008 included the tax effect on the sale of the *LifeStent* product line.

As of June 30, 2009, March 31, 2009, and December 31, 2008, the liability for income taxes associated with uncertain tax positions was \$43.0 million, \$38.0 million, and \$35.9 million, respectively. These liabilities could be reduced by \$3.8 million, \$1.9 million, and \$2.3 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 \$39.2 million, \$36.1 million, and \$33.6 million, respectively, if recognized, would favorably affect the Company's effective tax rate. Changes to potential interest expense upon settlement during the period were immaterial.

In February 2009, California enacted tax legislation which will be effective beginning 2011. The impact of the new legislation has been considered in determining the Company's tax provision for the three and six months ended June 30, 2009, including the realizability of its California research and development credit carryforward.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities, and cash from operations. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments. The Company is not currently experiencing any limitation on access to its credit facility as a result of the recent turmoil in global financial markets. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

The Company has a Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), which matures on September 29, 2011. The Credit Agreement provides up to an aggregate of \$500.0 million in one- to six-month borrowings in multiple currencies. Borrowings currently bear interest at the London interbank offering rate ("LIBOR") plus 0.40%, which includes a facility fee subject to adjustment for leverage ratio changes as defined in the Credit Agreement. The Company pays a facility fee regardless of available or outstanding borrowings, currently at an annual rate of 0.075%. All amounts outstanding under the Credit Agreement have been classified as long-term obligations, as these borrowings are expected to be refinanced pursuant to the Credit Agreement. As of June 30, 2009, borrowings of \$113.9 million were outstanding under the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with at June 30, 2009.

The Company previously securitized, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in the United States and Japan. In August 2008, the Company terminated its securitization program in the United States, and repurchased \$50.0 million of accounts receivable. In February 2009, the Company terminated its securitization program in Japan and paid \$39.0 million for the outstanding accounts receivable and February collections. The securitization programs no longer offered an attractive financing alternative.

In December 2007, the Company received notification that the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund in which the Company had

Table of Contents

invested \$50.1 million as of December 31, 2007, was being closed to new subscriptions or redemptions, resulting in the Company's inability to immediately redeem its investments for cash. During the three and six months ended June 30, 2009, the Company recognized unrealized gains of \$0.3 million and \$0.4 million, respectively, included in "*Accumulated Other Comprehensive Loss*." The fair value of the Company's remaining investment in this fund as of June 30, 2009 and December 31, 2008 was estimated to be \$7.1 million and \$10.9 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$5.2 million through the second quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of June 30, 2009. The remaining \$1.9 million of the investment is expected to be received after the second quarter of 2010, and has been classified as "*Other Assets*."

In June 2009, the Company entered into a definitive agreement to sell certain assets related to its hemofiltration product line. Under the terms of the agreement, the Company will receive a cash payment of approximately \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years. The Company will provide transition services to the buyer. The Company expects this transaction to close in the third quarter of 2009, pending regulatory approvals.

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company recorded a gain of \$23.0 million for the receipt of a *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval, and the remaining \$15.0 million milestone payment will be recorded upon the transfer of *LifeStent* device manufacturing to the buyer.

In July 2008, the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$250.0 million of the Company's common stock. During the six months ended June 30, 2009, the Company repurchased 0.9 million shares at an aggregate cost of \$54.5 million and as of June 30, 2009 had remaining authority to purchase \$139.0 million of common stock.

At June 30, 2009, 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, 2008.

Net cash flows provided by **operating activities** of \$27.9 million for the six months ended June 30, 2009 decreased \$31.0 million from the same period a year ago. This decrease was due primarily to a \$39.0 million cash payment during the first quarter of 2009 to terminate the Company's accounts receivable securitization program in Japan.

Net cash provided by **investing activities** of \$2.7 million for the six months ended June 30, 2009 consisted primarily of \$27.0 million of cash received for a milestone achievement associated with the *LifeStent* pre-market approval and a \$3.5 million cash advance related to the sale of the hemofiltration product line which is expected to close in the third quarter of 2009, partially offset by capital expenditures of \$28.2 million.

Net cash provided by investing activities of \$77.8 million for the six months ended June 30, 2008 consisted primarily of \$74.0 million of cash received from the sale of the *LifeStent* product line and

Table of Contents

\$23.4 million in cash redemptions associated with the Bank of America Columbia Strategic Cash fund, partially offset by capital expenditures of \$20.7 million.

Net cash used in **financing activities** of \$69.4 million for the six months ended June 30, 2009 consisted primarily of net payments on long-term debt of \$58.4 million and purchases of treasury stock of \$54.5 million, partially offset by the proceeds from stock plans of \$33.2 million.

Net cash used in financing activities of \$95.7 million for the six months ended June 30, 2008 consisted primarily of purchases of treasury stock of \$214.8 million, partially offset by net proceeds from long-term debt of \$74.5 million and the proceeds from stock plans of \$35.3 million.

Critical Accounting Policies

The consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States which require the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and revenues and expenses during the periods reported. Actual results could differ from those estimates. Information with respect to the Company's critical accounting policies which the Company believes could have the most significant effect on the Company's reported results and require subjective or complex judgments by management is contained on pages 38-43 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, 2008. Management believes that at June 30, 2009, there had been no material changes to this information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

For a complete discussion of the Company's exposure to interest rate risk, refer to Item 7A "*Quantitative and Qualitative Disclosures About Market Risk*" on pages 46-48 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008. There have been no significant changes from the information discussed therein.

Currency Risk

For a complete discussion of the Company's exposure to foreign currency risk, refer to Item 7A "*Quantitative and Qualitative Disclosures About Market Risk*" on pages 46-48 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008. There have been no significant changes from the information discussed therein.

Credit Risk

For a complete discussion of the Company's exposure to credit risk, refer to Item 7A "*Quantitative and Qualitative Disclosures About Market Risk*" on pages 46-48 of the Company's Annual Report on Form 10-K for the year ended December 31, 2008. 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.

Table of Contents

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, 2009, Edwards Lifesciences had \$20.3 million of investments in equity instruments of other companies and had recorded unrealized losses of \$2.4 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.

The Company holds an investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, which was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investments for cash. During the three and six months ended June 30, 2009, the Company recognized unrealized gains of \$0.3 million and \$0.4 million, respectively, included in "*Accumulated Other Comprehensive Loss*." The fair value of the Company's remaining investment in this fund as of June 30, 2009 was estimated to be \$7.1 million based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$5.2 million through the second quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of June 30, 2009. The remaining \$1.9 million of the investment is expected to be received after the second quarter of 2010, and has been classified as "*Other Assets*." The markets relating to these investments are subject to ongoing illiquidity and remain uncertain. There may be further decreases in the value of these investments until the fund is fully liquidated.

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, 2009. Based on their evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that such controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. There have been no changes in the Company's internal controls over financial reporting that were identified during this evaluation that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

Part II. Other Information

Item 1. Legal Proceedings

In August 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"); Cook, Inc. ("Cook"); and W.L. Gore & Associates ("Gore") alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. In September 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced in January 2006, Edwards Lifesciences settled this litigation with Medtronic. Edwards Lifesciences remains in litigation with Cook and Gore. In March 2008, the District Court granted summary judgment of non-infringement in favor of Cook and subsequently in favor of Gore. In 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals; the appeal was heard in July 2009.

In May 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007, and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. In January 2009, the United Kingdom Court determined that the Andersen patent was valid but not infringed by CoreValve. The parties have filed cross-appeals on the validity and infringement decisions. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. This lawsuit is ongoing.

In February 2008, 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 in each country are invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. As announced, the German Court ruled in March 2009 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. Cook is appealing the judgments in Germany and the United Kingdom.

In addition, Edwards Lifesciences is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matter or other claim, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations, or liquidity.

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

Table of Contents

will not have a material impact on Edwards Lifesciences' financial position, results of operations, or liquidity.

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

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (a)
April 1, 2009 through April 30, 2009	157,500	\$ 58.97	157,500	\$ 157.4
May 1, 2009 through May 31, 2009	150,000	63.20	150,000	147.9
June 1, 2009 through June 30, 2009	137,500	65.01	137,500	139.0
Total	445,000	62.26	445,000	

(a)

On July 11, 2008, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$250.0 million of the Company's common stock.

Item 4. Submission of Matters to a Vote of Security Holders

The Company's annual meeting of stockholders was held on May 7, 2009. Each of the nominees for directors, as listed in the proxy statement, was elected with the number of votes set forth below:

	In Favor	Against	Abstain
Mike R. Bowlin	42,309,022	8,538,109	58,856
William J. Link, Ph.D	50,535,212	312,524	58,251
Barbara J. McNeil, M.D., Ph.D	42,323,663	8,521,041	61,283
Michael A. Mussallem	41,895,125	8,954,048	56,814

In addition, as of May 7, 2009, the following directors' terms of office are continuing:

John T. Cardis
Robert A. Ingram
David E.I. Pyott

The results of the other matters voted upon at the annual meeting are as follows:

	In Favor	Against	Abstain
Amendment and restatement of the Company's Long-Term Stock Incentive Compensation Program	33,571,149	13,689,335	113,746
Ratification of the appointment of PricewaterhouseCoopers LLP as the independent registered public accounting firm for fiscal year 2009	49,864,651	1,001,409	39,926

Table of Contents

Item 6. Exhibits

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

- 10.14 2001 Employee Stock Purchase Plan for United States Employees (as amended and restated on July 9, 2009)
- 10.15 2001 Employee Stock Purchase Plan for International Employees (as amended and restated on July 9, 2009)
- 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

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 7, 2009

By: /s/ THOMAS M. ABATE

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

40

Table of Contents

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit

No.	Description
10.14	2001 Employee Stock Purchase Plan for United States Employees (as amended and restated on July 9, 2009)
10.15	2001 Employee Stock Purchase Plan for International Employees (as amended and restated on July 9, 2009)
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