

Edwards Lifesciences Corp
Form 10-Q
May 08, 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 March 31, 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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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

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

Large accelerated filer <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 April 30, 2009 was 56,004,555.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

FORM 10-Q

For the quarterly period ended March 31, 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>4</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>20</u>
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>32</u>
<u>Item 4.</u>	
<u>Controls and Procedures</u>	<u>33</u>
<u>Part II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	<u>34</u>
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>35</u>
<u>Item 6.</u>	
<u>Exhibits</u>	<u>35</u>
<u>Signature</u>	<u>36</u>
<u>Exhibits</u>	<u>37</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)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	\$ 146.7	\$ 218.7
Short-term investments (Note 3)	3.7	8.1
Accounts and other receivables, net of allowances of \$10.5 and \$9.9, respectively (Note 4)	255.8	204.7
Inventories, net	146.1	151.8
Deferred income taxes	35.6	42.4
Prepaid expenses	35.2	30.7
Other current assets	25.9	35.5
Total current assets	649.0	691.9
Property, plant and equipment, net	229.8	230.1
Goodwill	315.7	315.7
Other intangible assets, net	92.6	96.9
Investments in unconsolidated affiliates	16.6	14.7
Deferred income taxes	36.9	37.7
Other assets	18.3	13.2
	\$ 1,358.9	\$ 1,400.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 200.2	\$ 258.5
Long-term debt	123.0	175.5
Other long-term liabilities	92.4	87.4
Commitments and contingencies (Note 11)		
Stockholders' equity		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 74.3 and 73.7 shares issued, and 56.0 and 55.9 shares outstanding, respectively	74.3	73.7
Additional paid-in capital	969.0	940.4
Retained earnings	737.4	676.9
Accumulated other comprehensive loss	(33.8)	(35.4)
Treasury stock, at cost, 18.3 and 17.8 shares, respectively	(803.6)	(776.8)
Total stockholders' equity	943.3	878.8
	\$ 1,358.9	\$ 1,400.2

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

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(in millions, except per share information; unaudited)

	Three Months Ended March 31,	
	2009	2008
Net sales	\$313.5	\$296.8
Cost of goods sold	97.0	102.9
Gross profit	216.5	193.9
Selling, general and administrative expenses	121.9	114.6
Research and development expenses	39.9	32.9
Special (gains) charges, net (Note 2)	(30.8)	10.1
Interest expense, net	0.1	0.4
Other expense, net	0.4	1.2
Income before provision for income taxes	85.0	34.7
Provision for income taxes	24.5	16.5
Net income	\$ 60.5	\$ 18.2
Share information (Note 13)		
Earnings per share:		
Basic	\$ 1.08	\$ 0.32
Diluted	\$ 1.03	\$ 0.31
Weighted-average number of common shares outstanding:		
Basic	56.0	56.1
Diluted	58.5	58.5

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)

	Three Months Ended March 31,	
	2009	2008
Cash flows from operating activities		
Net income	\$ 60.5	\$ 18.2
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	14.2	13.5
Stock-based compensation (Note 10)	6.9	6.6
Deferred income taxes	1.7	(2.5)
Special (gains) charges, net (Note 2)	(27.4)	9.2
Loss on trading securities	0.5	1.3
Loss on investments		0.6
Other	2.4	(1.2)
Changes in operating assets and liabilities:		
Accounts and other receivables, net (Note 4)	(51.9)	(3.3)
Inventories, net	0.6	(0.2)
Accounts payable and accrued liabilities	(42.9)	(13.3)
Prepaid expenses and other current assets	(1.1)	(2.9)
Other	0.5	3.9
Net cash (used in) provided by operating activities	(36.0)	29.9
Cash flows from investing activities		
Capital expenditures	(11.1)	(9.1)
(Investments in) proceeds from unconsolidated affiliates, net	(1.6)	1.4
Investments in trading securities, net	(0.2)	
Proceeds from investments (Note 3)	3.2	16.6
Proceeds from sale of assets (Note 2)	27.0	74.0
Net cash provided by investing activities	17.3	82.9
Cash flows from financing activities		
Proceeds from issuance of long-term debt	30.0	13.2
Payments on long-term debt	(77.7)	(20.2)
Purchases of treasury stock	(26.8)	(100.0)
Proceeds from stock plans	16.7	6.2
Excess tax benefit from stock plans	4.3	1.3
Other	(0.4)	0.9
Net cash used in financing activities	(53.9)	(98.6)
Effect of currency exchange rate changes on cash and cash equivalents	0.6	6.9
Net (decrease) increase in cash and cash equivalents	(72.0)	21.1
Cash and cash equivalents at beginning of period	218.7	141.8
Cash and cash equivalents at end of period	\$ 146.7	\$ 162.9

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. 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 7 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 15 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 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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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 8 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.

New Accounting Standards Not Yet Adopted

In December 2008, the FASB issued FSP No. FAS 132(R)-1, "*Employers' Disclosures about Postretirement Benefit Plan Assets*" ("FSP 132R-1"). FSP 132R-1 requires additional disclosures about (a) how investment allocation decisions are made by management, (b) major categories of plan assets, (c) inputs and valuation techniques used to develop fair value measurements, including disclosures

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

similar to that required under SFAS 157, and (d) significant concentrations of risk. FSP 132R-1 is effective for fiscal years ending after December 15, 2009. The Company does not expect the adoption of FSP 132R-1 will have a material impact on its 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 is effective for interim and annual reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 157-4 will have a material impact on its 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 is effective for interim and annual reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 115-2 and 124-2 will have a material impact on its 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 Company does not expect the adoption of SAB 111 will 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 is effective for interim reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 107-1 and 28-1 will have a material impact on its consolidated financial statements.

2. SPECIAL (GAINS) CHARGES, NET

	Three Months Ended March 31,	
	2009	2008
(Gain) loss on sale of product line	\$(27.0)	\$ 8.1
Sale of distribution rights	(2.8)	
Reserve reversal	(1.0)	
Litigation settlement		2.1
Realignment expenses, net		(0.1)
Special (gains) charges, net	\$(30.8)	\$ 10.1

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

(Gain) Loss on Sale of Product Line

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 is 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 this 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 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 March 31, 2009, remaining payments of \$0.3 million for the executive severance charge are expected to be paid through the end of 2009.

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 March 31, 2009, remaining payments of approximately \$2.1 million are expected to be paid through the end of 2009.

Table of Contents**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 months ended March 31, 2009, the Company recognized an unrealized gain of \$0.1 million, included in "Accumulated Other Comprehensive Loss." During the three months ended March 31, 2008, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$0.6 million, included in "Other Expense, net." Since December 31, 2007, the Company has received cash redemptions of \$38.7 million. The fair value of the Company's remaining investment in this fund as of March 31, 2009 and December 31, 2008 was estimated to be \$7.8 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 for approximately \$3.7 million through the first quarter of 2010, which has been classified as "Short-term Investments" on the accompanying consolidated condensed balance sheet as of March 31, 2009. The remaining \$4.1 million of the investment is expected to be received after the first 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):

	March 31, 2009	December 31, 2008
Raw materials	\$ 35.1	\$ 36.5
Work in process	24.0	19.5
Finished products	87.0	95.8
	\$ 146.1	\$ 151.8

6. OTHER INTANGIBLE ASSETS

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

	Patents	Unpatented Technology	Other	Total
March 31, 2009				
Cost	\$ 205.0	\$ 35.0	\$ 13.4	\$ 253.4
Accumulated amortization	(131.5)	(25.3)	(4.0)	(160.8)
Net carrying value	\$ 73.5	\$ 9.7	\$ 9.4	\$ 92.6
December 31, 2008				
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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Patents include \$8.3 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of March 31, 2009.

Amortization expense related to other intangible assets was \$5.3 million and \$4.6 million for the three months ended March 31, 2009 and 2008, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2009	\$20.7
2010	19.1
2011	15.2
2012	12.9
2013	12.8

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 March 31, 2009.

7. FAIR VALUE MEASUREMENTS

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 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):

	March 31, 2009			Total
	Level 1	Level 2	Level 3	
Assets				
Investment in the Bank of America Columbia Strategic Cash fund	\$	\$	\$ 7.8	\$ 7.8
Investments held for executive deferred compensation plan	9.9			9.9
Investments in unconsolidated affiliates	6.3			6.3
Derivatives		5.9		5.9
	\$16.2	\$ 5.9	\$ 7.8	\$29.9

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

	December 31, 2008			
	Level 1	Level 2	Level 3	Total
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

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):

	Three Months Ended March 31, 2009		
	Investment in the Columbia Strategic Cash Fund	Residual Interest in Accounts Receivable Securitizations	Total
Balance at December 31, 2008	\$ 10.9	\$ 6.6	\$ 17.5
Total gains realized and unrealized:			
Included in other comprehensive loss	0.1		0.1
Purchases, sales, issuances, and settlements	(3.2)	(6.6)	(9.8)
Balance at March 31, 2009	\$ 7.8	\$	\$ 7.8

	Three Months Ended March 31, 2008		
	Investment in the Columbia Strategic Cash Fund	Residual Interest in Accounts Receivable Securitizations	Total
Balance at December 31, 2007	\$ 49.4	\$ 8.8	\$ 58.2
Total losses realized and unrealized:			
Included in earnings(a)	(0.6)		(0.6)
Purchases, sales, issuances, and settlements	(16.6)	4.4	(12.2)
Balance at March 31, 2008	\$ 32.2	\$ 13.2	\$ 45.4

(a)

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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

Table of Contents

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.

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 three months ended March 31, 2009, the Company had no impairments related to these assets.

8. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

Edwards Lifesciences maintains an overall risk management strategy that may incorporate the use of a variety of derivative financial instruments, as summarized below, to mitigate its exposure to significant unplanned fluctuations in earnings and cash flow caused by volatility in interest rates and currency exchange rates. Derivative instruments that are used as part of the Company's interest and foreign exchange rate management strategy can include interest rate swaps, option-based products, and forward exchange contracts. As of March 31, 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.

	March 31, 2009	
	Notional	Fair Value
	Amount	Asset
		(Liability)
	(in millions)	
Forward currency agreements	\$227.5	\$ 5.1
Currency option contracts	29.2	0.8

The Company utilizes forward exchange contracts 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. All derivative

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

financial instruments are with commercial banks and investment banking firms assigned investment grade ratings of "A" or better with national rating agencies.

Certain of the Company's derivative instrument contracts provide that if certain events of default occur, as outlined in the master-netting agreements, loss positions on these instruments must be fully collateralized beyond a threshold amount of \$15 million. Additionally, the Company would be required to collateralize liability positions should it be in default under its Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"). As of March 31, 2009, no derivative instruments with credit-risk-related contingent features were in a net liability position, and because the aggregate fair value of these instruments was less than the threshold amount, no collateral was required. As of March 31, 2009, the Company was in compliance with the Credit Agreement.

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

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated condensed balance sheet as of March 31, 2009 (in millions):

	March 31, 2009			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments under SFAS 133				
Foreign exchange contracts	Prepaid expenses	\$ 5.9	Accrued liabilities	\$

The following tables present the effect of derivative instruments on the consolidated statement of operations for the three months ended March 31, 2009 (in millions):

	Three Months Ended March 31, 2009	
	Location of Gain or (Loss)	Amount of Gain or (Loss)
	Recognized in Income on Derivative	Recognized in Income on Derivative
Derivatives in SFAS 133 fair value hedging relationships		
Foreign exchange contracts	Other expense, net	\$ 0.8

Table of Contents

Three Months Ended March 31, 2009		
Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)	Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Loss into Income	Amount of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Loss into Income (Effective Portion)
Derivatives in SFAS 133 cash flow hedging relationships		

Foreign exchange contracts	\$ 12.1	Cost of goods sold \$ 1.3
----------------------------	---------	---------------------------

The Company expects that during the next twelve months it will reclassify to earnings a \$4.8 million gain currently recorded in "Accumulated Other Comprehensive Loss." For the three months ended March 31, 2009, the Company did not record any expense related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness.

9. DEFINED BENEFIT PLANS

The components of net periodic benefit costs for the three months ended March 31, 2009 and 2008 were as follows (in millions):

	Three Months Ended March 31,	
	2009	2008
Service cost	\$ 1.4	\$ 1.0
Employee contributions		
Interest cost	0.4	0.3
Expected return on plan assets	(0.2)	(0.2)
Amortization of prior service cost and other	0.1	
Net periodic pension benefit cost	\$ 1.7	\$ 1.1

10. STOCK-BASED COMPENSATION

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three months ended March 31, 2009 and 2008 was as follows (in millions):

	Three Months Ended March 31,	
	2009	2008
Cost of goods sold	\$0.6	\$0.6
Selling, general and administrative expenses	5.2	4.6
Research and development expenses	1.1	1.4
Total stock-based compensation expense	\$6.9	\$6.6

At March 31, 2009, the total remaining compensation cost related to unvested stock options, restricted stock units, and employee stock purchase subscription awards amounted to \$40.7 million and will be amortized on a straight-line basis over a weighted-average vesting period of approximately 27 months.

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 March 31,	
	2009	2008
Risk-free interest rate	1.7%	2.7%
Expected dividend yield	None	None
Expected volatility	23.7%	18.5%
Expected term (years)	4.9	4.9
Fair value, per share	\$ 14.87	\$ 9.77

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 March 31,	
	2009	2008
Risk-free interest rate	0.3%	3.3%
Expected dividend yield	None	None
Expected volatility	25.5%	23.8%
Expected term (years)	0.6	0.6
Fair value, per share	\$ 12.49	\$ 10.58

11. 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 September 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

CoreValve. The Company is considering an appeal. 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 has counterclaimed, alleging infringement by Edwards. As announced, following the trial in Germany on infringement, the Court ruled on March 19, 2009, that the Company does not infringe the Cook patent.

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.

12. COMPREHENSIVE INCOME

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

	Three Months Ended March 31,	
	2009	2008
Net income	\$60.5	\$18.2
Other comprehensive income:		
Currency translation adjustments	(6.1)	18.0
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	1.1	(3.7)
Unrealized net gain (loss) on cash flow hedges, net of tax	6.6	(4.6)
Comprehensive income	\$62.1	\$27.9

13. EARNINGS PER SHARE

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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 March 31,	
	2009	2008
Basic:		
Net income	\$ 60.5	\$ 18.2
Weighted-average shares outstanding	56.0	56.1
Basic earnings per share	\$ 1.08	\$ 0.32
Diluted:		
Net income applicable to diluted shares	\$ 60.5	\$ 18.2
Weighted-average shares outstanding	56.0	56.1
Dilutive effect of stock plans	2.5	2.4
Diluted weighted-average shares outstanding	58.5	58.5
Diluted earnings per share	\$ 1.03	\$ 0.31

Stock options and restricted stock units to purchase 1.0 million and 3.4 million shares for the three months ended March 31, 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. For the three months ended March 31, 2008, the effect of 2.7 million potential common share equivalents relating to the Company's \$150.0 million convertible debentures were excluded from the computation of diluted earnings per share because the result would have been anti-dilutive. The convertible debentures were redeemed on June 9, 2008.

14. INCOME TAXES

The effective income tax rates were 28.8% and 47.6% for the three months ended March 31, 2009 and 2008, respectively. The income tax rate for the three months ended March 31, 2009 included the tax effect on the *LifeStent* milestone receipt. The income tax rate for the three months ended March 31, 2008 included the tax effect on the sale of the *LifeStent* product line.

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

Table of Contents

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 March 31, 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. Most of the provisions contained in the legislation are prospective in nature and take effect for taxable years beginning on or after January 1, 2011. The impact of the new legislation has been considered in the period in determining the Company's tax provision, including the realizability of its California research and development credit carryforward.

15. 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 will be expensed to "*Research and Development Expenses*" as incurred, and the regulatory approval milestones will be recorded as "*Other Intangible Assets*" and amortized over the useful life of the product. In addition, DexCom will receive either a profit-sharing payment of ten percent or a royalty of up to six percent of 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 \$2.1 million of product development costs for the three months ended March 31, 2009.

16. SEGMENT INFORMATION

Edwards Lifesciences conducts operations worldwide and is managed in four geographical regions: United States, Europe, Japan, and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease. The Company has reclassified certain prior period amounts to conform to internal methods of managing and monitoring performance at the segment level during the current period.

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 March 31,	
	2009	2008
Net Sales		
United States	\$ 134.9	\$ 135.5
Europe	100.9	85.3
Japan	41.3	37.4
Rest of world	34.0	30.3
Total segment net sales	\$ 311.1	\$ 288.5
Pre-Tax Income		
United States	\$ 72.4	\$ 71.0
Europe	34.6	25.9
Japan	19.4	15.7
Rest of world	8.0	7.2
Total segment pre-tax income	\$ 134.4	\$ 119.8

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 March 31,	
	2009	2008
Net Sales Reconciliation		
Segment net sales	\$ 311.1	\$ 288.5
Foreign currency	2.4	8.3
Consolidated net sales	\$ 313.5	\$ 296.8
Pre-tax Income Reconciliation		
Segment pre-tax income	\$ 134.4	\$ 119.8
Unallocated amounts:		
Corporate items	(85.3)	(70.3)
Special gains (charges), net	30.8	(10.1)
Interest expense, net	(0.1)	(0.4)
Foreign currency	5.2	(4.3)
Consolidated pre-tax income	\$ 85.0	\$ 34.7

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 March 31,	
	2009	2008
	(in millions)	
Net Sales by Geographic Area		
United States	\$ 134.9	\$ 135.5
Other countries	178.6	161.3
	\$ 313.5	\$ 296.8
Net Sales by Major Product and Service Area		
Heart Valve Therapy	\$ 170.4	\$ 146.7
Critical Care	104.5	106.7
Cardiac Surgery Systems	22.5	21.4
Vascular	16.1	22.0
	\$ 313.5	\$ 296.8

	March 31, 2009	December 31, 2008
	(in millions)	
Long-Lived Tangible Assets by Geographic Area		
United States	\$ 173.2	\$ 171.4
Other countries	91.5	86.6
	\$ 264.7	\$ 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 to treat advanced cardiovascular disease 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, artificial implantable grafts, and stents ("*LifeStent*" products) for which approval is being sought for use in the treatment of peripheral vascular disease. 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.

Table of Contents

There is mounting pressure to contain healthcare costs in the face of this increasing demand, which has resulted in pricing and market share pressures. The cardiovascular segment of the medical device industry is dynamic, and technology, cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs are expected to continue to drive change.

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

Table of Contents

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.

New Accounting Standards Not Yet Adopted

In December 2008, the FASB issued FSP No. FAS 132(R)-1, "*Employers' Disclosures about Postretirement Benefit Plan Assets*" ("FSP 132R-1"). FSP 132R-1 requires additional disclosures about (a) how investment allocation decisions are made by management, (b) major categories of plan assets, (c) inputs and valuation techniques used to develop fair value measurements, including disclosures similar to that required under SFAS 157, and (d) significant concentrations of risk. FSP 132R-1 is effective for fiscal years ending after December 15, 2009. The Company does not expect the adoption of FSP 132R-1 will have a material impact on its 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 is effective for interim and annual reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 157-4 will have a material impact on its consolidated financial statements.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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 is effective for interim and annual reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 115-2 and 124-2 will have a material impact on its 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 Company does not expect the adoption of SAB 111 will 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 is effective for interim reporting periods ending after June 15, 2009. The Company does not expect the adoption of FSP 107-1 and 28-1 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 March 31,			Percent Change
	2009	2008	Change	
United States	\$ 134.9	\$ 135.5	\$ (0.6)	(0.4)%
International	178.6	161.3	17.3	10.7%
Total net sales	\$ 313.5	\$ 296.8	\$ 16.7	5.6%

In the United States, the \$0.6 million decrease in net sales for the three months ended March 31, 2009 was due primarily to:

Vascular products, which decreased net sales by \$4.1 million, 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;

partially offset by:

Heart Valve Therapy products, which increased net sales by \$3.2 million, driven primarily by the *Magna* mitral valve and the *Carpentier-Edwards PERIMOUNT Magna* with *ThermaFix* valve.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

International net sales increased \$17.3 million for the three months ended March 31, 2009 due primarily to:

Heart Valve Therapy products, which increased net sales by \$20.5 million, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, and the launch of the *Magna* aortic valve in Japan in the second quarter of 2008;

partially offset by:

Vascular products, which decreased net sales by \$1.7 million, primarily due to the divestiture of the *LifeStent* product line.

Foreign currency exchange rate fluctuations included above decreased net sales by \$10.0 million for the three months ended March 31, 2009 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."

Net Sales by Product Line

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

	Three Months Ended March 31,			Percent Change
	2009	2008	Change	
Heart Valve Therapy	\$170.4	\$146.7	\$ 23.7	16.2%
Critical Care	104.5	106.7	(2.2)	(2.1)%
Cardiac Surgery Systems	22.5	21.4	1.1	5.1%
Vascular	16.1	22.0	(5.9)	(26.8)%
Total net sales	\$313.5	\$296.8	\$ 16.7	5.6%

Heart Valve Therapy

The \$23.7 million increase in net sales of Heart Valve Therapy products for the three months ended March 31, 2009 was due primarily to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$16.5 million; and

pericardial tissue valves, which increased net sales by \$8.7 million, 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 expects to introduce the *Magna Ease* valve into the United States in the third quarter of 2009, pending regulatory approval. The Company expects to launch an enhancement to its *Magna Mitral* valve, called the *Magna Mitral Ease*, in the second half of 2009 in the United States and Europe. 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*

Table of Contents

ETlogix ring during the first quarter of 2009, and expects to launch this product in Japan during the second quarter of 2009.

Critical Care

The \$2.2 million decrease in net sales of Critical Care products for the three months ended March 31, 2009 was due primarily to:

core Critical Care products, which decreased net sales by \$3.6 million, due primarily to decreased sales of advanced hemodynamic monitoring equipment; and

hemofiltration products, which decreased net sales by \$1.8 million;

partially offset by:

FloTrac systems, which increased net sales by \$3.2 million.

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 2008, the Company purchased intellectual property that is expected to be incorporated into a substantial upgrade for the *FloTrac* system, which is planned for launch in the third quarter of 2009. 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.

Cardiac Surgery Systems

The \$1.1 million increase in net sales of Cardiac Surgery Systems products for the three months ended March 31, 2009 was due primarily to MIS products, which increased net sales by \$1.2 million. In June 2009, the Company expects to launch its *EndoDirect* arterial cannula system, which provides cardiac surgeons with an additional minimally invasive alternative when femoral access is not an option.

Vascular

The \$5.9 million decrease in net sales of Vascular products for the three months ended March 31, 2009 was due primarily to the divestiture of the *LifeStent* product line in mid-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 March 31,		
	2009	2008	Change
Gross profit as a percentage of net sales	69.1%	65.3%	3.8 pts.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

The 3.8 percentage point increase in gross profit as a percentage of net sales for the three months ended March 31, 2009 was driven by:

a 1.8 percentage point increase in international gross profit as a percentage of net sales due to a more profitable product mix, primarily higher sales of Heart Valve Therapy products and *FloTrac* systems;

a 1.5 percentage point increase in the United States gross profit as a percentage of net sales 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

the impact from the expiration of foreign currency hedging contracts;

partially offset by:

the unfavorable impact of Critical Care manufacturing variations.

Selling, General and Administrative (SG&A) Expenses

	Three Months Ended March 31,		
	2009	2008	Change
	(dollars in millions)		
SG&A expenses	\$ 121.9	\$ 114.6	\$ 7.3
SG&A expenses as a percentage of net sales	38.9%	38.6%	0.3 pts.

The \$7.3 million increase in SG&A expenses and the 0.3 percentage point increase in SG&A expenses as a percentage of net sales for the three months ended March 31, 2009 was due primarily to (1) investments for the transcatheter heart valve program in Europe and (2) higher sales-related spending in the Heart Valve Therapy and Critical Care product lines. 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 amount of \$3.9 million.

Research and Development Expenses

	Three Months Ended March 31,		
	2009	2008	Change
	(dollars in millions)		
Research and development expenses	\$ 39.9	\$ 32.9	\$ 7.0
Research and development expenses as a percentage of net sales	12.7%	11.1%	1.6 pts.

The increase in research and development expenses for the three months ended March 31, 2009 was due primarily to additional investments in the transcatheter heart valve 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 U.S. Food and Drug Administration ("FDA") in March 2007 to initiate its PARTNER trial, a pivotal clinical trial of the Company's *Edwards SAPIEN* transcatheter heart valve technology. The PARTNER trial, which has two study arms, 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*

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

SAPIEN transcatheter heart valve. Cohort A will have 690 patients 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. Cohort B will have 350 patients and is a superiority analysis. The Company completed enrollment in Cohort B during the first quarter of 2009 and anticipates it will complete enrollment in Cohort A in August 2009. In addition, the Company received FDA approval for continued access to Cohort B for all of its existing PARTNER sites, under the same randomization scheme and protocol;

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, the Company received IDE approval to use its *RetroFlex III* delivery system in its U.S. 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 second 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. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, making it available to an even wider group of patients. The Company expects to complete enrollment in its CE Mark trial in the second quarter of 2009, and anticipates European approval in the first quarter of 2010. The FDA recently clarified that it expects submission of full and complete pre-clinical testing prior to starting any IDE trial. The Company is working to meet these requirements and continues to anticipate gaining an IDE approval to begin a clinical trial in the United States 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. This trial will study up to 150 patients with moderate to severe mitral regurgitation and heart failure. The Company is currently enrolling patients for this trial, and expects to complete enrollment by the end of 2009.

Special (Gains) Charges, net

	Three Months Ended March 31,	
	2009	2008
(Gain) loss on sale of product line	\$(27.0)	\$ 8.1
Sale of distribution rights	(2.8)	
Reserve reversal	(1.0)	
Litigation settlement		2.1
Realignment expenses, net		(0.1)
Special (gains) charges, net	\$(30.8)	\$ 10.1

Table of Contents

(Gain) Loss on Sale of Product Line

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 is 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 this 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 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 March 31, 2009, remaining payments of \$0.3 million for the executive severance charge are expected to be paid through the end of 2009.

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 March 31, 2009, remaining payments of approximately \$2.1 million are expected to be paid through the end of 2009.

Table of Contents***Interest Expense, net***

	Three Months Ended March 31,		
	2009	2008	Change
	(in millions)		
Interest expense	\$ 0.8	\$ 2.1	\$ (1.3)
Interest income	(0.7)	(1.7)	1.0
Interest expense, net	\$ 0.1	\$ 0.4	\$ (0.3)

The decrease in interest expense for the three months ended March 31, 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 for the three months ended March 31, 2009 resulted primarily from lower cash and short-term investment balances and lower average interest rates as compared to the prior year period.

Other Expense, net

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

	Three Months Ended March 31,	
	2009	2008
Foreign exchange (gains) losses, net	\$(0.5)	\$ 1.1
Investment impairment and realized losses		0.6
Accounts receivable securitization costs		0.6
Loss (gain) on investments in unconsolidated affiliates	0.9	(0.7)
Other		(0.4)
Other expense, net	\$ 0.4	\$ 1.2

The foreign exchange (gains) losses 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 the first quarter of 2009 compared to a net loss in the first quarter of 2008 due primarily to fluctuations in the Euro.

The investment impairment and realized losses represents 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 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 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 on the Company's available-for-sale investments.

Provision for Income Taxes

The provision for income taxes consists of provisions for federal, state, and foreign income taxes. The Company operates in an international environment with significant operations in various locations outside the United States, which have statutory tax rates lower than the United States tax rate. Accordingly, the consolidated income tax rate is a composite rate reflecting the earnings in the various locations and the applicable rates. The effective income tax rates were 28.8% and 47.6% for the three

Table of Contents

months ended March 31, 2009 and 2008, respectively. The income tax rate for the three months ended March 31, 2009 included the tax effect on the *LifeStent* milestone receipt. The income tax rate for the three months ended March 31, 2008 included the tax effect on the sale of the *LifeStent* product line.

As of March 31, 2009 and December 31, 2008, the liability for income taxes associated with uncertain tax positions was \$38.0 million and \$35.9 million, respectively. These liabilities could be reduced by \$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 \$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. Most of the provisions contained in the legislation are prospective in nature and take effect for taxable years beginning on or after January 1, 2011. The impact of the new legislation has been considered in the period in determining the Company's tax provision, 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 March 31, 2009, borrowings of \$123.0 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 March 31, 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 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 months ended March 31, 2009, the Company recognized an unrealized gain of \$0.1 million, included in "*Accumulated Other Comprehensive Loss*." The fair value of the Company's remaining investment in

Table of Contents

this fund as of March 31, 2009 and December 31, 2008 was estimated to be \$7.8 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 for approximately \$3.7 million through the first quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of March 31, 2009. The remaining \$4.1 million of the investment is expected to be received after the first quarter of 2010, and has been classified as "*Other Assets*."

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 is 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 upon receipt of the United States regulatory 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 three months ended March 31, 2009, the Company repurchased 0.5 million shares at an aggregate cost of \$26.8 million and as of March 31, 2009 had remaining authority to purchase \$166.7 million of common stock.

At March 31, 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 used in **operating activities** of \$36.0 million for the three months ended March 31, 2009 decreased \$65.9 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. In addition, operating cash flow was negatively impacted by compensation payments during the first quarter 2009 associated with the Company's strong 2008 performance.

Net cash provided by **investing activities** of \$17.3 million for the three months ended March 31, 2009 consisted primarily of \$27.0 million of cash received for a milestone achievement associated with the *LifeStent* pre-market approval, partially offset by capital expenditures of \$11.1 million.

Net cash provided by investing activities of \$82.9 million for the three months ended March 31, 2008 consisted primarily of \$74.0 million of cash received from the sale of the *LifeStent* product line and \$16.6 million in cash redemptions associated with the Bank of America Columbia Strategic Cash fund, partially offset by capital expenditures of \$9.1 million.

Net cash used in **financing activities** of \$53.9 million for the three months ended March 31, 2009 consisted primarily of net payments on long-term debt of \$47.7 million and purchases of treasury stock of \$26.8 million, partially offset by the proceeds from stock plans of \$16.7 million.

Net cash used in financing activities of \$98.6 million for the three months ended March 31, 2008 consisted primarily of purchases of treasury stock of \$100.0 million and net payments on long-term debt of \$7.0 million, partially offset by the proceeds from stock plans of \$6.2 million.

Table of Contents

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 March 31, 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.

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 March 31, 2009, Edwards Lifesciences had \$16.6 million of investments in equity instruments of other companies and had recorded unrealized losses of \$4.6 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.

Table of Contents

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 months ended March 31, 2009, the Company recognized an unrealized gain of \$0.1 million, included in "Accumulated Other Comprehensive Loss." The fair value of the Company's remaining investment in this fund as of March 31, 2009 was estimated to be \$7.8 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 for approximately \$3.7 million through the first quarter of 2010, which has been classified as "Short-term Investments" on the accompanying consolidated condensed balance sheet as of March 31, 2009. The remaining \$4.1 million of the investment is expected to be received after the first 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 March 31, 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 September 2008, Edwards Lifesciences appealed these judgments to the Federal Circuit Court of Appeals.

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 Company is considering an appeal. 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 has counterclaimed, alleging infringement by Edwards. As announced, following the trial in Germany on infringement, the Court ruled on March 19, 2009, that the Company does not infringe the Cook patent.

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)
January 1, 2009 through January 31, 2009	140,000	\$ 55.87	140,000	\$ 185.7
February 1, 2009 through February 28, 2009	142,500	60.01	142,500	177.1
March 1, 2009 through March 31, 2009	180,000	57.97	180,000	166.7
Total	462,500	57.96	462,500	

(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 6. Exhibits

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

- 10.2 Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem dated March 30, 2009
- 10.3 Edwards Lifesciences Corporation Chief Executive Officer Change-in-Control Severance Agreement, as Amended and Restated March 30, 2009
- 10.18 Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement
- 10.19 Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement
- 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: May 8, 2009

By: /s/ THOMAS M. ABATE

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

36

Table of Contents

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit No.	Description
10.2	Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem dated March 30, 2009
10.3	Edwards Lifesciences Corporation Chief Executive Officer Change-in-Control Severance Agreement, as Amended and Restated March 30, 2009
10.18	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement
10.19	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement
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