

Edwards Lifesciences Corp
Form 10-Q
November 06, 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 September 30, 2009

or

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

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

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

36-4316614
(I.R.S. Employer Identification No.)

One Edwards Way, Irvine, California
(Address of principal executive offices)

92614
(Zip Code)

(949) 250-2500

(Registrant's telephone number, including area code)

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

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

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

Large accelerated filer	Accelerated filer	Non-accelerated filer o	Smaller Reporting
<input checked="" type="checkbox"/>	<input type="checkbox"/>	(Do not check if a smaller reporting company)	Company o

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

The number of shares outstanding of the registrant's common stock, \$1.00 par value, as of October 31, 2009 was 56,569,115.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
FORM 10-Q
For the quarterly period ended September 30, 2009

TABLE OF CONTENTS

	Page Number
<u>Part I.</u>	
<u>FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	
<u>Financial Statements (Unaudited)</u>	
<u>Consolidated Condensed Balance Sheets</u>	<u>1</u>
<u>Consolidated Condensed Statements of Operations</u>	<u>1</u>
<u>Consolidated Condensed Statements of Cash Flows</u>	<u>2</u>
<u>Notes to Consolidated Condensed Financial Statements</u>	<u>3</u>
<u>Item 2.</u>	<u>4</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>22</u>
<u>Item 3.</u>	<u>36</u>
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>36</u>
<u>Item 4.</u>	<u>37</u>
<u>Controls and Procedures</u>	<u>37</u>
<u>Part II.</u>	
<u>OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>38</u>
<u>Legal Proceedings</u>	<u>38</u>
<u>Item 2.</u>	<u>39</u>
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>39</u>
<u>Item 6.</u>	<u>39</u>
<u>Exhibits</u>	<u>39</u>
<u>Signature</u>	<u>40</u>
<u>Exhibits</u>	<u>41</u>

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

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED BALANCE SHEETS

(in millions, except par value; unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	\$ 287.6	\$ 218.7
Short-term investments (Note 3)	1.9	8.1
Accounts and other receivables, net of allowances of \$11.9 and \$9.9, respectively (Note 4)	280.5	204.7
Inventories, net	168.7	151.8
Deferred income taxes	44.7	42.4
Prepaid expenses	40.7	30.7
Other current assets	53.1	35.5
 Total current assets	 877.2	 691.9
Property, plant and equipment, net	240.7	230.1
Goodwill	315.2	315.7
Other intangible assets, net	91.0	96.9
Investments in unconsolidated affiliates (Note 7)	24.8	14.7
Deferred income taxes	39.6	37.7
Other assets	13.6	13.2
	 \$ 1,602.1	 \$ 1,400.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 296.3	\$ 258.5
Long-term debt	102.3	175.5
Other long-term liabilities	113.1	87.4
Commitments and contingencies (Note 12)		
Stockholders' equity		
Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding		
Common stock, \$1.00 par value, 350.0 shares authorized, 75.4 and 73.7 shares issued, and 56.3 and 55.9 shares outstanding, respectively	75.4	73.7
Additional paid-in capital	1,019.5	940.4

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Retained earnings	858.4	676.9
Accumulated other comprehensive loss	(6.5)	(35.4)
Treasury stock, at cost, 19.1 and 17.8 shares, respectively	(856.4)	(776.8)
Total stockholders' equity	1,090.4	878.8
	\$ 1,602.1	\$ 1,400.2

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(in millions, except per share information; unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net sales	\$ 325.7	\$ 303.6	\$ 974.7	\$ 928.0
Cost of goods sold	98.5	104.9	297.4	320.8
Gross profit	227.2	198.7	677.3	607.2
Selling, general and administrative expenses	126.1	119.3	376.5	360.4
Research and development expenses	44.7	35.1	127.2	103.4
Special (gains) charges, net (Note 2)	(38.2)		(67.5)	9.3
Interest expense (income), net	0.6	(0.4)	0.9	0.4
Other (income) expense, net	(0.2)	1.1	(1.8)	3.3
Income before provision for income taxes	94.2	43.6	242.0	130.4
Provision for income taxes	20.7	10.7	60.5	39.6
Net income	\$ 73.5	\$ 32.9	\$ 181.5	\$ 90.8

Share information

(Note 14)

Earnings per share:				
Basic	\$ 1.30	\$ 0.59	\$ 3.23	\$ 1.63
Diluted	\$ 1.25	\$ 0.56	\$ 3.10	\$ 1.54
Weighted-average number of common shares outstanding:				
Basic	56.4	56.0	56.2	55.8
Diluted	58.7	59.0	58.6	60.1

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

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(in millions; unaudited)

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities		
Net income	\$ 181.5	\$ 90.8
Adjustments to reconcile net income to cash provided by operating activities:		
Depreciation and amortization	44.5	41.3
Stock-based compensation (Note 11)	20.5	21.0
Deferred income taxes	0.7	(2.1)
Special (gains) charges, net (Note 2)	(79.2)	8.4
(Gain) loss on trading securities	(2.6)	2.9
(Gain) loss on investments	(0.1)	0.9
Other	3.1	(1.1)
Changes in operating assets and liabilities:		
Accounts and other receivables, net (Note 4)	(52.1)	(68.8)
Inventories, net	(13.9)	(11.4)
Accounts payable and accrued liabilities	(11.5)	(0.4)
Prepaid expenses and other current assets	(4.0)	(5.9)
Other	12.5	(2.9)
Net cash provided by operating activities	99.4	72.7
Cash flows from investing activities		
Capital expenditures	(40.3)	(32.9)
Proceeds from sale of assets (Note 2)	92.4	74.0
Proceeds from investments (Note 3)	9.0	30.9
(Investments in) proceeds from unconsolidated affiliates, net	(4.0)	4.6
Investments in trading securities, net	(1.1)	(0.6)
Investments in intangible assets		(0.4)
Net cash provided by investing activities	56.0	75.6
Cash flows from financing activities		
Proceeds from issuance of long-term debt	129.3	196.3
Payments on long-term debt	(202.2)	(62.1)
Purchases of treasury stock	(79.6)	(285.5)
Proceeds from stock plans	43.9	50.7
Excess tax benefit from stock plans	12.9	12.5
Other		(0.4)
Net cash used in financing activities	(95.7)	(88.5)
Effect of currency exchange rate changes on cash and cash equivalents	9.2	0.8
Net increase in cash and cash equivalents	68.9	60.6
Cash and cash equivalents at beginning of period	218.7	141.8
Cash and cash equivalents at end of period	\$ 287.6	\$ 202.4

Supplemental disclosures:

Non-cash transactions:

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Issuance of common shares in redemption of
convertible debt

\$ \$ 147.7

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

3

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 ("GAAP") have been condensed or omitted.

In the opinion of management of Edwards Lifesciences Corporation (the "Company" or "Edwards Lifesciences"), the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair statement of the interim periods. All such adjustments are of a normal, recurring nature. In connection with the preparation of the consolidated condensed financial statements, the Company has evaluated subsequent events through November 6, 2009, which is the date the financial statements were issued. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued new accounting guidance on fair value measurements. This new guidance defined fair value, established a framework for measuring fair value, and expanded disclosures about fair value measurements. In February 2008, the FASB delayed the effective date of this guidance 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 this guidance, as it applies to those non-financial assets and liabilities affected by the one-year delay, did not have a material impact on the Company's consolidated financial statements. See Note 8 for further information.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") on accounting for collaborative arrangements. This new accounting guidance defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The guidance also established 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. The guidance was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented was required for all collaborative arrangements existing as of the effective date. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. See Note 16 for further information.

In December 2007, the FASB issued new accounting guidance on business combinations which established 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. This guidance also established principles and requirements for recognizing and measuring goodwill acquired in the business combination and determined 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, the guidance expanded the definition of a business combination, required acquisitions to be accounted for at fair value, and required transaction costs and

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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

In March 2008, the FASB issued new accounting guidance on disclosures about derivative instruments and hedging activities. The new guidance required 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. The guidance was effective for fiscal years and interim periods beginning after November 15, 2008. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. See Note 9 for further information.

In April 2008, the FASB issued new accounting guidance that amended the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The new guidance applied to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions and required expanded disclosure related to the determination of intangible asset useful lives. The guidance was effective for fiscal years beginning after December 15, 2008. The adoption of this guidance 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 which clarified the accounting for certain transactions and impairment considerations involving equity method investments. This new accounting guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance 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 which clarified 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. The new guidance required 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. The guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance which required 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 the FASB Accounting Standards Codification ("ASC") Topic 450, "*Contingencies*." The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance on estimating fair value when the volume and level of activity for the asset or liability have significantly decreased, and identifying circumstances that indicate a transaction is not orderly. The guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance that amended the other-than-temporary impairment guidance related to debt securities and expanded and increased the frequency of existing disclosures about debt and equity securities and other-than-temporary impairments for debt and equity securities. The new guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Table of Contents

In April 2009, the FASB issued new accounting guidance which required disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. The guidance was effective for interim reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In May 2009, the FASB issued new accounting guidance that established general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The new guidance required the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. The new guidance was effective for interim or annual financial periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In June 2009, the FASB issued a new accounting standard establishing the ASC as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The new accounting standard was effective for financial statements issued for interim and annual periods ending after September 15, 2009. The ASC does not change GAAP and did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIEs"). This new accounting guidance eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a VIE based on whether the entity (a) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (b) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. The guidance requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. The guidance is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2009, the FASB issued an amendment to ASC 820, "*Fair Value Measurements and Disclosures*," to clarify how an entity should measure the fair value of liabilities when a quoted price in an active market for the identical liability is not available. The guidance is effective for the first reporting period beginning after its issuance. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In October 2009, the FASB issued an amendment to ASC 605, "*Revenue Recognition*," to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. ASC 605 was also amended to eliminate the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

Table of Contents**2. SPECIAL (GAINS) CHARGES, NET**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in millions)			
(Gain) loss on sale of product lines	\$ (58.6)	\$	\$ (84.1)	\$ 8.1
Charitable fund contribution	15.0		15.0	
Litigation	3.8		3.8	2.1
Investment impairment	1.6		1.6	
Sale of distribution rights			(2.8)	
Reserve reversal			(1.0)	
Realignment expenses, net				(0.9)
Special (gains) charges, net	\$ (38.2)	\$	\$ (67.5)	\$ 9.3

(Gain) Loss on Sale of Product Lines

Effective September 1, 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years, of which \$0.6 million was earned in September 2009 and recorded in "Other (Income) Expense, net." The sale resulted in a pre-tax gain of \$43.6 million consisting of the cash proceeds of \$55.9 million, offset by \$8.5 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, a \$0.6 million satisfaction of a receivable, a \$0.5 million write-off of goodwill associated with this product line, and \$2.7 million of transaction and other costs related to the sale. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance related to the pending sale. The Company will provide transition services to the buyer. This transaction allows the Company to better focus on its global strategic priorities.

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of *LifeStent* device manufacturing to the buyer. The Company received \$8.9 million of this milestone in September 2009 and \$6.1 million in October 2009.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Charitable Fund Contribution

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

Litigation

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

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.

Investment Impairment

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

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.

Realignment Expenses, net

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

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

In December 2007, the Company recorded realignment expenses of \$13.9 million primarily related to (1) severance expenses associated with the sale of the Company's *LifeStent* product line and a global reduction in workforce, primarily in the United States, Europe, and Japan (impacting approximately 180 employees), and (2) the termination of the Company's intra-aortic balloon pump distribution agreement in Japan. As of September 30, 2009, remaining payments of approximately \$1.3 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. Since December 31, 2007, the Company has received cash redemptions of \$44.5 million. The fair value of the Company's remaining investment in this fund as of September 30, 2009 and December 31, 2008 was estimated to be \$2.4 million and \$10.9 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$1.9 million through the third quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2009. The remaining \$0.5 million of the investment is expected to be received after the third 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. During both the three and nine months ended September 30, 2009, the Company recognized realized gains of \$0.1 million, included in "*Other (Income) Expense, net*." Additionally, during the nine months ended September 30, 2009, the Company recognized unrealized gains of \$0.4 million, included in "*Accumulated Other Comprehensive Loss*." During the three and nine months ended September 30, 2008, the Company recognized realized losses and unrealized losses considered other-than-temporary of \$0.1 million and 0.9 million, respectively, included in "*Other (Income) Expense, net*."

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):

	September 30, 2009	December 31, 2008
Raw materials	\$ 33.6	\$ 36.5
Work in process	32.4	19.5
Finished products	102.7	95.8
	\$ 168.7	\$ 151.8

Table of Contents**6. OTHER INTANGIBLE ASSETS**

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

September 30, 2009	Patents	Unpatented Technology	Other	Total
Cost	\$ 214.8	\$ 35.0	\$ 12.7	\$ 262.5
Accumulated amortization	(140.8)	(26.5)	(4.2)	(171.5)
Net carrying value	\$ 74.0	\$ 8.5	\$ 8.5	\$ 91.0

December 31, 2008	Patents	Unpatented Technology	Other	Total
Cost	\$ 204.1	\$ 35.0	\$ 13.4	\$ 252.5
Accumulated amortization	(127.3)	(24.6)	(3.7)	(155.6)
Net carrying value	\$ 76.8	\$ 10.4	\$ 9.7	\$ 96.9

Patents include \$14.9 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of September 30, 2009.

Amortization expense related to other intangible assets was \$5.4 million and \$4.6 million for the three months ended September 30, 2009 and 2008, respectively, and \$16.1 million and \$13.8 million for the nine months ended September 30, 2009 and 2008, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2009	\$ 20.9
2010	20.5
2011	18.2
2012	15.2
2013	14.9

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

7. INVESTMENTS IN UNCONSOLIDATED AFFILIATES

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

	September 30, 2009	December 31, 2008
	(in millions)	
Available-for-sale investments		
Cost	\$ 9.4	\$ 10.9
Unrealized gains (losses)	3.0	(5.8)
Fair value of available-for-sale investments	12.4	5.1
Equity method investments		
Cost	10.9	9.7
Equity in losses	(1.8)	(1.1)
Carrying value of equity method investments	9.1	8.6
Cost method investments		
Carrying value of cost method investments	3.3	1.0

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Total investments in unconsolidated affiliates	\$	24.8	\$	14.7
---	----	------	----	------

Table of Contents

There were no sales of available-for-sale investments during the nine months ended September 30, 2009. Proceeds from sales of available-for-sale investments were \$1.5 million and \$3.8 million for the three and nine months ended September 30, 2008, respectively. The Company realized pre-tax gains from these sales of \$0.6 million and \$1.9 million for the three and nine months ended September 30, 2008, respectively. In September 2009, the Company recorded an other-than-temporary impairment charge of \$1.6 million related to one of its available-for-sale investments. See Note 2 for additional information.

8. FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS

The consolidated condensed financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on an historical cost basis. Financial instruments of the Company consist of cash deposits, short-term investments, accounts and other receivables, investments in unconsolidated affiliates, accounts payable, certain accrued liabilities, and debt.

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

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

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

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):

September 30, 2009	Level 1	Level 2	Level 3	Total
Assets				
Investment in the Bank of America Columbia Strategic Cash fund	\$	\$	\$ 2.4	\$ 2.4
Investments held for executive deferred compensation plan		13.9		13.9
Investments in unconsolidated affiliates		12.4		12.4
	\$ 26.3	\$	\$ 2.4	\$ 28.7
Liabilities				
Derivatives	\$	\$ 11.4	\$	\$ 11.4
	\$	\$ 11.4	\$	\$ 11.4

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 assets and liabilities that have been classified as Level 3 (in millions):

	Nine Months Ended September 30, 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 income	0.4		0.4
Included in earnings (a)	0.1		0.1
Purchases, sales, issuances, and settlements	(9.0)	(6.6)	(15.6)
Balance at September 30, 2009	\$ 2.4	\$	\$ 2.4

	Nine Months Ended September 30, 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)	(0.9)		(0.9)
Purchases, sales, issuances, and settlements	(30.9)	(3.2)	(34.1)
Balance at September 30, 2008	\$ 17.6	\$ 5.6	\$ 23.2

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

The Company's investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investment for cash. The fair value of the Company's remaining investment in this fund was estimated based on the net asset value of the fund. The fair value of the underlying securities held by the fund was determined based on quoted market prices or broker quotes, when possible. In the absence of

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

observable market quotations, the underlying securities were valued based on alternative valuation techniques using inputs that may not be observable. In these cases, the fair value was based on available information believed to be reliable,

Table of Contents

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 programs in the United States (August 2008) and Japan (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 nine months ended September 30, 2009, the Company had no impairments related to these assets.

9. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

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

	September 30, 2009	
	Notional Amount	Fair Value Asset (Liability)
	(in millions)	
Forward currency agreements	\$ 169.7	\$ (7.5)
Currency option contracts	133.4	(3.9)

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

Derivative instruments used by the Company involve, to varying degrees, elements of credit risk, in the event a counterparty should default, and market risk, as the instruments are subject to rate and price fluctuations. Credit risk is managed through the use of credit standard guidelines, counterparty diversification, monitoring of counterparty financial condition, and International Swap Dealers Association master-netting agreements in place with all derivative counterparties. The master-netting agreements reduce our counterparty payment settlement risk on any given maturity date to the net

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

amount of any receipts or payments due between us and the counterparty financial institution. Although these protections do not eliminate concentrations of credit, the Company does not consider the risk of counterparty default to be significant. All derivative financial instruments are with a diversified group of major financial institutions assigned investment grade ratings with national rating agencies. None of the Company's outstanding derivative instruments contain credit-risk related contingent features that may require the Company to post or permit the Company to call collateral from any counterparty.

All derivatives are recognized on the balance sheet at their fair value. On the date that the Company enters into a derivative contract, it designates the derivative as either (a) a hedge of a forecasted transaction or the variability of cash flows that are to be received or paid in connection with a recognized asset or liability (a "cash flow" hedge), or (b) a hedge of an exposure to changes in the 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 September 30, 2009 (in millions):

	September 30, 2009			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments				
Foreign exchange contracts	Prepaid expenses	\$	Accrued liabilities	\$ 11.4

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

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative	
		Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
		Derivatives in fair value hedging relationships	
Foreign exchange contracts	Other (income) expense, net	\$ (2.1)	\$ (2.5)

Table of Contents

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009		Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009

Derivatives in cash flow hedging relationships

Foreign exchange contracts	\$ (10.6)	\$ (5.6)	Cost of goods sold	\$ 2.7	\$ 8.8
----------------------------	-----------	----------	--------------------	--------	--------

The Company expects that during the next twelve months it will reclassify to earnings a \$3.8 million loss currently recorded in "Accumulated Other Comprehensive Loss." For the three and nine months ended September 30, 2009, the Company expensed \$0.3 million and \$0.8 million, respectively, related to the time value of option-based products and did not record any gains or losses due to hedge ineffectiveness.

10. DEFINED BENEFIT PLANS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Service cost	\$ 1.4	\$ 1.0	\$ 4.1	\$ 2.9
Employee contributions				
Interest cost	0.4	0.3	1.3	1.0
Expected return on plan assets	(0.3)	(0.3)	(0.7)	(0.7)
Amortization of prior service cost and other	0.2	0.1	0.5	0.1
Net periodic pension benefit cost	\$ 1.7	\$ 1.1	\$ 5.2	\$ 3.3

11. STOCK-BASED COMPENSATION

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three and nine months ended September 30, 2009 and 2008 was as follows (in millions):

	Three Months Ended September 30		Nine Months Ended September 30,	
	2009	2008	2009	2008
Cost of goods sold	\$ 0.6	\$ 0.8	\$ 1.7	\$ 2.0
Selling, general and administrative expenses	6.0	6.1	15.5	15.3
Research and development expenses	1.3	1.3	3.3	3.7
Total stock-based compensation expense	\$ 7.9	\$ 8.2	\$ 20.5	\$ 21.0

At September 30, 2009, the total remaining compensation cost related to unvested stock options, restricted stock units, and employee stock purchase subscription awards amounted to \$51.6 million and will be amortized on a straight-line basis over a weighted-average vesting period of approximately 31 months.

Table of Contents

During the nine months ended September 30, 2009, the Company granted 0.9 million stock options at a weighted-average exercise price of \$63.11 and 0.2 million shares of restricted stock units at a weighted-average grant-date fair value of \$63.26.

Fair Value Disclosures

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

Option Awards

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	2.3%	2.9%	1.9%	3.0%
Expected dividend yield	None	None	None	None
Expected volatility	28.1%	23.7%	28.1%	23.3%
Expected term (years)	4.9	4.9	4.6	4.7
Fair value, per share	\$ 19.14	\$ 15.12	\$ 17.08	\$ 14.35

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

ESPP

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Risk-free interest rate	0.4%	2.1%	0.4%	2.2%
Expected dividend yield	None	None	None	None
Expected volatility	36.6%	25.5%	36.3%	25.3%
Expected term (years)	0.6	0.6	0.6	0.6
Fair value, per share	\$ 17.92	\$ 14.36	\$ 17.43	\$ 14.04

12. COMMITMENTS AND CONTINGENCIES

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

In May 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007 and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively.

Table of Contents

against the three inventors of this patent alleging that the patent is invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. In January 2009, the United Kingdom Court determined that the Andersen patent was valid but not infringed by CoreValve. The parties have filed cross-appeals on the validity and infringement decisions. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents. This lawsuit is ongoing.

In February 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany, against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Court ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. Cook is appealing the judgments in Germany and the United Kingdom.

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

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

13. COMPREHENSIVE INCOME

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income	\$ 73.5	\$ 32.9	\$ 181.5	\$ 90.8
Other comprehensive income:				
Currency translation adjustments	20.0	(19.3)	29.0	(2.0)
Unrealized net gain (loss) on investments in unconsolidated affiliates, net of tax	5.3	(3.5)	8.6	(7.6)
Unrealized net (loss) gain on cash flow hedges, net of tax	(8.1)	8.6	(8.7)	7.1
Comprehensive income	\$ 90.7	\$ 18.7	\$ 210.4	\$ 88.3

Table of Contents**14. EARNINGS PER SHARE**

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Employee equity share options, nonvested shares, and similar equity instruments granted by the Company are treated as potential common shares in computing diluted earnings per share. Diluted shares outstanding include the dilutive effect of the conversion of convertible debt, restricted stock units, and in-the-money options. The dilutive impact of the restricted stock units and in-the-money options is calculated based on the average share price for each fiscal period using the treasury stock method. Under the treasury stock method, the amount that the employee must pay for exercising stock options, the amount of compensation expense for future service that the Company has not yet recognized, and the amount of tax benefits that would be recorded in additional paid-in capital when the award becomes deductible are assumed to be used to repurchase shares. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Basic:				
Net income	\$ 73.5	\$ 32.9	\$ 181.5	\$ 90.8
Weighted-average shares outstanding	56.4	56.0	56.2	55.8
Basic earnings per share	\$ 1.30	\$ 0.59	\$ 3.23	\$ 1.63
Diluted:				
Net income	\$ 73.5	\$ 32.9	\$ 181.5	\$ 90.8
Interest expense related to convertible debt, net of tax				1.7
Net income applicable to diluted shares	\$ 73.5	\$ 32.9	\$ 181.5	\$ 92.5
Weighted-average shares outstanding	56.4	56.0	56.2	55.8
Dilutive effect of convertible debt				1.6
Dilutive effect of stock plans	2.3	3.0	2.4	2.7
Dilutive weighted-average shares outstanding	58.7	59.0	58.6	60.1
Diluted earnings per share	\$ 1.25	\$ 0.56	\$ 3.10	\$ 1.54

Stock options and restricted stock units to purchase 1.0 million and 1.1 million shares for the three months ended September 30, 2009 and 2008, respectively, and 1.3 million and 2.0 million for the nine months ended September 30, 2009 and 2008, respectively, were outstanding, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive. Diluted shares included shares issuable pursuant to the Company's \$150 million convertible debentures until they were redeemed on June 9, 2008.

15. INCOME TAXES

The effective income tax rates were 22.0% and 25.0% for the three and nine months ended September 30, 2009, respectively, and 24.5% and 30.4% for the three and nine months ended September 30, 2008, respectively. The income tax rate for the nine months ended September 30, 2009 included the tax effect on a *LifeStent* milestone receipt and the sale of the hemofiltration product line. In connection with the sale of the hemofiltration product line, the Company has applied for a Swiss tax ruling with respect to treatment of the gain on the transaction. If the ruling is subsequently approved,

Table of Contents

the expected tax benefit would be approximately \$5.5 million. The income tax rate for the nine months ended September 30, 2008 included the tax effect on the sale of the *LifeStent* product line. See Note 2 for further information.

As of September 30, 2009, June 30, 2009, and December 31, 2008, the liability for income taxes associated with uncertain tax positions was \$46.5 million, \$43.0 million, and \$35.9 million, respectively. These liabilities could be reduced by \$4.0 million, \$3.8 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 \$42.5 million, \$39.2 million, and \$33.6 million, respectively, if recognized, would favorably affect the Company's effective tax rate. Changes to potential interest expense upon settlement during the period were immaterial.

As a result of on-going audits, the total liability for unrecognized tax benefits may change within the next 12 months due to either settlements of audits or expiration of statutes of limitations. Quantification of those potential changes cannot be estimated at this time. At September 30, 2009, the Company has concluded all United States federal income tax matters for years through 2006. All material state, local, and foreign income tax matters have been concluded for years through 2003. The Company is currently under examination by the Internal Revenue Service for 2007 and 2008.

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

16. COLLABORATIVE AGREEMENT

The Company has a collaboration agreement with DexCom, Inc. ("DexCom") to develop products for continuously monitoring blood glucose levels in patients hospitalized for a variety of conditions. The agreement provides Edwards Lifesciences with an exclusive license to all of DexCom's applicable intellectual property. In December 2008, at the inception of the agreement, the Company recorded a charge of \$13.4 million related to the upfront licensing and collaboration fee. The Company will also pay up to \$24 million over the next three years in product development costs and regulatory approval milestones. The product development costs are expensed to "*Research and Development Expenses*" as incurred, and the regulatory approval milestones are recorded as "*Other Intangible Assets*" and amortized over the useful life of the product. In addition, DexCom will receive either a profit-sharing payment or a royalty based upon commercial sales. Edwards Lifesciences will be responsible for global sales and marketing, which is expected to begin in 2010, and DexCom will be responsible for initial manufacturing. The Company recorded \$1.3 million and \$4.5 million of product development costs for the three and nine months ended September 30, 2009.

17. SEGMENT INFORMATION

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

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Segment Net Sales				
United States	\$ 137.0	\$ 134.4	\$ 415.4	\$ 408.0
Europe	92.2	83.3	295.3	263.9
Japan	45.3	42.0	132.6	121.7
Rest of world	39.0	33.1	112.5	96.6
Total segment net sales	\$ 313.5	\$ 292.8	\$ 955.8	\$ 890.2
Segment Pre-Tax Income				
United States	\$ 73.4	\$ 69.7	\$ 223.5	\$ 212.0
Europe	29.3	23.9	97.8	81.0
Japan	21.2	18.9	62.2	53.1
Rest of world	12.8	8.9	32.1	25.4
Total segment pre-tax income	\$ 136.7	\$ 121.4	\$ 415.6	\$ 371.5

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net Sales Reconciliation				
Segment net sales	\$ 313.5	\$ 292.8	\$ 955.8	\$ 890.2
Foreign currency	12.2	10.8	18.9	37.8
Consolidated net sales	\$ 325.7	\$ 303.6	\$ 974.7	\$ 928.0
Pre-Tax Income Reconciliation				
Segment pre-tax income	\$ 136.7	\$ 121.4	\$ 415.6	\$ 371.5
Unallocated amounts:				
Corporate items	(85.8)	(75.4)	(259.1)	(223.4)
Special gains (charges), net	38.2		67.5	(9.3)
Interest (expense) income, net	(0.6)	0.4	(0.9)	(0.4)
Foreign currency	5.7	(2.8)	18.9	(8.0)
Consolidated pre-tax income	\$ 94.2	\$ 43.6	\$ 242.0	\$ 130.4

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Enterprise-Wide Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
(in millions)				
Net Sales by Geographic Area				
United States	\$ 137.0	\$ 135.6	\$ 415.4	\$ 410.8
Other countries	188.7	168.0	559.3	517.2
	\$ 325.7	\$ 303.6	\$ 974.7	\$ 928.0
Net Sales by Major Product and Service Area				
Heart Valve Therapy	\$ 174.1	\$ 148.4	\$ 526.6	\$ 457.7
Critical Care	114.2	110.3	331.7	333.6
Cardiac Surgery Systems	22.3	21.4	68.9	66.3
Vascular	15.1	23.5	47.5	70.4
	\$ 325.7	\$ 303.6	\$ 974.7	\$ 928.0

	September 30, 2009	December 31, 2008
	(in millions)	
Long-Lived Tangible Assets by Geographic Area		
United States	\$ 180.2	\$ 171.4
Other countries	98.9	86.6
	\$ 279.1	\$ 258.0

Table of Contents

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

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The Company intends the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials, or regulatory approvals, any statements of plans, strategies, and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, and any statement of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "forecast," "intend" or other similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's future business, financial condition, results of operations, or performance to differ materially from the Company's historical results or those expressed in any forward-looking statements contained in this report. Investors should carefully review the information contained in, or incorporated by reference into, the Company's annual report on Form 10-K for the year ended December 31, 2008 for a description of certain of these risks and uncertainties.

Overview

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

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

Edwards Lifesciences' **Heart Valve Therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **Critical Care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring equipment used to measure a patient's cardiovascular function and in disposable pressure transducers. Through the end of August 2009, Edwards Lifesciences provided central venous access products for fluid and drug delivery ("hemofiltration product line"). The Company sold the hemofiltration product line effective September 1, 2009. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannula, **EMBOL-X** technologies, and other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also includes the Company's minimally invasive surgery ("MIS") product line. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, and artificial implantable grafts. Through early 2008, Edwards Lifesciences manufactured and sold *LifeStent* balloon-expandable and self-expanding non-coronary stents. The Company sold the *LifeStent* product line in January 2008, but continued to manufacture these products for the buyer until September 2009 when manufacturing was transferred 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

Table of Contents

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

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued new accounting guidance on fair value measurements. This new guidance defined fair value, established a framework for measuring fair value, and expanded disclosures about fair value measurements. In February 2008, the FASB delayed the effective date of this guidance 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 this guidance, 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") on accounting for collaborative arrangements. This new accounting guidance defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The guidance also established 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. The guidance was effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Retrospective application to all prior periods presented was required for all collaborative arrangements existing as of the effective date. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In December 2007, the FASB issued new accounting guidance on business combinations which established 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. This guidance also established principles and requirements for recognizing and measuring goodwill acquired in the business combination and determined 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, the guidance expanded the definition of a business combination, required acquisitions to be accounted for at fair value, and required transaction costs and restructuring charges to be expensed. The guidance was effective for fiscal years beginning on or after December 15, 2008 and will impact the Company if it is involved in a business combination.

In March 2008, the FASB issued new accounting guidance on disclosures about derivative instruments and hedging activities. The new guidance required 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. The guidance was effective for fiscal years and interim periods beginning after November 15, 2008. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2008, the FASB issued new accounting guidance that amended the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset. The new guidance applied to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions and required

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

expanded disclosure related to the determination of intangible asset useful lives. The guidance was effective for fiscal years beginning after December 15, 2008. The adoption of this guidance 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 which clarified the accounting for certain transactions and impairment considerations involving equity method investments. This new accounting guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance 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 which clarified 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. The new guidance required 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. The guidance was effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance which required 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 the FASB Accounting Standards Codification ("ASC") Topic 450, "*Contingencies*." The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance on estimating fair value when the volume and level of activity for the asset or liability have significantly decreased, and identifying circumstances that indicate a transaction is not orderly. The guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance that amended the other-than-temporary impairment guidance related to debt securities and expanded and increased the frequency of existing disclosures about debt and equity securities and other-than-temporary impairments for debt and equity securities. The new guidance was effective for interim and annual reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In April 2009, the FASB issued new accounting guidance which required disclosures about the fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. The guidance was effective for interim reporting periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In May 2009, the FASB issued new accounting guidance that established general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The new guidance required the disclosure of the date through which an entity has evaluated subsequent events and whether that date represents the date the financial statements were issued or were available to be issued. The new guidance was effective for interim or annual financial periods ending after June 15, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In June 2009, the FASB issued a new accounting standard establishing the ASC as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities

Table of Contents

in preparation of financial statements in conformity with generally accepted accounting principles ("GAAP"). Rules and interpretive releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The new accounting standard was effective for financial statements issued for interim and annual periods ending after September 15, 2009. The ASC does not change GAAP and did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

In June 2009, the FASB issued an amendment to the accounting and disclosure requirements for the consolidation of variable interest entities ("VIEs"). This new accounting guidance eliminates the exemption for qualifying special purpose entities and establishes a new approach for determining the primary beneficiary of a VIE based on whether the entity (a) has the power to direct the activities of the VIE that most significantly impact the entity's economic performance and (b) has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. The guidance requires an ongoing reconsideration of the primary beneficiary, and amends the events that trigger a reassessment of whether an entity is a VIE. Enhanced disclosures are also required to provide information about an enterprise's involvement in a VIE. The guidance is effective for the first annual reporting period beginning after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In August 2009, the FASB issued an amendment to ASC 820, "*Fair Value Measurements and Disclosures*," to clarify how an entity should measure the fair value of liabilities when a quoted price in an active market for the identical liability is not available. The guidance is effective for the first reporting period beginning after its issuance. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

In October 2009, the FASB issued an amendment to ASC 605, "*Revenue Recognition*," to require companies to allocate revenue in arrangements involving multiple deliverables based on estimated selling price in the absence of vendor-specific objective evidence or third-party evidence of selling price for the deliverables. ASC 605 was also amended to eliminate the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that have already been delivered. The guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect the adoption of this guidance will have a material impact on its consolidated financial statements.

Results of Operations*Net Sales Trends*

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

	Three Months Ended September 30,			Percent Change	Nine Months Ended September 30,			Percent Change
	2009	2008	Change		2009	2008	Change	
United States	\$ 137.0	\$ 135.6	\$ 1.4	1.0%	\$ 415.4	\$ 410.8	\$ 4.6	1.1%
International	188.7	168.0	20.7	12.3%	559.3	517.2	42.1	8.1%
Total net sales	\$ 325.7	\$ 303.6	\$ 22.1	7.3%	\$ 974.7	\$ 928.0	\$ 46.7	5.0%

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

In the United States, the \$1.4 million and \$4.6 million increases in net sales for the three and nine months ended September 30, 2009, respectively, were due primarily to:

Heart Valve Therapy products, which increased net sales by \$8.0 million and \$21.4 million, respectively, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna Ease* and *Magna* with *ThermaFix* valves, and the *Carpentier-Edwards Physio II* ring, which was launched in the first quarter of 2009;

partially offset by:

the divestiture of the *LifeStent* product line in mid-January 2008, which decreased net sales by \$7.4 million and \$18.1 million, respectively. Sales after the divestiture resulted from the on-going manufacturing requirements of the sale agreement, which continued until the transfer of manufacturing to the buyer in September 2009.

International net sales increased \$20.7 million and \$42.1 million for the three and nine months ended September 30, 2009, respectively, due primarily to:

Heart Valve Therapy products, which increased net sales by \$19.1 million and \$63.9 million, respectively, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, and the *Magna* aortic valve in Japan; and

FloTrac systems, which increased net sales by \$2.3 million and \$7.2 million, respectively;

partially offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$3.4 million and \$31.8 million, respectively, due primarily to the weakening of the Euro against the United States dollar.

The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs and the Company's hedging activities. For more information see Item 3, "*Quantitative and Qualitative Disclosures About Market Risk.*"

Net Sales by Product Line

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009	2008	Change	Percent Change	2009	2008	Change	Percent Change
Heart Valve Therapy	\$ 174.1	\$ 148.4	\$ 25.7	17.3%	\$ 526.6	\$ 457.7	\$ 68.9	15.1%
Critical Care	114.2	110.3	3.9	3.5%	331.7	333.6	(1.9)	(0.6)%
Cardiac Surgery Systems	22.3	21.4	0.9	4.2%	68.9	66.3	2.6	3.9%
Vascular	15.1	23.5	(8.4)	(35.7)%	47.5	70.4	(22.9)	(32.5)%
Total net sales	\$ 325.7	\$ 303.6	\$ 22.1	7.3%	\$ 974.7	\$ 928.0	\$ 46.7	5.0%

Heart Valve Therapy

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Net sales of Heart Valve Therapy products for the three and nine months ended September 30, 2009 increased by \$25.7 million and \$68.9 million, respectively, due primarily to:

the *Edwards SAPIEN* transcatheter heart valve, which increased net sales by \$13.6 million and \$46.3 million, respectively; and

Table of Contents

pericardial tissue valves, which increased net sales by \$11.3 million and \$33.0 million, respectively, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, the *Magna* with *ThermaFix* mitral valve, and the *Magna* aortic valve in Japan;

partially offset by

foreign currency exchange rate fluctuations, which decreased net sales by \$2.1 million and \$17.4 million, respectively, due primarily to the weakening of the Euro against the United States dollar.

The Company expects that its *SAPIEN* transcatheter heart valve will continue to be a strong contributor to 2009 sales. The Company received Food and Drug Administration ("FDA") approval for its *Magna Ease* aortic valve in May 2009. The *Magna Ease* valve is designed for easier implantation and has the potential for leadership in the largest segment of surgical valve replacement. In July 2009, the Company received United States regulatory approval for its *Magna Mitral* valve, called the *Magna Mitral Ease*. 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 received regulatory approval in Japan during the third quarter of 2009 and expects formal reimbursement approval in the fourth quarter of 2009. The Company expects this product to contribute to its growth in the repair segment. *Physio II* is the next generation repair product for the degenerative segment of mitral repair. In Japan, the Company received regulatory approval for its *IMR ETlogix* ring during the first quarter of 2009, and launched this product in Japan during the third quarter of 2009.

Critical Care

The \$3.9 million increase and the \$1.9 million decrease in net sales of Critical Care products for the three and nine months ended September 30, 2009, respectively, were due primarily to:

FloTrac systems, which increased net sales by \$3.5 million and \$9.5 million, respectively; and

core Critical Care products, which increased net sales by \$2.9 million and \$1.5 million, respectively, driven primarily by pressure monitoring products;

offset by:

foreign currency exchange rate fluctuations, which decreased net sales by \$0.5 million and \$10.0 million, respectively, due primarily to the weakening of the Euro against the United States dollar; and

hemofiltration products, which decreased net sales by \$1.9 million and \$2.3 million, respectively. The Company sold its hemofiltration product line effective September 1, 2009. For more information see "*Special (Gains) Charges, net.*"

The Company expects worldwide *FloTrac* systems sales will continue to be a significant contributor to 2009 Critical Care sales growth, 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. In the fourth quarter of 2009, the Company is planning a limited launch of a substantial upgrade designed to strengthen the *FloTrac* system's applicability in the medical intensive care unit. In addition, the Company anticipates launching a new hardware platform in the fourth quarter of 2009 with a simpler, more intuitive informational display, and expects to ultimately consolidate all parameters into one new hardware platform with a broad launch at the end of the first quarter of 2010.

Table of Contents

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 the third quarter of 2009, the first of two clinical studies to validate performance and support regulatory approval was completed. In October 2009, the Company received CE Mark approval and anticipates beginning clinical evaluation of its first generation product before the end of 2009 in a limited number of European sites.

Cardiac Surgery Systems

The \$0.9 million and \$2.6 million increases in net sales of Cardiac Surgery Systems products for the three and nine months ended September 30, 2009, respectively, were due primarily to MIS products, which increased net sales by \$0.6 million and \$3.7 million, respectively. Foreign currency exchange rate fluctuations decreased net sales by \$0.4 million and \$2.3 million, respectively.

Vascular

The \$8.4 million and \$22.9 million decreases in net sales of Vascular products for the three and nine months ended September 30, 2009, respectively, were due primarily to reduced sales of the *LifeStent* product line which was divested in January 2008. Sales after the divestiture resulted from the on-going manufacturing requirements of the sale agreement, which continued until the transfer of manufacturing to the buyer in September 2009.

Gross Profit

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
Gross profit as a percentage of net sales	69.8%	65.4%	4.4 pts.	69.5%	65.4%	4.1 pts.

The 4.4 and 4.1 percentage point increases in gross profit as a percentage of net sales for the three and nine months ended September 30, 2009, respectively, were driven by:

a 1.5 percentage point and a 1.3 percentage point increase in the United States gross profit as a percentage of net sales for the three and nine months ended September 30, 2009, respectively, due primarily to a more profitable product mix, primarily from reduced sales of *LifeStent* products under the manufacturing requirements of the *LifeStent* sale agreement;

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

the impact from the expiration of foreign currency hedging contracts.

Selling, General and Administrative (SG&A) Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
	(dollars in millions)					
SG&A expenses	\$ 126.1	\$ 119.3	\$ 6.8	\$ 376.5	\$ 360.4	\$ 16.1
SG&A expenses as a percentage of net sales	38.7%	39.3%	(0.6) pts.	38.6%	38.8%	(0.2) pts.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

The \$6.8 million and \$16.1 million increases in SG&A expenses for the three and nine months ended September 30, 2009, respectively, were due primarily to (1) investments for the transcatheter heart valve program in Europe and (2) higher sales-related spending in the Heart Valve Therapy product line. The increases were partially offset by the favorable impact of foreign currency (primarily the weakening of the Euro against the United States dollar) in the amounts of \$1.5 million and \$12.4 million, respectively.

Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
	(dollars in millions)					
Research and development expenses	\$ 44.7	\$ 35.1	\$ 9.6	\$ 127.2	\$ 103.4	\$ 23.8
Research and development expenses as a percentage of net sales	13.7%	11.6%	2.1 pts.	13.1%	11.1%	2.0 pts.

The increases in research and development expenses for the three and nine months ended September 30, 2009 were 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 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 is evaluating the *Edwards SAPIEN* transcatheter heart valve in patients who are considered at high risk for conventional open-heart valve surgery. In the first study arm ("Cohort A"), patients are randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. Enrollment of 690 patients in Cohort A, which is a non-inferiority analysis, was completed in the third quarter of 2009. In the second study arm ("Cohort B"), patients who are deemed non-operable are randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. Enrollment of 350 patients in Cohort B, which is a superiority analysis, was completed in the first quarter of 2009. In addition, the Company received FDA approval for non-randomized continued access for all of its existing PARTNER sites. The Company anticipates United States approval of the *Edwards SAPIEN* transcatheter heart valve in 2011;

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

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

first-in-man cases using the Company's next generation transcatheter heart valve, the *Edwards SAPIEN XT*, were performed during the first quarter of 2008. In December 2008, the first three implants were performed in the CE Mark trial. In the second quarter of 2009, the first implants

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

were performed with *SAPIEN XT* and *NovaFlex*, the Company's next generation transfemoral delivery system. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, enabling it to better address the requirements of transfemoral delivery. The Company anticipates European approval and limited launch of *SAPIEN XT* with *NovaFlex* in the first quarter of 2010. The first-in-man cases in the PREVAIL TA study, which uses the *SAPIEN XT* with the lower-profile *Ascendra 2* transapical delivery system, were performed in the third quarter of 2009. The Company anticipates a limited European launch of *SAPIEN XT* with *Ascendra 2* in the second quarter of 2010; and

in the United States, the Company submitted an IDE for *SAPIEN XT* in October 2009. This clinical trial, called PARTNER 2, will evaluate the *SAPIEN XT* with both the *NovaFlex* and *Ascendra 2* delivery systems and will target the same high risk patients studied in the PARTNER trial. The Company expects enrollment to begin in the first quarter of 2010.

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

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

Special (Gains) Charges, net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in millions)			
(Gain) loss on sale of product lines	\$ (58.6)	\$	\$ (84.1)	\$ 8.1
Charitable fund contribution	15.0		15.0	
Litigation	3.8		3.8	2.1
Investment impairment	1.6		1.6	
Sale of distribution rights			(2.8)	
Reserve reversal			(1.0)	
Realignment expenses, net				(0.9)
Special (gains) charges, net	\$ (38.2)	\$	\$ (67.5)	\$ 9.3

(Gain) Loss on Sale of Product Lines

Effective September 1, 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years, of which \$0.6 million was earned in September 2009 and recorded in "Other (Income) Expense, net." The sale resulted in a pre-tax gain of \$43.6 million consisting of the cash proceeds of \$55.9 million, offset by \$8.5 million related to the net book value of inventory, fixed assets, and intangible assets that were sold, a \$0.6 million satisfaction of a receivable, a \$0.5 million write-off of goodwill associated with this product line, and \$2.7 million of transaction and other costs related to the sale. In connection with this transaction, the Company also recorded a \$1.5 million charge in June 2009 for transaction costs and employee severance related to the pending sale. The Company will provide transition services to the buyer. This transaction allows the Company to better focus on its global strategic priorities.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

In January 2008, the Company sold certain assets related to the Edwards *LifeStent* peripheral vascular product line. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and was entitled to receive up to an additional \$65.0 million in cash upon the achievement of certain milestones. In addition, the Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. In December 2008, the Company received a \$23.0 million *LifeStent* milestone payment in connection with the transfer of its pre-market approval to the buyer. In February 2009, the Company received an additional \$27.0 million milestone payment associated with the *LifeStent* pre-market approval. In September 2009, the Company earned the remaining \$15.0 million milestone payment upon the transfer of *LifeStent* device manufacturing to the buyer. The Company received \$8.9 million of this milestone in September 2009 and \$6.1 million in October 2009.

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

Charitable Fund Contribution

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

Litigation

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

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.

Investment Impairment

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

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.

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

Realignment Expenses, net

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

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

In December 2007, the Company recorded realignment expenses of \$13.9 million primarily related to (1) severance expenses associated with the sale of the Company's *LifeStent* product line and a global reduction in workforce, primarily in the United States, Europe, and Japan (impacting approximately 180 employees), and (2) the termination of the Company's intra-aortic balloon pump distribution agreement in Japan. As of September 30, 2009, remaining payments of approximately \$1.3 million are expected to be paid through the end of 2009.

Interest Expense (Income), net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
	(in millions)					
Interest expense	\$ 0.9	\$ 1.5	\$ (0.6)	\$ 2.2	\$ 5.5	\$ (3.3)
Interest income	(0.3)	(1.9)	1.6	(1.3)	(5.1)	3.8
Interest expense (income), net	\$ 0.6	\$ (0.4)	\$ 1.0	\$ 0.9	\$ 0.4	\$ 0.5

The decreases in interest expense for the three and nine months ended September 30, 2009 resulted primarily from lower interest rates and a lower average debt balance as compared to the prior year periods. The decreases in interest income resulted primarily from lower average interest rates as compared to the prior year periods.

Other (Income) Expense, net

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Earn-out payments	\$ (0.6)	\$	\$ (0.6)	\$
Investment realized (gains) losses and impairment	(0.1)	0.1	(0.1)	0.9
Foreign exchange losses (gains), net	0.1	2.1	(2.4)	4.4
Loss (gain) on investments in unconsolidated affiliates	0.1	(0.8)	1.1	(2.1)
Accounts receivable securitization costs		0.4		1.5
Sale of property development rights		(0.5)		(0.5)
Other	0.3	(0.2)	0.2	(0.9)
Other (income) expense, net	\$ (0.2)	\$ 1.1	\$ (1.8)	\$ 3.3

In September 2009, the Company sold its hemofiltration product line. In connection with the transaction, the Company is entitled to earn-out payments up to \$9.0 million based on certain revenue objectives to be achieved by the buyer over the next two years. During September 2009, the Company earned \$0.6 million.

Table of Contents

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

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

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

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 22.0% and 25.0% for the three and nine months ended September 30, 2009, respectively, and 24.5% and 30.4% for the three and nine months ended September 30, 2008, respectively. The income tax rate for the nine months ended September 30, 2009 included the tax effect on a *LifeStent* milestone receipt and the sale of the hemofiltration product line (see the "*Special (Gains) Charges, net*" section for further information). In connection with the sale of the hemofiltration product line, the Company has applied for a Swiss tax ruling with respect to treatment of the gain on the transaction. If the ruling is subsequently approved, the expected tax benefit would be approximately \$5.5 million. The income tax rate for the nine months ended September 30, 2008 included the tax effect on the sale of the *LifeStent* product line.

As of September 30, 2009, June 30, 2009, and December 31, 2008, the liability for income taxes associated with uncertain tax positions was \$46.5 million, \$43.0 million, and \$35.9 million, respectively. These liabilities could be reduced by \$4.0 million, \$3.8 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 \$42.5 million, \$39.2 million, and \$33.6 million, respectively, if recognized, would favorably affect the Company's effective tax rate. Changes to potential interest expense upon settlement during the period were immaterial.

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

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities, and cash from operations. The Company believes that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments. The Company is not currently experiencing any limitation on access to its credit facility as a result of the conditions in global financial markets. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives.

Table of Contents

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 September 30, 2009, borrowings of \$102.3 million were outstanding under the Credit Agreement. The Credit Agreement contains various financial and other covenants, all of which the Company was in compliance with at September 30, 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. The fair value of the Company's remaining investment in this fund as of September 30, 2009 and December 31, 2008 was estimated to be \$2.4 million and \$10.9 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$1.9 million through the third quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2009. The remaining \$0.5 million of the investment is expected to be received after the third quarter of 2010, and has been classified as "*Other Assets*." During both the three and nine months ended September 30, 2009, the Company recognized realized gains of \$0.1 million, included in "*Other (Income) Expense, net*." Additionally, during the nine months ended September 30, 2009, the Company recognized unrealized gains of \$0.4 million, included in "*Accumulated Other Comprehensive Loss*."

In September 2009, the Company sold its hemofiltration product line. Under the terms of the agreement, the Company received a cash payment of \$55.9 million, and may receive up to an additional \$9.0 million upon the buyer's achievement of certain revenue objectives over the next two years. The Company will provide transition services to the buyer.

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

Edgar Filing: Edwards Lifesciences Corp - Form 10-Q

Table of Contents

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

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 nine months ended September 30, 2009, the Company repurchased 1.3 million shares at an aggregate cost of \$79.6 million and as of September 30, 2009 had remaining authority to purchase \$113.9 million of common stock.

At September 30, 2009, there had been no material changes in the Company's significant contractual obligations and commercial commitments as disclosed in its Annual Report on Form 10-K for the year ended December 31, 2008.

Net cash flows provided by **operating activities** of \$99.4 million for the nine months ended September 30, 2009 increased \$26.7 million over the same period a year ago. This increase was due primarily to a \$50.0 million cash payment during the third quarter of 2008 to terminate the Company's accounts receivable securitization program in the United States, compared 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 positively impacted by improved operating performance and lower tax payments in 2009.

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

Net cash provided by investing activities of \$75.6 million for the nine months ended September 30, 2008 consisted primarily of \$74.0 million of cash received from the sale of the *LifeStent* product line and \$30.9 million in cash redemptions associated with the Bank of America Columbia Strategic Cash fund, partially offset by capital expenditures of \$32.9 million.

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

Net cash used in financing activities of \$88.5 million for the nine months ended September 30, 2008 consisted primarily of purchases of treasury stock of \$285.5 million, partially offset by net proceeds from long-term debt of \$134.2 million and the proceeds from stock plans of \$50.7 million.

Critical Accounting Policies

The consolidated condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States which require the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and revenues and expenses during the periods reported. Actual results could differ from those estimates. Information with respect to the Company's critical accounting policies which the Company believes could have the most significant effect on the Company's reported results and require subjective or complex judgments by management is contained on pages 38-43 in Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*", of the Company's Annual Report on Form 10-K for the year ended December 31, 2008. Management believes that at September 30, 2009, there had been no material changes to this information.

Table of Contents

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 September 30, 2009, Edwards Lifesciences had \$24.8 million of investments in equity instruments of other companies and had recorded unrealized gains of \$2.9 million on these investments in "*Accumulated Other Comprehensive Loss,*" net of tax. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the decline in the investments' value may be considered other-than-temporary and impairment charges may be necessary.

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. The fair value of the Company's remaining investment in this fund as of September 30, 2009 was estimated to be \$2.4 million based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions of approximately \$1.9 million through the third quarter of 2010, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2009. The remaining \$0.5 million of the investment is expected to be received after the third quarter of 2010, and has been classified as "*Other Assets.*" During both the three and nine months ended September 30, 2009, the Company recognized realized gains of \$0.1 million, included in "*Other (Income) Expense, net.*" Additionally, during the nine months ended September 30, 2009, the Company recognized unrealized gains of \$0.4 million, included in "*Accumulated Other Comprehensive*

Table of Contents

Loss." 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 September 30, 2009. Based on their evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that such controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. There have been no changes in the Company's internal controls over financial reporting that were identified during this evaluation that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

Part II. Other Information

Item 1. Legal Proceedings

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

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

In February 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany, against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook counterclaimed, alleging infringement by Edwards. In March 2009, the German Court ruled that the Company does not infringe the Cook patent. In June 2009, the United Kingdom Court also ruled that the Company does not infringe the Cook patent and, further, that the Cook patent is invalid. Cook is appealing the judgments in Germany and the United Kingdom.

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

Edwards Lifesciences is subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance

Table of Contents

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

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

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (a)
July 1, 2009 through July 31, 2009	110,000	\$ 66.51	110,000	\$ 131.7
August 1, 2009 through August 31, 2009	145,000	64.22	145,000	122.3
September 1, 2009 through September 30, 2009	130,000	64.88	130,000	113.9
Total	385,000	65.10	385,000	

(a)

On July 11, 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.

Item 6. Exhibits

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

- 31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Table of Contents

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EDWARDS LIFESCIENCES CORPORATION

(Registrant)

Date: November 6, 2009

By: /s/ THOMAS M. ABATE

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

40

Table of Contents

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

Exhibit No.	Description
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

41