

EDWARDS LIFESCIENCES CORP
Form 10-Q
November 07, 2008

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**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, 2008

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

Large accelerated
filer

Accelerated
filer

Non-accelerated
filer

Smaller Reporting
Company

(Do not check if a

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smaller reporting
company)

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

The number of shares outstanding of the registrant's common stock, \$1.00 par value, as of October 31, 2008 was 55,662,837.

EDWARDS LIFESCIENCES CORPORATION
FORM 10-Q
For the quarterly period ended September 30, 2008

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Part I. Financial Information

Item 1. Financial Statements

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED CONDENSED BALANCE SHEETS

(in millions, except par value; unaudited)

| | September 30, 2008 | December 31, 2007 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 202.4 | \$ 141.8 |
| Short-term investments (Note 3) | 12.1 | 49.4 |
| Accounts and other receivables, net of allowances of \$10.5 and \$7.5, respectively (Note 4) | 213.6 | 145.3 |
| Inventories, net | 143.8 | 152.6 |
| Deferred income taxes | 28.0 | 30.2 |
| Prepaid expenses | 37.8 | 25.4 |
| Other current assets | 38.6 | 37.0 |
| | | |
| Total current assets | 676.3 | 581.7 |
| Property, plant and equipment, net | 224.0 | 228.2 |
| Goodwill | 315.7 | 350.3 |
| Other intangible assets, net | 107.9 | 122.5 |
| Investments in unconsolidated affiliates | 20.3 | 34.3 |
| Deferred income taxes | 19.7 | 13.8 |
| Other assets | 17.3 | 14.3 |
| | \$ 1,381.2 | \$ 1,345.1 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 229.9 | \$ 225.4 |
| Convertible debt (Note 7) | | 150.0 |
| | | |
| Total current liabilities | 229.9 | 375.4 |
| | | |
| Long-term debt | 202.8 | 61.7 |
| | | |
| Other long-term liabilities | 74.0 | 73.0 |
| | | |
| Commitments and contingencies (Note 11) | | |
| Stockholders' equity | | |
| Preferred stock, \$.01 par value, authorized 50.0 shares, no shares outstanding | | |
| Common stock, \$1.00 par value, 350.0 shares authorized, 73.3 and 68.6 shares issued, and 55.9 and 56.6 shares outstanding, respectively | 73.3 | 68.6 |
| Additional contributed capital | 912.6 | 680.6 |
| Retained earnings | 639.4 | 548.6 |
| Accumulated other comprehensive income | 5.0 | 7.5 |
| Treasury stock, at cost, 17.4 and 12.0 shares, respectively | (755.8) | (470.3) |
| | | |
| Total stockholders' equity | 874.5 | 835.0 |

\$ 1,381.2 \$ 1,345.1

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS

(in millions, except per share information; unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|--|----------|---------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Net sales | \$ 303.6 | \$ 261.4 | \$ 928.0 | \$ 798.1 |
| Cost of goods sold | 104.9 | 90.7 | 320.8 | 278.6 |
| Gross profit | 198.7 | 170.7 | 607.2 | 519.5 |
| Selling, general and administrative expenses | 119.3 | 103.2 | 360.4 | 303.5 |
| Research and development expenses | 35.1 | 30.9 | 103.4 | 88.8 |
| Special (gains) charges, net (Note 2) | | (2.5) | 9.3 | (2.5) |
| Interest (income) expense, net | (0.4) | 0.4 | 0.4 | 1.0 |
| Other expense (income), net | 1.1 | (0.1) | 3.3 | (1.5) |
| Income before provision for income taxes | 43.6 | 38.8 | 130.4 | 130.2 |
| Provision for income taxes | 10.7 | 9.7 | 39.6 | 33.0 |
| Net income | \$ 32.9 | \$ 29.1 | \$ 90.8 | \$ 97.2 |
| Share information (Note 13) | | | | |
| Earnings per share: | | | | |
| Basic | \$ 0.59 | \$ 0.51 | \$ 1.63 | \$ 1.69 |
| Diluted | \$ 0.56 | \$ 0.48 | \$ 1.54 | \$ 1.59 |
| Weighted-average number of common shares outstanding: | | | | |
| Basic | 56.0 | 57.1 | 55.8 | 57.5 |
| Diluted | 59.0 | 62.4 | 60.1 | 63.0 |

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS

(in millions; unaudited)

| | Nine Months Ended September 30, | |
|---|------------------------------------|----------|
| | 2008 | 2007 |
| Cash flows from operating activities | | |
| Net income | \$ 90.8 | \$ 97.2 |
| Adjustments to reconcile net income to cash provided by operating activities: | | |
| Depreciation and amortization | 41.3 | 41.1 |
| Stock-based compensation (Note 10) | 21.0 | 20.9 |
| Deferred income taxes | (2.1) | 1.0 |
| Special charges (gains), net | 8.4 | (2.5) |
| Other | 2.7 | (0.1) |
| Changes in operating assets and liabilities: | | |
| Accounts and other receivables, net (Note 4) | (68.8) | 0.8 |
| Inventories, net | (11.4) | (12.2) |
| Accounts payable and accrued liabilities | (0.4) | (7.5) |
| Prepaid expenses and other current assets | (5.9) | (8.1) |
| Other | (2.9) | 3.4 |
| Net cash provided by operating activities | 72.7 | 134.0 |
| Cash flows from investing activities | | |
| Capital expenditures | (32.9) | (43.1) |
| Investments in intangible assets | (0.4) | (1.0) |
| Proceeds from (investments in) unconsolidated affiliates, net | 4.6 | (3.0) |
| Investments in trading securities, net | (0.6) | (0.7) |
| Proceeds from investments (Note 3) | 30.9 | |
| Proceeds from sale of assets (Note 2) | 74.0 | 5.4 |
| Acquisition milestone payment | | (9.6) |
| Other | | (0.5) |
| Net cash provided by (used in) investing activities | 75.6 | (52.5) |
| Cash flows from financing activities | | |
| Proceeds from issuance of long-term debt | 196.3 | 44.2 |
| Payments on long-term debt | (62.1) | (71.4) |
| Purchases of treasury stock | (285.5) | (107.2) |
| Proceeds from stock plans | 50.7 | 32.6 |
| Excess tax benefit from stock plans | 12.5 | 7.4 |
| Other | (0.4) | 4.6 |
| Net cash used in financing activities | (88.5) | (89.8) |
| Effect of currency exchange rate changes on cash and cash equivalents | 0.8 | 1.2 |
| Net increase (decrease) in cash and cash equivalents | 60.6 | (7.1) |
| Cash and cash equivalents at beginning of period | 141.8 | 182.8 |
| Cash and cash equivalents at end of period | \$ 202.4 | \$ 175.7 |

Supplemental disclosures:

Non-cash transactions:

| | | |
|---|----------|----|
| Issuance of common shares in redemption of convertible debt | \$ 147.7 | \$ |
|---|----------|----|

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

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 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, 2007. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted.

In the opinion of management of Edwards Lifesciences Corporation (the "Company" or "Edwards Lifesciences"), the interim consolidated condensed financial statements reflect all adjustments considered necessary for a fair statement of the interim periods. All such adjustments are of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB Staff Position 157-2, "*Effective Date of FASB Statement No. 157*" ("FSP 157-2"), which delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FASB Staff Position 157-3, "*Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*" ("FSP 157-3"). FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not yet been issued. The Company's adoption of SFAS No. 157, except 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. The Company does not expect the adoption of SFAS 157 related to its non-financial assets and liabilities to have a material impact on its consolidated financial statements. The adoption of FSP 157-3 did not have an impact on the Company's consolidated financial statements. See Note 8 for further information.

In September 2006, the FASB issued SFAS No. 158, "*Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106, and 132(R)*" ("SFAS 158"). SFAS 158 requires employers to recognize the overfunded or underfunded status of a single-employer defined benefit postretirement plan as an asset or liability on its balance sheet and to recognize changes in that funded status in comprehensive income. In addition, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end balance sheet. SFAS 158 provides different effective dates for the recognition and related disclosure provisions, and for the required change to a fiscal year-end measurement date. In December 2006, the Company applied the requirements to recognize the funded status of its benefit plans and made the required disclosures. The requirement to measure plan assets and benefit obligations as of the date of the employer's fiscal year-end balance sheet is effective for the Company for the fiscal year ending December 31, 2008. SFAS 158 provides two approaches for transitioning to a fiscal year-end measurement date. The Company will adopt the measurement date provisions using the "one measurement" approach. Under this approach, the Company will use the measurement determined as

of October 31, 2007 and will recognize the net benefit expense for the transition period from November 1, 2007 through December 31, 2007 in retained earnings at December 31, 2008. The adoption of the measurement date provisions of SFAS 158 will not have a material impact on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" ("SFAS 159"). SFAS 159 allows reporting entities to choose to measure many financial instruments at fair value and incorporates an amendment to SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," which is applicable to all entities with trading securities or securities that are considered to be available for sale. The provisions within SFAS 159 are effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS 159 effective January 1, 2008. The Company has not elected the fair value option for its financial instruments. As required by SFAS 159, the Company has reclassified all cash flows related to its trading securities from operating to investing activities in the consolidated condensed statements of cash flows.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*" ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used in future research and development activities be deferred and capitalized until the related service is performed or the goods are delivered. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

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

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

In April 2008, the FASB issued FASB Staff Position No. 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "*Goodwill and Other Intangible Assets*." FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible

asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of FSP 142-3 on its consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, "*The Hierarchy of Generally Accepted Accounting Principles*" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective November 15, 2008. The Company does not expect the adoption of SFAS 162 to have a material impact on its consolidated financial statements.

In September 2008, the FASB issued FSP 133-1 and FIN 45-4, "*Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161*" ("FSP 133-1 and FIN 45-4"). FSP 133-1 and FIN 45-4 amends and enhances disclosure requirements for sellers of credit derivatives and financial guarantees. It also clarifies that the disclosure requirements of SFAS No. 161 are effective for quarterly periods beginning after November 15, 2008, and fiscal years that include those periods. FSP 133-1 and FIN 45-4 is effective for reporting periods (annual or interim) ending after November 15, 2008. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

2. SPECIAL (GAINS) CHARGES, NET

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|--|----------------|---------------------------------------|----------------|
| | 2008 | 2007 | 2008 | 2007 |
| | (in millions) | | | |
| Loss on sale of product line | \$ | \$ | \$ 8.1 | \$ |
| Litigation settlement | | | 2.1 | |
| Realignment expenses, net | | | (0.9) | |
| Gain on estimated insurance settlement | | (2.5) | | (2.5) |
| Special (gains) charges, net | \$ | \$(2.5) | \$ 9.3 | \$(2.5) |

Loss on Sale of Product Line

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. This divestiture is part of the Company's ongoing strategy to focus resources on its core heart valve and critical care businesses. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and will receive up to an additional \$65.0 million in cash upon the achievement of certain milestones, including the receipt of United States regulatory approval of the *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. Because of the Company's continued involvement in the operations of *LifeStent* after its sale, the Company did not report the loss on disposition or the results of *LifeStent's* operations as discontinued operations.

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

Litigation Settlement

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

Realignment Expenses, net

In 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, 2008, remaining payments of \$3.4 million are expected to be paid through the end of 2009.

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, 2008, remaining payments of \$1.0 million for the executive severance charge are expected to be paid through the end of 2009.

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

Gain on Estimated Insurance Settlement

During the third quarter of 2007, the Company experienced a fire that damaged certain inventory held at a third party warehouse in Brazil. The total amount of the loss related to the inventory was \$1.8 million, which was expected to be reimbursed by insurance. In addition, the Company held business interruption insurance to cover the lost profit of \$2.5 million due to the property damage. As of September 30, 2007, the Company had recorded a receivable from the insurance company of \$4.3 million and a gain of \$2.5 million for the estimated insurance settlement. In the fourth quarter of 2007, the Company reversed this gain as it will be recognized upon settlement.

3. INVESTMENTS

The Company holds an investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, which was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investments for cash. During the three and 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 Expense (Income), net.*" During 2008, the Company has received cash redemptions of \$30.9 million. The fair value of the Company's remaining investment in this fund as of September 30, 2008 and December 31, 2007 was estimated to be \$17.6 million and \$49.4 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions for approximately \$12.1 million through the third quarter of 2009, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2008. The remaining \$5.5 million of the investment is expected to be received after the third quarter of 2009, and has been classified as "*Other Assets.*" The entire investment of \$49.4 million at December 31, 2007 was classified as "*Short-term Investments*" based on the redemption schedule communicated to the Company at that time.

4. ACCOUNTS RECEIVABLE SECURITIZATION

The Company securitizes, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in Japan and, until August 2008, in the United States. Under the Japan Receivables Facility, the Company sells eligible accounts receivable directly to a financial institution. The Japan Receivables Facility expires on December 3, 2008 and the Company is in the process of renewing it. Previously, under the United States Receivables Facility, the Company sold eligible accounts receivable to a wholly owned, bankruptcy-remote entity formed for the purpose of buying and selling these receivables, which then sold undivided interests in the receivables to a financial institution. In August 2008, the Company terminated its securitization program in the United States, and repurchased \$50 million of accounts receivable. As of September 30, 2008, the Company had sold, under its Japan securitization program, a total of \$34.8 million of trade accounts receivable and received funding of \$29.2 million.

5. INVENTORIES

Inventories consisted of the following (in millions):

| | September 30, 2008 | December 31, 2007 |
|-------------------|-----------------------|----------------------|
| Raw materials | \$ 35.9 | \$ 30.5 |
| Work in process | 25.1 | 21.8 |
| Finished products | 82.8 | 100.3 |
| | \$ 143.8 | \$ 152.6 |

6. OTHER INTANGIBLE ASSETS

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

| | Patents | Unpatented Technology | Other | Total |
|---------------------------|----------|--------------------------|---------|----------|
| September 30, 2008 | | | | |
| Cost | \$ 209.8 | \$ 35.0 | \$ 13.5 | \$ 258.3 |
| Accumulated amortization | (123.0) | (24.0) | (3.4) | (150.4) |
| Net carrying value | \$ 86.8 | \$ 11.0 | \$ 10.1 | \$ 107.9 |
| December 31, 2007 | | | | |
| Cost | \$ 214.1 | \$ 35.0 | \$ 17.4 | \$ 266.5 |
| Accumulated amortization | (118.7) | (22.2) | (3.1) | (144.0) |
| Net carrying value | \$ 95.4 | \$ 12.8 | \$ 14.3 | \$ 122.5 |

Patents include \$14.1 million of capitalized legal costs related to the defense and enforcement of issued patents and trademarks for which success is deemed probable as of September 30, 2008.

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line (see Note 2). This transaction resulted in a net reduction in "*Other Intangible Assets, net*" of \$7.8 million.

Amortization expense related to other intangible assets was \$4.6 million and \$4.2 million for the three months ended September 30, 2008 and 2007, respectively, and \$13.8 million and \$12.6 million for

the nine months ended September 30, 2008 and 2007, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

| | |
|------|--------|
| 2008 | \$18.4 |
| 2009 | 17.3 |
| 2010 | 13.9 |
| 2011 | 12.1 |
| 2012 | 11.5 |

7. CONVERTIBLE DEBT

On May 9, 2008, the Company called for redemption its \$150.0 million of convertible senior debentures (the "Notes"). Prior to the redemption date of June 9, 2008, holders of approximately \$147.7 million principal amount of the Notes converted their debentures into approximately 2.7 million shares of Edwards Lifesciences common stock at a conversion price of \$54.66 per share. The remaining outstanding Notes of \$2.3 million were redeemed for cash on the redemption date.

8. FAIR VALUE MEASUREMENTS

The Company adopted SFAS 157 as of January 1, 2008. As explained in Note 1, the Company has only adopted the provisions of SFAS 157 with respect to its financial assets and liabilities. The Company has deferred the application of the provisions of this statement to its non-financial assets and liabilities in accordance with FSP 157-2. SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 establishes a fair value hierarchy that prioritizes the inputs used to determine fair values. Financial assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

Level 1 Quoted market prices in active markets for identical assets or liabilities.

Level 2 Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3 Unobservable inputs that are not corroborated by market data.

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

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of September 30, 2008 (in millions):

| | Level 1 | Level 2 | Level 3 | Total |
|--|---------|---------|---------|--------|
| Assets | | | | |
| Investment in the Bank of America Columbia Strategic Cash fund | \$ | \$ | \$ 17.6 | \$17.6 |
| Investments held for executive deferred compensation plan | 12.8 | | | 12.8 |
| Investments in unconsolidated affiliates | 10.8 | | | 10.8 |
| Residual interest in accounts receivable securitizations | | | 5.6 | 5.6 |
| Derivatives | | 5.5 | | 5.5 |
| | \$ 23.6 | \$ 5.5 | \$ 23.2 | \$52.3 |

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The following table summarizes the changes in fair value of the Company's financial assets and liabilities that have been classified as Level 3 for the nine months ended September 30, 2008 (in millions):

| | 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) |
| Included in other comprehensive income | | | |
| Purchases, sales, issuances, and settlements | (30.9) | (3.2) | (34.1) |
| Transfers in and/or out of Level 3 | | | |
| Balance at September 30, 2008 | \$ 17.6 | \$ 5.6 | \$ 23.2 |

(a)

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

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

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

9. DEFINED BENEFIT PLANS

The components of net periodic benefit costs for the three and nine months ended September 30, 2008 and 2007 were as follows (in millions):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|--------|---------------------------------|--------|
| | 2008 | 2007 | 2008 | 2007 |
| Service cost | \$ 1.0 | \$ 0.7 | \$ 2.9 | \$ 2.0 |
| Employee contributions | | | | |
| Interest cost | 0.3 | 0.6 | 1.0 | 1.8 |
| Expected return on plan assets | (0.3) | (0.6) | (0.7) | (1.8) |
| Amortization of prior service cost and other | 0.1 | | 0.1 | 0.1 |
| Net periodic pension benefit cost | \$ 1.1 | \$ 0.7 | \$ 3.3 | \$ 2.1 |

10. STOCK-BASED COMPENSATION

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the three and nine months ended September 30, 2008 and 2007 was as follows (in millions):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|-------|---------------------------------|--------|
| | 2008 | 2007 | 2008 | 2007 |
| Cost of goods sold | \$0.8 | \$0.8 | \$ 2.0 | \$ 2.3 |
| Selling, general and administrative expenses | 6.1 | 5.4 | 15.3 | 14.9 |
| Research and development expenses | 1.3 | 1.3 | 3.7 | 3.7 |
| Total stock-based compensation expense | \$8.2 | \$7.5 | \$21.0 | \$20.9 |

At September 30, 2008, the total remaining compensation cost related to unvested stock options, restricted stock units and employee stock purchase subscription awards amounted to \$53.0 million and will be amortized on a straight-line basis over a weighted-average vesting period of approximately 32 months.

During the nine months ended September 30, 2008, the Company granted 1.0 million stock options at a weighted-average exercise price of \$55.50 and 0.3 million shares of restricted stock units at a weighted-average grant-date fair value of \$54.35.

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, | |
|-------------------------|--|----------|---------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Risk-free interest rate | 2.9% | 4.8% | 3.0% | 4.6% |
| Expected dividend yield | None | None | None | None |
| Expected volatility | 23.7% | 18.5% | 23.3% | 18.7% |
| Expected term (years) | 4.9 | 4.9 | 4.7 | 4.9 |
| Fair value, per share | \$ 15.12 | \$ 13.36 | \$ 14.35 | \$ 13.09 |

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, | |
|-------------------------|--|----------|---------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Risk-free interest rate | 2.1% | 4.9% | 2.2% | 4.9% |
| Expected dividend yield | None | None | None | None |
| Expected volatility | 25.5% | 23.8% | 25.3% | 24.6% |
| Expected term (years) | 0.6 | 0.6 | 0.6 | 0.6 |
| Fair value, per share | \$ 14.36 | \$ 11.53 | \$ 14.04 | \$ 11.51 |

11. COMMITMENTS AND CONTINGENCIES

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

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

ReValving System infringes the Andersen patent in the United Kingdom. A trial in the United Kingdom on validity and infringement concluded in July 2008, and a decision is pending. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents.

In February 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook has counterclaimed, alleging infringement by Edwards.

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 claims, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

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

12. COMPREHENSIVE INCOME

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

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|--------|-------------------|---------|
| | September 30, | | September 30, | |
| | 2008 | 2007 | 2008 | 2007 |
| Net income | \$ 32.9 | \$29.1 | \$90.8 | \$ 97.2 |
| Other comprehensive income: | | | | |
| Currency translation adjustments | (19.3) | 10.1 | (2.0) | 15.5 |
| Unrealized net (loss) gain on investments in unconsolidated affiliates, net of tax | (3.5) | 6.5 | (7.6) | 8.1 |
| Unrealized net gain (loss) on cash flow hedges, net of tax | 8.6 | (4.8) | 7.1 | (4.9) |
| Comprehensive income | \$ 18.7 | \$40.9 | \$88.3 | \$115.9 |

13. EARNINGS PER SHARE

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

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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, | |
|--|---|-------------|--|-------------|
| | 2008 | 2007 | 2008 | 2007 |
| Basic: | | | | |
| Net income | \$32.9 | \$29.1 | \$90.8 | \$ 97.2 |
| Weighted-average shares outstanding | 56.0 | 57.1 | 55.8 | 57.5 |
| Basic earnings per share | \$0.59 | \$0.51 | \$1.63 | \$ 1.69 |
| Assuming dilution: | | | | |
| Net income | \$32.9 | \$29.1 | \$90.8 | \$ 97.2 |
| Interest expense related to convertible debt, net of tax | | 1.0 | 1.7 | 3.0 |
| Net income applicable to diluted shares | \$32.9 | \$30.1 | \$92.5 | \$100.2 |
| Weighted-average shares outstanding | 56.0 | 57.1 | 55.8 | 57.5 |
| Dilutive effect of convertible debt | | 2.7 | 1.6 | 2.7 |
| Dilutive effect of stock plans | 3.0 | 2.6 | 2.7 | 2.8 |
| Dilutive weighted-average shares outstanding | 59.0 | 62.4 | 60.1 | 63.0 |
| Diluted earnings per share | \$0.56 | \$0.48 | \$1.54 | \$ 1.59 |

Stock options and restricted stock units to purchase 1.1 million and 3.5 million shares for the three months ended September 30, 2008 and 2007, respectively, and 2.0 million and 2.8 million for the nine months ended September 30, 2008 and 2007, 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 the Company's \$150.0 million convertible debentures until they were redeemed on June 9, 2008.

14. INCOME TAXES

The Federal Research and Development Credit expired on December 31, 2007. Legislation was signed on October 3, 2008 extending the research credit retroactively from January 1, 2008 through December 31, 2009. No benefit related to the Federal Research and Development Credit has been taken in the first nine months of 2008. The benefit related to the retroactive extension of the research credit will be reflected in the fourth quarter of 2008, the quarter in which the legislation was enacted.

The effective income tax rates were 24.5% and 30.4% for the three and nine months ended September 30, 2008, respectively, and 25.0% and 25.3% for the three and nine months ended September 30, 2007, respectively. The income tax rate for the nine months ended September 30, 2008 included the tax effect on the sale of the *LifeStent* product line.

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As of September 30, 2008, the liability for income taxes associated with uncertain tax positions was \$48.5 million. This liability can be reduced by \$12.4 million from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$36.1 million, if recognized, would favorably affect the Company's effective tax rate. Changes during the period to potential interest expense upon settlement were immaterial.

The liability for income taxes associated with uncertain tax positions was \$40.5 million at June 30, 2008 and \$36.4 million at December 31, 2007. As of June 30, 2008 and December 31, 2007, these liabilities could be reduced by \$8.7 million and \$8.0 million, respectively, from offsetting tax benefits. The net amounts of \$31.8 million at June 30, 2008 and \$28.4 million at December 31, 2007, if recognized, would favorably affect the Company's effective tax rate.

During the third quarter of 2007, the Internal Revenue Service ("IRS") initiated an audit of the 2005 and 2006 tax years. This audit is expected to close in late 2008 or early 2009. No significant unexpected adjustments have been proposed.

In the next 12 months the amount of unrecognized tax benefits, and the amount of those benefits impacting the rate, may change as a result of settlements of tax authority examinations and the closing of statutes. The quantity and timing of potential tax settlements and payments cannot be estimated at this time. At September 30, 2008, the Company has concluded all United States federal income tax matters for years through 2004. All material state and local, and foreign income tax matters have been concluded for years through 2002.

15. SEGMENT INFORMATION

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

The Company evaluates the performance of its segments based on net sales and income before provision for income taxes ("pre-tax income"). The accounting policies of the segments are substantially the same as those described in Note 2, Summary of Significant Accounting Policies, in the Company's Annual Report on Form 10-K for the year ended December 31, 2007. Net sales and pre-tax income of reportable segments are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments, the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent.

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|------------------------------|--|----------|---------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Net Sales | | | | |
| United States | \$ 134.4 | \$ 118.2 | \$ 408.0 | \$ 362.8 |
| Europe | 83.3 | 53.9 | 263.9 | 172.4 |
| Japan | 42.0 | 43.3 | 121.7 | 131.3 |
| Rest of world | 33.1 | 28.5 | 96.6 | 82.4 |
| | | | | |
| Total segment net sales | \$ 292.8 | \$ 243.9 | \$ 890.2 | \$ 748.9 |
| Pre-Tax Income | | | | |
| United States | \$ 69.7 | \$ 60.4 | \$ 212.0 | \$ 192.3 |
| Europe | 23.9 | 11.1 | 81.0 | 42.7 |
| Japan | 18.9 | 17.0 | 53.1 | 50.0 |
| Rest of world | 8.9 | 6.7 | 25.4 | 18.2 |
| | | | | |
| Total segment pre-tax income | \$ 121.4 | \$ 95.2 | \$ 371.5 | \$ 303.2 |

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, | |
|--------------------------------------|--|----------|---------------------------------------|----------|
| | 2008 | 2007 | 2008 | 2007 |
| Net Sales Reconciliation | | | | |
| Segment net sales | \$ 292.8 | \$ 243.9 | \$ 890.2 | \$ 748.9 |
| Foreign currency | 10.8 | 17.5 | 37.8 | 49.2 |
| | | | | |
| Consolidated net sales | \$ 303.6 | \$ 261.4 | \$ 928.0 | \$ 798.1 |
| Pre-Tax Income Reconciliation | | | | |
| Segment pre-tax income | \$ 121.4 | \$ 95.2 | \$ 371.5 | \$ 303.2 |
| Unallocated amounts: | | | | |
| Corporate items | (75.4) | (65.7) | (223.4) | (192.9) |
| Special gains (charges), net | | 2.5 | (9.3) | 2.5 |
| Interest income (expense), net | 0.4 | (0.4) | (0.4) | (1.0) |
| Foreign currency | (2.8) | 7.2 | (8.0) | 18.4 |
| | | | | |
| Consolidated pre-tax income | \$ 43.6 | \$ 38.8 | \$ 130.4 | \$ 130.2 |

Enterprise-Wide Information

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

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|----------|-------------------|----------|
| | September 30, | | September 30, | |
| | 2008 | 2007 | 2008 | 2007 |
| (in millions) | | | | |
| Net Sales by Geographic Area | | | | |
| United States | \$ 135.6 | \$ 118.1 | \$ 410.8 | \$ 362.7 |
| Other countries | 168.0 | 143.3 | 517.2 | 435.4 |
| | \$ 303.6 | \$ 261.4 | \$ 928.0 | \$ 798.1 |
| Net Sales by Major Product and Service Area | | | | |
| Heart Valve Therapy | \$ 148.4 | \$ 122.8 | \$ 457.7 | \$ 383.6 |
| Critical Care | 110.3 | 96.5 | 333.6 | 284.8 |
| Cardiac Surgery Systems | 21.4 | 13.8 | 66.3 | 45.8 |
| Vascular | 23.5 | 22.4 | 70.4 | 64.9 |
| Other Distributed Products | | 5.9 | | 19.0 |
| | \$ 303.6 | \$ 261.4 | \$ 928.0 | \$ 798.1 |

| | September 30, December 31, | |
|--|----------------------------|----------|
| | 2008 | 2007 |
| (in millions) | | |
| Long-Lived Tangible Assets by Geographic Area | | |
| United States | \$ 175.9 | \$ 197.9 |
| Other countries | 85.7 | 78.9 |
| | \$ 261.6 | \$ 276.8 |

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, any statements of plans, strategies and objectives of management for future operations, any statements concerning the Company's future operations, financial conditions and prospects, any statements regarding the timing of regulatory approvals or new product introductions, 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," or "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, 2007 for a description of certain of these risks and uncertainties.

Overview

Edwards Lifesciences Corporation ("Edwards Lifesciences" or the "Company") is a global provider of technologies that are designed to treat advanced cardiovascular disease. Edwards Lifesciences focuses on providing products and technologies to address specific cardiovascular conditions including heart valve disease, critical care technologies and peripheral vascular disease.

The products and technologies provided by Edwards Lifesciences to treat advanced cardiovascular disease are categorized into five main areas: Heart Valve Therapy, Critical Care, Cardiac Surgery Systems, Vascular and Other Distributed Products.

Edwards Lifesciences' **Heart Valve Therapy** portfolio is comprised of tissue heart valves and heart valve repair products. A pioneer in the development and commercialization of heart valve products, Edwards Lifesciences is the world's leading manufacturer of tissue heart valves and repair products used to replace or repair a patient's diseased or defective heart valve. In the **Critical Care** area, Edwards Lifesciences is a world leader in hemodynamic monitoring equipment used to measure a patient's cardiovascular function and in disposable pressure transducers, and also provides central venous access products for fluid and drug delivery. The Company's **Cardiac Surgery Systems** portfolio comprises a diverse line of products for use during cardiac surgery including cannula, *EMBOL-X* technologies, and other disposable products used during cardiopulmonary bypass procedures. Cardiac Surgery Systems also included transmyocardial revascularization ("TMR") products until March 2007 when the Company sold the distribution rights to its TMR products. In December 2007, the Company acquired the *CardioVations* line of products used in minimally invasive heart valve surgery. Edwards Lifesciences' **Vascular** portfolio includes a line of balloon catheter-based products, surgical clips and inserts, artificial implantable grafts, and stents ("*LifeStent*" products) for which approval is being sought for use in the treatment of peripheral vascular disease. The Company sold the *LifeStent* product line in January 2008, but will continue to manufacture these products for the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer. Lastly, **Other Distributed Products** consisted primarily of intra-aortic balloon pumps. This business was terminated at the end of 2007.

The healthcare marketplace continues to be competitive with strong global and local competitors. The Company competes with many companies, ranging from small start-up enterprises to companies that are larger and more established than Edwards Lifesciences with access to significant financial resources. Furthermore, rapid product development and technological change characterize the market in which the Company competes. Global demand for healthcare is increasing as the population ages. There is mounting pressure to contain healthcare costs in the face of this increasing demand, which has resulted in pricing and market share pressures. The cardiovascular segment of the medical device industry is dynamic and technology, cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs are expected to continue to drive change.

Recently Adopted Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "*Fair Value Measurements*" ("SFAS 157"), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB Staff Position 157-2, "*Effective Date of FASB Statement No. 157*" ("FSP 157-2"), which delays the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed at fair value in the financial statements on a recurring basis, until fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FASB Staff Position 157-3, "*Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*" ("FSP 157-3"). FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not yet been issued. The Company's adoption of SFAS No. 157, except 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. The Company does not expect the adoption of SFAS 157 related to its non-financial assets and liabilities to have a material impact on its consolidated financial statements. The adoption of FSP 157-3 did not have an impact on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS No. 158, "*Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans - An Amendment of FASB Statements No. 87, 88, 106, and 132(R)*" ("SFAS 158"). SFAS 158 requires employers to recognize the overfunded or underfunded status of a single-employer defined benefit postretirement plan as an asset or liability on its balance sheet and to recognize changes in that funded status in comprehensive income. In addition, SFAS 158 requires employers to measure the funded status of a plan as of the date of its year-end balance sheet. SFAS 158 provides different effective dates for the recognition and related disclosure provisions, and for the required change to a fiscal year-end measurement date. In December 2006, the Company applied the requirements to recognize the funded status of its benefit plans and made the required disclosures. The requirement to measure plan assets and benefit obligations as of the date of the employer's fiscal year-end balance sheet is effective for the Company for the fiscal year ending December 31, 2008. SFAS 158 provides two approaches for transitioning to a fiscal year-end measurement date. The Company will adopt the measurement date provisions using the "one measurement" approach. Under this approach, the Company will use the measurement determined as of October 31, 2007 and will recognize the net benefit expense for the transition period from November 1, 2007 through December 31, 2007 in retained earnings at December 31, 2008. The adoption of the measurement date provisions of SFAS 158 will not have a material impact on the Company's consolidated financial statements.

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In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities*" ("SFAS 159"). SFAS 159 allows reporting entities to choose to measure many financial instruments at fair value and incorporates an amendment to SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," which is applicable to all entities with trading securities or securities that are considered to be available for sale. The provisions within SFAS 159 are effective for fiscal years beginning after November 15, 2007. The Company adopted SFAS 159 effective January 1, 2008. The Company has not elected the fair value option for its financial instruments. As required by SFAS 159, the Company has reclassified all cash flows related to its trading securities from operating to investing activities in the consolidated condensed statements of cash flows.

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ("EITF") in EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*" ("EITF 07-3"). EITF 07-3 requires that nonrefundable advance payments for goods and services that will be used in future research and development activities be deferred and capitalized until the related service is performed or the goods are delivered. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

New Accounting Standards Not Yet Adopted

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

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

In April 2008, the FASB issued FASB Staff Position No. 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "*Goodwill and Other Intangible Assets*." FSP 142-3 applies to intangible assets that are acquired individually or with a group of other assets acquired in business combinations and asset acquisitions. FSP 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of FSP 142-3 on its consolidated financial statements.

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In May 2008, the FASB issued SFAS No. 162, "*The Hierarchy of Generally Accepted Accounting Principles*" ("SFAS 162"). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS 162 is effective November 15, 2008. The Company does not expect the adoption of SFAS 162 to have a material impact on its consolidated financial statements.

In September 2008, the FASB issued FSP 133-1 and FIN 45-4, "*Disclosures about Credit Derivatives and Certain Guarantees: An Amendment of FASB Statement No. 133 and FASB Interpretation No. 45; and Clarification of the Effective Date of FASB Statement No. 161*" ("FSP 133-1 and FIN 45-4"). FSP 133-1 and FIN 45-4 amends and enhances disclosure requirements for sellers of credit derivatives and financial guarantees. It also clarifies that the disclosure requirements of SFAS No. 161 are effective for quarterly periods beginning after November 15, 2008, and fiscal years that include those periods. FSP 133-1 and FIN 45-4 is effective for reporting periods (annual or interim) ending after November 15, 2008. The Company does not expect the adoption of this standard to 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 | | | | Nine Months Ended | | | |
|------------------------|--------------------|-----------------|----------------|----------------|-------------------|-----------------|-----------------|----------------|
| | September 30, | | Change | Percent Change | September 30, | | Change | Percent Change |
| | 2008 | 2007 | | | 2008 | 2007 | | |
| United States | \$ 135.6 | \$ 118.1 | \$ 17.5 | 14.8% | \$ 410.8 | \$ 362.7 | \$ 48.1 | 13.3% |
| International | 168.0 | 143.3 | 24.7 | 17.2% | 517.2 | 435.4 | 81.8 | 18.8% |
| Total net sales | \$ 303.6 | \$ 261.4 | \$ 42.2 | 16.1% | \$ 928.0 | \$ 798.1 | \$ 129.9 | 16.3% |

In the United States, the \$17.5 million and \$48.1 million increases in net sales for the three and nine months ended September 30, 2008, respectively, were due primarily to:

CardioVations products, which increased net sales by \$5.9 million and \$17.7 million, respectively. The Company purchased the *CardioVations* product line in December 2007;

LifeStent products, which increased net sales by \$4.6 million and \$13.7 million, respectively. *LifeStent* sales include end-customer sales recorded prior to the divestiture of *LifeStent* in mid-January 2008, and sales after the divestiture resulting from the on-going manufacturing requirements of the sale agreement (all of which are recorded in the United States), which will continue until the earlier of mid-2010 or the transfer of manufacturing to the buyer;

Critical Care products, which increased net sales by \$3.6 million and \$11.1 million, respectively, driven primarily by the *FloTrac* minimally invasive monitoring system, hemofiltration products, and pressure monitoring products; and

Heart Valve Therapy products, which increased net sales by \$3.3 million and \$7.2 million, respectively, driven primarily by the *Carpentier-Edwards PERIMOUNT Magna* with *ThermaFix* valve.

International net sales increased \$24.7 million and \$81.8 million for the three and nine months ended September 30, 2008, respectively, due primarily to:

Heart Valve Therapy products, which increased net sales by \$22.2 million and \$66.8 million, respectively, driven primarily by the *Edwards SAPIEN* transcatheter heart valve, the *Carpentier-*

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Edwards *PERIMOUNT Magna Ease* valve and the launch of the *Magna* aortic valve in Japan; and

Critical Care products, which increased net sales by \$10.2 million and \$37.7 million, respectively, driven primarily by the *FloTrac* minimally invasive monitoring system, pressure monitoring products, and hemofiltration products;

partially offset by

decreases of \$9.4 million and \$27.6 million, respectively, related to the discontinuation of distributed sales in Japan of intra-aortic balloon pumps and the divestiture of the *LifeStent* product line.

The benefit of foreign currency exchange rate fluctuations included above increased net sales by \$11.2 million and \$43.7 million for the three and nine months ended September 30, 2008, respectively, due primarily to the strengthening of the Euro and Japanese yen against the United States dollar. The impact of foreign currency exchange rate fluctuations on net sales is not 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, | | | Percent Change | Nine Months Ended September 30, | | | Percent Change |
|----------------------------|----------------------------------|----------|---------|----------------|---------------------------------|----------|----------|----------------|
| | 2008 | 2007 | Change | | 2008 | 2007 | Change | |
| Heart Valve Therapy | \$ 148.4 | \$ 122.8 | \$ 25.6 | 20.8% | \$ 457.7 | \$ 383.6 | \$ 74.1 | 19.3% |
| Critical Care | 110.3 | 96.5 | 13.8 | 14.3% | 333.6 | 284.8 | 48.8 | 17.1% |
| Cardiac Surgery Systems | 21.4 | 13.8 | 7.6 | 55.1% | 66.3 | 45.8 | 20.5 | 44.8% |
| Vascular | 23.5 | 22.4 | 1.1 | 4.9% | 70.4 | 64.9 | 5.5 | 8.5% |
| Other Distributed Products | | 5.9 | (5.9) | (100.0)% | | 19.0 | (19.0) | (100.0)% |
| Total net sales | \$ 303.6 | \$ 261.4 | \$ 42.2 | 16.1% | \$ 928.0 | \$ 798.1 | \$ 129.9 | 16.3% |

Heart Valve Therapy

The \$25.6 million and \$74.1 million increases in net sales of Heart Valve Therapy products for the three and nine months ended September 30, 2008, respectively, were due primarily to:

the launch of the *Edwards SAPIEN* transcatheter heart valve in Europe during the fourth quarter of 2007, which increased net sales by \$12.8 million and \$34.2 million, respectively; and

pericardial tissue valves, which increased net sales by \$11.9 million and \$36.6 million, respectively, primarily as a result of the *Carpentier-Edwards PERIMOUNT Magna Ease* valve, the *Magna* with *ThermaFix* aortic valve, and the launch of the *Magna* aortic valve in Japan.

The Company expects that its *SAPIEN* transcatheter heart valve and its *PERIMOUNT Magna Ease* and *Magna* with *ThermaFix* valves will continue to be strong contributors to 2008 sales. The Company launched the *Magna Ease* valve in Europe in May 2007, and is expecting to introduce this product into the United States in 2009, pending regulatory approval. The Company's *PERIMOUNT Magna* mitral valve is gaining physician acceptance in Europe, and the Company received Food and Drug Administration ("FDA") approval during the third quarter of 2008 and launched this product into the United States during September 2008. In Japan, the Company received regulatory and reimbursement

approval for its *Magna* aortic valve in the second quarter of 2008, and introduced this product in Japan during June 2008. The Company expects this product to continue to accelerate its growth rate in Japan. The Company had its first implants of the *Carpentier-Edwards Physio II* ring during the third quarter of 2008 and concluded that some modifications to the ring accessories are necessary. Therefore, the Company now expects to launch the product in the United States and Europe during the first quarter of 2009. *Physio II* is the next generation repair product for the degenerative segment of mitral repair.

Critical Care

The \$13.8 million and \$48.8 million increases in net sales of Critical Care products for the three and nine months ended September 30, 2008, respectively, were due primarily to:

FloTrac systems, which increased net sales by \$6.1 million and \$15.5 million, respectively;

core Critical Care products, which increased net sales by \$5.4 million and \$25.0 million, respectively, driven primarily by market share gains in pressure monitoring products and *PreSep*, the Company's central venous oximetry catheter for early detection of sepsis; and

hemofiltration products, which increased net sales by \$2.3 million and \$8.3 million, respectively.

The Company expects worldwide *FloTrac* system sales to continue to be a significant contributor to Critical Care sales growth in 2008. During the second quarter of 2008, the Company introduced an enhancement to the *FloTrac* system that provides additional information in the operating room, and the Company plans to continue introducing additional product enhancements that will enable *FloTrac* to address a wider range of patients.

Cardiac Surgery Systems

The \$7.6 million and \$20.5 million increases in net sales of Cardiac Surgery Systems products for the three and nine months ended September 30, 2008, respectively, were due primarily to the acquisition of the *CardioVations* product line in December 2007, which increased net sales by \$7.4 million and \$22.2 million, respectively. These increases were partially offset by the discontinuation of the Brazil-based perfusion product line, which resulted in net sales decreases of \$0.8 million and \$4.0 million, respectively, for the three and nine months ended September 30, 2008.

Vascular

The \$1.1 million and \$5.5 million increases in net sales of Vascular products for the three and nine months ended September 30, 2008, respectively, were due primarily to increased sales of *LifeStent* products. In January 2008, the Company completed the sale of the *LifeStent* product line. The Company has agreed to provide transition services, including manufacturing, to the buyer until the earlier of mid-2010 or the transfer of manufacturing to the buyer, and will continue to pursue pre-market approval for a superficial femoral artery indication. *LifeStent* sales include end-customer sales recorded prior to the divestiture of *LifeStent* in mid-January and sales after the divestiture resulting from the on-going manufacturing requirements of the sale agreement.

Other Distributed Products

The \$5.9 million and \$19.0 million decreases in net sales of Other Distributed Products for the three and nine months ended September 30, 2008, respectively, were due to the termination at the end of 2007 of distributed sales in Japan of intra-aortic balloon pumps.

Gross Profit

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|-------------------------------------|-------|----------|------------------------------------|-------|----------|
| | 2008 | 2007 | Change | 2008 | 2007 | Change |
| Gross profit as a percentage of net sales | 65.4% | 65.3% | 0.1 pts. | 65.4% | 65.1% | 0.3 pts. |

The 0.1 and 0.3 percentage point increases in gross profit as a percentage of net sales for the three and nine months ended September 30, 2008, respectively, were driven by:

a 2.0 percentage point increase in the international gross profit as a percentage of net sales for both the three and nine months ended September 30, 2008, due to a more profitable product mix, primarily higher sales of Heart Valve Therapy products and *FloTrac* systems, combined with the discontinuation of lower margin perfusion products and intra-aortic balloon pumps;

partially offset by

a 0.2 percentage point and a 0.6 percentage point decrease in the United States gross profit as a percentage of net sales for the three and nine months ended September 30, 2008, respectively, due primarily to sales of *LifeStent* products under the on-going manufacturing requirements of the *LifeStent* sale agreement, partially offset by a more profitable product mix, primarily higher sales of *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, | | |
|--|-------------------------------------|----------|------------|------------------------------------|----------|----------|
| | 2008 | 2007 | Change | 2008 | 2007 | Change |
| | (dollars in millions) | | | | | |
| SG&A expenses | \$ 119.3 | \$ 103.2 | \$ 16.1 | \$ 360.4 | \$ 303.5 | \$ 56.9 |
| SG&A expenses as a percentage of net sales | 39.3% | 39.5% | (0.2) pts. | 38.8% | 38.0% | 0.8 pts. |

The \$16.1 million and \$56.9 million increases in selling, general and administrative expenses for the three and nine months ended September 30, 2008, respectively, and the 0.8 percentage point increase in selling, general and administrative expenses as a percentage of net sales for the nine months ended September 30, 2008, were due primarily to (1) the impact of foreign currency (primarily the strengthening of the Euro against the United States dollar), (2) higher sales related spending, including investments for the *Edwards SAPIEN* transcatheter heart valve launch in Europe, and (3) higher compensation expense related to the Company's strong sales performance.

Research and Development Expenses

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|--|-------------------------------------|---------|------------|------------------------------------|---------|---------|
| | 2008 | 2007 | Change | 2008 | 2007 | Change |
| | (dollars in millions) | | | | | |
| Research and development expenses | \$ 35.1 | \$ 30.9 | \$ 4.2 | \$ 103.4 | \$ 88.8 | \$ 14.6 |
| Research and development expenses as a percentage of net sales | 11.6% | 11.8% | (0.2) pts. | 11.1% | 11.1% | |

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The increases in research and development expenses for the three and nine months ended September 30, 2008 were due primarily to additional investments in transcatheter and surgical heart valve programs, and in Critical Care development efforts.

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

the Company received conditional Investigational Device Exemption ("IDE") approval from the FDA in March 2007 to initiate its PARTNER trial, a pivotal clinical trial of the Company's *Edwards SAPIEN* transcatheter heart valve technology. The PARTNER trial, which has two study arms, began enrollment during the second quarter of 2007 and will evaluate the *Edwards SAPIEN* transcatheter heart valve in patients who are considered at high risk for conventional open-heart valve surgery. In the first study arm ("Cohort A"), patients will be randomized on a 1:1 basis to either high risk surgery or the *Edwards SAPIEN* transcatheter heart valve. Cohort A will have 690 patients and is a non-inferiority analysis. In the second study arm ("Cohort B"), patients who are deemed non-operable will be randomized 1:1 to medical management or the *Edwards SAPIEN* transcatheter heart valve. Cohort B will have 350 patients and is a superiority analysis. The Company anticipates it will complete enrollment in Cohort B near the end of 2008 and complete enrollment in Cohort A by the end of the third quarter 2009;

the Company completed enrollment in its United States feasibility study of the *Ascendra* transapical delivery system in April 2007. The Company obtained FDA approval to add *Ascendra* to the PARTNER trial in January 2008, and during the second quarter of 2008 the first patients received the *SAPIEN* valve using *Ascendra*. The Company believes that having *Ascendra* in the trial will give cardiac surgeons an opportunity to partner in this technology and it will allow the Company to address a larger patient population. The *Ascendra* transapical delivery system is available for sale in Europe;

the Company received regulatory approval to add the *RetroFlex II* delivery system to the PARTNER trial and began selling *RetroFlex II* in Europe during the second quarter of 2008. The *RetroFlex II* further enhances the ease-of-use benefits of *RetroFlex I* by adding a customized atraumatic tip to enable clinicians to more easily navigate across the native stenotic aortic valve. The Company expects to introduce its new *RetroFlex III* delivery system in late 2008;

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; and

first-in-man cases using the Company's next generation transcatheter heart valve, the *Edwards SAPIEN XT*, were performed during the first quarter of 2008. The Company believes that this next generation valve's features will help reduce its delivery profile without compromising strength, making it available to an even wider group of patients than the *Edwards SAPIEN* valve. The Company is currently in discussions with the European regulatory agencies regarding a clinical trial design and expects to begin a trial before the end of the year in support of a CE Mark, receipt of which is expected by mid-2010.

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

in October 2008, the Company announced the continuation of the EVOLUTION II clinical trial of the *Edwards MONARC* mitral repair system (formerly *ev3*, Inc.'s percutaneous mitral valve repair program), a coronary sinus technology. This trial will study patients with moderate to

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severe mitral regurgitation and heart failure in Europe and Canada. The Company expects to begin enrollment in this trial by the end of 2008.

Special (Gains) Charges, net

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|--|----------------|---------------------------------------|----------------|
| | 2008 | 2007 | 2008 | 2007 |
| | (in millions) | | | |
| Loss on sale of product line | \$ | \$ | \$ 8.1 | \$ |
| Litigation settlement | | | 2.1 | |
| Realignment expenses, net | | | (0.9) | |
| Gain on estimated insurance settlement | | (2.5) | | (2.5) |
| Special (gains) charges, net | \$ | \$(2.5) | \$ 9.3 | \$(2.5) |

Loss on Sale of Product Line

In January 2008, the Company completed the sale of certain assets related to the *LifeStent* product line. This divestiture is part of the Company's ongoing strategy to focus resources on its core heart valve and critical care businesses. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and will receive up to an additional \$65.0 million in cash upon the achievement of certain milestones, including the receipt of United States regulatory approval of the *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer. Because of the Company's continued involvement in the operations of *LifeStent* after its sale, the Company did not report the loss on disposition or the results of *LifeStent's* operations as discontinued operations.

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

Litigation Settlement

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

Realignment Expenses, net

In 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, 2008, remaining payments of \$3.4 million are expected to be paid through the end of 2009.

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, 2008,

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remaining payments of \$1.0 million for the executive severance charge are expected to be paid through the end of 2009.

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

Gain on Estimated Insurance Settlement

During the third quarter of 2007, the Company experienced a fire that damaged certain inventory held at a third party warehouse in Brazil. The total amount of the loss related to the inventory was \$1.8 million, which was expected to be reimbursed by insurance. In addition, the Company held business interruption insurance to cover the lost profit of \$2.5 million due to the property damage. As of September 30, 2007, the Company had recorded a receivable from the insurance company of \$4.3 million and a gain of \$2.5 million for the estimated insurance settlement. In the fourth quarter of 2007, the Company reversed this gain as it will be recognized upon settlement.

Interest (Income) Expense, net

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---------------------------------------|-------------------------------------|---------------|-----------------|------------------------------------|---------------|-----------------|
| | 2008 | 2007 | Change | 2008 | 2007 | Change |
| | (in millions) | | | | | |
| Interest expense | \$ 1.5 | \$ 2.2 | \$ (0.7) | \$ 5.5 | \$ 6.8 | \$ (1.3) |
| Interest income | (1.9) | (1.8) | (0.1) | (5.1) | (5.8) | 0.7 |
| Interest (income) expense, net | \$ (0.4) | \$ 0.4 | \$ (0.8) | \$ 0.4 | \$ 1.0 | \$ (0.6) |

The decrease in interest expense for the three and nine months ended September 30, 2008 resulted primarily from a lower average debt balance and lower interest rates as compared to the prior year periods. The increase in interest income for the three months ended September 30, 2008 resulted primarily from higher cash and short-term investment balances as compared to the same period last year. The decrease in interest income for the nine months ended September 30, 2008 resulted primarily from lower average interest rates.

Other Expense (Income), net

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|--|-----------------|---------------------------------------|-----------------|
| | 2008 | 2007 | 2008 | 2007 |
| Foreign exchange losses (gains), net | \$ 2.1 | \$ (0.8) | \$ 4.4 | \$ (1.9) |
| Investment gains | (0.8) | (0.1) | (2.1) | (0.4) |
| Gain on sale of product line | | (0.4) | | (1.9) |
| Sale of property development rights | (0.5) | | (0.5) | |
| Accounts receivable securitization costs | 0.4 | 0.9 | 1.5 | 2.4 |
| Investment impairment and realized loss | 0.1 | | 0.9 | |
| Other | (0.2) | 0.3 | (0.9) | 0.3 |
| Other expense (income), net | \$ 1.1 | \$ (0.1) | \$ 3.3 | \$ (1.5) |

The net foreign exchange losses for the three and nine months ended September 30, 2008 relate primarily to foreign currency fluctuations on the Company's global trade and intercompany receivable

and payable balances. Foreign exchange resulted in a net loss in 2008 compared to a net gain in 2007 due primarily to fluctuations in the Japanese yen and the Euro.

The investment gains for the three and nine months ended September 30, 2008 represent realized gains on the Company's available-for-sale investments in unconsolidated affiliates.

The investment impairment and realized loss for the three and nine months ended September 30, 2008 represents the realized losses and estimated impairment in the value of the Company's investment in the Bank of America Columbia Strategic Cash fund. See the "*Liquidity and Capital Resources*" section for further information.

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 24.5% and 30.4% for the three and nine months ended September 30, 2008, respectively, and 25.0% and 25.3% for the three and nine months ended September 30, 2007, respectively. The income tax rate for the nine months ended September 30, 2008 included the tax effect on the sale of the *LifeStent* product line.

The Federal Research and Development Credit expired on December 31, 2007. Legislation was signed on October 3, 2008 extending the research credit retroactively from January 1, 2008 through December 31, 2009. No benefit related to the Federal Research and Development Credit has been taken in the first nine months of 2008. The benefit related to the retroactive extension of the research credit will be reflected in the fourth quarter of 2008, the quarter in which the legislation was enacted.

As of September 30, 2008, the liability for income taxes associated with uncertain tax positions was \$48.5 million. This liability can be reduced by \$12.4 million from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes and timing adjustments. The net amount of \$36.1 million, if recognized, would favorably affect the Company's effective tax rate. Changes during the period to potential interest expense upon settlement were immaterial.

The liability for income taxes associated with uncertain tax positions was \$40.5 million at June 30, 2008 and \$36.4 million at December 31, 2007. As of June 30, 2008 and December 31, 2007, these liabilities could be reduced by \$8.7 million and \$8.0 million, respectively, from offsetting tax benefits. The net amounts of \$31.8 million at June 30, 2008 and \$28.4 million at December 31, 2007, if recognized, would favorably affect the Company's effective tax rate.

Liquidity and Capital Resources

The Company's sources of cash liquidity include cash on hand and cash equivalents, amounts available under credit facilities, accounts receivable securitization 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 of access to its credit facility as a result of the recent turmoil in global financial markets. The Company further believes that it has the financial flexibility to attract long-term capital to fund short-term and long-term growth objectives. However, no assurances can be given that such long-term capital will be available to Edwards Lifesciences on favorable terms, or at all.

The Company has a Five-Year Unsecured Revolving Credit Agreement ("the Credit Agreement"), which matures on September 29, 2011. The Credit Agreement provides up to an aggregate of \$500.0 million in one-to-six month borrowings in multiple currencies. Borrowings currently bear interest

at 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 will continue to be refinanced pursuant to the Credit Agreement. As of September 30, 2008, borrowings of \$202.8 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, 2008.

On May 9, 2008, the Company called for redemption its \$150.0 million of convertible senior debentures (the "Notes"). Prior to the redemption date of June 9, 2008, holders of approximately \$147.7 million principal amount of the Notes converted their debentures into approximately 2.7 million shares of Edwards common stock at a conversion price of \$54.66 per share. The remaining outstanding Notes of \$2.3 million were redeemed for cash on the redemption date.

The Company securitizes, on a continuous basis, an undivided interest in certain eligible pools of trade accounts receivable in Japan and, until August 2008, in the United States. In August 2008, the Company terminated its securitization program in the United States, and repurchased \$50 million of accounts receivable. As of September 30, 2008, the Company had sold, under its Japan securitization program, a total of \$34.8 million of trade accounts receivable and received funding of \$29.2 million. The securitization program in Japan will expire on December 3, 2008 and the Company plans on renewing the program.

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, was being closed to new subscriptions or redemptions, resulting in the Company's inability to immediately redeem its investments for cash. During the three and 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 Expense (Income), net.*" During 2008, the Company has received cash redemptions of \$30.9 million. The fair value of the Company's remaining investment in this fund as of September 30, 2008 and December 31, 2007 was estimated to be \$17.6 million and \$49.4 million, respectively, based on the net asset value of the fund. Based on information received from the fund manager regarding the timing of the expected redemptions, the Company expects to receive cash redemptions for approximately \$12.1 million through the third quarter of 2009, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2008. The remaining \$5.5 million of the investment is expected to be received after the third quarter of 2009, and has been classified as "*Other Assets.*"

In January 2008, the Company completed the sale of certain assets related to the Edwards *LifeStent* product line. This divestiture is part of the Company's ongoing strategy to focus resources on its core heart valve and critical care businesses. Under the terms of the sale agreement, the Company received an initial cash payment of \$74.0 million at closing, and will receive up to an additional \$65.0 million in cash upon the achievement of certain milestones, including the receipt of United States regulatory approval of the Company's *LifeStent* products for a superficial femoral artery indication and the transfer of *LifeStent* device manufacturing. The Company has agreed to provide transition services until the earlier of mid-2010 or the transfer of manufacturing to the buyer.

In September 2007, the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to \$250.0 million of the Company's common stock. In July 2008, the Board of Directors approved a new stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$250.0 million of the Company's common stock. During the nine months ended September 30, 2008, the Company repurchased 5.4 million shares at an aggregate

cost of \$285.5 million and as of September 30, 2008 had remaining authority to purchase \$214.5 million of common stock.

At September 30, 2008, 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, 2007.

Net cash flows provided by **operating activities** of \$72.7 million for the nine months ended September 30, 2008 decreased \$61.3 million from the same period a year ago. This decrease was due primarily to a \$50 million cash payment during the third quarter of 2008 to terminate the Company's accounts receivable securitization program in the United States. In addition, operating cash flow was negatively impacted by net cash outflows from an increase in accounts receivable related to the securitization program in Japan.

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 by investing activities of \$52.5 million in the nine months ended September 30, 2007 consisted primarily of capital expenditures of \$43.1 million and a \$9.6 million milestone payment associated with the Percutaneous Valve Technologies, Inc. acquisition in 2004.

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.

Net cash used in financing activities of \$89.8 million for the nine months ended September 30, 2007 consisted primarily of purchases of treasury stock of \$107.2 million and net payments on long-term debt of \$27.2 million, partially offset by the proceeds from stock plans of \$32.6 million.

Critical Accounting Policies

The condensed consolidated 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 45-49 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, 2007. Management believes that at September 30, 2008, there had been no material changes to this information.

On January 1, 2008, the Company adopted SFAS 157 with respect to its financial assets and liabilities and non-financial assets and liabilities that are measured at fair value on a recurring basis. The Company has deferred the application of the provisions of this statement for its non-financial assets and liabilities in accordance with FSP 157-2. 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 at the measurement date. In determining fair value, the Company uses various valuation approaches, including market, income and/or cost approaches, and considers the principal or most advantageous market in which it would transact and assumptions that market participants would use

when pricing the asset or liability. Upon adoption of SFAS 157, the Company applied the following fair value hierarchy:

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.

When possible, the Company looks to active and observable markets to price identical assets or liabilities. When identical assets or liabilities are not traded in active markets, the Company looks to market observable data for similar assets and liabilities. If observable market prices are unavailable or impracticable to obtain, the Company must use alternative valuation techniques to derive a fair value measurement. The Company has procedures to independently verify and test valuations received from third parties.

The financial assets and liabilities that the Company records at fair value include investments in marketable securities, residual interests in securitizations and derivative instruments.

Investments in Marketable Securities

Bank of America Columbia Strategic Cash Fund

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 was estimated based on the net asset value of the fund. As of September 30, 2008, the net asset value of the fund was 95.72% of par.

The fair value of the underlying securities held by the fund was determined based on quoted market prices or broker quotes, when possible. In the absence of observable market quotations, the underlying securities were valued based on alternative valuation techniques using inputs that may not be observable. In these cases, the fair value was based on available information believed to be reliable, which may be affected by conditions in the financial markets. Different market participants may reach different opinions as to the value of any particular security based on their varying market outlooks, the market information available to them, and the particular circumstances of their portfolios. A decrease in the net asset value of 1%, or 96 basis points, would result in a decrease of approximately \$0.2 million in the investment fair value. The Company's investment in the fund is categorized as Level 3 based on the lowest level input that is significant to the fair value measurement in its entirety.

Investments Held for the Executive Deferred Compensation Plan

The Company holds investments in trading securities related to its executive deferred compensation plan. The fair values of the securities are based on quoted market prices and are categorized as Level 1.

Investments in Unconsolidated Affiliates

Certain of the Company's investments in unconsolidated affiliates are designated as available-for-sale in accordance with the provisions of SFAS 115, "Accounting for Certain Investments in

Debt and Equity Securities." These investments are carried at fair market value based on quoted market prices, and are categorized as Level 1.

Residual Interest in Securitizations

When the Company sells accounts receivable securitizations, a subordinated residual interest in the securitized portfolio is retained by the Company. The Company estimates the fair value of the residual interest 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. Reserves for credit losses included in the allowance for doubtful accounts are adjusted based on management's assessment of recovery.

The United States securitization program was terminated in August 2008 and all receivables sold under this facility were repurchased by the Company. The residual interest in the Japan securitization program is categorized as Level 3.

Derivative Instruments

The Company uses forward exchange contracts and option contracts to hedge a portion of its exposure to forecasted intercompany and third party foreign currency transactions. All derivatives are recognized on the balance sheet at their fair value. The fair value for derivatives is determined based on indicative mid-market data levels for spot rate and forward points as of the close of business on September 30, 2008. All values are discounted to present from the expiry date. The values of options are calculated based on the forward implied volatilities to the expiry date. The models used for valuations are based upon well recognized financial principles, and the predominance of market inputs are actively quoted and can be validated through external sources. Although readily observable data is used in the valuations, different valuation methodologies could have an effect on the estimated fair value. The derivative instruments are categorized as Level 2.

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 52-54 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007. 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 52-54 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007. 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 52-54 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007. 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, 2008, Edwards Lifesciences had \$20.3 million of investments in equity instruments of other companies and had recorded unrealized losses of \$0.1 million on these investments in "*Accumulated Other Comprehensive Income*," net of tax. Should these companies experience a decline in financial condition or fail to meet certain development milestones, the values of these investments may decline and be considered other than temporary. As a result, impairment charges may be necessary.

The Company holds an investment in the Bank of America Columbia Strategic Cash fund, a private placement money market mutual fund, which was closed to new subscriptions or redemptions in December 2007, resulting in the Company's inability to immediately redeem its investments for cash. During the three and 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 Expense (Income), net*." During 2008, the Company has received cash redemptions of \$30.9 million. The fair value of the Company's remaining investment in this fund as of September 30, 2008 was estimated to be \$17.6 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 \$12.1 million through the third quarter of 2009, which has been classified as "*Short-term Investments*" on the accompanying consolidated condensed balance sheet as of September 30, 2008. The remaining \$5.5 million of the investment is expected to be received after the third quarter of 2009, and has been classified as "*Other Assets*." The markets relating to these investments are subject to ongoing illiquidity and remain uncertain. There may be further decreases in the value of these investments until the fund is fully liquidated.

Item 4. Controls and Procedures

The Company's management, including the Chief Executive Officer and the Chief Financial Officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures as of September 30, 2008. 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.

Part II. Other Information

Item 1. Legal Proceedings

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

In May 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. As announced in October 2008, the Court rejected this assertion and dismissed the infringement lawsuit. The Company has appealed this decision. In May 2007, and June 2007, CoreValve filed separate lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid. Edwards Lifesciences subsequently purchased the Andersen patent family. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. A trial in the United Kingdom on validity and infringement concluded in July 2008, and a decision is pending. In February 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the U.S. Andersen patents.

In February 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany against Edwards Lifesciences alleging that the *Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. Edwards Lifesciences subsequently filed lawsuits in London, United Kingdom, and in Munich, Germany, against Cook alleging that the patents in each country are invalid. In the United Kingdom lawsuit, Cook has counterclaimed, alleging infringement by Edwards.

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 claims, 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.

Item 1A. Risk Factors

For a complete discussion of the Company's risk factors, refer to Item 1A "Risk Factors" on pages 10-20 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007. There have been no significant changes from the information discussed therein except for the new risk factor set forth below.

We face risks related to general domestic and global economic conditions and to the current credit crisis.

We currently generate sufficient operating cash flows, which combined with access to the credit markets, provides us with significant discretionary funding capacity. However, the current uncertainty arising out of domestic and global economic conditions, including the recent disruption in credit markets, poses a risk to the overall economy that could impact our customers, suppliers, creditors and counterparties to our derivative contracts, causing them to fail to meet their obligations to us.

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, 2008 through July 31, 2008 | 576,062 | \$ 62.20 | 576,062 | \$ 249.4 |
| August 1, 2008 through August 31, 2008 | 275,000 | 60.05 | 275,000 | 232.9 |
| September 1, 2008 through September 30, 2008 | 315,000 | 58.21 | 315,000 | 214.5 |
| Total | 1,166,062 | 60.61 | 1,166,062 | |

(a) On September 18, 2007, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions, up to \$250.0 million of the Company's common stock. This program was completed in July 2008. On July 11, 2008, the Company announced that the Board of Directors approved a stock repurchase program authorizing the Company to purchase on the open market and in privately negotiated transactions up to an additional \$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

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 7, 2008

By: /s/ THOMAS M. ABATE

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

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EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION

| Exhibit No. | Description |
|--------------------|--|
| 31.1 | Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
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QuickLinks

EDWARDS LIFESCIENCES CORPORATION FORM 10-Q For the quarterly period ended September 30, 2008

Part I. Financial Information

Item 1. Financial Statements

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED CONDENSED BALANCE SHEETS (in millions, except par value; unaudited)

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS (in millions, except per share information; unaudited)

EDWARDS LIFESCIENCES CORPORATION CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS (in millions; unaudited)

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

Part II. Other Information

Item 1. Legal Proceedings

Item 1A. Risk Factors

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

Item 6. Exhibits

SIGNATURE

EXHIBITS FILED WITH SECURITIES AND EXCHANGE COMMISSION