ST JUDE MEDICAL INC
Form 10-Q
November 10, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED OCTOBER 2, 2010 OR

o 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: 1-12441

ST. JUDE MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**41-1276891**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One St. Jude Medical Drive, St. Paul, Minnesota 55117
(Address of principal executive offices, including zip code)

(651) 756-2000
(Registrant s telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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, and (2) has been subject to such filing requirements for the past 90 days. x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
x Yes o 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. (Check one):

Large accelerated filer x | Accelerated filer o

Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company o

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

The number of shares of common stock, par value $.10 per share, outstanding on November 1, 2010 was 329,296,462.

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PART I - FINANCIAL INFORMATION
Item 1. FINANCIAL STATEMENTS

ST. JUDE MEDICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF EARNINGS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended		Nine Months Ended	
	October 2, 2010	**October 3, 2009**	**October 2, 2010**	**October 3, 2009**
Net sales	$ 1,239,905	$ 1,159,606	$ 3,814,370	$ 3,477,811
Cost of sales before special charges	339,819	299,670	1,006,290	899,709
Special charges		6,061		6,061
Total cost of sales	339,819	305,731	1,006,290	905,770
Gross profit	900,086	853,875	2,808,080	2,572,041
Selling, general and administrative expense	438,723	427,227	1,329,623	1,276,071
Research and development expense	150,135	142,224	456,469	424,627
Purchased in-process research and development charges	12,244		12,244	
Special charges		42,394		42,394
Operating profit	298,984	242,030	1,009,744	828,949
Other income (expense), net	(11,111)	(23,594)	(51,657)	(35,867)
Earnings before income taxes	287,873	218,436	958,087	793,082
Income tax expense	79,488	51,501	257,095	205,506
Net earnings	$ 208,385	$ 166,935	$ 700,992	$ 587,576
Net earnings per share:				
Basic	$ 0.63	$ 0.49	$ 2.14	$ 1.71
Diluted	$ 0.63	$ 0.48	$ 2.13	$ 1.69
Weighted average shares outstanding:				
Basic	328,231	340,651	326,822	344,423
Diluted	329,927	344,298	329,101	348,242

See notes to the condensed consolidated financial statements.

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ST. JUDE MEDICAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share amounts)

	October 2, 2010 (Unaudited)	January 2, 2010
ASSETS		
Current Assets		
Cash and cash equivalents	$ 851,614	$ 392,927
Accounts receivable, less allowance for doubtful accounts of $36,138 at October 2, 2010 and $34,947 at January 2, 2010	1,261,414	1,170,579
Inventories	688,657	659,960
Deferred income taxes, net	164,533	164,738
Other	251,294	172,002
Total current assets	3,217,512	2,560,206
Property, plant and equipment, at cost	2,152,548	1,949,416
Less: accumulated depreciation	(895,319)	(796,330)
Net property, plant and equipment	1,257,229	1,153,086
Goodwill	2,075,620	2,005,851
Other intangible assets, net	469,550	456,142
Other assets	365,375	250,526
TOTAL ASSETS	$ 7,385,286	$ 6,425,811
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities		
Current debt obligations	$	$ 334,787
Accounts payable	183,501	132,543
Income taxes payable		13,498
Accrued expenses		
Employee compensation and related benefits	269,801	269,293
Other	276,915	317,192
Total current liabilities	730,217	1,067,313
Long-term debt	1,988,266	1,587,615
Deferred income taxes, net	120,831	132,392
Other liabilities	355,336	314,940
Total liabilities	3,194,650	3,102,260
Commitments and Contingencies (Note 7)		
Shareholders Equity		
Preferred stock ($1.00 par value; 25,000,000 shares authorized; none outstanding)		
Common stock ($0.10 par value; 500,000,000 shares authorized; 328,768,791 and 324,537,581 shares issued and outstanding at October 2, 2010 and January 2, 2010, respectively)	32,877	32,454
Additional paid-in capital	180,125	5,860
Retained earnings	3,892,195	3,191,203
Accumulated other comprehensive income:		
Cumulative translation adjustment	72,276	82,033
Unrealized gain on available-for-sale securities	13,163	12,001
Total shareholders equity	4,190,636	3,323,551
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 7,385,286	$ 6,425,811

See notes to the condensed consolidated financial statements.

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ST. JUDE MEDICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

Nine Months Ended	October 2, 2010	October 3, 2009
OPERATING ACTIVITIES		
Net earnings	$ 700,992	$ 587,576
Adjustments to reconcile net earnings to net cash from operating activities:		
Depreciation and amortization	175,813	156,642
Amortization of debt discount	692	158
Stock-based compensation	53,142	44,133
Excess tax benefits from stock-based compensation	(10,963)	(19,133)
Investment impairment charges		8,300
Gain on sale of investment	(4,929)	
Purchased in-process research and development charges	12,244	
Deferred income taxes	(7,442)	1,115
Changes in operating assets and liabilities, net of business acquisitions:		
Accounts receivable	(89,313)	(53,945)
Inventories	(10,652)	(118,268)
Other current assets	(51,678)	(22,685)
Accounts payable and accrued expenses	22,678	(35,401)
Income taxes payable	977	4,885
Net cash provided by operating activities	791,561	553,377
INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(226,299)	(236,326)
Business acquisition payments, net of cash acquired	(128,903)	(14,793)
Other investing activities, net	(113,573)	(15,348)
Net cash used in investing activities	(468,775)	(266,467)
FINANCING ACTIVITIES		
Proceeds from exercise of stock options and stock issued	107,343	87,385
Excess tax benefits from stock-based compensation	10,963	19,133
Common stock repurchased, including related costs		(500,000)
Borrowings under debt facilities	671,094	1,405,753
Payments under debt facilities	(655,723)	(645,774)
Net cash provided by financing activities	133,677	366,497
Effect of currency exchange rate changes on cash and cash equivalents	2,224	8,431
Net increase in cash and cash equivalents	458,687	661,838
Cash and cash equivalents at beginning of period	392,927	136,443
Cash and cash equivalents at end of period	$ 851,614	$ 798,281

See notes to the condensed consolidated financial statements.

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ST. JUDE MEDICAL, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of St. Jude Medical, Inc. (St. Jude Medical or the Company) have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States (U.S. GAAP) for complete financial statements. In the opinion of management, these statements include all adjustments (consisting of normal recurring adjustments) considered necessary to present a fair statement of the Company s consolidated results of operations, financial position and cash flows. Operating results for any interim period are not necessarily indicative of the results that may be expected for the full year. Preparation of the Company s financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and footnotes. Actual results could differ from those estimates. This Quarterly Report on Form 10-Q should be read in conjunction with the Company s consolidated financial statements and footnotes included in its Annual Report on Form 10-K for the fiscal year ended January 2, 2010 (2009 Annual Report on Form 10-K). Certain prior period amounts have been reclassified to conform to the current year presentation.

NOTE 2 NEW ACCOUNTING PRONOUNCEMENTS

In October 2009, the Financial Accounting Standards Board (FASB) updated the revenue recognition accounting guidance of FASB Accounting Standards Codification (ASC) Topic 605, *Revenue Recognition*, relating to the accounting for revenue arrangements that involve more than one deliverable or unit of accounting. The updated guidance allows companies to allocate arrangement consideration in multiple deliverable arrangements in a manner that better reflects the economics of the transaction by revising certain thresholds for separation, and providing criteria for allocation of revenue among deliverables. The FASB also updated the scope of the revenue recognition accounting guidance of FASB ASC Topic 985, *Software*, removing both non-software components of tangible products and certain software components of tangible products from the scope of existing software revenue guidance, resulting in the recognition of revenue similar to that for other tangible products. The updated accounting guidance is effective for annual periods beginning after June 15, 2010. Early adoption is permitted and may be prospective or retrospective. In the first quarter of 2010, the Company elected to adopt both accounting guidance updates prospectively effective January 3, 2010. The Company s adoption did not have a material impact during the nine months ended October 2, 2010 and the Company does not expect any material impacts to the fourth quarter or annual 2010 periods.

In December 2009, the FASB issued Accounting Standards Update (ASU) 2009-17, *Consolidations (Topic 810): Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*. ASU 2009-17 requires a qualitative approach to identifying a controlling financial interest in a variable interest entity (VIE), and requires ongoing assessment of whether an entity is a VIE and whether an interest in a VIE makes the holder the primary beneficiary of the VIE. The adoption of ASU 2009-17 in January 2010 has not had a material impact on the Company s consolidated financial statements.

In January 2010, the FASB issued ASU 2010-6, *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*, which requires reporting entities to make new disclosures about recurring or nonrecurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU 2010-6 was effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for interim and annual periods beginning after December 15, 2010. The Company adopted the additional disclosures required for Level 1 and Level 2 fair value measurements in the first quarter of 2010 (see Note 13). The Company will adopt Level 3 disclosures beginning in the first quarter of 2011.

NOTE 3 ACQUISITION AND MINORITY INVESTMENT

The results of operations of businesses acquired have been included in the Company s consolidated results of operations since the dates of acquisition. Pro forma results of operations have not been presented for these acquisitions since the effects of these business acquisitions were not material to the Company either individually or in the aggregate.

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Acquisition: On July 6, 2010, the Company completed its acquisition of LightLab Imaging, Inc. (LightLab Imaging) for $92.2 million in net cash consideration. The Company recorded acquisition-related costs of $14.6 million, of which $12.9 million was recorded in selling, general and administrative expense and $1.7 million was recorded in cost of sales. LightLab Imaging is based in Westford, Massachusetts and develops, manufactures and markets Optical Coherence Tomography (OCT) for coronary imaging applications. OCT is a high resolution diagnostic coronary imaging technology that complements the Fractional Flow Reserve (FFR) technology acquired by the Company as part of the Radi Medical Systems acquisition in December 2008.

The aggregate LightLab Imaging purchase price was allocated on a preliminary basis to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition (in thousands):

	LightLab Imaging
Current assets	$ 15,424
Deferred income taxes	4,240
Goodwill	39,926
Other intangible assets	39,640
Acquired IPR&D	14,270
Other long-term assets	2,219
Total assets acquired	$ 115,719
Current liabilities	23,555
Net assets acquired	$ 92,164

The goodwill recorded as a result of the LightLab Imaging acquisition is deductible for income tax purposes and was entirely allocated to the Cardiovascular operating segment. In connection with the acquisition of LightLab Imaging, the Company recorded $39.6 million of developed and core technology intangible assets that have an estimated useful life of 15 years and capitalized acquired in-process research and development (IPR&D) of $14.3 million. IPR&D is defined as the value assigned to those projects for which the related products have not yet reached technological feasibility and have no future alternative use. All acquired IPR&D in a business acquisition is recorded at fair value and capitalized as an indefinite-lived intangible asset until completion of the IPR&D project or abandonment. Upon completion of the IPR&D project (generally, regulatory approval to market the product), the acquired IPR&D assets are amortized over their estimated useful life. Abandoned IPR&D projects would likely result in an impairment and write-down of the related IPR&D assets to the remaining fair value, if any.

Minority Investment: On September 3, 2010, the Company made an equity investment of $60.0 million in CardioMEMS, Inc. (CardioMEMS), a privately-held company that is focused on the development of a wireless monitoring technology that can be placed directly into the pulmonary artery to assess cardiac performance via measurement of pulmonary artery pressure. The investment agreement resulted in a 19% ownership interest and provided the Company with the exclusive right, but not the obligation, to acquire CardioMEMS for an additional payment of $375 million during the period that extends through the completion of certain commercialization milestones. The equity investment and allocated value of the fixed price purchase option are being carried at cost.

NOTE 4 GOODWILL AND OTHER INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for each of the Company s reportable segments (see Note 15) for the nine months ended October 2, 2010 were as follows (in thousands):

	CRM/NMD	CV/AF	Total
Balance at January 2, 2010	$ 1,218,329	$ 787,522	$ 2,005,851
LightLab Imaging		39,926	39,926
Foreign currency translation and other	10,423	19,420	29,843
Balance at October 2, 2010	$ 1,228,752	$ 846,868	$ 2,075,620

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The following table provides the gross carrying amount of other intangible assets and related accumulated amortization (in thousands):

	October 2, 2010		January 2, 2010	
	Gross carrying amount	Accumulated amortization	Gross carrying amount	Accumulated amortization
Amortized intangible assets:				
Purchased technology and patents	$ 546,847	$ 198,270	$ 506,893	$ 171,760
Customer lists and relationships	183,736	95,684	182,368	81,129
Trademarks and tradenames	24,347	7,381	24,286	6,336
Licenses, distribution agreements and other	6,049	4,364	5,693	3,873
	$ 760,979	$ 305,699	$ 719,240	$ 263,098
Indefinite intangible assets:				
Acquired IPR&D	$ 14,270	$	$	$

NOTE 5 INVENTORIES

The Company s inventories consisted of the following (in thousands):

	October 2, 2010	January 2, 2010
Finished goods	$ 496,294	$ 460,600
Work in process	67,350	60,702
Raw materials	125,013	138,658
	$ 688,657	$ 659,960

NOTE 6 DEBT

The Company s debt consisted of the following (in thousands):

	October 2, 2010	January 2, 2010
3.75% senior notes due 2014	$ 699,195	$ 699,036
4.875% senior notes due 2019	494,404	493,927
2.20% senior notes due 2013	467,380	
Term loan due 2011		432,000
2.04% Yen-denominated senior notes due 2020	152,371	
1.58% Yen-denominated senior notes due 2017	97,258	
1.02% Yen-denominated notes due 2010		226,787
Yen-denominated term loan due 2011	77,658	70,652
Total debt	1,988,266	1,922,402
Less: current debt obligations		334,787
Long-term debt	$ 1,988,266	$ 1,587,615

Expected future minimum principal payments under the Company s debt obligations are as follows: $77.7 million in 2011; $450.0 million in 2013; $700.0 million in 2014; and $749.6 million in years thereafter.

Senior notes due 2014: On July 28, 2009, the Company issued $700.0 million principal amount, 5-year, 3.75% unsecured senior notes (2014 Senior Notes) that mature in July 2014. Interest payments are required on a semi-annual basis. The 2014 Senior Notes were issued at a discount, yielding an effective interest rate of 3.784% at issuance. The debt discount is being amortized as interest expense through maturity. The Company may redeem the 2014 Senior Notes at any time at the applicable redemption price.

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Senior notes due 2019: On July 28, 2009, the Company issued $500.0 million principal amount, 10-year, 4.875% unsecured senior notes (2019 Senior Notes) that mature in July 2019. Interest payments are required on a semi-annual basis. The 2019 Senior Notes were issued at a discount, yielding an effective interest rate of 5.039% at issuance. The debt discount is being amortized as interest expense through maturity. The Company may redeem the 2019 Senior Notes at any time at the applicable redemption price.

Senior notes due 2013: On March 10, 2010, the Company issued $450.0 million principal amount of 3-year, 2.20% unsecured senior notes (2013 Senior Notes). The majority of the net proceeds from the issuance of the 2013 Senior Notes was used to retire the Company s 3-year, unsecured term loan due 2011 (2011 Term Loan). Interest payments are required on a semi-annual basis. The 2013 Senior Notes were issued at a discount, yielding an effective interest rate of 2.23% at issuance. The debt discount is being amortized as interest expense through maturity. The Company may redeem the 2013 Senior Notes at any time at the applicable redemption price.

Concurrent with the issuance of the 2013 Senior Notes, the Company entered into a 3-year, $450.0 million notional amount interest rate swap designated as a fair value hedge of the changes in fair value of the Company s fixed-rate 2013 Senior Notes. As of October 2, 2010, the fair value of the swap was a $17.7 million unrealized gain which was recorded in other assets on the condensed consolidated balance sheet, with a corresponding adjustment to the carrying value of the 2013 Senior Notes. Refer to Note 14 for additional information regarding the interest rate swap.

2.04% Yen-denominated senior notes due 2020: On April 28, 2010, the Company issued 10-year, 2.04% unsecured senior notes in Japan (2.04% Yen Notes) totaling 12.8 billion Yen (the equivalent of $152.4 million at October 2, 2010). The net proceeds from the issuance of the 2.04% Yen Notes were used to repay the 1.02% Yen-denominated notes that matured May 7, 2010 (1.02% Yen Notes). The principal amount of the 2.04% Yen Notes recorded on the balance sheet fluctuates based on the effects of foreign currency translation. Interest payments are required on a semi-annual basis and the entire principal balance is due on April 28, 2020.

1.58% Yen-denominated senior notes due 2017: On April 28, 2010, the Company issued 7-year, 1.58% unsecured senior notes in Japan (1.58% Yen Notes) totaling 8.1 billion Yen (the equivalent of $97.3 million at October 2, 2010). The net proceeds from the issuance of the 1.58% Yen Notes were used to repay the 1.02% Yen Notes. The principal amount of the 1.58% Yen Notes recorded on the balance sheet fluctuates based on the effects of foreign currency translation. Interest payments are required on a semi-annual basis and the entire principal balance is due on April 28, 2017.

1.02% Yen-denominated notes due 2010: On May 7, 2010, the Company repaid its 1.02% Yen Notes totaling 20.9 billion Yen utilizing proceeds from the issuance of its 2.04% Yen Notes and 1.58% Yen Notes.

Yen-denominated term loan due 2011: In December 2008, the Company entered into a 3-year, Yen-denominated unsecured term loan in Japan (Yen Term Loan) totaling 8.0 billion Japanese Yen. In December 2009, the Company voluntarily repaid 1.5 billion Japanese Yen, resulting in an outstanding balance of 6.5 billion Japanese Yen (the equivalent of $77.7 million at October 2, 2010 and $70.7 million at January 2, 2010). The Company can initiate future borrowings up to the 8.0 billion Japanese Yen term loan amount. The principal amount of the Yen Term Loan recorded on the balance sheet fluctuates based on the effects of foreign currency translation. The borrowings bear interest at the Yen LIBOR plus 0.4%. Interest payments are required on a semi-annual basis and the entire principal balance is due in December 2011.

Other available borrowings: In December 2006, the Company entered into a 5-year, $1.0 billion committed credit facility (Credit Facility) that it may draw on for general corporate purposes and to support its commercial paper program. Borrowings under the Credit Facility bear interest at the Prime Rate or LIBOR plus 0.235%, at the election of the Company. In the event that over half of the Credit Facility is drawn upon, an additional five basis points is added to the elected Prime Rate or LIBOR rate. The interest rates are subject to adjustment in the event of a change in the Company s credit ratings. As of October 2, 2010 and January 2, 2010, the Company has no outstanding borrowings under this facility.

The Company s commercial paper program provides for the issuance of short-term, unsecured commercial paper with maturities up to 270 days. The Company had no commercial paper borrowings outstanding as of October 2, 2010 or January 2, 2010. Any future commercial paper borrowings would bear interest at the applicable then-current market rates. The Company classifies all of its commercial paper borrowings as long-term debt, as the Company has the ability to repay any short-term maturity with available cash from its existing long-term, committed Credit Facility.

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NOTE 7 COMMITMENTS AND CONTINGENCIES

Litigation

Silzone® Litigation and Insurance Receivables: The Company has been sued in various jurisdictions beginning in March 2000 by some patients who received a heart valve product with Silzone® coating, which we stopped selling in January 2000. Some of these claimants allege bodily injuries as a result of an explant or other complications, which they attribute to these products. Others, who have not had their Silzone-coated heart valve explanted, seek compensation for past and future costs of special monitoring they allege they need over and above the medical monitoring of all other replacement heart valve patients receive. Some of the lawsuits seeking the cost of monitoring have been initiated by patients who are asymptomatic and who have no apparent clinical injury to date. The Company has vigorously defended against the claims that have been asserted and expects to continue to do so with respect to any remaining claims. While the Company has a small number of individual Silzone cases in federal and state courts outstanding, the Company s historical experience with similar cases and the Company s expectations for these specific cases are that it will be able to resolve them at minimal, if any, cost to the Company.

The Company has been able to successfully resolve class action matters in British Columbia and Quebec. As part of the British Columbia class action settlement, the Company made a $2.1 million payment in March 2010. As part of the Quebec class action settlement, the Company made a $5.7 million payment in April 2010. The Quebec class action settlement also resolved the claim raised by the Quebec Provincial health insurer seeking to recover the cost of insured services furnished or to be furnished to class members in the Quebec class action.

The Company has two outstanding class action cases in Ontario and one individual case in British Columbia by the Provincial health insurer. In Ontario, a class action case involving Silzone patients has been certified, and the trial began in February 2010. A second case seeking class action status in Ontario has been stayed pending resolution of the ongoing Ontario class action. The complaints in the Ontario cases request damages up to 2.0 billion Canadian Dollars (the equivalent of $1.9 billion at October 2, 2010). Based on the Company s historical experience, the amount ultimately paid, if any, often does not bear any relationship to the amount claimed. The British Columbia Provincial health insurer has a lawsuit seeking to recover the cost of insured services furnished or to be furnished to class members in the British Columbia class action, and that lawsuit remains pending in the British Columbia court.

The Company has recorded an accrual for probable legal costs, settlements and judgments for Silzone related litigation. The Company is not aware of any unasserted claims related to Silzone-coated products. For all Silzone legal costs incurred, the Company records insurance receivables for the amounts that it expects to recover. Any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered by the Company s product liability insurance policies or existing reserves could be material to the Company s consolidated earnings, financial position and cash flows. The following table summarizes the Company s Silzone legal accrual and related insurance receivable at October 2, 2010 and January 2, 2010 (in thousands):

	October 2, 2010	January 2, 2010
Silzone legal accrual	$ 23,133	$ 23,326
Silzone insurance receivable	$ 63,710	$ 42,538

Part of the Company s remaining product liability insurance for Silzone claims consists of a $50.0 million layer of insurance covered by American Insurance Company (AIC). In December 2007, AIC initiated a lawsuit in Minnesota Federal District Court seeking a court order declaring that it is not required to provide coverage for a portion of the Silzone litigation defense and indemnity expenses that the Company may incur in the future. The insurance broker that assisted the Company in procuring the insurance with AIC has also been added as a party to the case on the Company s behalf. The Company believes the claims of AIC are without merit and plans to vigorously defend against the claims AIC has asserted. In September 2010, the District Court issued a decision in favor of the Company in response to a motion for partial summary judgment on AIC being required to provide payment of certain indemnity expenses. A second motion for partial summary judgment was heard by the District Court on October 29, 2010.

Part of the Company s final layer of insurance was covered by Lumberman s Mutual Casualty Insurance, a unit of the Kemper Insurance Companies (collectively referred to as Kemper). Kemper is currently in run off, which means it is no longer issuing new policies, and therefore, is not generating any new revenue that could be used to cover claims made under previously-issued policies. In September 2010, Kemper agreed to settle its future insurance obligations with the Company, the amount of which was not material. The Company s remaining insurance for Silzone claims consists of $30 million of coverage with other insurance carriers that are responsible for claims incurred after the AIC insurance layer is exhausted. To the extent that the Company s future Silzone costs and expenses exceed our remaining insurance coverage, the Company would be responsible for such costs. The Company has not accrued for any potential losses relating to future costs as they are not probable or reasonably estimable at this time.

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Volcano Corporation & LightLab Imaging Litigation: The Company's recently acquired subsidiary, LightLab Imaging, Inc. (LightLab Imaging) has pending litigation with Volcano Corporation (Volcano) and Axsun Technologies, Inc. (Axsun), a subsidiary of Volcano, in the Superior Court of Massachusetts and in state court in Delaware. LightLab Imaging makes and sells optical coherence tomography (OCT) imaging systems. Volcano is a LightLab Imaging competitor in medical imaging. Axsun makes and sells lasers and is a supplier of lasers to LightLab Imaging for use in OCT imaging systems. The lawsuits arise out of Volcano's acquisition of Axsun in December 2008. Before Volcano acquired Axsun, LightLab Imaging and Axsun had worked together to develop a tunable laser for use in OCT imaging systems. While the laser was in development, LightLab Imaging and Axsun entered into an agreement pursuant to which Axsun agreed to sell its tunable lasers exclusively to LightLab in the field of human coronary artery imaging for a period of years.

After Volcano acquired Axsun in December 2008, LightLab Imaging sued Axsun and Volcano in Massachusetts, asserting a number of claims arising out of Volcano's acquisition of Axsun. In a phased trial in Massachusetts in February 2010, a jury found Axsun had breached its contract with LightLab Imaging, Volcano had intentionally interfered with that contract, and both Axsun and Volcano had misappropriated certain LightLab Imaging trade secrets. The jury also found Axsun was contractually required to sell a particular version of the laser to LightLab Imaging, rejecting Axsun's position that the contract only required the sale of an earlier version of the laser. The jury also found in LightLab Imaging's favor that the restriction on sales of tunable lasers to Volcano applied to all of Axsun's tunable lasers for OCT imaging, rejecting Axsun's and Volcano's position that the restriction on such sales applied only to a laser meeting a particular specification. Following the jury's verdict, LightLab Imaging, Axsun, and Volcano stipulated to the amount of damages a jury could award against Axsun and Volcano.

In a later phase of the Massachusetts lawsuit, the court ruled there was an insufficient basis to enjoin Axsun and Volcano from using certain information, not considered by the jury, that LightLab Imaging regards as trade secrets. LightLab presently expects the court will consider other trade secret issues in later stages, as well as considering whether Axsun's and Volcano's conduct constituted knowing or willful violations of a statute that prohibits unfair or deceptive acts or practices or acts of unfair competition, whether damages against Axsun or Volcano should be doubled or trebled under that statute, whether Axsun and Volcano should be ordered to reimburse LightLab for its attorneys fees and related litigation expenses, and whether any permanent injunctions should be entered against Axsun and Volcano.

In Delaware, Axsun and Volcano commenced an action in February 2010 against LightLab Imaging, seeking a declaration as to whether Axsun may supply a certain light source for use in OCT imaging systems to Volcano. Axsun's and Volcano's position is that this light source is not a tunable laser and hence falls outside Axsun's exclusivity obligations to Volcano. LightLab Imaging's position, among other things, is that this light source is a tunable laser. The parties are presently involved in expedited discovery, and a trial is expected to commence in early 2011.

Volcano Corporation & St. Jude Medical Patent Litigation: In July 2010, the Company filed a lawsuit in federal district court in Delaware against Volcano for patent infringement. The suit involves five patents and seeks injunctive relief and monetary damages. The infringed patents are used for the St. Jude Medical PressureWire® technology platform, which was acquired from Radi Medical Systems in December 2008. In September 2010, Volcano filed counterclaims against the Company, alleging certain St. Jude Medical patent claims are unenforceable and that

certain St. Jude Medical products infringe three Volcano patents. The Company believes the assertions and claims made by Volcano are without merit.

Boston U.S. Attorney Investigation: In October 2005, the U.S. Department of Justice (DOJ), acting through the U.S. Attorney s office in Boston, commenced an industry-wide investigation into whether the provision of payments and/or services by makers of ICDs and bradycardia pacemaker systems (pacemakers) to doctors or other persons constitutes improper inducements under the federal health care program anti-kickback law. As part of this investigation, the Company has received three subpoenas from the government requesting documents regarding the Company s practices related to ICDs, pacemakers, lead systems and related products marketed by the Company s Cardiac Rhythm Management (CRM) operating segment. The Company has cooperated with the investigation and has produced documents and witnesses as requested. In January 2010, the U.S. District Court for the District of Massachusetts unsealed a qui tam action (private individual bringing suit on behalf of the U.S. Government) filed by a former employee containing allegations relating to the issues covered by the subpoenas. Although in December 2009, the DOJ had declined to intervene in this qui tam suit, the DOJ filed a motion in August 2010 to intervene. The Court granted the DOJ s motion, without prejudice to the Company, and also directed the DOJ to file its complaint by August 31, 2010. The DOJ has indicated that it intends only to pursue alleged claims related to four post-market studies conducted by the Company primarily in 2004-2006. The Court also ruled that the Company may file its objection to the August 2010 DOJ intervention and argue that the DOJ has not established good cause to intervene. The Court vacated the deadline for DOJ to file its complaint, and scheduled the case for a status hearing on November 29, 2010. The Company will vigorously defend against the allegations in the lawsuit. It is not possible to predict the outcome of this matter at this time.

Additionally, in December 2008, the U.S. Attorney s Office in Boston delivered a subpoena issued by the OIG requesting the production of documents relating to implantable cardiac rhythm device and pacemaker warranty claims. The Company has cooperated with the investigation and has produced documents as requested.

U.S. Department of Justice - Civil Investigative Demand: In March 2010, the Company received a Civil Investigative Demand (CID) from the Civil Division of the U.S. Department of Justice. The CID requests documents and sets forth interrogatories related to communications by and within the Company on various indications for ICDs and a National Coverage Decision issued by Centers for Medicare and Medicaid Services. Similar requests were made of our major competitors. The Company is cooperating with the investigation and is continuing to work with the U.S. Department of Justice in responding to the CID.

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Securities Class Action Litigation: On March 18, 2010, a securities class action lawsuit was filed in federal district court in Minnesota against the Company and certain officers on behalf of purchasers of St. Jude Medical common stock between April 22, 2009 and October 6, 2009. The lawsuit relates to the Company s earnings announcements for the first, second and third quarters of 2009, as well as a preliminary earnings release dated October 6, 2009. The complaint, which seeks unspecified damages and other relief as well as attorneys fees, alleges that the Company failed to disclose that it was experiencing a slowdown in demand for its products and was not receiving anticipated orders for CRM devices. Class members allege that the Company s failure to disclose the above information resulted in the class purchasing St. Jude Medical stock at an artificially inflated price. The Company intends to vigorously defend against the claims asserted in this lawsuit. In October 2010, the Company filed a motion to dismiss the lawsuit, which is scheduled to be heard by the District Court in early January 2011.

Derivative Litigation: In September 2010, two separate derivative actions involving the Company were filed in the United States District Court for the District of Minnesota. In both of these matters, the defendants consist of members (or former members) of St. Jude Medical s Board of Directors (the Board) as well as various officers and former officers of the Company. The plaintiffs in these actions are asserting breach of fiduciary duty claims against the named defendants for their purported failure to stop the alleged underlying conduct (which relates to the contents of qui tam actions filed in Ohio and Massachusetts). In October 2010, the plaintiffs filed a motion before the Judicial Panel on MultiDistrict Litigation requesting that the two cases be transferred to the District of Massachusetts and consolidated with what they claim are related actions there. St. Jude Medical intends to oppose the transfer request and to vigorously defend against the claims asserted in these two derivative lawsuits.

Regulatory Matters

The FDA inspected the Company s manufacturing facility in Minnetonka, Minnesota at various times between December 8 and December 19, 2008. On December 19, 2008, the FDA issued a Form 483 identifying certain observed non-conformity with current Good Manufacturing Practice (cGMP) primarily related to the manufacture and assembly of the Safire™ ablation catheter with a 4 mm or 5 mm non-irrigated tip. Following the receipt of the Form 483, the Company s AF division provided written responses to the FDA detailing proposed corrective actions and immediately initiated efforts to address the FDA s observations of non-conformity. The Company subsequently received a warning letter dated April 17, 2009 from the FDA relating to these non-conformities with respect to this facility.

The FDA inspected the Company s Plano, Texas manufacturing facility at various times between March 5 and April 6, 2009. On April 6, 2009, the FDA issued a Form 483 identifying certain observed nonconformities with cGMP. Following the receipt of the Form 483, the Company s Neuromodulation division provided written responses to the FDA detailing proposed corrective actions and immediately initiated efforts to address FDA s observations of nonconformity. The Company subsequently received a warning letter dated June 26, 2009 from the FDA relating to these non-conformities with respect to its Neuromodulation division s Plano, Texas and Hackettstown, New Jersey facilities.

With respect to each of these warning letters, the FDA notes that it will not grant requests for exportation certificates to foreign governments or approve pre-market approval applications for Class III devices to which the quality system regulation deviations are reasonably related until the violations have been corrected. The Company is working cooperatively with the FDA to resolve all of its concerns.

On April 23, 2010, the FDA issued a warning letter based upon a July 29, 2009 inspection of our Sunnyvale, California facility and a review of our website. The warning letter cites the Company for its promotion and marketing of the Epicor LP Cardiac Ablation System and the Epicor UltraCinch LP Ablation Device based on certain statements made in the Company s marketing materials. The Company is working cooperatively with the FDA to resolve all of its concerns. The warning letter is not expected to have any material impact on the Company s business.

Customer orders have not been and are not expected to be impacted while the Company works to resolve the FDA s concerns. The Company is working diligently to respond timely and fully to the FDA s requests. While the Company believes the issues raised by the FDA can be resolved without a material impact on the Company s financial results, the FDA has recently been increasing its scrutiny of the medical device industry and raising the threshold for compliance. The government is expected to continue to scrutinize the industry closely with inspections, and possibly enforcement actions, by the FDA or other agencies. The Company is regularly monitoring, assessing and improving its internal compliance systems and procedures to ensure that its activities are consistent with applicable laws, regulations and requirements, including those of the FDA.

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Other Matters

In connection with the pending acquisition (see Note 16) of AGA Medical Holdings, Inc. (AGA Medical), the Company, in addition to AGA Medical and other defendants, has been named as a defendant in two putative stockholder class action complaints, one filed in the Fourth Judicial District Court of Minnesota on October 27, 2010 and the other filed in the Deleware Court of Chancery on October 28, 2010. The plaintiffs in the complaints allege, among other claims, that AGA Medical s directors breached their fiduciary duties to AGA Medical s stockholders by accepting an inadequate price, failing to make full disclosure, and utilizing unreasonable deal protection devices and further alleges that AGA Medical and the Company aided and abetted the purported breaches of fiduciary duty. The complaints seek injunctive relief, including to enjoin the transaction, in addition to unspecified compensatory damages, attorneys fees, other fees and costs and other relief. On November 8, 2010, the parties to this action entered into a memorandum of understanding (MOU) to settle the litigation. The settlement contemplated by the MOU is subject to several conditions, including the negotiation and execution of a stipulation of settlement and the approval of the Delaware Court of Chancery.

The Company is also involved in various other lawsuits, claims and proceedings that arise in the ordinary course of business.

Product Warranties

The Company offers a warranty on various products, the most significant of which relates to its ICDs and pacemakers systems. The Company estimates the costs that may be incurred under its warranties and records a liability in the amount of such costs at the time the product is sold. Factors that affect the Company s warranty liability include the number of units sold, historical and anticipated rates of warranty claims and cost per claim. The Company periodically assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary.

Changes in the Company s product warranty liability during the three and nine months ended October 2, 2010 and October 3, 2009 were as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Balance at beginning of period	$ 22,213	$ 17,505	$ 19,911	$ 15,724
Warranty expense recognized	2,154	1,700	5,536	4,728
Warranty credits issued	(575)	(552)	(1,655)	(1,799)
Balance at end of period	$ 23,792	$ 18,653	$ 23,792	$ 18,653

Other Commitments

The Company has certain contingent commitments to acquire various businesses involved in the distribution of the Company s products and to pay other contingent acquisition consideration payments. While it is not certain if and/or when these payments will be made, as of October 2, 2010, the Company estimates it could be required to pay approximately $86 million in future periods to satisfy such commitments. Refer to Part II, Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations Off-Balance Sheet Arrangements and Contractual Obligations* of the Company s 2009 Annual Report on Form 10-K for additional information.

NOTE 8 PURCHASED IN-PROCESS RESEARCH AND DEVELOPMENT (IPR&D) & SPECIAL CHARGES

IPR&D Charges: During the third quarter of 2010, the Company recorded IPR&D charges of $12.2 million in conjunction with the purchase of cardiovascular-related intellectual property since the related technological feasibility had not yet been reached and such technology had no future alternative use.

Special Charges: During 2009, the Company incurred charges totaling $107.7 million, of which $71.1 million related to severance and benefit costs for approximately 725 employees. These costs were recognized after management determined that such severance and benefits were probable and estimable, in accordance with ASC Topic 712, *Nonretirement Postemployment Benefits*. Of the total $71.1 million severance and benefits charge, $6.6 million was recorded in cost of sales. The Company also recorded $17.7 million of inventory related charges to cost of sales associated with inventory that would be scrapped in connection with the Company s decision to terminate certain product lines in its CRM and AF divisions that were redundant with other existing products lines. Additionally, the Company recorded $5.9 million of fixed asset related charges to cost of sales associated with the accelerated depreciation of phasing out older model diagnostic equipment and $6.1 million of asset write-offs related to the carrying value of assets that will no longer be utilized. Of the $6.1 million charge, $3.5 million was recorded in cost of

sales. The Company also recorded charges of $1.8 million associated with contract terminations and $5.1 million of other unrelated costs.

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A summary of the activity related to the 2009 special charge accrual is as follows (in thousands):

	Employee termination costs	Inventory charges	Fixed asset charges	Other	Total
Balance at January 3, 2009	$	$	$	$	$
Special charges	71,158	17,735	11,982	6,869	107,744
Non-cash charges used		(17,735)	(11,982)		(29,717)
Cash payments	(22,560)			(349)	(22,909)
Foreign exchange rate impact	(758)				(758)
Balance at January 2, 2010	$ 47,840	$	$	$ 6,520	$ 54,360
Cash payments	(28,958)			(4,118)	(33,076)
Foreign exchange rate impact	(1,187)			(118)	(1,305)
Balance at October 2, 2010	$ 17,695	$	$	$ 2,284	$ 19,979

In order to enhance segment comparability and reflect management s focus on the ongoing operations of the Company, the 2009 special charges were not recorded in the individual reportable segments.

NOTE 9 NET EARNINGS PER SHARE

The table below sets forth the computation of basic and diluted net earnings per share (in thousands, except per share amounts):

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Numerator:				
Net earnings	$ 208,385	$ 166,935	$ 700,992	$ 587,576
Denominator:				
Basic weighted average shares outstanding	328,231	340,651	326,822	344,423
Dilutive options and restricted stock	1,696	3,647	2,279	3,819
Diluted weighted average shares outstanding	329,927	344,298	329,101	348,242
Basic net earnings per share	$ 0.63	$ 0.49	$ 2.14	$ 1.71
Diluted net earnings per share	$ 0.63	$ 0.48	$ 2.13	$ 1.69

Approximately 21.1 million and 13.0 million shares of common stock subject to stock options and restricted stock were excluded from the diluted net earnings per share computation for the three months ended October 2, 2010 and October 3, 2009, respectively, because they were not dilutive. Additionally, approximately 19.1 million and 20.5 million shares of common stock subject to stock options and restricted stock were excluded from the diluted net earnings per share computation for the nine months ended October 2, 2010 and October 3, 2009, respectively, because they were not dilutive.

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NOTE 10 COMPREHENSIVE INCOME

The table below sets forth the principal components in other comprehensive income (loss), net of the related income tax impact (in thousands):

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Net earnings	$ 208,385	$ 166,935	$ 700,992	$ 587,576
Other comprehensive income (loss):				
Cumulative translation adjustment	108,001	68,560	(9,757)	105,541
Unrealized gain on available-for-sale securities	1,659	2,163	4,243	2,717
Reclassification of realized gain to net earnings	(3,081)		(3,081)	
Total comprehensive income	$ 314,964	$ 237,658	$ 692,397	$ 695,834

Upon the sale of an available-for-sale investment, the unrealized gain (loss) is reclassified out of other comprehensive income and reflected as a realized gain (loss) in net earnings. In the third quarter of 2010, the Company sold an available-for-sale investment, recognizing a realized after-tax gain of $3.1 million. The total pre-tax gain of $4.9 million was recognized as other income.

NOTE 11 OTHER INCOME (EXPENSE), NET

The Company s other income (expense) consisted of the following (in thousands):

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Interest income	$ 785	$ 643	$ 1,507	$ 1,720
Interest expense	(14,714)	(14,855)	(50,299)	(27,425)
Other	2,818	(9,382)	(2,865)	(10,162)
Total other income (expense), net	$ (11,111)	$ (23,594)	$ (51,657)	$ (35,867)

During the third quarter of 2010 the Company recognized a $4.9 million realized gain in other income associated with the sale of an available-for-sale investment. During the third quarter of 2009, the Company recognized an $8.3 million investment impairment charge in other expense after determining that the fair value of a cost method investment was below its carrying value and that this impairment was other-than-temporary.

NOTE 12 INCOME TAXES

As of October 2, 2010, the Company had $136.7 million accrued for unrecognized tax benefits, all of which would affect the Company s effective tax rate if recognized. The Company had $33.7 million accrued for interest and penalties as of October 2, 2010. The Company recognizes interest and penalties related to income tax matters in income tax expense. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. At January 2, 2010, the Company had $120.5 million accrued for unrecognized tax benefits and $28.3 million accrued for interest and penalties.

The Company is subject to U.S. federal income tax as well as income tax of multiple state and foreign jurisdictions. The Company has substantially concluded all U.S. federal income tax matters for all tax years through 2001. Additionally, substantially all material foreign, state, and local income tax matters have been concluded for all tax years through 1999. The U.S. Internal Revenue Service (IRS) completed an audit of the Company s 2002 through 2005 tax returns and proposed adjustments in its audit report issued in November 2008. The Company is vigorously defending its positions and initiated defense of these adjustments at the IRS appellate level in January 2009. An unfavorable outcome could have a material negative impact on the Company s effective income tax rate in future periods.

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NOTE 13 FAIR VALUE MEASUREMENTS AND FINANCIAL INSTRUMENTS

The fair value measurement accounting standard, codified in ASC Topic 820, provides a framework for measuring fair value and defines fair value as the price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. The standard establishes a valuation hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability developed based on independent market data sources. Unobservable inputs are inputs that reflect the Company s assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available. The valuation hierarchy is composed of three categories. The categorization within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement.

The categories within the valuation hierarchy are described as follows:

Level 1 Inputs to the fair value measurement are quoted prices in active markets for identical assets or liabilities.
Level 2 Inputs to the fair value measurement include quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly.
Level 3 Inputs to the fair value measurement are unobservable inputs or valuation techniques.

Assets and Liabilities that are Measured at Fair Value on a Recurring Basis

The fair value measurement standard applies to certain financial assets and liabilities that are measured at fair value on a recurring basis (each reporting period). These financial assets and liabilities include money-market securities, trading marketable securities, available-for-sale marketable securities and derivative instruments. The Company continues to record these items at fair value on a recurring basis and the fair value measurements are applied using ASC Topic 820. The Company does not have any material nonfinancial assets or liabilities that are measured at fair value on a recurring basis. A summary of the valuation methodologies used for the respective financial assets and liabilities measured at fair value is as follows:

Money-market securities: The Company s money-market securities include funds that are traded in active markets and are recorded at fair value based upon the quoted market prices. The Company classifies these securities as level 1.

Trading securities: The Company s trading securities include publicly-traded mutual funds that are traded in active markets and are recorded at fair value based upon the net asset values of shares. The Company classifies these securities as level 1.

Available-for-sale securities: The Company s available-for-sale securities include publicly-traded equity securities that are traded in active markets and are recorded at fair value based upon the closing stock prices. The Company classifies these securities as level 1.

Derivative instruments: The Company s derivative instruments consist of foreign currency exchange contracts and interest rate swap contracts. The Company classifies these instruments as level 2 as the fair value is determined using inputs other than observable quoted market prices. These inputs include spot and forward foreign currency exchange rates and interest rates that the Company obtains from standard market data providers. The fair value of the Company s foreign currency exchange contracts was not material at October 2, 2010 or January 2, 2010.

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A summary of financial assets and liabilities measured at fair value on a recurring basis at October 2, 2010 and January 2, 2010 is as follows (in thousands):

	October 2, 2010	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money-market securities	$ 693,091	$ 693,091	$	$
Trading marketable securities	173,286	173,286		
Available-for-sale marketable securities	30,409	30,409		
Interest rate swap	17,684		17,684	
Total	$ 914,470	$ 896,786	$ 17,684	$

	January 2, 2010	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money-market securities	$ 258,936	$ 258,936	$	$
Trading marketable securities	160,285	160,285		
Available-for-sale marketable securities	31,711	31,711		
Total	$ 450,932	$ 450,932	$	$

The Company s money-market securities are classified as cash equivalents as the funds are highly liquid investments readily convertible to cash. The Company also had $158.5 million and $134.0 million of cash equivalents invested in short-term time deposits and interest and non-interest bearing bank accounts at October 2, 2010 and January 2, 2010, respectively.

Assets and Liabilities that are Measured at Fair Value on a Nonrecurring Basis

The fair value measurement standard also applies to certain nonfinancial assets and liabilities that are measured at fair value on a nonrecurring basis. For example, certain long-lived assets such as goodwill, intangible assets and property, plant and equipment are measured at fair value in connection with business combinations or when an impairment is recognized and the related assets are written down to fair value.

The following table provides information by level for assets and liabilities that were measured at fair value on a nonrecurring basis. This table provides the fair value of net identifiable tangible and intangible assets and liabilities (excluding goodwill) for business combinations that closed during the first nine months of 2010. For business combinations, the Company uses inputs other than quoted prices that are observable, such as interest rates, cost of capital and market comparable royalty rates, which are applied to income and market valuation approaches. A summary of the nonfinancial assets and liabilities measured at fair value in conjunction with our business combination is as follows (in thousands):

	Fair Value	Quoted Prices In Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Description				
Business Combination	$ 52,238	$	$ 52,238	$

The Company did not make any material business combinations during the first nine months of fiscal year 2009. Additionally, no material impairments of the Company s long-lived assets were recognized during the first nine months of 2010 or fiscal year 2009.

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The Company also holds investments in equity securities that are accounted for as cost method investments, which are classified as other assets and measured at fair value on a nonrecurring basis. The carrying value of these investments approximated $129 million at October 2, 2010 and $57 million at January 2, 2010. The fair value of the Company s cost method investments is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of these investments. When measured on a nonrecurring basis, the Company s cost method investments are considered Level 3 in the fair value hierarchy, due to the use of unobservable inputs to measure fair value. The Company did not have any Level 3 fair value measurements as of October 2, 2010.

Fair Value of Other Financial Instruments

The aggregate fair value of the Company s fixed-rate senior notes at October 2, 2010 (measured using quoted prices in active markets) was $2,040.2 million compared to the aggregate carrying value of $1,910.6 million (inclusive of the interest rate swap). The fair value of the Company s other debt obligations at October 2, 2010 approximated their aggregate $77.7 million carrying value due to the variable interest rate and short-term nature of these instruments.

NOTE 14 DERIVATIVE FINANCIAL INSTRUMENTS

The Company follows the provisions of ASC Topic 815 in accounting for and disclosing derivative instruments and hedging activities. All derivative financial instruments are recognized on the balance sheet at fair value. Changes in the fair value of derivatives are recognized in net earnings or other comprehensive income depending on whether the derivative is designated as part of a qualifying hedging transaction. Derivative assets and derivative liabilities are classified as other current assets, other assets, other current liabilities or other liabilities, as appropriate.

Foreign Currency Forward Contracts

The Company hedges a portion of its foreign currency exchange rate risk through the use of forward exchange contracts. The Company uses forward exchange contracts to manage foreign currency exposures related to intercompany receivables and payables arising from intercompany purchases of manufactured products. These forward contracts are not designated as qualifying hedging relationships under ASC Topic 815. The Company measures its foreign currency exchange contracts at fair value on a recurring basis. The fair value of outstanding contracts was immaterial as of October 2, 2010 and January 2, 2010. For the three months ended October 2, 2010 and October 3, 2009, the net amount of gains (losses) the Company recorded to other income (expense) for its forward currency exchange contracts not designated as hedging instruments under ASC Topic 815 was a net loss of $8.4 million and a net loss of $3.8 million, respectively. During the first nine months of 2010 and 2009, the net amount of gains (losses) recorded to other income (expense) for its forward currency exchange contracts not designated as hedging instruments was a net loss of $1.7 million and a net loss of $7.2 million, respectively. These net gains and net losses were almost entirely offset by corresponding net losses and net gains on the foreign currency exposures being managed. The Company does not enter into contracts for trading or speculative purposes. The Company s policy is to enter into hedging contracts with major financial institutions that have at least an A (or equivalent) credit rating.

Interest Rate Swap

The Company hedges the fair value of certain debt obligations through the use of interest rate swap contracts For interest rate swap contracts that are designated and qualify as fair value hedges, the gain or loss on the swap and the offsetting gain or loss on the hedged debt instrument attributable to the hedged risk are recognized in net earnings. Changes in the value of the fair value hedge are recognized in interest expense, offsetting the changes in the fair value of the hedged debt instrument. Additionally, any payments made or received under the swap contracts are accrued and recognized as interest expense. The Company s current interest rate swap is designed to manage the exposure to changes in the fair value of its 2013 Senior Notes. The swap is designated as a fair value hedge of the variability of the fair value of the fixed-rate 2013 Senior Notes due to changes in the long-term benchmark interest rates. Under the swap agreement, the Company agrees to exchange, at specified intervals, fixed and floating interest amounts calculated by reference to an agreed-upon notional principal amount. As of October 2, 2010, the fair value of the interest rate swap was a $17.7 million unrealized gain which was recorded to other assets on the condensed consolidated balance sheet.

NOTE 15 SEGMENT AND GEOGRAPHIC INFORMATION

Segment Information

The Company s four operating segments are Cardiac Rhythm Management (CRM), Cardiovascular (CV), Atrial Fibrillation (AF), and Neuromodulation (NMD). The primary products produced by each operating segment are: CRM ICDs and pacemakers; CV vascular closure devices, heart valve replacement and repair products and pressure measurement guidewires; AF electrophysiology (EP) introducers and catheters, advanced cardiac mapping, navigation and recording systems and ablation systems; and NMD neurostimulation devices.

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The Company has aggregated the four operating segments into two reportable segments based upon their similar operational and economic characteristics: CRM/NMD and CV/AF. Net sales of the Company s reportable segments include end-customer revenues from the sale of products they each develop and manufacture or distribute. The costs included in each of the reportable segments operating results include the direct costs of the products sold to customers and operating expenses managed by each of the reportable segments. Certain operating expenses managed by the Company s selling and corporate functions, including all stock-based compensation expense, impairment charges, certain acquisition-related charges, purchased in-process research and development charges and special charges, have not been recorded in the individual reportable segments. As a result, reportable segment operating profit is not representative of the operating profit of the products in these reportable segments. Additionally, certain assets are managed by the Company s selling and corporate functions, principally including trade receivables, inventory, corporate cash and cash equivalents and deferred income taxes. For management reporting purposes, the Company does not compile capital expenditures by reportable segment; therefore, this information has not been presented as it is impracticable to do so.

The following table presents net sales and operating profit by reportable segment (in thousands):

	CRM/NMD	CV/AF	Other	Total
Three Months ended October 2, 2010:				
Net sales	$ 830,902	$ 409,003	$	$ 1,239,905
Operating profit	514,788	225,637	(441,441)	298,984
Three Months ended October 3, 2009:				
Net sales	$ 773,651	$ 385,955	$	$ 1,159,606
Operating profit	481,658	207,842	(447,470)	242,030
Nine Months ended October 2, 2010:				
Net sales	$ 2,549,768	$ 1,264,602	$	$ 3,814,370
Operating profit	1,595,378	713,748	(1,299,382)	1,009,744
Nine Months ended October 3, 2009:				
Net sales	$ 2,307,332	$ 1,170,479	$	$ 3,477,811
Operating profit	1,428,712	610,714	(1,210,477)	828,949

The following table presents the Company s total assets by reportable segment (in thousands):

Total Assets	October 2, 2010	January 2, 2010
CRM/NMD	$ 2,136,527	$ 2,124,534
CV/AF	1,573,779	1,294,009
Other	3,674,980	3,007,268
	$ 7,385,286	$ 6,425,811

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Geographic Information

The following table presents net sales by geographic location of the customer (in thousands):

	Three Months Ended		Nine Months Ended	
Net Sales	**October 2, 2010**	**October 3, 2009**	**October 2, 2010**	**October 3, 2009**
United States	$ 657,627	$ 619,600	$ 1,996,655	$ 1,870,599
International				
Europe	281,017	282,820	949,540	867,140
Japan	141,089	119,578	399,344	350,485
Asia Pacific	83,773	67,392	233,080	185,993
Other (a)	76,399	70,216	235,751	203,594
	582,278	540,006	1,817,715	1,607,212
	$ 1,239,905	$ 1,159,606	$ 3,814,370	$ 3,477,811

(a) No one geographic market is greater than 5% of consolidated net sales.

The amounts for long-lived assets by significant geographic market include net property, plant and equipment by physical location of the asset. The following table presents long-lived assets by geographic location (in thousands):

Long-Lived Assets	**October 2, 2010**	**January 2, 2010**
United States	$ 918,553	$ 876,462
International		
Europe	83,874	77,790
Japan	20,470	18,756
Asia Pacific	67,514	39,946
Other	166,818	140,132
	338,676	276,624
	$ 1,257,229	$ 1,153,086

NOTE 16 SUBSEQUENT EVENTS

On October 15, 2010 the Company entered into a definitive agreement to acquire all the outstanding shares of AGA Medical (NASDAQ: AGAM) for $20.80 per share in an evenly divided cash and stock transaction valued at an estimated $1.1 billion. The transaction will be conducted as an exchange offer followed by a merger and is expected to close by the end of the 2010 fiscal year. AGA Medical is a global innovator and manufacturer of a comprehensive line of devices used to treat structural heart defects and vascular abnormalities through minimally invasive transcatheter treatments. The AGA Medical acquisition will expand the Company s current product portfolio and future product pipeline. Upon completion of the transaction, AGA Medical will become part of the CV operating segment.

On October 15, 2010, the Company s Board of Directors authorized a share repurchase program of up to $600.0 million of the Company s outstanding common stock. On October 21, 2010, the Company s Board of Directors authorized an additional $300.0 million of share repurchases as part of this share repurchase program.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

Our business is focused on the development, manufacture and distribution of cardiovascular medical devices for the global cardiac rhythm management, cardiology, cardiac surgery and atrial fibrillation therapy areas and implantable neurostimulation medical devices for the management of chronic pain. We sell our products in more than 100 countries around the world. Our largest geographic markets are the United States, Europe, Japan and Asia Pacific. Our four operating segments are Cardiac Rhythm Management (CRM), Cardiovascular (CV), Atrial Fibrillation (AF), and Neuromodulation (NMD). Our principal products in each operating segment are as follows: CRM tachycardia implantable cardioverter defibrillator systems (ICDs) and bradycardia pacemaker systems (pacemakers); CV vascular closure devices, heart valve replacement and repair products and pressure measurement guidewires; AF electrophysiology introducers and catheters, advanced cardiac mapping, navigation and recording systems and ablation systems; and NMD neurostimulation devices. References to St. Jude Medical, St. Jude, the Company, we, us and our are to St. Jude Medical, Inc. and its subsidiaries.

Our industry has undergone significant consolidation in the last decade and is highly competitive. Our strategy requires significant investment in research and development in order to introduce new products. We are focused on improving our operating margins through a variety of techniques, including the production of high quality products, the development of leading edge technology, the enhancement of our existing products and continuous improvement of our manufacturing processes. We expect competitive pressures in the industry, cost containment pressure on healthcare systems and the implementation of U.S. healthcare reform legislation to continue to place downward pressure on prices for our products, impact reimbursement for our products and potentially reduce medical procedure volumes.

In March 2010, significant U.S. healthcare reform legislation was enacted into law. As a U.S. headquartered company with significant sales in the United States, this health care reform legislation will materially impact us. Certain provisions of the legislation are not effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation. The legislation does levy a 2.3% excise tax on all U.S. medical device sales beginning in 2013. This is a significant new tax that will materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what impacts these provisions will have on patient access to new technologies. The Medicare provisions also include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

We participate in several different medical device markets, each of which has its own expected growth rate. A significant portion of our net sales relate to CRM devices ICDs and pacemakers. During early March 2010, a principal competitor in the CRM market, Boston Scientific Inc. (Boston Scientific), suspended sales of its ICD products in the United States. Although Boston Scientific resumed sales on April 16, 2010, we experienced an incremental ICD net sales benefit in the range of approximately $35 million to $40 million. While the long-term impact on the CRM market is uncertain, management remains focused on increasing our worldwide CRM market share, as we are one of three principal manufacturers and suppliers in the global CRM market. We are also investing in our other three major growth platforms atrial fibrillation, neuromodulation and cardiovascular and expanding our growth programs through acquisitions of LightLab Imaging, Inc. (LightLab Imaging) and AGA Medical Holdings, Inc. (AGA Medical) during the third quarter of 2010 - to increase our market share in our product markets.

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Net sales in the third quarter and first nine months of 2010 were $1,239.9 million and $3,814.4 million, respectively, increases of 7% and 10% over the third quarter and first nine months of 2009, respectively. Our net sales increases were led by sales growth of our ICDs and products to treat atrial fibrillation. During the third quarter and first nine months of 2010, our ICD net sales grew 13% and 15%, respectively, to $439.3 million and $1,362.0 million, respectively. Our AF net sales increased 9% and 13% during the third quarter and first nine months of 2010, respectively, to $168.8 million and $514.7 million, respectively. Foreign currency translation comparisons decreased our third quarter 2010 net sales by $10.4 million and increased our first nine month 2010 net sales by $37.3 million. Total St. Jude Medical operational sales growth (sales changes excluding the impacts of foreign currency translation and acquisitions) was 7% and 8% for the third quarter and first nine months of 2010, respectively. Refer to the Segment Performance section for a more detailed discussion of the results for the respective segments.

Net earnings and diluted net earnings per share for the third quarter of 2010 were $208.4 million and $0.63 per diluted share, increases of 25% and 31%, respectively, compared to the same prior year period. Net earnings and diluted net earnings per share for the first nine months of 2010 were $701.0 million and $2.13 per diluted share, increases of 19% and 26%, respectively, over the first nine months of 2009. These increases for both the third quarter and first nine months of 2010 compared to the same prior year periods were due to incremental profits resulting from higher sales as well as lower outstanding shares resulting from repurchases of our common stock. From July 2009 through December 2009, we returned $1.0 billion to shareholders in the form of share repurchases.

We generated $791.6 million of operating cash flows during the first nine months of 2010, compared to $553.4 million of operating cash flows during the first nine months of 2009. We ended the third quarter with $851.6 million of cash and cash equivalents and $1,988.3 million of total debt. During the first nine months of 2010, we issued $450.0 million principal amount of senior notes in the United States and 20.9 billion Yen senior notes in Japan. We used the proceeds to repay our 1.02% Yen-denominated notes due in May 2010 (1.02% Yen Notes) totaling 20.9 billion Yen and retire our 3-year, unsecured term loan due 2011 (2011 Term Loan) using the majority of the remaining proceeds. During 2009, we issued $1,200.0 million principal amount of debt, consisting of $700.0 million of 3.75% Senior Notes due 2014 (2014 Senior Notes) and $500.0 million of 4.875% Senior Notes due 2019 (2019 Senior Notes).

NEW ACCOUNTING PRONOUNCEMENTS

Certain new accounting standards will become effective for us in future periods. Information regarding new accounting pronouncements that impacted the first nine months of 2010 or our historical consolidated financial statements and related disclosures is included in Note 2 to the Condensed Consolidated Financial Statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2010-6, *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*, which requires reporting entities to make new disclosures about recurring or nonrecurring fair value measurements including (i) significant transfers into and out of Level 1 and Level 2 fair value measurements and (ii) information on purchases, sales, issuances and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. ASU 2010-6 was effective for interim and annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures which are effective for interim and annual periods beginning after December 15, 2010. We adopted the additional disclosures required for Level 1 and Level 2 fair value measurements in the first quarter of 2010. Currently, we have no Level 3 fair value measurements, however, we will incorporate the additional disclosures regarding the valuation techniques and inputs used to measure fair value, as applicable. Further, we will adopt the Level 3 reconciliation disclosures required, beginning in our first quarter of 2011, as applicable.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We have adopted various accounting policies in preparing the consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our significant accounting policies are disclosed in Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended January 2, 2010 (2009 Annual Report on Form 10-K).

Preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires us to adopt various accounting policies and to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and assumptions, including those related to accounts receivable allowance for doubtful accounts; inventory reserves; valuation of purchased in-process research and development (IPR&D), other intangible assets and goodwill; income taxes; litigation reserves and insurance receivables; and stock-based compensation. We base our estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances, and the results form the basis for making judgments about the reported values of assets, liabilities, revenues and expenses. Actual results may differ from these estimates. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations* included in our 2009 Annual Report on Form 10-K.

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SEGMENT PERFORMANCE

Our four operating segments are Cardiac Rhythm Management (CRM), Cardiovascular (CV), Atrial Fibrillation (AF), and Neuromodulation (NMD). The primary products produced by each operating segment are: CRM ICDs and pacemakers; CV vascular closure devices, heart valve replacement and repair products and pressure measurement guidewires; AF electrophysiology introducers and catheters, advanced cardiac mapping, navigation and recording systems and ablation systems; and NMD neurostimulation devices.

We aggregate our four operating segments into two reportable segments based upon their similar operational and economic characteristics: CRM/NMD and CV/AF. Net sales of our reportable segments include end-customer revenue from the sale of products they each develop and manufacture or distribute. The costs included in each of the reportable segments operating results include the direct costs of the products sold to customers and operating expenses managed by each of the reportable segments. Certain operating expenses managed by our selling and corporate functions, including all stock-based compensation expense, impairment charges, certain acquisition-related charges, IPR&D charges and special charges, have not been recorded in the individual reportable segments. As a result, reportable segment operating profit is not representative of the operating profit of the products in these reportable segments.

The following table presents net sales and operating profit by reportable segment (in thousands):

	CRM/NMD	CV/AF	Other	Total
Three Months ended October 2, 2010:				
Net sales	$ 830,902	$ 409,003	$	$ 1,239,905
Operating profit	514,788	225,637	(441,441)	298,984
Three Months ended October 3, 2009:				
Net sales	$ 773,651	$ 385,955	$	$ 1,159,606
Operating profit	481,658	207,842	(447,470)	242,030
Nine Months ended October 2, 2010:				
Net sales	$ 2,549,768	$ 1,264,602	$	$ 3,814,370
Operating profit	1,595,378	713,748	(1,299,382)	1,009,744
Nine Months ended October 3, 2009:				
Net sales	$ 2,307,332	$ 1,170,479	$	$ 3,477,811
Operating profit	1,428,712	610,714	(1,210,477)	828,949

The following discussion of the changes in our net sales is provided by class of similar products within our four operating segments, which is the primary focus of our sales activities.

Cardiac Rhythm Management

	Three Months Ended			Nine Months Ended		
(in thousands)	October 2, 2010	October 3, 2009	% Change	October 2, 2010	October 3, 2009	% Change
ICD systems	$ 439,333	$ 388,607	13.1%	$ 1,362,042	$ 1,183,037	15.1%
Pacemaker systems	298,669	301,228	(0.8)%	915,574	887,355	3.2%
	$ 738,002	$ 689,835	7.0%	$ 2,277,616	$ 2,070,392	10.0%

Cardiac Rhythm Management net sales increased 7% in the third quarter of 2010 compared to the third quarter of 2009 and increased 10% in the first nine months of 2010 compared to the same period in 2009. These increases were driven by operational sales growth of 8% and 9%, respectively. Foreign currency translation had a $9.1 million unfavorable impact on third quarter 2010 net sales compared to the third quarter of 2009, but a $16.0 million favorable impact on net sales during the first nine months of 2010 compared to same period in 2009.

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ICD net sales increased 13% and 15% in the third quarter and first nine months of 2010, respectively, compared to the same prior year periods, due to operational sales growth of 14% and 15%, respectively. The improved operational sales growth in ICD net sales during the third quarter and first nine months of 2010 was broad-based across both U.S. and international markets, reflecting our continued market penetration into new customer accounts and market demand for our cardiac resynchronization therapy ICD devices. During the second quarter of 2010, we launched a number of new ICD products, including the Unify™ cardiac resynchronization therapy defibrillator (CRT-D) and Fortify™ ICD, which were both launched in the United States and European markets. The Unify CRT-D and Fortify ICD are smaller, deliver more energy and have a longer battery life than comparable conventional devices. In the United States, third quarter 2010 ICD net sales of $284.0 million increased 15% over the prior year s third quarter. The first nine months of 2010 U.S. ICD net sales of $864.0 million increased 14% over the same period last year. The incremental benefit resulting from the suspension of U.S. ICD sales by a principal competitor in the CRM market during 2010 was approximately $35 million to $40 million. Internationally, third quarter 2010 ICD net sales of $155.3 million increased 10% compared to the third quarter of 2009, driven by operational sales growth of 14%. Foreign currency translation had a $5.7 million unfavorable impact on international ICD net sales during the third quarter of 2010 compared to the third quarter of 2009. Internationally, the first nine months of 2010 ICD net sales of $498.0 million increased 18% compared to the first nine months of 2009, driven by operational sales growth of 15%. Foreign currency translation had a $5.8 million favorable impact on international ICD net sales during the first nine months of 2010 compared to the same period in 2009.

Pacemaker net sales were flat in the third quarter of 2010 with minimal foreign currency translation impact compared to the third quarter of 2009. Pacemaker net sales in the first nine months of 2010 increased 3% compared the same prior year period, due to operational sales growth of 2%. In the United States, both our third quarter and first nine month 2010 pacemaker net sales of $133.9 million and $401.4 million, respectively, were flat compared to the same periods in 2009. Internationally, our pacemaker net sales of $164.8 million were flat compared to the third quarter of 2009 with minimal foreign currency translation impact. Internationally, the first nine months of 2010 pacemaker net sales of $514.2 million increased 5% compared to the first nine months of 2009. Operational sales growth of 2% and $10.2 million of favorable foreign currency translation increased international pacemaker net sales during the first nine months of 2010 compared to the same period in 2009.

Cardiovascular

	Three Months Ended			Nine Months Ended		
(in thousands)	October 2, 2010	October 3, 2009	% Change	October 2, 2010	October 3, 2009	% Change
Vascular closure devices	$ 86,321	$ 90,526	(4.6)%	$ 282,505	$ 286,987	(1.6)%
Heart valve products	78,076	79,889	(2.3)%	250,298	244,295	2.5%
Other cardiovascular products	75,788	60,083	26.1%	217,116	182,132	19.2%
	$ 240,185	$ 230,498	4.2%	$ 749,919	$ 713,414	5.1%

Cardiovascular net sales increased 4% and 5% during the third quarter and first nine months of 2010, respectively, compared to the same periods in 2009. The CV net sales increase during the third quarter of 2010 was due to incremental sales from our LightLab Imaging acquisition, as operational sales growth was flat and the impact of foreign currency translation was minimal compared to the third quarter of 2009. During the first nine months of 2010, CV net sales increased due to operational sales growth of 2% and $13.1 million of favorable foreign currency translation, compared to the same period in 2009.

Vascular closure net sales decreased during both the third quarter and first nine months of 2010 compared to the same prior year periods. Foreign currency translation decreased third quarter 2010 net sales by $1.5 million and increased the first nine month 2010 net sales by $1.9 million compared to the same periods in 2009. Heart valve net sales decreased during the third quarter of 2010 but increased during the first nine months of 2010 compared to the same prior year periods. Foreign currency translation comparisons resulted in a minimal impact to third quarter 2010 heart valve net sales, but a favorable impact during the first nine months of 2010, increasing heart valve net sales by $4.6 million. Net sales of other cardiovascular products increased $15.7 million and $35.0 million during the third quarter and first nine months of 2010, respectively, compared to the same prior year periods, driven by incremental sales from our LightLab Imaging acquisition completed in July 2010 and sales volume growth of our PressureWire™ FFR (fractional flow reserve) measurement systems.. Favorable foreign currency translation increased other cardiovascular products net sales by $2.2 million and $6.6 million for the third quarter and first nine months of 2010, respectively, compared to the same prior year periods.

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Atrial Fibrillation

(in thousands)	Three Months Ended October 2, 2010	Three Months Ended October 3, 2009	% Change	Nine Months Ended October 2, 2010	Nine Months Ended October 3, 2009	% Change
Atrial fibrillation products	$ 168,818	$ 155,457	8.6%	$ 514,683	$ 457,065	12.6%

In our AF division, our access, diagnosis, visualization, recording and ablation products assist physicians in diagnosing and treating atrial fibrillation and other irregular heart rhythms. Atrial Fibrillation net sales increased 9% and 13% during the third quarter and first nine months of 2010, respectively, compared to the same periods last year with the increases in AF net sales driven by operational sales growth of 9% and 11%, respectively. Foreign currency translation had a $1.1 million unfavorable impact on third quarter 2010 AF net sales, but a $6.5 million favorable impact on the first nine months of 2010 AF net sales compared to the same prior year periods in 2009.

Neuromodulation

(in thousands)	Three Months Ended October 2, 2010	Three Months Ended October 3, 2009	% Change	Nine Months Ended October 2, 2010	Nine Months Ended October 3, 2009	% Change
Neurostimulation devices	$ 92,900	$ 83,816	10.8%	$ 272,152	$ 236,940	14.9%

Neuromodulation net sales increased 11% and 15% during the third quarter and first nine months of 2010, respectively, compared to the same prior year periods. The increases in NMD net sales were driven by 11% and 14% operational sales growth for the third quarter and first nine months of 2010, respectively. Foreign currency translation had a minimal impact on NMD net sales during the third quarter of 2010 and a $1.6 million favorable impact on NMD net sales for the first nine months of 2010 compared to the same prior year periods.

RESULTS OF OPERATIONS

Net sales

(in thousands)	Three Months Ended October 2, 2010	Three Months Ended October 3, 2009	% Change	Nine Months Ended October 2, 2010	Nine Months Ended October 3, 2009	% Change
Net sales	$ 1,239,905	$ 1,159,606	6.9%	$ 3,814,370	$ 3,477,811	9.7%

Overall, net sales increased 7% in the third quarter of 2010 and 10% during the first nine months of 2010, compared to the same prior year periods. Net sales growth was favorably impacted by operational sales growth, driven primarily by our CRM and AF product sales. Foreign currency translation comparisons decreased our third quarter 2010 net sales by $10.4 million due to the strengthening of the U.S. dollar against the Euro, but increased our first nine month 2010 net sales by $37.3 million as a result of the overall weakening of the U.S. Dollar against the Yen and most other international currencies. These amounts are not indicative of the net earnings impact of foreign currency translation for the third quarter and first nine months of 2010 due to partially offsetting foreign currency translation impacts on cost of sales and operating expenses.

Net sales by geographic location of the customer were as follows:

Net Sales	Three Months Ended October 2, 2010	Three Months Ended October 3, 2009	Nine Months Ended October 2, 2010	Nine Months Ended October 3, 2009
United States	$ 657,627	$ 619,600	$ 1,996,655	$ 1,870,599
International				
Europe	281,017	282,820	949,540	867,140
Japan	141,089	119,578	399,344	350,485

Asia Pacific	83,773	67,392	233,080	185,993
Other (a)	76,399	70,216	235,751	203,594
	582,278	540,006	1,817,715	1,607,212
	$ 1,239,905	$ 1,159,606	$ 3,814,370	$ 3,477,811

(a) No one geographic market is greater than 5% of consolidated net sales.

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Gross profit

	Three Months Ended		Nine Months Ended	
(in thousands)	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Gross profit	$ 900,086	$ 853,875	$ 2,808,080	$ 2,572,041
Percentage of net sales	72.6%	73.6%	73.6%	74.0%

Gross profit for the third quarter of 2010 totaled $900.1 million, or 72.6% of net sales, compared to $853.9 million, or 73.6% of net sales for the third quarter of 2009. Gross profit for the first nine months of 2010 totaled $2,808.1 million, or 73.6% of net sales, compared to $2,572.0 million, or 74.0% of net sales, for the first nine months of 2009. The decrease in our gross profit percentage during the third quarter and first nine months of 2010 compared to the same periods in 2009 was primarily due to higher remote monitoring and wireless telemetry costs in our pacemaker product line. For the first nine months of 2010, these unfavorable impacts on our gross profit percentage were partially offset by favorable foreign currency translation and positive sales mix impacts.

Selling, general and administrative (SG&A) expense

	Three Months Ended		Nine Months Ended	
(in thousands)	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Selling, general and administrative	$ 438,723	$ 427,227	$ 1,329,623	$ 1,276,071
Percentage of net sales	35.4%	36.8%	34.9%	36.7%

SG&A expense for the third quarter of 2010 totaled $438.7 million, or 35.4% of net sales, compared to $427.2 million, or 36.8% of net sales, for the third quarter of 2009. SG&A expense for the first nine months of 2010 totaled $1,329.6 million, or 34.9% of net sales, compared to $1,276.1 million, or 36.7% of net sales, for the first nine months of 2009. The decrease in SG&A expense as a percent of net sales was a result of cost savings experienced from the restructuring actions initiated in the last half of 2009. Refer to Note 8 of the Condensed Consolidated Financial Statements.

Research and development (R&D) expense

	Three Months Ended		Nine Months Ended	
(in thousands)	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Research and development expense	$ 150,135	$ 142,224	$ 456,469	$ 424,627
Percentage of net sales	12.1%	12.3%	12.0%	12.2%

R&D expense in the third quarter of 2010 totaled $150.1 million, or 12.1% of net sales, compared to $142.2 million, or 12.3% of net sales, for the third quarter of 2009. R&D expense in the first nine months of 2010 totaled $456.5 million, or 12.0% of net sales, compared to $424.6 million, or 12.2% of net sales, for the first nine months of 2009. While 2010 R&D expense as a percent of net sales was flat compared to 2009, total R&D expense has continued to increase year over year, reflecting our continuing commitment to fund future long-term growth opportunities. We continue to balance delivering short-term results with our investments in long-term growth drivers.

Purchased in-process research and development (IPR&D) charges

	Three Months Ended		Nine Months Ended	
(in thousands)	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Purchased in-process research and development charges	$ 12,244	$	$ 12,244	$

During the third quarter of 2010, we recorded IPR&D charges of $12.2 million in conjunction with the purchase of cardiovascular-related intellectual property since the related technological feasibility had not yet been reached and such technology had no future alternative use.

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Special charges

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Cost of sales special charges	$	$ 6,061	$	$ 6,061
Special charges		42,394		42,394
	$	$ 48,455	$	$ 48,455

During the third quarter of 2009, we incurred special charges totaling $48.5 million primarily related to severance and benefit costs for 469 employees. The terminations consisted of 229 employees in our U.S. and international selling divisions relating to enhancing the efficiency and effectiveness of our sales and customer service operations in these organizations and 240 employees in our manufacturing divisions relating to our continuing efforts to streamline our production activities.

Other income (expense), net

	Three Months Ended		Nine Months Ended	
	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Interest income	$ 785	$ 643	$ 1,507	$ 1,720
Interest expense	(14,714)	(14,855)	(50,299)	(27,425)
Other	2,818	(9,382)	(2,865)	(10,162)
Total other income (expense), net	$ (11,111)	$ (23,594)	$ (51,657)	$ (35,867)

The increase in interest expense during the first nine months of 2010 is the result of higher average debt interest rates and higher average outstanding debt balances (approximately $1.9 billion) compared to the average outstanding debt balances (approximately $1.4 billion) and interest rates during the first nine months of 2009. The change in other income (expense) during the third quarter of 2010 compared to the third quarter of 2009 was due to the recognition of a $4.9 million realized gain associated with the sale of an available-for-sale common stock investment. Additionally, during the third quarter of 2009, we recognized an $8.3 million investment impairment charge in other income (expense) upon determining that the fair value of a cost method investment was below its carrying value and that the impairment was other-than-temporary.

Income taxes

	Three Months Ended		Nine Months Ended	
(as a percent of pre-tax income)	October 2, 2010	October 3, 2009	October 2, 2010	October 3, 2009
Effective tax rate	27.6%	23.6%	26.8%	25.9%

Our effective income tax rate was 27.6% and 23.6% for the third quarter of 2010 and 2009, respectively, and 26.8% and 25.9% for the first nine months of 2010 and 2009, respectively. Our effective tax rates for the third quarter and first nine months of 2010 do not include the impact of the Federal Research and Development tax credit (R&D tax credit), as the R&D tax credit expired at the end of 2009 and has not yet been enacted and extended. Because the R&D tax credit was not extended, our effective tax rates for both the third quarter and first nine months of 2010 were negatively impacted by 2.0 percentage points. Additionally, our effective tax rates were negatively impacted by 1.1 and 0.3 percentage points for the third quarter and first nine months of 2010, respectively, due to the $12.2 million nondeductible IPR&D charge recognized in the third quarter of 2010. Correspondingly, our 2009 effective tax rates for both the third quarter and first nine months of 2009 were favorably impacted by 2.9 and 0.6 percentage points, respectively, from special charges and an investment impairment charge recorded during the third quarter of 2009.

LIQUIDITY

We believe that our available borrowing capacity under our $1.0 billion long-term committed credit facility (Credit Facility) and related commercial paper program, existing cash balances and future cash generated from operations will be sufficient to fund the pending acquisition of AGA Medical, meet our working capital, capital investment and debt service requirements over the next twelve months and in the foreseeable future thereafter. Although we believe that our earnings, cash flows and balance sheet position will permit us to obtain additional debt financing

or equity capital should suitable investment opportunities arise, additional disruptions in the global financial markets may adversely impact the availability and cost of capital. As of October 2, 2010, we had $1.0 billion of available borrowing capacity under our Credit Facility and related commercial paper program.

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At October 2, 2010, a portion of our cash and cash equivalents was held by our non-U.S. subsidiaries. These funds are only available for use by our U.S. operations if they are repatriated into the United States. The funds repatriated would be subject to additional U.S. taxes upon repatriation; however, it is not practical to estimate the amount of additional U.S. tax liabilities we would incur. We currently have no plans to repatriate funds held by our non-U.S. subsidiaries.

We use two primary measures that focus on accounts receivable and inventory days sales outstanding (DSO) and days inventory on hand (DIOH). We use DSO as a measure that places emphasis on how quickly we collect our accounts receivable balances from customers. We use DIOH, which can also be expressed as a measure of the estimated number of days of cost of sales on hand, as a measure that places emphasis on how efficiently we are managing our inventory levels. These measures may not be computed the same as similarly titled measures used by other companies. Our DSO (ending net accounts receivable divided by average daily sales for the quarter) increased from 89 days at January 2, 2010 to 93 days at October 2, 2010 due to normal seasonality impacts on our collection process. Our DIOH (ending net inventory divided by average daily cost of sales for the most recent six months) decreased from 184 days at January 2, 2010 to 183 days at October 2, 2010.

A summary of our cash flows from operating, investing and financing activities is provided in the following table (in thousands):

	Nine Months Ended	
	October 2, 2010	October 3, 2009
Net cash provided by (used in):		
Operating activities	$ 791,561	$ 553,377
Investing activities	(468,775)	(266,467)
Financing activities	133,677	366,497
Effect of currency exchange rate changes on cash and cash equivalents	2,224	8,431
Net increase in cash and cash equivalents	$ 458,687	$ 661,838

Operating Cash Flows

Cash provided by operating activities was $791.6 million during the first nine months of 2010 compared to $553.4 million during the first nine months of 2009, a 43% increase. Operating cash flows can fluctuate significantly from period to period due to payment timing differences of working capital accounts such as accounts receivable, accounts payable, accrued liabilities and income taxes payable.

Investing Cash Flows

Cash used in investing activities was $468.8 million during the first nine months of 2010 compared to $266.5 million during the same period last year. Investing cash flows can fluctuate from period to period due to the timing of when we choose to make business acquisitions and/or other strategic investments. Our purchases of property, plant and equipment, which totaled $226.3 million and $236.3 million in the first nine months of 2010 and 2009, respectively, primarily reflect our continued investment in our product growth platforms currently in place. Additionally, during 2010 we acquired LightLab Imaging for $92.2 million in net cash consideration, invested $60.0 million in CardioMEMS, Inc. (CardioMEMS) and made our final scheduled acquisition payment of $31.3 million for MediGuide, Inc. CardioMEMS is a privately-held company focused on the development of a wireless monitoring technology that can be placed directly into the pulmonary artery to assess cardiac performance via measurement of pulmonary artery pressure.

Financing Cash Flows

Cash provided by financing activities was $133.7 million during the first nine months of 2010 compared to $366.5 million of cash provided by financing activities during the first nine months of 2009. Our financing cash flows can fluctuate significantly depending upon our liquidity needs and the amount of stock option exercises. During the first nine months of 2010, we received net proceeds of $671.1 million from debt borrowings consisting of $450.0 million principal amount of 2.2% Senior Notes due 2013 (2013 Senior Notes), 10-year 2.04% unsecured senior notes in Japan (2.04% Yen Notes) totaling 12.8 billion Yen and 7-year 1.58% unsecured notes in Japan (1.58% Yen Notes) totaling 8.1 billion Yen. The proceeds from these debt issuances were used to repay $655.7 million of outstanding debt borrowings consisting of a 3-year unsecured 2011 Term Loan ($432.0 million) and 1.02% Yen Notes (20.9 billion Yen). During the first nine months of 2009, we issued $1.2 billion of 2014 Senior Notes and 2019 Senior Notes, made borrowings of $180.0 million under a 3-year unsecured term loan and repaid all of our commercial paper borrowings (net $19.4 million) and outstanding borrowings of $500.0 million under our $1.0 billion long-term committed Credit Facility. Total net proceeds provided by borrowings made in the first nine months of 2009 were $760.0 million. Additionally, the Company repurchased $500.0 million of its common stock during the first nine months of 2009.

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DEBT AND CREDIT FACILITIES

We have a long-term $1.0 billion committed Credit Facility used to support our commercial paper program and for general corporate purposes. Borrowings under this facility bear interest at the United States Prime Rate (Prime Rate) or the United States Dollar London InterBank Offered Rate (LIBOR) plus 0.235%, at our election. In the event over half of the Credit Facility is drawn upon, an additional five basis points is added to the elected Prime Rate or LIBOR rate. The interest rates are subject to adjustment in the event of a change in our credit ratings. There were no outstanding borrowings under the Credit Facility as of October 2, 2010 or January 2, 2010.

Our commercial paper program provides for the issuance of short-term, unsecured commercial paper with maturities up to 270 days. As of October 2, 2010 and January 2, 2010, we had no outstanding commercial paper borrowings. Any future commercial paper borrowings would bear interest at the applicable then-current market rates. We historically have only issued commercial paper up to the amount of our available borrowing capacity under the Credit Facility, as commercial paper has lower interest rates.

In July 2009, we issued $700.0 million aggregate principal amount of 2014 Senior Notes and $500.0 million aggregate principal amount of 2019 Senior Notes. In August 2009, we used $500.0 million of the net proceeds from the 2014 Senior Notes and 2019 Senior Notes to repay all amounts outstanding under our Credit Facility. We may redeem the 2014 Senior Notes or 2019 Senior Notes at any time at the applicable redemption prices. Both the 2014 Senior Notes and 2019 Senior Notes are senior unsecured obligations and rank equally with all of our existing and future senior unsecured indebtedness.

In March 2010, we issued $450.0 million principal amount of 2013 Senior Notes. We used $432.0 million of the net proceeds to repay our 2011 Term Loan. Interest payments are required on a semi-annual basis. We may redeem the 2013 Senior Notes at any time at the applicable redemption price. The 2013 Senior Notes are senior unsecured obligations and rank equally with all of our existing and future senior unsecured indebtedness.

Concurrent with the issuance of the 2013 Senior Notes, we entered into a 3-year, $450.0 million notional amount interest rate swap that was designated as a fair value hedge of the changes in fair value of our 2013 Senior Notes. As of October 2, 2010, the fair value of the swap was a $17.7 million unrealized gain which was recorded in other assets on the condensed consolidated balance sheet with an offsetting fair value adjustment recorded as an increase to the carrying value of the debt. Refer to Note 14 of the Condensed Consolidated Financial Statements for additional information regarding the interest rate swap.

In April 2010, we issued 10-year, 2.04% Yen Notes totaling 12.8 billion Yen (the equivalent of $152.4 million at October 2, 2010) and 7-year, 1.58% Yen Notes totaling 8.1 billion Yen (the equivalent of $97.3 million at October 2, 2010). We used the net proceeds from these issuances to repay our 1.02% Yen Notes totaling 20.9 billion Yen. Interest payments on the 2.04% Yen Notes and 1.58% Yen Notes are required on a semi-annual basis and the principal amounts recorded on the balance sheet fluctuate based on the effects of foreign currency translation.

In December 2008, we entered into a 3-year, Yen-denominated unsecured term loan in Japan (Yen Term Loan). As of October 2, 2010, 6.5 billion Japanese Yen is outstanding (the equivalent of $77.7 million at October 2, 2010 and $70.7 million at January 2, 2010). We can initiate future borrowings up to the 8.0 billion Japanese Yen term loan amount. The borrowings bear interest at the Yen LIBOR plus 0.4%. Interest payments are required on a semi-annual basis and the entire principal balance is due in December 2011. The principal amount recorded on the balance sheet for the Yen Term Loan fluctuates based on the effects of foreign currency translation.

Our Credit Facility and Yen Notes contain certain operating and financial covenants. Specifically, the Credit Facility requires that we have a leverage ratio (defined as the ratio of total debt to EBITDA (net earnings before interest, income taxes, depreciation and amortization)) not exceeding 3.0 to 1.0. The Yen Notes require that we have a ratio of total debt to total capitalization not exceeding 60% and a ratio of consolidated EBIT (net earnings before interest and income taxes) to consolidated interest expense of at least 3.0 to 1.0. Under the Credit Facility, our senior notes and Yen Notes we also have certain limitations on how we conduct our business, including limitations on additional liens or indebtedness and limitations on certain acquisitions, mergers, investments and dispositions of assets. We were in compliance with all of our debt covenants as of October 2, 2010.

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COMMITMENTS AND CONTINGENCIES

We have certain contingent commitments to acquire various businesses involved in the distribution of our products and to pay other contingent acquisition consideration payments. While it is not certain if and/or when these payments will be made, as of October 2, 2010, we could be required to pay approximately $86 million in future periods to satisfy such commitments. A description of our contractual obligations and other commitments is contained in Part II, Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations Off-Balance Sheet Arrangements and Contractual Obligations,* included in our 2009 Annual Report on Form 10-K. As of October 2, 2010, the only significant change to our contractual obligations and other commitments as previously disclosed in our 2009 Annual Report on Form 10-K relates to our debt as a result of the issuance of our 2013 Senior Notes, 2.04% Yen Notes and 1.58% Yen Notes as well as our repayment of our 2011 Term Loan and 1.02% Yen Notes.

The following schedule presents a summary of our debt obligations as of October 2, 2010 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual obligations reflected in the balance sheet:					
Debt obligations (a)	$ 2,718,623	$ 114,514	$ 303,669	$ 1,318,580	$ 981,859

a) These amounts also include scheduled interest payments on our debt obligations. See Note 6 to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q for additional information regarding our debt obligations.

We have no off-balance sheet financing arrangements other than that previously disclosed in our 2009 Annual Report on Form 10-K. Our significant legal proceedings are discussed in Note 7 to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

CAUTIONARY STATEMENTS

In this Quarterly Report on Form 10-Q and in other written or oral statements made from time to time, we have included and may include statements that constitute forward-looking statements with respect to the financial condition, results of operations, plans, objectives, new products, future performance and business of St. Jude Medical, Inc. and its subsidiaries. Statements preceded by, followed by or that include words such as may, will, expect, anticipate, continue, estimate, forecast , project, believe or similar expressions are intended to id the forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are included, along with this statement, for purposes of complying with the safe harbor provisions of that Act. These forward-looking statements involve risks and uncertainties. By identifying these statements for you in this manner, we are alerting you to the possibility that actual results may differ, possibly materially, from the results indicated by these forward-looking statements. We undertake no obligation to update any forward-looking statements. Actual results may differ materially from those contemplated by the forward-looking statements due to, among others, the risks and uncertainties discussed in the sections entitled *Off-Balance Sheet Arrangements and Contractual Obligations, Market Risk and Competition and Other Considerations* in Part II, Item 7, *Management s Discussion and Analysis of Financial Condition and Results of Operations* of our 2009 Annual Report on Form 10-K and in Part II, Item 1A, *Risk Factors* of this Quarterly Report on Form 10-Q as well as the various factors described below. Since it is not possible to foresee all such factors, you should not consider these factors to be a complete list of all risks or uncertainties. We believe the most significant factors that could affect our future operations and results are set forth in the list below.

1. Any legislative or administrative reform to the U.S. Medicare or Medicaid systems or international reimbursement systems that significantly reduces reimbursement for procedures using our medical devices or denies coverage for such procedures, as well as adverse decisions relating to our products by administrators of such systems on coverage or reimbursement issues.

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2. Assertion, acquisition or grant of key patents by or to others that have the effect of excluding us from market segments or requiring us to pay royalties.
3. Economic factors, including inflation, contraction in capital markets, changes in interest rates, changes in tax laws and changes in foreign currency exchange rates.
4. Product introductions by competitors that have advanced technology, better features or lower pricing.
5. Price increases by suppliers of key components, some of which are sole-sourced.
6. A reduction in the number of procedures using our devices caused by cost-containment pressures or the development of or preferences for alternative therapies.
7. Safety, performance or efficacy concerns about our products, many of which are expected to be implanted for many years, some of which may lead to recalls and/or advisories with the attendant expenses and declining sales.
8. Declining industry-wide sales caused by product quality issues or recalls or advisories by our competitors that result in loss of physician and/or patient confidence in the safety, performance or efficacy of sophisticated medical devices in general and/or the types of medical devices recalled in particular.
9. Changes in laws, regulations or administrative practices affecting government regulation of our products, such as FDA regulations, including those that decrease the probability or increase the time and/or expense of obtaining approval for products or impose additional burdens on the manufacture and sale of medical devices.
10. Regulatory actions arising from concern over Bovine Spongiform Encephalopathy, sometimes referred to as mad cow disease, that have the effect of limiting our ability to market products using bovine collagen, such as Angio-Seal , or products using bovine pericardial material, such as our Biocor®, Epic and Trifecta tissue heart valves, or that impose added costs on the procurement of bovine collagen or bovine pericardial material.
11. The intent and ability of our product liability insurers to meet their obligations to us, including losses related to our Silzone® litigation, and our ability to fund future product liability losses related to claims made subsequent to becoming self-insured.
12. Severe weather or other natural disasters that cause damage to the facilities of our critical suppliers or one or more of our facilities, such as an earthquake affecting our facilities in California or a hurricane affecting our facilities in Puerto Rico.
13. Healthcare industry changes leading to demands for price concessions and/or limitations on, or the elimination of, our ability to sell in significant market segments.
14. Adverse developments in investigations and governmental proceedings.
15. Adverse developments in litigation, including product liability litigation, patent or other intellectual property litigation, qui tam litigation or shareholder litigation.
16. Inability to successfully integrate the businesses that we have acquired in recent years and that we plan to acquire.
17. Failure to successfully complete or unfavorable data from clinical trials for our products or new indications for our products and/or failure to successfully develop markets for such new indications.
18. Changes in accounting rules that adversely affect the characterization of our results of operations, financial position or cash flows.
19. The disruptions in the financial markets and the economic downturn that adversely impact the availability and cost of credit and customer purchasing and payment patterns.
20. Conditions imposed in resolving, or any inability to timely resolve, any regulatory issues raised by the FDA, including Form 483 observations or warning letters, as well as risks generally associated with our regulatory compliance and quality systems.
21. Governmental legislation, including the recently enacted Patient Protection and Affordable Care Act and the Health Care and Educational Reconciliation Act, and/or regulation that significantly impacts the healthcare system in the United States and that results in lower reimbursement for procedures using our products, reduces medical procedure volumes or otherwise adversely affects our business and results of operations, including the recently enacted medical device excise tax.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes since January 2, 2010 in our market risk. For further information on market risk, refer to Part II, Item 7A, *Quantitative and Qualitative Disclosures About Market Risk* in our 2009 Annual Report on Form 10-K.

Item 4. CONTROLS AND PROCEDURES

As of October 2, 2010, the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the Exchange Act)). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures were effective as of October 2,

2010.

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There were no changes in the Company s internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the third quarter of 2010 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

We are the subject of various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We record a liability in our consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where we have assessed that a loss is probable and an amount can be reasonably estimated. Our significant legal proceedings are discussed in Note 7 to the Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q and are incorporated herein by reference. While it is not possible to predict the outcome for most of the legal proceedings discussed in Note 7, the costs associated with such proceedings could have a material adverse effect on our consolidated earnings, financial position or cash flows of a future period.

Item 1A. RISK FACTORS

Our business faces many risks. Any of the risks discussed below, or elsewhere in this Form 10-Q or our other SEC filings, could have a material impact on our business, financial condition or results of operations.

We face intense competition and may not be able to keep pace with the rapid technological changes in the medical devices industry.

The medical device market is intensely competitive and is characterized by extensive research and development and rapid technological change. Our customers consider many factors when choosing suppliers, including product reliability, clinical outcomes, product availability, inventory consignment, price and product services provided by the manufacturer, and market share can shift as a result of technological innovation and other business factors. Major shifts in industry market share have occurred in connection with product problems, physician advisories and safety alerts, reflecting the importance of product quality in the medical device industry. Our competitors range from small start-up companies to larger companies which have significantly greater resources and broader product offerings than us, and we anticipate that in the coming years, other large companies will enter certain markets in which we currently hold a strong position. For example, Boston Scientific acquired one of our principal competitors, Guidant Corporation, in 2006. In addition, we expect that competition will continue to intensify with the increased use of strategies such as consigned inventory, and we have seen increasing price competition as a result of managed care, consolidation among healthcare providers, increased competition and declining reimbursement rates. Product introductions or enhancements by competitors which have advanced technology, better features or lower pricing may make our products or proposed products obsolete or less competitive. As a result, we will be required to devote continued efforts and financial resources to bring our products under development to market, enhance our existing products and develop new products for the medical marketplace. If we fail to develop new products, enhance existing products or compete effectively, our business, financial condition and results of operations will be adversely affected.

We are subject to stringent domestic and foreign medical device regulation and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our medical devices. The process of obtaining marketing approval or clearance from the FDA and comparable foreign bodies for new products, or for enhancements or modifications to existing products, could:

- take a significant amount of time,
- require the expenditure of substantial resources,
- involve rigorous pre-clinical and clinical testing, as well as increased post-market surveillance,

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involve modifications, repairs or replacements of our products, and

result in limitations on the indicated uses of our products.

We cannot be certain that we will receive required approval or clearance from the FDA and foreign regulatory agencies for new products or modifications to existing products on a timely basis. The failure to receive approval or clearance for significant new products or modifications to existing products on a timely basis could have a material adverse effect on our financial condition and results of operations.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. For example, we are required to comply with the FDA s Quality System Regulation (QSR), which mandates that manufacturers of medical devices adhere to certain quality assurance requirements pertaining to, among other things, validation of manufacturing processes, controls for purchasing product components, and documentation practices. As another example, the Federal Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, that a malfunction occurred which would be likely to cause or contribute to a death or serious injury upon recurrence. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA, which may result in observations on Form 483, and in some cases warning letters, that require corrective action. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize such medical devices, order a recall, repair, replacement, or refund of such devices, or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA has recently been increasing its scrutiny of the medical device industry and the government should be expected to continue to scrutinize the industry closely with inspections, and possibly enforcement actions, by the FDA or other agencies. Additionally, the FDA may restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by foreign governmental authorities in the future. Penalties for a company s noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company s business license and criminal sanctions. Any domestic or foreign governmental medical device law or regulation imposed in the future may have a material adverse effect on our financial condition and business operations.

Our products are continually the subject of clinical trials conducted by us, our competitors or other third parties, the results of which may be unfavorable, or perceived as unfavorable by the market, and could have a material adverse effect on our business, financial condition or results of operations.

As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors or by third parties, or the market s or FDA s perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

If we are unable to protect our intellectual property effectively, our financial condition and results of operations could be adversely affected.

Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. We pursue a policy of generally obtaining patent protection in both the United States and in key foreign countries for patentable subject matter in our proprietary devices and also attempt to review third-party patents and patent applications to the extent publicly available to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. We currently own numerous United States and foreign patents and have numerous patent applications pending. We are also a party to various license agreements pursuant to which patent rights have been obtained or granted in consideration for cash, cross-licensing rights or royalty payments. We cannot be certain that any pending or future patent applications will result in issued patents, that any current or future patents issued to or licensed by us will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide a competitive advantage to us or prevent competitors from entering markets which we currently serve.

Any required license may not be available to us on acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore our competitors may have access to the same technologies as us. In addition, we may have to take legal action in the future to protect our trade secrets or know-how or to defend them against claimed infringement of the rights of others. Any legal action of that type could be costly and time consuming to us and we cannot be certain of the outcome. The invalidation of key patents or proprietary rights which we own or an unsuccessful outcome in lawsuits to protect our intellectual property could have a material adverse effect on our financial condition and results of operations.

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Pending and future patent litigation could be costly and disruptive to us and may have an adverse effect on our financial condition and results of operations.

We operate in an industry that is susceptible to significant patent litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the rights of other companies to prevent the marketing of new devices. Companies that obtain patents for products or processes that are necessary for or useful to the development of our products may bring legal actions against us claiming infringement and at any given time, we generally are involved as both a plaintiff and a defendant in a number of patent infringement and other intellectual property-related actions. Defending intellectual property litigation is expensive and complex and outcomes are difficult to predict. Any pending or future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may cause a significant diversion of the efforts of our technical and management personnel. While we intend to defend any such lawsuits vigorously, we cannot be certain that we will be successful. In the event that our right to market any of our products is successfully challenged or if we fail to obtain a required license or are unable to design around a patent, our financial condition and results of operations could be materially adversely affected.

Pending and future product liability claims and litigation may adversely affect our financial condition and results of operations.

The design, manufacture and marketing of the medical devices we produce entail an inherent risk of product liability claims. Our products are often used in intensive care settings with seriously ill patients, and many of the medical devices we manufacture and sell are designed to be implanted in the human body for long periods of time or indefinitely. There are a number of factors that could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products which we manufacture or sell, including component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information. Product liability claims may be brought by individuals or by groups seeking to represent a class.

We are currently the subject of various product liability claims, including several lawsuits in the United States and a lawsuit being allowed to proceed as a class action in Canada relating to products incorporating Silzone® coating. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time. We believe that the final resolution of the Silzone litigation matters may take a number of years and cannot reasonably estimate the time frame in which any potential settlements or judgments would be paid out or the amounts of any such settlements or judgments. In addition, the cost to defend any future litigation, whether Silzone-related or not, may be significant. We believe that many settlements and judgments relating to the Silzone litigation and our other litigation may be covered in whole or in part under our previously-issued product liability insurance policies and existing reserves. Any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered under our previously-issued product liability insurance policies and existing reserves could have a material adverse effect on our consolidated earnings, financial position and cash flows.

Our product liability insurers may refuse to cover certain losses on the grounds that such losses are outside the scope of our product liability insurance policies.

One of our prior product liability insurers has filed a suit seeking a court order declaring that it is not required to provide coverage for some of the costs we have incurred or may incur in the future in the Silzone® litigation described above. This insurer, as well as other insurers from whom it had purchased product liability insurance, may deny coverage of these and other past and/or future losses relating to our products on the grounds that such losses are outside the scope of coverage of those previously-issued insurance policies. To the extent that we suffer losses that are outside of the scope or range of coverage of those previously-issued product liability insurance policies, those losses may have a material adverse effect on our consolidated earnings, financial position and cash flows.

Our self-insurance program may not be adequate to cover future losses.

Consistent with the predominant practice in our industry, we do not currently maintain or intend to maintain any insurance policies with respect to product liability in the future. This decision was made based on current conditions in the insurance marketplace that have led to increasingly higher levels of self-insured retentions, increasing number of coverage limitations and high insurance premium rates. We will continue to monitor the insurance marketplace to evaluate the value to us of obtaining insurance coverage in the future. We believe that our self-insurance program, which is based on historical loss trends, will be adequate to cover future losses, although we can provide no assurances that this will remain true as historical trends may not be indicative of future losses. These losses could have a material adverse impact on our consolidated earnings, financial condition or cash flows.

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The loss of any of our sole-source suppliers or an increase in the price of inventory supplied to us could have an adverse effect on our business, financial condition and results of operations.

We purchase certain supplies used in our manufacturing processes from single sources due to quality considerations, costs or constraints resulting from regulatory requirements. Agreements with certain suppliers are terminable by either party upon short notice and we have been advised periodically by some suppliers that in an effort to reduce their potential product liability exposure, they may terminate sales of products to customers that manufacture implantable medical devices. While some of these suppliers have modified their positions and have indicated a willingness to continue to provide a product temporarily until an alternative vendor or product can be qualified (or even to reconsider the supply relationship), where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes employed by many suppliers. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to cease operations. A reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

Cost containment pressures and domestic and foreign legislative or administrative reforms resulting in restrictive reimbursement practices of third-party payors or preferences for alternate therapies could decrease the demand for products purchased by our customers, the prices which they are willing to pay for those products and the number of procedures using our devices.

Our products are purchased principally by healthcare providers that typically bill various third-party payors, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of customers to obtain appropriate reimbursement for their services and the products they provide from government and third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new technology. After we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payors.

Major third-party payors for healthcare provider services in the United States and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to healthcare provider charges for services performed and in the shifting of services between inpatient and outpatient settings. Initiatives to limit the growth of healthcare costs, including price regulation, are also underway in several countries in which we do business. Implementation of healthcare reforms in the United States and in significant overseas markets such as Germany, Japan and other countries may limit the price of, or the level at which, reimbursement is provided for our products and adversely affect both our pricing flexibility and the demand for our products. Healthcare providers may respond to such cost-containment pressures by substituting lower cost products or other therapies for our products.

In March 2010, significant health care reform was enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. It is uncertain what consequences these provisions will have on patient access to new technologies and what impacts these provisions will have on Medicare reimbursement rates. Legislative or administrative reforms to the U.S. or international reimbursement systems that significantly reduce reimbursement for procedures using our medical devices or deny coverage for such procedures, or adverse decisions relating to our products by administrators of such systems in coverage or reimbursement issues, would have an adverse impact on the products, including clinical products, purchased by our customers and the prices our customers are willing to pay for them. This in turn would have an adverse effect on our financial condition and results of operations.

Our failure to comply with restrictions relating to reimbursement and regulation of healthcare goods and services may subject us to penalties and adversely affect our financial condition and results of operations.

Our devices are subject to regulation regarding quality and cost by the United States Department of Health and Human Services, including the Centers for Medicare and Medicaid Services (CMS), as well as comparable state and foreign agencies responsible for reimbursement and regulation of healthcare goods and services. Foreign governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare goods and services. U.S. federal government healthcare laws apply when we submit a claim on behalf of a U.S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government funded healthcare program, such as Medicare or Medicaid. The principal U.S. federal laws implicated include those that prohibit the filing of false or improper claims for federal payment, those that prohibit unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs, known as the anti-kickback laws, and those that prohibit healthcare service providers seeking

reimbursement for providing certain services to a patient who was referred by a physician that has certain types of direct or indirect financial relationships with the service provider, known as the Stark law.

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The laws applicable to us are subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by CMS. If we are excluded from participation based on such an interpretation, it could adversely affect our financial condition and results of operations.

Consolidation in the healthcare industry could lead to demands for price concessions or limit or eliminate our ability to sell to certain of our significant market segments.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the medical device industry as well as among our customers, including healthcare providers. This in turn has resulted in greater pricing pressures and limitations on our ability to sell to important market segments, as group purchasing organizations, independent delivery networks and large single accounts, such as the Veterans Administration in the United States, continue to consolidate purchasing decisions for some of our healthcare provider customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances which may exert further downward pressure on the prices of our products and adversely impact our business, financial condition and results of operations.

Failure to integrate acquired businesses into our operations successfully could adversely affect our business.

As part of our strategy to develop and identify new products and technologies, we have made several acquisitions in recent years and may make additional acquisitions in the future. Our integration of the operations of acquired businesses requires significant efforts, including the coordination of information technologies, research and development, sales and marketing, operations, manufacturing and finance. These efforts result in additional expenses and involve significant amounts of management s time that cannot then be dedicated to other projects. Our failure to manage successfully and coordinate the growth of the combined company could also have an adverse impact on our business. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so. If our acquisitions are not successful, we may record unexpected impairment charges. Factors that will affect the success of our acquisitions include:

- the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;
- adverse developments arising out of investigations by governmental entities of the business practices of acquired companies;
- any decrease in customer loyalty and product orders caused by dissatisfaction with the combined companies product lines and sales and marketing practices, including price increases;
- our ability to retain key employees; and
- the ability of the combined company to achieve synergies among its constituent companies, such as increasing sales of the combined company s products, achieving cost savings and effectively combining technologies to develop new products.

The success of many of our products depends upon strong relationships with physicians.

If we fail to maintain our working relationships with physicians, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products. The research, development, marketing and sales of many of our new and improved products is dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and the marketing of our products. Physicians assist us as researchers, marketing consultants, product consultants, inventors and as public speakers. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our financial condition and results of operations.

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Instability in international markets or foreign currency fluctuations could adversely affect our results of operations.

Our products are currently marketed in more than 100 countries around the world, with our largest geographic markets outside of the United States being Europe, Japan and Asia Pacific. As a result, we face currency and other risks associated with our international sales. We are exposed to foreign currency exchange rate fluctuations due to transactions denominated primarily in Euros, Japanese Yen, Canadian Dollars, Australian Dollars, Brazilian Reals, British Pounds and Swedish Kronor, which may potentially reduce the U.S. Dollars we receive for sales denominated in any of these foreign currencies and/or increase the U.S. Dollars we report as expenses in these currencies, thereby affecting our reported consolidated revenues and net earnings. Fluctuations between the currencies in which we do business have caused and will continue to cause foreign currency transaction gains and losses. We cannot predict the effects of currency exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposures and the volatility of currency exchange rates.

In addition to foreign currency exchange rate fluctuations, there are a number of additional risks associated with our international operations, including those related to:

- the imposition of or increase in import or export duties, surtaxes, tariffs or customs duties;
- the imposition of import or export quotas or other trade restrictions;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- compliance with import/export laws;
- longer accounts receivable cycles in certain foreign countries, whether due to cultural, exchange rate or other factors;
- changes in regulatory requirements in international markets in which we operate; and
- economic and political instability in foreign countries, including concerns over excessive levels of national debt and budget deficits in countries where we market our products that could result in an inability to pay or timely pay outstanding payables.

The medical device industry is the subject of numerous governmental investigations into marketing and other business practices. These investigations could result in the commencement of civil and/or criminal proceedings, substantial fines, penalties and/or administrative remedies, divert the attention of St. Jude Medical s management and have an adverse effect on its financial condition and results of operations.

We are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities have been increasing their scrutiny of our industry. We have received subpoenas and other requests for information from state and federal governmental agencies, including, among others, the U.S. Department of Justice and the Office of Inspector General of the Department of Health and Human Services. These investigations relate primarily to financial arrangements with health care providers, regulatory compliance and product promotional practices. We are cooperating with these investigations and responding to these requests.

In October 2005, the U.S. Department of Justice, acting through the U.S. Attorney s office in Boston, commenced an industry-wide investigation into whether the provision of payments and/or services by makers of ICDs and bradycardia pacemaker systems (pacemakers) to doctors or other persons constitutes improper inducements under the federal health care program anti-kickback law. As part of this investigation, we have received three subpoenas from the government requesting documents regarding our practices related to ICDs, pacemakers, lead systems and related products marketed by our CRM operating segment. We have cooperated with the investigation and produced documents and witnesses as requested. In January 2010, the U.S. District Court for the District of Massachusetts unsealed a qui tam action (private individual bringing suit on behalf of the U.S. Government) filed by a former employee containing allegations relating to the issues covered by the subpoenas. Although in December 2009, the U.S. Department of Justice had declined to intervene in this qui tam suit, the U.S. Department of Justice filed a motion in August 2010 to intervene. The Court granted the U.S. Department of Justice s motion, without prejudice to us, and also directed the U.S. Department of Justice to file its complaint by August 31, 2010. The U.S. Department of Justice has indicated that it intends only to pursue alleged claims related to four post-market studies conducted by us primarily in 2004-2006. The Court also ruled that we may file an objection to the August 2010 U.S. Department of Justice intervention and argue that the U.S. Department of Justice has not established good cause to intervene. The Court vacated the deadline for the U.S. Department of Justice to file its complaint, and scheduled the case for a status hearing on November 29, 2010.

Additionally, in December 2008, the U.S. Attorney s Office in Boston delivered a subpoena issued by the OIG requesting the production of documents relating to implantable cardiac rhythm device and pacemaker warranty claims.

In March 2010, we received a Civil Investigative Demand (CID) from the Civil Division of the U.S. Department of Justice. The CID requests documents and sets forth interrogatories related to communications by and within our company on various indications for ICDs and a National Coverage Decision issued by Centers for Medicare and Medicaid Services. Similar requests were made of our major competitors.

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We are fully cooperating with these investigations and are responding to these requests. However, we cannot predict when these investigations will be resolved, the outcome of these investigations or their impact on the company. An adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties and/or administrative remedies, including exclusion from government reimbursement programs. In addition, resolution of any of these matters could involve the imposition of additional and costly compliance obligations. Finally, if these investigations continue over a long period of time, they could divert the attention of management from the day-to-day operations of its business and impose significant administrative burdens on it. These potential consequences, as well as any adverse outcome from these investigations or other investigations initiated by the government at any time, could have a material adverse effect on our financial condition and results of operations.

Regulatory actions arising from the concern over Bovine Spongiform Encephalopathy may limit our ability to market products containing bovine material.

Our Angio-Seal vascular closure device, as well as our vascular graft products, contain bovine collagen. In addition, some of the tissue heart valves we market, such as our Biocor® and Epic tissue heart valves, incorporate bovine pericardial material. Certain medical device regulatory agencies may prohibit the sale of medical devices that incorporate any bovine material because of concerns over BSE, sometimes referred to as mad cow disease, a disease which may be transmitted to humans through the consumption of beef. While we are not aware of any reported cases of transmission of BSE through medical products and are cooperating with regulatory agencies considering these issues, the suspension or revocation of authority to manufacture, market or distribute products containing bovine material, or the imposition of a regulatory requirement that we procure material for these products from alternate sources, could result in lost market opportunities, harm the continued commercialization and distribution of such products and impose additional costs on us. Any of these consequences could in turn have a material adverse effect on our financial condition and results of operations.

We are not insured against all potential losses. Natural disasters or other catastrophes could adversely affect our business, financial condition and results of operations.

Our facilities could be materially damaged by earthquakes, hurricanes and other natural disasters or catastrophic circumstances, including acts of war. For example, we have significant CRM facilities located in Sylmar and Sunnyvale, California. Earthquake insurance in California is currently difficult to obtain, extremely costly and restrictive with respect to scope of coverage. Our earthquake insurance for these California facilities provides $10 million of insurance coverage in the aggregate, with a deductible equal to 5% of the total value of the facility and contents involved in the claim. Consequently, despite this insurance coverage, we could incur uninsured losses and liabilities arising from an earthquake near one or both of our California facilities as a result of various factors, including the severity and location of the earthquake, the extent of any damage to our facilities, the impact of an earthquake on our California workforce and on the infrastructure of the surrounding communities and the extent of damage to our inventory and work in process. While we believe that our exposure to significant losses from a California earthquake could be partially mitigated by our ability to manufacture some of our CRM products at our manufacturing facilities in Sweden and Puerto Rico, the losses could have a material adverse effect on our business for an indeterminate period of time before this manufacturing transition is complete and operates without significant problems. Furthermore, our manufacturing facilities in Puerto Rico may suffer damage as a result of hurricanes which are frequent in the Caribbean and which could result in lost production and additional expenses to us to the extent any such damage is not fully covered by our hurricane and business interruption insurance.

Even with insurance coverage, natural disasters or other catastrophic events, including acts of war, could cause us to suffer substantial losses in our operational capacity and could also lead to a loss of opportunity and to a potential adverse impact on our relationships with our existing customers resulting from our inability to produce products for them, for which we would not be compensated by existing insurance. This in turn could have a material adverse effect on our financial condition and results of operations.

Our operations are subject to environmental, health and safety laws and regulations that could require us to incur material costs.

Our operations are subject to environmental, health and safety laws and regulations concerning, among other things, the generation, handling, transportation and disposal of hazardous substances or wastes, particularly ethylene oxide, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and expect to incur expenditures in the future in connection with compliance with environmental, health and safety laws and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or become the basis for new or increased liabilities that could be material.

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Failure to successfully implement a new enterprise resource planning (ERP) system could adversely affect our business.

We are in the process of converting to a new ERP system. Failure to smoothly execute the implementation of the ERP system could adversely affect the Company s business, financial condition and results of operations.

Current economic conditions could adversely affect our results of operations.

The global financial crisis has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. There can be no assurance that there will not be further deterioration in the global economy, and these and other factors beyond our control may adversely affect our ability to borrow money in the credit markets and to obtain financing for acquisitions or other general corporate and commercial purposes. Our customers may experience financial difficulties or be unable to borrow money to fund their operations which may adversely impact their ability or decision to purchase our products or to pay for products they do purchase on a timely basis, if at all. The strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown may negatively impact our average selling prices, our net sales and profit margins, procedural volumes and reimbursement rates from third party payors. In addition, the current economic conditions may adversely affect our suppliers, leading them to experience financial difficulties or to be unable to borrow money to fund their operations, which could cause disruptions in our ability to produce our products.

Our business, financial condition, results of operations and cash flows could be significantly and adversely affected by recent healthcare reform legislation and other administration and legislative proposals.

The Patient Protection and Affordable Care Act and Health Care and Educational Reconciliation Act (the Acts) were enacted into law in March 2010. As a U.S. headquartered company with significant sales in the United States, this health care reform legislation will materially impact us as well as the U.S. economy. Certain provisions of the Acts will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation.. The legislation does levy a 2.3% excise tax on all U.S. medical device sales beginning in 2013. This is a significant new tax that will materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our financial condition and results of operations.

We are subject to income taxes as well as non-income based taxes, in both the United States and various foreign jurisdictions. We are subject to ongoing tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes of these audits could have a material impact on our net income or financial condition. Additionally, changes in tax laws or tax rulings could materially impact our effective tax rate. For example, proposals for fundamental U.S. international tax reform, such as the recent proposal by the Obama administration, if enacted, could have a significant adverse impact on our future results of operations. In addition, recent health care legislation levies a 2.3% excise tax on all U.S. medical device sales beginning in 2013.

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Item 6.	**EXHIBITS**
12	Computation of Ratio of Earnings to Fixed Charges.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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101	Financial statements from the quarterly report on Form 10-Q of St. Jude Medical, Inc. for the quarter ended October 2, 2010, formatted in XBRL: (i) the Condensed Consolidated Statements of Earnings, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements.

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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.

ST. JUDE MEDICAL, INC.

November 9, 2010
DATE

/s/ JOHN C. HEINMILLER
JOHN C. HEINMILLER
Executive Vice President
and Chief Financial Officer
(Duly Authorized Officer and
Principal Financial and
Accounting Officer)

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INDEX TO EXHIBITS

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Filed as an exhibit to this Quarterly Report on Form 10-Q.
* Furnished herewith.