ST JUDE MEDICAL INC
Form 10-Q
November 09, 2004

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 SEPTEMBER 30, 2004 OR

___ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ to _____.

Commission File Number: 0-8672

ST. JUDE MEDICAL, INC.

(Exact name of Registrant as specified in its charter)

MINNESOTA	**41-1276891**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
One Lillehei Plaza **St. Paul, Minnesota 55117**	**(651) 483-2000**
(Address of principal executive offices, including zip code)	(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. Yes _X_ No ___

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes _X_ No ___

The number of shares of common stock, par value $.10 per share, outstanding on

November 1, 2004 was 357,539,476.

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 September 30,		*Nine Months Ended September 30,*	
	2004	***2003***	***2004***	***2003***
Net sales	$ 578,319	$ 477,454	$ 1,683,497	$ 1,413,931
Cost of sales:				
Cost of sales before special charges	165,918	146,713	491,614	447,477
Special charges	12,073		12,073	
Gross profit	400,328	330,741	1,179,810	966,454
Selling, general and administrative expense	188,741	157,586	568,045	460,586
Research and development expense	69,645	58,637	204,095	174,782
Special charges	23,310		23,310	
Operating profit	118,632	114,518	384,360	331,086
Other income (expense)	680	(822)	(764)	(741)
Earnings before income taxes	119,312	113,696	383,596	330,345
Income tax expense	28,134	29,560	98,421	85,889
Net earnings	$ 91,178	$ 84,136	$ 285,175	$ 244,456
Net earnings per share:				
Basic	$ 0.26	$ 0.24	$ 0.81	$ 0.69
Diluted	$ 0.25	$ 0.23	$ 0.77	$ 0.65
Weighted average shares outstanding:				
Basic	354,570	351,992	352,116	356,782
Diluted	370,814	369,052	369,960	373,314

See notes to condensed consolidated financial statements.

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

	September 30, 2004 (Unaudited)	*December 31, 2003 (See Note)*
ASSETS		
Current assets		
Cash and equivalents	$ 585,186	$ 461,253
Accounts receivable, less allowance for doubtful accounts of $34,506 in 2004 and $31,905 in 2003	592,869	501,759
Inventories	314,782	311,761
Deferred income taxes	94,583	112,376
Other	92,225	105,188
Total current assets	1,679,645	1,492,337
Property, plant and equipment at cost	795,715	751,095
Less accumulated depreciation	(484,340)	(449,442)
Net property, plant and equipment	311,375	301,653
Other assets		
Goodwill	563,687	407,013
Other intangible assets, net	179,896	154,404
Other	240,350	198,075
Total other assets	983,933	759,492
TOTAL ASSETS	$ 2,974,953	$ 2,553,482
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Short-term debt	$	$ 12,115
Accounts payable	124,309	128,206
Income taxes payable	71,717	72,376
Accrued expenses		
Employee compensation and related benefits	205,306	190,152
Other	152,377	107,466
Total current liabilities	553,709	510,315
Long-term debt	305,704	351,813
Deferred income taxes	54,519	89,719
Commitments and contingencies		

	September 30, 2004 (Unaudited)	*December 31, 2003 (See Note)*
Shareholders equity		
Preferred stock		
Common stock (355,666,890 and 346,028,334 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively)	35,566	34,602
Additional paid-in capital	208,960	18,326
Retained earnings	1,827,062	1,541,887
Accumulated other comprehensive income (loss):		
Cumulative translation adjustment	(16,126)	(4,246)
Unrealized gain on available-for-sale securities	5,559	11,066
Total shareholders equity	2,061,021	1,601,635
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 2,974,953	$ 2,553,482

NOTE: The balance sheet at December 31, 2003 has been derived from the Company s audited financial statements after consideration of the adjustments described in Note 2 to condensed consolidated financial statements. See notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30, 2004	*2003*
Operating Activities		
Net earnings	$ 285,175	$ 244,456
Adjustments to reconcile net earnings to net cash from operating activities:		
Depreciation	48,563	46,996
Amortization	12,220	8,412
Equity in losses of Epicor Medical, Inc., net of income taxes	962	2,084
Special charges	35,383	
Deferred income taxes	1,769	28,286
Changes in operating assets and liabilities, net of business acquisitions:		
Accounts receivable	(96,526)	(45,710)
Inventories	(14,607)	(17,217)
Other current assets	2,104	(4,128)
Accounts payable and accrued expenses	19,162	31,739
Income taxes payable	82,739	30,856
Net cash provided by operating activities	376,944	325,774
Investing Activities		
Purchase of property, plant and equipment	(63,046)	(33,627)
Business acquisition payments, net of cash acquired	(197,986)	(230,361)
Other	(45,072)	(56,227)

	Nine Months Ended September 30,	
Net cash used in investing activities	(306,104)	(320,215)
Financing Activities		
Proceeds from exercise of stock options and stock issued	107,870	73,801
Common stock repurchased, including related costs		(520,025)
Net (repayments) borrowings under short-term debt facilities	(11,964)	22,592
Issuance of long-term notes		173,350
Borrowings under debt facilities	1,832,400	544,300
Payments under debt facilities	(1,872,250)	(283,112)
Net cash provided by financing activities	56,056	10,906
Effect of currency exchange rate changes on cash	(2,963)	9,708
Net increase in cash and equivalents	123,933	26,173
Cash and equivalents at beginning of period	461,253	401,860
Cash and equivalents at end of period	$ 585,186	$ 428,033

See notes to condensed consolidated financial statements.

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

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation: The accompanying unaudited condensed consolidated financial statements 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 for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the interim periods are not necessarily indicative of the results that may be expected for the full year.

Preparation of the financial statements of St. Jude Medical, Inc. (the Company) in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates. For further information, refer to the consolidated financial statements and footnotes included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

Stock-Based Compensation: The Company accounts for its stock-based employee compensation plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations. The following table illustrates the effect on net earnings and net earnings per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation*, to its stock-based employee compensation (in thousands, except per share amounts):

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2004	*2003*	*2004*	*2003*

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
Net earnings, as reported	$ 91,178	$ 84,136	$ 285,175	$ 244,456
Less: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(13,150)	(9,489)	(37,558)	(27,378)
Pro forma net earnings	$ 78,028	$ 74,647	$ 247,617	$ 217,078
Net earnings per share:				
Basic as reported	$ 0.26	$ 0.24	$ 0.81	$ 0.69
Basic pro forma	0.22	0.21	0.70	0.61
Diluted as reported	$ 0.25	$ 0.23	$ 0.77	$ 0.65
Diluted pro forma	0.21	0.20	0.67	0.58

NOTE 2 ACQUISITIONS

Epicor Medical, Inc.: On June 8, 2004, the Company completed its acquisition of the remaining capital stock of Epicor Medical, Inc. (Epicor), a development stage company focused on developing products which use high intensity focused ultrasound (HIFU) to ablate cardiac tissue. In May 2003, the Company made an initial $15.0 million minority investment in Epicor and acquired an option to purchase the remaining ownership of Epicor prior to June 30, 2004 for $185.0 million. The Company considered the future cash flows of the business when it negotiated the purchase price of Epicor. Pursuant to the option, the Company paid $185.0 million in cash to acquire the remaining outstanding capital stock of Epicor on June 8, 2004. The original investment was accounted for under the cost method until the date the remaining shares were purchased. As a result, the Company did not recognize any portion of Epicor s losses during this period. At the date of the subsequent acquisition, in accordance with step-acquisition accounting treatment, the Company s historical financial statements were adjusted retroactively to reflect the portion of Epicor s operating losses attributable to the Company s ownership from the date of the original investment until the final purchase and the Company s portion of in-process research and development that would have been recognized as of the date of the original investment. These amounts totaled $3.6 million, net of tax, for the period described, and were recognized in the income statement on the line item captioned other income (expense). Net consideration paid for the total acquisition was $198.0 million, which includes closing costs less $2.4 million of cash acquired.

The Company acquired Epicor to strengthen its product portfolio related to the treatment of atrial fibrillation. The goodwill recognized as part of the acquisition represents future product opportunities that did not have regulatory approval at the date of acquisition and is not deductible for tax purposes. The goodwill recognized in connection with the Epicor acquisition was allocated entirely to the Company s Cardiac Rhythm Management/Cardiac Surgery (CRM/CS) reportable segment.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as a result of the Epicor acquisition (in thousands):

Current assets	$ 2,867
Goodwill	159,121
Purchased technology	21,700
Deferred income taxes	15,086
Other long-term assets	743

Total assets acquired	$ 199,517
Current liabilities	$ 2,707
Total liabilities assumed	$ 2,707
Net assets acquired	$ 196,810

The goodwill recorded as a result of the Epicor acquisition is not deductible for income tax purposes.

In connection with the acquisition of Epicor, the Company recorded purchased technology valued at $21.7 million that has a useful life of 12 years. The Epicor acquisition did not provide for the payment of any contingent consideration.

Getz: On April 1, 2003, the Company completed its acquisition of Getz Bros. Co., Ltd. (Getz Japan), a distributor of medical technology products in Japan and the Company s largest volume

distributor in Japan. The Company paid 26.9 billion Japanese Yen in cash to acquire 100% of the outstanding common stock of Getz Japan. Net consideration paid was $219.2 million, which includes closing costs less $12.0 million of cash acquired.

On April 1, 2003, the Company also acquired the net assets of Getz Bros. & Co. (Aust.) Pty. Limited and Medtel Pty. Limited (collectively referred to as Getz Australia) related to the distribution of the Company s products in Australia for $6.2 million in cash, including closing costs.

The Company acquired Getz Japan and Getz Australia (collectively referred to as Getz) in order to further strengthen its presence in the Japanese and Australian medical technology markets. The Company considered the future cash flows of the businesses and the valuation of the publicly-traded shares of Getz Japan (a minority of the Getz Japan shares were traded on the Tokyo Stock Exchange) when it negotiated the purchase price of Getz. The goodwill recognized as part of the Getz acquisitions relates primarily to the operating efficiencies that these businesses were able to achieve and the increased levels of efficiencies anticipated in the future as the Company expands its presence in the Japanese and Australian medical technology markets. The goodwill recorded in connection with the Getz acquisitions was allocated entirely to the Company s Cardiac Rhythm Management/Cardiac Surgery (CRM/CS) reportable segment.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as a result of the Getz acquisitions (in thousands):

Current assets	$ 124,696
Goodwill	67,901
Intangible assets	64,106
Other long-term assets	33,144
Total assets acquired	$ 289,847
Current liabilities	$ 27,094
Deferred income taxes	25,390
Total liabilities assumed	$ 52,484
Net assets acquired	$ 237,363

The goodwill recorded as a result of the Getz acquisitions is not deductible for income tax purposes.

In connection with the acquisitions of Getz, the Company recorded intangible assets valued at $64.1 million that each have a weighted average useful life of 10 years. Total intangible assets subject to amortization include distribution agreements of $44.9 million, customer lists and relationships of $9.5 million, and licenses and other of $5.6 million. Intangible assets not subject to amortization include trademarks of $4.1 million.

The Getz acquisitions did not provide for the payment of any contingent consideration. The third party appraisal used by the Company for purposes of the purchase price allocation did not include any in-process research and development.

The results of operations of the Getz and Epicor acquisitions 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 aggregate.

Other: During the first nine months of 2004 and fiscal year 2003, the Company also acquired various businesses involved in the distribution of the Company s products. Aggregate consideration paid in cash was $17.7 million during the first nine months of 2004 and $5.4 million during the full fiscal year 2003.

NOTE 3 INVENTORIES

Inventories consist of the following (in thousands):

	September 30, 2004	*December 31, 2003*
Finished goods	$ 223,559	$ 209,236
Work in process	29,282	32,547
Raw materials	61,941	69,978
	$ 314,782	$ 311,761

NOTE 4 GOODWILL AND OTHER INTANGIBLE ASSETS

The changes in the carrying amount of goodwill for each of the Company s reportable segments for the nine months ended September 30, 2004 are as follows (in thousands):

	CRM/CS	*Daig*	*Total*
Balance at December 31, 2003	$ 352,144	$ 54,869	$ 407,013
Goodwill recorded from the Epicor transaction	159,121	--	159,121
Foreign currency translation	(2,872)	(11)	(2,883)
Other	436	--	436

	CRM/CS	*Daig*	*Total*
Balance at September 30, 2004	$ 508,829	$ 54,858	$ 563,687

The following table provides the gross carrying amount of other intangible assets and related accumulated amortization at September 30, 2004 and December 31, 2003 (in thousands):

	September 30, 2004		*December 31, 2003*	
	Gross Carrying Amount	*Accumulated Amortization*	*Gross Carrying Amount*	*Accumulated Amortization*
Amortized intangible assets:				
Purchased technology and patents	$ 97,945	$ 24,586	$ 76,189	$ 21,253
Distribution agreements	47,759	7,164	49,348	3,701
Customer lists and relationships	67,830	11,690	50,511	7,278
Licenses and other	6,492	1,064	6,679	610
	$ 220,026	$ 44,504	$ 182,727	$ 32,842
Unamortized intangible assets:				
Trademarks	$ 4,374		$ 4,519	

NOTE 5 COMMITMENTS AND CONTINGENCIES

Silzone®Litigation: In July 1997, the Company began marketing mechanical heart valves which incorporated a Silzone® coating. The Company later began marketing heart valve repair products incorporating a Silzone® coating. The Silzone® coating was intended to reduce the risk of endocarditis, a bacterial infection affecting heart tissue, which is associated with replacement heart valves.

In January 2000, the Company voluntarily recalled all field inventories of Silzone® devices after receiving information from a clinical study that patients with a Silzone® valve had a small, but statistically significant, increased incidence of explant due to paravalvular leak compared to patients in that clinical study with non-Silzone® heart valves.

Subsequent to the Company s voluntary recall, the Company has been sued in various jurisdictions and now has cases pending in the United States, Canada, and United Kingdom by some patients who received a Silzone® device. Some of these claims allege bodily injuries as a result of an explant or other complications, which they attribute to the Silzone®devices. Others, who have not had their device explanted, seek compensation for past and future costs of special monitoring they allege they need over and above the medical monitoring all 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.

The Company has settled a number of these Silzone®-related cases and others have been dismissed. Cases filed in the United States in federal courts have been consolidated in the federal district court for the district of Minnesota under Judge Tunheim. A number of class-action complaints have been consolidated into one case seeking certification of two separate

classes. One proposed class in the consolidated complaint seeks injunctive relief in the form of medical monitoring. A second class in the consolidated complaint seeks an unspecified amount of monetary damages. In a March 27, 2003 ruling, the Court conditionally certified two separate classes, and also certified a class for patients claiming relief under Minnesota s Consumer Protection Statutes.

On January 5, 2004, the judge issued further rulings concerning the classes that he had conditionally certified. More specifically, the judge declined to grant class-action status to personal injury claims; however, he granted class-action status for patients from a limited group of states to proceed with medical monitoring claims.

Judge Tunheim also ruled against the Company in a separate order on the issue of preemption and held that the plaintiff s causes of action were not preempted by the U.S. Food and Drug Act.

In a July 15, 2004 order, Judge Tunheim added three additional states to the limited group of states from which he determined residents with Silzone® valves could proceed with a class action involving medical monitoring claims so long as they did not have a clinical injury. (In other words, Judge Tunheim concluded that residents from 17 states could proceed with a class action involving medical monitoring, while residents from other states could not be part of that class). In this order, the Court also indicated that the class action he certified under Minnesota s Consumer Protection Statutes should proceed.

The Company requested the Eighth Circuit Court of Appeals to review Judge Tunheim s class certification orders and his preemption order. In a September 2, 2004 order, the appellate court indicated it would accept the appeal of Judge Tunheim s certification orders and set forth a briefing schedule for that appeal. The appellate court also indicated that it would not accept review of Judge Tunheim s decision regarding federal preemption at this time. It is not expected that the appellate court would complete its review and issue a decision concerning the appeal of the rulings regarding class certification until sometime in mid to late 2005.

In addition to the class-type claims, as of October 22, 2004, there are 19 individual Silzone® cases pending in various federal courts where plaintiffs are each requesting damages ranging from $9.5 thousand to $120.5 million and, in some cases, seeking an unspecified amount. These cases are proceeding in accordance with the orders issued by Judge Tunheim. There are also 22 individual state court suits pending as of October 22, 2004 involving 30 patients. The complaints in these cases each request damages ranging from $50 thousand to $100 thousand and, in some cases, seek an unspecified amount. These state court cases are proceeding in accordance with the orders issued by the judges in those matters.

In addition, a lawsuit seeking a class action for all persons residing in the European Economic Union member jurisdictions who have had a heart valve replacement and/or repair procedure using a product with Silzone® coating has been filed in Minnesota state court. The complaint seeks damages in an unspecified amount for the class, and in excess of $50 thousand for the representative plaintiff individually. The complaint also seeks injunctive relief in the form of medical monitoring. The Company removed this matter to the federal court in Minnesota, but the plaintiffs challenged this removal. In an August 5, 2004 order, the federal court returned the case to Minnesota state court. The Company has filed motions in the state court seeking to have the claims dismissed.

There are also four class-action cases and one individual case pending against the Company in Canada. In one such case in Ontario, the court certified that a class action may proceed involving Silzone® patients. The most recent decision on certification was issued by the Ontario court on January 16, 2004, but the Company has moved for leave to appeal the rulings on certification. A second case seeking class action in Ontario has been stayed pending resolution of the other Ontario action, and the matter seeking class action in British Columbia has been relatively inactive. A court in the Province of Quebec has certified a class action. In the United Kingdom, two cases involving two separate plaintiffs have been filed. The complaints in these cases request damages of unspecified amounts. One of these matters has not been served upon the Company, and the other is only in very preliminary stages.

The Company is not aware of any unasserted claims related to Silzone® devices. Company management believes that the final resolution of the Silzone® cases will take several years. While management reviews the claims that have been asserted from time to time and periodically engages in discussions about the resolution of claims with claimants representatives, management cannot reasonably estimate at this time the time frame in which any potential settlements or judgments would be paid out. The Company accrues for contingent losses when it is probable

that a loss has been incurred and the amount can be reasonably estimated. The Company has recorded an accrual for probable legal costs that it will incur to defend the various cases involving Silzone® devices, and the Company has recorded a receivable from its product liability insurance carriers for amounts expected to be recovered (see Note 6). The Company has not accrued for any amounts associated with probable settlements or judgments because management cannot reasonably estimate such amounts. However, management believes that no significant claims will ultimately be allowed to proceed as class actions in the United States and, therefore, that all settlements and judgments will be covered under the Company s remaining product liability insurance coverage (approximately $155.0 million at October 22, 2004), subject to the insurance companies performance under the policies (see Note 6 for further discussion on the Company s insurance carriers). As such, management believes that 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 will not have a material adverse effect on the Company s statement of financial position or liquidity, although such costs may be material to the Company s consolidated results of operations of a future period.

Guidant 1996 Patent Litigation: In November 1996, Guidant Corporation (Guidant) sued the Company alleging that the Company did not have a license to certain patents controlled by Guidant covering ICD products and alleging that the Company was infringing those patents. The Company s contention was that it had obtained a license from Guidant to the patents at issue when it acquired certain assets of Telectronics in November 1996. In July 2000, an arbitrator rejected the Company s position, and in May 2001, a federal district court judge also ruled that the Guidant patent license with Telectronics had not transferred to the Company.

Guidant s suit originally alleged infringement of four patents by the Company. Guidant later dismissed its claim on one patent and a court ruled that a second patent was invalid. This determination of invalidity was appealed by Guidant, and the Court of Appeals upheld the lower court s invalidity determination. In a jury trial involving the two remaining patents (the 288 and 472 patents), the jury found that these patents were valid and that the Company did not infringe the 288 patent. The jury also found that the Company did infringe the 472 patent, though such infringement was not willful. The jury awarded damages of $140.0 million to Guidant. In post-

trial rulings, however, the judge overseeing the jury trial ruled that the 472 patent was invalid and also was not infringed by the Company, thereby eliminating the $140.0 million verdict against the Company. The trial court also made other rulings as part of the post-trial order, including a ruling that the 288 patent was invalid on several grounds.

In August 2002, Guidant commenced an appeal of certain of the trial judge s post-trial decisions pertaining to the 288 patent. Guidant did not appeal the trial court s finding of invalidity and non-infringement of the 472 patent. As part of its appeal, Guidant requested that the monetary damages awarded by the jury pertaining to the 472 patent ($140 million) be transferred to the 288 patent infringement claim. The Company believes that such a request is not supported by the facts or law.

On August 31, 2004, a three judge panel of the Court of Appeals for the Federal Circuit (CAFC) issued a ruling on Guidant s appeal of the trial court decision concerning the 288 patent. The CAFC reversed the decision of the trial court judge that the 288 patent was invalid. The court also ruled that the trial judge s claim construction of the 288 patent was incorrect and, therefore, the jury s verdict of non-infringement was set aside. The court also ruled on other issues that were raised by the parties. The Company has requested a re-hearing of the matter by the panel and the entire CAFC court. As of October 22, 2004, no decision has been issued by the CAFC in response to the Company s rehearing requests.

While it is not possible to predict the outcome of the appeal process, the Company believes that the decision of the trial court in its post-trial rulings, which is publicly available, was correct.

The 288 patent expired in December 2003. Accordingly, the final outcome of the appeal process cannot involve an injunction precluding the Company from selling ICD products in the future. Sales of the Company s ICD products which Guidant asserts infringed the 288 patent were approximately 18% of the Company s consolidated net sales during the fiscal year ended December 31, 2003.

The Company has not accrued any amounts for losses related to the Guidant 1996 patent litigation. Although the Company believes that the assertions and claims in these matters are without merit, potential losses arising from this litigation are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company.

Guidant 2004 Patent Litigation: In February 2004, Guidant sued the Company, alleging that the Company s Epic HF ICD, Atlas®+ HF ICD and Frontier device infringe U.S Patent No. RE 38,119E (the 119 patent). Guidant also sued the Company in February 2004 alleging that the Company s QuickSite 1056K pacing lead infringes U.S. Patent No. 5,755,766 (the 766 patent). Guidant is seeking an injunction against the

manufacture and sale of these devices by the Company in the United States and compensation for what it claims are infringing sales of these products up through the effective date of the injunction. At the end of the second quarter 2004, the Company received U.S Food and Drug Administration (FDA) approval to market these devices in the United States. The Company has not submitted a substantive response to Guidant s claims at this time. Another competitor of the Company, Medtronic, Inc., which has a license to the 119 patent, is contending in a separate lawsuit with Guidant that the 119 patent is invalid.

The Company has not accrued any amounts for losses related to the Guidant 2004 patent litigation. Potential losses arising from this litigation are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company.

Symmetry Litigation: As of October 22, 2004, there are sixteen cases in the United States pending against the Company which allege that its Symmetry Bypass System Aortic Connector (Symmetry device) caused bodily injury or might cause bodily injury. In addition, a number of persons have made a claim against the Company involving the Symmetry device without filing a lawsuit. The first lawsuit involving the Symmetry device was filed against the Company on August 5, 2003, and the most recently initiated case was served upon the Company on September 24, 2004. Each of the complaints in these cases request damages ranging from $50 thousand to $100 thousand and, in some cases, seek an unspecified amount. Four of the sixteen cases are seeking class-action status. One of the cases seeking class-action status has been dismissed but the dismissal is being appealed by the plaintiff. In a second case seeking class action status, a Magistrate Judge has recommended that the matter not proceed as a class action, and the parties are presently awaiting the Court to review the Magistrate s decision. A third case seeking class action status has been indefinitely stayed by the Court, and is presently inactive. The Company believes that the plaintiffs in those cases seeking class-action status seek or will seek damages for injuries and monitoring costs.

The Company s Symmetry device was cleared through a 510(K) submission to the FDA, and therefore, is not eligible for the defense under the doctrine of federal preemption that such suits are prohibited. Given the Company s self-insured retention levels under its product liability insurance policies, the Company expects that it will be solely responsible for these lawsuits, including any costs of defense, settlements and judgments. Company management believes that class-action status is not appropriate for the claims asserted based on the facts and case law.

During the third quarter of 2004, the number of lawsuits involving the Symmetry device increased, and the number of persons asserting claims outside of litigation increased as well. With this background, the Company determined that it was probable that future legal fees to defend the cases will be incurred and the amount of such fees was reasonably estimable. As a result, the Company recorded a pretax charge of $21.0 million in the third quarter of 2004 to accrue these costs.

Potential losses arising from settlements or judgments are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company. However, management believes that no significant claims will ultimately be allowed to proceed as class actions in the United States.

Management currently believes that any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered by its reserves will not have a material adverse effect on the Company s statement of financial position or liquidity, although such costs may be material to the Company s consolidated results of operations of a future period.

Other Litigation Matters: The Company is involved in various other product liability 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 pacemaker and ICD 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 September 30, 2004 and 2003 were as follows (in thousands):

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2004	***2003***	***2004***	***2003***
Balance at beginning of period	$ 13,338	$ 15,952	$ 15,221	$ 14,755
Warranty expense recognized	166	513	523	2,701
Warranty credits issued	(115)	(1,392)	(2,355)	(2,383)
Balance at end of period	$ 13,389	$ 15,073	$ 13,389	$ 15,073

Other Contingencies: The Company has contingent commitments to acquire various businesses involved in the distribution of its products that could total approximately $54.9 million in aggregate during 2004 to 2010, provided that certain contingencies are satisfied. The purchase prices of the individual businesses range from approximately $0.4 million to $5.8 million.

The Company is required to make additional payments related to its 1999 acquisition of Vascular Science, Inc. (VSI) based upon the achievement of certain regulatory milestones and minimum sales levels. To date, the Company has paid $15 million related to the achievement of three regulatory milestones. Achievement of the final regulatory milestone, U.S. regulatory approval of the distal connector, requires an additional $5 million payment. This contractual commitment continues indefinitely; however, as discussed in Note 6, the Company committed to a plan to discontinue the product line for which the final regulatory milestone is measured.

The terms of the VSI acquisition also include contingent consideration that requires the Company to make additional payments totaling 5% of sales once cumulative sales exceed $50 million for the proximal and distal connectors collectively. There is no maximum amount of contingent consideration that could be paid related to sales. This contractual commitment ceases in 2009 if the minimum sales threshold is not attained prior to such date. If the minimum sales threshold is met prior to 2009, the commitment will extend for 10 years from the date the minimum sales threshold is met. Cumulative proximal and distal connector sales totaled $37.1 million through September 30, 2004. As further discussed in Note 6, the Company committed to a plan to discontinue this product line and therefore it is highly unlikely that the cumulative sales levels required for contingent consideration to be paid will be met.

NOTE 6 SPECIAL CHARGES

Symmetry Bypass System Aortic Connector Product Line Discontinuance:

On September 23, 2004, management committed the Company to a plan to discontinue developing, manufacturing, marketing and selling its Symmetry device. The decision to discontinue developing, manufacturing, marketing and selling the Symmetry device was primarily based on losses incurred related to the product over the previous three years and the prospect of ongoing operating losses, resulting from a decrease in the number of coronary artery bypass graft surgery cases and an apparent slow down in the adoption of off-pump procedures for which the Symmetry device was developed.

In conjunction with the plan, the Company recorded a pretax charge in the third quarter of 2004 of $14.4 million. The charge is comprised of $4.4 million of inventory write-offs, $4.1 million of fixed asset write-offs, $3.6 million of sales returns, $1.3 million of contract termination and other costs, primarily related to a leased facility, and $1.0 million in workforce reduction costs. These activities are expected to be completed by December 31, 2004, and all payments required in connection with the charge are expected to be made by March 31, 2005. The portion of the charges that are expected to result in future cash expenditures is estimated to be $2.3 million. In addition, the Company expects to incur additional future expense for related matters totaling approximately $6.5 million in periods prior to 2007. A summary of the activity related to the remaining accruals for customer returns, contract termination, and workforce reduction costs during the three and nine months ended September 30, 2004 is as follows (in thousands):

	Customer Returns and Related Costs	Contract Termination and Related Costs	Workforce Reduction and Related Costs	Total
Balance at December 31, 2003	$	$	$	$
Accrual for Product Discontinuance	3,600	1,308	1,002	5,910
Cash payments or credits issued	(8)			(8)
Balance at September 30, 2004	$ 3,592	$ 1,308	$ 1,002	$ 5,902

Symmetry Bypass System Aortic Connector Litigation:

In addition, as discussed in Note 5, there are sixteen legal cases in the United States pending as of October 22, 2004 alleging that the Company s Symmetry device caused bodily injury or might cause bodily injury. Four of these matters seek class action status (one of these has already been dismissed, but is now on appeal, another is presently stayed). There are also a number of persons who have made a claim against the Company involving the Symmetry device without filing a lawsuit. During the third quarter of 2004, the number of cases increased, and the number of persons asserting claims outside of litigation increased as well. With this background, the Company determined that it was probable that a liability for future legal fees to defend the cases had been incurred and the amount of such fees was reasonably estimable. As a result, the Company recorded a pretax charge in the third quarter of 2004 of $21.0 million to reflect this liability.

Silizone® Litigation:

On January 21, 2000, the Company initiated a worldwide voluntary recall of all field inventories of heart valve replacement and repair products incorporating Silzone® coating. The Company concluded that it would no longer utilize Silzone® coating. As a result of the voluntary recall and product discontinuance, the Company recorded a special charge totaling $26.1 million during the first quarter of 2000. The $26.1 million special charge consisted of asset write-downs ($9.5 million), legal and patient follow-up costs ($14.4 million) and customer returns and related costs ($2.2 million).

The $9.5 million of asset write-downs related to inventory write-offs associated with the physical scrapping of inventory with Silzone® coating ($8.6 million), and to the write-off of a prepaid license asset and related costs associated with the Silzone® coating technology ($0.9 million). The $14.4 million of legal and patient follow-up costs related to the Company s product liability insurance deductible ($3.5 million) and patient follow-up costs ($10.9 million) related to contractual and future monitoring activities directly related to the product recall and discontinuance. The $2.2 million of customer returns and related costs represented costs associated with the return of customer-owned Silzone® inventory.

In the second quarter of 2002, the Company determined that the Silzone® reserves should be increased by $11 million as a result of difficulties in obtaining certain reimbursements from the Company s insurance carriers under its product liability insurance policies ($4.6 million), an increase in management s estimate of the costs associated with future patient follow-up costs as a result of extending the time period in which it planned to perform patient follow-up activities ($5.8 million) and an increase in other related costs ($0.6 million).

The Company s product liability insurance coverage for Silzone® claims consists of a number of policies with different carriers. During 2002, Company management observed a trend where various insurance companies were not reimbursing the Company or outside legal counsel for a variety of costs incurred, which the Company believed should be paid under the product liability insurance policies. These insurance companies were either refusing to pay the claims or had delayed providing an explanation for non-payment for an extended period of time. Although the Company believes it has legal recourse from these insurance carriers for the costs they are refusing to pay, the additional costs the Company would need to incur to resolve these disputes may exceed the amount the Company would recover. As a result of these developments, the Company increased the Silzone® reserves by $4.6 million in the second quarter of 2002, which represented the existing disputed costs already incurred at that time plus the anticipated future

costs where the Company expects similar resistance from the insurance companies on reimbursement.

There were no Silzone® special charges recorded during the three or nine months ended September 30, 2004 and 2003. A summary of the activity related to the remaining accruals for legal and follow-up costs and customer returns and related costs during the three, six and nine months ended September 30, 2004 is as follows (in thousands):

	Legal and Follow-up Costs	Customer Returns and Related Costs	Total
Balance at December 31, 2003	$ 27,906	$ 486	$ 28,392
Cash payments or credits issued	(77)	(5)	(82)
Balance at March 31, 2004	27,829	481	28,310
Cash payments or credits issued	1	(123)	(122)
Balance at June 30, 2004	27,830	358	28,188
Cash payments or credits issued	(231)	(7)	(238)
Balance at September 30, 2004	$ 27,599	$ 351	$ 27,950

In addition to the amounts available under the above Silzone® reserves, the Company has approximately $155.0 million as of October 22, 2004 remaining in product liability insurance available for the Silzone®-related matters. This is based on the Company s understanding of amounts that have been submitted for payment by insurance and includes a reduction of insurance for some amounts which the insurers have initially rejected but for which the Company continues to seek payment. The Company s remaining product liability insurance for Silzone® claims consists of a number of layers, each of which is covered by one or more insurance companies. The present layer of insurance, which is a $30 million layer, is covered by Lumberman s Mutual Casualty Insurance, a unit of the Kemper Insurance Companies (collectively referred to as Kemper). Kemper s credit rating by A.M. Best has been downgraded to a D (poor). Kemper is currently in run off, which means that it is not issuing new policies and is, therefore, not generating any new revenue that could be used to cover claims made under previously-issued policies. In the event Kemper is unable to pay part or all of such claims, the Company believes the other insurance carriers in its program will take the position that the Company will be directly liable for any claims and costs that Kemper is unable to pay. Kemper also provides part of the coverage for Silzone® claims in the Company s final layer of insurance ($20 million of the final $50 million layer).

Although the Company understands that Kemper has paid approximately $2.0 million as of October 22, 2004 on behalf of the Company in connection with Silzone related matters, it is possible that Kemper will be unable to continue to meet its obligations to the Company. If this were to happen, the Company could incur a loss of up to $48 million. The Company has not accrued for any such losses.

NOTE 7 DEBT

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

	September 30, 2004	*December 31, 2003*
Short-term debt	$	$ 12,115
Long-term debt		
1.02% Yen-denominated notes, due 2010	188,154	194,413
Commercial paper borrowings	117,550	157,400
	305,704	351,813
	$ 305,704	$ 363,928

The Company had a short-term, unsecured bank credit agreement that provided for borrowings of up to 3.8 billion Yen. Borrowings under the short-term, bank credit agreement bore interest at the floating Yen London InterBank Offered Rate (LIBOR) plus 0.50% per annum. The Company repaid the remaining borrowings under this agreement in April 2004.

In May 2004, the Company obtained a 1.0 billion Yen credit facility that expires in June 2005. Borrowings under the credit facility bear interest at the floating Tokyo InterBank Offered Rate (TIBOR) plus 0.50% per annum. There were no outstanding borrowings under this credit facility at September 30, 2004.

The Company has 1.02%, unsecured notes outstanding totaling 20.9 billion Yen, due in May 2010. The Company also issues short-term, unsecured commercial paper with maturities up to 270 days. These commercial paper borrowings bear interest at varying market rates.

On September 28, 2004, the Company entered into a $400 million credit agreement with a consortium of lenders. The credit agreement creates a $400 million unsecured revolving credit facility that the Company can draw upon for general corporate purposes or use to support its commercial paper program. This credit agreement replaced a $150 million credit agreement which expired in September 2004. The credit agreement expires on September 28, 2009. Borrowings under the credit agreement bear interest at LIBOR plus 0.39%, or in the event over half of the facility is drawn on, LIBOR plus 0.515%, in each case subject to adjustment in the event of a change in the Company s credit ratings. There were no outstanding borrowings under this credit facility at September 30, 2004.

Additionally, the Company has a $350 million unsecured, revolving credit facility that expires in September 2008. This credit facility bears interest at the LIBOR plus 0.60% per annum subject to adjustment in the event of a change in the Company s debt ratings. There were no outstanding borrowings under this credit facility at September 30, 2004 and December 31, 2003.

The Company classifies all of its commercial paper borrowings as long-term on its balance sheet as the Company has the ability to repay any short-term maturity with available cash from its existing long-term, committed credit facilities. Management continually reviews the Company s cash flow projections and may from time to time repay a portion of the Company s borrowings.

The Company s 1.02% notes and revolving credit facilities contain various operating and financial covenants. Specifically, the Company must have a ratio of total debt to total capitalization not exceeding 55%, have a leverage ratio (defined as the ratio of total debt to EBITDA (net earnings before interest, income taxes, depreciation and amortization) and the ratio of total debt to EBIT (net earnings before interest and income taxes)) not exceeding 3.0 to 1.0, and an interest coverage ratio (defined as the ratio of EBITDA to interest expense and the ratio of EBIT to interest expense) not less than 3.0 to 1.0 and 3.5 to 1.0 for the Company s 1.02% notes and revolving credit facilities, respectively. The Company also has limitations on additional liens or indebtedness and limitations on certain acquisitions, investments and dispositions of assets. However,

these agreements do not include provisions for the termination of the agreements or acceleration of repayment due to changes in the Company s credit ratings. The Company was in compliance with all of its debt covenants at September 30, 2004.

NOTE 8 SHAREHOLDERS EQUITY

Capital Stock: On October 11, 2004, the Company s Board of Directors declared a two-for-one stock split effected in the form of a 100% stock dividend payable on November 22, 2004 to shareholders of record on November 1, 2004. Net earnings per share, shares outstanding and weighted average shares outstanding have been restated to reflect the stock dividend. The Company s authorized capital consists of 25 million shares of $1.00 per share par value preferred stock and 500 million shares of $0.10 per share par value common stock. The Company has designated 1.1 million of the authorized preferred shares as a Series B Junior Preferred Stock for its shareholder rights plan. There are no shares of preferred stock issued or outstanding.

Share Repurchases: In August 2004, the Company s Board of Directors authorized the repurchase of up to $300 million of the Company s outstanding common stock. This authorization expires on December 31, 2006. The Company has not repurchased any shares of its common stock during 2004.

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 September 30,		*Nine Months Ended September 30,*	
	2004	***2003***	***2004***	***2003***
Numerator:				
Net earnings	$ 91,178	$ 84,136	$ 285,175	$ 244,456
Denominator:				
Basic-weighted average shares outstanding	354,570	351,992	352,116	356,782
Effect of dilutive securities:				
Employee stock options	16,230	17,038	17,832	16,510
Restricted shares	14	22	12	22
Diluted-weighted average shares outstanding	370,814	369,052	369,960	373,314
Basic net earnings per share	$ 0.26	$ 0.24	$ 0.81	$ 0.69
Diluted net earnings per share	$ 0.25	$ 0.23	$ 0.77	$ 0.65

Diluted-weighted average shares outstanding have not been adjusted for certain employee stock options and awards where the effect of those securities would not have been dilutive.

NOTE 10 COMPREHENSIVE INCOME

Other comprehensive income (expense) consists of unrealized gains or losses on available-for-sale marketable securities and foreign currency translation adjustments, net of taxes. Other comprehensive income (expense) was $0.7 million and $2.1 million for the three months ended September 30, 2004 and 2003, respectively, and $(17.4) million and $50.7 million for the nine months ended September 30, 2004 and 2003, respectively. Total comprehensive income combines reported net earnings and other comprehensive income (expense). Total comprehensive income was $91.9 million and $86.2 million for the three months ended September 30, 2004 and 2003, respectively, and $267.8 million and $295.2 million for the nine months ended September 30, 2004 and 2003, respectively.

NOTE 11 OTHER INCOME (EXPENSE)

Other income (expense) consisted of the following (in thousands):

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2004	***2003***	***2004***	***2003***
Equity method loss in Epicor	$	$ (656)	$ (1,311)	$ (2,817)
Interest income	2,084	1,666	5,261	5,344
Interest expense	(1,358)	(1,591)	(3,765)	(2,061)
Other	(46)	(241)	(949)	(1,207)
	$ 680	$ (822)	$ (764)	$ (741)

NOTE 12 SEGMENT INFORMATION

Segment Information: The Company develops, manufactures and distributes cardiovascular medical devices for the global cardiac rhythm management (CRM), cardiac surgery (CS), and cardiology and vascular access (C/VA) therapy areas. The Company has three operating segments, Cardiac Rhythm Management (CRM), Cardiac Surgery (CS) and Daig, which focus on the development and manufacture of products for the three therapy areas. The primary products produced by each segment are: CRM pacemaker and ICD systems; CS mechanical and tissue heart valves; Daig electrophysiology catheters, vascular closure devices and other cardiology and vascular access products. The Company has aggregated the CRM and CS segments into one reportable segment based primarily upon their similar operational and economic characteristics.

The Company s reportable segments include end-customer revenues from the sale of products they each develop and manufacture. The costs included in each of the reportable segments operating results include the direct costs of the products sold to end customers and operating expenses managed by each of the segments. Certain costs of goods sold and operating expenses managed by the Company s non-manufacturing and corporate functions are not included in segment operating profit. Consequently, segment operating profit presented below is not representative of the operating profit of the Company s products in these segments.

The following table presents certain financial information about the Company s reportable segments (in thousands):

	CRM/CS	Daig	Other	Total
Three Months ended September 30, 2004:				
Net sales	$ 441,134	$ 113,848	$ 23,337	$ 578,319
Operating profit [(a) (b)]	234,083	65,624	(181,075)	118,632
Three Months ended September 30, 2003:				
Net sales	$ 365,816	$ 91,501	$ 20,137	$ 477,454
Operating profit [(a)]	217,870	51,547	(154,899)	114,518
Nine Months ended September 30, 2004:				
Net sales	$ 1,272,404	$ 339,691	$ 71,402	$ 1,683,497
Operating profit [(a) (b)]	739,466	192,576	(547,682)	384,360
Nine Months ended September 30, 2003:				
Net sales	$ 1,110,667	$ 262,433	$ 40,831	$ 1,413,931
Operating profit [(a)]	651,114	143,761	(463,789)	331,086

(a) Other operating profit includes certain costs of goods sold and operating expenses managed by the Company s selling and corporate functions.

(b) CRM/CS operating profit includes a special charge totaling $35,383 for the three and nine months ended September 30, 2004.

There have been no material changes in total assets of the Company s reportable segments since December 31, 2003.

Net sales by class of similar products were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Sales	**2004**	**2003**	**2004**	**2003**
Cardiac rhythm management	$ 420,047	$ 338,550	$ 1,190,880	$ 1,007,761
Cardiac surgery	64,066	62,361	208,564	198,897
Cardiology and vascular access	94,206	76,543	284,053	207,273
	$ 578,319	$ 477,454	$ 1,683,497	$ 1,413,931

Geographic Information: The following tables present certain geographical financial information (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net Sales [(a)]	**2004**	**2003**	**2004**	**2003**

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
United States	$ 335,703	$ 277,478	$ 935,292	$ 843,984
International				
Europe	132,153	109,028	421,062	336,490
Japan	63,979	57,746	193,547	142,348
Other [(b)]	46,484	33,202	133,596	91,109
	242,616	199,976	748,205	569,947
	$ 578,319	$ 477,454	$ 1,683,497	$ 1,413,931

Long-Lived Assets	***September 30, 2004***	***December 31, 2003***
United States	$ 983,795	$ 741,833
International		
Europe	92,225	96,520
Japan	144,923	152,772
Other	74,365	70,020
	311,513	319,312
	$ 1,295,308	$ 1,061,145

(a) Net sales are attributed to geographies based on location of the customer.

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

NOTE 13 SUBSEQUENT EVENTS

Acquisition of Irvine Biomedical, Inc.: On October 7, 2004, the Company completed its acquisition of Irvine Biomedical, Inc. (IBI), a privately held company which develops electrophysiology (EP) catheter products used by physician specialists to diagnose and treat cardiac rhythm disorders. The Company paid approximately $44.8 million to acquire the remaining 86% of the capital stock of IBI it did not already own. This amount was net of cash acquired from IBI as well as consideration from the exercise of IBI stock options.

In addition, the purchase agreement provides for additional incentive payments of up to $13.0 million to the non- St. Jude Medical shareholders if IBI receives approval by certain specified dates in 2005 and 2006 from the FDA of certain EP catheter ablation systems currently in development. The Company expects to record an in-process R&D charge of $9.1 million in the fourth quarter associated with the completion of this transaction.

The results of operations of the IBI business acquisition will be included in the Company s consolidated results of operations beginning in the fourth quarter of 2004.

Acquisition of Endocardial Solutions, Inc.: On September 23, 2004, the Company announced that it signed a definitive agreement to acquire Endocardial Solutions, Inc. (ESI) for $11.75 per share in cash consideration which represents an aggregate purchase price of approximately $273 million. ESI is publicly traded on the NASDAQ market under the ticker symbol ECSI. ESI develops, manufactures, and markets the EnSite® System used for the navigation and localization of diagnostic and therapeutic catheters used in atrial fibrillation (AF) ablation and other

electrophysiology catheterization procedures. The Company expects to record an in-process R&D charge of approximately $10-$12 million associated with the completion of this transaction.

The results of operations of the ESI business acquisitions are expected to be included in the Company s consolidated results of operations beginning in the fourth quarter of 2004 or the first quarter of 2005 once the transaction closes.

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

OVERVIEW

Our business is focused on the development, manufacturing and distribution of cardiovascular medical devices for the global cardiac rhythm management (CRM), cardiac surgery (CS) and cardiology and vascular access (C/VA) therapy areas. Our principal products in each of these therapy areas are as follows:

CRM

- bradycardia pacemaker systems (pacemakers),
- tachycardia implantable cardioverter defibrillator systems (ICDs), and
- electrophysiology (EP) catheters

CS

- mechanical and tissue heart valves, and
- valve repair products

C/VA

- vascular closure devices,
- angiography catheters,
- guidewires, and
- hemostasis introducers

Our products are sold in more than 120 countries around the world. Our largest geographic markets are the United States, Europe and Japan.

References to St. Jude Medical, St. Jude, the Company, we, us and our are to St. Jude Medical, Inc. and its subsidiaries.

Financial Summary

Net sales in the third quarter and first nine months of 2004 increased approximately 21% and 19% over the third quarter and first nine months of 2003, respectively, led by growth in several product categories, including ICDs, pacemakers and vascular closure devices, and the positive impact of foreign currency translation. In addition, the Company recorded $42.3 million of incremental revenue as a result of our acquisition of Getz Bros. Co., Ltd. in Japan (Getz Japan) during the nine months ended September 30, 2004. In the third quarter of 2004, ICD net sales grew approximately 57% to $156.9 million, pacemaker net sales grew approximately 9% to $224.7 million and vascular closure net sales increased approximately 28% to $70.8 million. In the first nine months of 2004, ICD net sales grew approximately 31% to $403.0 million, pacemaker net sales grew approximately 11% to $674.8 million, and vascular closure net sales increased approximately 36% to $210.8 million.

Net earnings and diluted net earnings per share for the third quarter of 2004 increased approximately 8% over the third quarter of 2003, and net earnings and diluted net earnings per share for the first nine months of 2004 increased approximately 17% and 18%, respectively, over 2003. These increases were due to incremental profits resulting from higher sales and to operating margin improvements which were partially offset by $35.4 million of special charges related to Symmetry Bypass Aortic Connector (Symmetry Device) product line discontinuance and litigation recorded during the third quarter of 2004.

Our cash flows from operations remained strong during the first nine months of 2004, helping to further strengthen our balance sheet and providing cash to repay outstanding debt, partially offsetting the impact of funding our acquisition of Epicor Medical, Inc. in June 2004. We ended the quarter with $585.2 million of cash and equivalents and $305.7 million in long-term debt.

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 December 31, 2003.

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; estimated useful lives of property, plant and equipment; income taxes; Silzone® special charge accruals; and legal reserves. 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 Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

RESULTS OF OPERATIONS

Acquisitions & Investments

Acquisitions have an impact on the comparison of our operating results and financial condition from year to year.

On September 23, 2004, we announced the signing of a definitive agreement to acquire Endocardial Solutions, Inc. (ESI) for $11.75 per share in cash consideration which represents an aggregate purchase price of approximately $273 million. ESI is publicly traded on the NASDAQ market under the ticker symbol ECSI. ESI develops, manufactures, and markets the EnSite® System used for the navigation and localization of diagnostic and therapeutic catheters used in atrial fibrillation (AF) ablation and other electrophysiology catheterization procedures. We expect to record an in-process R&D charge of approximately $10-$12 million associated with the completion of this transaction.

The results of operations of the ESI business acquisitions are expected to be included in our consolidated results of operations beginning in the fourth quarter of 2004 or the first quarter of 2005 once the transaction closes.

On October 7, 2004, we completed our acquisition of Irvine Biomedical, Inc. (IBI), a privately held company which develops electrophysiology (EP) catheter products used by physician specialists to diagnose and treat cardiac rhythm disorders. We paid approximately $44.8 million to acquire the remaining 86% of the capital stock of IBI we did not already own. This amount was net of cash acquired from IBI as well as consideration from the exercise of IBI stock options.

In addition, the purchase agreement provides for additional incentive payments of up to $13.0 million to the non- St. Jude Medical shareholders if IBI receives approval by certain specified dates in 2005 and 2006 from the FDA of certain EP catheter ablation systems currently in development. We expect to record an in-process R&D charge of $9.1 million in the fourth quarter associated with the completion of this transaction.

The results of operations of the IBI business acquisition will be included in our consolidated results of operations beginning in the fourth quarter of 2004.

On June 8, 2004, we completed our acquisition of the remaining capital stock of Epicor Medical, Inc. (Epicor), a development stage company focused on developing products which use high intensity focused ultrasound (HIFU) to ablate cardiac tissue. In May 2003, we made an initial $15.0 million minority investment in Epicor and acquired an option to purchase the remaining ownership of Epicor prior to June 30, 2004 for $185.0 million. Pursuant to the option, we paid $185.0 million in cash to acquire the remaining outstanding capital stock of Epicor on June 8, 2004. Our original investment was accounted for under the cost method until the date the remaining shares were purchased. As a result, we did not recognize any portion of Epicor s losses during this period. At the date of the subsequent acquisition, in accordance with step-acquisition accounting treatment, our historical financial statements were adjusted retroactively to reflect the portion of Epicor s operating losses attributable to our ownership from the date of the original investment until the final purchase and our portion of in-process research and development that would have been recognized as of the date of the original investment. These amounts which totaled $3.6 million, net of tax, for the period described, were recognized in other income (expense). Net consideration paid for the total acquisition was $198.0 million, which includes closing costs less $2.4 million of cash acquired.

On April 1, 2003, we completed the acquisition of Getz Japan, a distributor of medical technology products in Japan and our largest volume distributor in Japan. We paid 26.9 billion Japanese Yen in cash to acquire 100% of the outstanding common stock of Getz Japan. Net consideration paid was $219.2 million, which includes closing costs less $12.0 million of cash acquired.

On April 1, 2003, we also acquired the net assets of Getz Bros. & Co. (Aust.) Pty. Limited and Medtel Pty. Limited (collectively referred to as Getz Australia) related to the distribution of our products in Australia for $6.2 million in cash, including closing costs.

The results of operations of the Getz Japan and Getz Australia (collectively referred to as Getz) and Epicor acquisitions have been included in our consolidated results of operations from the date of acquisition.

Segment Review

We have two reportable segments, the Cardiac Rhythm Management/Cardiac Surgery (CRM/CS) segment and the Daig segment, which focus on the development and manufacture of our products. The primary products produced by each segment are: CRM/CS pacemaker and ICD systems, mechanical and tissue heart valves and other cardiac surgery products; Daig electrophysiology catheters, vascular closure devices and other cardiology and vascular access products.

Our reportable segments include end-customer revenues from the sale of products they each develop and manufacture. The costs included in each of the reportable segments operating results include the direct costs of the products sold to end customers and operating expenses managed by each of the segments. Certain costs of goods sold and operating expenses managed by our non-manufacturing and corporate functions are not included in segment operating profit. Consequently, segment operating profit is not representative of the operating profit of our products in these segments.

The following table presents certain financial information about our reportable segments (in thousands):

	CRM/CS	Daig	Other	Total
Three Months ended September 30, 2004:				
Net sales	$ 441,134	$ 113,848	$ 23,337	$ 578,319
Operating profit [(a) (b)]	234,083	65,624	(181,075)	118,632
Three Months ended September 30, 2003:				
Net sales	$ 365,816	$ 91,501	$ 20,137	$ 477,454
Operating profit [(a)]	217,870	51,547	(154,899)	114,518
Nine Months ended September 30, 2004:				
Net sales	$ 1,272,404	$ 339,691	$ 71,402	$ 1,683,497
Operating profit [(a) (b)]	739,466	192,576	(547,682)	384,360
Nine Months ended September 30, 2003:				
Net sales	$ 1,110,667	$ 262,433	$ 40,831	$ 1,413,931
Operating profit [(a)]	651,114	143,761	(463,789)	331,086

(a) Other operating profit includes certain costs of goods sold and operating expenses managed by the Company s selling and corporate functions.

(b) CRM/CS operating profit includes a special charge totaling $35,383 for the three and nine months ended September 30, 2004.

There have been no material changes in total assets of our reportable segments since December 31, 2003.

We do not generally manage our business or allocate resources based on the measure of segment operating profit or loss because these measures are not indicative of the operating results of the

products sold by these segments. Rather, we utilize the segment results to measure performance against targets for each segment s controllable activities. Additionally, we review global and product line sales information to assess performance of the business.

The following discussion of the changes in our net sales is provided by class of similar products, which is the primary focus of our sales activities. That analysis sufficiently describes the changes in our sales results for our two reportable segments.

Net Sales

Net sales by class of similar products were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Cardiac rhythm management				
Pacemaker systems	$ 224,652	$ 206,841	$ 674,787	$ 610,486
ICD systems	156,920	99,998	403,047	308,424
Electrophysiology catheters	38,475	31,711	113,046	88,851

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	420,047	338,550	1,190,880	1,007,761
Cardiac surgery				
Heart valves	59,121	57,420	192,359	185,268
Other cardiac surgery products	4,945	4,941	16,205	13,629
	64,066	62,361	208,564	198,897
Cardiology and vascular access				
Vascular closure devices	70,755	55,086	210,765	154,821
Other cardiology and vascular access products	23,451	21,457	73,288	52,452
	94,206	76,543	284,053	207,273
	$ 578,319	$ 477,454	$ 1,683,497	$ 1,413,931

Overall, net sales increased 21% in the third quarter of 2004 over the third quarter of 2003. For the first nine months of 2004, net sales increased 19% over the same period one year ago. Third quarter 2004 net sales were favorably impacted by growth in unit volume of approximately 23%. For the first nine months of 2004, net sales were favorably impacted by growth in unit volume of approximately 17% and incremental revenue of $42.3 million related to the Getz acquisitions. The additional revenue from Getz was generated from the sale of non-St. Jude Medical manufactured products sold by Getz and the incremental revenue on the sale of St. Jude Medical manufactured products. Prior to April 1, 2003, we recognized revenue from the sale of our products to Getz as our distributor. Foreign currency translation had a favorable impact on third quarter and first nine months net sales in 2004 as compared with these same periods in 2003 of approximately $13.6 million and $56.5 million, respectively, due primarily to the strengthening of the Euro and the Yen against the U.S. dollar. This amount is not indicative of the overall impact of foreign currency translation on net earnings due to partially offsetting unfavorable foreign currency translation of operating costs. Overall, average selling price declines negatively impacted net sales in the third quarter and first nine months of 2004 by approximately 2% compared with the third quarter and first nine months of 2003. We also experienced an additional 2% and 3% decline in net sales in the third quarter and first nine months of 2004, respectively, due to a larger portion of our sales mix coming from lower-priced markets outside of the United States.

Cardiac rhythm management net sales increased 24% in the third quarter of 2004 over the third quarter of 2003, and 18% in the first nine months of 2004 over the same period one year ago. Third quarter 2004 CRM net sales were favorably impacted by growth in unit volume of approximately 25% driven by sales of traditional pacemaker and ICD products and the introduction of products into the cardiac resynchronization therapy (CRT) segments of the U.S. pacemaker and ICD market. For the first nine months of 2004, CRM net sales increased due to unit growth of approximately 18% and incremental revenue of approximately $19.8 million related to the Getz acquisitions. Foreign currency translation also had a favorable impact on CRM net sales in the third quarter and first nine months of 2004 as compared with these same periods in 2003 of approximately $9.0 million and $37.8 million, respectively. The increases in CRM net sales were partially offset by average selling price declines of approximately 2% in both the third quarter and the first nine months of 2004 as compared with the same periods in 2003. We also had an additional decline in CRM net sales of approximately 1% in the third quarter of 2004 and 3% in the first nine months of 2004 due to a larger portion of our CRM sales mix coming from lower-priced markets outside of the United States. Net sales of pacemaker systems increased 9% in the third quarter of 2004 due to an increase in pacemaker unit sales and approximately $5.5 million of favorable impact from foreign currency translation. Net sales of pacemaker systems increased 11% in the first nine months of 2004 due to an increase in pacemaker unit sales, $12.5 million of favorable impact from the Getz acquisitions and approximately $24.0 million of favorable impact from foreign currency translation. These increases in the third quarter and first nine months of 2004 were offset in part by low single-digit percentage declines in average selling prices and a larger portion of our sales mix coming from lower-priced markets outside of the United States. Net sales of ICD systems increased 57% in the third quarter of 2004 and 31% in the first nine months of 2004 due to growth in ICD unit sales offset in part by low single-digit percentage declines in average selling prices. Net sales of ICD systems in the third quarter and first nine months of 2004 also included favorable impact from foreign currency translation of approximately $2.2 million and $9.6 million, respectively. Electrophysiology catheter net sales increased 21% in the third quarter of 2004 due primarily to an increase in unit sales and approximately $1.2 million of favorable impact from foreign currency translation. Electrophysiology catheter net sales increased 27.2% in the first nine months of 2004 due

primarily to an increase in unit sales, $7.3 million of favorable impact from the Getz acquisitions and approximately $4.2 million of favorable impact from foreign currency translation.

Cardiac surgery net sales increased 3% in the third quarter of 2004 over the third quarter of 2003, and 5% in the first nine months of 2004 over the same period one year ago. The increase in third quarter 2004 CS net sales over the third quarter of 2003 was due primarily to an increase in unit volume of approximately 12% and approximately $2.1 million of favorable impact from foreign currency translation, partially offset by a global average selling price decline of approximately 13%. The increase in first nine months 2004 CS net sales was due primarily to an increase in unit volume of approximately 2%, approximately $9.6 million of favorable impact from the Getz acquisitions and approximately $9.5 million of favorable impact from foreign currency translation, partially offset by a decrease in a global average selling price of approximately 6%. Heart valve net sales increased 3% in the third quarter of 2004 due primarily to an increase in unit volume of approximately 13% and approximately $1.8 million of favorable impact from foreign currency translation. These increases in the third quarter of 2004 were offset in part by a 13% decline in global average selling price. Heart valve net sales increased 3% in the first nine months of 2004 due primarily to $4.6 million of favorable impact from the Getz acquisitions and approximately $8.6 million of favorable impact from foreign currency translation and by a slight

increase in unit sales. These increases in the first nine months of 2004 were offset in part a 7% decline in global average selling price. Net sales of other cardiac surgery products remained consistent in the third quarter of 2004. Net sales of other cardiac surgery products increased 19% in the first nine months of 2004 due primarily to $5.0 million of favorable impact from the Getz acquisitions, partially offset by a reduction in unit volumes.

Cardiology and vascular access net sales increased 23% in the third quarter of 2004 over the third quarter of 2003, and 37% in the first nine months of 2004 over the same period one year ago. Third quarter 2004 C/VA net sales were favorably impacted by growth in unit volume of approximately 22% and $2.5 million of favorable impact from foreign currency translation. For the first nine months of 2004, C/VA net sales were favorably impacted by growth in unit volume of approximately 29%, incremental revenue related to the Getz acquisitions of $12.9 million, and approximately $9.1 million of favorable impact from foreign currency translation. Partially offsetting these increases in the third quarter and first nine months of 2004 was a decline in global average selling price of approximately 2 and 3%, respectively, due to a larger portion of our C/VA sales mix coming from lower-priced markets outside of the United States. Net sales of vascular closure devices increased 28% in the third quarter and 36% in the first nine months of 2004 due to increases in Angio-Seal unit sales and approximately $1.5 million and $6.0 million, respectively, of favorable impact from foreign currency translation. These increases were partially offset by a low single-digit percentage decline in global average selling prices due to a larger portion of our sales mix coming from lower-priced markets outside of the United States. Net sales of other cardiology and vascular access products increased 9% in the third quarter due to an increase in unit sales. For the first nine months of 2004, net sales of other cardiology and vascular access products increased 40% due primarily to $12.9 million of sales of non-St. Jude Medical manufactured products distributed by Getz Japan and an increase in unit sales.

Gross Profit

Gross profit for the third quarter of 2004 totaled $400.3 million, or 69.2% of net sales, as compared with $330.7 million, or 69.3% of net sales, for the third quarter of 2003. For the first nine months of 2004, gross profit was $1,179.8 million, or 70.1% of net sales, compared with $966.5 million, or 68.4% of net sales, for the first nine months of 2003. The decrease in our gross profit percentage during the third quarter of 2004 is due to the $12.1 million special charge for the write off of inventory and return of products held by customers related to the discontinuance of the Symmetry product line. These decreases were partially offset by increases in our gross profit percentage during the third quarter of 2004 relating to lower CRM cost of sales in Japan now that we have sold through the CRM inventory on hand at the time of the Getz acquisition, reduced material costs and increased labor efficiencies due to continued improvements in our CRM manufacturing processes, and increased sales of higher margin ICD systems. The increase in our gross profit percentage during the first nine months of 2004 is the result of lower CRM cost of sales in Japan now that we have sold through the CRM inventory on hand at the time of the Getz acquisition, reduced material costs and increased labor efficiencies due to continued improvements in our CRM manufacturing processes, and to increased sales of higher margin ICD systems. These increases were partially offset by the $12.1 million special charge for the write off of inventory and return of products held by customers related to the discontinuance of the Symmetry product line.

Selling, General and Administrative (SG&A) Expense
SG&A expense for the third quarter of 2004 totaled $188.7 million, or 32.6% of net sales, as compared with $157.6 million, or 33.0% of net sales, for the third quarter of 2003. The decrease in SG&A as a percentage of sales was primarily due to leveraging the investments made in sales and marketing programs in prior quarters to prepare for our launch of products into the cardiac resynchronization therapy (CRT) segments of the U.S. pacemaker and ICD markets at the end of the second quarter.

For the first nine months of 2004, SG&A expense totaled $568.0 million, or 33.7% of net sales, compared with $460.6 million, or 32.6% of net sales, for the first nine months of 2003. This increase is due primarily to increased selling and marketing expenses related to our CRT product launch as noted above and the addition of the Getz direct sales organization beginning April 1, 2003, which included approximately 400 sales, sales support and marketing personnel.

Research and Development (R&D) Expense
R&D expenses in the third quarter of 2004 totaled $69.6 million, or 12.0% of net sales, compared with $58.6 million, or 12.3% of net sales, for the third quarter of 2003. For the first nine months of 2004, R&D expense totaled $204.1 million, or 12.1% of net sales, compared with $174.8 million, or 12.4% of net sales, for the first nine months of 2003. The increase in the dollar amount of R&D expenses was due primarily to our increased spending on the development of new products and related clinical trials, including our CRT devices and other products to treat emerging indications including atrial fibrillation.

Special Charges
Symmetry Bypass System Aortic Connector Product Line Discontinuance:

On September 23, 2004, management committed the Company to a plan to discontinue developing, manufacturing, marketing and selling its Symmetry Bypass System Aortic Connector (Symmetry device). The decision to discontinue developing, manufacturing, marketing and selling the Symmetry device was primarily based on losses incurred related to the product over the previous three years and the prospect of ongoing operating losses, resulting from a decrease in the number of coronary artery bypass graft surgery cases and an apparent slow down in the adoption of off-pump procedures for which the Symmetry device was developed.

In conjunction with the plan, we recorded a pretax charge in the third quarter of 2004 of $14.4 million. The charge is comprised of $4.4 million of inventory write-offs, $4.1 million of fixed asset write-offs, $3.6 million of sales returns, $1.3 million of contract termination and other costs, primarily related to a leased facility, and $1.0 million in workforce reduction costs. These activities are expected to be completed by December 31, 2004, and all payments required in connection with the charge are expected to be made by March 31, 2005. The portion of the charges that are expected to result in future cash expenditures is estimated to be $2.3 million. In addition, we expect to incur additional future expenses for related matters totaling approximately $6.5 million in periods prior to 2007. A summary of the activity related to the remaining accruals for customer returns, contract termination, and workforce reduction costs during the three and nine months ended September 30, 2004 is as follows (in thousands):

	Customer Returns and Related Costs	Contract Termination and Related Costs	Workforce Reduction and Related Costs	Total
Balance at December 31, 2003	$	$	$	$
Accrual for Product Discontinuance	3,600	1,308	1,002	5,910
Cash payments or credits issued	(8)			(8)
Balance at September 30, 2004	$ 3,592	$ 1,308	$ 1,002	$ 5,902

Symmetry Bypass System Aortic Connector Litigation:
In addition, as discussed in Note 5 to the Condensed Consolidated Financial Statements, there are sixteen legal cases in the United States pending as of October 22, 2004 alleging that the Company s Symmetry device caused bodily injury or might cause bodily injury. Four of these matters seek class action status (one of these has already been dismissed, but is now on appeal, another is presently stayed). There are also a

number of persons who have made a claim against the Company involving the Symmetry device without filing a lawsuit. During the third quarter of 2004, the number of cases increased, and the number of persons asserting claims outside of litigation increased as well. With this background, we determined that it was probable that a liability for future legal fees to defend the cases had been incurred and the amount of such fees was reasonably estimable. As a result, we recorded a pretax charge in the third quarter of 2004 of $21.0 million to reflect this liability.

Silizone® Litigation:
On January 21, 2000, we initiated a worldwide voluntary recall of all field inventories of heart valve replacement and repair products incorporating Silzone® coating on the sewing cuff fabric. We concluded that we would no longer utilize Silzone® coating. As a result of the voluntary recall and product discontinuance, we recorded a special charge totaling $26.1 million during the first quarter of 2000. The $26.1 million special charge consisted of asset write-downs ($9.5 million), legal and patient monitoring costs ($14.4 million) and customer returns and related costs ($2.2 million).

The $9.5 million of asset write-downs related to inventory write-offs associated with the physical scrapping of inventory with Silzone® coating ($8.6 million), and to the write-off of a prepaid license asset and related costs associated with the Silzone® coating technology ($0.9 million). The $14.4 million of legal and patient follow-up costs related to the Company s product liability insurance deductible ($3.5 million) and patient follow-up costs ($10.9 million) related to contractual and future monitoring activities directly related to the product recall and discontinuance. The $2.2 million of customer returns and related costs represented costs associated with the return of customer-owned Silzone® inventory. In the second quarter of 2002, we determined that the Silzone® reserves should be increased by $11.0 million as a result of difficulties in obtaining certain reimbursements from our insurance carriers under our product liability insurance policies ($4.6 million), an increase in our estimate of the costs associated with future patient follow-up as a result of extending the time period in which we planned to perform patient follow-up activities ($5.8 million) and an increase in other related costs ($0.6 million).

The Company s product liability insurance coverage for Silzone® claims consists of a number of policies with different carriers. During 2002, Company management observed a trend where various insurance companies were not reimbursing the Company or outside legal counsel for a variety of costs incurred, which the Company believed should be paid under the product liability insurance policies. These insurance companies were either refusing to pay the claims or had delayed providing an explanation for non-payment for an extended period of time. Although the Company believes it has legal recourse against these insurance carriers for the costs they are refusing to pay, the additional costs the Company would need to incur to resolve these disputes may exceed the amount the Company would recover. As a result of these developments, the Company increased the Silzone® reserves by $4.6 million in the second quarter of 2002, which represented the existing disputed costs already incurred at that time plus the anticipated future costs where the Company expects similar resistance from the insurance companies on reimbursement.

There were no Silzone® special charges recorded during the three or nine months ended September 30, 2004 and 2003. A summary of the activity related to the remaining accruals for legal and follow-up costs and customer returns and related costs during the three and nine months ended September 30, 2004 is as follows (in thousands):

	Legal and Follow-up Costs	***Customer Returns and Related Costs***	***Total***
Balance at December 31, 2003	$ 27,906	$ 486	$ 28,392
Cash payments or credits issued	(77)	(5)	(82)
Balance at March 31, 2004	27,829	481	28,310
Cash payments or credits issued	1	(123)	(122)
Balance at June 30, 2004	27,830	358	28,188
Cash payments or credits issued	(231)	(7)	(238)
Balance at September 30, 2004	$ 27,599	$ 351	$ 27,950

	Legal and Follow-up Costs	*Customer Returns and Related Costs*	*Total*

In addition to the amounts available under the above Silzone® reserves, we have approximately $155.0 million remaining in product liability insurance currently available for the Silzone®-related matters. See the discussion of one of our product liability insurance carriers, Kemper, in Note 6 to the Condensed Consolidated Financial Statements.

Other Income (Expense)
Other income (expense) consisted of the following (in thousands):

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2004	*2003*	*2004*	*2003*
Equity method loss in Epicor	$	$ (656)	$ (1,311)	$ (2,817)
Interest income	2,084	1,666	5,261	5,344
Interest expense	(1,358)	(1,591)	(3,765)	(2,061)
Other	(46)	(241)	(949)	(1,207)
	$ 680	$ (822)	$ (764)	$ (741)

The increase in other income (expense) during the third quarter of 2004 compared with the third quarter of 2003 was primarily due to a decrease in equity method losses incurred by Epicor, which is now included in our consolidated results, and an increase in interest income. Other income (expense) during the first nine months of 2004 compared with the same period in 2003 was consistent as a decrease in equity method losses incurred by Epicor was offset by higher interest expense as a result of increased borrowings.

Income Taxes
Our effective income tax rate was 23.6% and 25.7% for the third quarter and first nine months of 2004, respectively, and 26.0% for the same periods in 2003. The decline is due to the impact of the tax benefit recorded at statutory rates related to the special charge recorded in third quarter of 2004.

Outlook
We expect that market demand, government regulation and reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry resulting in further business consolidations and alliances. We participate with industry groups to promote the use of advanced medical device technology in a cost-conscious environment.

The global medical technology industry is highly competitive and is characterized by rapid product development and technological change. Our products must continually improve technologically and provide improved clinical outcomes due to the competitive nature of the industry. In addition, competitors have historically employed litigation as part of their strategy to attempt to gain a competitive advantage.

The pacemaker and ICD markets are highly competitive. There are currently three principal suppliers to these markets, including us, and each of our two principal competitors has substantially more assets and sales than we do. Rapid technological change in these markets is expected to continue, requiring us to invest heavily in R&D and to effectively market our products. Two trends began to emerge in these markets during 2002. The first involved a shift of some traditional pacemaker patients to ICD devices in the United States, and the second involved the increasing use of resynchronization devices in both the U.S. ICD and pacemaker markets. Our competitors in CRM have had approved resynchronization devices in the U.S. market during this period. We obtained U.S. regulatory approval to market our

resynchronization devices in May and June 2004. A large portion of our sales growth in CRM products in the near-term is dependent on market acceptance of our resynchronization devices.

The cardiac surgery markets, which include mechanical heart valves, tissue heart valves and valve repair products, are also highly competitive. Since 1999, cardiac surgery therapies have shifted to tissue valves and repair products from mechanical heart valves, resulting in an overall market share loss for us. Competition is anticipated to continue to place pressure on pricing and terms, including a trend toward vendor-owned (consignment) inventory at the hospitals. Also, healthcare reform is expected to result in further hospital consolidations over time with related pressure on pricing and terms.

The cardiology and vascular access therapy area is also growing and has numerous competitors. Over 70% of our sales in this area are comprised of vascular closure devices. The market for vascular closure devices is highly competitive, and there are several companies, in addition to St. Jude Medical, that manufacture and market these products worldwide. Additionally, we anticipate other large companies will enter this market in the coming years, which will likely increase competition.

We operate in an industry that is susceptible to significant product liability claims. These claims may be brought by individuals seeking relief for themselves or, increasingly, by groups seeking to represent a class. In addition, product liability claims may be asserted against us in the future relative to events that are not known to us at the present time. Our product liability insurance coverage for the period April 1, 2004 through April 1, 2005 is $425 million, with a $75 million deductible per occurrence. In light of our significant self-insured retention, our product liability insurance coverage is designed to help protect against a catastrophic claim.

Group purchasing organizations (GPOs), independent delivery networks (IDNs) and large single accounts such as the Veterans Administration (VA) in the United States continue to consolidate purchasing decisions for some of our hospital customers. We have contracts in place with many of these organizations. In some circumstances, our inability to obtain a contract with such an organization could adversely affect our efforts to sell our products to that organization s hospitals.

FINANCIAL CONDITION

Our liquidity and cash flows remained strong during the first nine months of 2004. Cash provided by operating activities was $376.9 million for the nine months ended September 30, 2004, a $51.2 million increase over the same period one year ago due primarily to increased earnings. Our ratio of current assets to current liabilities was 3.0 to 1.0 at September 30, 2004, as compared to 2.9 to 1.0 at December 31, 2003.

At September 30, 2004, we had $585.2 million of cash and equivalents, up from $461.3 million at December 31, 2003. At September 30, 2004 and December 31, 2003, substantially all of our cash and equivalents were held by our non-U.S. subsidiaries. These funds are available for use by our U.S. operations; however, assuming we accomplished a repatriation under current law by paying an intracompany dividend, the amount paid would be subject to additional U.S. taxes upon repatriation which could total as much as 33% of the amount repatriated. Recent U.S. legislation, the American Jobs Creation Act of 2004, provides for the repatriation of cash and

cash equivalents held by non-U.S. subsidiaries at a reduced tax rate. The Company is currently analyzing the impact of this legislation and believes it has the potential to repatriate up to $500 million of cash and cash equivalents held by our non-U.S. subsidiaries at a reduced tax rate.

Our capital structure consists of equity and interest-bearing debt. Our debt to total capital ratio (total interest-bearing debt as a percentage of total interest-bearing debt and equity) was 12.9% and 18.5% at September 30, 2004 and December 31, 2003, respectively. Total interest-bearing debt at September 30, 2004 was $305.7 million. Interest bearing debt decreased $58.2 million from December 31, 2003 due to excess cash generated from operations and $107.9 million of proceeds from employee stock option exercises utilized to repay interest bearing debt offset by cash utilized to fund the Epicor acquisition.

We had a short-term, unsecured bank credit agreement that provided for borrowings of up to 3.8 billion Yen. Borrowings under the short-term, bank credit agreement bore interest at the floating Yen London InterBank Offered Rate (LIBOR) plus 0.50% per annum. We repaid the remaining borrowings under this agreement in April 2004.

In May 2004, we obtained a 1.0 billion Yen credit facility that expires in June 2005. Borrowings under the credit facility bear interest at the floating Tokyo InterBank Offered Rate (TIBOR) plus 0.50% per annum. There were no outstanding borrowings under this credit facility at September 30, 2004.

We have 1.02%, unsecured Yen-denominated notes outstanding totaling 20.9 billion Yen, or $188.2 million and $194.4 million at September 30, 2004 and December 31, 2003, respectively. These notes are due in May 2010.

We have a $400 million unsecured, revolving credit facility that expires in September 2009 and a $350 million unsecured, revolving credit facility that expires in September 2008. These credit facilities bear interest at LIBOR plus 0.625% and 0.60% per annum, respectively, subject to adjustment in the event of a change in the Company s debt ratings. There were no outstanding borrowings under these credit facilities at September 30, 2004 and December 31, 2003.

We maintain a commercial paper program that allows us to issue debt securities at varying market rates with maturities up to 270 days from the date of issuance (effective rates of 1.8% and 1.2% at September 30, 2004 and December 31, 2003, respectively). Our outstanding commercial paper borrowings were $117.6 million and $157.4 million at September 30, 2004 and December 31, 2003, respectively. We classify all of our commercial paper borrowings as long-term debt on the balance sheet as we have the ability to repay any short-term maturity with available cash from our existing long-term, committed credit facility. We continually review our cash flow projections and may from time to time repay a portion of the borrowings.

Our 1.02% notes and revolving credit facilities contain various operating and financial covenants (see Note 7 to the Condensed Consolidated Financial Statements). We were in compliance with all of our debt covenants at September 30, 2004. We believe that these covenants will not have a material impact on our ability to borrow in the future.

There have been no significant changes in our contractual obligations and other commitments as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003. We have no off-balance sheet financing arrangements other than certain operating leases

as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

We believe that our existing cash balances, borrowings under our commercial paper program and/or committed credit facilities and future cash generated from operations will be sufficient to meet our working capital and capital investment needs in the next twelve months and in the foreseeable future thereafter. Should suitable investment opportunities arise, we believe that our earnings, cash flows and balance sheet will permit us to obtain additional debt financing or equity capital, if necessary.

CAUTIONARY STATEMENTS

In this discussion and in other written or oral statements made from time to time, we have included and may include statements that may constitute forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but instead represent our belief regarding future events, many of which, by their nature, are inherently uncertain and beyond our control. These statements relate to our future plans and objectives, among other things. 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.

Various factors contained in the previous discussion and those described below may affect our operations and results. We believe the most significant factors that could affect our future operations and results are set forth in the list 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.

1.

Legislative or administrative reforms to the U.S. Medicare and Medicaid systems or similar reforms of international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for such procedures. Adverse decisions relating to our products by administrators of such systems in coverage or reimbursement issues.

2. Acquisition of key patents by others that have the effect of excluding us from market segments or requiring us to pay royalties.
3. Economic factors, including inflation, changes in interest rates and changes in foreign currency exchange rates.
4. Product introductions by competitors which 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 preferences for alternate therapies.
7. Safety, performance or efficacy concerns about our marketed products, many of which are expected to be implanted for many years, leading to recalls and/or advisories with the attendant expenses and declining sales.
8. Changes in laws, regulations or administrative practices affecting government regulation of our products, such as FDA laws and regulations, that increase pre-approval testing requirements for products or impose additional burdens on the manufacture and sale of medical devices.

9. Regulatory actions arising from the concern over Bovine Spongiform Encephalopathy (BSE), sometimes referred to as mad cow disease , that have the effect of limiting the Company s ability to market products using collagen, such as Angio-Seal™, or that impose added costs on the procurement of collagen.
10. Difficulties obtaining, or the inability to obtain, appropriate levels of product liability insurance.
11. The ability of our Silzone® product liability insurers, especially Kemper, to meet their obligations to us.
12. A serious earthquake affecting our facilities in Sunnyvale or Sylmar, California, or a hurricane affecting our operations in Puerto Rico.
13. Healthcare industry consolidation leading to demands for price concessions or the exclusion of some suppliers from significant market segments.
14. Adverse developments in litigation including product liability litigation and patent litigation or other intellectual property litigation including that arising from the Telectronics and Ventritex acquisitions.
15. Enactment of a U.S. law repealing the tax benefit of the extraterritorial income exclusion.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes since December 31, 2003 in our market risk. For further information on market risk, refer to Item 7A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

Item 4. CONTROLS AND PROCEDURES

As of September 30, 2004, the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Chief Executive Officer (CEO) and Chief Financial Officer (CFO), 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 (Exchange Act)). Based on that evaluation, the CEO and CFO concluded that the Company s disclosure controls and procedures were effective as of September 30, 2004 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

During the fiscal quarter ended September 30, 2004, there were no changes in the Company s internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) 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

Silzone® Litigation: In July 1997, the Company began marketing mechanical heart valves which incorporated a Silzone® coating. The Company later began marketing heart valve repair products incorporating a Silzone® coating. The Silzone® coating was intended to reduce the risk of endocarditis, a bacterial infection affecting heart tissue, which is associated with replacement heart valves.

In January 2000, the Company voluntarily recalled all field inventories of Silzone® devices after receiving information from a clinical study that patients with a Silzone® valve had a small, but statistically significant, increased incidence of explant due to paravalvular leak compared to patients in that clinical study with non-Silzone® heart valves.

Subsequent to the Company s voluntary recall, the Company has been sued in various jurisdictions and now has cases pending in the United States, Canada, and United Kingdom by some patients who received a Silzone® device. Some of these claims allege bodily injuries as a result of an explant or other complications, which they attribute to the Silzone® devices. Others, who have not had their device explanted, seek compensation for past and future costs of special monitoring they allege they need over and above the medical monitoring all 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. Some of these cases have been settled, some have been dismissed and others are on-going. Some of these cases, both in the United States and Canada, are seeking class-action status. A summary of the number of Silzone® cases by jurisdiction as of October 22, 2004 follows:

U.S. Cases

- Multi-District Litigation (MDL) and federal district court in Minnesota:
  - Eight original class-action complaints have been consolidated into one case seeking certification of two separate classes. The first complaint seeking class-action status was served upon the Company on April 27, 2000 and all eight original complaints seeking class-action status were consolidated into one case on October 22, 2001. One proposed class in the consolidated complaint seeks injunctive relief in the form of medical monitoring. A second class in the consolidated complaint seeks an unspecified amount of monetary damages.

  - 19 individual cases are pending as of October 22, 2004 in the MDL. The first individual complaint that was transferred to the MDL court was served upon the Company on November 28, 2000, and the most recent individual complaint that was transferred to the MDL court was served upon the Company on September 15, 2004. The complaints in these cases each request damages ranging from $9.5 thousand to $120.5 million and, in some cases, seek an unspecified amount.
- 22 individual state court suits involving 30 patients are pending as of October 22, 2004. Cases are venued in the following states: California, Florida, Illinois, Minnesota, Nevada, New York, South Carolina, Tennessee, Wyoming and Texas. The first individual state court complaint was served upon the Company on March 1, 2000 and the most recent individual state court complaint was served upon the Company on September 3, 2004. The complaints in these cases each request damages ranging from $50 thousand to $100 thousand and, in some cases, seek an unspecified amount.
- A lawsuit seeking a class action for all persons residing in the European Economic Union member jurisdictions who have had a heart valve replacement and/or repair procedure using a product with Silzone® coating was filed in Minnesota state court and served upon the Company on February 11, 2004. The complaint seeks damages in an unspecified amount for the class, and in excess of $50 thousand for the representative plaintiff individually. The complaint also seeks injunctive relief in the form of medical monitoring. The Company removed this matter to the federal court in Minnesota, but the plaintiffs challenged the removal and the Court issued a ruling returning the case to Minnesota state court. The Company has filed motions in the state court seeking to have the claims dismissed.
- Two cases involving 70 patients were dismissed in Texas by the trial court on April 25, 2002 and February 14, 2003, respectively; the plaintiffs in these two cases have appealed. The first of these cases was served upon the Company on October 29, 2001, and the second case was served upon the Company on November 8, 2002. The complaints in these cases request damages in an unspecified amount.

Non-U.S. Cases

Canada:

- Four class-action cases involving five named plaintiffs and one individual case involving two named plaintiffs are pending (cases are venued in the provinces of British Columbia, Ontario and Quebec); in Ontario and Quebec the courts have certified class actions. The first complaint in Canada was served upon the Company on August 18, 2000, and the most recent Canadian complaint was served upon the Company on March 14, 2004. The complaints in these cases each request damages ranging from 1.5 million to 500 million Canadian dollars.

UK:

- Two cases involving two separate plaintiffs have been filed. The first complaint in the UK was filed on August 28, 2003, and the most recent complaint was filed on February 10, 2004. One of these two complaints has been served upon the Company. The complaints in these cases request damages of unspecified amounts.

The Silzone® litigation reserves established by the Company are not based on the amount of the claims because, based on our experience in these types of cases, the amount ultimately paid, if any, often does not bear any relationship to the amount claimed by the plaintiffs and is often significantly less than the amount claimed by the plaintiffs.

In 2001, the U.S. Judicial Panel on Multi-District Litigation ruled that certain lawsuits filed in U.S. federal district court involving products with Silzone® coating should be part of Multi-District Litigation proceedings under the supervision of U.S. District Court Judge John Tunheim in Minnesota. As a result, actions in federal court involving products with Silzone® coating have been and will likely continue to be transferred to Judge Tunheim for coordinated or consolidated pretrial proceedings.

Certain plaintiffs requested Judge Tunheim to allow some cases to proceed as class actions. Judge Tunheim issued a ruling on plaintiffs motions for class certification on March 27, 2003. In his ruling, Judge Tunheim certified one class of plaintiffs under the Minnesota Consumer Protection Statutes and conditionally certified two additional classes.

On January 5, 2004, Judge Tunheim issued further rulings concerning the classes that he had conditionally certified. More specifically, the judge declined to grant class-action status to personal injury claims; however, he granted class-action status for patients from a limited group of states to proceed with medical monitoring claims, so long as they do not have a clinical injury.

Judge Tunheim also ruled against the Company in a separate order on the issue of preemption and held that the plaintiff s causes of action were not preempted by the U.S. Food and Drug Act.

In a July 15, 2004 order, Judge Tunheim added three additional states to the limited group of states from which he determined residents with Silzone® valves could proceed with a class action involving medical monitoring claims so long as they did not have a clinical injury. In this order, the Court also indicated that the class action he certified under Minnesota s Consumer Protection Statutes should proceed. The Company sought to appeal Judge Tunheim s class certification decisions, and in a September 2, 2004 order, the appellate court indicated it would accept the appeal of Judge Tunheim s certification orders and set forth a briefing schedule for that appeal. The appellate court also indicated that it would not accept review of Judge Tunheim s decision regarding federal preemption at this time. It is not expected that the appellate court would complete its review and issue a decision concerning the appeal of the rulings regarding class certification until sometime in mid to late 2005.

In the meantime, the cases involving Silzone® products not seeking class-action status which are consolidated before Judge Tunheim are proceeding in accordance with the scheduling orders he has rendered. There are also other actions involving products with Silzone® coating in various state courts in the United States that may or may not be coordinated with the matters presently before Judge Tunheim.

On January 16, 2004, the court in Ontario, Canada issued further rulings certifying a class of Silzone® patients in a class-action suit against the Company. The Company has sought leave to appeal the Court s decision in this regard. The Court in the Province of Quebec has also certified a class action in that jurisdiction.

The Company is not aware of any unasserted claims related to Silzone® devices. Company management believes that the final resolution of the Silzone® cases will take several years. While management reviews the claims that have been asserted from time to time and periodically engages in discussions about the resolution of claims with claimants representatives, management cannot reasonably estimate at this time the time frame in which any potential settlements or judgments would be paid out. The Company accrues for contingent losses when it is probable that a loss has been incurred and the amount can be reasonably estimated. The Company has recorded an accrual for probable legal costs that it will incur to defend the various cases involving Silzone® devices, and the Company has recorded a receivable from its product liability insurance carriers for amounts expected to be recovered (see Note 6 to the Condensed Consolidated Financial Statements). The Company has not accrued for any amounts associated with probable settlements or judgments because management cannot reasonably estimate such amounts. However, management believes that no significant claims will ultimately be allowed to proceed as class actions in the United States and, therefore, that all settlements and judgments will be covered under the Company s remaining product liability insurance coverage (approximately $155.0 million as of October 22, 2004), subject to the insurance companies performance under the policies (see Note 6 to the Condensed Consolidated Financial Statements for further discussion on the Company s insurance carriers). As such, management believes that any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered by its product liability insurance policies or existing reserves will not have a material adverse effect on the Company s statement of financial position or liquidity, although such costs may be material to the Company s consolidated results of operations of a future period.

Guidant 1996 Patent Litigation: In November 1996, Guidant Corporation (Guidant) sued St. Jude Medical in federal district court for the Southern District of Indiana alleging that the Company did not have a license to certain patents controlled by Guidant covering ICD products and alleging that the Company was infringing those patents. St. Jude Medical s contention was that it had obtained a license from Guidant to the patents in issue when it acquired certain assets of Telectronics in November 1996. In July 2000, an arbitrator rejected St. Jude Medical s position, and in May 2001, a federal district court judge also ruled that the Guidant patent license with Telectronics had not transferred to St. Jude Medical.

Guidant s suit originally alleged infringement of four patents by St. Jude Medical. Guidant later dismissed its claim on one patent and a court ruled that a second patent was invalid. This determination of invalidity was appealed by Guidant, and the Court of Appeals upheld the lower court s invalidity determination. In a jury trial involving the two remaining patents (the 288 and 472 patents), the jury found that these patents were valid and that St. Jude Medical did not infringe the 288 patent. The jury also found that the Company did infringe the 472 patent, though such infringement was not willful. The jury awarded damages of $140.0 million to Guidant. In post-trial rulings, however, the judge overseeing the jury trial ruled that the 472 patent was invalid and also was not infringed by St. Jude Medical, thereby eliminating the $140.0 million verdict against the Company. The trial court also made other rulings as part of the post-trial order, including a ruling that the 288 patent was invalid on several grounds.

In August 2002, Guidant commenced an appeal of certain of the trial judge s post-trial decisions pertaining to the 288 patent. Guidant did not appeal the trial court s finding of invalidity and non-infringement of the 472 patent. As part of its appeal, Guidant requested that the monetary damages awarded by the jury pertaining to the 472 patent ($140 million) be transferred to the 288 patent infringement claim. The Company believes that such a request is not supported by the facts or law.

On August 31, 2004, a three judge panel of the Court of Appeals for the Federal Circuit (CAFC) issued a ruling on Guidant s appeal of the trial court decision concerning the 288 patent. The CAFC reversed the decision of the trial court judge that the 288 patent was invalid. The court also ruled that the trial judge s claim construction of the 288 patent was incorrect and, therefore, the jury s verdict of non-infringement was set aside. The court also ruled on other issues that were raised by the parties. The Company has requested a re-hearing of the matter by the panel and the entire CAFC court. As of October 22, 2004, no decision has been issued by the CAFC in response to the Company s rehearing requests.

While it is not possible to predict the outcome of the appeal process, the Company believes the decision of the trial court in its post-trial rulings, which is publicly available, was correct.

The 288 patent expired in December 2003. Accordingly, the final outcome of the appeal process cannot involve an injunction precluding the Company from selling ICD products in the future. Sales of the Company s ICD products which Guidant asserts infringed the 288 patent were approximately 18% of the Company s consolidated net sales during the fiscal year ended December 31, 2003.

The Company has not accrued any amounts for losses related to the Guidant 1996 patent litigation. Although the Company believes that the assertions and claims in these matters are without merit, potential losses arising from this litigation are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company.

Guidant 2004 Patent Litigation: In February 2004, Guidant sued the Company in federal district court in Delaware alleging that the Company s Epic HF ICD, Atlas®+ HF ICD and Frontier device infringe U.S Patent No. RE 38,119E (the 119 patent). Guidant also sued the Company in February 2004 alleging that the Company s QuickSite 1056K pacing lead infringes U.S. Patent No. 5,755,766 (the 766 patent). This second suit was initiated in federal district court in Minnesota. Guidant is seeking an injunction against the manufacture and sale of these devices by the Company in the United States and compensation for what it claims are infringing sales of these products up through the effective date of the injunction. At the end of the second quarter 2004, the Company received FDA approval to market these devices in the United States. The Company has not submitted a substantive response to Guidant s claims at this time. Another competitor of the Company, Medtronic, Inc., which has a license to the 119 patent, is contending in a separate lawsuit with Guidant that the 119 patent is invalid.

The Company has not accrued any amounts for losses related to the Guidant 2004 patent litigation. Potential losses arising from this litigation are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company.

Symmetry Litigation: As of October 22, 2004, there are sixteen cases in the United States pending against the Company which allege that its Symmetry Bypass System Aortic Connector (Symmetry device) caused bodily injury or might cause bodily injury. In addition, a number of persons have made a claim against the Company involving the Symmetry device without filing a lawsuit. The first lawsuit involving the Symmetry device as filed against the Company on August 5, 2003, in federal district court for the Western District of Tennessee, and the most recently initiated case was served upon the Company on September 24, 2004. The sixteen cases are venued in state court in Minnesota, federal court for the District of Minnesota, federal court in the Western District of Tennessee, federal court for the Northern District of Illinois, federal court in the Eastern District of Arkansas and federal court for the Eastern District of Pennsylvania. Each of the complaints in these cases request damages ranging from $50 thousand to $100 thousand and, in some cases, seek an unspecified amount. Four of the sixteen cases are seeking class-action status. One of the cases seeking class-action status has been dismissed, but the dismissal is being appealed by the plaintiff. In a second case seeking class action status, a Magistrate Judge has recommended that the matter not proceed as a class action, and the parties are presently awaiting the court to review the Magistrate s decision. A third case seeking class action status has been indefinitely stayed by the court, and is presently inactive. It appears that the plaintiffs in those cases seeking class-action status seek or will seek damages for injuries and monitoring costs.

The Company s Symmetry device was cleared through a 510(K) submission to the FDA, and therefore, is not eligible for the defense under the doctrine of federal preemption that such suits are prohibited. Given the Company s self-insured retention levels under its product liability insurance policies, the Company expects that it will be solely responsible for these lawsuits, including any costs of defense, settlements and judgments. Company management believes that class-action status is not appropriate for the claims asserted based on the facts and case law.

During the third quarter of 2004, the number of lawsuits involving the Symmetry device increased, and the number of persons asserting claims outside of litigation increased as well. With this background, the Company determined that it was probable that legal costs to defend the cases will be incurred and the amount of such fees was reasonably estimable. As a result, the Company recorded a pretax charge of $21.0 million in the third quarter of 2004 to reflect this liability.

Potential losses arising from settlements or judgments are possible, but not estimable, at this time. The range of such losses could be material to the operations, financial position and liquidity of the Company. The Company has not accrued for any amounts associated with probable settlements or judgments because management cannot reasonably estimate such amounts. However, management believes that no significant claims will ultimately be allowed to proceed as class actions in the United States.

Management currently believes that any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered by its reserves will not have a material adverse effect on the Company s statement of financial position or liquidity, although such costs may be material to the Company s consolidated results of operations of a future period.

Other Litigation Matters: The Company is involved in various other product liability lawsuits, claims and proceedings that arise in the ordinary course of business.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND, USE OF PROCEEDS

(a) None

(b) None

(c) In August 2004, the Company s Board of Directors authorized the repurchase of up to $300,000 of the Company s outstanding common stock. This authorization expires on December 31, 2006. The Company has not repurchased any shares of its common stock during 2004.

Item 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) *Exhibits*

Exhibit 2.1 Amended and Restated Agreement and Plan of Merger, dated as of September 29, 2004, among the Company, Dragonfly Merger Corp., and Endocardial Solutions, Inc. is incorporated by reference from Exhibit 99.1 of the Company s Current Report on Form 8-K filed on September 29, 2004.

Exhibit 4.1 Multi-Year $400,000,000 Credit Agreement, dated as of September 28, 2004, among the Company, as the Borrower, Bank of America, N.A., as Administrative Agent, L/C Issuer and Lender, the Bank of Tokyo-Mitsubishi, Ltd., as Syndication Agents, Bank One, NA, Wells Fargo Bank, N.A. and Suntrust Bank, as Co-Documentation Agents, and the other lenders party thereto.

Exhibit 31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit 32.1 Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Exhibit 32.2 Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) *Reports on Form 8-K*

The Company filed a Form 8-K on July 21, 2004 to furnish pursuant to Item 12 its press release issued on July 21, 2004 to report earnings for the second quarter of 2004.

The Company filed a Form 8-K on August 17, 2004 to furnish pursuant to Item 9 our press release issued on August 16, 2004 concerning a share repurchase program of up to $300 million of its outstanding common stock.

The Company filed a Form 8-K on September 1, 2004 to report pursuant to Item 8.01 a summary of the ruling on Guidant s appeal of the trial court decision and jury verdict on the 288 patent controlled by Guidant.

The Company filed a Form 8-K on September 3, 2004 to report pursuant to Item 8.01 a summary of the order granting St. Jude Medical, Inc. s Petition under Federal Rule of Civil Procedure 23(f) for Permission to Appeal a Class Certification Order.

The Company filed a Form 8-K on September 29, 2004 to report pursuant to Item 2.05 costs associated with exit or disposal activities to discontinue developing, manufacturing, marketing and selling its Symmetry Bypass System Aortic Connector.

The Company filed a Form 8-K on September 29, 2004 to report pursuant to Item 1.01 that the Company has signed a definitive agreement to acquire Endocardial Solutions, Inc.

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 8, 2004	/s/ John C. Heinmiller
DATE	JOHN C. HEINMILLER Executive Vice President and Chief Financial Officer (Duly Authorized Officer and Principal Financial and Accounting Officer)