Boston Scientific

Boston Scientific Announces Agreement With DOJ On Pre-Acquisition Investigation of Guidant

PRNewswire
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Nov. 6 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has reached an agreement in principle with the U.S. Department of Justice (DOJ) related to product advisories issued by its Guidant subsidiary in 2005. The alleged conduct and product sales occurred prior to Boston Scientific's 2006 acquisition of Guidant.

Boston Scientific had previously disclosed an investigation by the U.S. Attorney's Office in Minneapolis into alleged violations of the Food, Drug, and Cosmetic Act by Guidant. Under the terms of the agreement, Guidant will plead to two misdemeanor charges related to failure to include information in reports to the U.S. Food and Drug Administration (FDA), and Boston Scientific will pay $296 million on behalf of Guidant.

U.S. Generally Accepted Accounting Principles (GAAP) require that this agreement be recorded in the third quarter, as it occurred after the October 19 release of the Company's third quarter financial results and before the filing of the Company's Quarterly Report on Form 10-Q. Accordingly, the Company has updated its financial results for the third quarter and nine months ended September 30, 2009, recording a third quarter charge of $294 million, on both a pre-tax and after-tax basis. This amount represents the $296 million charge associated with the agreement net of a $2 million reversal of a related accrual.

"We are pleased this investigation has been resolved," said Ray Elliott, President and Chief Executive Officer of Boston Scientific. "Guidant and its employees acted in good faith and believed they complied with applicable laws and regulations. We elected to resolve this matter so we could put it behind us and devote our full energies and resources to developing our innovative technologies."

The only products involved in the investigation were the VENTAK PRIZM(®) 2, the CONTAK RENEWAL(®) and the CONTAK RENEWAL 2 devices, which were the subjects of the 2005 product advisories.

The table below reconciles the Company's updated third quarter and year-to-date 2009 financial results to those previously reported. The adjustments in the table are also reflected in the Company's Form 10-Q, which will be filed later today.

	Q3 2009 Results		
(in millions, except per share data)	Previously Reported	Litigation-Related Charge	As Updated
Income (loss) before income taxes	$250	$(294)	$(44)
Net income (loss)	$200	$(294)	$(94)
GAAP EPS	$0.13	$(0.19)	$(0.06)
Adjusted EPS	$0.19		$0.19

	Q3 2009 YTD Results		
(in millions, except per share data)	Previously Reported	Litigation-Related Charge	As Updated
Income before income taxes	$333	$(294)	$39
Net income	$345	$(294)	$51

GAAP EPS	$0.23	$(0.20)	$0.03
Adjusted EPS	$0.58		$0.58

In addition, the Company has updated its full-year 2009 GAAP earnings per share guidance as a result of recording this charge. The Company now expects net income on a GAAP basis of $0.23 to $0.28 per share for the full year ending December 31, 2009. The Company continues to expect adjusted earnings -- excluding intangible asset impairment charges; acquisition-, divestiture-, and litigation-related net charges; restructuring and restructuring-related costs; discrete tax items; and amortization expense -- of between $0.75 and $0.79 per share. The table below reconciles the Company's updated full-year guidance to that previously reported.

	2009 Full-year Guidance		
	Previously Reported	Litigation-Related Charge	As Updated
GAAP EPS - low	$0.43	$(0.20)	$0.23
GAAP EPS - high	$0.48	$(0.20)	$0.28
Adjusted EPS - low	$0.75		$0.75
Adjusted EPS - high	$0.79		$0.79

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding financial performance, resolution of government proceedings, regulatory compliance and product performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this

document.

Use of non-GAAP Financial Information

A reconciliation of the Company's non-GAAP financial measures to the corresponding GAAP measures, and an explanation of the Company's use of these non-GAAP measures, is included in the exhibits attached to this press release.

BOSTON SCIENTIFIC CORPORATION
NON-GAAP NET INCOME AND NET INCOME PER COMMON SHARE RECONCILIATIONS
(Unaudited)

	Three Months Ended September 30, 2009			
	Previously Reported		As Updated	
In millions, except per share data	Net income	Impact per diluted share	Net (loss) income	Impact per diluted share
GAAP results	$200	$0.13	$(94)	$(0.06)
Non-GAAP adjustments:				
Restructuring-related charges	21	0.01	21	0.01
Litigation-related net (credits) charges	(37)	(0.02)	257	0.17*
Amortization expense	107	0.07	107	0.07*
Adjusted results	$291	$0.19	$291	$0.19

* Assumes dilution of 10.9 million shares for all or a portion of these amounts.

	Nine Months Ended September 30, 2009			
	Previously Reported		As Updated	
In millions, except per share data	Net income	Impact per diluted share	Net income	Impact per diluted share
GAAP results	$345	$0.23	$51	$0.03
Non-GAAP adjustments:				
Intangible asset impairment charges	8	0.01	8	0.01
Acquisition-related charges	17	0.01	17	0.01
Divestiture-related gains	(2)	(0.00)	(2)	(0.00)
Restructuring-related charges	69	0.05	69	0.05
Litigation-related net charges	203	0.13	497	0.33
Discrete tax items	(74)	(0.05)	(74)	(0.05)
Amortization expense	312	0.20	312	0.20
Adjusted results	$878	$0.58	$878	$0.58

An explanation of the Company's use of these non-GAAP measures is provided at the end of this document.

BOSTON SCIENTIFIC CORPORATION
NON-GAAP NET INCOME AND NET INCOME PER COMMON SHARE RECONCILIATIONS
(CONT.)
(Unaudited)

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2009	
	Previously Reported	As Updated	Previously Reported	As Updated
Intangible asset impairment charges:				
Intangible asset impairment charges	$10	$10		
Less: Income tax benefit (a)	(2)	(2)		
Intangible asset impairment charges, net of tax	$8	$8		
Acquisition-related charges:				
Purchased research and development	$17	$17		
Less: Income tax benefit (a)				
Acquisition-related charges, net of tax	$17	$17		
Divestiture-related gains:				
Net gain on sale of investments (b)	$(3)	$(3)		
Less: Income tax expense (a)	1	1		
Divestiture-related gains, net of tax	$(2)	$(2)		
Restructuring-related charges:				
Restructuring charges	$9	$9	$44	$44
Restructuring-related charges (c)	19	19	50	50
	28	28	94	94
Less: Income tax benefit (a)	(7)	(7)	(25)	(25)
Restructuring-related charges, net of tax	$21	$21	$69	$69
Litigation-related net (credits) charges:				
Litigation-related credits	$(58)	$(58)	$(58)	$(58)
Litigation-related charges	294	287	581	
	(58)	236	229	523
Less: Income tax expense (benefit) (a)	21	21	(26)	(26)
Litigation-related net (credits) charges, net of tax	$(37)	$257	$203	$497
Discrete tax items:				

Discrete tax items			$(74)	$(74)
Amortization expense:				
Amortization expense	$126	$126	$381	$381
Less: Income tax benefit (a)	(19)	(19)	(69)	(69)
Amortization expense, net of tax	$107	$107	$312	$312

(a) Amounts are tax effected at the Company's effective tax rate, unless the amount is a significant unusual or infrequently occurring item in accordance with FASB Accounting Standards Codification section 740-270-30, "General Methodology and Use of Estimated Annual Effective Tax Rate."
(b) Recorded to other, net.
(c) In the third quarter of 2009, recorded $13 million to cost of products sold; $5 million to selling, general and administrative expenses; and $1 million to research and development expenses. In the third quarter of 2008, recorded $4 million to cost of products sold; $9 million to selling, general and administrative expenses; and $1 million to research and development expenses. In the first nine months of 2009, recorded $36 million to cost of products sold; $11 million to selling, general and administrative expenses; and $3 million to research and development expenses. In the first nine months of 2008, recorded $11 million to cost of products sold; $24 million to selling, general and administrative expenses; and $5 million to research and development expenses.

An explanation of the Company's use of these non-GAAP measures is provided at the end of this document

BOSTON SCIENTIFIC CORPORATION
ESTIMATED NON-GAAP NET INCOME PER COMMON SHARE RECONCILIATIONS
(Unaudited)

	2009 Estimate (Low)	2009 Estimate (High)
GAAP results	$0.23	$0.28
Estimated intangible asset impairment charges	0.01	0.01
Estimated acquisition-related net credits	(0.11)	(0.11)
Estimated restructuring-related charges	0.07	0.06
Estimated litigation-related net charges	0.33	0.33
Estimated discrete tax items	(0.05)	(0.05)
Estimated amortization expense	0.27	0.27
Adjusted results	$0.75	$0.79

An explanation of the Company's use of these non-GAAP measures is provided at the end of this document.

Use of Non-GAAP Financial Measures

To supplement Boston Scientific's condensed consolidated financial statements presented on a GAAP basis; the Company

discloses certain non-GAAP measures that exclude certain amounts, including non-GAAP net income, non-GAAP net income per share, and regional and divisional revenue growth rates that exclude the impact of foreign exchange. These non-GAAP measures are not in accordance with, or an alternative for, generally accepted accounting principles in the United States.

The GAAP measure most comparable to non-GAAP net income is GAAP net income and the GAAP measure most comparable to non-GAAP net income per share is GAAP net income per share. Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP measure are included in the accompanying schedules.

To calculate regional and divisional revenue growth rates that exclude the impact of foreign exchange, the Company converts actual current-period net sales from local currency to U.S. dollars using constant foreign exchange rates. The GAAP measure most comparable to this non-GAAP measure is growth rate percentages based on GAAP revenue. A reconciliation of this non-GAAP financial measure to the corresponding GAAP measure is included in the accompanying schedules.

Use and Economic Substance of Non-GAAP Financial Measures Used by Boston Scientific

Management uses these supplemental non-GAAP measures to evaluate performance period over period, to analyze the underlying trends in the Company's business, to assess its performance relative to its competitors, and to establish operational goals and forecasts that are used in allocating resources. In addition, management uses these non-GAAP measures to further its understanding of the performance of the Company's operating segments. The adjustments excluded from the Company's non-GAAP measures are consistent with those excluded from its reportable segments' measure of profit or loss. These adjustments are excluded from the segment measures that are reported to the Company's chief operating decision maker and are used to make operating decisions and assess performance.

The following is an explanation of each of the adjustments that management excluded as part of its non-GAAP measures for the nine months ended September 30, 2009 and 2008 and for the forecasted three month period and full year ending December 31, 2009, as well as reasons for excluding each of these individual items:

- Intangible asset impairment charges - These amounts represent non-cash write-downs of certain of the Company's intangible assets. Following the Company's acquisition of Guidant in 2006, and the related increase in the Company's debt, management has heightened its focus on cash generation and debt pay down. Management removes the impact of these charges from the Company's operating performance to assist in assessing the Company's cash generated from operations. Management believes this is a critical metric for the Company in measuring the Company's ability to generate cash and pay down debt. Therefore, these charges are excluded from management's assessment of operating performance and are also excluded from the measures management uses to set employee compensation. Accordingly, management believes this may be useful information to users of its financial statements and therefore has excluded these charges for purposes of calculating these non-GAAP measures to facilitate an evaluation of the Company's current operating performance, particularly in terms of liquidity.

- Acquisition-related net charges (credits) - These adjustments consist of purchased research and development and a gain resulting from the receipt of an acquisition-related milestone payment. Purchased research and development is a highly variable charge based on the extent and nature of external technology acquisitions during the period. The acquisition-related milestone received in the third quarter of 2008 is one of two receipts the Company expects to receive as a result of Guidant Corporation's sale of its vascular intervention and endovascular solutions businesses to Abbott Laboratories and is not indicative of future operating results. Management removes the impact of these charges (credits) from the Company's operating results to facilitate an evaluation of the Company's current operating performance and a comparison to the Company's past operating performance.

- Divestiture-related gains and losses - These amounts represent gains and losses, and related tax impacts, that the Company recognized related to the sale of non-strategic assets, including the sale of certain businesses, development programs and non-strategic investments. The sale and transfer of these non-strategic assets were substantially completed during 2008. These gains and losses are not indicative of future operating performance and are not used by management to assess operating performance. Accordingly, management excluded these amounts for purposes of calculating these

non-GAAP measures to facilitate an evaluation of the Company's current operating performance and a comparison to the Company's past operating performance.

- Restructuring and restructuring-related costs - These adjustments primarily represent severance, employee-related retention incentives, asset write-offs, accelerated depreciation, costs to transfer production lines from one facility to another, and other costs associated with the Company's Plant Network Optimization and 2007 Restructuring plans. These expenses are not indicative of the Company's on-going operating performance and are excluded by management in assessing the Company's operating performance, as well as from the Company's operating segments' measures of profit and loss used for making operating decisions and assessing performance. Accordingly, management excluded these charges for purposes of calculating these non-GAAP measures to facilitate an evaluation of the Company's current operating performance and a comparison to the Company's past operating performance.

- Litigation-related charges -These amounts represent significant charges related to litigation. During the third quarter of 2009, the Company recorded a pre-tax charge of $294 million associated with a U.S. Department of Justice investigation. Also during the third quarter of 2009, the Company recorded a pre-tax credit of $58 million associated with the reduction of previously recorded reserves related to certain other litigation matters. In addition, the Company recorded pre-tax charges of $287 million during the first quarter of 2009 and $334 million during the third quarter of 2008 associated with certain patent litigation matters. Management does not believe these items reflect expected on-going operating expenses. Accordingly, management excluded these (credits) charges for purposes of calculating these non-GAAP measures to facilitate an evaluation of the Company's current operating performance and for comparison to the Company's past operating performance.

- Discrete tax items - These items represent current period adjustments of certain tax positions, which were initially established in prior periods as a result of acquisitions or as a result of divestiture- and litigation-related charges, or restructuring and restructuring-related costs. These adjustments do not reflect expected on-going operating results. Accordingly, management excluded these amounts for purposes of calculating these non-GAAP measures to facilitate an evaluation of the Company's current operating performance and for comparison to the Company's past operating performance.

- Amortization expense - Amortization expense is a non-cash charge and does not impact the Company's liquidity or compliance with the covenants included in its debt agreements. Management removes the impact of amortization from the Company's operating performance to assist in assessing the Company's cash generated from operations. Management believes this is a critical metric for the Company in measuring the Company's ability to generate cash and pay down debt. Therefore, amortization expense is excluded from management's assessment of operating performance and is also excluded from the measures management uses to set employee compensation. Accordingly, management believes this may be useful information to users of its financial statements and therefore has excluded amortization expense for purposes of calculating these non-GAAP measures to facilitate an evaluation of the Company's current operating performance, particularly in terms of liquidity.

- Foreign exchange on net sales - The impact of foreign exchange is highly variable and difficult to predict. Accordingly, management excludes the impact of foreign exchange for purposes of reviewing regional and divisional revenue growth rates to facilitate an evaluation of the Company's current operating performance and comparison to the Company's past operating performance.

Material Limitations Associated with the Use of Non-GAAP Financial Measures

Non-GAAP net income, non-GAAP net income per diluted share, and regional and divisional revenue growth rates that exclude the impact of foreign exchange may have limitations as analytical tools, and these non-GAAP measures should not be considered in isolation from or as a replacement for GAAP financial measures. Some of the limitations associated with the use of these non-GAAP financial measures are:

- Items such as purchased research and development, gains on acquisition-related milestones and divestiture-related gains and losses reflect economic costs and benefits to the Company and are not reflected in non-GAAP net income and non-GAAP net income per diluted share.

- Items such as restructuring and restructuring-related costs, litigation-related (credits) charges, and discrete tax items that are excluded from non-GAAP net income and non-GAAP net income per diluted share can have a material impact on cash flows and GAAP net income and net income per diluted share.

- Amortization expense and intangible asset impairment charges, though not directly affecting Boston Scientific's cash flow position, represent a reduction in value of intangible assets. The expense associated with this reduction in value is not included in Boston Scientific's non-GAAP net income or non-GAAP net income per diluted share and therefore these measures do not reflect the full effect of the reduction in value of those intangible assets.

- Revenue growth rates stated on a constant currency basis, by their nature, exclude the impact of foreign exchange, which may have a material impact on GAAP net sales.

- Other companies may calculate non-GAAP net income, non-GAAP net income per diluted share, or regional and divisional revenue growth rates that exclude the impact of foreign exchange differently than Boston Scientific does, limiting the usefulness of those measures for comparative purposes.

Compensation for Limitations Associated with Use of Non-GAAP Financial Measures

Boston Scientific compensates for the limitations on its non-GAAP financial measures by relying upon its GAAP results to gain a complete picture of the Company's performance. The non-GAAP numbers focus instead upon the core business of the Company, which is only a subset, albeit a critical one, of the Company's performance.

The Company provides detailed reconciliations of each non-GAAP financial measure to its most directly comparable GAAP measure in the accompanying schedules, and Boston Scientific encourages investors to review these reconciliations.

Usefulness of Non-GAAP Financial Measures to Investors

The Company believes that presenting non-GAAP net income, non-GAAP net income per share, and regional and divisional revenue growth rates that exclude the impact of foreign exchange in addition to the related GAAP measures provides investors greater transparency to the information used by Boston Scientific management for its financial and operational decision-making and allows investors to see Boston Scientific's results "through the eyes" of management. The Company further believes that providing this information better enables Boston Scientific's investors to understand the Company's operating performance and to evaluate the methodology used by management to evaluate and measure such performance.

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