

Boston Scientific Announces Results For First Quarter 2019

MARLBOROUGH, Mass., April 24, 2019 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) generated sales of \$2.493 billion during the first quarter of 2019. This represents growth of 4.8 percent on a reported basis, 7.8 percent on an operational¹ basis and 6.3 percent on an organic² basis, all compared to the prior year period. The company reported GAAP earnings of \$424 million or \$0.30 per share (EPS), compared to GAAP earnings of \$298 million or \$0.21 per share a year ago, and achieved adjusted earnings per share of \$0.35 for the period, compared to \$0.33 a year ago.

"Our global team and differentiated portfolio enabled us to deliver good sales and earnings growth this quarter, despite some revenue softness compared to our estimates," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "With our strong pipeline and category leadership strategy, we are confident in our top tier 2019 outlook and how we can help improve outcomes for patients around the world for years to come."

First quarter financial results and recent developments:

- Reported first quarter sales of \$2.493 billion, representing an increase of 4.8 percent on a reported basis, compared to the company's guidance range of 6 to 7 percent; 7.8 percent on an operational basis; and 6.3 percent on an organic basis, compared to the company's guidance range of 7 to 8 percent, all compared to the prior year period.
- Reported GAAP earnings of \$0.30 per share compared to the company's guidance range of \$0.32 to \$0.33 per share. Achieved adjusted earnings per share of \$0.35 compared to the guidance range of \$0.35 to \$0.36 per share.
- Achieved first quarter revenue growth in all segments, compared to the prior year period:
 - MedSurg: 7.7 percent reported, 10.4 percent operational and 6.7 percent organic
 - Rhythm and Neuro: 2.8 percent reported, 5.6 percent operational and organic
 - Cardiovascular: 4.2 percent reported, 7.8 percent operational and 6.8 percent organic
- Reported the following regional revenue changes, compared to the prior year period:
 - U.S.: 7.1 percent reported and operational
 - EMEA (Europe, Middle East and Africa): (0.3) percent reported and 7.9 percent operational
 - APAC (Asia-Pacific): 5.3 percent reported and 10.1 percent operational
 - Emerging Markets³: 13.3 percent reported and 22.0 percent operational
- Received U.S. Food and Drug Administration (FDA) approval for, and commenced controlled launch in Europe of, the LOTUS Edge™ Aortic Valve System, a minimally invasive transcatheter aortic valve replacement (TAVR) technology for patients with severe aortic stenosis who are considered at high risk for surgical valve replacement via open heart surgery.
- Announced results from the VIRTUS study demonstrating the VICI VENOUS STENT™ System exhibited a primary patency rate of 84% at 12 months and a 98.5% rate of freedom from major adverse events at 30 days, with both measures surpassing the predefined efficacy and safety performance goals in patients with iliofemoral venous tract obstructions.
- Commenced enrollment of the global CLEAR-DVT study which will evaluate whether thrombectomy with the AngioJet™ ZelanteDVT™ Thrombectomy Catheter significantly reduces the two-year occurrence of post-thrombotic syndrome in patients with iliofemoral deep vein thrombosis.
- Announced results from the AF-FICIENT I study highlighting positive safety and efficacy data for the LUMINIZE™ Radiofrequency (RF) Balloon Catheter for isolation of pulmonary veins (PV) when treating patients with atrial fibrillation (AF).
- Received approval of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device from the Pharmaceuticals and Medical Devices Agency in Japan, and obtained CE Mark and initiated a limited market release for the next generation WATCHMAN FLX™ LAAC Device in Europe. Both devices are intended to reduce the risk of stroke in patients with non-valvular AF.
- Received insurance coverage from United Healthcare, the largest commercial insurer in the U.S., for the SpaceOAR™ Hydrogel, a therapy used to reduce common and debilitating side effects that men may experience after receiving prostate cancer radiotherapy.
- Commenced global commercial launch of the ORISE™ Submucosal Lifting Agent, designed for use in endoluminal surgery to lift polyps, adenomas, early-stage cancers and other gastrointestinal mucosal lesions prior to resection.
- Launched the Jagwire™ Revolution High Performance Guidewire, a low-profile guidewire offering enhanced steerability in the pancreaticobiliary system, enhancing the company's leadership in the biliary space.
- Commenced the full commercial launch of the Spectra WaveWriter™ Spinal Cord Stimulator (SCS) System in Europe.
- Completed a public offering of \$4.3 billion aggregate principal amount of senior notes, a portion of which is intended to finance the proposed acquisition of BTG plc. In late February, BTG plc announced its requisite shareholder approval for the proposed acquisition, which is expected to close mid-year.
- Following an FDA device reclassification and subsequent order for manufacturers to stop U.S. sales, the company ceased global sales and distribution of surgical mesh products indicated for transvaginal repair of pelvic organ prolapse. As a result, the company now anticipates an approximate \$30 million negative impact globally to 2019 full year revenue, including an approximate \$5 million sales return reserve recorded in the first quarter. In addition, the company recorded an approximate \$18 million charge to net income in the first quarter. Adjusted net income was negatively impacted by \$11 million in the first quarter of 2019.
- Announced plans to host and webcast investor events featuring presentations and question-and-answer sessions with members of senior management on the following dates:
 - May 9, 2019, 12:00 p.m. to 1:00 p.m. EDT, focused on the company's Cardiac Rhythm Management and Electrophysiology portfolio in connection with attendance at the 40th Annual Heart Rhythm Society Scientific Sessions in San Francisco;
 - May 20, 2019, 10:30 a.m. to 11:30 a.m. EDT, focused on the company's Endoscopy portfolio in connection with attendance at Digestive Disease Week 2019 in San Diego;
 - June 26, 2019, 7:30 a.m. to 1:00 p.m. EDT, Investor Day business review meeting in New York.

1. Operational revenue growth excludes the impact of foreign currency fluctuations.

2. Organic revenue growth excludes the impact of foreign currency fluctuations and sales from the recent acquisitions of NxThera, Inc. (NxThera), Claret Medical, Inc. (Claret) and Augmenix, Inc. (Augmenix), each with no prior year comparable sales.

3. We define Emerging Markets as the 20 countries that we believe have strong growth potential based on their economic conditions, healthcare sectors and our global capabilities. Periodically, we assess our list of Emerging Markets; effective January 1, 2019, we updated our list of Emerging Market countries. We have revised prior year amounts to the current year's presentation (as denoted with † throughout).

Net sales for the first quarter by business and region:

	Three Months Ended March 31,		Reported Basis	Less: Impact of Foreign Currency Fluctuations	Change		Organic Basis
	2019	2018			Operational Basis	Less: Impact of Recent Acquisitions	
(in millions)							

Endoscopy	\$ 440	\$ 418	5.2%	(2.9)%	8.1%	—%	8.1%
Urology and Pelvic Health	326	293	11.4%	(2.2)%	13.6%	9.0%	4.6%
MedSurg	766	711	7.7%	(2.7)%	10.4%	3.7%	6.7%
Cardiac Rhythm Management	491	493	(0.4)%	(3.0)%	2.6%	—%	2.6%
Electrophysiology	79	75	6.4%	(3.6)%	10.0%	—%	10.0%
Neuromodulation	186	169	10.5%	(1.9)%	12.4%	—%	12.4%
Rhythm and Neuro	757	736	2.8%	(2.8)%	5.6%	—%	5.6%
Interventional Cardiology	661	645	2.5%	(3.7)%	6.2%	1.4%	4.8%
Peripheral Interventions	311	288	7.9%	(3.3)%	11.2%	—%	11.2%
Cardiovascular	972	933	4.2%	(3.6)%	7.8%	1.0%	6.8%
Net Sales	\$ 2,493	\$ 2,379	4.8%	(3.0)%	7.8%	1.5%	6.3%

	Three Months Ended March 31,			Change Less: Impact of Foreign Currency Fluctuations	Operational Basis
(in millions)	2019	2018	Reported Basis		
U.S.	\$ 1,403	\$ 1,310	7.1%	—%	7.1%
EMEA	561	563	(0.3)%	(8.2)%	7.9%
APAC	437	415	5.3%	(4.8)%	10.1%
Latin America and Canada	92	91	0.3%	(7.2)%	7.5%
Net Sales	\$ 2,493	\$ 2,379	4.8%	(3.0)%	7.8%
Emerging Markets†	\$ 297	\$ 262	13.3%	(8.7)%	22.0%

Amounts may not add due to rounding. Growth rates are based on actual, non-rounded amounts and may not recalculate precisely.

Sales growth rates that exclude the impact of foreign currency fluctuations and/or the impact of recent aforementioned acquisitions are not prepared in accordance with U.S. GAAP.

Guidance for Full Year and Second Quarter 2019

The company now estimates revenue growth for the full year 2019, versus the prior year period, to be in a range of approximately 7 to 8 percent on a reported basis (compared to prior guidance of 7 to 9 percent), and a growth range of approximately 7 to 8 percent on an organic basis (compared to prior guidance of 7 to 8.5 percent). Full year organic guidance excludes the impact of foreign currency fluctuations and contribution of approximately 110 basis points from the acquisitions of NxThera, Claret and Augmenix, each with no prior period related net sales. The company now estimates income on a GAAP basis in a range of \$1.09 to \$1.13 per share (compared to prior guidance of \$1.13 to \$1.18 per share) and estimates adjusted earnings, excluding certain charges (credits), in a range of \$1.54 to \$1.58 per share (compared to prior guidance of \$1.53 to \$1.58 per share).

The company estimates revenue growth for the second quarter of 2019, versus the prior year period, to be in a range of approximately 5 to 7 percent on a reported basis and a growth range of approximately 6 to 7 percent on an organic basis. Second quarter organic guidance excludes the impact of foreign currency fluctuations and contribution of approximately 140 basis points from the acquisitions of NxThera, Claret and Augmenix, each with no prior period related net sales. The company estimates earnings on a GAAP basis in a range of \$0.23 to \$0.25 per share and adjusted earnings, excluding certain charges (credits), in a range of \$0.37 to \$0.39 per share.

Conference Call Information

Boston Scientific management will be discussing these results with analysts on a conference call today at 8:00 a.m. EDT. The company will webcast the call to interested parties through its website: www.bostonscientific.com. Please see the website for details on how to access the webcast. The webcast will be available for approximately one year on the Boston Scientific website.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for 40 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and [Facebook](#).

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend," "aiming" 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 our expected net sales, GAAP, operational and organic revenue growth rates, GAAP earnings and adjusted earnings for the second quarter and full year 2019, our financial performance, our business plans and our positioning for revenue and earnings growth. 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 risks and uncertainties, in some cases, have affected and in the future 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.

Risks and uncertainties that may cause such differences include, among other things: future economic, political, competitive, reimbursement and regulatory conditions, new product introductions and the market acceptance of those products, markets for our products, expected pricing environment, expected procedural volumes, the closing and integration of acquisitions, clinical trial results, demographic trends, intellectual property rights, litigation, financial market conditions, the execution and effect of our restructuring program, the execution and effect of our business strategy, including our cost-savings and growth initiatives and future business decisions made by us and our competitors. New risks and uncertainties may arise from time to time and are difficult to predict. 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 statement 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 press release.

Note: Amounts reported in millions within this press release are computed based on the amounts in thousands. As a result, the sum of the components reported in millions may not equal the total amount reported in millions due to rounding. Certain columns and rows within tables may not add due to the use of rounded numbers. Percentages presented are calculated from the underlying numbers in dollars.

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 financial measures, is included in the exhibits attached to this press release.

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BOSTON SCIENTIFIC CORPORATION
CONDENSED CONSOLIDATED GAAP RESULTS OF OPERATIONS
(Unaudited)

<i>in millions, except per share data</i>	Three Months Ended March 31,	
	2019	2018
Net sales	\$ 2,493	\$ 2,379
Cost of products sold	730	672
Gross profit	1,763	1,707
Operating expenses:		
Selling, general and administrative expenses	869	860
Research and development expenses	280	261
Royalty expense	16	18
Amortization expense	160	141
Intangible asset impairment charges	67	1
Contingent consideration expense (benefit)	(28)	5
Restructuring charges (credits)	6	13
Litigation-related net charges (credits)	(148)	—
	1,222	1,300
Operating income (loss)	541	407
Other income (expense):		
Interest expense	(109)	(61)
Other, net	25	(23)
Income (loss) before income taxes	457	323
Income tax expense (benefit)	33	26
Net income (loss)	\$ 424	\$ 298
Net income (loss) per common share - basic	\$ 0.31	\$ 0.22
Net income (loss) per common share - assuming dilution	\$ 0.30	\$ 0.21
Weighted-average shares outstanding		
Basic	1,387.7	1,376.5
Assuming dilution	1,408.4	1,396.8

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

<i>(in millions, except per share data)</i>	Three Months Ended March 31, 2019						
	Cost of Products Sold	SG&A Expenses	R&D Expenses	Operating Income (Loss)	Pre-Tax Income (Loss)	Net Income (Loss)	Impact per Share
GAAP net income (loss)	\$ 730	\$ 869	\$ 280	\$ 541	\$ 457	\$ 424	\$ 0.30
<i>Non-GAAP adjustments to net income (loss):</i>							
Amortization expense	—	—	—	160	161	143	0.10
Intangible asset impairment charges	—	—	—	67	67	62	0.04
Acquisition-related net charges (credits)	(13)	(12)	(8)	5	(24)	(22)	(0.02)
Restructuring and restructuring-related net charges (credits)	(4)	(2)	—	12	12	10	0.01
Litigation-related net charges (credits)	—	—	—	(148)	(148)	(127)	(0.09)
Investment impairment charges	—	—	—	—	1	1	0.00
Adjusted net income	\$ 714	\$ 855	\$ 271	\$ 638	\$ 527	\$ 490	\$ 0.35
<i>(in millions, except per share data)</i>	Three Months Ended March 31, 2018						
	Cost of Products Sold	SG&A Expenses	R&D Expenses	Operating Income (Loss)	Pre-Tax Income (Loss)	Net Income (Loss)	Impact per Share
GAAP net income (loss)	\$ 672	\$ 860	\$ 261	\$ 407	\$ 323	\$ 298	\$ 0.21
<i>Non-GAAP adjustments to net income (loss):</i>							
Amortization expense	—	—	—	141	141	119	0.08
Intangible asset impairment charges	—	—	—	1	1	1	0.00
Acquisition-related net charges (credits)	(6)	(7)	(7)	25	25	20	0.01
Restructuring and restructuring-related net charges (credits)	(7)	(8)	—	28	28	22	0.02
Investment impairment charges	—	—	—	—	5	5	0.00
Discrete tax items	—	—	—	—	—	(9)	(0.01)
Adjusted net income	\$ 659	\$ 846	\$ 254	\$ 603	\$ 524	\$ 455	\$ 0.33

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

BOSTON SCIENTIFIC CORPORATION
ESTIMATED REVENUE NON-GAAP GROWTH RATES AND NON-GAAP NET INCOME PER SHARE RECONCILIATIONS
(Unaudited)

Q2 and Full Year 2019 Estimated Revenue Growth Rates

	Q2 2019 Estimate		Full Year 2019 Estimate	
	(Low)	(High)	(Low)	(High)
Estimated GAAP sales growth	5%	7%	7%	8%
Less: Estimated impact of foreign currency fluctuations and the aforementioned acquisitions	(1)%	—%	—%	—%
Estimated sales growth, organic*				

6% 7% 7% 8%

*Q2 2019 Estimate excludes contribution of approximately 140 basis points from the aforementioned acquisitions, each with no prior year comparable sales. Full Year 2019 Estimate excludes contribution of approximately 110 basis points from the aforementioned acquisitions, each with no prior year comparable sales.

Q2 and Full Year 2019 Earnings per Share Guidance

	Q2 2019 Estimate		Full Year 2019 Estimate	
	(Low)	(High)	(Low)	(High)
GAAP results	\$ 0.23	\$ 0.25	\$ 1.09	\$ 1.13
Estimated amortization expense	0.10	0.10	0.41	0.41
Estimated intangible asset impairment charges	—	—	0.04	0.04
Estimated acquisition-related net charges (credits)	0.02	0.02	0.03	0.03
Estimated restructuring and restructuring-related net charges (credits)	0.02	0.02	0.06	0.06
Estimated litigation-related net charges (credits)	—	—	(0.09)	(0.09)
Estimated investment impairment charges	—	—	0.00	0.00
Adjusted results	\$ 0.37	\$ 0.39	\$ 1.54	\$ 1.58

Prior Guidance Estimate - Q1 2019 and Full Year 2019 Sales Growth

	Q1 2019 Estimate		Prior Full Year 2019 Estimate	
	(Low)	(High)	(Low)	(High)
Estimated GAAP sales growth	6%	7%	7%	9%
Less: Estimated impact of foreign currency fluctuations and the aforementioned acquisitions	(1)%	(1)%	—%	0.5%
Estimated sales growth, organic*	7%	8%	7%	8.5%

*Q1 2019 Estimate excluded contribution of approximately 160 basis points from the aforementioned acquisitions, each with no prior year comparable sales. Prior Full Year 2019 Estimate excluded contribution of approximately 110 basis points from the aforementioned acquisitions, each with no prior year comparable sales.

Prior Guidance Estimate - Q1 2019 and Full Year 2019 Earnings per Share

	Q1 2019 Estimate		Prior Full Year 2019 Estimate	
	(Low)	(High)	(Low)	(High)
GAAP results	\$ 0.32	\$ 0.33	\$ 1.13	\$ 1.18
Estimated amortization expense	0.10	0.10	0.40	0.40
Estimated acquisition-related net charges (credits)	0.02	0.02	0.05	0.05
Estimated restructuring and restructuring-related net charges (credits)	0.01	0.01	0.05	0.05
Estimated litigation-related net charges (credits)	(0.10)	(0.10)	(0.10)	(0.10)
Adjusted results	\$ 0.35	\$ 0.36	\$ 1.53	\$ 1.58

Use of Non-GAAP Financial Measures

To supplement our unaudited condensed consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income (earnings) and adjusted net income (earnings) per share that exclude certain amounts, operational net sales, which exclude the impact of foreign currency fluctuations and organic net sales, which exclude the impact of foreign currency fluctuations and the impact of recent aforementioned acquisitions. These non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States and should not be considered in isolation from or as a replacement for the most directly comparable GAAP financial measures. Further, other companies may calculate these non-GAAP financial measures differently than we do, which may limit the usefulness of those measures for comparative purposes.

To calculate adjusted net income (earnings) and adjusted net income (earnings) per share we exclude certain charges (credits) from GAAP net income. Amounts are presented after-tax 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." Please refer to Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report filed on Form 10-K filed with the Securities and Exchange Commission for an explanation of each of these adjustments and the reasons for excluding each item.

The GAAP financial measures most directly comparable to adjusted net income and adjusted net income per share are GAAP net income and GAAP net income per share.

To calculate operational net sales, which exclude the impact of foreign currency fluctuations, we convert actual net sales from local currency to U.S. dollars using constant foreign currency exchange rates in the current and prior period. To calculate organic net sales, we remove the impact of recent aforementioned acquisitions with no prior period related net sales from operational net sales. The GAAP financial measure most directly comparable to operational net sales and organic net sales is net sales on a GAAP basis.

Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP financial measure are included in the accompanying schedules.

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

We believe that presenting adjusted net income and adjusted net income per share, operational net sales and organic net sales, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for its operational decision-making and allows investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

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