Boston Scientific

Boston Scientific Announces Results For First Quarter 2021

MARLBOROUGH, Mass., April 28, 2021 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) generated net sales of $2.752 billion during the first quarter of 2021. This represents growth of 8.2 percent on a reported basis, 5.6 percent on an operational[1] basis and 5.9 percent on an organic[2] basis, all compared to the prior year period. The company reported GAAP net income available to common stockholders of $327 million or $0.23 per share (EPS), compared to GAAP net income of $11 million or $0.01 per share a year ago, and achieved adjusted EPS of $0.37 for the period, compared to $0.28 a year ago.

"We are pleased by the trajectory of our recovery," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "Our global team remains committed to helping patients and our customers by delivering a robust portfolio of innovative solutions, and that commitment will continue to fuel our future growth."

First quarter financial results and recent developments:

- Reported net sales of $2.752 billion, representing an increase of 8.2 percent on a reported basis, compared to the company's guidance range of 0 to 6 percent; 5.6 percent on an operational basis; and 5.9 percent on an organic basis, compared to the company's guidance range of (3) to 3 percent, all compared to the prior year period.

- Reported GAAP net income available to common stockholders of $0.23 per share compared to the company's guidance range of $0.05 to $0.11 per share. Achieved adjusted EPS of $0.37 compared to the guidance range of $0.28 to $0.34 per share.

- Achieved net sales growth in each reportable segment[4], compared to the prior year period:
  - MedSurg: 11.1 percent reported, 8.6 percent operational and 9.5 percent organic
  - Rhythm and Neuro: 6.8 percent reported, 4.0 percent operational and 1.6 percent organic
  - Cardiovascular: 10.0 percent reported, 7.4 percent operational and organic

- Achieved the following regional[5] net sales growth, compared to the prior year period:
  - U.S.: 8.6 percent reported and operational
  - EMEA (Europe, Middle East and Africa): 9.4 percent reported and 1.9 percent operational
  - APAC (Asia-Pacific): 15.6 percent reported and 9.1 percent operational
  - Emerging Markets[3]: 16.0 percent reported and 13.2 percent operational

- Received U.S. Food and Drug Administration (FDA) approval for the **TheraSphere™ Y-90 Glass Microspheres** for the treatment of patients with hepatocellular carcinoma, the most common type of primary liver cancer, and secured FDA Breakthrough Device designation for TheraSphere treatment for patients with glioblastoma, a type of brain cancer.[6]

- Received approval for the **Ranger™ Drug-Coated Balloon** from Japan's Ministry of Health, Labor and Welfare (MHLW) and initiated a full launch in the region.

- Launched **Vercise Genus™ Deep Brain Stimulation (DBS) System** in the U.S. Additionally, the system is being used with the world's first 16-channel directional leads —Cartesia™ X and HX leads—in the eXTend 3D Study in Europe.

- Commenced U.S. launch of the **WaveWriter Alpha™** portfolio of spinal cord stimulator (SCS) systems, consisting of four full-body MR conditional, Bluetooth-enabled devices, new **FAST** paresthesia-free therapy and all supported by **Cognita™ Solutions**—a suite of digital tools that helps physicians and patients navigate the pain management journey.

- Surpassed 50,000 patients worldwide treated with the **SENTINEL™ Cerebral Protection System**, the first and only FDA-cleared device to protect patients from stroke risk during transcatheter aortic valve replacement (TAVR) procedures.

- Published positive 12-month results from the PINNACLE FLX clinical trial in Circulation, demonstrating the next-generation **WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device** is a safe and effective alternative to oral anticoagulation therapy for stroke risk reduction in patients with non-valvular atrial fibrillation and increased risk of bleeding. The trial met its primary safety endpoint with a low adverse event rate of 0.5%, as well as its primary effectiveness endpoint with a 100% rate of LAA closure at 12 months.

- Presented five-year outcomes from the EFFORTLESS study, the largest post-market registry of the **Subcutaneous Implantable Defibrillator (S-ICD) System**, further validating the long-term efficacy of the device. Results demonstrated 98% overall efficacy over five years, consistent with results of previous S-ICD studies and comparable to or higher than many large transvenous ICD studies.

- Received FDA approval to modify the design of the ACURATE IDE trial—evaluating the **ACURATE neo2™ Aortic Valve System**—to an "all-risk" protocol to study patients with severe, symptomatic aortic stenosis who are at low risk of open-heart surgery, in addition to those at intermediate, high and extreme risk.

- Initiated the NEwTON AF IDE clinical trial to evaluate the safety and effectiveness of the **INTELLANAV STABLEPOINT™ Ablation Catheter** enabled with **DIRECTSENSE™ Technology** in patients with paroxysmal atrial fibrillation.

- Named eighth on the *Forbes* list of America's Best Employers for Diversity 2021, based on a survey of 50,000 Americans working for businesses with at least 1,000 employees.

- Completed the acquisition of Preventice Solutions, Inc., a privately-held company which offers a full portfolio of mobile cardiac health solutions and services, for an upfront cash payment of ~$720 million, with up to an additional ~$230 million in a potential commercial milestone payment, given a preexisting 22 percent equity stake.

- Completed the sale of the BTG Specialty Pharmaceuticals business to Stark International Lux S.A.R.L. and SERB SAS, affiliates of SERB, for ~$800 million in cash.

- Announced a definitive agreement with an affiliate of Baring Private Equity Asia to acquire the global surgical business of Lumenis LTD., a privately-held company that develops and commercializes energy-based medical solutions, for an upfront cash payment of ~$1.07 billion, subject to customary closing conditions and adjustments.

- Announced plans to host a virtual Investor Day business review meeting for the investment community on Wednesday, September 22, 2021.

1. Operational net sales growth excludes the impact of foreign currency fluctuations.
2. Organic net sales growth excludes the impact of foreign currency fluctuations and net sales from the recent acquisition of Preventice Solutions, Inc. (Preventice). Organic net sales growth rates also exclude the intrauterine health franchise, which we divested in Q2 2020 and the Specialty Pharmaceuticals business, which we divested in Q1 2021.
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 countries, and effective January 1, 2021, modified our list to include the following countries: Brazil, Chile, China, Colombia, Czech Republic, India, Indonesia, Malaysia, Mexico, Philippines, Poland, Russia, Saudi Arabia, Slovakia, South Africa, South Korea, Taiwan, Thailand, Turkey and Vietnam. We have revised prior year amounts to conform to the current year's presentation. The revision had an immaterial impact on previously reported Emerging Markets net sales.
4. We have three historical reportable segments comprised of Medical Surgical (MedSurg), Rhythm and Neuro, and Cardiovascular, which represent an aggregation of our operating segments that generate revenues from the sale of medical devices (Medical Devices).
5. On March 1, 2021, we completed the sale of the Specialty Pharmaceuticals business. Our consolidated net sales include Specialty Pharmaceuticals up to the date of the closing of the transaction. Specialty Pharmaceuticals net sales were substantially U.S. based and presented as a stand-alone operating segment alongside our Medical Device Reportable segments.
6. Consistent with Section 515B of the FD&C Act, devices designated as Breakthrough Devices will receive prioritized review (Section II.F).

Net sales for the first quarter by business and region:

	Three Months Ended March 31,		Change				
(in millions)	2021	2020	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis	Less: Impact of Recent Acquisitions / Divestitures	Organic Basis
Endoscopy	$ 499	$ 442	12.9%	3.0%	9.9%	—%	9.9%
Urology and Pelvic Health	361	332	8.7%	1.9%	6.8%	(2.0)%	8.8%
MedSurg	**860**	**774**	**11.1%**	**2.5%**	**8.6%**	**(0.9)%**	**9.5%**
Cardiac Rhythm Management	469	437	7.4%	2.9%	4.4%	3.9%	0.5%
Electrophysiology	83	74	11.9%	4.2%	7.7%	—%	7.7%
Neuromodulation	198	191	3.5%	1.8%	1.7%	—%	1.7%
Rhythm and Neuro	**750**	**703**	**6.8%**	**2.8%**	**4.0%**	**2.4%**	**1.6%**
Interventional Cardiology	696	633	9.9%	2.7%	7.1%	—%	7.1%
Peripheral Interventions	433	392	10.3%	2.6%	7.7%	—%	7.7%
Cardiovascular	**1,129**	**1,026**	**10.0%**	**2.7%**	**7.4%**	**—%**	**7.4%**
Medical Devices[4]	**2,739**	**2,502**	**9.5%**	**2.7%**	**6.8%**	**0.4%**	**6.4%**
Specialty Pharmaceuticals[5]	**13**	**41**	**(67.5)%**	**0.5%**	**(68.0)%**	**(23.6)%**	**(44.4)%**
Net Sales	**$ 2,752**	**$ 2,543**	**8.2%**	**2.6%**	**5.6%**	**(0.3)%**	**5.9%**

	Three Months Ended March 31,		Change		
(in millions)	2021	2020	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis
U.S.	$ 1,577	$ 1,452	8.6%	—%	8.6%
EMEA	604	552	9.4%	7.5%	1.9%
APAC	473	409	15.6%	6.5%	9.1%
Latin America and Canada	85	89	(3.8)%	(1.6)%	(2.2)%
Medical Devices[4]	**2,739**	**2,502**	**9.5%**	**2.7%**	**6.8%**
Specialty Pharmaceuticals[5]	**13**	**41**	**(67.5)%**	**0.5%**	**(68.0)%**
Net Sales	**$ 2,752**	**$ 2,543**	**8.2%**	**2.6%**	**5.6%**
Emerging Markets[3]	**$ 317**	**$ 273**	**16.0%**	**2.8%**	**13.2%**

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

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

Guidance for Full Year and Second Quarter 2021

The company now estimates net sales growth for the full year 2021, versus the prior year period, to be in a range of approximately 16 to 19 percent on a reported basis, and

approximately 15 to 18 percent on an organic basis. Full year organic net sales guidance excludes the impact of foreign currency fluctuations and the acquisition of Preventice Solutions, Inc., with no prior period related net sales, as well as the intrauterine health franchise, which we divested in Q2 2020 and the Specialty Pharmaceuticals business, which we divested in Q1 2021. The company now estimates earnings on a GAAP basis in a range of $0.81 to $0.88 per share and estimates adjusted earnings, excluding certain charges (credits), of $1.53 to $1.60 per share.

The company estimates net sales growth for the second quarter of 2021, versus the prior year period, to be in a range of approximately 46 to 50 percent on a reported basis and approximately 44 to 48 percent on an organic basis. Second quarter organic net sales guidance excludes the impact of foreign currency fluctuations and the acquisition of Preventice, with no prior period related net sales, as well as the intrauterine health franchise, which we divested in Q2 2020 and the Specialty Pharmaceuticals business, which we divested in Q1 2021. The company estimates earnings on a GAAP basis in a range of $0.16 to $0.18 per share and adjusted earnings, excluding certain charges (credits), of $0.36 to $0.38 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. ET. 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 more than 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" 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 2021; our financial performance; our business plans and product performance; and the impact of the COVID-19 pandemic on the company's results of operations. 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, political, 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 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
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

in millions, except per share data	Three Months Ended March 31, 2021	2020
Net sales	$ 2,752	$ 2,543
Cost of products sold	894	806
Gross profit	1,858	1,737
Operating expenses:		
Selling, general and administrative expenses	1,019	978
Research and development expenses	276	300
Royalty expense	12	12
Amortization expense	185	201
Intangible asset impairment charges	—	198
Contingent consideration net expense (benefit)	(6)	(108)
Restructuring net charges (credits)	5	10
Litigation-related net charges (credits)	4	—
Gain on disposal of business	(6)	—
	1,488	1,591
Operating income (loss)	370	146
Other income (expense):		
Interest expense	(82)	(88)
Other, net	37	(36)
Income (loss) before income taxes	325	22

Income tax (benefit) expense		(16)		12
Net income (loss)	$	341	$	11
Preferred stock dividends		(14)		—
Net income (loss) available to common stockholders	**$**	**327**	**$**	**11**
Net income (loss) per common share - basic	**$**	**0.23**	**$**	**0.01**
Net income (loss) per common share - assuming dilution	**$**	**0.23**	**$**	**0.01**
Weighted-average shares outstanding				
Basic		1,418.7		1,397.4
Assuming dilution		1,430.8		1,413.5

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

	Three Months Ended March 31, 2021								
(in millions, except per share data)	**Gross Profit**	**Operating Expenses**	**Operating Income (Loss)**	**Other Income (Expense)**	**Income (Loss) Before Income Taxes**	**Net Income (Loss)**	**Preferred Stock Dividends**	**Net Income (Loss) Available to Common Stockholders**	**Impact per Share [1]**
Reported	**$ 1,858**	**$ 1,488**	**$ 370**	**$ (45)**	**$ 325**	**$ 341**	**$ (14)**	**$ 327**	**$ 0.23**
Non-GAAP adjustments:									
Amortization expense	—	(185)	185	—	185	167	—	167	0.12
Acquisition / divestitures-related net charges (credits)	14	(37)	50	(198)	(148)	(153)	—	(153)	(0.11)
Restructuring and restructuring-related net charges (credits)	18	(31)	49	—	49	44	—	44	0.03
Litigation-related net charges (credits)	—	(4)	4	—	4	4	—	4	0.00
Investment portfolio net losses (gains)	—	—	—	146	146	112	—	112	0.08
EU MDR implementation costs	7	(3)	11	—	11	10	—	10	0.01
Deferred tax expenses (benefits)	—	—	—	—	—	17	—	17	0.01
Discrete tax items	—	—	—	—	—	(3)	—	(3)	(0.00)
Adjusted	**$ 1,897**	**$ 1,228**	**$ 669**	**$ (97)**	**$ 572**	**$ 538**	**$ (14)**	**$ 524**	**$ 0.37**

(1) For the three months ended March 31, 2021, the effect of assuming the conversion of Mandatory Convertible Preferred Stock (MCPS) into shares of common stock was anti-dilutive, and therefore excluded from the calculation of EPS. Accordingly, GAAP net income and adjusted net income were reduced by cumulative Preferred stock dividends, as presented in our unaudited consolidated statements of operations, for purposes of calculating net income available to common stockholders.

	Three Months Ended March 31, 2020								
(in millions, except per share data)	**Gross Profit**	**Operating Expenses**	**Operating Income (Loss)**	**Other Income (Expense)**	**Income (Loss) Before Income Taxes**	**Net Income (Loss)**	**Preferred Stock Dividends**	**Net Income (Loss) Available to Common Stockholders**	**Impact per Share**
Reported	**$ 1,737**	**$ 1,591**	**$ 146**	**$ (124)**	**$ 22**	**$ 11**	**$ —**	**$ 11**	**$ 0.01**
Non-GAAP adjustments:									
Amortization expense	—	(201)	201	—	201	180	—	180	0.13
Intangible asset impairment charges	—	(198)	198	—	198	168	—	168	0.12
Acquisition / divestitures-related net charges (credits)	37	69	(32)	9	(23)	(36)	—	(36)	(0.03)
Restructuring and restructuring-related net charges (credits)	15	(15)	30	—	30	25	—	25	0.02
EU MDR implementation costs	4	(1)	5	—	5	5	—	5	0.00
Deferred tax expenses (benefits)	—	—	—	—	—	26	—	26	0.02
Discrete tax items	—	—	—	—	—	13	—	13	0.01
Adjusted	**$ 1,794**	**$ 1,245**	**$ 549**	**$ (115)**	**$ 434**	**$ 391**	**$ —**	**$ 391**	**$ 0.28**

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

BOSTON SCIENTIFIC CORPORATION
Q2 and FY 2021 GUIDANCE
RECONCILIATIONS
(Unaudited)

Net Sales

	Q2 2021 Estimate		Full Year 2021 Estimate	
	(Low)	**(High)**	**(Low)**	**(High)**
Estimated GAAP sales growth	46%	50%	16%	19%
Less: Estimated impact of foreign currency fluctuations	4%	4%	2%	2%
Estimated sales growth, operational	42%	46%	14%	17%
Less: Estimated impact of recent acquisitions / divestitures	(2)%	(2)%	(1)%	(1)%
Estimated sales growth, organic	44%	48%	15%	18%

Earnings per Share

	Q2 2021 Estimate		Full Year 2021 Estimate	
	(Low)	(High)	(Low)	(High)
GAAP results	**$ 0.16**	**$ 0.18**	**$ 0.81**	**$ 0.88**
Estimated amortization expense	0.11	0.11	0.45	0.45
Estimated acquisition / divestitures-related net charges (credits)	0.03	0.03	(0.04)	(0.04)
Estimated restructuring and restructuring-related net charges (credits)	0.04	0.04	0.13	0.13
Estimated other adjustments	0.03	0.03	0.19	0.19
Adjusted results	**$ 0.36**	**$ 0.38**	**$ 1.53**	**$ 1.60**

Use of Non-GAAP Financial Measures

To supplement our unaudited consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income (loss), adjusted net income (loss) available to common stockholders and adjusted net income (loss) per share (EPS) 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 and divestitures. 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 (loss), adjusted net income (loss) available to common stockholders and adjusted net income (loss) per share we exclude certain charges (credits) from GAAP net income and GAAP net income available to common stockholders. 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 or any Quarterly Report on Form 10-Q that we file thereafter 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 (loss), adjusted net income (loss) available to common stockholders and adjusted net income (loss) per share are GAAP net income (loss), GAAP net income (loss) available to common stockholders and GAAP net income (loss) per common share - assuming dilution, respectively.

To calculate operational net sales growth rates, 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 periods. To calculate organic net sales growth rates, we also remove the impact of recent aforementioned acquisitions and divestitures with less than a full period of comparable 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. 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 (loss), adjusted net income (loss) available to common stockholders, adjusted net income (loss) 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.

SOURCE Boston Scientific Corporation
