Boston Scientific Announces Results For Second Quarter 2020

MARLBOROUGH, Mass., July 29, 2020 / PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) generated sales of \$2.003 billion during the second quarter of 2020. This represents a decline of (23.9) percent on a reported basis, (23.1) percent on an operational basis and (28.7) percent on an organic basis, all compared to the prior year period. The company reported a GAAP loss of \$147 million or \$(0.11) per share (EPS), compared to GAAP earnings of \$154 million or \$0.11 per share a year ago, and achieved adjusted earnings per share of \$0.08 for the period, compared to \$0.39 a year ago.

"We remain focused on the safety of our team, our customers and the patients they serve, and were pleased to see the business recovering over the course of the quarter," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "With a strong pipeline of differentiated products and an agile global team, we'll continue to execute on our strategy and make prudent decisions to position us for success as deferred procedures resume."

Second quarter financial results and recent developments:

- Reported a GAAP loss of \$(0.11) per share. Achieved adjusted earnings per share of \$0.08. The company did not provide second quarter sales and EPS guidance due to ongoing uncertainty associated with the scope and duration of the COVID-19 pandemic.
- Second quarter sales declined in each of our reportable segments, compared to the prior year period:
 - MedSurg: (29.6) percent reported, (29.1) percent operational and (28.4) percent organic
 - Rhythm and Neuro: (33.2) percent reported, (32.7) percent operational and (33.4) percent organic
 - Cardiovascular: (18.7) percent reported, (17.6) percent operational and (25.3) percent organic
- Second quarter regional⁵ sales declined, compared to the prior year period:
 - U.S.: (28.4) percent reported and operational
 - EMEA (Europe, Middle East and Africa): (27.2) percent reported and (25.6) percent operational
 - APAC (Asia-Pacific): (14.8) percent reported and (14.0) percent operational
 - Emerging Markets³: (19.7) percent reported and (14.6) percent operational
- Received U.S. Food and Drug Administration (FDA) approval for the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device which is indicated to reduce the risk of stroke in patients with non-valvular atrial fibrillation. This next-generation implant is the first LAAC device that can be fully recaptured, repositioned and redeployed in the left atrial appendage, with additional design features to enhance safety and performance while treating a wider range of patient anatomies than the previous WATCHMAN LAAC device.
- Received FDA approval for the SYNERGY™ XD Bioabsorbable Polymer (BP) Drug-Eluting Stent (DES) System, the next-generation SYNERGY BP-DES
 platform with the only 48 mm length DES available in the U.S. and enhanced deliverability features to enable improved arterial navigation in percutaneous
 coronary intervention (PCI) cases. The system was recently launched in Japan following approval from the Japanese Pharmaceuticals and Medical Devices
 Agency (PMDA).
- Received FDA 510(k) clearance and began limited market release for the LUX-Dx™ Insertable Cardiac Monitor (ICM) System, a new, long-term diagnostic device implanted in patients to detect arrythmias associated with conditions such as atrial fibrillation (AF), cryptogenic stroke and syncope. The LUX-Dx ICM System can be programmed remotely and have settings adjusted without requiring patients to visit their physician's office and is designed with a dual-stage algorithm that detects and then verifies potential arrhythmias before an alert is sent to clinicians.
- Received approval for the Eluvia™ Drug-Eluting Vascular Stent System from China's Center for Medical Device Evaluation and will begin a limited market release by the end of the year. Also announced results of a sub-study of patients from the IMPERIAL trial who were treated with the Eluvia stent during the 2020 Vascular Interventional Advances (VIVA) Late-Breaking Clinical Trials Livestream event. Data demonstrated the Eluvia stent offers durable and consistent results in complex and long lesions, with an average lesion length of 162.8 mm and that patients treated with the Eluvia stent had a 77.2% Kaplan-Meier primary patency rate, a 13.6% clinically-driven target lesion revascularization rate and no stent thrombosis, despite long, heavily calcified lesions.
- Received CE Mark and began limited European release for theINTELLANAV STABLEPOINT™ Ablation Catheter enabled with DIRECTSENSE™ Technology.
 This first-of-its-kind catheter combines measures of mechanical contact, or contact force, with local impedance to provide insight into the cardiac tissue's response to ablation
- Received Centers for Medicare & Medicaid Services (CMS) approval for a new transitional pass-through (TPT) payment category to describe single-use
 endoscopes, including the EXALT™ Model D Single-Use Duodenoscope, to facilitate Medicare beneficiary access to the advantages of new and innovative
 devices by allowing for adequate payment while cost data is collected, starting July 1, 2020. The EXALT™ duodenoscope is the world's first and only single-use,
 flexible duodenoscope cleared by the U.S. Food and Drug Administration (FDA), which eliminates the risk of infection from inadequate scope reprocessing
 between procedures.
- Presented positive findings from the largest reported clinical experience to date with the LOTUS EdgeTM Aortic Valve System at TVT Connect. Data from a prespecified interim analysis of the first 50 patients enrolled in the European RESPOND EDGE post-market registry demonstrated no reports of mortality, no repeat procedures for valve-related dysfunction or re-hospitalization for valve-related symptoms and excellent valve hemodynamics, the lowest PVL rates in this valve category and a reduced permanent pacemaker implantation rate in line with competitive valves in real-world experience.
- Commenced enrollment of the FROZEN-AF investigational device exemption (IDE) clinical trial which will evaluate the safety and effectiveness of the POLARXTM Cryoablation System for the treatment of paroxysmal atrial fibrillation (AF), an intermittent form of AF which causes an irregular and often abnormally fast heart rate.
- Announced at HRS 2020 Science final results from the UNTOUCHED study of the EMBLEM™ Subcutaneous Implantable Defibrillator (S-ICD) System, the only FDA-approved implantable defibrillator without wires touching the heart, demonstrating high efficacy and safety of the device and a lower rate of inappropriate shock than many similar devices. Also presented as a late-breaking clinical trial at the virtual meeting were results from the investigator-sponsored PRAETORIAN trial confirming that the S-ICD can be the preferred therapy choice for the majority of ICD-indicated patients without a need for pacing.
- Published a meta-analysis of 1,011 prostate cancer patients in The Journal of the American Medicine Association (JAMA) Network Open which found that placing
 SpaceOAR Hydrogel® before radiation is an effective preventative strategy to reduce treatment-induced rectal complications. Each year, more than 1.1 million

men are diagnosed with prostate cancer worldwide and approximately 400,000 men will undergo prostate radiotherapy. Recently, SpaceOAR surpassed 100,000 patients treated worldwide.

- Announced The Lancet Neurology publication of the INTREPID study—a double-blind, randomized study evaluating the Vercise™ Deep Brain Stimulation
 (DBS) system for Parkinson's disease. One-year results demonstrated a significant 51% improvement in motor symptoms (UDPRS III scores) compared to presurgery screening and six additional hours of ON time or daily symptom control over medication.
- Launched a multi-year program to combat racism, inequity and injustice, including\$3.5 million in philanthropic commitments, focused on five pillars: community, economic empowerment, education, healthcare disparities and government/legislative change.
- Increased financial flexibility by completing a public offering of\$1.7 billion aggregate principal amount of Senior Notes, as well as completing an approximately
 \$2.0 billion public offering of common stock and mandatory convertible preferred stock, and using a portion of the proceeds of both offerings to repay borrowings under our revolving credit facility and a significant portion of our pre-payable bank debt.
- 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 Vertiflex, Inc. and BTG plc (BTG), each with no prior year comparable sales. Organic revenue growth also excludes the impact of the divestiture of our global embolic microspheres portfolio, a transaction entered into in connection with obtaining the antitrust clearances required to complete the BTG transaction, as well as the Q2 divestiture of our intrauterine health franchise
- 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.
- 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). As part of our acquisition of BTG on August 19, 2019, we acquired an Interventional Medicine business, which is now included in our Peripheral Interventions operating segment's revenues from the date of acquisition.
- 5. As part of our acquisition of BTG on August 19, 2019, we acquired a specialty pharmaceuticals business (Specialty Pharmaceuticals). Subsequent to acquisition, Specialty Pharmaceuticals is now a stand-alone operating segment presented alongside our Medical Device reportable segments. Specialty Pharmaceuticals net sales are substantially U.S. based. Our chief operating decision maker (CODM) reviews financial information of our globally managed Specialty Pharmaceuticals operating segment at the worldwide level without further disaggregation into regional results. As such, Specialty Pharmaceuticals net sales are presented globally, and our Medical Devices reportable segments regional net sales results do not include Specialty Pharmaceuticals.

Net sales for the second quarter by business and region:

							Change		
	Т	hree Moi Jun	nths e 30			Less: Impact of Foreign		Less: Impact of Recent	
(in millions)	2	2020	:	2019	Reported Basis	Currency Fluctuations	Operational Basis	Acquisitions / Divestitures	Organic Basis
Endoscopy	\$	348	\$	470	(26.0)%	(0.5)%	(25.5)%	—%	(25.5)%
Urology and Pelvic Health		228		348	(34.5)%	(0.4)%	(34.1)%	(1.7)%	(32.4)%
MedSurg		576		818	(29.6)%	(0.5)%	(29.1)%	(0.7)%	(28.4)%
Cardiac Rhythm Management		351		498	(29.4)%	(0.6)%	(28.8)%	—%	(28.8)%
Electrophysiology		51		84	(39.2)%	(0.3)%	(38.9)%	—%	(38.9)%
Neuromodulation		122		204	(40.0)%	(0.3)%	(39.7)%	2.9%	(42.6)%
Rhythm and Neuro		525		786	(33.2)%	(0.5)%	(32.7)%	0.7%	(33.4)%
Interventional Cardiology		495		706	(29.9)%	(1.1)%	(28.8)%	—%	(28.8)%
Peripheral Interventions		340		320	6.0%	(1.0)%	7.0%	24.4%	(17.4)%
Cardiovascular		834		1,026	(18.7)%	(1.1)%	(17.6)%	7.7%	(25.3)%
Medical Devices ⁴		1,935		2,631	(26.5)%	(0.8)%	(25.7)%	3.0%	(28.7)%
Specialty Pharmaceuticals ⁵		68		n/a	n/a	n/a	n/a	n/a	n/a
Net Sales	\$	2,003	\$	2,631	(23.9)%	(0.8)%	(23.1)%	5.6%	(28.7)%

					Change	
	Three Montl June	-	ed		Less: Impact of Foreign	
(in millions)	2020	2	2019	Reported Basis	Currency Fluctuations	Operational Basis
U.S.	\$ 1,058	\$	1,478	(28.4)%	—%	(28.4)%
EMEA	416		571	(27.2)%	(1.6)%	(25.6)%
APAC	410		481	(14.8)%	(0.8)%	(14.0)%
Latin America and Canada	51		101	(49.4)%	(6.3)%	(43.1)%
Medical Devices ⁴	1,935		2,631	(26.5)%	(0.8)%	(25.7)%
Specialty Pharmaceuticals ⁵	68		n/a	n/a	n/a	n/a
Net Sales	\$ 2,003	\$	2,631	(23.9)%	(0.8)%	(23.1)%
Emerging Markets ³	\$ 255	\$	318	(19.7)%	(5.1)%	(14.6)%

Sales 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.

Conference Call Information

Boston Scientific management will be discussing these results with analysts on a conference call today at8:00 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" 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 business plans and product performance, and the impact of the COVID-19 outbreak 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 document.

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)

	Three Mo Ju	Six Months Ended June 30,				
in millions, except per share data	2020	2019	2020	2019		
Net sales	\$ 2,003	\$ 2,631	\$ 4,546	\$ 5,124		
Cost of products sold	791	758	1,596	1,488		
Gross profit	1,212	1,873	2,950	3,636		
Operating expenses:						
Selling, general and administrative expenses	798	968	1,776	1,837		
Research and development expenses	242	280	542	559		
Royalty expense	8	17	20	32		
Amortization expense	197	161	398	321		
ntangible asset impairment charges	34	37	233	105		
Contingent consideration expense (benefit)	_	10	(108)	(18)		
Restructuring charges (credits)	3	1	13	7		
Litigation-related net charges (credits)	_	15	_	(133)		
	1,283	1,489	2,875	2,711		
Operating income (loss)	(71)	384	75	925		
Other income (expense):						
nterest expense	(91)	(89)	(179)	(198)		
Other, net	(18)	(150)	(54)	(125)		

Income (loss) before income taxes Income tax expense (benefit)		(181) (33)		145 (9)		(159) (22)		602 24	
Net income (loss)	\$	(147)	\$	154	\$	(137)	\$	578	
Preferred stock dividends		(5)		_		(5)		_	
Net income (loss) available to common stockholders	\$	(153)	\$	154	\$	(142)	\$	578	
Net income (loss) per common share - basic Net income (loss) per common share - assuming dilution		(0.11) (0.11)	\$ \$	0.11 0.11	\$ \$	(0.10) (0.10)	\$ \$	0.42 0.41	
Weighted-average shares outstanding Basic Assuming dilution		1,410.9 1,410.9		,391.0 ,408.6		1,404.1 1,404.1		,389.4 ,408.5	

BOSTON SCIENTIFIC CORPORATION

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

	Three Months Ended June 30, 2020													
(in millions, except per share data)		Gross Profit		Operating Expenses		Operating Income (Loss)		Other Income (Expense)		ome (Loss) Before ome Taxes	Net Income			npact per Share ⁽¹⁾
Reported	\$	1,212	\$	1,283	\$	(71)	\$	(110)	\$	(181)	\$	(153)	\$	(0.11)
Non-GAAP adjustments:														
Amortization expense		_		(197)		197		_		197		177		0.12
Intangible asset impairment charges		_		(34)		34		_		34		27		0.02
Acquisition / divestitures-related net charges (credits)		30		(31)		61		(1)		60		50		0.04
Restructuring and restructuring-related net charges (credits)		16		(7)		23		_		23		20		0.01
EU MDR implementation costs		5		(2)		7		_		7		6		0.00
Deferred tax expenses (benefits)		_		_		_		_		_		(18)		(0.01)
Discrete tax items		_		_		_		_				11		0.01
Adjusted	\$	1,263	\$	1,012	\$	252	\$	(111)	\$	141	\$	120	\$	0.08

⁽¹⁾ Assumes dilution of 12.6 million shares for all or a portion of the non-GAAP adjustments

^{*} Net income (loss) available to common stockholders

	Three Months Ended June 30, 2019													
(in millions, except per share data)		Gross Profit		Operating Expenses		Operating Income (Loss)		Other Income (Expense)		ome (Loss) Before ome Taxes	Net Income		lm	npact per Share
Reported	\$ 1,8	373	\$	1,489	\$	384	\$	(239)	\$	145	\$	154	\$	0.11
Non-GAAP adjustments:														
Amortization expense		_		(161)		161		1		162		144		0.10
Intangible asset impairment charges		_		(37)		37		_		37		35		0.02
Acquisition-related net charges (credits)		19		(45)		64		161		225		177		0.13
Restructuring and restructuring-related net charges (credits)		6		(5)		11		_		11		10		0.01
Litigation-related net charges (credits)		_		(15)		15		_		15		12		0.01
Investment impairment charges		_		· —		_		1		1		1		0.00
Discrete tax items		_		_		_		_		_		18		0.01
Adjusted	\$ 1,8	397	\$	1,226	\$	672	\$	(76)	\$	596	\$	550	\$	0.39

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

BOSTON SCIENTIFIC CORPORATION

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

						Six Mon	iths	Ended Ju	ne 30	, 2020				
in millions, except per share data				perating xpenses	Operating Income (Loss)		Other Income (Expense)		Income (Loss) Before Income Taxes			Net Income (Loss)*		npact per Share ⁽¹⁾
Reported	\$	2,950	\$	2,875	\$	75	\$	(234)	\$	(159)	\$	(142)	\$	(0.10)
Non-GAAP adjustments:														
Amortization expense		_		(398)		398		_		398		356		0.25
Intangible asset impairment charges		_		(233)		233		_		233		195		0.14
Acquisition / divestitures-related net charges (credits)		67		38		29		8		37		13		0.01
Restructuring and restructuring-related net charges (credits)		32		(22)		53		_		53		45		0.03
EU MDR implementation costs		9		(3)		12		_		12		11		0.01
Deferred tax expenses (benefits)		_		_				_		_		8		0.01
Discrete tax items		_		_		_		_		_		24		0.02
Adjusted	\$	3,057	\$	2,257	\$	801	\$	(226)	\$	575	\$	511	\$	0.36

⁽¹⁾ Assumes dilution of 14.4 million shares for all or a portion of the non-GAAP adjustments

^{*} Net income (loss) available to common stockholders

	Six Months Ended June 30, 2019													
in millions, except per share data		Gross Profit	Operating Expenses		perating Income (Loss)	Other Income (Expense)		ome (Loss) Before ome Taxes		Income Loss)	lm	pact per Share		
Reported	\$	3,636	\$ 2,711	\$	925	\$ (323)	\$	602	\$	578	\$	0.41		
Non-GAAP adjustments:														
Amortization expense		_	(321)		321	2		323		287		0.20		
Intangible asset impairment charges		_	(105)		105	_		105		97		0.07		
Acquisition / divestitures-related net charges (credits)		31	(38)		69	132		201		155		0.11		
Restructuring and restructuring-related net charges (credits)		10	(14)		23	_		23		19		0.01		
Litigation-related net charges (credits)		_	133		(133)	_		(133)		(116)		(80.0)		
Investment impairment charges		_	_			2		2		2		0.00		
Discrete tax items		_			_	_				18		0.01		
Adjusted	\$	3,677	\$ 2,367	\$	1,310	\$ (187)	\$	1,123	\$	1,040	\$	0.74		

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

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 (loss) 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) and adjusted net income (loss) per share we exclude certain charges (credits) from 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) and adjusted net income (loss) per share are GAAP net income (loss) and GAAP net income (loss) per share available to common stockholders.

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 period. To calculate organic net sales growth rates, we remove the impact of recent aforementioned acquisitions with no prior period related net sales from operational net sales. In addition, to calculate organic net sales growth rates, we remove from prior year, sales from product lines that we divested. 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) and 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