

Boston Scientific Announces Results For Fourth Quarter And Full Year 2020

MARLBOROUGH, Mass., Feb. 3, 2021 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) generated net sales of \$2.708 billion during the fourth quarter of 2020. This represents a decline of (6.8) percent on a reported basis, (8.3) percent on an operational¹ basis and (8.0) percent on an organic² basis, all compared to the prior year period. Included within organic results is a negative 370 basis point impact associated with the conversion of U.S. WATCHMAN™ customers to a consignment inventory model and transition to the next-generation WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device. The company reported GAAP net income available to common stockholders of \$138 million or \$0.10 per share (EPS), compared to GAAP net income of \$3.996 billion or \$2.83 per share a year ago and achieved adjusted EPS of \$0.23 for the period, compared to \$0.46 a year ago. In the fourth quarter of 2019, reported GAAP net income included a net income tax benefit of \$4.102 billion or \$2.90 per share related to an intra-entity asset transfer of intellectual property.

For the full year 2020, the company generated net sales of \$9.913 billion. This represents a decline of (7.7) percent on a reported basis, (7.8) percent on an operational¹ basis and (11.3) percent on an organic² basis, all compared to the prior year period. Included within organic results is a negative 170 basis point impact associated with the WATCHMAN™ conversion. The company reported a GAAP net loss available to common stockholders of \$(173) million or \$(0.12) per share, compared to GAAP net income of \$4.700 billion or \$3.33 per share a year ago, and delivered full year adjusted EPS of \$0.96, compared to \$1.58 a year ago. Full year 2019 GAAP EPS included a net income tax benefit of \$2.91 per share related to the intra-entity asset transfer of intellectual property discussed above.

"As we look to 2021 and beyond, we are well-positioned given the strength of our global team and our diversified portfolio," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "I'm excited about our outlook for growth—from our category leadership positions to our innovative pipeline and commercial execution—and I am incredibly proud of how Boston Scientific delivered on our mission to transform lives amid the challenges of 2020."

Fourth quarter financial results and recent developments:

- Reported GAAP net income available to common stockholders of \$0.10 per share and adjusted EPS of \$0.23 per share. Included in adjusted EPS is:
 - a (\$0.06) impact associated with the WATCHMAN™ conversion mentioned above, which is now substantially complete, and
 - an (\$0.07) impact related to the voluntary recall of the LOTUS Edge™ Aortic Valve System and discontinuation of the LOTUS platform
- Generated the following sales growth/(declines) in each reportable segment⁴, compared to the prior year period:
 - MedSurg: 1.5 percent reported, 0.1 percent operational and 1.1 percent organic
 - Rhythm and Neuro: (6.1) percent reported, (7.7) percent operational and organic
 - Cardiovascular: (12.0) percent reported, (13.5) percent operational and organic
- Generated the following regional⁵ sales declines, compared to the prior year period:
 - U.S.: (9.2) percent reported and operational
 - EMEA (Europe, Middle East and Africa): (1.1) percent reported and (5.9) percent operational
 - APAC (Asia-Pacific): (1.1) percent reported and (5.6) percent operational
 - Emerging Markets³: (9.9) percent reported and (8.9) percent operational
- Received U.S. Food and Drug Administration (FDA) approval for **Vercise Genus™** family of Deep Brain Stimulation Systems, approved for MR conditional use in a magnetic resonance imaging (MRI) environment.
- Received FDA approval for **WaveWriter Alpha™** portfolio of Spinal Cord Stimulator Systems, offering expanded personalization based on patient needs to treat multiple areas of chronic pain.
- Received FDA Breakthrough Device designation for the **AGENT™ Drug-Coated Balloon (DCB)**,⁶ which is designed for percutaneous transluminal coronary angioplasty to treat coronary artery disease. Breakthrough Device designation provides patients more timely access to novel devices that may provide a substantial improvement over existing therapies.
- Received FDA approval for the **SYNERGY MEGATRON™ Bioabsorbable Polymer Stent**⁷, the only stent platform that is purpose built for use in large proximal vessels with the ability to expand to 6.0 mm in diameter.
- Received FDA approval for the **Ranger™ Drug-Coated Balloon**, developed for the treatment of patients with peripheral artery disease in the superficial femoral artery and proximal popliteal artery. Positive 24-month data from the COMPARE trial was also presented at the Leipzig Interventional Course (LINC) congress, demonstrating non-inferiority of the low-dose paclitaxel-coated Ranger DCB (2.0 µg/mm2) compared to the higher dose IN.PACT™ DCB (Medtronic) balloon (3.5 µg/mm2).
- Received approval for the **Eluvia™ Drug-Eluting Vascular Stent System** from China's Center for Medical Device Evaluation and initiated a full launch in the region.
- Received FDA clearance for the **ORISE™ ProKnife**, a cutting tool designed for endoluminal surgeries for tissue removal and motility disorders of the gastrointestinal tract.
- Received Japanese Pharmaceuticals and Medical Devices Agency approval and Japanese National Health Insurance reimbursement approval for the **WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device**, with plans to launch later this year, and surpassed 150,000 cumulative WATCHMAN implants worldwide.
- Announced the initiation of CHAMPION-AF—a randomized head-to-head trial to study the safety and efficacy of the next-generation **WATCHMAN FLX** device vs. non-vitamin K antagonist oral anticoagulants outcomes across a broad spectrum of patients with non-valvular atrial fibrillation, to evaluate the technology as a potential first-line therapy.
- Received Class I designation for the **EMBLEM™ Subcutaneous Implantable Defibrillator System** in recently updated American Heart Association and American College of Cardiology guidelines on treating patients with hypertrophic cardiomyopathy.
- Received approval from the FDA to begin the early feasibility study in the U.S. for the **Millipede Transcatheter Annuloplasty Ring System**⁸, which will assess the safety and feasibility of the system in patients with functional mitral regurgitation.
- Announced a definitive agreement to acquire Preventice Solutions, Inc., a privately-held company which offers a full portfolio of mobile cardiac health solutions and services, for a purchase price of \$925 million, with up to an additional \$300 million in a potential commercial milestone payment. Boston Scientific is currently an investor in Preventice and holds an equity stake of approximately 22 percent, which is expected to result in a net payment of approximately \$720 million upon closing and a milestone payment of up to approximately \$230 million.
- Signed definitive agreement to divest BTG Specialty Pharmaceuticals business to Stark International Lux S.A.R.L. and SERB SAS, affiliates of SERB, for \$800 million in cash.

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

2. Organic net sales growth rates exclude the impact of foreign currency fluctuations and net sales from the recent acquisitions of Vertiflex, Inc. and BTG plc (BTG), each with no prior year comparable net sales. Organic net sales growth rates also exclude 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 prior period net sales associated with our intrauterine health franchise, which we divested in Q2 2020.

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. In Q4 2020, we signed a definitive agreement to sell Specialty Pharmaceuticals. The sale is expected to close in the first half of 2021, pending customary closing conditions.

6. Agent is an investigational device. Limited by Federal law for investigational use only. Not available for sale.
7. Synergy Megatron indicated for use in coronary arteries 3.5mm to 5.0mm in diameter.
8. Millipede is an investigational device. Limited by Federal law for investigational use only. Not available for sale.

Net sales for the fourth quarter by business and region:

	Three Months Ended December 31,		Change				
(in millions)	2020	2019	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis	Less: Impact of Recent Acquisitions / Divestitures	Organic Basis
Endoscopy	\$ 515	\$ 499	3.4%	1.9%	1.5%	0.0%	1.5%
Urology and Pelvic Health	376	379	(0.8)%	1.0%	(1.8)%	(2.3)%	0.6%
MedSurg	892	878	1.5%	1.5%	0.1%	(1.0)%	1.1%
Cardiac Rhythm Management	451	473	(4.6)%	1.8%	(6.4)%	0.0%	(6.4)%
Electrophysiology	85	84	1.1%	2.8%	(1.8)%	0.0%	(1.8)%
Neuromodulation	232	261	(11.2)%	0.8%	(12.0)%	0.0%	(12.0)%
Rhythm and Neuro	767	817	(6.1)%	1.6%	(7.7)%	0.0%	(7.7)%
Interventional Cardiology	585	748	(21.9)%	1.5%	(23.4)%	0.0%	(23.4)%
Peripheral Interventions	429	403	6.5%	1.7%	4.8%	0.0%	4.8%
Cardiovascular	1,014	1,151	(12.0)%	1.6%	(13.5)%	0.0%	(13.5)%
Medical Devices ⁴	2,673	2,847	(6.1)%	1.5%	(7.7)%	(0.3)%	(7.4)%
Specialty Pharmaceuticals ⁵	36	58	(38.5)%	0.3%	(38.8)%	0.0%	(38.8)%
Net Sales	\$ 2,708	\$ 2,905	(6.8)%	1.5%	(8.3)%	(0.3)%	(8.0)%

(in millions)	Three Months Ended December 31,		Change		
	2020	2019	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis
U.S.	\$ 1,502	\$ 1,654	(9.2)%	0.0%	(9.2)%
EMEA	590	597	(1.1)%	4.8%	(5.9)%
APAC	489	495	(1.1)%	4.6%	(5.6)%
Latin America and Canada	91	101	(10.5)%	(7.2)%	(3.2)%
Medical Devices⁴	2,673	2,847	(6.1)%	1.5%	(7.7)%
Specialty Pharmaceuticals⁵	36	58	(38.5)%	0.3%	(38.8)%
Net Sales	\$ 2,708	\$ 2,905	(6.8)%	1.5%	(8.3)%
Emerging Markets³	\$ 293	\$ 325	(9.9)%	(1.0)%	(8.9)%

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

Net 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.

Net sales for the full year by business and region:

	Year Ended December 31,		Change				
<i>(in millions)</i>	2020	2019	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis	Less: Impact of Recent Acquisitions / Divestitures	Organic Basis
Endoscopy	\$ 1,780	\$ 1,894	(6.0)%	0.3%	(6.3)%	0.0%	(6.3)%
Urology and Pelvic Health	1,286	1,413	(9.0)%	0.0%	(9.0)%	(1.7)%	(7.3)%
MedSurg	3,066	3,307	(7.3)%	0.2%	(7.5)%	(0.7)%	(6.7)%
Cardiac Rhythm Management	1,704	1,939	(12.1)%	0.2%	(12.4)%	0.0%	(12.4)%
Electrophysiology	287	329	(12.8)%	0.8%	(13.5)%	0.0%	(13.5)%
Neuromodulation	761	873	(12.8)%	0.1%	(13.0)%	2.8%	(15.7)%
Rhythm and Neuro	2,752	3,140	(12.4)%	0.3%	(12.7)%	0.8%	(13.4)%
Interventional Cardiology	2,299	2,816	(18.4)%	(0.1)%	(18.2)%	0.0%	(18.2)%
Peripheral Interventions	1,577	1,392	13.3%	0.2%	13.1%	15.6%	(2.5)%
Cardiovascular	3,876	4,208	(7.9)%	0.0%	(7.9)%	5.2%	(13.1)%
Medical Devices ⁴	9,694	10,654	(9.0)%	0.1%	(9.1)%	2.1%	(11.2)%
Specialty Pharmaceuticals ⁵	219	81	n/a	n/a	n/a	n/a	n/a
Net Sales	\$ 9,913	\$ 10,735	(7.7)%	0.1%	(7.8)%	3.5%	(11.3)%

(in millions)	Year Ended December 31,		Change		
	2020	2019	Reported Basis	Less: Impact of Foreign Currency Fluctuations	Operational Basis
U.S.	\$ 5,508	\$ 6,097	(9.7)%	0.0%	(9.7)%
EMEA	2,097	2,264	(7.4)%	1.0%	(8.4)%
APAC	1,781	1,898	(6.2)%	1.0%	(7.1)%
Latin America and Canada	307	395	(22.2)%	(7.0)%	(15.2)%
Medical Devices⁴	9,694	10,654	(9.0)%	0.1%	(9.1)%
Specialty Pharmaceuticals⁵	219	81	n/a	n/a	n/a
Net Sales	\$ 9,913	\$ 10,735	(7.7)%	0.1%	(7.8)%
Emerging Markets³	\$ 1,093	\$ 1,252	(12.7)%	(3.5)%	(9.2)%

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

Net 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.

Guidance for First Quarter and Full Year 2021

The company estimates revenue growth for the first quarter of 2021, versus the prior year period, to be in a range of approximately 0 to 6 percent on a reported basis and a growth range of approximately (3) to 3 percent on an organic basis. First quarter organic guidance excludes the impact of foreign currency fluctuations and the divestiture of our intrauterine health franchise, which we divested in Q2 2020, and includes net sales of the Specialty Pharmaceuticals business, assuming the previously announced divestiture closes on April 1, 2021. First quarter guidance excludes the previously announced acquisition of Preventice Solutions, Inc. which is projected to close by mid-2021, subject to customary closing conditions. The company estimates earnings on a GAAP basis in a range of \$0.05 to \$0.11 per share and estimates adjusted earnings, excluding certain charges (credits) in a range of \$0.28 to \$0.34 per share.

The company estimates revenue growth for the full year 2021, versus the prior year period, to be in a range of approximately 13 to 19 percent on a reported basis and a growth range of approximately 12 to 18 percent on an organic basis. Full year organic guidance excludes the impact of foreign currency fluctuations and the divestiture of our intrauterine health franchise, which we divested in Q2 2020, and includes net sales of the Specialty Pharmaceuticals business through the first quarter of 2021 assuming the previously announced divestiture closes on April 1, 2021. Full year guidance excludes the previously announced acquisition of Preventice Solutions, Inc. which is projected to close by mid-2021, subject to customary closing conditions. The company estimates income on a GAAP basis in a range of \$0.72 to \$0.82 per share and estimates adjusted earnings, excluding certain charges (credits) in a range of \$1.50 to \$1.60 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](https://twitter.com/BostonScientific) and [Facebook](https://www.facebook.com/BostonScientific).

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 first quarter and full year 2021, our financial performance, 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 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.

CONTACT:

Media:	Kate Haranis 508-683-6585 (office) Media Relations Boston Scientific Corporation kate.haranis@bsci.com	Investors:	Susie Lisa, CFA 508-683-5565 (office) Investor Relations Boston Scientific Corporation BSXInvestorRelations@bsci.com
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BOSTON SCIENTIFIC CORPORATION CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
<i>in millions, except per share data</i>				
Net sales	\$ 2,708	\$ 2,905	\$ 9,913	\$ 10,735
Cost of products sold	1,000	851	3,465	3,116
Gross profit	1,708	2,054	6,448	7,620
Operating expenses:				
Selling, general and administrative expenses	1,027	1,092	3,787	3,941
Research and development expenses	286	309	1,143	1,174
Royalty expense	14	17	45	65
Amortization expense	194	201	789	699
Goodwill impairment charges	131	—	131	—
Intangible asset impairment charges	8	—	460	105
Contingent consideration expense (benefit)	2	(26)	(100)	(35)
Restructuring charges (credits)	36	28	52	38
Litigation-related charges (credits)	18	223	278	115
	1,716	1,843	6,586	6,102
Operating income (loss)	(8)	210	(138)	1,518
Other income (expense):				
Interest expense	(96)	(179)	(361)	(473)
Other, net	352	(37)	362	(358)
	248	(6)	(138)	687
Income (loss) before income taxes	96	(4,002)	2	(4,013)
Income tax expense (benefit)				
Net income (loss)	\$ 152	\$ 3,996	\$ (140)	\$ 4,700
Preferred stock dividends	(14)	—	(33)	—
Net income (loss) available to common stockholders	\$ 138	\$ 3,996	\$ (173)	\$ 4,700
Net income (loss) per common share - basic	\$ 0.10	\$ 2.87	\$ (0.12)	\$ 3.38
Net income (loss) per common share - assuming dilution	\$ 0.10	\$ 2.83	\$ (0.12)	\$ 3.33

Weighted-average shares outstanding

1,427.7 1,394.3 1,416.7 1,391.5
1,440.6 1,413.1 1,416.7 1,410.6

Three Months Ended December 31, 2020

(1) For the three months ended December 31, 2020, 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 condensed consolidated statements of operations, for purposes of calculating net income available to common stockholders.

Three Months Ended December 31, 2019

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

Year Ended December 31, 2020

(1) For the year ended December 31, 2020, 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 loss and adjusted net income were reduced by cumulative Preferred stock dividends, as presented in our unaudited condensed consolidated statements of operations, for purposes of calculating EPS. We have assumed dilution of 13.8 million common stock equivalents related to employee stock options for all or a portion of the non-GAAP adjustments, which were anti-dilutive for GAAP purposes due to our net loss position.

Year Ended December 31, 2019

[illegible]

Reported	\$ 7,620	\$ 6,102	\$ 1,518	\$ (831)	\$ 687	\$ 4,700	\$ —	\$ 4,700	\$ 3.33
<i>Non-GAAP adjustments:</i>									
Amortization expense	—	(699)	699	—	699	628	—	628	0.44
Intangible asset impairment charges	—	(105)	105	—	105	102	—	102	0.07
Acquisition / divestiture-related net charges (credits)	114	(161)	275	350	626	672	—	672	0.48
Restructuring and restructuring-related net charges (credits)	32	(50)	82	—	82	68	—	68	0.05
Litigation-related net charges (credits)	—	(115)	115	—	115	72	—	72	0.05
Investment impairment net charges (credits)	—	—	—	4	4	3	—	3	0.00
EU MDR implementation costs	4	(1)	6	—	6	5	—	5	0.00
Debt extinguishment charges	—	—	—	86	86	67	—	67	0.05
Deferred tax expenses (benefits)	—	—	—	—	—	(4,102)	—	(4,102)	(2.91)
Discrete tax items	—	—	—	—	—	18	—	18	0.01
Adjusted	\$ 7,769	\$ 4,970	\$ 2,800	\$ (390)	\$ 2,409	\$ 2,234	\$ —	\$ 2,234	\$ 1.58

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)

Q1 and Full Year 2021 Estimated Revenue Growth Rates

	Q1 2021 Estimate		Full Year 2021 Estimate	
	(Low)	(High)	(Low)	(High)
Estimated GAAP sales growth	—%	6%	13%	19%
Less: Estimated impact of foreign currency fluctuations	4%	4%	3%	3%
Estimated sales growth, operational	(4)%	2%	10%	16%
Less: Estimated impact of recent acquisitions / divestitures	(1)%	(1)%	(2)%	(2)%
Estimated sales growth, organic	(3)%	3%	12%	18%

Q1 and Full Year 2021 Earnings per Share Guidance

	Q1 2021 Estimate		Full Year 2021 Estimate	
	(Low)	(High)	(Low)	(High)
GAAP results	\$ 0.05	\$ 0.11	\$ 0.72	\$ 0.82
Estimated amortization expense	0.11	0.11	0.43	0.43
Estimated acquisition / divestitures-related net charges (credits)	0.03	0.03	0.08	0.08
Estimated restructuring and restructuring-related net charges (credits)	0.06	0.06	0.15	0.15
Estimated other adjustments	0.03	0.03	0.12	0.12
Adjusted results	\$ 0.28	\$ 0.34	\$ 1.50	\$ 1.60

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), 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." The following is an explanation of each adjustment type that management excluded as part of these non-GAAP financial measures, as well as the reason for excluding each item:

- **Amortization expense** - We record intangible assets at historical cost and amortize them over their estimated useful lives. Amortization expense is excluded from management's assessment of operating performance and is also excluded from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Goodwill and other intangible asset impairment charges** - This amount represents write-downs of certain goodwill and/or other intangible asset balances during each period. We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment and test our goodwill and other indefinite-lived intangible assets at least annually for impairment. If we determine the carrying value of the amortizable intangible asset is not recoverable, if we determine goodwill of a reporting unit is impaired or we conclude that it is more likely than not that the indefinite-lived asset is impaired, we will write the carrying value down to fair value in the period identified. Impairment charges are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Acquisition/divestiture-related net charges (credits) or payments** - These adjustments may consist of (a) contingent consideration and Zytiga™ licensing arrangement fair value adjustments; (b) gains on previously held investments; (c) due diligence, deal fees and other fees and costs related to our acquisition and divestiture transactions; (d) inventory step-up amortization and accelerated compensation expense; (e) integration and exit costs; and (f) separation costs and gains primarily associated with the sale of a business or portion of a business. The contingent consideration and Zytiga licensing arrangement fair value adjustments represent accounting adjustments to state contingent consideration liabilities and Zytiga-related assets and liabilities at their estimated fair value. These adjustments can be highly variable depending on the assessed likelihood and amount of future contingent consideration and Zytiga royalty payments. In addition, we have sold our rights to retain any future royalties related to Zytiga. Refer to *Note D - Hedging Activities and Fair Value Measurements* for further information on the Zytiga licensing arrangement. Gains on previously held investments, due diligence, deal fees and other fees and costs, inventory step-up amortization, accelerated compensation expense, and other expenses and gains associated with prior and potential future acquisitions and divestitures can be highly variable and not representative of ongoing operations. Integration and exit costs, include contract cancellations, severance and other compensation-related charges and costs, project management fees and costs, and other direct costs associated with the integration of our acquisitions. Examples of integration and exit activities include the movement of business activities; the elimination or combination of redundant roles and business processes; the consolidation or closure of facilities and legal entities; and the transfer of product lines between manufacturing facilities. These integration and exit activities take place over a defined timeframe and have a distinct project timelines, are incremental to activities and costs that arise in the ordinary course of our business and are not considered part of our core, ongoing operations. In addition, our acquisition-related charges in 2019 included expenses for instruments entered into solely for the purpose of financing or hedging the BTG Acquisition, including net interest expense and hedging expenses. Subsequent to September 30, 2019, we did not incur and will not incur any hedging gains or losses related to the BTG Acquisition, and we are not classifying any interest expense subsequent to the BTG acquisition date as an acquisition/divestiture-related item. Acquisition/divestiture-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Restructuring and restructuring-related net charges (credits) or payments** - These adjustments primarily represent compensation-related charges, fixed asset write-offs,

contract cancellations, project management fees and other direct costs associated with our restructuring plans. These restructuring plans each consist of distinct initiatives that are fundamentally different from our ongoing, core cost reduction initiatives in terms of, among other things, the frequency with which each action is performed and the required planning, resourcing, cost and timing. Examples of such initiatives include the movement of business activities, facility consolidations and closures and the transfer of product lines between manufacturing facilities, which, due to the highly regulated nature of our industry, requires a significant investment in time and cost to create duplicate manufacturing lines, run product validations and seek regulatory approvals. Restructuring initiatives take place over a defined timeframe and have a distinct project timeline that begins subsequent to approval by our Board of Directors. In contrast to our ongoing cost reduction initiatives, restructuring initiatives typically result in duplicative cost and exit costs over this period of time, are one-time shut downs or transfers and are not considered part of our core, ongoing operations. These restructuring plans are incremental to the core activities that arise in the ordinary course of our business. Restructuring and restructuring-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

- **Litigation-related net charges (credits) or payments** - These adjustments include certain significant product liability and other litigation-related charges and credits. We record these charges and credits, which we consider to be unusual or infrequent and significant, within the litigation-related charges line in our consolidated statements of operations; all other legal and product liability charges, credits and costs are recorded within selling general and administrative expenses. Litigation-related net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **EU MDR implementation costs** - These adjustments represent incremental costs or payments specific to complying with the new European Union Medical Device Regulation (EU MDR) for previously registered products. EU MDR is a replacement of the existing European Medical Devices Directive (MDD) regulatory framework, and manufacturers of medical devices are required to comply with EU MDR beginning in May 2021 (previously May 2020) for new product registrations and by May 2024 for medical devices which have a valid CE Certificate to the current Directives (issued before May 2021). We expect to incur significant expenditures in connection with the adoption of the EU MDR requirements and we consider the adoption of EU MDR to be a significant change to a regulatory framework, and therefore, these expenditures are not considered to be ordinary course expenditures in connection with regulatory matters. As such, these medical device regulation charges are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Debt extinguishment net charges (credits)** - These amounts relate to the early extinguishment of certain outstanding principal amounts of our senior notes in November 2019. Certain debt extinguishment net charges (credits) are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Investment impairment net charges (credits)** - These amounts represent write-downs or fair value remeasurement gains and losses related to our investment portfolio that are considered unusual and/or infrequent, or are the result of factors outside of the control of management. Each reporting period, we evaluate our investments without a readily determinable fair value to determine if there are any events or circumstances that are likely to have a significant adverse effect on the fair value of the investment. If we identify an impairment indicator, we will estimate the fair value of the investment and compare it to its carrying value and determine if the impairment is other-than-temporary, and recognize an impairment loss. In addition, for those investments accounted for under the measurement alternative method of accounting, we record gains and losses to remeasure the carrying value of the investments to their fair values based on observable market prices or implied market values. Certain investment impairment charges and fair value remeasurements are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Deferred tax expenses (benefits)** - This adjustment relates to a \$4.1 billion non-cash tax benefit arising from an intra-entity asset transfer of intellectual property completed in the fourth quarter of 2019. The effects of this transfer were excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.
- **Discrete tax items** - These items represent adjustments of certain tax positions including those which a) are related to the finalization of the enactment date impact of the TCJA, or b) are related to the tax consequences of a non-GAAP adjustment item booked in a prior period. These discrete tax items are excluded from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance.

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 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. With the exception of the impact of the recent aforementioned acquisitions and divestitures, 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, 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.

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<https://news.bostonscientific.com/2021-02-03-Boston-Scientific-Announces-Results-For-Fourth-Quarter-And-Full-Year-2020>