

Boston Scientific Announces LOTUS Edge™ Aortic Valve System Voluntary Recall and Product Discontinuation

MARLBOROUGH, Mass., Nov. 17, 2020 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) has announced it has initiated a global, voluntary recall of all unused inventory of the LOTUS Edge™ Aortic Valve System due to complexities associated with the product delivery system. The voluntary recall is related solely to the delivery system, as the valve continues to achieve positive and clinically effective performance post-implant. There is no safety issue for patients who currently have an implanted LOTUS Edge valve.

Given the additional time and investment required to develop and reintroduce an enhanced delivery system, the company has chosen to retire the entire LOTUS product platform immediately. All related commercial, clinical, research & development and manufacturing activities will also cease.

"While we have been pleased with the benefits the LOTUS Edge valve has provided to patients, we have been increasingly challenged by the intricacies of the delivery system required to allow physicians to fully reposition and recapture the valve," said Mike Mahoney, chairman and chief executive officer, Boston Scientific. "The complexity of the delivery system, manufacturing challenges, the continued need for further technical enhancements, and current market adoption rates led us to the difficult decision to stop investing in the Lotus Edge platform. We will instead focus our resources and efforts on our ACURATE neo2™ Aortic Valve System, Sentinel™ Cerebral Embolic Protection System and other high growth areas across our portfolio."

This decision is expected to result in estimated total pre-tax GAAP charges of approximately \$225 million to \$300 million due to inventory, fixed asset, intangible asset and certain other exit charges and approximately \$100 million to \$150 million of these charges will impact the company's adjusted results. The vast majority of these charges will be recorded during the fourth quarter of 2020. The decision is expected to be accretive to GAAP and adjusted earnings per share in 2021 by approximately one to two cents and neutral thereafter.

Conference Call and Webcast Information

Boston Scientific will be hosting a conference call for investors on November 17, 2020 at 8:00 a.m. EST to discuss the announcement. To participate in the conference call, please dial (833) 685-0550 or (412) 317-5733. The live webcast and archived replay of this call will be available at our Investor Relations website investors.bostonscientific.com in the Events section.

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, financial performance, product launches and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

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

the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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