

BOSTON SCIENTIFIC CORP
Form 8-K
February 23, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 23, 2017

BOSTON SCIENTIFIC CORPORATION
(Exact name of registrant as specified in charter)

DELAWARE 1-11083 04-2695240
(State or other (Commission (IRS employer
jurisdiction of file number) identification no.)
incorporation)

300 Boston Scientific Way, Marlborough, Massachusetts 01752-1234
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (508) 683-4000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 8.01. OTHER EVENTS.

On February 23, 2017, Boston Scientific announced a voluntary removal of all Lotus™ Valve devices, including Lotus with Depth Guard™, from global commercial and clinical sites due to reports of premature release of a pin connecting the Lotus Valve to the delivery system. As with the prior announced suspension of our Lotus Edge™ Valve System device, we believe that the issue is caused by excess tension in the pin mechanism introduced during the manufacturing process.

We expect to bring the Lotus™ Valve platform back to market in Europe and other regions in the fourth quarter of 2017. We anticipate filing the U.S. PMA submission for the Lotus Edge™ Valve System, the next generation platform, in the fourth quarter of 2017, with a U.S. launch planned for mid-2018.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K 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,” “plan,” “believe,” 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 when we anticipate that Lotus™ Valve platform to return to market in Europe and other regions, the timing of regulatory filings, and the launch of the Lotus Edge™ Valve System in the United States. 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; the closing and integration of acquisitions; 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 and Part I, Item 1A - Risk Factors in Annual Reports on Form 10-K 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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date:

February

BOSTON SCIENTIFIC CORPORATION

23,

2017

By: /s/ Vance R. Brown

Vance R. Brown

Vice President and Chief Corporate Counsel