

BOSTON SCIENTIFIC CORP
Form 8-K
April 17, 2019

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): April 16, 2019

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 7.01. REGULATION FD DISCLOSURE

On April 16, 2019, the U.S. Food and Drug Administration (FDA) ordered that all manufacturers of surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse stop selling and distributing their products in the United States immediately, stemming from the FDA's 2016 reclassification of these devices to class III (high risk) devices. The FDA's order applies to two Boston Scientific product lines, Uphold™ LITE Vaginal Support System and Xenform™ Soft Tissue Repair Matrix. As a result, Boston Scientific anticipates an approximate \$25 million negative impact globally to 2019 full year revenue. Boston Scientific continues to assess any potential additional impact to the business and will provide a further update on its conference call discussing financial results and business highlights for the first quarter ended March 31, 2019 on Wednesday, April 24, 2019 at 8:00 a.m. EDT.

The information contained in Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

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," "aiming" 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, our financial performance and our business plans. 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 risks and uncertainties, in some cases, have affected and in the future 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.

Risks and uncertainties that may cause such differences include, among other things: future economic, political, competitive, reimbursement and regulatory conditions, new product introductions and the market acceptance of those products, markets for our products, expected pricing environment, expected procedural volumes, the closing and integration of acquisitions, clinical trial results, demographic trends, intellectual property rights, litigation, financial market conditions, the execution and effect of our restructuring program, the execution and effect of our business strategy, including our cost-savings and growth initiatives and future business decisions made by us and our competitors. New risks and uncertainties may arise from time to time and are difficult to predict. 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 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: April 17, 2019 BOSTON SCIENTIFIC CORPORATION

By: /s/ Vance R. Brown
Vance R. Brown
Vice President and Chief Corporate Counsel