

BOSTON SCIENTIFIC CORP
Form 8-K
March 15, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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):

March 15, 2010

Boston Scientific Corporation

(Exact name of registrant as specified in its charter)

Delaware

1-11083

04-2695240

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(I.R.S. Employer
Identification No.)

One Boston Scientific Place, Natick,
Massachusetts

01760-1537

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

508-650-8000

Not Applicable

Former name or former address, if changed since last report

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 communications 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))

Top of the Form

Item 8.01 Other Events.

Today we announced that we have stopped shipment and are retrieving field inventory of all our implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). We have determined that some manufacturing process changes were not submitted for approval to the U.S. Food and Drug Administration (FDA). At this time, we have identified two instances of changes that, while successfully validated, were not submitted to the FDA. We have informed the FDA and plan to work closely with the agency to resolve this situation as soon as possible.

We have no indication that the manufacturing process changes pose any risk to patient safety, and we are not recommending explantation of the devices. Given the financial uncertainty involved, these actions could have a material impact on our previously issued guidance, including revenue, operating profit and cash flows for the first quarter and full year of 2010.

A copy of the press release is attached hereto as Exhibit 99.1.

Top of the Form

SIGNATURES

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

Boston Scientific Corporation

March 15, 2010

By: *Lawrence J. Knopf*

Name: Lawrence J. Knopf

Title: Senior Vice President and Deputy General Counsel

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Top of the Form

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued by Boston Scientific Corporation dated March 15, 2010.