

Covidien plc
Form 8-K
March 14, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported): March 14, 2011

COVIDIEN PUBLIC LIMITED COMPANY

(Exact Name of Registrant as Specified in Charter)

Ireland
(State or Other Jurisdiction

of Incorporation)

001-33259
(Commission

File Number)

98-0624794
(I.R.S. Employer

Identification No.)

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20 on Hatch, Lower Hatch Street

Dublin 2, Ireland

(Address of Principal Executive Offices, including Zip Code)

+353 1 438-1700

(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

- .. 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))

Item 7.01. Regulation FD Disclosure.

Following a meeting with the Data Safety Monitoring Board (DSMB) overseeing the SWIFT (Solitaire FR With Intention For Thrombectomy) Investigational Device Exemption trial, the DSMB recommended that Covidien stop enrolling patients and take the trial data to the U.S. Food and Drug Administration (FDA). The trial includes Covidien's SolitaireFR Flow Restoration device and we are seeking FDA clearance to utilize Solitaire FR to restore blood flow in patients with acute ischemic stroke within eight hours of symptom onset. We will continue to conduct follow-up with the patients already enrolled in the trial. Covidien is collaborating with the FDA with respect to next steps, and we anticipate moving forward with the 510(k) process (the clearance process for medical devices that are substantially equivalent to other legally marketed devices) once the FDA has completed its review of the data.

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.

COVIDIEN PUBLIC LIMITED COMPANY

By: /s/ John W. Kapples
John W. Kapples
Vice President and Corporate Secretary

Date: March 14, 2011