

Mallinckrodt plc
Form 8-K
November 13, 2014

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): November 13, 2014

Mallinckrodt public limited company

(Exact name of registrant as specified in its charter)

Ireland (State or other jurisdiction of incorporation)	001-35803 (Commission File Number)	98-1088325 (IRS Employer Identification No.)
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Damastown, Mulhuddart
Dublin 15, Ireland
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: +353 1 880-8180

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))

- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On November 13, 2014, the Company issued a press release announcing that the Company has been informed by the U.S. Food and Drug Administration that the agency has reason to believe that the Company's methylphenidate hydrochloride extended-release (ER) tablets USP (CII) may not be therapeutically equivalent to the category reference drug Concerta®. As a result, the agency indicated that it has reclassified the Company's ANDA 202608 for methylphenidate ER dosage strengths of 27 mg, 36 mg and 54 mg from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent). A copy of the press release is furnished as exhibit 99.1 to this Current Report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated November 13, 2014.

SIGNATURES

Pursuant to the requirements of Section 12 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.

MALLINCKRODT PUBLIC LIMITED COMPANY
(registrant)

Date: November 13, 2014

By: /s/ Peter G. Edwards
Name: Peter G. Edwards
Title: Senior Vice President and General Counsel