

Mallinckrodt plc
Form 8-K
October 24, 2016

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): October 24, 2016

Mallinckrodt public limited company

(Exact name of registrant as specified in its charter)

Ireland	001-35803	98-1088325
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Perth House, Millennium Way,
Chesterfield, Derbyshire S41 8ND, United Kingdom
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: +44 124 626 3051

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))

Item 7.01 Regulation FD Disclosure

On October 21, 2016, the United States Court of Appeals for the Fourth Circuit issued an Order removing Mallinckrodt Inc.'s pending litigation with the U.S. Food and Drug Administration (FDA) from the Court's oral argument calendar and placing that litigation in abeyance pending the outcome of the Approval Withdrawal Proceedings initiated by the FDA on October 17, 2016. In response, on October 21, 2016, Mallinckrodt Inc. filed a Motion to Reconsider with the Court requesting that the oral arguments be placed back on the Court's calendar and that the litigation be allowed to proceed. On October 24, 2016, the Court affirmed its earlier decision and stayed the litigation pending the outcome of FDA's Approval Withdrawal Proceedings.

It remains Mallinckrodt Inc.'s position that its generic methylphenidate ER product is a safe and effective treatment option for patients who suffer from ADHD. As such, Mallinckrodt Inc. plans to vigorously set forth its position in the Approval Withdrawal Proceedings and is exploring additional options regarding this matter.

The information furnished pursuant to Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed "filed" under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be incorporated by reference into any filings by the Company under the Securities Act of 1933, as amended (the "Securities Act") or under the Exchange Act, except as expressly set forth by specific reference in such a filing. The furnishing of information pursuant to this Item 7.01 will not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely by Regulation FD.

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

Date: October 24, 2016 By: /s/ Kenneth L. Wagner
Kenneth L. Wagner
Vice President and Corporate Secretary