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

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:

- **o** Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- **o** Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- **o** 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))

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

Exhibit 99.1

MALLINCKRODT PLC RESPONDS TO FDA'S EXPECTED RECLASSIFICATION OF METHYLPHENIDATE ER

DUBLIN - November 13, 2014 - Mallinckrodt plc (NYSE: MNK) has been informed by the U.S. Food and Drug Administration (FDA) 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 Mallinckrodt's ANDA 202608 for methylphenidate ER dosage strengths of 27mg, 36 mg and 54 mg from AB (freely substitutable at the pharmacy level) to BX (presumed to be therapeutically inequivalent). The agency said that this change was based on the application of its new Draft Guidance for determining bioequivalence of methylphenidate hydrochloride products just published on November 6, 2014. Although the Draft Guidance has an open comment period through January 5, 2015, the agency nevertheless confirmed that this change would be reflected on November 13, 2014 in the on- line Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

Mallinckrodt strongly believes its methylphenidate ER products are safe and effective when used in accordance with the approved labels.

"We believe that the FDA's actions are not supported by sound scientific evidence and not consistent with the best interests of patients," said Mark Trudeau, President and Chief Executive Officer of Mallinckrodt. Mallinckrodt methylphenidate ER products have consistently met all quality specifications and the regulatory requirements originally defined by the FDA, and in the 21 months since launch more than 88 million Source, IMS Health doses of these products have been prescribed. In that time, and across all of those patient exposures, the company has received only 68 confirmed adverse events related to a lack of efficacy when the patient switched from the reference listed drug (Concerta) to the company's methylphenidate ER products. "We believe this very low reporting rate is in line with response rates recorded for patients switching between different formulations of existing products," continued Trudeau. "Based on our review of Mallinckrodt's safety data base and the conclusions FDA has shared with the company, we remain confident in the safety of our methylphenidate ER products."

"In the face of the agency's precipitous decision, Mallinckrodt will continue to defend the safety and efficacy of our methylphenidate products," said Trudeau. "We are considering all of our options to persuade the agency to engage in a meaningful dialog with us regarding the science, including potential legal action." In Mallinckrodt's view, the FDA's recent unilateral decision, and apparent reluctance to engage with the company in a thorough scientific discussion and evaluation of these issues, could result in a variety of negative impacts including patient anxiety and uncertainty, potential disruption to effective therapy in vulnerable patients, possible market shortages, and unfavorable changes in the economics for ADHD patients and providers. "We have expressed to the FDA our earnest desire to have a robust scientific dialog about these important issues," Trudeau concluded, "and it is our hope that this dialog will take place soon."

This action by the agency was not contemplated on October 14, 2014 when Mallinckrodt provided financial guidance for fiscal 2015. The company plans to update its guidance at some point in the future once it has had time to fully assess this impact. As previously announced, Mallinckrodt will report its fiscal 2014 results on Wednesday, November 19, 2014. Mallinckrodt has an established toll-free information line (800-778-7898) to answer any questions that patients or providers may have.

About Methylphenidate ER:
On December 28, 2012, the FDA approved Mallinckrodt's methylphenidate ER drug for marketing in three strengths as therapeutically bioequivalent to Concerta. In December 2012, Mallinckrodt launched the product as the first generic alternative to Concerta, which was first approved in August 2000. Since its launch, the company's product has provided a cost effective alternative to hundreds of thousands of patients suffering from attention-deficit hyperactivity disorder (ADHD).

Mallinckrodt's formulation was approved as AB rated (readily substitutable at the pharmacy level) based on evidence that the product demonstrated bioequivalence in terms of (a) the same extended-release pharmacokinetic profile as Concerta; and (b) was, until November 13, 2014, AB-rated to (i.e., therapeutically equivalent to or substitutable for) Concerta because it met established FDA regulatory approval requirements.

ABOUT MALLINCKRODT:
Mallinckrodt is a global specialty biopharmaceutical and medical imaging business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. Areas of focus include therapeutic drugs for autoimmune and rare disease specialty areas like neurology, rheumatology, nephrology and pulmonology along with analgesics and central nervous system drugs for prescribing by office- and hospital-based physicians. The company's core strengths include the acquisition and management of highly regulated raw materials; deep regulatory expertise; and specialized

chemistry, formulation and manufacturing capabilities. The company's Specialty Pharmaceuticals segment includes branded and specialty generic drugs and active pharmaceutical ingredients, and the Global Medical Imaging segment include contrast media and nuclear imaging agents. Mallinckrodt has more than 5,500 employees worldwide and a commercial presence in roughly 65 countries. The company's fiscal 2013 revenue totaled $2.2 billion. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

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FORWARD-LOOKING STATEMENTS

Statements in this press release that are not strictly historical, including statements regarding, future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting our business and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties. There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: general economic conditions and conditions affecting the industries in which we operate; the commercial success of our products, including H.P. Acthar® Gel ("Acthar"); our ability to protect intellectual property rights; our ability to maintain important business relationships; the lack of patent protection for Acthar, and the possible United States Food and Drug Administration ("FDA") approval and market introduction of additional competitive products; our reliance on certain individual products that are material to our financial performance; our ability to continue to generate revenue from sales of our products to treat on-label indications and to develop other therapeutic uses for them; our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; our ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities; customer concentration; cost containment efforts of customers, purchasing groups, third-party payors and governmental organizations; our ability to successfully develop or commercialize new products; competition; our ability to achieve anticipated benefits of price increases; our ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings; the reimbursement practices of a small number of large public or private issuers; complex reporting and payment obligations under healthcare rebate programs; changes in laws and regulations; conducting business internationally; foreign exchange rates; material health, safety and environmental liabilities; product liability losses and other litigation liability; information technology infrastructure and restructuring activities. Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in (i) our SEC filings, including our Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and our Quarterly Reports on Form 10-Q for the quarterly periods ended December 27, 2013, March 28, 2014 and June 27, 2014; (ii) the SEC filings of Cadence Pharmaceuticals, Inc., which was acquired by Mallinckrodt on March 19, 2014, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2013; and (iii) the SEC filings of Questcor Pharmaceuticals, Inc.'s, which was acquired by Mallinckrodt on August 14, 2014, including its Annual Report on Form 10-K for the year ended December 31, 2013 (and the amendment thereto on Form 10-K/A), its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2014 and June 30, 2014, and its Current Report on Form 8-K filed with the SEC on July 10, 2014. The forward-looking statements made herein speak only as of the date hereof and neither Mallinckrodt nor any of its affiliates assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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