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 16, 2020

Mallinckrodt plc

(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.)

3 Lotus Park, The Causeway, Staines-Upon-Thames
Surrey TW18 3AG, United Kingdom
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **+44 017 8463 6700**

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, par value $0.20 per share	MNK	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On March 16, 2020, Mallinckrodt plc (“Mallinckrodt” or the "Company") issued a press release confirming that its subsidiary, Mallinckrodt ARD LLC, received a decision from the U.S. District Court for the District of Columbia in its suit against the U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) regarding the Company’s calculation of Medicaid drug rebates for Acthar Gel® (repository corticotropin injection). A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Cautionary Statements Related to Forward-Looking Statements

Statements in this document that are not strictly historical, including statements concerning the dispute between Mallinckrodt, HHS and CMS with regard to Medicaid drug rebates for Acthar Gel; the litigation filed by Mallinckrodt against HHS and CMS in connection with this dispute and any plans to appeal the recent decision from the District Court in such litigation; the impact of this dispute and any related litigation on Mallinckrodt’s future financial condition, operating results, ability to fund future investments in Acthar Gel, and patients’ ability to access Acthar Gel; the impact of this dispute and any related litigation on the agreement in principle for a global opioid settlement and related debt financing activities; and any other statements regarding events or developments that Mallinckrodt believes or anticipates 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: governmental investigations and inquiries, regulatory actions and lawsuits brought against Mallinckrodt by government agencies and private parties with respect to its historical commercialization of opioids, including the non-binding agreement in principle regarding terms and conditions of a global settlement to resolve all current and future opioid-related claims; scrutiny from governments, legislative bodies and enforcement agencies related to sales, marketing and pricing practices; pricing pressure on certain of Mallinckrodt’s products due to legal changes or changes in insurers’ reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; the reimbursement practices of governmental health administration authorities, private health coverage insurers and other third-party payers; complex reporting and payment obligations under the Medicare and Medicaid rebate programs and other governmental purchasing and rebate programs, including as they relate to the pending dispute with HHS and CMS; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; changes in or failure to comply with relevant laws and regulations; Mallinckrodt’s and its partners’ ability to successfully develop or commercialize new products or expand commercial opportunities; Mallinckrodt’s ability to navigate price fluctuations; competition; Mallinckrodt’s and its partners’ ability to protect intellectual property rights; limited clinical trial data for Acthar Gel; clinical studies and related regulatory processes; product liability losses and other litigation liability; material health, safety and environmental liabilities; potential indemnification liabilities to Covidien pursuant to the separation and distribution agreement; business development activities; retention of key personnel; the effectiveness of information technology infrastructure including cybersecurity and data leakage risks; customer concentration; Mallinckrodt’s reliance on certain individual products that are material to its financial performance; Mallinckrodt’s ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; complex manufacturing processes; conducting business internationally; Mallinckrodt’s ability to achieve expected benefits from restructuring activities; Mallinckrodt’s significant levels of intangible assets and related impairment testing; labor and employment laws and regulations; natural disasters or other catastrophic events; Mallinckrodt’s substantial indebtedness and its ability to generate sufficient cash to reduce its indebtedness; the proposed refinancing of certain near-term debt maturities; future changes to U.S. and foreign tax laws or the impact of disputes with governmental tax authorities; and the impact of Irish laws.

These and other factors are identified and described in more detail in the “Risk Factors” section of Mallinckrodt’s Annual Report on Form 10-K for the fiscal year ended December 27, 2019. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press release of Mallinckrodt plc dated March 16, 2020.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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.

MALLINCKRODT PLC
(registrant)

Date: March 16, 2020

By: /s/ Mark J. Casey
Mark J. Casey
Executive Vice President and Chief Legal Officer

Mallinckrodt Confirms Court Decision in Lawsuit against U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) and Provides Update Related to Global Opioid Settlement and Present Financing Activities

-- Court allows CMS to change Medicaid rebate calculations for Acthar® Gel resulting in full retroactive payments --

-- Retroactive liability of approximately $650 million and prospective loss of Acthar Gel Medicaid net sales of roughly $90 million to $100 million in net sales annualized --

-- Company will move for a stay and reconsideration of the ruling and, if necessary, an appeal to the U.S. Court of Appeals for the D.C. Circuit --

STAINES-UPON-THAMES, United Kingdom - Mar. 16, 2020 - Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today confirmed that its subsidiary, Mallinckrodt ARD LLC, received a decision from the U.S. District Court for the District of Columbia in its suit against HHS and CMS (or the Agency) regarding the company's calculation of Medicaid drug rebates for Acthar® Gel (repository corticotropin injection). The District Court upheld CMS' decision to reverse its previous determination of the base date average manufacturer price (AMP) used to calculate Acthar Gel rebates.

"This is clearly a disappointing ruling by the District Court. We continue to believe that a bedrock principle of administrative law is that the government is required to give fair notice and a clear, legal basis for a change in position, particularly when that position has been relied upon by a regulated entity like Mallinckrodt," said **Mark Casey, Executive Vice President and Chief Legal Officer of Mallinckrodt**. "Because we believe the decision's legal reasoning is significantly flawed in several respects, we will move for a stay and reconsideration of the decision with the District Court and, if necessary, appeal to the United States Court of Appeals for the D.C. Circuit. Mallinckrodt remains committed to ensuring Medicaid patients have access to Acthar Gel therapy long term."

In the absence of court intervention and based on the effective date of the ruling and change to the base date AMP, the company will pay roughly $650 million for the period from January 1, 2013 to present, and this will be reflected as a non-GAAP adjustment in the first quarter results. Based on current Medicaid patient volume, Mallinckrodt estimates the annualized prospective change to the Medicaid rebate calculation will reduce Acthar Gel net sales by roughly $90 million to $100 million.

Certain legal contingencies, including the CMS matter, were contemplated in reaching the agreement in principle for a global opioid settlement. The company is engaged in constructive dialogue with the plaintiff parties to address the impact of the District Court's decision.

Mark Casey continued, "A number of contingencies were identified as part of the proposed global opioid settlement. We will continue to work collaboratively with the various parties to the agreement in principle to appropriately consider the District Court ruling and what impact this ruling will have on the terms of the settlement. We remain committed to working with these parties to achieve a satisfactory outcome."

As previously announced on Feb. 25, Mallinckrodt continues to work toward executing its refinancing and exchange transactions to address near term maturities coming due in April 2020 and August 2022, which are key elements of, and conditions to, a global opioid settlement.

ABOUT MALLINCKRODT

Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt, a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; analgesics and

gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients.

Mallinckrodt Pharmaceuticals uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

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