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): June 15, 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 June 15, 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. Court of Appeals for the District of Columbia on its request for a temporary injunction related to 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 including any related appeals; the change of the base date AMP for Acthar Gel and the resulting payment of any retroactive non-recurring charges; the impact of such dispute and any such litigation on Mallinckrodt's ability to fund research and development activities (including COVID-19 related activities) or on its ability to effectuate its proposed opioid settlement; the impact of any of the foregoing on Mallinckrodt's future financial condition, operating results, and other pending litigation; 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: the dispute between Mallinckrodt, HHS and CMS, including the outcome of the lawsuit filed by Mallinckrodt and any related appeals, as well as the time and expense of litigating this dispute; the impact of this dispute on Mallinckrodt's expectations for performance in 2020, as well as the potential retroactive financial impact on Mallinckrodt of an adverse outcome or any other impacts; 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; 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; future changes to U.S. and foreign tax laws or the impact of disputes with governmental tax authorities; the impact of Irish laws; and the impact of the outbreak of the COVID-19 coronavirus.

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 and the "Risk Factors" section of Mallinckrodt's Quarterly Report on Form 10-Q for the quarterly period ended March 27, 2020. 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 June 15, 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: June 15, 2020

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

Mallinckrodt to Proceed with Appeal Despite Appellate Court Decision Denying Temporary Injunction in Ongoing Acthar Gel Medicaid Drug Rebate Dispute with the Centers for Medicare and Medicaid Services (CMS)

-- Company remains committed to opioid settlement in principle but says allowing District Court ruling to stand could adversely impact settlement completion --

-- Appeals Court sets expedited briefing and oral argument schedule --

-- Company continues to explore all options to address its long-term liabilities and risks --

STAINES-UPON-THAMES, United Kingdom - June 15, 2020 - Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, announced its disappointment with the U.S. Court of Appeals for the District of Columbia decision to deny its request for a temporary injunction preventing the U.S. Centers for Medicare and Medicaid Services (CMS) from enforcing a change in Medicaid drug rebate calculation for Acthar® Gel (repository corticotropin injection). Mallinckrodt had asked for the temporary injunction as it appeals a lower court ruling that allowed CMS to reset the base date average manufacturer price (AMP). The Appeals Court also ordered an expedited briefing and oral argument schedule that will likely lead to fall oral arguments, and potentially a ruling by end of year.

As a result of today's appeals court ruling, Mallinckrodt will change the base date AMP for Acthar Gel, as directed by CMS. The effect of the change is an immediate recognition of retroactive non-recurring charges (estimated at approximately $650 million through mid-June) and the prospective loss of Acthar Medicaid net sales, which has historically contributed to Acthar Gel net sales of $90 to $100 million annually. The company will continue to appeal the March 16 ruling by the U.S. District Court for the District of Columbia that upheld CMS' position. Barring other arrangements, the cash payments for retroactive Medicaid rebate charges will be processed over time, in accordance with the normal rebate payment schedule, and the company expects the cash outlays will most likely commence in the fourth quarter of 2020.

Despite the ruling, Mallinckrodt remains committed to ensuring that Medicaid patients have access to Acthar Gel.

"We are disappointed in the appeals court decision not to issue a temporary injunction to prevent CMS from enforcing this change in Medicaid rebate calculations while our case is still under appeal," said **Mark Casey, Executive Vice President and Chief Legal Officer of Mallinckrodt**. "We will continue our appeal, which could be decided as early as end of year, and strongly believe that the District Court misinterpreted the statute that governs the Medicaid drug rebate program and failed to hold CMS accountable to the Administrative Procedure Act. CMS twice confirmed in writing its approval of the Acthar Gel Medicaid rebate calculation in use today, before it later reversed its position without giving fair notice or any clear legal basis for doing so."

In legal filings requesting the temporary injunction, Mallinckrodt warned that the retroactive non-recurring charges - if allowed to stand by the appeals court - "would have a dramatic impact upon the company's existing financial obligations and its efforts to settle other litigation." While Mallinckrodt has reached an agreement in principle on a global settlement of opioids litigation, and continues to work collaboratively with the parties involved to expedite a reasonable resolution, the agreement could be in jeopardy if the appeals court upholds CMS' position. The company continues to explore all options to address its long-term liabilities and risks.

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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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; future changes to U.S. and foreign tax laws or the impact of disputes with governmental tax authorities; the impact of Irish laws; and the impact of the outbreak of the COVID-19 coronavirus.

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