

**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
(State or other jurisdiction
of incorporation)

001-35803
(Commission
File No.)

98-1088325
(I.R.S. 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.

As previously disclosed, Mallinckrodt ARD LLC, a subsidiary of Mallinckrodt plc (“Mallinckrodt” or the “Company”), 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). On March 16, 2020, Mallinckrodt filed an emergency motion for reconsideration and stay of entry of judgment pending reconsideration or, alternatively, injunction pending appeal. In response to this motion, the defendants in the litigation notified the District Court on March 16, 2020 that they informed Mallinckrodt that CMS will voluntarily refrain from locking Mallinckrodt out of CMS’s online data reporting system for at least the next 60 days. The defendants’ notice further stated that this would delay any potential suspension of Mallinckrodt from the Medicaid program until August 31, 2020, assuming that Mallinckrodt enters its data through the end of May. Mallinckrodt’s motion remains pending before the District Court, but if necessary, the Company will appeal the District Court’s decision to the U.S. Court of Appeals for the District of Columbia Circuit.

As previously disclosed, the Company has been seeking to amend its credit agreement and obtain new term loans thereunder. After receiving informal communications from advisors to the Lender Parties to the Support Agreement (each as defined in the Company’s Current Report on Form 8-K filed on February 25, 2020) that Lender Parties did not expect to fund the new term loans, the Company does not expect that the credit agreement will be amended or the new term loans will be obtained, and is seeking to engage in discussions with certain debt holders of the Company regarding potential refinancing alternatives.

As stated in the Company’s press release issued on March 16, 2020, certain legal contingencies, including the CMS matter, were contemplated in reaching the agreement in principle for a global opioid settlement. The Company continues to be engaged in constructive dialogue with the plaintiff parties to address the impact of the District Court’s decision.

Cautionary Statements Related to Forward-Looking Statements

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, legal, economic, business, competitive and/or regulatory factors affecting Mallinckrodt’s businesses, and any other statements regarding events or developments the Company 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; 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 potential 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.

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

By: /s/ Bryan M. Reasons

Bryan M. Reasons

Executive Vice President & Chief Financial Officer

Date: March 18, 2020