
**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): September 10, 2024

Mallinckrodt plc

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-35803
(Commission
File Number)

98-1088325
(IRS Employer
Identification No.)

**College Business & Technology Park, Cruiseraith,
Blanchardstown, Dublin 15, Ireland**
(Address of principal executive offices)

+353 1 696 0000
(Registrant's telephone number, including area code)

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: None

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 7.01 Regulation FD Disclosure.

At the direction of the Board of Directors of Mallinckrodt plc (“Mallinckrodt”, the “Company”, “we” or “our”), we are engaged in a process of evaluating the assets across our portfolio, in both our Specialty Brands and Specialty Generics segments, and pursuing divestiture opportunities or other transactions, with a goal of further reducing our debt and maximizing shareholder value. In connection with the Company’s evaluation of divestiture and/or financing initiatives involving our Specialty Generics segment, the Company is furnishing the information set forth in Exhibit 99.1 to this Current Report on Form 8-K to facilitate discussions with certain parties that may be interested in participating in such transactions. Except as otherwise required by law, the Company does not intend to disclose updates with respect to such initiatives unless and until it enters into a definitive agreement providing for any such transaction.

The information contained in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit
99.1	Supplemental financial information about Mallinckrodt plc’s Specialty Generics segment (furnished pursuant to Item 7.01).
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

Statements in this Current Report on Form 8-K that are not strictly historical, including statements regarding the ongoing evaluation of assets across our portfolio and divestiture and/or financing initiatives involving our Specialty Generics segment, 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 ongoing evaluation of assets across our portfolio and divestiture and/or financing initiatives involving our Specialty Generics segment, including the possibility that no definitive agreement or transaction may result from such process; risks related to the pending divestiture of the Therakos business (which include, among other things, the parties’ ability to satisfy the conditions to the divestiture of the Therakos business (including required regulatory approvals), and the ability to complete the divestiture on the anticipated timeline or at all; the potential impact of the divestiture on our businesses and the risk that consummating the divestiture may be more difficult, time-consuming and costly than expected); changes in Mallinckrodt’s board of directors, business strategy and performance; the exercise of contingent value rights by the Opioid Master Disbursement Trust II (the “Trust”); Mallinckrodt’s repurchases of debt securities; the liquidity, results of operations and businesses of Mallinckrodt and its subsidiaries; governmental investigations and inquiries, regulatory actions, and lawsuits, in each case related to Mallinckrodt or its officers; Mallinckrodt’s contractual and court-ordered compliance obligations that, if violated, could result in penalties; historical commercialization of opioids, including compliance with and restrictions under the global settlement to resolve all opioid-related claims; matters related to Acthar Gel, including the settlement with governmental parties to resolve certain disputes and compliance with and restrictions under the related corporate integrity agreement; the ability to maintain relationships with Mallinckrodt’s suppliers, customers, employees and other third parties following the emergence from the 2023 bankruptcy proceedings, as well as perceptions of the Company’s increased performance and credit risks associated with its constrained liquidity position and capital structure; the possibility that Mallinckrodt may be unable to achieve its business and strategic goals even now that the emergence from the 2023 bankruptcy proceedings was successfully consummated; the non-dischargeability of certain claims against Mallinckrodt as part of the bankruptcy process; developing, funding and executing Mallinckrodt’s business plan; Mallinckrodt’s capital structure since its emergence from the 2023 bankruptcy proceedings; 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’ or other payers’ 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; any undesirable side effects caused by Mallinckrodt’s approved and investigational products, which could limit their commercial profile or result in other negative consequences; Mallinckrodt’s and its partners’ ability to successfully develop, commercialize or launch new products or expand commercial opportunities of existing products, including Acthar Gel (repository corticotropin injection) Single-Dose Pre-filled SelfJect™ Injector and the INOmax Evolve platform; Mallinckrodt’s ability to successfully identify or discover additional products or product candidates; Mallinckrodt’s ability to navigate price fluctuations; competition; Mallinckrodt’s and its partners’ ability to protect intellectual property rights, including in relation to ongoing and future litigation; limited clinical trial data for Acthar Gel; the timing, expense and uncertainty associated with clinical studies and related regulatory processes; product liability losses and other litigation liability; material health, safety and environmental liabilities; business development activities or other strategic transactions; attraction and retention of key personnel; the effectiveness of information technology infrastructure, including risks of external attacks or failures; customer concentration; Mallinckrodt’s reliance on certain individual products that are material to its financial performance; Mallinckrodt’s ability to receive sufficient procurement and production quotas granted by the U.S. Drug Enforcement Administration; complex manufacturing processes; reliance on third-party manufacturers and supply chain providers and related market disruptions; conducting business internationally; Mallinckrodt’s ability to achieve expected benefits from prior or future restructuring activities; Mallinckrodt’s significant levels of intangible assets and related impairment testing; natural disasters or other catastrophic events; Mallinckrodt’s substantial indebtedness and settlement obligation, its ability to generate sufficient cash to reduce its indebtedness and its potential need and ability to incur further indebtedness; restrictions contained in the agreements governing Mallinckrodt’s indebtedness and settlement obligation on Mallinckrodt’s operations, future financings and use of proceeds; actions taken by third parties, including the Company’s creditors, the Trust and other stakeholders; Mallinckrodt’s variable rate indebtedness; Mallinckrodt’s tax treatment by the Internal Revenue Service under Section 7874 and Section 382 of the Internal Revenue Code of 1986, as amended; future changes to applicable tax laws or the impact of disputes with governmental tax authorities; the impact of Irish laws; the impact on the holders of Mallinckrodt’s ordinary shares if Mallinckrodt were to cease to be a reporting company in the United States; the comparability of Mallinckrodt’s post-emergence financial results and the projections filed with the Bankruptcy Court; and the lack of comparability of Mallinckrodt’s historical financial statements and information contained in its financial statements after the adoption of fresh-start accounting following emergence from the 2023 bankruptcy proceedings.

The “Risk Factors” and “Management's Discussion and Analysis of Financial Condition and Results of Operations” sections of Mallinckrodt’s Annual Report on Form 10-K for the fiscal year ended December 29, 2023, Quarterly Report on Form 10-Q for the quarterly period ended March 29, 2024, Quarterly Report on Form 10-Q for the quarterly period ended June 28, 2024, and other filings with the SEC, which are available from the SEC’s website (www.sec.gov) and Mallinckrodt's (www.mallinckrodt.com), identify and describe in more detail the risks and uncertainties to which Mallinckrodt’s businesses are subject. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business. 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. Given these uncertainties, one should not put undue reliance on any forward-looking statements.

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: September 10, 2024

By: /s/ Bryan M. Reasons

Bryan M. Reasons

*Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)*

MALLINCKRODT PLC
SPECIALTY GENERICS SEGMENT ADJUSTED EBITDA

(unaudited, in millions)

	Three Months Ended June 28, 2024	Three Months Ended March 29, 2024	Three Months Ended December 29, 2023	Three Months Ended September 29, 2023	Three Months Ended June 30, 2023	Three Months Ended March 31, 2023
Specialty Generics Adjusted EBITDA ¹	\$ 94.6	\$ 67.6	\$ 46.1	\$ 64.8	\$ 46.1	\$ 43.1

MALLINCKRODT PLC
SEGMENT OPERATING INCOME TO ADJUSTED EBITDA RECONCILIATIONS

(unaudited, in millions)

	Successor Three Months Ended June 28, 2024	Successor Three Months Ended March 29, 2024
Specialty Generics Segment Operating Income per SEC Filings ²	\$ 62.4	\$ 38.2
Adjustments:		
Fresh-start inventory-related expense	32.1	29.3
Other income, net ³	0.1	0.1
Specialty Generics Adjusted EBITDA	<u>\$ 94.6</u>	<u>\$ 67.6</u>

MALLINCKRODT PLC
SEGMENT OPERATING INCOME TO ADJUSTED EBITDA RECONCILIATIONS - CONTINUED

(unaudited, in millions)

	Successor November 15, 2023 to December 29, 2023	Predecessor September 30, 2023 to November 14, 2023	Non-GAAP Combined Three Months Ended December 29, 2023
Specialty Generics Segment Operating Income per SEC Filings ²	\$ 5.8	\$ 24.3	\$ 30.1
Adjustments:			
Fresh-start inventory-related expense	16.1	—	16.1
Other expense, net ³	—	(0.1)	(0.1)
Specialty Generics Adjusted EBITDA	<u>\$ 21.9</u>	<u>\$ 24.2</u>	<u>\$ 46.1</u>

¹ The supplemental financial information contains Adjusted EBITDA, which is considered a “Non-GAAP” financial measure under the applicable U.S. Securities and Exchange Commission’s rules and regulations, together with the reconciliation to the most directly comparable GAAP financial measure. Management strongly encourages readers to review the Company’s audited and unaudited condensed consolidated financial statements and publicly filed reports in their entirety.

² As disclosed in the Company’s quarterly report on Form 10-Q for the three months ended June 28, 2024 (Successor), management measures and evaluates the Company’s operating segments based on segment net sales and operating income. Management excludes corporate expenses from segment operating income. In addition, certain amounts that management considers to be non-recurring or non-operational are excluded from segment operating income because management and the chief operating decision maker evaluate the operating results of the segments excluding such items. These items may include, but are not limited to, depreciation and amortization, share-based compensation, net restructuring charges, non-restructuring impairment charges and liabilities management and separation costs. Although these amounts are excluded from segment operating income, as applicable, they are included in reported consolidated operating loss. Management believes that the segment operating income is the most directly comparable U.S. GAAP measure for the segment Adjusted EBITDA.

³ Excludes intercompany expense of \$5.3 million, \$3.7 million, \$1.0 million, \$24.4 million, \$7.3 million, \$2.7 million and \$3.7 million for the three months ended June 28, 2024 (Successor), the three months ended March 29, 2024 (Successor), the period from November 15, 2023 to December 29, 2023 (Successor), the period from September 30, 2023 to November 14, 2023 (Predecessor), the three months ended September 29, 2023 (Predecessor), the three months ended June 30, 2023 (Predecessor) and the three months ended March 31, 2023 (Predecessor), respectively. These intercompany expenses primarily related to an allocation of corporate overhead costs to the Specialty Generics reportable segment.

MALLINCKRODT PLC
SEGMENT OPERATING INCOME TO ADJUSTED EBITDA RECONCILIATIONS - CONTINUED
(unaudited, in millions)

	Predecessor		
	Three Months Ended September 29, 2023	Three Months Ended June 30, 2023	Three Months Ended March 31, 2023
Specialty Generics Segment Operating Income per SEC Filings ²	\$ 64.0	\$ 35.1	\$ 32.8
Adjustments:			
Fresh-start inventory-related expense	0.7	11.0	10.3
Other income, net ³	0.1	—	—
Specialty Generics Adjusted EBITDA	<u>\$ 64.8</u>	<u>\$ 46.1</u>	<u>\$ 43.1</u>

MALLINCKRODT PLC
SELECT PRODUCT LINE NET SALES
(unaudited, in millions)

	Successor	
	Three Months Ended June 28, 2024	Three Months Ended March 29, 2024
Specialty Generics		
Opioids	\$ 95.2	\$ 81.9
ADHD	41.8	31.7
Addiction treatment	21.0	15.4
Other	3.6	1.5
Generics	161.6	130.5
APAP	47.3	51.7
Controlled Substances	26.4	22.9
Other	4.5	5.4
API	78.2	80.0
Specialty Generics	<u>\$ 239.8</u>	<u>\$ 210.5</u>

MALLINCKRODT PLC
SELECT PRODUCT LINE NET SALES - CONTINUED
(unaudited, in millions)

	Successor	Predecessor	Non-GAAP Combined
	November 15, 2023 to December 29, 2023	September 30, 2023 to November 14, 2023	Three Months Ended December 29, 2023
Specialty Generics			
Opioids	\$ 31.6	\$ 30.5	\$ 62.1
ADHD	13.5	18.5	32.0
Addiction treatment	10.5	8.8	19.3
Other	1.6	0.6	2.2
Generics	57.2	58.4	115.6
APAP	32.5	21.2	53.7
Controlled substances	11.6	14.1	25.7
Other	1.9	1.7	3.6
API	46.0	37.0	83.0
Specialty Generics	<u>\$ 103.2</u>	<u>\$ 95.4</u>	<u>\$ 198.6</u>

MALLINCKRODT PLC
SELECT PRODUCT LINE NET SALES - CONTINUED

(unaudited, in millions)

	Predecessor		
	Three Months Ended September 29, 2023	Three Months Ended June 30, 2023	Three Months Ended March 31, 2023
Specialty Generics			
Opioids	\$ 65.9	\$ 72.1	\$ 62.2
ADHD	41.5	19.0	22.4
Addiction treatment	15.1	16.1	15.6
Other	3.4	2.4	1.8
Generics	125.9	109.6	102.0
APAP	57.4	59.8	46.4
Controlled Substances	22.0	20.9	18.5
Other	5.5	4.6	5.7
API	84.9	85.3	70.6
Specialty Generics	<u>\$ 210.8</u>	<u>\$ 194.9</u>	<u>\$ 172.6</u>