

**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): **May 28, 2019**

Mallinckrodt public limited company

(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.)

**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:

<u>(Title of each class)</u>	<u>(Trading Symbol(s))</u>	<u>(Name of each exchange on which registered)</u>
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 7.01. Regulation FD Disclosure.

On May 28, 2019, Mallinckrodt plc (“Mallinckrodt” or the “Company”) issued a press release announcing an update on the Company’s previously announced spin-off of its Specialty Generics business to its shareholders. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. 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, 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, except as otherwise expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On May 28, 2019, the Company announced updated plans for its previously announced spin-off of a new company (“SpinCo”) consisting of Mallinckrodt’s Specialty Generics/Active Pharmaceutical Ingredients business to Company shareholders. It was previously announced, and reflected in the preliminary registration statement on Form 10 filed by SpinCo, with the U.S. Securities and Exchange Commission (“SEC”), that SpinCo would include AMITIZA (lubiprostone). As part of the newly announced updated plans for the spin-off, it has been determined that the Company will retain the AMITIZA product.

The spin-off is expected to be completed in the second half of 2019, subject to the satisfaction of a number of conditions, including final approval of the Company’s board of directors, an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Company shareholders, and the SEC declaring SpinCo’s Form 10 registration statement effective. There can be no assurance regarding the final allocation of assets between the two companies, the ultimate timing of the spin-off, or that it will be completed.

Cautionary Statements Related to Forward-Looking Statements

Statements in this Current Report on Form 8-K that are not strictly historical, including statements regarding future financial condition and operating results, 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: the proposed spin-off of the Specialty Generics business, including the allocation of assets and liabilities between the two companies, the anticipated indebtedness of the two companies upon and following completion of the separation, the costs associated with the contemplated separation and spin-off, the expected benefits of the transaction, and the expected timeframe to complete such a transaction; general economic conditions and conditions affecting the industries in which Mallinckrodt operates; the commercial success of Mallinckrodt’s products; Mallinckrodt’s ability to realize anticipated growth, synergies and cost savings from acquisitions; conditions that could necessitate an evaluation of Mallinckrodt’s intangible assets for possible impairment; changes in laws and regulations; Mallinckrodt’s ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings; Mallinckrodt’s and Mallinckrodt’s licensors’ ability to successfully develop or commercialize new products; Mallinckrodt’s and Mallinckrodt’s licensors’ ability to protect intellectual property rights; Mallinckrodt’s ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; customer concentration; Mallinckrodt’s reliance on certain individual products that are material to its financial performance; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; the reimbursement practices of a small number of public or private insurers; 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; limited clinical trial data for H.P. Acthar Gel; complex reporting and payment obligations under healthcare rebate programs; Mallinckrodt’s ability to navigate price fluctuations; future changes to U.S. and foreign tax laws; Mallinckrodt’s ability to achieve expected benefits from restructuring activities; complex manufacturing processes; competition; product liability losses and other litigation liability; ongoing governmental investigations; material health, safety and environmental liabilities; retention of key personnel; conducting business internationally; the effectiveness of information technology infrastructure; and cybersecurity and data leakage risks.

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 28, 2018. 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

<u>Exhibit No.</u>	<u>Exhibit</u>
99.1	Press Release of Mallinckrodt plc, dated May 28, 2019.

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 PUBLIC LIMITED COMPANY

By: /s/ Mark J. Casey

Mark J. Casey

General Counsel

Date: May 28, 2019

**Mallinckrodt Updates Plans for Company Separation and Spin-Off of Specialty Generics
Business to Shareholders**

- Announces James Sulat as chairman of the board of directors and Michael Atieh as audit committee chair nominees for new Specialty Generics company --
- Reconfirms Matthew Harbaugh as President and Chief Executive Officer, announces Eric Slusser as Chief Financial Officer for new Specialty Generics company upon spin-off; full management team now in place --
- Changes composition of companies; Specialty Brands company will retain AMITIZA® (lubiprostone) --
- Provides insights on potential capital structure for new Specialty Generics company, anticipates up to \$300 million in new debt to be raised --
- Expects Specialty Brands company to be renamed Sonorant Therapeutics plc upon separation with NYSE ticker symbol SRTX; Specialty Generics company to retain Mallinckrodt name and MNK ticker symbol --
- Targets separation completion in second half of 2019 --

STAINES-UPON-THAMES, United Kingdom - May 28, 2019 - [Mallinckrodt plc](#) (NYSE: MNK), a global biopharmaceutical company, today announced updated plans for its spin-off of a new company consisting of Mallinckrodt's Specialty Generics/Active Pharmaceutical Ingredients (Specialty Generics) business to Mallinckrodt plc shareholders. The separation is intended to create two independent, appropriately capitalized, publicly traded companies - one focused on innovative specialty branded pharmaceuticals, the other concentrated primarily in specialty generic products and APIs¹ manufacturing - with each positioned to optimize future success as they pursue independent growth strategies. The separation is subject to final Mallinckrodt plc board approval.

As previously announced, the planned separation is expected to be executed through a pro-rata distribution of common stock of Mallinckrodt Inc. - a newly formed company that, at the time of the separation, will hold the Specialty Generics business - to Mallinckrodt plc's shareholders, generally tax-free for U.S. federal income tax purposes. The completed spin-off is projected to occur in the second half of 2019. It is anticipated that Mallinckrodt Inc. will be listed on the New York Stock Exchange (NYSE) and will assume the MNK ticker symbol along with the Mallinckrodt name. At separation, the remaining Specialty Brands company will continue to be listed on the NYSE, renamed Sonorant Therapeutics plc, and is expected to adopt SRTX as its ticker symbol.

Anticipated Board of Directors of the New Specialty Generics Company

James Sulat has been nominated as the independent chairman of the board of the new company upon separation. Most recently, Sulat was the chief executive officer of Maxygen, Inc., and also served as chief executive officer of Memory Pharmaceuticals. He has extensive board experience and his current involvement includes AMAG Pharmaceuticals.

Michael Atieh has been nominated as chair of the audit committee of the new board of directors. Atieh is the former executive vice president and chief financial officer of Ophthotech Corporation. He currently serves as a member of Chubb Ltd.'s board of directors, where he is a member of the risk and finance committee, and previously served as chairman of the audit committee from 2012 to 2018. Atieh is also a

¹Active Pharmaceutical Ingredients

member of the board of directors of electroCore Inc., where he serves as chairman of the audit committee.

“We are very pleased with the progress being made in building the board of the new Specialty Generics company,” said Sulat. “Michael brings exceptional experience to the audit chair role, and we have a number of well-suited candidates we are actively assessing and expect to create a well-rounded board in the near term. Equally important, Matt Harbaugh has formed a management team with deep experience and business acumen, and I am excited to work with them to advance a strong strategic vision for the company.”

As progress is made toward separation completion, the new board of directors for Mallinckrodt Inc. will be expanded and announced as appropriate.

Eric Slusser to Serve as CFO of the New Specialty Generics Company

As previously announced, **Matthew Harbaugh**, current President of Mallinckrodt’s Specialty Generics business and formerly the company’s Chief Financial Officer (CFO), is projected to become President and Chief Executive Officer of the new company upon completion of the separation.

Eric Slusser has joined the company and is expected to serve as CFO of the new company upon separation. Slusser has more than 35 years of experience in corporate finance, audit, business development, information technology, financial planning and analysis, controllership, real estate and investor relations. He previously served as CFO for a number of notable public companies including Express Scripts, Gentiva Health Services and Centene Corporation.

A full management team is now in place and the two businesses are on track to be operationally ready for separation.

“I am very pleased with the highly experienced management team we have assembled,” said Harbaugh. “We are well positioned for separation and eager to advance the strategic goals we’ve established for our new company.”

Revised Business Profile of the New Specialty Generics Company

It was previously announced, and reflected in the preliminary registration statement on Form 10 filed by Mallinckrodt Inc. with the U.S. Securities and Exchange Commission (SEC), that the new spun-off company would include AMITIZA (lubiprostone). Given the strong, return-to-growth performance of the Specialty Generics business, it has been determined that the AMITIZA product should remain with the Specialty Brands company.

“When we announced our intent to separate the Specialty Generics business through a spin-off in December 2018, we noted the final allocation of assets between the two companies could change. Our goal from the outset has been to establish two new, appropriately capitalized, independent companies well positioned to unlock and increase value over the long term,” said **Mark Trudeau, President and Chief Executive Officer of Mallinckrodt**. “We now believe retaining the AMITIZA product will better serve the needs of the Specialty Brands company, providing revenue diversification and stronger cash flows to support our commitment to debt reduction. Importantly, as a result of this change we believe the new Specialty Generics company will emerge with significantly less debt than previously anticipated, and have greater flexibility to pursue growth and investment strategies aligned with its goals.”

Without the AMITIZA product, for the twelve months ended March 29, 2019, the collective net sales from the Specialty Generics business were \$722.6 million on an as-reported basis.

With approximately 1,600 employees, the newly separated company will include a leading acetaminophen business, a portfolio of both APIs and generic finished dose forms of controlled substances and other drugs, a complex specialty generics development portfolio, and a strong U.S.

manufacturing footprint. The Specialty Generics business' outlook for 2019 is largely driven by volume-based market share recapture. Its pipeline is progressing toward long-term advances with nearly 20 products in development, approximately 70% of which are non-controlled substance molecules, and the branded versions of those products currently aggregate to more than \$10 billion of net sales.

Harbaugh said, "We have a diversified revenue base across APIs, contract manufacturing and finished dosage form generics with solid cash flows and a long-standing leadership position in controlled substances. With expected 2019 pro forma, stand-alone adjusted EBITDA of roughly \$150² million, we believe we have a compelling story that investors should find attractive."

While a final capital structure has yet to be determined, prior to spin-off the new Specialty Generics company anticipates raising a conservative amount of debt of up to \$300 million. Net proceeds from the debt will be distributed to the parent after deducting for standard transaction costs and operating needs.

Specialty Brands Revised Net Sales; Impact to Previous Debt Repayment Guidance

Recast net sales for the Specialty Brands segment for the twelve months ended March 29, 2019, inclusive of the AMITIZA product, were \$2.528 billion on an as-reported basis.

"This composition change to the more modest leverage assumptions for the new spin-off company does not change our stated goal of reducing net debt by more than \$1 billion utilizing free cash flow and spin-off proceeds, though the goal attainment may be later in the second half of the year." said **Bryan Reasons, Executive Vice President and Chief Financial Officer of Mallinckrodt**. "Debt repayment will remain our top capital allocation priority through the separation and beyond, and we remain focused on reducing our net debt leverage to under 4.0x as expeditiously as possible following the separation."

Next Steps in the Separation Process

A revised Mallinckrodt Inc. registration statement on Form 10 which, among other things, will reflect the removal of the AMITIZA product from the assets to be held by the new Specialty Generics company at separation, is expected to be filed in June. Recast historical financials for the consolidated Specialty Generics segment, moving AMITIZA to the Specialty Brands segment, are estimated to be provided in June as well.

Completion of the separation transaction remains subject to certain conditions, including final Mallinckrodt plc board approval; an opinion from tax counsel regarding the treatment of the spin-off as generally tax-free for U.S. federal income tax purposes to Mallinckrodt shareholders; and the SEC declaring the registration statement on Form 10 effective. There can be no assurance regarding the final allocation of assets between the two companies, the ultimate timing of the proposed separation, or that the spin-off will be completed.

Advisors

Goldman, Sachs & Co. is acting as financial advisor on the spin-off and Wachtell, Lipton, Rosen & Katz is acting as legal advisor.

²This press release contains adjusted EBITDA which is considered a "non-GAAP" financial measure under applicable SEC rules and regulations. Adjusted EBITDA is prepared in accordance with accounting principles generally accepted in the U.S. (GAAP) and represents net income (loss), prepared in accordance with GAAP, adjusted for interest expense, taxes, depreciation and amortization; certain items that management believes are not reflective of the operational performance of the business. These adjustments include, but are not limited to, non-restructuring impairment charges; restructuring and related charges, net; inventory step-up expenses; discontinued operations; changes in fair value of contingent consideration obligations; acquisition-related expenses; losses/gains on divestiture; significant legal and environmental charges; historical EBITDA of companies acquired during the period; separation costs and other items identified by the company.

ABOUT AMITIZA

AMITIZA (lubiprostone), a leading global product in the branded constipation market, is approved by the U.S. Food and Drug Administration for treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women 18 years of age and older, and opioid-induced constipation in adult patients with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation. The AMITIZA product is a chloride channel activator which increases fluid secretion and motility of the intestine, facilitating passage of stool.

ABOUT MALLINCKRODT

Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Mallinckrodt Pharmaceuticals' 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. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt 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 SEC 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

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, 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.

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H.P. Acthar Gel; complex reporting and payment obligations under healthcare rebate programs; Mallinckrodt's ability to navigate price fluctuations; future changes to U.S. and foreign tax laws; Mallinckrodt's ability to achieve expected benefits from restructuring activities; complex manufacturing processes; competition; product liability losses and other litigation liability; ongoing governmental investigations; material health, safety and environmental liabilities; retention of key personnel; conducting business internationally; the effectiveness of information technology infrastructure; and cybersecurity and data leakage risks.

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 28, 2018. 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.

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