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): August 28, 2023

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, Cruiserath, Blanchardstown, Dublin 15, Ireland (Address of principal executive offices) (Zip Code)

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

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</u>
		<u>registered)</u>
Ordinary shares, par value \$0.01 per share	MNK	NYSE American LLC
Frank Prank Prank		

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 \Box

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 1.03. Bankruptcy or Receivership.

As contemplated by the previously announced restructuring support agreement dated August 23, 2023, by and among Mallinckrodt plc ("Mallinckrodt" or the "Company"), certain of its subsidiaries, certain creditors and the Opioid Master Disbursement Trust II (the "RSA"), and with the authorization of the Company's board of directors, on August 28, 2023 (the "Petition Date"), the Company and certain of its subsidiaries voluntarily initiated proceedings (the "Chapter 11 Cases") under chapter 11 of title 11 of the United States Code (the "Bankruptcy Code") in the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). The entities that filed the Chapter 11 Cases include the Company, substantially all of the Company's U.S. subsidiaries, including its specialty generics-focused subsidiaries (collectively, "Specialty Brands"), and certain of the Company's international subsidiaries (together with the Company, Specialty Generics and Specialty Brands, the "Debtors"). The Debtors have filed a motion with the Bankruptcy Court seeking joint administration of the Chapter 11 Cases under the caption *In re Mallinckrodt plc*, Case No. 23-11258.

The Debtors continue to operate their businesses as debtors-in-possession under the jurisdiction of the Bankruptcy Court and in accordance with applicable provisions of the Bankruptcy Code and the orders of the Bankruptcy Court. The Debtors are seeking approval from the Bankruptcy Court of a variety of "first day" motions, including motions to obtain debtor-in-possession financing and other customary relief intended to assure the Debtors' ability to continue their ordinary course operations.

Item 2.04. Triggering Events that Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.

The commencement of the Chapter 11 Cases constituted an event of default under a number of instruments and agreements relating to direct financial obligations of certain of the Debtors (the "Financial Obligations"). The material Financial Obligations include:

- Credit Agreement, dated as of June 16, 2022, by and among Mallinckrodt plc, Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, Acquiom Agency Services LLC and Seaport Loan Products LLC, as co-administrative agents, Deutsche Bank AG New York Branch, as collateral agent, and the lenders party from time to time thereto;
- Indenture, dated as of April 7, 2020, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the guarantors party thereto from time to time, Wilmington Savings Fund Society, FSB, as first lien trustee and Deutsche Bank AG New York Branch, as first lien collateral agent, and the 10.00% First Lien Senior Secured Notes due 2025 issued pursuant thereto;
- Indenture, dated as of June 16, 2022, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC the guarantors party thereto from time to time, Wilmington Savings Fund Society, FSB, as first lien trustee, and Deutsche Bank AG New York Branch, as first lien collateral agent, and the 11.50% First Lien Senior Secured Notes due 2028 issued pursuant thereto;
- Indenture, dated as of June 16, 2022, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the guarantors party thereto from time to time, Wilmington Savings Fund Society, FSB, as second lien trustee and second lien collateral agent, and the 10.00% Second Lien Senior Secured Notes due 2025 issued pursuant thereto; and
- Indenture, dated as of June 16, 2022, by and among Mallinckrodt International Finance S.A., Mallinckrodt CB LLC, the guarantors party thereto from time to time, Wilmington Savings Fund Society, FSB, as second lien trustee and second lien collateral agent, and the 10.00% Second Lien Senior Secured Notes due 2029 issued pursuant thereto.

Subject to any applicable provisions of the Bankruptcy Code, the instruments and agreements relating to the Financial Obligations described above provide that, as a result of the commencement of the Chapter 11 Cases, the principal amount, together with accrued and unpaid interest thereon, and in the case of the indebtedness outstanding under each of the indentures described above, premium, if any, thereon, shall be immediately due and payable. Any efforts to enforce payment obligations under the Financial Obligations are automatically stayed as a result of the Chapter 11 Cases and the creditors' rights in respect of the Financial Obligations are subject to the applicable provisions of the Bankruptcy Code.

In addition to the Financial Obligations described above, ST US AR Finance LLC, a non-debtor affiliate of the Debtors, is party to that certain ABL Credit Agreement, dated as of June 16, 2022 (as amended), by and among ST US AR Finance LLC, the Lenders and the L/C Issuers (as defined in the ABL Credit Agreement) party thereto and Barclays Bank plc, as administrative agent and collateral agent. The commencement of the Chapter 11 Cases would constitute an event of default under the ABL Credit Agreement but for certain amendments thereto, entered into prior to the date hereof.

Item 7.01. Regulation FD Disclosure.

Chapter 11 Cases

In connection with the commencement of the Chapter 11 Cases, the Company issued a press release on August 28, 2023, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Important information about the Chapter 11 Cases, including court filings and other information, are available on a separate website administrated by the Company's claims agent, Kroll, at https://restructuring.ra.kroll.com/mallinckrodt2023. Such information may be filed with the Bankruptcy Court without the filing of an accompanying Current Report on Form 8-K. This website contains third-party content and is provided for convenience only. The documents and other information available on this website are not incorporated by reference into, and do not constitute a part of, this Current Report on Form 8-K.

Subpoena

On August 22, 2023, the Company received a grand jury subpoena from the U.S. Attorney's Office for the Western District of Virginia ("USAO") seeking production of data and information for the time period from July 17, 2017 to the present, including information and data relating to the Company's reporting of suspicious orders for controlled substances, chargebacks and other transactions, and communications between the Company and the U.S. Drug Enforcement Administration ("DEA") regarding those issues. The Company's legal representatives discussed the intended scope of the subpoena and initial timeline with the USAO on August 24, 2023.

The Company is in the process of responding to the subpoena and intends to cooperate in the investigation and share information with the USAO about the operating injunction under which the Company's Specialty Generics segment has been operating since October 2020 and which was agreed to by 50 state and territory attorneys general and entered by the U.S. Bankruptcy Court for the District of Delaware ("operating injunction"). Among other things, the operating injunction provides that Specialty Generics must retain an independent monitor to evaluate and audit compliance with the operating injunction. R. Gil Kerlikowske, former Director of the Office of National Drug Control Policy and former Commissioner of U.S. Customs and Border Protection, currently serves as the monitor and issues periodic reports on Specialty Generics' compliance program, which can be found on the Company's web site at https://www.mallinckrodt.com/corporate-responsibility/corporate-compliance/.

The Company believes that Specialty Generics is in compliance with its obligations through its industry-leading compliance program for controlled substances. Prior to the existing operating injunction, Specialty Generics operated under a compliance-related memorandum of understanding with DEA established in July 2017 that expired in July 2020.

The Company cannot predict the eventual scope, duration or outcome of the investigation at this time.

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 such information 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.

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, 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 forwardlooking 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 bankruptcy process, including the possibility that certain parties, such as creditors that are not party to the RSA or the Company's equityholders, may object to the plan proposed by the RSA; changes to the Chapter 11 Cases, whether as a result of amendments or supplements to the plan of reorganization, the disclosure statement or other documents, third-party actions, or otherwise; the ability of Mallinckrodt and its subsidiaries to obtain approval from the Bankruptcy Court with respect to motions or other requests made to the Bankruptcy Court throughout the course of the Chapter 11 Cases and to negotiate, develop, obtain court approval of, confirm and consummate the plan of reorganization contemplated by the RSA or any other plan that may be proposed within the Company's currently expected timeline or at all; the effects of the Chapter 11 Cases, including increased professional costs, on the liquidity, results of operations and businesses of Mallinckrodt and its subsidiaries; the ability of the Debtors to operate their business during the pendency of the Chapter 11 Cases; the consummation of the transactions contemplated by the RSA, including the ability of the parties to negotiate definitive agreements with respect to the matters covered by the term sheets included in the RSA, the occurrence of events that may give rise to a right of any of the parties to terminate the RSA, and the ability of the parties thereto to receive the required approval by the Bankruptcy Court and to satisfy the other conditions of the RSA; the eventual scope, duration or outcome of the USAO investigation; Mallinckrodt's ability to comply with the continued listing criteria of NYSE American LLC and the potential suspension of trading of Mallinckrodt's ordinary shares on, or delisting from, NYSE American LLC and the effects of Chapter 11 on the interests of various constituents; fluctuations in market price and trading volume of Mallinckrodt's ordinary shares; the ability to maintain relationships with Mallinckrodt's suppliers, customers, employees and other third parties as a result of, and following, its 2022 emergence from bankruptcy and any emergence upon completion of the Chapter 11 Cases, as well as perceptions of the Company's increased performance and credit risks associated with its constrained liquidity position and capital structure, which reflects a recently increased risk of additional bankruptcy or insolvency proceedings; Mallinckrodt's substantial indebtedness, its ability to generate sufficient cash to reduce its indebtedness and its potential need and ability to incur further indebtedness; Mallinckrodt's ability to generate sufficient cash to service indebtedness even now that the pre-petition indebtedness has been restructured and in light of the proposed financial restructuring plan contemplated by the RSA; developing, funding and executing Mallinckrodt's business plan and ability to continue as a going concern; Mallinckrodt's capital structure upon completion of the Chapter 11 Cases; the comparability of Mallinckrodt's post-emergence financial results to its historical results and the projections filed with the Bankruptcy Court in the Company's 2020 Chapter 11 proceedings and the projections disclosed in connection with the transactions contemplated by the RSA; changes in Mallinckrodt's business strategy and performance; Mallinckrodt's tax treatment by the Internal Revenue Service under Section 7874 and Section 382 of the Internal Revenue Code of 1986, as amended; governmental investigations and inquiries, regulatory actions and lawsuits, in each case related to Mallinckrodt or its officers; matters related to the 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 settlement with governmental parties to resolve certain disputes and compliance with and restrictions under the corporate integrity agreement; 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, including in relation to ongoing litigation; 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; business development activities; attraction and 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; reliance on third-party manufacturers and supply chain providers; conducting business internationally; Mallinckrodt's ability to achieve expected benefits from prior restructuring activities or those contemplated in the future; Mallinckrodt's significant levels of intangible assets and related impairment testing; labor and employment laws and regulations; natural disasters or other catastrophic events; restrictions on Mallinckrodt's operations contained in the agreements governing Mallinckrodt's indebtedness; Mallinckrodt's variable rate 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 risks, uncertainties and factors described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended December 30, 2022 and the Company's Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2023 and June 30, 2023, as filed with the SEC and available on the Company's website at http://www.mallinckrodt.com and http://www.sec.gov.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit	
<u>99.1</u>	Press Release, dated August 28, 2023.	
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

By: /s/ Mark Tyndall

Mark Tyndall Executive Vice President, Chief Legal Officer & Corporate Secretary

Date: August 28, 2023

Mallinckrodt plc Takes Next Step to Implement Comprehensive Financial Restructuring Plan to Address Long-Term Debt and Opioid Obligations

Initiates Voluntary Prepackaged Chapter 11 Proceedings with Overwhelming Support of Key Stakeholders, Including 85%+ of First and Second Lien Debtholders

Continuing to Operate Normally, Serve Customers and Deliver High-Quality Therapies to Patients

Vendors and Suppliers Expected to be Paid in Full in the Ordinary Course

DUBLIN – **August 28, 2023** – Mallinckrodt plc (NYSE American: MNK) ("Mallinckrodt" or the "Company"), a global specialty pharmaceutical company, today announced that it has taken the next step to implement the comprehensive financial restructuring plan contemplated by a Restructuring Support Agreement ("RSA") the Company previously entered into with more than 85% of each of the Company's first and second lien debtholders and the Opioid Master Disbursement Trust II (the "Trust"), as announced on August 23, 2023.

Pursuant to the RSA and with the authorization of the Company's Board of Directors, Mallinckrodt and certain of its subsidiaries¹ today initiated voluntary prepackaged Chapter 11 proceedings in the U.S. Bankruptcy Court for the District of Delaware. With the overwhelming support of its key stakeholders, the Company expects to complete the court-supervised process in the fourth quarter of 2023.

Implementing the financial restructuring contemplated by the RSA will reduce the Company's total funded debt by approximately \$1.9 billion, increase free cash flow generation, extend maturity runway and better position the business for long-term success. The RSA also provides for, among other consideration, a final, one-time payment of \$250 million that was made to the Trust on August 24, 2023. This payment, in addition to the \$450 million the Company previously paid, is intended to support the Trust's mission to address the U.S. opioid crisis and fund addiction treatment.

Siggi Olafsson, President and Chief Executive Officer of Mallinckrodt, said, "We are moving forward with the anticipated next steps for our financial restructuring plan and appreciate the significant support of our key stakeholders to reach this milestone. Implementing this agreement will meaningfully enhance Mallinckrodt's financial foundation and better position the business for the future. We expect to complete this process on an expedited basis and emerge as a stronger organization that will continue to help improve outcomes for patients with severe and critical conditions."

Mr. Olafsson continued, "I would like to thank the Mallinckrodt team for their resilience and dedication to our company's mission. We also thank our customers, vendors, suppliers and other partners for their ongoing support as we work together to meet our patients' needs. As we move forward, we are continuing to deliver the important therapies that patients depend on us to provide."

Continuing to Operate as Normal

Mallinckrodt is operating normally, supporting patients with high-quality therapies, serving customers and working with its business partners. Additionally, the Company's Specialty Generics business will continue to operate under the previously agreed upon operating injunction, which provides for enhanced compliance and independent monitoring measures and has been in place since October 2020. The Company also fully intends to continue supporting patient groups and patient advocacy programs, including through its Patient Advocacy Advisory Board and patient assistance programs.

Following Court approval, which the Company expects to receive shortly, Mallinckrodt will have in excess of \$450 million of liquidity comprising cash, commitments received for \$250 million in new financing from certain of its creditors in connection with the RSA and new borrowing availability from lenders under its asset-based loans. Together with cash generated from ongoing operations, this liquidity is expected to be sufficient to support the Company's continued operations during the court-supervised process.

¹Filing entities include Mallinckrodt plc, substantially all of its U.S. subsidiaries and certain of its international subsidiaries.

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The Company has filed a number of customary motions seeking Court approval to support its operations during this process, including the continued payment of employee wages, salaries and benefits without interruption. Mallinckrodt expects to receive approval for these requests shortly. The Company intends to pay vendors and suppliers in the ordinary course, including for any pre-petition amounts owed at the time of filing.

In connection with the Chapter 11 filing, Mallinckrodt also intends to make certain filings to commence Examinership Proceedings in Ireland, which are required to implement certain Irish law aspects of the financial restructuring and allow for emergence.

Additional Information

Additional information is available on Mallinckrodt's restructuring website at www.MNKrestructuring.com.

Court filings and other information related to the proceedings are available on a separate website administrated by the Company's claims agent, Kroll, at <u>https://restructuring.ra.kroll.com/mallinckrodt2023</u>; by calling Kroll representatives toll-free at +1-844-245-7926, or +1-646-440-4855 for calls originating outside of the U.S. or Canada; or by emailing Kroll at <u>mallinckrodt2023info@ra.kroll.com</u>.

Vendors, suppliers and trade partners should direct any inquiries to the Company at +1-908-238-5650 or Supplier.Inquiry@mnk.com.

Latham & Watkins LLP, Wachtell, Lipton, Rosen & Katz, Arthur Cox LLP, Richards, Layton & Finger PA, and Hogan Lovells US LLP are serving as Mallinckrodt's counsel. Guggenheim Securities, LLC is serving as investment banker, and AlixPartners LLP is serving as restructuring advisor.

About Mallinckrodt

Mallinckrodt is 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, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. To learn more about Mallinckrodt, visit <u>www.mallinckrodt.com</u>.

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 U.S. Securities and Exchange Commission (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, expected product launches, legal, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses, and any other statements regarding events or developments 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 bankruptcy process, including the possibility that certain parties, such as creditors that are not party to the RSA or the Company's equity holders, may object to the plan of reorganization contemplated by the RSA; the ability of Mallinckrodt and its subsidiaries to obtain approval from the U.S. Bankruptcy Court for the District of Delaware (the "Court") with respect to motions or other requests made to the Court throughout the course of the Chapter 11 proceedings and to negotiate, develop, obtain court approval of, confirm and consummate the plan of reorganization contemplated by the RSA or any other plan that may be proposed within the Company's currently expected timeline or at all, the effects of the Chapter 11 proceedings, including increased professional costs, on the liquidity, results of operations and businesses of Mallinckrodt and its subsidiaries, including the Company's ability to operate normally, support patients, serve customers, work with business partners and abide by previously agreed upon compliance and monitoring measures; the consummation of the transactions contemplated by the RSA, including the ability of the parties to negotiate definitive agreements with respect to the matters covered by the term sheets included in the RSA, the occurrence of events that may give rise to a right of any of the parties to terminate the RSA and the ability of the parties thereto to receive the required approval by the Court and to satisfy the other conditions of the RSA; Mallinckrodt's ability to comply with the continued listing criteria of NYSE American LLC and the potential suspension of trading of Mallinckrodt's ordinary shares on, or delisting from, NYSE American LLC and the effects of Chapter 11 on the interests of various constituents; fluctuations in market price and trading volume of Mallinckrodt's ordinary shares; the ability to maintain relationships with Mallinckrodt's suppliers, customers, employees and other third parties as a result of, and following, its 2022 emergence from bankruptcy and any emergence upon completion of its current Chapter 11 proceedings, as well as perceptions of the Company's increased performance and credit risks associated with its constrained liquidity position and capital structure, which reflects a recently increased risk of additional bankruptcy or insolvency proceedings; Mallinckrodt's substantial indebtedness, its ability to generate sufficient cash to reduce its indebtedness and its potential need and ability to incur further indebtedness; Mallinckrodt's ability to generate sufficient cash to service indebtedness even now that the pre-petition indebtedness has been restructured and in light of the proposed financial restructuring plan contemplated by the RSA; developing, funding and executing Mallinckrodt's business plan and ability to continue as a going concern; Mallinckrodt's capital structure upon completion of the Chapter 11 proceedings; the comparability of Mallinckrodt's post-emergence financial results to its historical results and the projections filed with the U.S. Bankruptcy Court for the District of Delaware in the Company's 2020 Chapter 11 proceedings and the current Chapter 11 proceedings; changes in Mallinckrodt's business strategy and performance; Mallinckrodt's tax treatment by the Internal Revenue Service under Section 7874 and Section 382 of the Internal Revenue Code of 1986, as amended; governmental investigations and inquiries, regulatory actions and lawsuits, in each case related to Mallinckrodt or its officers; matters related to the 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 settlement with governmental parties to resolve certain disputes and compliance with and restrictions under the corporate integrity agreement; 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, including in relation to ongoing litigation; 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; business development activities; attraction and 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; reliance on third-party manufacturers and supply chain providers; conducting business internationally; Mallinckrodt's ability to achieve expected benefits from prior restructuring activities or those contemplated in the future; Mallinckrodt's significant levels of intangible assets and related impairment testing; labor and employment laws and regulations; natural disasters or other catastrophic events; restrictions on Mallinckrodt's operations contained in the agreements governing Mallinckrodt's indebtedness; Mallinckrodt's variable rate indebtedness; future changes to U.S. and foreign tax laws or the impact of disputes with governmental tax authorities; and the impact of Irish laws.

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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 30, 2022 and Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2023 and March 31, 2023, and other filings with the SEC, all of which are on file with the SEC and available on Mallinckrodt's website at http://www.sec.gov and http://www.sec.gov ana

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