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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 7, 2023

**Mallinckrodt plc**

(Exact name of registrant as specified in its charter)

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<b>Ireland</b> (State or other jurisdiction of incorporation)	<b>001-35803</b> (Commission File Number)	<b>98-1088325</b> (IRS Employer Identification No.)
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**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 registered)</u>
Ordinary shares, par value \$0.01 per share	MNK	NYSE American LLC

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.

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**Item 7.01 Regulation FD Disclosure.**

On March 7, 2023, Mallinckrodt plc will make a presentation at Cowen's 43<sup>rd</sup> Annual Health Care Conference in Boston, Massachusetts. A copy of the presentation is furnished with this report as Exhibit 99.1. Individuals who cannot attend the meeting in person can find webcast information on the Company's investor relations page at [ir.mallinckrodt.com](http://ir.mallinckrodt.com).

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Exhibit</u>
<a href="#">99.1</a>	<a href="#">Presentation Provided By Mallinckrodt plc on March 7, 2023</a>
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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**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: March 7, 2023

By: /s/ Mark Tyndall

Mark Tyndall

Executive Vice President, Chief Legal Officer & Corporate Secretary

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# Mallinckrodt Pharmaceuticals

Listening for needs. Delivering solutions.

43rd Annual TD Cowen Health Care Conference  
March 7, 2023

# Forward-looking statements

Statements in this document that are not strictly historical, including statements regarding future clinical trials and commercial launches, 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 that 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.

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 comparability of Mallinckrodt's post-emergence financial results to its historical results and the projections filed with the bankruptcy court, changes in Mallinckrodt's business strategy that may be implemented by its board of directors, the listing of Mallinckrodt's ordinary shares on NYSE American LLC, the emergence of an active trading market for Mallinckrodt's ordinary shares and fluctuations in market price and trading volume, Mallinckrodt's tax treatment by the Internal Revenue Service under Section 7874 and Section 362 of the Internal Revenue Code of 1986, as amended, Mallinckrodt's repurchases of debt securities, the effects of the emergence from bankruptcy on the liquidity, results of operations and businesses of Mallinckrodt and its subsidiaries; 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 global settlement to resolve all opioid-related claims; the settlement with governmental parties to resolve certain disputes relating to Acthar Gel; the ability to maintain relationships with Mallinckrodt's suppliers, customers, employees and other third parties as a result of, and following, the emergence from bankruptcy; the possibility that Mallinckrodt may be unable to achieve its business and strategic goals even now that the emergence from bankruptcy plan 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 and continuing as a going concern; Mallinckrodt's post-bankruptcy capital structure, 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; 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; 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, 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 prepetition indebtedness has been restructured; 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

#### Risk and Uncertainties

Risks and uncertainties are identified and described in detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 30, 2022. 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.

#### Non-GAAP Financial Measures

This document contains financial measures, including adjusted EBITDA, which are considered "non-GAAP" financial measures under applicable SEC rules and regulations.

Adjusted EBITDA represents net income or loss prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and adjusted for certain items that management believes are not reflective of the operational performance of the business. Adjustments to GAAP amounts include, as applicable to each measure, interest expense, net; income taxes; depreciation; amortization; restructuring charges, net; non-restructuring impairment charges; inventory step-up expense; discontinued operations; changes in fair value of contingent consideration obligations; significant legal and environmental charges; divestitures; separation costs; gains on debt extinguishment, net; unrealized gain or loss on equity investment; reorganization items, net; share-based compensation; fresh-start related expenses; and other items identified by the Company.

**Sigurdur (Siggi) Olafsson**  
President and Chief Executive Officer



# Rooted With a Deep History of Science & Innovation Focused On the Future



**1867** Leading chemical supplier founded with the purpose of supplying local pharmacists with much needed drugs

**1900s** International thought leader in industry, science and technology; skilled at handling and manufacturing complex compounds; drove partnerships with the U.S. government

**1940s**

**1980s** Evolved through a series of divestitures and strategic investments; utilizing core strengths, focused on complex generic and innovative branded products

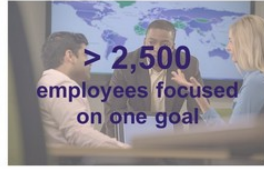
**2000s**

**2022**

- Emerged from Chapter 11
- Appointed New Board and Executive Team
- Received U.S. FDA Approval and Launches Terlivaz® (terlipressin for injection)
- Submitted Next Generation EVOLVE™<sup>(1)</sup> to FDA
- Listed on the NYSE American

Product logos shown: Acthar GEL (depotary corticotropin injection) 80 U/mL, Therakos PROTOPIC 2022, INomax (INOMAX), StrataGraft (topical tacrolimus and steroid), amitiza (lubiprostone), and Mallinckrodt Specialty Generics.

## Who We Are



**Notes:**  
1. Submitted to the FDA for review. Pending 510(k), not available for sale within the United States.



# Diversified Global Specialty Pharmaceutical Company Operating in Two Segments



	Specialty Brands	Specialty Generics
<b>2022A Product Mix (% of Whole Company)</b>	<p>Acthar 27% INOmax 18% Therakos 12% Amitiza 8% Other <sup>(1)</sup> 1% Specialty Generics 34%</p>	<p>APAP Products 11% Other APIs <sup>(2)</sup> 6% Opioids 11% Other Generics <sup>(3)</sup> 6% Specialty Brands 66%</p>
<b>Segment Highlights</b>	Highly Profitable & Strong Hospital Presence	Stable & Highly Diversified
<b>2022A Net Sales (total company)</b>	\$1.914 Billion	
<b>2022A EBITDA (total company)</b>	\$675 Million <sup>(4)</sup>	
<b>Strategic Focus</b>	Stabilize Acthar and INOmax, launch execution, and lifecycle management	Producing high-quality generic medicines in complex markets, utilizing domestic footprint

**Notes:**

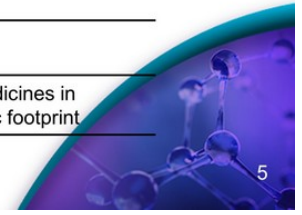
1. Includes StratGratt, Terivaz, Ofirmev, and contract manufacturing revenues

2. Includes opioids, ADHD, addiction treatment, international non-promoted brands and other APIs

3. Includes ADHD, addiction treatment, international non-promoted brands and other dosage products

API = Active Pharmaceutical Ingredients

4. Refer to the GAAP to Non-GAAP reconciliation in the Supplemental Materials





# Focused on Driving Long-Term Shareholder and Stakeholder Value



## Long-Term Shareholder Value

**Stabilize Key Products**

**Launch New Products**

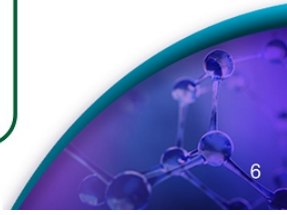
**Return to Growth**

**Maximize Value**

## Pipeline Focused on Lifecycle Management

<p><b>INOmax<sup>(1)</sup> EVOLVE™</b></p>	<p><b>Acthar® Gel Delivery Device<sup>(2)</sup></b></p>	<p><b>StrataGraft®</b></p>	<p><b>Therakos Device Enhancements</b></p>	<p><b>Specialty Generics &gt;20 ANDAs</b></p>
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Notes:  
 1. Submitted to the FDA for review. Pending 510(k), not available for sale within the United States.  
 2. Development complete, awaiting submission to the FDA for review  
 ANDA = Abbreviated New Drug Application



# Terlivaz<sup>®</sup> is the First FDA-Approved Treatment for HRS<sup>(1)</sup> with Rapid Reduction in Kidney Function



Terlivaz offers an important therapeutic option in an area with significant unmet medical need

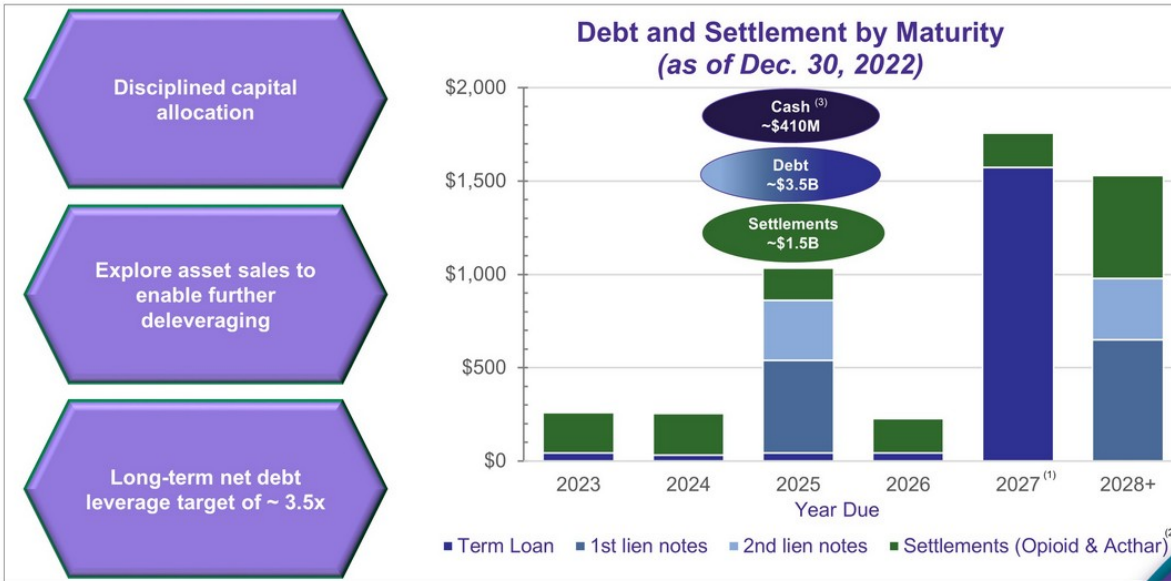
- **Approved in September of 2022, with first sale recorded in October 2022**
- **Anticipated 7-year marketing exclusivity**
- **HRS is estimated to affect 30,000-40,000 Americans each year**
  - >80% 3-month mortality if left untreated
- **Full commercial launch underway, with primary focus on ~260 hospitals treating the majority of HRS patients**
  - Product is available via 5 leading specialty pharmacies
  - Focused on obtaining formulary inclusions for the appropriate HRS patients
- **Strong momentum in the early launch process provides optimism for 2023 and beyond**
  - Strong scientific interest in the product, with additional publications and presentations on key clinical topics
  - Already recommended as a first-line therapy in leading treatment guidelines

**Terlivaz<sup>®</sup>**  
*terlipressin for injection*



Notes:  
1. HRS = Hepatorenal syndrome

# Strengthen Balance Sheet with a Disciplined Approach to Capital Allocation



(1) Term loan balance is equivalent to the principal that will be due after factoring in the normal quarterly amortization payments

(2) Includes interest on Acthar settlement

(3) On February 28, 2023, the Company received \$112.1 million of cash, plus interest, of the \$135.9 million CARES Act income tax refund receivable. The remaining refund is expected to be received during fiscal 2023.

# Mallinckrodt Full Year 2023 Guidance



\$ in millions

Metric	2023 Guidance
Total Company net sales	\$1,700 to \$1,820
Adjusted EBITDA <sup>(1)</sup>	\$510 to \$560

The Company does not provide a reconciliation of forward-looking non-GAAP guidance to the comparable GAAP measures as these items are inherently uncertain and difficult to estimate and cannot be predicted without unreasonable effort. Please see the "Reconciliation of Non-GAAP Financial Guidance" included in this presentation for a reconciliation of GAAP and non-GAAP financial measures for the year to date.

**Notes:**

1. Adjusted EBITDA is a Non-GAAP measure; for a full definition please refer to the Non-GAAP financial measures on slide 2



**Key Strategic Areas of Focus**



# Thank You

Mallinckrodt, the "M" brand mark, the Mallinckrodt Pharmaceuticals logo and other brands are trademarks of a Mallinckrodt company. © 2023 Mallinckrodt.



# Appendix

## Supplemental Materials



## Reconciliation of Non-GAAP Measures

	Successor	Predecessor	Non-GAAP Combined	Predecessor
	Period from June 17, 2022 through December 30, 2022	Period from January 1, 2022 through June 16, 2022	Fiscal Year Ended December 30, 2022	Fiscal Year Ended December 31, 2021
Net loss	\$ (598.0)	\$ (313.1)	\$ (911.1)	\$ (717.4)
Adjustments:				
Interest expense, net	320.4	108.0	428.4	220.7
Income tax benefit	(52.0)	(497.3)	(549.3)	(106.3)
Depreciation	28.8	40.0	68.8	94.7
Amortization	318.7	281.8	600.5	581.1
Restructuring charges, net <sup>(1)</sup>	11.1	9.6	20.7	26.9
Non-restructuring impairment charges	—	—	—	154.9
Income from discontinued operations	(0.3)	(0.9)	(1.2)	(6.1)
Change in contingent consideration fair value	0.5	—	0.5	(7.4)
Significant legal and environmental charges <sup>(2)</sup>	—	11.1	11.1	159.3
Losses on divestiture	—	—	—	0.8
Separation costs <sup>(3)</sup>	21.2	9.0	30.2	1.2
Unrealized (gain) loss on equity investments	(9.2)	22.2	13.0	(4.7)
Reorganization items, net	23.2	630.9	654.1	428.2
Share-based compensation	1.4	1.7	3.1	10.2
Japanese consumption tax credit	—	—	—	(6.8)
Gain on debt extinguishment at par	(21.4)	—	(21.4)	—
Fresh-start impact on debt extinguishment	22.4	—	22.4	—
Bad debt expense - customer bankruptcy	6.4	—	6.4	—
Fresh-start inventory-related expense <sup>(4)</sup>	298.7	—	298.7	—
As adjusted:	<u>\$ 371.9</u>	<u>\$ 303.0</u>	<u>\$ 674.9</u>	<u>\$ 829.3</u>

**Notes:**

- 1) Includes \$0.8 million and \$0.2 million of accelerated depreciation in cost of sales and SG&A, respectively, related to restructuring charges incurred during the period from June 17, 2022, through December 30, 2022 (Successor) and \$2.1 million of accelerated depreciation in SG&A related to restructuring charges incurred during the twelve months ended December 31, 2021 (Predecessor).
- 2) Fiscal 2021 (Predecessor) includes a \$125.0 million charge related to the opioid-related litigation settlement liability and a \$34.3 million increase in environmental liabilities.
- 3) Non-GAAP combined fiscal year ended December 30, 2022, represents costs included in SG&A expenses, primarily related to expenses incurred related to severance for the former Chief Executive Officer ("CEO") and certain former executives of the Predecessor and the Predecessor directors' and officers' insurance policies, in addition to professional fees and costs incurred as we explore potential sales of non-core assets to enable further deleveraging post-emergence.
- 4) Includes \$268.7 million and \$30.0 million of inventory fair-value step up expense and fresh-start inventory-related expense primarily related to a change in accounting estimate, respectively, during the period from June 17, 2022, through December 30, 2022 (Successor).

