

Mallinckrodt (Q1 2025)
May 6, 2025

Corporate Speakers:

- Siggı Olafsson; Mallinckrodt PLC; Chief Executive Officer
- Bryan Reasons; Mallinckrodt PLC; Chief Financial Officer
- Gerard Meuchner; Mallinckrodt IR & Communications

Participants:

- Hamed Khorsand; BWS Financial; Analyst
- Madison Aron; JP Morgan; Analyst

PRESENTATION

Operator^ Good day and thank you for standing by. Welcome to the Mallinckrodt first quarter 2025 results conference call. At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a question-and-answer session. (Operator Instructions). Please be advised that today's conference may be recorded. I would now like to hand the conference over to your speaker today, Gerard Meuchner. Please go ahead.

Gerard Meuchner^ Thank you, operator, and welcome, everyone. With me this morning are Mallinckrodt CEO, Siggı Olafsson, and CFO, Bryan Reasons. Before we begin, let me remind you that we will make forward-looking statements on this call, and it's possible that actual results could be materially different from our stated expectations.

Please note these forward-looking statements are made as of today, and we assume no obligation to update them, even in the event of new information or of actual results or future expectations change materially. We encourage you to refer to the cautionary statements contained in our SEC findings for a more in-depth explanation of the inherent limitations of such forward-looking statements. We will also provide select non-GAAP-adjusted measures related to our financial performance on this call.

A reconciliation of these non-GAAP measures is included in our earnings release, which can be found on our website, Mallinckrodt.com. We use our website as a channel to distribute important and time-critical company information, and you should look to the investor relations page of our website for this information. This call does not constitute an offer to buy or sell, or the solicitation of an offer to buy or sell, any securities, or a solicitation of any vote or approval.

In connection with the potential combination between Mallinckrodt and Endo, Mallinckrodt has filed with the SEC a registration statement that includes a joint proxy statement of Mallinckrodt and Endo and a prospectus for Mallinckrodt shares. The joint proxy statement, prospectus, and other relevant documents filed by Mallinckrodt and Endo with the SEC will be available free of charge at the respective company's investor relations webpage or at the SEC's website.

You should review such materials filed or to be filed with the SEC carefully because they contain or will contain important information about Endo, Mallinckrodt, the business combination, and related matters, including information about certain of their respective directors, executive officers, and other employees who may be deemed to be participants in the solicitation proxies in connection with the business combination and about their interest in the solicitation.

As noted in our earnings release, our first quarter ended on March 28, 2025. Additionally, unless otherwise specified, the net sales percentage changes we discussed will be on a constant currency basis. I'll now turn the call over to Soggi.

Soggi Olafsson^ Thanks, Gerard, and good morning, everyone. I'm pleased to report that Mallinckrodt had a great start to the year, and we continued to build on our positive momentum from 2024. Our teams delivered another quarter of strong performance that kept us on track to achieve our full-year guidance, a sign of our confidence in the business.

In the first quarter, we achieved a top-line growth when adjusting for Therakos divestiture last year, demonstrating the meaningful progress we have made on our key strategic priorities. Acthar sales grew for the fifth consecutive quarter, and the launch of our SelfJect device has been tracking well ahead of our initial expectations, as we continue to see a strong physician and patient demand. In light of this, we are increasing our marketing investments behind Acthar, which is reflected in our decision to reaffirm full-year guidance.

In addition, our rollout of the INOmax Evolve DS delivery system continued to hospital nationwide, and the ongoing efforts to expand adoption of Terlivaz remains underway. On the Specialty Generic side of the business, overall performance was strong, and we continue to see the benefits of the high-quality product and stable supply we offer customers. Our positive momentum also reinforces our excitement for the planned combination with Endo that we announced in March.

The merger will create a global scale diversified pharmaceutical leader, and we see even greater potential ahead for our business through the combination. I'll speak more on that shortly, but I want to highlight up front how proud I am of our teams for continuing to execute at a high level and deliver for our patients while doing the significant planning work to bring our two companies together. I'll turn now to the detailed update on our business segment.

Starting with specialty brands and Acthar Gel, as I mentioned, we are pleased to deliver our fifth consecutive quarter of year-over-year growth with a 12.3% increase in net sales in the first quarter. This was driven by growth in the overall market and the successful launch of SelfJect, where the team has done really outstanding work.

Feedback from the healthcare providers and patients on SelfJect has been overwhelmingly positive, and this innovative device now accounts for over 70% of all new Acthar brand prescriptions, a number that is even higher for certain therapeutic areas and reflects the great momentum we have with both new and returning healthcare providers.

We expect positive momentum in the SelfJect rollout and patient demand growth to continue. As a result, we are raising our 2025 net sales guidance for Acthar from a low single-digit range to a high single-digit range. Moving to INOmax, our multi-year rollout of the Evolved DS delivery system into U.S. hospitals remains underway.

As of the end of March, more than 400 devices were placed in over 50 hospitals nationwide, and we continue to benefit from customer interest in the portability and new features offered by the product reflecting the importance of the system for the appropriate patients. As a reminder, we expect this rollout to continue throughout the end of next year, and we will be working closely with hospitals and providers to drive further adoption throughout this period and beyond. While INOmax sales continue to be impacted by competition in the U.S. market, we were encouraged to see a stronger performance and growth outside of the U.S., particularly in Japan, where sales grew 12% as compared to the first quarter of 2024.

Next, with Terlivaz, we delivered a 23.3% net sales growth as compared to the first quarter of 2024. As a reminder, Terlivaz is the first and only FDA-approved product indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. While hospital demand growth has not been as strong as we would like, we continue to believe in the opportunities ahead for this treatment, as well as the meaningful benefit it can deliver to patients and their caregivers.

Turning to specialty generics, we continue to build on our track record of consistent growth in the segment, delivering our ninth consecutive quarter of net sales growth. Strong performance in the ADHD business product business was offset primarily by a global competitive pressure on the API business, particularly our APAP products. In a period of supply chain uncertainty, Mallinckrodt's generics business benefits from both leading product quality and consistency of supply, and we continue to expect a flat to low-single digit sales growth for the segment in full year 2025.

Before I hand it over to Bryan, I'd like to give a brief update on our previously announced combination with Endo. Over the last month, we have spoken extensively with our stakeholders about the combination and are pleased with the positive feedback we have received to date. We remain confident in the bright future ahead of our companies as a one combined organization which will benefit from increased scale to develop new therapies to address unmet patient needs.

Our team has already hit the ground running in our work to complete the transaction, which we continue to expect will occur in the second half of 2025. In April, we filed our Form S4 registration statement with the SEC to begin the SEC process, a key milestone towards holding the shareholder meetings to consider and vote on the transaction. The transaction planning team to support our integration efforts post-close.

I look forward to sharing additional details in the coming months as we continue to work to bring our two companies together. With that, I'll turn the call over to Brian to discuss our financial performance and expectations for the balance of Fiscal 2025 in more detail.

Bryan Reasons^ Thank you, Siggie. Mallinckrodt's net sales in the first quarter of 2025 were \$419.9 million as compared to \$467.8 million in the first quarter of 2024, reflecting a 10.2% decrease on a reported and constant currency basis. Excluding the impact of the Therakos divestiture, total net sales grew by 2.5%.

Net loss for the first quarter of 2025 was \$27.7 million compared to a net loss of \$65.4 million in the prior year period. Adjusted EDA in the first quarter of 2025 was \$102.3 million as compared to \$144.9 million in the prior year period. This was driven by strength in both the Specialty Generics segment and Acthar Gel, largely offset by the impact of the Therakos divestiture, incremental commercial investments for Acthar Gel, and the impact of nitric oxide competition in the U.S.

The specialty brand segment reported net sales of \$207.3 million as compared to \$257.3 million in the prior year period. This 19.4% decrease includes the impact of the Therakos divestiture. Excluding Therakos, Specialty Brand net sales grew by 4.1%. Driven primarily by growth in Acthar Gel and the uptake in Selfject.

Acthar Gel net sales were \$115.4 million in the first quarter, an increase of 12.3% compared to the prior year period. As Siggie mentioned, we are raising our full-year sales guidance for Acthar and now expect high single-digit Acthar net sales growth in 2025. INOMAX generated net sales of \$62.5 million in the first quarter, a decrease of 11% compared to the prior year period.

Terlivaz generated net sales of \$7.4 million in the first quarter, an increase of 23.3% compared to the prior year period. The Specialty Generics segment reported net sales of \$212.6 million as compared to \$210.5 million in the first quarter of 2024. This growth of 1% was driven by continued strong ADHD product sales, offset by decline in the API business, particularly APAP products, driven primarily by global competition.

With respect to operating matrix in the quarter, adjusted gross profit as a percentage of net sales was 61.3% as compared to 64% for the first quarter of 2024. Adjusted SG&A as a percentage of net sales was 32.9% as compared to 27.3% in the prior year. And adjusted R&D as a percentage of net sales was 4.7% as compared to 5.9% in the prior year.

Turning to our balance sheet, we ended the first quarter with a cash balance of \$422.2 million. Total outstanding principal debt was \$864.6 million, a reduction of 47.5% compared to the first quarter of 2024. And outstanding net debt was \$451.4 million, a reduction of 67.6% compared to the first quarter of 2024.

Our net debt leverage ratio was .8 times at quarter end. For the full year fiscal 2025, we are reiterating our previous guidance ranges and expect total net sales of between \$1.7 billion and \$1.8 billion, and adjusted EBITDA of between \$480 million and \$520 million. Our decision to reaffirm our previously stated guidance reflects our strong performance, partially offset by elevated SG&A levels due to incremental commercial investments related to Acthar. I'll now hand the call back to Siggie for closing remarks.

Siggie Olafsson^ Thank you, Bryan. To wrap up, I'm incredibly proud of the way our entire team has delivered on the strategic priorities for the ultimate goal of improving the lives of our patients. As we look ahead to close of the merger with Endo later this year, I am more confident than ever in the value we can deliver to our shareholders, customers, and patients. We will now open the call for Q&A. Operator.

Operator^ Thank you. (Operator Instructions) One moment while we compile our Q&A roster. Our first question is going to come from the line of Hamed Khorsand with BWS Financial. Your line is open. Please go ahead.

Hamed Khorsand^ Thank you good morning. Thank you for taking my questions. First, could you just elaborate on the marketing strategy behind Acthar Gel and what you're hoping to achieve? Is it more from the patient standpoint or is it from the physician standpoint as far as demand is concerned?

Siggie Olafsson^ Yes. Very good question. I think overall, the two things that are playing in is that the overall market is growing. There is a competition for corticotropin out there, so we can see the overall market is growing for corticotropin today. And we are clearly benefiting from that. We have a strong sales support on it, but we also have a big patient support system to support the patients through the experience of going on Acthar, which is very important. I think that's number one.

Number two, we've seen a huge benefit on the launch of SelfJect. SelfJect makes it so much easier to use it. What we call new prescriptions, those are prescriptions for patients that haven't been on prescription for a long time or are totally new to Acthar not there at all, over 70% of those patients are going on SelfJect.

Then some other indication I will call out, even though I didn't do it in the script, in ophthalmology, it's closer to 80% of all new prescriptions are on SelfJect. These two things together are benefiting. And we have used, as I mentioned in the script, we are putting more marketing emphasis now behind the product when you see the growth.

Obviously, Acthar was a challenging story, declining from 2018 up until the beginning of last year. And then in the last five quarters, we have shown every quarter of growth of this product. The doctors, the physicians are seeing the benefit of it. Patients are getting more comfortable. And SelfJect was a piece of that that was missing in the parcel. So, we are very pleased, but it's both on the patient side we are seeing the benefits, but also on the physician side.

Hamed Khorsand^ Okay. And then is this taking away any resources from the rest of the business at all?

Siggie Olafsson^ No, it's not.

Hamed Khorsand^ And given the timing of when you're expecting the merger and the close, do you have any new intentions with the cash or will the cash balances continue to increase?

Siggie Olafsson^ No. We obviously are limited with the merger agreement with Endo, what to do with the cash. There's a limitation of what to do with the cash until the merger will close in the second half of this year.

Hamed Khorsand^ Okay. Great. Thank you.

Siggi Olafsson^ Thank you.

Operator^ Thank you. One moment for our next question, please. Our next question is going to come from the line of Madison Aron with JP Morgan. Your line is open. Please go ahead.

Madison Aron^ Hi, thanks for taking my questions. Just starting with Acthar, can you quantify the marketing support that you're putting behind the drug? And then you noted that the market is growing for the drug. Can you just walk us through which indications are you seeing that growth? And then maybe define it a little further. Is it more just new patients that they're staying, that adherence has improved? And then just lastly on Acthar, you talked about the patient support system that you have for SelfJect. Can you quantify or just walk us through how that support system differs from the vial?

Siggi Olafsson^ Yes. So, if I start on the marketing, so we haven't broken out the marketing cost of product. But what we have said is for Acthar is our largest marketing support in the brand business.

We have a sales force, we have marketing, but we also have the patient support system in place. So clearly a great support for this product. In terms of the indications, which are the growing indications, so we are roughly in six to seven, even though I think Acthar is approved for 19 indications in the FDA label.

But there's really four indications that are growing the most. It's rheumatology, pulmonology, nephrology, and I mentioned ophthalmology, which is growing faster. And especially we have seen that with the benefit on rheumatology and ophthalmology.

Those are two indications where the SelfJect device has changed the delivery system and experience for the patients of this drug. This drug has been approved for many, many years. It has a lot of experience. Many patients have been using it through the years but continues to be a very important drug for patients out there going forward. The third part of the questions, if you could repeat that again.

Madison Aron^ The patient support that you have for subject, how does that differ from the vial? Assuming that you're trying to drive more patients towards that.

Siggi Olafsson^ Yes, so we don't differentiate. We support all the patients, whether they are on vial or on SelfJect, but it's mainly around the nursing support when patients start. When a patient starts on a vial, there is a little bit more involvement in teaching them how to draw the drug from the vial and inject them themselves. Where on SelfJect, that is so much significantly easier. We still have the nurse support around that, but that's probably the single most differentiated issue between the vial and the SelfJect. It is simpler to use SelfJect than it is with a vial going forward.

Madison Aron^ Okay, great. There's a lot of commentary out there about tariffs and Ireland and, I guess, attacking the tax system that is coming out of Ireland. I would love to just get your thoughts on what you're seeing. I know it's early. We don't have a lot of details, but I'd love to hear your thoughts on what you're trying to do to circumvent any of these challenges.

Bryan Reasons^ Yes, it's Bryan. I'll jump in there. As far as the tariffs, when we looked at it, we feel like we're in pretty good shape and don't have a ton of exposure. We have some inputs into our APAP business coming from Ex-US. We manufacture the bulk API for Acthar, but not a lot of exposure. Your question hinted at the IP structure. Our IP is largely held offshore, but we're an Irish company. We have significant substance in Ireland, including a plant where we manufacture the API for our largest product. This is my view.

For them to eliminate that type, it's probably -- that type of structure, it would take probably more of an act of Congress, but we don't necessarily see a lot of tariff exposure for us right now. Obviously, we aren't sure exactly where the tariffs are going to find the land either. There's a lot of uncertainty there.

Siggi Olafsson^ Yes. The difference between us and many other companies here in the U.S. is we have most of our manufacturing in the U.S. So, the generic, finished dose manufacturing is in the U.S. The API -- More than 50% of the API, we manufacture ourselves for our generic business, which is in St. Louis, in North Carolina, and Greenville. So, that changes the pictures on the tariffs. Yes, some of the starting material for our API, we might have to bear tariffs on that, but overall, we feel the company is in good shape if the tariffs come through.

Madison Aron ^ If I could just squeeze one in. Given the fact that you have a lot going on in the U.S., can you just walk us through or quantify the tariff tailwind as it relates to the APAP and API business?

Siggi Olafsson^ Yes it's difficult to do the tailwind, but how we position things is like with all our generics are manufactured up in Hobart, New York, where with most of our competitors, although not on controlled substances, in the generic industry, a majority of the volume is manufactured outside of the U.S. So I think overall, we are in well-positioned from that point of view more than anything else, but to go further than that is probably not wise.

Because there is so -- as you started your question, there's so many uncertainty around what the administration will do going forward, but we feel with the infrastructure that we have, we are well-positioned whatever comes down the road.

Madison Aron^ Great. Thank you.

Operator^ Thank you. I would now like to hand the conference back over to Gerard Muechner for closing remarks.

Siggi Olafsson^ Yes. Thanks, operator. Thanks again for joining us all today. We look forward to engage with you in the coming days and weeks ahead. If you have any questions, the best way to get a hold of us is via email, and we will work with you to get back to you and set up investor meetings. But thanks a lot for all of you to join us today. Thank you.

Operator^ This concludes today's conference. Thank you for participating. You may now disconnect. Everyone have a great day.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional Information about the Combination and Where to Find It

In connection with the proposed transaction, Mallinckrodt has filed with the U.S. Securities and Exchange Commission (“SEC”) a registration statement on Form S-4 (as amended and as may be further amended from time to time, the “Registration Statement”) that includes a preliminary joint proxy statement of Mallinckrodt and Endo and that also constitutes a preliminary prospectus of Mallinckrodt ordinary shares. Each of Mallinckrodt and Endo may also file other relevant documents with the SEC regarding the proposed transaction. This document is not a substitute for the joint proxy statement/prospectus or Registration Statement or any other document that Mallinckrodt or Endo may file with the SEC. The definitive joint proxy statement/prospectus (if and when available) will be mailed to shareholders of Mallinckrodt and Endo. **INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE REGISTRATION STATEMENT, JOINT PROXY STATEMENT/PROSPECTUS, AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE, BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.** Investors and security holders will be able to obtain free copies of the Registration Statement and joint proxy statement/prospectus (if and when available) and other documents containing important information about Mallinckrodt, Endo, and the proposed transaction, once such documents are filed with the SEC through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by Mallinckrodt will be available free of charge on Mallinckrodt’s website at <https://ir.mallinckrodt.com>. Copies of the documents filed with the SEC by Endo will be available free of charge on Endo’s website at <https://investor.endo.com>.

Participants in the Solicitation of Proxies

Mallinckrodt, Endo, and certain of their respective directors, executive officers, and other members of management and employees may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information about the directors and executive officers of Mallinckrodt, including a description of their direct or indirect interests, by security holdings or otherwise, is set forth in (i) Mallinckrodt's proxy statement for its 2025 Annual Meeting of Shareholders, which was filed with the SEC on April 30, 2025 (and which is available at https://www.sec.gov/ix?doc=/Archives/edgar/data/0001567892/000110465925031453/tm252514-2_def14a.htm), including under the headings "Our Director Nominees", "Corporate Governance", "Board of Directors and Board Committees," "Compensation of Non-Employee Directors," "Compensation of Executive Officers," "Security Ownership and Reporting," "Equity Compensation Plan Information" and "Proposals 1(A) Through 1(E): Election of Directors", (ii) Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended December 27, 2024, which was filed with the SEC on March 13, 2025 (and which is available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/1567892/000156789225000010/mnk-20241227.htm>), including under the headings "Item 10. Directors, Executive Officers and Corporate Governance", "Item 11. Executive Compensation", "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters", "Item 13. Certain Relationships and Related Transactions and Director Independence", and (iii) to the extent holdings of Mallinckrodt's securities by its directors or executive officers have changed since the amounts set forth in Mallinckrodt's proxy statement for its 2025 Annual Meeting of Shareholders, such changes have been or will be reflected on Initial Statement of Beneficial Ownership of Securities on Form 3, Statement of Changes in Beneficial Ownership on Form 4, or Annual Statement of Changes in Beneficial Ownership on Form 5 filed with the SEC, which are available at EDGAR Search Results (https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001567892&type=&dateb=&owner=only&count=40&search_text=).

Information about the directors and executive officers of Endo, including a description of their direct or indirect interests, by security holdings or otherwise, is set forth in (i) the Registration Statement, (ii) Endo's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 13, 2025 (and which is available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/2008861/000200886125000007/ndoi-20241231.htm>), including under the headings "Item 10. Directors, Executive Officers and Corporate Governance", "Item 11. Executive Compensation", "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters", "Item 13. Certain Relationships and Related Transactions and Director Independence", and (iii) to the extent holdings of Endo's securities by its directors or executive officers have changed since the amounts set forth in the Registration Statement, such changes have been or will be reflected on Initial Statement of Beneficial Ownership of Securities on Form 3, Statement of Changes in Beneficial Ownership on Form 4, or Annual Statement of Changes in Beneficial Ownership on Form 5 filed with the SEC, which are available at EDGAR Search Results (https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0002008861&type=&dateb=&owner=only&count=40&search_text=). Other information regarding the participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, is contained in the preliminary joint proxy statement/prospectus and will be contained in other relevant materials to be filed with the SEC regarding the proposed transaction when such materials become available. Investors should read these materials carefully before making any voting or investment decisions. You may obtain free copies of these documents from Mallinckrodt or Endo using the sources indicated above.

Information Regarding Forward-Looking Statements

Statements in this communication that are not strictly historical 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:

- (i) transaction-related risks, including the parties’ ability to successfully integrate our business and Endo’s business and unanticipated costs of such integration, which may result in the combined company not operating as effectively and efficiently as expected; uncertainties related to a future separation of the combined generics pharmaceuticals businesses of Mallinckrodt and Endo and Endo’s sterile injectables business; the risk that the expected benefits and synergies of the proposed transactions may not be fully realized in a timely manner, or at all; the risk associated with Mallinckrodt’s and Endo’s ability to obtain the approval of their shareholders and stockholders, respectively, required to consummate the proposed business combination transaction; uncertainty regarding the timing of the closing of the proposed business combination transaction; the risk that the conditions to the proposed business combination transaction may not be satisfied (or waived to the extent permitted by law) on a timely basis or at all or the failure of the proposed business combination transaction to close for any other reason or to close on the anticipated terms, including the intended tax treatment; the risk that any regulatory approval, consent or authorization that may be required for the proposed business combination transaction may not be obtained or may be obtained subject to conditions that are not anticipated; the occurrence of any event, change or other circumstance that could give rise to the termination of the proposed business combination transaction; unanticipated difficulties, liabilities or expenditures relating to the proposed transactions; the effect of the announcement, pendency or completion of the proposed transactions on the parties’ business relationships and business operations generally; certain restrictions on the ability of Mallinckrodt and Endo to pursue certain business activities or strategic transactions during the pendency of the proposed business combination transaction; the effect of the announcement, pendency or completion of the proposed transactions on the long-term value of Mallinckrodt’s ordinary shares and Endo’s common stock; risks that the proposed transactions may disrupt current plans and operations of Mallinckrodt and Endo and their respective management teams and potential difficulties in hiring, retaining and motivating employees as a result of the proposed transactions; risks related to our increased indebtedness as a result of the proposed business combination transaction; significant transaction costs related to the proposed business combination transaction; potential litigation relating to the proposed transactions that could be instituted against Mallinckrodt, Endo or their respective officers or directors; rating agency actions and Mallinckrodt’s and Endo’s ability to access short- and long-term debt markets on a timely and affordable basis; and risks related to the financing in connection with the transaction;
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(ii) risks related to Mallinckrodt's business, including potential changes in Mallinckrodt's business strategy and performance; Mallinckrodt's initiative to explore a variety of potential divestiture, financing and other transactional opportunities; the exercise of contingent value rights by the Opioid Master Disbursement Trust II (the "Trust"); 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; 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; 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) Selfject™ and the INOmax Evolve DS delivery system; Mallinckrodt's ability to successfully identify or discover additional products or product candidates; Mallinckrodt's ability to navigate price fluctuations and pressures, including the ability to achieve anticipated benefits of price increases of its products; competition; Mallinckrodt's 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 laws and related 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 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; 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; and

(iii) risks related to Endo's business, including future capital expenditures, expenses, revenues, economic performance, financial conditions, market growth and future prospects; Endo changes in competitive, market or regulatory conditions; changes in legislation or regulations; global political changes, including those related to the new U.S. presidential administration; Endo's use of artificial intelligence and data science; the ability to obtain and maintain adequate protection for intellectual property rights; the impacts of competition such as those related to XIAFLEX[®]; the timing and uncertainty of the results of both the research and development and regulatory processes; health care and cost containment reforms, including government pricing, tax and reimbursement policies; litigation; the performance including the approval, introduction and consumer and physician acceptance of current and new products; the performance of third parties upon whom Endo relies for goods and services; issues associated with Endo's supply chain; Endo's ability to develop and expand its product pipeline and to launch new products and to continue to develop the market for XIAFLEX[®] and other branded, sterile injectable or generic products; the effectiveness of advertising and other promotional campaigns; and the timely and successful implementation of business development opportunities and/or any other strategic priorities.

The registration statement on Form S-4 filed with the SEC describes additional risks in connection with the proposed transaction. While the list of factors presented here is, and the list of factors presented in the registration statement on Form S-4 are, considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. For additional information about other factors that could cause actual results to differ materially from those described in the forward-looking statements, please refer to Mallinckrodt's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and other filings with the SEC, which are available from the SEC's website (www.sec.gov) and Mallinckrodt's website (www.mallinckrodt.com) and Endo's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q and other filings with the SEC, which are available from the SEC's website (www.sec.gov) and Endo's website (www.endo.com). 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 and Endo do 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.
