

Mallinckrodt and Endo Q4 2024 Earnings and Joint Transaction Call Transcript

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Companies' Participants:

Laure E. Park - Senior Vice President of Investor Relations & Corporate Affairs, Endo, Inc.
Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc
Scott Hirsch – Interim Chief Executive Officer, Endo, Inc.
Mark Bradley - Executive Vice President and Chief Financial Officer, Endo, Inc.
Bryan Reasons - Executive Vice President and Chief Financial Officer, Mallinckrodt plc

Other Participants:

Leszek Sulewski – Analyst, Truist Securities
Doug Tsao – Analyst, H.C. Wainwright & Co.

Presentation:

Operator

Good morning, and welcome to today's conference call to discuss the proposed combination of Mallinckrodt plc and Endo, Inc. At this time, all participants are in 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 is being recorded. A copy of the investor presentation is available on the investor relations pages for both companies' websites.

I would now like to hand the conference over to Laure Park, Senior Vice President, Investor Relations and Corporate Affairs at Endo. Please go ahead.

Laure E. Park - Senior Vice President of Investor Relations & Corporate Affairs, Endo, Inc.

Thank you, Li Wei, and welcome, everyone. During this conference call, the participants may make certain forward-looking statements relating to the transaction and the financial condition of both companies, results of operations, plans, objectives, future performance and businesses.

We caution you that actual results could differ materially from those that are indicated in these forward-looking statements due to a variety of factors. Information concerning those factors can be found in the company's filings with the SEC. This call does not constitute an offer to buy or sell, 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 intends to file with the SEC a registration statement that will include 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 companies' 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 may 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 of proxies in connection with the business combination and about their interests in the solicitation.

Now let's turn to slide 3. On today's call, you will hear from Mallinckrodt's Chief Executive Officer, Siggı Olafsson, and Chief Financial Officer, Bryan Reasons, as well as Scott Hirsch, Endo's Interim CEO, and Mark Bradley, Endo's CFO.

With that, I will turn the call over to Siggı.

Siggı Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thanks, Laure, and good morning, everyone. I'm pleased to be here with Scott to announce the combination of our two companies. This is an important and exciting step in the continued execution of the strategies for both Mallinckrodt and Endo.

Mallinckrodt and Endo are both diversified pharmaceutical companies with branded and generics businesses. Together, we will create a global, scaled, further diversified industry leader, with additional capabilities, expertise and resources to support growth and value creation.

On a pro-forma basis, we expect to generate 2025 revenue of approximately \$3.6 billion and adjusted EBITDA of \$1.2 billion, with an adjusted EBITDA margin of 34%. There are also meaningful synergy opportunities. We expect to achieve at least \$150 million of annual, pre-tax, run-rate synergies by year 3, and approximately \$75 million in the first year.

Importantly, the combined company will have a strong balance sheet and ample financial flexibility to invest in innovation, business development and growth opportunities, both organic and external.

On today's call, we will walk through the transaction, our vision for the combined company, and the meaningful benefits we believe it will deliver for both companies' shareholders and other stakeholders. Additionally, both Mallinckrodt and Endo reported financial results for the fourth quarter and full year 2024 this morning. We will take some time on this call to discuss those results before we open the floor to you for questions.

Turning to slide 5, we'll spend a moment on the portfolios.

Our two businesses are highly complementary. On the brands side, we both have durable, on-market products and portfolios focused on unmet patient needs, including rare and orphan diseases. Mallinckrodt's branded portfolio is led by Acthar[®] Gel, INOmax[®], and Terlivaz[®]. We are in the midst of two ongoing launches for the next-generation products with our Acthar Gel SelfJect[™] Device and INOmax EVOLVE[™] DS Delivery System. Endo's branded portfolio includes the leading XIAFLEX[®], SUPPRELIN[®] LA, and AVEED[®] franchises.

On the sterile injectables and generics side, we both have extensive capabilities across the value chain, as well as complementary portfolios and capabilities. Mallinckrodt has a diversified portfolio of high-quality generic drugs and active pharmaceutical ingredients, which has been delivering double-digit growth driven in large part by our ability to consistently and reliably deliver high-quality products. Endo has a broad portfolio of sterile injectables, including approximately 40 on-market-hospital-based products and a pipeline of more than 40 projects currently in development. Endo also has over 80 generic products on the market, across a range of delivery technologies, dosage forms and formulations.

Importantly, both companies are well-established industry players with robust commercial and manufacturing infrastructures. And both of our teams have deep clinical and regulatory expertise to drive approvals of complex drugs and devices, together with experience commercializing complex and highly regulated products.

Turning to the structure of the transaction on slide 6, which we can think about in two steps.

The initial step is the transaction we are announcing today – combining Mallinckrodt and Endo.

After the close of this transaction, we plan to establish two focused businesses designed to pursue distinct value-maximizing strategies: a leading, scaled brands business and a focused sterile injectables and generics business. Then, for the second step, we intend to pursue a separation of the combined injectables and generics business from the broader combined company.

This separation would enable us to ultimately move forward as a scaled and diversified, pure-play branded pharmaceuticals company. With a strong balance sheet and a cash flow profile to invest in growth, an enhanced commercial position and an executable growth story, we will be well-positioned to create equity multiple expansion.

The combined sterile injectables and generics business will also be poised for success, with a complementary product portfolio, leading controlled substances franchise, robust commercial and manufacturing infrastructure, extensive supply chain capabilities and strong compliance culture. This business expected to be highly profitable and generate strong free cash flow. Separating it from the combined company would unlock additional value by enabling the consistent return of capital to shareholders. This separation will be subject to approval by the combined company's Board of Directors and other conditions.

Slide 7 outlines the key terms. Under the terms of the agreement, Endo shareholders will receive a total of \$80 million in cash and Endo shareholders will own 49.9% of the combined company on a pro forma basis. After cash consideration, Mallinckrodt shareholders will own 50.1% of the combined company on a pro forma basis, for the implied pro forma enterprise value of \$6.7 billion. Mallinckrodt will be the holding company for the combined business, and Endo will become a wholly owned subsidiary of Mallinckrodt.

At close, I will serve as the President and CEO and as a member of the Board of Directors of the combined company. Paul Efron, who is currently a member of the Endo Board, will serve as the combined company's Board Chair. The new Board is expected to have a total of nine directors, including three additional directors from Mallinckrodt, three additional directors from Endo, and one new, external director. We will announce additional leadership team appointments, and the names of the other directors, prior to the closing of the transaction. The transaction has been approved by the Boards of both companies and is expected to close in the second half of 2025, subject to approval by shareholders of both companies, regulatory approvals and customary closing conditions.

The combined company will have a strong balance sheet. On a pro-forma basis, we expect to have a net leverage of 2.3x at closing. Mallinckrodt and Endo will finance the transaction with cash on hand and \$900 million of committed financing provided to Endo by Goldman Sachs. Following close, Mallinckrodt's headquarters in Dublin, Ireland will serve as the combined company's global headquarters. The location of the combined company's U.S. headquarters, as well as its name, will be announced in due course.

I will now turn the call over to Scott to speak more about our combined businesses.

Scott Hirsch – Interim Chief Executive Officer, Endo, Inc.

Thank you, Siggi and thank you all for joining us on this exciting day for Endo.

It occurred to me this morning that this is only my second earnings call here at Endo and yet in this short time we find ourselves announcing two transformative transactions this week after beating our 2024 budget, meeting our raised 2024 guidance, generating record Xiaflex revenues exceeding \$500 million and looking forward to a 2025 guidance with revenue growth for the first time in half a decade.

I would usually end with gratitude but today I want to start by thanking my Endo teammates – who I have been so impressed by and proud of for their tireless and selfless efforts to create the environment for growth and for this transaction.

I met Sigg almost 15 years ago when Watson acquired Actavis and from both our many investor meetings together and our time working on this transaction - I know we share the view that a company is the output of its people.

Our combined teams, the collective skills in bringing to market specialty pharmaceutical products across a wide range of therapeutic conditions, from rare disease, urology, neonatology, orthopedics, and hepatology, along with a collective manufacturing breadth, will provide the go forward opportunity for this transaction.

Now, on slide 8, let's walk through an overview of the combined branded business. Bringing together Mallinckrodt's and Endo's branded pharmaceutical portfolios will add both scale and diversification, with multiple on-market brands. The brands portfolio will comprise leading pharmaceutical products across a range of therapeutic areas. This includes two high-growth power brands – Endo's Xiaflex and Mallinckrodt's Acthar Gel. Xiaflex benefits from an exciting pipeline of new indication expansions, and Acthar Gel is positioned for continued growth following the recent launch of its SelfJect device.

The combined portfolio of well-established, on-market products will enhance the commercial portfolio of the business, which will be poised to deliver very strong growth. This pure-play branded business will have the attractive cash flow profile and balance sheet capacity to opportunistically pursue strategic business development and external growth opportunities. On a pro forma basis, this business delivered 2024 revenues of \$1.7 billion.

Turning to slide 9, which shows the combined sterile injectables and generics business. This business will bring together two highly complementary product portfolios. Our products together span multiple delivery technologies, dosage forms and formulations, including patches, powders, liquids and pre-filled syringes, and covers a wide range of therapeutic areas. The business will also benefit from robust commercial capabilities, established manufacturing infrastructure and an extensive supply chain capability. Our experienced teams bring deep expertise in complex, highly regulated products, and share a strong commitment to quality and compliance that will underpin all operations. We also see opportunities for backward integration of API. On a pro forma basis, 2024 revenues for the combined injectables and generics business were \$1.7 billion.

Turning to slide 10, the combined company, including both the branded business and generics business, will benefit from significant scale and capacity. At closing, we will have approximately 5,700 employees and a heavily-U.S. focused footprint, with 30 distribution centers and 17 manufacturing facilities – including seven facilities for the combined brands business and 10 for the combined sterile injectables and generics business. Additionally, outside of the U.S., we will have capabilities and resources on four continents.

I'll now hand it back over to Sigg to discuss future growth opportunities and wrap up the transaction portion of this call.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thank you, Scott. Turning to slide 11. With a strong balance sheet, the combined company will have ample financial flexibility to enable the combined company's strategic focus, and we see multiple avenues of growth for the branded business. In the near term, we plan to pursue business development opportunities. Longer term, we will have the resources and flexibility to pursue innovation across our platform.

One particular category we are excited about is rare and orphan diseases, where both Mallinckrodt and Endo have strong foundations through Acthar Gel, Terlivaz and Supprelin LA. Together, we will be positioned to expand our leadership and help address significant unmet patient need. Over time, we may also look to expand into other strategic therapeutic areas.

In summary, we believe this combination represents a unique opportunity for both Mallinckrodt and Endo to deliver significant value, not only for our stakeholders, but for our patients, customers, healthcare providers and other stakeholders.

I will now turn the call over to Scott and Endo CFO Mark Bradley to discuss Endo's financial results. Scott?

Scott Hirsch – Interim Chief Executive Officer, Endo, Inc.

Thanks, Saggi. I will now provide a brief Endo performance and business update. Mark Bradley will then walk you through the financial results and 2025 outlook, and then we will turn it back over to Mallinckrodt to review their results.

Starting with slide 4 in Endo's deck that is posted on the Endo's IR website, 2024 was a year of meaningful progress and milestone achievement toward Endo's ongoing transformation. Full-year 2024 total revenues of \$1.8 billion and adjusted EBITDA of \$637 million were in-line with our increased guidance expectations for the year. As we expected, our year-over-year revenue performance progressively improved each successive quarter throughout the year.

Our 2024 revenue performance was anchored by Xiaflex, with total revenue growth of 9% and exceeding the \$500 million mark for the first time. Full year 2024 Xiaflex revenues grew high-single digit across both on-market indications driven by strong underlying demand.

We also advanced our sterile injectables business. In the fourth quarter, we launched three sterile injectable products, including ADRENALIN RTU bags, which is our 7th ready-to-use product. In addition, we received our first U.S. FDA approval for our new sterile manufacturing facility at Indore. This is a significant milestone for Endo as we continue to invest and innovate in our sterile injectables business. I want to make note that you will see this investment show up in our forward expectations within the cost of goods line versus the R&D line as the sterile injectables investment is really operational versus clinical.

Lastly, earlier this week, we announced an agreement to divest our International Pharmaceutical business to Knight Therapeutics. We believe this transaction provides clear benefits to both parties. It continues our ongoing transformation and sharpens our focus on our core growth businesses. My gratitude to our Paladin colleagues for their unparalleled professionalism.

Turning to the next slide and diving into the segment level performance.

Starting with the branded pharmaceutical segment, fourth-quarter 2024 branded and Xiaflex revenues were comparable to the prior year on a reported basis. However, as a reminder, fourth quarter 2023 revenues – or the comparator period - included a one-time benefit of approximately \$14 million related to the application of the final Inflation Reduction Act for Xiaflex. Excluding this one-time benefit in the 2023 comparator period, year over year branded segment and Xiaflex revenues grew a healthy 7% and 11%, respectively, in the fourth quarter of 2024.

During the fourth quarter of 2024, both Xiaflex indications delivered strong revenue growth. Excluding the one-time benefit in fourth quarter 2023 I just mentioned, fourth quarter revenue from Peyronie's disease and Dupuytren's contracture grew 9% and 15%, respectively, compared to prior year. This revenue growth was primarily driven by an 8% increase in Xiaflex volume due to strong underlying demand coupled with an increase in average net selling price.

This performance reflects the results of our continued efforts to increase consumer awareness and patient access along with our focus on the provider experience. Additionally, during the fourth-quarter, Supprelin LA revenues increased by 9% as well, compared to prior year driven by underlying demand.

Moving to the sterile injectables segment, fourth quarter 2024 revenues were \$92 million compared to \$96 million in the prior year. This change was primarily driven by competitive pressures on Vasostriect, offset partially by increased volumes across multiple other products in the portfolio. Turning to the new product launches, I am very pleased with the strong fourth-quarter performance from Adrenalin RTU bag which we introduced early in the quarter. We intend to increase both the availability of supply and the base of customers for Adrenalin RTU during the first half of 2025 with increased pull-through and additional presentations in the second half of the year.

Fourth quarter 2024 generic pharmaceutical segment revenues were \$111 million, compared to \$139 million in the prior year. Lidocaine patch revenues increased 46% compared to the prior year as we continue to provide the market with reliable supply. This growth partially offset competitive pressure across a number of products, including dexlansoprazole delayed release capsules.

Fourth quarter 2024 revenues from the International Pharmaceuticals segment were \$17 million, essentially unchanged compared to the prior year.

Moving onto the next slide and diving deeper into our Xiaflex franchise, we remain bullish on Xiaflex as a durable and long-term growth driver for the Company.

Looking back over the past 10 years, Xiaflex has grown at a compound annual growth rate of 15%. The current diagnosis and treatment rates for both on-market indications remain low providing the opportunity for continued future growth. To drive continued growth, we plan to invest in the direct-to-consumer activation, the patient and provider experience and potential future musculoskeletal and urological indications. Lastly, we continue to believe that Xiaflex is protected by a robust IP estate as well as high barrier-to-entry market dynamics.

Turning to the next slide, sterile injectables and acute care capabilities continue to represent an attractive growth option for us. Last quarter I shared that we launched a thorough review of our sterile injectables business, our capabilities, and the commercial opportunities of the projects in our sterile injectable and generic pipelines. This comprehensive review confirmed our strategy, our focus on ready-to-use and differentiated products, and our know-how and capability to succeed in this segment.

As a result of this review, we made changes to personnel, we made changes to our prioritization, and in turn we are making the additional investments into our sterile injectable operations to drive execution. The pipeline efforts for SI now report directly to me. As part of this updated effort, we have decided to focus on a reduced number of projects across the portfolio which will provide us with increased probability of success against this prioritized pipeline. We believe these changes will help us better leverage our sterile injectable capabilities, improve execution and position us to deliver growth in the segment.

Our sterile injectables pipeline continues to be heavily focused on differentiated products that help reduce complexity and improve efficiency in the hospital and acute care settings, with approximately 60% of the pipeline being ready-to-use and differentiated projects. In 2025, we expect to launch approximately three sterile injectable products and submit seven FDA filings. Since the beginning of the year, we have already completed two of these FDA submissions. Looking forward, we expect to launch approximately 20 products over the next three years and we plan to provide updates on both our submissions and our launches as the measure of our progress. We believe the successful launch of these new products will drive our sterile injectables business to grow between mid and high single digit compounded annual growth rate over the next five years.

Before turning the call to Mark, I want to again thank our team members for their commitment to our patients and delivering life-enhancing products. With that, let me turn the call to Mark who will take us through the rest of the financial discussion.

Mark Bradley - Executive Vice President and Chief Financial Officer, Endo, Inc.

Thank you, Scott.

Turning to slide 8, I'll start with a summary of our enterprise revenue and non-GAAP financial results for fourth quarter 2024 compared to prior year. As Scott mentioned, fourth-quarter 2024 revenues decreased compared to prior year primarily due to competition across multiple products in our generic segment.

Fourth quarter 2024 adjusted EBITDA decreased slightly compared to prior year as lower revenue and slightly higher operating expenses were partially offset by slightly higher adjusted gross margin. Fourth quarter 2024 adjusted net income was approximately \$70 million compared to approximately \$151 million in the fourth quarter 2023. This decrease was primarily due to an increase in interest and adjusted income tax expenses compared to prior year. We ended 2024 with approximately \$387 million of unrestricted cash and cash equivalents and a net debt to adjusted EBITDA ratio of approximately 3.3x.

Turning to my final slide, we expect full year 2025 revenues to be between \$1.78 billion and \$1.86 billion and adjusted EBITDA to be between \$620 million and \$650 million. Our full year 2025 guidance does not incorporate the impact from the divestiture of the International Pharmaceuticals business, which is expected to occur in the middle of 2025.

Our full year 2025 revenue guidance range reflects a low to mid-single digit growth rate compared to 2024. This reflects a high-single digit growth rate in Xiaflex revenue, expected growth in revenue from recently launched sterile products, including the Adrenalin RTU bags, and expected growth in revenue from the lidocaine patch. This anticipated growth is expected to be partially offset by competitive pressures on several products across all portfolios.

Our full year 2025 adjusted EBITDA guidance assumes an adjusted gross margin of approximately 64% and operating expenses between \$590 million and \$610 million. Adjusted gross margin reflects changes in business mix as well as additional investments in our sterile injectable manufacturing network. Operating expenses reflect continued advertising and promotional investments to support the growth of Xiaflex on-market indications, investments to support the development of new Xiaflex indications and investments to support the development of new sterile injectable product candidates.

I would like to note that adjusted EBITDA is expected to be lower in the first half of 2025 than the second half of 2025. This phasing is expected to be primarily driven by Xiaflex revenues, which are typically higher in the second half of the year, as well as the ramp up in revenues from recently launched sterile injectable products, including the Adrenalin RTU. Operating expenses are also expected to be higher in the first half of the year. Accordingly, we expect our net debt to adjusted EBITDA ratio will increase through the first half of 2025 compared to the fourth quarter 2024 and then decrease through the second half of 2025.

For a reconciliation of all non-GAAP numbers to the most directly comparable GAAP financial measure, please see the reconciliations in the appendix to the presentation.

I will now turn the call over to Mallinckrodt's CFO Bryan Reasons to review Mallinckrodt's results.

Bryan Reasons - Executive Vice President and Chief Financial Officer, Mallinckrodt plc

Thanks, Mark. Before diving in, I'll note that unless otherwise specified, the net sales percentage changes we discuss are on a constant currency basis.

2024 was truly an outstanding year for Mallinckrodt. We achieved the high end of our net sales guidance range for the full year, and this was despite having only 11 months of sales contributions from Therakos[®], which we completed the sale of at the end of November. We also achieved the midpoint of our raised adjusted EBITDA guidance for the year.

Across our businesses, we were proud to return a key brand, Acthar Gel, to growth, bring two new innovations to the market and deliver an exceptional year of double-digit growth in our specialty generics segment.

Our results underscore our strong performance and the successful execution of our strategy as our teams have been focused on stabilizing our base businesses and positioning Mallinckrodt for long-term growth.

Turning to our financial results for the fourth quarter and full year, as well as our 2025 guidance. Mallinckrodt's total net sales in the fourth quarter were \$492.1 million, as compared to \$469.3 million in the fourth quarter of 2023, reflecting a 4.9% growth on a reported basis and a 4.8% growth on a constant currency basis. Excluding Therakos, net sales grew by 11.5%.

Adjusted EBITDA in the fourth quarter of 2024 was \$124.2 million, essentially flat compared to \$123.8 million in the prior year period. This stability was driven by strength in both the specialty generics segment and Acthar Gel, largely offset by approximately \$9.0 million of transaction-related compensation expenses related to the sale of Therakos, the impact of the Therakos transaction, incremental commercial investments for Acthar Gel and Terlivaz and the impact of nitric oxide competition in the United States.

The specialty brands segment reported net sales of \$265.6 million in the fourth quarter of 2024, as compared to \$270.7 million in the fourth quarter of 2023. Excluding Therakos, specialty brands net sales grew by 8.9%. In terms of results by each product, Acthar net sales were \$138.8 million in the fourth quarter, up 33% compared to the prior year. Our fourth quarter growth was largely driven by the successful launch of SelfJect in August of 2024, which was responsible for over 70% of the new Acthar brand prescriptions, as well as an overall prescriber enthusiasm and patient demand. Looking to 2025, we expect positive momentum in our rollout of SelfJect to continue and anticipate full-year net sales growth for Acthar Gel to be in the low-single-digit range.

INOmax generated net sales of \$60.8 million in the fourth quarter, a decline of 14% compared to the prior year period. INOmax performance continued to be impacted by competitive pressures in the U.S. throughout the year. This said, we began the multi-year rollout of the INOmax EVOLVE™ DS delivery system into U.S. hospitals last March. We believe that this is an important innovative offering that will drive stability for the brand as we continue hospital and provider engagement to expand adoption over time.

Terlivaz generated net sales of \$6.1 million in the fourth quarter, an increase of 8.9% compared to prior year period. We are seeing signs of positive traction for Terlivaz, with 15% higher hospital demand in the second half of 2024 versus the first half of the year. We continue to have conviction in Terlivaz as the first and only FDA-approved product indicated to improve kidney function in adults with HRS with rapid reduction in kidney function.

The specialty generics segment reported net sales of \$226.5 million, as compared to \$198.6 million in the fourth quarter of 2023. Growth was driven by strong performance in finished-dosage products, increased demand for Controlled Substance API and Mallinckrodt's differentiated position as a consistent supplier of high-quality products. We also continued to see softening demand in the APAP business from excess supply in the broader market as customers adjust their inventories.

Moving forward, we will continue building on our strong market position in this segment and expect to deliver flat to low-single-digit net sales growth in 2025. For the full year, Mallinckrodt reported full-year net sales of \$1.98 billion, an increase of 6.1% compared to the prior year, and adjusted EBITDA of \$603.7 million, an increase of 5.6%. Excluding the impact of the Therakos business, adjusted EBITDA grew 12.9%.

Turning to our guidance, for the full-year fiscal 2025, we expect total net sales of between \$1.7 billion and \$1.8 billion and adjusted EBITDA of between \$480 million and \$520 million.

Mallinckrodt has positive momentum as we move into the new year, and we are all energized to keep pushing forward, advancing our strategic priorities and delivering results while we work toward closing the combination with Endo.

I'll now turn the call back to Siggi.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thank you, Bryan.

In closing, I'd like to recognize the talented Mallinckrodt team.

This transaction is a testament to their contributions, which have enabled us not only to achieve but surpass our goals.

It has taken a lot of hard work to get us to where we are today, and I am grateful for their continued commitment and dedication to our company and the patients, healthcare providers and customers we serve.

We'll now open it up for your questions.

Operator

(Operator Instructions)

And one moment please for your first question.

Our first question comes from the line of Leszek Sulewski of Truist Securities. Your line is now open.

Leszek Sulewski – Analyst, Truist Securities

Good morning. Thank you for taking my questions and very interesting transaction in this time. Perhaps, maybe just start off on, how can we think about the Merge Co as an entity? You know, which categories do you plan to invest in? I did pick up that you've wanted to, I guess a little bit, investment towards the rare disease front, but maybe any specific areas. And then how do you think about kind of the pipeline and R&D engine internally? Or are you more inclined towards the BD plans across the branded portfolio? And I do have a follow up.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thanks for that. It's Siggi here. If we focus on it, I think you need to think about this transaction in a way that we are establishing two different, two distinct businesses, the branded pharmaceutical business and the specialty injectables and generics business.

How I think about it is the branded business is growing. You know, it's exciting. Two strong brands on the market with Xiaflex and Acthar and quite a few other smaller brands which make an impact, and has a huge impact, and patients need those brands. I think both companies have mainly been focused on expanding the current brands on the market. That has been the focus on the R&D effort in-house today, not so much has been done outside.

I think, as you see from our presentation, when this combination happens, this changes the scene completely. The opportunity is with a much stronger balance sheet. You saw at closing our net debt will be 2.3x, so there will be an opportunity for investment in R&D. Probably to begin with, look for opportunities in business development. You know, it depends on at which stage which we would license that in. I think we need to work on what therapeutic areas we could go.

The beauty of this transaction is this specialty brand company will cover so many therapeutic areas, as Scott mentioned, and we could even go into a new one. So, it's an open opportunity for us. We have the balance sheet, we have the team, we are excited about that.

On the generics and sterile injectables, I'm very excited about the injectable pipelines that Endo is working on. As I mentioned in my points, over 40 projects are being worked on. I have a little bit of a background from my previous job in working in the U.S. injectables business, and I'm excited with the projects that they are working on, on the ready-to-use portfolio to bring to the market and maybe there is more opportunity there.

On the generic side, I think there will be continuing there, but more I think the first focus will be to deliver the pipeline of the sterile injectables to the market and then, of course, there is an opportunity in the active pharmaceutical ingredients. But that business will have a very strong cash flow in that business unit, and what we see in the branded business is the balance sheet will allow us to do this business development we talk about. So that's in a way the fundamental of the excitement around this combination.

Leszek Sulewski – Analyst, Truist Securities

I appreciate all that color, Sigg, and maybe just to touch on the generics. What's the rationale on the separation and have you gauged interest across different counterparties?

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

No, so no decision has been done. The Board will make a decision on the separation when the time comes. What we want to do is to, when this deal closes, which we expect in the second half of the year, we will work on integrating the sterile injectables and the two generics businesses into one unit and then we make the best decision going forward and the timing to do that of the separation.

But, we're excited. There are opportunities with a much larger portfolio. I think the combined company, the combined businesses, will be one of the larger generics and sterile injectable businesses in the U.S., has amazing customer service, has really a good manufacturing platform, focused on U.S., platform but also outside of the U.S., which is so good in today's competitive environment in generics. So, we are not -- we haven't explored any further steps than identifying that we want to combine the businesses and then we will make decision on the next steps.

Leszek Sulewski – Analyst, Truist Securities

Excellent color. Maybe last one for me. Can you just provide a little bit more color around the \$150 million expected in synergies? Is this mostly across OpEx or is there any sort of overlap across the portfolio that can be reallocated? And is there any synergies across marketing and sales that could enhance the branded portfolio specifically? Thank you and congrats on the transaction.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Yes, so on the synergies, how we are thinking about that. We are basically two fully fledged companies that are getting together. So, there will be overlapping roles for sure, which we will identify during preparation for the integration.

But really, where the opportunity is, is obviously around the infrastructure of the company, better use of resources. We will be a stronger purchaser as a combined company, we are buying more. We have doubled the size that individually the company was before, so we feel good about that, about the synergy opportunities. There is, you know, small things like, you know, buying information data from external sources, both companies invest hugely in that part of the business, just to give you a small example of how we think about it.

In terms of sales and marketing, as I sit here today, we haven't made a prediction. I think the impact there will not be – very little, because we are in distinct therapeutic areas and we want to continue the sales with the sales force in place. We can never say never, but as I'm sitting here today, I think the impact on sales will be minimal, if any, because we want to grow these businesses. We have many brands that we want to support. So that is not the focus and the source of the \$150 million in synergies.

Leszek Sulewski – Analyst, Truist Securities

Great. Thank you for the additional color and congrats on the transaction.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thank you.

Operator

Thank you so much. And your next question comes from the line of Douglas Tsao of H.C. Wainwright. Your line is now open.

Doug Tsao – Analyst, H.C. Wainwright & Co.

Hi, good morning. Thanks for taking the questions and congrats on the transaction. So, I guess, Siggi maybe as a start, I'm just curious in terms of business development to build out the branded business, which seems to be a focus, I'm just curious, you know at what stage of development are you going to be looking for assets? Will they be largely commercial assets or will you be looking for assets in different stages of development as well? Thank you.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Yeah, good morning, Doug.

So, I think the opportunity for us is we need to think in the beginning especially around the risk profile of this company. So, I don't see this company going into any research or early development. We simply are not at that stage, but we obviously need to evaluate, and in my mind now, I think we can evaluate products in phase three, early commercialization or commercial brands that have synergies with our current therapeutic areas. As I mentioned, we have a wide reach in terms of our sales force, and that's an opportunity.

And we also will be a very well and strongly established U.S. brand company. There might be a European player that are looking for partners for their development product to bring to the U.S., so I feel there's a lot of opportunities in the business development front due to the wide range of therapeutic areas, due to the knowledge and expertise we have. I think both companies have expertise out of this world in market access, both companies have very challenging products in market access. Acthar, obviously one of the more complex products in that category, Xiaflex is the same.

I think both companies have shown they do an excellent execution, and we could be, I think, a good home for products going forward in the U.S. brand market.

Doug Tsao – Analyst, H.C. Wainwright & Co.

And maybe as a follow-up, Siggi, I know Mallinckrodt has had a focus on immunology. Will you sort of stick to the same therapeutic areas or will there be some sort of expansion just given the fact that there'll be zeroing in on orphan disease? It doesn't necessarily take a huge commercial investment to go into your category. Thank you.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Yeah, so we are not – we are basically fixating us on our current therapeutic areas. I think we will start the exploration based on current to gain some synergies, you know, we would be able to get maybe some sales synergies if we introduce a second product into like urology with Xiaflex or into immunology with Acthar, but we are not eliminating anything.

I think it's unlikely we go into a therapeutic areas where the big pharmas are competing. I probably wouldn't see this company, although no decision is made, that we would enter oncology, that's not our core, but we are covering so many of the other therapeutic areas where the competition and the opportunities are for us to put our foot down.

Doug Tsao – Analyst, H.C. Wainwright & Co.

Okay, great. Thank you.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

Thanks Doug.

Operator

Thank you so much and, again, if you would like to ask a question, please press star one.

This concludes the Q&A session. I will now hand the call back to Siggi for closing remarks.

Siggi Olafsson – President and Chief Executive Officer, Mallinckrodt plc

First of all, thank you everybody for joining us today.

On behalf of both companies' management teams, we are really eager to hit the ground running as we work to complete the transaction and realize the full potential of this combination.

I want to congratulate employees of both companies. Both companies have done amazing jobs over the last two years, two, three years, in re-finding the core of the business, serving patients, that led really to this combination today. Thank you.

Operator

Thank you so much and thank you all for joining today's conference call. You may now disconnect.

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 intends to file with the U.S. Securities and Exchange Commission (“SEC”) a registration statement on Form S-4 that will include a joint proxy statement of Mallinckrodt and Endo and that also constitutes a 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 2024 Annual Meeting of Shareholders, which was filed with the SEC on April 15, 2024 (and which is available at https://www.sec.gov/Archives/edgar/data/1567892/000110465924046964/tm242936-1_def14a.htm), including under the headings "Corporate Governance," "Our Director Nominees," "Board of Directors and Board Committees," "Compensation of Non-Employee Directors," "Executive Officers" "Compensation of Executive Officers," "Pay Versus Performance," "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 29, 2023, which was filed with the SEC on March 26, 2024 (and which is available at <https://www.sec.gov/ix?doc=/Archives/edgar/data/1567892/000156789224000008/mnk-20231229.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 2024 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) Endo's registration statement on Form S-1, which was filed with the SEC on July 31, 2024 (and which is available at <https://www.sec.gov/Archives/edgar/data/2008861/000119312524185328/d15705ds1a.htm>), including under the headings "Management," "Executive and Director Compensation of Endo International plc," "Certain Relationships and Related Party Transactions," and "Principal and Registering Stockholders" and (ii) to the extent holdings of Endo's securities by its directors or executive officers have changed since the amounts set forth in Endo's S-1 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, will be contained in the definitive 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 (including, among other things, statements regarding the proposed business combination transaction between Mallinckrodt and Endo, Mallinckrodt and Endo's plans to combine their generics pharmaceuticals businesses and Endo's sterile injectables business after the close of the proposed business combination and separate that business from the combined company at a later date, the anticipated benefits of the proposed transactions, the anticipated impact of the proposed transactions on the combined company's business and future financial and operating results, the expected amount and timing of synergies from the proposed transactions, the anticipated closing date for the proposed business combination transaction and any other statements regarding events or developments Mallinckrodt and Endo believe or anticipate 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:

- (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;

- (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 and proxy statement/prospectus that will be filed with the Securities and Exchange Commission (the “SEC”) will describe additional risks in connection with the proposed transaction. While the list of factors presented here is, and the list of factors to be presented in the registration statement on Form S-4 and proxy statement/prospectus 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.

Non-GAAP Financial Measures

To supplement the financial measures prepared in accordance with U.S. generally accepted accounting principles (GAAP), this communication includes certain financial information of the combined company in this release that are not prescribed by or prepared in accordance with GAAP. We utilize these non-GAAP financial measures as supplements to financial measures determined in accordance with GAAP when evaluating operating performance and we believe that these measures will be used by certain investors to evaluate operating results. We believe that presenting these non-GAAP financial measures provides useful information about performance across reporting periods on a consistent basis by excluding certain items, which may be favorable or unfavorable.

Despite the importance of these measures to management in goal setting and performance measurement, these are non-GAAP financial measures that have no standardized meaning prescribed by GAAP and, therefore, have limits in their usefulness to investors. Because of the non-standardized definitions, non-GAAP adjusted EBITDA (unlike GAAP net income and its components) may differ from, and may not be comparable to, the calculation of similar measures of other companies. These non-GAAP financial measures are presented solely to permit investors to more fully understand how management assesses performance.

These non-GAAP financial measures should not be viewed in isolation or as substitutes for, or superior to, financial measures calculated in accordance with GAAP. We are not providing reconciliations of projected non-GAAP financial measures to GAAP financial measures, nor are we providing comparable projected GAAP financial measures for such projected non-GAAP financial measures. We are unable to provide such reconciliations without unreasonable efforts due to the inherent difficulty in forecasting and quantifying certain amounts that are necessary for such reconciliations, including adjustments that could be made for asset impairments, contingent consideration adjustments, legal settlements, gain / loss on extinguishment of debt, adjustments to inventory and other charges reflected in the reconciliation of historic numbers, the amounts of which could be significant.