Endo, Inc.
Third quarter 2024 Earnings Call Prepared Comments
November 5, 2024

**Laure Park:**

Good morning and thank you for joining us to discuss Endo, Inc.'s third quarter 2024 financial results. Joining me on today's call are Scott Hirsch, Interim CEO and member of the Board of Directors, Mark Bradley, Executive Vice President and CFO, and Patrick Barry, Executive Vice President and President, Global Commercial Operations.

We have prepared a slide presentation to accompany today's webcast and that presentation, as well as other materials, are posted online in the Investor section at endo.com. Later this morning, a copy of our prepared comments will also be posted to our website.

I would like to remind you that any forward-looking statements made by management on today's call are covered under the U.S. private securities litigation reform act of 1995 and are subject to significant changes, risks and uncertainties described in our earnings release and other press releases, and in our SEC filings. Actual results may differ materially from those set forth in any forward-looking statements.

As previously disclosed, substantially all of Endo International's assets were acquired by Endo, Inc. on April 23, 2024, pursuant to Endo International's Plan of Reorganization. Endo, Inc.'s third quarter 2024 financial results reflect the effects of the Plan of Reorganization and the application of fresh start accounting.

So, to clarify, during this call, all references to third quarter 2024 results refer to Endo, Inc. All references to third quarter 2023 results refer to Endo International plc.

In addition, during today's call, we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used by other companies. Investors are encouraged to review our current report on Form 8-K furnished with the SEC for our reasons for including those non-GAAP financial measures in our earnings release and presentation. The reconciliations of non-GAAP financial measures to the most directly comparable GAAP financial measures are contained in our earnings release issued earlier this morning, unless otherwise noted therein.

I would now like to turn the call over to Scott.

**Scott Hirsch:**

Thank you, Laure, and thank you to everyone joining us this morning.

**Starting with slide 5**, During today's call, I will provide a third-quarter performance and business update, including some thoughts on the company's opportunities given my sixty days inside. Mark

Bradley will then walk you through the financial results and outlook and then I will return with some closing comments before we open it up to your Q&A.

**Slide 7** provides our third quarter operating performance and recent business highlights. Third-quarter 2024 total revenues of $427 million and adjusted EBITDA of $151 million were just above our pre-announced result estimates from two-weeks ago which were issued as part of our term loan repricing.

Compared to prior year, third quarter revenues decreased 6%, primarily attributable to competitive pressure across the Generic and Sterile segments, partially offset by solid revenue growth from our Branded Pharmaceutical segment. This is sequential improvement in performance compared to prior quarters as the competitive impact of losing exclusivity of key products, including VASOSTRICT and varenicline, had begun to stabilize. Importantly, we are on-track to deliver our full-year 2024 revenue and EBITDA expectations as well as transition to growth.

Our performance in the third quarter was anchored by XIAFLEX, with total revenue growth of 13% and strong performances across both on-market indications. We also advanced our sterile injectable capabilities, including launching ADRENALIN ready-to-use bags during the first week of October.

In addition, we saw the cash generation strength of the business. Adjusted EBITDA grew 6%, our net leverage was reduced to 3.3 times from 3.5 times last quarter, and we successfully completed the repricing of our 1.5-billion-dollar Term Loan. I would like to thank our credit holders for their continued confidence.

**Moving to slide 8** and diving into the segment level performance.
Starting with the Branded Pharmaceutical segment, which represents about 50% of company revenues, segment revenues grew 7% versus third quarter 2023. This increase was primarily driven by strong XIAFLEX performance. XIAFLEX revenues were $128 million in the quarter, an increase of 13% compared to prior year.

This increase was driven by strong underlying demand and increased average net selling price. Volume increased approximately 7% and average net selling price increased by approximately 6% compared to the prior year.

During the quarter, XIAFLEX demand improved across both indications. Peyronie's Disease revenues grew a very strong 16% and Dupuytren's Contracture revenues grew 8% compared to prior year. This performance reflects our continued focus on increasing patient and physician awareness as well as improving the HCP experience.

The remainder of the Branded Segment, including the Established Products, generated 89 million dollars in the quarter which was minus 1% relative to the previous year.

Third quarter 2024 Sterile Injectables revenues of $80 million were below prior year revenues of $95 million. This change was primarily attributable to the year-over-year competitive pressure related to VASOSTRICT, as well as temporary supply disruptions on several products.

Importantly, we expect to see substantial resolution of the supply disruptions by the end of the year as well as overall moderation in the impact from VASOSTRICT competition as we lap the erosion from loss of exclusivity.

**Turning to slide 9**, third quarter 2024 Generic Pharmaceutical segment revenues were $111 million, a decrease of 18% compared to prior year. This decrease was primarily due to competition for varenicline tablets and dexlansoprazole (dex-lan-zoprazole) delayed release capsules. It was partially offset by revenue upside from Lidocaine patch, the generic version of LIDODERM.

Importantly, excluding varenicline and dexlansoprazole (dex-lan-zoprazole), the Generics segment grew 6% and gross margin improvements drove approximately 200 basis points of benefit relative to the prior year.

Third quarter 2024 revenues from the International Pharmaceuticals segment were $18 million, which was essentially unchanged compared to the prior year.

Looking forward, I would like to highlight some of the future performance levers the business is utilizing within our branded and sterile growth pillars.

**Turning to slide 10**, XIAFLEX is the only FDA approved non-surgical therapeutic option for patients with Peyronie's Disease and Dupuytren's Contracture. Both conditions have low diagnosis and treatment rates and a small increase in these diagnosis rates can have a significant impact for patients who prefer non-surgical options.

We are increasing our investment in a combination of branded and unbranded direct-to-consumer awareness campaigns focused on motivating potential patients to both seek a diagnosis and inquire about a non-surgical treatment option. We continue to be pleased by the patient activation across both indications, including the overall increase in visits to our websites and physician locators, where disease-related education and tailored access to a local trained specialist increases patient adoption.

Increasing patient knowledge and adoption is critical for both our business and that of our health care practitioners. Five years ago, Pro Football Hall of Famer John Elway helped to increase awareness of Dupuytren's Contracture by telling his Xiaflex treatment story. In the coming weeks, we plan to launch a new Dupuytren's contracture PR campaign, sharing a patient's XIAFLEX experience.

We believe that a high touch provider approach focused on education and a seamless XIAFLEX acquisition experience will increase physician loyalty and support the preferential use of Xiaflex as a non-surgical treatment option.

Accordingly, last month at the annual meeting of the American Society for Surgery of the Hand, we unveiled our Mixed Reality Injection Simulator to over 300 hand specialists. The simulator provides an immersive physician learning experience to help hand specialists refine their technique by allowing them to interact with physical and digital objects simultaneously. We believe this technology will support injection training and help build injector confidence.

It is also important that we continue to advance real-world studies and provide information to help HCPs better support their patients. At the recent Sexual Medicine Society of America annual meeting, there were seven presentations related to Peyronie's disease and XIAFLEX.

**Turning to slide 11**, in addition to the growth potential for XIAFLEX on-market indications, we have been exploring the potential to drive XIAFLEX growth by expanding into new musculoskeletal and urological indications.

This morning, we provided an update from our early Phase 2 plantar fasciitis clinical study. While study participants receiving one treatment of Xiaflex 0.6 mg showed numerical improvement from baseline on the Pain Intensity Numeric Rating Scale compared to placebo, the difference was not statistically significant. However, an initial post-hoc analysis indicates that the results were clinically meaningful for a subpopulation of patients with moderate-to-severe pain at baseline. We will evaluate the data in more detail to determine if further clinical work in the moderate-to-severe patient population is warranted.

Alongside Dupuytren's Contracture, the plantar indications are opportunities to expand our orthopedic platform, specifically to garner incremental presence in the sports medicine category, which is a high-growth sub-specialty within orthopedics, and to do so with a synergistic utility of our ortho sales force. Our other musculoskeletal and urological indications provide similarly attractive life cycle opportunities.

This was a logical, clinical R&D shot on goal with very capitated risk for substantial upside, and with a biologic that has long durability. As I noted, we will look at the best next steps for the plantar fasciitis program and also use this opportunity to take a fresh look at our full range of future indications for XIAFLEX, as well as assess both organic and inorganic capital allocation opportunities for the entire business.

**Turning to slide 12**, Sterile Injectable and acute care capabilities are the second critical pillar of our future growth. Over the past several years, we have evolved and expanded our pipeline and manufacturing capabilities to support the introduction of more unique products that meet the evolving needs of our customers. Recently, we received the Establishment Inspection Report for our Indore sterile site and we are hopeful to receive final FDA approval by year end.

The potential in this segment and the long-term pipeline of over 50 projects is something that I've been digging into over the last several weeks and, in my view, it is a very exciting opportunity. So, I wanted to take a brief moment to outline several thoughts.

Currently, greater than 95% of U.S. hospitals use an Endo product and that foundation is a critical factor in our future pipeline's success.

The opportunity in front of our sterile injectables business is to leverage our hospital footprint along with our commercial and manufacturing capabilities to provide a unique offering within the acute care segment – meaning hospital ORs, ERs, and surgical centers. While the U.S. has arguably the best hospitals in the world, the operating environment within the acute care setting is subject to an ever-growing demand. This translates into greater patient volumes and expanding treatment protocols. Hospitals further operate under DRG procedure-based reimbursement, which means it is ultimately up to the hospital to manage both quality of patient outcome and costs under the capitated procedure rates.

This is where our Sterile Injectables business comes into play with the provision of medications in final and finished forms such as prefilled syringes and pre-dosed bags that are ready-to-use, accurately measured, and most importantly are FDA approved medications manufactured in FDA approved facilities. Not only does this offering provide a step function improvement in the simplicity to a hospital environment - which if you've ever been to an ER you know is subject to a great deal of complexity and time constraint - but also has the potential to reduce error rates, reduce pharmacy tech, nursing staff and hospital labor costs, as well as product waste. This creates an opportunity for a hospital to achieve better patient outcomes with faster, more accurate patient dosing along with less waste from multi-dose vials and hence higher profitability under their reimbursement codes.

Approximately 60% of our Sterile Injectable pipeline projects are planned in ready-to-use formulation that help to meet this need.

We recently launched ADRENALIN ready-to use bags in early October and we are pleased with the early demand for the product. Our bag is the first and only FDA-approved epinephrine IV bag prepared by a manufacturer and allows for improved time to treatment and workflow efficiencies.

We expect to launch two more sterile injectable products before the end of 2024 and plan to continue progressing our sterile injectable development pipeline.

**Moving to slide 13**, following the financial restructuring that was completed earlier this year, Endo now has a healthy balance sheet and is free of legacy overhangs.

Specifically, the Company has significantly lower funded debt and lower interest payments, including the impact of the Term Loan repricing last week. Net leverage is now approximately 3.3 times, a significant improvement from prior to emergence and even decreasing quickly with a reduction from 3.5 times at the end of last quarter. In addition, the company has significantly improved both its freedom to operate and its focus on value creation, having now alleviated litigation, tax, and other overhangs associated with legacy matters.

With that, let me turn the call to Mark who will take us through the rest of the financial discussion.

**Mark Bradley:**

Thank you, Scott.

**On slide 15**, you will see a summary of our enterprise financial results for the third quarter 2024 compared to prior year.

As Scott previously discussed, third quarter 2024 revenue decreased compared to prior year as declines in revenue from our Sterile and Generics businesses were only partially offset by the strong growth in revenue from our Branded business.

Third quarter 2024 adjusted EBITDA increased compared to prior year primarily due to higher adjusted gross margin and lower adjusted operating expenses. Adjusted gross margin was approximately 67% in third-quarter 2024, compared to approximately 64% in the prior year. This increase was primarily driven by changes in product mix coupled with manufacturing productivity improvements, primarily in our Generics business, compared to prior year. Adjusted operating expenses decreased compared to prior year primarily driven by lower R&D expenses associated with certain non-recurring contractual credits that were received during the quarter.

Third quarter 2024 adjusted net income was approximately $62 million compared to approximately $131 million in the third quarter 2023. This decrease was primarily due to an increase in interest and adjusted income tax expenses compared to prior year.

We ended the third quarter with approximately $368 million of unrestricted cash and cash equivalents, compared to approximately $294 million at the end of second quarter 2024. As Scott previously mentioned, we also ended the third quarter with a net debt to adjusted EBITDA ratio of approximately 3.3 times compared to 3.5 times at the end of the second quarter. This improvement was driven by the higher unrestricted cash balance coupled with higher adjusted EBITDA over the last 12-month period compared to the second quarter.

When looking at the statement of cash flows, I would like to highlight that cash from operations in third quarter 2024 reflects the final payment of certain escrowed professional fees incurred in connection

with Endo International plc's plan of reorganization, which are also reflected in the $79 million decrease in restricted cash, coupled with an increase in both interest and income tax payments compared to prior year.

As Scott also previously mentioned, last week we successfully completed a repricing of our $1.5 billion senior secured term loan. The repricing reduced the applicable interest rate on the term loan by 50 basis points to SOFR plus 400 basis points. All other terms remain substantially unchanged. The repricing will reduce cash interest expense by approximately $8 million annually.

**Advancing to slide 16**, based on our third quarter performance and fourth quarter expectations, we are reaffirming our full year 2024 financial expectations for total revenues and adjusted EBITDA.

As a reminder, full year 2024 financial results include the results of Endo International plc from January 1st through April 23rd and the results of Endo, Inc. from January 1st through December 31st.

Based on third-quarter results and fourth-quarter expectations, we continue to expect total 2024 revenues to be between $1.72 billion and $1.78 billion and adjusted EBITDA to be between $635 million and $655 million. We are a highly cash generative business and continue to expect a high EBITDA to pre-tax unlevered free cash flow conversion ratio.

While total revenue expectations for the full-year remain unchanged, based on third quarter results, we are refining our full-year segment revenue assumptions for Sterile Injectables and Generic Pharmaceuticals. We now expect Sterile Injectables revenues to be between $350 million and $370 million and Generic Pharmaceuticals revenues to be between $430 million and $440 million.

With respect to Branded revenue assumptions, as we previously disclosed, fourth quarter 2023 XIAFLEX revenues benefited from a non-recurring adjustment of approximately $14 million associated with the application of the final vial wastage rebate determination.

Adjusted gross margin for the full year 2024 is expected to remain unchanged at approximately 67% of total revenues. Gross margin in the fourth quarter is expected to be slightly lower than the first three quarters of the year primarily due to the shift in product mix, mainly within the Sterile and Generics segments, coupled with certain credits and other adjustments that benefited the first three quarters that are not expected in the fourth quarter.

We continue to expect adjusted operating expenses for full year 2024 to be between $595 million and $615 million.

Finally, we are on track to grow total company revenues in 2025 and will provide more detailed 2025 financial expectations in the normal course as part of year end 2024 earnings in early 2025.

I will now turn the call back over to Scott for a few closing remarks.

**Scott Hirsch:**

Thank you, Mark.

Before my closing comments, I want to give a quick update on the CEO search and national exchange listing process.

First, we have met with impressive candidates and the Board is working with deliberate speed to identify and appoint the best individual to lead the Company forward. I do not have a more specific timeline to communicate at this point.

With regard to our goal of uplisting our stock to a national exchange, we have been actively engaged in that process and believe we will have achieved the eligibility requirements to transition to the NYSE during this month. However, after consultation with our capital markets advisors, we have decided to defer the timing of our NYSE uplisting from the very end of 2024 to an appropriate date in 2025.

**Turning to slide 18** and closing our comments – Our on market XIAFLEX indications are showing strong growth with meaningful future opportunities to increase diagnosis and treatment rates, along with the potential for additional musculoskeletal or urological indications to expand the longer-term growth profile of our biologic.

With regards to our Injectable Solutions and acute care platform, we believe Endo has a significant advantage in a complex and high barrier to entry market with the potential to generate attractive future revenue growth.

We have a healthy balance sheet and strong cash flow, and the opportunity to deploy those cash flows toward both organic and inorganic growth drivers.

Finally, over the past 2 months, I have met many of the Endo team members and appreciate the commitment they bring to work every day.  I want to thank them for their hard work and service to our customers and their patients.