Endo, Inc.
Second quarter 2024 Earnings Call Prepared Comments
August 27, 2024

Laure Park:

Good morning and thank you for joining us to discuss Endo, Inc.'s second quarter 2024 financial results. Joining me on today's call is Paul Herendeen, the Chairman of Endo's Board, 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. Additionally, later this morning a copy of our prepared comments will also be posted online in the Investor section at endo.com.

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.

Substantially all of Endo International's assets were acquired by Endo, Inc. on April 23, 2024, pursuant to Endo International's Plan of Reorganization. The combined second quarter financial results presented today reflect the effects of the Plan of Reorganization and the application of fresh start accounting.

For clarification, during this call, all references to second quarter 2024 results refer to combined Endo, Inc. and Endo International plc results. All references to second quarter 2023 results refer to Endo International plc results. A complete discussion of the impact of the accounting adjustments related to the transactions contemplated in the Plan of Reorganization, which became effective on April 23, 2024, the application of fresh start accounting in accordance with Accounting Standards Codification No. 852, and related disclosures will be found in our Form10Q to be filed in the coming days.

In addition, during the course of 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 Endo's current report on Form 8-K furnished with the SEC for Endo's reasons for including those non-GAAP financial measures in its 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 Paul.

Paul Herendeen:

Thank you, Laure. Good morning everyone and thank you for joining us.

Earlier today, we announced that the Board is starting the search for Endo's next CEO and that Scott Hirsch, another of Endo's Directors, has been appointed Interim CEO.

On behalf of the Board, I want to thank Blaise Coleman for his many contributions to Endo. We appreciate his successful leadership of the company during very challenging times. We wish him all the best.

As a Board, we believe there are significant opportunities on the horizon for Endo. With our restructuring complete, the Company is free from legacy overhangs and ready to enter its next phase.

We sit here today with a clean balance sheet, modest leverage, a diversified portfolio, returning to growth, generating cash and now have opportunities to deploy that cash for future growth.

The decision to transition to a new CEO at this time was to tailor leadership to our emerging growth opportunities.

We will be looking for a leader with the experience, skill set and strategic vision to help us leverage our capabilities and pursue additional strategies to drive long-term value for stakeholders.

The Board will work with purpose to identify and appoint the best candidate to lead the Company forward.

In the near term, we are confident that Scott is the right person to lead Endo through this transition. He brings deep operating and industry experience and is committed to advancing our mission.

Scott was the CEO of Solta Medical, where he led a growing global business through an expansion cycle. Prior to that, he was the Chief Business Officer and President of the Ortho Dermatologics and OraPharma business segments at Bausch Health.

I worked closely with Scott during his time at Bausch and can personally attest to his ability to adapt to situations quickly, make sound decisions, and keep his eye on the prize. We are all grateful that he has agreed to step in to lead Endo while the search process is ongoing.

With that, I will turn the call over to Mark for a review of our financial results.

Mark Bradley:

Thank you, Paul. **Starting on slide 5,** For those that are new or just returning to the Endo story, Endo, Inc. is a purpose-driven diversified specialty pharmaceutical company. We are a company that is inspired by our vision to help everyone we serve live their best life; united by our mission to develop and deliver life-enhancing products through focused execution; and driven by our aspiration to be a vibrant growth company.

We operate across four businesses: Branded Pharmaceuticals, Sterile Injectables, Generic Pharmaceuticals and International Pharmaceuticals.

Our growth businesses include our Branded Pharmaceuticals and Sterile Injectables segments. We believe these businesses have the potential for sustainable revenue growth and profitability. We have invested, and plan to continue investing in those businesses to drive profitable growth.

Our established businesses include the Generic Pharmaceuticals and International Pharmaceuticals segments. Our objective for those businesses has been to drive steady and stable future cash flows through targeted investments.

We have a strong foundation consisting of a broad, durable, and diverse product portfolio with over 180 on-market commercial products across our businesses and an unencumbered balance sheet. Accordingly, we believe Endo is well positioned to achieve sustainable growth.

Turning to slide 6, We have a growing and durable Branded Pharmaceuticals business anchored by XIAFLEX. XIAFLEX is a complex enzyme-based “pipeline in a product” growth platform. Patrick will cover the XIAFLEX on-market indications and the potential new indications that are currently in clinical development later in the presentation.

Our Sterile Injectables business is on the verge of returning to growth fueled by a deep and differentiated pipeline of over 50 potential new products. The Sterile Injectables pipeline is concentrated in ready-to-use and other differentiated and durable products. The Sterile injectable business is supported by scalable development and commercial capabilities and modernized manufacturing, including our new state-of-the-art Indore, India facility and our expanded Rochester, Michigan facility.

Our Generic Pharmaceuticals business is focused on the U.S. generic retail market and consists of a portfolio of products spanning several different technologies and dosage forms.

Lastly, our small International business primarily consists of Paladin Pharma in Canada. This business has a scalable commercial model with portfolio growth that is fueled through product in-licensing.

Slide 8 includes a snapshot of our segment and total revenues and adjusted EBITDA. Second quarter 2024 total revenues of $447 million were better than we expected due to slightly higher revenues from our Generic, Branded, and International Pharmaceuticals segments. Compared to prior year, total revenues decreased by approximately 18% primarily due to lower varenicline and dexlansoprazole revenues in our Generics segment. Second quarter 2023 also included a non-recurring payment of $33 million in our Sterile Injectables segment to settle a dispute related to a previous manufacturing and services agreement.

Second quarter 2024 adjusted EBITDA of $176 million was better than internal expectations due to higher revenue and favorable product mix, as well as the timing of certain operating expenses. Adjusted EBITDA decreased compared to prior year primarily due to lower revenues.

Let me now turn the call over to Patrick who will cover our segment results.

Patrick Barry:

Thank you Mark. **Turning to slide 9**, second quarter 2024 Branded Pharmaceuticals segment revenues were $225 million, an increase of 6% compared to prior year.

XIAFLEX revenues were $127 million in second quarter 2024, an increase of 8% compared to prior year. This increase was driven by higher average net selling price and underlying demand which were in line with our expectations.

As expected, XIAFLEX volume increased 8% compared to first quarter 2024 and decreased slightly compared to second quarter 2023.
As we have previously discussed, XIAFLEX growth has been impacted by a number of disruptions over the last several years, most notably the COVID pandemic and the acquisition of our 3rd party specialty pharmacy provider in 2022. However, we believe that business conditions and utilization patterns for XIAFLEX began to normalize in the second half of 2023 and these normalized patterns are reflected in our second half 2024 XIAFLEX revenue expectations.

Non-XIAFLEX specialty products revenues were $36 million in second quarter 2024 compared to $48 million in second quarter 2023. This decrease was driven by lower SUPPRELIN ® LA volumes and the impact of generic competition on NASCOBAL ® Nasal Spray.

Established products revenues were $63 million in second quarter 2024, an increase of 33% compared to prior year. This increase was primarily driven by a $10 million favorable change in non-recurring, non-cash adjustments across both the second quarter of 2024 and the second quarter of 2023 related to previously discontinued products, coupled with increased revenues related to products that experienced temporary supply disruptions in 2023.

Moving to slide 10. XIAFLEX is the only FDA approved non-surgical therapeutic option for patients suffering from Peyronie's Disease and Dupuytren's Contracture.

It is estimated that 1 in 10 men between the ages of 40 and 70 in the U.S. have Peyronie's Disease while more than 14 million people in the U.S. have Dupuytren's Contracture. Despite these relatively high prevalence levels, both have low diagnosis and treatment rates.

Given these conditions' prevalence, a small increase in diagnosis rates can have a significant impact on XIAFLEX volumes. Accordingly, a major element of our growth strategy is to continue to fund investments that drive sustainable increases in diagnosis rates for both Peyronie's Disease and Dupuytren's Contracture.

To accomplish this, we are investing in Direct-to-Consumer advertising for both indications, including unbranded condition awareness TV campaigns accompanied by targeted digital and streaming branded advertising.

Our direct-to-consumer investments have proven effective at motivating potential patients to seek a diagnosis and inquire about a non-surgical treatment option. Additionally, our digital platforms make it easy to locate a trained specialist in their area.

In addition to integrated consumer activation strategies, we are also focused on the healthcare provider experience. We believe that a high touch provider approach focused on education and a seamless XIAFLEX acquisition and user experience will increase physician loyalty and will support growing patient demand.

We are pleased with XIAFLEX performance to date, which is on-track with our expectations.

Moving to slide 11, as part of our consumer activation strategy, in June we launched an unbranded Dupuytren's Contracture campaign, *Simple Reminders*. The campaign is focused on emboldening patients living with Dupuytren's Contracture to take charge of their own health and provides 5 simple reminders to help them ask for a non-surgical treatment they feel is right for them. The campaign builds on the awareness from our prior campaigns and includes broadcast, streaming and online TV along with a full digital ecosystem.

Slide 12 provides information related to the overall durability of XIAFLEX, including its robust patent estate which includes indication-specific patents and patents not limited by indication.

We believe that our pending indication-specific patents for additional XIAFLEX indications in development would extend into the 2040's once issued. As such, we believe there will be a significant period of intellectual property protection for those indications based on anticipated launch dates.

With respect to the XIAFLEX patents that are not indication specific, we have issued patents extending into the late 2030's, including patents that we believe cover recombinant biosimilars of XIAFLEX through September 2033.

For context, a non-recombinant biosimilar would require the use of our Clostridium histolyticum cell line, which is physically held under lock and key.

A recombinant-biosimilar is a biosimilar derived from a different vector or host than our cell line and is a more common pathway in biologics development.

That said, it is important to note that the recombinant pathway requires large investments, involves highly technical chemistry, manufacturing, and controls work, and has an expansive timeline due to required clinical studies.

We are not aware of any approved or filed collagenase or enzyme-based biosimilar products in the U.S.

Based on the foregoing, we feel confident in the strength and robustness of our XIAFLEX patent estate and the long-term durability of XIAFLEX.

Turning to slide 13, in addition to the growth potential for XIAFLEX on-market indications, we have the potential to drive significant long-term sustainable XIAFLEX growth by expanding into new indications.

Currently, we have Plantar Fibromatosis in Phase 3 and Plantar Fasciitis in Phase 2 development. During the second quarter 2024, we completed patient recruitment for Plantar Fasciitis ahead of schedule and now expect to report top-line results later this year. Assuming positive Phase 2 results, we believe we could potentially begin Phase 3 development in 2025.

Beyond those two potential indications, we have an early-stage opportunity for Arthrofibrosis of the knee and are pursuing several other interesting potential indications in which the build-up of excess collagen plays a key role.

We're very excited by the opportunity to bring potential innovation to these orthopedic areas.

Moving to Slide 14. our second quarter 2024 Sterile Injectables revenues were $91 million, compared to $137 million in the prior year. This decrease was primarily driven by a $33 million non-recurring payment received from Novavax in second quarter 2023 to settle a dispute related to a previous manufacturing and services agreement, as well as decreased VASOSTRICT revenues in second quarter 2024. These decreases were partially offset by the impact of revenues from new products launched in 2023.

Second quarter 2024 Generic pharmaceutical segment revenues were $110 million, a decrease of 38% compared to prior year. This decrease was primarily due to competitive pressure across multiple products, including varenicline tablets and dexlansoprazole delayed release capsules. This decrease was partially offset by increased revenues from Lidocaine patch, the generic version of LIDODERM®, which was driven by new business opportunities that began in first quarter 2024.

Second quarter 2024 revenues from the International Pharmaceuticals segment were approximately $21 million, an increase of 10% compared to prior year. This increase was driven by increased volumes across multiple products.

Turning to slide 15, our deep sterile injectable pipeline is a critical element of our growth strategy. Over the past several years, we have evolved and expanded our pipeline and our manufacturing capabilities to support the introduction of products meeting the evolving needs of our customers. We currently have over 50 Sterile Injectable projects in our product pipeline, with a focus on RTUs and other more durable products. RTU presentations reduce preparation time, minimize preparation error and streamline inventory management. Approximately 60% of our Sterile Injectable pipeline are RTU and other durable products.

Year-to-date, we have launched 2 generic products and look to launch 3-4 sterile injectable products in the second half of the year.

I would like to note that we have experienced some slippage on our pipeline project timelines, including with respect to certain products previously expected to launch in 2024 and 2025. These delays are primarily related to manufacturing readiness delays by certain of our external contract manufacturers and challenges with obtaining qualified API supply from our 3rd party providers.

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

Mark Bradley:

Thank you, Patrick. **On slide 16,** you will see a summary of our enterprise financial results for the second quarter 2024 combined compared to prior year.

As I previously mentioned, second quarter 2024 total revenues decreased by approximately 18% primarily due to lower second quarter 2024 varenicline and dexlansoprazole revenues in our Generics segment, coupled with the non-recurring payment of $33 million in our Sterile Injectables segment in the second quarter 2023.

Second quarter 2024 adjusted EBITDA decreased compared to prior year primarily due to lower revenues as both adjusted gross margin as a percent of revenues and adjusted operating expenses in the second quarter 2024 were comparable to the second quarter 2023.

Second quarter 2024 adjusted net income was approximately $105 million compared to approximately $231 million in the second quarter 2023. This decrease was primarily due to the decrease in adjusted EBITDA, coupled with an increase in interest and income tax expenses compared to prior year.

We ended the second quarter 2024 with a net debt to adjusted EBITDA ratio of approximately 3.5 times.

Advancing to slide 17, based on our second quarter performance, we are raising our full year 2024 financial expectations for revenues and adjusted EBITDA.

As a reminder, full year 2024 financial results include the results of Endo International plc from January 1 through April 22 and the results of Endo, Inc. from January 1 through December 31.

We now expect 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.

Adjusted gross margin for the full year is expected to remain unchanged at approximately 67% of total revenues. Second half 2024 gross margin as a percentage of total revenues is expected to be slightly lower than the first half 2024 due to the expected shift in product mix, primarily within the sterile and

generics segments, coupled with certain credits and other adjustments that benefited the first half that are not expected to occur in the second half of 2024.

Adjusted operating expenses for the full year are now expected to be between $595 million and $615 million. The increase from prior expectations is primarily driven by higher expected depreciation resulting from the step-up in certain asset values following the application of fresh-start accounting.

Moving to slide 18 and wrapping up the financial discussion, in light of the recent developments related to the expected timing of certain new product launches that Patrick mentioned and that were included in long-term projections disclosed by Endo International plc in connection with its Chapter 11 process, we are providing expected 2025 growth rates for total and segment level revenues and total adjusted EBITDA. While we expect a return to growth in 2025, the delayed product launches have impacted our previously anticipated growth rates, primarily relating to the Sterile Injectables segment.

Specifically, we now expect the 2025 growth rate for total revenues to be in the low-single digits and the 2025 growth rate for adjusted EBITDA to be in the mid-to-high-single digits compared to the mid-point of our 2024 financial expectations.

At the segment level, we now expect the 2025 growth rates for both Branded Pharmaceuticals and Sterile Injectables revenues to be in the low to mid-single digits compared to the mid-point of our 2024 guidance. In addition, we expect Generic Pharmaceuticals revenues to be flat to decline in the mid-single digit percentage range and International Pharmaceuticals revenues to be flat compared to the mid-point of our 2024 guidance.

I would like to emphasize that the guidance being provided is forward-looking information, and it updates and supersedes all prior forward-looking information provided by Endo International plc or Endo, Inc.

We plan to provide more detailed 2025 financial guidance in the normal course in early 2025.

Before opening the call to any questions, I would like to turn the call back over to Paul for a few closing remarks.

Paul Herendeen:

Thank you, Mark. As I shared in my earlier comments, Endo has made considerable progress and is in a strong position to execute on a growth strategy that delivers long-term value for stakeholders.

I would like to thank all Endo team members for their passion and commitment to serving our customers and their patients. We have great team at Endo!