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MNK - Q2 2014 Mallinckrodt Earnings Conference Call

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1

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CORPORATE PARTICIPANTS

John Moten *Mallinckrodt plc - VP of IR*

Mark Trudeau *Mallinckrodt plc - President & CEO*

Matthew Harbaugh *Mallinckrodt plc - CFO*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Mallinckrodt second-quarter earnings conference call.

(Operator Instructions)

As a reminder this conference call is being recorded. I'll now introduce your host for today's conference, John Moten, Vice President of Investor Relations. You may begin.

John Moten - Mallinckrodt plc - VP of IR

Good morning. This is John Moten, Vice President of Investor Relations for Mallinckrodt plc. The press release with details of our second-quarter results was issued earlier this morning, and is available on our website and the newswires. As a reminder, shortly after this call, we will be hosting a fireside chat that can be found on the Investor Relations page on the Company's website, and also as a separate call.

Today, we will be making some forward-looking statements, and it is possible that actual results could be materially different from our current expectations. Please note that under the Safe Harbor rules, we are under no obligation to update the information contained in these forward-looking statements, even if actual results or future expectations change materially. We ask you to please refer to the cautionary statements contained in our SEC filings for a more detailed explanation of the inherent limitations of such forward-looking statements.

We will also discuss some non-GAAP financial measures with respect to our performance today. A reconciliation of non-GAAP measures to GAAP measures can be found in our earnings release and related financial tables. With that, I will turn the call over to Mark Trudeau, President and Chief Executive Officer of Mallinckrodt plc. Mark?

Mark Trudeau - Mallinckrodt plc - President & CEO

Thank you, John, and thank you all for joining the call today. Let me start my remarks by saying that Mallinckrodt is continuing to have a great year, so strong in fact, that we're again raising our guidance for revenues and adjusted diluted earnings per share.

Despite the challenging comparisons to last year when we had not yet spun off to become an independent Company, we've had another very solid quarter, and made significant additional strides toward achieving our strategic vision. Our evolution to become a top-performing specialty pharmaceutical company is progressing quickly, as we continue to see strong results across our base business, as well as the addition of new assets to our portfolio via acquisition. Furthermore, our year-to-date performance continues to be strong, particularly on the bottom line, with adjusted diluted earnings per share up over 10%.

In the quarter, we closed the Cadence acquisition and moved integration forward, saw our brands business grow 15.3%, which included FDA approval and launch of both Xartemis XR and Pennsaid 2%, and the addition of Ofirmev. Continued to drive stronger profitability with strategic pricing and implementation of significant projects under our restructuring program, saw stabilization of our nuclear imaging supply chain, with a return to more normal levels, and last but certainly not least, announced our intended acquisition of Questcor Pharmaceuticals. We'll provide more specific details on each of these activities on this call.

In terms of the second quarter, though sales and earnings were down versus the same period a year ago, these results stemmed from tough comparisons to launch activities we were undertaking in the same prior year period, and a variety of strategic profit-building actions on our part. Mallinckrodt's underlying business drivers continue to grow.

What's most important is that overall, our adjusted diluted earnings per share significantly exceeded expectations. Our very strong first-half results clearly spotlight the rapidly increasing strength of the base business, performance that even without the recent Cadence Pharmaceuticals acquisition was surpassing expectations.

This performance, coupled with the addition of Cadence, led to our decision to increase our financial guidance in key areas. Matt will address the specifics of that new guidance later in the call.

For the fiscal second quarter, the 4.2% decline in total Company net sales on an operational basis reflects strategic decisions implemented to strengthen the bottom line of our business on a full year basis, and unfavorable comparisons to the prior-year quarter, in which we were launching and stocking methylphenidate ER. Underlying profitability is improving, driven by strategic pricing initiatives in our specialty pharmaceuticals segment, and complemented by ongoing benefits from restructuring.

Though adjusted diluted earnings per share in the quarter were down 5% compared to the prior year, this was due again to the sales timing of last year's methylphenidate ER product launches, and interest expense related to \$900 million of debt issued in April of 2013. It's easier to see the momentum building in our business by comparing year-to-date results, where we see first-half FY14 adjusted diluted earnings per share up about 10%, compared to the prior year. Importantly, key products in Mallinckrodt's specialty pharmaceuticals portfolio including Exalgo, Gablofen, and methylphenidate ER are up significantly year-to-date, contributing to the increase in our guidance.

The global medical imaging business has stabilized somewhat in the quarter, and profitability modestly improved. Second-quarter net sales were down 2.1% on an operational basis for this segment, with the nuclear imaging business once again affected by supply chain issues. Both the high flux reactor, or HFR, in the Netherlands, and the moly processing facility there were off line for large portions, or all of the quarter.

The good news is that both have now resumed operations. The HFR on February 14, and the moly processing facility on April 17. Although we do expect profitability to improve somewhat in nuclear imaging, the new normal in this business includes permanently increased costs, which will limit our ability to return to historical profitability levels. Our focus in both nuclear imaging and contrast media and delivery systems remains on seeking efficiencies and managing this segment for cash flow, while we continue to evaluate strategic alternatives for the businesses.

Turning to Mallinckrodt specialty pharmaceuticals segment. The net sales decrease of 5.7% on an operational basis primarily reflects the comparison we've previously mentioned to the prior-year quarter, in which initial stocking of certain methylphenidate ER dosage strengths was underway, though this unfavorable comparison was partially offset by increases in branded products.

Notably ongoing product demand for methylphenidate ER has remained strong, with year-to-date net sales of 40.5%. As noted in our revised guidance, we now expect revenues of no less than \$160 million for the product in FY14.

In specialty controlled substance generics, the selected strategic price increases we implemented previously continued to positively impact profitability, as evidenced by improved operating margins in the overall specialty pharmaceuticals segment, a trend we expect to continue. The positive impact of this strategy can also be seen clearly in the growth of the other controlled substances category, where sales are up \$40 million year-to-date over the same period a year ago.

Oxycodone sales were down in the quarter, primarily reflecting timing of strategic pricing actions. Based on the market response and recently-improved order trends, we expect results from oxycodone will improve in the second half of the fiscal year.

In the highly competitive, lower-margin hydrocodone market volumes continue to trend down due to ongoing aggressive competitive pricing activities. Despite this, overall, our specialty controlled substance generics business continues to perform above expectations.

Our brands business posted solid results, with net sales up 15.3% for the quarter, led by revenue from the recently-acquired Ofirmev, the launch of Xartemis XR and ongoing increases in our intrathecal products. Net sales and brands are up 21.5% on a year-to-date basis, reflecting both ongoing Exalgo growth and new product introductions. Exalgo continues to post solid results, due in part to the continued lack of expected generic competition.

In fact, while Exalgo's second-quarter net sales were essentially flat with the prior-year quarter, year-to-date results are up 12.2% compared to a year ago. As we've said previously, we still anticipate generic competition this fiscal year, and that will likely impact Exalgo's future results, which is factored into our guidance.

We continue to successfully commercialize our internal pipeline, and in late March launched Xartemis XR extended-release tablets. As a reminder, Xartemis XR is the first and only extended-release oral combination of two clinically-proven pain medicine, oxycodone and acetaminophen for acute pain.

Xartemis XR has both immediate and extended-release components. Though we expect the product to provide very modest revenue contributions to our FY14 results, over time, we believe Xartemis XR has the potential to contribute substantial revenues to our brands portfolio.

We began commercial shipments, pharmacy stocking and physician detailing of the product toward the end of March. Initial market access trends are positive, with payers granting coverage at the tier 3 level, with no prior authorization. Initial prescribing with surgeons is particularly promising, which may lead to interesting future synergies with the newly-acquired Ofirmev.

In addition to Xartemis XR, we also launched Pennsaid 2% in the quarter, further extending this franchise. Pennsaid 2% is a topical non-steroidal anti-inflammatory drug, approved for use in the treatment of pain from osteoarthritis of the knee. This product comes in a convenient metered dose pump, an improved delivery form that should provide for easier patient use.

We've already seen the new pump product grow to account for 40% of overall Pennsaid prescription volume, reflecting positive responses from clinicians and patients. We also continued to advance other branded products in our clinical pipeline, like MNK-155, another controlled-release, long-acting combination product that contains the same active ingredients as Vicodin.

Similar to Xartemis XR, MNK-155 is targeting indications for the acute, moderate to severe pain market, and we continue to see a large market opportunity for both products. And we're continuing to invest in our specialty controlled substance generics portfolio, where we have filed multiple Abbreviated New Drug Applications in the quarter.

Now turning to the Cadence acquisition. On March 19, we closed the acquisition of Cadence Pharmaceuticals, and integration is well underway. This transaction adds Ofirmev to our brands portfolio, enhancing our franchise in pain management with a non-opioid product and significantly broadening our capabilities in the important hospital channel.

Today, Ofirmev is on formulary in over 2,300 hospitals in the US, and is primarily used with patients undergoing surgical procedures. To date an estimated 6 million to 7 million patients have been treated with the product.

The integration of Cadence into the Mallinckrodt organization is moving forward as planned. We are now some seven weeks in, and we're pleased to see Ofirmev continue its strong growth trajectory, and believe it will become a meaningful contributor to our FY14 revenues, with the potential to contribute peak year sales of at least \$0.5 billion in revenues to our brands portfolio.

We're more convinced than ever that there is a significant untapped value in Ofirmev, and believe that it is currently undervalued as a treatment, relative to the potential it may have to reduce hospital stays for surgical patients. We see additional growth opportunities to be gained in several key areas. First, by expanding its use in hospital departments and surgical specialty areas, where Ofirmev is already on formulary, and secondly, by expanding the number of vials used per patient, where medically beneficial. Over time, we also believe that we can expand the network of hospitals in which Ofirmev is used.

Now, I'd like to briefly discuss Questcor. Questcor is another ideal strategic fit for Mallinckrodt. If successfully completed, the transaction will be immediately accretive to Mallinckrodt's FY14 adjusted diluted earnings per share, and significantly accretive to our adjusted diluted earnings per share in FY15 and beyond.

But more important is what the transaction does to position us for future growth. With the acquisition of Questcor and its products, H.P. Acthar Gel, and Synacthen, added to our already solid core business in brands and specialty controlled substance generics, and the newly-acquired Ofirmev franchise, we will create a strong, nicely balanced, specialty pharmaceutical platform with the breadth of both portfolio and channel reach to position us for significant sustainable future growth.

Acthar is an exciting product. A naturally-derived injectable complex biological product, Acthar is approved by the FDA for the treatment of 19 separate indications, with the bulk of sales driven by four key areas of focus. Acute exacerbations in multiple sclerosis, proteinuria in idiopathic types of nephrotic syndrome, infantile spasms in children less than two years old, and rheumatology-related conditions.

The Questcor transaction will also bring Synacthen into Mallinckrodt's future pipeline. In June of 2013, Questcor acquired the rights to develop Synacthen and Synacthen Depot in the US, as well as in certain countries outside the US. Questcor is in the early stages of evaluating Synacthen in several potential indications for possible clinical development.

We believe that Mallinckrodt is the owner best positioned to maximize the value of these great products, because of the considerable skills and experience we bring to the transaction, including relationships with rheumatology and neurology specialists, which we believe will ultimately make the value understood by more physicians, and available to more patients. Our longstanding manufacturing expertise with complex substances, including those that come from naturally-derived sources.

The ability to use our strong payer relationships to further standardize and optimize the efficiency and speed of reimbursement processes, to make the product more accessible to a broader number of patients. Substantial synergies, including relatively modest synergies in general and administrative areas and R&D, and more significant ones in tax, and possible long-term opportunities to market both Acthar and Synacthen internationally.

Following on the heels of the Cadence acquisition, as well as FDA approvals of Xartemis XR and Pennsaid 2%, the acquisition of Questcor, when completed will solidify our position in the specialty pharmaceuticals industry by significantly increasing the scale, cash flow, and profitability of our business and adding a strong product to our growing portfolio. These two transactions have also created a clear frame for us to further focus both our ongoing strategic BD&L and R&D activities.

In BD&L, we will continue to be aggressive and opportunistic in looking for complementary external assets, including those that will bring value to hospital patients in highly specialized therapeutic areas like CNS, rheumatology, and autoimmune disorders. In R&D, in addition to our efforts in abuse deterrent and formulation technologies, we intend to focus on further developing the current indication set for Acthar, as well as potentially new indications in these same highly specialized therapeutic areas.

In summary, we believe that added to our strong core business, the recent acquisition of Cadence, and the pending acquisition of Questcor will create substantial, sustainable value for Mallinckrodt shareholders, by significantly accelerating our transformation to become a leading global specialty pharmaceuticals company. Now, let me turn the call over to Matt to provide more detail on our quarterly results and revised guidance. Matt?

Matthew Harbaugh - Mallinckrodt plc - CFO

Thanks, Mark. Let me add my welcome to everyone on the call this morning.

I'll discuss our fiscal second quarter results which include Cadence from the period beginning March 19, through March 28. I will also provide revised guidance for full-year revenue and full-year adjusted diluted earnings per share to include Ofirmev.

At some point, we plan to again update our guidance to reflect the addition of Questcor. As noted in the April 7 press release, we expect the Questcor transaction to close in the third calendar quarter of 2014, and to be immediately accretive to adjusted diluted earnings per share for FY14, and significantly accretive to FY15. As a reminder, our second quarter ended on March 28, and all our results were compared against our performance for the same period in the prior year.

We're happy to report the second quarter was one of significant achievement as we executed on our key strategies to build our specialty pharmaceuticals segment. This morning, we raised our FY14 revenue guidance to \$2.28 billion to \$2.38 billion, and our adjusted diluted earnings per share guidance to \$3.30 per share to \$3.60 per share, driven primarily by the improving profitability of our specialty pharmaceuticals segment, as well as the addition of Ofirmev.

Turning to the quarter, net sales were \$558 million versus \$585 million, or down 4.2% on an operational basis, compared to the prior-year quarter. As Mark previously mentioned, prior-year net sales comparison reflect strong sales of methylphenidate ER last year when we saw initial stocking of the 36 and 54-milligram dosage strengths in the distributor channel. Current quarter net sales reflect benefits from strategic pricing action in certain specialty controlled substance generics products.

Oxycodone net sales declines were due to a combination of market competition, strategic pricing actions, quarterly timing, and contractual payments. Overall, we feel positive about our specialty pharmaceutical segment, based on results posted year-to-date, in addition to expected trends in the back half of the year.

Global medical imaging net sales for the quarter were down 2.1% on an operational basis. In nuclear imaging, net sales were essentially flat, despite supply chain disruptions, due to facility shutdowns.

As Mark mentioned earlier, we have restarted our moly processing facility in the Netherlands, which should slightly improve our profitability for the year, largely in the fourth quarter. One item of note, we have continued to undertake significant restructuring in this segment since the initiation of the program last August, and we believe this has led to improved results in the second quarter.

Net sales in our specialty pharmaceuticals segment were \$324 million, a decline of 5.7% on an operational basis. The decline in segment net sales reflects the methylphenidate ER launch comparisons and the initial reduced volume of oxycodone, due to the impact of the strategic pricing initiatives we have undertaken.

These pricing actions, which began last fall, continue to gain traction, and as I mentioned, we expect improved top line and bottom line performance in the second half of the year. Net sales for our brands portfolio were up 15.3% for the quarter, reflecting the initial inclusion of Ofirmev, the late March launch of Xartemis XR, and increases in our intrathecal products.

Total Company gross profit was \$263 million, down \$11 million. Gross profit as a percentage of net sales was 47.1% compared to 46.7%. This increase was driven by improved profitability from strategic pricing initiatives in the specialty pharmaceuticals segment, partially offset by our global medical imaging segment, where gross profit was lower compared to the prior year due to roughly \$9 million of incremental raw material costs, reflecting the temporary shutdown of the HFR and our moly processing facility.

Selling, general and administrative expenses, or SG&A, for the quarter were \$194 million, compared with \$161 million in the prior-year quarter, reflecting current year expenses of \$23 million for an environmental remediation charge, and \$19 million for BD&L transaction costs. Additionally, we incurred launch expenses for Xartemis XR and Pennsaid 2%, though these expenses were more than offset by restructuring savings.

Shortly after spin, we announced a three-year \$100 million to \$125 million restructuring program. We've moved aggressively on this initiative, already implementing one-third of the program in eight short months, and we'll continue to seek efficiencies wherever possible. As previously discussed, our current restructuring initiatives have focused on projects with a relatively quick payback. In particular, there is a direct correlation to the restructuring actions we have taken in global medical imaging, and you see that reflected in our profits posted this quarter.

In the second quarter, we incurred \$22 million in restructuring charges overall, taking actions which will further streamline our cost profile. Our restructuring actions have expanded beyond SG&A to also now include a focus on cost of goods sold. R&D spending during the quarter was \$41 million, up slightly from \$39 million in the prior-year quarter due to the advance of MNK-155, our continued pursuit of abuse deterrent labeling for Xartemis XR, and further development of our specialty controlled substance generics and intrathecal portfolios.

Operating income for the quarter was \$4 million compared to \$54 million in the prior year, primarily attributable to the \$23 million environmental remediation charge, and \$15 million in higher restructuring charges and Cadence transaction costs. In the specialty pharmaceuticals segment, operating income as a percentage of net sales was 32.7% compared to 30.5% in the prior year, reflecting the benefits from pricing initiatives.

You'll notice our non-GAAP effective tax rate for the quarter was 23.7%, which reflects the close of the Cadence transaction. The base Mallinckrodt tax rate would have fallen into our February guidance range of 25% to 28%. You'll also note that we've taken our tax rate guidance lower as we continue to achieve efficiencies, and to reflect the Cadence acquisition.

We currently have \$335 million in cash, compared to \$288 million at the end of December. Keep in mind, this change in our cash balance is net of roughly \$100 million in cash utilized in the Cadence transaction. We expect our cash generating capabilities to improve significantly as a result of the robust cash profile of our base business, combined with Ofirmev, and ultimately, the expected addition of Questcor, which will allow us to aggressively reduce our post-acquisition debt.

Second-quarter adjusted diluted earnings per share was \$0.95, down 5% compared to the prior-year quarter. For the first half of FY14, adjusted diluted earnings per share were up 10.2%. As evidenced by our updated increased financial guidance, FY14 will be a very strong year for Mallinckrodt.

This performance will be driven by the strength of our specialty pharmaceuticals segment, and in particular, the specialty controlled substance generics business, along with restructuring to streamline our organization, and the addition of Cadence, all of which will provide meaningful top and bottom line growth. I will now hand the call back over to Mark to make some closing comments.

Mark Trudeau - Mallinckrodt plc - President & CEO

Thanks, Matt. As I said earlier, this has been another exciting quarter, in a year that looks very promising by any measure. Our actions and accomplishments in the second quarter and the first half of the fiscal year clearly demonstrate our focus on rapidly accelerating growth and profitability to levels consistent with those of a leading global specialty pharmaceuticals company.

As you track our progress, watch for us to implement strategies that will capitalize on the broad growth platforms we have created. First, we'll execute on the opportunities we've created in our specialty pharmaceuticals business, leveraging our core strengths in brands, specialty generics, and active pharmaceutical ingredients, to accelerate the shift towards the specialty pharmaceuticals segment.

Second, we'll advance our internal pipeline to deliver long term growth, utilizing our expertise in managing controlled substances, and our skill in developing difficult formulations. Third, we'll continue to drive for increased profitability by improving efficiency across the business, and executing our restructuring plan. And finally, we'll continue to pursue focused BD& L opportunities in core businesses and adjacent therapies.

We're confident these strategies will drive sustainable growth, improve our profitability, and deliver a bright future for Mallinckrodt, and long-term value to shareholders. Thank you for your interest in Mallinckrodt, and for joining us on today's call. I'll now turn the call back over to John to provide some logistical details related to the Q&A session.

Thanks, Mark. Let me remind you that materials concerning today's earnings release and the replay of this call will be available on the Investor Relations page of our website.

Our live Q&A session will begin at 8:15 AM Eastern Time at the St. Regis New York Hotel, and also will be available by conference call and webcast. Further details are contained in the press release on our website.

We hope you will join us for that session. Thank you very much.

Operator

Ladies and gentlemen, thank you for participating in today's program. Listeners dialed in, you may stay on the line to automatically be transferred to the Q&A session. Listeners on the webcast, you will need to close the webcast player and open a second Q&A webcast. Thank you.

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approval of Synacthen; Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; Mallinckrodt's ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities; customer concentration; cost-containment efforts of customers, purchasing groups, third-party payors and governmental organizations; Mallinckrodt's ability to successfully develop or commercialize new products; competition; Mallinckrodt's ability to integrate acquisitions of technology, products and businesses generally; product liability losses and other litigation liability; the reimbursement practices of a small number of large public or private issuers; complex reporting and payment obligation under healthcare rebate programs; changes in laws and regulations; conducting business internationally; foreign exchange rates; material health, safety and environmental liabilities; litigation and violations; information technology infrastructure; and restructuring activities. Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in (i) Mallinckrodt's SEC filings, including its Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and Quarterly Report on Form 10-Q for the quarterly period ended March 28, 2014; (ii) the SEC filings of Cadence Pharmaceuticals, Inc., which was acquired by Mallinckrodt on March 19, 2014, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2013; and (iii) Questcor's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2013 and its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014. The forward-looking statements made herein speak only as of the date hereof and none of Mallinckrodt, Questcor or any of their respective affiliates assumes 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.

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Participants in the Merger Solicitation

Mallinckrodt, Questcor, their respective directors and certain of their executive officers and employees may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the Mallinckrodt and Questcor shareholders in connection with the proposed merger and a description of their direct and indirect interests, by security holdings or otherwise, will be set forth in the joint proxy statement/prospectus when it is filed with the SEC. Information about the directors and executive officers of Mallinckrodt is set forth in its proxy statement for its 2014 annual meeting of stockholders, which was filed with the SEC on January 24, 2014. Information about the directors and executive officers of Questcor is set forth in its proxy statement for its 2013 annual meeting of stockholders, which was filed with the SEC on April 15, 2013.