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MNK Q3 2014 Mallinckrodt plc Earnings Call

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Mark Trudeau - *Mallinckrodt plc - President and CEO*

On the acquisition front, we are very excited about the prospect of bringing H.P. Acthar Gel into our business once we closed the Questcor transaction and we were very pleased to see the strong performance that they highlighted in their recent quarterly earnings report. Acthar will extend our Brands platform into the highly specialized therapeutic areas of autoimmune and rare diseases and significantly enhance the sustainability and durability of our portfolio.

This acquisition coupled with our recent Cadence acquisition will also provide a strategic roadmap for future business development and R&D investments in key autoimmune and rare disease specialty areas like neurology, rheumatology, nephrology and pulmonology, and also in the important hospital channel.

Our pre-integration plans for Questcor are well underway and the respective shareholders of each company are scheduled to vote on the transaction on August 14 with the close expected shortly thereafter.

While our immediate focus will be to successfully integrate Questcor, we will continue to look proactively for other business development and licensing opportunities that will allow us to build out the strategic platforms we have created. We will continue to focus future business development opportunities on highly specialized, highly profitable, fast-growing and durable Specialty Pharmaceuticals which will create sustainable growth for the long-term.

In just over a year since becoming an independent company, we have substantially increased shareholder value executing on our strategy to drive growth and enhance our profitability. But let's be clear, while we have been acquiring transformational assets like OFIRMEV in the hospital channel and the pending acquisition of Acthar Gel to help secure our future success, simultaneously we have also been effectively executing on a number of internal fronts.

Matt Harbaugh - *Mallinckrodt plc - SVP and CFO*

Before I discuss Mallinckrodt's third-quarter results and our updated guidance, let me first talk about the pending Questcor acquisition which we expect to close shortly after the shareholders' meeting scheduled next week. Clearly Questcor has had an exceptional year from a sales perspective. Should we close mid-August, Mallinckrodt will add roughly six weeks of revenue into our fourth fiscal quarter and an adjusted gross profit level that we expect will be in line with what Questcor has achieved historically.

In the second quarter, Questcor's selling and marketing expenses were \$57 million and we believe will maintain similar levels post close. As it relates to G&A synergies, we are unlikely to see much decline in their current spending levels in fiscal 2014 but we will see benefit in fiscal 2015 which will be reflected in the full-year Company guidance we provide in October. For now we also encourage you to keep R&D spending in your models at their current rate and as stated on the call announcing the Questcor transaction, you should also assume a tax rate for Questcor in the range of Mallinckrodt's current guidance which we provided in the release this morning.

[. . .]

Total Company operating loss for the quarter was \$4 million compared to \$1 million in the prior year quarter. Keep in mind the \$52 million in higher amortization of intangibles and fair value adjustment of inventory primarily related to the Cadence acquisition is included in these numbers along with \$17 million of Questcor transaction costs and the \$12 million in recent legal settlement costs noted previously.

[. . .]

As of the end of the quarter, we had \$328 million in cash on hand. We continue to see our cash generation capabilities improve due to the performance of our base business and the addition of OFIRMEV. With the addition of H.P. Acthar Gel, we expect our cash flow generation to substantially accelerate potentially allowing us to reduce our post acquisition debt while also accommodating future business development opportunities.

Please also note that last week we largely completed our financing needs as it relates to the Questcor transaction and we feel we are in great shape to close.

Third-quarter adjusted diluted earnings per share was \$1.20 compared to \$0.49 in the prior-year quarter. Year-to-date adjusted diluted earnings per share is \$3.04, up 41%. As evidenced by our increased financial guidance today, fiscal 2014 continues to be a remarkably strong year for Mallinckrodt. We will be providing guidance for fiscal 2015 which will include Questcor in October. Thank you.

Question and Answer

David Amsellem - Piper Jaffray & Co. - Analyst

Secondly on a general question on business development, beyond the closing of the Questcor transaction, can you give us a sort of roadmap of how high you would lever up to get additional deals done, the potential scale of additional deals, is there a sort of sweet spot that you are looking at? That would be helpful. Thanks.

Mark Trudeau - Mallinckrodt plc - President and CEO

With regards to business development again as we mentioned in the prepared comments, we believe that we have really established several platforms for growth for the Company. Not only that, we have really identified several areas where we believe there are opportunities now to focus both our R&D efforts as well as our business development

efforts and we tend to focus on areas where we believe we can bring incremental value to the marketplace. There is relatively

less competition in other areas and we are going to bring some type of basis or infrastructure and support to an area. And so for example, the specialty areas where there are autoimmune and rare disease categories we mentioned some of those specialty areas previously, neurology, nephrology, pulmonology, rheumatology and also the hospital channel are areas that we believe are assets available in the marketplace that are accessible that we can add into now a platform of growth that we have already in the hospital channel with the acquisition of OFIRMEV and Cadence and we expect to have with the acquisition of Questcor and Acthar Gel.

So the roadmap going forward we believe is very clear and the focus is very clear as to what we are going to be looking for in terms of future assets and our plan is to continue to be opportunistic and add assets into our portfolio because again, we are looking to build out a broad portfolio of highly durable, highly profitable fast-growing assets like the ones that we have already acquired with OFIRMEV and expect to acquire with Acthar. Matt?

Matt Harbaugh - *Mallinckrodt plc - SVP and CFO*

So as it relates to leverage, David, a few things I would say. The first thing is Mallinckrodt has a little over \$400 million in cash as we sit here today. You will see in the release that we were in the low 300s spent our cash generation continues to be strong. Questcor in their end-of-June release had nearly \$400 million in cash as well so both companies have very strong cash balances if you will. I think this is an area that has not been well-characterized in general. I don't think people have spent the time to really figure out what our net debt leverage ratios are going to look like as we move forward.

If you look at post close on Questcor and you look at our net debt leverage ratio, we are below 4 and that is an enviable place and when we look at our competitive set, that is where a lot of our competitors are. So we feel really good about our balance sheet. If you combine our EBITDA and Questcor's EBITDA for instance, you are over \$1 billion alone so the cash should continue to roll in here as we move forward on a combined basis.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

And then maybe secondly, on Acthar, I know you are not guiding yet. Thanks for the comments about the September quarter but conceptually would you agree that it would be reasonable to assume a period of some level of sales disruption of the key product as a new organization applies new strategies and reimbursement, marketing, etc.? Again not specific guidance but just conceptually to help set the bar there. Thanks.

Mark Trudeau - *Mallinckrodt plc - President and CEO*

So, Gregg, with regards to the potential for sales disruption around Acthar Gel and during the acquisition period of Questcor, while there is certainly the potential for that and clearly Questcor has generated significant momentum now for this product based on their most recent quarterly results, we have obviously been planning for this transaction and

this integration now for several months with the specific intent being to minimize that potential for disruption as we do the transition.

Part of our plan for that is that the commercial organization comes over largely intact including all of their leadership reporting directly to me. Again as we learn this business even more and learn how to run it, we want to make sure that we maintain that momentum. So there is certainly some potential in the short term for there to be disruption but we believe we have taken significant steps and will continue to do so to minimize that.

Over time of course the main reason to do this transaction is that we believe that as part of Mallinckrodt we can continue to actually enhance the value that Acthar Gel brings to both patients and to shareholders through the combined efforts of the two companies. So we expect that this is going to be a very, very well performing product both near and long term.

Christopher Caponetti - Morgan Stanley - Analyst

Thanks very much for taking my question. Operator, I thought I got a promotion. On guidance, why would fiscal 4Q EPS be down sequentially? Then I know you are not giving updated guidance for Questcor, but should we expect you guys to raise guidance for the fourth quarter on August 15 once the deal closes?

Matt Harbaugh - Mallinckrodt plc - SVP and CFO

Congratulations on your promotion. As it relates to guidance, our third-quarter historically has always been our strongest quarter from a bottom-line viewpoint so it is more of a timing thing than anything else. As it relates to Questcor obviously we haven't closed and a few days matter significantly as it relates to what the bottom-line performance will be. So as we are thinking about this typically you will see our third quarter being our strongest quarter from a financial viewpoint albeit our business has been strong for a number of months now.

But as it relates to Questcor, we feel strongly and I did my best to give guidance as to how we are thinking about it in the stub period but we are planning to give you guidance in October with Questcor included so we will have brought it into the fold, had an opportunity to really do a lot of forecasting and scenario planning as it relates to H.P. Acthar Gel, and then come back and give you a real solid explanation of how we see 2015 unfolding.

Tim Chiang - CRT Capital - Analyst

Mark, maybe just one follow-up. I know you are going to give guidance later this fall with Questcor but how do you guys sort of look at R&D spend for Acthar Gel? Is it going to increase dramatically? Will it stay around the same level that Questcor has been at in the historical past? Could you give a little bit of color on that?

Mark Trudeau - *Mallinckrodt plc* - *President and CEO*

What I would like to talk about is how we are going to think about investing in our R&D for Acthar. Clearly one of the things that Questcor has done recently is significantly increase the investment around R&D. Primarily in creating additional data, both clinical and preclinical data, characterize the product more fully to provide additional clinical data in support of the product's use and also to develop potential new indications. We believe that all of those continue to be very worthy endeavors and we will look to enhance those efforts as we look to also create additional data, additional published data to support the safe and efficacious use of Acthar in its 19 indications.

With regards to specific amounts of R&D spend however, one of the opportunities that we want to consider is the fact that now through the acquisition of Cadence, pending acquisition of Questcor, and our base R&D business, there is clearly an opportunity for us to do some synergies there. The collective three organizations together should do more at a lesser spend rate than the independent entities alone.

So we are evaluating now what is going to make the most sense from an R&D spend level but we want to be quite focused on driving additional data and support for Acthar as well as continuing to build out lifecycle management opportunities for OFIRMEV while we also continue to support our base business.

Matt Harbaugh - *Mallinckrodt plc - SVP and CFO*

You can see it, Tim, in our results. Our R&D spending actually was down from this year versus last year. Part of that is timing of spend and part of it also as you can see, we are preparing to bring all of this on board. From a financial viewpoint obviously we will have a lot of room for reinvestment in R&D. But I would just echo what Mark said. We are going to get some leverage as it relates to R&D spend across the portfolio when we bring all these entities together and we can accommodate adding in programs because we are getting synergy elsewhere.

I would echo what I said in my prepared remarks though for 2014 as you are modeling out Questcor coming into the fold, I would just keep it flat because there is a lag effect when you are doing these types of integrations where we want to be very judicious and careful as we think about bringing these together and integrating them so the benefit of all of this will likely come in fiscal year 2015 which we will include in the guidance we provide.

David Maris - *BMO Capital Markets - Analyst*

Then separately, The Wall Street Journal did a profile on Acthar a couple of weeks ago. There has been all lot of noise this past quarter about changes to formularies. Can you explain what the changes were in the quarter, whether this changes your expectation or your enthusiasm for the drug or why investors should look at that a little bit differently?

Mark Trudeau - *Mallinckrodt plc - President and CEO*

With regards to Acthar Gel, so you are right, there have been some changes to the published guidelines for reimbursement of Acthar by some of the national payers and again this is really something that Questcor has seen happen with a couple of payers over the last couple of years.

What we continued to see and we have seen this in the due diligence of the product is that the reimbursement status or the actual reimbursement of the product continues to remain strong really regardless of what the changes to the reimbursement policies tend to be. And the simple reason for that is that this is a product that is used really by very few patients. There are very few patients on Acthar. There are really only about 10,000 patients that are on Acthar. It

is a product that tends to be used at the end of the line for many patients in very debilitated conditions and when it gets down to that, when the choice is between the use of Acthar versus any other alternative, in many cases the payer decision is fairly straightforward because those other alternatives are many times much more expensive than Acthar.

So we continue to feel very good about the reimbursement for Acthar just because of the nature of the way the product is used and I think these changes that have been published really are designed to ensure that the product continues to be used in that manner, that it is used after virtually everything else has been tried and that is the appropriate place for the product to be used.

Again based on what you see with Questcor's recent quarter, you see that the prescription volume that the number of vials, the sales for this product continue to rise over time. We feel very good about the pending close of the transaction and this will be a significant product for us going forward.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this document that are not strictly historical, including statements regarding the proposed acquisition, the expected timetable for completing the transaction, future financial and operating results, benefits and synergies of the transaction, future opportunities for the combined businesses and any other statements regarding events or developments that we 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: general economic conditions and conditions affecting the industries in which Mallinckrodt and Questcor operate; the commercial success of Mallinckrodt's and Questcor's products, including H.P. Acthar[®] Gel; Mallinckrodt's and Questcor's ability to protect intellectual property rights; the parties' ability to satisfy the merger agreement conditions and consummate the merger on the anticipated timeline or at all; the availability of financing, including the financing contemplated by the debt commitment letter, on anticipated terms or at all; Mallinckrodt's ability to successfully integrate Questcor's operations and employees with Mallinckrodt's existing business; the ability to realize anticipated growth, synergies and cost savings; Questcor's performance and maintenance of important business relationships; the lack of patent protection for Acthar, and the possible United States Food and Drug Administration (FDA) approval and market introduction of additional competitive products; Questcor's reliance on Acthar for substantially all of its net sales and profits; Questcor's ability to continue to generate revenue from sales of Acthar to treat on-label indications associated with nephrotic syndrome, multiple sclerosis, infantile spasms or rheumatology-related conditions, and Questcor's ability to develop other therapeutic uses for Acthar; volatility in Questcor's Acthar shipments, estimated channel inventory, and end-user demand; an increase in the proportion of Questcor's Acthar unit sales comprised of Medicaid-eligible patients and government entities; Questcor's research and development risks, including risks associated with Questcor's work in the areas of nephrotic syndrome and lupus, and Questcor's efforts to develop and obtain FDA approval of Synacthen Depot; 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 its 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 achieve anticipated benefits of price increases; 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 obligations 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, its Quarterly Reports on Form 10-Q for the quarterly periods ended December 27, 2013 and 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 the

amendment thereto on Form 10-K/A), its Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2014 and June 30, 2014, and its Current Report on Form 8-K filed with the SEC on July 10, 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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