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MNK - Mallinckrodt Guidance Call

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PRESENTATION

Operator

Good morning. At this time I would like to welcome everyone to the Mallinckrodt fiscal year 2014 financial guidance conference call.

(Operator Instructions) As a reminder, this call is being recorded today, October 16, 2013. I would now like to turn the call over to Mallinckrodt.

John Moten - *Mallinckrodt plc - VP, IR*

Thank you, operator. Good morning and welcome to today's call. This is John Moten, Vice President of Investor Relations for Mallinckrodt plc. Joining me on today's call is Matt Harbaugh, Senior Vice President and Chief Financial Officer.

Earlier today Mallinckrodt issued a press release outlining our financial guidance for fiscal year 2014. This release is available on our website at www.mallinckrodt.com. A replay of today's call will be available beginning shortly after the call concludes and for the next week on the Investor Relations section of our website.

As we announced in a press release on October 7, we will hold a conference call to review our fourth-quarter and full-year fiscal 2013 earnings on November 7. So during this call we will talk exclusively about fiscal 2014 guidance and will not discuss fiscal 2013 results, either in our prepared remarks or during our Q&A session.

On today's call we will be making some forward-looking statements. It is possible that actual results could differ materially 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 statement contained in our SEC filing 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. I will now turn the call over to Matt Harbaugh.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Thanks, John. Let me add my welcome to everyone on the call this morning. As we have now entered our first year as a public company we look forward to ongoing discussions with you about how we will manage the Company to drive future growth. We continue to believe that Mallinckrodt has tremendous potential value to be realized over time.

I will now outline for you our financial guidance for the 2014 fiscal year which will end September 26, 2014. I will also provide some additional insight into each of our businesses and briefly review some of our largest near-term pipeline opportunities. Let's start with the top line.

For fiscal 2014 net sales are expected to be in the range of \$2.15 billion to \$2.25 billion on an operational basis, excluding the impact of fluctuations in foreign exchange rates. Net sales for the Specialty Pharmaceuticals segment are expected to be in the range of \$1.22 billion to \$1.27 billion.

This forecast includes sales of at least \$120 million for Methylphenidate ER, the Company's generic version of Concerta. The product remains an important contributor to our overall generics portfolio, despite increased competition.

Our guidance also assumes generic competition for EXALGO beginning in November, which will likely significantly reduce net sales for the product in fiscal 2014. Given the volatility we expect from generic competition, we will no longer provide guidance for EXALGO.

As a partial offset to these expected sales declines, we are implementing selected strategic price increases in our brands and generics portfolios. Net sales for the Global Medical Imaging segment are expected to be in the range of \$885 million to \$930 million.

While we see selected pockets of international growth in developing markets, particularly in contrast media and delivery systems, this business remains challenging due to continuing commoditization in mature markets such as the United States and Western Europe. Our focus will remain on managing the Global Medical Imaging segment for cash with an emphasis on driving operating efficiencies.

Turning to expenses, let me address a few items of note. We expect selling, general, and administrative expenses to be higher in fiscal 2014, reflecting additional sales and marketing investments required to successfully launch MNK-795 and, to a lesser extent, MNK-395. We plan to add 150 to 200 US contract sales representatives to our brands business, which will supplement our current base of roughly 200 sales representatives. This will bring our total US brand salesforce to between 350 and 400 total representatives.

We will also incur incremental marketing and medical affairs expenses for the launch. At the same time, we continue to look for SG&A cost reduction opportunities across all businesses. More specific to G&A expense, the significant corporate buildout related to the spend is essentially complete, the cost of which has been largely offset by fiscal 2013 restructuring activities.

As mentioned on the August 9 third-quarter earnings call, restructuring is and will remain a key focus area for us as we seek to lower our cost structure to a level more in line with our industry peers.

Research and development expenses for fiscal 2014 are expected to be between 6% and 8% of net sales, consistent with our previously stated long-term goal. Ongoing support of clinical programs for MNK-155 will be a significant investment for us as we continue to build our brands portfolio.

While we are on the subject of our pipeline, I would like to remind you about key upcoming opportunities for our brands business. MNK-795 is an investigational, extended release, oral formulation of oxycodone and acetaminophen with the same active ingredients as the branded drug Percocet. MNK-795 has been studied for the management of moderate to severe acute pain where the use of an opioid analgesic is appropriate.

The tablet was designed using technology with immediate and extended release components and potentially tamper-resistant properties. In July 2013 the US Food & Drug Administration, or FDA, accepted the filing of the new drug application, or NDA, for MNK-795 and granted priority review.

If approved, as mentioned earlier, significant expenses to support the launch and marketing of the product are expected in fiscal 2014 and are reflected in our EPS guidance today.

MNK-395, which is an extension of our PENNSAID franchise, is a 2% formulation of diclofenac topical solution that has been studied in twice-daily administration for the potential indication of the treatment of pain associated with osteoarthritis of the knee. The FDA accepted the filing of the NDA for MNK-395 in August 2013.

Finally, MNK-155 is a novel reformulation of hydrocodone and acetaminophen, the same active ingredients as the branded drug Vicodin, the single most widely prescribed opioid medication in the United States. MNK-155 also has potentially tamper-resistant characteristics designed to deter abuse. It entered Phase 3 clinical development in the first half of fiscal 2013.

Turning back to the income statement, Mallinckrodt expects fiscal 2014 adjusted diluted earnings per share to be in the range of \$2.45 a share to \$2.65 per share. The non-GAAP effective tax rate is expected to be between 26% to 29%. Capital expenditures are forecasted to be between \$140 million and \$160 million.

In addition to our internal growth pipeline, we continue to evaluate business development opportunities where we have core strengths to add significant value in the market. We do see possibilities to expand our brands and generic product portfolios and have the financial flexibility to do meaningful acquisitions that meet our strategic and financial objectives. The timing of these future activities is not in any way predictable and we do not assume any material transactions in our guidance.

We are excited about Mallinckrodt's prospects and look forward to realizing the value that our management team and employees see in our business. As you track our progress, let me share the key actions that we plan to take.

First, we will expand our core brands and generic businesses and grow in adjacent areas through business development and licensing. Second, we will pursue targeted growth in select international markets. Third, we will focus our R&D investments to leverage core formulation capabilities.

And, finally, we will expand profitability through operating leverage and specialty pharmaceuticals growth. We are confident these initiatives will drive growth, improve our margins, and deliver sustainable value for our shareholders.

Before we take your questions I would like to let you know that we will be hosting an investor briefing on November 14 in New York and we look forward to seeing many of you there. For those who were unable to attend live, the information regarding the webcast and call-in number will be provided.

With that we are ready for the Q&A portion of the call. Operator, may we please have the first question?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Gary Nachman, Goldman Sachs.

Gary Nachman - Goldman Sachs - Analyst

My first question, Matt, on the new branded products what sort of contribution are you assuming for MNK-795 and 395 in fiscal 2014? Is that in your revenue guidance, because you clearly have a lot of expenses built in the numbers for it?



Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Yes. Thanks for the question and good morning. We are not giving specific guidance on MNK-795 or MNK-395 as it relates to fiscal year 2014. We do have it in the plan.

Obviously, we don't have the final approvals just yet so we need to work through that process. But much like we have had for many years, as you know, we have been very robust from an R&D perspective in getting products approved over time. Every year since I have been here, six years now, we have had new products in the plan, so this is not atypical.

But at this point we are not going to be providing any specific guidance on the product. Obviously, there is a lot of swing factors, whether it be the label, timing of the launch, and all of that. This being said, long term we still think MNK-795 is in the couple hundred million range and MNK-395 long term is in the tens of millions range.

Gary Nachman - *Goldman Sachs - Analyst*

Okay, but you have something in there; you're just not saying exactly what?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

We do.

Gary Nachman - *Goldman Sachs - Analyst*

Okay. Then a follow-up on generic Concerta. It seems like a pretty strong number. What are you assuming for the competitive dynamics with KUDCo and then potentially impacts if they get approved? And how much of that helped your gross margins out in fiscal 2014? Thanks.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Sure. We certainly have been watching the market very closely with UCB KUDCo. Obviously, they are in the marketplace today. They are getting orders.

We are assuming that we will have competition in the back half of next year. Obviously, we have been following very closely Impax; we believe that they are working on a formulation. So in the guidance that we have provided, which is no less than \$120 million, we are assuming to have more competitive entry.

A couple other things around Concerta, just in the interest of clarity. We are hopeful to get the 18 milligram in the portfolio in fiscal year 2014 and we do have that in this guidance.

The other thing I would add is, unlike what you saw in fiscal year 2013 where we had more lumpy sales, obviously we haven't provided the fourth quarter just yet, but our guidance is out there. Our generic Concerta business should be more consistent over the quarters and have less lumpiness as you are thinking about quarterly timing around revenue.

Gary Nachman - *Goldman Sachs - Analyst*

Okay. Then just how it should help the gross margin in fiscal 2014, because that is a high margin product.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Yes, it certainly is. We don't disclose what the margin is, but obviously, with a guidance of no less than \$120 million, if you kind of smooth that out over the quarters it certainly is on the higher end of our margin. Generally our brands and our specialty generics portfolio have the higher margins.

Gary Nachman - *Goldman Sachs - Analyst*

Okay, thank you.

Operator

Jason Gerberry, Leerink Swann.

Jason Gerberry - *Leerink Swann - Analyst*

Thanks for the guidance update. First question, just wanted to get a little more detail on your comments in the prepared remarks about selective price increases. Just curious is there room for meaningful price increases I guess on the generic and API portfolio? Is this Concerta or is this kind of the other brands' part of the business?

Just kind of wondering if you can provide a little more color there.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

So we don't disclose specific product lines where we are raising price, but we are looking at pricing opportunities both in brands and generics. We did take a price increase on one of our product categories called Roxicodone, which we have been asked about over time. But certainly there are some opportunities and we will aggressively pursue them where possible.

Most of it would be in brands and generics. It is much more competitive and more challenging to raise price in our Global Medical Imaging segment, particularly in North America and Western Europe.

Jason Gerberry - *Leerink Swann - Analyst*

Got it. Then just as a follow-up, what are your assumptions in 2014 regarding imaging margins. Should we be thinking about some of the headwinds persisting and your assumptions regarding I guess Nuclear Imaging margins and whether there will be a recovery there?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Yes, we will see some modest recovery in margins in Nuclear. Obviously the HFR reactor was down from November through June last year and we had to procure raw materials at a much higher price. So we will see some modest recovery, but it is a challenging market.

We are really driving that business, as I said in the prepared remarks, for cash. We're trying to drive operational efficiencies. Obviously we have been doing some restructuring in that platform which we have talked about. So I would say a modest recovery, but it remains a challenging marketplace.

Jason Gerberry - *Leerink Swann - Analyst*

Okay. Thanks, guys.



Operator

Doug Tsao, Barclays.

Ann Trimble - Barclays Capital - Analyst

It is Ann Trimble for Doug; thanks for taking the question. In terms of fiscal year 2014 how should we think about the overall gross margin as well as segment profitability targets for Spec Pharma and Medical Imaging?

Matt Harbaugh - Mallinckrodt plc - SVP & CFO

So we haven't given any guidance on margins. We have made the shift, as you can see, that we are giving adjusted diluted EPS versus adjusted EBITDA. Part of the reason why we made that change is that is how you are viewing our business and we want to be consistent so that we are thinking about our financials from an apples-to-apples perspective.

A few things to think about as it relates to operating income margins or EBIT margins. The first is, as we have in the last few years, the lion's share of our R&D spending is going to be allocated over to our Specialty Pharmaceutical side of the house, so that puts some pressure on the bottom line.

Then, as we were asked earlier, as it relates to MNK-795 and to a lesser extent MNK-395, we certainly will incur significant sales and marketing expenses to launch those products. So it will be a year of investment for Specialty Pharmaceuticals.

As it relates to Global Medical Imaging, I pretty much talked a fair bit about margins on the previous question. The only thing I would add is that we are hoping to see more stability in the nuclear franchise than what we saw last year and a bit of a lift on that side of the house, whereas in contrast media and delivery systems it is going to continue to be a real challenge for us.

Ann Trimble - Barclays Capital - Analyst

Okay, thanks very much. Just in terms of the amortization, what is the guidance for the year? And what line item or line items are you removing that from to get to the cash adjusted EPS?

Matt Harbaugh - Mallinckrodt plc - SVP & CFO

So we typically put depreciation and amortization together, and amortization tends to roll through your SG&A but you can find it through the P&L. But from a D&A perspective you should be thinking in the \$135 million to \$140 million range on an annualized basis, much like we saw last year.

Now, we are going to have some increase in depreciation, as you can see with the guidance, from a capital expenditure viewpoint of \$140 million to \$160 million. Barring any sort of acquisitions, the amortization remains relatively consistent.

Ann Trimble - Barclays Capital - Analyst

Okay, great. Thank you very much.

Operator

Gregg Gilbert, Merrill Lynch.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Thanks, good morning. My first question is about the restructuring you previously announced. Can you quantify what savings you will realize in fiscal 2014?

Matt, I am trying to understand if that savings is versus a fiscal 2014 cost base or a fiscal 2013 cost base or some other cost base that we don't know about. And then I have a follow-up.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Gregg, I will tell you that I am really looking forward to the earnings call on the 7th because I can share a lot more with you as to some of the activities that we already started as it relates to fiscal year 2013. Obviously, we announced the restructuring program on our first earnings call post spin and we have not been resting.

What I can tell you, Gregg, is back when we were providing our initial guidance, as I'm sure you will recall, we had talked about a \$40 million incremental expense that we would incur post spend for infrastructure cost to take the company public. And with all the restructuring that we have incurred, both under Covidien as well as into the fourth quarter, we feel the lion's share of that expense burden has been ameliorated and we are looking to drive even more operating efficiencies as we move forward.

The lion's share of the restructuring that we did before we were spun were more in SG&A, which gives you a more immediate payback versus when you do restructuring in your cost of goods sold, which tends to take more time as you are streamlining processes in your plants. And so that is why we feel pretty good that we have been able to reduce that overhead burden, if you will, as a result of the spin.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

But there is no way for us to calculate how much of the \$100 million to \$125 million has been realized or not?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

I will be sharing more color on that with you on the earnings call. Obviously those charges would've gone into our fourth quarter, so I need to reserve that conversation for then.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Sure. My other question relates to your go-to-market strategy for 795; you talked today about the number of reps you are hiring. Does that mean you are no longer considering partnerships to launch that product or are you still considering options there? Thanks.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Certainly we will look at all the array of options out there in the marketplace. We have moved forward with the CSO and we are in the process of getting prepared for launch. There is a lot of excitement in the organization.

We had a national sales meeting last week in Orlando and we are pretty excited with all the new products we have coming down the pipe. So if something comes up that makes good strategic and financial sense for us, we would do that, Gregg, but right now we have got our heads down and we are really preparing for a robust launch.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Thanks.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Good morning. First question is on the comment you made about the imaging side and margins. You said a modest recovery.

This was a margin business in the 20%, 21% range just a few quarters ago and now we are in the single digits. So I guess I was curious what are you thinking about -- is this -- to get back to the 20% margin? Is this going to take a couple of years? Do we ever get back there?

And when you say modest recovery are we assuming that we can actually get into the double digits, the margins, in this fiscal year?

Then overall for the whole company and just the way you think about EBITDA margins, obviously there is investment in the first half. You get the products coming in the second half. So how should we be thinking about first half versus second half margins to help us understand what the run rate is going forward in the out years? Thanks.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Great question. So let's start with the imaging question. I would say from where we were in the first quarter of last year, to your point, it was above the 20% threshold.

One, that was a very strong quarter for us in the Global Medical Imaging segment and we didn't see impact from the HFR shut down at that point in time. It was early days as to the cost hits that we took in the second and the third quarter.

But what has happened throughout the course of last year is we have had a lot of pressure in contrast media and delivery systems business and so that has put some downward pressure on the margins. And we don't see that kind of coming back into the fold.

A lot of the restructuring that we did in the first half of the calendar last year or this year was really focused on driving operating efficiencies, but it is unlikely that we are going to recover or get back to those types of percentages. But we are doing everything that we can to drive those efficiencies.

As it relates to your question around calendarization, generally how I think about our business we are not a run ratable business as one might expect. A lot of that has to do with when DEA quota comes out and just the nature of the products we sell.

Generally, our first quarter is our toughest quarter from a top-line and bottom-line perspective and then the second and the third quarter tend to be where the lion's share of our earnings come in. And then our fourth quarter tends to be a little bit less robust than what you see in the second and the third quarter. So as you are thinking about that calendarization I would encourage you to take that into consideration.

I would also add, certainly with generic Concerta, it will be smoother than what you will see so as you are modeling this I would really take a hard look at each quarter. We have been pretty explicit with revenue generated out of generic Concerta. I would kind of more smooth that out throughout the year.



Then as it relates for new products, certainly for MNK-795 and MNK-395 it should be more robust in the back half of this upcoming year.

Operator

David Maris, BMO.

David Maris - BMO Capital Markets - Analyst

Good morning. Mark, can you talk a little bit about the rationale for the contract salesforce versus your own and whether or not you think that impacts the launch trajectory? Should that change how people think about it?

And also it seems like the number that you are hiring is slightly smaller. So again, should that affect the trajectory or how should we be thinking about that? Then I have a follow-up.

Matt Harbaugh - Mallinckrodt plc - SVP & CFO

So it is Matt; Mark is not here this morning. So as it relates to the salesforce build, it is pretty transparent to us whether it is our own employee versus an employee through a contract sales organization. We think we will get great productivity out of the organization.

In fact, the real key is, as you know, we have about 200 reps that are Mallinckrodt-specific company reps and then we have said 150 to 200 in addition to the base of 200. We are going to look at the productivity rep by rep, region by region like we always do and I think we have got a very robust territory mapping system internally. We are very careful to track where all the scripts are.

So we feel like we have got a pretty good system in-house to really understand the efficacy of the reps, but I don't expect a huge difference between one or the other.

From a financial viewpoint, it is really about driving as much script activity as possible and getting the best reps out there in the field possible. For someone that was here when we launched EXALGO and PENNSAID, I will tell you that the quality of the reps out there is very high right now and so that should aid our cause as well.

David Maris - BMO Capital Markets - Analyst

Then separately, in the prepared remarks you mentioned the guidance obviously doesn't include any transactions, but you are contemplating them. Then you separately mentioned that international expansion may be part of that.

Can you give us a little bit more color on what the Company might be looking for? Is this to build out further in the brands, further in the generics, both? What are you thinking -- how should investors be thinking about that?

Matt Harbaugh - Mallinckrodt plc - SVP & CFO

Sure, yes. So I think as it relates to the international business it is more likely to be organic. As you know, the business is more heavily weighted to contrast media and delivery systems right now and there is not a lot of opportunities as it relates to acquisitions in that part of the world.

So as you are thinking about any sort of business development and licensing that we would be contemplating it would more likely be in brands and generics and it would more likely probably be in the United States. This being said we will always look for opportunities around the world and when it makes strategic and financial sense we will pursue it, but a lot of the opportunities that we see right now are in the United States.

David Maris - *BMO Capital Markets - Analyst*

Great, thank you very much.

Operator

Tim Chiang, CRT Capital.

Tim Chiang - *CRT Capital Group - Analyst*

I know you guys give guidance of this -- at least \$120 million on Concerta in fiscal 2014. What are you guys seeing in pricing in that market right now, especially since UCB has come out with all four strengths?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

So from a pricing perspective I would say the market is unfolding pretty much as we had thought it was going to unfold. Obviously when new competitors come in they tend to drop price to get share.

We will be sharing with you, Tim, in early November our results for fiscal year 2013 so I can't get into that now, but I would say the range that we have provided we had dialed that into our consideration prior to providing it. So we are not going to speculate any further as it relates to pricing in the marketplace.

If Impax does come into the marketplace in the back half of next year, certainly that will be something we will be very focused on.

Tim Chiang - *CRT Capital Group - Analyst*

Matt, just one follow-up. There is a lot of questions on business development. How important is accretion to you when you guys look at business development?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Great question, I'm glad you asked that. Obviously we would prefer accretion. If there are some opportunities that are short-term dilutive, but not hugely dilutive, we might pursue those, but we are probably more focused on accretive deals.

Tim Chiang - *CRT Capital Group - Analyst*

Okay, great. Thanks.

Operator

Chris Caponetti, Morgan Stanley.



Chris Caponetti - *Morgan Stanley - Analyst*

I just have a couple quick follow-up questions to previous questions that I promise will be brief. First, in terms of the \$100 million to \$125 million three-year cost savings program that you guys announced on the 3Q call, what annualized run rate should we expect the Company to have achieved by the end of the fiscal year?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

So we haven't provided specific guidance on restructuring. What I would tell you is we were very confident that we can deliver on that plan and we are going to be as aggressive as possible in realizing those savings.

I think by nature of what I mentioned earlier that we have already been able to ameliorate the corporate cost for the spin as an indication that we are moving very aggressively as it relates to this program. We certainly will be sharing more with you on November 7 on the earnings call.

But, directionally, I would say it wouldn't be bad from a modeling perspective to think in kind of a third, a third, a third for now. But beyond that give us some time and we will have a more robust dialogue in the not-too-distant future.

Chris Caponetti - *Morgan Stanley - Analyst*

That is very helpful. Then my last two questions. On the acetaminophen franchise in fiscal 2014, given some changes in regulations, what sort of pricing and volume assumptions should we be assuming on that product line?

Then, finally, thinking longer term in terms of your tax rate. You have done a great job in marching the tax rate down from about 40% now to 26% to 29%. How should we think about the tax rate trending longer term?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Great, so I will address your question on acetaminophen first. We will have some impact, but I don't think you will see it in the aggregate of total Mallinckrodt sales. We do have some assumptions in there that we will have some pressure.

But we have been preparing for this for three years and we have seen the market kind of play its way out as it relates to getting in line with the expectations of the FDA, so I am not overly concerned that there is going to be any bumps in the night as it relates to acetaminophen. That particular part of our business does not have as strong a margins when compared with what we have in our brands and our specialty generics franchise, so less material.

As it relates to the tax rate, you will see our tax rate go down over time but it is going to take us some time. If you think about the fact that MNK-795 and MNK-395, as well as Concerta, are all US products right now, we are feeling good that we are working our way down on the tax rate but it is certainly going to take some time.

We have only been doing our own tax planning on our own now here for 3.5 months or so, so we have got a lot of work to do. But it will trend down over time. If you look at Covidien, when they were spun it kind of came down over time and I would expect us to kind of have that same type of trajectory, albeit we are starting at a higher point than they did.

Chris Caponetti - *Morgan Stanley - Analyst*

Great. Thanks so much.

Operator

David Krempa, Morningstar.

David Krempa - *Morningstar - Analyst*

Thanks for taking the question. Can you guys talk about the impact of the Express Scripts formulary on sales of EXALGO? Was there any dialogue around that; was Express Scripts looking for a price cut before they removed the drug? And also if that has any impact on your future plans for the rest of your pipeline?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Yes, thank you for the question. We don't talk about our conversations with managed care obviously. But as it relates to EXALGO, with generic competition coming in, it is going to be a tough year no matter how many ways you cut it for the EXALGO franchise. We expect competition to come in later in the first quarter here in November.

So will there be some impact? Perhaps, but it won't be as noticeable with all the change going on with that part of our portfolio. We are certainly taking into consideration the impact to our new product launches with MNK-795 and MNK-395 and MNK-155, but it is early days.

And I would say we really feel positively that these drugs are going to have great patient benefits and should resonate in the marketplace. And so we have dialed what we know into our plan, but we still feel pretty good about the guidance we have provided on those products both for 2014 and for the long term.

David Krempa - *Morningstar - Analyst*

Okay. Then one on the M&A strategy. Would you guys be open to a big merger that could leverage your tax rate rather than just small bolt-on deals?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

We would be open. If something makes strategic and financial sense we would be open to that, but I would say we feel pretty good that we have got a robust internal pipeline and a lot of products to launch. And so we are probably spending more of our time looking at things that really supplement the portfolio and add to our controlled substance portfolio, but we are open to considering multiple different options for sure.

David Krempa - *Morningstar - Analyst*

Great, thank you.

Operator

[Philip Guson], [Mitsubishi Securities].

Philip Guson - *Mitsubishi Securities - Analyst*

My question is actually a rather simple one with regard to MNK-795 and 395, which are currently under review with the FDA. The current shutdown in Washington, is that having any impact on those entities within the FDA that are doing the review? And any expected change or slippage in the timeline here?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

We are hopeful that we won't have any timing delays, although this is very hard to predict. But we are hopeful that the review continues and that things keep moving along.

Should we learn more on this front, we certainly will share that with you as we dialogue with you both on November 7 on the earnings call as well as at investor briefing that we mentioned as well. So we are very happy to be able to share with you a lot more as we move forward and we have got a couple of opportunities here to speak more in the public domain.

Philip Guson - *Mitsubishi Securities - Analyst*

But at this moment you are not aware of there being any potential delays, correct?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

No, right now I am not aware of a potential delay.

Philip Guson - *Mitsubishi Securities - Analyst*

Okay. I appreciate that very much. Thank you.

Operator

David Maris, BMO.

David Maris - *BMO Capital Markets - Analyst*

Mark, just a follow-up. Are the technologies used in 795 and 395 the same? And if not, how are they different?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Yes, so MNK-795 and MNK-155 are very similar. As you know, we have the Accuform technology that we license from Depomed. Then we have also added our own technology into the products.

As it relates to MNK-395, that is more akin to our current PENNSAID franchise. MNK-395 is a 2% diclofenac topical solution. So if you were comparing 395 to 795 it is a bit of an apple, orange; if you are thinking about 795 and 155 they are very similar.

David Maris - *BMO Capital Markets - Analyst*

Then separately, a number of investors have brought up that they believe payers or -- the approvability isn't the issue, it is the payers. And then you mentioned that you -- just now that your belief, the Company's belief, is that it has several -- the products have large patient benefits.

I know you don't want to speak specifically about discussions with payers so far, but when you meet with investors and that is their biggest pushback how do you respond to that?

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

Well, we are looking to get Tier 3 coverage. We have been working in this environment for a number of years. We have the same challenges today that we had when we launched both EXALGO and PENNSAID.

We are working through that process as we speak with managed care, but this is not unfamiliar territory to us. If we get Tier 3, we feel like we will be very successful with these products within the guidance we have provided over the long haul.

David Maris - *BMO Capital Markets - Analyst*

Great, thank you.

Operator

Gregg Gilbert, Merrill Lynch.

Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Two follow-ups, Matt, and I promise not to call you Mark. But on CapEx, a little higher than I would've thought; are there any specific programs to call out there?

Secondly, as it relates to generic EXALGO, do you get a royalty or some payment from Actavis on their sales once they begin? And can you launch your own generic after six months on that an initial batch of strengths that Actavis can launch starting in November? Thanks.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

So, Gregg, as it relates to your first question for CapEx, it is a bit higher and the guidance, as you know, is the same as what we provided for fiscal year 2013. We will be providing you the exact number in the not-too-distant future for CapEx.

The way I would encourage you to think about it is we are going to have some transition costs that live on post spin. So there is no impediment from our parent as it relates to being able to deliver products every day, but as we have identified in the Form 10 and in our public disclosures, we do have transition service agreements with Covidien that will last a couple of years post spin. And that is because we need to put in systems to pull all that work out of Covidien, particularly in Europe, and that is unfolding.

So we are putting an ERP system in and that is what is kind of bumping up our CapEx right now. It is really that transition. Longer term, I think CapEx will get down to more normalized levels.

As the CFO for this business, I can tell you our CapEx always ranged between \$110 million to \$130 million before we got into this whole spin process, and I would expect it to get there over time. It's really just a holdover from the spin. But, again, no limitation on our ability to ship, which is great. And Covidien has done great work for us to date, so we have had no bumps in the road as we transition.

The other thing I would add is that we are basically doing a buy/sell for the work that is being performed from Covidien, so it is not material in the aggregate of our financials but it is buried in the guidance. We will no longer receive allocations from Covidien like we saw in the third quarter.

As it relates to EXALGO, no, we will not be seeing any royalties from that. We do intend at some point in the future to get into the generics market. It is one of the real luxuries we have with our portfolio that while it is tough to go generic in EXALGO, at least we longer term can pick up some revenue in our generics portfolio with that product. But beyond that we don't want to discuss it any further.



Gregg Gilbert - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

Thank you. I would now like to hand over to Matt Harbaugh for closing comments.

Matt Harbaugh - *Mallinckrodt plc - SVP & CFO*

We would like to thank everyone for your interest in Mallinckrodt today and thanks for joining us on the call. If you have any further questions, please feel free to give us a call. Have a great day.

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