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EDITED TRANSCRIPT

MNK - Mallinckrodt at Piper Jaffray Healthcare Conference

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PRESENTATION

David Amsellem - *Piper Jaffray - Analyst*

Okay, let's get started. This is David Amsellem from the specialty pharma team at Piper Jaffray. Our next company is Mallinckrodt, which we are collectively in the investor and buy-side/sell-side community getting to know over the past few months.

With us today is Mark Trudeau, President and CEO, and Matt Harbaugh, CFO. What I would like to do is turn it over to Mark for some brief introductory remarks and then we can get into Q&A. So thanks, guys, for joining us and I will turn it over to you.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Great. Thank you, David. For those of you that are just getting to know Mallinckrodt, just a very quick snapshot here. Our objective is to grow the Company as a specialty pharmaceuticals business. We spun out from Covidien about a little longer than five months ago, in July of this year.

We spun out as about a 50% imaging business, 50% spec pharma business, based on our 2012 fiscal-year revenues. But we've very quickly been looking to drive significant growth in our business primarily by enhancing our spec pharma business. For us, spec pharma includes a brands business, a generic business, and also a vertically integrated API business that supports our generics business.

Fiscal 2013 for us was a very successful year. We drove revenues on the top line approximately 8% year-on-year, primarily driven by our spec pharma business. The big drivers of growth for us were our Exalgo branded pain product and methylphenidate ER, which is the generic form of CONCERTA, where we were first to file in fiscal 2013 to introduce that generic formulation in three strengths.

So we are very happy to show the fact that we have really been moving the composition of our business from that 50-50 business that we inherited to what in fiscal 2013 was about a 57% spec pharma business, 43% imaging. Over time we would expect to continue to drive growth on the spec pharma side.

Our imaging business is a global business. It gives us a global platform. In addition to that, it provides a very good source of cash for us to invest in our spec pharma side.

In addition to driving growth around spec pharma, around Exalgo and methylphenidate ER, in fiscal 2013 we were also able to advance our portfolio. We filed NDAs on two branded products: Pennsaid 2% and Xartemis XR.

Xartemis XR received priority review. And we expect Xartemis XR, which is a combination pain product, extended-release acute pain product combining oxycodone and acetaminophen, will be a long-term driver of growth for the business going forward.

We also indicated just a month or so ago when we had an investor briefing that we were able to enhance our intellectual property estate around Xartemis XR. We believe now that Xartemis XR actually has a fairly long runway from an intellectual property perspective.

So while we were very excited about our Xartemis XR, we looked at it as a short-term opportunity with three to four years of exclusivity. Now with our enhanced intellectual property estate we think Xartemis XR has a much longer runway, and we are starting to think about how do we develop that platform more for the long term.

As we look forward in fiscal 2014, we have described fiscal 2014 as a bit of a transition year. A transition year primarily because we are going to likely lose exclusivity around our lead branded pain product Exalgo and we also are experiencing -- expecting further competition for methylphenidate ER. We also have the opportunity -- we expect to launch Xartemis XR in the marketplace, so we are going to need invest in the launch of that product.

So we think that fiscal 2014 is a transition year. We gave guidance as to how to characterize that transition year. But we expect to position Mallinckrodt for future growth by enhancing our commercial portfolio, primarily our branded portfolio, which we believe will drive growth over the long term.

So we are quite excited about the progress that we have made so far. Fiscal 2013 was a very important year for us, and we delivered on a number of the objectives that we set forth, which was to really drive this spec pharma business. We look forward to continued growth for the business over the long term, again primarily on the spec pharma side.

David Amsellem - *Piper Jaffray - Analyst*

Okay, great. Thanks for the intro. I'm going to jump right into questions. I would like to go through your thoughts on M&A, BD. You have been pretty open in talking about your pursuit of additional assets to bolster the specialty pharma business.

So I guess the question here -- and it's really a two-part question -- is: what are the areas in terms of bus dev that you are focusing on? And, I guess, how large can you go in terms of a deal before you would need to access additional capital?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. Let me start with the first one -- or the second one first, then we will talk about the areas that we are focused on.

David Amsellem - *Piper Jaffray - Analyst*

Sure.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

One of the things that we do like is that we think we have the capital structure in place to enable us to do transformational deals if we choose to. Transformational deals for us we consider to be anything that would be, say, above $1 billion or so in acquisition price.

More than likely, though, we are likely to do larger tuck-in deals. Larger, meaning something larger than we did with CNS Therapeutics.

CNS Therapeutics we acquired in October of 2012. It was about a $100 million deal, brought with it a branded product called Gablofen, which is an intrathecal spasticity product, and also a development portfolio of intrathecal pain products.

But we think that what makes the most sense for us is to target things that are between that transformational level and something larger than what we did with CNS Therapeutics. And there are several near-term actionable assets where we think we are likely to be the best owner.

What do we mean by best owner? Well, Mallinckrodt is very good at a couple of things. I mean, we are not great at everything, but we are really good at a couple of things.

One of the things that we are very good at doing is managing controlled substances or difficult-to-handle things. We are also very, very good at formulation.

I think our introduction of methylphenidate ER is an example of that: a difficult formulation that was a controlled substance. We were able to be first to file and as a result of exploiting things that we do well.

But as we look at business development, and we look at our core business and our strengths and our core competencies, we have been primarily a controlled substance pain business and we have a certain platform in that area. Certainly a natural place for us to go would be to look for other pain assets out of the box.

But we are also very good at controlled substances. So it doesn't have to be pain; some other controlled substances would make sense for us as well.

But we also have certain commercial expertise, certain manufacturing expertise and development expertise, in say neurologic products or orthopedic products or hospital products. Those would be other natural adjacencies where you could see us exploiting our strengths.

I think most importantly, we see clearly opportunities for us to enhance shareholder value by being opportunistically acquisitive in the marketplace, but by focusing on assets whereby we are going to bring some incremental value to the marketplace. We think there are a number of those assets available to us that are near-term actionable. We are not talking about hundreds, but we are talking about more than a few.

And our objective would be to look to enhance shareholder value by bringing some of those assets in, in the near term.

David Amsellem - *Piper Jaffray - Analyst*

Okay. That's helpful. Then in terms of size, in terms of -- is there a size beyond which you would have to raise capital? Is it $300 million, is it $400 million, $500 million? How should we think about that?

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Yes. At the end of September we had about $275 million in cash on our balance sheet and we have about $920 million in debt. So there is that cash that is sitting there.

Now, by nature of being an Irish entity we don't have a lot of trapped cash, which other companies have challenges with. So we can access a fair bit of that cash.

We also put in place in April a $250 million revolver, so we can draw on that. So plus or minus I would say $500 million or less we have got a number of levers at our disposal right now. Anything above $500 million we would need to go into the markets.

I would also add, though, that by nature of the fact that we are not doing share repurchase programs or dividends, we have given ourselves from a cash viewpoint, from a flexibility viewpoint, the opportunity to do any sort of BD&L that comes our way, in addition to giving ourselves the ability and the room to not only fuel the Xartemis XR launch but also to deliver on our restructuring programs. Because typically when you do restructuring you may take a short-term cash flow hit, but the payoff is more than worth it.

So we feel pretty good that we have got a nice cash reserve. We have got that revolver in place.

But we have got some things we are funding internally, and as I mentioned on both the guidance call as well as the earnings call, our first quarter tends to be our toughest from a cash flow viewpoint. On a full-year basis we feel good about our underlying opportunity to generate cash; but our first quarter tends to be a challenge.

David Amsellem - *Piper Jaffray - Analyst*

I wanted to switch gears to Xartemis XR and also, to a lesser extent, MNK-155 as well. The idea here is to talk about how you think about managed care access.

Abuse and diversion are obvious public health concerns. But how does that weigh or not weigh on the thinking of managed care? And how do you see access for these products evolving in what is a competitive space?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. One of the things that has been very interesting is to watch the evolution of the importance of abuse deterrence when we talk to managed care plans. When we did market research say a year or so ago, the level of interest, even the level of recognition around abuse-deterrent technology within managed care was relatively low.

We just showed some information at our investor briefing a couple of weeks ago, where we showed our market research and we showed where abuse deterrence is now following by customer basis -- managed care prescribers and patients. What we are finding is that the recognition of abuse deterrence within managed care is rising at the moment.

It hasn't risen to the point yet where managed care on the commercial side is feeling compelled to have to give preferential treatment, preferential access in formularies because of abuse-deterrent technology. But there is clearly recognition that this is something that they need to consider over time.

From our standpoint with regards to the launch of Xartemis XR, we have said all along that we think a distinguishing feature for the formulation is the potential to have abuse deterrent and tamper-resistant language in the label at some point. At this point it is not a driver of our launch strategy, but we do think it will be a differentiator for us longer-term as this becomes, we think, more important particularly in managed care.

So in terms of our access strategy at launch, essentially what we are going to be looking at is primarily a Tier 3 access strategy. Our objective would be to provide the appropriate information to get Tier 3 access without prior authorization, to enable us to be able to get access to reimbursement, albeit at a slightly higher co-pay.

That has been a pretty successful strategy for us with Exalgo. We think we can duplicate that with Xartemis XR and that over time the potential for abuse deterrence may provide us additional leverage in managed care. But it is probably not quite here yet.

David Amsellem - *Piper Jaffray - Analyst*

In terms of how you are thinking about pricing, for Xartemis would pricing be analogous to the kind of price points you see for OxyContin and brand Opana ER? In other words, the extended-release opioids.

Or is there some sort of middle ground below that? What is a good way to think about that?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. We have done a lot of this modeling, and one potential strategy would be that you would go for volume and low price. The other potential strategy obviously is you go for a higher price and accept lower volume.

In the modeling that we have done, it clearly looks to be the winning strategy to go for the higher-price/lower-volume approach. So typically you should expect to see pricing for us in the range of what other competitive branded products would be.

David Amsellem - *Piper Jaffray - Analyst*

Okay. That's helpful. Then I guess the next question is just in terms of adoption. I guess what we see for Percocet and for Vicodin is that the average number of pills in a given prescription then to be small; these are shorter-term and typically acute usage paradigms.

So do you think that doctors will not necessarily perceive much of a tampering and abuse issue compared to the extended-release opioids? What has your own market research told you on that?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. You're absolutely right. The indication at least at launch for Xartemis XR, we are pursuing an acute pain indication, acute moderate to severe pain. Typically those prescriptions are less than 30 days.

And it's to be expected, because this is the type of pain that you have, say, immediately post-outpatient surgery, for example. So it is something where you need to get through the pain for less than 30 days.

In terms of abuse deterrence, though, one of the interesting things is that Percocet and Vicodin -- and all the generic equivalents of those -- are two of the most widely prescribed product categories in the entire pharmaceutical industry. Consequently, they tend to be two of the most widely abused products in the industry.

You are right; in general, more of the abuse tends to be focused on the longer-acting pure form opioids that are used for chronic pain because they have a bigger payload of the opioid. But in general, if you can provide an abuse-deterrent technology it is a differentiator and it is a long-term advantage.

Where we think the real differentiation, though, at least initially at launch, is in the fact not only the abuse, the potential for abuse-deterrent technology, but it is in the extended-release component. The extended release means instead of having a dose every four to six hours you can have an extended efficacy over 12 hours.

Our market research clearly shows that that is an advantage for patients and prescribers, and it makes good sense. The big time frame where you want to have extended pain relief is overnight. You don't want to have to wake up in the middle of the night, have to get up and take new pain medication.

And that is not available to patients at the moment. We would be the first, we believe, the first extended-release combination opioid/acetaminophen in the marketplace. And clearly there is a value to patients and prescribers for that type of product.

David Amsellem - *Piper Jaffray - Analyst*

Okay. How should we think about the expansion of the sales organization to support the launch? Is this something that you could potentially do with a partner? What is your general latest thinking there?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. We have been pretty clear about this. We believe that the appropriate total salesforce footprint for Xartemis XR and Pennsaid 2%, which we also believe is going to be approved sometime in fiscal 2014, we believe that that footprint requirement is on the order of 350 to 400 sales representatives plus a relatively smaller group, a focus group in managed care.

But for prescribers we need about 350 to 400. We currently have about 200 salespeople today that are selling Exalgo and PENNSAID 1.5%; so we need then to increase our current footprint by about 150 to 200.

We have been public to say that we have partnered with a CSO, inVentiv, to help us do that primarily because that is the quickest way to ramp up that many sales representatives. And then over time we have the ability to bring on the best of those sales representatives, if we choose to, as Company employees.

So we think that is the winning strategy. And again our approach here would be to ramp up that salesforce when we know with good confidence that approval is imminent.

David Amsellem - *Piper Jaffray - Analyst*

Then in terms of the physician audience you are going to target, I would imagine the usual suspects: pain specialists, neurologists. Is there going to be any sort of GP presence?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. If you look at who we cover right now with the salesforce that we have, it is primarily the specialists; and those tend to be pain specialists, neurologists, and orthopedics, and a few other specialties. You can cover just the specialty audience with that group.

But with a product like a Percocet, and this is essentially -- Xartemis is an extended-release Percocet formulation, you get a lot broader prescribing audience. Therefore you are going to go to a certain deeper set of physicians in the specialty arena and some high-prescribing primary care physicians that in their prescribing habits for products like Percocet look like specialists. And that is how we came to the 350 to 400 number.

David Amsellem - *Piper Jaffray - Analyst*

Okay. Any questions in the audience before we switch gears to some additional topics? Go ahead.

QUESTIONS AND ANSWERS

Unidentified Audience Member

(inaudible - microphone inaccessible)

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. Our objective, again, as I mentioned in my opening comments, is to transform this business into a spec pharma business. And again our definition of spec pharma is brands plus generics. We do have a bit of an API business, but most of that is in controlled substances supporting our generics business.

We would expect that over time, since the growth of our business is going to come from the spec pharma side, that we would see margin expansion. Typically branded and generic products are going to come with higher margins than our corporate average. And we would strive for a margin profile that is more similar to competitive companies that are in that combination of brand plus generic.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

The other thing I would add is Mark's comments are absolutely right; as we grow specialty pharmaceuticals you get a nicer gross profit as a percent of sales. You get a nice mix shift.

In addition to that we have a $100 million to $125 million program we announced shortly after spin. So from an operating income viewpoint or EBIT or EBITDA, pick your measure, we are also looking at taking out cost wherever possible throughout the P&L.

And that does include COGS and particularly G&A. So we are looking at all the line items of cost in addition to driving the top line.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. In the short term, obviously, we're going to be building up some of our commercial platform to launch Xartemis XR in particular. That is going to put some pressure from a cost of salesforce on our P&L. But longer-term we think there is plenty of room to drive margin expansion through the growth of these new products.

David Amsellem - *Piper Jaffray - Analyst*

I think we had a question over there.

Unidentified Audience Member

Yes. You mentioned about the (inaudible) high-prescribing family physician, and you mentioned one other group as well, but I didn't catch that.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Well, typically we look at any specialists that drive pain products. That is pain specialists; there are CNS, neurologists typically are in that space. Some orthopedic surgeons drive that as well, and high-prescribing primary care physicians.

David Amsellem - *Piper Jaffray - Analyst*

Question in the back.

Unidentified Audience Member

Can you better describe where your comfort is with that margin profile, considering (inaudible) either have dramatically more international scale than you -- considering the Walgreens (inaudible) Alliance Boots global procurement center. Is that something that you guys currently (inaudible) and that is not an apples-to-apples relationship; plus you guys are more a controlled substances business.

So when we look at [global] comps they are not going to be apples-to-apples. Could you better help us understand what that (inaudible)?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, I think you're right it is tough to get an exact comp for our business, even if you take the imaging business out of play. I would just to look at spec pharma companies that have a relatively narrower focus in their specialty that also have a generic part of their business.

That is not a big group; I understand that. But that is the type of companies that we would model ourselves against.

David Amsellem - *Piper Jaffray - Analyst*

I wanted to touch on CONCERTA. Obviously an important product. We have seen Kudco get to the market; haven't really seen much of an impact yet.

So I wanted to ask you: what are the dynamics here that could drive upside to what you have outlined for 2014, which is that there will be an impact to Concerta because of competition? Could we see a potential where your share actually is relatively stable?

You have talked about your API presence, your expertise in controlled substances, and as a major selling point your ability to work with the DEA. So how does that play into your ability to hold on to share?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. This marketplace so far has played out almost exactly the way we had modeled it and very consistent, where you see a relatively few number of competitors coming in, in a staggered fashion, and those competitors all behaving rationally. That has been our assumption all along.

You asked about what could drive additional upside. Well, one of the things that we have assumed is that we are going to have the our 18-milligram formulation in the market at some point in 2014. If that approval were to come a little bit earlier that would be a slight upside for us, but that is not a big driver of upside.

The other potential upside would be -- we have also assumed additional competition in the market at some point in 2014. We know that Impax has a Paragraph IV filing, and we have assumed that they are going to come into the market at a certain point.

If for some reason they were delayed and didn't come in in 2014, that would drive additional potential upside in that marketplace. But so far the market has played out almost exactly the way you would expect.

David Amsellem - *Piper Jaffray - Analyst*

Great. Any other questions in the audience? Okay. Well, we are out of time. So thanks, guys for joining us. Thank you in the audience.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Thank you.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Thank you.