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MNK - Q2 2014 Mallinckrodt Earnings Conference Call
(Fireside Chat Q&A)

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Mallinckrodt Fireside Chat investment 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

(Inaudible) Senior Vice President Corporate Strategy and Business Development. And next to him is Hugh O'Neill, President of the US Specialty Pharmaceuticals division. And on the far end, many of you know Mr. Matt Harbaugh, Chief Financial Officer and Senior Vice President. We also have joining us today our Chief Legal Counsel, Mr. Peter Edwards, who's our Senior Counsel. We have also Ms. Meredith Fischer, our Senior Vice President of Communications. We also have Ms. Miriam Singer, who is our Vice President, Corporate Secretary.

So what I'll do is I got to get through the customary forward-looking statements, as you all know. So today we'll be making some forward-looking statements and it is possible that actual results could be materially different from our current expectations. Under the Safe Harbor Rules, we are under no obligation to update the comments from our forward-looking statements.

As you both — we ask you both to look at Questcor's and SEC filings for the limitations of these forward-looking statements.

So let's start off with the Q&A session.

QUESTION AND ANSWER

John Moten - Mallinckrodt plc - VP of IR

Mark, could you currently discuss this current state of Mallinckrodt business both for the quarter and year to date and how does the Mallinckrodt portfolio, how has it changed over the last year and since then?

Mark Trudeau - Mallinckrodt plc - President & CEO

Sure, thanks, John, and thanks for everybody for joining us this morning. A lot has happened in this quarter and so we thought it was a really good idea to do this live, and certainly welcome the opportunity to answer as many of your questions as we can in the next hour.

If you had a chance to listen to our call this morning, I think you can see that the second fiscal quarter for Mallinckrodt was a very strong quarter. It was a very strong quarter on top of the strong first quarter. So clearly the first half of the year is lined up even better than we expected. We've exceeded expectations now two quarters in a row.

And obviously given the fact that we've raised our guidance for the second half, we feel quite positive about our prospects going forward. The strength of the quarter and the strength of the first half has really been driven by our base business. And if you look, our base business on the Spec Pharma side is very strong, both on the controlled substance generic side where our strategy of taking selected, strategic price increases is starting to bear some fruit.

But also on the branded side where we see strength from our Exalgo business, particularly in light of the fact that we have not yet seen a generic for that product. And then of course Methylphenidate ER sales continue to be very strong, up over 40% versus a year ago. So our base businesses had a very strong start, and as we look at the trends going forward, we expect that the strength in our base business will continue.

The other piece of it though is that we've made significant advances on our strategic platform. Currently we've added now OFIRMEV with the integration of Cadence, and this provides us yet another platform for growth. We believe that OFIRMEV is an undervalued product currently in the market, and in our hands we believe that we can accelerate the very strong growth trajectory that the product has already seeing when it was part of Cadence.

And then of course we announced the acquisition of Questcor. And when that deal closes, this will provide us yet another significant platform for both top line growth, improved profitability and significantly enhanced cash flow. So we believe that not only are we managing the base business that we have very well, but we're creating significant additional opportunities for Mallinckrodt to expand its growth platforms over time.

And then the last point, which I think has been somewhat less well understood, is that we've been really focused on driving the efficiency of our business. We announced the restructuring program last year and we've been very aggressively going after efficiencies in our business to the point we've used about one-third of the allocation that we had originally described. And all of that, or most of that, to this point, has been focused on things that are going to have a quick payback, and again that's enhancing our profitability as well.

So overall we believe that the prospects for Mallinckrodt going forward are very positive and that led to our decision to increase guidance significantly this morning.

John Moten - Mallinckrodt plc - VP of IR

Operator, I'd like to go to the line to David Ansellem's line from Piper Jaffray,

Operator

David Ansellem.

David Amsellem - Piper Jaffray & Co. - Analyst

Had a couple. First I wanted to touch on the pricing action in the specialty generics business and I wanted to ask, broadly, how sustainable you think pricing can be on that controlled substances business? And also talk — if you can talk about what you think changed in the marketplace that enables you to do this?

And then secondly, on XARTEMIS, I know it's very early in the launch, but could you provide any early color on managed care access? I know your expectations, your stated expectations in the past, where you're aiming for a broad tier III unrestricted access, is that still a reasonable expectation? Thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

Thanks, David, let me start briefly and then I'm going to turn it to Hugh O'Neill, Hugh runs our North American Specialty Pharmaceutical business, both the controlled substance generics as well as the launch of XARTEMIS and is responsible for Cadence as well.

With regards to our pricing, you can see the positive impact of our pricing actions. It's largely in our other controlled substance line or category in our report. And you can see that we've had significant growth in that category. That reflects pricing actions that we actually took late in 2013 and early 2014. We're seeing the same type of impact, or we expect to see the same type of impact in the rest of our business going forward.

But let me ask Hugh to talk a little bit more about the mechanics of that and then Hugh maybe talk a bit about where you see XARTEMIS with regards to access.

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

Thanks, Mark.

So again thanks for the question and we'll start with the strategic pricing initiatives. When we take a pricing initiative there's a couple of things you have to realize about mechanically how it works. When we do this on the specialty generics side, it resets and there are some penalties that are required based on contracts we have with distributors. And those penalties usually take a couple of quarters to actually clean themselves out and reset. We realize the penalties during the quarters that we take the pricing action and then we see volume pick up once the market actually resets to that new price.

So you see the benefit as Mark said in our other controlled substances, which is up about \$40 million over last year, and primarily driven by the impact of some of the products that we took late last year and as it's heading into 2014. When you look at other pieces of our portfolio and you look at things like hydrocodone which tends to be extremely competitive, significant amount of competitors and very much a price driven market, you don't see that type of response there.

But we do have something in line with Oxy and this quarter you'll see that as well that you saw some drop in volume utilization of Oxy. But that's natural based on the pricing that we've taken and the penalties that we've paid in the first two quarters of this year. And we expect that to pick up on the back end of the year as well. So we always look for value in our specialty generic market and we always look for opportunities to drive as much value out of those products as possible.

As it relates to XARTEMIS XR, so let's start with where we are to the question that was raised specifically around market access. At this point actually we're ahead of where we thought we otherwise would have been. We have roughly about 70% of our commercial lives where we are in a tier III open access situation. Which allows us to obviously have access for prescriber utilization and the appropriate patients that we're dealing with.

Some early signs, and it is very early in the launch I need to reiterate that, we launched that at the end of March, we had the field team out in April, so it's very early as it relates to the uptake. But some early signs that point towards a positive future for the product and our continued enthusiasm on the product is what we see in intent to prescribe amongst certain specialties especially surgeons, orthopedic surgeons, where we see some very positive feedback and week-on-week their intent to prescribe actually is growing.

We also see a significant amount of opportunity as it relates to length of therapy and duration of therapy and continued penetration for XARTEMIS. Add that on top of what we shared with you back in the fall, which is a stronger, intellectual property position for this product, and we believe over time this will be an important piece of our overall branded portfolio.

Mark Trudeau - Mallinckrodt plc - President & CEO

David, let me follow up on one thing that you asked which was regarding the sustainability of the pricing actions that we've been taking. So again getting back to the mechanics of this, as Hugh mentioned, we're very selective about where we take price. And we take price in markets where again keep in mind this is a controlled substance marketplace, so the supply is very strictly controlled by the DEA. So there's a certain amount of floor that is in this market.

And what we do is we look at markets where there are relatively few competitors and there hasn't been much price taken in the past. And we typically are going to have a pretty significant share of that micro market. That's where we — that's where the recipe for a place where you can take price. Now we've taken price in some of these micro markets, keep in mind that we participate in about 40 plus different categories of controlled substances. We haven't taken price in all of the categories and it's difficult to take price in all the categories.

This is likely to be a very dynamic marketplace going forward. There will continuously be opportunities to take price over time, to what degree they'll be successful and what magnitude we can take those will be highly dependent on both supply and competition. But we think that this is a pricing strategy that's certainly is a very good short-term strategy and will likely have some sustainability over time.

John Moten - Mallinckrodt plc - VP of IR

Matt, could you discuss the SG&A in the quarter? If we back out the enviro bill and transaction costs, SG&A was below last year.

And I was wondering if you could explain to me what were the factors for that especially in light that we're in the midst of launching XARTEMIS?

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

Yes, you bet. So one of the areas that we find people are struggling to get their mind wrapped around is really where we are with the restructuring program. So I think it makes sense to start there.

We incurred charges of a little under \$22 million in the second quarter, and roughly two thirds of that would be really aimed at our SG&A line. And so that bears a direct correlation with the question that John asked which is if you take out the environmental charge that we took, which I would briefly say is a non-cash charge this is a long-term issue for Mallinckrodt, and then you back out the transaction charges that we had for Cadence and Questcor, in fact we are down.

And so what we're seeing is at the end of the first quarter, we had been very clear to say that we had been able to offset the lion share of the cost that we took on to spin out as a publicly traded Company, which back in May we said was about \$40 million. So we've chipped that away. Now what we're seeing is, is with the aggressive approach we've taken to our restructuring program here, historically and as we said on the call, we've used up 40% of that \$100 million to \$125 million reserve already in eight short months.

So what we've seen is we were able to actually mitigate some of the launch cost for XARTEMIS XR and PENNSAID 2% because we're taking SG&A out elsewhere. So that would be a line item I would encourage you to focus on because I think it's probably declining faster than what we see in some of the models.

As we get into the back half of the year I would also remind you that to Hugh's point earlier is XARTEMIS XR was launched late in the quarter and PENNSAID 2% was no where near as extensive launch (technical difficulty) that flow into our third and fourth quarter. This being said, we are still very active with our restructuring program.

John Moten - Mallinckrodt plc - VP of IR

And I'd like to turn some of the question to Questcor, is that small acquisition we made in April that I think many of the people in the room have a lot of questions about.

Mark I got a couple questions for you. The first one is, is could you explain the strategic rationale for Questcor, number one? And number two, what type of due diligence did we do in terms of ascertaining Questcor as a viable acquisition candidate?

Mark Trudeau - Mallinckrodt plc - President & CEO

(Technical difficulty) minority of currently — current neurologist and rheumatologist use HP Acthar Gel to the degree that we believe that they can. So there's clearly an opportunity for us to further expand access into those key specialties.

The second piece of this is, is this a very complex molecule, it's actually a blend, a complex biological blend with a very complex manufacturing processes. This is something that we actually know quite well, we're very familiar and comfortable with complex manufacturing particularly naturally derived substances. We've been doing naturally derived substance manufacture for over 100 years in our pain franchise.

The third thing is that from a reimbursement standpoint, one of the things that we do know is that it takes time from the time an Acthar prescription is written to the time it actually gets filled, and the simple reason for it is each one of these prescriptions because they're being prescribed for patients that are — have some very debilitating conditions, each one is individually adjudicated. So the process itself takes a fare bit of time and it's a very customized process.

One of the things that we believe is that we can actually optimize that process, make it smoother and faster and more efficient because we have some very good relationships and experience on the market access side coupled with what Questcor currently does in reimbursement. I think there's room for opportunity to further streamline that process which is good news for patients and good news for the healthcare system as well.

There are significant synergies in this transaction, certainly some modest ones on the R&D side and on the G&A side. But significant synergies from a tax perspective. And then finally we have a global footprint and we believe that over time there's the opportunity for us to market Acthar and Synacthen potentially in a number of key international markets around the world, which is something that Questcor would have had difficulty doing on their own.

So for a variety of reasons we think this is a very compelling strategic fit for us and the financials clearly are equally, if not more compelling. And they really provide us with an additional platform for growth on top of the strong platforms we have in our core business and in our hospital platform. It gives us a fourth area of focus now in the highly specialized therapeutic areas where there's relatively little competition. And again we think this is going to be an outstanding acquisition for Mallinckrodt.

With regards to the due diligence, as I've mentioned, we did extensive due diligence on this particular acquisition, as you can imagine, really across the board on virtually every aspect of this business, like we would do with any acquisition, including what we did with Cadence. But for this one, we really took an extra step and we used to not only our internal expertise but we really brought on board a whole variety of the best external experts that we can find.

And I'm actually going to ask Gary Phillips to describe a bit more in detail our approach to due diligence. Gary and I were the primary architects of this deal as well as the Cadence deal, and Gary actually headed up the due diligence as well as he's focusing on the integration of (technical difficulty).

Gary Phillips - Mallinckrodt plc - SVP & Chief Strategy Officer

(Technical difficulty) the fact that HP Acthar Gel is a really interesting quite exciting product. I've been reflecting on — if a company has a complex biologic that in 2010 the FDA approved in 19 indications, including some of the most difficult to treat diseases like systemic lupus erythematosus, rheumatoid arthritis, multiple sclerosis, inflammatory pulmonary disease, that the product (technical difficulty) we read the press just like everybody else does, we've seen reports as well. So we wanted to circle around the things where we wanted to understand that both were they real and what else could we learn.

And again we relied not only on our internal expertise but external. I know that used to run immunological part of the large pharmaceutical business and I've been at multiple pharmaceutical companies over my career including Wyeth, Novartis, Merck Serono who were deep in immunology. I've treated patients with these diseases when I used to practice medicine. So we have a certain amount of internal expertise but we didn't want to rely on that.

So what we did is we focused on value drivers like commercial sustainability, potential legal risk, manufacturing how robust is the manufacturing process, R&D and looking at data around that, financial diligence, cultural diligence. So we really rallied the wagons around these major headers and then we used internal expertise as well as world experts to really pour through the data. It was an all hands on deck exercise, it was intensive and thorough, broad and deep and in the end we felt comfortable. I hope that answers the questions.

John Moten - Mallinckrodt plc - VP of IR

Thank you. At this point I'd take questions from the audience. Sumant?

Sumant Kulkarni - BofA Merrill Lynch - Analyst

Sumant Kulkarni, Bank of America Merrill Lynch. The first question is on, you've done a couple of transactions or announced a couple of transactions in the Specialty Pharma branch side, and both of those cases the key assets are the duration of life there are significant variables.

Could you talk about how you're thinking about the duration from a strategic perspective? And from a financial perspective any specifics on the number of [viewers] there?

And the second question is on the Specialty Pharma generic side, would you characterize your business as having optimal scale? If not, how would you address that?

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes, so let me start and I'm going to ask Gary and actually Peter to give some additional commentary. First, let's talk about the durability of the two assets, and again we're talking about two dramatically different situations. We talk about the Cadence acquisition, with regards to due diligence, while our due diligence was comprehensive, our real focus or [depth] was on the durability of the asset.

And one of the things that we were encouraged by was despite the fact that there had been a number of Paragraph IV filings around the OFIRMEV asset, before we acquired the asset, Cadence had actually been remarkably successful in either litigating successfully or settling the majority of the Paragraph IV filing challenges. And so we've got a date where most of these cases have now settled.

That really left one remaining case that being with Fresenius which is a slightly different case than the others. And we're very well aware and deep on that particular case. And what I might do is ask Peter to comment a little bit about further about how we've thought about that and how we're approaching it, with respect to Cadence and the Fresenius case.

Peter Edwards - Mallinckrodt plc - Chief Legal Counsel

So glad to speak to that. As you know, Cadence had a variety of Paragraph IV filers and frankly we're thrilled with the way they've managed to resolve four out of five of those, either through resolution — resolution through settlement or by trial.

So we plan to do the same thing with Fresenius. And if you look at the trial that took place with Exela, it's exact same set of issues that would be tried in the Fresenius case. So we feel really good about the merits of that case but of course we're open to any possibilities for settlement if we can make that happen.

Mark Trudeau - Mallinckrodt plc - President & CEO

So that's the Cadence situation. Now the durability of the Acthar asset is a completely different animal and of course this was a very important component of our diligence because not only were we interested in how durable was the Acthar asset but we also wanted to understand how does Synacthen fit into that. And again Gary I think is best positioned to give some detail on how we thought about the durability of this.

The bottom line is we believe that Acthar is an extremely durable asset as is Synacthen and again that led to the decision, partly led to the decision to go forward with the transaction. But Gary maybe give a little more color?

Gary Phillips - Mallinckrodt plc - SVP & Chief Strategy Officer

Sure thanks, Mark.

Yes, so I won't talk about Synacthen really because it's early in development. It's commercialized in some parts of the world, but in the United States it's really early days so it's hard to talk about durability of Synacthen. So let me just focus on Acthar. So I'll start with by saying that it's been pretty durable so far, I mean it's been on — it's been commercialized for 62 years, proof in 1952. So in 62 years there hasn't been — it's been pretty do durable. With regards to future, the interesting thing is it has 19 indications.

In some indications it's considered gold standard like infantile spasm. Some medications is being used broadly like in MS players, it's gaining increasing acceptance for things like nephrotic syndrome. But we're just getting started, we're — I say Questcor is just getting started with regards to other indications like lupus, which just recently paper published dermatomyositis, polymyositis and they have just started to commercialize in things like symptomatic sarcoidosis. There are other indications where nothing has even been done.

So like in ophthalmology as well as dermatology. So there are additional indications of the 19 which have not even started to be commercialized or promoted yet. So we believe that there's a long growth trajectory still left in the product.

Now with regards to potential competition, I think everyone understands that this is a very complex naturally derived biologic product. Again having been at Wyeth early in my career, it reminds me a bit of Premarin in that's an animal derived product where it has a complex manufacturing process, a complex mixture and therefore generic competition is really not an option because it's a complex manufacturing procedure.

That manufacturing procedure is a trade secret. And in fact, Questcor purchased the manufacturer of — contract manufacturer of the product so they own that. So I think it's safe to say that the product is been around for 62 years, there's a long runway still left with it and that we believe it's a durable product.

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes, again if a generic were somehow to come you'd be into the bio similar type route which there appears to be a very difficult if any pathway for generic to come on.

John Moten - Mallinckrodt plc - VP of IR

Yes, Anthony, please. Anthony Petrone.

Anthony Petrone - Jefferies & Company - Analyst

Maybe to begin on Acthar, your comments Mark were interesting on reimbursement coverage. So maybe you can review the diligence specifically around managed care coverage for Acthar, what in your diligence process made you comfortable that there is sustainability to coverage going forward and a couple of follow ups? Thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

So again very briefly, this is an area of very deep and broad diligence as you can imagine. Understanding and getting comfortable with the reimbursement scenario for a product like this was quite important. And we came away feeling very positive about the durability of the reimbursement, but Hugh is really our expert in that area and lead this part of due diligence and Hugh maybe you can describe exactly what we did and what we found?

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

Thanks, Mark, I will, I'd be more than happy to.

So let me go back to a point that Gary raised before about you have to understand, to understand reimbursement and understand how this product is actually looked at, you have to start with the patients that the product is being treated by. These patients are on serious debilitating diseases and they've gone through different pathways of treatment before they get access to Acthar.

And what we've realized through our due diligence is a significant portion of the reimbursement that happens for Acthar is actually driven through what is referred to as prior authorization, which requires the physician as well as the payer to agree on the appropriate patient to gain access to that product. And it's pretty well understood when we looked across all of the commercial payers as well as the major payers for Acthar that that prior authorization is well in place and these patients are verified, they have utilized other products and these are the patients that require the product. And we see significant reimbursement rates that are relatively the same across multiple payers.

Now let me talk a little bit about where the opportunity sits. We believe because Questcor has significantly focus their efforts on reimbursement in front of the physician and begun to realize that there's an untapped potential to actually focus on the payer, adding our skills on top of what they already do to Mark's point earlier, we actually believe we can increase the efficiency of the reimbursement process. By actually driving towards standard policies and looks from a payer perspective of how Acthar should be reimbursed. And that will help a little bit on the volatility.

But overall what we found was significant reimbursement rates. Patient by patient, individual patient reimbursement, in that case it's a little bit like an orphan drug which I'm familiar with based on my previous experience at Sanofi specifically around Genzyme, but each patient is handled one by one and that has increased our confidence level that this product will continue to be reimbursed.

Anthony Petrone - Jefferies & Company - Analyst

Very helpful.

And then switching gears to Imaging, maybe Mark can you provide an update on how that fits in the portfolio as you look forward. And to get Matt in the mix, if Questcor closes maybe an update on the debt capital structure where the leverage ratios are and where they can go say within 2 to 3 years? Thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

So again we've I think been very clear now for a number of months that Imaging across the board is unlikely to be part of our long-term portfolio from a strategic and financial standpoint, it's inconsistent with where the business is heading. That being said, we've been clearly focused on driving for efficiency in that business, managing it for cash flow. But we've also been quite active in investigating a variety of strategic alternatives.

We are somewhat constrained if — and those alternatives would include divestment as well as other things. We're somewhat constrained in our ability within the first two months of — or our first two years of spinning out from Covidien we're somewhat constrained in the volume of assets that we could divest. So that essentially meant that — means that we couldn't divest both contrast media and nuclear imaging within the first three years but we could do one or the other.

And again divestiture is just one option on a variety of different things that we're considering. But again longer term for us, Imaging right now is an opportunity for us to drive cash flow and we're very focused on efficiency and you see a lot of our restructuring activities have been squarely at driving that efficiency out of that business.

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

Yes and just to be clear it's two years with the Covidien agreement. And other thing I would add on the Global Medical Imaging business is you'll notice in the release that we put out this morning that we were spun we were in about 90 countries around the world, we're down to 65. And so what we've done now that we're post spin is we've really looked at every single country in which we're doing business and what we said is, is these businesses need to be profitable and if they're not, then we focus on restructuring.

We want to preserve the optionality from a growth from a Specialty Pharmaceutical base, as Mark mentioned, with Acthar longer term. So we're preserving countries that we really see opportunity in long term. But there are a number of countries that as we've really dug in deep and really focused on underlying profitability it's not there. And that a lot of that has to do with some allocations we were getting historically that were kind of a peanut butter approach versus really understanding one country at a time. You're likely to see the number of countries continue to go down as we move forward into the future of the restructuring program continues to unfold.

Turning to your question as it relates to our debt capital structure, our leverage ratio more specifically. We did take on the debt for Cadence, we do have about \$2.2 billion in debt. Our leverage ratio is exactly where we said it was going to be when we announced the transaction, we're in the upper 4s.

As we look forward, one of the most exciting elements of the transaction with Questcor for myself as the CFO is the fact that when you just look at the underlying cash generating capabilities of Mallinckrodt on its own, and keep in mind on the call I said we generated about \$150 million in the quarter, \$100 million of which we used for the cadence acquisition.

So you don't see it necessarily as straightforward on the statement of cash flows, but we had very strong cash generating throughout the quarter. Then you add OFIRMEV to that which we've said is going to be accretive, and that's driving further cash. And then you add Questcor and their company generates a lot of cash they don't have to put as much back in capital as we do with our base businesses. So we'll see that leverage ratio drop pretty quickly in a relatively short timeframe.

John Moten - Mallinckrodt plc - VP of IR

Mark Goodman?

Mark Goodman - UBS - Analyst

Yes, Mark Goodman at UBS. So three questions, first how did the tax rate come down so quickly given that the transaction was so little in the quarter? So I don't know if there were NOLs that were used, and if so, how do we think about them going forward in the tax rate?

Second question is on the generic ANDAs, you mentioned that you did some filings in the quarter, can you give us an update on where you stand on that, how many products have been filed and how many were filed a couple years ago such that we might actually start to see some get approved, will we see some this year or not?

And then third, on the hydrocodone, a little more color. You mentioned pricing competition so obviously we've seen revenues come down quite a bit. So is this the new normal down here? How our volumes? Did you lose share and your planning on getting the share back? There's nothing or was there something unusual in the quarter or was this pretty normal? Thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

Matt, you want to start with tax and I'll take the other one?

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

Yes. So the tax rate is very straightforward, we're planning to file our Q very shortly, so I encourage you to dig in because the devil is in the details there. I would focus you on the non-GAAP tax rate. So our guidance was 25% to 28% on the February call after we closed out the first quarter. And if we look at base Mallinckrodt, Mark, we were right in that zone in the second quarter. The decrease down and the new guidance today is really bringing in the Cadence acquisition and really it's an accounting convention when you acquired a business because the way in which the tax rate drops is the way in which you calculate over a 12-month cycle the impact on the tax rate.

So stated simply, I would focus on the non-GAAP tax rate because the way in which the transaction closed so close to the end of the quarter, created some accounting conventions, if you will. But we feel really good that the 23% to 26% is a good underlying tax rate to use for Mallinckrodt on a full-year basis. And I want to highlight and reiterate what I said on the call which is, this does not include Questcor. So this is Mallinckrodt and Cadence on its own, all of the guidance.

Mark Trudeau - Mallinckrodt plc - President & CEO

Mark, what was your second question?

John Moten - Mallinckrodt plc - VP of IR

It's about the ANDAs?

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes, so we did file some additional ANDAs this quarter. Again in keeping with our overall development strategy for specialty controlled substance generics, we're very focused in just the controlled substance arena at this point. And while we have single-digit ANDAs in process with the FDA currently, we've added now a couple more single digit ANDAs. And again we haven't given a lot of disclosure to exactly what that ANDA portfolio looks like.

What I can tell you going forward is that's likely to be our strategy to have relatively few but very focused in the controlled substance arena, that's because that's what we do well. And most of these ANDAs are going to be again less the blockbuster type that you see with Methylphenidate ADR for example and more singles and doubles that really round out our portfolio of controlled substances.

So that was the ANDA question, then the other question was around hydrocodone, right? So keep in mind that the hydrocodone for us is probably amongst our entire portfolio of controlled substances. It's one of the more competitive and lower margin parts of our specialty controlled pharma generics business. We haven't taken any price increases in hydrocodone. And what we are seeing is a decline overall in the hydrocodone market. We're also seeing a decline in our business as well.

What we are seeing is a transition of what appears to be some of that hydrocodone business to other parts of our Specialty Pharma business, generics business that are higher margin like morphine ER, or the morphine line and oxycodone products for example. So overall, we're expecting that hydrocodone is going to continue to be lower. But again it's actually a good trade off for us because as we see offsetting increases in other parts of our business, it's a bit of a margin lift for us.

John Moten - Mallinckrodt plc - VP of IR

Yes, Operator, I'd like to take a call on the line Jason Gerberry from Leerink Partners.

Operator

Jason Gerberry.

Jason Gerberry - Leerink Partners - Analyst

Thanks for taking my question and thanks for holding the event.

First question is around OFIRMEV and pricing actually. So a lot of investors have been wondering how you'd price that product once it's in your hands, the peak sales target that you provided. Curious how you're thinking about the increase in net pricing driving that number versus some of your volume growth initiatives. That's my first question then I have a couple follow ups.

Mark Trudeau - Mallinckrodt plc - President & CEO

So let me just start and then I'll ask Hugh to give the rest of the detail. Again as we said on the call, we believe that OFIRMEV is a very cost effective product at the current price. And we believe that there's potential for this product to deliver significant value to the healthcare system because it does seem to have the potential to reduce hospital stays when it's used versus other IV pain products in surgical procedures.

So we're looking carefully at that value proposition but we also think there are a number of ways that we can increase the volume and continue to accelerate the trajectory from of volume perspective that Cadence has been able to generate on their own.

But Hugh maybe you want to give some detail on how you think about that?

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

Yes, thanks, Mark and thanks for the question.

So to Mark's point, when we looked at OFIRMEV clearly the placement of OFIRMEV in the treatment of pain in an operating surgical setting has actually generated significant value data. And we believe that it is a — there is untapped value in OFIRMEV and we're doing a lot of work now to determine what that value looks like.

But more importantly we also think the way that this product has been put into the marketplace, there is opportunity for continued volume growth specifically around how many actually targeted institutions are utilizing the product because it is relatively concentrated. As well as how many vials per surgery is currently being utilized and how many different departments and types of surgeries within those institutions are using it.

So we're looking at the entire thing saying we realize right now that with OFIRMEV it's done well, it's on a good growth trajectory, we think there's more opportunity both in terms of value, and in terms of volume growth and we're doing that a lot of that work right now post the integration of the Company.

John Moten - Mallinckrodt plc - VP of IR

The gentleman in the back, Marissa, in the green tie.

Shane Shaw - Albert Fried & Co. - Analyst

Hi it's [Shane Shaw], Albert Fried. I wanted to talk about M&A and inversions. There's been a lot of deals, it's been in the headlines, everybody's been talking about it, everybody's been doing it. So I wanted to talk about the speculation that's been out in regards to the Company. It's almost become conventional wisdom that you guys are a potential target for somebody even Sweden's [Ameta] yesterday, CEO on their annual meeting basically said you're either the predator or the prey. And they are the predator.

And so how can you dispel the speculation out there that you are not the prey? That's the first part.

The second part is obviously the spread right now as far as the Questcor transaction is concerned is more than \$10. Some of that for various reasons but some of the also because of my initial first question.

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes so let me take the first part and maybe Matt you take the spread piece of that, right?

And so look Mallinckrodt is in business for two reasons. We're in business to create and get medicines to patients that can benefit from them. And the second reason is to maximize shareholder return. We think we're doing a very good job of that at the moment.

We've clearly demonstrated that we are predators in the M&A environment. We've been quite aggressive I think and very quickly taking on one acquisition and announcing a very transformational acquisition that we plan to close later this year.

But we're also for sale every day. And if somebody wants to come to our Board with a full value offer that's better than what Management can do, then of course we have the fiduciary responsibility and our Board has the fiduciary responsibility to listen to that.

But we're driving significant shareholder return. And we believe that our strategy is aligned to deliver even greater shareholder return and it's up to the shareholders to decide whether we can do a better job of that or whether somebody else can do a better job of that.

But with regards to being predator or prey, I think we've made a pretty clear statement that we're a predator in the M&A space. Matt, did you want to add to that?

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

Sure. As it relates your question on the spread, we certainly calculate it on an ongoing basis. What I would tell you is both in talking with the Questcor team as well as what we're seeing, generally we've seen strong support for the transaction.

So — and I would say in the last week or so we have seen some of that spread start to close. So I think once we file the proxy in the not-too-distant future that'll also further clarify some of the details that people are looking for. But right now, we're all systems go and we look forward to closing on that transaction.

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes, the one other thing I might mention on this, is Matt mentioned the fact that the Questcor acquisition and the underlying cash generating capabilities of our base business and OFIRMEV really enable us to rapidly pay down our debt and to get our debt ratio down into a place that enables us as well to generate more deals and do more deals.

Also the deals that we've done so far have been designed to set ourselves up to do more deals. The Cadence acquisition is a perfect example.

We created a platform with a hospital commercial infrastructure that is tailor made to bring on additional hospital products. It was done to complement what we do, to provide growth and profitability but for also — also for us to give a clear platform to bring in additional deals. And we'll do those types of things. Questcor's got the same objectives behind it as well.

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

I would also add in case anyone missed it on the call, we did say that we — Mark said in his prepared remarks, that we do see OFIRMEV being \$0.5 billion product. And one of the real strong compelling drivers behind that Cadence transaction is that we're not putting a lot of capital back in to facilitate that growth. It really falls to the bottom line in larger respects once you pay for the field sales force because we did get G&A leverage as well as tax leverage out of that deal.

So I would strongly encourage everyone to really focus on really calculating out what the underlying cash generating capabilities are. I'm not sure people really realize the full cash value of what we see as we move forward.

John Moten - Mallinckrodt plc - VP of IR

Yes, state your name and firm.

Tony Reiner - Imperial Capital - Analyst

Tony Reiner, Imperial Capital, and thanks for hosting. A little more follow up on what my friend [Shasheen] was asking. Can you make a more generic 30,000-foot statement on M&A which clearly is a theme tax version regulatory as far as that goes?

Is there a race before any regulatory — a more macro generic statements tax wise and M&A wise? Clearly you've heard some of your competitors say we're not done buying, we're looking to grow, blah, blah, blah. So more macro comments, if did you don't mind and thanks very much.

Mark Trudeau - Mallinckrodt plc - President & CEO

Yes, of course. So again I hope I can be very clear on this. We are very aggressive and opportunistic when it comes to M&A.

We believe we've already demonstrated that and we believe that we've set ourselves up to further that. What we do look for though is we look for deals that are strategically aligned and financially compelling.

And we believe that we've got a team now in place that not only can close these deals, and we've demonstrated that, but we're in the process of integrating these effectively to fully capture the value. What we're about is creating shareholder value.

We believe that M&A is a very important part of accelerating and creating that shareholder value. And we believe Mallinckrodt is extremely well positioned to do that, and in fact we demonstrated that not only are we going to do that but we've done it and will continue to do it.

John Moten - Mallinckrodt plc - VP of IR

Yes, David Buck.

David Buck - Buckingham Research - Analyst

Thanks for taking the question and holding the event. David Buck, Buckingham Research.

Couple of quick ones, first on Cadence since you've now closed the transaction. Standalone Cadence SG&A it seemed relatively high given just the one product being marketed, can you talk about the current sales force size behind OFIRMEV and whether there's been any — what type of SG&A synergies you might be realizing this year from the combination?

And separately on the Questcor transaction, obviously you gave a peak sales expectation for OFIRMEV a, would you like to opine what you think Acthar's peak sales are? But more specifically on the due diligence, one of the questions raised was manufacturing process and more specifically quality control of the product. Can you talk a little bit about your diligence there? Thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

So a lot of stuff in there, David, we'll try to get it all.

Let's start with Cadence and again I'm going to turn to Hugh in just a minute. But you're right, we did see in the Cadence transaction an opportunity for some synergies in SG&A primarily in G&A frankly. But from an S perspective, one of the reasons actually to do the transaction was because we wanted access to that commercial platform. And again we plan to retain at least initially a good chunk of that.

But Hugh maybe speak a little bit about how you think about that going forward.

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

Thanks, Mark, and thanks, David for the question.

So where we are in the integration of Cadence into the business, and to confirm, when we purchased Cadence we looked at not just OFIRMEV as a product but it's very important to understand, we looked at building out a hospital strategy. So when we looked at Cadence as an acquisition target, the value was not just in OFIRMEV in itself, which fit very nicely with our pain franchise, but also the hospital sales team. And what Cadence did extremely well is when they built their hospital sales team they built people who knew institutions. They weren't therapeutically focused, primarily they were hospital specialist. And that opens a lot of doors for us.

So we are at this point have about 130 or so hospital specialist in the Cadence team that we just secured and they are staying with us going forward. And we actually see the future of the promotion of our hospital platform not just in the sales representatives inside the institutions, but also the evolution into an account management discussion as it relates to the value of our offerings to hospitals. So we're very excited about it and to Mark's point we think that the sales side actually is a key to our future growth in our hospital strategy.

Mark Trudeau - Mallinckrodt plc - President & CEO

The other bit is we've also continued our M&A activities and part of our strategy was to identify actionable hospital assets that we could quickly add to this platform that we've created. We've identified those and we're actively pursuing them. So we're going to be able to amortize the cost of this infrastructure over a number of products over time.

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

The only other thing I'd add as it relates to your question from a synergy viewpoint, the G&A synergies are modest. Okay, we would be taking out overlap, right, we only need one Corporate Controller, one CFO and so on.

And I would say, we will start to see some of that benefit in our fourth quarter and then we will realize the benefit next year. But as evidenced by the updated guidance this morning, one of the real value drivers from a cost viewpoint is certainly what we see in the tax line.

Mark Trudeau - Mallinckrodt plc - President & CEO

So then David, your second question was around Acthar and whether or not we care to speculate on future sales for Acthar. Given that we don't own the asset just yet, it's probably a little premature but certainly you can go to what Questcor has described, but you'll also get a view to this when we file the proxy on this proposed transaction in another 10 days or so. So you'll have a pretty good idea about how we think about it.

With regards though to the due diligence around manufacturing and quality, again a very important component of our due diligence. And keep in mind this is an area where we actually have considerable expertise for complex substances, but particularly those that are naturally derived. So we went and looked at the manufacturing quality, we kind of knew what we were looking for but this is something a little bit different. And so we took our expertise but we really partnered up as Gary has described with some of the best biologic manufacturing advisors that we could find in the industry.

And again we looked at the available data, we visited the facilities and we're quite comfortable with regards to the product quality and manufacturing. This is exactly what we would have expected and we're quite confident that the issues there are fully understood and well characterized.

John Moten - Mallinckrodt plc - VP of IR

David Maris, BMO.

David Maris - BMO Capital Markets - Analyst

David Maris with BMO. A couple questions, Mark and Matt, about 1.5 years ago when we first got together you asked me what investors were saying about the spin out at the time and I told you that they thought the Company was sleepy and boring and cast offs from an old tired company. And you said at the time, look five years from now people won't recognize the Company.

And so far you've gone a long way to that, so my question Mark is in that evolution, how far along would you say you are when you were looking out five years? Is this no, this is we're in the middle of a process or we — no, we have two big assets that we've just acquired and we're pretty far along there?

Then my second question is maybe Matt you can address what's the thinking behind allowing a shareholder to go to 20% ownership, and what does that discussion like, what's the benefit of it, what are the drawbacks and how did that evolve? Thank you.

Mark Trudeau - Mallinckrodt plc - President & CEO

So I'll take the first question, Matt, you take the second one.

So yes you're absolutely right, David. We have I think been very clear to say our aspirational goal is to become a top-tier Specialty Pharmaceutical Company, and we knew that was going to require a significant transformation in our portfolio. And we set about doing that very aggressively from the beginning. I would say we're still in early innings of that. What we have been able to do is execute on the strategic levers that we described as being important to make that happen.

One was to really tune up our base business and we've done that on the spec generic side in controlled substances, primarily by price. The second thing is that we said we were going to develop other branded products out of our own internal portfolio. And we've done that, we brought PENNSAID 2% to the market, we brought XARTEMIS XR to the market and we're developing MNK-155 so that part of it has advanced very nicely.

Then we said we were also going to be very opportunistic and aggressive on M&A. And I think this is the part where at that time we could only talk about what our goals and aspirations were without it really been able to fully articulate and described what we meant by that. And clearly the actions that we've taken over the last several months have now lined up the pathway to demonstrate not only are we going to talk about it, but we're going to do it.

We're going to do it in a way — in ways that are complementary to and supportive to the strategy of being a top-tier Pharma company. And we're going to do things that are financially compelling. And we're also going to create a much broader platform, a more diversified platform and much more robust growth and profitability platform in Spec Pharma than we could have possibly had with the base business that we had before.

So what we've done so far, I believe is we've set the stage. We've laid out a platform, we've laid out a pathway to become a top tier Spec Pharma Company. To really deliver on that now, we got to fill up the platforms. And we're going to fill up the hospital platform, we're going to fill up the immunology platform and a lot of that's going to come again from more M&A.

So again I would say we're in early stages because what we've done is built a foundation or we built a foundation, a good solid well diversified fast growing highly profitable foundation that we want to add to that to really enhance it.

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

And David I would add, over the last 1.5 years, if you look at all of our public closures and you look at a lot of the leverage points and the transactions that we're focusing on, it's all been there. We've been communicating it, now what we're doing is showing it, if you will, through our actions and our words.

As a relates to your question around investors, we've had a number of investors that have been very supportive of Mallinckrodt since the beginning and we have a number of investors that really truly understand where we're going with the Company and the strategies that we're employing. And so to us it makes good sense to be open to dialogues with investors that want to join us in realizing what we see is a very robust outlook as evidenced by raising our guidance today and having a very strong quarter.

John Moten - Mallinckrodt plc - VP of IR

Yes, Operator, I'd like to take Gary Nachman on the line.

Operator

Gary Nachman.

Gary Nachman Analyst

So first regarding operating margins for the base business, the 4.6% for Medical Imaging was pretty low, the 33% for Spec Pharma certainly improved. Talk about directionally where you think operating margins for those businesses could get to over time in a steady state? And then I have a follow up on Qcor.

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

So I would encourage you to go back and look at the last few quarters and you see that we just keep strengthening and strengthening and strengthening the underlying business in our Specialty Pharmaceuticals business. You're going to continue to see that.

The line item that I tend to really focus on is our gross profit or gross margin as a percent of sales. One of the areas that investors have focused on historically is that our gross profit as a percent of sales is in mid to upper 40s as you can see in our release this morning. And a lot of our industry peers are significantly higher than that.

And so in the backdrop of doing Cadence as well as Questcor, you'll see a significant growth rate in that particular line item which will translate to operating income over time. So we definitely see a very robust outlook for the Specialty Pharmaceuticals business.

As it relates to Global Medical Imaging, there are two things I would highlight for you. The first is we are continuing to see the benefits from restructuring, which we talked about earlier and we saw that in the second quarter already. We also as we said this morning, and I want to make sure this is crystal clear, the HFR reactor did come up in the second quarter and then the moly processing facility did come back on line in mid April.

We are going to see some financial pressure continuing in the nuclear business in the third quarter. And that's because when these challenges presented themselves in the first quarter, we wanted to make sure that we took care of our customers. And we're very proud of our track record despite some of these challenges we've been able to meet the needs of our customers throughout these unfortunate issues.

But we did find sign long-term contracts to make sure we could meet the needs of our customers and that continued in — will continue into our third quarter. In the fourth quarter, we will see a bit more recovery in our nuclear franchise which should further help us as it relates to Global Medical Imaging.

Mark Trudeau - Mallinckrodt plc - President & CEO

Gary you had a follow-up question on Questcor?

John Moten - Mallinckrodt plc - VP of IR

Okay, moving on. Let's work this side of the room. [Tim Chiang].

Tim Chiang Analyst

Great thanks. I had a couple questions on Questcor, I know you did a lot of due diligence on the company and the product. I think Questcor — Acthar is definitely unique product you guys have talked about. How do you optimize this product going forward assuming the deal closes?

How do you look at integrating your sales force with Questcor's sales force? Because do you actually think that Acthar as a part you could roll into a 800 or 900 person type sales force? And then the last part of it is, how do you further capture the expensive label that Acthar has? That's really it, thanks.

Mark Trudeau - Mallinckrodt plc - President & CEO

Sure so let me take the first part of that and then I'll ask Gary to add a little bit of thought to it and maybe Hugh as well.

So if you look at the way Acthar is promoted today, there are a number of relatively small sales forces that are specifically targeted by specialty. So there's a neurology sales force, there's a rheumatology sales force and so on. Our initial plan for the commercial part of Questcor coming over is to operate that business as of business unit that reports to me directly. And the back office part of it, the manufacturing piece of the R&D piece of it, all of the support functions will be fully integrated relatively quickly into the overall Mallinckrodt business. And the commercial side we'll keep it somewhat intact at least initially.

Our thinking though is that again there's an opportunity clearly in some of the specialties where we have coverage, broad coverage, like neurology and rheumatology, where our sales force won't necessarily go in and sell Acthar. But what they will be able to do is provide some further access to the current Questcor sales force that focuses on those specialties. Over time, our thinking is that again because each one of these indications disease states are very specialized, we're likely to have relatively small sales forces set up by specialty.

So for example in the pulmonology indication for sarcoidosis for example, Acthar is indicated there but the product is not really promoted very readily in pulmonology. So that's something that over time particularly as more data accumulates, there would be the opportunity potentially to create a pulmonology sales force. And you might see the same thing in dermatology or ophthalmology.

And I think one of the compelling things about this product is of the 19 indications, really only a couple of them are actually actively promoted. Even within rheumatology, it's really just a limited set of those rheumatology indications. So there's plenty more room to promote further particularly in rheumatology. But that's our thinking about it from a commercial standpoint. On an overall basis,

Gary or Hugh, you may want to add some of your thoughts as well.

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

Yes, so the thing I would add to it, it's really a unique product like we talked about earlier because when you look at 19 different indications, the way we think about it from a commercial perspective is really 19 different products sell to specific specialties. And to Mark's point, I think the way we try to put the strategy together on this, is it's unique sales force is specific to those specialties that will realize the benefit of the appropriate utilization of Acthar for that patient population.

So I'm not so sure you're ever going to see a broad spectrum 900 person field force promote this, that's not probably the most cost effective or the most impactful way to deliver the message to the specialist that actually will see the value of the product. But it is an opportunity because there are untapped specialist here that we believe by building out those unique field forces and building on some of these skills we already have, that we can take full advantage of it.

Mark Trudeau - Mallinckrodt plc - President & CEO

But what it does do for us though is again gives us a framework for other areas where we may want to focus our M&A activity. So for example in nephrology, really Acthar is used quite a bit in nephrology that's the only product in our portfolio when the deal closes that we would have in nephrology. But that's a very interesting and potentially valuable therapeutic area, so we may want to look at adding additional assets into those types of specialties longer term.

Gary Phillips - Mallinckrodt plc - SVP & Chief Strategy Officer

Yes, I'll make a couple, one more comment around how else could you grow the asset. In addition, to what's been said, part of it is if you're able to actually streamline the reimbursement process, you can actually potentially drive more utilization. That's part of the diligence process I've talked to a number of physicians, as been referenced, I'm a physician myself, so I've been able to have more of a clinical conversation about how the product is used. In some instances, physicians aren't necessarily using it saying in exacerbation of multiple sclerosis. If someone has an optic neuritis and has difficulty seeing because of MS [flare].

Some docs are not wanting to use it because the time it takes for patients to get the product is delayed, and as a result they may potentially use another product or not at all. By shortening that time it actually has a better opportunity to intervene in the patient's pathophysiology and therefore it creates greater value to the doctor and to the patient. So part of the streamlining, it's not only just improving reimbursement but also getting greater clinical utility.

The second is all around evidence generation. And I actually think that Questcor has done a great job of starting to generate evidence. And you may have seen just within the past few weeks, there has been an article that came out in the Journal that was around nephrotic syndrome and the use of the product in nephrotic syndrome. Just last week in lupus, looking at a case series of looking at patients who are already on steroids, they're on Benlysta, they're on immunosuppressant and then you add Acthar on top and the patients get resolution. So generating evidence is important.

And then as Mark said there are additional indications. I spent six years running Bausch and Lomb's ophthalmics business and I know that inflammatory conditions of the eye, including uveitis, keratitis, there is at least in uveitis an opportunity hasn't been tapped yet. In addition to all of that, there are additional number of other opportunities. It's in clinical development for additional indications in amyotrophic lateral sclerosis, or Lou Gehrig's disease, in diabetic nephropathy because has a different effect potentially on blood glucose than say cortisol does.

And then also in ARDS, adult respiratory distress system, which is high unmet need area. There's also a poster just came out last week at the AAN where it was used in a case study in refractory migraine. Don't understand necessarily the mechanism of action, but it does seem to have potential activity. So we don't know what the opportunity is. We have a sense, but we're really excited about all the different avenues in which you could potentially drive throughout the product.

Hugh O'Neill - Mallinckrodt plc - President- US Specialty Pharmaceuticals

What we do know is there's a lot of opportunity.

Gary Phillips - Mallinckrodt plc - SVP & Chief Strategy Officer

There's a lot of opportunity.

John Moten - Mallinckrodt plc - VP of IR

Yes, Lori, the gentleman in the back with the vest.

Tim Wallach - Halcyon Asset Management - Analyst

Tim Wallach from Halcyon. You were talking about predator or prey and you say you see yourselves as the predator. Can you confirm for us that in the recent past, last two or three months, that you haven't been contacted by anyone interested in doing an acquisition of your Company?

Mark Trudeau - Mallinckrodt plc - President & CEO

Well of course I can't speculate on that, right. What I can tell you is exactly what I just said which is we believe that we are doing a tremendous job of generating shareholder return and we're going to continue to do that. If in fact we were to be contacted or our Board was to be contacted and it was a full value offer, our Board would consider that. But at this point we believe that we're driving significant shareholder value and significant benefit for patients.

Tim Wallach - Halcyon Asset Management - Analyst

Thank you.

John Moten - Mallinckrodt plc - VP of IR

Chris Caponetti, you're the last question.

Chris Caponetti - Morgan Stanley - Analyst

So I have a couple, easiest to hardest. On guidance, when's the expectation for generic Exalgo and how should we think about that impacting the Specialty margins? Should I stop there or —?

Matt Harbaugh - Mallinckrodt plc - CFO & SVP

Sure absolutely, I'd be happy to answer that. Yes, so we factored into our guidance that Actavis would be in the marketplace in the back half this year. They've been a bit more explicit recently about their intentions there apparently they've had more visibility as it relates to labeling. So we are assuming they're coming in.

I think from a margin viewpoint I would juxtapose what we'll see in Exalgo with what we see with the addition of OFIRMEV into the portfolio. And then further to that, Acthar because Acthar and OFIRMEV are going into the brands business. So I get that there's a bit of complexity in there, but you've got significant products that have growth in their future and that will mitigate some of the challenges we likely will see with Exalgo once Actavis does come into the marketplace.

Chris Caponetti - Morgan Stanley - Analyst

That's great. And on due diligence, and I don't mean to spoil the surprise of the proxy in 10 days, but can you also think about when did due diligence begin in earnest for Questcor? And who were your external consultants that you used?

And then on Cadence thinking about Fresenius and the generic patent challenge there, is there anything in the settlement that would prevent Fresenius from potentially launching earlier than the other generics, would that push forward the other settlers. And then finally, in terms of your organic growth aspirations for the business, how do you see the business evolving over the next three years pre M&A?

Mark Trudeau - Mallinckrodt plc - President & CEO

Sure so let me make sure I've got all of these. With regards to the due diligence, right, so a couple of things, I'll ask Gary to comment on this as well. A couple of things, remember that over the last probably 6 to 9 months, we've been very explicit to say we had identified several near-term actionable assets that we felt were strategically and financially compelling for Mallinckrodt.

Clearly Cadence was one of those, clearly Questcor was one of those. And clearly given the fact that these two assets were announced so close to one another obviously we were advancing diligence on both of these things simultaneously.

What's important to understand is not necessarily the duration of the diligence but clearly it was significant, was the depth and the intensity and the range of things that we looked at for both assets but certainly with enhanced activity around Questcor asset. So again our diligence I think has been tremendously thorough, tremendously detailed and has as we said included not only our own internal expertise but as well as the best experts that we could find in the industry.

With regards to identifying those experts, we wouldn't do that at this point. But I can tell you that we went to some of the best names that you could find in each individual area.

With regards to Fresenius and the Fresenius case, again I might just ask Peter to comment with a little bit more specificity on Chris's question specifically?

Peter Edwards - Mallinckrodt plc - Chief Legal Counsel

Yes, sure happy to do that. So the Cadence folks have very successfully settled with a number of the Paragraph IV challengers. Can't really comment on the details of those settlements other than to say, as I'm sure most of you know, it's very common in fact it happens in almost every one of these agreements that there is an acceleration provision that if there's some triggering event such as earlier entry, than the person who signed the agreement usually gets to come in early as well. Very common.

Mark Trudeau - Mallinckrodt plc - President & CEO

And then the question I guess Chris is around how do we see the business growing in the future. Well clearly if you just were to look at our base business and the trajectory that you've already seen, you can see that we were tracking along in the mid single-digit range currently and that's what we would have projected going forward.

With the addition of Cadence and the perspective addition of Questcor with H.P. Acthar Gel, obviously our top line growth as well as our bottom line growth rate should significantly enhance — or be significantly enhanced because those products are growing so much faster than our base business and they're so much more profitable on a per capita basis.

John Moten - Mallinckrodt plc - VP of IR

Thank you, Operator, I will turn it over to you now.

Operator

Thank you. Ladies and gentlemen, thank you for participating in today's conference. This concludes today's program, you may all disconnect. Everyone have a great day.

Mark Trudeau - Mallinckrodt plc - President & CEO

Thank you.

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Cautionary Statements Related to 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 uncertainty of approval under the Hart Scott Rodino Antitrust Improvements Act; 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 area of nephrotic syndrome and Lupus, and Questcor's efforts to develop and obtain FDA 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.

Important Information for Investors and Shareholders

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the proposed transaction between Mallinckrodt and Questcor, Mallinckrodt will file with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 that will include a joint proxy statement of Mallinckrodt and Questcor that also constitutes a prospectus of Mallinckrodt. The definitive joint proxy statement/prospectus will be delivered to shareholders of Mallinckrodt and Questcor. INVESTORS AND SECURITY HOLDERS OF MALLINCKRODT AND QUESTCOR ARE URGED TO READ THE DEFINITIVE JOINT PROXY STATEMENT/PROSPECTUS AND OTHER DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and security holders will be able to obtain free copies of the registration statement and the definitive joint proxy statement/prospectus (when available) and other documents filed with the SEC by Mallinckrodt and Questcor through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed with the SEC by Mallinckrodt will be available free of charge on Mallinckrodt's internet website at www.Mallinckrodt.com or by contacting Mallinckrodt's Investor Relations Department at (314) 654-6650. Copies of the documents filed with the SEC by Questcor will be available free of charge on Questcor's internet website at www.Questcor.com or by contacting Questcor's Investor Relations Department at (714) 497-4899.

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.