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PRESENTATION

Unidentified Company Representative

Ladies and gentlemen, please welcome John Moten, Vice President, Investor Relations, Mallinckrodt Pharmaceuticals.

John Moten *- Mallinckrodt plc - VP IR*

Good morning, everyone. My name is John Moten; I am the Vice President of Investor Relations for Mallinckrodt plc. I would like to take this opportunity to welcome you to our investor briefing this morning. As you know our business has undergone significant transformation.

Before we begin, I would like to remind you of the customary forward-looking statements. This morning we will be making some forward-looking statements, and it is possible that actual results could materially be different than our actual results. We ask you to please review our SEC disclosures for the risks associated with these forward-looking statements.

I want to give you a brief overview of what we are to discuss today. We are going to begin today's discussion with a lead by Mark Trudeau, our President and CEO, of Mallinckrodt's business transformation; and that, as you know, it's been quite significant over the last 12 months or so. We will then follow that up with a commentary and overview of our Specialty Pharmaceutical division, led by Hugh O'Neill, President of our Specialty Pharmaceutical division. Then we will follow that conversation up with a discussion of H.P. Acthar Gel, led by Dr. Gary Phillips; we will discuss Acthar's business background and history as well as the physician and patient experience.

And then you saw the press release earlier this morning: we will discuss fiscal 2015 guidance. That will be led by Senior Vice President and Chief Financial Officer, Matt Harbaugh. Then finally we will have a summary and concluding remarks by Mark Trudeau, followed by an investor Q&A session.

With that I would like to turn this investor briefing over to Mark Trudeau, President and CEO of Mallinckrodt Pharmaceuticals. Mark?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Thank you, John, and welcome, everybody. It's really been a remarkable year for Mallinckrodt, and I want to open this briefing by talking a little bit about the transformational value-creation story that we have been embarking on since we spun from Covidien just about 15 months ago.

What is really remarkable is that we have actually been able to increase shareholder value approximately fourfold since we spun. And we are very pleased, of course, to be included in the S&P 500.

We want to spend some time today talking not only about what we have done but, more important, where we are going and how we are going to accelerate this value-creation story that we have initiated in our first year as an independent company. But we also want to spend a little bit of time today telling you how we are going to do that.

So, while I'll provide an overview of our business -- both where we are today, where we are going, and how we are going to get there -- and Matt, of course, is going to give some color to the 2015 guidance that we provided a little bit earlier this morning, the real meat of the program, the real depth of the program, is to spend some time really diving deep into our commercial businesses. You will hear from our two commercial leaders, Hugh O'Neill, leading our Specialty Pharmaceuticals business, and Gary Phillips, leading our Autoimmune and Rare Disease business, so that you can really get a flavor for just how much growth opportunity and value-creation opportunity these two businesses provide.

Let's start by talking a little bit about the Mallinckrodt story. Mallinckrodt is essentially a company that is driving transformational growth with an emphasis on creating shareholder value by improving revenue growth and profitability. This transformational growth story is really built on a very solid foundation: a solid foundation that has actually been developed and honed over our almost 150 years in the business.

We think of ourselves as a diversified, global, specialty pharmaceutical company that is focused on both brand and generic products, but with emphasis on products that are highly durable. We operate in both the office and in the hospital arena.

And while we have built our business on a traditional therapeutic area around pain management, we continue to expand that business. We have also now started to branch out into some other key therapeutic areas which are pretty much underserved, and those would be in the autoimmune and rare diseases area. We also have a Global Medical Imaging business, which provides us diversification and also a global platform.

So if we think about the focus of our business, what is it that we are really trying to do? We are looking to increase shareholder value, and our focus is really around driving top-line growth and significantly enhanced profitability. That delivers value not only for shareholders, but it creates value and solutions for patients in some very devastating diseases.

We focus on developing a portfolio of unique products, products that are sustainable, that are going to develop and deliver sustainable growth and profitability over the long term. And we also have a very strong foundation on a core strength; and that core strength is listed here: We believe that we manage complexity very, very well.

Keep in mind, we have been in business for 150 years. And whether that is managing complexity of naturally derived products from either plant or animal sources, or managing a highly complex supply chain delivering radioactive medical products safely and efficiently, or simultaneously executing on a number of transformational initiatives, when you think about Mallinckrodt you think about the fact that we take the complex and we make it simple.

Fundamentally, our goal is to deliver top-quartile performance based on total shareholder return compared to our competitive peer set. Throughout the course of our first year as an independent company, we have been consistently delivering that top-quartile performance, and our objective is to continue to perform at that level.

Let's spend a minute thinking about our portfolio. Our primary strategy to achieve the goal that I have just described -- that is, delivering top-level shareholder returns -- is to focus on developing a different (technical difficulty) durable, fast-growing, highly profitable Specialty Pharmaceutical products.

What I am showing here is the mix of our business by segment, compared to where we started at spin versus where we are projecting to be as the result of our guidance this morning. I think what you see is really a dramatic transformation in our business, and that transformation has been favoring the Specialty Pharmaceutical side of our business.

As you see, at spin we were roughly half and half Specialty Pharmaceuticals and Global Medical Imaging. And based on our guidance this morning, you can see that roughly 80% of our revenues in 2015 are projected to come from the Specialty Pharmaceutical side of the business.

That actually conveys a number of benefits. Not only does it enhance our growth and our profitability, because the margins from Specialty Pharmaceutical products are typically higher than our corporate average, but it also provides us enhanced durability to our portfolio. As we have been bringing products into the portfolio, whether they had been developed internally or acquired, we have been looking to add things to our Specialty portfolio that really drive durability; and we think that we are developing a very attractive and very durable portfolio.

But one of the other benefits of favoring the Specialty Pharmaceutical part of our business is that we reduce the volatility of our earnings. Certainly, our Global Medical Imaging business over time has had some variability in supply chain, and that has led to some volatility in earnings. Of course, as we reduce the overall proportion of Global Medical Imaging in our portfolio, we simultaneously reduce the volatility.

Now, this is based on a revenue basis. But of course if we were to do this on an earnings basis it would be even more dramatic, as the bulk of our earnings -- the vast bulk of our earnings -- are being generated now by the Specialty Pharmaceuticals side.

So here is where we are today. But if we look forward and we think about our strategy for the future, you can see that we are setting the table, really, for a well-diversified portfolio of products in both the brand and the specialty generics area across four platforms: three branded platforms and one generic.

What we are showing here is just the lead product in each one of our platforms. You see Xartemis XR in our office-based brands; Ofirmev in our hospital brands; Acthar in our autoimmune and rare diseases. And we have represented our specialty controlled substance generics business by our largest product, which is methylphenidate ER.

Let's spend a minute on our office brands and our hospital brands. Clearly this is a pain portfolio at the moment. We have a focus in pain; we have historically had a focus in pain.

Keep in mind, Xartemis XR is really an acute pain product and Ofirmev is a product that is used primarily for managing pain in surgeries in the hospital. What we believe is that there is a synergistic opportunity between these two parts of our business.

As we focus on surgical specialties, which we are doing with both products, essentially we are developing a continuum of care around pain management in surgical specialties. You will hear a lot more about this from Hugh O'Neill in just a couple of minutes.

But we see this continuum of care in managing surgeries starting with the inpatient surgical arena with Ofirmev, all the way through to the office-based setting of managing acute pain with surgery specialties with Xartemis XR. And in between there is an opportunity to also manage outpatient surgeries with both Ofirmev and Xartemis XR.

When we focus now on our autoimmune and rare disease business, our foundational asset is Acthar. Keep in mind that Acthar is used for a variety of devastating autoimmune and rare diseases. It is a product with 19 indications, only which approximately nine are currently marketed.

We see this as a highly durable platform, and you will hear more about its durability in a few minutes from Gary Phillips. But this foundational platform, while it has tremendous growth opportunities in and of itself, it also enables us to build out specialties in key areas like neurology, rheumatology, nephrology, and pulmonology -- all specialties which are relatively underserved.

These are areas where the product is marketed today. Longer term, there are opportunities certainly in ophthalmology and dermatology for future growth expansion.

Let me turn now to our specially controlled substance generics business. In this category, we really participate very broadly -- in 43 different categories of controlled substances. A number of pain categories, but also we have products for ADHD, as represented by methylphenidate ER here; and we also do products for addiction treatment.

This is really the solid foundation that I was describing before. Our specialty controlled generics business we expect to drive modest growth but continue to deliver very strong cash flow.

And keep in mind, we've been doing this business for over 100 years. We believe we have one of the broadest portfolios of controlled substances in the industry, and we have been a leading competitor, as I said, for over 100 years.

So when you think about this model, it really enables us to drive growth and profitability in a number of ways. First of all, we are very clearly down a specialty commercial model, which really enables us to drive profitability because it requires relatively modest infrastructure to drive the growth of these various products. But importantly, it also forms a blueprint for us for the future to guide and direct our future business development and licensing activities as well as our research and development investments.

We will look to develop and acquire products in each one of these platforms to further build out the opportunity set and also drive efficiency in that commercial model. Our concept is to continue to be opportunistically aggressive. We look for undervalued assets where Mallinckrodt is the best owner, where we can create value in a way that the previous owner could not. Our emphasis will continue to be primarily on late-stage assets, both commercial and developmental assets -- those assets that enable us to be rapidly or immediately accretive.

Of course, as much as we have been focused on M&A over the past year from an acquisitive standpoint, we are also quite aggressive in looking at our portfolio as it is today, and looking at businesses which are lower margin and lower growth, and look to actively divest those. That is likely to include our Global Medical Imaging business as well.

Let's talk a little bit now about -- you've heard a little bit of the overview of the business; you've heard a little bit about where we are; heard a little about where we are going strategically; and you've heard a little bit about where we are going to go and how we are going to get there. You're going to hear a lot more detail from the leaders of these businesses in just a couple of moments, but I did want to take this opportunity to introduce my management team.

I think many of you know my background. I have been in the industry for 30 years. I started as -- I started in research and development and manufacturing as a chemical engineer; but I have also had extensive commercial expertise across multiple therapeutic areas including autoimmune diseases; and I have got general management experience as a leader of multiple businesses in a number of regions around the world.

But you may not know so much about some of the management team that is here today. What I have tried to do over the last 2 years is assemble the best management team in the industry.

Let me spend just a minute talking about Matt Harbaugh. Many of you have met Matt and you know he is our CFO. Matt has been with the Company about 7 years.

But you may not know that Matt also has considerable general management experience, where he has run businesses both in Canada and Latin America as a general manager. He was also the Interim President before I arrived, and he has excellent knowledge of our core business, particularly our Global Medical Imaging business; and he is managing that on an operational basis today.

Gary Phillips was a practicing physician before he came into industry. He was most recently our Senior Vice President responsible for strategy, and really with me was one of the primary architects of the two major acquisitions we have done over the last year. Gary has now taken on responsibility for the Autoimmune and Rare Disease business.

Gary has extensive commercial and general management experience, including running businesses in the autoimmune category. Gary also has experience as a global executive, having run operations in a number of different places around the world.

That brings me to Hugh O'Neill, who is our next speaker. Hugh has had over 25 years of experience in the industry. He is our Senior Vice President for our Specialty Pharmaceuticals unit.

Hugh has significant experience, primarily on the commercial side, but significant expertise in the hospital sector as well, which is a big part of our business, of course, and a big part of Hugh's business. He has also had extensive general management experience, having run businesses both here in the US as well as in Canada. Hugh has a real expertise in market access, and he manages and leads that part of our business as well, which is a key driver for our entire portfolio.

So without further ado, let me introduce Hugh O'Neill to talk to you about our Specialty Pharmaceuticals unit. Hugh?

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

Thanks, Mark. Good morning. It's great to be here this morning. Hopefully over the next 10 minutes or so I will give you a little deeper dive into how we see the evolution of the Specialty Pharmaceutical platform for Mallinckrodt.

As Mark mentioned, there's really three different components to the Specialty Pharmaceutical business outside of Autoimmune/Rare Diseases. Think about this as a business that is building durable assets and platforms that are positioned for growth; and I am going to talk about each one of these in a little more detail.

If you think about our office brand business, that has a very different strategic imperative than our hospital and our specialty generic business. That is focused really on investing for long-term growth.

You know we launched Xartemis XR in March of this year; and what we have learned post that launch, obviously, is that this is a longer runway. We have strong intellectual property on the product, which we knew at the time of launch.

We also knew that with a controlled substance pain medication indicated for acute pain, especially a CII, that that was going to take a little bit of a longer runway to begin to take traction. What we found actually post that launch in a very positive way is one of the audiences that has reacted strongly to the message of Xartemis XR, which is both immediate and extended relief in the acute pain management arena, is our surgery specialties.

So we're going to take a longer focus and a more dedicated focus to those surgery specialties, which are going to be important to the future of that product. And I will explain in a little bit about how we see that playing out with Ofirmev.

On the hospital side, Ofirmev has been a tremendous product. As you all know, we took a price reset in May, and I will share with you what we have seen since that price reset. But I can unequivocally tell you that actually that price reset strategy has worked to our expectation.

Why? One of the reasons why is because the product provides such strong pharmacoeconomic value to not only the institutions that utilize the product, to the patients that benefit for the product, but also to the overall healthcare system. And that has helped us not only retain position, but also position this product for long-term growth.

The other thing I want you to think about with Ofirmev is, even before the price reset, at its highest level it only penetrated about 12% of the surgeries that it was eligible to be utilized within. So we see significant opportunity to continue to drive growth on that product in three areas: the number of hospitals that actually are utilizing the product; the number of surgeries in which the product is being utilized within; and then certainly the number of vials per procedure that's being utilized within that hospital as well. Continued investment around health economic and developing that value story will be critical to the long-term growth of our hospital platform.

On the generic side, it comes down to a couple of major points. Mark mentioned methylphenidate ER, which continues to perform extremely well. For multiple reasons, one of the things we do well as a Company -- Mark talked about the idea that we take the complicated and we relatively make it simple.

We are very comfortable in controlled substance markets that have significant requirements. Markets that are not easy to operate within, not easy to enter, we actually have no issue competing there, and I think our success with Methylphenidate ER demonstrates that.

It also demonstrates our ability to manage something like be hydrocodone rescheduling. As everyone knows recently hydrocodone was up-scheduled from a CIII to a CII. Not only were we aware of it, we were fully prepared for it.

We most recently launched our version, our hydrocodone CII version, into the marketplace and that has begun to take hold. Again, we were prepared for all the requirements that come with that up-scheduling, including the ability to handle the product differently, to distribute the product differently, and to be able to meet those needs of our customers at the retail pharmacy level.

We turn to the future of these three platforms, a couple of things are going to drive our long-term success. On the office side, clearly it will be getting prepared to launch MNK-155 while continuing to drive Xartemis XR penetration in the surgery specialties. We expect to launch MNK-155 in fiscal-year 2015, and we are preparing for that launch as we move forward.

On Ofirmev, on the hospital side we have opportunities in the next generation of potentially how this product is thought about, in the whole idea around what kind of formulations and future opportunities we can bring to the market for Ofirmev. There is a significant amount of work being done on that as we speak.

On the specialty controlled generics side, it is all about improving our pipeline productivity, adding more abbreviated New Drug Applications behind our existing products, and continuing to invest and look at the future of potential abuse-deterrent technology for that portfolio as well.

So where are we with Ofirmev? As I mentioned in the previous slide, we did take a price reset, which as we said, I will tell you, and I think this chart bears it out, the strategy has worked incredibly well. Our revenues were up 100% over the same time last year, which is a testament to not only the strength of the product, but also, quite honestly, the value that the product brings to the marketplace.

The volume growth, as you can see in the slide represented by the purple bar, is flattening. Now it is the volume growth that, if you look year on year, we are relatively flat; but you can also see at the same time, we are well positioned to take this product back to growth during fiscal-year 2015.

Why do we believe that? As I mentioned, there's three major areas we see growth for this product: in the number of hospitals that are utilizing it; the number of surgeries that it's used within; and the number of vials per procedure.

But the other thing to remember is that post the reset we have been able to retain roughly 95% of the 2,400 hospitals that had this product on formulary. And even in those instances where the product was removed from formulary post price reset, we have been able to rechallenge that; and in some of those institutions we have been able to bring the product back.

We have one of the industry-leading hospital teams out there dealing with our customers every day. They know how to navigate this, and they have been extremely successful in staying the course, communicating the value of Ofirmev, and ensuring that patients that can benefit from the product continue to have access to it as they enter institutions.

The real opportunity for Ofirmev and X XR, as Mark mentioned, is this whole idea of multimodal analgesia. This is an unprecedented opportunity and, we actually believe, a competitive position for Mallinckrodt.

As you can tell if you go all the way to the right side of the chart, surgery specialties managing in a group practice -- so we are in that group, we are highly focused on delivering the value message for Xartemis XR as well as helping them identify what postsurgical patients would benefit from that product. To give you an idea, that is roughly about 6 million prescriptions that are filled in that arena or surgery specialties in an office-based setting that is primarily driven through oxycodone-based pain products. So we see an opportunity for X XR to hyperfocus, continue to grow that business over time.

The interesting thing, however, is if you think about where we are focusing on surgeries and on surgeon specialties, that these surgeons actually perform the surgery in the inpatient hospital, in the inpatient setting. So we believe and we are in the middle of transitioning to this as well, is that our representatives will carry both Ofirmev and Xartemis into those surgery specialties and continue to build the momentum for Ofirmev as patients enter those institutions.

The other interesting situation that is occurring within the healthcare marketplace is you begin to see more surgeries taking place in an outpatient environment. So we will begin to cover those outpatient facilities, as well as our strong inpatient team, focusing on the hospital.

So we have a continuum of care story here which we believe actually cannot be met from our competition. That means we can take care of the patient as they enter in for surgery with Ofirmev; as they transition out into the outpatient facility and back into physician's care with Xartemis XR. So a significant amount of opportunity for us from a commercial perspective and a volume opportunity that we think will help drive our top-line growth.

At the end, this is really about being a competitive advantage. We take a space here in the pain business that allows us to provide solution for analgesic effect for those patients that undergo surgery and as they are discharged back into the community.

I look forward to answering your questions later. With that, I am going to transition to my colleague, Dr. Gary Phillips, who will go a little deeper into the Autoimmune/Rare Disease business. Gary?

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Good morning, everyone. It is a real pleasure for me to be here this morning. I have the distinct honor to introduce some of you and actually to reintroduce others of you to what is actually a quite fascinating, remarkable product: H.P. Acthar Gel.

Let's start off with -- what is Acthar? Acthar is a naturally derived, complex, biological product. It is actually a mixture of organic molecules.

Acthar has been on the market for over 60 years, and it actually currently has 19 approved indications by the FDA. It is a product which is approaching $1 billion in revenue; it is growing double-digit rates.

It is a biologic product, and it is indicated in some of the most devastating diseases where there is extremely high unmet need. Has a remarkable profile.

Even more remarkable is that today Acthar is only commercialized in nine of those indications. And actually if you look on the left side of the slide behind me, these are the indications in which it's currently commercialized. You'll see that they are actually in four specialty areas: neurology, nephrology, rheumatology, and pulmonology.

The way that Acthar is used is fairly far down the treatment paradigm, fairly far down the treatment pathway. It is going to patients who have tried other therapies and who really need the product.

The other thing that makes me quite interested and excited about this slide is that there are 10 indications and two specialty areas where Acthar hasn't even been commercialized. One of those areas, ophthalmology, is an area I actually know quite well. For six years, I ran Bausch + Lomb's global pharmaceutical business, and I know the devastating effects of blinding diseases like posterior uveitis; and Acthar has this indication on its label.

I think you will see from this slide that not only is it in a number of areas and being utilized today, but there are untapped opportunities, and I will talk about that a little bit more in a second.

Now that we know what Acthar is -- how is it made? The manufacturing process for Acthar is well established and it follows FDA Current Good Manufacturing Practices.

Let me walk you through the way it is made. As I said, it is naturally derived. Porcine, or pig, pituitaries are at the BioVectra facility. BioVectra is a manufacturing facility which is actually is subsidiary wholly owned by Mallinckrodt.

The pituitaries then undergo a bio-extraction process whereby active pharmaceutical ingredient is derived. All the while of the extraction process, there is actually constant quality and potency testing to assure that the product is having a biologic effect.

After the extraction process is complete, API is generated. API is then moved to a third-party manufacturer called Emergent BioSolutions. Emergent BioSolutions then takes the active pharmaceutical ingredient, puts it into its final form. Again, potency and quality is assured.

After that, it moves to a specialty distributor. And from the specialty distributor, it goes ultimately to the patients and to the doctors who need the product.

I think the two things that we need to keep in mind -- and I have mentioned one already -- is that quality and potency are assured at all steps of the process. The other thing to keep in mind is that the manufacturing and purification process, as well as the precise characterization and ratio of organic elements in Acthar remain a trade secret which is proprietary to Mallinckrodt.

Okay. We know what Acthar is now. We know how it is made. So who does it serve?

Again, these are patients who are suffering from devastating disease. If we add up just in the nine indications where Acthar is currently commercialized, we add up all the patients who have these diseases in the United States today, we come up with a number that is roughly 4 million. But as I said, not all 4 million of these patients are necessarily candidates or perfect candidates for Acthar, because it is used further down the treatment path.

If we just look, then, at the patients who are candidates for Acthar, kind of fall into that part of the patient population, that is around 300,000 patients. When you consider this 300,000 number, today Acthar is only used in about 3% of those patients: that is, 9,000 of the total 4 million across the United States in the nine indications alone.

So once we understand this diagram, we can then start thinking about the strategy. The strategy is pretty straightforward.

First, we want to continue to document and to publish clinical experience and evidence as well as the health economic and patient outcomes that Acthar provides. We have a long way to go in terms of penetrating the current indications in which Acthar is currently commercialized; so we want to grow the utilization of Acthar in the underserved but currently promoted indications, the nine that I discussed.

But as I said, there is a lot of untapped opportunity. There are another 10 indications, another two therapy areas.

So we want to initiate commercial efforts in the approved indications that have high unmet medical need. We will increase payer engagement to support reimbursement; that's part of our strategy.

Focus R&D investment. Because we believe that the current regulatory guidelines drive complicated development and make a generic to this product unlikely. So this product is a very durable asset in the Mallinckrodt portfolio.

So now we know what Acthar is, how it is made, whom it serves. Let's see what the commercial results have been.

As I said, it has been on the market for over 60 years, but only in fiscal-year 2012, around the end of fiscal 2011 -- Acthar was really only being used in the neurologic space. So you see the neurology sales represented here on the chart.

At the end of fiscal-year 2011, roughly around the beginning of fiscal-year 2012, the predecessor company initiated commercial efforts in a new specialty area, that is, nephrology, given the indications on the label. Once physicians became aware of the product and its utility in the patients who need it, sales followed.

So, now used in neurology and used in nephrology. So in fiscal 2013 the predecessor company said: Let's start to commercialize the rheumatologic indications; and there are five of those. Effort was made, physicians became aware, they started using the product in their patients. Sales followed.

Just this year, in fiscal-year 2014, efforts were begun in the area pulmonology and symptomatic sarcoidosis. And, as you would expect, we are starting to see sales.

So, every time the doctors become aware of the product, the indications that the FDA has approved, and the potential utility in these patients with high unmet need, we see sales follow. The other thing to note in this chart is that there is quarter-to-quarter variability, and that is the other thing that is interesting.

The trend is obviously strongly positive, but there is quarter-to-quarter variability. That is a bit -- a function of a number of things, including the seasonality of the health around these patients.

Now what? Now what does Mallinckrodt do?

Well, there is over 60 years of clinical experience with Acthar. But Mallinckrodt is committed to enhancing the science and technology investment, continue to develop the data and the evidence around Acthar and its indications.

In the past 3 years alone -- 3 to 4 years -- there has been over $190 million invested in science and technology around Acthar. This has resulted in over 300 funded studies.

As you would expect in R&D and in science and technology, there is a lag between the investment and in the results. So what you can expect in fiscal-year 2015 is a publication ramp-up as the result of the investment.

But we are not stopping there. We are going to actually accelerate investment in science and technology around this product.

There has been increasing year-on-year investment in science and technology. As you see on the right hand of this chart, in 2015 Mallinckrodt will accelerate this investment so you can expect over the 4-year period a 55% compound annual growth rate in investment behind the product.

What will be our areas of investment? Where will we focus? As you can expect, it follows along what I have already discussed.

We will invest in health economics and outcomes research. We will invest in clinical evidence around the indications which are already on-label. We will develop preclinical data that continue to show the evidence that Acthar is unique in its molecular action. And we will also consider branching out into new clinical indications were Acthar may provide benefit to patients.

This is Acthar by the numbers, and some of the numbers I have already reviewed with you. As I said, over 60 years on the market, 19 approved indications.

The other ones you may not know as well, is that if you look on clinical trials.gov, there are over 35 studies listed on ClinTrials.gov that have Acthar in them. There are over 140 studies of all sorts being run on Acthar in 2014 alone.

There have been over 80 publications referencing Acthar in the historical medical literature. In fact, if you look in the back of the presentation which we are providing you today, you will see a bibliography of Acthar, which references some of these 80 references I discussed.

And there have been more than 6,000 physicians who have used Acthar over the past 7 years alone. So we have a substantive body of knowledge around Acthar and one which is expanding.

Let me just take a second to take you through this slide. It is a little complicated.

On the top of the slide you see a timeline, okay? Then you will see diamonds under the timeline; and each of the diamonds represents a publication or a projected publication.

The blue diamond represents non-clinical and preclinical studies. The dark green diamond represents clinical studies which are Company-sponsored. And the light-green diamond represents clinical studies that are performed through an outside source, usually investigator initiated.

What you see is a lot -- you see that a large number of publications is planned over the next several years, a high density occurring in the next 18 months alone. So, we are very excited by this.

What will the focus be of these publications? In the short term, we will continue to document the different way in which Acthar -- the different molecular mechanism by which Acthar works. Differentiating it from steroids, because it is not a steroid.

In the medium term, we will continue to expand on the safety and efficacy data substantiating this product as well as to develop healthcare outcomes data and evidence as well. And over the long term, we are committed to strengthening the clinical confidence and the healthcare economics by a large number of studies from investment.

Let's get a little more specific here. If we look just on ClinTrials.gov and we look at the studies which are Company-sponsored and enrolling, there are two which I want to bring your attention to, because data should be coming out within the next year and because they have been completed enrollment and data analysis will commence shortly.

They are in two areas. One, amyotrophic lateral sclerosis, ALS, Lou Gehrig's disease. You probably know it because you dumped ice on your heads.

But ALS -- Acthar has been -- had a trial in ALS. That trial has completed enrollment, and the database will be locked and analyzed in early calendar-year 2015.

In systemic lupus erythematosus, there is an efficacy, safety, and pharmacodynamic study in 36 patients which is double-blind, randomized. Again, this is a study which has completed enrollment; database lock and analysis will occur in calendar-year 2015.

You see the other two, which are kidney diseases. So these are some of the publications or some of the data which you can expect in the relatively short term.

If we turn our attention to reimbursement, Acthar reimbursement will continue to be important to reach the underserved addressable patient populations. I want to explain the left-hand side of the chart first.

On the left-hand side you see a fairly complicated bar and line chart. The way you read this is from fiscal 2012 to fiscal 2014 on a quarterly basis, the stack bars represent -- and off the left y-axis -- represent the growth in prescriptions, or the growth in referrals for Acthar. Again, this essentially concurs to the revenue slide I showed previously.

But what is even -- what is equally important is that volume has grown while reimbursement among payers has remained relatively consistent across the years. That is represented by the blue band and the green line at the top.

So even as volume has grown, reimbursement has stayed consistent. Well, why?

It is a function of how Acthar is used, when it is used, and where it is used. It is also a function of the fact that our predecessor company established a strong foundation: a support network which was established to help patients with the reimbursement process, with a primary focus on appropriate access and accelerated reimbursement time so patients get the product when they need it.

We will at Mallinckrodt continue this, but we were going to build on it as well. As Hugh talked about, we do a lot of work in the areas of access and reimbursement already in our base business. We plan to engage with payers at plan-wide policy level, demonstrating the benefit of Acthar, documenting and communicating patient benefit for treatment, and publishing clinical experience and health outcomes.

So now you have heard a little bit from me about the business and about the product. But what I want to do -- you hear a certain amount from me, but it is best to hear from the doctors and the patients who use and benefit from this product.

So I am very pleased and honored to welcome to the stage two of the prescribers of Acthar. We have Dr. Jim Tomlin, Dr. Todd Levine, who are going to say a few things.

Let me first introduce Dr. Jim Tumlin. Dr. Tumlin is a Board-certified nephrologist who has been using Acthar for a number of years. He has a practice and research institute, Chattanooga, Tennessee.

What I want to do is just have Dr. Tumlin share some of his thoughts around Acthar. Dr. Tumlin?

Jim Tumlin - *Southeast Renal Research Institute - Medical Director*

Thanks, Gary. Well, good morning, everybody. As Gary said, I am Jim Tumlin; I am a Professor of Medicine and Nephrology at the University of Tennessee. And I want to thank Mallinckrodt for the opportunity to give my experience in treating nephrotic syndrome with Acthar Gel.

Okay, before we get started on this I thought I would give a primer and a background on what one of the major indications for the usage of ACTH Gel is. It includes nephrotic syndrome.

What is the nephrotic syndrome? The nephrotic syndrome is a clinical condition; and it is important that the audience understand it has multiple different mechanisms and diseases that impinge upon it. But it's characterized by the loss of protein in the urine.

Now hopefully for you and I and myself included we never have more than 150 milligrams of protein in our urine. By definition, a person with a nephrotic syndrome has over 3,000 milligrams of protein per 24 hours. In my personal career, I have seen patients have as much as 60,000 milligrams of protein, really devastating numbers.

As a consequence of this, there is a lowering of serum albumin in the blood due to the protein losses. There is also a rather profound hyperlipidemia -- so elevation of cholesterol and triglycerides. Cholesterols can be well over 1,000 in these patients.

And probably one of the most debilitating aspects of the disorder is anasarca, which is generalized swelling of all of the tissues of the body. This is a cartoon to give you a diagram of this. This is one of the real problems for most patients, is persistent lower-extremity edema that is quite uncomfortable, oftentimes painful.

But it is not limited to the extremities. This fluid accumulation can occur in the abdomen, causing what is referred to as ascites. It can collect around the outside of the lungs and outside of the heart as well.

Now, this is not at all to be an exhaustive list, but it is an idea of the many types of glomerular diseases and renal diseases that cause the nephrotic syndrome. Diseases such as amyloidosis, which is an abnormal protein deposition disorder; the very familiar diabetic nephropathy; membranoproliferative, focal segmental glomerular sclerosis, which is a disease that is increasing in prevalence particularly in the African-American community; lupus; IgA; and other disorders.

It is important to understand that there is a growing body of evidence that looks at the corticotropins. Target of action may in fact be a cell called the podocyte; and this cartoon is to give you an idea of what happens.

Any type of injury that affects the podocyte leads to either its cell death or its detachment in the kidney, leading to the possibility of proteins going directly through the blood, through the kidney, and into the urine. This unchecked level of proteinuria brings about the nephrotic syndrome and often contributes to progressive renal disease and possibly dialysis.

This is another cartoon to give you an idea. The red cell is actually the podocyte. And this is just a listing of the multiple different types of injuries that can affect this cell. So any type of therapeutic maneuver that spares the functionality of the podocyte can potentially benefit the patient.

The corticotropins, are they potential podocyte stabilizers? Again, there is a body of evidence that in fact the corticotropins work through multiple mechanisms; it does not involve simply the release of cortisol.

There are five different melanocortin receptors, and this cartoon demonstrates to you that they are expressed broadly throughout the body. In the adrenal glands, the melanocortin 2 receptor releases intracellular blood levels of cortisol.

But if you looked at -- MCR 1 and MCR 3 are also expressed in the inflammatory cells, including T cells, B cells, natural killer cells, and explains in part an independent immunomodulatory effect of these agents. In the kidney, there have been two different melanocortin receptors identified, MCR 1 and MCR 5, which there are active investigations on to delineate the mechanism of this drug in the kidney.

This is a complex cartoon, but it really is to illustrate for the audience two central points. That in corticotropins through its activation of the MCR 1 receptor could stabilize very important proteins, one of which is called synaptophysin -- in the yellow -- that is involved in regulating protein losses. And the second effect of the corticotropins is to prevent the cell death of the podocyte. Again, by improving its function and preventing cell death, it may in fact have a direct effect on the proteinuria.

This is again just in my personal practice diseases -- this is not exhaustive -- of what I have been using Acthar Gel for. Membranoproliferative GN, focal segmental GN, membranous lupus IgA, and C1q nephropathy are all diseases that I have Acthar experience with this.

But having said that, I think what I will do is let -- Suzanne is supposed to come up and is a video of one of my patients that I have been treating. She was a referral from a private physician who had had nephrotic syndrome for over 37 years until we used Acthar Gel on her. And I think her words will be best to explain it. (video playing)

Just in closing on my comments -- and that is just an example; Suzanne has become a dear friend of mine. One of the great joys for a physician is to see a really refractory disease come under control with new agents. So we look forward to seeing additional aspects and furthering of this product in the nephrology realm. Thank you very much.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Thank you. I love hearing from the providers as well as seeing the videos of the patients, because in the end that is what we are here for, and it really reinforces for me the remarkable product that this is.

What I would like to do, though, is to turn to another provider, another physician who you has been using Acthar, Dr. Todd Levine. Dr. Todd Levine is a Board-certified neurologist. He actually specializes in neuromuscular disease. He has a research institute, and his practice is in Phoenix, Arizona.

So I would like to welcome Dr. Levine to the stage to also share his impressions of the product. Thank you.

Todd Levine - *Banner Good Samaritan Medical Center ALS Clinic - Director*

Well, thank you for having me this morning. Actually I'm not going to have any slides; I am just going to talk a little bit.

I thought what I would try to do is to give you a view of the patient's perspective and the physician perspective in treating poly and dermatomyositis and where Acthar may have a role in that. So, I think the first question is: well, what is poly and dermatomyositis?

What we know about it is that it's an autoimmune disease. A patient's immune system, which is supposed to fight bacteria and viruses, for some reason decides to start attacking the muscle.

And even though we talk about poly and dermatomyositis in that way, we actually know that it's a really broad group of diseases. So when you ask: Well, who gets it? It could be children in dermatomyositis all the way up to 80-year-olds with polymyositis.

We know some patients have cancer as a trigger for having this disease. We know some patients have abnormal antibodies; and the number of those antibodies now is over 20 different antibodies that patients can have, but they all manifest in the same way. So the important message there is: these are complex group of diseases, and we need a broad variety of different medications that can target the triggers in the different patients.

The way that a patient might typically present is with gradual weakness, and this can present over weeks or sometimes months. But the patients will lose the ability to walk; they can lose the ability to use their arms; they can lose the ability to swallow.

In some patients with these diseases, it also involves the lungs. So they can have scarring in their lungs that can be very severe. In the patients with dermatomyositis, they get a very severe skin rash, which is painful and often leads to complete baldness in some cases.

The patients usually end up in one of two sets of doctors' hands. They either come to neurologists or rheumatologists; and it is about 50-50 split.

The diagnosis is usually not that difficult, so that we see a patient with progressive weakness, there are specific blood tests you can show that shows that the muscles are being damaged; and then that usually leads to a muscle biopsy. And once you have the muscle biopsy, what you see is that there is inflammation in the muscles.

But that inflammation, again, often looks very different from one patient to another patient, which is another argument that the specific trigger that is causing the damage to the muscle can be very different.

The patients are usually pretty scared by that point. I have seen patients that are quadriplegic and in the intensive care unit on a breathing machine with these diseases. Or some patients present a little more subtly, where they are now in a walker or a wheelchair.

But over 3 to 6 months people have just not been able to find the answer. So what the patient wants, obviously, is to be made better.

One of the nice things about this disease, unlike some of the other diseases I treat, like Lou Gehrig's disease, is this is a disease that most people we can make better. So as physicians, we like to treat them.

The typical starting pathway for these patients is going to be corticosteroids. Corticosteroids have a number of advantages in treating this disease. They are cheap; they are easy for patients to take because they are pills; and they work pretty quickly, meaning in weeks or months patients can do better.

So across the country physicians will say: that is where we start. The problem is about half of patients may have difficulty tolerating corticosteroids or may not respond to corticosteroids. Once you get past that first decision point, the only other FDA-approved medicine to treat poly and dermatomyositis is Acthar.

Now, physicians use many other off-label medications to treat this disease. There is very poor data and there are, again, no indications for those, because there are just not good controlled studies.

So it becomes a matter of trying to find the right medicine that is going to work for the right patient, and that often requires trial and error, and it's very frustrating for patients. Because if you choose the next medicine after corticosteroids, it could take 3, 6, or 12 months before you know if that medicine is going to work.

During that time, the patient is bedbound or homebound or nursing-homebound. And then if that one doesn't work you go to the third choice and the fourth choice.

So many of these refractory patients require multiple different medications before we are able to find one that works for that patient. So it is a little bit of trial and error because we just don't understand the pathophysiology of how the immune system is really targeting the muscle in these diseases. So we need to have those different treatment options.

What I would like to show you is actually one of my patients, again, who I have taken care of for many years. When she initially presented, she presented with severe muscle weakness and lung involvement and was in the hospital. After trying multiple medications, we were able to put her on Acthar; and I think you can hear in her own words how she felt about that. (video playing)

Obviously, those are great patients for us, and it makes what we do enjoyable. She has continued to do just exceptionally well, and I think it really points out the fact that even though we have multiple medications available for these patients, it is a matter of trying to find the right medicine for each patient. And the physicians really have to be able to make those decisions with the patient together and embark on this process together. I will turn it back over.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Thank you. Again, it's remarkable the effect that the product has had for these two patients with these quite debilitating diseases.

Before I let you go off the stage I do want to ask each one of you a question. Luckily it will be the same question; so Dr. Tumlin, you get some time to actually consider the answer.

Jim Tumlin - *Southeast Renal Research Institute - Medical Director*

Okay.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

So, Dr. Levine, in your estimate or in your experience, as you think about Acthar and Mallinckrodt's ownership of this asset, what are the greatest challenges and opportunities for us and for the product?

Todd Levine - *Banner Good Samaritan Medical Center ALS Clinic - Director*

I think the greatest opportunity is that clearly Acthar has a broad spectrum of potential biological effects. I think the slide that Dr. Tumlin showed you showed that just one of those mechanisms works through steroids, and there are these other melanocortin receptors which really have been elucidated in the last 20 years that have broad effects, from kidney to immune system to brain. And what that means really is that there is the potential for Acthar to have benefit for many patients that suffer from these diseases.

I think that is also the greatest challenge, which -- as I hope I made the point in my presentation -- not every patient with polymyositis is the same. And not every patient with dermatomyositis is the same.

There is no autoimmune disease where that really can be said to be true, and so you have to have available as the physician an armamentarium of agents that you can use to target different parts of the immune system. So I think the challenge for Mallinckrodt is to continue with that research and allow us to identify which are the best patients for Acthar.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Okay, thank you. Dr. Tumlin, what are your thoughts?

Jim Tumlin - *Southeast Renal Research Institute - Medical Director*

Yes, I would agree with Todd and echo many of his sentiments. I think another potential benefit for Acthar is that, because it has more than one corticotropin in its mixture -- so the very real possibility, to Dr. Levine's point, of simultaneous activation of more than one melanocortin receptor type giving you a specific biologic effect is a real strength.

I think one of the disadvantages, the very nature of the type of illnesses that Todd and I treat are, by nature, very rare. Therefore deconstructing and finding out those symptoms and doing it in clinically controlled trials will be difficult, simply because the patient numbers are in fact limited.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Okay, thank you. Thanks so much. What I want to do is just wrap up here before I turn it over to my colleague. I hope that after this short stint this morning, hearing from me, hearing from doctors, hearing from patients, you have the same kind of enthusiasm that I do for this product and for the opportunity around it.

We believe that Acthar is a durable asset and it has tremendous, significant, untapped growth potential. We are going to reach underserved patients in the current indications; and in particular, as I said, the efforts around rheumatology and pulmonology have just begun, and the areas of ophthalmology and dermatology have not yet begun. So we think there are areas to capitalize on growth opportunity.

We are going to invest in R&D. We are going to solidify and enhance our publication strategy, to continue to develop the evidence in the experience and use of this product.

We are going to support the reimbursement access for patients that are appropriate, who need this product. And we will continue to invest in infrastructure to continue the quality and the potency of this product in an uninterrupted way.

So with that, what I would like to do is turn to my colleague, Matt Harbaugh, who is our Chief Financial Officer. Matt?

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Thank you, Gary.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Thank you.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Thank you and good morning. I hope you all had a chance to see our guidance from this morning that we put out on the release. Just wanted to give you some color around the financials and hopefully ward off some of the questions you may have in mind after having looked at the data this morning.

As you can see, our adjusted diluted earnings per share guidance is $6.70 to $7.20 a share. And I will walk you through the P&L, so let's start with sales.

For our Specialty Pharmaceutical segment, you have to go one layer down below the top line. I will just walk you through some of the key product categories.

The first would be Xartemis XR. As Hugh mentioned earlier today, that product is going to take some time to build. It is a CII product. We have had modest sales in this fiscal year, but we have got a long exclusivity period for Xartemis XR; so some of the predictions in the marketplace are higher than what we have in our own internal models.

I would also encourage you, as you are thinking about modeling MNK-155, to also recognize that this is now a CII product as well and so that launch curve is going to take time. This being said, we've got fantastic intellectual property protection on this product, so we've got plenty of time to build it.

Exalgo is a product that I was at the Company when we launched and, again, it took some time to really get that launch going. But obviously we were happy with the results when it was all said and done. The difference this time around, though, is that we have got a much longer runway here for this product.

Turning to Ofirmev, very excited with what we can do with Ofirmev, as Hugh mentioned earlier. As we look at the analysts' reports that have come out on Ofirmev, they are actually in the same range as we are.

Everyone is centering in the same data set, and so it seems like everyone has really gotten their mind wrapped around the volume/price trade-offs that are occurring with that product category. So it should be a good year of growth for us as we move forward into next year.

Turning to Acthar, we anticipate Acthar will continue to be a double-digit growth product in our portfolio. As Gary mentioned in his prepared remarks, we have other therapeutic areas to explore as we move forward into the future; so a pretty strong, robust outlook for Acthar as we move forward.

Methylphenidate ER. I am very pleased to report to you today that we were able to exceed the guidance that we provided on our last earnings call. Just to make sure everyone is level-set, we had said methylphenidate ER would be no less than $190 million in revenue; and we were able to exceed that. So a very significant product for us in the portfolio this year -- and last year, as I am sure many of you remember.

As we think about 2015, we are hopeful that methylphenidate ER will land in the same zone as to what we have seen this year. So a very strong product for us.

I also want to highlight that Pennsaid should be removed from your models. You may or may not have seen the fact that we had a settlement that we were very happy with as it relates to Pennsaid; so take that data out of your model. We didn't see a lot of people focusing on that particular settlement, therefore we thought we would highlight it today.

Turning to the Global Medical Imaging segment, my guess is we are going to read some reports later today that there is a bit of a surprise around the Global Medical Imaging segment as it relates to the top line. I want to go back to the base, which is -- this time last year we were talking about our restructuring program, and that restructuring program, just to get everyone on the same page, was $100 million to $125 million, and that was over a 3-year period. Through the end of June -- so 1-year anniversary of that program -- we had used $70 million of that reserve.

As we move forward in 2015 and 2016 under that 3-year program, two things are going to be a bit different from what we have seen historically. The first is we are going to see more charges incurred against that reserve going against our cost of goods sold. We spent a ton of time over the last few years looking at ways to streamline our cost of goods sold base. And even though we have brought in some really attractive margin products with Ofirmev and Acthar, we still need to work against that Mallinckrodt base of cost of goods sold.

As many of you know, when we came out our gross profit as a percent of sales was below 50%. So we have got some work we can do there to further streamline our operations and improve our cost of goods sold profile.

The other area -- and I hope you feel we have been transparent about this -- this time last year we were in 90 countries in the Global Medical Imaging segment. If you look at our public filings over the last 3 to 6 months, you will see that we are in 65 countries.

The reason that is dropping is that once we were spun we actually were able to activity base cost out every single country in which we do business in. And what we realized is we were doing a lot of business in countries where we were not driving a return for our shareholders.

We have said all along we are managing the Global Medical Imaging business for cash. So when we are restructuring we are trying to drive more cash and, hopefully, supplementing our operating income in that segment.

The other thing that is going on in there is we do have a third-party supply agreement that has had about, roughly, historically in the $50 million range. You are going to find we are going to have a charge in our fourth-quarter results, which we will share with you in November, that we are actually leaving that contract.

The driver behind that is we weren't making any money. So there is no reason to have hollow revenue within the portfolio. We have got a lot of great products that we can grow in Acthar and Ofirmev and Xartemis longer-term, so we are really trying to reshape the portfolio as we move forward.

Turning to the tax line, I just want to take everyone back to a year ago May. If you take the median of the tax guidance that we gave at that time, it was a 30%; we gave a range of 28% to 32%. As you can see over the last year and a half, we have gotten great efficacy in our tax line.

We still have more work to do. As we have said, we want to glide-path the tax rate down over time. But we have had a very significant decrease just in our 18 months or so since we gave that guidance.

One thing that is really important and timely for me is that our reported tax rates and the guidance that we are putting in front of you today does not reflect any benefits from the use of a double Irish structure. That is not a structure that we have used, so we feel comfortable with the guidance that we have provided to you today.

My final comment around capital expenditures: What is going on in the capital expenditures? This is very consistent with what we have presented to you before.

We are actually reducing our infrastructure investment in Global Medical Imaging and we're moving those dollars over to our Specialty Pharmaceuticals segment, particularly focused on supply chain in Acthar. So we feel good about that reinvestment cycle as we move forward.

Two final comments before I hand it back over to Mark. The first is we hope to continue to get more leverage out of our SG&A, driven by the restructuring program. And our R&D spend, it will go up in aggregate dollars year-over-year and will continue to be in that range that you have seen historically from us, in the 6% to 8% range.

I look forward to taking some of your questions, but for now I will hand it back over to Mark.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Thank you, Matt. Let me just take a couple of minutes to close the formal part of our presentation. Let me summarize just quickly a couple things that you have heard today.

First and foremost, it should be quite clear that Mallinckrodt is focused on driving value for shareholders and patience. We have truly tried to emphasize how we are going to do that.

You heard a strategic overview from me, how we think about our business, how we have developed growth platforms for the future, and how we are going to drive value across each one of those platforms. You heard in some detail from Hugh O'Neill, who is the President of our Specialty Pharmaceuticals business, how we are excited about the opportunity to drive value and volume by a synergistic approach focusing on surgery and a continuum of care, providing options with both Ofirmev and Xartemis XR to treat surgical patients in both the inpatient, the outpatient, and the office-based setting.

You have also heard from Gary Phillips on how we think about Acthar and the opportunities to grow Acthar, a product that we think is very highly durable and also has a number of indications which are currently being promoted, driving that growth, but a number of other indications that we think provide growth opportunities for the future. You heard from Gary the way we are going to invest in the commercial business and how we are going to drive volume for Acthar across our commercial platform.

But you also heard about the investments and the focus we are going to create out of our scientific platform. We talked about science and technology. Recognize that is both investments in research and development as well as medical affairs, with a big focus on publication of data that has already been created through clinical experience for Acthar.

You also heard Gary speak a bit about how we think about access for Acthar going forward, and the fact that access and reimbursement for Acthar has continued to be consistent across all payer types for the last number of years as the product has continued to grow across a variety of indications. I thought it was particularly interesting to hear from the physicians who are actually treating Acthar patients, and you heard from some of those patients themselves on how big a difference this product can make in the lives of these patients who are faced with some very devastating diseases.

Of course you heard from Matt, giving some color on our 2015 numbers and how our guidance around both the revenue and earnings per share stack up across our businesses. So we are quite excited about the opportunity to drive value for shareholders in 2015.

Let me just now take a minute to summarize for you where Mallinckrodt is going and what to look for from us in 2015 and in the future. Recognize that we believe we have set up a solid set of growth platforms for our business.

We have created essentially a well-diversified platform in Specialty Pharmaceuticals, creating products that have high durability, fast growth, and great profitability. We think that is a winning recipe for creating value for shareholders.

You can see that we are going to drive a lot of value through our pain portfolio in both the office and the hospital-based arena, but a lot of volume growth opportunities for Acthar. But it is also important, while we are developing the assets that we have -- whether they have come from our own research and development activities or whether we have acquired them -- to continue to be aggressive and opportunistic with regards to business development and licensing. Again, we have set up these platforms for growth with a very nice specialty model, and we can drive efficiency by acquiring additional assets that are undervalued and put these into our platforms, essentially without taking on any incremental SG&A expense.

I think you have also heard from Matt that we are very proud of the fact that we have really been able to deliver consistently. We have been able to execute on our strategy and our operations consistently over the time that we have been an independent company. And that has enabled us to simultaneously drive growth in our portfolio but enhance profitability.

Essentially, we operate a very lean and efficient business model, and we are going to continue to drive that lean and efficient approach going forward. Again, our objective is to really consistently deliver top-quartile performance based on total shareholder return. We don't have to be the largest Company or the fastest-growing or the most diversified, but what we really focus on is creating value.

Thank you all very much for your time and attention regarding the prepared portion of our presentation this morning. We are now going to move into a Q&A session, and I would like to invite to the stage Matt, Hugh, and Gary; and also John Moten to help us manage the Q&A process.

John Moten - *Mallinckrodt plc - VP IR*

Thanks, Mark. I'm going to give some brief instructions on how we are going to manage the Q&A process this morning. There are two ways you can ask questions. We have some colleagues in the audience who will have mics, where you can feel free to ask your question. We would ask you to state your name as well as your firm affiliation.

In addition to that, if you would also like to ask a question, you should see a white index car where you can also write questions as well. So with that, we can begin the Q&A session. Marc?

QUESTIONS AND ANSWERS

Marc Goodman - *UBS - Analyst*

Hi, Marc Goodman at UBS. So, Gary, can you talk about what is changing with respect to the sales and marketing for Acthar versus what Questcor was doing? What are the big changes? Can you talk about the number of reps before, and what you have now, and what the plan is?

And you pointed to ophthalmology and dermatology as new potential opportunities. When do you plan on starting to move into those areas?

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Sure. Some of the questions I will answer specifically and some questions I won't, so let me just lead off with that.

Questcor I think did a fine job of building the revenue year-over-year; and I showed the one slide that showed with promotional effort come revenues. In a couple of those areas, as I referenced, both in rheumatology and in pulmonology, the salesforce size is relatively small. In pulmonology it is just a handful; in rheumatology it is small, not fully developed in terms of number.

So the one thing we are thinking about just in the next fiscal year is to expand significantly the salesforce size in both of those indications or both of those therapy areas or specialty areas, so that we can reach more physicians, we can reach more patients. So you will see us increase our sales reps in both of those areas.

In the areas of neurology and nephrology, they are both still growing; there is still opportunity. As I said, they are relatively underpenetrated in those areas. But we think that the salesforce size is reasonable; it is appropriate.

In terms of the next therapeutic areas in ophthalmology and dermatology, the nearest term will be ophthalmology. As I said, from my B&L days, diseases like posterior uveitis and optic neuritis -- though optic neuritis is probably being treated already through the MS specialists -- but in posterior uveitis, this is a blinding disease, affects young people.

And any therapeutic option that can help people to restore their vision when they are blind I think is a remarkable product. So we are going to explore expanding into ophthalmology now in the next fiscal year.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, just to add a little bit of color to that, Marc, keep in mind in rheumatology Acthar actually has five separate indications, right? And while the salesforce that we have in place has been primarily focused on just a couple of those -- and in particular lupus, for example, is an emerging indication

where we really haven't focused quite a bit. So as Gary said, there is clearly an opportunity, we believe, to invest further in commercial activities around rheumatology to fully exploit that set of five indications.

Again as Gary said, our efforts are -- the efforts in pulmonology I would characterize to this point as being largely in a pilot fashion. And the pilot has actually proved to be quite interesting, and so therefore we think it makes good sense to further expand the investment in pulmonology to cover more broadly the full pulmonology universe of prescribers based on the result of the pilot.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Yes, that's right.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

I would add we are well on our way for driving G&A out, both with the -- both acquisitions that we have done over the last 6 months. So much like you saw a year ago how we were trying to chip away at all that corporate cost that was required to be spun, we want to accommodate all the reinvestment in sales and marketing wherever possible because we have got a product here that is growing double digits. But we can get some more leverage because we have got some G&A opportunities.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

In each one of these specialties, as you can imagine, there aren't a lot of targets. So you can really cover the universe of prescribers with relatively small salesforce size.

John Moten - *Mallinckrodt plc - VP IR*

Gregg?

Gregg Gilbert - *Deutsche Bank - Analyst*

Hi, gentlemen. It's Gregg Gilbert from Deutsche Bank. On the business development front, are you operationally and financially ready to do another significant deal?

And given the number of platforms you have, can you focus us on any particular areas that you would like to leverage sooner rather than later? Thanks.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes. Let me start with our strategic intent around business development and where we are focused, and then I will ask Matt to comment a little bit on our financial capabilities. From an operational standpoint, we are fully capable operationally on taking actually a number of additional acquisitions onboard if we chose to do that.

Again, what we are looking for are undervalued assets and, as you can imagine, those aren't particularly easy to find. But we have a pretty well-established process now for identification and evaluation of those assets. Of course, given the fact that we have now actually acquired three different companies, we have developed an integration capability to rapidly create value as a result of the integrations.

The way we have structured our business along these platforms, you can see that we could take on different acquisitions in different parts of the business simultaneously. But the way we would tend to think about this is in areas where we have got a bit more of a mature portfolio or where we have bedded in some of the recent acquisitions, those are the places where we feel quite confident that we could add something on top.

The way I would characterize that is certainly anything in our pain portfolio, anything in the hospital arena, anything in our generics business. And within the specialties that Acthar is used, particularly neurology and nephrology, which tend to be the more mature indications, those would all be areas that would make good sense for us strategically. We would be certainly capable of bringing additional assets into those categories.

So again, we are less concerned about the size of the acquisition or our ability to integrate. We are more looking at things that we think are undervalued, where we are the best owners and we can create immediate impact as a result of bringing the products onboard.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Yes, Gregg, to add on to what Mark just said, we finished the year -- and we'll be sharing more with you -- I will give you more color on this in November when we do the fourth-quarter earnings call. We had a little over $700 million in cash in the bank, if you will, as we finished out this fiscal year.

So for opportunities in that $1 billion or less range, more than likely the balance of that would be financed with cash, because the cash keeps coming in. And that is really driven by the base specialty controlled substance generics business, combined with Ofirmev, because Ofirmev did turn positive as we have talked about, combined with Acthar. So you have got a couple engines there that's generating cash.

As I think you and I talked about at the time, we also put out a release shortly after the acquisition of Acthar, bringing that into the portfolio, and our net debt leverage at that time was around 3, 3.1. So I have given you the cash balance, so that can give you a good sense as to the amount of opportunity that we could go pursue.

Obviously, with the deal that we structured bringing Acthar into the portfolio, we did use equity at that point in time to keep our balance sheet in order.

John Moten - *Mallinckrodt plc - VP IR*

David?

David Maris - *BMO Capital Markets - Analyst*

David Maris with BMO. Maybe for Gary or Mark, on Acthar you showed a slide that show the number of potential patients; then you mentioned that about 6,000 physicians had experience with the product. You mentioned about 9,000 patients are currently on the product, which -- I didn't do the math -- but about 1.2 patients per physician that's used the product. Which would mean a lot of physicians have dropped out or presumably haven't signed up a lot of additional patients.

So just playing devil's advocate, how would you look at -- or how would you respond to someone who says: Well, look, Acthar has been on the market for a long time; you have a large patient population; but the penetration rate is extremely small.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Yes, so I will start, and maybe Mark (multiple speakers).

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Sure, yes.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

So actually --

John Moten - *Mallinckrodt plc - VP IR*

Gary, before you begin, David, I also want to highlight the fact that we do have Dr. Tumlin and Levine; they might be able to give you some physician perspectives on that as well.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Yes, let me just re-correct, just correct the numbers. There are around 3,000 active prescribers today and 9,000 patients; so roughly three patients per prescriber.

The issue has been, I think, awareness of the product and its utility. I tell the story -- just before I joined Mallinckrodt, which is about a year ago, when we were looking -- and I was running the business development and strategy function, we were looking at potential targets for M&A. And for the first time, actually, I was made aware of Questcor and Acthar.

Never heard of it. Here I am, having practiced medicine, went to medical school, did my training, been in industry 25 years, I never heard of Acthar or Questcor.

And then when I heard about it, I said: okay, ACTH, I get it. Steroids.

The thing that got me really excited was when I realized -- I actually think that the steroid story has clouded what Acthar does or the way in which it's different than steroids. Because as physicians you are taught ACTH stimulates the adrenal cortex, releasing cortisol, and that is the mechanism by which it works.

What I think -- what got me excited was when I understood the melanocortin story, and then also the fact that biology is complicated. It is dirty in some ways, and this product works in a very interesting mechanism.

This product -- early in my career, I worked at Wyeth, I knew of -- I know Premarin very well. This product has Premarin-like characteristics, ensure its durability. So the combination of the emerging science and the durability of the product -- I just got really excited about this.

And the more I probed into it, the more I understand that, as physicians understand this is not a steroid story, it is a melanocortin story, believe that that -- the evidence and the mechanism, and also the results in the patients, will drive additional use. But I would turn to --

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Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, let me just add one quick thing to that and then certainly ask the physicians to comment. The numbers here shouldn't be surprising at all. I mean, think about the fact -- that is how we described Acthar and the way it is used. It is a product that is used for rare diseases.

So consequently, any individual physician may only see a patient or two a year that is even a candidate for Acthar. So it is not surprising that you have some physicians that in a given year will treat a patient; another year they mightn't, because they just don't see that patient.

As Gary said, the average numbers are what he described. If we look at the active prescribers, about 3,000; 9000 patients; three on average. But of course there is a lot of variability there.

Again, you heard that from the physicians. With the type of the disease, the rareness of the disease, the fact that Acthar is typically used for patients that are pretty far down the treatment paradigm, the actual available population for any individual physician is going to be pretty low. Gentlemen, do you have something to add?

Todd Levine - *Banner Good Samaritan Medical Center ALS Clinic - Director*

I think in neurology, there is two ways to think about that. One is in multiple sclerosis, where most neurologists will treat MS, but a typical course of Acthar for a patient with multiple sclerosis is 5 days long or maybe 10 days long at the most. So even if you are treating many patients, if you look at the active number of patients that are being treated at a given time, one prescriber may have multiple patients. So that is number one.

Then I think in the other diseases, the autoimmune diseases, where patients need more long-term treatment, I think those are where the studies are coming out now. And again, in my experience like with Charlotte, I have been able to leave her on therapy for a year to a year and a half, and she continues to do well.

So in neurology we have had this difference of experience between short-term treatment in MS and now longer-term treatment where you will see patient numbers grow as doctors become much more comfortable with the drug.

Jim Tumlin - *Southeast Renal Research Institute - Medical Director*

Right, yes. It's a very similar thing also with the nephrology. I mean, I think your statement is quite right: the drug has been around for a long time, but really a pivotal study was in 2008 when the melanocortin pathways were looked at and membranous GN really took off.

That is when -- so really the exposure to nephrology has been a relatively compressed period of time, 5 to 6 years. And the understanding of the complexity of the melanocortin systems and how it plays a role in podocyte function is constantly being elucidated.

So again, back to Mark's comment, I have had one or two C1q nephropathies in my academic career, and so -- that's it. I have had them, and I have seen them, and they had been prescribed both drugs and have had very good outcomes with it.

So again, it is important to remember these are rare disorders.

John Moten - *Mallinckrodt plc - VP IR*

Doug?

Doug Tsao - *Barclays Capital - Analyst*

Thank you. Doug Tsao from Barclays. Following up, maybe Gary, if you could help us understand in terms of the universe of prescribers, how about -- or going away from thinking about the universe of potential prescribers, how many do you think are unfamiliar with the product versus those who know about the product but for whatever reason aren't using the product and need to be reeducated perhaps on the product?

Then perhaps a follow-up for Matt in terms of your thinking in terms of volumes for Ofirmev through the course of the year, now that we have seemed to have hit a trough.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

With regards to the universe of potential prescribers, I don't know the exact numbers, honestly. I know how many prescribers are out there; but I don't know how many of those doctors actually know about the product.

My hypothesis is that relatively few understand the product and how it is used and the benefit it provides. And that is really the challenge or the opportunity I think that exists for me in leading that business, is to go out and get the word out and understand, and have many of the other doctors having experiences like Drs. Levine and Tumlin.

So I don't know the exact numbers, but I think it is a relatively small number.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Doug, the way I would think about this is, much like any other drug that is prescribed, you cover the universe. Typically a certain set of physicians prescribe it and a certain set of physicians don't, whether it is Acthar or any other drug. We see that with Ofirmev, with Xartemis, and every other drug.

So again, the fact that you have had thousands of physicians prescribing the drug over a number of years across a number of indications gives us good confidence that there is tremendous opportunity as we continue to invest in commercial and scientific activities to further inform those physicians that have had some experience about the options; but also to continue to demonstrate with the scientific and clinical experience for those physicians that haven't yet.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Yes, Doug, as it relates to the your Ofirmev question, I am going to turn it over to my colleague, Hugh O'Neill, and then I will come back with a few comments.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

Doug, you are right. What we have seen now, post the reset, is we have seen the bottom. We think we are in the bottom, the trough of the volume loss erosion in growth rate. We are confident based on what I shared with you about the formulary position, as well as the ability to penetrate increased hospitals, number of surgeries, and number of vials that we can get back to growth rate during fiscal-year 2015.

The reason we think that way is synergistic effect between both products -- both in the surgery specialties as well as in the inpatient facilities as well as the outpatient facilities -- will allow us to get to physicians earlier on the surgery side as well as increasing the ability to demonstrate the value of the product. So we feel confident that you could see back to historic growth rates by the back end of fiscal-year 2015. I think that is a fair assessment.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Yes. Doug, that is absolutely right, and I think the analysts are pretty close. As I mentioned in my remarks earlier, that we look at all the estimates and they are -- everyone is thinking about this product the way we are.

The one area that does give me a bit of pause -- and Gary brought it up in his presentation -- is the calendarization, now that we have given guidance. The calendarization of the quarters is really important to think about at this point in time.

You saw the variability in Acthar, particularly in our second quarter. It just naturally has some challenges to it.

As you know, Mallinckrodt had a phenomenally strong third quarter. Acthar had a phenomenally strong third quarter.

For Mallinckrodt base business, our first quarter tends to be one of our tougher quarters. So I would encourage everyone really to look at calendarization.

But as it relates to Ofirmev, can't wait to share with you the results in November for the fourth quarter; but I would say that back half of the year is where you will likely hear us talking about what those volume rates are.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, the thing I would add here is this whole pricing reset strategy I think has played out exactly as we expected. In fact, it has gone a little bit better than we expected.

What Hugh is referring to is -- again, if you look at volume, year-over-year it is essentially flat, same period this year versus same period last year. What we show is that from peak to trough -- and we think we have now hit the bottom of the trough -- there has been roughly a 20% decline only from peak to trough.

But again, that is actually better than we expected. In fact, you heard from Hugh that we have had amazingly durable formulary performance.

I think the thing that is most encouraging is the fact that even in the cases where we have had some restrictions to the use of the product, or in some small number of cases the product has been removed from formulary, it has been almost a knee-jerk reaction. And when we go back in and we talked to the surgeons, we talk to the anesthesiologists, and in particular when we go to hospital, to administration and show the pharmacoeconomic benefit of Ofirmev, that enables us to re-challenge the formulary decision; and in several cases we have been able to reverse that.

Which gives us a lot of confidence in the back half of the year that this product is going to return to traditional growth rates.

John Moten - *Mallinckrodt plc - VP IR*

Sumant?

Sumant Kulkarni - *BofA Merrill Lynch - Analyst*

Sumant Kulkarni, Bank of America Merrill Lynch. You mentioned a hospital-based continuum. Do you see any gaps in that continuum right now from a product class or a therapeutic area perspective?

Than a follow-up for Mark. There seems to be a significant potential for cash flow generation here. So how should we think about operating cash flow per year, or maybe free cash flow yield goals?

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

I will take the continuum question.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, sure.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

When you look at both Ofirmev and X XR, we have pretty good coverage on that continuum. But clearly there's opportunities to bring potential more solutions into the surgery suite and the inpatient environment. They don't just use -- the whole basis of multimodal analgesia is starting with one non-opioid-based pain reliever and then adding as necessary. So there certainly could be an opportunity to add more to that component to increase our breadth of product and offering in that surgery center, in that surgery suite.

I think as it relates to outpatient, clearly opioid-based extended-release for acute pain, both immediate and extended-release analgesia, is important. But not opioid-based pain medications could play a role there as well.

So we see this actually as a framework that not only fits currently what our portfolio is, but could eventually lead towards other products being added in that could add greater value to the system.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, just one other thing I would add to that is, clearly, Sumant, you are right: this right now is a continuum of care that is pretty specific. It is specific to managing surgical patients from the inpatient situation all the way to the office situation, with the outpatient surgeries in between. We see it right now as a pain management continuum of care focused on surgery.

Clearly over time, we think there is a tremendous opportunity to add products into our portfolio. Particularly in the hospital, where we actually strengthen our offerings to the hospital by having more products in that particular commercial infrastructure. Likewise, on the office space side.

But what we are really trying to do is create opportunities, complementary opportunities, for growth for both Xartemis XR and Ofirmev in areas where other companies are not necessarily competing and there is unmet need. We think in particular the outpatient surgical setting is a great place for Ofirmev and Xartemis XR to really offer a complementary solution to surgeons.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

One last thing I will add to that. I think it is important to remember that this whole strategy is built around aligning our incentives with the incentives of the marketplace. Getting patients out of the hospital sooner, managing their pain better is a key component to what has happened through healthcare reform, and I think this is a strategy that lines up very well with it.

John Moten - *Mallinckrodt plc - VP IR*

Yes, we will take Anthony --

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

John, he had a follow-up question on cash flow. So following up on your question as it relates to cash flow, obviously you have our earnings per share and you can back your way into EBIT and EBITDA, our operating income.

We feel really positive about the cash generating capabilities of Mallinckrodt. When I look at where we were this time last year from a cash generation capability versus where we are now, it is literally night and day.

I would tell you that we have chipped away at our internal inventory. I don't think there is a lot of room in our receivables and payables. We are working on it, but those are relatively tight.

We have done a lot of work in our inventory area. And as I mentioned earlier, as it relates to our restructuring program, as we streamline our cost of goods sold we are hoping to significantly improve our inventory turns. We made great progress in the last, I would say, 12 to 24 months as it relates to inventory, but we still see more room.

Then I have given you the CapEx of reinvestment, so that should get you in the zone on cash flow. But keep in mind, as I mentioned early, we've got over $700 million in cash at the end of September. So we feel really good about accommodating any sort of strategic moves we would like to make.

John Moten - *Mallinckrodt plc - VP IR*

Anthony?

Anthony Petrone - *Jefferies & Company - Analyst*

Thanks a lot. Anthony Petrone from Jefferies. Maybe a couple on the schedule shift for hydrocodone combination products, just near-term what you are expecting in the generics business, and maybe longer-term what that means for 155.

Then a follow-up on Acthar would be: How is Mallinckrodt going to shift its approach to pricing and reimbursement for Acthar versus what was in place with Questcor? Thanks.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

I will take the hydrocodone question. The first thing you have to remember, like I mentioned, is this is something we do. So we know this well; this is part of our strength.

We were aware of the hydrocodone rescheduling and we were prepared for the hydrocodone rescheduling. I can tell you that is not necessarily the case in the entire market.

So we were aware. We were able to actually bring product to the market, handle the infrastructure, as you know, that is required with vaults and everything else they have to do to handle the product differently.

So we put a new CII product in the marketplace. We actually think that that will take hold and work well for us.

Now, as it relates to the overall market, I think one of the other strengths we have, especially in the generic business, is where we are in multiple pain medications, multiple opioid presentations for patients. The thing you have to remember and what I would encourage you to think about is if you look at other things that have happened here with rescheduling, is the pain doesn't go away. The patient has to treat that pain; and the question is: where do you have that opportunity to treat it? We think from a competitive position, especially on the generic side, we have multiple formulations that will allow us to stay not only relative but actually take a strong market leadership position.

As it relates to 155, we are looking at that right now. Which is: what do we see this as a -- as long term? Matt mentioned it and I would encourage you to think about it a little bit more like Xartemis, now that it is a CII product, less of a CIII product, which is going to take some time.

But the value equation for the product remains the same, which is: you have one of the most widely prescribed pain medications in a better formulation for the treatment of acute pain in both immediate and extended-release analgesia. So I think the story is solid; it is just going to change the way the product is prescribed and take a little more time.

Why we are optimistic about that is because we have that stronger intellectual property on it. We actually think we have that time to build that into an asset that can be an important piece of our portfolio.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Anthony, I would add, having been with the Company 7 years, our key, overriding focus was making sure patients got treated for pain. So this is a bit of a disruption downstream. I can tell you Mallinckrodt has plenty of capacity should there be any shortages as a result of this rescheduling.

We can meet that need. We have got a very sizable vault at our plant.

And since we are competing in 43 different controlled substance categories, as Hugh mentioned, this is what we do. This is like breathing to us.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

And to build on that, I mean -- I'm sorry, go ahead, Matt.

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

No, go ahead, please.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Just to build on that very quickly, think about what I talked about as Mallinckrodt's core strength: we manage complexity; we manage it extremely well, particularly when it comes to controlled substances.

We have been doing this business for over 100 years. And in fact, when things become more complex we believe that is an opportunity for us to step in and make some changes in the marketplace. And we would really see it potentially as a growth opportunity.

So we welcome that degree of complexity. As Hugh described, Matt described, we were well prepared for it. We have been able to essentially be seamless in the marketplace as this change has occurred. We see this as a real opportunity and real strength for us.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

The only thing is I will just quickly talk about Acthar pricing and reimbursement. I tried to cover that a bit on the one slide that showed that the volume growth has continued to grow quarter-over-quarter, year-over-year, over the past several years, while having relatively consistent reimbursement across all payers.

So we think that former Questcor did a nice job of actually -- so first of all, on the pricing, this is a product which is used in devastating diseases, relatively far down the treatment path, as we talked. It is really where patients have often been -- or almost always used other treatments first. So they have been on many other treatments and then they get Acthar far down.

So there aren't that many patients. They have been on all other therapies. So when the reimbursement process is gone through, you find that reimbursement stays relatively high.

This has been through very much field level, pulling script, pulling reimbursement through for each patient, patient by patient. We want to continue that, and we are going to expand on that, really leveraging the relationships that exist from historical Mallinckrodt. So I just want to turn it to Hugh just to for (multiple speakers)

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Let me just summarize it. There is two things that we will do differently from what was done previously, which we think actually have the potential to be fairly significant in the marketplace.

The first thing is we are clearly going to engage with payers at a much different level than was done historically. As Gary described the approach previously, which was effective, was to engage at the physician and the patient level, which we will continue to do that. However, what we have traditionally done across our portfolio is to engage at the senior level policymaking level, and we think that that is a very effective way to cover the continuum of market access.

You need to manage reimbursement at the prescriber level, but you also need to engage at the policymaking level. That is a big difference and one that we think we are going to bring significant value.

The second piece -- and it goes somewhat hand-in-hand -- is the fact we think that, particularly for a couple of the indications where Acthar is currently used, there is a compelling pharmacoeconomic argument. You heard from Gary that one of the things that we are embarking on already is looking at ways that we can partner with managed care and payers to create the value data that supports that very compelling argument.

So if you put those two things together, partnering on pharmacoeconomic research and using that information at a high-level policy discussion, we think that that is a very distinctive difference than what was done previously.

With regards to pricing, the way I'd think about it is, if you look at the pricing history of Acthar, outside of one significant price increase that was taken almost now 7 years ago, the price of Acthar, the pricing policy that was employed previously, has been relatively modest. And while we believe that the biggest opportunity for value creation, the fastest opportunity for value creation for Acthar is continue to drive volume and provide access to more patients -- you saw the vastly underserved patient population -- certainly, we will look at all levers over time. And if there is a rationale and a pharmacoeconomic rationale to consider a different pricing policy, we will do that as well.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

Mark, I'd just add two pieces to it, just to clarify on a couple points. Right? The thing -- the issue on reimbursement that I think you need to put in context is reimbursement pressure is a market event across multiple therapeutic areas. So it is not unique only to Acthar, especially if you look at what has happened over the last 5, 6 years, as payers have become more engaged and more aggressive as it relates to rare diseases, oncology, and other things.

So the discussion has to change to one of value, which is where Mark was going. How is the product being utilized? What impact does it have on the patient? How do you define that in outcomes? So that is one.

The other thing I think it is important to remember is, as we build this story and as we work together, there is an effect that needs to take place between the story -- the value creation you bring to the payer and the message that is carried down in order to ensure that that reimbursement time gets shrunk. That is really important, because one of the things that is critical for this product is that patients not only get access to the product but they get the product within a timely manner so that it can help begin to treat that disease.

The tighter we can make that window by improving reimbursement over time is going to be important to the long-term impact of the product.

John Moten - *Mallinckrodt plc - VP IR*

Chris, then Gary. Chris Caponetti, then Gary Nachman.

Chris Caponetti - *Morgan Stanley - Analyst*

Hi, Chris Caponetti, Morgan Stanley. I have 19 proof questions, but I will only keep it to a couple for Gary. First on Ofirmev, you had mentioned a next-generation product. Can you just talk a little bit about how we should be thinking about that?

Second, on Acthar double-digit growth for next year. Is that going to be primarily coming from rheumatology and pulmonology, or more some of the legacy indications?

Then also in terms of the clinical trials that you're going to be running and presenting, how many of these would include steroids as an active comparator? Any of them statistically powered such that they could hopefully someday be added to the Acthar label? Thank you.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

Let me take the Ofirmev question first; and Mark, feel free to jump in if need be. As you know, right now with Ofirmev we have a pretty good idea of the product's patent situation, which is through December 2020. So our goal right now is to begin to establish what type of opportunities do we have in reformulation that would provide greater value for the existing formulation to the marketplace, and how quickly can we get that done.

We don't have any refined answers of what that looks like yet. But what I can tell you, it is a significant effort that we are ongoing with our R&D and our medical affairs colleagues to put that together. I don't know if you want to add.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, the way I'd think about this, Chris, is very simply we think there's probably two potential avenues for extending the exclusivity period for Ofirmev. One is clearly the product is at this point only offered in vials. We think there is certainly potential additional presentations that we can bring this product in, whether that is bags or other presentations.

But as Hugh described, we are looking at a number of different formulation options. Again, keep in mind, complex formulation is one of the strengths and hallmarks of Mallinckrodt. And also keep in mind that acetaminophen is a product that we have been making literally for decades. We probably know as much about the acetaminophen molecule as any company in the industry.

So our scientists have really taken onboard the challenge of identifying alternative formulations whereby you can consider either extending the durability of the product from the actual length of efficacy, if you will, to other more efficient formulations. Again, there is a range of options at the moment; but it is really this combination of looking at alternative formulations as well as additional presentations that we think has the potential to extend the exclusivity period.

The last thing I would say is that -- recognize that acetaminophen in IV solution has proven to be a very challenging manufacturing undertaking. While this product does have generic alternatives in Europe, many of those alternatives do not have as much shelf life as the formulation that we have, for the simple reason that in the minutest presence of oxygen the product rapidly degrades in an IV solution. The product then tends to yellow; and while that may be more acceptable in a European format, it is typically not very acceptable here in the US.

So again, we think that while certainly there is the possibility that there will be a generic product at some point after 2020, we think that we have a number of different avenues to continue to potentially extend the life of this product.

Gary Phillips - *Mallinckrodt plc - SVP, President of Autoimmune and Rare Diseases*

Yes. With regards to Acthar growth, the growth opportunity is a function not only of the number of indications but also the length of treatment, as Dr. Levine said before. Rheumatology is a large growth potential area. If you look at Acthar's label, there are five indications in rheumatology;

and these are indications that in addition to polymyositis, dermatomyositis, include rheumatoid arthritis flares and systemic lupus erythematosus. These are very large patient populations.

And in many instances, like in PM/DM, patients are treated over long periods of time, so the growth potential in rheumatology is quite significant. So I would envision growth coming from there.

But also in nephrology, because nephrotic syndrome patients require long-term treatment, every time that you end up having a patient put on therapy it is actually a quite large per-script cost of therapy, or it is a revenue opportunity. So we actually see that nephrology and rheumatology in terms of absolute dollar growth probably present the largest opportunities in fiscal 2015.

Pulmonology also gives an opportunity. But again, we need to expand the salesforce, get doctors much more aware of the product to tap that growth potential. So the magnitude may not be as great.

With regards to studying Acthar, as you saw there are 140 ongoing trials in 2014. We are going to increase investment in the next year.

You are going to find almost every kind of trial design. So will it be against corticosteroids? Yes, there will be trials against corticosteroids. There will be trials against Acthar, one dose against Acthar; in combination; alone. It is hard to describe the full gamut of types of studies that will be out there.

The one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Yes, just two things I would add. One is that -- keep in mind that outside of infantile spasms where about 50% or better of available patients are actually treated with Acthar, even in some of the indications that are, quote, more mature, like some of the neurologic indications and the nephrology indications, still the penetration rate of available patients is somewhere on the order of maybe 10% to 20%. So we think there is a lot more room where these patients could benefit from Acthar, even in those indications where it has been a little bit more mature.

Then with regards to our study design and Company-sponsored trials going forward, we are in the process of evaluating the trials that are currently ongoing as well as considering additional trials. Our emphasis is going to be on creating data sets that aid physicians in scientific evidence that are going to help them understand how to use the product in specific types of patients, as you heard the physicians describe.

Our objective would be to design trials in a way that inform that clinical practice to provide more evidence and more valuable data to help those physicians decide which patients are going to best benefit from Acthar.

John Moten - *Mallinckrodt plc - VP IR*

Gary?

Gary Nachman - *Goldman Sachs - Analyst*

Hi, Gary Nachman from Goldman Sachs. I wanted to follow up on the pricing discussion and the double-digit growth for Acthar. Any pricing assumed in there specifically for next year?

On specialty generics, could you comment on the pricing environment and how sustainable you think that is? Have you been getting any pushback? There has been some noise in Washington recently on that.

And then anything you could highlight on the generics pipeline? Is that an area you'll look to beef up over time? Is that an area you will look at for M&A?

Mark Trudeau - *Mallinckrodt plc - President, CEO*

The way I would think about pricing, Gary, is pretty straightforward. We value price, right? You have seen us do that on a variety of different parts of our portfolio.

Where we think there is a compelling pharmacoeconomic, then we look at the price of our product, the value that it is. So we reserve the right to take price across our portfolio and, again, we will do that where there is an opportunity to create value.

With regards to the sustainability of the actual model that we have had in specialty generics, keep in mind that we have taken some price in some of the 43 categories across which we participate, but we certainly haven't done it across all of them. Again, it is all based on value and the fact that what really drives the value in the Specialty Pharmaceutical arena, the controlled substance generics arena, is the consistency and availability of supply and being able to consistently deliver supply.

And that is, again, one of the hallmarks of Mallinckrodt. So we think about our pricing strategy in that context.

So the prices that we have established in specialty generics at this point, keep in mind that many of the prices in these categories hadn't been touched in 10 years or so. So we feel like we are almost just modernizing the price, reflective of the value that they are bringing to the marketplace and reflective of the fact that ensuring supply is the overriding concern in this category.

John Moten - *Mallinckrodt plc - VP IR*

Jason? And that will be the last question.

Jason Gerberry - *Leerink Partners - Analyst*

Hey, Jason Gerberry from Leerink Partners. Just a couple, maybe first on Ofirmev.

You talked about historical growth. I guess when I talk to investors my sense is that there is probably a little bit of, I guess, confusion as to whether you get there via volume or price. So I was wondering if you can maybe just define what you view as a historical growth rate for Ofirmev.

Then, I guess just secondly on the abuse-deterrent label claims for Xartemis and 155, we have seen Perdue now with a second product get AD claims. Just wondering what your guys' plan is for potentially getting a more competitive label.

Then just lastly, on Acthar, you guys have given peak sales guidance on a number of your products. Wondering when you guys might consider giving a peak sales target for Acthar. Thanks.

Hugh O'Neill - *Mallinckrodt plc - SVP, President of U.S. Specialty Pharmaceuticals*

Let me take the Ofirmev question first. As I mentioned, we see the growth on Ofirmev primarily being volume, because of the opportunity. Even before the reset, we only had about 12% of the surgeries penetrated to where the product could be utilized, so there is significant opportunity for volume.

We also believe that because of the fact we see the number of vials that are used per procedure and the number of surgeries that this product could potentially be played in. So much more of a volume opportunity, much less of a price opportunity.

To Mark's point earlier, though, we always look at value for price. Right now we feel very strongly that when we took the reset on Ofirmev, which was absolutely the right strategy and as you can see has borne out extremely well, is that we set the price based on where we see the value.

Now there is always continued investment we are making in pharmacoeconomic data, but I want to focus on this, that we see this primarily as a volume opportunity, significantly, with the amount of surgeries that we could penetrate, the number of hospitals that utilize the product, and this embracement around multimodal analgesia, which we think could help build the product long-term.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Matt, you want to speak to the guidance?

Matt Harbaugh - *Mallinckrodt plc - SVP, CFO*

Yes. It is still early days with bringing Acthar into the fold. I know for you it probably feels like a year or 2, but for us, we are still a few months in.

We are doing a lot reviews of what the market opportunities are, of which you got a glimmer today with Gary's presentation around the addressable patient population. So it is still a bit early to go down that path, and that is why double-digit top line was the directional guidance we gave today.

John Moten - *Mallinckrodt plc - VP IR*

Well, with that, I would like to have Mark give some concluding remarks.

Mark Trudeau - *Mallinckrodt plc - President, CEO*

Sure, just very briefly. First of all, I want to thank you all for your time and attention today.

Again, keep in mind our objective was to do a couple of things. One was to give you clear direction for how we are going to create value in the future. Hopefully we have shown you that pathway.

We are going to drive value through these four growth platforms that we have created, and we're going to build upon the acquisitions and the products that we've brought into our portfolio through development.

We are going to continue to remain active and aggressive on the business development and licensing front, and we will continue to look for undervalued assets to put into these growth platforms, to continue to drive growth and profitability.

And at the end of the day, the way you should think about Mallinckrodt is a company that is a top-performing organization, one that is focused on creating shareholder value for the long term. Thank you very much.
