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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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PRESENTATION

Jason Gerberry - *BofA Merrill Lynch Asset Holdings Inc - Analyst*

For the next company presentation at the BofA Annual Healthcare Conference, my name is Jason Gerberry. I cover pharma and biotech at BofA, and I'm pleased to be moderating our next fireside discussion with Johnson & Johnson and John Reed, Executive Vice President, Pharma R&D.

So, John, thanks so much for joining us.

John Reed - *Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D*

Great to be here. Looking forward to the chat.

Jason Gerberry - *BofA Merrill Lynch Asset Holdings Inc - Analyst*

Well, look, as a company, have had a lot of momentum, I think, in the R&D organization. So looking forward to just maybe at a high-level framing first, where you're at in terms of the pipeline and BD consideration versus in-house developed, you guys have shown a propensity, obviously, to have success on both fronts. And I imagine you're always opportunistically looking for best science, right? (laughter)

QUESTIONS AND ANSWERS

Jason Gerberry - *BofA Merrill Lynch Asset Holdings Inc - Analyst*

So we get that dynamic, but are there priority areas within the portfolio that from your seat you're looking at saying, hey, we maybe want to address and augment through external innovation? I know you probably don't want to tell your hand too much to the external community, but maybe if you can just frame that dynamic first because there's been so much activity with your pharma peers on the M&A front that it's topical.

John Reed - *Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D*

First, I would say that we really have become a more focused company in the last few years; Oncology, Immunology, and Neuroscience are really the foundational elements. We do a little bit here and there and some other areas, but those are the key areas. And our strategy for some time has really been one of trying to roughly have half of our products coming from internal discovery and internal invention and half through BD M&A. And we tend to track pretty closely. I think right now about 60% of the development stage portfolio actually happens to be internally derived but even many of those started with some collaboration or something.

So it's a mixed picture like that. And we're both interested in products and sometimes platforms. And maybe a good example of a recent one that kind of checked both those boxes was towards the end of last year, we acquired a small company called Halda that had a lead candidate, an oral for prostate cancer. J&J is number one in prostate cancer, so that's a good fit for us. That is based on a technology called

RIPTAC that uses these cleverly designed bidentate oral small molecules that will grab onto a target of interest. In this case, it was the androgen receptor. And then also grab some essential protein and sequester it so the cell can't have it, and without it, the cell dies, so it's a hold-and-kill mechanism.

So we're able to bring in essentially a Phase 3 ready asset, but on top of that, got this nifty chemistry platform with several other projects in various stages of progression that we're excited about taking across a number of areas in Oncology, but also in some other therapeutic areas too. So it's a nice example, I think.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

So it wouldn't be, I feel like every year at our conference, there's a little bit of drama with FDA and there's been some recent headlines. I'm not sure the net outcome, what that's going to look like, but if you can maybe frame how productive the interactions have been with the agency with a lot of change and potentially more change coming.

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, I've had the opportunity to interact quite a bit with Makary and his and the leadership there at the agency. They recognize that it's become progressively more difficult to do clinical development in this country compared to some other locations and that we need to speed some elements of that and rethink some elements of that and with a mindset to what would it take to make America a more attractive place to see studies conducted. So I certainly applaud the agency for many things they're trying to do to rethink the requirements for INDs, the pace with which INDs can be approved in this country, and a number of other dimensions too. I mean, you saw that they also now provided some fresh thinking about how many clinical trials do you actually need to get an approval and some other things too.

So I think there's a lot of good opportunity there and good intention and the commissioner has invited members of the pharma companies community from time to time to even submit white papers with our suggestions so that he's not trying to read our minds but to understand what are the things that might make it easier for us to do manufacturing in this country or do studies in this country etc. and then he and his team can take it under advisement.

So I feel there's been goodwill there to work collaboratively. Obviously, there were big impacts on the agency with the DOGE effort etc. that has created, I think, some workload issues for the agency. I certainly, the more I interact with the staff there, the more I appreciate just how hardworking they are (laughter). They turn these applications around and they've got a big full plate, so appreciative for their service.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Well, maybe we'll switch gears to some of the therapeutic areas and Immunology is one of the core TAs for you guys as a company and let's start with ICOTYDE, which the company, I would argue, maybe a more bullish tone coming out of 1Q just on the revenue opportunity and we have validated set of indications for where ICOTYDE will have an opportunity in psoriasis is the nearer term opportunity. But I guess I wonder first, it's a drug with lower bioavailability. And so, as we think about in UC, you're still approximating the efficacy of the biologics, right?

And so there's perhaps some underpinnings there in terms of receptors in the gut that might make it feasible for you to achieve that level of efficacy. Is it realistic to think that you could push dose in psoriasis to narrow that efficacy gap that you see with IL-23 biologics? I guess that's one question. And then how confident are you in kind of your dosing strategy broadly in IBD?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Right. Yeah, so several dimensions to the question, but first, just to remind the audience, if you're not aware or know, that ICOTYDE was just approved this year for psoriasis. It's an oral therapy that targets the IL-23 receptor, a targeted oral peptide. And what we've been seeing is biologics like efficacy combined with a very pristine safety profile and the convenience of a once a day.

The reason that we're excited about it is because if you look at the patient populations in this country and elsewhere that have an autoimmune disease, they're eligible for a biologic. Only 20% to 30% of them are actually taking one. Many people just do not want to commit to a lifelong of injections with a biologic. So this offers an oral option with efficacy on par with biologics.

And in psoriasis, for example, if you look at the data that we generated, we have five out of five positive Phase 3 studies published in the New England Journal, published in the Lancet head-to-head against the leading TYK2 inhibitor. But in psoriasis one out of every two patients had completely clear skin. That's the IGA 0. That's right on par with the best biologics.

So we were able to get that done with a 200-milligram dose. As you know the health authorities make us do dose ranging because they want us to use the minimally effective dose. They don't want us to push doses any more than we have to in order to reduce risks of some safety event. And so we do dose ranging in all our indications. We'll see where we land in the end with the inflammatory bowel disease, as you said because it's orally absorbed, maybe you'll get higher local concentrations in the gut but we'll do the studies and we'll land on whatever the minimally effective dose is for those indications. Feel quite confident because the IL-23 class is validated there so we'll have to see if we get that kind of on par with biologics type of efficacy.

I'd say one other thing, too, that we're really happy, since you mentioned FDA, is with the adjudication of the label with them, we were able to get a very clean label. So there's no laboratory monitoring required. There's not a requirement to do TB testing upfront, unlike many other biologics. So it's really easy for the dermatologist to write the script and feel confident around the safety of ICOTYDE.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

How quickly do you think old ways change, right? These doctors are almost preconditioned to look for these things, right? And so, what some doctors have said to us is, well, maybe there's a psychological predisposition to doing these things still, right? Is that at all a factor, when you guys think about how these dynamics change with Otezla, right, which was the last successful oral therapy in psoriasis, commercially speaking, it was kind of an easy write, for community dermatologists. And it seems like, at least in psoriasis, right, the idea is to kind of expand the category.

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, I think the clean label really helps in that regard so that you don't have to do a bunch of laboratory testing or wait for a TB test to come back or things like that. As we know in medical practice in the community, it does take some time for patient education, etc. But the interactions we've had, and that's with the KOLs, which maybe are not always representative of your average dermatologist, but they're really excited because what they talk about is they have patients with psoriasis, they're trying to manage it with topicals, but it's a systemic disease, really.

So at some point, they realize this is just not cutting it. And then historically, the dermatologists would say, okay, I think it's time for you to go on an injectable. And what they would describe to us is the patients would go, let me think about that. I'll get back to you. And then they don't come back. So this way, you write a script, they start taking a pill once a day. It's just an easy transition from the patient to get from trying to manage their disease with topicals to now on a systemic therapy. So we're excited. We think it's going to be a real market expander.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Now, with IBD, this is a big component, I think, of the peak sales outlook for ICOTYDE. So I guess what I wonder is, we haven't seen a really great commercially successful oral outside of maybe Mesalamine, right, which had a lot of volume utilization.

If you listen to how AbbVie frames it, and they're looking at I&I combinations, you had the recent DUET data. You want to go with your biggest gun early, avoid things like fistulas. Later downstream in the patient. So I guess I wonder where ICOTYDE fits in all that, right, where you and competitors are looking at these combination products. You've got biologics that work really well there (laughter). So how do you think about the oral like that opportunity in IBD?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, I think, again, there are a large percentage of patients that are eligible for a biologic but not taking one in IBD as well. So I think there must be a, there's clearly a large patient population there that would like an alternative.

I think the key for us will be the efficacy data that we deliver in the studies is it is right there on par with the biologics and then that gives patients and healthcare providers another option to consider. You mentioned DUET. For those who don't know, that's some studies we did with patients who are on the more severe refractory end of the scale where a monotherapy is not getting the job done for them.

We've created a co-formulation of our TNF inhibitor and our IL-23 inhibitor, two antibodies co-formulated at the right doses, so that a single injection, the patient gets both of those, and had seen that in patients who have failed two or more prior lines, that this really then started to get into range of efficacy is essentially double what you saw with the monotherapies in that patient population, where monotherapy is just not getting the job done for them.

So it won't be a one-size-fits-all, I think, with these patients -- some will gravitate to an oral, others injectable. Some may need more than one drug, depending on their disease. Unfortunately with IBD, as you know, fewer than half of patients achieve and sustain a complete remission. So it is one of those diseases, despite even our best medicines, there's room for improvement and we're going to keep pushing at it.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Well, maybe that's a segue for DUET, which was recent data that you presented and AbbVie a week or two earlier had interim data for its IL-23 integrin. And so I'm just curious the strategy and why prioritization of say TNF versus say other combination partners that you could have paired with your IL-23?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Right. Well, to some extent, it was logical for us at J&J because we brought the first TNF inhibitors to market with REMICADE and golimumab, which is the product of SIMPONI, was in our portfolio and then guselkumab, TREMFYA. And so it made sense for us to do exploratory work with those combos.

What we did first, though, was pilot studies where they were biomarker-driven, where we put patients on one or both and then take biopsies from the intestine and do deep molecular profiling, single-cell transcriptomics. And that taught us that the two together really had a synergistic suppression of inflammatory pathways. So we thought, okay, this could really make sense.

And then as we got in the clinic, we were, of course, watching safety, because when you start taking out a couple of these cytokines, what's going to happen to safety, but there we found that the safety was consistent with each of the underlying components. We did not see incremental adverse events, so we were good on those and then when we did the studies, we started to see these really promising data.

So that's how we started in this journey, it's not to say that other combos wouldn't be logical to also give a try and we'll probably do some of that ourselves down the road, but this was a good entry point for us to bring together two mechanisms.

And we're poised to be the company that delivers the first of a dual mechanism with these co-antibody therapeutic. So we're trailblazing with this and really excited to be able to offer more hope to these patients who are really tough to treat.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

So your just general thoughts on having TNF-based combinations and potential with a black box warning, others in the space would say, hey, we want to like combine two really safe MOAs orthogonal that lack the black box warning. Maybe the counterargument to that is when you start to deal with settings like IBD or RA, you need big guns and that risk benefit wise, a black box warning in the grand scheme may be an acceptable trade-off.

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, I mean the black box in this case goes with the TNF class. And because that class has been around so long, we find patients are very comfortable managing those risk profiles, so it's something that they're very familiar with. IL-23 doesn't really have the black box issues, so that pair -- but I mean, if you compare it, some patients who end up on a JAK inhibitor, all right, talk about your black box warning. They have the infection risk warning, they have the cancer risk warning, they have cardiovascular event warnings, they have thrombosis warnings.

So I think, when patients are desperate enough and physicians are desperate enough, sometimes they'll even put up with that. But, compared to a JAK inhibitor, this is far more benign. And yet we see, people reaching for JAK inhibitors with some of these refractory patient populations. So I think, the risk-benefit is, it's very attractive, I think, for many physicians and patients.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

And so with -- following the DUET data, what are next steps with that? Would the plan be to go directly to Phase 3? Are you happy with what you saw? If you can kind of outline (multiple speakers) --

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, we're going straight to Phase 3 in ulcerative colitis because we already did a dose ranging Phase 2. We have defined what the dose will be. In Crohn's, we're doing a seamless Phase 2B, Phase 3, so we'll do some dose ranging and then start the Phase 3 component. I don't think we've revealed all the details of that, but that's the plan there.

We're also going to do a study in psoriatic arthritis, which is another one of the autoimmune diseases where there are significant percentage of patients where monotherapy is just not enough, so we're going to do a study there as well and we'll go head-to-head against -- in the case of the inflammatory bowel disease, we're going head-to-head against guselkumab, TREMFYA.

The regulators agreed that we did not need to do also the TNF single therapy. So it's just -- it's basically guselkumab versus the co-antibody therapeutic, those two arms, basically.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

And then any efforts, it sounds like, to interrogate different orthogonal mechanistic combinations, either with a co-formulation or bispecifics. Is that something that J&J can do internally? Does it need to go out externally to find assets that can facilitate that strategy?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Right. I think it's some of both. So in some cases, we certainly, from a technology standpoint, we have a very robust bispecific platform. We have the ability to do the co-antibody therapeutics, and as we bring more and more orals, there could be oral-oral combinations, and sometimes those could be co-formulated, a fixed dose combo. But because there are different targets that you might want to pair in different ways, in some cases, we might have both targets in hands. In other cases, we might want to go externally and grab one from another partner. So it'll be some of each, I think, as we get into this sort of combinatorial aspect of autoimmune diseases.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Maybe we'll shift to Neuroscience, an area that you guys have been acquisitive in. But my question was around SPRAVATO, just given the surprising commercial success that you guys have had. I think it speaks to just the unmet need in MDD. I feel like every time there's a new category, it's not zero-sum game. It's expanding the market.

And so when we talk to physicians who treat patients either with ketamine clinics or with SPRAVATO, it seems like it's a very unique segment of the market relative to typical SSRIs or even atypical antipsychotics. So there's some changing going on in the landscape too around psychedelic therapies that could be potentially, at least if you listen to how some of them portray their therapies as more of a durable benefit. You don't need to have as many follow-up treatments as SPRAVATO, which can be time consuming.

So as you look at like what's going on in the psychedelic therapy pipeline competitively, is that a risk to SPRAVATO or is that something that's like an opportunity for you to augment SPRAVATO in the portfolio down the line potentially?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

I think we're waiting for data to come in on the psychedelics to really understand it all. But just to back up a little bit on SPRAVATO, so it's a particular enantiomer of ketamine that's formulated for delivery to the intranasal route with a device. So it's another good collaboration between MedTech and Innovative Medicine at J&J.

And it was the first example of an antidepressant that had rapid action. So in other words, within minutes to hours, patients could see their depression symptoms relieved, was approved for treatment-resistant depression, which is patients who failed two prior antidepressants at least as well as for the really urgent situation of depression with suicidal ideation.

Altogether, we've taken it through 33 clinical trials. Approximately quarter of a million people have been treated with SPRAVATO. It's approved in multiple countries and it really added a new weapon to the battle against chronic depression, which affects a quarter of a billion people around the world, and is a heterogeneous disease, right? It's not a one-size-fits-all, so we need different mechanisms and SPRAVATO was the only [depressant] (sic – “antidepressant”) ever awarded breakthrough designation by the FDA. Twice we got priority review, too. So it's really a new step forward.

Now, how does it work? It's thought to work by affecting neural plasticity. Which is what the psychedelics are thought to do, right? Different mechanisms SPRAVATO works through a thing called NMDA receptors. The psychedelics, it's not entirely clear, but there's theories that it might be a certain type of serotonin receptor.

But the idea is you're affecting this phenomenon called neuroplasticity. And that's where this may be then giving this real breakthrough in terms of getting at that really treatment-resistant depression as well as maybe the more durability because you're actually changing the connections of the neurons.

In the case of SPRAVATO, we have data showing that 50% of patients stay at remission for five years on SPRAVATO. Now, they need to take it at different schedules, some are once a week, some are twice a week. Different schedules for different people, but great durability

for an antidepressant, if you think about it. So real breakthrough, excited to have that in our armamentarium with other mechanisms now to try to help patients battling with depression.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

This just occurred to me, but is there the possibility that over time, as the drugs gets better characterized to lessen the need to do the inhalation, the nose inhalation at home potentially for patients?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, I think that we could see it moving that way. The issue was that sometimes when patients initially take SPRAVATO, they have these dissociative out-of-body-like sensations. They typically last only minutes. And some patients don't even get them at all, or they only get them on the first few doses. So I think it's something that we will be continuing to have conversations with the regulatory authorities around, is there an opportunity to start bringing this more into the home as opposed to having to, go to the clinic and sit in a quiet room while you wait for two hours for your[post-dose] SPRAVATO, so to speak, (laughter) to see how you're faring?

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Maybe we'll pivot to multiple myeloma. You've got arguably an embarrassment of riches with assets here, right? I guess the one thing that I really struggle with, on the one hand, BCMA-directed therapies, the book says go with the CAR-T first because you'll have lessened efficacy if you use a BCMA-directed bispecific in advance of that, right?

But you have data now for both modalities that look pretty competitive, right? And I think you guys have said we're just going to give patients choices and providers choices. If you want them one and done, we've got the option for you. And if you want, as a community oncologist, not that this is what you want per se, but community oncologists don't want to give up their patient. That's just the practical reality of that. How do you see this playing out?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Well, as you said, we have a lot of tools to work with, five-approved therapies, more in the pipeline and it is becoming a very dynamic space in terms of how the therapies can come together and that's what we've been doing now is to bring them together in combinations in different lines of therapy.

We started the journey with Velcade, the world's first proteasome inhibitor. And then behind that, daratumumab, DARZALEX, the first biologic for myeloma, the CD38. And even with those two combined with other medicines. When we started this journey at J&J, the average life expectancy of a myeloma patient was two years. Now, with DARZALEX, Velcade, plus other meds, the life expectancy for the transplant eligible is almost two decades. And for the transplant ineligible, almost a decade. So even there, we have achieved enormous benefits for patients, but, we're not stopping there.

Bringing now the T-cell engagers, TECVAYLI, our first-in-class BCMA, TALVEY, our first-in-class GPRC5D, these together with DARZALEX and earlier lines are giving miraculous data, the most recent approval was for TECVAYLI, where in second line, the data were so impressive that the FDA called us. And said, may we offer you a commissioner's priority review voucher because we'd like to get this to the American people as fast as possible, 55 days from submission to approval, and just unprecedented progression-free and overall survival data scene.

Now we want to move into frontline, where we've been doing pilot studies and seeing that if we can combine a T-cell engager, which could be tec [TECVAYLI]- tal [TALVEY], or now we have a trispecific, ramantamig, that does both tec [TECVAYLI] and tal [TALVEY] in a single

molecule with data [DARZALEX], we can get 100% MRD negativity, so minimal residual disease negativity, which that was recognized as a valid surrogate endpoint by the FDA last year for progression-free survival.

So, really excited about involving these paradigms, T-cell engagers, data [DARZALEX] in the front line, CARVYKTI, CAR T-cells probably for second line, but even there, who knows? One of our investigators at Dana-Farber took patients with smoldering myeloma, gave them CARVYKTI, 20 out of 20 have minimal residual disease, negativity, no evidence of disease, a one and done treatment, nipping it in the bud. So there's so many opportunities now to offer patients different ways to try to tackle this.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

So as you say, you're testing a lot of permutations in frontline. And if we think about the frontline strategy, do you think MRD would be enough to both enable accelerated approval, but ultimately be practice changing for physicians to want to adopt. There are certain settings, right, of oncology, right, where you could get by on PFS, but if you don't have OS data, you're not getting used, or you're not getting used at a high rate. So when you think about maybe the commercial bar, right, for frontline, is MRD enough?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

We would always do PFS and OS as well. Although it would be nice if the FDA would allow us to have an accelerated approval based on MRD but we would continue to follow patients, the rest of the world hasn't adopted that standard of MRD might be sufficient, so since we try to bring our patients -- we try to bring our product globally to the patients around the world.

We know that we're going to be held to more of the traditional endpoints, but it is exciting to think that particularly in frontline where the current standard care is so good that you would have to wait a long time to find out, it is exciting to think that perhaps FDA would allow us to have an accelerated approval so we can bring these innovations to patients faster because we really say we are on the cusp of curing myeloma and that would be so exciting if we could use that as a way to just get these new combinations to the patients even faster.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

Well, we've got less than two minutes here. So maybe ahead of ASCO, RYBREVANT, you've got some data in head and neck. What is the OrigAMI-4 trial Cohort 1, right? I think it's described in the titles as pivotal data. So maybe if you can just set the table because as we think about sort of the opportunities beyond lung cancer, head and neck, and CRC have been flagged as big opportunities. And just trying to think through your second-line monotherapy strategy and if these data are fileable?

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

Yeah, now we think they could be, so RYBREVANT, just to contextualize, is a bispecific antibody that neutralizes the two growth factor receptors approved in lung cancer for EGF receptor mutant. It was the first bispecific ever approved for a solid tumor indication, incidentally in head and neck, which is the eighth most common cancer, we saw really promising data. KOLs tell us they've never seen a more active agent in head and neck. So the first entry is in patients who failed front line, so now they're in second line.

The bar gets where we're going. Typically, those patients have been treated with either cetuximab or taxanes, and overall response rates 10% to 20% on a good day. So that's the bar. And that's why I think FDA is open to even a single monother --study, which is where we have breakthrough designation.

So at ASCO, you'll be able to see what kind of responses and durability of responses we're able to bring there. We also, I think, are going to show some of our pilot data in frontline where we're doing combo of pembro and oxaliplatin in frontline and then going against the standard of care regimen, the chemo immunotherapeutic standard care there too.

That regimen only has overall response rates of about 30 to 35 per and the durability of less than seven months. So, we'll see what RYBREVANT brings. You'll get a little hint of the data, but super excited about what RYBREVANT possibility to really create the next standard of care in head and neck. And then we're also pursuing a colorectal. We've got two big Phase 3 studies going there, one in front line, one in second line. So RYBREVANT is just getting started.

Jason Gerberry - BofA Merrill Lynch Asset Holdings Inc - Analyst

All right (laughter). Awesome. Well, thank you so much. We're out of time but appreciate the conversation.

John Reed - Johnson & Johnson - Executive Vice President - Pharmaceuticals, R&D

All right, Jason. Thank you.

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