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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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CORPORATE PARTICIPANTS

John Reed *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

CONFERENCE CALL PARTICIPANTS

Timothy Anderson *BofA Securities, Inc. - Analyst*

PRESENTATION

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. I think we're live. Thank you for joining us. Sorry for the few-minute delay.

I'm Tim Anderson, the large-cap and US pharma analyst and biotech analyst at Bank of America.

We're excited to have Johnson & Johnson with us today; specifically, Dr. John Reed, currently Executive Vice President, Innovative Medicine, R&D. Joined the company in 2023. Prior to that, he was in various leadership positions at Sanofi as well as Roche, served on their respective executive committees. He was in academia for a long period prior to that.

So John, thanks for joining us.

QUESTIONS AND ANSWERS

Timothy Anderson - *BofA Securities, Inc. - Analyst*

I thought we'd start off with some high-level questions -- that are ones that a head of R&D can answer. So I won't ask you about tariffs.

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes, please, let's stick with those.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

So let's talk about FDA, HHS. There's changes going on there, turmoil, change in leadership. I think there's a sense that it could have an impact that's kind of incalculable. And it could manifest in various ways.

Are you, guys, seeing anything at this ,point in terms of disruption to process?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yeah. So far, so good. Knock on wood.

Despite the significant change there, I'm speaking of the FDA, in particular. All of our PDUFA dates and other regulatory deadlines and interactions have occurred on schedule. Requests for meetings of various sorts have been honored.

So, so far, so good. Kudos to the professionals there for managing to keep the trains running.

In terms of HHS too early to, beyond the FDA, I think, to say. But at least with respect to adjudication of our various applications and whatnot with the FDA, so far, so good.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

So I've been covering the space for 26 years. To me, this is absolutely unquestionably the biggest disruption we've seen, where different views are being espoused on what the drug development pathway should look like, what the regulatory BARDA approval should be. Would you concur with that?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

I would say that I haven't seen seismic shifts of this proportion in any other time in my career of being involved with this industry. So yes.

But I still think there's so much we don't know, in terms of where the dust will settle. I noticed, for example, a new commissioner had decided to, last I heard, to keep the FDA structure largely intact, rather than breaking it into these different divisions.

So let's see where the dust settles, as we get through the latter part of this year.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

If you look at FDA, you've interacted with the agency for a very long time, are there positives that could come out of this? I have frankly viewed FDA as being pretty objective, doing a pretty good job, and not really needing a lot of change.

We tend to have pretty fast approvals. Relative to a lot of countries around the world, launches often occur in the US first.

So are there some positives that could happen? Or even a year ago, if I ask you, were there certain things the FDA could do better, anything rise to the surface? Or would you agree that it's generally a pretty well-functioning agency?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Well, I guess one thing comes to mind for me -- and again, I'm totally speculating but this administration seems to be very enamored with AI and data at scale. And so, there certainly are opportunities to have data sharing with the regulatory authorities occur in more robust ways, where primary data could be uploaded directly, where analyses could be conducted in more automated ways or more consistent ways.

So I think there's some opportunities there. But to be determined.

Tim, I was hoping we'd talk about the pipeline and not much about these ecosystem changes, which, again, they're -- it's hard to speculate exactly where things will land.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Well, yeah. You'll be getting these questions from others, not just me. I'm sure, unfortunately.

Okay. So with that, yes, we'll shift to tariffs next -- no, I'm joking. Let's shift to immunology.

So another product that's in the pipeline is icotrokinra. So this is an oral IL-23. Your partner is a biotech company, Protagonist. And we've seen some Phase III data, looks quite compelling. It's complementary to some of the current products you have because you have an injectable IL-23 that does quite well.

So how do you think this layers into your immunology portfolio? And what about possible cannibalization of your injectable IL-23?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Well, a couple of things. First, I just want to -- for those who aren't that familiar with the story, this is an oral targeted peptide inhibitor of the IL-23 receptor. A very potent once-a-day dosing. I think it's an example of J&J at its best.

We started with a collaboration with Protagonist by making an equity investment in the company to help nurture along this peptide drug discovery platform they had. Licensed the lead candidate from them. But it quickly failed in the clinic.

And then, our chemists went to work, synthesized more than 700 of these complex cyclic peptides. More than 20 crystal structures got the optimized lead.

And then, the real work started because we had to find a way to manufacture this at a commercially viable way. And so, we went from a 20-plus synthesis, solid state, very expensive to a completely solution-phased conversion synthesis that we can make this, now, a multi-kilogram scale, the cost of goods more than 100-fold lower than what we started with.

It's a great story. So, now, the data coming out have shown biologics like efficacy with IL-23-like very pristine safety profile. And where it fits in is that if you look across autoimmune diseases and you look at the percentage of patients who are eligible for an advanced therapy biologic -- and no matter what disease you look at -- it's only a minority of patients that have taken that plunge and have agreed to go on a biologic.

So we see huge parts of these markets, whether it's psoriasis, psoriatic arthritis, IBD where more than 2/3 of patients on average are not getting an advanced therapy even though they're eligible. So this will have efficacy and safety that you make them comfortable, once-a-day, convenient dosing, and really give patients that choice.

I think one indicator of how much demand there is for this, on our psoriasis studies, for example, our Phase IIIs, they enrolled at one-third the time that it normally takes us to do these studies.

So we had so much demand from patients and investigators. So we're really excited about the potential of icotrokinra.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. Let me ask you a commercial question. Just like you liked it when I asked you a policy question, I'm sure you'll like me asking a commercial question.

So we have had another oral out there in the last few years from Bristol, Sotyktu. It really struggled to gain traction, frankly. Different class of drugs. Your data, I think, indisputably is better.

You do though have one structural impediment. It's a peptide, an oral peptide. So you do have to not eat, I think, for 30 minutes before you take the pill. That's a little bit cumbersome.

But why would your product at psoriasis do better than Bristol's in as much as the commercial team, and you talked about this --

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John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Right. Well, principally, because the efficacy is so much better. We haven't yet disclosed the difference between the TYK2 inhibitor and our molecule. That will be presented at a future medical meeting.

But just to give you a preview, think Eagles versus Chiefs in the last Super Bowl. It's not a trivial difference. It's really head-and-shoulders efficacy on par with biologics. And so, we're really excited that Ico can become a go-to therapy.

In terms of the food effect you mentioned, indeed, one takes it for half an hour before eating. We are doing studies just to verify if you can take a black coffee, black tea, and just so you can go ahead and enjoy your morning coffee or tea before you have your breakfast.

But that's probably the only thing that's a convenience factor with this. Again, once a day, oral dosing, otherwise.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

So early data or Phase II data in ulcerative colitis looked quite good, so very different setting than the inflammatory bowel disease. Is that likely to be the bigger opportunity for this product, where there is more of an established paradigm, I think, with oral therapies?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

If you just look at our biologics leg, STELARA, it very well could be about 70% of STELARA sales -- that's a nonselective IL-23 inhibitor biologic, for those who don't know. Although it's approved for psoriasis, psoriatic arthritis, and Crohn's and colitis, about 70% of the sales are coming from IBD.

So it very well could be that in this IL-23 class, that that is going to be the biggest of the opportunities.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Last question on IBD for this product, competitive space not a regulatory requirement. But, effectively, do you need to run a head-to-head trial in Phase III, against an active drug to really find a home for this problem?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

We intend to do that. We did that with TREMFYA where we went head-to-head against our STELARA in a rigorous double-blind controlled study, unlike the way some others have done head-to-heads. And we will do the same with this molecule.

That is important outside the US, in particular, for, sometimes, for reimbursement, particularly now that STELARA has gone biosimilar. So we will need to have data that's sort for the payer conversations, especially overseas.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. I want to pivot to neuroscience if we can. So the company recently paid about $15 billion to acquire a company, Intra-Cellular Therapies. And really, the cornerstone product there is CAPLYTA, which is for schizophrenia and other indications. There's a follow-on molecule, and it really hasn't gotten much attention.

You, guys, didn't really highlight it at the time you did the transaction. It's called ITI-1284 and it's deuterated formulation, so a slight tweak to the chemical structure. So what excites me about this is that, when I look at the development program, you're running quite a few number of "Phase II trials" in Alzheimer's psychosis and Alzheimer's agitation.

You're also running trials in generalized anxiety. So you take Phase II, okay, long pathway to approval. When I look at these Phase IIs, they're randomized trials, they're large, large enough, they're running duplicate, so to me, it feels like it's registrational. So is this a Phase II product that's actually a Phase III product that could come to the market a lot quicker than folks are thinking?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes. Tim, you're very astute. First, let me just back up a little bit. We're super excited to have brought the Intra-Cellular colleagues and their pipeline of products into J&J. J&J is number 1 in psychiatry.

And so, this -- the marketed product CAPLYTA is a great fit for our portfolio. Approved for schizophrenia, approved for depression in the context of bipolar 1 and 2. It's the only drug approved in both 1 and 2. And then the thing that tipped us over the edge to take the plunge was their Phase III data in adjunctive treatment of major depressive disorder.

That's your more garden variety of depression. There are more than 0.25 billion people around the world struggling with depression today. That's been submitted. The PDUFA date is later this year. But those data are just outstanding. So we say broad utility.

And then, 1284, as you said, is son of CAPLYTA. It's slightly chemically modified. And those studies that you mentioned are indeed of a size that normally could constitute grounds for the equivalent of a Phase III for the regulators that want to see two independent well-controlled studies.

So let's see what the data look like. They are technically exploratory. Sometimes one is adjusting what your final endpoints will be and other patient eligibility requirements based on the data. We'll see what we learn from it. But if the data sets are rock-solid and the FDAs and other health authorities agree, yes this can count as one of the two required studies, then we'll be one step further to approval.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

And that would take the product into areas potentially that CAPLYTA is not yet, things like Alzheimer's, psychosis. And that's relevant to products like Bristol's Cobenfy which is trying to get there as well.

Okay. So timing of news flow for these data sets, it's not '25. It looks like it's maybe '26 or even '27?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

That's correct -- well, I think we're, next year on the 1284 readouts that you mentioned.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. And I'd ask you -- so we did one of our Pipelines Unplugged call with you a while back where we covered lots of things. And I'd asked at the time, $15 billion purchase price, how much was ascribed to this product? Couldn't answer at the time, deal hadn't closed. Do you have an answer now?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

No. I mean most of that, obviously, was the marketed product, although we do see a lot of potential for 1284.

I would say though, although, yes, that was a big acquisition and J&J has the largest balance sheet in the industry, so we can certainly do those, is pretty atypical for us that we do big acquisitions.

We tend to go in much earlier to do small bolt-ons. And from that, we tend to really -- that's really where a lot of the value in our pipeline comes from.

And you can see that in recent examples like the Momenta acquisition where nipocalimab just got approved, our FcRn inhibitor, for a broad diversity of autoantibody-driven diseases or the Taris platform for bladder cancer that's gaining a lot of interest. So these are just a few examples.

So we tend to do a lot of these little bolt-ons and rather than the big product-based companies like Intra-Cellular.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. Let's move to oncology, hematology. So in multiple myeloma, you guys have really chartered the course more than any other company in really making a meaningful difference to this disease over the years with a host of products.

Newer ones include cell therapies like CARVYKTI and then bispecifics like TECVAYLI and TALVEY. So I wanted to talk about those last two products. So bispecifics versus CAR-T. So CAR-T gets held back in terms of usage because of certain toxicities like cytokine release syndrome. But the bispecific T-cell engagers also share some of these toxicities.

Again, the feedback that we sometimes get is that community hematologists are reluctant to engage with those products because of that safety profile. CAR-T gives you great efficacy, these other products like TECVAYLI give you good efficacy, they are off the shelf or easier to use.

But what is J&J doing to assuage those concerns and better define the safety profile such that there's a better commercial future for those products?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes. No, with any of these new therapies and the regimens in which they're included, there's always a journey in really devising the most convenient and best tolerated ways to get there. This is not unlike the journey we went through with good old DARZALEX where, in the beginning, it was pretty much limited to the academic community.

And then, over time, we figured out how to manage things like infusion reactions and other issues. And they became more and more integrated into the community practice. We're going through that same journey right now. We're doing a lot with community oncology groups. We just got to ameliorate the cytokine release syndrome.

As you know, many times one uses an IL-6 receptor inhibitor, namely toci. We recently have that now in the NCCN guidelines to be used together with the bispecific, so that ameliorates the cytokine release syndrome, and are now working with community practices to make that part of the routine that the toci is reimbursed as well in this country. So we're certainly getting there.

And then, I think what's more exciting is that, of course, we start, as always, in late line and our overall response rates were groundbreaking. These are first-in-class bispecifics and the launches have been the most successful of any bispecifics in the industry. So take that into account as well.

But now we're moving into frontline and earlier lines of treatment in combinations. So the last hematology meetings of American Society of Hematology, we showed, for example, if you take our DARZALEX and pair it with either Tec or Tal in patients with just 1 to 3 prior lines therapy, we were getting 100% minimalresidual disease negativity in these studies.

MRD is now recognized by the FDA as a bona fide surrogate for disease-free survival based on pronouncements they had last year. So we're seeing this now, the ability to take combinations of molecules from our portfolio and bringing them to the early lines, literally going to define the next regimens of the future.

And we'll work with community practices to teach them how to use them and make them well tolerated.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Let's move to RYBREVANT, which is a newer product for you. This is your EGFR, cMet bispecific used partly in conjunction with small molecule EGFR in frontline lung. It's notable because J&J has high views, you, guys, are getting peak sales that are at least $5 billion, and the Street is a fraction of that.

So there's a discrepancy in how the Street gives it. One of the reasons is the safety of that regimen going up against the current gold standard, which is Astra's Tagrisso, which is only just a single pill; it's quite easy to use.

So how is this being used in the frontline now? It's more of a commercial question. But what are you seeing is the uptake in the frontline setting versus the second-line setting?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes. No ever since we shared our overall survival data in the frontline setting, we're seeing the uptake really increasing exponentially.

Just a few months ago at the European lung cancer meetings, we showed that going head to head against the standard of care, that we were delivering this combined drug regimen of RYBREVANT plus LAZCLUZE, a chemo-free regimen, is able to extend survival by more than a year.

And the other thing that is really insightful is that if you look at the Kaplan-Meier curves, as time goes on, the curves between standard of care and RYBREVANT-LAZCLUZE are actually diverging even more. It's what we call a fish tail type of shape, as opposed to what you might see with the standard of care, protein tyrosine kinase inhibitor, OZ, together with chemo, where the curves initially diverge, but then they converge and you get more of this banana-shaped type of thing. So we really like what we're seeing in the data.

And then, on top of that, mind you that those data were not an optimized regimen. That was our first shot. But now we have a subcu rather than an IV, which looks to be not only more convenient but also safer in terms of the injection site reactions; also, more efficacious.

And we also have learned a lot about how to ameliorate the side effects related to skin, thrombosis, et cetera. And so we now have an optimized protocol that we're testing in community oncology centers, particularly in this country, to gather more data.

But we feel that we're really on the right trajectory with this. And that's why we have high hopes for the molecule in both first and second-line lung.

But beyond that, Tim, we're now in Phase III in colorectal cancer, 2 different Phase IIIs there, in first and second line, as well as we've achieved POC or moving into Phase III with head and neck squamous cell carcinoma.

So there's more to the RYBREVANT story than lung cancer.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

And early stage lung, my guess. Is the subcu formulation, better tolerability, probably allows you to go into early station like Astra did with Tagrisso?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes. That's certainly on the list of things to explorer, getting even into adjuvant, et cetera.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

So just admittedly, we used to be pretty skeptical of that program, but the survival data does actually look quite compelling. Do you have any idea, is that actually preventing the emergence of Met formation and Met resistance? Is that why the shape what of the curve looks like that?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

We do know that. We actually did that analysis. And for those who aren't following this, so RYBREVANT is the world's first bispecific antibody ever approved for a solid tumor indication.

One arm neutralizes the EGF receptor, which is commonly mutated in lung cancers. And the other cMet, which is another growth factor receptor, often called HGF receptor, that becomes over-expressed as a resistance mechanism when you block the EGF receptor.

And so, we did do analysis in the MARIPOSA study and looked at how often did cMet over-expression occur in the RYBREVANT-LAZCLUZE arm compared to the OZ. And we significantly suppressed the emergence of cMet over-expression.

We also suppressed the emergence of additional mutations in the EGF receptor as well.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. Let's finish up in the cardiovascular space with milvexian. This is your partnered product oral Factor XI in three different indications in Phase III, the biggest of which is atrial fibrillation.

So it's been a class marked by some setbacks here and there. Some companies have dropped out, others are pushing ahead.

Just your updated level of, confidence, some totality of all the industry data and where things are today. Would you describe this as a low-risk, medium-risk or a high-risk program?

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Well, I won't do the pronouncement. But maybe just say, look, we're very dedicated to the program. We've already completely enrolled the AF, the atrial fibrillation study, more than 20,000 patients.

We think we got the pharmacology right in collaboration with BMS in that the molecule has been really well behaved. It was well tested in Phase II studies using total knee replacement as a playground in which you can adjust and define doses that have historically translated to the AF situation.

In fact, all oral anticoagulants that are approved for AF went through that Phase II testing. We're actually the only Factor XI that has done that at this point that's still in the hunt for AF. So we think we got the dose right. As my mentors always told me, dose matters.

And so, that's where we put a lot of emphasis on that, some companies not as much. And we feel that we've got a molecule where, for the AF indication, which is more like a venous stasis type of situation for coagulation rather than an arterial side, where we know from our experience with XARELTO, a Factor X inhibitor, we know you have to push the dose.

What we've got with milvexian is a molecule that is safe enough that we can push the dose and get it to the right level for that AF indication. So we're very bullish on the study. It addresses a huge unmet need, particularly as our populations become more aged.

And while I'm at it, maybe I'd put in a plug for the med tech colleagues who do a lot with ablations in AF. So those patients who prefer not to stay on the medicine forever, they can have the option of trying an ablation.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Okay. Last question on this end of the session here. So would you say that secondary stroke, which is one of your trials, is riskier than atrial fibrillation?

It's a relevant question, in my opinion, because we've got the Bayer stroke data coming up at the end of the year, and that's, naturally, people are going to look at that as a read across to the mechanism, whatever the indication.

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Yes. I think just by the nature of the more heterogeneous aims of mechanisms that can lead to stroke, you'd probably say it is higher risk than the Afib. But again, there, we're -- we feel confident that we've got a great mechanism in Factor XI.

For those who have followed it, there's great genetics where people are sometimes born without Factor XI. They have decreased risk of thrombosis, but they don't have major bleeding problems. So we feel like we've got that shot at both efficacy and safety.

And when it comes to a disease like stroke, so many patients are not on therapy because of the risk of bleeding in the brain. So this will be able to address an unmet need due to the safety of Factor XI inhibition, which is believed to block the formation of pathologic clots that might plug a vessel, but still allow the homeostatic clotting mechanisms that prevent bleeding.

So we're excited about the stroke prevention, as well. And this new mechanism, we think, fits right there where the current anticoagulants are thought to be not safe for that an indication in many cases.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Great. Okay. Well, we're going to call it there.

Thanks so much, John, for joining us today and for participating in our conference this year.

John Reed - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Great, Tim. Thank you.

Timothy Anderson - *BofA Securities, Inc. - Analyst*

Thanks.