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EDITED TRANSCRIPT

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OVERVIEW:

Company Summary

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Lee Hambright *Sanford C Bernstein & Co LLC - Analyst*

PRESENTATION

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

All right. I think we'll jump in here. So thanks, everybody, for joining. I'm Lee Hambright, US med tech analyst at Bernstein. We're thrilled to host Company Group Chairman, Johnson & Johnson, Innovative Medicine North America, Tom Cavanaugh.

Tom, thanks so much for being here.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Thank you for having me.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

So we're scheduled for a 40-minute fireside chat. You should all have the pigeonhole link if you want to submit questions. We've got the iPad up here.

So Tom, you've been in the Chairman role here for almost two years now. Maybe you can just kick us off with some opening remarks on how you see the state of the business at J&J.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah, I'd be happy to. Hello, everyone. Pleasure to be here with all of you. It's an exciting time at our company, at Johnson & Johnson, and I'm happy to share some major catalysts for our business and outlook for the coming quarters and years.

Look, I think Johnson & Johnson, what sets us apart is really our depth and breadth and strength of our portfolio against any of our industry peers. And we are what we like to say in a new era of growth in the innovative medicine business. I think as many of people had realized, we were facing the loss of exclusivity of STELARA, the biggest asset that we had in Johnson & Johnson, and I would tell you that's behind us.

I think we've proven ourselves to be able to -- what we set out to do is grow through loss of exclusivity at STELARA in the coming years. In the first two quarters, we've proven just that. We're quite excited about our portfolio, the breadth and depth of it but also some of the most recent launches that we have.

Just recently, we got the approval for INLEXZO for bladder cancer. We're anticipating the launch of CAPLYTA for AMDD. In fact, we just closed that acquisition for Intra-Cellular earlier this year and excited to welcome the employees on board to Johnson & Johnson, and they're ready to launch this product for major depressive disorder.

We're also quite excited about the momentum that we had in some of our most critical launches, whether it be TREMFYA in IBD that's off to an incredible start. RYBREVANT and LAZCLUZE for non-small cell lung cancer for those with an EGFR mutation, again, off to a very strong start, as well

as some of our underlying base business and portfolio, really the in-line markets growing above expectations, really centered around DARZALEX, really the gold standard for multiple myeloma, and the foundational therapy across all lines of therapy in multiple myeloma.

And I have to tell you, it's going to be an exciting time to be at Johnson & Johnson innovative medicine. And I will say, based on all of this, we are really confident to live into our long-term projections of 5% to 7% compound annual growth through the remainder of the decade. And quite frankly, we feel we're on the upper range of that where we have the momentum going.

QUESTIONS AND ANSWERS

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent, excellent. A great kickoff, lots to dig into there. So maybe we start with some macro. Just a lot of moving parts over the last year or so, MFN, Medicaid cuts, expiration of the exchange subsidies, PBM reform, changes at HHS, cuts at FDA and CDC, tariffs, all these things. How would you just frame your latest thinking on all that policy uncertainty?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

That's a lot. Look, there has been a lot going on. A lot of discussions taking place, especially from a policy perspective. I can tell you, at Johnson & Johnson, we have experience in navigating these times, 140-year-old company. We've dealt with 24 administrations with different complexity, different policy reforms, our proposed policy reforms. I'd tell you, we'd be able to weather the storm.

I think, first and foremost, on the foundation of the strength of our portfolio, the breadth and depth of our portfolio allows us the ability to navigate these uncertain times as people would call it. I'll tell you, giving you more confidence due to these uncertain times, we've raised our guidance. So it just reassures you our confidence in our ability to grow through this.

And it's not without some potential challenges that we might face. I will say, as we think about the administration, the current administration, it really comes to be about finding commonalities, common grounds, ways in which we can work together. And we're quite pleased with an open door policy that we see on both ends, both from a pharma perspective, whether through our trade groups, whether it be pharma or bio but also the administration. They're willing and able to work with us and are listening to us. Sometimes it wasn't the case in some of our previous administrations.

And with that said, I do think as we come together and able to have those open dialogues, we got to find common ground. You mentioned a few things, MFN, IRA, effectuation, some other things with regards to macro policy changes. I would tell you, I do think there's some more alignment than not. I'll say one thing when you think about it. Some of the things we just recently announced earlier this year, Johnson & Johnson committed to $55 billion in manufacturing here in the US, kicking off our state-of-the-art biologics facility down in Wilson, North Carolina.

This is something the administration was very focused on, bringing US economy and jobs back to the US as well as domestic manufacturing. And we are committed to that. And we are already working along the way, even during this first term when we made some tax changes to allow and incentivize us to come back to the US.

I will tell you, a lot of our industry peers are doing that. So here we are, it brings resilience to our supply chain as well, but bringing the economy back to the US and really domestic manufacturing in one area, I think, we saw eye to eye with and are moving forward.

Other areas, I think we talked about lowering healthcare costs. And really, what it comes down to is the consumer or the patient, and we are fully committed to that as well. One of the things you think about MFN as pricing is looking equally across some of the countries or the intent is everybody paying the fair share, so to speak. I think at the end of the day, if you think about list versus net price, some of the things in the intermediaries is where we need to focus on. And the administration is willing to work with us on that, whether it be PBM reform or 340B reform.

Just recently, they allowed HRSA to move forward with our industry to do a rebate model for 340B really to understand the transparency in the system, ensure the right patients are getting the right discounts or the providers are seeing these discounts to the appropriate patients. And I think that's important.

If we can really reduce those costs in the intermediaries -- I mean, we have our transparency report, 10th-year we've published it online. I welcome anybody to go to it. But $0.58 to every dollar goes to the intermediaries. So if you can reduce that, you can reduce overall healthcare costs, and consumption ultimately hit the consumer and lower the out-of-pocket cost for them as well.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent. Okay. Great. One policy question from the crowd. Just somebody wondering what is the tenor of the conversations with the government with respect to IRA. I think there's a little bit of a thought that maybe the negotiations get a little harder this next time around.

Any comment on that?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. I can tell you, we went through the first round. We had two products ourselves, and we're looking -- we're preparing and working with the government CMS on effectuations to the model to be able to effectuate the prices in the system, very open dialogue, willingness to work with us. We haven't seen anything from a single standpoint that they're going to be harder on negotiations. I think some may say the first round was not necessarily negotiations. That was in the other administration.

So it's always going to be dynamic. We expect that for us is continue to recognize the value and defend the value because we are really changing the lives of many patients worldwide.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent. Okay. Great. Let's talk about targets. At your last EBR, December 2023, you set a target to hit $57 billion in pharma sales by 2025, and you got there a year early in '24.

I think you're proving that you can grow the business through STELARA LOE, as you said. Consensus now expects almost $60 billion in sales for 2025. Maybe talk a little bit about the drivers that enable you to fill that gap.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. Thanks for recognizing that. We did hit it a year ahead of expectations. And hopefully, now maybe you can get a little change, maybe an upgrade coming out of this conversation like Guggenheim did yesterday. But I would say people are starting to realize our growth and our opportunity ahead of us, and we are quite excited about where that growth is coming from.

A few areas I'll focus on, TREMFYA, we have said we believe TREMFYA will be a $10 billion-plus asset. And I don't necessarily say the Street is recognizing all of that and realizing all of that. If you look at the underlying source of business. Predominantly, it has been in psoriatic disease, were about $4 billion worldwide in 2024. And now we just launched in the last year globally our indications in IBD. So both in ulcerative colitis about a year ago, Crohn's disease in the US earlier this year, and now fully a subcutaneous induction therapy for both Crohn's and ulcerative colitis. And I'll tell you why that's important.

But I bring this up because if you think about a proxy, I talked about STELARA as the largest asset or was the largest asset in Johnson & Johnson, $11 billion peak year sales, 75% of that was IBD. So if you just think about that, the promise that we have for TREMFYA in IBD, we are off to an

incredibly good start. We foresee absolutely every chance to be able to achieve the $10 billion plus, really with the best-in-class asset that we see our customers are saying that simplicity and ease of administration, the subcutaneous formulation based on our customers' reaction is a game changer. No other IL-23 has that, and our growth -- and we're starting to see that growth already.

And IL-23 in ulcerative colitis is the fastest-growing class, and we're the fastest growing assets. So we feel very confident in our ability to deliver TREMFYA. That also helps close that gap as we think about the $60 billion that you highlighted.

Another area I would talk about is lung cancer. RYBREVANT-LAZCLUZE, we've launched across multiple patient types in lung cancer with EGFR mutation. I'll tell you, with the positive data, the overall survival advantage that we've communicated earlier this year, nothing has shown a survival advantage to that magnitude versus standard of care, osi, I would say. And we do believe RYBREVANT-LAZCLUZE has the ability to become a $5 billion-plus peak year sales asset. So we're well underway to achieving that.

And then not to mention the underlying growth of our in-line business, really back on the DARZALEX FASPRO. I think you can continue to see momentum there and the breadth of our portfolio. We do believe in oncology, by 2030, we're going to see a $50 billion peak year sales, really based on the backbone of our multiple myeloma franchise. So I feel more confident we're going to be able to live into the 5% to 7% and achieve more than what we expect.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

That's great. Excellent. Okay. Great. Let's go one by one and try to jump into some of these.

So maybe starting with immunology on STELARA. It's been a few months now. The biosimilar launches are out there. Last quarter, J&J sales grew 3% organic despite the 710 bps headwind from STELARA LOE. Can you just talk a little bit more about how the erosion curve is playing out versus your expectations?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah, as expected. I think we gave -- we felt a proxy for STELARA erosion would be HUMIRA year 2 erosion. And we're tracking along those lines. So as I said before, we do believe STELARA is in the backseat or in our rearview mirror, and we are ready to grow well above where we were with STELARA in our hands.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Could that move even faster as TREMFYA really starts to take off?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

You raised a very good point. We have molecular -- erosion of the molecules, so the brand within the molecule. But then we also have erosion of the actual class, let's call it, the IL-12/23. With TREMFYA and the momentum that we have, we can also cut that erosion by really growing through it with our launch in UC and also in -- as well as CD and across the other indications such as psoriatic disease.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Excellent. So you talked -- you highlighted TREMFYA already as a key driver, 30% growth last quarter, great feedback for the IBD indication, strong start in Crohn's, and you see -- what are you hearing in the field? I mean, what do you hear from physicians?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. I can tell you, I think, first and foremost, they are recognizing TREMFYA is differentiated, the only dual-acting IL-23 on the market. As I highlighted, they do believe in ulcerative colitis, really best-in-class endoscopic remission in histological endpoints, similar to that in Crohn's disease, first head-to-head study against in a registration trial versus STELARA and definitely winning on multiple endpoints there that are very important to the patient, but also the provider. As you think about it, we feel it is a best-in-class asset.

We have fulfillment, so the patients to be able to receive the product is simple and easy as we were launching it. It's the first time they've seen it where in 24 hours, the patient would be able to receive the product. And why is that important? And why were they able to do that?

One, subcutaneous induction, so self-administration. They can go directly to their house, and they can administer versus the other IL-23s and quite frankly, what we had with STELARA, where you actually have to have it infused for induction, and then you go to maintenance where it's subcutaneous and self-administered. So that is really what physicians are calling game changer.

Like when we just got approval in UC for subcutaneous induction, we sent out communications to many of our thought leaders and customers, and they were just like this is practice changing, game changers. These are actual quotes. So incredible enthusiasm, where we are so confident and excited about this.

And so confident, we also went forward with a head-to-head study against Skyrizi in Crohn's disease. So we just recently announced that as well. So we feel very confident in the molecule to really get us well beyond $10 billion-plus.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

So that was a PR just five days ago or so, advancing the head-to-head trial to demonstrate superiority of TREMFYA for Skyrizi. And I think, as you mentioned, you like your chances given the fully subQ regimen. Can you just elaborate maybe a little bit on what you're trying to achieve with that study?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

It is just what you said, like we do believe in Crohn's disease, we are differentiated. We want to show that clinically. I think everybody cross compares trials. But until you go head to head, it's really where you can -- proof is in the pudding.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Great. So you've highlighted this is as a $10 billion-plus asset. Any chance you might be willing to offer sort of a timeline to that number?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

It's hard to speculate. I think we're still in the early phases of the IBD launch. I think we need a little bit more time to really reassure the timing of that. But I will say just knowing the unmet medical need in this disease, still in this disease, the need for complete and histological remissions is very important.

And that bar is raised, and we're raising that bar each and every day. And we have a pipeline of assets that come on after that as well. So I would say it's definitely within reach before 2030, but give us some time.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Okay. Got it. Speaking of pipeline, you filed Icotrokinra with the FDA in the third quarter as the first targeted oral peptide to selectively block the IL-23 receptor with similar efficacy to a biologic. So this is a once-a-day pill, potential to set new standard of treatment in plaque psoriasis. Maybe can you just talk about the market expansion opportunity with Icotrokinra?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Absolutely. We are incredibly excited about Icotrokinra. If we think about the profile of this product based on the data, whether it be head-to-head against deucravacitinib or against placebo in some even hard-to-treat populations, we've shown remarkable efficacy. You've mentioned biologic like, but really complete clearance is what you're looking for, and we're seeing equally the amount of complete clearance with this drug.

And it's from a profile of safety which is very important in this patient population, similar to placebo from an A/E rate. So I think if you think about safety and efficacy, it's there, and then the convenience of a once-a-day oral pill.

We still see in this marketplace, basically, there's around 5 million patients that are eligible to receive advanced biologics that are not receiving advanced biologics. Some of it is safety. Safety is still a big concern. They don't want something in their body, and they just may not feel comfortable with it.

The other is needle phobia or just for other reasons. And if you think about really the treatment journey for a patient, sometimes when they present with plaque psoriasis or moderate to severe, they might want to start with a topical. It depends on how many plaque psoriasis that they have on their skin or how much lesions that they have, and then maybe go to an oral.

Sometimes they go do a methotrexate, conventional, and then maybe some of these other orals that are in the marketplace. And then they think about the biologics. So Icotrokinra is uniquely positioned in that to be the first-line systemic treatment based on the profile I acknowledged and highlighted. So I do think we have an opportunity to really not just expand the market but penetrate the current marketplace on what's being used because there's a lack of satisfaction and there's absolutely a need from a patient's convenience.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

How do you think about like kind of market segmentation and development over time between the orals and the injectables, like how big can oral get as a percentage of this market over time?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. It really depends. I think that's where we're going to be able to really test Icotrokinra because of the profile of the product. Unfortunately, the current orals don't satisfy the needs of the marketplace. And you see that based on share uptake in those that will be able to tolerate and go on long-term treatment.

So that population, I talked about the 5 million, you have also the population as you think about into the topicals, like these are moderate to severe plaque psoriasis. It's still the same indication but they're on topicals. Why are they on topicals? We need to understand that.

So I do think there's opportunities to penetrate earlier. And then those that are not satisfied in the biologics. They just want the convenience. They see the safety and efficacy of this product and are ready and willing to switch.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Excellent. Okay. Can you just remind us the catalyst path or the timeline on Icotrokinra?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

We're currently under FDA review right now for plaque psoriasis.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Got it. Excellent. So oncology, let's talk about DARZALEX. There's been some debate on IRS price negotiation inclusion. Maybe you talk a little bit about J&J's position regarding when it could be potentially up for negotiation.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

So DARZALEX FASPRO, we still remain committed based on the interpretation of the draft guidance for CMS of 2034. We truly believe DARZALEX FASPRO is clinically different than DARZALEX IV, and we feel very confident in that number.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Got it. No time -- nothing soon. Great. So DARZALEX has done really well, obviously, 21% growth in the second quarter. It's clearly a foundational treatment for multiple myeloma.

What are the growth expectations in '25 and beyond?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah, I can tell you, I've been in this space, so I had the opportunity to launch some of the previous, I would say, standard of care in multiple myeloma in my previous company. And then coming over to Johnson & Johnson a little less than eight years ago, I've not seen a drug like this in any other marketplace. I mean, DARZALEX FASPRO is truly unique.

It is foundational therapy when we say that, combinable with most of our products, every patient population, we're seeing survival rates where in multiple myeloma used to be two to three years survival overall. With DARZALEX, whether in combination with a quad-based regimen or a triplet basin regimen like Revlimid-dexamethasone, we're seeing survival rates close to eight years and PFS rates in the decades. I mean, this is truly remarkable. I mean, you're really talking about chronic care here.

And DARZALEX is the backbone treatment across all lines of therapy, even with new products coming in, our own products, TECVAYLI, TALVEY, we're combining with DARZALEX. So you'll see significant opportunities still to grow in the earlier lines of treatment. About half the patients are going on DARZALEX-based therapies in any line. So there's opportunity to grow as you could bring in earlier. We just recently, in Europe, got approval for CEPHEUS which is in the transplant-ineligible population, and we're anxiously awaiting that also in the US, so there's opportunities to move earlier.

The other area for growth with DARZALEX is duration, so as you think about this, whether it be in combinations or just continuing through a maintenance phase. Highly convenient, it gets to a monthly based dosing, quick injection, five minute, less than five-minute injection for the healthcare provider, subcutaneous. So we see tremendous opportunity, and truly it has revolutionized the treatment of multiple myeloma.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Amazing. Okay. So hitting CARVYKTI, new five-year data shows a single treatment of CAR T therapy has the potential to deliver long-term remission. You have firm conviction, I think in CARVYKTI as a $5 billion-plus asset, and the commercial ramp is moving along really nicely. What do you see as key to kind of keeping that current momentum for CARVYKTI?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. So every year, they have a congress. It used to because The Myeloma Workshop now it's called IMS, International Myeloma Society. I bring that up because it was just last week. So this is relatively new. In that, this is basically a congress of world experts in multiple myeloma. They've been doing this for 20 years-plus.

They come together, and they look at consensus. But the topic of this one was definition of cure. And they went down the list of what -- how to define cure and really what it comes down to is time, five years relapse-free. So in remission for over five years.

I bring that up because we just recently released data with CARVYKTI in the CARTITUDE-1 trial. So this was five lines of prior therapy, so very heavily refractory patient population. A third of those patients are five years out remission free. So based on that definition that was coming out from the IMS, they would call that cure. So that, to me, is really the goal of any oncology agent.

So if you take that, that was in previously treated, five lines of previous treatment. We have approval previously with line 1 and beyond. So CARTITUDE-4 data lines 1 through 4 lines of therapy, showing the only cell therapy to demonstrate overall survival advantage versus the standard treatment with a one-time infusion.

So we do believe, as you think about CARTITUDE-4, CARVYKTI to be able to move it up in earlier lines, the magnitude of benefit, not only for the patient, but if you think about the immune system being intact, the ability to really transfer lines is really going to be amazing.

And we'll -- let's look at the long-term efficacy of that as that continues to play out just with time. But rest assure, we could see ourselves having even greater impact in earlier lines. And we have ongoing trials in frontline as well. So we do believe CARVYKTI is well within reach of achieving greater than $5 billion peak year sales. It is truly the most efficacious treatment in multiple myeloma.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Amazing.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

And you mentioned, I do give a lot of complements to our manufacturing and supply chain. We were able to increase our supply, our scale, our consistency. So we're well within -- that would not be an impediment on any of our opportunities.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

That would be a manufacturing, not a gating item.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Not a gating item. We have over 8,000 patients infused with CARVYKTI in over 11 countries now. So that's the other expansion opportunity as we look outside of the US and other markets.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

What is the gating item at this point if it's not manufacturing?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

It is the ability to precise to be able to step up. So that is part of the strategy. As you think about the community right now, it's been heavily concentrated in more academic centers, those that have infrastructure in place. So it's expanding beyond.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Can you just talk about the competitive environment there a little bit, maybe some stuff coming at some point? Do you feel like you got a good lead there?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah, we definitely feel we have a good lead there. I think, as you said, like you really got to prove an improvement over the standard of care. So we are the -- there's two that have registration trials, Phase 3 registration trials against the comparator. There's another one that's being developed by another company. That has a lot of time to go, I would say, before they can get into anywhere near the frontline setting where we are at.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Okay. Great. All right. Let's talk about bladder cancer. You got FDA priority review for TAR-200, first of its kind drug-releasing system. And INLEXZO just got FDA approval on September 9. So how's the kind of prep for launch early phase looking at this point?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Again, this is truly game changing, first of its class. This is the first time. So INLEXZO is, as you said, an intravesical drug release system. People refer to it as a pretzel because it looks like a pretzel.

It's a simple procedure done in a urology practice. So this is another thing that's important about INLEXZO, why we foresee [the TARIS platform](corrected by company after the call) to be a $5 billion-plus peak year sales asset.

It's a product that locally administers gemcitabine in the bladder. It's inserted within a five-minute simple procedure through a catheter, an Ethicon catheter, nonetheless. And it can be done by a nurse, an APP or an advanced practice provider or physician, and then simply removal in the same period of time. I bring this up because of the simplicity of the procedure to be able to deliver that localized delivery also.

The data that we've seen in non-muscle invasive, high-risk, BCG-exposed carcinoma in situ bladder cancer, it's more of a narrow indication first. It's truly remarkable. 82% complete remission, where over 50% of them were out for more than 12 months. So it's truly durable, complete remission. That's really the game changer here for bladder cancer.

The other alternative to these patients is the removal of the bladder. This is bladder preservation. So this was the first indication. We have ongoing trials.

We have a robust development plan, looking in papillary disease, a much larger patient population. And they were going head to head against the standard of care. There hasn't been much innovation in bladder cancer, and that's BCG. So those that have been on BCG, what we hear from the patients is really a tough treatment to have.

Sometimes they refer to it as a tiger clawing at the bladder. It's fluid that's injected into the bladder, and it needs to be held there for about four hours. So you can imagine your bladder really wants to get rid of that fluid. So highly complex, and it's something that we believe we want to displace and really maximize the potential for patients.

There's roughly a million patients -- it's the eighth largest tumor, a million patients suffering from bladder cancer. Unfortunately, 600 of them are newly diagnosed, 400 reoccurring. So we see this to be a tremendous opportunity potential.

And then we talk about the technology in this drug releasing system. We also have TAR-210. TAR-210 is erdafitinib in this device, our drug-releasing system. And it's important because it's targeting FGFR mutations. And there's a high prevalence of FGFR mutation in intermediate-risk bladder cancer.

So we're in high risk for TAR-200 or INLEXZO. We have the ability to have a portfolio of products. So we really are excited about what we can do in bladder cancer, significant unmet medical need, and we're bringing transformational medical innovation.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

That's great. On the last earnings call, when you're talking about the Street's disconnect with your $50 billion oncology target, I think this is the one that came up first. You talked about it, I think it's a $5 billion plus, but maybe it's bigger than that.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah, yeah. You can model it. We're excited about it. I would say we're really excited about it. And you mentioned our ability like we had the product available within four days.

They're working through the systems. It's a buy-and-bill product. So people, temporary J codes, we were able to work through the process with our providers. But there's tremendous excitement. There's a race to see who's going to be the first one to insert.

We have people on the ground training on how to do the insertion, whether it's in practice, in office alongside of them. So this is some of the stuff where we see a little bit of the synergy and learning from our med tech colleagues. This is something new for us from a pharma or innovative medicine that we're able to get the training, the catheter, and things from our medtech. So there was a bit of synergy there, and we're centrally capitalizing on the expertise from our medtech colleagues.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

That's great. Excellent. Okay. So moving on to RYBREVANT-LAZCLUZE. So consensus estimates for '27, '28, a little bit over $2 billion.

You've just suggested I think that it could be $4 billion by 2028. We're just getting started, just $180 million or so in Q2. So it is a steep ramp there to get to that $4 billion. Can you just talk a little bit about the path to get there over the next few years?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. I would say, unfortunately, as any of you know, lung cancer, the five-year survival rate is still less than 30%. So the ultimate goal is survival. And with RYBREVANT-LAZCLUZE, we do believe we're bringing a game-changing therapy, what will become the new standard of care in frontline EGFR non-small cell lung cancer. And I'll tell you why.

One, it's a chemo-free regimen. Two, it's targeted multiple targets. Not just EGFR, it's EGFR-cMet, and it harnesses the immune system. I bring that up, and that's important because it's changing the underlying biology of the disease. We just recently released data where the data because of this suppression of resistant mechanisms, as you think about resistant mechanisms, are what leads to relapse and further relapse and resistance and ultimately death, unfortunately.

So the ability to be able to suppress that is very important as we think about it. And if you think about the Kaplan-Meier curve, so we have demonstrated at least a 12-month advantage over osi for overall survival. We haven't hit median. You're starting to see a little bit of a plateau of the curve. If you just use correlations to other lung cancer agents such as the checkpoint inhibitors, you saw that there.

We saw it in the earlier indications with exon 20, so a tough, difficult-to-treat disease population of EGFR, but you're actually seeing that as well. So we have significant promise. We do believe it's going to become the standard of care. And that's just in lung cancer.

So we do believe RYBREVANT itself, we've seen -- already have preliminary data, both in head and neck cancer, significant unmet medical need as well as colorectal cancer. So we see tremendous opportunities for RYBREVANT overall. But RYBREVANT-LAZCLUZE becoming the standard of care in lung cancer.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

That's great. So AstraZeneca is marketing TAGRISSO plus chemotherapy as a way to raise the bar versus competition. I hear some investors who worry that they may be winning the narrative battle in some places. How do you respond to that competitive threat?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. They just recently released data. I think we need to wait to see our longer-term data of overall survival because I think survival is really what it is. And I will say one of the other things that I think will be a catalyst for us, we have approval ex-US with RYBREVANT subcutaneous formulation.

So we do recognize right now, they are accustomed, they're used to treating with osi and sometimes adding in chemo. And we have a lot of education that we had to do with RYBREVANT-LAZCLUZE, and we're doing just that. We've had protocols in place to manage the AEs. They call it cocoon. We want to make sure that they're able to manage the rash and skin toxicity and potential for that as well as IRRs, infusion-related reactions.

Now subq doses are significantly reduced. And what you'll also see is a convenience of a five-minute injection just like DARZALEX. So you have that ability, much easier and simple for the provider.

And then what we also saw that was uniquely different with RYBREVANT FASPRO, I would say the subcutaneous formulation versus IV improvement in duration of response and efficacy. So we do believe it to be a game changer. We're doing a clinical trial now with that treatment regimen in the frontline setting, and we look forward to that to help differentiate the product.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent. Okay. I missed an audience question about immunology. How long is the induction period for your competitors in IBD?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

It's two to three inductions, depending on the competitor.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent. And we've got one more on what are your strategies for in-sourcing versus outsourcing clinical trials to adapt to the changing landscape?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

We absolutely continue to look at ways that we should find efficiency in the model. I think that is one of the areas from an R&D perspective, we have a lot of focus. There are definitely times when you want to make sure it's in source, but you definitely want to have a hybrid model for flexibility and scale.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Got it. Okay. Let's hit a couple of neuroscience things. SPRAVATO grew 53% last quarter, strong momentum. Maybe you could talk a little bit about its role in treatment-resistance depression and what's that opportunity look like?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. The profile of SPRAVATO is truly unique. And it is absolutely a first in its class agent. And if you talk to any patients, it absolutely is a lifesaver game changer. Many of them, their lives have been turned around because they've been on SPRAVATO.

The efficacy can work within 24 hours of administration, and the resolution of AEs in the same period with strong durability, like once they're on it, they can see years of durability as long as they're taking the product. I would say if you think about it, and that was one area where I think there was a disconnect also with the Street, and rightfully so, I would say, somewhat because when we launched SPRAVATO, this was not a simple administration, and we launched it during the time of COVID, so in-office procedures, not necessarily available to a provider base, which as psychiatrist that are not typically accustomed to treating patients physically. Like this is where they need to sit there and administer the product and observe for over two hours.

So from an infrastructure perspective, they didn't have it -- if you think about some of the sites, they have one office, that's where they see their patients. They don't have observation rooms. So they had to make sure they could be able to operationalize this. We've gotten that right. We've helped them out.

We've worked a long way, and we have treatment centers all over the US. So site of care being able to get to these places is readily available. And that's where you've seen our growth really accelerate. They absolutely believe in the product for what I just said. It's truly differentiated.

It's unique. It's both for monotherapy and adjunctive. We just recently got monotherapy approval, so highly flexible in how they want to administer it, but we really see that to continue with growth momentum.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Great. Great. And CAPLYTA is you got a couple of indications there, schizophrenia, bipolar, depression, maybe another indication coming later this year. What are the expectations there with CAPLYTA?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yes. Yeah. I would tell you for CAPLYTA, especially in the pending AMDD launch. Right now, it's currently approved for bipolar 1 and 2 as well as schizophrenia and growing quite nicely. I will tell you, we are anxiously awaiting, it's under FDA review right now, the adjunctive major depressive disorder indication.

If you just think about the data right now, the effect size versus what you see in the marketplace is 2 times from an efficacy standpoint. We've never seen anything like this in depression.

And when you think about some of the traditional antipsychotics, right now, if you think about the marketplace, 21 million patients unfortunately suffering from depression. The penetration of the branded market is only about 10%, so about 90% are cycling through the generics, some of it for convenience, some of it for what they were used to -- the providers are used to using it. But a lot of the challenges of some of these treatments, even the branded ones, are the side effects. There's the efficacy component, but we feel we've got that covered.

So from a side effect perspective, one of the most side effects that they see is weight gain, and what patients don't want to get is weight gain. Sexual dysfunction is another one as well as movement disorder. So all three of these, if you think about it, if you look at CAPLYTA, it's the ideal product because really zero effect versus placebo in those three areas.

So you now have a simple once-a-day pill, no titration needed, to convenience. If you think about a primary care physician or advanced practitioner provider, they can simply administer the product and feel that they're going to get the draws and not get the weight gain that they might on some of the others.

So we do believe this is going to be a catalyst for growth for CAPLYTA. We do believe CAPLYTA is going to be another $5 billion-plus asset. We're quite excited to have it in our portfolio and the entire Intra-Cellular organization. So that's another one that we foresee to be a significant growth opportunity and really will transform patients with major depressive disorder.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Awesome. Great. that's another one where there might be a little bit of a Street disconnect, I think.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

I think there is a little bit.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah, $5 billion in that window, maybe before 2030.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Let's see. We're excited about that. And we are ready. I would tell you, this organization is ready to go.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Excellent, excellent. Okay. Let's talk about pharma R&D. Pharma companies continue to spend more and more money on R&D. At the same time, you've got price pressure, regulatory scrutiny, putting pressure on returns on investment.

How do you think about returns on R&D investment in the pharma business? And do you expect the ROI to increase, decrease, stay the same next 5 or 10 years?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

I think at Johnson & Johnson, we always disproportionately invest in R&D than we do in sales and marketing. We do believe our strategy is built on three pillars, three therapeutic areas: oncology, immunology, and neuroscience, and some select area, disease area strongholds that we like to say. I bring that up because that allows us to really have end-to-end expertise from discovery all the way through commercialization, customer intimacy and understanding of the business and all the way through that value chain.

I bring that because we also then can leverage AI to understand the science and look for efficiencies. I do believe AI, machine learning, are really going to help us grab favor efficiency and better returns. So I foresee us continue to double down there. As we talked about some of the challenges, maybe macro challenges, the best way to weather those storms is to innovate.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Okay. Excellent. Maybe quickly on the M&A front. Obviously, you just closed intracellular, a bigger deal, almost $15 billion deal. Can you talk about the M&A strategy in pharma as these many areas of interest or priorities in terms of deal size?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

I would say, since we have declared the three major therapeutic areas, we're always going to be looking within those, whether adjacencies and disease areas within these three therapeutic areas, but be opportunistic. We're going to follow the science we have, I would like to call them, drug hunters in the organization that understand the science and following the science, and then we're going to be opportunistic. We typically – you know our sweet spot is some of these tuck-ins, some of the early deals, some maybe pre-proof of concept or right around that area, where we can then develop a product and really take it to a full-fledged development. I mean, DARZALEX FASPRO or DARZALEX is a great example of that, but we're able to do that.

We saw a little signal, took that and did a robust development plan and demonstrated our success, and you see that with Darzalex right now.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Excellent. Let's talk about modalities, new modalities briefly. You mentioned it. Do you think you have the necessary tools in the toolkit for those new modalities, cell therapy, mRNA, gene editing, gene silencing all those where you have gaps? Are you looking to fill those gaps via licensing deals or build those in-house capabilities?

Like how do you think about the plan for modalities?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. We don't look at a modality approach as we look more at the disease area strategy approaches. And if we see the disease and innovation, we'll find that modality and be able to make that modality work. I will say, if you think about it, we were one of the first products, or first organizations to have a biologic, REMICADE, and we've mastered that, I believe, that we've already got bispecifics. And now I'd love to talk to you about our trispecific that we're putting in the clinic, already have in the clinic. So if we think about modalities, we have expertise there.

Cell therapy is another one. With CARVYKTI, now we have a Bi-CAR that we brought in. We've learned as we go. And then we also have ADCs and radioligand and things like that. So if the data is there and the technology, we'll find a way to bring it to the marketplace.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Okay. Great. All right. I'm a medtech analyst, and I just went 38 minutes without talking about medtech even when you brought up TAR-200.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

I tried to give you a little bit of that.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Maybe to that point though on TAR-200, obviously, you're showing the benefits of having pharma and medtech under one roof. Should we expect more of that in other disease areas?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. I would say we are already doing that organically. We like to say let's become number one in our categories and then look for synergy, and I think that's what we're focused on doing. But I would tell you, naturally, as you think about one of the areas we have a partnered product for thrombosis, atrial fibrillation, for example. We have a significant presence there with medtech. We're definitely leaning on them. We have XARELTO in the US as well.

So we're looking at areas and we can look at patients, data science, analytics, understanding customer intimacy. So we're absolutely doing it organically.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Yeah. Excellent, excellent. It's been a bunch of PRs just in the last few weeks. It's hard to keep up with all the things that you guys are up to.

Anything we missed here, pipeline opportunities? Is there any sort of final comments you want to highlight?

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Yeah. Real quickly on the pipeline. I mentioned it. I think if we think about our end-to-end expertise in multiple myeloma, we learned a lot as the introduction of our bispecifics, Tecvayli and Talvey, we now have a trispecific that we have engineered or -- kudos to our scientists who are able to engineer this to really look at reducing some of the AEs associated with these bispecifics to make it a more community-friendly therapy.

We're able to space the dosing, have incredible efficacy, and you see that already in the preliminary results. And it could really transform the treatment of multiple myeloma. We talked about Milvexian.

I'll just end and say, at the end of the day, we believe we're in another era of growth for exciting opportunities ahead of us. We feel more than confident we're going to be able to deliver the 5% to 7% compound annual growth rate even in the upper limit due to this transformational medical innovation that we're bringing in, and we're excited to be there.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Awesome, awesome. Thanks so much for being here.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

Thank you, Lee.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Really appreciate it.

Tom Cavanaugh - *Johnson & Johnson - Company Group Chairman, Johnson & Johnson Innovative Medicine, North America*

All right.

Lee Hambright - *Sanford C Bernstein & Co LLC - Analyst*

Thank you.