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PRESENTATION

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Great. All right. Thanks for joining us, everybody. I'm Terence Flynn, the US large cap biopharma analyst. Very pleased to be hosting Johnson & Johnson this morning. For important disclosures, please see the Morgan Stanley Research disclosure website at www.morganstanley.com/researchdisclosures.

Very pleased to be hosting Joaquin Duato, who is the company's CEO and Chairman; and John Reed, who is Head of Pharma R&D. Thank you both for joining us. And Joaquin was just -- we were just chatting, this is his 35th anniversary at Johnson & Johnson, so a pretty big milestone. Congratulations on that. That's been a great run. And I know you have a lot more to do here in the CEO role on the forward.

I guess I'm turning it over to you guys, if you want to make any prepared remarks before we go into questions. Or we can go right into questions, whatever works for you.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

No, let's go right into questions.

QUESTIONS AND ANSWERS

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

All right. Well, let's do it. Maybe obviously, there's been a lot of focus on kind of longer-term outlook. So as you think about kind of the near-term growth target that you've given for next year in terms of 3%, maybe just help us think about that.

And then confidence level in continuing that growth where, again, you guys have targeted for each of your business segments at above industry growth for each of the pharma segment and the MedTech business. I know there are a lot of puts and takes as you think about that with some of the new growth assets and then you obviously have the STELARA LOE. So maybe talk to us about kind of the confidence in the 2025 targets and then those longer-term targets that you put out at the Enterprise Review Day, I think it's about a year ago now.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Yes. Thank you, and thank you, everybody, for joining us. So we feel very confident about our ability to reach the targets that we put forward in our December last year Enterprise Business Review. So to refresh the targets, what we said is that we were going to grow 3% or more than 3% in 2025.

And then in our Innovative Medicine Group, in particular, that we were going to grow 5% to 7% from 2025 to 2030. So we feel very confident about our ability to hit those targets.

Where is the confidence coming from? The confidence is coming from the strength of our performance. And if we look at our performance in 2024 and we look at the first six months of the year, the growth for Johnson & Johnson in totality, the revenue growth was north of 7%, with 11% EPS growth.

And if I divide it between Innovative Medicine and medical technology, was north of 8% in Innovative Medicine and north of 5% in MedTech. So we feel very confident in our ability to be able to hit our revenue targets based on the strength of the business that you can see today.

If I focus now in Innovative Medicine, where the growth is coming from in 2024? It's coming from our multiple myeloma franchise, which is an area strength for us with DARZALEX, CARVYKTI, TECVAYLI, and TALVEY. It's coming from our prostate cancer franchise with ERLEADA. It's coming from our Neuroscience Group with our long-acting injectables in schizophrenia and the growth of SPRAVATO. And it's also coming from our pulmonary arterial hypertension franchise, which is growing strongly, both UPTRAVI and OPSUMIT.

The positive things that are occurring now that are going to happen in fact in 2025 are mainly two. One is the launch of RYBREVANT plus LAZCLUZE in first-line EGFR mutated non-small cell lung cancer, which is occurring as we speak. It was approved a couple of weeks ago. And I am sure we have an opportunity to talk more about that regimen later, and John is here too. And that is going to be an important growth driver. We see that regimen, chemo-free regimen, becoming standard of care in first line. And there's about [320,000] (corrected by company after the call) patients with EGFR mutated non-small cell lung cancer globally.

The second big opportunity is the approval of TREMFYA in inflammatory bowel disease, both in ulcerative colitis and in Crohn's disease that should occur in the second half of this year or early 2025. So those are two very important growth drivers moving into 2025 that give me significant confidence on us being able to reach our targets in Innovative Medicine.

At the same time, in the second half of this year, moving into 2025, you're going to have a number of potential regulatory milestones and data readouts that are going to be important, that I'm sure we'll discuss later. We have already filed for nipocalimab in myasthenia gravis. We are presenting data soon as ESMO on TARIS and our SunRISe-1 study in non-muscle invasive bladder cancer in patients that are BCG-unresponsive. And that could be something that may get into 2025. And we are going to be presenting data too of our oral IL-23 Phase 3 in psoriasis and Phase 2 in IBD in particular in UC. So those are other three important opportunities that give me confidence beyond 2025, to your point earlier. So that's how I see our trajectory in Innovative Medicine and our ability to be able to deliver on the targets that I described.

If I move into MedTech, our growth in the first half of the year was 5.2%. We see our growth and our momentum moving into the second half of the year and also into 2025, and are optimistic based on a number of factors. One is our continued growth in our vision franchise with the global rollout of the launch of ACUVUE OASYS MAX. The other one is the launch of our premium IOLs, intraocular lenses, both ex US and in the US. So that is going to help us in the growth of our vision franchise second half of the year next year.

If I continue in other areas, I'm optimistic about our trajectory in cardiovascular. We may have an approval of our PFA catheters by the end of the year or beginning of this year here in the US. They are already approved in Japan and in Europe. We are optimistic about the trajectory of our Impella franchise based on the results of the DanGer Shock study that were presented this year. And next year, we will also add Shockwave to our cardiovascular franchise and growth. And Shockwave as you saw in the second quarter, is growing robustly.

On the orthopaedics side, we also just announced the approval of two new additions to our robotics VELYS offering. One is the unicompartmental knee and also our spine robots. So that's going to help the continuous expansion of VELYS. And then importantly, in the second half of this year, we have an important milestone for us which is the IDE of our robotic system called Ottava, which is our soft tissue robotics system.

So all these it's going to continue to move us into higher growth markets, build the momentum of our MedTech franchise into 2025. So I'm confident on our targets in 2025. And I'm also confident that you are going to see from 2025 onwards an acceleration of our growth once we digest the STELARA biosimilar entry in 2025.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Great. I guess the one corollary is just the margins as we think about 2025, I know you're not going to guide there. But just as you think about those puts and takes you walked through, there's obviously ongoing investments behind some of these new products, you have the STELARA which from a mix perspective is probably a headwind. How should we think high level about kind of the near-term margin picture?

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Yes. So what we have commented is that, and I'm going to quote literally, that we expect competitive revenue growth and commensurate margin growth. What you are going to be seeing is that there's going to be periods that our margins are going to be more tempered based on the factor that you just described. And then you're going to see periods of margin expansion once we are able to cycle through the STELARA erosion. So that's the way you have to look at it.

We're always aiming to have margin growth or EPS growth higher than sales. That's going to be what you will see in the totality of the period. But you can expect periods in our margin will be more tempered and the margin expansion once we anniversary that.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Great. Maybe just, again, moving on another high-level question here, is on the M&A side, you've really leaned in on what I'd call growth MedTech assets. You talked about Shockwave, Abiomed obviously, brought in Impella. It seems like that's been a focus. Then you look back at your history on the pharm side where you've leaned in and done one of the best jobs, I think, arguably across the industry at finding assets early and generating a very high return there when you think back to DARZALEX, IMBRUVICA.

And so is that the right framework to think about on the forward whereas like MedTech is more -- kind of these growth MedTech assets is really where you'll be focusing on, and then pharma because of that ability to kind of find assets early and generate a very strong return, that's kind of the framework we should think about? Or are there any differences now that STELARA is going LOE and that maybe changes the playbook a little bit?

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Generally speaking, that's the framework, so you are right. And for us, M&A and external innovation is always a key component of our growth. In the first half of 2024, we've invested about $18 billion in M&A. We've done the Shockwave transaction, but also we have acquired and we announced it weeks ago, V-Wave, in heart failure, and several companies in the Innovative Medicine pharm side, like Ambrx with antibodies that are conjugates, Proteologix with bispecific antibodies, and also Yellow Jersey in bispecific antibodies in atopic dermatitis. So that's only in the first six months of the year.

At the same time, and they have less headlines, we have done 20 other smaller deals. And oftentimes, to your point, those smaller deals that do not make the headlines are the ones in which we create disproportionate value. I don't think TARIS made any headline, and we are now saying that it is going to be a $5 billion platform for us. I don't think that the deal that we made with Protagonist to develop the oral IL-23 made any headlines, and now it's going to be one of our most important products in the pipeline. So that's really been a source of value for us, and we will continue to be able to invest in earlier-stage deals, which we think we have a special ability to identify them.

And yes, sometimes in MedTech, as we try to move into higher-growth markets, we need to get into platforms like Shockwave or Abiomed that are already more mature and more developed. In general, I would tell you, we have the financial muscle to be able to be agnostic in size and sector. And the criteria that we apply are three. One is a strategic criteria, the other one is a scientific criteria, and the third one is a financial criteria. Our belief is that we do better when we go into areas in which we have established capabilities.

So that's why we expand into ADS, for example, as we do in oncology or in immunology or in cardiovascular. And sometimes, we go into adjacencies like we are doing in atopic dermatitis because it's connected with our immunology franchise. But we do better when we stay in areas in which we can understand very well what's good and what's going to be best-in-class, best in disease. Hence, our success, because we are able to understand that.

The second one is scientific. We want to look for things that are improving the standard of care that are first-in-class, best-in-class. And we are not interested in me-toos and we don't look for me-toos. We prefer to go into higher risk areas and have a number of opportunities in order to be able to identify the best ones. And then financial, we need to be very disciplined in the way we use our capital, and we always try to create a favorable return for our shareholders.

So that's the way we frame M&A, and it will continue to be an important growth idea for us, with the nuances that you described between MedTech and pharmaceuticals, although I always feel compelled to reiterate that we are agnostic to size and to sector and that we are open to any opportunity, preferably, we have been able to make and to create more value in what you would call bolt-ons or earlier-stage opportunities.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Right. What – and again, at this point, given the size of – and focus on obesity, it seems like every company has to have a view internally on if that's something they want to pursue or not. And so given your comments that you outlined in the framework, where does obesity fit in that framework?

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

It would hit on the scientific one. If we were able to identify assets in obesity that were sufficiently differentiated, it would be an area of interest to us. We are not interested into another me-too, but if we were able to identify assets in obesity that could be sufficiently differentiated, it would be an area of interest to us. And diabetes and metabolic disease is not an area that is foreign to Johnson & Johnson. As you know, we've been there and we have a legacy there, too.

I can let John talk about it. What do you think, John?

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

Yes. I think one of the areas that we're kind of doing some exploration around pertains to the fact that J&J is number one in psychiatry. And these sensations of hunger and satiation, these things are all controlled in the brain and the reward centers of the brain. So that's an area where we have something there with pharmacology and we're looking where there may be some opportunity there, and this perhaps been overlooked. So that would be the kind of thing that's on our radar.

But as Joaquin said, we're, first of all, committed to medicines that are practice-changing, first or best-in-class, what is it that patients are waiting for. And so if we find something that is something that patients are waiting for that addresses a problem that others haven't addressed, then we would certainly be interested, yes.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Great. Maybe the other high-level one is we're on the other side of the first IRA M'dicare Part D negotiations. J&J had two drugs on that list. So just as you think about reflecting on the implications here, just any lessons or takeaways as you think about the other side of IRA? And anything you're doing to adapt the strategy in a post-IRA world to kind of mitigate the impact?

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

So when I look at the IRA, as we have always stated, we believe that this is something which is going to be negative to innovation and to investment in R&D, for all the ecosystem, not only for companies like Johnson & Johnson. So we are concerned about the long-term consequences of IRA, let's make that clear.

Now the products that were in the list that were negotiated were not – were products, as you know, that were at the end of cycle. Even STELARA was in the list that is going to have biosimilars before the actual price of IRA takes effect, which is in '26. So in terms of the impact on the guidance that we have provided, it's already embedded in the guidance.

So let's make it clear. So the impact of the IRA prices, it's already on the revenue guidance that we have provided. And our lesson is that we have to adapt to the situation. And John can comment what are we doing from a development perspective in order to do that.

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

Yes. I mean you've noticed that we do a lot of multiple parallel indication seeking. You take nipocalimab as a good example, 10 different indications. So that rather than sequentially developing a molecule, we're trying to get as many indications we can out front. We fortunately have been in the position to have the resources to do that. So that's certainly one of the dimensions.

And then a lot of times with our biologics, we start off with an IV but move to a sub-q, and sometimes that can become new medical entity, particularly if you're using things like hyaluronidase together with it. We've done that with DARZALEX, so it starts a fresh clock for you.

But I would just reiterate what Joaquin said, we really see this as an innovation reduction act in many ways and not to the benefit of patients. If you think about oncology, for example, where the typical paradigm is you start in late line, maybe third line, fourth line, patients who've already failed standard of care, try to get your first approval, then move to second, move to first, all those studies take more and more investment longer long time, and if it's a solid tumor, even on the adjuvant therapy, I mean, with the current paradigm, those investments are really just not going to add up in the future.

I mean we just published or presented in the last few months, even with IMBRUVICA in combination with a BCL2 inhibitor now, the standard of care in chronic lymphocytic leukemia study, I think it cost us $600 million to do that. These kind of things just become untenable in IRA world. So oncology, in particular, will be disproportionately impacted.

But it's true across many medicines. In psychiatry, we often start like we are with [aticaprant] and seltorexant with depression, but we want to move into other areas where those mechanisms could play. And these things just become less -- and particularly for a small molecule, less attractive in an IRA world.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Do you think there be -- is there any movement in D.C. to mitigate that small molecule versus biologic difference? Or do you think that's spelled out?

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

It is something that is an anomaly that stands out and perhaps this is one of the elements that is more feasible to address.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Right. Okay. The last one before we go into some of the more exciting pipeline questions, just on -- any update on next steps on the talc litigation here? I know there were some headlines a couple of weeks ago over the summer.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Thank you. We have always said that we are determined to resolve the talc issue and leave it behind, and that's what we are trying to do. We are trying to work in a prepackaged bankruptcy for our ovarian cancer claims. And at this point, we are waiting for the votes to be certified. We think the process will still take about a month. And we feel very confident that we are going to be able to meet the threshold of 75% of the claimants voting in favor of the prepackaged bankruptcy.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Yes. And then what would be the next step after that, if they were certified above the 70%.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Then the next step would be to file. And after that, I cannot comment on the outcome of that because it's not in our control, but the next step would be to file.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Great. One of the pipeline assets, you alluded to this earlier, Joaquin, is your 113, is the oral IL-23 inhibitor. As you said, it was kind of below the radar for a while here. But then obviously, there were some very exciting Phase 2 data in psoriasis. You're running a Phase 2 trial now in the IBD side. We're waiting on the Phase 3 psoriasis data later this year.

Generally high level, should we expect that efficacy to replicate what we saw in Phase 2? Or are there any differences, and this may be more a question for John, any differences in the trial design or the patient population that we need to think about as we think about kind of the level of efficacy we should expect to see out of the Phase 3?

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

Yes. We have a broad program in psoriasis. And just to back up, the Phase 2 data were really impressive and showed that with an oral, we could deliver everything that a biologic does. The PASI 75 data were around 70%. PASI 100 where you have complete clearance of skin was 40-ish percent. So really impressive Phase 2 data.

So the Phase 3 program in psoriasis has three different studies. One of them is pretty much a repeat of the Phase 2 placebo-controlled, a very typical population. Another though is in a hard-to-treat population that has the disease affecting anatomic locations that have particularly been more difficult to clear. So you wouldn't expect as high an effective size on that. And then the final one is a head-to-head with a TYK2 inhibitor. So that will be a really interesting and important study.

So it will be a broad program, broad package. But we remain super excited, super committed to that molecule. We'll have the, as you referenced, the Phase 2 data in ulcerative colitis this year, which is dose ranging, where we'll figure out what is the appropriate dose. I was joking, we kind of have some bets internally for a six-pack of beer, a bottle of wine, whether dose will be higher, same or lower because of different thoughts around being oral and it's a disease that affects the gut and whether it might be lower versus higher, harder to treat.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

What's your bet?

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

We'll see. Yes. I think, if anything, it will be lower, but it'll probably be about the same, I'm guessing. So at any rate, now that's -- and of course, the IL-23 is approved in mechanism in IBD. So the confidence in the target biology is extremely high, and the pharmacology has been robust. So really excited about that molecule.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Yes. And those trials -- this is sequential, I'm assuming, so we get like the monotherapy, the kind of Phase 2 trial population, that one will come first. And then the other two trials are after that. Or is this like a all-in, we're going to get data from all three of these around the same time?

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

So with -- in IBD, we just picked UC as a starting point to get the dose figured out.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Sorry, I meant psoriasis, the three psoriasis trials. The psoriasis trials. Are we going to get all those at the same time, or are they staggered?

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

No, they will get the first one this year, which I can't remember which one. I think it might be the tough-to-treat areas. The other two come in next year. They're all fully recruited. And if it's any indication about how much physicians and patients are interested, we recruited these studies in one third of the time that it takes us to do these.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

This is a paradigm change in the treatment of psoriasis and IBD. Having a medication with the efficacy of the advanced therapies, the side effect profile and the tolerability of a biologic in a pill form, it's going to change the market. And why is that? Because there's still about 5 million patients that are candidates for advanced therapy that are not moving into injectables. Why? Some of them may have fear of going into an injectable. Some of them may simply wait and be in orals that are less effective.

So this is going to expand the market in a significant way and reach patients that today are not getting advanced therapies by having the efficacy of the -- and the tolerability of the advanced therapies in a pill form. So this is going to be a market changing event. And this is coming from a company that has been in this area since the late '90s, because we were the ones launched Remicade too. So this is going to be a massive change in the market. And it cannot be read with the lens of the existing orals or the existing injectables. This is going to be a market-changing event.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Yes. So where -- how do you position it relative to TREMFYA then? Because obviously, TREMFYA great medicine as well, same pathway. So it sounds like it's more -- this is for people who don't want an injection as opposed to like you actively look to switch patients for some reason, or it seems like there's two different pockets of population. Is that the right way to think --

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Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Yes. I mean we see how the market pans out. But there's enough room today for patients that do not get into injectable therapy because they either are in orals that are not as effective and have side effect issues, or they just don't want to go into injectables because they want to delay that. So all these patient population that we estimate is about 5 million people, will be candidates for the oral. So there's room for injectables and advanced therapies and orals like that.

Not only that, I mean John can tell you, we are working, on TREMFYA in IBD, which I think it's the biggest opportunity that we have in the short term. Keep in mind that TREMFYA -- STELARA in IBD is 75% of the sales of STELARA. So I mean, for us, the majority of the potential of TREMFYA, which is already a $3 billion medicine, is in IBD. And that is one of the growth drivers that you're going to see there. So in the short term, you're going to see TREMFYA in IBD being a major growth driver. And as John can explain to you, TREMFYA in IBD has been able to show the highest level of endoscopy, complete remission.

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

Yes. So one of the, I think, the real indicators of whether you've truly silenced the disease is endoscope and look for residual disease or the extent of that. And when you see zero evidence of disease, that makes you feel good. And we have the highest levels, about a third of patients, even a year out, that have ever been seen.

The other thing about TREMFYA that we think is underlying this mechanism is it localizes to the site of the inflammation where the IL-23 is being produced. It actually binds to the surface of those cells that are making the IL-23. So we like to think that it catches it right out the gate.

And then the other thing that's a real differentiator is TREMFYA is the only IL-23 class inhibitor that can be delivered subcutaneously both for induction and maintenance. Everyone else has to do an IV delivery in the induction phase, patients have to get to an IV center, it's even a different code for billing and stuff. So this really brings that convenience factor home for the patients as well. So we feel really good about what we're bringing there.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Great. Well, I want to get to a couple more assets just in the last few minutes or so here. TAR-200, again, you highlighted this as one of the $5 billion assets, obviously, greater appreciation now for this opportunity. It sounds like we're going to get an update at the ESMO conference. Is that going to be the data that you're going to submit to the FDA for filing? And maybe just what are we going to see there in terms of patient numbers, follow-up?

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

Right. So TAR-200 for those who have been following is a med device combo, something that J&J can do well with MedTech and pharma. And it basically delivers the cancer-fighting medicine. It's placed into the bladder and then it delivers the cancer fighting medicine with very continuous pharmacology in this first iteration, what we call TAR 200 for three weeks of gemcitabine. And we saw unprecedented rates of complete response, north of 80%. Got breakthrough designation from the FDA.

So we'll show a longer-term follow-up at ESMO in a couple of weeks, and that will be among the data that will be presented. We're still in negotiation with the FDA exactly what all needs to be in the package. But feel pretty confident that first quarter roughly of next year, we should be ready to file on that.

And that's -- the population of patients who failed the standard care, which is BCG, an attenuated bacteria that one puts in the bladder and tries to rev up an inflammatory immune response, not well tolerated. Only one out of eight patients actually even completes the therapy because it's like having a urinary tract infection for two years. So our therapy fits right in the urology practice. It takes [three] minutes to put it in, [one] minute to take it out (corrected by company after the call). No special equipment needed, no special nursing staff, no special precautions or isolation. So it really looks like a winner.

And then 210 is the targeted therapy. That's where we took our erdafitinib, our pan FGF receptor inhibitor, formulated in a different device. Again, this is where MedTech and pharma come together to get the delivery right. We had to come up with another device. That gets three months, not three weeks, but three months of pharmacology. It's continuous pharmacology.

And there in the FGF receptor mutant population, which instantly is 70% of early bladder cancers, we saw north of 90% complete response rates. So we really feel like this is a whole game-changing approach to urology. And incidentally, early bladder is the most expensive of all oncology indications to care for the lifetime of the patient. I don't know if you knew that. And most of them go on to lose their bladder, have radical cystectomy, which, as you can imagine, has quite a deleterious impact on your quality of life, trying to live without a bladder. So this is really transformational stuff.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

And in terms of market size, because sometimes it's difficult to calculate, that there's about 600,000 cases of bladder cancer, so it's one of the very frequent cancers. And with this therapy, to John's point, we're going to save thousands of bladders.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Okay. Great. Maybe just in the last minute. Congratulations. You mentioned the RYBREVANT-lazertinib approval in first line. Maybe just why you're confident in that $5 billion number. Because I think consensus is south of that just given the profile of Tagrisso and they're obviously entrenched competitor oral option. So how do you think about the commercial opportunity and confidence there?

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

Maybe I can start a bit on the --

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

No. I mean I think this is going to be very much driven by the data. So John can tell you the data that is coming and the formulation that we have.

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

Right. So the data we presented already were progression-free survival where we're going head to head. I guess just to put it in context, though, as we all know, the problem with cancer is resistance mechanisms, right? So if you just look at the lazertinib component, oral third-generation, TKI inhibitor, inhibits multiple different mutations of EGF receptor, just like OSI, brain penetrant.

On top of that, then we have RYBREVANT, which is the world's first bispecific to ever be approved for a solid tumor indication. So there, you have the EGF receptor binder, which then inhibits signaling also by mutants that OSI doesn't get, like Exon-20. You have the met binder, which is another

growth factor receptor that's often a bypass mechanism. So you're already shutting down these resistance mechanisms. And then as a final kicker, the Fc region, the [tail] antibody, recruits immune cells. And that also adds to the tumor fighting thing. That's something you don't get with OSI.

So altogether, in the PFS, we had a hazard ratio of 0.7, as you know, so a significant reduction. The OS data were not yet mature, but we're going to show at World Lung next weekend, a next cut of those OS data. And we're really pleased with the trajectory we're on there.

And then we showed at ASCO going from IV now to sub-q. So from a couple of hour infusion now to a 5-minute push. And at the same time, that reduced infusion-related reactions by fivefold. So much more tolerated now is in addition to being much more convenient. And a bit amazingly to all of us, we were simply looking for non-inferiority. We did a head-to-head IV sub-q. But we actually saw superiority with respect to efficacy on both progression-free and overall survival. So that's an interesting additional kicker.

FDA gave us priority review for the sub-q. They've never done that before. They've never given -- going from IV to sub-q, they've never given priority review. First time in FDA history. So that kind of tells you something about how they're thinking about what we're bringing here.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

So it's going to be a combination of the efficacy level that you're going to see in the overall survival data when it comes. And now with the sub-q formulation, we are addressing the convenience and efficient related reactions. So we think that this is going to be the new standard of care in first-line EGFR-mutated non-small cell lung cancer.

Terence Flynn - *Morgan Stanley Co. LLC - Analyst*

Great. Well, I think we have to end it there in time. But thank you so much, Joaquin and John. And congrats again, Joaquin, on the anniversary.

Joaquin Duato - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Thank you.

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

Thank you.
