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CORPORATE PARTICIPANTS

Robert M. Davis *Merck & Co., Inc. - CEO & Chairman*

CONFERENCE CALL PARTICIPANTS

Chris Shibutani *Goldman Sachs Group, Inc., Research Division - Research Analyst*

PRESENTATION

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Good morning, and happy new year to everybody. My name is Chris Shibutani. I'm the U.S. large cap pharmaceuticals analyst, and I also cover some of the biotech and biopharma sector. So I was really pleased to see the expectations for performance out of both of those.

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Me, too.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Outstanding. We are thrilled to kick off the year. Literally, this is the start of the year, and with Merck being able to be the first voice as the industry and the investor community comes together once again, and we look forward to 2023, where, obviously, expectations for performance there.

Really pleased to have joining with us Rob Davis, CEO, and now Chairman as well, which, I think, is an interesting context. Also our slide should be updated for that. But I also did want to express special thanks to the entire Merck team. Peter Dannenbaum from the Investor Relations group is here as well, made extra effort.

Everybody is going to be going through quite a deluge next week of news and information. And if San Francisco weather forecasts on my iPhone are correct, deluge in terms of rain as well. Pack an umbrella.

So I think I want to also thank the entire Goldman Sachs research health care team for its planning efforts here to organize this. It's great to be back in person for this, and appreciate all of you who are coming here to join us especially this morning, and as well to people who are online with the webcast. So looking forward to connecting.

QUESTIONS AND ANSWERS

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

So Rob, as you have been, I think the last time we sat down and talked at the Goldman conference in June, so it's kind of a periodic update. I really appreciate you making the effort to come here and talk to us in person here and really be the cornerstone for our discussion through this event today and really to start off the year here.

Can you talk about how you're feeling in your role? I think last time we kind of colored you as a newbie because it had been kind of 12 or 16 months. Like when people have a baby, they stop talking about the months of age and weeks of age. But you're also now the Chairman. So talk about, reflect a little bit about 2022, how you're feeling about the state of the business and thoughts that you're prioritizing as we kick off 2023.

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Sure. No, I appreciate it. Well, first of all, thank you for having me. And obviously, 2022 for Merck was really a phenomenal year. So I give all credit to my colleagues around the world and everything they did.

But if I look at where I see the state of the business, I would tell you the business is healthy. Our results are strong. We're growing. We see good momentum in the business. I feel very good about our key growth drivers. They're intact. They're continuing to deliver, whether it be in oncology, in vaccines, in our Animal Health business.

And probably, most importantly, our pipeline is progressing. As I look at it and think back 15, almost 16 months ago, as I stepped into the role of CEO and where we are today, I can tell you my confidence about how the business is progressing.

The progress we've made over that window is quite high, and it gives me a lot of confidence as I look forward. So whether you talk about scientific performance, commercial performance, operational performance, all going extremely well.

As we think about priorities coming into 2023, largely, it's the same as what they were in 2022. We continue to focus internally. I'm always saying, especially to the commercial side of the business, we have to focus on operational execution and discipline to continue to deliver in the short term. And I think we've shown to the pandemic resiliency an ability to do that. That is something that we are very focused on.

But obviously, I know that the value long term for us is our ability to drive sustainable growth, and that is about the pipeline and what we're doing there. So we're very focused on how do we continue to invest in, but, probably, more importantly, accelerate and then augment the pipeline. And that's something we've been focused on in '22. It's going to continue to be in '23 and years forward.

And then lastly, it's about how do you transform the business. We know the world is changing. We need to be faster. We need to be nimbler. That's something I push. We're trying to drive for more focus, more simplification.

What I always say internally in the company is focus on what matters, put the patient at the center, do that, move with urgency as one team. Always think about it. As we are within Merck, we always talk about the fact when a crisis happens, we rise and we address it.

I try to tell everyone internally, there's a crisis every day. That's when one of our family members, someone we know, is suffering from some medical condition. Keep that in your mind. That is what we're focused on. Stay there and drive for that, and that's about skewing everything else, pushing everything else to the side and driving for that simplicity.

The Organon spin was an enabler of that. It's helped. I see that operationally when I'm out meeting in the markets, their ability to focus on the key areas of the business is stronger today than it was. I see it in our labs. I've seen it in our manufacturing operations.

So that move is working. We need to continue to do that more, and we have to embrace digital and data. That's a big area for us. especially in discovery and development, but, frankly, across the whole piece of the value chain.

And then lastly, how do you think about value demonstration and, probably, most importantly, driving access. We talk a lot internally about how can we continue to expand access to our medicines globally. It's influencing our R&D strategy. It's influencing our commercial strategy. So those are the key areas.

And then lastly, and I put it last because it's foundational not because it's least important, investing in our people. We don't do anything else if we don't have great people. And so that's what we're thinking about. That, frankly, were -- was the priorities in 2022. That's what we're going to continue to focus on in '23. And as I said, I continue to believe that's what we'll look at as we move into the future. But I would just summarize it as the business is strong, and I'm feeling good.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

That's very reassuring to have. The continuity, there's a lot of [echoes] and similarities with what you've articulated really since you've been in the seat as well. I think the strategy has to be somewhat long in arc, and having that consistency is very valuable.

You did start off by talking about the pipeline. And clearly, everybody is trying to solve for that sustainable growth dimension and what's clear towards the back end of the decade. As much as KEYTRUDA has been successful, it represents a challenge in the post 2028 period.

And that always brings front and center when any investor is communicating with us, and we're having discussions with Merck about capital allocation and the M&A strategy, which you guys have been very upfront about, making clear that it is a priority for the company.

Perhaps, again, at this juncture, at this time, if you're -- get you to reflect back a little on '22 and '21 and think about how it's perhaps shaping your thoughts on '23. '22, I would argue, you were a little bit less active, right? So on Pandion in '21. '22, broadly speaking, business development is not just headline generating conference call iterative kind of M&A, but there was a little bit of less activity there.

So this pipeline, any color you can give us in regard to what shaped that 2022 sort of M&A result and maybe how you're thinking about strategy in '23?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Sure. No. If you look at it, and again, it's very similar to the theme of the comments I made to your first question, our strategy has been unchanged. In 2021, we were very clear. We said we understand we need to move with urgency. We need to move with focus.

We continue to believe we have opportunities in our internal pipeline. We needed to accelerate those, but there was a recognition we needed to augment those. And I think you saw us move very quickly.

When I became CEO with the Acceleron deal at the time, it seems like -- from my perspective, it felt like a risky bet. It was a large transaction as a new CEO. It was for a Phase II asset. As it worked out, I think it's been a wildly successful transaction.

All credit to my scientific colleagues. They were the ones that came forward and said, "Rob, this is a meaningful area." We knew the PAH space because we had an inhaled sGC working in that space. So they understood the space. They understood the opportunity and they said, "This is something real. We need to move."

And I put confidence and credence in their conviction, and I'm glad we did because I think you saw the results from the STELLAR study were just really phenomenal. And we're very excited about what that means is, if you will, a foundational element of a growing cardiometabolic pipeline as well.

But if you look in '22, we came into '22 with the same focus we had in '21. Obviously, we -- I would say, activity level in '22 was no less than in '21. Ability to successfully bring deals to fruition was a little bit less in '22. But frankly, hopefully, what you take from that is we act with urgency and focus, but we act disciplined.

I'm confident in the future. We don't have to move and do things. We do them when we see a strategic alignment. Scientific value is always the core of what we start with. If we see a scientific need, if we see an opportunity, if it fits with our strategy, and then if we can get to value, we'll move. And sometimes, it works. Sometimes, it doesn't. But we hold to the discipline.

But if I look at 2022 in total, I think people -- because we did a lot, frankly, in the last 1.5 months, 2 months of the year, I think a lot of people actually probably aren't giving credit to that. And the other thing I would just comment on, people in this -- and I understand why, but people tend to want the flash of a large acquisition or an acquisition of any kind.

Often, the best deals, look at what we did with ESI, look what we did with AstraZeneca, collaborations and partnerships that give you access to great science, especially where you have insight into the science, can -- and oftentimes give you opportunities than an acquisition well because not everything is there to be acquired. And so we look for the best science and where we see it based on relationships we move.

If you look at what we did, the collaboration we've done with ORION, giving us a very interesting asset in prostate cancer, targeted therapy, very complementary to the growing position we have in prostate cancer. What we did at the very end of the year with the acquisition of Imago, giving us access from a hematology perspective into blood-borne cancers and continuing to grow that.

Those are both very important assets. Both companies we knew well. Imago, we had an early investment in, so we were tracking that. So you should assume when we've moved, we've moved because there's scientific rigor behind our decision.

And then obviously, what we did with Orna for circular RNA, interesting longer-term capability. We announced some deals for a suite of ADC programs with Kelun late in the year, building on an earlier program we did with them. We have actually a TROP2 moving into Phase III. ADC that we're very excited about, we've been able to accelerate in combination with Kelun.

And then finally, we did the deal with PeptiDream for the peptide conjugate drug antibody approach. So I look at all of those and, importantly, at least several of those, Imago, ORION and then the one -- biggest one I didn't mention, the personalized cancer vaccine with Moderna, all of those are going to be Phase III programs in 2023. That's 3 Phase III program, just from those alone. And the TROP2 will be moving into Phase III.

So I just gave you 4 important assets to this company that we have accessed not through traditional acquisition in every case, but important business development in each case based on the understanding we built over a relationship in every one of those cases that were years in the making.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Right. I imagine that there are just so many things that factor into the calculus within the war room about -- thinking about doing deals. You and several other management teams have articulated kind of the value proposition that is inherent with the partnerships. How much would you say for Merck was related to -- and you talked about having kind of this M&A pipeline. You're mindful of keeping an eye on certain opportunities that have potential there.

How much is sort of related to your own decision-making and perhaps of the party that could be across the table, whether you engaged or not versus -- there were quite a few things that happened. When you and I spoke in June, the FTC was having their very public panel in terms of talking about across different industries, but specifically within health care about their voice that they will have as regulators to M&A.

We had in August, at that time, the IRA and those implications. Interest rates were not going in a helpful direction as well. How much was external versus sort of Merck and potential target specific?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. Most of what you saw in '22 was based on what we saw as the great scientific opportunity where we could align value and where we couldn't align value through an acquisition. And we could get it through collaboration or partnership, that's what we did. Where we couldn't align on value, overall, we walked away. We held discipline because, as I said, we are focused, but we're not desperate by any stretch of imagination.

Most of that was all driven by what we saw as the dynamics in the marketplace as we dealt with partners, less so about implications from the FTC, the IRA. I mean, obviously, those are things we factor, and we can talk about that because they definitely have occasion.

But as we saw in '22, it's not causing us to change course or not do something we otherwise see the scientific opportunity, the strategic fit and value, and I don't think it will in '23 either. The strategy in '23 is going to be the same as it was in '22 and as it was in '21.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Got it. And you mentioned that, obviously, the Organon spin was a fundamental restructuring of the portfolio and, I think, are becoming a little bit notorious given the seat that I'm sitting in to talk to you about the Animal Health business.

Can you give us your latest and greatest in terms of your view about the appropriateness of the Animal Health business with the human health and the fit there?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Yes, yes. As we look at it, we always are very objective about understanding the portfolio and the dynamics of the portfolio as a whole. As I sit here today, I continue to believe that looking at the growth profile of the Animal Health business, what we've been able to do through investments in it to drive its innovation, to drive its growth and what will be the drivers of its performance over the next several years, I continue to believe there are stronger synergies with Merck and our ability to drive those together than if we drove them independently.

So as we sit here today, I continue to see this as a core strategic asset for the company and one that we will continue to invest in. And it's a -- I view it as a large and growing product that is an annuity-like revenue stream, that is a great diversification for the broader business and one where we can invest and where it's a top performing asset.

So to me, it's something we should continue to invest in and keep as part of the portfolio. But again, that's not a forever statement, and it's not a philosophical belief. It's based on objective analysis we do on a regular basis. We just always come to the same answer.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Let's talk about within the human health pharmaceuticals portfolio, therapeutic areas, obviously, oncology has always been kind of the center of gravity, very consistent in how you articulated the aspiration to continue to maintain leadership in that whole sector, broadly speaking, within oncology.

In the past year, however, you have highlighted quite a bit, and things that have been actionable have been more in the cardiovascular realm. Vaccines is another very significant presence that you have. And as I go through comments the management team has made, you have not been disregarding certainly, keeping an eye or doing discovery work or early development work in areas like cardiometabolic, immunology. Neuroscience often gets mentioned.

I think when we were over visiting you guys, who talked about how it may not have been headline generative, perhaps the largest number of specific business development-type engagements, whether it was a licensing, were actually in the neuroscience yield. So you're in many different areas. Talk to us about how you are thinking about the therapeutic areas and prioritizing that as you're looking forward to building that pipeline.

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Sure, sure. As we look at it, and I think our approach has been consistent, the therapeutic area is important. But in some ways, it is an outcome of the decision. It's not the driver of the decision.

It starts for us where do we see the best science, where is the best science, where do we see an unmet need, where the science matches it, where we believe we bring some capability to really harness that and deliver something for the future in the format of an invention or innovation, that always is the first thing we ask.

Now that being said, and you've heard me in the past say, "I want to be portfolio-informed." What I really mean by that is I'm not blind to the realities of the portfolio. But I don't ever believe that the best way to do it is to say, "I'm going to start saying I want to be in the therapeutic area," and then I try to go buy something because I think that can lead to bad decisions because it might not be the best area to invest at that time.

If you look naturally how it works, I think it tends to evolve into being diversified or evolving over time. It's interesting. You started your comment saying, "Well, clearly, you guys are an oncology company." Well, when I joined Merck in 2014, Ken's reason for trying to bring me and his selling point was look what we will be in oncology. But the first meetings I had with investors were, "What the hell does Merck know about oncology?"

Fast forward, here we sit in 2022, and we're a leader. We had JANUVIA. We were a leader in diabetes. I think we've shown that we can pivot to where the opportunity is. As we sit here today, there continues to be real opportunity in oncology. And I think we can leverage the position we have with KEYTRUDA to take advantage of that, and we will.

That being said, we have seen in our own pipeline growing opportunities in the cardiometabolic space. And obviously, that led us to the Accelleron deal, but we have a suite of programs internally we're very excited about. And I think we will see us be a major player in the cardiometabolic space going forward across the whole suite of opportunities, both late stage and even stuff we're seeing coming through early stage, which we can get into.

But the oral PCSK9 or Factor XI, we can go through the whole range of those several programs in NASH. That is an area where we will continue to invest. And then as you said, from an oncology perspective, Dean has been very focused on looking at immuno-oncology and understanding that the first half of that is the immune system.

And so we are now leveraging our understanding from immuno-oncology to move into immunology. That led us actually to Pandion. The IL-2 mutein that we did that's part of the Pandion deal, actually, our learnings for that came from that same mechanism from an oncology space we leveraged into the non-oncology.

So often, something you turn off on one side on the oncology side, if you turn it on, it does something else in the immune system. So it's allowing us to learn and move, and immunology is an area where you're going to see us continue to invest and grow.

And then as you mentioned, from a neuroscience perspective, we don't have a lot in late stage. We have 2 Phase II assets. We have a Phase II asset in treatment-resistant depression. Another one in schizophrenia. But we have made probably the biggest dollar investment from a collaboration perspective in their early space in neuroscience, and we're going to see play itself out.

So I am very focused on understanding the portfolio. If I have the choice to diversify between 2 equal things, I will take the diversification. But always, I start with the science, and that drives us. And if we do that, we will be robust, and we will have consistent solid long-term performance.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

And how do you think about sort of like capabilities or platforms or modalities in that context? For instance, it sounds as if the mRNA deal enhanced some of the long historical trend that you've had with that. Are there any particular areas that you feel that you're more keen to perhaps fortify?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. Well, if you think from a -- and I would say this is something that Dean has brought a little bit different. It's a nuance from where we've been historically. Obviously, we've always said a platform for platform's sake is dangerous. But where you can find a product that brings a platform, there's a real opportunity. And Dean is very focused on understanding that and driving that.

And so we are much more balanced, I think, today in thinking about platform and product. And as we think about technology platforms, clearly, we are investing in mRNA. We did it through our partnership with Moderna. We're doing it on the personalized cancer vaccine. We have internal programs of our own. We're looking at next-generation technologies through the deal we did with Orna.

So that is a technology platform. We're continuing to roll out the macrocyclic peptide technology. That's the basis of our oral PCSK9. We think that same technology can apply to a lot of historically undruggable large molecules. That's something we're very interested in, and we're continuing to drive.

ADCs is something that we continue to believe are important. That's why we did the deal with Kelun. We've done multiple deals. We're building our own capabilities as well. So we are balanced in thinking about the platforms. We are understanding we want to be diversified in touching them.

We've often talked about cell therapy. We're now starting to do more in cell therapy, particularly as we look at how do we see the opportunities if you can move it from an allogeneic space and into solid tumor.

We've got several deals. One I would highlight with Dragonfly as an example with their TriNKET technology, a trispecific natural killer cell approach for cell therapy.

So we're in all of the key areas. What Dean has always said is we're not going to go what is neat and sexy. We're going to wait until it's ripe and robust. And -- but we move, and we stay nimble. And I think we've shown we can leverage that.

So it's a balanced approach between product and pipeline, as we think about how we then we think the total portfolio of assets we have across the different therapeutic areas.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Got it. Of course, the holy grail is both sexy and robust. How are you feeling about like the importance of having a really significant asset versus this diversification, which you seem to be describing?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. Well, I -- in the end of the day, you have to always balance making sure you don't spread yourself too thin. And I will tell you what Dean has brought and what he continues to espouse within the company. He is very much with me around this notion of we have to move with speed and urgency. But I would say the thing that he's brought probably the strongest, and I actually use him internally as an example to the rest of the company, is focus.

Dean always starts with, "Let's not talk about what we are going to do. Let's talk about what we're not going to do." And so I don't want to give you the sense that we're casting our net widely. I think we're casting it appropriately, but we're very focused on making sure we move things forward quickly and see success as opposed to moving everything forward slowly, seeing nothing get over the finish line.

So it's a balance. But I think we've struck the right balance between enough breadth to make sure we're -- for a company of our scale and size, we can absorb it, and we can prosecute it. But we haven't lost that focus, and my confidence in that comes through how I watch Dean prosecute the pipeline, how he prosecutes the challenges he puts to the scientists as they try to bring forward ideas.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Got it. Touch base with you on something that you actually were very good about [containing] consistently through last year, and it's the environment and valuations in the broader ecosystem, particularly with the small cap potential targets -- potential prospective partners there.

There was significant focus on whether there would be any evolution or shift or change in the expectations for kind of at what valuation they would be willing to reach across the table and shake hands, a bid-ask spread, so to speak. Your latest view on whether that has shifted or appears to be in position to shift.

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. I think our experience has been -- obviously, we've commented a little bit about that on why we didn't get more done in 2022. But as I look at where we sit today, you have seen a pullback in the biotech sector. But my own experience is, right now, I don't think you can apply a monolithic approach to how you're thinking about it because what we're seeing is most -- there are companies clearly who are becoming cash constrained.

The amount of capital flowing is less. But the reality is most of the companies with really intriguing science that are showing data, they're getting access to capital. They're getting funding. They're becoming the haves and the have-nots. And the haves, who are doing well who, frankly, would be the ones that you would want to go after, their views of value haven't changed.

If anything, they continue to expect a significant premium. And if you look at some of the deals they have done recently or if you've watched the prices of some of the assets that have had positive data readouts, I think it shows that, that even the market is understanding that.

So net-net, as we're out there in discussions, I have not seen a fundamental shift in expectation from the seller side that is, if you will, made things cheap from the buyer side. There still are premiums being demanded. But I continue to believe there's opportunity to get deals done.

If you are very diligent, if you're selective and you look where you find some value proposition that either is asymmetric to what others have or that others haven't fully identified, go back to Acceleron. I think we saw the value in Acceleron before others did. We moved ahead, we got it, had the data and before others.

In other cases, I think we bring real capability. A lot of what we've done in the oncology space is because people want to partner with us because of the opportunity, the access and what KEYTRUDA brings. So whether it's asymmetry of information or synergies or us taking a position based on our own scientific belief, there's opportunity. You just have to be selective on how you go after it.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Got it. And then to touch quickly on a couple of items that are typically in Caroline's script, she has often articulated that the company for the right opportunity is not constrained in terms of capital structure and that you would be willing to take a one notch downgrade if that was part of the total picture. Any update on that? Does that remain the case?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. Our view remains the same. We are for the right strategic move. We would take a temporary one notch downgrade. I don't see it as something necessarily we have to do. But if the opportunity, based on the criteria I've already laid out, scientific fit, strategic fit, value, demonstration aligns, we'll move. But if I don't see that, we're not going to move.

But the short answer is if the right thing would present itself, meeting all those criteria, yes. For the strategic move, I would take the downgrade because I believe, long term, growth in our business through new science is what creates value.

And I'll invest behind that and use the balance sheet. But it has to be a strategic fit, and it's not something I feel like I have to do. It's going to be based on an opportunity where I see clear value creation.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Got it. And then to run off the capital allocation discussion, share repurchases is something that's also in the toolkit. Comment the latest there, Caroline had referenced. I think during the third quarter call that potentially that there would be more visibility on that in the event that a transaction of size didn't appear to be timely. I forget the exact wordage, but the share repurchases, where is that at?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Yes. Well, so I think what we really -- we've been consistent -- and first and foremost, we're going to invest in the business. We're going to invest in our pipeline. If we have capital left over, obviously, we are committed to our dividend and growing the dividend. But if you have capital after those, it's, in my mind, investing into the business, growth through augmenting our pipeline and bringing in science is a better use of funds than a share repurchase.

So our priority has not changed. But we've also been very clear to say if those things don't materialize, I also don't believe sitting on a lot of excess cash for an extended period of time creates value. We will return that. But I want to make sure I don't foreclose an opportunity to invest to grow the business by doing it.

And as we sit here today, no different than what I indicated on the third quarter call, I do see several opportunities that we're still looking at, and I want to let this all play itself out before we commit to a share repurchase. But if those things don't, and depending on what we see at that time, when we truly believe that we're in a situation where we have excess cash, we will return it.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Got it. And let's talk about an aspiration that you've described, which is to continue to grow through the LOE of KEYTRUDA in 2028. And there's some clear strategies with consistent descriptors such as extend and expand that you guys have used as part of the vernacular at Merck.

Amongst those efforts, some of the key readouts don't play out until 2024 through '26. There's kind of that span. So here we sit at the start of '23, talk to us in terms of how much that is factoring in your decision making. Do you need to see those results? Are you still proceeding with the same degree of alacrity even ahead of those results? What is the role that those readouts will play?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Well, I would say those -- one, as I started with the original comments at the start of the presentation, my confidence today over the progress we've made in the last 15 months is much higher than would have been then. And frankly, we made more progress in those 15 months than I would have expected.

So if we can continue to demonstrate that kind of growth, both through continuing to accelerate and see maturation in our own pipeline and continue to augment it the way we've been doing, the LOE period for KEYTRUDA will take care of itself.

I'm more focused on do we have a sustainable engine. And don't take from those comments, we are very focused, and I'm moving with urgency, but I'm doing it in a space where I feel I have confidence that we have a path forward. If we can just continue to execute the way we have, we have a path.

So I feel very good. And you might say, "Well, why?" Well, maybe just to give some senses of it, you go back 12, 15 months ago. We weren't telling you we expected over \$10 billion coming from our cardiometabolic portfolio with potential losses.

Sitting here today, based on the STELLAR data out read -- readout we had, I even feel more confident about that. If anything, I think the number is bigger because I think the opportunity with what we have with sotatercept is even -- is coming sooner and likely to be bigger based on the strength of the scientific data we're seeing there.

Plus, we're seeing all the other programs moving forward with. Our oral PCSK9, it's moving. The Factor XI is moving, all of the programs. So as we sit here today, that gives me a lot of confidence. That's over \$10 billion in the mid-2030s.

If you look from an oncology perspective, I just listed off to you 3 Phase III studies that, if we had talked 6 months ago, you wouldn't even had in your mind, that are going to be starting in 2023. And in oncology, those move quickly. Those will have an impact in the '25 to 2030 period. There's more than just those. I just happen to pick 3. There's more.

So you look at those and say, "Those are meaningful new opportunities that didn't exist." And then you look at our own internal pipeline, the way VAXNEUVANCE is starting to show opportunity in the pediatric space, what we're seeing with V116 in the adult space for pneumococcal disease, meaningful opportunity.

We just recently, in December, you maybe missed it, our partner, Butantan read out Phase III data from their dengue study for a vaccine against dengue in Brazil. This is very important because we have been doing our own Phase II studies using fundamentally the same vaccine that they have.

The fact that they showed such strong data with a single dose now allows us to think about how do we accelerate bringing our own dengue vaccine to the rest of the world, where we have rights.

Recall that deal. They have rights in Brazil. We have rights to the rest of the world. Half of the world's population lives in an endemic area for dengue. That's huge. That's something that's not on anyone's radar screen. That's an underappreciated opportunity.

That all came just in December. And so I'll stop there because I don't want to use all the time. I could, frankly, use all the time just giving you all these. But I think you get the point.

Things are moving, things are moving. The team is responding. The urgency is there. We are delivering. So I sit here today and feel very confident about where we are. And from that perspective, we'll see where it goes, but you should hopefully take the message of my confidence. I went so long. I even forgot the question you asked.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

No, no, not at all actually. And I think so much of what we're perceiving and the value of being in person for these events is that we see your body language, the confidence, the ability to iterate beyond what might have been. This is CEOs unscripted, and what's clear is that you can reel through all sorts of areas to have -- and as we move into the second part of our 2-hour conversation that we're going to have here. But I mean, there's plenty to talk about.

And certainly, I think the Street is going to do a lot of sharpening of pencils because I think for vaccines, we think about GARDASIL, we think about PNEUMOVAX, et cetera. But what goes beyond that, and you've really helped us articulate that.

A couple of specifics with KEYTRUDA. So on the subcu formulation, and I think you've highlighted that you're going to do the hyaluronidase version of that a little bit. Can you just talk to us about reasons behind that decision? I think Eliav sort of mentioned that during some investor events. And how quickly can this possibly come to market?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. So just to -- for -- in case not everyone is familiar with where we are on this, we have 2 programs we're looking at to move into with a subcu approach for KEYTRUDA. And one is in combination with hyaluronidase and one is through a dosing formulation. The reason these are so important, as we look at our strategy, and you mentioned it as far as extend, expand, deepen that we've talked a lot about, when we look at KEYTRUDA, what you see is the drug that is foundational in the treatment of people with cancer.

But what sometimes we miss is, well, it is phenomenal and it's really unprecedented in what it's done. The reality of it is average overall response rate is 30%. Strong duration could be better. Efficacy depends on the patient. So you might have a response, the durability, and that is based on the tumor type and the patient. There is still a significant opportunity to extend KEYTRUDA's value to patients.

And then the last one that relates specifically to the subcu is if we are successful in moving into earlier and earlier lines of therapy, which, right now, we have 6 approvals in areas in adjuvant, neoadjuvant space, we have right now 20 registration-enabling studies underway to move others into that space, over 100 studies being done in total in that space, so this is very important to us because it allows you to start to move into in earlier stages of disease and to treat patients and to hopefully drive cancer from a death sentence to a manageable disease. That's ultimately the goal.

As you do that, as you get patients earlier in the disease, the last thing someone wants to do, if they believe their life is somewhat returning to normal, because they were caught early, and we were able to address it, is, think, "Gosh, I'm going to have to go into a hospital and I'm going to have to be hooked up to an IV and be infused and sit in a chair. I'm not going to have to do that every 3 weeks or every 6 weeks for years." No one wants to do that.

If you can save that patient, you know what? You don't have to go the hospital. You can do it in an alternate site, and you can do it through a subcu formulation. That's a benefit. That's a true patient benefit. That's an innovation, and I think bringing real value to patients. So I start there because that's the most important thing.

With that, that should allow us to continue to allow people to see a differential benefit we bring to KEYTRUDA with the earlier indication and a combination in subcu. And if in this case of the co-formulation with the hyaluronidase, if you look at that, and this gets to your question why are we prioritizing this approach, the benefit of it, we believe it can be a Q3 week or Q6 week. So it has flexibility of dosing.

The speed with which the KEYTRUDA disperses under the skin is faster with the hyaluronidase because it allows basically what hyaluronic acid does, it breaks down. Hyaluronic acid is the -- is what actually it [allows] you the structure of your skin. And what hyaluronidase does is it temporarily breaks down that skin structure, and it allows fluid to flow under your skin. That's why you can disburse a lot more fluid in combination with hyaluronidase through subcu.

So it has faster dispersion, and it has flexibility. That's why we're prioritizing that one over the other form, but we're moving both forward because you don't know what -- ultimately, where the science is going to go. But we are prioritizing because we see the clinical benefit better for the hyaluronidase form. But I think important -- most importantly is this is an opportunity to bring real value and, in turn, continue our leadership in oncology well beyond 2028.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Right. And as part of the strategy to advance in adjuvant, there's a specific goal by 2025 of having 25% of KEYTRUDA revenues. How are we tracking?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes, we're probably, I would say, on or ahead of schedule. If you look, for instance, probably the 3 big ones we have right now, adjuvant renal cell carcinoma doing extremely well both in the United States and starting now. It was later in its launch in Europe, doing well in Europe and doing -- actually starting to do quite well in Asia.

Adjuvant melanoma continuing to do extremely well. Adjuvant triple-negative breast cancer, which is adjuvant -- neoadjuvant in 2022 in the United States, unbelievable. The uptake, much bigger and better than we expected, and we're starting to see that launching in Europe. Good results in some of the early markets there. So all in all, we're -- everything is moving. We feel very good that we're going to achieve that goal.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Another's key pillar, GARDASIL, demand. You set out an objective 2030, doubling the revenues you posted in '21. The push-pull there is that you have to have the manufacturing of the product as well. How are we tracking there, your confidence in being able to meet that demand through your supply manufacturer?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes, we're very confident. So as you recall, we have 2 new bulk manufacturing plants coming online in 2023. Those are moving. Those will be phased up. Their capacity will phase up through 2025. By 2025, we will be unconstrained to meet the demand we see. Between now and then, we continue to expect to see growth because of the fact we have been driving higher-than-expected productivity through our existing assets.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Got it. And touch upon something against sotatercept. You highlighted, really, we have some more data coming through, but the actual readout of the Phase III data that you announced, STELLAR, the details, something that you want to amplify here in terms of the time line. I think that was 2023.

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes, yes. So important. Thank you for raising that. We are going to -- obviously, we top line that we're going to give the detailed data. And actually, we've decided we're going to present that at ACC. You're also going to see the Phase II data for our oral PCSK9 at ACC in March, both of those. And then we are going to have an investor conference to help people understand why we're so excited about both of those as we move forward.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Got it. So we're putting New Orleans on our calendars for early March. Touch quickly on LAGEVRIO transition this year into an anticipated commercial market there. Do you see this as something that could be a meaningful contributor to Merck beyond 2023? And any comments about the pricing dynamic as we switch to commercial?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Sure. As we look at it, one, I think LAGEVRIO has been such an important addition to the armamentarium to address COVID. Obviously, there's a lot of patients with drug-drug interactions. A lot of the comorbidities, especially as you look at elderly patients who, frankly, are contraindicated for the PAXLOVID product, so we continue to see good uptake as we address that population.

Frankly, much better outside the United States than inside the United States. Very strong growth across Asia, in Japan and Australia. So it is continuing to be something we are focused on. It continues to be primarily under the emergency use authorization in most markets. It is commercial, for instance, in Japan. But in many markets, it's still under emergency use.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Is it going to be an opportunity in China?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

There is an opportunity. You might have just seen, we just actually got approval under a conditional approval, similar to a U.S. emergency use, if you want to think of it that way. They call it a conditional approval in China. That came just in the last couple of weeks.

So there's an opportunity there. How big, we're going to have to wait and see. I mean, clearly, LAGEVRIO is not going to be what it was in 2022. We have to see how the pandemic plays itself out, what happens with the EMA approval, what happens with the U.S. moving to a commercial launch, as you mentioned.

So a lot of things have to play out. I wouldn't -- just to be clear, it's not like it was in 2022, but as an important tool for patients long term, it's something we're continuing to investigate. And we're actually doing a study now looking at use of LAGEVRIO in RSV because the mechanism by which it works actually works beyond just COVID. It works across any RNA-based respiratory virus. So you can think of the old SARs, MERS, that works in all of those. And we believe it will work in RSV. So we're doing those studies.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Great. In our last 2 or 3 minutes, 2 quick hits. Margins, you have a 2025 articulated goal of 43% target. Obviously, there's going to be some benefit from the roll-off of certain royalties for products KEYTRUDA and GARDASIL as well as -- can you talk a little bit about the contribution, relatively speaking, of the roll-off versus product mix versus any just OpEx level?

Robert M. Davis - *Merck & Co., Inc. - CEO & Chairman*

Sure. Yes, I mean, the biggest drivers are mix and, obviously, the royalties coming off in 2024. But the operating expense synergies are part of it. As we look at it, we are continuing to be confident we're going to achieve that goal of being in excess of 43% in 2025. So nothing's changed in our commitment.

The one thing I will say to you is I am very focused on making sure we're making the appropriate investments in the business. So we are going to continue to invest in R&D and make sure that, as we see the pipeline of opportunities, I just mentioned several Phase IIIs were starting in '23 that weren't planned for if we talked a year ago, those take money.

So we're going to invest behind them. Hopefully, that's what you all want us to do because it means we're investing for future growth. So we're going to invest in R&D. We're committed to hitting the margin targets and confident in it, but I want to make sure that no one is taking this as we're trying to rob the business to drive margin. The business is driving the margin, not us trying to pull back on spend to do it.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

And then last question, big picture, very relevant for everybody in the industry here. IRA became a law. Now we have questions about implementation. We're going to learn a lot presumably before September 1. What would you and Merck most like to see clarified? Can you name a couple of things at the top of your list?

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Yes. I mean, if you kind of just think through it, there's a lot of areas that are important to understand. How will the drugs be classified and selected? It's not yet clear how there's going to be racked -- ranked, if you will, and stacked. And what will be the determinant?

So for instance, is it going to be gross or net pricing? Those are important things. We need to understand that. How the biosimilar exceptions will work, we need to understand that. The type of data they're going to use to make the assessments, how will that work? What -- when they say they want costing data, are they going to understand that it's not just the cost of the drug you're launching, it's the cost of all the drugs that failed as well? How do we think about that?

So those are some of the key areas that we're very focused on. How would they set maximum fair price? What does that actually mean? So those are some things that we're obviously -- as an industry, we're very engaged in discussions with HSS or HHS. And we're going to continue to do that.

And -- but my focus is making sure, as we think about business development, as we think about our own pipeline, that we factor this in, and it influences the decisions we make because, to be clear, I do believe it's going to impact R&D. And I don't think it's going to change whether we invest. It's going to change how you think about strategically bringing assets forward. I think it will change the way we assess assets in the business development context because you're going to have to understand that.

I can tell you with Imago, the deal we did recently, it factored into our thinking. I will tell you, in that case, it actually fortunately is -- hits the rare disease exception for what is the major indication we're coming out with probably first. So it's in there, but it was in our valuation. It was in our diligence, and it's how we thought about the strategy.

So it is affecting what we're doing today. And hopefully, over time, people recognize the unintended consequence on this, on hurting innovation. Ultimately hurting patients is my concern. I don't think this was fully understood.

And as an industry, we're trying to educate. And if we had more time, we could talk about it. But that's something that I think you're going to see a lot of dialogue and dynamic about in the industry as we move into '23.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Excellent. I have to say I'm so struck by how robust and energetic you are as we enter this period in 2023. You clearly seem to be very comfortable in your own skin in this role. And we look forward to another sexy and robust performance for the stock in 2023.

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Thank you very much. I appreciate everyone's support and belief in the company.

Chris Shibutani - Goldman Sachs Group, Inc., Research Division - Research Analyst

Excellent. Thank you, Rob.

Robert M. Davis - Merck & Co., Inc. - CEO & Chairman

Thank you.

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