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# EDITED TRANSCRIPT

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Unscripted Conference

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## CORPORATE PARTICIPANTS

**Peter Dannenbaum** Merck & Co., Inc. - VP of IR

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

## CONFERENCE CALL PARTICIPANTS

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

## PRESENTATION

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

I suspect that people are going to be strolling in, but I don't like to penalize people who are on time. And let's try to stay on time, so let's get underway here.

Welcome to what is, by definition, in my opinion, the keynote presentation of this conference. We are thrilled to have Merck, in particular, Chief Executive Officer, Rob Davis, who is back for a second consecutive year. And we're going to make this an annual tradition. Peter promises me this. He didn't, but I just put the words in his mouth.

So Rob Davis, thank you so much for joining us; and Peter Dannenbaum, the esteemed Investor Relations head and -- who's with us for this conversation here.

Chris Shibutani, member of the Goldman Sachs research team for the health care group. So Rob, I hope you are ready to once again kick off this year providing voice for Merck as we start.

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## QUESTIONS AND ANSWERS

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

And I think just a generally overview round question about how you're seeing 2024, how you're feeling at the start of this year. And maybe frame for us kind of the key priorities for you.

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

Yes, yes. Well, first, I would just start by saying Happy New Year to everyone.

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

Happy New Year.

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

As we look at coming out of '23, starting into '24, I continue to be very proud of the way the team is executing. If I look back over the last 2-plus, 3 years, our operational execution has -- I actually feel has been pretty flawless. In the fact that we've been able to meet or achieve expectations pretty much quarter-on-quarter. Our pipeline is advancing quite nicely. I feel very good about what we've been able to do through augmenting the pipeline with, I think, some important business development. And I'm sure we'll get into that more as we get into the session.

So whether it's commercial execution, scientific execution, operational execution, the business is delivering. And that's important because it allows us internally to focus on the longer term. And I feel like we've made a lot of progress. I think last year, I made the comment that we're -- if I look back 18 months, what I'd expect to be where we were, I can repeat the same comments. Say, sitting here today at the beginning of 2024, we're further along now than I would have thought even 12 months ago. So everything is moving in the right direction and the momentum of the business is continuing.

As I think about priorities, they're really unchanged. I believe consistency of priority is important. It keeps people focused. And as I said last year, first and foremost, we have to deliver in the short term, which we're doing. We have to continue to accelerate the pipeline, which is a focal area. We have to augment it through business development. All of those continue to be where we focus our efforts, where we think about our time.

And lastly, as you look longer term, how do we have to transform the business, and what capabilities do we need to build to do that? We're making meaningful investments in artificial intelligence, machine learning across what we're doing in the labs, starting to think differently about how we approach customers.

So that all is work that's underway and continuing. All of it always with a centering point focused on the patient, is what matters. I always say focus on what matters with the patient at the center and deliver for the patients with urgency. And if we do that, good things will happen. They'll happen for the patients. And in turn, it will happen for the company.

So it's very much steady as she goes, continue the course. But I will tell you, if the momentum continues as it is now, my confidence that we will be a sustainable, growing business well into the next decade, is high as it's ever been.

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

There's like -- I'm so struck typically by the overriding sense of calmness that your tenure thus far has been characterized by. And I go back from decades of paying attention to Merck. And I think about other players in the industry where there's often sprockets of drama or these dramatic overhangs.

And theoretically, as you started your tenure as CEO, people talked about, wow, KEYTRUDA, congratulations. But as we get towards the later innings, you'll get that flip side of, now what are you going to do? The overhang of having such a significant franchise. And as I think about your approach, it's been very calm, what you've described and outlined there.

There's a New York Times best seller list about like Atomic Habits. And it says the operational execution has been very much a manifestation in the industry of these atomic habits. And you're -- when I put together what some of those habits are and think about how this has shaped things, I think about a bit of a diversification strategy, which is very logical and yet you've methodically executed upon us.

We think about some of the deals that you've done. Acceleron has really reintroduced the company to kind of a rare disease, Imago into hematology, et cetera. I presume that this is an element of something that's deliberate. And where are we in this journey of potential diversification? And should we continue -- expect us to see more of this?

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

Yes. Well, in -- it's been consistent in the way we've communicated this, but I think it's important to reinforce. We always start with the science. So we will continue -- have been and will continue to be science-led. But I would say the way Dean and I have really embraced how do we think about the portfolio, you've heard me say we're science-led, but we're portfolio-informed. And what really that means is, as we look at the strengths in the business, we look at where can we leverage our strengths to broaden into new areas that bring synergy.

A great example of that, immuno-oncology has its basis in immunology. It was really through the work there that we started to see opportunities, first caused us to do the deal with Pandion. We started to rebuild, and we set up now a separate immunology group within the labs, and then that

led to the deal for Prometheus. And again, that is something where we're leveraging the synergies and the learnings. And so that was a very conscious decision to diversify into an area where we see really interesting science that could leverage our strength.

We did the same thing in the cardiovascular space, moving -- in that case, we had some very interesting internal programs, initially NPH. But it was through that, that we started to get to know what Acceleron had. And it was our scientists who came to me and said, "This is something special. Sotatercept is going to be a special drug, a foundational drug. We need to have this." And we moved very quickly and frankly ahead of a lot of the data. And now are, as you said, moving into that space in a meaningful way. So cardiovascular is an area very much. And now we've looked how do we flesh out that more broadly.

We've done that in vaccines. Obviously, we're going to continue to focus on leadership in oncology and leveraging the strength of KEYTRUDA with multiple new programs, including now a significant move into the ADC space. We did a deal with Daiichi Sankyo and the other deal we did with Kelun, plus some of our internal programs.

So each of those were very thoughtful, conscious decisions about how could we both deepen the portfolio, but also broaden it, understanding that we have to have a balance between we don't want to get too broad, because then, you lose focus. And Dean is always very much always -- first thing he always says is not what should I do, what am I not going to do, to allow focus.

And so we're very focused on bringing that balance. And I think we've gotten to a place where we're in a nice balance between the ability for focused execution, but a breadth of a portfolio, in addition to a deepening portfolio, that I think is going to bring meaningful value. And we didn't get into it, but earlier investments in neuroscience as well. So those are all areas where we're really fleshing out the business.

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

Yes. No, I think there's some very clear expressions of intent on certain verticals, cardiovascular. And you enumerated, and Caroline has been very clear about a \$10 billion revenue opportunity into the early 2030s, which is a nice, round number and kind of vague and I think kind of conservative.

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

I think it was in excess of \$10 billion.

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

Okay. There we go. Okay. So the greater than symbol is very useful because I think that's where I'd potentially lean towards, particularly with sotatercept, and we'll talk a little bit there.

And something that is a little bit off-script here, but that -- you brought it up. And it's like what we do, what we don't do, which inevitably then leads me to ask the somewhat pregnant question of cardiovascular adjacency, the metabolic disease, the history with JANUVIA being in diabetes. Obesity has seemed to be the shiny object that has blocked the sun for most investors, GLP-1s in particular, for which you have an asset which is going after a NASH indication. So is there an opportunity here? What is your point of view on whether that's a realm to consider?

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

Well, as you point out, obviously, we had strength in diabetes in the DPP-4 space through JANUVIA. And in many ways, frankly, JANUVIA is an indirect actor on the GLP-1, so we were just at a different point in the cascade. So rightly or wrongly, through activities we did early in the labs, we did not see the GLP-1s early to potentially have the activity they've had. But now as we've seen what has transpired, as you mentioned, we do have an important program in a -- it's a GLP-1 glucagon, I guess, a bispecific.

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

Co-agonist.

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

Co-agonist that is important, has really good data in the liver and has a weight benefit. So we'll see where that goes. We're going to continue to invest behind that program.

We remain open to the broader space. Metabolic disease is an area. When we talk about cardiovascular, we often talk about cardiometabolic. And so that is an area where you're going to see us look, but we're going to be thoughtful.

And Dean has been very clear that, really, we're -- we've seen the first wave. I think the next wave is more around combination therapy aimed more at how do you drive outcomes where weight benefit is a benefit, but not the driver. I think everyone recognizes because weight management is a hard thing to get reimbursed.

But if you can show cardiovascular outcome, if you can show diabetes outcome, which we're -- you're starting to see data for. If you can see fatty liver disease benefits through focusing on these pathways that bring weight along with them and the total metabolic syndrome, if you will, that is an area where we think there's opportunity. And we are both pursuing that in our discovery areas and thinking through it from a business development perspective as well.

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

That makes a lot of sense. And there is white space there and significant underappreciated unmet need because of the complexity of the diseases, particularly in some of those realms.

Then the other logical "mega TAM" to bring up would be in CNS disease. You frequently talked about kind of like the headcount of the sort of like full-time equivalents that you have in discovery and development in the CNS neurosciences is very material in terms of number here. Alzheimer's disease -- I mean, 2020s is going to be the decade of the brain. And we have made some progress clearly with the anti-beta amyloid therapies getting approved and now doing their journey into the early launch. Where do you see a potential for all of this R&D and investment and thoughtful work manifesting in some way into a commercial realm within CNS?

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

Yes. Well -- so we have one asset that's in late stage in schizophrenia, which is 8189. That's an important program. We're going to continue to drive that through. Most everything else we have is in earlier stages. Obviously, we have a tau program and several programs aimed at different neurodegenerative diseases.

We recently did a deal with Caraway -- to buy Caraway, which brought in additional platforms. So we have a lot in that space. I will say that's earlier, so that's probably -- year out, later. We're very much more focused, if you think about the midterm, it's what we're going to be doing, continuing growth across the oncology space and our vaccine space and the cardiovascular space. Those are the things that are going to drive into the late 2020s, early 2030s.

I see most of the cardiovascular opportunity -- or neuroscience opportunity for us probably into the 2030s. We continue to invest, but I don't see that as prominent in the message of Merck today as those other areas.

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

Got it. So the twist on the decade of the brain is more 2030s for Merck.

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

For Merck, yes.

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

Which is logical because, frankly, here we are in 2024, so eyes are certainly turning in that direction.

You have been one of the more consistent and articulate commentators about the M&A environment. And I want to ask you sort of like a recurring question. So we longitudinally monitor the tone and timbre of your response on this.

With the valuation backdrop for the small, mid-cap biotech companies that are out there, what are you seeing in terms of your view on the attractiveness of doing these deals, the receptivity of those companies? What's the mood and temperament? You've been active, you've been engaged. We just had our panel of our team's bankers discuss sort of like competitiveness and the fact that some of the assets is pretty defined in terms of what the solutions that they're addressing. Update us on the January 2024 Rob Davis view on what the environment is like, particularly in the context of valuation.

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

Yes. Sure. So as we look at it, and I think I share this view in it's pretty much similar to where we were through 2023. I definitely think we've moved into a world of the haves and the have-nots. And what I mean by that is, obviously, the ability to think about fundraising if you're a small biotech, whether it's through IPO, through debt raise or other private equity raise, clearly, the market is not what it was. It's getting better, but it's not back to where it was.

That being said, what you have continued to see, and I think this is due both to the scarcity value and the competitiveness that is out there to get deals done, when companies, especially in the late -- mid- to late Phase II, early Phase III, area of development show positive clinical data, those deals still command high premiums, are very competitive. And so in that sense, I think that environment will continue as you look forward.

Now for us, I think what we've demonstrated is, because of our approach, because of the strength of our science, where we see synergy, a strategic fit and we are compelled by the science, we will move quickly. And we've been able to move successfully in deals that not only bring strategic value, but I am quite confident are positive economic value-returning for the business as well.

And so my belief, confidence that we can execute what we need to get done continues to be there. The fact that we did the deal with Daiichi Sankyo is, I think, just one example. We have both done it through collaborations. We've done it through acquisitions like Prometheus, like Acceleron. All of those types of deals will be the deals we'll continue to pursue as we move forward.

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

Yes. And you bring up, and it's a great segue into this question of doing acquisitions versus strategic partnerships. And I think a year ago, we talked about, you brought that up proactively, not to under-recognize the fact that this is a very valid and useful and strategically balanced kind of tool. It's a way of sort of mitigating risk and measuring. And to a certain extent, when you do an acquisition, you risk doing something, besides capturing the asset, maybe you lose some of the intrinsic value of the people, et cetera. So partnerships are very interesting here.

And maybe, again, once again having you here, with tremendous gratefulness on our part as the CEO of one large-cap companies, I have to ask 2 questions. What's your point of view on the impact of regulatory oversight, the FTC in particular, on how that factors or influences your thinking about doing M&A versus a partnership? And then the follow-up question will be the IRA. And what is the mood of how that threads into the conversation?

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

Sure, sure. Yes. So first and foremost, as we think about strategically our approach from a business development perspective, it remains unchanged. As I said, we start with the science. We look at where we see strategic synergies. And then if we see something where we see value that's compelling, we move. That's unchanged. And frankly, whether you look at the impact of the IRA or you look at the impact of what's happening with the FTC, it has not altered our approach.

Clearly, as you've asked about what's happening with the FTC, clearly, it's a different environment. The hurdles are harder. But I think what you've seen is that if you can show that you're bringing and going to accelerate innovative science in a science-led deal, where you can demonstrate that you will be able to drive access for medicines, often better than the small company or even the medium-sized company can do alone, those deals get done and they get approved. And so -- which it hits the sweet spot of the way we think anyway.

So from our perspective, it's something to navigate. It affects strategically how you think about executing the deal, but it does not change fundamentally the strategy of the deals we would go after or ultimately our confidence and success.

And it's no different for the IRA. I mean, obviously, we think about the IRA. And I can tell you now, when we model deals, we will model -- we always model assuming the IRA as it is currently envisioned is in place. So we -- to be clear, when we -- when any deal you've seen us do, whether for a biologic or for a small molecule, we're doing it assuming the IRA is in place as contemplated. And it's built into all of our expectations, all of our models.

Now obviously, we have currently challenged provisions of the IRA that we think are unconstitutional. That all represents upside if we're successful there. We continue to think from a policy perspective, the IRA, while well-intentioned, missed the mark on preserving innovation while providing better access and affordable medication for patients. We would like to see a different approach.

But from that perspective, we will continue to pursue the -- our activities in the courts. From a business development perspective, it hasn't really changed the deals. And for most assets that bring meaningful scientific benefit or we see as transformative care, frankly, the value is still there. Maybe less than it would have been, but still enough to justify why we're doing the deals.

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

Got it. And I meant to ask this later, but you brought it up, in particular, the legal aspects of the IRA. It was literally the early part of the week right after ASCO, that you guys were the first to boldly go forth and challenge that from a legal context. And then a couple of other companies scurried behind you as well as, et cetera, and some people exited it as well. It's kind of interesting.

Any sort of progress points that we should be aware of? 2024 is just a year of Washington, D.C. infiltrating the skies. Lots of clouds remain in the sky. Any update in terms of the legal challenge would be helpful.

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

The short answer is no meaningful update. Obviously, we filed the suit, we have exchanged briefs. So we're now -- we're done with briefs, and we are awaiting ruling by the judge. Recall that this -- there's no question of fact in this case. It's only a question of law. So it's a brief -- it's ruled based on briefs by a judge, who's going to determine as a matter of law whether or not there's a constitutional question or not.

That, we would expect to happen some time this year. It's in the hands of the court, waiting for the judge to determine that. And then depending on where that goes, we would appeal to the D.C. circuit and ultimately, potentially to the Supreme Court if need be. All of that on a time line that would put us as we move into the late '25 or early '26, kind of approaching when you see the first wave of implementation of the IRA.

But again, yes, that is, if we are successful, our expectation is then, we would start a discussion on how do we make adjustments to the legislation that are more pro-innovation, more pro-negotiation and true negotiation. Because as you know, we've argued, we don't believe the IRA as contemplated is actually a negotiation. We don't see it that way.

So we're very open to having those discussions with the government and moving that forward. But all of that is moving on a timetable kind of that is unchanged from our initial expectations.

Our focus right now, both as Merck and frankly as an industry, is to continue to work with CMS on the implementation of the current language and make sure that, where we can, we can influence in a positive way what's happening from that perspective. So a lot of work is being done there, as well as continuing to educate in Congress on some of the unintended consequences of the IRA and why we want to make sure people understand like, for instance, the difference between the small molecule and the 9 to 13 in the large molecule, what are the implications that could have.

So a lot of efforts are underway there, but all of that is more longer-term focused as far as any legislative change. Near term, it's about impacting the regulatory language and then continuing with the lawsuit.

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

And I want to press you a little bit further in terms of potential for some dimension to change. You brought up the small molecule, large molecule 9 and 13 difference. Should I interpret that to mean that, that is something that is of the highest priority or that has a higher potential of actually being modified? Or is there something else that you think is maybe most likely to happen?

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

I would say that is clearly, both as Merck and as an industry, the area where we are focused with greatest concern because there's no logic for the difference between 9 and 13. It was driven off of exclusivity language that was adopted that actually had no actual bearing to what it should have had in the way the IRA was structured.

So our view is that is a very important area to focus on. So I'm not implying we think we're going to get that changed or not. I don't want to give any directional view of that or not. We will continue to have those conversations. I think there is some receptivity and understanding to the unintended consequence. Whether that translates into a legislative change, we will have to see.

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

Got it. Okay. And then that was my detour a little bit into the IRA. Returning to this question of strategy, Mr. CEO, and sort of capital allocation priorities. The diversification that you've done has been significant: Immunology with Prometheus; the focus on neuroscience, early stage; we talked about cardiovascular. How much more is there to do?

And one of the things that is in the vernacular of Caroline is that she remains unconstrained by size and capital. And so it sort of leaves open the question of what's the possibility of doing a deal of size beyond the kind of tuck-in single digits to \$10 billion, \$12 billion? What's the appetite and opportunity there?



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

Well, I would start by saying our focus continues to be looking for interesting assets where we see a true scientific difference. And for us, that tends to be more in those small and midsized deals. So clearly, our focus is not on the large transformative deal of any kind. I don't think we need it. And frankly, it would be a distraction at this point to our labs and to the progress we've made.

We are very interested in continuing to do deals like the deals you've seen us do. So if you look at the Prometheuses of the world; Accelerons have a little bit smaller size; what we did with Orion, which is a collaboration; the acquisition of Imago, all of those types of deals will be deals we will continue to pursue. So you'll probably -- that 10 -- 0 to \$10 billion to \$15 billion is more of the range. I will tell you that you are seeing, for late Phase II, early Phase III opportunities where there's transformative assets with good clinical data, the prices have gone up. And that's why I think you are going to see that is a little bit more. But it's in that range we're looking at.

We're not foreclosing the opportunity. But if we ever looked at something bigger, it would be because the science took us there and we saw something that we thought would be a sustainable long-term growth driver, not because we were trying to fill a void in the near term. That's not our strategy. And clearly, we would not pursue any form of cost-driven M&A or transformative deals. I don't think we need to. Our strength is in executing what we have in hand and then adding to it selectively around the portfolio we have today.

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

Great. And it's very consistent, very clear. Leading with science is always the first thing out of the mouths of you and Caroline. Peter has trained you very well.

A little bit more on portfolio, and I've been a bit of a bully about this with you the last couple of years. Animal Health. You've characterized it as a business that is a right fit for the Human Health business. Objectively, if I look at performance, 7 out of the last 10 quarters, however, have come in below Street expectations. Do you continue to feel this way? And are the synergies that you have described worth the risk in terms of the top line numbers? Give us a sense for that.

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

Yes. So maybe start with the end, and then I'll work backwards. I continue to believe there is meaningful strategic value to the Animal Health business, to the synergies we enjoy with our Human Health business and to the diversification strength it brings us with an annuity-like revenue stream that's a very different risk profile than what you take on the Human Health business. So for a lot of reasons, I continue to believe there's significant value to be created through the combination of Human Health and Animal Health business.

If you look in the short term in 2023, we did see the business slow a little bit. There were both some factors happening across the human health space as a whole. So the market as a whole slowed down a little bit.

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

Animal Health.

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

I'm sorry, I'm sorry, Animal Health business, yes. And really, that was driven by what had been a surge in that business through the pandemic. So some of that's just working through the normal course of the seasonality coming out of the pandemic as we move forward.

But as I sit here today, looking forward for our business in Animal Health, our ability to drive significant growth well ahead of the animal health market, and growth which will be accretive to Merck as a whole, continues to be there. And it's driven on both the in-line products we have, but importantly, the strength of the pipeline we have in Animal Health.

Our strategy in Animal Health, frankly, is exactly the same as our strategy in Human Health. And in some ways, that's where the synergies come from: Strength in vaccines, next-generation vaccines, continuing to drive now into the companion animal space, leveraging the Human Health catalog of opportunities we have.

We're going to be driving meaningful growth through new product launches in vaccines and in the companion animal space as well as the investments we've made in technology that, frankly, is the leading edge of that business and, frankly, ahead of where we are on the human health side, that gives me strong confidence in the long-term growth capability of that business. And as a result, I continue to believe the synergies and that growth are valuable to the company.

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

Got it. And then just to close out the whole capital allocation discussion. Additional forms to distribute to shareholders include dividends and share repurchases. And it's kind of a Caroline question. But what's the latest vocabulary on how you'd respond to that? It's gone through different periods in terms of excess capital would be you'd maintain the dividend. What's the latest version of that?

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

Yes. So we continue to believe that the best use of our cash flow is investment into the business, and that's unchanged. Starting with, we're going to do everything we can to accelerate and drive our R&D investments, continue to build out the capacity we need from a manufacturing perspective across both Human Health and Animal Health, and then leverage anything that's left into business development. So that is -- that's our priority.

I continue to believe there are opportunities there such that I would not want to weaken my balance sheet by doing some form of large share repurchase. As you know, in 2023, we did start a modest share repurchase. It was aimed primarily at offsetting the dilution that comes through all of the equity that people within the company get. That is continuing as we move into 2024.

Would we ever expand that? Only if we see a change in the landscape on the business development side, which as of right now, I don't see. So -- and I do not believe we would have what I would characterize as excess cash that I would want to deploy into share repurchase. I would rather put any capital or cash we're generating into long-term sustainable growth for the business. But obviously, we revisit that on an ongoing basis. But that view has been pretty much where we've been for the last couple of years.

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

So all of this time that I've spent talking about the capital allocation and the strategy is really addressing this question which we started the conversation with, that KEYTRUDA is just such a transformational drug franchise, \$25 billion going to north of \$30 billion according to Street projections by the time we get to the end of the decade here.

And usually for companies that approach this, and I think about some of your industry peers, Abbvie approaching HUMIRA. Lilly is going to have this issue as part of the question complex that's going to come up as we think about the obesity complex into the 2030s, et cetera.

And investor questions are, as you get towards that 2028 and through that period, do you expect to see continuous growth, a tapering or a slowing of growth, a flattening and then a resumption of growth? Is there anything that you can update us with what your vocabulary is on the shape of that?

And I know you haven't given specific guidance, although there's clear building blocks, \$10 billion here, greater than \$10 billion there, so people can do the math. But what is the CEO's words on how do we get through that end of the decade? And what is the revenue shape?

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

Yes. Well, I would say that our confidence in our ability to address long-term growth of the business is quite high. As I mentioned in the opening comments, the progress we've made, whether it's through our cardiovascular program, which, as you mentioned, will be greater than \$10 billion in the -- as you move into the early 2030s. What we're doing in our oncology business, where we've also put out there that if you look at just what we have through the ADCs, and this excludes what we did with Daiichi Sankyo. So putting that aside, which we think each of those are multibillion-dollar opportunities. Those, plus the other small molecules, we saw as a \$10 billion-plus opportunity. Continuing to expect that our vaccines business will continue to grow. With GARDASIL as a foundation, we continue to believe it will be excess of \$11 billion as we approach at 2030, which is the guidance we've given.

So each of those, as you point out, are important building blocks. As I sit here today looking at the culmination of all of those and the fact that almost every program we focused on as a makeup of the portfolio over the last 12, 24 months, we've really had no major failures or falling out. In fact, everything is advanced, and in several cases, has moved faster than expected. I don't think anyone would have expected sotatercept to be what that potentially can be, as just one example.

So I sit here today and you've heard me say, I see 2028 as more of a hill, not a cliff. I'm much more focused on sustainable growth into the 2030s, and I'm confident we are in a position to deliver that kind of sustainable growth. We continue to aspire to grow through KEYTRUDA. But I'm very confident that if we do see a dip, it will be a small dip and a short dip, and we'll get back to sustainable growth into the 2030s.

I don't think we're done. We're -- we will continue to not only try to accelerate what we have in-house but continue to augment it through business development. So I don't want anyone to have a perspective that we're viewing our -- the job is finished.

But the progress we've made should give everyone confidence that we have a plan, we have a strategy, we're executing. The consistency of our message, I think, hopefully should give you confidence, and the fact that I can give proof points along the way that says what we've committed to, we've delivered. And we're confident based on that, that this is -- 2028 will take care of itself.

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

Got it. No, that's very clear. So there's tons of questions that I had on the list, many of which will probably be ones that I'll interrogate Dean on in the next month or so. But let's...

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

I just wanted to show my scientific knowledge, but that's okay.

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

Yes. No, no, we'll get there. We'll let you flex a little bit there.

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

Just kidding, just kidding.

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

Let's talk ADCs because it's interesting how you go through this phenomenon and like what's hot and what flares. And ADCs is certainly hot flared. ESMO was standing ovation for EV through its data, et cetera. The Daiichi deal actually really intrigues me because when you look at how that was structured, there was a pretty healthy upfront and there's some milestones that are due. And it's an interesting concept that I think Caroline has said is just like she's hoping she's paying all those milestone payments to the tune of, what is it, \$5.5 billion per ADC. There's kind of 3 assets there.

What's the -- what's an important way that we should be understanding about the ADC approach, and in particular the Daiichi portfolio, that you think is not quite getting through to everybody yet?

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

Well, hopefully -- first and foremost, I actually think that deal, if you look at how we structured it, that was -- from a risk mitigation perspective, I think that was a very smart deal. It's very similar. It followed the exact construct of what we did with Eisai and what we did with AstraZeneca for Lynparza and Lenvima. And so it's a model we understand and we've utilized.

And to your point, if you look at the upfronts that we paid, they were pretty consistent with what we did in Lynparza and Lenvima and what you've seen others do in the industry. So the upfronts weren't really out of line. I think they were -- for what you're getting, which are assets, late-stage assets, as you know. Hopefully, you all saw it happen in end of December. So you might have missed it.

We -- when we did that deal, we had not publicly made any comment on the fact we had expected it. But we had not publicly commented on the fact that we already have now filed for approval with HER3 in non-small cell lung cancer, which is one of the ADCs we brought in. That was accepted. And we have a PDUFA in what is it, June?

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

June.

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

June of 2024. So already, you're going to see assets paying off.

But all of the milestones in that deal largely are tied to sales milestones. So obviously, if we are paying those milestones, it's because those assets, the 3 main assets we did the deal for, are all being highly successful commercial assets, which we think they will be. And I think that's why Caroline smartly says we should all hope we're writing those checks. Because we will be -- they will be economically very positive to the company in terms of the value creation, not to mention the revenue growth those products will bring as we move into this decade and into the next.

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

Right. No, that's very helpful. And I think there was a little bit of a blurriness over what these assets -- so 3 assets, the HER3 furthest along that progress, and which you just confirmed for us here on this stage...

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

B7-H3.

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

Then the B7-H3 is also next, potentially the largest in terms of the sort of end-market indications there, small cell lung cancer with and without PD-1, prostate cancer and then the CDH6. Very healthy opportunity in ovarian, a significant unmet need here. Each of these is a \$5.5 billion milestone, \$16.5 billion in total, which Caroline is poised to write those checks if we see some success...

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

Well, I think you recall, when we did the deal, we did communicate, we expect each of those to be multibillion-dollar revenue potentials. And the indications we ultimately will seek. Obviously, we communicated the first tumors we're focusing on, but we see the breadth across each of those as more than the initial indications. So the rest we haven't disclosed, but we're doing work with Daiichi in alignment that we will fully optimize these assets. We're going to invest to win with those assets. And I think each of them, as I said, multibillion-dollar potential, are meaningful.

On top of what we already did with Kelun, where we have the TROP2, the Claudin and the Nectin-4. So we have -- I think we'd have to look, but probably if not the broadest ADC portfolio in clinical development, it's clearly up there with everyone else. And if Dean was here, he would say, if you look at the total capital we've deployed to achieve that, it's actually not very much relative to the potential it creates, which I think was all the credit to Dean and our business development folks, good dealmaking.

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

Yes. No, smart structure and it's -- this update about the PDUFA coming up in June is another way to push back against what's kind of a lazy criticism of the stock, is that no, there aren't enough catalysts, but I think we'll pay attention. Communication with regard to progress across that, is that going to be shared, balanced with Merck-Daiichi? Or who should we be signing up for the e-mail or something?

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

This is clearly -- this is a partnership. And so any communication on progress will be brought together from both of us through joint agreements. So it is a partnership.

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

Got it. Okay. I'm going to have to go a little quicker, a couple quick hits to make sure we're covering some topics. IO plus IO combinations, TIGIT, take your temperature on your confidence here because it's been not the most confidence-inspiring realm. IO-IO is difficult, but where are you guys on TIGIT?

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

Yes. So we continue to believe there's a lot of justification to continue to advance those programs into Phase III. You saw we had Phase II data that we shared recently. Importantly, that was in a very difficult-to-treat patient population, and we did see effect from TIGIT in that population. Those studies were not powered for -- to achieve statistical significance. So I would tell you, if you'd ask Dean, if you'd ask Dr. Barr, who runs clinical, they say they were encouraged by that data. And definitely, we are moving forward with our studies and we'll see where it comes out. So we continue to believe that's worth the investment.

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

Okay. Yes, Dr. Barr. Eliav. He's a great meeting. Important meeting him live. He is currently my top choice for most expressive eyebrows in the business. So when you ask the questions, you can get a sense for what's happening there.

Another quick hit. Moderna, the individualized neoantigen...

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

Therapy.

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

Therapy. INT, right, exactly. So the question that we get from investors sometimes is like adjuvant melanoma, Merck's got a lot going on. What's their level of enthusiasm about prioritizing this? Respond?

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

Very enthusiastic to prioritize this, along with all the programs. If you look at what is evolving in the cancer space, I don't believe, and I know our scientists do not believe, it's a one size fits all. There is plenty of space for multiple approaches. Our goal is to make sure we have the broadest number of approaches across each specific tumor type and the breadth of oncology as a whole.

So for us, it's not an either/or, it's an and. Because the reality of it is, as much as KEYTRUDA is a miracle drug, truly foundational, overall response rates are still not that high. And the reality of it is there's still the vast majority of people who have cancer are still going to struggle. And so the more we can bring different approaches in combination with KEYTRUDA or independent of KEYTRUDA, we believe that's the approach. That includes what we're doing with the individualized neoantigen therapy as well as what we're doing across other programs. So we're moving all of them.

But as it relates to Moderna specifically, we'll see where this goes, but the potential from what we've seen in the data in melanoma, now as you know, we've started a Phase III in non-small cell lung cancer. This could be a very significant opportunity. We need to see the data, we need to finish the studies, but we are committed to investing behind them.

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

Survival studies take a long time, particularly in the adjuvant setting. You capture the flag with that. Any chance for an interim read?

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

Well, these are outcomes-driven studies. So there are opportunities for interims, but they'll be based on speed of enrollment and clinical outcome that we see.

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

Okay. touch base on vaccines, particularly for GARDASIL. People are almost sleeping on GARDASIL because it's been such a reliable player, the trajectory. There's -- probably The Street is doing lazy linear modeling, et cetera. A couple of things have to happen, however. Manufacturing has to come through, and Caroline has been very reassuring. But what's the January 2024 perspective on that?

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

So the short answer is we're bringing up the new lines, the new facilities. One is up, second one is coming up. You'll see supply from those facilities ramp over the next several years. So we continue to believe we'll be in a position where we will be unconstrained in our ability to meet demand.

We're not there yet, but we're on a path to get there. And we continue to believe the opportunity to address, what really is the truly only anticancer vaccine in GARDASIL, to meet what is still a high unmet need is there.

It's going to take a lot of work. We're moving into harder spaces as we start to try to engage the private market around the med adult segment globally as you look at moving into the low- and middle-income countries where we obviously will see slightly lower margins or lower margins in that space, or what we're having to do to drive for gender-neutral, which is still only in a minority of countries. All of those strategies we've talked about, we're continuing to pursue. And through all of those, the culmination of that with our supply, is we remain very confident in that business.

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

And then, Peter, if I could confirm the vocabulary on unconstrained on supply, the year is still 2025?

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**Peter Dannenbaum** - *Merck & Co., Inc. - VP of IR*

2025.

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

Okay. No change there. And then China, naturally, actually, the market has been more dynamic and a little bit uncertain. There were competitors in there as well. Confidence in the China as a source of growth?

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

Continue to see it as an opportunity for growth. The next wave of opportunity there is going to be gender-neutral. So obviously, we've seen great success on the female cohort. As we start to address it with the male cohort, we have to get the approvals, obviously. But that process is underway. But once we are able to achieve that, that is still a meaningful opportunity in that market.

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

Okay. Getting towards the end, but I have a couple of favorite assets. I love sotatercept. I love the PAH market. I think the word disruption is potentially very valid here in this indication. A lot of confidence. March PDUFA. Commentary has been, and our own KOL work, has been for a relatively rapid uptake in adoption. What is the message that you'd like to give about sotatercept in 2024?

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

The -- look, if you see the STELLAR data, it's phenomenal, the confidence, the excitement that's creating among the key opinion leaders, both in the United States and across Europe. As you know, we filed for approval in Europe. We weren't expecting originally to have that until a few years down the road. The fact that we could have approval in 2024 is a statement of the strength of the data and the excitement for that asset.

Our belief in what this can be as a transformative therapy is as high as it's always been or more so, and we are going to fully pursue it. We're ready. The team is in place. And from everything we hear, doctors are excited and, frankly, awaiting this drug to the marketplace. So your belief of a fast launch is consistent with our belief.

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

And Peter, the potential to hear something about the either HYPERION earlier stage or ZENITH later stage during 2024 or...

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

So if you look HYPERION, I think cadence are both in 2025, is probably the first time you're going to hear something.

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

Okay. And then ZENITH in the late stage?

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

ZENITH is later. It's...

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

ZENITH is '25, Hyperion is...

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

Oh, ZENITH is '25 and Hyperion is later.

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

Correct.

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

Okay. My bad.

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

Okay. There's -- certainly, the KOL community has been very intrigued there.

And then on the Prometheus opportunity, this was a story that talked about targeted immunotherapy, and then all of a sudden the data was spectacular across all-comers population in the ulcerative colitis opportunity. And one of the things that I know that Eliav takes particular pride, and [Umbridge] when I asked him, was that when you do these acquisitions, the kind of like the arrows that go across clinical development time lines, you guys are merciless about keeping things on track.

So I used to cover Prometheus. How are we doing in terms of keeping things on track for things like Crohn's disease or some of the other indications?

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

Everything is moving at pace, on track, and we're very confident in our clinical execution.



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

Is there anything I haven't asked that, as we start 2024, that you think is underappreciated that you would want to highlight? That's like I wish Chris had asked me about this? I want to send a message.

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

Yes. Probably the one asset that I think is underappreciated a little bit, I would say, as we think about what the potential total revenue potential is for sotatercept. As great as it is, and I think everyone now is growingly appreciating that as an asset, probably still underappreciated. But the one I would focus on is V116. I think that is very underappreciated.

Our ability to fundamentally change the dynamic in that space, in pneumococcal disease with an asset that is unique, it's an asset targeted to adults. It addresses 85% of the residual cause of disease in adults. That's significantly higher than anything out there, including PCV20, which is potentially in that space as well as some future drugs that are coming from other companies. I think that has not fully been baked in at all. So I'm quite happy to have an upside catalyst as we move into '24, which you'll see us bring approval.

When is the PDUFA for that? It's...

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

June.

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

June of '24. So I fully expect that will be an upside surprise for people.

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

And minor point. But we now say 83% of adults.

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

83%.

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

Okay. Well, June sounds very exciting, separate from the fact that it's the Goldman Healthcare Conference. But these PDUFA's coming up for you is pretty...

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

The only -- the last thing I'd add, too, is just -- if you look at the number of programs we now have in Phase III, either programs that have started or that are moving into Phase III across the breadth of modalities. This is, I believe, we haven't actually gone back and look, but if it's not the most Merck has ever had, it's got to be pretty damn close. And clearly, the fact that we have it across such a broad segment of therapeutic areas.

I think people keep saying, what are the catalysts? There's a lot. I think they get lost in the umbrella of KEYTRUDA. But I'm quite confident as we move into '24 and beyond, as you see these programs read out, we mentioned one, important one, the HER3 ADC. We recently got approval ahead

of expectations to move into broader RCC with WELIREG. Those are just 2. I mean, we have multiple things going on. Watch for those, understand those, because I think as you dig into those, you're going to realize that the potential to drive growth for this business is significant.

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

And then to make sure. I'm always keeping one foot in my Excel spreadsheet. With all of these investments in deals with all the late-stage pipeline, remind us the correct interpretation of the margin outlook should be. I think there was a little bit of discussion following the third quarter in terms of like what is Caroline saying in terms of the operation margin outlook? Set some clarity here.

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

Sure. So first, we continue to believe -- and the guidance we've given is that we'll be at greater than 43% in 2025, right? That's unchanged. So we continue to believe we'll achieve that. It's being driven by improvements in our product mix. Obviously, the biggest thing here in '24 is the step-down in royalty on both KEYTRUDA as well as GARDASIL that's going to be important as a lift. Plus, we're getting productivity through manufacturing, and we're driving a lot of productivity through SG&A. So nothing's changed there.

I think the message she wanted to ensure people of is, as we're seeing the clinical readouts of so many programs, we will never choose to drive for a margin goal over investing for sustainable long-term revenue growth. And we have the potential with so many meaningful opportunities to drive sustainable revenue growth. We're going to invest behind those. It happens to be that the strength of our business, and the portfolio, and the profile that gives our margin is it also implies we're also going to have a strong operating margin, but it's not because we're sacrificing investment for sustainable long-term growth. We always will go where the science takes us and invest behind it.

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

Clarity behind strategy, consistency of execution, calmness which should not be mistaken for a lack of drama or sexiness, so to speak. I think that's been very much the characteristic here that I think investors should appreciate. And thank you for adding to the sort of the portfolio of vocabulary. As we think about cliffs, we now talk about a hill.

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

Yes.

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

I will attribute that to you. And Rob Davis, Peter Dannenbaum, thank you very much for joining us.

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

Thank you for having us. I appreciate it.

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**Peter Dannenbaum** - Merck & Co., Inc. - VP of IR

Thank you.

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