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PRESENTATION

Daina Michelle Graybosch - *SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst*

Hello, everyone. Welcome to our session this afternoon with Merck. I am really pleased to host Caroline Litchfield and Peter Dannenbaum.

And if you don't know me, I am the immuno-oncology analyst here at SVB Leerink. You may say, "Well, why do you cover Merck?" And it is because immuno-oncology is important to Merck. And actually, I love it because I love thinking about things other than immuno-oncology as well. And so always happy to talk with Merck management and really excited to have you both with us today.

Caroline Litchfield - *Merck & Co., Inc. - Executive VP & CFO*

Thank you, Daina.

Daina Michelle Graybosch - *SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst*

And one point of process for people listening, if you'd like me to pose a question to Caroline or Peter, please look at the box below my finger, put it there. If you e-mail it to me, I probably won't see it. So please send it in the box, and I'll try to fit into the conversation.

And so I'm going to start broad, getting to business development, operations and then end with some sort of quick round on the -- on some programs.

QUESTIONS AND ANSWERS

Daina Michelle Graybosch - *SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst*

So at the highest level, I'd like to just hear what you're most excited about for Merck this year.

Caroline Litchfield - *Merck & Co., Inc. - Executive VP & CFO*

So first, thank you for having Merck here and myself representing our company. We're very excited as we look at 2022, coming into the year with great momentum in our business. '21 was a year that we had excellent execution across our operations in the financial performance that we achieved across our pipeline as we continue to progress the pipeline. And also, we managed to do the spinout of Organon and some important business development.

So coming into 2022, we've got great momentum in our business and an expectation for very strong growth in our company. The guidance that we've just issued has revenue expectations of growth of 15% to 18% leverage in the P&L, so faster growth on the bottom line of 18% to 21%.

But importantly, when I take out the headwind that we think foreign exchange is, we have 17% to 20% top line growth in our business. And that's as a result of molnupiravir. We've stated we expect between \$5 billion and \$6 billion of revenue, really as a result of contracts, agreements that are in our hands today.

And when I exclude molnupiravir, the underlying business on a constant currency basis will grow by 10% this year at the midpoint of our guidance range. So we're excited about the opportunities we have in our key pillars to drive that growth. We have oncology with significant progress still to have in immuno-oncology, as you've just noted, Daina, with KEYTRUDA and the impact that can have across the world, with Lynparza and Lenvima.

In vaccines, we've got significant headway on GARDASIL and the opportunity to protect more people from HPV-related cancers. So we'll expect significant continued performance and growth there. We have the launch of VAXNEUVANCE, which we're excited about. It's an important next-generation pneumococcal vaccine that we believe will be competitive in the marketplace. And we have our Animal Health business, a significant driver of growth for our company. And we expect continued industry-leading growth in 2022.

So it's a great time to be at Merck. We've got a lot of strong growth in our business. And we will continue to focus on our pipeline and driving and delivering on our pipeline, including augmenting that with business development. So we're excited about '22 and also what that will do to enable further growth in the years to come.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

That sounds exciting. And I wonder, as you put yourself in investors' feet, what do you think they may be overlooking for Merck for the next couple of years?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So I'd say -- the first thing I'd say is when you've got stellar double-digit growth like that, it's impressive. So we feel we have every opportunity to deliver on strong growth for our company across those key pillars.

One of the products that we've cited that we think has significant opportunity is GARDASIL. And with GARDASIL, we've been increasing the supply to the marketplace. We still have only vaccinated about 9% of the global eligible population. We have significant growth ahead of us. And indeed, at the JPMorgan conference, Rob stated, our expectations that we could double the sales of GARDASIL in the year 2030 compared with the \$5.7 billion we achieved in 2021.

So if I was to call out some areas that I think have real opportunity that aren't always necessarily seen as strongly as we see them, GARDASIL would be one of those.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

That's really helpful. How about maybe extending it a bit more as near term? And you answered mid to long term actually. Are there any other midterm revenue potential opportunities that you think there's a gap in understanding?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So I think that our company will continue to drive really strong growth through to 2025 if we class that as midterm. And the growth that we're expecting there will be in oncology. With KEYTRUDA, we're expecting a significant part of our growth, 50% of our growth, to come from the earlier stage disease. Indeed, by 2025, we think that about 25% of our business will be in that early stage disease. And we've got 50-plus approvals coming across KEYTRUDA, Lynparza and Lenvima in this time line. So we have a lot of excitement for our oncology business with KEYTRUDA, but also importantly, Lynparza and Lenvima. So a lot there.

I think in the vaccine space, as I noted for '22, we are really looking forward to our next-generation pneumococcal vaccine in VAXNEUVANCE. We have that approved now in adults. PDUFA date in April for pediatrics. And we have further iterations of the vaccine that we're working on with V116 for adults and V117 for pediatrics that will be more targeted towards the prevailing serotypes for those populations. So that's an area that we have, I think, significant opportunity to have impact and to compete in the marketplace.

And I've touched on Animal Health. Animal Health has been a robust business for Merck, and we continue to expect to see strong, industry-leading growth in that segment.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

(inaudible) on the guidance for 2022 as it comes to VAXNEUVANCE. How aggressive or conservative do you expect to be able to ramp up commercialization and sales in that guidance?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So our guidance that we've issued for the year includes our expectation of VAXNEUVANCE in adults and the hope that we will have pediatric approval later this year. Our commercial teams have been working really well since we had the ACIP unanimous recommendation late last year and the MMWR approval just earlier this year, late January to make sure we're doing all the contracting that we should be doing. We have the product available. We've been investing heavily actually in manufacturing capacity for a number of our growth drivers, VAXNEUVANCE is one of them. So we're in a really good place, Daina, to make sure that we can deliver, I think, on the promise that VAXNEUVANCE is.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

I think -- actually, there's a couple of questions that have come in from investors on this, one on GARDASIL. They're asking, what's the timing on GARDASIL site opening 2023? Is it going to be the beginning of year or later? And I think they mean manufacturing site. And how much supply will that unlock?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Okay. So this is a great question, and thank you for it. We today -- let's start with today. We have been very effective within our manufacturing operations to really drive productivity in the existing assets that we have. And as a result, we saw an increase in the level of supply to the market in 2021 relative to '20. And again, this year, we're expecting another increase in the level of supply that we'll be able to produce from our existing assets, although not quite at the same level of increases we achieved in 2021.

As we go to 2023, we have 2 bulk manufacturing facilities that will be coming online. And we expect that the supply will be coming online over a period during '23 and '24. So it's not like you're here and we'll jump right up to a certain step change. It will be gradual, but an impactful increase over time.

And I'd just close with saying for GARDASIL, today, we protect just 9% of the global eligible population. The opportunities to protect more lives, to have significant growth in our business -- enduring growth in our business is there. And we're investing in the capacity and in national immunization programs as we have that supply to enable protection of lives globally.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

That's helpful. A couple on capital allocation. First, what would lead Merck to restart share repurchases?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So maybe I'll start first with what our capital allocation priorities are, and then I'll be specific because it should hopefully answer. Our company is focused, first and foremost, in investing in our business, investing in growth, investing in innovation. So priority #1 is to invest in research and development, invest behind those key pillars of growth that we have and invest behind capacity so that we can support the demand that exists globally.

A second priority for our company is to have value for our shareholders with a competitive dividend. So we're committed to our dividend and to growing that dividend over time.

Our next priority is business development. It's a critical, strategic priority for our company to augment the current assets that we have and the pipeline that we have with the best of science that we see externally. So we're looking to put our strong balance sheet and our strong EBITDA growth to good use through investing in our business and business development. If we have excess cash, we will return that to shareholders through share repurchase.

Now for 2022, we've guided a share count that indicates we have a modest level of share repurchase built in to our expectations this year. If business development doesn't materialize, we will return further value to our shareholders through increasing the level of share buybacks.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Another one on -- you talked sort of strategically at a high level about capital allocation. I wonder if you have any sort of sublevel priorities, and maybe I'll explain what I mean. Like are you trying to aim for diversification or try to split across therapeutic areas or scientific approaches?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So the first priority we have on our business development is really looking at the science. So we're looking for innovation. So we are really focused on seeing whether there is that scientific benefit, whether it's in an area of unmet medical need. And then in Merck's hands, we can drive for value creation for both patients that we serve as well as for our shareholders.

Now where we look for that is, I would say, in a few areas. One is augmenting certain areas where we do have expertise. And you've seen us do that in oncology, where we've built out oncology assets through acquisitions.

We've also harnessed the power that oncology -- immuno-oncology has given us in better understanding immunology with the acquisition that we did there with Pandion. And you've seen us further bolster our cardiovascular presence with the acquisition we did late last year in Acceleron. So I would say we're looking at augmenting different therapeutic areas where we really do have strength and expertise. And by having that strength and expertise, we see something in external assets that we can bring in to Merck and truly add value and drive value.

But at the same time, we are open-minded to have sciences evolving. Dr. Dean Li, our colleagues in research, have an active network so that we're staying abreast of what's happening outside of Merck as well as obviously what's inside of Merck so that as we see science move, that we can pivot quickly and urgently to bring the best of what's outside of Merck inside of Merck.

So I'd say to summarize, Daina, it's building on the strengths we have, but also enabling some level of diversification where we see the scientific merit.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Very helpful. Another one on this to an investor, and it gets us into business development. But they ask, on capital allocation, what is the potential maximum deal size that Merck could be willing to do?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So I'll quote our CEO first, and then I'll be maybe a little bit more specific. So our CEO has stated that we have a strong balance sheet, and financial capacity isn't a constraint for our company. So what I would say is, as a company, we have strong balance sheet, strong credit rating, and we're willing to temporarily take an increase in our leverage to enable the right kind of strategic transaction.

How we look at that transaction isn't the dollar size, it's really on the scientific merit. And the one hurdle that we do have is to ensure that it does not disrupt the internal R&D engine.

Now we're obviously very open to doing deals that are adding to that R&D engine, but we don't want to disrupt the great work that we have on our own existing pipeline. So that would be the major constraint, I would say, that we put on our view of business development.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Is it fair -- I think how maybe I've interpreted it sometimes is you wouldn't do maybe another Schering-Plough deal. But if there were a big company that had a particularly bolt-on science or platform that was really different than what you do internally, that would decrease the organizational complexity, maybe increase the size of infrastructure and organization you'd be willing to take on?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

I think you say that well, Daina. Schering-Plough at the time was somewhat a merger vehicles and a synergy play, albeit it played out somewhat differently, too. We're not looking at doing some kind of put 2 companies together to take out costs. We're looking at bringing excellent science in. And we're not constrained on the size of that organization to your point. So yes, you summarized it well.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Very helpful. We've answered several questions here. I guess just thinking back on past negotiations and targets, Merck did find science that were interesting. Wonder, how often does valuation, negotiation of targets hold Merck back from a business development deal?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So maybe I'd start with how we're looking at it today because I can comment more accurately on that. We look at companies, I think, with the appropriate level of value in how we look at the science, how we think we can create value for that science, and we're being appropriately aggressive, I would say -- financially responsible, but appropriately aggressive in that measurement.

And so when we see that value when we talk to the other side of the table, where those 2 perspectives on value align will move and will move fast, and we're prepared to pay the appropriate value to do so. And I think Acceleron was a great example of that.

From our company's perspective, we've been doing that for some time. I would say, at this stage, we continue to look at assets. We're looking at it with the appropriate level of rigor. We're looking at it with the appropriate level of financial discipline, but also being appropriately aggressive to ensure that we do continue to do meaningful BD. And meaningful BD in terms of value that they'll bring to patients, the value they'll bring to our shareholders.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

(inaudible) any shift from biotech management or Board sort of on their self appreciation or what kind of value they bring to that negotiation table with the recent market declines?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Yes. So there's been -- from the highs that we've seen in the biotech sector over the last few years, we've seen and are watching what's happened to the biotech valuations so far this year. Now has that changed the sentiment of those companies on their value? I'm not sure yet.

One area that we are watching very much is the level of cash inflow to those businesses. And I think as we will see some of those companies who have more need for cash, we may see a change in what the expectation is of value as time unfolds. But I think it's too early to say what does that look like and is this permanent or temporary.

What I would say is for our company, we continue to focus on BD. It's a significant priority. We're focused on the science. We're focusing on valuing the assets for the strength we think we can bring to them, and we'll approach targets in an appropriate way to try and create that value.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

The challenging capital markets, ultimately, depending on how long it lasts, could -- would hurt Merck and other large companies because clearly you rely on the pool of investment in this new innovation.

Do you -- at some point, do you start thinking about business development and acquisitions and licensing in a different way? Would you take on higher risk than you normally would because you know we need to get capital out there into these biotechs from the large pool of cash that's sitting in large companies?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So you make a really important point, Daina. It's important that there is a vibrant ecosystem for innovation. Merck's just one part of that vibrant ecosystem.

In terms of how we would operate, I think the transaction that we did last year with Acceleron shows we are willing to take a different risk posture in the types of assets we're looking at and not waiting for a Phase III data readout, for example, and similarly with Pandion.

So we, today, continue to look at assets in that light. And we will move where we see the conviction on the science, the unmet medical need and therefore, the potential commercial opportunity. So we'll do that today in the same way as we did it back in November last year.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Let's move on to commercial operations. Most of the investors are asking me pipeline questions. So let's dip through these, and then we'll get to some of those.

I guess the pandemic has changed pretty much everyone and everything. And I wonder, as you look across your organization of things that used to be more in person, whether it's sales reps, field, medical; CRAs in your clinical channel operations, do you expect that virtual interaction is here to stay? And then, I guess, what kind of impact do you think it has on your operational spend? And are we there yet? Or do we still need more technology processes, culture shifts to get to the final structure?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So it's a really important question on what the model looks like for business going forward. Within Merck, prior to the pandemic, especially in our commercial area, we were moving to interacting with health care practitioners through both in-person meetings and detailing as well as virtual using technology, using digital.

And we have been on that journey, really driven in part by what our customers wanted from us, and it was different in different geographies around the world. And what the pandemic has done is just accelerated that journey. So through the pandemic, Merck was well positioned to continue to converse with the key stakeholders, educate key stakeholders, ensure that we continued with our clinical trials because we were already having some of that infrastructure and practice in place.

Do I see a world where we're back to complete in-person everything? No. I think the world has changed, and it's changed for forever. What that means for our company is we're positioned well where we are today, but we continue to invest in technology, in digital to better enable our company and better enable our colleagues within the company and better enable the outcomes, whether it's how we're sharing information, how we're prosecuting clinical trials.

So as such, what I'd say from how our business will operate going forward and the cost structure of the business, we will continue to see investments in technology. It's important for the future. At the same time, I think we'll continue to see productivity in the way we are organized in the activities that we're taking on.

And that productivity will come from many different ways, actually. I think as we think about how digital is transforming our company, we're looking at it from a research perspective and how it accelerates our discovery efforts. We're looking at it from a manufacturing perspective.

During the pandemic, we were able to do some of our quality work remotely versus having to be there at the facility. So how that can really be accelerated. And obviously, in the back office and the work that we do in the back office to enable the company, and I think all of that will enable operating improvements for our business.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Great. Okay. Let's get to some programs because I have so many questions from everybody and a lot of investors and myself. So maybe at a top club, I wonder if Merck has any perspectives on the ODAC last week for Lilly and Innovent? What impact might it have on near-term KEYTRUDA sales or long term on the platform?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So prior to ODAC, when we were always asked the questions about our views of competition, our response then, which is the same response today, is we see oncology as a really data-driven area. And our program with KEYTRUDA, which has an extensive clinical trial program behind it, a wall of data that we've developed in support of 34 indications across 16 tumor types and with 2 tumor-agnostic indications that we have, really says the standard that we have set, the bar that we have set with regards to the data for KEYTRUDA and the impact that we're having on patients.

We also have significant familiarity with prescribers in their use of KEYTRUDA as well as familiarity and confidence in the product. So we have always stated that we remain confident in the role that KEYTRUDA has for cancer, confident in the growth that we expect, not complacent around competition.

Today, we have, I think, it's 7 PD-1s, PD-L1s that we compete with. But even with that competition, the wall of data, the survival data that we have for KEYTRUDA is meaningful.

And so the ODAC outcome last week, in some ways, plays to the sentiment that we've had. What it showed was having diversity in your clinical trial matters so that the population that you will be utilizing the product in is a population that you've studied to ensure the benefit of the product.

And I think the other point would be the right comparator. KEYTRUDA has set a new bar for what the standard of care is. And I think as we have new entrants, we need to ensure that those entrants really do provide benefit beyond what the current standard of care is.

So we remain confident in KEYTRUDA, confident in our ability to see growth, not complacent, but we see strong trajectory for the product this year and many years to come.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Very helpful. A couple from investors. Given the competitive landscape in pneumococcal vaccines, do you expect the combination of VAXNEUVANCE and PNEUMOVAX to be a long-term growth franchise?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So the quick answer is yes. We are really excited about our pneumococcal program. So with VAXNEUVANCE and Pneumo 23, we have a 2-dose regimen that provides significant benefit for patients, covering more serotypes than competition does and also improved immunogenicity within serotype 3, a leading cause of adult PCV disease.

So we're confident in what we have. We have our pediatric PDUFA date in April, and we believe will be meaningful for the pediatric segment. But we're not stopping there. We also have V116 that we're studying at the moment, which is really focused further on adult pneumococcal disease. We believe it will cover, I think it's 80% of the disease area. And we have a next-generation for pediatrics in V117, which is a little bit later out.

So across the entirety of our program, we think we have a very important offering for both adults and pediatrics and a very competitive offering. It's a large market. It's a market that I think has room for more than one player. And we feel good about the opportunities that are in front of us.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Moving on, chronic cough. Can you provide any more context on why the application for gefapixant received a CRL? And what will it take for Merck to address FDA's concerns?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Yes, of course. So we received the CRL earlier this year. And to state upfront, there is absolutely no concern with gefapixant itself in terms of its efficacy and the impact that it can have on chronic cough.

The real questions are around the device that was used to measure the number of coughs through the program. And that's a device that's used by Merck and indeed by other companies who are equally assessing innovation in this space. So the work that we're doing right now is to show the data that we have around the way that the coughs were counted during the clinical program.

And that's something that the team in Merck are working expeditiously on doing so that we can provide further details to the FDA and hopefully get gefapixant approved here in the United States in the way that it is today approved in Japan and people with chronic coughs are getting access to a meaningful medicine that will change this debilitating actual disease for them.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

On molnupiravir -- maybe we'll get in just 2 more here. Do you expect EU approval? Or will you need new data for EU approval? And would you have that?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

So first, we stand behind the data that we have for molnupiravir and the impact that it can have in the world. And we're seeing that play out right now in the number of different supply agreements that we have globally and the utilization that we're seeing of molnupiravir globally.

And indeed, our partner, one of our voluntary license partners yesterday shared at CROI their data that they've seen in the real world that showed molnupiravir reduced hospitalization by 65%, and that was in a population that was at standard risk, not high risk.

So we stand behind the data that we have. We've been working with the EU, and they will be having a meeting next week to determine what the next steps are for molnupiravir in Europe.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

Okay. With that -- I have a guest behind me, too. He figured out how to get a key. Maybe I can sneak in one last question, which is, can you -- they would want to know when you'll start the oral PCSK9? And when might we see the Phase II data?

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Gosh, that's what I'm going to have to phone a friend here and ask Peter if we've said anything publicly. As a team, we're going to be sharing more about our total cardiovascular program in the spring. And we've got a lot that we're really excited about. PCSK9 is one of them, sotatercept another, Factor XI another, our inhaled sGC compound another.

So we will be holding an event in spring to really share information and ensure, hopefully, our investors share the same excitement that we have. But I need to phone my friend here and ask Peter, have we disclosed...

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

So we'll be moving into Phase II in 2022. So we presented the Phase I data at AHA in November.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

(inaudible) right. Okay. So on that, thank you, everybody, for listening and your engagement. I'm sorry I didn't get to many questions. A lot of interest in pipeline. So I'll relay that to everybody. That's what came in.

And thank you so much for your time and your insights. I really enjoyed the conversation.

Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Likewise. Thank you for having us, and thank you all for your interest in Merck.

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

Thank you, Daina.

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