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PRESENTATION

Geoffrey Christopher Meacham - *BofA Securities, Research Division - Research Analyst*

Welcome to the second day of the Bank of America Healthcare Conference. My name is Geoff Meacham. I'm the senior biopharma analyst here. And we're thrilled today to have Merck on stage with us, and we have Caroline Litchfield. Caroline, welcome.

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

Thank you. Excited to be here and thanks for joining this session.

QUESTIONS AND ANSWERS

Geoffrey Christopher Meacham - *BofA Securities, Research Division - Research Analyst*

It's great to do these in person now. I know we've all been pretty tired of Zoom. But let's talk sort of higher level. A lot of the questions on Merck that we've got, and I'm sure a lot of the ones you've gotten are your oncology business is very successful, but it's just grown in concentration. And today's sort of TIGIT news kind of shows that drug development is a risky business. But how are you thinking about that on the back of the Organon spin and looking forward? You did Acceleron, which was people perceive to be a very good deal. That adds a bolt-on, a different TA. But help us with kind of the thinking on that.

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

So let me start with, our company has a pretty broad portfolio across oncology, vaccines, some hospital specialty areas and animal health. And our goal really is to drive as much patient impact and growth across those different segments. Within oncology, we hope to be a leader in this space with the backbone of Keytruda, but the broad assets that we have to enable leadership in 2025, in 2028 and beyond. In vaccines, we've got a great portfolio here and Gardasil. I'm sure we'll talk about that. PCV vaccines coming, so tremendous growth opportunity there. Cardiovascular, you touched on that, is another great opportunity for growth for us. And of course, we have the animal health business.

So our goal is to really augment what we have within our company with business development. And the way we look at business development is science-led. We're looking for the best science that is out there that in Merck's hands we can drive incremental value, incremental impact for patients, value for our company and shareholders. So we are therapeutic-agnostic in how we look at business development, and the examples that Geoff quoted kind of say that.

We look to leverage our position in oncology as we've done different transactions in oncology. We've looked to leverage our immuno-oncology experiences. We went into immunology with the Pandion acquisition. And our cardiovascular experience, we've leveraged with the acquisition of Acceleron. So as a team, we're looking at BD based on science. And when that science and value align, we will move.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Perfect. That's helpful. And you mentioned BD being a priority, but you're generating a ton of cash. You've grown the dividend pretty meaningfully. Going back a few years, there is a thought that you'd have meaningful margin expansion. And then the Organon deal, sort of that was the focus for a year and almost 2 years. Where are you now with respect to expectations for margin expansion in the back half?

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

So we have made good progress on our margin expansion. In the year 2020, I think the margin, operating margin of the company was 34%. In 2021, we're at 36%. And midpoint of our guidance for this year will be at 38%. And we've guided that as of 2025, we expect an operating margin of greater than 43%. And our journey towards that expansion is based on, first, top line. So driving growth on the top line and the mix of that top line will improve the margins of our company.

The second area is productivity within our manufacturing processes, which will drive some cost of sales improvement. We also will see a step down in royalties that we pay on both Gardasil as well as Keytruda. That step-down happens at the end of '23. So we'll see the benefit of that coming through in '24. And we'll manage the rest of the P&L efficiently while driving investments for growth in the future. So we feel pretty confident about where we are with the margin expansion to date and our march towards stronger operating margin.

Now one area I should note on all of these numbers that I quote is there has been the recent change in the accounting or I should say reporting of IPR&D, and that will adjust some of those numbers. Indeed, we'll adjust our 2021 numbers as we have restated the Pandion acquisition into non-GAAP. But the underlying health of that operating performance has improved and will continue to improve.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

And just from the margin side of things, when you look at the investments you guys have made in Keytruda, it's been very dramatic and comprehensive to say the least. But a lot of the adjuvant studies, bigger studies and larger metastatic first-line trials and the range of tumor types are starting to sunset a little bit. So are you going to reinvest that into sort of I/O-I/O? What's the sort of the longer-term strategy? Should we see a benefit from the massive Keytruda investment kind of maturing as we move forward?

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

So the quick answer is yes. My hope is our R&D spend stays very strong because that talks to the health of our pipeline in the company. So as a research-intensive biopharmaceutical company, our goal is to invest in research and to invest in the next wave of innovation that will make a difference.

As Geoff rightly said, a part of that research effort has been behind Keytruda, and we've seen the level of activity behind the monotherapy studies come down. Now we've seen the great readouts. And therefore, our spend level has come down. But our focus now in oncology is more around moving into earlier lines of therapy, looking at co-formulation opportunities, combination opportunities or subcutaneous formulation opportunity. So we'll continue to invest behind oncology. But also we're investing behind the other wave of assets. We have spend in cardiovascular, vaccines, infectious disease, neurology and I can go on.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right, right. And help us out with the, a lot of the evolution of the Keytruda trials has gone from monotherapy, right, to adjuvant, but also to I/O-I/O. There's still a lot of unknown, retreatment with respect to PD-1. Also cold tumors, that's still a big box that hasn't been checked. What's the appetite sort of for expanding the investment in those opportunities, in those indications versus bringing something else out to solve it? In other words, do you have to solve that with Keytruda?

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

So our appetite is to advance the science here. And we know while Keytruda is such a miracle product and the impact that it's having for patients, there are still so many patients that need some form of cancer care because it doesn't work or the other agents do not work. So we're continuing to invest to see, does Keytruda, which is special, with something else have improved benefit or does something else have an improved benefit for patients? And we'll continue on that path in order to drive, I think, patient benefit and long-term hopeful impact for our oncology business.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Perfect. One of the things when you look at, of all the companies here and where the space has gone in the biotech side of things, on gene therapy, cell therapy, a lot of technology sort of centric kind of modalities. Merck is obviously the leader in I/O. But from a gene therapy, from a technology perspective, you guys have made some investments, but you're not at the leading edge. Where does that fall in your R&D kind of priorities, exposure to that technology?

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

So I'll talk more in general. Our goal as an organization and the goal of our Merck Research Laboratories is to really stay in tune with how science is developing both within Merck and outside of Merck. So we remain focused on these different technologies. Some we're making direct investments in. Some we're partnering with companies so that we can stay close to that. And as we see signals, we will move.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Okay. And then you'll have to make the investments subsequent to that with respect to manufacturing and the like?

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

Exactly.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Okay. And when you look at the landscape, kind of a little bit of a hybrid follow-up to that on the BD side of things. When you look at the landscape, there's a lot of SMID biotechs that have great technologies, maybe not quite yet proven. Is Merck looking to be opportunistic to take advantage of the current environment? Or is it really all about the science, doesn't really matter kind of where you are in the valuation spectrum from a BD or from an M&A perspective?

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

Yes. So I think the heart of our company is all about the science, and that's how we're looking at the BD landscape and looking at our overall pipeline and how we would augment it.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Perfect. Let's switch gears to the vaccine business. So give us a sense for Gardasil, the intermediate to kind of long-term growth. What are the drivers there?

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

So I'll start with the demand side of it. Gardasil has increasingly been seen as a gender-neutral vaccine that can help prevent HPV-related cancers. So as a result, we've got a significant opportunity in front of us and I would say an obligation to protect more lives from those types of cancers. Now to date, we have only vaccinated 9% of the world's eligible population with this vaccine. And the opportunities exist all around the world.

Here in the United States, obviously, vaccination rates are higher. We're in the 70s percent for vaccinations of both boys and girls in the adolescent segment. So we have an opportunity to increase that level of vaccination, and we have the opportunity to get into the mid-adult cohorts or age group 27 to 45. That will need some energizing of that cohort to go and get the vaccine, but it presents an opportunity as well as an important health benefit for those people.

Outside of the United States, we've got great opportunities. In China, we've really just started. There's 150 million to 200 million females that we are looking to access with this vaccine, and there's the potential that we may get approval for the vaccine in boys. In Japan, we've just received the recommendation for the vaccine for girls in the age cohort 12 to 16 and a catch-up through to the age of 25. So we're actively working on providing that coverage there. And in Europe, there's the opportunity to increase vaccination rates. They're not as high as they are here in the United States as well as on gender-neutral programs. And of course, there's the opportunity to support the lower-income market. So there's a significant demand opportunity that exists around the world.

From a supply perspective, our company has really tried to build on the supply since we've seen the inflection in Gardasil as it was then seen as a cancer-preventing vaccine. So we, today, are working really hard to drive as much productivity as we can within our existing manufacturing assets. And we've been pretty effective at that. We had sales of around \$4 billion in the year 2020. That was \$5.7 billion in the year 2021. And we believe in '22, we'll have strong growth, albeit not quite at the same level as we experienced in '21. And we have 2 new bulk manufacturing facilities coming online commencing '23. And those will come online gradually over '23, '24.

So we are really moving to a place where we are unconstrained then in our ability to supply and able then to activate and reach as many people around the world to provide protection. And we've now stated that we think in the year 2030, the sales will be double the \$5.7 billion we achieved in 2021. It's a great opportunity.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right. So it sounds like near-term priority is obviously to expand supply and to grow access, but you're also investing in next generation. V114 was a next gen. So you have some other ones in the pipeline. So help us with sort of multivalency as a priority.

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

Yes. So pivoting here to our pneumococcal vaccines, and we've got a few that I can talk about. So Vaxneuvance V114 is our pneumococcal vaccine that has been approved here for adults. Now V114 is used in combination with Pneumovax 23, and this 2-dose regimen provides the broadest coverage against pneumococcal disease for adults.

In addition, we have within the label data that supports at-risk and high-risk patients. So we have a great opportunity with Vaxneuvance for adults. It's a competitive field. There is a single dose competitor in this field, but we have an important vaccine for adults.

Now moving forward, though, we also have an adult-specific vaccine in V116. V116 is our next-generation adult pneumococcal vaccine. It has 21 serotypes to it. Importantly, 11 serotypes that are unique to V116. And it provides 85% coverage of the residual pneumococcal disease for adults. So this is really meaningful. And we have Phase I/II data that we'll be sharing in June at the ISPPD meeting, and we're moving on to Phase III. So really excited about the opportunity there.

And then to conclude, we're working on a pediatric indication for V114. The FDA has recently asked for information, and that information was at a subgroup of the pediatrics, and we've provided that information. So we're hopeful that we will get approval from the FDA ahead of the ACIP vote that would take place late June. And if we're successful, this vaccine will provide broad coverage for pediatrics. It will be competing against Prevnar for a period before we'll see any further vaccines. And we think we've got a great opportunity to provide great coverage to pediatrics.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right. Give us a sense, though, with the competitive positioning, the lead time that your competitor has here and what you need to do to sort of overcome that from a share perspective.

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

So I'll take it in 2 segments on adult and pediatric. From an adult perspective, here we are with Vaxneuvance approved. And we think it's an important vaccine, and we're moving quickly with V116 that will be a very potent 85% coverage vaccine over the short term. So all eyes are on making that happen. In the pediatric segment, we have a head start there with a more broad-based vaccine for pediatrics that we will be working with the customer groups as soon as we have the approval to do so.

It's a big market. This market was \$7 billion or so in 2020. \$10 billion, I think, is the projection for '25 and growing beyond that thereafter. Today, it's 70% pediatrics, 30% adults. We've got a real opportunity to be an effective player in this market.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

It sounds like the theme here is, when you look out to the end of the decade, the number that people sort of put out there is the Keytruda \$30 billion number. And there's a number of, in your infectious disease, your vaccine portfolio, you can diversify as is, right? That's why I think there's a lot of focus on BD. But COVID is something where that could potentially also offer diversification. But what are your thoughts as we shift from pandemic to endemic, what are the investments Merck is going to make on molnupiravir to, a, to be competitive near term; or b, down the road, to use that as a longer-term additional product to diversify?

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

So molnupiravir or Lagevrio is a really important product at this stage in the fight against COVID-19. It is a product that has shown its effectiveness in the many different variants of COVID-19, and we believe it has applicability in many different coronaviruses, which sadly this world may face. And it has applicability in other respiratory-related viruses, such as RSV and influenza. On top of that, it's a product that has a low, it has a great resistance profile, and it also does not have drug-to-drug interactions. So we are working really hard to ensure that molnupiravir or Lagevrio plays an important role for this world in preventing deaths through COVID-19.

At the moment, we have really guided on what we think Lagevrio will be this year, but we're working should the pandemic unfold to an endemic phase, given the properties that I've just shared around molnupiravir, to ensure that we are there to provide solutions to the world. And if it's needed, that in turn will provide some longevity to the revenue we're seeing.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right. And then, I mean, the opportunity should we see new variants in sort of hotspots for the foreseeable future, what would the investment be like for Merck? Is there a next gen that you're thinking about? Is there an analysis of kind of the resistance that we've seen so far if that is a risk?

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

Yes. So first, from a product perspective, we have great members of our teams who are constantly looking at how you can evolve the compound, and we're doing that with molnupiravir now. From looking at will molnupiravir be better in combination with something else, we have no clinical trials underway at the moment, but we obviously look at preclinical data models to assess that. We've invested in our manufacturing capability, and we're investing in some of the studies that I alluded to earlier in its broader capability.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Okay. I think you'll be in a better position towards the end of the year to kind of provide a little bit longer-term view on that?

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

Let's see. I mean, some of this is crystal ball gazing in what is going to happen with regards to the pandemic. I think as we see real-world evidence play out in utilization in the market, a better understanding of the needs of governments and bodies around the world, we'll have more insights. And we are, as a team, doing as much as we can to be transparent with our investors as we get those insights.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

And just with respect to COVID, there's a lot of companies over the past couple of years have had sort of varying impact from the pandemic. I think in oncology, physician office visits were a little lumpy, unpredictable. On a high level, like where do you see that right now for Merck? Are we 100% sort of seamless? Are we back to pre-pandemic? Just wanted to get a sense for the flow, mostly for the oncology business, but overall there, too.

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

Yes. Absolutely. So we shared that we believe the impact of the pandemic on our business in 2021 was approximately \$1.3 billion approximate. And there's an art, right, to that kind of calculation. And that was felt in the businesses that Geoff just shared. So we saw that in our oncology business as people weren't going to the doctor's offices to the extent they maybe were pre-pandemic. We felt it with vaccinations. We felt it on Gardasil. And we felt it in Bridion, which is our product that reverses you out of anesthetic following surgery.

Now as we saw 2021 unfold, I think health care systems and we, as human beings, are getting more used to this norm that we are living in. So as we sit here today, what we've seen in oncology is our new patient starts on to immuno-oncology medicines, and Keytruda gets a lion's share of those, is pretty much at the pre-pandemic levels, especially for all cancers with the exception of lung. So lung is an area where we haven't yet seen it return fully to the pre-pandemic levels, but it continues to improve as lung cancer patients are seeking care and hopefully are asking for help when they've got a cough that they think may be COVID, but actually could be something more sinister than even COVID. So that's the area that really is not quite where it was.

We are seeing vaccination rates improve. We did have some impact in the first quarter due to booster shots for adolescents for COVID, which impact slightly our Gardasil business in the first quarter, but I think we're largely seeing us get through that. And indeed, surgical procedures during the first quarter got through Omicron very well. So I think we are seeing we're almost back to where we were pre-pandemic.

The one area we are watching, we've not seen a significant impact within our company at this stage is China. So as countries or areas move to a complete lockdown, that does impact access to care. For our company and the key pillars of growth in China, patients are still getting access to Januvia because they're ordering that online and it's being delivered to their homes. Gardasil is a vaccine that there's more demand than we have supplies. We are able to see our Gardasil business come through as expected. And for Keytruda, we're watching. Patients in Shanghai are not getting to the hospitals, and that's an area that we'll watch.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right. While we're on the topic of China, it's interesting with the NRDL listing, it opened the country up more broadly to innovative medicines, but at a pretty steep price, right, of pretty material discounts. How does China rank in sort of Merck's sort of priorities, growth priorities in terms of the level of investment? It was, I think, pretty high priority going back 3 or 4 years ago. But with the NRDL sort of volatility, maybe that's changed.

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

So China remains an important market for our company, a market that we do invest in and a market that we're seeing great growth from our innovative products, and I just alluded to Keytruda, Gardasil, also Januvia as part of that. We are on NRDL for Lenvima. We're not on NRDL for Keytruda. So we'll make choices in the market based on ensuring the right access to patients for the medicines we have at the appropriate price point for our global business, and we'll continue to do that.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Got you. And that includes the cardiovascular portfolio, right? So you guys hosted a very helpful Cardiovascular Day. So 8 products approved, I guess, by 2030.

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

Indications.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Indications, sorry. So walk us through like which ones you think are the most impactful or maybe not as appreciated by investors. I know the whole cardio portfolio in general, it seems like it's somewhat an afterthought in a lot of my discussions with investors. But obviously, there's a lot there.

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

Yes. So there's a lot there, and I'll try to stay high level, but there's a lot of excitement in our company for cardiovascular and the impact we can have on patients. For sotatercept, which is the product that we have through our Acceleron acquisition, this could be a real game changer for patients with PAH. We are currently doing 3 Phase III studies. We have the STELLAR study, which actually closed enrollment early at the beginning of March. And here, we'll be testing the 6-minute walking distance for patients after they've been on the therapy for 24 weeks. So if we're successful there, 24 weeks from early March, we could be moving to filing in the first quarter of 2023. We have another study in sotatercept that's looking at time to clinical worsening and another one that's looking at mortality. So across sotatercept, significant patient impact, multibillion-dollar opportunity for our company.

We have today Verquvo in the market for heart failure. And we have a study, VICTOR, which is looking at actually extending the reach of Verquvo threefold to the number of patients that we touch as we look at heart failure patients who have not yet had a worsening heart failure event. So another blockbuster opportunity for us.

We have our Factor XI compound. Here, we're looking at end-stage renal disease as the first population where we're trying to stop clotting without worsening a bleeding risk. If we're successful there, we will extend that to other patient populations. And we have our inhaled sGC compound again in PAH and COPD. So that's 2 of the 8.

And I think my final to get to the 8 is we have our oral PCSK9, which is a real opportunity to provide oral, which I think physicians and patients may prefer to lower LDL. And there's 70% of high-risk patients not at the right LDL level, so great opportunity. And to your platform point earlier, the Merck Research scientists are very energized and excited by this platform that it exists on and potential applicability more broadly.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Right. Again, in PAH, I think the market hasn't seen a lot of innovation. It's the same mechanisms. And you guys have an add-on therapy. It is still a somewhat niche population. I mean, some call it orphan. You guys view it more as a cardiovascular indication. But is that a reasonable sort of trajectory to look at maybe smaller market but high-impact drugs in cardiovascular disease? Or are you thinking like let's see as many patients that we can treat with respect to heart failure? I'm just trying to get a sense for the priorities. Is it more orphan, sort of narrow, but high dollar or is it broader with respect to bigger volume kind of drugs?

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

And I actually think it's both. So what we've described Factor XI end-stage renal disease then could go further. But an oral PCSK9 and the global applicability that could have to the mass market exist as well. So we're at both ends of the spectrum based on the product and the populations that it can best serve. And I should say, as CFO, if successful on these products, we have the potential to achieve peak revenue of in excess of \$10 billion by the mid-2030s. So we're playing in all segments but significant patient and financial benefit.

Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Perfect. All right, Caroline. Well, thank you very much.

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

Thank you. Thank you very much all.

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