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PRESENTATION

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Okay. Excellent. Well, listen, guys, thank you all for joining us. It's a pleasure to have Rob as well as Peter join us. Peter is here in spirit and also on the phone and Rob's there live. Jon and I will be hosting Merck. So thank you for joining us.

And before we dig into all our random questions, Rob, let me first turn it over to you to highlight what's on top of your mind and the key priorities for you as we head into the new year?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Sure. Well, thank you, Umer, and thank you for having us. What I would just leave you with is maybe some opening thoughts. Coming out of the third quarter and as we look to the full year of 2020 and based on the guidance we give we gave at the third quarter, I think it really shows the operational underlying strength of our business. If you look at it, the guidance we provided would imply our top line growth, if you adjusted for COVID, would be 8% to 10% in 2020, which is a strong growth. And then delivering above that, I think it's 16% to 18% on the bottom line in earnings per share.

So our strategy focused on innovation and science where we prioritize that within the company where we drive discipline in how we manage our spend to make sure we're driving spend to the highest areas of priority, namely our KEYTRUDA programs, our broader oncology portfolio, our growing vaccines portfolio and then making sure we're fully invested to commercialize those through is working. It's working and driving top line and it's working, driving overall operating margin leverage that we've talked about. And it's why we continue to have such confidence as we look long term.

Obviously, we need to get through the pandemic and understand that. But nothing we've seen has said that the fundamentals of the business are any different and our confidence is any different. That's why we've continued to indicate we think our growth is underappreciated through 2024, both in the top line and that we continue to believe we're going to see strong operating margin growth to over 40% by that same year. So all things are going well.

Our early-stage pipeline is feeling as good or better than ever. Our late-stage derisked pipeline looks good and the products we have on the market are all driving great growth. So we feel good about where we are and the prospects not only in '21, but frankly, over the next coming years. So maybe with that, I'll turn it over to you, and you can jump into your questions.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Fantastic. No, that was really helpful start. So Rob, I know -- I want to talk a lot of financials with you. And I want to talk about all that stuff in detail. But I feel like where I want to start, though, is perhaps a little more on the pipeline for the first 10 to 15 minutes, partially because -- it's my opinion,

we -- much of these conversations end up either being about KEYTRUDA or longer-term margin profile and not about what's happening beyond. So let's start there today if -- for a change, if that's okay.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Sure, yes.

QUESTIONS AND ANSWERS

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

So there's not much conversation of Merck in the context of everything that's happening in -- on the antiviral side as well as on the vaccine side. So let me start with this, and Jon can follow up, but let me start with this. When should we be expecting Merck to initiate a pivotal trial with a COVID vaccine?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So if you look, maybe just to ground us in where are we right now and then we can get into what we see coming forward. We do have the 2 vaccines right now, V590, V591, both are replicating viral vector vaccines. One is based off of a measles platform. The other is based off of an rVSV platform. Both, we think, have the potential to be single-dose vaccines and both are fairly friendly from a storage and shipment perspective.

So as we think about the ability to go for the broad population that has been our strategy to go with tried and true approaches that we think will offer good efficacy, good safety and durability based on the history that we -- these are proven platforms, that we can get out to patients and hopefully do in a single dose. So that's the goal, and that's why we started the 2 programs.

Where we are right now is both programs are in Phase I as we speak. And we need to see the data coming out of those Phase I studies, the complete data sets before, frankly, we can really predict what -- either the next study or Phase III would look like, especially in light of now, I would say, given what we've seen with the mRNA vaccines and the fact that they have been as efficacious, which frankly exceeded our expectations and as well with great -- so far, it appears anyway, good safety profiles. They set a high hurdle. And so we're going to have to continue to look at the prospects for our vaccines relative to that and relative to the data we show. As soon as we have that data, and we talked about this as a leadership team, we will communicate the strategy going forward based on all of that and driving it.

I would maybe pivot to the antivirals, and I think you were going to go there, but those are where we're particularly excited. I think that's really, if you say, what really excites us because where there are, hopefully now for society's benefit, some potentially good vaccine candidates, less clear that there's any good antivirals out there. Remdesivir is there. We can -- we all read what's happening with remdesivir. What we think we have in molnupiravir is really a very important asset. This is in a Phase II/III study. We started that study in October. We think you could see interim data in the next couple of months. So you could see it early in 2021.

Right now, the completion date of that study is April of 2021. So we're fast approaching that. And every indication we continue to get is that, that drug has really great characteristics, and we believe we'll make a meaningful difference. It is an oral dose drug. It's a small molecule. We're studying it in both nonhospitalized and hospitalized patients. So the opportunity to intercede much earlier is there.

And not only do we see it as, obviously, more -- we're studying it first and foremost right now is high priority for the SARS-CoV-2 virus. Importantly, it's shown activity in other coronaviruses like MERS and like SARS and we believe could have activity even in other RNA-based respiratory viruses.

So its breadth, potentially longer term, is even bigger than what we have right now with SARS-CoV-2. But our focus is right now moving with speed to get it out, to get those studies done and to get it out and be able to bring it to the marketplace as quickly as possible. So as I said, from an

expectation, you should hopefully be able to hear something in the next couple of months from the interims. And then we know we have the final completion date still scheduled for April.

The other one we're very excited about is the asset we just got from Oncolmmune. This asset is more for patients who are in the -- who are either severe or extremely ill in the hospital, who are on oxygen and who are being treated with the standard of care, remdesivir or steroids that was tested as an add-on to those. And what we showed in some of the early data that was published, or I should say, Oncolmmune published is that it showed a 50% reduction in the risk of death over the standard of care and 50% reduction in the risk of respiratory failure as well as a much faster recovery time.

So it also, we think, is a very important drug and both we are moving as quickly as we can because we realize we're in the middle of the -- another wave. So we're pushing as fast as we can. And at the right time, open to engaging with regulatory agencies about how to drive accelerated access, assuming the data continues to prove out to be as positive as we think it will. So we're very excited about both of those and are really placing priority on getting those things to the market.

Jonathan Miller - *Evercore ISI Institutional Equities, Research Division - Associate*

Great. If I could jump in for a second, Umer. I've got questions about all of those programs. But maybe let's focus now on that oral antiviral that you got from Ridgeback and say we're expecting data coming soon.

I think remdesivir, people are still talking about being a multibillion-dollar commercial opportunity with all its limitations. Moving to an oral -- even without having an additional benefit on efficacy potentially is a meaningful differentiator. But as you suggested, we're hoping to see a much greater efficacy signal out of the molecule as well.

What sort of commercial opportunity is likely to remain in the pandemic setting by the time we -- as you say, we're getting towards a vaccine distribution. What sort of commercial opportunity is likely to remain in a pandemic setting? And how does that relate to potentially post-pandemic stockpiling opportunities sort of in a different [faith]?

Robert M. Davis - *Merck & Co., Inc. - Executive VP of Global Services & CFO*

Yes. So we haven't given specific guidance to the size of it. I would say we think it is meaningful for all the reasons you said. And even though, obviously, the question is with the fact that we now have a vaccines potentially, we'll see. But assuming the Pfizer and Moderna vaccines prove out to be what we think they are, the reality of it is, we're still -- we're a long ways away from being able to have the population vaccinated. You're going to continue to see people with the virus for, unfortunately, months and potentially years into the future.

And in fact, we continue to believe there's a reasonable probability this will convert from a pandemic into an endemic, which means this could be something we're living with, no different than we do with the flu and everything else. And in that regard, we do see this having opportunity potentially with legs beyond the initial pandemic for SARS-CoV-2.

And then as I mentioned, we haven't started the work, but we see early signs that we could even go into broader other viruses. So I think this will be a meaningful asset, a significantly meaningful commercial asset for the company. But I don't want to get into specific dollar value.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

That's interesting. And Rob, so it sounds like you think it's a meaningful opportunity, not just in 2021, but also beyond. So that's interesting.

So speaking of antiviral, there's another antiviral, which -- at Merck, which has made a lot of progress, which even many of your HIV competitors like a lot, but I don't think it's in many investor conversations. And I'd be curious how you guys are thinking about the opportunity with your 8591. I always mispronounce it. Islatravir?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Islatravir.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Islatravir. All right.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Islatravir. It's rare that I also get the pronunciation right myself. So -- but no, so if you look at islatravir, to your point, and I would almost compare islatravir to KEYTRUDA and say much as we've now shown that KEYTRUDA has become foundational therapy in cancer, where it -- both as a stand-alone agent, but then in combination with other agents because of its unique properties, is the backbone therapy. We think islatravir has that same kind of foundational therapy capability given its characteristics in HIV.

It's very highly potent, has a very long half-life. It has high barriers of resistance, which means that we don't need the normal backbone. It can be a 2-drug regimen as opposed to a 3-drug regimen, which gets away with a lot of the toxicities you normally get with some of the 3-drug regimens.

And so as we look at it, the opportunity to have it across both treatment and PrEP are meaningful. And in combination with other assets are meaningful. And to that end, we are pursuing it in combination with our own assets, with doravirine, with 8507, which is an NNRTI we have in house that we are doing once weekly and feel very good about. And then we're open to also looking at external partnerships with the assets that have good characteristics that mesh with islatravir. So we see it as a meaningful opportunity in the HIV space.

Jonathan Miller - Evercore ISI Institutional Equities, Research Division - Associate

Great. If I could just jump in. I think the comparison you made to KEYTRUDA was very interesting to me because KEYTRUDA, as you said, a foundational asset and a backbone therapy across a lot of oncology now. But from my perspective, a lot of the development of KEYTRUDA has been characterized by the inability to find combination agents that are -- that really (inaudible) brings to the table. So obviously, you have chemotherapy. But for all the other combination assets that have been attempted, none has really declared themselves as being on KEYTRUDA's level in terms of those wonderful characteristics that KEYTRUDA has.

And so I guess thinking about islatravir, with all of its distinguishing characteristics, especially from a PK perspective, are we going to see a similar amount of trouble finding the right combination agents that deliver that sort of synergy, deliver that potential across a full combination regimen? And in particular, what you just said about external partnerships, are there particular assets that you think have the PK profile to take advantage of some of what islatravir offers?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So I don't want to get into specifics of some of the external assets because, obviously, competitively, we're thinking through partnerships and other discussions. So I think it would stay broader than that. But the key here is if you look at islatravir and its ability to bring a highly potent long-acting agent, we do believe, whether it's through an insertion with a rod that we're continuing to study, which is in Phase I and showing some good data, or through the weekly or the daily, we do think we are going to see good results in our own studies. So we're -- we have multiple Phase III studies with doravirine right now in both in heavily treated populations and the naive population and a couple with switch.

So those are all in Phase III and moving. And then we have the weekly we're doing with 8507. We feel good about both of those. And then we feel very good about what we're talking about combo. Looking at it as monotherapy and PrEP, we feel very good about it in the monthly indication for PrEP, which I think you saw we recently indicated we'd be moving -- starting a Phase III study. And so we feel very good about that.

So maybe it's not a great comparison to KEYTRUDA for the reasons you say. But the point being is, if you look at HIV, that is a combination therapy market. And I do believe we will find agents that combine well with it and that it will be that therapy. We need to do the work. And as we find those, we'll bring them forward like we have 8507.

But the fundamental theory that this is foundational and can really bring a new option for people suffering from HIV, which is still -- while there's great treatments out there, there's still a lot of toxicity. There's issues with having patients staying on therapy. So there's still a lot of opportunity to bring new therapies.

And one of the interesting things about -- we have with his islatravir is its -- because of its duration, you do see it's fairly forgivable. And if you miss a dose, you don't necessarily -- it's not as catastrophic as with some other therapies, which in itself presents opportunity. So for all those reasons, we're excited about islatravir. We're going to have to continue to do the work. And as we have combined agents, we'll bring those forward. But I'm not going to go into specifics beyond that today.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

So Rob, this is very interesting, antiviral. So what's even more interesting to me is we're not talking KEYTRUDA right now. We're only sticking to non-KEYTRUDA stuff. So antiviral in COVID, you called it meaningful. The antiviral in HIV, you're calling it foundational, so way more than meaningful.

The third one is your pneumococcal vaccine. And I think Merck certainly thinks that's very meaningful. Street's confused whether ACIP would say, "Hey, Prevnar, no more Prevnar as standard of care. It should be V114." But then only 2 years later, there could be PCV20 out there. I guess that's the question. Does Merck expect V114 to be the standard of care in infants perhaps almost right away?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So I don't want to get into predicting what ACIP will do. But I think what I would focus you on is what are the characteristics you see with V114. And what we see with V114 is we start with the question, are we sure we do no harm? In other words, are we sure that we can show equal immunogenicity relative to Prevnar 13 to PCV13 across all of the serotypes? And the answer to that is we can. We've shown that in the adults and we're confident you'll see that in the peds as well.

And then we ask, where do we drive incremental benefit? What we do know is serotype 3, which is a higher driver of disease currently. We actually show improved efficacy or immunogenicity in serotype 3. And then we add on 22F and 33F. So in that regard, we think we have a vaccine that matches Prevnar 13 across all of its strengths, builds on that in serotype 3 and then adds 2 more with 22F and 33F.

And so -- and that's vaccine with good fit-for-purpose immunogenicity in infants in the first year of life, which is when they are at the highest risk. And we believe that you are going to see that continue to progress and do well. We're in Phase III. And you didn't ask, but it's worth commenting for those on the phone, we did recently file for V114 for approval in the U.S. and Europe in adults. So that filing was put in place. And obviously, we -- hopefully, we'll have data from the Phase III in the pediatric setting, potentially even some this year and then into early next year. So -- and then we'll file at pace as soon as we have the data to do that in ped. So we feel good about both those programs.

And then I would build upon it and say, well, to your question, do we think V114 is a meaningful vaccine for infants and children? The answer is yes. But we're not stopping there. We have V117, which we are now studying, which will extend disease coverage beyond what we have. And we believe -- because it will be a pediatrically -- a pediatric design, pediatric directed vaccine with specific serotypes aimed to that population will be a meaningful opportunity beyond V114.

And then we're doing the same thing with V116 in adults, which will be a tailored vaccine, which we think could extend coverage to 80% of the disease-causing serotypes or disease-causing vectors within that space beyond what you have today. So with V116, you're going to see extension of disease coverage for adults, fit-for-purpose to adults. V117, you're going to see that for infants, both building upon a strong position we're going to establish with V114 across both adults and peds.

And then the ACIP, I laid out, I think, what are very compelling characteristics, we'll have to make their determination based on those compelling characteristics.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Okay. Jon?

Jonathan Miller - Evercore ISI Institutional Equities, Research Division - Associate

Great. Let's maybe switch gears a little bit to oncology, which, of course, we have to get to at some point. But before we jump into KEYTRUDA specifically, I'd like to ask about some of the other assets in the oncology pipeline.

Let's start with HIF-2, which is a target, I think, that's gotten some meaningful attention or there's been some confusion about what exactly it's worth. What's the most important trial here, the key trial that could provide the most expeditious path to market? Do you see this as a multibillion-dollar product or really meaningful oncology drug in its own right?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So the answer to the last part of the question is, yes, we do see it as a blockbuster drug. We do see this as a blockbuster opportunity. And if you look at what we see as the path, you know we have breakthrough designation in von Hippel-Lindau disease, which is a form of renal cell carcinoma. And so obviously, that is a nice path to get this product to market. We showed very positive data at both ASCO and ESMO coming out of the Phase II studies for that.

And right now, we do have 2 Phase III studies underway, focusing on patients who are refractory to PD-1 -- PD-L1. One is a monotherapy study, and then we're doing one in combination with LENVIMA. So we see this as a real opportunity in renal cell carcinoma, one of many shots we have in renal cell carcinoma that we're excited about, and we do think it's a blockbuster drug.

Jonathan Miller - Evercore ISI Institutional Equities, Research Division - Associate

Well, since we're on renal cell carcinoma, let's stick with that. What do you -- obviously, you have multiple [tracks on goal] in renal cell between this and LENVIMA combos of various sorts. What are the key combinations and market segments in renal cell that you think are amenable to being divided up given these multiple different programs? And how do you approach HIF-2 versus LENVIMA versus combinations of those with KEYTRUDA, (inaudible) KEYTRUDA as you segment that market?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. Well -- and so I'll leave some of that -- the more detailed answer to that to the scientists because you're going to extend beyond my -- I've heard it explained. Whether or not I can explain it to you, we'll see. But I would maybe go a level up and say, as we look at renal cell carcinoma, starting right now with what we have in the combination with axitinib and our ability to show that we can really have a meaningful impact and drive growth, we're already seeing growth with that approved indication. Then you have KEYNOTE-581, which is a combination with LENVIMA, which we've recently, I think, top -- did we top line the data?

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

Top line. Yes.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

We did top line the data there, very strong data and we think a real opportunity with that TKI inhibitor. How that -- we have the opportunity to have different segments of the renal cell carcinoma market. We're going to pursue all of them to cover the waterfront. And then obviously, now with what we have with the HIF-2 alpha, yet another approach.

So our approach is we're really going after all the different vectors to try to approach renal cell. I wouldn't say right now, we're pointing to one over another as the strength. I would say the fact that we were going to have such breadth means you should expect us to have a very strong, if not leading, market share in renal cell carcinoma because we're going to be coming out of so many different angles at the same time.

Jonathan Miller - Evercore ISI Institutional Equities, Research Division - Associate

Sure, sure. Makes sense. In other IO targets, I think we've been very interested in LAG-3, in TIGIT as -- not to mention all of your work in IO adjuvant settings. So just briefly before we move on to some other topics, you're the only people with monotherapy activity in TIGIT. How important is that drug? LAG-3, upcoming data updates, what is the catalyst flow and the meaningfulness of these potential next-gen IO target?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

So both are -- we feel good about both assets. And I would broaden it out to say if you look at what we're doing in combination therapy and really, I think, a very smart strategy where we're using umbrella studies to look for fast signals and then leveraging those to move quickly into pivotal studies. We did that with TIGIT.

So as you know, we're potentially now moving TIGIT into Phase III in non-small cell lung cancer. That came out of a signal we saw in the umbrella studies, and we're moving very fast. TIGIT is one we see as a real opportunity. We've published data on that where you've seen it does have a meaningful effect in combination with KEYTRUDA. You're right, it does have some monotherapy. It's not that material. But really, we're looking at it as the combination with KEYTRUDA, and we're moving that into Phase III. We have the CTLA-4 asset that is going to go into Phase III in a coformulation. And then LAG-3, we're also moving forward.

So across all of those -- and I'd add to that, ILT-4 is another one we're very excited about. All of those are moving forward. And what we're really looking at across each of these is the opportunity. While KEYTRUDA, obviously, as we said, is foundational, the reality of it is it's still the overall response rates and the effectiveness is still only in a minority of the patient population. There's still a huge opportunity to expand the population that has -- it has effect in, and that's why we're looking at the combinations and to drive better efficacy.

And so all of these, we believe, present that opportunity. You're starting -- if we go back a year or 2 ago, people were asking us, are you even playing in these spaces and do we have any signals at all? And now we're talking about having meaningful signals across multiples of these and moving into Phase III studies.

So I think the ability to look at combination therapy as a way to expand KEYTRUDA as a meaningful growth opportunity, that's underappreciated. And it's on these assets -- and where we can, we will look to coformulate or do fixed-dose combinations, especially where there's not as much monotherapy activity, which has beyond the benefits to patients of extending the reach and the efficacy potentially has ability to extend the product life of KEYTRUDA beyond 2028. So in that sense, all of these are exciting opportunities, and we can focus on the specifics, but I don't want to lose the broader picture.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Jon, do you want to touch on BTK before we move on to some of the financials?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes.

Jonathan Miller - Evercore ISI Institutional Equities, Research Division - Associate

Well, I was going to stop torturing him on science questions, but...

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Well, I would just say to that point, I didn't mention, but we are -- I do think the BTK inhibitor we have through the ArQule acquisition is important. Because like [Bells Bio], it allows us now to start to move into hematologic cancers as well. So we're broadening beyond some solid tumors with these opportunities, and we'll probably get into it, but we're obviously broadening with several of the ADC, both deals we've done for acquisition and partnerships. So we are broadening our reach beyond even those specific molecules we talked about. But I'll let you jump to your question.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

So Rob, it sounds like -- and maybe just to summarize this, because I want to make sure we get -- we wanted to talk about these individual opportunities and now to sum it all up into financials and broader from your -- from a CFO seat in particular. But it sounds like what you're saying is -- we talked about antivirals, and they're very important in HIVs that might even be foundational. You remain very confident in pneumococcal. And then on HIF-2, TIGIT, BTK and ADC, they're all fairly important from an oncology perspective. And I'm talking non-KEYTRUDA assets only for a second. Is that a reasonable [objective]?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

I think that's a very good way of describing it. The way I look at it is -- question you haven't asked, but it is often asked, which is on the business development front, if you take each of these assets and look at them individually, they're interesting. You start to layer them on top of each other.

If you think of it filling the bucket, each of these, what we've gone through with Peloton, with the HIF-2 alpha, what we have with the BTK inhibitor, we could go through the list, LENVIMA, LYNPARZA, all the ones you mentioned, you start filling the bucket. Each of these -- many of those are blockbuster opportunities. And so together, I think it is a meaningful opportunity outside of KEYTRUDA. It also leverages KEYTRUDA and potentially even can drive KEYTRUDA synergy, but they are also meaningful outside of KEYTRUDA. And I think that is underappreciated as well as our ability then to look at moving into the adjuvant, neoadjuvant space.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Got it. Rob, just before I turn into financials and really start to get a sense broadly speaking. Bo, you want to -- there's a client question that came in. You want to ask the investor question?

Bo Chen - Evercore ISI Institutional Equities, Research Division - Research Analyst

Yes, sure. We got an investor question. At the start of the COVID, you chose to study the traditional vaccine approaches. Why didn't you also started the mRNA approach? Because our understanding is that you have access to the mRNA technology through some venture funds.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So when we looked at the opportunities, and I think Roger -- Dr. Perlmutter has laid this out in other settings. But our feeling was, as we looked at the opportunity -- and what was the need? Our view was what will bring the potential for the broadest reach of applicability across the largest patient population? What do we think has the highest chance of getting to a single dose? What do we think have the highest chances of being durable and being safe?

And so from our perspective, while mRNA, we understand and know it, at that point, there has yet to be actually an approved mRNA vaccine. And so as we were sitting going back now, at the beginning of COVID looking at it, what we did know is that we had a proven technology in the measles approach. We had a proven technology in the rVSV approach, which led to the approval of the only approved Ebola vaccine. And we knew that because those were replicating viral vectors, they had the opportunity or the potential to be single-dose administered drugs. And as I think -- I can't remember I mentioned it earlier in this call or in prior calls, but -- and then from a supply chain perspective, we think fairly favorable friendly as far as to be able to get it out to the broadest population.

So as we looked at it, we felt that the ability to have what we had, which was proven safety, we felt would be durable and good chance at efficacy, given the history that while we knew it was a slower approach, we felt that it was an approach that needed to be taken when you think about trying to cover 7.5 billion people or whatever now the population globally is.

Obviously, Moderna was already underway with their mRNA approach. And Pfizer and BioNTech were underway with theirs. So we knew there were people already approaching that to go fast. And we felt the way -- as we looked at it in the ecosystem, to complement that was to come with the more tried and true durable approach, not knowing if mRNA would work.

As it has proven out, I think what we found is that the -- and I'm not a scientist, but what I hear from the scientists is that the nature of the spike protein of the coronavirus has turned out to be very amenable to an mRNA approach. And so you've seen that with the success and the efficacy and safety we've seen from Moderna and Pfizer, so that's great news. But that wasn't necessarily what we fully expected or anticipated at the beginning, and that's why we took the strategy we did. And I think that hopefully explains it.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Got it. So Rob, as we start to construct a Merck corporate-level financial picture around everything we just discussed, the first thing that comes -- screens out to me is that we need to have a sense for what your expectation is on KEYTRUDA LOE. And there's a broader -- there's a wide held market expectation, perhaps KEYTRUDA doesn't go past late 2020, which appears to me to be too accelerated, considering -- we haven't even seen a HUMIRA biosimilar yet.

And I got to believe across various formulation patents as well as across these coformulations you guys are doing between KEYTRUDA plus TIGIT as well as the KEYTRUDA every-6-week regimen, all of that to me, just tracking it from a distance, reads like a mid-2030s at least kind of runway. How are you thinking about that as you build out your 50-year model on Merck?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Well, I think, again, I got to be careful because I don't want to give specific guidance. So what do we know? We do know that the LOE for KEYTRUDA is in 2028. We do know that we are pursuing now 950 plus combination studies with KEYTRUDA. And some of those -- and at least we know one now because it's moving to it, will be a coformulated asset with CTLA-4. We talked about the exciting Phase IIIs we have with some of the others, TIGIT, ITL4, LAG-3, all the ones we talked about, which we will pursue. There are more beyond that. There are more coming.

And so the ability to see KEYTRUDA being a meaningful contributor for the company beyond 2028, I do think we will see KEYTRUDA still be a meaningful part of the company beyond 2028. How much so depends on how all these things play themselves out. But we are very much pursuing that and believe that through the combination of KEYTRUDA with all of these assets, plus where we're pursuing other independent oncology assets

based on the learnings we now have in the oncology space, means that we will be an important player in oncology broadly, I think, well beyond 2028 regardless -- without KEYTRUDA.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

And it wouldn't be unreasonable for us to assume that you would obviously have dosing patents and formulation patents as well as dosing patents on things like the every-6-week formulation, dosing patent -- chemo combo and first line. Like those are all obvious things you probably have IP on.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes, they are. Now I would just highlight on one specific you just referenced. Q 6-week does not extend the patent beyond '28, just to clarify. So that does not give any patent extension. Obviously, as I said, we're pursuing a lot of different combination studies primarily focused on how can we improve efficacy, improve reach of the drug. And then if they are amenable to coformulation or fixed dose, we will go there. But we're -- the science is taking us based on the value proposition we bring. And then that then will lead us to the delivery mechanism, which could allow for that extension that we talked about.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Got it. So Rob, the way consensus has thought about Merck at a high level is Street assumes the \$48 billion top line goes to \$60 billion. Again, that's before the \$6 billion extraction for women's health. So let's stick to the overall company for a second.

But when I look at the key driver of \$48 billion going to \$60 million, \$10 billion comes from KEYTRUDA, meaning there's a \$10 billion additional KEYTRUDA expansion built into the numbers currently. And that -- the animal health business grows about 35% over the next 5 years between now and then.

I'm curious from your perspective, I'm sure you've looked at some of these numbers with an additional \$10 billion worth of KEYTRUDA coming in, are those reasonable based on the cadence of new indications, the way you guys see it?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. And again, I don't want to -- I'm not going to give guidance to confirm what consensus is, specifically. What I would tell you, and it's what we've been saying for quite some time, and it continues to be true that as we look out to 2024, for instance, we continue to believe that if you look across each of our growth pillars, the Street underappreciates our growth potential, whether it be in KEYTRUDA, whether it be in LYNPARZA, LENVIMA. GARDASIL, you didn't mention, but GARDASIL continues to be, we think, also a significant growth driver as well as the broader vaccines portfolio. So that's not just GARDASIL's vaccines in total is going to show good growth.

And then you've got animal health, which we do think will grow well above the market for animal health and will be a strong contributor to growth and is also, frankly, underappreciated. So interestingly, across almost every growth pillar we've talked about, we think we have largely derisked assets that have great growth that are going to carry us not only into 2024, but frankly, beyond. And then we have a next wave of products coming that set us up very nicely as we get into 2024 to '28. And then not to mention the continuation of all of the oncology assets, everything we've talked about beyond '28, and then you start layering in even some of the further vaccines that are earlier in development.

And what we see is a burgeoning and but exciting early-stage pipeline, which the Street doesn't yet have full visibility to, but I can tell you, our confidence internally and the confidence from our scientists around what we have there, relative to where we've been for years, is extremely high. And I think we've shown in the oncology space, for instance, we can go from having a concept to market very quickly and with the right opportunities.

Now that doesn't apply across every therapeutic area. But point being -- across the 150 programs we have in discovery development, which one of those, beyond the ones we've talked about, which are on mainly later stage, are going to be adding to that opportunity? And we see that in cardiometabolic. We see that in neuro. So we're playing in a lot of spaces beyond just oncology in our earlier stage pipeline.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Got it. Rob, is it fair to assume, again, looking at broader industry comps, that KEYTRUDA'S gross margins are materially higher than Merck's overall gross margins?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Well, so KEYTRUDA is accretive to the gross margin. Except for -- then I would say -- so if you look at our -- so let's just look at our gross margin overall. If you look at what's happening in gross margin, KEYTRUDA is accretive. Actually, GARDASIL is accretive. So our vaccines are accretive. GARDASIL, oncology is accretive. And so as we are shifting towards a more of a specialty mix business, there is a natural lift in the margin -- gross margin as a result of that.

However, you have things that are creating headwinds that is what's kind of pulling that back down. Price pressure, we were assuming, as we've talked about in the past, you're going to see increasing price pressure that will erode a big portion of that mix shift benefit in gross margin. We have the fact that we have royalties on GARDASIL and on KEYTRUDA that as those obviously become bigger and bigger percentages of our business, that sits in the gross margin line.

Now importantly, the KEYTRUDA royalty will step down in 2024 from -- is it 7.5% -- 6.5%, 7.5% -- 6.5% to 2.5%. And then you're also going to see some of the GARDASIL royalties also phase out in that same time frame. So that's a natural margin lift that comes in '24 beyond the mix benefit in that -- between now and then, though, that's why we've kind of indicated the impact of pricing, the royalties and FX, which has frankly been a kind of a headwind for us for a little while here, we'll see that could be -- we don't know, has largely muted the mix benefit we get. And that's why our gross margins have largely kind of held close to where they are.

Now whether they go up a little bit, down a little bit, will depend on how those different things come together. What's really driving the operating margin improvement in the nearer term through '24 until you get these royalties beyond this is more coming in the operating expense line, and that's due to the fact that we're going to continue to see very good discipline around SG&A, which I think we've demonstrated, that we can reallocate dollars to our growth areas to make sure those are fully funded and really capture value everywhere else to maintain SG&A at either low growth or flat. We've been actually largely flat.

And then over time, we do think R&D still will slow down as a -- its growth will slow as a percent of sales and start to then decline as a percent of sales out in the outer years. So that's what drives the margin benefit. And then that is going to be leveraged by the spin-off of Organon and then the \$1.5 billion of incremental operating margin improvements. We'll get through that on top of those efficiencies. So that's really the margin for us.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

You said what on SG&A again?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

What's that?

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

What did you say on SG&A again?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

I said SG&A has largely been flat, and we will continue to be disciplined looking forward and you're going to see SG&A continue to perform at a rate. So you're going to see it improve as a percent of sales going forward.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Rob, the more I hear you lay out the parameters for the income statement and the more I look at the pipeline options, if you put those 2 things together without looking at the guidance you've put out, number one, it feels like you guys probably exceed that 40% operating margin. There's a lot of cushion in there is what it feels, in part because gross margin has a lot more than what's embedded in there. You can kind of get there on R&D, SG&A alone.

And if that's the case, it's not inconceivable that the earnings power at Merck may top \$10. I know you guys don't have a guidance out there, but is it unrealistic to think there are scenarios that exist where those are realistic possibilities? And I'm not talking 2030. I'm talking in the next 4-, 5-year time frame?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. So I don't want to go that specific. What I will say is I think our ability to drive meaningful top line growth through our portfolio of largely derisked assets we've talked about and then to leverage that to expanding growth and EPS at a faster pace is quite strong. And I'm quite confident we'll be able to deliver it. And so we feel very good about the profile of both the top and the bottom line and the potential for this business, not only out to the next 5 years, but frankly, 10 years and beyond.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

So Rob, if that's the case, I note -- I feel like in investor conversations, across large biotech and in large pharma, Lilly is singled out as the one company, which is a growth pharma, maybe with Zoetis. I almost never hear Merck brought up from long-only investors on the growth camp as a growth company. Would there be any openness for Merck to -- at some form, when you lay out -- hey, look, we do at least 5% growth for next -- something along those lines. Is that a possibility?

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Philosophically, our view internally has been not give that specific of long-term guidance, primarily because we don't then want to have that in inadvertently start to impact the decisions we make because now you're trying to hold to an artificial target that you put out. That's why we've been broader in the way we've tried to indicate our confidence in the business.

I am very confident that the Street underappreciates our growth. And that right there is a statement. And so -- but to go beyond that, we worry about -- our view is we want to make the right long-term decisions for this business and not be constrained by artificial targets to that decision. And if we do that well, we're going to deliver above expectation growth. We're going to deliver above expectation value long term, which is the way we look at it is how do we have sustainable value creation through an approach focused on science as a core competitive advantage and then leverage through the discipline that we bring that science to the market. That's our strategy. And I'm confident that if we continue to follow it the way we have, we will deliver for our shareholders.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Got it. Rob, I think we're just over time. Bo, is there any investor question and e-mail you want to bring up? Rob, maybe a one-liner on the women's health business. I should have brought it up, but I just don't think it's very consequential from the Merck story perspective.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Yes. No. I mean, I would just say that the spin of Organon is continuing on pace. We still think the second quarter, all indications from our ability to drive through the infrastructure changes we have to make to enable it through legal entity, through getting the organization set up from a headcount perspective, doing the stand-up of all the financial systems. Everything is moving on pace, and we feel good about that.

And we feel good about what that business will offer as a stand-alone business that by having 2 focused companies who are both simpler and more mission-focused to their specific missions, we're going to have 2 faster-growing businesses that will deliver for their respective patient populations. We feel good about that.

But what I would leave you with is just where you were going with your questioning, which is our confidence in the long-term growth potential, both top and bottom of this business, is extremely strong. Our confidence in our growing pipeline is strong. That said, we continue to aggressively look for opportunities to augment that through business development. We're not complacent with the growth we have. But I feel we are in a position of strength, from our balance sheet, from our cash flow from our growth, that should allow us to both invest for the future while we deliver in the short-term for shareholders. We feel very good about that. I'd leave you with that.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Fantastic. Rob, thank you so much. Peter, thank you so much. You're there somewhere.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

He's a voice from above.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

He's holding the card in the back.

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

Thank you, Umer. Thank you, Jon.

Robert M. Davis - Merck & Co., Inc. - Executive VP of Global Services & CFO

Thank you, everyone. Thank you.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Thank you, guys.

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