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PRESENTATION

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Good afternoon. I'm Chris Schott at JPMorgan, and it's my pleasure to be wrapping up day 1 of the JPMorgan conference with the presentation from Merck. From the company, we have the company's Chairman and CEO, Rob Davis; as well as Dean Li, who is President of Merck Research Labs. After a very successful 2022 for the company, looking forward to Rob's presentation and comments on '23 and beyond. And then after the presentation, we'll go to some fireside chat Q&A on the stage here.

So with that, I'll turn it over to Rob.

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

Thanks a lot.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Thanks so much.

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

Appreciate it. Thank you. Good afternoon, everybody. Obviously, we will be making forward-looking statements, and I'd refer you to our statement here on the screen.

If you look at 2022, it was truly an exceptional year for Merck. And I can tell you, I couldn't be more proud of what the team has delivered scientifically, commercially and operationally. As we look at it, our science-led strategy is working. We're focusing on what matters. We're putting the patient at the center. We're acting together as one team, and we're doing it with urgency and speed. And I think you're now starting to see those results. And it's reflecting not only in our commercial and financial results, but most importantly, it's coming across in what we're seeing and how we're advancing our pipeline. You're going to hear more about that from Dean here in a minute. But I can tell you, I feel very good about where we are, the progress we're making. We're starting to see some important programs mature and really starting to see some real good visibility as we look to growth long term.

As we look at what we're doing externally, we're continuing to augment that pipeline through important business development. I'll spend a little bit of time talking to you about that and how we see the progress we're making, really starting to set ourselves up for a pipeline that is positioned to grow as we look well into the next decade. And obviously, beyond the idea of how we can do commercially or scientifically, we always focus on what we do from a sustainability perspective, making sure that we act in a way with objectives tied to sustainability. And I think if you bring it all together, it's why we're so confident in our ability to drive value for the patient and, in turn, for the shareholders.

No. Go back one slide, if I could. Now if you look at the business from a commercial and operational perspective, we're really delivering across all of our growth pillars. In 2022, we delivered 15% growth if you exclude the impact of LAGEVRIO, and we were able to leverage that to important operating margin expansion. The business is performing extremely well. And as we look forward, the underlying growth drivers are there. So as we think about 2023, I can tell you we have confidence that you're going to see the momentum we've had in those underlying growth drivers continue.

And part of what gives us that confidence is the track record. If you look across all of the growth drivers, what you see in '22 is a continuation of sustained growth over the last 4 years. And importantly, that growth is in derisked assets, and it's growth that we feel is quite sound, robust and will continue. And so that's why as we look forward, we continue to feel so good about the business. But obviously, while we're very excited about what we've been able to do in the short term, we recognize value creation is about the long term and do you have a sustainable engine. And increasingly, we focus on that. We ask that question, do we have a sustainable engine? And I can tell you today, my confidence, sitting here now, given the progress we made in the last 15 months, couldn't be higher that we are making meaningful progress to have that sustainable engine.

And really, we're doing it through 4 levers. We raised these last year to you all, and we've made a lot of good progress. It's focusing on our important durable growth drivers in the Animal Health business, in the vaccines business. It's deploying cash flow to business development. It's understanding the position we have in oncology today and leveraging that leadership well into the next decade. And it's not stopping with oncology. It's advancing our broad pipeline, whether it's in cardiometabolic, in vaccines, in neuroscience and in our infectious disease and immunology space. So as we look at it, we're making progress across all 4, and you'll hear me speak a little bit about the first 2. I'm going to ask Dean to talk about the second 2, but the message is the progress is there. We have more to do, but the path is in front of us, and we are delivering.

As you look at the durable growth drivers, what's important as you think about our vaccines business and our Animal Health business, these are very much annuity-like businesses with stable growth. And in both cases, we have a growing pipeline. So as you see, what we showed to be nice and robust growth across both, we expect that to continue into the long term. We've talked about starting with the vaccines business, which is really anchored in our product, GARDASIL, that, that product will continue to grow meaningfully. And in fact, we expect it to more than double off of 2021 sales. So that -- if you look forward, what that means is growth in excess of \$11 billion by 2030. We're excited about we have -- what we have with our pneumococcal conjugate vaccine suite of products and portfolios. We're going to continue to make advancements there. Our VAXNEUVANCE product is now approved in both adults and peds. And importantly, V116, which is the next-generation adult product we have, will have its Phase III data readout in 2023, and we're very excited about that. And in addition, we have late-stage programs in RSV, and recently, we had some important data readouts in progress with dengue, which we're very excited about.

On the Animal Health business, it's continued growth well above what the animal health business market can do, driven by the companion animal business, by what we have in livestock and importantly, a growing way on what we're doing to invest in technologies. So as we look at this and we think about what the business is doing, it's generating revenue growth, it's generating margin expansion, it's generating strong cash flow, and we're going to leverage that cash flow to continue to build the pipeline. That continues to be an important priority. It's about the science, it's about focusing on how can we find the best opportunity where there's an unmet need, a scientific opportunity to address that need that fits strategically with us where we see value. Where science and value align, we will act.

But what's also important is that we're not desperate. We're disciplined, we're focused. But I can tell you, we have a lot of confidence given the track record of the BD we've done over the last few years and growing and broadening pipeline that Dean is going to talk to you about. So we're in a position where we can be selective. We can look for the best science. But when we see it, we will move, and I'm confident we will do so in a value-creating way. And if you look at 2022, you can see an example of what we've been doing. During this year, and a lot of this actually happened and almost all of it in the last half of the year in 2022, we made a lot of important deals. And importantly, it's beyond just looking at acquisitions. It's looking at licensing deals, at collaborations. But whether it's moving forward with next-generation approaches in vaccines, for instance, what we've done with Orna and circular RNA; with our personalized cancer vaccine collaboration with Moderna; programs in oncology in Imago, which is in hematology; Kelun with a portfolio of ADC products; and also what we're doing with ORION in prostate cancer.

If you look across those top 4 programs alone, Imago, Kelun, Moderna and ORION, those 4 deals will bring assets all starting Phase III studies in 2023. All programs we didn't have 6, 9 months ago. So in just 1 year, we've brought 4 new programs into Phase III. And some of those, for instance,

the personalized cancer vaccine, all we think can be very meaningful. So I feel very good about the progress we're making. We're going to continue to focus on this. We've deployed \$36.5 billion to business development over the last 5 years.

To give you context of that, that's about 90 deals a year. And what we are achieving from that currently is 16 mid- to late-stage active clinical programs, in addition to early- and discovery-stage programs as well coming from those deals. So there's a lot going on, and I'm confident that we will continue to drive the same kind of progress as we look forward. And if we can do that, I'm quite confident that as we think about the engine not only through R&D, but how we will augment it through business development, building on the commercial execution we've shown we can deliver, we're in very good -- we're in a very good position to continue to drive the business.

So with that, I'll turn it over to Dean to give you a little bit more insights into the portfolio of R&D before I come back up and close. Dean?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Thank you. It's great to be in person here at JPMorgan. We aspire to be the premier research-intensive biopharmaceutical company. And in 2022, we've made significant advances towards that aspiration. In oncology, we have continuing approvals in KEYTRUDA and in Lynparza that are reshaping how oncology treatment is happening today. We, with our partners, Moderna, announced Phase IIb results of a personalized cancer vaccine that really, I think, is going to be an important area of investment, both for us and for Moderna.

In cardiometabolic, we announced the top line data for the Phase III STELLAR trial in PAH. And in vaccines, we are advancing a population-specific strategy: the right vaccine to the right patient at the right time. As Rob also noted, we, with our partners Instituto Butantan, had important data at the end of the year in relationship to dengue. And we're excited about resuming our islatravir HIV program as well.

What do we want to achieve in oncology? We want to achieve the fact that over the last 10 years, we have had the privileged position and the honor to reshape cancer care throughout the world. And what we intend to do for the next 10 years and beyond is to do more of the same. We have KEYTRUDA, Lenvima, Lynparza and WELIREG. They continue to provide important readout that lead to filings that we will be having from now over the next 5 years. Not only that, I think a critical important point is that we are moving from late stage to early stage. The early stage is especially exciting to us because that's a place where the tumor burden is much less. And if we can truly affect in early stage, we began to open up the prospect that in some patients, we could actually cure them.

What is our strategy? Our strategy is we have built a strong immuno-oncology pipeline. We have also built an increasing precision-targeted or molecular-targeted series of assets that ranges from VEGF RTK inhibitors that we've done with ESI. It deals with the PARP class of inhibitors that we have collaboration with AstraZeneca, includes LSD1 that we've just done with Imago, RAS, BTK and importantly, WELIREG with HIF-2 alpha. Not only do we have precision-targeted ones, but increasingly, we've revealed what we've done into the tissue-targeted space. We have had ongoing collaborations with Daiichi Sankyo, Seagen and Gilead. And more recently, we've announced what our partnership with Kelun has provided us. And over this next year, we will be providing that data of the Phase II readouts that will launch a large series of Phase III studies.

The modalities that we go, go from small molecules to antibody drug conjugates to immune engagers to biologics to cell therapy and, more recently, to RNA. The collaboration Moderna leverages their undisputed expertise in mRNA and matches it up with our deep experience in cancer and especially immuno-oncology.

What are we trying to do? KEYTRUDA reveals the preexisting immunity to cancer. What we're hoping to do with the personalized cancer vaccine is to tickle the immune system. And the data that we have received in the positive Phase IIb results have been the results of a 6-year partnership. In that Phase II trial, we show that in adjuvant treatment to patients with Stage III and IV melanoma, following resection, there was a demonstrated statistically significant and clinically meaningful improvement with the vaccine on top of KEYTRUDA.

How big of that reduction? It's 44%. So the vaccine, on top of KEYTRUDA, was an additional 44%. I need to remind everyone what KEYTRUDA does by itself an adjuvant. So that was a high bar to beat, and it was a very clear signal that we had with a positive Phase IIb. We have a lot of work. We have a lot of work ahead of us following this Phase IIb result. We must advance this to Phase III trials in melanoma. We must ask the question of

how early can we go, how late can we go. And we must examine not just melanoma, but signals that we have looked for in other immune-sensitive cancers such as non-small cell lung cancer and other cancers, especially that have been susceptible to KEYTRUDA.

We plan to discuss this Phase II with regulatory authorities, and we will be initiating these Phase IIIs this year. We have advanced throughout the therapeutic areas in cardiometabolic. We'll talk about sotatercept, but it's not just sotatercept. We have other agents in pulmonary arterial hypertension, and we're excited about our MK-0616, our oral PCSK9 inhibitor as well as our Factor XI inhibitor. In the vaccine field, again, it's this population-specific strategy that we're advancing with VAXNEUVANCE and with the readouts that Rob talked about in terms of our V116 investigational adult pneumococcal vaccine. We have important readouts in terms of schizophrenia, treatment-resistant depression and Alzheimer's. And as I've spoken before, we're excited about resuming our HIV programs with islatravir in collaboration with Gilead and also in assets that are wholly owned by Merck.

Sotatercept has the potential to transform the treatment of patients with PAH. I have treated patients with PAH. This is a rapidly progressing and fatal disease. The positive results for the Phase III STELLAR trial demonstrated a profound impact in the 6-minute walk distance. Equally important is that it met 8 of the 9 secondary endpoints such as time to clinical worsening. We target filing for this with regulatory agencies in the first quarter of 2023. We will host an event at ACC because we will be presenting the full data of the STELLAR data at ACC, the American College of Cardiology, in March. And at that time, we will also present the PCSK9 Phase II studies as well. We have much to do. We are advancing sotatercept in multiple Phase III trials as we want to really transform the treatment of PAH.

I've talked about this population-specific approach to pneumococcal disease. Why do we want to do this? Just look at this incidence curve. It is bimodal. You have a pediatric incidence and you have an adult incidence. But it's not just bimodal in terms of the timing. The serotypes, the combination of serotypes responsible for pediatric pneumococcal disease is different than that from adult. So what are we doing with VAXNEUVANCE? We're expanding coverage, while importantly, maintaining production against the historically invasive disease-causing serotypes. Also from this graph, what you will see is how important it is to give protection within the first year of life, where much of the invasive pneumococcal disease occurs. In V116, we're advancing our Phase III investigational candidate, and it specifically targets adult disease. It's covering serotypes that account for 85% of all invasive pneumococcal disease. So we are excited at advancing a strategy that is the right vaccine to the right patient population at the right time.

We have an extensive discovery efforts. They are throughout all therapeutic areas. We're investing in multiple modalities. We are here because we are looking for partners that we have been successful at working with, and we encourage all these partners to come see us because we're open for business, and we're interested in advancing our pipeline with you. One of the major advantages that our discovery organization has is that we have an excellent global clinical development organization that knows how to reveal the unambiguous, promotable advantage of the innovative medicines and vaccines that we move forward.

With that, let me turn it back over to Rob.

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

Well, hopefully, as you can see, we've made meaningful progress in 2022. And importantly, we have increasing confidence that we do have that sustainable engine to drive this company and to drive growth well into the next decade. And to give you just 2 proof points of this, we've been talking about the cardiometabolic space. We have the potential, as we've talked about over the last year, for 8 approvals coming in the latter part of this decade, that will allow us to have in excess of \$10 billion of revenue by mid-2030s. That's important. But equally important is the benefit we're getting from the business development we've been doing in the oncology space.

And as we've been talking about, it's about broadening our space and broadening our reach in oncology to take the strength we have in KEYTRUDA to go into new targeted areas, into new therapies into new modalities. And I'm happy to say that as we look at just what we've done in the last couple of years, we see the potential for greater than \$10 billion in revenue coming from our suite of ADCs and our suite of small molecules. And it's important to know this excludes all of what we're doing to expand, deepen and extend KEYTRUDA, Lynparza, Lenvima and WELIREG for the benefit of patients into the future. It excludes what we have in our early-stage development. It excludes further business development, and it excludes the personalized cancer vaccine we just talked about.

So as we sit here today, our ability to drive the type of leadership we want to have in oncology is there. We're confident about it. We're going to continue to do more. I can tell you, I couldn't be more energized by the value we're bringing, by the patients we're helping, but we have more to do. The progress is there. The confidence is there. But we're going to stay on task, and we're going to deliver. So with that, I'll turn it over to Chris, and we'll open it up for Q&A. Chris?

QUESTIONS AND ANSWERS

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. Thanks for those comments, Rob. Maybe just to kick off the Q&A. Right or wrong, I think that Merck narrative has -- this KEYTRUDA concentration has kind of dominated the narrative for a few years now. And it feels like we're maybe finally starting to shift away from that with the pipeline progress that we've seen. But how are you thinking about the company's ability to manage through that LOE? I know you've talked about some of those pieces in the presentation here, but just your confidence today versus let's say, 16 or 18 months ago when you took the CEO seat?

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

Yes. Well, hopefully, you're getting the sense that my confidence is quite high.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Yes.

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

No, as I sit here today, do I think we're done? I don't. I don't want anyone to believe that we're taking our eye off the ball or we're not focused. We are. But as I was saying in the prepared comments, if you look at the progress we've made in 15 months, that's why I wanted to give the proof point around the cardiometabolic space. We weren't talking about cardiometabolic 15 months ago. We weren't talking about the ability to bring this many new targeted therapies outside of KEYTRUDA as well as in ADCs and the small molecules you saw us talk about. Those didn't exist 12, 24 months ago. So we're making progress.

So as I sit here today, we continue to aspire to grow through the LOE of KEYTRUDA. We'll see whether we're able to do that. We've got more work to do. At a minimum, I'm quite confident that we are making meaningful progress in both lessening the impact and shortening the time before we will definitely be back to strong growth into the next decade. So that's where our focus is. But as I think about it and what I've been talking with the folks inside of Merck, and I've been talking with some folks here today, increasingly, we're starting to talk less about 2028. It's not 2028. We're talking about, do we have a sustainable engine? And if you have a sustainable engine, 2028 will take care of itself. And we are starting to really build that engine. I have a ton of confidence in what Dean and his team are doing, the progress they're making. And so as we sit here today, I'm feeling good, I'm feeling good.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Good to hear. Good to hear. Maybe first starting on business development. I know it's a big topic for the story. Just elaborate a little bit more on your priorities and how you're thinking about kind of size and stage and what's really the sweet spot for Merck at this point as you think about capital [deployment]...

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

So as we sit here today and as we just commented a moment ago, it starts with the science. So we always start with, is there a scientific opportunity that we see to an unmet need? And once we see that, we ask how does it inform the portfolio? Does it fit in the portfolio? What's the strategic fit and we can drive value? So as we drive that strategy, I can tell you, we tend to see more of that, and our focus is in smaller bolt-on acquisitions. And increasingly, in the more recent time, it's been through collaborations, licenses and partnerships.

That's why I wanted to highlight in the prepared remarks because I think people often want to talk about the acquisition. They forget that every one of these collaborations we're doing, we're accessing great science, and we're usually doing it through relationships that are 3, 4, 5 years in the making. So we know these assets. We know the people behind them. We have a lot of confidence in them. So that strategy is going to continue, focusing more on that bolt-on.

We're obviously opportunistic and willing to consider anything that fits that framework, but it always starts science. Does it meet value, if it does? And obviously, we want to make sure we're not disruptive to what we have in-house. So that's the way we think about it, and you're going to see us continue to do more as we move forward into 2023 as what we've been doing in the past. And I can tell you, as we sit here today, we have several opportunities we're looking at as we speak. So hopefully, we'll have more to bring forward as we move later into the year.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

So in that context, can I just -- when I think about if the deals are skewing maybe towards smaller acquisitions or collaborations, the company generates a tremendous amount of cash. Balance sheet is healthy. How do you think about whether it's share repo or further interest in the dividend, like how do you think about where that -- the cash flow goes going forward?

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

Yes. Well, the capital allocation strategy we follow, first and foremost, is we're going to invest in the business. And so we're going to invest first in R&D. We're going to invest in ensuring we have the capacity to drive commercially the products once the demand is there. We're committed to the dividend. We're going to continue to drive and grow the dividend. Beyond that, as I look at how we think about the remaining free cash flow that's there, I think the best path to long-term value creation is about reinvestment back into the business. There is plenty of opportunities and great science for us to invest in. And I think we're showing that. We're demonstrating that. So that is, first and foremost, where we will go.

But to your point, we've been very clear, we will not sit on excess cash if we don't see the opportunity. So over time, if we don't see that opportunity, we will return it to the shareholders. But right now, based on the portfolio of what we see out there, I want to see those things play themselves out before I give up that dry powder because I think everyone out here wants us to invest for sustainable long-term growth, and that's what we're going to do.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Yes, absolutely. And maybe just one more question on this. When you think about the landscape for acquisitions, it seems like, on one hand, biotech valuations have been depressed. On the other hand, it seems like if you're going for kind of really well-positioned science, et cetera, those may not be the assets that are seeing the pressures that some others are. How do you think about the landscape right now in terms of accessibility of assets?

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

Yes. And I think you almost hit upon it in your comment, which is, to me, it is more of a have and have not. I mean, obviously, we have seen from a macro perspective, biotech valuations have come down. But for those assets, in those companies that are showing promise, they are still able to get capital. And frankly, and what we've seen recently, when people have had positive data readouts, the prices are still rising and performing quite well, and the premiums they're expecting are still there. So as we see it with the type of assets we're looking at, I haven't seen a fundamental shift.

That being said, I believe either through ability to have asymmetric view of information or the science and/or synergies we bring, we can still find deals that make sense and create value even if you don't see that repricing.

Accelaron is the best example of that. Our scientists came forward. They had conviction based on the work we were already doing in the space and said this is real, this is important. You need to move. We met, and I put a lot of confidence in the team. We got ahead of the Phase III data, and it paid off. So that's the way we're going to continue to pursue that. And I think on the oncology side, you've seen a lot of opportunities or examples where those synergies we bring through the leverage we now have, people want to work with us. And so those -- that's what's driving our business development. I think that will bring forward progress even if we don't see a valuation change in the marketplace.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great. Great. A question for Dean. As we think about the mRNA personalized cancer vaccine that you're working on with Moderna, can you just help put this program in data into context, both, I guess, in melanoma and kind of directionally where this could go, like seems like you're pretty excited about the data that you're seeing there.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

So let me just -- I got asked this at a different form. So I just want to make sure that we emphasize. So when we talk about GARDASIL, we're talking about essentially, a cancer vaccine, but it's a preventative cancer vaccine. When we're talking about this personalized cancer vaccine, it's essentially a therapy, right? It's taking a bunch of neoantigens, personalized neoantigen, and trying to tickle the immune system. So I think it's very important that we understand that this is a therapy.

In some sense, people talk about immuno-oncology plus immuno-oncology. They talk about the 2 different checkpoint inhibitors. This is a checkpoint inhibitor plus another I-O agent. And when we look at the data, the bar is high for adjuvant melanoma when you have KEYTRUDA. I mean that bar itself, when you saw the approval just for that was high. So for the ability for a personalized cancer vaccine that's being used as a therapy on top of that, to have a 44% reduction in melanoma, it catches your attention. It feels a little bit like the 2012, 2013 sort of inflection when we were first getting the initial readouts of KEYTRUDA in melanoma in the first place.

Now this is Phase II drug data. We have a lot of work to do. But the question that arises is, is this limited to melanoma? Are there other immune-sensitive cancers? And the track record of the immune-sensitive cancers is where KEYTRUDA works. How broad is this among different tumors? And how early and how late can it go? So we have a lot of work to do, but we are excited because this has been a holy grail for the field for 20 years to make a personalized cancer vaccine that can work as a therapy. And we have a hint that it can work, and we have a lot of work to do it, and we're going to move very fast with Moderna, who we are very lucky to have had a 6-year partnership on this program.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

So when I look at your I-O/I-O kind of opportunities you're developing, how would you rank this one versus whether it's TIGIT or other...

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

How do I like -- which kid do I like better, is that right? So they're all different, and we'll have to see how they play out. But the personalized cancer vaccine clearly has to be something important when you see a Phase II readout with a 44% improvement over KEYTRUDA that already has what a substantial improvement. In terms of the checkpoint inhibitors, we are very interested in the checkpoint inhibitors. I know people was asking about TIGIT. We have a very good molecule. It's very specific. It's very potent. And we have 8 clinical trials. I think 5 are registrational. I would just tell you that not only are we expanding our partnership with Moderna in terms of personalized cancer vaccine, we listed a fifth registrational trial, KEYVIBE-010, just over December. So I've tried to advance in both of them.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Okay. So it's not an either or necessarily approach. And maybe just last one on as I think about the KEYTRUDA franchise. Just the role of subcu and how we think about the programs you have there and the time lines for those to move forward.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Well, let me just sort of reset because there are different context of how people talk about subcu KEYTRUDA. I can tell you how I think about it. I think about it as scientific innovation that drives access to a life-saving medicine. If you have -- especially in the early stage, you have patients, don't want to be tethered. They can't be tethered to an infusion center. If you can remove that for them, you will increase access not just in the cities, but in the world, throughout the United States, but in other countries. So this is important innovation. So we think that, that's a huge place. When you have KEYTRUDA working with an oral agent and you can remove the infusion center, that's a huge place.

I think there's some debate, and not everyone agrees with me, but I actually worked in a health care system. I believe that even when you have an infusion medicine plus infusion KEYTRUDA, if I change it to subcu, I can really, really limit the time that you spend in an infusion center and also stage it in the quite correct sequence depending on the sequencing of other drugs.

So we're very excited to move to a different route of administration because we think it's a way to use scientific innovation to produce access to life-saving medicine. We have a series of programs and relationship with subcu. Some of them are in Phase III. Some of them are moving to Phase III quickly. And they're all going to read out before the 2028 sort of LOE, and we're interested in advancing. Some of them will be '23-'24, '24-'25, that would be the timing that we're...

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

And will you kind of wait for one of them to kind of take...

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Well, I can just tell you that, at least for me, the one that I really think is important is the one that allows me to give both Q3 weeks and Q6 weeks is going to be really important. And that one is the pembro with the high (inaudible). That gives you the most optionality for patients, for health systems and for that concept that we want, which is advancing scientific innovation to make sure that there is access to life-saving medicine.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great. Rob, on GARDASIL, this product clearly has exceeded expectations pretty consistently here. I know you talked about \$11 billion-plus in 2030 sales. What do we need to do to bridge from where we are today to get to that peak sales level? And I guess part of my -- the second piece of that would be -- is that peak? Or is that just -- can this actually get even much larger than that given the...

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

Well, if you look at where we are in the journey, obviously, it starts with a growing recognition, which I think is now really taking hold that as Dean said, this is a cancer vaccine, which is important. So we're going to continue to drive it. But if you look across the global population, it's still -- there's still a huge unmet need, and it's pretty underpenetrated. The focus areas, how can we drive geographically to drive for greater reach, continue to drive for gender neutral. There still is a situation and underappreciation that it's not only protecting the female, you need to get the male protected because that brings protection for the female. But increasingly, people are recognizing there are a lot of cancers that affect the males as well, head and neck and others, that it's important that you bring both. So we're going to continue to drive for gender neutral.

And then increasingly, we're now, as we start to bring online additional capacity, we can start to drive also into the mid-adult population. We've obviously been limited to trying to do it more in the pediatric setting because we were limited in what we had. As we go to having an unconstrained situation, we'll be able to go more fully across all of these areas. And if you look at where we are today, actually in 2023, we're bringing online 2 new bulk facilities. Those will be ramping up between 2023 and 2025. So as we get to '25, we will be unconstrained in our ability to drive global demand.

In the meantime, we've shown we can drive productivity in our existing facilities. That's why we've been able to drive the growth we've had. And I'm confident you're going to see us grow. We're very confident in hitting the \$11 billion number. I don't want to get into projections beyond that, but let's just say that the global need is still significant, and we're committed to trying to address it.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great. The one on the vaccine side, the pneumococcal franchise. And this is one that it seems like an area that Merck's pretty excited about. It feels like the Street, I don't say skeptical, but I was trying to still get their hands around where the role Merck plays here just given some entrenched competition. So can you just help us in terms of what you think the Street, what we're kind of missing here and giving you such confidence in your role?

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

Yes. Maybe I'll start commercially and then Dean can comment as well. I think, one, there's a misnomer that if I just have more serotypes, it's better, more is better. That is not necessarily true. Because what Dean showed on the slides and what we're really focused on, the serotypes that cause disease in infants is very different than the serotypes that cause disease in adults. And so we really are taking a more of a bespoke approach to this and how we're thinking about it. And what's very important as you think about in the pediatric setting, with VAXNEUVANCE, we show very good protection in the first year.

We'll have to wait and see what the competition does. But importantly, if you can't show protection in the first year where 45% of the pneumococcal disease happens, it's in the first year. So if you think of your first 18 years of life, it's actually 45% of all disease is in your first year. So it's very important that you have coverage that way, not only by the time you get the full booster in the 3 plus 1, but before you get the booster. So we're going to have to see how that plays itself out.

If you look in the adults with V116, as Dean talked about, we're able to cover 85% of the residual disease in what we're going to have with V116, 30% more than even what PCV20 would have and with serotypes that are different and driven for the adult disease. So our approach is to make it very bespoke, specific to children, specific to adults. It's going to be a commercial battle. I have no doubt. But I will tell you that I have a lot of confidence in our clinical profile.

And as we sit here today, this is a market roughly \$7 billion in 2020. It's probably going to be \$13 billion, \$14 billion by 2030. So this is a large and growing market. And I'm quite confident we're going to have a meaningful portion of it. How much depends on how some of these dynamics in the final clinical profile play themselves out when we see the full suite of data once all the products are in the market.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great, great. And maybe just in the last minute or so here. I know we're going to put your guidance in a few weeks here. But can you just talk about pushes and pulls for '23 that we should be keeping in mind for the story?

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

Well, as I made the comments, if you think about our underlying growth drivers, you're going to continue to see good growth in our oncology portfolio, in our vaccines portfolio. I would highlight, LAGEVRIO was a very important product for what it did for COVID patients in 2022. Through the third quarter, we have about \$4.9 billion in revenue. We're guiding to \$5.2 billion to \$5.4 billion for the full year of 2022. We're going to see meaningfully less than that as we look at '23, just given what's happening with the pandemic and the fact that there's still a lot of inventory of LAGEVRIO in the marketplace.

So that is going to be a headwind. But actually, from a margin perspective, that's a tailwind because it actually -- our margins -- it's a drag on our margin. And so our margins are going to go up as we look at that. Beyond that, the JANUVIA, JANUMET situation, while we feel very good about the fact that we potentially have now proven out we can extend in the United States through 2026, we'll see. We won a court battle that gives us that. It's being appealed.

But as of right now, we have protection in the U.S. through 2026. But for the rest of the world, namely in some of the big markets, China and Europe, we've already lost protection. So we will see that LOE hit in '23 versus 2022. And then the other 2 areas, obviously, foreign currency continues to be a headwind. Pricing is a headwind. But with all that said, we are confident you're going to see good growth, and you're going to see margin expansion.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Great. Well, we're just out of time. Really appreciate the comments, and thanks for joining us.

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

Great. Thank you.

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