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PRESENTATION

Operator

Good morning. My name is Lara, and I will be your conference operator today. At this time, I would like to welcome everyone to Merck & Co. Q1 sales and earnings conference call. (Operator Instructions) I would now like to turn the call over to Peter Dannenbaum, Vice President, Investor Relations. Sir, please go ahead.

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

Thank you, Lara, and good morning. Welcome to Merck's First Quarter 2021 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our President; Dr. Dean Li, President of Merck Research Labs; Frank Clyburn, President of Human Health; and Caroline Litchfield, Chief Financial Officer.

Before we get started, I'd like to point out a few items. You will see that we have items in our GAAP results such as acquisition-related charges, restructuring costs and certain other items. You should note that we have excluded these from our non-GAAP results and provided a reconciliation in our press release. I would also like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the safe harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck's management and are subject to significant risks and uncertainties.

If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 1A in the 2020 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck

undertakes no obligation to publicly update any forward-looking statements. Our SEC filings, today's earnings release and an investor presentation with highlights of our results are all posted on merck.com.

With that, I'd like to turn the call over to Ken.

Kenneth C. Frazier - *Merck & Co., Inc. - CEO & Chairman*

Thank you, Peter. Good morning, and thank you for joining today's call. 2021 marks Merck's 130th year, which provides an opportunity to reflect on our company's heritage of bringing forward transformative innovation that changed medical paradigms across many therapeutic areas. Today, we are well positioned to achieve sustained future success given our highly talented employees, our scientific expertise, our promising pipeline and our financial and operational strength. We also are taking the right steps to evolve Merck's operating model to best position the company for the future as the industry landscape continues to evolve.

The upcoming spin-off of Organon will further enhance our focus on innovation and on our key growth drivers, and this will enable necessary investments in cutting-edge science. Merck's leadership progressions have been thoughtfully planned and seamless succession is well underway. Each of our newly appointed leaders have a proven track record of success and embodies the mission of the company. I am confident that this team, led by Rob, is more than ready to take the helm and lead this company into the future.

Reflecting on the results of this quarter. While the pandemic continued to impact both patient access and health care provider capacity to treat, we delivered solid performance, especially considering the high proportion of physician-administered products in our portfolio, particularly on that theme. And speaking of the pandemic, Merck remains committed to the development of molnupiravir as an important potential treatment for COVID-19, and we are proud to partner with Johnson & Johnson on the production of their vaccine.

This will be my final earnings call as CEO before I retire from the role on June 30. I want you to know that I appreciate the helpful and constructive input you all have given me over the year. And I look forward to serving as Executive Chairman of the Board of Directors and acting in an advisory role and importantly, to watching Merck achieve even greater success.

And with that, I'll turn the call over to Rob Davis.

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

Thanks, Ken, and good morning, everyone. This is Ken's 42nd and final earnings call as CEO. And on behalf of all of us here at Merck, we thank him for his profound contributions to this company, to the scientific community and to our customers and patients around the world. We wish him much success and happiness as he embarks on life after his distinguished career as the CEO of Merck, and we look forward to his continuing counsel as he serves as our Executive Chairman.

As I transition to the CEO role, one of my immediate priorities is to ensure that our experienced and empowered leadership team continues building on the strong foundation and positive momentum we have across the company. To that end, I'm very pleased to welcome Caroline Litchfield to the Executive Committee as our new Chief Financial Officer. Caroline most recently served as Merck's Treasurer and prior to this, was Head of Finance for our Human Health business. She's had a distinguished 30-year career at Merck, serving in finance roles across different regions and businesses and is exceptionally well positioned to lead our finance organization and provide strategic insight as a member of our senior leadership team.

I'm also very pleased by the expansion of Frank's role to the President of our Human Health business, including both our commercial and marketing operations. Frank's insight and leadership have been critical drivers of Merck's success over the past decade, particularly as we've built out our oncology business and achieved extraordinary commercial success. In addition, I've been working closely with Dean to ensure that the connection between the commercial and research operations remain strong. R&D is the lifeblood of Merck. And Dean and his team are fully committed to driving scientific innovation and in efficiently allocating resources to our most promising pipeline opportunities.

While our portfolio continues to feel the impacts of the pandemic, we are confident that underlying demand for our products remain strong, and we are optimistic that a more normal environment is beginning to emerge. We've executed important business development transactions this quarter and we made meaningful advancements in our pipeline. Frank, Caroline and Dean will speak to this in a moment, but I'll first give you an update on where I've been focusing during this transition period.

I've been spending a lot of time with the leadership team and many others across the company to ensure we have open lines of communication and a clear path towards continued success. I'm using my time as President to listen to employees throughout the organization to help me flesh out further my own perspectives on our go-forward strategy and to begin to shape our priorities to deliver it. In the meantime, I'm focused on ensuring that we continue to execute on the significant commercial and development opportunities we have in the short term to realize our meaningful growth potential while also taking the necessary steps to transform our operating model to best prepare us for the evolving health care landscape over the long term.

To that end, we will continue to focus on delivering our late-stage pipeline and advancing programs out of our robust and growing early-stage pipeline. And we will continue to augment our efforts through internal business development focused on meaningful asset additions. The acquisitions of Pandion and its potentially foundational immunology asset and the HIV collaboration with Gilead Sciences are great examples of transactions completed this quarter that each has significant value creation potential.

Finally, we will continue to take the necessary steps to help shape Merck into a leaner, more focused and agile company such as the upcoming spin-off we're working on. We look forward to hosting an Investor Day on Monday, during which the full Organon leadership team will highlight its strategy and opportunities for growth. We expect to complete the spin-off on June 2, with trading on the new stock commencing on June 3.

In closing, we remain confident that our business is well positioned for strong long-term growth. Our mission will continue to be the fuel that drives our company forward and gives us purpose. Namely, we will continue to be focused on scientific innovation aimed at addressing significant unmet medical needs that improve the lives of the patients we serve. I firmly believe that by keeping patients at the center of everything we do, we create the most value for all of our stakeholders, including our shareholders.

With that, I'll turn the call to Frank.

Franklin K. Clyburn - *Merck & Co., Inc. - Executive VP & President Human Health*

Thanks, Rob. Good morning. I'm excited to expand my role as President of Human Health and to build on the commercial success we are driving. We are very confident in the underlying demand for our key products and we continue to anticipate strong growth for our business for the full year.

That said, the underlying strength in our Human Health business was impacted this quarter due to the increase in cases and additional lockdowns across the globe. These headwinds were, in part, the continuation of reduced patient access to physician offices and lower-than-normal wellness visits and were more pronounced early in the quarter given the wave of infections that occurred. The rollout of the COVID-19 vaccines and recommendations against co-administration have also impacted parts of our vaccine business. As a reminder, roughly 70% of our pharmaceutical revenue is comprised of physician-administered products.

It is important to keep in mind as well that our year-over-year growth was impacted by the particularly strong first quarter we had in 2020, along with quarter-to-quarter variability in sales of GARDASIL. As a result of these factors, our sales were roughly flat compared to last year, or negative 3%, excluding the positive impact of foreign exchange. I'll walk you through some of our expectations for future trends in just a moment, but first, I'll turn to the first quarter performance of our key brands. My comments will be on an ex exchange basis.

In oncology, KEYTRUDA sales grew 16% to $3.9 billion, reflecting continued strong demand. In the United States, KEYTRUDA continues to maintain its leadership position in lung cancer, including capturing 8 out of 10 eligible new patients and is benefiting from strong usage across all key tumor types, including renal cell carcinoma, bladder, adjuvant melanoma or MSI high indication, triple-negative breast cancer as well as the Q 6-week

dosing regimen. Outside the United States, growth continues to be driven by lung cancer indications and our ongoing launches in head and neck cancer and renal cell carcinoma.

Lynparza grew 51% in the quarter, benefiting from ongoing launches and broader reimbursement that continue to solidify its position as the leading PARP inhibitor. Lenvima was essentially flat, reflecting competitive entrants in hepatocellular carcinoma and a onetime accrual related to the recent NRDL listing for hepatocellular carcinoma in China.

Our vaccine portfolio was impacted by lower-than-normal wellness visits, particularly in the United States, along with headwinds related to the rollout of COVID vaccines in adults. GARDASIL sales were negatively impacted by the timing of shipments to China last year and the timing of U.S. public sector purchases in both periods as well as pandemic impacts in the United States and in Europe. PNEUMOVAX sales declined due to a challenging year-over-year comparison given strong demand for pneumococcal vaccination at the start of the pandemic last year and the impact of CDC COVID vaccine coadministration guidelines partially offset by higher ex U.S. sales.

Our hospital business continued its recovery from pandemic impacts. BRIDION sales grew 11% year-over-year driven by broader usage along with updated operating room protocols that allow for more normal levels of elective procedures. We remain confident in the underlying demand for our innovative portfolio given the meaningful values of our products to patients. With the strong rollout of the COVID vaccines, we expect that patients will be more comfortable to seek care in a timely manner. In fact, we are encouraged by the recovery trends we saw as we exited the first quarter, with March wellness visits in the United States tracking above prepandemic levels.

In oncology, since the start of the pandemic, there has been an unfortunate reduction in the level of cancer screenings, which has resulted in fewer patient diagnoses and reduced new patient starts for many oncology agents, particularly in areas like lung cancer. With the rollout of the COVID vaccines, especially among the elderly where cancer incidence is highest, along with increased awareness campaigns, we believe screenings and diagnosis will soon return to normal levels. We expect continued strong growth of KEYTRUDA, given its leadership position across many current indications.

In addition, we're excited by the recent launch in esophageal cancer and by potential additional indications in renal cell carcinoma, including in combination with Lenvima and as monotherapy in the adjuvant setting. In vaccines, the recent improvement in wellness visits is encouraging as our awareness campaigns would help raise the potential for catch-up vaccinations across the portfolio as patient access improves. We expect COVID vaccines to be available in the adolescent population in the future.

And we will monitor the impact on GARDASIL, especially in the back-to-school season. That said, in the United States, in order to enable safe return to in-person learning in the fall, there is heavy attention being put on accelerating adolescents' physician visits to catch up on missed routine vaccinations and to schedule new vaccinations around the COVID vaccine rollout to this cohort. We will also monitor many ex U.S. markets where the rate of COVID vaccination has been slower than in the United States and where there have been renewed lockdowns that are expected to impact physician well visits and school-based vaccination programs. Overall, however, we believe there is strong global demand for GARDASIL, particularly in ex U.S. markets like China. We have seen improvements in our capacity to manufacture this year, which will also benefit our sales. Given this, we expect strong global growth for GARDASIL this year.

To conclude, we are confident in the strength and resilience of our portfolio of innovative medicines and vaccines. We expect to return to more normal operations later this year and strong full year growth. There is underlying patient demand for our products, and we believe that once we move through the temporary market dynamics created by the pandemic, our business will resume to a strong growth trajectory long into the future.

With that, I'll turn the call over to Caroline.

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

Thank you, Frank. Good morning, everyone. I am extremely honored to be Merck's new Chief Financial Officer and work more closely with the team of extraordinary leaders who share my deep passion for Merck's mission. I am excited by the opportunity to lead the finance organization and to

help ensure that Merck remains well positioned to make the investments in science and innovation necessary to sustain our unique legacy of making a difference in the world and in creating value for patients and shareholders.

Now turning to our first quarter results. Total company revenues were $12.1 billion in the quarter, roughly flat year-over-year on a nominal basis or down 1% excluding the positive impact of foreign exchange. These results were broadly in line with our initial expectations. Frank describes the underlying strength in the human health business as well as the ways in which the pandemic affected the quarter, and we estimate the impact was approximately $600 million.

Animal Health delivered a particularly strong quarter, growing 15% year-over-year driven by demand across both companion animal and livestock, which grew 24% and 9%, respectively. In companion animal, growth was driven by higher global demand for our parasiticides, primarily the BRAVECTO line of products, as well as strength in vaccine. Performance in livestock reflects increased demand in international markets across ruminants, poultry and swine as well as strong growth of our Intelligence products.

I'll now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis. Gross margin was 75.7% in the quarter, a decrease of 0.8%, driven largely by higher costs associated with COVID programs. Operating expenses increased to 10% year-over-year to $4.9 billion driven largely by higher clinical development costs, including our COVID-19 program, increased investment in our early-stage pipeline and higher provision costs in support of key growth drivers. The effective tax rate for the quarter was 14.1%, a decrease of 2.8% from a year ago driven by favorable earnings mix and discrete items. Together, we earned $1.40 per share, a decrease of 7%.

Turning to our updated 2021 guidance for Merck, including Organon. First quarter revenues were broadly in line with our expectations, and we continue to expect revenues of $51.8 billion to $53.8 billion, representing growth of 8% to 12% versus 2020. The underlying strength of our growth pillars provides us with confidence that we will see strong acceleration in revenues throughout the remainder of the year despite a slightly less favorable impact from foreign exchange and a higher projected impact from the pandemic.

Our revenue guidance does not include revenue from the potential launch of molnupiravir. Our gross margin is now expected to be roughly 76%, slightly less than prior guidance as a result of the impact of COVID. We now expect operating expenses to grow at a mid- to high single-digit rate, a lower growth rate compared to our prior guidance largely driven by diligent management of SG&A expenses. Normalized for the impact of COVID, operating expenses would be expected to grow closer to a mid-single-digit rate. Our guidance for other income and expense, tax rate and shares outstanding remain unchanged from last quarter. Taken together, we continue to expect non-GAAP EPS to be between $6.48 to $6.68, reflecting growth of 12% to 15%. This range includes the positive impact from foreign exchange of less than 3%.

With respect to Organon, on a pro-forma basis, assuming it's operated as an independent company for the full year, Organon is now expected to achieve revenues of $6.1 billion to $6.4 billion. Assuming completion of the spinoff, Merck anticipates full year revenues from continuing operations to be $45.8 billion to $47.8 billion. We continue to expect operating efficiencies enabled by the spin of approximately $1.5 billion over 3 years, including $500 million in 2021.

Due to the high profitability of the Organon products versus overall Merck, we expect Merck's operating margin from continuing operations to be slightly lower in 2021 versus what it would have been without the spin-off but to accelerate and be higher within 12 to 24 months versus where they would have been in the absence of the spin-off and to be greater than 42% in 2024. We remain confident the transaction will benefit the patients that both Merck and Organon serve and create value for shareholders.

Merck expects its revenue and earnings growth rate to be higher after the spin-off. Given the faster growth of Merck and the operating efficiencies we expect to achieve as a result of the spin, combined with the faster growth we expect the Organon products to achieve in an independent structure, we expect combined EPS of the 2 companies to be higher within 12 to 24 months versus what would have been achieved without the spin.

Upon the close of the Organon spin-off, we expect to receive a special tax-free dividend of $9 billion, which we hope to deploy in value-enhancing strategic business development opportunity. In the absence of meaningful business development, we intend to return cash to shareholders through

share repurchases. As always, we remain committed to ensuring appropriate investment in our business, both in support of our key brands but also to drive forward the innovation progressing in our pipeline. And we will look to increase our dividend payout ratio over time.

In summary, I am excited to embark upon my journey as CFO and to be stepping in at a time in which our company is in such a strong financial position. We remain confident in the outlook of our business. And I look forward to doing my part to ensure Merck remains well positioned financially to drive sustainable value to patients and shareholders.

With that, I'd now like to turn the call over to Dean.

Dean Y. Li - *Merck & Co., Inc. - EVP*

Thank you, Caroline. For my remarks today, I will cover key regulatory milestones and clinical updates initially in oncology and then in our broader pipeline. And finally, I will discuss recent business development activities.

In the first quarter, the FDA accepted and granted priority review for a new drug application for belzutifan, our investigational HIF-2 alpha inhibitor that we acquired from Peloton for the treatment of certain patients with von Hippel-Lindau disease-associated renal cell carcinoma with a September PDUFA date. We are evaluating this asset further in 3 ongoing Phase III studies in RCC. We initiated a Phase III study evaluating vibostolimab, our investigation on anti-TIGIT antibody in combination with KEYTRUDA in patients with non-small cell lung cancer whose tumor has expressed PD-L1. This is one of several co-formulated assets we are on track to advance this year from our oncology portfolio that builds on the success of KEYTRUDA.

Turning to FDA approvals. KEYTRUDA was indicated in combination with chemotherapy for the treatment of certain patients with advanced esophageal carcinoma regardless of PD-L1 expression based on KEYNOTE-590. This marks the 11th approved indication based on a clinical study that demonstrated overall survival. Now outside the United States, the European Commission approved new indications for KEYTRUDA for adult and pediatric patients with relapsed or refractory classical Hodgkin lymphoma based on the results from KEYNOTE-204 and for patients with microsatellite instability-high or mismatch repair deficient previously untreated colorectal cancer based on KEYNOTE-177.

Now earlier this month, we announced that following an interim analysis, KEYNOTE-564, our Phase III study evaluating KEYTRUDA as an adjuvant monotherapy treatment in patients with renal cell carcinoma met its primary endpoint of disease-free survival. These data will be shared with regulatory authorities and presented at ASCO. This provides another proof point for the benefit of KEYTRUDA in earlier lines of therapy, where we expect additional readouts in several other tumor types this year and it also supports our broad development program in patients with renal cell carcinoma.

We recently received a positive opinion from the CHMP for Q 6-week dosing across KEYTRUDA combination regimens for patients in the EU, which builds upon the 6-week dosing schedule already approved in monotherapy indications. And at the AACR Annual Meeting, initial results from KEYNOTE-555, evaluating a subcutaneous formulation of KEYTRUDA in patients with metastatic melanoma, were presented. We are continuing to study this new formulation and other innovative modes of administration and dosing aimed at providing increased benefit and access for patients.

Along with our partners at Eisai, we presented potentially practice-changing data, demonstrating the benefit of KEYTRUDA plus Lenvima in the first-line treatment of patients with advanced renal cell carcinoma and in second-line advanced endometrial carcinoma based on results from KEYNOTE-581 and KEYNOTE-775, respectively. These studies demonstrated statistically significant improvements across primary and secondary endpoints, and we look forward to working with global regulatory authorities on these filings.

In February, in collaboration with AstraZeneca, we announced that following an interim analysis, the Phase III OlympiA trial, studying Lynparza as maintenance therapy in the adjuvant treatment of certain patients with germline BRCA-mutated high-risk HER2-negative early-stage breast cancer crossed the superiority boundary for its primary endpoint of invasive disease-free survival versus placebo. The trial continues to evaluate the dual primary endpoints of overall survival and distant disease-free survival, and this data will be presented at ASCO. We are also pleased with the positive outcome of yesterday's Oncologic Drugs Advisory Committee review of our first-line advanced bladder cancer indication and recognition of the efficacy and safety that KEYTRUDA has demonstrated in clinical trials. We look forward to further discussions with the committee on other accelerated approvals under review.

Last month, we announced the decision to voluntarily withdraw an indication for KEYTRUDA for the third-line treatment of patients with metastatic small cell lung cancer. As announced, we received a complete response letter from the FDA for a supplemental biologics application for KEYTRUDA for the neoadjuvant and adjuvant treatment of patients with triple-negative breast cancer based on KEYNOTE-522. We anticipate the next interim analysis from this trial in the third quarter of 2021, and we look forward to further discussions with the FDA.

Now turning to our broader pipeline. On molnupiravir, along with our partners at Ridgeback Biotherapeutics, we announced interim results from the dose-finding phase of Phase II/III studies in both outpatient and hospitalized patients. After analysis of the data, we have decided to proceed to Phase III in outpatients with enrollment focused on higher-risk populations. We will be evaluating molnupiravir as a postexposure prophylactic option in a study starting later this year. As previously discussed, we have made the decision to discontinue the development of MK-7110 for COVID-19 and plan to focus our pandemic efforts on advancing molnupiravir and on producing Johnson & Johnson's COVID-19 vaccine.

In HIV, we continue to make good progress in our development program for islatravir, our potentially first-in-class nucleoside reverse transcriptase translocation inhibitor. Data presented at the CROI meeting last month supports the potential of islatravir in long-acting dosings regimens in both the treatment and in the PrEP settings. Of note was early data supporting the potential for the subdermal islatravir implant to provide drug concentrations above the target pharmacokinetic threshold for at least 1 year.

We are pleased to build upon our legacy of innovation in HIV through our collaboration with Gilead Sciences to co-develop and co-commercialize islatravir and lenacapavir. Both have unique properties that we believe have the potential to enable the creation of effective long-acting oral and injectable regimens that provide important new treatment options and address remaining unmet need for people living with HIV.

Our pneumococcal vaccine, V114, remains on track for potential FDA approval for adults in July and a readout of pediatric data and associated filings by year-end. V114 is the first of a suite of promising pneumococcal vaccine candidates, which also include V116, our adult-focused vaccine, where a readout from our Phase I/II study is expected later this year. Finally, we announced that the FDA accepted our new drug application for gefapixant, a potentially first-in-class P2X3 inhibitor in adult patients with refractory and unexplained chronic cough. The decision is expected in December. This application will be subject of an upcoming advisory committee meeting.

We continue to pursue business development across the most exciting areas of science. Our acquisition of Pandion Therapeutics expands and complements our internal pipeline of candidates targeting autoimmune diseases. Pandion's lead IL-2 candidate has the potential to be meaningfully differentiated based on high selectivity, and we plan to initiate the Phase Ib/II study this year. We continue to make strong progress with the pipeline. This momentum is due to the passion and commitment to the scientists within our research laboratories to bring life-saving medicines and vaccines to patients around the world.

Now I will turn the call back to Peter.

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

Thank you, Dean. Lara, we're ready for questions, but I'd like to end the call today at 9:00. We ask that questioners limit themselves to one question, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question will come from the line of Terence Flynn from Goldman Sachs.

Terence C. Flynn - *Goldman Sachs Group, Inc., Research Division - MD*

Great. I guess I was just wondering on the KEYTRUDA KEYNOTE-564 study in RCC, if you believe you'll be able to file on disease-free survival. Or if FDA will also require survival data? And then regarding the commercial opportunity here, maybe a question for Frank. I think the current treatment rate here in the neoadjuvant/adjuvant setting for RCC is around 10% to 15%. Can you give us any thoughts on how much higher that might move if KEYTRUDA is approved here?

Dean Y. Li - *Merck & Co., Inc. - EVP*

So I'll address the KEYNOTE-564 question. In relationship to what the regulatory agencies will accept, we're clearly going to have discussions with them. But the endpoint that we reported is a registrational endpoint. And we hope to have further discussions with the FDA. Clearly, we are advancing the study to do the other endpoints that you outlined in terms of overall survival as well.

Franklin K. Clyburn - *Merck & Co., Inc. - Executive VP & President Human Health*

Okay, Terence, and this is Franklin. The opportunity the majority of renal cell carcinoma patients do present in the adjuvant setting with the remaining in the metastatic setting, so think of it about 75% are presenting at the early stage. So it is a very nice opportunity for us. When we do look at our study, when we see and evaluate the eligible patients, it's probably about even turns between the adjuvant opportunity and metastatic opportunity. But we are very excited about this opportunity, if approved, going forward.

Operator

Your next question will come from the line of Umer Raffat from Evercore ISI.

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

I just wanted to focus on the molnupiravir outpatient trial, if I may. And a couple of pieces to that. One, what percentage of the Phase II portion of this trial had older adults over 60? And I guess what would the Phase III portion -- what percentage of the Phase III has to be older to get to the number of events you have in mind over the target time frame? And also, I know the endpoints' focused on hospitalizations and deaths. But the trial sites are primarily in U.S. and Europe, where there's a lot of vaccination going on. So is there openness to perhaps adding sites like India, et cetera, where hospitalizations are high?

Dean Y. Li - *Merck & Co., Inc. - EVP*

So let me take that question. Thank you very much for that question. We're very confident in our molnupiravir program. As you outlined, we are advancing the outpatient. And I should also say that we are poised to start the Phase III portion of that outpatient study imminently. As you know, this is a global trial with a recruitment strategy focused in areas where we are looking at vaccination rates that are unfortunately low. So we are in Africa, we are in South America. Those will be very important sites. We anticipate that there will be more than 100 sites to contribute. This is a global study.

In terms of your question in relationship with India, we are -- we have entered into a voluntary license agreement with 5 Indian generic manufacturers to expand global access to molnupiravir. At this time, we are not extending our clinical trial for MOVe-OUT into India. And then finally, what I would say is our clinical safety and virologic data gives us great confidence to evaluate molnupiravir, not just in the MOVe-OUT study, but also for postexposure prophylaxis in a study starting later this year.

Operator

Your next question will come from the line of Chris Schott from JPMorgan.

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

I just had a 2-part question on BD. You're getting $9 billion with the Organon spin. The company obviously generates a lot of cash. I guess if we continue the current pace of these tuck-in-type acquisitions, it seems like Merck at some point becomes overcapitalized. So I guess when you look at the BD landscape, are you confident that there are actionable opportunities to deploy this capital into transactions? Or does it reach a point where we need to think about further capital return to shareholders?

And maybe as you talk about the BD landscape and just sort of experience in the -- the environment you're seeing, I guess, is a string of smaller tuck-ins kind of more likely for Merck, given the environment we have? Or is there still the opportunity to think about larger or later-stage acquisitions over the near to intermediate term?

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

Yes. Chris, this is Rob. Maybe I'll address the question. As you point out, the company is very well-capitalized, and we are looking forward to getting the $9 billion special dividend as part of the spin-off of Organon. As we look at it, and as Caroline made in her prepared comments, we intend to use that capital both for business development and potentially share repurchase, but our clear priority is business development. We believe that's the most value-enhancing use of our capital, long term.

To the question of whether or not I think there's enough assets out there, there are a lot of opportunities. So our goal is to deploy that capital to BD. And more time will have to pass to be able to see how that evolves. But that is our goal. But to your other question, if we do not ultimately use that capital for business development, I'm not looking to build excess cash or improve our ratings. We would return that to shareholders.

And then to the last part of your question about size, we've been very clear. We are open to any opportunity to add a meaningful asset. Size is not determined by dollars. Size is determined by complexity and the disruption it brings to our business. So as we look at it, we are open to all forms of deals, and we have the capital to go after all forms of deals. We continue to believe where we add a lot of value is in products that are in earlier stages of development, which is what's driven a lot of the deals we've done, but we're not limiting ourselves to that, and we're looking at all opportunity.

Operator

Next question will come from the line of Andrew Baum from Citi.

Andrew Simon Baum - *Citigroup Inc., Research Division - Global Head of Healthcare Research and MD*

Thanks to Ken for the strong leadership within Merck more broadly. And a question for Rob. Our conversations with investors on Merck are surprisingly dominated by the KEYTRUDA concentration risk, particularly post-Organon. My question is do you believe the market is anywhere close to reflecting the revenue potential of the current pipeline products, drugs such as islatravir, belzutifan or TIGIT? Or would Merck ever think about giving an aggregate forecast for the existing pipeline, or even as GSK have intended to do, give a 2030 guidance just to help investors gain some visibility about the ability of Merck to manage the pending LOE associated with KEYTRUDA?

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

Yes. Well, I think to maybe just hit the nail on the head of the first part of your question. I do think that our belief and confidence in the overall value of our pipeline, both what we have in the mid- to late stage, and I can go into more specifics on what that is, as well as in the early stage on top of what we see as continued opportunities to expand in oncology, in the neoadjuvant/adjuvant spaces, in combinations, in co-formulation, if you look at the totality of everything, we continue to believe, and over time, I recognize we're going to have to demonstrate, but we continue to believe that, frankly, The Street is underestimating the potential in our pipeline.

And thus, while we are very aware of the potential LOE of KEYTRUDA, we do not see the cliff in the same way The Street does. I think we're very well positioned with what we have internally to address a meaningful part of that. And then obviously, as we said, we understand we need to continue to be urgent and looking at business development to continue to augment it. But I do think there is a disconnect. And over time, I'm confident we will be able to demonstrate.

As it goes to long-term guidance, I don't want to take a specific position today on whether or not we would ever do that, but I can tell you historically, I do agree with the position Merck has had, which is that can paint you into corners that caused you to make decisions that are not always in the best long-term interest. So I doubt you're going to see us giving 10-year guidance on what you've heard from others. But we'll have to see. I think, though, what is important to understand is I recognize also, though, over time, we're going to have to pull the cover back in a balanced way around our portfolio. I respect our science and I want to make sure we keep the integrity of our science pure, and that's very important. That's who Merck is. But I also understand that there is a balance to give some sense of understanding of what's in the pipeline to share our confidence over time.

Operator

Your next question will come from the line of Geoff Meacham from Bank of America.

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

Just had a follow-up on molnupiravir. As you guys get closer to the Phase III results, how are you thinking about the commercial picture, assuming that it'll have a rest of world bias, especially given the with case burden in India?

And then when you guys look at the prophylaxis or the outpatient setting, what's the right way to stage patients from either a viral load or inflammation perspective? Just trying to think about the -- as the pandemic moves on, how can you more broadly address the -- maximize the number of patients that you could address?

Dean Y. Li - *Merck & Co., Inc. - EVP*

Yes. That's a great question. This is Dean. I'll try to give a scientific point of view and then I'll now send it to Frank to give a more commercial sort of point of view.

In relationship to molnupiravir, we think we are imminently going to do the Phase III trial in the outpatient setting, as was noted in the previous question. We're tightening up the inclusion criteria, reducing the allowable symptom duration for enrollment to be less than 5 days, and we're trying to enroll patients early in the course of disease who have a high risk for poor outcomes. That includes age and other risk factors such as obesity and diabetes. So we think that will be critically important to have a successful and timely trial.

In relationship to the postexposure prophylaxis, there's a number of ways one can design that trial. But if I can just take it as a higher elevation, we think that this MOVe-OUT and the prophylaxis studies is going to be very important, not just for Merck but for the world. As one sees the different places of vaccination, some of it albeit extremely low, it's creating a reservoir for variants -- the ability to have a small molecule that can easily be delivered orally is going to be really important for the world. So that's what we've been focused on.

But let me turn it to Frank to focus on the framework that you've asked in terms of the commercial impact.

Franklin K. Clyburn - *Merck & Co., Inc. - Executive VP & President Human Health*

Yes. I think you covered it well. Obviously, we'll have to see how the endemic phase evolves around the world in vaccination rates, but we see this as a really important therapeutic, to Dean's point, having a small-molecule oral option, especially in many markets outside the U.S. We have significant commercial experience, strong execution in getting our therapeutics vaccines to patients around the world, and that will be a significant focus for us. So we think this is a really important opportunity, especially in markets -- you think about what's happening now in India, but you think about the low- to middle-income countries, you think about what's happening in Europe. So upon -- if we're successful, we think this is a really important opportunity for us as we go forward.

Operator

Your next question will come from the line of Ronny Gal from Bernstein.

Aaron Gal - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

A question over the mRNA technology. Can you let us know a little bit how you're thinking about integrating messenger RNA vaccine technology into your business or not? And can you speak specifically about GARDASIL? And do messenger RNA technology poses a risk to that? Can they reach the necessary polyvalency to develop those vaccines? And it seems to be simply a cheaper way of making the same vaccine from a cheaper cost of manufacturing perspective.

Dean Y. Li - *Merck & Co., Inc. - EVP*

Thank you for that excellent question. This is Dean. Let me give a little bit of framework for the mRNA. I would reemphasize that Merck has been very interested in mRNA and other nucleic acid technology and specifically in the vaccine in mRNA. For the past 5 to 6 years, Merck has partnered with Moderna on vaccines for infectious disease and vaccines for cancer. The validation of the mRNA technology in COVID is impressive and at least, personally, is deserving of admiration and thanks. We continue to be interested in mRNA and other nucleic-acid-based technologies, including viral-based platforms, for vaccines.

I would highlight, and specific to your question about GARDASIL, when you have multiple sort of antigens that you have to deliver, I think there is a role for those sort of platforms, protein-based. I think there's going to be many different platforms that need to be done specifically for the vaccine and the threat that you're trying to prevent. So RNA and other nucleic-acid-based technologies is important to us, including viral-based platforms. But we also think that broader speaking, there are other protein subunit, other vaccine platforms that will still be relevant moving forward.

Operator

Your next question will come from the line of Luisa Hector from Berenberg.

Luisa Caroline Hector - *Joh. Berenberg, Gossler & Co. KG, Research Division - Co-Head of Global Pharmaceutical Team*

It's on the PNEUMOVAX franchise, and I just wonder whether we should effectively look at 2020 as a peak for PNEUMOVAX, specifically. And then, how should we think about the competitive landscape here versus your own pipeline suite with V114 emerging very soon and then everything else behind that versus the competitors?

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

Yes. So on PNEUMOVAX, what I would say is that if you look at what happened in the first quarter of this year, we were down versus prior year because of the strong 2020 and the prioritization of the pneumococcal vaccination. We do anticipate, as you build around the rest of 2021, pneumococcal vaccination will start to be prioritized along with flu vaccinations. So we do anticipate, as you get to the back half of the year, you'll see PNEUMOVAX really have an important role to play.

We have also mentioned that we were supply-constrained as you look at PNEUMOVAX, especially in some of our markets around the world. But overall, we see it as a very important product going forward. As we introduce V114 and V116 and the initial introduction of V114, we still see PNEUMOVAX playing a very important role for pneumococcal disease going forward.

Operator

Your next question will come from the line of Gregg Gilbert from Truist.

Gregory B. Gilbert - *Truist Securities, Inc., Research Division - Analyst*

Ken, good luck and hope to see in Happy Valley from time to time.

And for Rob, we've heard from Merck how the Organon spin will benefit Merck in terms of complexity and focus. But what are some of the tangible things Merck has done to set up that spin for success beyond the obvious stuff? And I realize we're going to hear more on Monday, but I know you've been familiar with separations in the past. So curious what some of those less obvious features are that you think Organon is poised to benefit from.

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

Well, as you look and, again, just to reiterate what you just commented, on our call on Monday is really solely focused on building out and helping explain the growth story for Organon. But if you look at where Merck has been over the last few years, we've been in a situation where we've been blessed with the benefits of what KEYTRUDA has been able to do. That has required us to do heavy investments to build out our oncology platform, to invest in the clinical studies for oncology and now more broadly, as we look at all of what we have going on in vaccines and even now with this islatravir in infectious diseases. So the challenge has been, in new ways, we had to prioritize, and we made a decision to deprioritize some of the assets that fit within the Organon portfolio. Many of those are still very good assets. And as you know, particularly in the women's health area, an opportunity for real growth.

So I believe through focus, through being able to actually drive their own capital allocation aimed at building those businesses and the focus they'll be able to bring, they will accelerate the growth across, not only the women's health business, but excitement around what they have in their biosimilars business. And then there are several areas, if you look that they'll highlight next week where I think they can get to a point of growth. So a lot of it is really about focus and capital allocation in a way that we haven't been able to do.

While on our side, we believe with the spin, the simplification it brings will allow us to go after a lot of -- and I've talked about this in the past, a lot of the, as I've called it, if you will, think of it as the muscle. The fat that is chewing throughout the muscle in this company, given the complexity of our structure that's been built up over time, looking at those areas that sit between our divisions, as we think about manufacturing and commercial, as we think about supply chain and all of those are opportunities for us to simplify and to take out unneeded bureaucratic complexity, that simplification and focus will allow us to bring more resources to bear against our innovative portfolio and to drive faster growth that Caroline commented on.

So I think both businesses, you're going to see grow better as independent businesses than they would as a combined entity, and I'm confident in the story for both. And frankly, I'm excited about having a women's-health-focused business at this time in where we are as a society. I think there's a real opportunity for us to lead there. And that's what I'm looking forward to see Organon do.

Operator

Your next question will come from the line of Seamus Fernandez from Guggenheim.

Seamus Christopher Fernandez - *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

So just wanted to follow up on the 2024 42% operating margin target. Hoping you could just walk us through the pushes and pulls as it relates to the reduced royalty burdens as well as what's happening with the REMICADE, SIMPONI agreement at that point in time. I know that comes with a very high royalty burden as well. And it was our understanding that there are several sunsets in that period that will bolster margin meaningfully without necessarily coming from top line leverage.

And then separately, a question as it relates to the type of business development that's occurring. Just wanted to get a better sense of when you feel we're really going to start to see some of the various smaller tuck-in deals start to produce data that's, let's call it, Phase II compelling from the earlier-stage deals that are really going to drive the next leg of growth. Is that sort of in a similar 2024, 2025 time frame? It's just that the visibility on the pipeline currently to The Street remains, I think, relatively modest.

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

Caroline?

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

Seamus, thank you for the question. Let me first start with the near term. Our company's guidance for this year implies margins of 38%, a growth of 120 basis points compared with last year, and we're driving that growth as a result of the strong revenue and mix of revenue in our business as well as continued diligent but focused investments within our business. As we look out over the coming years, we will see margin improvement as a result of the $1.5 billion of productivity we expect to achieve as a result of the spin, and we are well on track towards that with $500 million included in 2021. As we move forward over time, the real strength for operating margin for Merck will primarily come from the growth opportunities we have with our assets in oncology, in vaccines. In addition, you will see continued investment in our business, but we are confident in achieving the 42%.

As you note, we also have the tailwind of a step down in the royalty rate as it pertains to KEYTRUDA and actually GARDASIL, and that will help in the achievement of the 42%, which we are very confident in. As it pertains to the product mix over time, our company has been diligent and focused in the types of business development we are doing. And Peloton is an ideal example, where we have the opportunity to see the fruit of that impact the top line of our company therefore, the bottom line, as well as support the patients that we serve. Your final point on REMICADE or SIMPONI, it's really not a major contributor to that bottom line expansion.

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

Dean, Rob, anything else to add there?

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

Maybe I'll just start, and then I'll turn it over to Dean. As you look at the opportunities, I do think you're going to see, in that '24 to '25 time frame, more information. The best example you can look at is what's happened with Peloton. And most recently, we're already seeing HIF-2 alpha move forward in important ways. There's many data coming out on that and see that as a meaningful opportunity.

But maybe I'll turn it to Dean to give a sense because I do believe you are going to see more information as we get in the time frame you're talking about from a lot of these business development deals, given the nature of a lot of the oncology assets.

Dean Y. Li - *Merck & Co., Inc. - EVP*

Yes. Thank you for that question. Let me just take a high level and then answer the temporal question that was asked. The sort of opportunities that we look for, both in our internal pipeline and external pipeline, we like -- or I like assets that give me concentration leverage, foundational drugs where clear monotherapy efficacy gives me a fulcrum for combination. And specifically in relationship to cancer, that allows us to expand, deepen and extend. And as we look for these foundational medicines and the recent discussions with Gilead and Pandion, it just shows that, that sort of attitude of how we want to sort of proceed where we're taking foundational medicines and we're matching them with internal and external pipeline so that we can diversify the pipeline.

And specific to your question, I would look at the '21 to '24 range. There's a whole slew of Lynparza, Lenvima, KEYTRUDA study that you will see, a lot of it driving to adjuvant at earlier stages. I think there's at least 20 registrational trials. I sort of laid out maybe 4 or so that you'll see in the next year. In relationship to the business development, what you will see is in the '24, '25 time frame, things like the islatravir, Tilos, Seagen, that was also CTLA-4, LAG-3 TIGIT, all of them will be in striking range to not just see sort of Phase II studies but potentially interim analysis or even complete analysis of those assets in that time frame. So you'll see these different ways going through.

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

Thank you, everybody. We're right at the top of the hour. We appreciate the questions this morning and the discussion, and we look forward to any follow-ups in the coming days. Thank you all very much.

Operator

Thank you, sir. Thank you so much, presenters. And again, thank you, everyone, for participating. This concludes today's conference. You may now disconnect. Stay safe. Have a lovely day.
