Q4 2019 Earnings Call

Company Participants

- Frank Clyburn, EVP and Chief Commercial Officer
- Kenneth C. Frazier, Chairman, President & Chief Executuive Officer
- Kevin Ali, President, Emerging Markets
- Peter Dannenbaum, Vice President of Investor Relations
- Robert M. Davis, Executive Vice President of Global Services & Chief Financial Officer
- Roger M. Perlmutter, President

Other Participants

- Andrew Baum, Analyst, Citi
- Chris Schott, Analyst, JPMorgan
- Daina Graybosch, Analyst, SVB Leerink
- David Risinger, Analyst, Morgan Stanley
- Geoff Meacham, Analyst, Bank of America
- Louise Chen, Analyst, Cantor Fitzgerald
- Mara Goldstein, Analyst, Mizuho Securities
- Seamus Fernandez, Analyst, Guggenheim Securities
- Steve Scala, Analyst, Cowen & Company
- Terence Flynn, Analyst, Goldman Sachs
- Tim Anderson, Analyst, Wolfe Research
- Umer Raffat, Analyst, Evercore ISI

Presentation

Operator

Good morning. My name is Carlo and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. Quarter Four Sales and Earnings Conference Call. (Operator Instructions) Thank you.

I would now like to turn the call over to Peter Dannenbaum, VP of Investor Relations. Please go ahead.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Carlo; and good morning. Welcome to Merck's fourth quarter 2019 conference call. Today I'm joined by Ken Frazier, our Chairman and Chief Executive

Officer; Rob Davis, our Chief Financial Officer; Dr. Roger Perlmutter, President of Merck Research Labs; and Kevin Ali, who will be named Chief Executive Officer of the new company we have announced today. Each will have prepared remarks. In addition, I'm also joined by Frank Clyburn, our Chief Commercial Officer; and Mike Nally, our Chief Marketing Officer, who will be available for the Q&A portion of the call.

Before I turn the call over to Ken, 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 cost and certain other items. You should note that we have excluded these from our non-GAAP results and provide a reconciliation in our press release. We have also provided a table in our press release to help you understand the sales in the quarter for the business units and products.

I would 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 US 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 2018 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. You can see our SEC filings, as well as today's earnings release on merck.com. We have also posted a presentation to the Investors section of merck.com, which includes some of the highlights from our results and announcement.

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

Kenneth C. Frazier {BIO 1391636 <GO>}

Thank you, Peter. We are very pleased to speak with you this morning as we close out what we consider to be an exceptional year for Merck. And we are excited to announce our intention to create two leading growth companies through the spin-off of our Women's Health, Legacy Brands and Biosimilar Products into a new company.

As you can see from our results and our 2020 guidance, Merck had an extraordinary year and is in a position of operational and financial strength driven by strong execution of our strategy and focus on our key growth drivers and innovative pipeline. It is this position of strength born of that focus that gives us the confidence to do what we believe will best position us to deliver even greater value to patients and shareholders.

Throughout my entire tenure as CEO we have consistently focused on science as core to our strategy to not only benefit the most patients, but also as a means of creating the most value. As you've seen, Merck's portfolio have evolved from one focused largely on primary care products to one focused on oncology, vaccines, hospital and animal health. It is this purposeful shift, coupled with greater prioritization and focus on key growth drivers that has led to the unprecedented growth that we are now experiencing.

Going forward, we see even greater opportunities to invest behind our innovative growth drivers. In placing greater focus and prioritization behind these products, we must also think carefully about how to make the best possible use of the remainder of our expansive human health portfolio, which has comprised of more than 160 products in total.

Our responsibility to patients and shareholders has led us to think about how we can maximize the impact of this vast array of human health products. Therefore, after careful consideration over time, we've made the decision to separate into two companies: one, a research-intensive biopharmaceutical leader; the other, a new company focused on becoming a leader in women's health with the capability to realize the full potential of a portfolio of trusted and medically-important legacy products and a rapidly expanding biosimilars business.

By spinning off NewCo as a distinct business, we can better prioritize and support a set of products that no longer fit in Merck's strategic framework, but which remains important to public health and the patients who rely on them; and which if managed and resourced appropriately, present real opportunities for growth.

We're also mindful of the changing industry landscape and believe that evolving our operating model in this way will allow Merck to benefit from an even more intense focus on breakthrough science and innovation. As I stated on our Investor Day in June, our mission and rich legacy of inventing to save and improve the lives is the foundation of our Company. The separation of NewCo will help us in our aspiration to be the premier research-intensive biopharmaceutical company by allowing us to focus on innovations that prevent and treat diseases. And over the past few years, we have seen how more focus and more prioritization leads to more growth, more efficiency and more value creation.

The spin-off will also create significant opportunities for NewCo. As an independent company, NewCo will pursue its strategic intent of becoming a global leader in Women's Health, an area where the future opportunities are significant. In addition to the growth potential in Women's Health, NewCo's growth will be fueled by more fully realizing the full potential of a portfolio of trusted Legacy Brands and pain, dermatology, cardiovascular and other areas, as well as its rapidly-expanding biosimilars business. This new company will have a strategic freedom to pursue additional growth opportunities through lifecycle management and targeted acquisitions and partnerships in women's health, dermatology and other fields.

NewCo will be led by a highly experienced leadership team including Kevin Ali who has been named Chief Executive Officer. Kevin has a proven track record of leadership at Merck with deep experience in global pharmaceutical market and diverse therapeutic areas. In addition, NewCo's Board will be shared by Carrie Cox, who has extensive experience in pharmaceutical commercialization, particularly in women's health, as well as broad leadership and Board experience including as former Chairman and CEO of Humacyte, former Chairman of Array BioPharma and as President of Global Pharmaceuticals at Schering-Plough prior to its merger with Merck.

We are confident that the NewCo will be in experienced and capable hands with this leadership team. Our industry faces emerging challenges such as the rising cost of innovation and increasing pressures around pricing and market access. In this environment, we must maximize our opportunities to act with greater operational agility, efficiency and productivity.

As separate, more focused companies with more optimal resource allocation, both Merck and NewCo will be better positioned to continue to positively impact the lives of patients, improve global public health and achieve faster growth. As a result, we expect Merck shareholders to benefit through ownership of two focused companies each with attractive financial characteristics and growth profile.

In summary, we are seeing the benefit of focusing our organization on its best growth opportunities. As we look out to 2024, we believe the strength of our business is under-appreciated. We are more confident than consensus on every key financial metric, including revenue, operating margins and EPS growth. Our commitment to maintaining and growing the Merck dividend is evidence of the confidence we have in the long-term prospects for our business.

Our fundamental operating and financial strength allow us to take bold step to stay ahead of the curve by reshaping our operating structure, focusing and streamlining Merck, enabling Merck to become an even stronger, more agile and faster growing company. I strongly believe that this is the right thing for patients, for public health and for shareholders.

With that, I'll now pass it on to Rob to discuss our results and provide more details on the spin-off. Rob?

Robert M. Davis {BIO 6955931 <GO>}

Thanks, Ken; and good morning, everyone. I'm excited to speak to you this morning about our 2019 results, as well as our decision to spin off a portion of our Human Health business, a decision that will enhance the value of both Merck and NewCo. 2019 was a year of exceptional growth for our business with revenues increasing 13% and non-GAAP EPS increasing 21% excluding the impact of foreign exchange. Our strong performance reflects the continued execution of our science-led strategy and we expect our business momentum to continue, particularly as we enhance our focus on our key growth drivers through the spin-off.

I'll start by highlighting our strong fourth quarter results before providing more details on the transaction and 2020 guidance. Total company revenues were $11.9 billion in the quarter, an increase of 8% year-over-year or 9% excluding the negative impact from foreign currency. Both our Human Health and Animal Health divisions contributed to the growth this quarter.

The remainder of my comments pertaining to sales will be on an ex-exchange basis. Our Human Health revenues grew 8%, led by products in oncology and hospitals. In Oncology, KEYTRUDA fourth quarter sales were $3.1 billion and for the full year sales exceeded $11 billion, representing 58% growth versus 2018.

In the US, growth was driven by strong demand across all indications. KEYTRUDA continues to lead across many indications, including lung, bladder, and head and neck cancers with strong momentum in adjuvant melanoma and renal cell carcinoma, where we are seeing strong uptake across all patient subgroups.

Outside the US, KEYTRUDA sales in the quarter grew 50% driven by lung globally with reimbursement for KEYNOTE-189 now secured across all major markets in the EU and strong uptake in lung following approvals in Japan and China.

We are also seeing positive uptake from early launches in both renal cell carcinoma and adjuvant melanoma in the EU and expect to see strong global growth as these and other new indications continue to rollout. Our results also reflect continued strength for both Lynparza and Lenvima, important products from our collaborations with AstraZeneca and Eisai respectively. Lynparza continues to have strong growth in ovarian cancer and maintains a greater than 60% total patient share in the PARP inhibitor class in the United States.

Growth of Lenvima benefited from the launch of the endometrial carcinoma indication in combination with KEYTRUDA, and continued strong demand with first line hepatocellular carcinoma where Lenvima is now the leading treatment agent. Our vaccines business declined this quarter due to the impact from the replenishment of GARDASIL to the CDC stockpile in 2018, and our borrowing from the stockpile in the fourth quarter of 2019, which notably impacted the year-over-year comparison of GARDASIL revenues by $245 million on a combined basis. Excluding these impacts, GARDASIL revenues grew 16% driven by continued strong underlying global demand.

Our Hospital business benefited from 24% growth in BRIDION, which reached $1 billion in annual sales for the first time, this quarter. Growth was largely driven by an increased share in the US reversal market. For the full-year, we achieved strong growth of 14% in our Human Health business driven by our growth pillars across most geographies.

Animal Health revenues increased 10% this quarter to $1.1 billion. Growth for the quarter was driven largely by the products acquired in the Antelliq acquisition.

Now, turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 72.6% in the quarter, a decrease of 240 basis points year-over-year, primarily reflecting the impact of unfavorable manufacturing variances and higher inventory write-offs. Operating expenses of $5.2 billion increased 10% year-over-year. Administrative and promotional expenses drove higher SG&A costs in the quarter, while clinical development spend and cost associated with our discovery efforts were responsible for the increase in R&D expense.

Other income and expense was positively impacted by income from our equity securities portfolio, partially offset by higher net interest expense. Our effective tax rate for the quarter was 16.9%, driven by lower and favorable earnings mix. Taken together, we earned $1.16 per share, an increase of 12% excluding exchange.

Now, turning to our announced spin-off. As Ken noted, by further evolving our operating model and separating into two simpler, more focused and agile companies, both will be better positioned to respond to the changing external landscape, improved efficiency and accelerate growth, creating greater value for patients and shareholders than would be achieved as a single company.

Spinning off NewCo accelerates Merck's revenue growth by up to 1 percentage point on a compounded average basis through 2024. But more importantly, it allows Merck to enhance focus on its key growth drivers and robust pipeline. This gives us confidence that Merck will realize even greater incremental revenue growth over time. We will also benefit from more streamlined processes and operations, enabling further operating model efficiencies across the value chain.

For context, the products to be spun-off into NewCo represent about 15% of Merck's Human Health revenues based on 2020 forecast, while consuming a much larger share of our operations and resources. In fact, separating NewCo will reduce Merck's Human Health manufacturing footprint by about 25%, the number of products by 50% and the number of SKUs by 60%.

As a result of a more optimized operating model, Merck will achieve even higher operating margins over time, creating additional headroom to invest in innovation, which we continue to believe is the key to our long-term growth and value creation as Ken has referenced. Merck will continue to benefit from broad commercial scale driven by its key growth pillars in oncology, vaccine, animal health, as well as our diabetes franchise.

Merck will continue to have a strong balance sheet with significant cash flows and financial flexibility, which will allow for investments in innovation and meaningful business developments to augment its pipeline and portfolio, while continuing to return capital to shareholders. We expect to complete the transaction in the first half of 2021. Until then, we will remain focused on continuing to successfully execute our strategy and maintaining our strong financial and operational performance.

Now, let's move to our outlook for 2020, the year in which we continue to operate as a combined entity. My remaining comments will be on a non-GAAP basis. We expect full-year 2020 revenue to be between $48.8 billion and $50.3 billion, which represents 4% to 7% growth versus 2019. This range assumes a negative impact from foreign exchange of less than 1 percentage point, using mid-January rates.

Our gross margin will be roughly 75.5%. We expect operating expenses to increase by a low-single digit rate year-over-year due to higher R&D spending as we remain committed to fully funding the meaningful opportunities in our pipeline. SG&A expenses will remain tightly managed. We expect other expense of roughly $200 million, driven by higher net interest expense. We expect our tax rate to be roughly 17.5% to 18.5% for the year. We project average diluted shares to be 2.54 billion for 2020 and we expect EPS to be between $5.62 and $5.77, which represents growth of 8% to 11%, including a roughly 1.5 percentage point negative impact from foreign exchange, using mid-January rates.

Longer term, Merck continues to expect strong revenue growth driven by growing demand for our innovative products. When looking out to 2024, we believe our revenue growth potential is under-appreciated, even more so as we begin to realize the benefits of this transaction. We continue to expect meaningful operating margin expansion over time.

The separation of NewCo enables $1.5 billion in pre-tax operating efficiencies, ratable over three years. While initially Merck's operating margins will decline slightly, we expect to achieve operating margins of greater than 40% in 2024, higher than Merck would have achieved as a combined company. The transaction is expected to result in $8 billion to $9 billion of proceeds from a special tax-free dividend from NewCo.

Merck's capital allocation priorities remain unchanged and we expect to maintain a very solid financial and credit profile. First and foremost, we will fund our best growth opportunities through investments in R&D, product launches and capacity expansion, and we believe the spin-off allows us to better focus on these activities. Merck's dividend will be unaffected by this transaction and we anticipate future dividend increases from the current 2020 dividend of $2.44 per share post-separation with a goal of achieving a 47% to 50% payout ratio over time. We will continue to have ample capacity for value enhancing business development and finally, we will continue to repurchase shares as a way to return excess cash to shareholders.

Turning now to NewCo's financial profile. The products represented by the new company portfolio are expected to achieve 2020 revenue of approximately $6.5 billion with an operating margin of approximately 45% as part of the Merck. As an independent company, NewCo is expected to achieve low-single digit revenue growth off of a 2021 base of $6 billion to $6.5 billion. Taking into consideration, the cost to operate as an independent company operating margins from NewCo are expected to be in the mid-30% range and increase over time. And finally, we

anticipate EBITDA margins to be in the low-to-mid 40% range in 2021 and also increase over time.

NewCo will have strong cash flows and a balance sheet position to invest in growth opportunities and expects to pay a meaningful dividend, which will be at least as competitive as any likely pure company and entirely incremental to Merck's dividend. In total, we expect combined EPS of NewCo and Merck together to initially be nominally lower than what Merck would have achieved without the spin-off, but as a result of the incremental growth that NewCo will achieve stand-alone, combined with the benefit of the operating efficiencies that Merck will realize, we expect that shareholders owning both companies will realize higher EPS within 12 months to 24 months.

In summary, we are confident that through the spin-off both companies will have strong prospects for future success and sustainable profitable growth given the clear benefits each will realize as independently operated entities including: enhanced strategic and operational focus on our key drivers to accelerate growth, improved agility to anticipate and respond to customer needs and evolving market dynamics, simplified operating models with reduced complexity and improved efficiencies, optimized capital structures and resource allocation to pursue their distinct strategic agendas, and improved financial profiles making for unique and compelling investment cases. We are excited by this opportunity to create two patient-focused growth companies and look forward to continuing to deliver significant long-term value to our patients and shareholders.

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

Roger M. Perlmutter {BIO 3077183 <GO>}

Thanks, Rob. Looking back on 2019, and in particular on our fourth quarter results, there is much to celebrate. In December, our KEYNOTE-057 data were reviewed at an FDA Oncologic Drugs Advisory Committee meeting, which was followed three weeks later by FDA approval of KEYTRUDA as monotherapy for the treatment of certain patients with high risk non-muscle invasive bladder cancer. This represents the 23rd FDA-approved indication for KEYTRUDA, broadening still further the benefit that can be expected from the use of KEYTRUDA in the urologic setting.

KEYTRUDA also gained three new approvals in Japan during the fourth quarter as combination therapy and the first-line treatment of advanced renal cell carcinoma, based on the KEYNOTE-426 study, and for the first-line treatment of metastatic squamous cell carcinoma of the head and neck either as monotherapy or when combined with chemotherapy based on results of the KEYNOTE-048 trial. The KEYNOTE-048 data also permitted approval of KEYTRUDA in Europe with a similar indication. Finally, we gained approval of KEYTRUDA in China for the treatment of metastatic squamous cell carcinoma of the lung, in combination with chemotherapy based on data obtained in the KEYNOTE-407 study.

Substantial progress was also made in the registration of Lynparza, our leading PARP inhibitor that we are developing in collaboration with colleagues at AstraZeneca. At the December FDA Oncologic Drugs Advisory Committee, a majority of committee members supported the use of Lynparza as first-line maintenance therapy for patients with germline BRCA-mutated metastatic pancreatic cancer, whose disease had not progressed for at least 16 weeks of first-line platinum-based chemotherapy. All based on data from the Phase 3 POLO trial, which demonstrated a 47% reduction in the risk of disease progression or death in the Lynparza treatment arm. FDA granted approval for Lynparza in this setting at the end of 2019.

I should also note that data from our PAOLA-1 trial of Lynparza were accepted by the FDA for priority review with a PDUFA date in the second quarter of this year. And PAOLA-1 maintenance Lynparza plus bevacizumab treatment of women with advanced ovarian cancer that have responded to first-line platinum-based chemotherapy plus bevacizumab reduced the risk of disease progression or death by 41%.

Additional file supporting the use of Lynparza in the treatment of men with mutation-selected metastatic castrate-resistant prostate cancers based on the results of the Phase III profound study was also accepted by the FDA for priority review with the PDUFA date in the second quarter of 2020. While we are clearly very active and advancing new cancer treatments during the fourth quarter, we also made important progress in other areas. For example, in the management of highly resistant bacterial infections, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion for RECARBRIO, our novel combination of imipenem, cilastatin, and relebactam for the treatment of infections due to aerobic gram-negative bacteria with demonstrated resistance to other agent. RECARBRIO is also under priority review by the FDA and the treatment of adult patients with hospital-acquired ventilator-associated bacterial pneumonia caused by susceptible organisms with a PDUFA date of June 4.

Important progress was also made in cardiovascular medicine with the completion of the Phase 2 VICTORIA study, in which vericiguat and novel guanylate cyclase activator being developed in collaboration with colleagues at Bayer, was found to reduce the composite risk of heart failure hospitalization or cardiovascular mortality as compared with placebo in patients with worsening heart failure with a reduced ejection fraction, who were receiving standard heart failure therapies.

Time does not permit me to list the many other regulatory and clinical milestones that we achieved in the fourth quarter. However, I cannot fail to note that Ervebo, the first effective vaccine against an ebolavirus, was approved by the FDA and received conditional approval from the EMA for the prevention of disease caused by Zaire ebolavirus. We have now provided more than 275,000 doses of this vaccine by experimental and use protocols to support the efforts of the World Health Organization and other agencies attempting to halt the spread of ebolavirus disease in the Democratic Republic of the Congo.

Approvals have also been obtained at certain African nations, including Burundi, Zambia and the Democratic Republic of the Congo itself, which should greatly improve the process whereby individuals at high risk can be immunized. It has taken many years to reach this important moment. My colleagues and I feel privileged who have contributed in this way in the control of an otherwise fatal diseases caused by the Zaire ebolavirus.

Lastly, I wish to comment on the spin-off of the new company that we have announced this morning. I begin with a deep belief in the power of simplification to enhance productivity. My colleagues and I have important objectives over the next few years that will leave hope, improve treatment for malignant disease and heart failure and provide vaccines that reduce suffering from infectious diseases. Simplification of our corporate structure can only sharpen our focus on these critically-important programs. I have confidence that we can achieve this increased focus internally, while providing the near-term support necessary to implement NewCo to establish itself as a highly effective separate entity.

I'll now turn the call back to Ken.

Kenneth C. Frazier {BIO 1391636 <GO>}

Thank you, Roger. And before turning the call over to Kevin, I'd like to take a few minutes to share with you some details on his background. Kevin brings a wealth of knowledge to NewCo based on three decades of pharmaceutical and commercial experience at Merck. His experience ranges from leading different regions, including our entire International Human Health business and the emerging markets region to leading markets such as Germany and Turkey. Most recently, Kevin has been instrumental in evaluating Merck's options to optimize the entire Human Health portfolio and in envisioning what success looks like for NewCo while providing invaluable counsel to me and the rest of the senior management team. I'm confident that under Kevin's leadership NewCo will reach its full potential and drive greater value for patients, shareholders and employees.

And with that, I'd like to turn the call over to Kevin.

Kevin Ali {BIO 17730029 <GO>}

Thanks, Ken; and good morning. I'm excited to share with you today the creation of our new company, which we believe has a remarkable opportunity to unleash the potential of a leading portfolio of assets in Women's Health, a rapidly-growing Biosimilars business and a portfolio of trusted and medically important Legacy Brands.

NewCo revenue was expected to be flat to declining through 2024 within Merck due to limited investment and focus. However, we believe that by allocating the appropriate resources and by focusing management attention, NewCo will achieve sustainable growth and create value outside of Merck. Although revenues are expected to decline in 2021 versus 2020 to a base of approximately $6 billion to

$6.5 billion, largely due to the loss of exclusivities of ZETIA in Japan, and NuvaRing in the US, the new company will be well-positioned to achieve low-single digit revenue growth off of that base. As no new LOEs loom and we have identified lifecycle management and commercial investment opportunities, some already underway.

NewCo will have a strong global scale and geographic diversification. And as a standalone entity, will be better positioned to capitalize on attractive opportunities across this portfolio. NewCo will pursue global leadership and sustainable growth in women's health through its growing contraceptive and fertility business, including NEXPLANON, which grew 14% in 2019 and is the leading implantable long-acting reversible contraceptive worldwide with US patent protection through 2027.

In fact, we expect NEXPLANON to be our first $1 billion women's health product. The growing $40 billion women's health market is highly fragmented with over 400 products in development industry-wide. NewCo will be well-positioned to capitalize on this attractive market opportunity to become an industry leader through investments in both organic growth and business development opportunities and to deliver better and more innovative and holistic care to women. NewCo growth will also be driven by our biosimilars business in the early stages of a long-term growth opportunity with three products currently on the market through its partnership with Samsung Bioepis.

Revenues of the three currently marketed products are expanding rapidly and were approximately $250 million in 2019. NewCo is well-positioned to benefit from increased biosimilar demand as markets around the world continue to seek healthcare cost savings through greater biosimilar adoption in a growing market.

The women's health and biosimilar businesses will represent a larger proportion of NewCo's revenues over time and are expected to account for more than 50% of sales by 2024. NewCo will also have the opportunity to realize the full potential of its portfolio of globally trusted Legacy Brands to increase focus and targeted investment. Importantly, the infrastructure and cash generation within this broad portfolio provides a scale, geographic reach and capital to support the growth opportunities that the women's health and biosimilar business is present.

In addition to its strong product portfolio, NewCo's global scale and geographic reach will serve as an important competitive advantage. The company will have the capability to potentially commercialize and distribute for other innovative industry players. Finally, NewCo will be a highly profitable with stable and strong cash flows. As a standalone company, it will be able to make the capital allocation decisions that best suit its long-term interests, including organic and inorganic growth opportunities, paying a meaningful dividend, debt pay-down or returning cash to shareholders through share repurchases.

In summary, I'm very excited about the future of NewCo and the opportunity to work with Carrie Cox. This company will have a distinct opportunity to address the health

needs of women around the world and to build off of important growth pillars such as NEXPLANON, pain and dermatology and biosimilars. As a focused company with dedicated resources, a strong global footprint, and talented and experienced employees who embody the shared values of the Merck culture, NewCo will be better positioned to create value for patients and shareholders.

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

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Kevin. We recognize today's upfront comments ran longer than normal. So we're prepared to extend the call beyond 9:00 AM, if necessary. So, Carlo, will you please line up the queue for Q&A.

Questions And Answers

Operator

Thank you, sir. (Operator Instructions) Our first question is from Chris Schott from JPMorgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much for the questions. Obviously a lot of news there today. I just had two really both related to the spin. I guess first on this, you mentioned you've been considering deal like this or some structure for these assets for quite some time. I guess, why now on the timing, is there something that's either happened with the business or the pipeline that made this -- make particular sense now versus, I guess, when you've looked at this in the past?

And my second question is I just want to make sure I'm understanding the $1.5 billion in operating synergies correctly. Should we think about that as a net reduction in OpEx relative to what the combined company would have spent or is that savings that goes to the main co and should be balanced against some of the stand-up costs that you're referring to with the NewCo? Thanks very much.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Okay. So, this is Ken Frazier. Let me start with the why now. Reason why we're doing this now is that our fundamental and financial strength, which has been driven by the focus on our best opportunities for growth allows us now to do what strategically correct for the Company in the long-term. This is about taking actions today that will serve the long-term growth and viability of Merck, as well as allowing products that no longer fit into our strategic framework to prosper in a new organizational structure.

So from our standpoint, this is the right time. A few years ago when we were looking at this, we saw the opportunity, but for example, the cash flow generation of our Legacy Products was being employed at that time and standing up our oncology

business from which we grew from the ground up, and as you know, has been extremely successful. That success has been due to our ability to allocate capital to a business that we didn't have before and getting the entire organization focused and aligned around an opportunity that we had around KEYTRUDA and other compounds behind KEYTRUDA.

So that is why we can do it now. And I said before, we are confident about our long-term growth prospect, and one of the ways in which we try to manifest that is by saying we will maintain and grow the dividend on the Merck side irrespective of losing these brands.

A - Robert M. Davis {BIO 6955931 <GO>}

Good morning, Chris. On your question, so the way you should think about the $1.5 billion of operating efficiencies, our incremental cost savings in Merck after the spin-off is completed the stand-up costs that are required to support the new company are really contemplated if you take the fact that we commented that there's 45% operating margin for the new company within Merck and it goes to 35% roughly mid-30s after the stand-up that 10 percentage point delta is really the stand-up cost. So those are not -- those are separate independent from the $1.5 billion of net benefits -- net synergies that will be joined by Merck going forward in its operating results.

Operator

Next question is from Tim Anderson from Wolfe Research. Go ahead please.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions on spin and then a science question. On the new company to be spun out, will that be doing real R&D and have its own R&D engine? When you talk about sustainable growth, I'm just wondering if probably that's going to come from genuine R&D.

And then on RemainCo, updated views on Animal Health, should we assume that this new split means that the remaining parent Merck company is even more likely than ever to keep the Animal Health in perpetuity?

And then last question is on the adjuvant IO opportunity, Roger, in my past discussions with you, you've been highly confident the PD-1s will work in the adjuvant setting, recently we saw Roche field and bladder, there has been some timeline slippage, we haven't seen any adjuvant trial timelines pulled forward, no trial stopped at an interim unlike we have with metastatic disease in the PD-1. So my question to you is, are you still highly confident that PD-1s are going to work broadly across tumor types and adjuvant?

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Tim. Kevin, on the research and development capabilities of NewCo.

A - Kevin Ali {BIO 17730029 <GO>}

Thanks and good morning, Tim. Yeah, the NewCo will have a high quality development capability, and it's really well-positioned to the partner of choice for other biopharmaceutical innovators, who are looking to realize commercial growth through our global scale and presence in selected international market to increase patient access. Over time, the NewCo will build a research capability in selected therapeutic areas, starting with women's health as a core pillar of its business development strategy and then will move further from there.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Tim, on to your question about Animal Health, I'll start by saying, we never say what's going to happen in perpetuity, because we regularly review our entire portfolio and make decisions about which parts of that portfolio belong in our portfolio and which ones would be better off. As we look at Animal Health, we believe, if you look at its growth, if you look at its profitability, we continue to believe that we are in effect advantage owners of that business going forward. We also believe that that is an important key growth pillar that actually helps us in the long run. As you know, there are ups and downs in the pharmaceutical business and having a business like vaccines having a business like Animal Health gives us the long-term stability that actually allows us to confidently pursue our R&D mission.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Tim, on the question of the immuno-oncology in the adjuvant setting, I can't speak generally about PD-L1 and PD-1 antagonist, but I can talk about KEYTRUDA. First of all, KEYTRUDA is already effective in the adjuvant setting as we've shown in melanoma. And we also showed the effects in the neoadjuvant setting in breast cancer in the I-SPY 2 study and as well in the 522 study most recently, and that is a combined neoadjuvant/adjuvant study and we'll be seeing the adjuvant data in not too long time.

And you shouldn't really expect adjuvant data to be pulled forward, because by definition, patients who are receiving adjuvant therapy are patients who have better overall survival over a longer period of time. So unexpected to see those adjuvant results rollout with a -- more defined cadence and I think that's exactly what we'll see and I -- based on our success in two prior settings, I would think KEYTRUDA should be as successful in these settings as well. In general, it works better when used earlier.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please, Carlos.

Operator

Next question is from Steve Scala of Cowen. Go ahead please.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you very much. One of the concerns investors have with Merck is the view that its outlook is heavily dependent on KEYTRUDA and formation of NewCo would seem to increase this risk and concern. So Merck appears to not agree that this is a concern, and I'm wondering if you can elaborate on why. And then second, what was the rationale for leaving JANUVIA within Merck as opposed to NewCo? It seems placing JANUVIA within NewCo would have made Merck's outlook appreciably clear going forward. Thank you very much.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Well, let me start on the JANUVIA question. We continue to believe that our diabetes franchise is going to be an important contributor to Merck now and into the future. We are also continuing to do significant research in the whole cardio metabolic area. So that's an area of focus for us going forward. In terms of the issue around KEYTRUDA concentration risks, we are mindful of that. We think KEYTRUDA revenues as a proportion of total revenues only increased by small amount because of this. I think the most important thing that I would say about KEYTRUDA is that right now we continue to see the benefits of our focus both in terms of R&D and commercial execution.

Going forward, we see it as driving more growth going forward for the Company, but we also see the benefits of our other opportunities in oncology, we have more than KEYTRUDA we have Lenvima and Lynparza we also have 20 molecules behind that. We also have our vaccines business, hospital and specialty business. So we are looking to optimize our entire portfolio and augment our pipeline through business development, that's how we see our future growth, not so much these brands, which, as Kevin said, left to their own would probably decline more steeply than they are in the NewCo.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Rob, anything to add?

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah. Steve, just to kind of build on your point about why JANUVIA in Merck as opposed to NewCo, as we looked at it, clearly, we continue to benefit from the fundamental cash flow and strength of that business gives, while it's not a growing business facility generating a lot of cash flow. But in the near-term as we approach LOE we'll continue to be important for Merck. This is an important brand for us and frankly, if you look at the NewCo company, while the loss of exclusivity to Merck frankly does not affect our ability to deliver growth as we've already commented, even through the loss of exclusivity in 2023-2024, we grow each and every year through that period. So we're able to absorb the loss of exclusivity benefit from the cash now that type of the cliff would be insurmountable to the new company. And then finally, and Roger can comment on it in more detail, but we continue to do some pretty interesting science in the cardio metabolic area and feel exciting opportunities are there. And so, continue to see from a scientific perspective a fit as well for all those reasons, we felt keeping it within Merck made more sense than moving that over to the NewCo.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks. Next question please, Carlo.

Operator

Next question is from Andrew Baum of Citi. Go ahead please.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. Couple of questions please. Firstly, you initiated your islatravir oral combination trials. Is there any possibility within that and being able to differentiate your combination versus (inaudible) on the back of lesser weight gain given the absence of an integrase inhibitor and whilst you're waiting for the long-acting trials to complete does that provide any kind of commercial advantage.

And the second question relates to TIGIT. One of your competitors, Roche, had indicated they're opening a Phase 3 program. They've already run a head-to-head data in combination with that PD-L1 and non-small cell lung. I know that you have a program ongoing and have had for some time. Could you talk to your relative levels of excitement with the molecule and perhaps give us some timelines and when it may be able to enter registration trials? Thank you.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Great. Thank you, Andrew. First of all, with respect to the islatravir combination, the reality is we really have to wait for the data. I think that we are very confident in the behavior of islatravir which we've demonstrated through our reasonably large Phase 2 studies and also (Technical Difficulty). It's a terrific molecule, it behaves extremely well. How it will behave with this in combination study, we have pretty good evidence that indicates to us that it will be a leading combination and especially valuable in treatment. We also know islatravir either by itself or potential in combination is a good preventive regimen. But we need to see the data from all of those and that's what we'll be getting.

And with regard to what I call TIGIT, we do have a program and we have been working on this for some time. We have studies going on where we had tried to ask the question of whether this molecule in combination with KEYTRUDA behaves better than KEYTRUDA alone and is there any circumstance under which it can be used. We recognize that KEYTRUDA is a very impressive compound in the whole variety of different settings that we have to find the right place in which to use it. So we're enthusiastic about it and we're moving forward.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Roger. Next question please, Carlo.

Operator

Our next question is from Louise Chen of Cantor. Go ahead please.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thanks for taking my questions. So my first question to you is that you noted in the call that you are more confident than consensus on every metric through 2024. I was wondering if you can elaborate more on what you think the Street is missing here. And then second question is just on KEYTRUDA in Japan. Curious, what kind of impact you assume for price cuts this year for KEYTRUDA in Japan and is there another potential price cut coming? Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah. Louise, this is Rob. Thanks for the question. Really, if you look at the comments that Ken made, he said we feel confident that the Street under-appreciates our revenue, our operating margin and our EPS growth as we look forward through time. And if you look at it in the components, clearly on revenue, we continue to believe all of our growth pillars have meaningful growth opportunity, and in most cases, continue to be under-appreciated across oncology platform within the vaccines platform given GARDASIL and Animal Health, just to name a few.

So that story, which we've been talking to you about over the last several quarters continues. And then, as you look beyond that, clearly with the spin-off getting up to 1 percentage point improvement in our growth rate as a result of the spin itself that's even further growth, it's not appreciated, not to mention the fact that we think through core focus and really directed efforts by our leadership team, we can drive even faster growth. So that is an important part as well.

And then, as you look at operating margin, today, we've indicated that by 2024 or in 2024, we expect operating margins now as a result of what the spend enables, which enabling $1.5 billion of incremental cost efficiency on top of the already improving natural mix we've been benefiting from in our business. We're going to achieve an operating margin of greater than 40% in 2024 and if you take that acceleration in operating margin combine it with potentially accelerated EPS, when you think about us deploying to $8 billion to $9 billion of proceeds from this transaction, it puts us share repurchase for instance we can get further acceleration.

So as you look out into 2024, that's why across those select factors, we believe the Street under-appreciates revenue, under-appreciates operating margin under-appreciates the EPS growth.

A - Peter Dannenbaum {BIO 20569031 <GO>}

And Frank, on the Japanese price cuts.

A - Frank Clyburn {BIO 20654315 <GO>}

Hi, Louise. It's Frank. In Japan, we did see or we will be seeing, I should say, in February of this year, a huge sales repricing of 17.5%. We've seen significant strong performance based off of our lung cancer indications in Japan and because of the sales projection, February we'll see the price reduced 17.5%. It's also important to note that we will face another significant reduction in April. That significant reduction

is going to be within the same range as the first cut in February. Important to note, that will have an impact likely on our Q1 results in Japan. But also as we take a step back, when you look at the rollout of renal cell carcinoma and our other indications in Japan, we do believe despite the price cuts over time we will be able to grow in Japan. And then I want to reinforce that if we elevate outside of Japan, we still see very significant growth in 2020 and beyond as we continue to roll out many indications globally, very strong uptake we're continuing to see in Europe, and as Roger mentioned, we now have 23 indications in the US. So we feel very good about our outlook for KEYTRUDA, clearly the Japan repricing will have the near-term impact in Japan with confident as we go forward.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please, Carlo.

Operator

Next one is from Umer Raffat of Evercore. Go ahead please.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my questions and I'd appreciate you bearing with me a little bit on it. I guess, let me start with this, a simple one, which is, can you confirm that the standalone EPS goes down by about $1? That's first.

Second, if I add up Women's Health, cardiology and diversified, that's about $6 billion, which is roughly what you're saying is what's being divested to the NewCo. But if the goal is to focus on the innovative and pharma in the RemainCo, I notice there is a $5 billion line for your other pharma, which is not being included. And I'm curious why that is.

And finally, I think, it's very interesting that you're not doing a split. You're doing a spin, very specifically, and I also noticed when you talk about the proceeds you're mentioning biz-dev before you mention share repurchase. So it almost seems to me that there might possibly be interest in replacing that lost dollar. So my question is, are you looking at a company which is more on the pipeline side, or is the focus more on a accretive deal which gets to that dollar EPS back immediately? Thank you very much.

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah. Thanks for the question, Umer. So if you look at, thinking about what is the subtraction, if you will, away from Merck by pulling out this business, and I know the math you're doing to get to roughly $1. The only thing I would advise you on is, I don't think you're giving any credit for the operating efficiencies, the $1.5 billion which we said we will get ratably, so that's $500 million even in 2021, the first year, which is I think where your math is coming from. And you're not giving any credit to what we're doing with $8 billion to $9 billion of cash proceeds. But if you deploy that to share repurchase, in reality, is that dollar you're quoting then goes down to $0.60,

$0.70 in the range. So thinking of in terms of percentage, you're closer to 15% and we believe the answer is probably closer to 10%.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Umer asked as well what's included in NewCo?

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah. So if you look at the other line, the other pharma line picks up a lot of our hospital and specialty products and fixed-up products like Zerbaxa which is still early in its launch, but a product which we are very excited about. So as we looked at the portfolio, those products that are sitting in the hospital specialty space are ones that we continue to believe long-term, create value for us and we wanted to maintain and then there is other to be launched revenue numbers sitting in there or products that are smaller in there as well. So it really is a profile products different than what we put into the NewCo and are very aligned with the core growth drivers that we've already identified.

A - Peter Dannenbaum {BIO 20569031 <GO>}

And then I think Umer's last question was capital allocation priorities, combined with a question about what our interest in BD might be. So let's start with Rob and then turn it over to Ken.

A - Robert M. Davis {BIO 6955931 <GO>}

So if you look at the capital allocation priorities, they really remain unchanged. First and foremost, we're going to ensure we appropriately fund research and development, we're going to fund the opportunity to launch new products and we're going to fund the capacity expansion that we have underway to ensure we have the capacity to meet what is very strong demand across all of our growth pillars in Vaccines, oncology and Animal Health. We will remain committed to the dividend. We've talked about that you heard today, very importantly, we are not lowering the dividend as a result of the spin-out of NewCo, we're going to hold our dividend at $2.44, which it is in 2020 and then grow it off of that base with a goal to get to 47% to 50% as a payout ratio.

So you're actually going to see a maintain dividend, growing over time and then you have the benefit of the incremental dividend that NewCo is going to have. So all-in-all, you should have overall more dividend if you hold those stocks than we do today. And then finally, as we've always said, our goal is to use excess cash flow first and foremost for value creating business development, to the extent that we can't find those or we don't find ones that bring us the combination of strategy and value.

We will return excess cash to shareholders moving forward. And specifically, as you look at the $89 billion of special dividend where we're going to receive from NewCo as a result of this transaction, as we said in the comments, it will be deployed either to business development or to share repurchase it will not be used for debt pay down, and that's why I believe it will be accretive over time.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Umer, this is Ken. I think, you also asked about spin versus split. We still spin because we thought that was the quickest path in a tax efficient way of doing this for our shareholders. As it relates to business development, I'll just say, as we've always said, it's an important priority and first and foremost, we are always looking for the best science and innovation that will drive long-term growth and value for shareholders. So we're still very much focused on those deals that augment our pipeline and you saw last year, we did a number of deals, about 80 transactions spanning licensing, technology deals and clinical collaborations. We'll continue to look for those opportunities to augment our pipeline with the best science.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Next one is Geoff Meacham of Bank of America. Go ahead please.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, everyone. Thanks for the question; just have a few. Rob, on the spin, I get the operating margin benefit to Merck longer term, but did I hear you right that op margins to be lower this year in post-spin initially and then with freed up capital, there is a spin effect where you guys have previously discussed on the moderation of R&D investments looking to 2021-2022. And then, Frank, real quick, can you talk about the growth strategy in China for IO at this point with the NRDL decision in first-line lung? I know, you guys just got approval in this indication November. Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

Geoff, thank you for the question. So on your question about operating margin, if you look at what's NewCo is within Merck today is about 45%, so it's obviously higher than Merck's operating margins. So it will be initially nominally dilutive when we pull it out in the first year. But importantly, because of the fact we are getting the operating efficiencies started even in the first year of $500 million and then growing with an additional $500 million in year two, another $500 million in year three. So cumulative $1.5 billion, that offsets a lot of that dilution. And so net when you look at it, it's only about 1 percentage point of dilution to our op margin in the first year and then very quickly, you're going to see our operating margins continue to grow. And by the time we get to over 40% by 2024 we will be at a rate higher than we would have achieved as a combined company, largely as a result of that $1.5 billion operating efficiency. So -- and the then that was I think the first question.

The second one was what's happening with, I think, R&D as we look at going forward. So we have never been capital constrained in what we're doing. R&D, what's driving the inflection point, we've talked about which is the slowdown of growth in R&D in 2021 as a percent of sales, it's still going to grow, it's going to grow, it's just going to grow slower than sales in 2021. That inflection point is driven more

by where we see the clinical programs at this time, if we find opportunities to invest and I'm confident given the productivity that we've seen from the labs this far, but they very well might do that. We will obviously increase our investment as those opportunities present themselves. But as of right now, our expectation is that inflection point continues to happen in 2021.

A - Peter Dannenbaum {BIO 20569031 <GO>}

And Frank?

A - Frank Clyburn {BIO 20654315 <GO>}

Geoff, in your question on China, first, I wanted to make sure that we do mention that our primary focus is on ensuring the safety of our employees' families and supporting the people of China. I think that's on all of our minds and also the continuity of supply of our human health medicines and vaccines and products. And we're going to have to see how China evolves, we'll likely see some impact in Q1; too early to quantify.

As far as your specific question on IO, our overall strategy as we've discussed in particular as we rolled out in the self-pay market, we still feel very confident on our position. We are still the only IO therapy that's approved in non-small cell lung cancer. We recently got approval for KEYNOTE-407 in the squamous cell carcinoma population and we feel as though we have a very significant opportunity in the self-pay market. And we've also adjusted our patient assistance programs in China to increase the affordability for patients that we're trying to provide access to as we move forward. So we feel confident going forward in our growth prospects for KEYTRUDA in China.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please, Carlo.

Operator

Next one is Seamus Fernandez of Guggenheim. Your question please.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thanks for the question. So maybe just a follow-up on one of Steve's questions. The concentration of the business, Merck's business to KEYTRUDA going forward; can you just talk a little bit about the competitive pressure points that could emerge going forward? You talked a little bit about China, but there also are potential Chinese assets that could be introduced into the US following successful lung cancer clinical program. Just trying to get a better sense of the growth opportunity for KEYTRUDA and where you see potential pressure points.

And if you could also comment on some of the administration efforts around international pricing, again, a potential risk point for KEYTRUDA, that would be helpful.

And then just as a follow-up on for Roger; Roger, how quickly -- the Company emphasized a lot of vaccine opportunities for the business going forward, but most of them are Phase 1. How quickly could we see some of those programs advancing and potentially coming to market and maybe you could just tell us which one or two you're most excited to see in the near-term? Thanks.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great, thanks. So first, Frank, kind of the performance and outlook for KEYTRUDA.

A - Frank Clyburn {BIO 20654315 <GO>}

Yeah. So on KEYTRUDA, as far as we -- if we look back at 2019 we're one very pleased that our growth of 58% excluding exchange and almost $4 billion and eclipsing $11 billion in sales. We feel very well positioned as we've been saying with regards to KEYTRUDA, not only with regards to our significant penetration in non-small cell lung cancer within the US, but also the significant impact that we're having for patients with renal cell carcinoma adjuvant melanoma head and neck, as you heard Roger mention are recent approval non-muscle invasive bladder cancer. So the breadth of our indications and the strength of our data gives us a lot of confidence to continue to grow. In particular, not only in the US, but ex-US and is especially as we roll out our broader indications in non-small cell lung cancer and we're now reimbursed in Europe in all markets for lung, which I see is an important aspect of our growth in 2020.

The other thing I would add on the concentration piece too. I think we tried to highlight, this is not just about KEYTRUDA it's Lynparza it's Lenvima, it's our pipeline in oncology that we've discussed. We also feel very good about our vaccine performance this year. Gardasil this year grew 21%, as well as our hospital and specialty products, we continue to see good growth with Bridion. So from a concentration perspective, we feel very confident on the portfolio not only KEYTRUDA, but the breadth of opportunities that we have going forward.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Okay. So on the ITI [ph] question specifically, we understand the administration's concern that certain countries don't pay their fair share of the cost of the innovation. We do keep continuing to make the point that incorporating additional price control is not the solution to the problem. We continue to work with the administration, the Congress and other stakeholders to provide a perspective. I think patient groups are also providing very strong perspective on these issues as it relates to that.

But if you take a step back and think about what we announced today, the reason why we're taking these kinds of proactive steps now is because we want to make sure that we position the company for long-term growth and viability in the future environment, that's about being much more focused on innovation and it's about driving efficiency within our operating model. So this is about staying ahead of the curve rather than waiting until something happens in the pricing environment that we have to react to.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Seamus, thanks for the question. On vaccines, I mean, first of all, as you recognize, we have an enormously large program in (inaudible) program having 15 Phase 3 studies that are rolling out over the next 18, 24 months. We're going to see a lot of those studies coming this year, in fact. And so you will be hearing a lot of data from those studies, which will ultimately permit filing. So that's a very near-term opportunity. We have a lot of enthusiasm about our dengue virus vaccine, that vaccine is -- we are collaborating with colleagues at Butantan, where they have a registration-enabling study ongoing and that study will deliver results at some point.

So that's pretty exciting as well. In addition, of course, we have our CMV vaccine. We have a lot of interesting things going on respiratory syncytial virus and those programs are actually fairly advanced. So things are moving along quite well. I can't fail to mention the fact that the demand for Gardasil 9 remains enormous and we have invested a huge amount of capital together with our manufacturing colleagues and building the additional capability to meet that demand and that will be rolling out in not too longer time and it will be very important obviously for the company.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. We have several more questioners in queue. We're going to have a hard stop at 9.15, but we're going to keep going. Next question please.

Operator

Next one is from Daina Graybosch of SVB Leerink. Go ahead please.

Q - Daina Graybosch {BIO 20659414 <GO>}

Hi. Thanks for the question. Two of them. First on NewCo; what do you see as the long-term relationship between NewCo and Merck? And then the next question for Roger, as you reflect on all the internal and external immuno-oncology data that came out in 2019, what novel mechanisms are you most excited about, to add on top of KEYTRUDA to provide further benefit for patients?

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Well, in terms of the long-term relationship that's to be decided as both companies look to the future and decide how they want to make sure that they optimize their best opportunities. So I can't say anything other than what we've announced today in terms of the products that are going over, but obviously what I would say about NewCo that makes me excited is I think they will have many of the same standards and values that Merck has going forward.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

Yeah. Thanks for the question, Daina. In many respects, so things we're most excited about, you can tell by looking at the things that we're investing in. You can see that quite remarkably the Lenvima and as it's been demonstrated in the endometrial

cancer registration combination with KEYTRUDA most recently. But we've also seen really spectacular data in renal cell carcinoma, we presented those Phase 2 data, and we have ongoing Phase 3 data demonstrate that the protein tyrosine kinase inhibitors with special characteristics can combine very effectively with KEYTRUDA.

We also have data which we presented in combination with Lynparza that are very impressive. Let me have this very large set of new molecules, which some of which we prefer to already that include antibodies directed against other potential checkpoints Lag-3, TIGIT and a whole bunch of other things and there really are quite provocative data available now already in those settings. We're hopeful that we'll begin to tease out how best to use those things in combination. So a lots of exciting things going on here.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Right. Next question please.

Operator

Next one is from David Risinger of Morgan Stanley. Go ahead please.

A - Peter Dannenbaum {BIO 20569031 <GO>}

David, are you on the line?

Q - David Risinger {BIO 1504228 <GO>}

Sorry. Yes. Can you hear me now?

A - Kenneth C. Frazier {BIO 1391636 <GO>}

Yes.

Q - David Risinger {BIO 1504228 <GO>}

Great. So I have a few questions. First, could you provide an update on where GARDASIL manufacturing supply stands and the GARDASIL revenue growth prospects in 2020?

And then, Roger, could you discuss potential proof of concept results for Merck's early-to-mid stage pipeline to watch in 2020. And in addition, could you provide a framework for the timeline for the second pneumococcal vaccine that Merck is developing for infants, which would be added to V114 to offer broader coverage longer term? Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. I think, the first question is on GARDASIL supply and outlook. So Frank?

A - Frank Clyburn {BIO 20654315 <GO>}

Yeah, Dave, so with regards to GARDASIL, we do continue to see very strong demand around the world. Currently our supply is not able to meet that demand. As we mentioned, we saw a growth of 21% this year. The growth we do believe will continue in 2020 will be slightly tempered from the rates you've seen in 2019 and 2018. And we're focused with our manufacturing colleagues to do everything we can with contract manufacturers in the near-term to try to help our supply. And then ultimately, in 2023 as we've been mentioning we'll be bringing on two new bulk manufacturing facilities that will really allow us to ramp our supply up to meet the strong demand that we're seeing globally.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

So, David, on the early-to-mid stage pipeline, well, we've already discussed that earlier in a lot of programs in for oncology in combination with KEYTRUDA, but we have a lot of other areas as well that are moving forward. Of course, building on the results of (inaudible) in heart failure, the Phase 3 data which will be presented in the results for the near future and which are quite interesting. We actually have a lot of other interesting things going on in soluble guanylate cyclase activators. So that's an important area for us and something that we expect to see quite a lot of data on. And we're going to be seeing a lot of data on of course our vaccine programs that I mentioned just a few minutes ago.

So there will be a lot of data coming forward in 2020. And speaking of vaccines, you mentioned the additional vaccine program. I think you were referring to V117 in the pediatric context, which is not an add-on, but a separate and independent vaccine all by itself. And that program, which we just given the name to, will be moving forward shortly. We emphasize that the V11 core program is very far advanced with lots of Phase 3 data coming forward this year and next year and will be a leading program in both adult and pediatric settings, ultimately V116 and V117 will provide further coverage, so more to discuss there.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Next question please.

Operator

Next one is from Terence Flynn of Goldman Sachs. Go ahead please.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Good morning. Thanks for taking the questions. Just maybe a couple on the spin as well. Does this change at all how you approach M&A and business development from a timing perspective. Just wondering if we shouldn't expect any sizable bolt-ons until after the spin's completed. And then are there any tax rate implications that we need to consider. And then any update on the path forward for KEYTRUDA in neoadjuvant breast cancer regarding discussions with FDA and then when can we expect your Phase 3 frontline data and metastatic triple-negative breast and is that important in terms of the conversations with the regulators? Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Okay. I think we'll start with Ken and the timing of BD and our strategy around that.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

I expect to see no change in our approach to BD from a timing or strategy standpoint as a result of the spin. We still see the need to augment our pipeline going forward, and we see opportunities and we're going to be very focused on that.

A - Robert M. Davis {BIO 6955931 <GO>}

Yeah. And I would add to that point and then I'll address the tax question. As I said in the prepared remarks, but it's worth reemphasizing, we will have ample capital to do anything we want to do. So this also in a way constraints us from a capital perspective. But with regards to the tax rate, generally speaking, you should not see any meaningful change to our tax rate as a result of this transaction.

A - Roger M. Perlmutter {BIO 3077183 <GO>}

In terms with respect to neoadjuvant breast cancer triple-negative breast cancer of course the 522 data we presented at ASMO, the effective neoadjuvant in that setting, in terms of pathologic complete response is very clear. And we also had very provocative event-free survival data that we discussed. There is more data that will be coming forward in that and we continue to have conversations with regulatory agencies about that study. And you're right as we have an ongoing Phase 3 study in triple-negative breast cancer that could yield data in principle that would have an impact on thinking with regard to the neo-adjuvant study, but of course we have to wait to see the data. So that should be coming forward sometime relatively soon as well. It's event-driven, of course. I don't know exactly when.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. We're going to squeeze in one last question please, Carlo.

Operator

Last one is Mara Goldstein from Mizuho. Go ahead please.

Q - Mara Goldstein {BIO 2458369 <GO>}

Great. Thanks very much. Just a quick question on the NewCo spin-off and the targets around achieving an R&D organization and how should we think about that from a metric perspective. And then, just quickly on China, I know we've covered it, but Merck has spoken to China as a component of growth strategy on a go-forward basis and understanding that KEYTRUDA has been a part of that, but Merck has other portfolio of products in China. So I'm wondering how much of NewCo's business is responsible for the growth in that region and how RemainCo will be able to advance its growth initiative in the absence of NRDL listing, which didn't occur as expected?

A - Peter Dannenbaum {BIO 20569031 <GO>}

So the first question I believe was on R&D metrics around NewCo. Rob or Kevin, I don't think we have much to add there at this point.

A - Robert M. Davis {BIO 6955931 <GO>}

Clearly, I would just say that as we think about the 35% operating margin, growing over time that contemplates investments in research and development in the business. And so it is fully covered there is an assumption that they will be doing R&D moving forward, and we feel like it's been adequately covered in a way we resourced these investments in the business and -- Kevin wanted to add anything about R&D.

A - Kevin Ali {BIO 17730029 <GO>}

I think just to recap what we said earlier, that over time will build more of the research and development capabilities as we start to do meaningful business development and start to see opportunities to start to do development.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. And the second question, China growth.

A - Kenneth C. Frazier {BIO 1391636 <GO>}

With China, as we discussed and we're very pleased with the growth this year of 58%. And our growth, to your point is very broad-based, it's KEYTRUDA, it's GARDASIL, it's Lynparza, it's Lenvima, it's our innovative portfolio has done very well JANUVIA is on the NRDL (inaudible) was recently placed on the NRDL. So we see our growth going forward in China and we see significant opportunities, obviously, as I mentioned, we're all thinking about the coronavirus, we'll have to see how that unfolds, but nothing has changed in the mid-to-long term about our opportunities in China. Okay. Thank you all for joining us today. As I said in our third quarter call, we are confident that we're not complacent and this separation is evidence of just that. We are convinced that the decision is the right one for the business and we believe that now is the right time to capitalize on a position of strength to secure even stronger future for Merck. As a more focused research-intensive biopharmaceutical company we'll be better positioned to carry out our mission of inventing to save and improve lives and drive lasting value for the patients and shareholders we exist to serve. Thank you very much.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thank you all.

Operator

Thank you. This concludes today's conference call. Thank you all for attending. You may now disconnect.