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MRK - Q3 2019 Merck & Co Inc Earnings Call

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OVERVIEW:

Co. reported 3Q19 total Co. revenues of $12.4b and non-GAAP EPS of $1.51. Expects 2019 revenues to be $46.5-47.0b and non-GAAP EPS to be $5.12-5.17.

CORPORATE PARTICIPANTS

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PRESENTATION

Operator

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

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

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

Thank you, Jerome, and good morning. Welcome to Merck's Third Quarter 2019 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; and Dr. Roger Perlmutter, President of Merck Research Labs, who will each have prepared remarks.

In addition, I'm also joined by Mike Nally, our Chief Marketing Officer; and Frank Clyburn, our Chief Commercial 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 costs and certain other items. You should know that we've 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'd 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 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.

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

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

Thank you, Peter. Good morning and thank you all for joining the call.

We're extremely pleased by the performance of our business this year. Execution both in the Merck Research Labs and in our commercial operations has been exceptional and Merck, again, achieved one of its best quarters in many years. This success reinforces our belief that our science-led approach and the significant focus and resources we are putting into innovation is the right strategy and the best path towards delivering meaningful and sustained value to our patients and shareholders.

As we highlighted at our Investor Day in June, we have good visibility into the growth of our derisked portfolio of innovative products over the next 5 years. We are also confident that the investments we are making now in cutting-edge science focused on areas of significant unmet medical need, from discovery through late-stage clinical development, will help us deliver breakthroughs over the next decade and beyond.

Notwithstanding the strong momentum we are seeing in our business, we will continue to prioritize business development aimed at supplementing our portfolio and strengthening our pipeline, and we are very happy with additions of Antelliq, Peloton, Immune Design and Tilos this year.

We are realizing the benefits of focusing on our key growth drivers and are now operating from a position of strength. With that said, we're also mindful of the changing industry landscape.

At Investor Day, Rob spoke about our efforts to best position Merck for the future by becoming a more focused, innovation-driven company. In order to realize this vision, we are evolving our operating model, driving productivity across our operations and looking for ways to optimize our human health portfolio, all in an effort to create sustainable growth.

With that, I'll now pass it over to my colleague, Rob, to review the details of our quarterly performance.

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

Thanks, Ken. Good morning, everyone. As Ken stated, the strong results we achieved across our clinical and commercial operations this quarter highlight the successful execution of our strategy to drive sustained revenue growth through innovation. As such, we remain committed to continuing to fully invest in our pipeline while also delivering meaningful operating margin expansion over time through disciplined resource allocation and improved operating efficiencies.

Now turning to our results. Total company revenues were $12.4 billion, an increase of 15% year-over-year or 16% 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 16% led by key products in our oncology, vaccines and hospital businesses.

In oncology, KEYTRUDA sales increased 64% year-over-year and for the first time exceeded $3 billion in a quarter. In the U.S, growth was driven by strong demand across all indications. In squamous and non-squamous first-line lung, KEYTRUDA continues to penetrate all eligible patient populations, including (inaudible) and non-PD-L1 expressors. The survival benefits demonstrated across our 4 first-line lung cancer trials have firmly established KEYTRUDA as the standard of care in these settings.

We are also encouraged by our recent launches in new indications. In advanced first-line renal cell carcinoma, we are seeing strong uptake across all 3 patient risk groups for which we are indicated. And in adjuvant melanoma, the positive momentum continues since our approval earlier this year.

We're early in the launch of KEYTRUDA monotherapy and in combination with chemo and first-line head and neck cancer, and we've received positive feedback from both scientific leaders and the prescribing community.

Outside the United States, KEYTRUDA sales grew 75% driven by lung globally. In Europe and the EU, we recently received additional reimbursements for KEYNOTE-189, and we look forward to bringing KEYTRUDA to more patients in those markets.

In Japan, we're seeing strong usage across all PD-L1 patient subgroups in lung, and we continue to grow our share in bladder cancer.

And in China, first-line lung is the primary driver of growth, and we are excited by the recent approval based off of KEYNOTE-042.

Our results also reflect continued strength for both Lynparza and Lenvima, important products from our collaborations with AstraZeneca and Eisai, respectively. In fact, our revenue from both products more than doubled in the third quarter.

Lynparza growth reflects further uptake in ovarian cancer based on results of SOLO-1 in the United States as well as strength in Europe, China and Japan. In the United States, Lynparza has over 60% total patient share in the PARP inhibitor class. This leadership sets us up well as we look to broaden the use of Lynparza across additional indications in the future.

Launches in hepatocellular carcinoma, particularly in the United States, China and Japan, continue to drive increased use of Lenvima. Also, we are early in the launch of the first approved combination of Lenvima and KEYTRUDA to treat certain patients with endometrial carcinoma, and we expect more approvals in the future.

Turning to vaccines. Our vaccines business reflects continued growth in our pediatric portfolio as well as strength in GARDASIL, which is primarily due to growth outside of the United States. The timing of public sector purchases negatively impacted our U.S. revenue in the third quarter.

Our hospital business benefited from 32% growth in BRIDION, reflecting strong performance in the United States due to increased share within the reversal market.

Animal Health revenue increased 12% this quarter to $1.1 billion. Livestock grew 12% due to the contributions from the products acquired in the Antelliq acquisition. Companion animal sales also grew 12% driven by our BRAVECTO line of products partially due to the timing of purchases last year.

Turning to the rest of our P&L. My comments will be on a non-GAAP basis.

Gross margin was 75.9% in the quarter, a decrease of 80 basis points year-over-year driven by unfavorable manufacturing variances.

Operating expenses of $4.8 billion increased 6% year-over-year. Higher administrative and promotional expenses for our growth pillars drove higher SG&A costs in the quarter, while higher clinical development spend and costs associated with our discovery efforts drove higher R&D expense.

Other income and expense was unfavorably impacted by lower income in our equity securities portfolio as well as higher net interest expense.

Our effective tax rate for the quarter was 15.7% driven by a lower assumed full year effective tax rate as a result of favorable earnings mix. This represents a decrease of 320 basis points year-over-year.

Taken together, we earned $1.51 per share, an increase of 27% excluding exchange.

Now turning to our outlook for the year. We are narrowing and raising both our revenue and non-GAAP EPS guidance ranges for the full year of 2019. We now expect revenues of $46.5 billion to $47 billion, which represents a 10% to 11% growth versus 2018. This includes the impact of the GARDASIL CDC stockpile borrowing, which will negatively impact our fourth quarter revenue by approximately $120 million.

Our updated revenue range assumes a negative impact from foreign exchange of roughly 2 percentage points using mid-October rates.

We are lowering our non-GAAP expected tax rate to roughly 17.5% for the year.

Our revised non-GAAP EPS range is now $5.12 to $5.17, which represents growth of approximately 18% to 19% versus 2018, including a roughly 1 percentage point negative impact from foreign exchange. All other elements of our guidance provided in July remain unchanged.

Before I conclude, I'd like to take a moment to put our 2019 results into context. Our expected top and bottom line growth rates for the full year are exceptional.

While we continue to expect strong revenue and EPS growth in 2020, there are a few things I'd like you to keep in mind as you think about your models.

First, we expect increased pricing pressure in 2020. Second, demand for GARDASIL continues to outpace supply, and we expect tempered growth rates for the product versus what we reported over the last couple of years. And third, as you'll recall, we expect to face elevated pressure mainly on Noxafil and NuvaRing.

That being said, we remain very confident in our business. We continue to expect strong revenue growth each year through and including 2023, a year where we still believe our revenue prospects are underappreciated.

In summary, our third quarter results and updated guidance are another proof point of the confidence we have in our business and our strategy. More importantly, our innovation-led approach continues to positively impact the patients we serve. As such, we will continue to invest in research and development, which we believe will be the source of significant and sustainable value for both patients and shareholders.

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

Roger M. Perlmutter - *Merck Research Laboratories - President*

Thanks, Rob.

During the third quarter, we advanced important new indications for key products, presented significant new data at scientific meetings and made meaningful progress in building our research portfolio.

Turning first to progress in oncology approval. During the third quarter, received accelerated approval from the U.S. FDA for KEYTRUDA when given in combination with Lenvima in patients with advanced endometrial cancer whose disease have progressed following prior systemic therapy and whose tumors are not mismatched repair deficient or [MSI-R].

This approval marks the first of what we believe will be a large set of opportunities that combine Lenvima we're developing in collaboration with our colleagues at Eisai in Japan with KEYTRUDA in the treatment of advanced malignancies, including hepatocellular carcinoma, non-small cell lung cancer, renal cancer, squamous cell carcinoma of the head and neck and urothelial cancer.

As noted in our press release, the FDA also accepted our sBLA filing for the use of KEYTRUDA as monotherapy in the treatment of recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation with a PDUFA date of June 29, 2020.

Separately, we also received European Medicines Agency approval for the combination of KEYTRUDA and Pfizer's Inlyta based on data from our KEYNOTE-426 study. This regimen, as Rob mentioned, is one that is gaining substantial traction in the United States.

Meanwhile, in China, full approval of KEYTRUDA for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer whose tumors express PD-L1 on at least 1% of tumor cells based on our KEYNOTE-042 study was also obtained. We are optimistic that this new indication will provide benefit to the very large number of patients in China who each year are diagnosed with non-small cell lung cancer.

Outside of oncology, the U.S. FDA granted approval for PIFELTRO when combined with other agents and DELSTRIGO as a single-tablet combination in HIV-infected patients who are virologically suppressed and on a stable regimen. This is the so-called SWITCH indication.

We believe that PIFELTRO, our second-generation non-nucleoside reverse transcriptase inhibitor, offers many opportunities for combined regimens, including with islatravir, our investigational nucleoside transcription (sic) [nucleoside reverse transcriptase] and translocation inhibitor.

Also in the infectious disease area, we obtained Phase III data in the hospital-acquired and ventilator-associated bacterial pneumonia, where RECARBRIO met its primary endpoint of non-inferiority versus the combination of piperacillin and tazobactam. Together with ZERBAXA, RECARBRIO will offer, we believe, a full suite of options for the treatment of serious bacterial pneumonias.

I'm exceedingly proud of my colleagues in clinical development and in regulatory affairs whose exemplary performance in 2019 has led to these approvals.

The third quarter also saw the presentation of important new data at the European Society for Medical Oncology, including the PAOLA-1 trial demonstrating the activity of Lynparza, which we are developing with colleagues at AstraZeneca, in this case in combination with bevacizumab for the treatment of advanced ovarian cancer in patients who had previously responded to platinum-based therapy. But we also have the PROfound trial in which delayed radiographic progression of malignancy was demonstrated in men with metastatic castration-resistant prostate cancer whose tumor cells bear homologous recombination repair gene defects. And we have progressed our next-generation hormonal ablation therapy. Studies incorporating Lynparza have now yielded positive Phase III data in 4 different tumor types: breast, ovarian, pancreatic and prostate.

Phase II trials encourage the view that the addition of KEYTRUDA to Lynparza therapy could prevent (inaudible), especially in the treatment of metastatic castration-resistant prostate cancer.

Phase III trials exploring this hypothesis are currently under way.

Also at the European Society for Medical Oncology meetings, data from our KEYNOTE-522 study of KEYTRUDA as neoadjuvant therapy for triple-negative breast cancer demonstrated a statistically significant increase in pathologic complete response rate, confirming what we have seen previously in the Phase II I-SPY 2 trial.

These data, coupled with additional results from the adjuvant portion of KEYNOTE-522, which demonstrated a trend favoring KEYTRUDA administration on event-free survival, auger well for future outcome measurements in this ongoing Phase II trial.

Time does not permit me to highlight the many advances that have been made in earlier segments of the pipeline where critical work is being done. However, I wish to note that as the third quarter came to a close, we celebrated the opening of our new discovery research facility in South

San Francisco, where we expect over a period of time to accelerate the translation of fundamental breakthroughs in biologic understanding into therapies that improve and extend lives around the world.

In this context, I cannot fail to mention that the Committee For Medicinal Products for Human Use of the European Medicines Agency has recently adopted a positive opinion for V920, our experimental vaccine designed to prevent transmission of the Zaire strain of Ebola virus.

As all of you are aware, V920 has been thoughtfully deployed to help slow the spread of a recent outbreak of Ebola virus disease in the Democratic Republic of the Congo. Our teams have shipped nearly 0.25 million doses of V920 with colleagues in the World Health Organization and other agencies, health care workers who are performing heroic work in very dangerous environments by immunizing those at highest risk for exposure to this deadly virus. They and we believe that approval of the V920 vaccine will ultimately permit routine use of this important tool to prevent outbreaks of Ebola virus infection wherever and whenever it is needed.

We will now take your questions.

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

Jerome, can you line up the queue, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of David Risinger with Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

So obviously, the results were very impressive. Congrats on the quarter. My questions are first, could you just talk a little bit about what inning Merck is in with respect to 189 adoption in Europe? My understanding is that you haven't booked any 189 sales in certain countries yet in the third quarter, but I just don't know how you would characterize the adoption of 189 in Europe to date.

And then second, Roger, could you please discuss the market opportunities and timing for KEYNOTE-604 in small cell lung cancer and KEYNOTE-355 in triple-negative breast cancer?

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

Frank, do you want to start off?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure. With regards to Europe in 189, we received reimbursement in Germany in mid-Europe. That was approximately last year. It's almost been a year when we had launched in Germany and got reimbursement. We now are very pleased that we have reimbursement in all of the major European markets. Spain just came onboard with reimbursement this past quarter, and we now have added Italy for reimbursement, which is just taking place this month, as well as France. So we are in early innings in some of the markets with regards to 189. As I mentioned, Germany and mid-Europe, we've had that product in combination reimbursed now for a while.

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

And Roger?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Right. David, look, clearly, the major opportunity in lung cancer is in non-small cell lung cancer. But small cell lung cancer is important as well, and so we are encouraged to think the [breadth] of activity of KEYTRUDA are ambiguous, and we're encouraged to believe that there will be meaningful opportunity in small cell lung cancer as well based on the 604 trial.

For triple-negative breast cancer, I mean, again, I would highlight that the KEYNOTE-522 data demonstrate a really quite dramatic improvement in pathologic complete response rate under circumstances where optimal neoadjuvant therapy is given, and the trend is really quite impressive. I mean there's a 27%, roughly, improvement in pathologic complete response; the event-free survival data had -- has a ratio of 0.63. That's really quite remarkable. And although we had set an extremely high bar there and didn't meet our statistical test at that point, as I said, it certainly augurs well for what the subsequent outcome measures will look like.

Over time, I think that will really have a big effect on the how triple-negative breast cancer is treated. And those individuals who are not treated with a neoadjuvant kind of regimen, KEYNOTE-355 offers a real opportunity. Obviously, we have to wait for the data, and we're looking forward to seeing that at some point in the future.

Operator

Our -- your next question comes from the line of Chris Schott with JPMorgan.

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

Congrats on the quarter. I guess my first question was just on operating margin expansion. I know you had previously moderated some near-term operating margin expectations based on investments you're making, et cetera, but we are seeing strong year-over-year improvement. So can we think about continued strong margin improvements as we look out into 2020 and 2021 assuming solid top line trends? Or is there another step-up of investments we need to be keeping in mind as we think about margins over the next year or two?

My second question was on GARDASIL capacity at this point. I think you noted that growth may moderate in 2020. Can you just give us a bit more color on how much capacity you have left at this point as we think about just how to kind of quantify that slowdown?

And then as a follow-up to that, longer term, can you just give us an update of when we should think about more substantial expansion of GARDASIL capacity?

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

Great. Rob, you want to start off on margins?

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

Yes. Yes. To your question about operating margins, I think what you're looking at as you see the results year-to-date in the third quarter of 2019 is really just the power of what happens when you get accelerated revenue growth. And frankly, we've seen revenue growth, as you've seen from the way we've been raising guidance for the year, is outpacing even our own expectations. So as a result of that, we have actually seen stronger operating margin improvement in 2019 than we expected.

As we look forward, we continue to see increases in operating margin every year, but our view really hasn't changed that as we look at 2020, that is still a year of investment where we do expect to continue to make sure we fully invest behind what is a growing and exciting pipeline of opportunities, both in oncology and vaccines and other areas that Roger has touched upon. And then we really do expect to see operating margin then to be more meaningful as we look in 2021 and beyond as we see the rate of R&D growth slow to rates lower than sales. So our overall view hasn't changed, 2019 is just really exceptional because of the strength we're seeing in the top line.

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

And Frank, on GARDASIL capacity?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure, Chris. And so we are seeing continued strong underlying demand, which was highlighted once again for GARDASIL, this quarter growing 27% and significant growth outside the U.S.

What we have done and put in place is we are increasing our production from our existing plants. And as we mentioned on Investor Day, we commissioned the construction of 2 new bulk GARDASIL manufacturing facilities, which we hope to bring online in 2023. So in 2023, that is when we will expect to be able to ramp our supply up to meet the ex U.S. demand.

We decided to borrow from the stockpile, as Rob mentioned in his comments, really to support routine vaccinations in the U.S. as well as to free up some manufacturing capacity to make doses for other parts of the world. So anticipate additional supply coming onboard significantly in 2023. We do believe we can still grow GARDASIL over the next several years as we continue to match and move supply to match our demand around the world.

Operator

Your next question comes from the line of Tim Anderson with Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

A couple of questions. The first is on your tax rate. You mentioned favorable product mix impacting the tax rate guidance for the year and in the quarter. Is KEYTRUDA one of those favorable mix drivers? And specifically, is it set up in a tax-advantaged way such that as this product continues to do very well, the tax rate for Merck could continue to drift lower beyond where it is in 2019?

Second question is on KEYTRUDA. Data sets starting to roll in showing that CTLA-4 has activity in lung. Data sets like Checkmate-9LA and Poseidon, you have a program in this area. When can we expect Phase III data from Merck on KEYTRUDA plus Yervoy in lung.

And then more broadly, can you just kind of comment on the market's perception and fears that we've got competitive threats coming to KEYTRUDA in front-line lung from Bristol and Astra and whether that's something that analyst models accurately capture in your view?

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

Thank you, Tim. Rob will start off with the tax rate.

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

Yes. Tim, with regard to your question, actually I think the comment I made in the prepared remarks is that it's due to favorable earnings mix. And the reason I'd just clarify that is that both are based on product mix as well as geographic mix. So it's both and it's more than just what you see with KEYTRUDA, although KEYTRUDA is produced in a tax-favored jurisdiction. So we do get benefit from seeing growth in KEYTRUDA, but it's not the only thing driving it.

I would highlight as you look at this year's tax rate, and just to remind you that in the first quarter, we did have some discrete items that drove our rates a couple of points lower. So we are benefiting from that as well. And as we look forward into 2020, we have not finalized our plans, so I'll only give official guidance. But I would just make sure you kind of keep that view in your mind as you balance your thinking around positive trend forward relative to where we are and where we've been.

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

And Roger, on CTLA-4 and maybe to Frank on the competitive dynamics.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Yes. So of course, we do expect that over time, there will be many, many different programs that will try and address non-small cell lung cancer, and it's important that, that happen. I should point out that the set of studies that we have already performed provide an enormously strong foundation for treatment of non-small cell lung cancer. When you look at monotherapy, the 024 data and PD-L1 greater than 50%, that's an extremely strong data set. Similarly with KEYNOTE-189, similarly with 407. So the platform is enormously strong, and that's what you see reflected in the market.

I think all of us are eager to understand whether anything else could be added to KEYTRUDA. But thus far, we don't have any data that really support that. Our own study, our 598 study with KEYTRUDA and ipilimumab will provide, we hope, definitive information on whether the addition of ipilimumab, CTLA-4-directed monoclonal antibody, actually improves results as compared to what is seen with KEYTRUDA alone. Now thus far, it's kind of a mixed bag from what we can see. Of course, we don't have the data to really look at with respect to 9LA or Poseidon. And so we'll have a chance to look at those data and, on the basis of that, to make a judgment about benefit/risk profile and how best to treat these patients. Frank?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

And what I'll add is that in the marketplace right now, and I'll separate a couple of things, in the U.S., we have established KEYTRUDA very strongly as a standard of care in first-line non-small cell lung cancer. Approximately 8 out of every 10 eligible patients are receiving a KEYTRUDA regimen, either a monotherapy or in combination. And what we're hearing from both the academic community or academic physicians, I should say, and the community physicians is that they really believe KEYTRUDA now has established itself as a standard of care in lung.

I think also importantly, we have to note that there's significant real world experience based on our first-mover advantage with KEYTRUDA in lung. So while we know it'll be eventually competitive in this space, we feel very confident on our position.

If I look outside the U.S., I think it's important to note not only the significant regulatory approvals we received but also the HTA reimbursements we now have. And that takes time. And it also is important to note that HTA bodies really do look at the magnitude of the effect of the data that you're bringing compared to other standards of care, and we have done extremely well from a reimbursement perspective and positioned well, as I mentioned, in Europe.

China, we also are very well positioned with our first-mover advantage in lung based off of 189 and KEYNOTE-042 now in monotherapy. And also, we're very well established in Japan.

So as I look around the world, I feel very confident about our overall lung position. Clearly, as Roger mentioned, we'll have to wait and see some of the additional data sets. But going forward, we're very confident in our ability to continue to grow KEYTRUDA and continue to grow in lung cancer.

Operator

Your next question comes from the line of Seamus Fernandez with Guggenheim.

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

So I was hoping, Roger might be able to give us some thoughts on data that were presented at ESMO in combination with an antibody drug conjugate in bladder cancer. Specifically, Roger, I'd just love to get your thoughts on how you think about ADC technology at this point in time. And just sort of your broader thoughts on the ability of ADCs, which historically have been a little bit difficult to manage as linkers have improved, as data has improved along those lines. Just wondering what your thoughts are on the -- how validated ADC technology is. I know it's not an area where Merck has an obvious presence. So just wondering what other work might be -- Merck might be doing there.

And then a second question. Rob, as we see the numbers continue to expand, I have to imagine that the cash on the balance sheet that continues to accumulate, it needs to have some thoughts around capital deployment. Can you just give us your thoughts on where Merck is most focused in terms of deploying that building cash forward in the context of sort of the concentration that we're starting to see increasing in KEYTRUDA and GARDASIL going forward? And we've certainly had a very narrow conversation around Merck and the future of Merck on the call so far today.

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

Roger, take ADCs.

Roger M. Perlmutter - *Merck Research Laboratories - President*

Seamus, so with respect to ADC technology, well, as you point out, there's a long history here on the attempt to couple toxins to anybodies with the idea in mind that one could selectively deliver toxins to tumor cells goes back nearly 50 years to work, for example done at Texas Southwestern by [Jonathan Orr] and [Alan Butteta] over a period of decades now, refinements have taken place first with the substitution of more selective monoclonal antibodies, a better linker technology. As you point out initially, hydrolyzable and non-hydrolyzable and back. And the choice of toxins. It started out with ricin and then more convention toxins -- more conventional toxins were used. And I think we're beginning to see some evidence of selectivity. I think there are a few points to make. First, it's worth keeping in mind that when you're administering this toxin conjugate, there still is a pretty significant body burden of toxin. And so the benefit/risk profile has to be examined very carefully in such setting. And second is that what we've learned over time is that the choice of the anybody target really matters a lot. And finding selective tumor targets is extremely important.

With that as background, I would say that the data that we obtained in collaboration with our colleagues at Seattle genetics, using the EV, I'll abbreviate it that way, toxin conjugate that they've developed really were very impressive. They have -- monotherapy results which they presented in a combination with KEYTRUDA looked really quite impressive on a first pass, which certainly is intriguing. And we're looking at all of those kinds of things and asking ourselves, are those areas where additional leverage can be made and gained in combination with KEYTRUDA?

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

Thanks, Seamus. To the question on cash flow, you are correct that the business is doing quite a nice job of generating cash flow really, which is testament to the overall strength we see in the business. As you look at our capital allocation as you're going forward, it's really unchanged. First and foremost, we will continue to fund the operations. As you know, we continue to invest meaningfully within our growing R&D portfolio of opportunities. We are investing meaningfully in capacity expansion to address the growth we see in our vaccines business, oncology business and

our Animal Health business. And so we will continue to do that. Beyond that, we are still very committed to our dividend. But as you look at the excess cash flow beyond that, our goal continues to be to invest in business development.

I would point out to your one comment about the call being narrowly focused on KEYTRUDA. I do think it's important that people continue to realize while KEYTRUDA is truly a foundational product, we are a lot more than just KEYTRUDA. We have growing excitement about the broader oncology pipeline we have with Lynparza, Lenvima, the over 20 mechanisms we have in development that Roger has talked about in the past. Our vaccines portfolio continues to grow very nicely. I think overall, vaccines grew 18% in the quarter. And you saw, obviously, good growth with GARDASIL, our pediatric vaccines. I mean we have a great pipeline with CMV, dengue, RSV. A lot of excitement around our HIV portfolio we have that Rogers touched upon in his prepared comments and broader in our antibiotic space. And then obviously, Animal Health. So we have a lot internally to be excited about. But with that said, we are looking to continue to augment that through business development. And that's our hope, to deploy the cash flow we'll generate to that. And then obviously, to the extent we have any cash left over after those efforts, we will return it to shareholders. So that is our strategy and pretty consistent with where we've been.

Operator

Your next question comes from the line of Daina Graybosch with SVB Leerink.

Daina Michelle Graybosch - *SVB Leerink LLC, Research Division - MD & Senior Research Analyst*

I have a few on the early-stage setting and how I-O and KEYTRUDA may evolve there. You have several adjuvant studies that have a neoadjuvant component like KEYNOTE-756 and KEYNOTE-7 -- 671, among other. The first question is do you expect these to release the neoadjuvant results from the interim analysis.

The second question is what do you think will be required for regulatory approval in neoadjuvant settings in breast cancer, triple negative as well as hormone positive and other indications. And then finally, what are your expectations that you do get approval for KEYTRUDA in neoadjuvant settings? Do you think physicians will also use KEYTRUDA in the adjuvant setting? Or will they wait for adjuvant data for that use?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Well, Daina, lots of questions there. Let me try and break them out. First of all, we do have a lot of studies in neoadjuvant, and those studies are driven by fundamental observations. I think what we've come to recognize is that KEYTRUDA works well in settings where there is an inflammatory response in the tumor. And tumor cell death, however it's caused, whether that's the result of radiotherapy or the result of chemotherapy or potentially even the result of surgical wounds, that inflammation that takes place is augmented by the presence of KEYTRUDA, which improves responsiveness. And we see that in preclinical models and it's played out in the clinic as well and are -- has driven a lot of our thinking about combination studies. And so that naturally led us to perform neoadjuvant studies, and we began these some time ago. And we're beginning to see results in early stage and even in Phase III studies. And I talked about the KEYNOTE-522 neoadjuvant data in triple-negative breast cancer, which, of course, were built on the I-SPY 2 data we have earlier, all of which suggest that neoadjuvant can provide good responses.

You specifically asked, though, about release of data from interim analyses. And clearly, we will release those data as those data are important and that we -- people need to hear about them. So it's really just a function of the -- what data we get. And generally, we tend to see these as important results that we want to present in scientific meetings, so we generally don't provide detailed information in the context of an investor presentation. But we tend to present these in a scientific setting, as we did at the European Society meeting in September.

Now the requirements for regulatory approval are the traditional requirements here, and that is the agency is going to be interested either in evidence of a favorable benefit/risk profile in the outcomes of treatment, or they're going to want to have a surrogate that they believe is validated with respect to those kinds of endpoints. And I think that, that will be true for the neoadjuvant studies and adjuvant studies, as we've seen in the past.

And our expectations are, as I've indicated, that this is going to prove to be an extremely important area, which is why we have so many neoadjuvant and adjuvant studies currently under way. We have something on the order of 100 of them altogether in various different settings. So it's really quite an important area for us.

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

(Operator Instructions)

Operator

Your next question comes from the line of Umer Raffat with Evercore.

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

Rob, I actually wanted to touch up on operating margin a little more specifically. And by my math, I'm seeing 37.1% operating margin this quarter, which is materially higher than where consensus is in 2020 and 2021 as well. And my question is do you expect operating margin to be lower in the next couple of years versus where it stood in 3Q '19.

And then secondly, maybe (inaudible) Animal Health for a second. It seemed like BRAVECTO has been a very strong driver over the last several years. And my question is how do you expect your reported Animal Health revenues to change now going into next couple of years with Zoetis launching their Trio. And what's your timing of a potential Trio filing?

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

Yes, I appreciate the questions. On the operating margin, I don't want to get into specific guidance. As I said, I think if you look at this year, the growth we had in operating margin is exceptional because of the fact that sales outpaced our expectations and frankly outpaced our spend. So that's really driven by the power of what the revenue line can give. And beyond that, I would wait till we get to our 2020 guidance to get more specific as we look forward.

With regard to Animal Health and what we're seeing there, so you are correct, BRAVECTO has been an important growth driver for that business. We're now actually now also, though, seeing good growth overall coming from the production side of the business as well. You saw that livestock grew 12% in the quarter driven by the benefits of the Antelliq products we brought into the company as well as good growth in companion animal.

As we look forward, we continue to believe that the Animal Health business will grow at a rate faster than the overall market driven by the innovative products we have, both in companion animal as well as across the broader vaccines portfolio and other portfolio of products we have. So our view of the strength of the growth in that business hasn't changed long term.

As we look at the triple combo that's coming from competitors, we actually have some programs in development. We haven't really commented specifically on those, but safe to say we're aware of that and work is under way in our own portfolio.

But I'd bring you back to the benefits we see from our BRAVECTO product. It is the only 12-week oral therapy in the marketplace today, and we continue to see that in very good demand and frankly believe that, that will be a competitive product, even in light of an evolving competitive set, through innovation, which we will eventually match through our own development efforts.

Operator

Your next question comes from the line of Geoff Meacham with Bank of America Merrill Lynch.

Geoffrey Christopher Meacham - *BofA Merrill Lynch, Research Division - Research Analyst*

Just have a couple of quick ones. Rob or Frank, when you talk about the opportunity in China broadly, can you talk about the pricing strategy at a high level? I'm just trying to understand given the size of the population, the upcoming competitive I-O backdrop when you think about companies in the region.

And the second one is for Roger. I know 522 questions have already been asked, but I wanted to ask you more broadly. Given the results in triple-negative breast, is this an indicator of success in the bigger segments of the market in cold tumors? I know you got to look at each study individually, but I-O activity in cold tumors, obviously, has thus far been pretty underwhelming.

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

Great, thanks. Frank on China?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure. So on China, we feel very pleased, and we mentioned this, too, on Investor Day, at our current growth rate. This quarter, you see we grew 98%, and year-to-date we've seen very strong growth in China. It's really been driven by KEYTRUDA, GARDASIL, Lynparza, Lenvima and also JANUVIA when it was added to the NRDL in 2017.

With regards to some of the pricing dynamics in China, we do anticipate, based off of volume-based pricing and the rollout to additional provinces, that there will be some headwinds and pressure on some of our more mature brands in China. As we mentioned, even with that, we're still very confident because the majority of our portfolio is now pivoted to the innovation side, and that is what is going to drive the growth going forward.

As far as NRDL and access, we are still working -- we are actually working through the NRDL process right now in China. We'll have to wait and see how all that plays out, but we're encouraged about China both today in the self-pay market. And then obviously, if we do receive NRDL reimbursement, it opens up a significant amount of new patients that we could treat with KEYTRUDA as well as other parts of our portfolio.

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

Great. Roger?

Roger M. Perlmutter - *Merck Research Laboratories - President*

And Geoff, thanks for the question. I think as you point out, the fundamental issue is that while we see terrific results with KEYTRUDA in a substantial fraction of cancer patients, that still leaves a substantial fraction -- a very substantial fraction in some tumor settings who just don't respond, and the question is why. And we've published sort of data in which we presented 2-axis plot of inflammatory response versus tumor mutational burden, which are related but only weakly. And it is the case that tumors with higher mutational burden, especially very high mutational burden, as you see in the MSI population, respond extremely well. The question that is -- that we are asking in a whole variety of studies is how can we take this less responsive tumor populations and make them more recognizable and a better trigger for immune responsiveness. That can involve combinations with other agents, that can involve interventions that cause mutations to become fixed, a whole variety of other things that we're pursuing. Ultimately, that will be an important frontier.

We do see KEYTRUDA as a foundation for that treatment. It will be KEYTRUDA plus other things that will enable us to gain access to these less responsive patient populations. But we're hard at work on it.

Operator

Your next question comes from the line of Mara Goldstein with Mizuho.

Mara Goldstein - *Mizuho Securities USA LLC, Research Division - MD of Equity Research Department*

The first one is I recognize that China has had very good growth at 90-plus percent this quarter. But I'm just wondering what the thoughts are around economic sensitivity. Should there be some type of projected economic slowdown? And then I want to ask a question on gefapixant and the endometrial pain study. We noticed in ClinicalTrials.gov that there is a slight lengthening of the estimated completion, and I'm wondering if this is a function of why was this rolled out in that indication.

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

Frank, on China?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So on China, what is happening is with regards to the 4 plus 7 pilots, so there are pilots that are under way in China that are looking at tendering processes for some of the more mature brands across the industry. Right now the impact to us has pretty much been Cozaar and SINGULAIR the 2 products. However, for us, as we go forward and as that process, we do anticipate, will expand into the 31 provinces over time in China, it really will put some additional pricing pressure on our more mature portfolio, as I mentioned.

Just to give you a perspective, the reason why we're seeing the significant growth in China is because 2/3 of our portfolio already is in the innovative part of our business. So those products we feel very confident will not be a part of the volume-based procurement rollout, which we believe will allow us to continue to grow not only near term but also over the next several years and long term in China. And it's really being driven by the innovative portfolio of KEYTRUDA, Lynparza, Lenvima, GARDASIL, JANUVIA and some other additional launches that we plan. So while there'll be headwinds to the older portion of the portfolio, we feel very good that our pivot to innovation has really helped us not only in the near term but will continue to help us in the long term.

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

Roger, on gefapixant

Roger M. Perlmutter - *Merck Research Laboratories - President*

On gefapixant, I mean we -- as you indicated, Mara, we're pursuing a set of interesting indications with this P2X3 antagonist set because we think it could turn out to be broadly useful beyond the kind of cough indication where we are in Phase III. But I wouldn't read anything into the timing of completion of studies. We update ClinicalTrials.gov as we get more information from clinical operations. When we start out, particularly in these syndications, endometrial pain and other areas where we're not 100% sure about feasibility, we make a guess on what we think enrollment rates are going to be in sites. And of course, every study is different because the enrollment criteria are different. And as we prosecute these studies and we get better estimates of when trials will actually complete, we update ClinicalTrials.gov. It's not a tool that helps one resolve specifically what's going on in the marketplace.

Operator

Your next question comes from the line of Navin Jacob with UBS.

Navin Cyriac Jacob - *UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic*

Two questions. On GARDASIL, the U.S. was strong this quarter despite a tough comp from last year. Wondering if that's partly what you're attributing the decline in Q4 to. You're saying Q4 will be down, I think, $150 million or there'll be a work-down of $150 million. Is that part of just a pushout of what was supposed to happen this quarter on a relative basis? Or is there growth this quarter in underlying demand above and beyond, I think, what any of us expected?

And then just maybe a question for Roger. Roger, wondering your thoughts on cell therapy, some of the new modalities, whether it's TILs or APCs as a means for targeting particularly checkpoint inhibitor refractory patients.

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

Great. Frank, U.S. GARDASIL?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

So GARDASIL grew in the U.S. approximately 3% if you exclude -- or excluding FX. Underlying demand growth and price did drive growth, which was partially offset in Q3 by CDC purchasing timing. So we did not see CDC purchases in 3Q as we expected, which is why you saw a 3% growth.

The borrowing that we mentioned or that Rob mentioned earlier on in the call will be borrowing that will take place in the fourth quarter of this year, which will reduce our fourth quarter sales by approximately $120 million compared to Q4 of '18.

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

And Roger, on cell therapy?

Roger M. Perlmutter - *Merck Research Laboratories - President*

On cell therapy, we love the data in hematologic malignancy, and I think it challenges how to translate into -- that into solid tumors, where the tumor-specific antigens are less clear. Obviously, if you're targeting CD19 and you get rid of all the lymphocytes, well, patients can live with the elimination of all the lymphocytes, including, of course, the malignant ones but normal ones, too.

If you're targeting, on the other hand, antigens which are not sufficiently tumor specific in solid tumors, then you potentially do enormous damage to normal structures, and that's problematic. I think there are some things on the horizon which will improve that, and we're watching them carefully. And clearly, with the other areas you mentioned, tumor infiltrating lymphocytes, so better protocols are evolving. So it's an area of great interest and clearly something that we would want to incorporate as time goes by and things get better.

Operator

Your next question comes from the line of Steve Scala with Cowen.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

First, Roger, as a medical doctor, if you were caring for a first-line lung cancer patient, where would you prescribe Opdivo plus Yervoy instead of KEYTRUDA plus chemo? And how big is that population?

And then one for Frank. PROQUAD had a strong Q3, which followed a strong Q2, which in Q2 you said was attributed in part to buying in the private sector. So how sustainable is the strength we've now seen several quarters in a row?

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

Great. Roger?

Roger M. Perlmutter - *Merck Research Laboratories - President*

Well, Steve, with respect to first-line non-small cell lung cancer, it is -- looking at the data that we've seen presented in some detail, which is the 227 data both in publication and presentation at ESMO, it's difficult to identify the patient population in which a combination of, in this case, Opdivo and Yervoy would be the right choice. But I think that the argument that has been made by our colleagues at Bristol-Myers is in particular, they're looking at those individuals in whom there is less PD-L1 expression. I think you'd have to look at those data very carefully because, of course, our data in PD-L1-negative patients in the chemo combo setting is, I think, really quite strong and the safety profile that we've rollout to a KEYNOTE-189 data and as it's being used in the marketplace is also very good.

So I'm just not sure where I see a special niche for the use of a combination of a CTLA-4 antibody. And I'm eager to see our own data, as I indicated, for the 598 study to actually get a better sense of what ipilimumab, Yervoy will add to KEYTRUDA. And that might help to refine that question a little bit, but I can't really come up with a specific answer to it.

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

And Frank, on pediatric vaccines?

Franklin K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. And so we saw, to your point, another very strong quarter of 19% growth. In the U.S., the growth was about 12%; ex U.S., 52%. The growth is being driven in the third quarter by increasing demand. There were some price benefits. And there is some offset by a buyout that did take place in Q2. We'll expect to see some additional buyout as we get into Q4. But overall, the demand for our pediatric vaccines continues to remain strong.

Operator

Your last question comes from the line of Terence Flynn with Goldman Sachs.

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

Maybe 2 follow-ups. Just wondering if you are planning to file for approval of KEYTRUDA in neoadjuvant triple-negative breast based on the pCR data from 522 or if you're going to wait for the EFS data. And then Rob, you mentioned pricing pressure in 2020. Can you quantify the impact there relative to what you're seeing in 2019? And any particular areas to call out?

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

Great. Roger, on 522?

Roger M. Perlmutter - *Merck Research Laboratories - President*

On 522, we are -- pulled the data together, and we're having discussions with regulatory agencies. And we'll see exactly how that goes over time. And of course, in the meanwhile, additional data will accrue, so we'll see where we get to.

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

Frank -- Rob?

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

Yes. And on the question of pricing pressure, really the context in which I was commenting was just to make sure as we look at what is truly exceptional growth in revenue and earnings in both the quarter of 2019, third quarter of 2019 as well as what we had guided for the full year, as we think about growth going into next year and as you think about your models, to be cognizant of the fact that we do expect to see incremental price pressure over and above where we have been in 2019. I'm not going to specifically quantify it, but it was really to give you directional thinking as you look at your growth models for next year.

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

Great. And Ken?

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

Okay. In closing, 2019 is shaping up to be a year of very exciting growth for our company, and we're looking forward with great confidence in our ability to execute and innovate. We're confident, but we're not complacent. To the contrary, we're determined to use our strong current position as an opportunity to take the steps necessary to ensure Merck's continued success long into the future, including pursuing the best avenues for inorganic and organic growth as well as evolving our operating model to drive productivity across the operations and look for ways to optimize our human health portfolio, all in an effort to create sustainable growth for the long term.

Thank you very much, and we look forward to updating you on our progress as we go forward.

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

Great. Thank you all very much.

Operator

Thank you. This concludes Merck & Co. Third Quarter 2019 Sales and Earnings Conference Call. You may now disconnect.
