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PRESENTATION

Operator

Good morning. My name is Dorothy, and I will be your conference operator today. At this time, I would like to welcome everyone to Merck's Second Quarter 2018 Sales and Earnings Conference Call. (Operator Instructions)

I would now like to turn the call over to Teri Loxam. Please go ahead.

Teri Loxam *- Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thank you, Dorothy, and good morning. Welcome to Merck's Second Quarter 2018 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; Adam Schechter, President of Global Human Health; and Dr. Roger Perlmutter, President of Merck Research Labs.

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 note that we have excluded these from our non-GAAP results and provide a reconciliation of these 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 U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the

current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 1A in the 2017 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.

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

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

Thank you, Teri. Hello, everyone, and thank you for joining the call.

During the second quarter, Merck delivered strong growth. We also further advanced our leadership in oncology through focused commercial execution, the achievement of important regulatory milestones and the presentation of clinical data at ASCO for KEYTRUDA, Lynparza and LENVIMA.

Following the unprecedented results in first-line non-small cell lung cancer presented at AACR, we followed up with similarly impressive data at ASCO. This included more than 140 abstracts across 25 tumor types, which is a substantial increase from just 5 years ago when we presented the first clinical data for KEYTRUDA, a single abstract for advanced melanoma. KEYTRUDA is becoming foundational for the treatment of cancer, and add in Lynparza and LENVIMA as well as our other oncology assets in the pipeline, and we believe that Merck's oncology portfolio has the breadth and depth to further expand our leadership position.

Our Vaccines business is also an important growth driver. We are pleased to see the growing momentum around HPV vaccination worldwide. The WHO director general recently called for all countries to take action to help eliminate cervical cancer, which is predominantly caused by HPV. We have seen several countries offer expanded recommendations, and we recently gained approval for GARDASIL in China, all of which contributes to our long-term confidence in this brand.

Briefly, turning to Animal Health. This business continues to deliver strong results, growing faster than Human Health. In addition to our global scale and the synergies we gain from sharing innovations across the 2 businesses, it also diversifies our portfolio and is a key pillar of our long-term growth strategy. Delivering innovative products is at the core of who we are as a company. We will continue to augment our Animal and Human Health pipelines through internal investments as well as externally through business development.

As our results have demonstrated so far this year, we have good momentum. And we are focused on continuing to execute across our business to drive growth and create long-term shareholder value. With that,

I will now turn the call over to our Chief Financial Officer, Rob Davis, to go through our results in more detail. Rob?

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

Thanks, Ken, and good morning, everyone. Please note that my comments today will be based on a non-GAAP earnings basis.

In the second quarter, we delivered strong performance in both our Human and Animal Health businesses, resulting in meaningful revenue and EPS growth. Total company revenues were $10.5 billion, an increase of 5% year-over-year. Excluding the impact of exchange, second quarter revenues grew 4%. Our Human Health business grew 3% excluding exchange, and Adam will provide more color on those results in a moment.

Animal Health sales totaled $1.1 billion in the quarter, an increase of 14%. Excluding the impact of exchange, sales grew 12%, with livestock sales growing 7% and companion animal sales growing 19%. Animal Health segment profits were $450 million in the second quarter, an increase of 14% compared to the prior year or 10% excluding exchange.

Turning to the expense line. Gross margin was 74.4% in the quarter, a decrease of 290 basis points versus the second quarter of 2017. The decrease reflects increased amortization, including a sizable catch-up adjustment for an accrued sales milestone related to Adempas. In addition, gross margin was impacted by unfavorable manufacturing variances, partly due to last year's cyber event as well as FX.

Operating expenses of $4.4 billion increased 4% year-over-year, including a negative 2 percentage point impact from foreign exchange. The increase was driven by our continued investment in R&D, primarily for the clinical development of Lynparza and LENVIMA as well as for our early-development efforts. The tax rate was 17.9% in the second quarter, reflecting the benefit of tax reform. Taken together, we earned $1.06 per share, an increase of 6% excluding exchange.

Turning to the outlook for the year. Based on continued operational strength, we are narrowing our revenue guidance range and narrowing and raising our EPS guidance range for 2018 despite a less favorable exchange environment versus our prior expectations in May.

For the full year, we now expect revenues to be between $42 billion and $42.8 billion, including a slightly positive impact from foreign currency at mid-July rates. We anticipate our gross margin will now be lower year-over-year by approximately 1 percentage point, with the slight change primarily being driven by the Adempas milestone-related amortization this quarter. We continue to expect OpEx to increase year-over-year by low to mid-single digits.

We have slightly lowered our tax rate assumption and now expect it to be between 18.5% and 19.5%. We continue to anticipate approximately $2.7 billion in average -- or 2.7 billion shares outstanding as of end of the year. Taken together, we now expect EPS to be between $4.22 and $4.30, including a roughly 1 percentage point negative impact from foreign currency at mid-July rates.

In summary, we continue to execute well on our strategy, driving top and bottom line performance. We are allocating resources to effectively support our commercial opportunities in the near term while making the necessary investments in R&D to support long-term growth.

With that, I'd like to turn the call over to Adam to provide more detail on our Human Health business. Adam?

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Thank you, Rob, and good morning, everyone. This morning, I'll provide highlights on the performance of Global Human Health for the second quarter of 2018. My comments will be on a constant-currency basis.

Global Human Health sales grew 3% to $9.3 billion. Consistent with last quarter, our key growth drivers, including KEYTRUDA, GARDASIL and BRIDION, performed very well. Roughly 60% of our sales were from outside of the U.S. and grew 8%, highlighting our global commercial presence and solid execution around the world.

I'll now focus on a few of our key franchises, and I'll start with oncology. Our oncology business is benefiting from the rapid worldwide uptake of KEYTRUDA, Lynparza and LENVIMA. KEYTRUDA with global sales of nearly $1.7 billion is now approved in 12 indications across 8 tumor types in the U.S. and similarly approved in multiple indications across tumor types in countries around the world. We believe our breadth of current indications with significant opportunities yet to come will be a competitive advantage and will help us continue to be a leader in this field for many years.

In the United States, KEYTRUDA remains the leading immunotherapy in new patient starts when looking at all indications combined. Sales this quarter benefited from accelerated adoption in metastatic lung cancer as well as growth in bladder and MSI high cancers.

In patients diagnosed with non-squamous first-line lung cancer, the significant survival benefits demonstrated in KEYNOTE-189 is resulting in sharply broader use of KEYTRUDA in combination with chemotherapy. Physicians now clearly see the benefit of using this combination across all of their first-line patients regardless of PD-L1 expression. We are currently capturing roughly 2/3 of new patient starts, excluding EGFR and ALK, approximately 20 share points higher than prior to AACR. We expect continued substantial adoption in this indication in the second half of 2018 and beyond.

In addition, the strong survival benefits in patients with squamous non-small [cell] lung cancer from KEYNOTE-407 should enable us to become standard of care in this population which represents roughly 20% of the market. With the strength shown in our clinical program, KEYTRUDA indication should be able to represent roughly 80% of all non-small cell lung cancer patients with an overall survival benefit, which is the gold standard.

Outside the U.S., we're seeing significant growth with KEYTRUDA and now represents over 40% of total sales. We have seen strong uptake in first-line lung, and we've secured reimbursement in most major markets worldwide for our monotherapy indications. Sales also continued to grow in melanoma, head and neck and bladder cancers.

We continue to be very confident in the near- and long-term growth prospects of KEYTRUDA, driven by continued penetration of approved indications as well as the potential for many additional indications in the future. The potential benefit of KEYTRUDA in patients with breast, gastric, hepatocellular, renal, head and neck and other, including various adjuvant-stage cancers, are exciting opportunities for us.

Now turning to Lynparza, which we're co-commercializing and codeveloping with AstraZeneca. Our oncology business benefited from the strong performance of Lynparza, which leads the PARP inhibitor class in both new and total prescriptions. U.S. sales grew significantly, driven by continued growth in ovarian cancer as well as a strong launch in a new breast cancer indication.

Ex-U.S. sales benefited from the recent launch in ovarian cancer in Japan. Going forward, we expect the recent breast cancer approval in Japan and expectations for ovarian cancer approval in China to continue to enable strong growth.

Our partnership with Eisai for LENVIMA is also off to a fast start. In the United States, our sales representatives started promoting LENVIMA in renal cell carcinoma in June, and we look forward to a potential hepatocellular carcinoma approval this quarter with an August 24 PDUFA date. Over the next 6 months, we'll begin promoting LENVIMA in many key countries in both Europe and Asia Pacific. So as you can see, we are very confident about our future growth with Lynparza and LENVIMA, both as a monotherapy and in combination with other agents.

Now moving to Vaccines, which represents another key pillar of growth. Global Vaccines grew 7% and exceeded $1.5 billion this quarter, led by GARDASIL, which remains in very high demand. The transition to the 2-dose regimen in the U.S. is nearly complete, and we continue to see strong underlying demand.

Outside of the U.S., growth remains very strong as the benefits of HPV vaccination continue to become more broadly understood by health care systems worldwide. In addition, uptake in China has been particularly robust following the launch there. We're excited about the FDA acceptance of our sBLA for the use of GARDASIL in women and men ages 27 to 45 and believe GARDASIL will remain a significant growth opportunity moving forward.

Now moving to diabetes. Our diabetes franchise continues to be relatively stable. Global sales were nearly $1.6 billion, flat with year-ago levels. Trends worldwide remain largely consistent, with strong demand-driven growth in ex-U.S. markets being largely offset by continued pricing pressure in the U.S.

Lastly, in our hospital specialty portfolio, BRIDION reported another very strong quarter of growth both in the U.S. and worldwide. The neuromuscular blockade market continues to grow because of increases in robotics and minimally invasive surgical procedures, and BRIDION continues to gain market share as a reversal agent of choice. We recently launched BRIDION in China and believe our prospects for growth both in the U.S. and ex U.S. remains strong.

In total, we are pleased by the performance of our Global Human Health business this quarter, and we are very optimistic about our future potential, driven by our key growth areas including oncology, Vaccines and hospital specialty.

With that, I'll turn it all over to Roger.

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

Thanks, Adam. During the second quarter, we had the opportunity to present important data related to our programs in oncology and infectious diseases at multiple scientific meetings, and we advanced so many of our key programs.

Looking first at KEYTRUDA. Since our last earnings call, we gained U.S. registration for the treatment of relapsed or refractory mediastinal B-cell lymphoma and for the treatment of recurrent or metastatic cervical cancer in women whose tumors express PD-L1, that is with CPS greater than or equal to 1. In all, the FDA has now granted approval for the use of KEYTRUDA in 12 different indications spanning 8 different tumor types and the broader category of patients whose tumors demonstrate microsatellite instability.

Also, during the second quarter, the FDA granted priority review to our sBLA submission for the use of KEYTRUDA in the treatment of patients with advanced hepatocellular carcinoma with a PDUFA date of November 9 and for the use of KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with metastatic squamous cell carcinoma of the lung with a PDUFA date of October 30. The latter submission was based on our recently completed KEYNOTE-407 study, the results of which were presented at the American Society for Clinical Oncology or ASCO meeting in June. These data were described by the ASCO commentator as representing a new standard of care for patients suffering from advanced squamous cell carcinoma of the lung.

Similarly, the results of our KEYNOTE-189 study, which tested the utility of KEYTRUDA in combination with chemotherapy in patients receiving first-line treatment for non-squamous non-small cell lung cancer, were incorporated into a supplementary BLA that was accepted for priority review, with a PDUFA date of September 23, by the FDA earlier in the quarter. Data supporting the filing showed a greater than 50% improvement in overall survival in patients receiving simultaneous KEYTRUDA plus chemotherapy as compared with those receiving chemotherapy alone.

Separately, our supplementary BLA for the use of KEYTRUDA in the adjuvant treatment of patients undergoing definitive surgical resection of cutaneous melanoma was also accepted by the FDA, with an action date of February 16, 2019.

Outside of the United States, yesterday, we announced that KEYTRUDA was approved in China for the second-line treatment of unresectable or advanced melanoma, the first approval of a PD-1-directed therapy for melanoma in China. These numerous approvals and filings are really just the beginning of what will be a very robust period of evaluation for KEYTRUDA in both combination therapy and monotherapy settings. At the ASCO meeting in June, my colleagues presented more than 100 abstracts related to KEYTRUDA alone, many of these represented progress reports that we expect will yield data supportive of registration in the not-too-distant future, including for the treatment of small cell lung cancer and renal cell carcinoma. At some greater remove, we expect the data will also emerge supporting the use of KEYTRUDA in the treatment of breast cancer and prostate cancer.

Beyond KEYTRUDA, a very substantial progress was made in our other oncology programs. With our colleagues at AstraZeneca, we achieved registration for the use of Lynparza tablets in the maintenance treatment of platinum-sensitive ovarian cancer in the European Union and for the treatment of BRCA-mutated HER2-negative breast cancer in Japan.

Our joint efforts on LENVIMA with colleagues at Eisai also yielded an important regulatory action. With approval of this multi-kinase inhibitor for the treatment of hepatocellular carcinoma in Japan, LENVIMA is under review for the same indication in the United States.

Progress has continued in other areas as well. Earlier this week at the 22nd International AIDS Conference in Amsterdam, we presented 96-week data from our DRIVE-FORWARD study of doravirine, our investigational non-nucleoside reverse transcriptase inhibitor, used in combination with other antiretroviral agents in treatment-naïve HIV-infected patients, showing long-term suppression of HIV viral burden with this new agent. Doravirine both as a single agent and as a combination with single-tablet regimen is currently under review with the FDA with an action date of

October 23. We're also studying doravirine in combination with MK-8591, our first-in-class nucleoside derivative, that durably blocks both reverse transcriptase translocation as well as polymerase activity. The data from this Phase II study will become available later this year.

Also in the infectious disease arena, as Adam mentioned, the FDA has accepted a supplementary BLA and granted priority review for the use of GARDASIL in women and men ages 27 to 45, with an action date of October 6. Earlier in the quarter, we announced that GARDASIL 9 was approved in China for use in girls and women 16 to 26 years old. We see these new regulatory actions as emblematic of an increased focus on the impact of human papillomavirus-induced diseases, especially cervical cancer.

At the ASCO meeting in June, Doug Lowy of the National Cancer Institute, who shared last year's Lasker award for his studies of HPV median diseases, spoke persuasively about the importance of mounting worldwide immunization campaigns against HPV, and both the American Cancer Society and the National Cancer Institute of the United States at their designated cancer centers have endorsed the goal of eliminating cancers caused by HPV through effective gender-neutral vaccination of adolescents. GARDASIL and especially GARDASIL 9 will play a pivotal role in these worldwide efforts.

We have many other important vaccine initiatives underway, including V114, our 15-valent pneumococcal conjugate vaccine currently under investigation in Phase III trials; and V160, our novel vaccine for the prevention of primary CMV infection in healthy seronegative women, which is currently being evaluated in a large Phase II study. But today, I wish to pay tribute to the many dedicated health care workers in the Democratic Republic of Congo and especially the Congolese Ministry of Health and the World Health Organization for the successful containment of the recent Ebola virus disease outbreak in the Democratic Republic of Congo.

My colleagues at Merck Research Laboratories worked tirelessly to supply nearly 13,000 doses of our investigational V920 vaccine, which we previously demonstrated have protective activity in the 2014/2015 Ebola disease outbreak in Guinea. These data were published as part of the Ebola assessment [field] trial in The Lancet in 2017. This permitted vaccination of health care workers and people at high risk of contracting Ebola virus disease during this most recent outbreak. We're proud to have been able to contribute to this effort and are continuing to make rapid progress towards of the registration of V920, which has been described as a game-changer in the control of Ebola virus infection.

I will now turn the call back over to Teri.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Roger. Dorothy, we'll move on to the question-and-answer section. (Operator Instructions)

So Dorothy, if we can move on, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Steve Scala with Cowen.

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

Roger, what is Merck's strategy in stage 3 unresectable lung cancer, where Astra has done well with PACIFIC? At the ASCO meeting, you were asked the question but did not answer, suggesting that Merck is pursuing approval perhaps on its single-arm trial. So I'm wondering if you could update us there. And secondly, Adam, could you provide us KEYTRUDA's market share by tumor type in the U.S. and EU?

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

Yes, Steve. The specific registrational strategy for pursuing different aspects of lung cancer approval is not something that we generally comment on. Suffice it to say that we do have some data available in advanced cancer, non-resectable cancer that is nonmetastatic, and we expect that there will be additional data that will come forward in the months and years ahead that will permit a specific indication. But we're not commenting on the regulatory strategy.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Just with regard to your question, I'll give you a rough estimate. As you know, the data is not perfect in this area. So let me start with the U.S. The rough estimate is about 60% to 65% is in lung, about 15% in melanoma, about 5% in bladder, about 5% in MSI high and then the rest is in all other indications. And then if you look at Europe, the data is even harder to get exact numbers on. What I would say is if you look at Europe and Japan, lung is the majority of revenue and then followed by melanoma, which is the second largest contributor. And then all the other tumor types like head and neck and bladder are the rest of the numbers in there. But it's clearly lung followed by melanoma and then all others.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks.

Operator

Your next question comes from the line of Andrew Baum with Citi.

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

A question for Ken and then one for Roger. So I guess you might have seen this coming. Could you comment on the proposals that have been made by HHS to the White House to either remove or significantly amend the rebate structure by taking away the safe harbor? In particular, could you comment on your understanding of, under the regs, whether this is limited just to federal plans? Or do you believe that there could be any direct or indirect impacts on commercial book of business, either through the actual administration or more likely through the PBMs that (inaudible)? And then, separately, on potential timing, whether we should expect something on this 12 months from now or whether you think there's any possibility that it can happen faster than that . So I know there's lots of uncertainties there, but I think (inaudible) would be helpful. And then for Roger, as far as I can see, the anticipated expansion of olaparib trial that was spoken about previously hasn't happened yet, unless I've missed them. So I was wondering whether this is just the challenges of dealing with a partner company rather than your own internal assets or whether it's being compounded by the departure of some of your (inaudible) employees, meaning that you're resource-constrained.

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

So thank you, Andrew. Let me start with your first question about the proposal to remove the safe harbor for rebates for plans and PBMs. So I have to start by saying it's rather difficult to comment on specifics at this point. As you know, there's so many different proposals being considered to address the high out-of-pocket cost of drugs to patients. What I would say is we will work with the administration and the Congress to help find appropriate solutions to these issues. We do think it's important to make sure that patients do have meaningful access, and lowering the out-of-pocket costs for patients is something that we're strongly in support of.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Roger?

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

Yes. And Andrew, with respect to the expansion of the olaparib trial, well, as you know and as I've described, we've done quite a lot with Lynparza since the partnership with AstraZeneca was consummated. The -- we have a lot of new studies that we've gone through, and it's taken a little bit longer than we wanted to, to -- for the 2 organizations to come together and agree on exactly what we should study and where we should study it. But you'll be seeing a lot of those trials roll out very soon. In response to your question, it is not because we are in any way constrained by personnel. And we have -- our clinical team is truly firing in all cylinders, no doubt.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks for your question, Andrew.

Operator

Your next question comes from the line of Jami Rubin with Goldman Sachs.

Jamilu E. Rubin - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

I have a couple of questions. First, just wondering, Ken and Rob, if you're comfortable with the way The Street is thinking about the cadence of KEYTRUDA uptake. Given the stickiness in the second-line lung market as reported by Bristol-Myers, we really have yet to see an inflection point in KEYTRUDA. Yes, it's doing well, but we haven't really seen a meaningful impact from KEYNOTE-189. And even more importantly, when do you expect to see the operating margin pull-through from KEYTRUDA? Even this quarter, if you adjust for the Adempas milestone, operating margins are below where they were a year ago despite KEYTRUDA sales up over $800 million. So I mean, are we thinking about operating margins correctly? Should they go up? And when do they go up? And then, Ken, for you, a question on Animal Health. We heard you loud and clear in your opening comments, fully committed to Animal Health, pillar of your growth, et cetera, et cetera, but I'm sure you've noticed, outside of Merck, this wave of corporate simplification that is going across the industry. We've seen that with Lilly, with Novartis, et cetera, et cetera. Investors are rewarding companies that are unlocking value through spinning off assets such as Animal Health. And I'm sure you've also noticed the big difference in valuation between Merck and Zoetis. So while we understand it's an important growth driver, I think if the company is fully committed to KEYTRUDA and confident in KEYTRUDA and that business, I'm not sure I understand why this digging in on Animal Health. So if you could address those 2 questions, I'd appreciate it.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Jami. So we'll start with Adam, talk about the commercial uptake of KEYTRUDA; then go to Rob for the operating margins; and then follow up with Ken on Animal Health.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Yes, Jami. So first, we're very pleased with the performance of KEYTRUDA. And if you look at the sales for the first half of '18, it's doubled versus the first half of 2017, and we've seen robust growth sequentially every single quarter since launch both in the U.S. and outside the U.S. And what I think people sometimes don't recognize is the fact that 40% -- more than 40% of our sales are outside the U.S., and we've only launched the monotherapy there. We have not yet launched the combination therapy. Well, I can tell you the feedback on the chemo combo in the U.S. use has been very well received. And as I mentioned, about 2/3 of new patients are now starting on KEYTRUDA when you exclude EGFR and ALK, and that's a 20 point share increase since AACR. I've always said this is not going to be a big bolus of patients because these are patients coming into the market as they're diagnosed each and every day and month. But as we continue to grow new patient share, those patients become part of the Rx base, and

that represents a very large opportunity for growth for us moving forward. And in addition to that, we've done really well with head and neck, bladder and MSI high, and we're looking forward to all the additional indications that Roger has spoken about.

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

Yes, Jami. And to your question about operating margin, obviously, as we look at the profile of the company, I think we've been fairly consistent with this, clearly, as we look to long term, we intend and expect to see both a leveraged P&L and operating margin expansion over time. But as we've said previously, in the near term, as we look at 2018 , we are continuing through a period of pretty meaningful investment both in the ongoing clinical studies for KEYTRUDA. And as you saw this quarter, we're now starting to see the clinical studies for Lynparza and LENVIMA also start to pick up, and that is driving a lot of the growth in R&D you're seeing in the quarter as well as continuing to advance several programs through our Vaccines portfolio. So obviously, we're very cognizant of the need to get the operating leverage and the margin expansion, but we also want to make sure we're making the appropriate investments for the long term. And so you're probably not going to see that type of expansion you're looking for until we get through this bolus of spend over the next year or so. And then on the gross margin line, you mentioned Adempas. Recall that as we came into the quarter, we did expect -- or into the year actually, we did expect to see a slight decline in our gross margins year-on-year. This is really due to the fact that we did have, coming into the year, the expectation of larger negative manufacturing variances. Part of that was due to the carryover effect of cyber, and part of it is due to the fact that, a few years ago, we actually benefited quite a bit from the start-up of commercialization of KEYTRUDA that brought with it very positive onetime manufacturing variances as we converted from our pilot plants to our commercial plants. So you are seeing that happening through the gross margin line. As we've said in the past, while we're not giving specific guidance on gross margin, if you look forward long term, we do see both the tailwinds of margin expansion from important products like KEYTRUDA, BRIDION and other new products launching which are margin-positive, being offset by the LOEs, ZETIA being an important one that had a very high margin and then products like ZEPATIER coming down, which also had a high margin. So those headwinds and tailwinds are largely offsetting. And as we look forward, whether or not we end up with a slightly higher margin or slightly lower margin will really depend on how product mix and currency play themselves through as we look forward. So that hopefully gives you a sense of what's happening both at the gross and operating margin line.

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

And Jami, thanks for your question about Animal Health. Let me start by letting you know and assuring you that we consistently reevaluate our corporate portfolio in light of various factors, including the environment, to determine how we can generate the highest value for our shareholders over the long term. You mentioned the growth impact that we talked about earlier in the call from Animal Health. In addition to growth, we believe our Animal Health business provides us diversification from KEYTRUDA and the rest of our Human Health portfolio. We also think it's important to note the important synergy of having Animal and Human Health together within Merck. We'll point out that our Animal Health business is growing more quickly than its industry peers, and a great deal of that has to do with the fact that we're able to achieve synergies between our Animal Health R&D and our Human Health R&D. For example, we have integrated protein and vaccine technology that is shared across that portfolio. Animal Health have access to our Human Health catalog, which has led to innovations on the Animal Health side. Right now, they're investigating oncology and diabetes for our companion animals. And there are other examples of Human Health leveraging discovery from Animal Health as well. So we see -- for all those reasons, as we sit here today, we see Animal Health still fitting with our strategic intent and our intrinsic capability as a research-based pharmaceutical company. And we believe these synergies will help our Animal Health business grow faster in its market, and it will also have an impact on overall Merck.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Thanks for your questions, Jami.

Operator

Your next question comes from the line of Chris Schott with JPMorgan.

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

Just had 2 here. Maybe first on KEYTRUDA. Where do you think penetration rates can go for PD-1s in front-line lung when we think about those non-ALK, non-EGFR patients? You mentioned you're right now at 2/3 of new starts. Where does that go over time? Can that go to 75%, 85%? Just any color there would be appreciated. My second question, GARDASIL, you got a $2.4 billion, $2.5 billion kind of run rate business now. You're talking about significant growth. I guess my question here is, how much larger could this product be over time? And maybe as part of that, what are the biggest growth markets? How quickly can you get to those markets? Just a little bit there just because we're trying to get our hands around how we should think about the ramp of the product from here.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Yes. Chris, this is Adam. First of all, with regard to KEYTRUDA penetration rates in first-line lung, a couple of things to note. First of all, the 2/3 and the 20 share point increase have happened very quickly, and we believe that there's still substantial opportunity for that to grow even further. And as I mentioned, that if you exclude ALK and EGFR, we now have survival benefit in 80% of the market. So we believe that we'll continue to see good growth. Outside the U.S., the opportunity remains very big because we've only launched the monotherapy. We have not yet launched the chemo combo therapy and some other data. So I think the growth opportunity there remains significant. So there's no doubt that our lung indication will continue to be a good driver of growth for us in the future, but as I said before, it doesn't end there. With all the new indications that we're expecting and some of those to be rather large, we're excited about the potential future opportunity. And the 2/3 that I talked about are new patients. Those are patients that are just being diagnosed coming into the market. So I do believe that there's a significant opportunity there moving forward. With regard to GARDASIL, there is opportunity, frankly, globally. In the United States, there's still opportunity to increase vaccination rates in 11- and 12-year olds, but also in the 19 to 26-year olds. I also believe the opportunity for the 27- to 46-year olds, as we discussed. That indication will represent another very important opportunity for us in the United States. Outside the United States, there's opportunity in new geographies, and China is an exemplar of that. And the uptake in China continues to be very strong. And then with new data that's been introduced in countries like Australia, there really is a lot of talk about elimination campaigns in markets around the world. So I believe that the opportunity for GARDASIL in the short term and long term for growth remains very significant.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks for your questions, Chris.

Operator

Your next question comes from the line of Vamil Divan with Crédit Suisse.

Vamil Kishore Divan - *Crédit Suisse AG, Research Division - Senior Analyst*

Maybe just following up on Chris'. Just I think (inaudible) 80% where you have the overall survival benefit now of the front-line market in metastatic lung cancer. I guess, what is a reasonable sort of penetration rate, do you think, if we look out, say, 12, 18 months? I think some of the comments from Bristol yesterday suggests maybe the penetration won't be as high as some people think. So maybe you can just give your sense of, out of that 80%, what would you be satisfied with if we looked out 12, 18 months in terms of how much KEYTRUDA alone or maybe PD-1, PD-L1s combined can penetrate. And then my second question is more for Ken on the business development side, and I appreciate that it remains a priority. I think investors maybe have been a little bit surprised that you have been more active. You've done some of these collaborations, which I think might be a little bit underappreciated. But just in terms of business development, as you look out now, thoughts around maybe a larger deal or any change in your perspective on the focus on innovation, [just give us] commentary about what's held you back and what might change to get you more aggressive going forward.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Yes. So this is Adam. So we're currently capturing, as I said, roughly 2/3 of the new patient starts when you exclude EGFR and ALK. I also said that's about a 20 share point higher increase than what we had prior to AACR. But I would expect continued substantial adoption in this indication as we go through the rest of this year, so I do believe it will continue to grow. Also, if you look at patients with squamous non-small cell lung cancer from KEYNOTE-407, that should enable us to become the standard of care in this population as well, and that's about 20% of the market. So again, with strength that we've seen in our clinical program, our indications should be able to represent about 80% of all non-small cell lung cancer patients with overall survival. And overall survival is the gold standard, so that's why I believe there's still significant opportunity there.

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

And on business development, I'd start by, again, reinforcing how important that priority is for the company, and we are actively looking for the best opportunities across all kinds of structures, including acquisitions and partnerships, collaborations and licensing. And with respect to acquisitions, over the past couple of years, as I've said previously, we have looked at some but didn't pan out either because the target was just not a willing seller or because there was the kind of competition for that asset that made the price untenable based on our assumptions. I think, as you've seen, there has also been, generally, a dearth of M&A across the industry recently. There's been significant funding flowing in the small biotech, including via IPOs, which are at multiyear highs. So as a result, biotech have access to ample capital, and they have perhaps less need or desire to sell right now. And the deals that are getting done are being done at very high prices and premiums. But I want to assure you that augmenting our pipeline through business development, nevertheless, remains an important priority. And so we'll continue to scour the landscape carefully.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Vamil.

Operator

Your next question comes from the line of David Risinger from Morgan Stanley.

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

So I have 2 questions. First, when do you expect to provide more clarity on the longer-term outlook? And I guess that includes the early to mid-stage pipeline and the financial prospects beyond 2018. And then second, with respect to GARDASIL, could you just discuss the things that are holding it back right now, supply shortages? I'm assuming the 3- to 2-dose conversion is over. And then finally, and I'm sorry for all the questions, but just China, could you comment on net pricing there versus the U.S?

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

So David, I'll take your first question, which has to do with explaining or helping people to understand our longer-term prospects. So we continue to evaluate the best way to do that, including perhaps the possibility of giving longer-term guidance as we appreciate the desire of investors for additional insights into our own internal expectations. Obviously, we want investors to understand why we are so confident in our long-term prospects so that they continue to evaluate Merck versus other investments. They can do that. I will say that we are thinking about the best way to do that, and we will get back to you in that regard.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

And with regard to GARDASIL, again, we remain optimistic about the long-term growth opportunity there. We're still in the beginning, frankly, of the launch in China, and we're excited about that opportunity. Regarding the U.S., the transition to the 2-dose regimen is nearly complete. It's not

entirely complete, but we are overlapping the vast majority of that change. So I think we'll start to see some growth there as we finalize the 2-dose transition. And then lastly, I would say that ensuring that we've got the right amount of product in the right parts of the world will always be something that we're going to be working on. And frankly, the uptake in China has been larger than what we would have initially anticipated, and we're still trying to ensure that we understand what's the demand there because it is such a large opportunity. There are so many people there that we've got to understand how much product we'll need to get into that country.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Dave.

Operator

Your next question comes from the line of Gregg Gilbert with Deutsche Bank.

Gregory B. Gilbert - *Deutsche Bank AG, Research Division - MD and Senior Analyst*

I'm going to start with Roger. On the pneumococcal vaccine front, the stakes are pretty huge, albeit a few years out, from things changing. But it appears that you could leapfrog Pfizer in a few years and then possibly get re-leapfrogged by them with their 20-valent product. Obviously, the studies have to be done, but can you shed some light on your views on how that space will evolve? And any other nuances we should be aware of in terms of the potential for differentiation other than sort of whose is bigger than whose? And then, Adam, can you talk about the commercial opportunity for doravirine? It seems to be something where there's a disconnect between the company's enthusiasm and The Street's focus.

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

Well, thanks, Gregg. On pneumococcal vaccine, clearly, I think this is an area where we've been very active for a long time. With PNEUMOVAX, we have a lot of understanding of the marketplace, and the needs in terms of invasive pneumococcal disease continue to evolve because of the availability of vaccines, particularly in the younger, susceptible population. So as new vaccines are introduced, there are changes in the epidemiology of pneumococcal serotypes, which we follow quite closely. My expectation is that there will be need in the marketplace for multiple pneumococcal vaccines. We've advanced V114. We're advancing V116 (sic) [V160]. There will be other things that will be coming forward. There will be others in the marketplace. Obviously, our colleagues and competitors at Pfizer are hard at work on these too, and we'll see how it plays out. But I think there's clearly need for many vaccines in this extremely important area given the breadth of pneumococcal disease and its impact on human population.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

And with regard to doravirine, it's important to have options outside the (inaudible) inhibitor class, and that is the most frequently prescribed class at the moment. But NNRTI-based regimens are one of the most commonly used treatment regimens in early lung patient populations. And if you look at doravirine's profile, it does improve on some of the limitations with the NNRTI class. We won't be able to see, in that side effect profile, a [no-food] effect. But I look at it more as a bridge, and it's a way to continue to build on our legacy in HIV, a bridge to that product that Roger talked about, which is the MK-8591 novel product. So I would look at it as a near-term way for us to continue to be relevant in the market, but a real growth opportunity as we bridge into the future with our pipeline.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks for the question.

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*

I wanted to focus on KEYTRUDA, maybe start off a little broader and perhaps then, a bit more specific. So first, on KEYTRUDA experience to date across all the indications that you have commercially, my question is, how does the duration of therapy track relative to the PFS you've put up in each of those indications? Mostly trying to understand that for our own modeling purposes. Is it 2/3 of PFS, which has been the proxy mentioned by some other companies in the past? Or is it similar to PFS in the case of KEYTRUDA or even higher than PFS? Just wanted to understand that. Secondly, I wanted to focus a bit more on KEYNOTE-522, the neoadjuvant and the adjuvant trial in triple-negative breast. And my question was, what's the bar for a very competitive profile? And perhaps, Roger, if could speak to the variety of pCR definitions incorporated in the secondary endpoints and whether you would sort of focus more on one definition over the other. And perhaps Adam could speak to the commercial opportunity in that indication as well.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Yes. So with regard to KEYTRUDA, it's very hard to get data, and you really do need to have quite a bit of data over time to understand the exact duration of therapy. So I'd be hesitant to give any specific numbers. We are collecting real-world evidence data. We are working on various data sources to have better estimates of that. And over time, we may be able to provide more specific information on that.

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

And on the -- with respect to neoadjuvant breast, we are -- first of all, I mean, just to elevate it and say we're very excited about the opportunities that exists for adjuvant and neoadjuvant therapy with KEYTRUDA across a broad range of tumor types. And I think the neoadjuvant experience is particularly instructive because of the proinflammatory effect of surgery in a variety of contexts. I draw your attention, and you don't need your attention drawn to it because you already know it very well, to the I-SPY data -- I-SPY 2 data that we've had the opportunity to present previously. And the pathologic complete response results there are extremely impressive. Without going into any -- attempting in any way to compare different definitions of pathologic complete response, I think there is a good understanding in breast cancer in particular about the relationship between pathologic complete response as studied in I-SPY 2 and outcomes. And that's the kind of analysis that we are using -- or will use in KEYNOTE-522 and in other studies going forward. I'm very enthusiastic about where that could lead.

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

And with regard to the indication, I mean, as I've mentioned before, having a whole host of indications just reinforces how foundational KEYTRUDA is to overall cancer care. So every indication is important. With regard -- to this point, we're excited to get into the breast cancer market, but we're also starting to (inaudible) since this is already with Lynparza. So we are ready to launch with KEYTRUDA as soon as the data would be available and the indication available.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Thanks for the question.

Operator

Your next question comes from the line of Jason Gerberry from Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

Just firstly on -- we talked a lot about U.S. KEYTRUDA in lung. Can you talk a little bit about in terms of regulatory and then pricing and reimbursement? When do you actually expect to see meaningful contribution from KEYTRUDA in lung ex U.S., outside of the monotherapy, PD-L1-high group? And then my second question, just on JANUVIA/JANUMET, a little bit higher than we were expecting for the quarter. Can you talk a little bit about the pricing environment? It seemed as though, oral antidiabetic drugs, we're continuing to see gross-to-net adjustment spike and the pricing pressure, but maybe has it stabilized a little bit? Or are you guys just including your SGLT2 combo in that line? Any clarity just around how to think about that would be helpful.

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

Yes. So I'll start with the JANUVIA question. As I said before, outside the U.S., we continue to see strong growth. In the -- and most of that is offset by the pricing pressure that we see in the U.S. And as I said for the last couple of years, each year is tougher than the last year. This year, there's more pricing pressure than there was last year, and I believe, next year, there'll be more pricing pressure than there is this year. So I believe that, that will continue. The good news is we are seeing growth outside of the U.S., and we're in the middle of launching in China, for example, where we think there's still growth opportunity there. So what's happening is the growth outside the U.S. is offset by the U.S. pricing pressure, albeit, in the U.S., we still continue to see good volume there. With regards to KEYTRUDA outside of the United States, I mean, lung cancer is the majority of revenue already outside the U.S., even though it's coming from the monotherapy. We already have most of the major markets reimbursing for lung for the monotherapy. We're waiting to be able to promote the combo, and I think that will represent an additional opportunity for us outside the U.S. moving forward.

Operator

Your next question comes from the line of John Boris with SunTrust.

John Thomas Boris - *SunTrust Robinson Humphrey, Inc., Research Division - MD*

Question for Ken on -- at the conclusion of the last call, Ken, you mentioned that Merck was transitioning from a primary care to a specialty care business and that the 3 most important franchises would be, certainly, oncology, Vaccines and Animal Health going forward. When we look at the revenue generated from those businesses, it's basically 2/3 of your revenue around the time of the loss of exclusivity of JANUVIA in the U.S. And when we benchmark the incremental revenue that you're driving from those 3 businesses and benchmark oncology versus Roche, Vaccines versus GSK and Animal Health versus Zoetis, it certainly implies that operating margins expand quite substantially, especially beyond 2022. Can you provide any color on magnitude of operating margin expansion going forward, especially when you benchmark against those key players? Second question for Rob. If you look at the 35% tail of revenue, there's some old legacy assets, respiratory assets, women health care assets and [infective] assets that carry high fixed costs, most notably women's health and Animal Health because you need dedicated manufacturing facilities. Any thoughts about divestitures out of that tail?

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

Great. So maybe I'll jump on the operating margin question, and I can hit the second question. Or did you want, Ken...

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

No. No problem, take it, Rob.

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

So -- and to your question of what we think long term for operating margin, we're not going to give specific guidance, but we have been consistent to say, in general, we do believe we're going to see operating margins expand as we move forward as a result of what you pointed out, which is, if you look at the mix of businesses with oncology and Vaccines relative to what you would think of as the traditional primary care infrastructure, clearly, those are more efficient businesses. But I would point out, as you look at -- and maybe just some general thoughts to give context. As you think about a pure specialty, we are a little bit different than what you think of as a pure specialty-type company for a couple of reasons. Starting with oncology. You really have never seen a situation in oncology like what we have right now with KEYTRUDA because this is the first time you have a drug that is crossing so many different tumor types, so many different indications. And as a result of that, you're really dealing with the need to promote and to sell to multiple different specialists. So the infrastructure burden for a product like KEYTRUDA probably is going to be more than what you would see for a traditional oncology company just given that, although it still is very beneficial to where we are today. So we are going to expand, but I just would say be cautious not to look at a pure oncology play with a more limited indication profile as a comparator. And then, likewise, in Vaccines, if you look at our Vaccines portfolio, several of the products in our Vaccines portfolio and as we look forward to some of the products in our pipeline, actually, several of those will not only go to specialists but also will be marketed to the primary care doctors. So that in and of itself will mean a little bit more of a footprint. So I just want to give you a sense of that to say that while we do expect to see margins expand, I think it's hard to think in terms of what a pure specialty company would look like. And then with regards to the portfolio and what we're thinking about, as Ken mentioned in his earlier comments at the beginning of the call, we are always reevaluating our portfolio. And so we are not foreclosed to any opportunity to optimize the portfolio. If it makes sense for both the short term and the long term, I think that's the important thing. In everything we look at, we try to measure what is the long-term path to sustainable value creation, sustainable growth and make the decisions balancing that relative to what we see in the short term. But to your point, as we look across diversified brands and in particular, products like women's health, we're always asking the question, "Would it be more valuable in someone else's hands, including the manufacturing assets?" And if we see something that makes sense from a deal perspective, we would consider it.

Operator

Your next question comes from the line of Alex Arfaei with BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Adam, follow-up on your commentary on KEYTRUDA. You mentioned a number of future indications for growth opportunities. Could you please prioritize those in terms of which ones you think have greater commercial potential? And then a follow-up on Animal Health. Obviously, very strong growth, it seems to be growing above the market rate. Just wondering how long you think that is sustainable. When should we expect this to, I guess, as it gets larger, to return closer to the market growth rate?

Adam H. Schechter - *Merck & Co., Inc. - Executive VP & President of Global Human Health*

Yes. So as I look at KEYTRUDA, as I said, each of these indications is important and represents value to patients and the -- the patients suffering from cancer. As I look at the size and our order of entry and those types of things, obviously, the breast cancer indication, the gastric cancer indication are important. Hepatocellular is important, to be able to compete in renal as well. And then as we look even further out, the adjuvant-stage cancers are also very exciting opportunities for us.

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

Yes. And then with your question to Animal Health, you're right, as you look at the quarter, we had very strong growth in the quarter. And if you look back over the last couple of years, we've been consistently outpacing the market -- the Animal Health market and our growth. And as Ken mentioned earlier, this is largely due to the fact that we have both a robust in-line portfolio of products, but also we're having meaningful new product launches across Vaccines, across companion animals. So it really is a story of innovation that is driving the above-market growth. And as we look forward, we expect -- we're not going to give specific guidance, but I would say, as we look forward over the next several years, I would

expect to continue to see above-market growth on the basis of the new products as well as the strength of in-line products we have, which really ties to the whole nature of the innovation story and innovation synergies that Ken mentioned earlier.

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

Okay. Thank you all for participating in today's call. I want to reiterate that we are focused on commercial execution and continuing to advance our portfolio. I'm very optimistic about the rest of the year and our long-term outlook.

I want to thank you, and have a good day.

Operator

Ladies and gentlemen, that does conclude today's conference call. You may now disconnect.
