Q1 2017 Earnings Call

Company Participants

- Dominic J. Caruso, Executive Vice President, Chief Financial Officer
- Joseph Wolk, Vice President-Investor Relations

Other Participants

- Bob Hopkins, Analyst
- Dane Leone, Analyst
- David Ryan Lewis, Analyst
- Jami Rubin, Analyst
- Joanne Karen Wuensch, Analyst
- Larry Biegelsen, Analyst
- Matt Miksic, Analyst
- · Michael Weinstein, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning and welcome to Johnson & Johnson's first quarter 2017 earnings conference call. All participants will be in listen-only mode until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time.

I would now like to turn the conference call over to Johnson & Johnson. You may begin.

Joseph Wolk {BIO 19812977 <GO>}

Hello. This is Joe Wolk, Vice President of Investor Relations, and it is my pleasure to welcome you to review Johnson & Johnson's business results for the first quarter of 2017. Accompanying me on the webcast is Dominic Caruso, Executive Vice President, Chief Financial Officer. Thank you for joining us today.

Our results for the first quarter were consistent with our expectations and aligned to the guidance we provided in January. As you have likely seen in this morning's press release, we are updating our 2017 guidance to include Actelion, assuming closing of the transaction in June. The public tender offer for Actelion is nearing completion and has been declared successful based on the number of shares tendered, subject to satisfaction of remaining closing conditions. We sought regulatory approval in seven jurisdictions and

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have satisfied requirements in six of them, with antitrust approval by the European Commission pending.

Dominic will provide further insights on the transaction as well as the impact on all elements of guidance in his remarks following my commentary on results for the company and the three business segments.

A few logistics before we get into the details. This review is being made available via webcast, accessible through the Investor Relations section of Johnson & Johnson website at investor.jnj.com, where you can also find additional materials including today's presentation and accompanying schedules.

Please note that this morning's presentation includes forward-looking statements. We encourage you to review the cautionary statement regarding such statements included in today's presentation as well as the company's Form 10-K, which identify certain factors that could cause the company's actual results to differ materially from those projected. Our SEC filings, including our 2016 Form 10-K, along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures, are all available at investor.jnj.com.

A number of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships.

After prepared remarks from Dominic, the remaining time of today's webcast will be made available to answer your questions. We anticipate today's webcast to last approximately 60 minutes.

Now on to the results for the first quarter of 2017. Worldwide sales were \$17.8 billion for the first quarter of 2017, up 1.6% versus the first quarter of 2016. On an operational basis, sales were up 2% as currency had a negative impact of 0.4%.

In the U.S., sales were up 0.6%. In regions outside the U.S., our operational growth was 3.6% as the effective currency exchange rates negatively impacted our reported OUS results by 0.8 points. Excluding the net impact of acquisition and divestitures, operational sales growth was 1.2% worldwide, declining 0.7% in the U.S. and increasing 3.4% outside the U.S. I will provide the same reference for each segment.

Turning now to earnings. For the quarter, net earnings were \$4.4 billion and diluted earnings per share were \$1.61 versus \$1.59 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were \$5 billion and adjusted diluted earnings per share were \$1.83, representing increases of 3.8% and 5.8%, respectively, compared to the same period in 2016. On an operational basis, adjusted diluted earnings per share grew 7.5%. Dominic will provide further detail regarding earnings in his remarks.

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I'll now comment on quarterly business segment sales performance beginning with Consumer, highlighting items that build upon the slides that are currently being presented. Unless otherwise stated, percentages quoted represent operational sales change in comparison to the first quarter of 2016 and therefore exclude the impact of currency translation.

Worldwide Consumer segment sales totaled \$3.2 billion, growing operationally 0.8%. Excluding the net impact of acquisitions and divestitures, total adjusted operational sales growth declined 2.3% worldwide.

As an overarching theme across most consumer franchises, the first quarter results were negatively impacted by global category slowdown as commented to in numerous reports published in recent weeks by consumer staples analysts and peer commentary highlighting higher gas prices, retailers reducing inventory levels and delayed tax refunds among many factors for slower growth. That slowdown is reflected in results for five out of the six categories we compete in.

Additionally, after several quarters of higher consumption for many of our products, we did see that moderate, primarily in Baby Care and Wound/Other. Finally, we did see macroeconomic conditions such as high unemployment, high inflation and low consumer confidence impacting our performance in the Latin America region.

Switching to specific platforms, the Beauty franchise includes the acquisitions of Vogue, NeoStrata and La Lumiere Light Mask, which in total contributed approximately 13 points of growth for the franchise. Vogue sales globally totaled \$98 million for the quarter.

While worldwide and U.S. market shares remain relatively flat compared to the same period of 2016, the U.S. beauty market is estimated to have contracted by a little more than 1%. AVEENO Adult and NEUTROGENA were each down approximately 1 point.

The OTC franchise grew 1.5%, but when accounting for divestitures, the adjusted growth was approximately 2.4%. Both adult and children's TYLENOL outpaced their respective categories and adult TYLENOL has ascended to be the number two branded product.

Growth for the franchise was negatively impacted by approximately 4 points due to unfavorable comparisons for the ZYRTEC and RHINOCORT brands in the U.S., where promotional inventory builds were experienced in the first quarter of 2016.

Concluding the Consumer segment, Oral Care was impacted by the market contracting versus the first quarter of 2016 by approximately 3%. Worldwide market share is flat. However, U.S. market share is down by about 0.5 point compared to Q1 2016.

Regarding our Pharmaceuticals segment, worldwide sales of \$8.2 billion grew 1.4%. Excluding the net impact of acquisitions and divestitures, operational adjusted sales growth was 2.2% worldwide.

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As we commented to in the first quarter of 2016, favorable prior-period price adjustments or gross- to-net contributed approximately \$200 million to the first quarter 2016 results in the U.S. This is a comparative headwind for the first quarter 2017 growth rate of 2.5 points, which when added, would take the worldwide pharmaceutical growth rate to 4.7%. On a product basis, the negative impact on U.S. growth rates is approximately 13 points for STELARA and 4 points each for XARELTO and REMICADE.

In Oncology, DARZALEX continued its strong performance with worldwide sales of \$255 million and is experiencing strong adoption following midyear 2016 launches outside the U.S. DARZALEX maintains its leadership in line four-plus multiple myeloma, and we are seeing accelerated adoption in the U.S. for the multiple myeloma one prior line setting, pursuant to the approvals of those indications late last year.

IMBRUVICA in the U.S. gained approximately 8 points of market share across all lines of therapy based on the fourth quarter data, and the CLL market is estimated to have grown approximately 20%. Outside the U.S., we continue to experience strong uptake in the G5 countries.

Negative ZYTIGA growth in the U.S. was the result of higher utilization of independent patient assistance foundations, a dynamic that has carried over from the fourth quarter of 2016.

In Immunology, the U.S. market is estimated to have grown approximately 5%. STELARA in the U.S. gained 0.6 points of market share in psoriasis versus the first quarter of 2016. We are very pleased with the uptake of STELARA in Crohn's disease following the launch late last year of this new indication, as more than 6,000 patients are utilizing STELARA for Crohn's treatment.

REMICADE in the U.S., when accounting for the 2016 prior-period price adjustments referenced earlier, was modestly higher, with volume growth partly offset by increased discounting. The REMICADE export business continues to see the impact of biosimilar competition in Europe.

INVOKANA/INVOKAMET sales in the U.S. were negative due to lower price. In addition to increasing discounts for managed care contracting, there was also an impact from channel mix, with a higher composition of sales now occurring in the Medicaid channel.

For XARELTO, total prescription market share is up more than 2 points versus a year ago, as warfarin share is down to 51% versus 58% in the first quarter of 2016. We are seeing some higher discounting in managed care and government channels for preferred access positions.

We equalize annual costs associated with the Medicare coverage gap, also known as the donut hole, over each quarter throughout the year. The timing of when these costs were assigned to each brand in 2016 had an impact for year-on-year comparisons. Taking this into account coupled with the impact from last year's favorable prior-period price

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adjustment previously referenced, growth for XARELTO for the quarter was approximately a positive 2%.

In Neuroscience, our paliperidone palmitate long-acting injectable portfolio achieved strong results in all major regions due to increasing market share. CONCERTA in the U.S. is experiencing negative price due to the reentry of generic competition. Other Neuroscience was impacted by the 2016 divestiture of the Noramco API business, which accounted for \$60 million of lower sales.

I'll now turn our attention to the Medical Device segment. Worldwide Medical Devices sales were \$6.3 billion, growing 3.4%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 1.7% worldwide.

Vision Care results now include the Medical Optics business, which we acquired from Abbott in a transaction that closed on February 27. The one month of sales totaled \$124 million for that business. The Contact Lens business grew approximately 5%, continuing its trend of market share gains through new product introduction, namely OASYS 1-Day products globally and variants of the DEFINE Lens outside the U.S.

Hospital Medical Device growth of 2% was driven by our priority platforms, which as a reminder, we consider to be electrophysiology, endocutters, energy, knees, and trauma. Combined, that set of businesses grew operationally 6.5%.

Electrophysiology grew approximately 17% worldwide, as atrial fibrillation procedures continue to grow, estimated at 11% for the quarter in the U.S. and 14% outside the U.S. Strong adoption of newer product offerings in ablation and advanced catheters continued. This business has grown double-digit percentages in 29 out of last 30 quarters.

Within the advanced surgery category, endocutters grew 10%, primarily driven by GST and PVS growth globally. Energy growth of 6.9% was driven by the inclusion of the Megadyne acquisition and strong OUS performance from new products in China and Europe. The specialty surgery business was down compared to the first quarter of 2016, driven by U.S. declines in the aesthetics and advanced sterilization businesses.

Within Orthopaedics, knee growth was driven by continued uptake of ATTUNE outside the U.S., particularly in China and the Middle East-Africa region. Trauma, including sales from the acquisition of BioMedical Enterprises, was flat versus a year ago. Growth in hips was generated by continued uptake of the CORAIL primary stem system in the U.S. and the launch of the GRIPTION platform in China.

Pricing pressure continued across the major categories in Orthopaedics, but was partially offset by favorable mix. For the quarter in the U.S., net price in hips was negative 2.1%, knees negative 1.7%, positive 0.2% in trauma, and positive 2.8% in spine.

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That concludes the segment highlights for Johnson & Johnson's 2017 first quarter. For your reference, here is a slide summarizing notable developments that occurred in the first quarter. It is now my pleasure to turn the call over to Dominic Caruso.

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Joe, and good morning, everyone.

As Joe has outlined for you, our first quarter results were largely in line with our expectations for the quarter as part of the full-year guidance that we provided in January. Though we had some challenging dynamics and difficult comparisons regarding sales this quarter, we remain on track to achieving our full-year sales and earnings guidance.

Since Joe walked you through the sales results for each business, I would like to add some overall commentary on those results, discuss our operating performance and what we expect for the balance of the year.

We continue to make very good progress on our near-term priorities as well as our long-term growth drivers as our CEO, Alex Gorsky, described for you on our last conference call.

In our Pharmaceutical business, we saw very little impact in the first quarter from biosimilar competition to REMICADE in the U.S. Joe mentioned some of the comparative challenges we encountered this quarter. But adjusting for those factors and the impact of divestitures, we grew at 4.7% operationally, which we believe is at or even slightly above projected market growth rates.

Our newer products in immunology, oncology and neuroscience continue to deliver solid growth, and we have one of the best pipelines in the industry. We look forward to providing an in-depth review of that pipeline at our upcoming Pharmaceutical Business Review Meeting on May 17.

In our Consumer business, we saw category deceleration in Q1 across many of the markets we compete in, along with continued macroeconomic factors in Latin America and Asia which impacted growth. Many industry reports suggest that the consumer category will rebound in the near term, and we believe we will be well-positioned to grow above market through geographic expansion of current products, the acceleration of our recent acquisitions and the introduction of new products, which are expected to generate approximately 2 points of incremental growth going forward in 2017.

And in Medical Devices, our Vision Care business had solid growth from recently launched products, and our newly acquired Surgical Vision business is growing at over twice the rate it grew in the first quarter of 2016.

In our Hospital Medical Device group, we saw our priority growth platforms that now represent approximately 40% of our sales deliver solid growth of approximately 6.5%

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operationally, while some of the core categories did experience slower growth.

As you know, we have been managing our portfolio through divestitures and strategic acquisitions, including several new products and technologies in faster areas of growth such as our recently announced acquisition of Neuravi, a novel technology for ischemic stroke. And we expect new products to accelerate our growth for the balance of the year by 1.5 to 2 points.

Our guidance from January also included the expectation that our adjusted pre-tax operating margins should be stable to slightly higher in 2017. We were pleased to see that our disciplined expense management delivered on this expectation in the first quarter with a 50-basis-point improvement in our adjusted pre-tax operating margin to 33.4%. And while we expect investment levels to increase throughout the year, we continue to expect that we will maintain to slightly improve adjusted pre-tax operating margin for the full year.

Finally, as Joe pointed out earlier, we have had many positive developments concerning the steps needed to close the Actelion transaction, and we expect to complete our acquisition of Actelion by the end of the second quarter.

As a result, in a few minutes, I will provide 2017 guidance for you to update your models that includes the expected impact of Actelion on our full-year 2017 results. But first, I'd like to highlight some key points regarding our first quarter operating results. I will now turn to our consolidated statement of earnings for the first quarter of 2017.

As we've mentioned, our operational sales growth this quarter was 2% and excluding the impact of acquisition and divestitures, it was 1.2%. If you direct your attention to the boxed section of the schedule, you will see we have provided our earnings adjusted to exclude intangible amortization and special items.

As referenced in the table of non-GAAP measures, the 2017 first quarter net earnings were adjusted to exclude intangible amortization expense and special items of approximately \$616 million on an after-tax basis, which consisted primarily of the following: intangible asset amortization expense of \$244 million, a charge for the continuing restructuring of our Hospital Medical Device business of \$121 million and the AMO acquisition-related cost of approximately \$251 million.

Our adjusted earnings per share is therefore \$1.83, exceeding the mean of the analyst estimates as published by First Call. This is an increase in adjusted EPS of 5.8% versus the prior year. And adjusted EPS on a constant currency basis was \$1.86 or up 7.5% over the prior year.

Now, let's take a few moments to talk about the other items on the statement of earnings. Cost of goods sold decreased by 20 basis points, primarily due to manufacturing cost improvements which are partially offset by transactional currency impacts. Selling, marketing and administrative expenses were 26.6% of sales or 20 basis points lower as compared to the first quarter of 2016 due to cost management. Our investment in

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research and development as a percent of sales was 11.6% and in line with the prior year as we continue to advance our promising product pipelines.

Interest expense net of interest income was higher than last year due to higher debt levels. Other income and expense was a net gain of \$160 million in the quarter compared to a net gain of approximately \$40 million in the same period last year. There are no significant items in this line in either of the current or the prior-year periods.

Excluding special items, the effective tax rate was 17.5% compared to 16.3% in the same period last year. This rate is consistent with our expectations as a component of the full-year effective tax rate. The first quarter rate is lower than the annual effective tax rate we provided in January and likely lower than many of your models as the timing of the benefit associated with stock-based compensation tax accounting primarily impacts the first quarter as we described last year.

Turning to the next slide, I'll now review adjusted income before tax by segment. On our 2016 year-end call, we commented on our segment results adjusted for income tax adjusted for – earnings before tax versus the prior year. Now that our competitors have reported their results for 2016, I'd like to take the opportunity to point out that our 2016 adjusted income before tax was 31.7% compared to 26.7% weighted average for our competitive set.

In the first quarter of 2017, our adjusted income before tax for the enterprise improved 120 basis points versus the first quarter of 2016, driven by higher operating profit, some favorability and other income.

Looking at the adjusted pre-tax income by segment, Medical Devices at 31.6% is lower than the previous year, primarily due to unfavorable transaction currency within cost of goods sold. Pharmaceutical margins improved from the prior year by 400 basis points, primarily driven by lower manufacturing costs and favorable product mix. In Consumer, margins improved to 20.2%, now estimated at benchmark levels, while still making the necessary investments to deliver future growth.

Now, I will provide some guidance for you to consider as you refine your models for 2017. Today, we will be providing guidance that assumes we close on our acquisition of Actelion by the end of the second quarter. Before I move to that guidance, I would like to reiterate our guidance from January, which remains unchanged without the impact of Actelion.

As a reminder, that guidance was as follows. We expected operational sales to increase 4% to 5% for the year. This would result in sales for 2017 on a constant currency basis of approximately \$74.8 billion to \$75.5 billion. Our operational sales guidance for 2017 on an underlying basis, excluding the impact of acquisitions/divestitures, was expected to reflect growth of 3% to 3.5%.

Our adjusted EPS guidance expected a range of \$7.05 to \$7.20 per share on a constant currency basis, reflecting operational or constant currency growth of approximately 5% to

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7%.

I will now provide our complete full-year 2017 guidance now including the expected impact of Actelion.

At the end of the quarter, we had approximately \$7 billion of net cash, which consists of approximately \$39 billion of cash and marketable securities and approximately \$32 billion of debt, which reflects our cash position following the close of Abbott Medical Optics and our recent debt offering. As a reminder, we plan to complete our share repurchase program by the end of the second quarter.

Also, by the end of the second quarter, we expect that we will have closed on the Actelion acquisition at a purchase price of approximately \$30 billion. Therefore, for purposes of your models and assuming no other significant uses of cash, I suggest you consider modeling net interest expense of between \$600 million and \$700 million.

Regarding other income and expense, as a reminder, this is the account where we record royalty income as well as gains and losses arising from such items as litigation, investments by our development corporation, divestitures, asset sales and write-offs.

We would be comfortable with your models for 2017 reflecting net other income and expense excluding special items as a net gain, ranging from approximately \$1.1 billion to \$1.3 billion, which is consistent with our previous guidance. And for taxes, our guidance today does not include any assumptions about potential tax reform measures. Our effective tax rate guidance for 2017, excluding special items, is approximately 19% to 20%, also consistent with our previous guidance.

Now, turning to sales and earnings. Our sales guidance for 2017 now includes the expected impact of Actelion and already had included the impact of Abbott Medical Optics which closed in the first quarter, as well as the expected impact of REMICADE biosimilars, which we consider to be at risk due to ongoing patent litigation. In addition, we do not anticipate any impact from generic competition this year for ZYTIGA, RISPERDAL CONSTA, PROCRIT, PREZISTA or INVEGA SUSTENNA.

As we've done for several years, our guidance will be based first on a constant currency basis, reflecting our results from operations. This is the way we manage our business, and we believe this provides a good understanding of the underlying performance of our business. We will also provide an estimate of our sales and EPS results for 2017 with the impact that current exchange rates could have on the translation of those results.

We would be comfortable with your models reflecting an operational sales increase on a constant currency basis of between 5.8% and 6.8% for the year. This would result in sales for 2017 on a constant currency basis of approximately \$76.1 billion to \$76.8 billion. This is higher than our January guidance as it now includes the expected impact of Actelion.

Although we're not predicting the impact of currency movements using the euro as an example as of last week at \$1.07, the negative impact of foreign currency translation will be approximately 1%. Plus, under this scenario, we expect reported sales to reflect the change in the range of 4.8% to 5.8% for total expected level of reported sales of approximately \$75.4 billion to \$76.1 billion.

And now, turning to earnings. We expect adjusted earnings per share to be in the range between \$7.12 and \$7.27 per share on a constant currency basis, reflecting an operational or constant currency growth rate of 6% to 8%, an increase of \$0.07 over our January adjusted EPS guidance.

If currency exchange rates for all of 2017 were to remain where they were as of last week, then our reported adjusted EPS will be negatively impacted by approximately \$0.12 per share due solely to currency movements. Therefore, we would be comfortable with our reported adjusted earnings per share ranging from \$7 to \$7.15 per share, or a growth rate of between 4% and 6%. As it is still early in the year, we would be comfortable with your models reflecting the midpoint of this range.

Our estimate of the immediate positive impact to adjusted earnings from the anticipated second quarter closing of the Actelion transaction assumes we will exercise an option related to one of the R&D programs in the R&D spin-off company, Idorsia, later this year, which will increase our R&D expense for 2017.

At this early stage, we remain comfortable with our estimate of a positive first full-year impact to adjusted earnings per share of between \$0.35 and \$0.45 per share. We will, of course, update you further on this estimate when we provide full-year 2018 guidance.

So, in closing, we are raising our operational sales and EPS guidance to include the expected impact of our acquisition of Actelion, and we remain optimistic with what we see ahead for the full year. Namely, we're expecting operational sales growth of between 5.8% and 6.8%; we continue to deploy good cost management and expect to maintain or slightly improve our pre-tax operating margins; our operational adjusted earnings per share growth in our guidance remains strong in the range of 6% to 8%, consistent with our goal of growing earnings faster than sales; and our businesses are continuing to invest while also delivering on our near-term priorities.

And we're pleased to continue seeing significant milestones in our pharmaceutical pipeline and are confident in the continued growth expectations for that business. In fact, we look forward to discussing this with you in more detail at our May 17 Pharmaceutical Business Review Day.

Now, I'd like to turn things back over to Joe to open up the Q&A portion of the call. Joe?

Joseph Wolk {BIO 19812977 <GO>}

Thank you, Dominic. Manny, can you please provide instructions for those on the line wishing to ask a question?

Q&A

Operator

Thank you. With that, our first question is from Jami Rubin of Goldman Sachs. Please go ahead.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Dominic, just a couple questions for you. I mean, I'm just trying to get my head around the new guidance, and you did a nice job explaining all the pieces.

So this quarter, you beat by \$0.10, but for the full-year, you're only raising guidance by \$0.07 and that does include the impact of Actelion. You did mention that this is just a half-a-year impact, so even if I assume that you wouldn't experience the full half-year impact, even if I assume that the synergy impact is back half-weighted and assume that you'll only benefit from, say, a third of the synergy, I'm still coming up a little short.

Perhaps, it's this R&D expenditure that explains the difference, but that would seem to be - that might explain only a part of the difference. So, if you could just walk through again the different pieces. I'm surprised that the guidance didn't come in above given your original Actelion guidance. But, again, I'm sure that there are timing issues in this R&D expense. That would be helpful. And then I have a follow-up question on REMICADE. Thanks.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Okay. Hi. Good morning, Jami.

Q - Jami Rubin {BIO 1527982 <GO>}

Good morning.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Well, just a few things. So, regarding our first quarter results of \$1.83, that's about \$0.06 higher than current estimates. But you could break that down between \$0.03 or \$0.04 related to a lower tax rate than is in the Street's models for the first quarter and the balance related to basically good cost management.

With respect to that tax rate, we did not change the tax rate for the year. So the lower tax rate in the first quarter compared to what is in many of your models really is just timing related to the stock-based compensation accounting, which is mostly reflected in the first quarter. And through the balance of the year, we do expect some increased investment, which would offset some of that favorability in expenses in the first quarter.

Regarding next year for Actelion, in the first full-year 2018, we're still confident with our \$0.35 to \$0.45 per share. If you look at this half year, it's a couple things going on. First of all, you're exactly right. I mentioned the R&D, the option that we have with respect to one

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of the R&D programs in the spin-off company, and we're assuming that we will exercise that option, which will impact our R&D expense in the latter half of the year as a cost. That's worth about \$0.08.

We gave guidance, that's about \$0.07 higher related to adding Actelion. Let's call that \$0.15 for half a year of Actelion assuming that the option wasn't exercised, and that's just slightly lower than the half a year at \$0.35 or so for next year and that's because all of the synergies related to transaction really ramp up in 2018, not in the early stages of the integration in 2017. So, hopefully, that clears things up.

Q - Jami Rubin {BIO 1527982 <GO>}

Yeah. No, that definitely helps. So the \$0.35 to \$0.40 is really a second - the first full year.

A - Dominic J. Caruso {BIO 1423936 <GO>}

That's correct, yeah.

Q - Jami Rubin {BIO 1527982 <GO>}

That's not including the - I mean, because the original press release said first full year...

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yeah.

Q - Jami Rubin {BIO 1527982 <GO>}

...which was from the time you close. So, I...

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yeah. The \$0.35 to \$0.45 is 2018's estimate.

Q - Jami Rubin {BIO 1527982 <GO>}

Okay. That's helpful.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yeah.

Q - Jami Rubin {BIO 1527982 <GO>}

Just second question on REMICADE. The impact from biosimilars has been very minimal. What are your expectations for the remainder of the year? And then, lastly, I'm curious your thoughts, Dominic, on prospects for corporate tax reform and repatriation just given some of the dysfunction in Washington. Thanks very much.

A - Dominic J. Caruso {BIO 1423936 <GO>}

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Sure. With REMICADE, we saw very little impact in the first quarter. Of course, it's early because the product just launched at the end of last year.

As you know, there's no interchangeability, so we certainly don't expect that physicians will switch patients. They may start new patients on therapy. But with the long history that we have of REMICADE's efficacy and safety, we believe patients will move slowly to switch to a biosimilar. And we've incorporated that planned utilization in our guidance for the year. and it hasn't changed from the time we gave guidance in January, which is well before we saw any impact in the quarter.

With respect to tax reform and what we expect to happen, I was actually just in Washington last week. And one of the things that I think is very clear is that the House has a plan that they want to move forward, which includes the border adjustment tax. That has not yet been adopted by the Senate, although everyone agrees that some innovation in the way jobs will be created in the U.S. is important.

And I would say that the grand summary from my takeaway was that both the House and the Senate are waiting for guidance from the White House on whether they prefer the border adjustment tax or whether they have another vehicle that they would like to implement. And while everyone is waiting for that, things have in fact stalled, as you said, but I am confident that we're talking about the right things. We're talking about a lower U.S. tax rate. We're talking about a territorial system, and we're talking about some innovation and some incentive for job creation in the U.S. And that latter point is the one that's up for discussion waiting for some clarity and preference from the White House.

Thanks, Jami.

A - Joseph Wolk {BIO 19812977 <GO>}

Manny, next question? And maybe before we take the question, I just want to make sure in the last dialogue, there was a reference to \$0.35 to \$0.45 and \$0.30 to \$0.40. I just want to – for clarity for your models, it's \$0.35 to \$0.40 for the first full year of Actelian. Next question, Manny, please?

Operator

The next question is from Mike Weinstein of JPMorgan. Please go ahead.

Q - Michael Weinstein {BIO 20602373 <GO>}

Thanks. And maybe just to add to that, Joe, the \$0.35 to \$0.40 is a net number that assumes a certain level of reinvestment back into the company. So Actelion itself...

A - Dominic J. Caruso {BIO 1423936 <GO>}

Right.

Q - Michael Weinstein {BIO 20602373 <GO>}

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Right, on a gross basis.

A - Joseph Wolk {BIO 19812977 <GO>}

That's correct, Mike.

A - Dominic J. Caruso {BIO 1423936 <GO>}

That's correct, Mike. That's correct, yes.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay. And, Dominic, I think what would be helpful is you've made a number of comments about both Consumer and Pharmaceuticals, and I think that it would probably be helpful to help give your perspective on what you saw this quarter that you think was one-time in nature and what you think will persist over the balance of 2017 for both those businesses.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure. With Consumer, I would say that what was a little bit more pronounced than our expectation going into the year was the level at which the category growth that we compete - the categories that we compete in decelerated. That of course then turns into inventory destocking, if you will, by the various trades. That's a phenomenon that we think is not long-lived because, obviously, eventually as consumption either picks up or even continues at a reasonable pace, inventory will need to be restocked at the trades, so we'll see some correction to that.

Plus, with respect to our own business, we have a number of new product launches. Very few of them hit the first quarter. They're all scheduled now second quarter, third, and fourth. And those, as I said earlier, could impact our total growth rate by an incremental 2 points of growth going forward. So we don't think that the first quarter results for Consumer will continue at that pace that we just saw. We think they'll improve throughout the year.

With respect to Pharmaceuticals, I mentioned that we were pleased to not see much of an impact in REMICADE biosimilar. There may be some additional impact as we go through the year, but nothing has changed our estimates for that. It's all baked into our guidance. We did see some pricing dynamics, particularly in the Cardiovascular and Metabolic space, so INVOKANA and XARELTO. Those are competitive markets, lots of entries in that market, and therefore the payer dynamics are more competitive there. So we saw some lower pricing there. That's also baked into our estimates for the quarter, so not something dramatically different than what we expected.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay, that's helpful. Let me ask about a couple of items just to follow up. So one, I wanted to get some clarity on your view of the upcoming IPR decision on ZYTIGA. This is on the 438 patent. Does the outcome of the 438 IPR have any impact on your 30-month stay? Our impression is no, and that regardless you wouldn't see generic competition prior to October 2018.

A - Dominic J. Caruso {BIO 1423936 <GO>}

That's correct, Mike. That's our position as well, that whatever the outcome is of that hearing, it will not impact the 30-month stay.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay, then last item. On the upcoming presentation of the CANVAS trial, there's been some discussion on the Street about the study and what you may or may not know about the results of the trial today. Is there anything you want to add relative to just J&J's expectations of that study?

A - Dominic J. Caruso {BIO 1423936 <GO>}

We're going to unveil the results of that study in June at the ADA meeting, so it would be premature to comment there. Joe, do you have anything else to add?

A - Joseph Wolk {BIO 19812977 <GO>}

No, that's currently the only scheduled release date at this point in time.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay, I'll let it drop.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

I appreciate it.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Mike. Next question, Manny?

Operator

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Next question is from Joanne Wuensch of BMO Capital Markets. Please go ahead.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Good morning, Joanne.

Q - Joanne Karen Wuensch {BIO 2379289 <GO>}

Hi, good morning, and thank you very much for taking the question. Could we take a look at big picture med tech, what you are seeing as it relates to the usual suspects of volume, price, and how we're entering the year?

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure, a couple things. In terms of our med tech business, as you know, we have a focus on certain priority platforms that are about 40% of our business, and I said earlier, they're growing about 6.5%. And that does have some pricing pressure in it, so the volume seemed very good there.

Overall, med tech or let me just call it hospital procedures and overall volumes in the U.S. hospital setting seem to be relatively flat, not much growth from quarter to quarter, so relatively stable but no inflection point in growth, for sure. And with respect to products in our core platforms, those products are generally more susceptible to the more significant price impacts. Joe, anything else you want to add to that?

A - Joseph Wolk {BIO 19812977 <GO>}

Yes. Joanne, one way we typically answer this question is around utilization trends, and so this data lags a little bit. But in the fourth quarter for hospital admissions, it was up almost 1%. Surgical procedures were down about 0.5%, and lab procedures were up 1%. We see anywhere based on our very preliminary estimates for the first quarter of 2017 anywhere from flat to 1% up across all three of those categories.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Look, I would say no significant acceleration or change in the pricing dynamics that we've been seeing. So steady as she goes with respect to slightly negative price across the industry.

Q - Joanne Karen Wuensch {BIO 2379289 <GO>}

That's very helpful. Can we turn also to some of your portfolio management? Specifically, last quarter, you talked about your Diabetes franchise being evaluated on strategic basis, and then also early comments on the AMO integration. Thank you.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure. With respect to Diabetes, we continue that process. We're evaluating various options for that business, whether it be partnership or outright divestiture, whatever is best in terms of giving that business the best position to succeed and, obviously, if we were to divest it getting the right return for our shareholders.

With respect to the AMO acquisition, it's going really, really well. I mean, it just obviously was integrated in February. We welcome the AMO colleagues to Johnson & Johnson. They're a very important part of now a complete health offering that we have at Johnson & Johnson, coupled with the ACUVUE brand, which obviously has great recognition; the innovation that we already know about and know how to do well, both in manufacturing and lens technology. I think this is going to be a fantastic acquisition for us.

It's off to a great start. And quite frankly, before we acquired them in the quarter, they were doing really well with new product launches growing at a rate that was double the

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rate that they were growing at last year's first quarter. So we're very pleased. It's off to a great start.

A - Joseph Wolk {BIO 19812977 <GO>}

And just for clarity, as folks look at the schedules that we provide, the AMO business will be split into two categories. The consumer solutions business will be put in with the contact lens portion of the business and surgery will be carved out on its own. So, for the quarter, we had \$124 million recognized in sales from the AMO acquisition. \$115 million of that was in the surgery category.

Q - Joanne Karen Wuensch {BIO 2379289 <GO>}

Very helpful. Thanks.

A - Joseph Wolk {BIO 19812977 <GO>}

Great. Thank you, Joanne. Next question, Manny?

Operator

The next question is from Larry Biegelsen of Wells Fargo. Please go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the questions. Dominic, can you please confirm that the \$1 billion from the – or tell us if the \$1 billion from the Codman Neuro business divestiture, that's included in the current guidance or not, and if you will include it in operational EPS in 2017?

And second, Dominic, you maintained the 3% to 3.5% underlying growth, but then you did about \$1.2 billion in Q1. So what gets better in Q2 through Q4? And do you still expect the Medical Device and Consumer divisions' growth rate to accelerate in 2017 over 2016? I think you said that on the Q4 call. Thanks. And I just have one follow-up.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure. Larry, we have a number of plans with respect to various divestitures. We announced Codman because it was the most significant of those that we have plans with, but the basket of all those is what we have included in our earnings guidance for the year of \$1.1 billion to \$1.3 billion in the other income line. So it will be part of that other income line and not excluded from our earnings.

And as you know, we always take the opportunity to reinvest those gains back into the business, so we don't expect that it will have that much of a significant impact on overall earnings. As I mentioned earlier, our investment levels will go up. The system was recognizing those gains.

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A couple things with respect to Medical Devices and Consumer. As I mentioned earlier, we do expect product launches in the remaining part of the year, adding about 1.8% growth to Medical Devices and about 2% growth versus the current levels to Consumer.

In Medical Devices, we also had some tough comparisons in the first quarter. We still have some inventory destocking and distributor issues in China, which obviously won't repeat going forward in the year. And likewise in Consumer, we have, as I mentioned, this category deceleration which we think will improve throughout the balance of the year.

We currently expect that Consumer will do about the same as it did last year, and if the deceleration in the category growth continues further than we expected, that it would do slightly less. Medical Devices about on par now with next year, but I do think that it will be at or very close to the market growth rates for the industry, overall.

A - Joseph Wolk {BIO 19812977 <GO>}

The headwinds in the first quarter, Larry, to be aware of in Medical Devices, we had approximately 0.4 less selling days, if you will. It's obviously not selling days, but procedure days. So that was worth about 60 basis points. And then also in Consumer, you had about a 50-basis-point impact due to some remaining effects from India demonetization as well as Article 94 in China.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful. Guys, on the - your ortho, hip and knee, your recon business is doing well, but the spine continues to struggle. You talked about product gaps there. What are those product gaps? How do you address them? And trauma, that was also soft. When do you expect that to bounce back? Thanks for taking the questions.

A - Dominic J. Caruso {BIO 1423936 <GO>}

So with trauma, let me take that. With trauma, that's the business that we saw this inventory destocking issue with changes and distributors in China as I mentioned earlier. So that was an impact in the first quarter that we don't expect to continue. Spine, some products gaps there that I would point to are expandable cage, and we just did acquire an expandable cage, so we expect we'll have a good offering in that particular segment of the market as well.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Larry.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Larry.

A - Joseph Wolk {BIO 19812977 <GO>}

Manny, next question, please?

Operator

Thank you. The next question is from Matt Miksic of UBS. Please go ahead.

A - Joseph Wolk {BIO 19812977 <GO>}

Matt.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks, good morning. Thanks for taking the questions. So I had one on the recent acquisition that you announced here, Neuravi, and sort of backing up and looking at your Med Device strategic activity over the last year or so. This is, I guess, maybe the third or fourth. It's the latest in a series of these kind of smaller acquisitions, putting AMO aside.

And I just wonder, some of those in AFib; some of those in surgery. This one, of course, I don't believe lines up with the current field force or call point that you have. But, Dominic, it'd be helpful maybe if you could just talk a little bit about how this fits in with your strategy, whether these kinds of things are what we should expect going forward and if there's anything in particular about Neuravi, whether it's data or a build-out that we should know about. And then I have one follow-up.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yeah. Well, Matt, thanks for the question. In our neurovascular and neurosurgery business, we obviously have sales presence. And as you recall, we announced that we have an offer to divest the Codman Neurosurgery business.

What we're talking about with Neuravi is the piece of the Codman business where we already have a sales force in place dealing with ischemic stroke as opposed to hemorrhagic stroke, which is dealt within the other part of the business. And this is consistent with our strategy of moving our portfolio to the higher growth areas of any category.

And so, you're right to point out that we've been doing this quite often. We've been divesting slower growth areas or areas that we think are better off in someone else's hands and investing in higher growth areas and new technologies. This particular ischemic stroke treatment from Neuravi is already on the market in Europe and expected to be approved this year in the U.S., and it provides for faster blood flow and more accurate retrieval of the clot within the neurovascular system. So we're very excited about it.

By the way, our entire Medical Device business has largely been grown by these smaller tuck-in, bolt-on acquisitions with technologies that advance the standard of care. And with our scale and distribution, we're able to do much better with that asset in our hands than in the hands of the previous owner.

Q - Matt Miksic {BIO 6990080 <GO>}

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That's helpful. And then one follow-up on some of the Pharma comments that you made. You talked a little bit about some pricing pressure in competitive markets. You, of course, have put out this recent report on transparency in pricing. And just wondering if you could comment at all on any changes we should be thinking about in terms of whether it is more competition like this and pressure related in that way, or whether it's a different sort of price increase profile for your portfolio of Pharma. Any kind of color you can lay out for us in terms of what we should be dialing in or thinking about in terms of changes in rebates and pricing in Pharma? Thanks.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Right. Well, overall, Matt, we have an innovative portfolio in Pharma, and the innovation comes with greater patient outcome and therefore evidence that supports the pricing for the products. That's the vast majority of the portfolio in Oncology, Immunology, Neuroscience.

In certain parts of the portfolio, Cardiovascular and Metabolics in particular, that's a little bit more crowded. It's not as specialty-focused, more primary care-focused and that's where the payer community has more influence over rebates and the like.

I don't think that we're going to see a dramatic change in our pricing methodologies. It's all evidence-based. We look at it annually. And as you know, from our last report that you just mentioned, the difference between list price and net price is pretty dramatic and we think that will continue. And so, we've had modest price increases on a net price basis and we think that will be the case going forward.

A - Joseph Wolk {BIO 19812977 <GO>}

Great. Thank you, Matt. Next question, Manny?

Operator

The next question is from Bob Hopkins of Bank of America Merrill Lynch. Please go ahead.

Q - Bob Hopkins {BIO 2150525 <GO>}

Hi. Thanks very much for taking the question.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Hi, Bob.

Q - Bob Hopkins {BIO 2150525 <GO>}

Hey. So two things. First on Devices and then on Pharma.

And then, on Devices, it's sort of a follow-up to some of the things that's been asked in terms of the leadership changes and the divestitures and acquisitions. I was wondering, Dominic, if you can just give us a sense as to kind of where are we in the processes.

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Should we expect kind of more strategic activity in Devices? Is there a potential for larger transactions in Devices? Given kind of the level of activity and changes at the top in Devices over the course of last year, would love to get an update on kind of where we are in your process.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure. Well, couple things, Bob. The restructuring was announced more than a year ago, I guess, January of 2016. So we've been in the process of restructuring the Medical Device business. We've been making changes to the portfolio well before any leadership changes were announced. I think that will just continue. It's not going to dramatically change as a result of any leadership changes. That's a strategic point of view that we have on various markets. I don't think that will change.

I don't think any one particular leadership group will have an influence one way or another over whether we do larger or smaller transactions. They're all individually analyzed. We're very disciplined about it. They have to be strategic. They have to return a weighted average IRR that's higher than our weighted average cost of capital. So none of that changes just because the leadership changes. I don't think that you should expect any dramatic change there.

I would expect a continual improvement in the business over time, all of which has been started over a year ago. It takes time to improve a business that's so widespread and diverse as our Medical Device business, but we're making good progress. And I would just reiterate that we expected to have nearly \$1 billion of cost improvements in that business achieved by 2018 and we're well on our way of doing that, so I don't expect any changes there as well.

Q - Bob Hopkins {BIO 2150525 <GO>}

So I guess just in terms of the potential for larger transactions in Devices, how would you comment on that? And then the other quick thing I just wanted to get your view on, and this is just a quick question on the Pharma growth. The difference between the 2.2% that you mentioned in terms of the Pharma growth this guarter and the 4.7% I think you said, I know it has a lot to do with pricing, but maybe you could just break that down into as many pieces as you're willing to give. Thank you very much.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure, Bob. With respect to larger, and Devices are larger in any business, it's really the same for us. It's not really focused on any one business being more focused on larger or smaller. It has to do with whether or not it's an area of strategic importance for us, whether the asset is one that we think we can grow better in our hands than in the hands of the previous owner and whether we're going to get a return for our shareholders that's commensurate with the risk that we have by putting our shareholders' capital to work.

So it really doesn't vary in Devices, Consumer, or Pharma in any regard with respect to whether one business would be more likely to have a larger versus a smaller acquisition. It depends on each individual transaction, and we're really agnostic. Although I will say in

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Medical Devices, our history has been a great deal of bolt-on acquisitions and now and then a pretty large acquisition. The largest one we did was Synthes, now five years ago or thereabouts.

With respect to your question on Pharma 2.2% versus 4.7%, the 2.2% growth is Pharma exacquisitions and divestiture impact. And the 4.7% Pharma growth has to do with simply adjusting for the \$200 million of purchase price adjustments that were recorded in the first quarter of 2016 or they were prior-period adjustments, I should say. They were related to Medicaid rebates, managed care rebates that were late in reporting into us, and therefore we've recorded all those in the first quarter of 2016. They had nothing to do with 2016. They were all from prior periods. So we excluded that in the calculation of the 4.7% to give you an apples-to-apples underlying growth rate for the Pharma business. Hopefully, that's clear now. Okay.

A - Joseph Wolk {BIO 19812977 <GO>}

Great, thanks. Next question, Manny?

Operator

Thank you. The next question is from Dane Leone of BTIG. Please go ahead.

Q - Dane Leone {BIO 15203956 <GO>}

Hi, thank you for taking the questions. So when you think about the Actelion merger and just the general strategy in Pharma, several times during the call, it's come up at just different trends in pricing and how competitive markets are. I was just curious. Could you just reiterate the strategy in terms of going more into the Cardiovascular space even though there's more differentiation BH (58:07)? But just in general to the comments of Cardiovascular and Metabolic being more competitive and having more of an effect on pricing especially in the U.S., how do you see Actelion fitting in and the diversification of the portfolio?

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure, Dane. In the Cardiovascular space with respect to Actelion, that's not primary care. It's more specialty-based. So therefore it's consistent with our overall strategy of being focused in specialty pharmaceutical areas more so than in primary care. So I don't see the same kind of pricing dynamics in the specialty area that you do in the primary care area. Hopefully that's clear.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Dane.

Q - Dane Leone {BIO 15203956 <GO>}

Thanks.

A - Joseph Wolk {BIO 19812977 <GO>}

Manny, it looks like we've got time for one more question.

Operator

Thank you. The next question is from David Lewis of Morgan Stanley. Please go ahead.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Hi, good morning. Thanks for squeezing me in. Dominic, I just wanted to come back to Consumer and a quick follow-up. Just the things you mentioned in Consumer this quarter all seemed largely either transitory or tied to the broader industry. But the big thing we've talked about this quarter in Consumer has really been accelerating e-commerce risk, and I wonder if you could talk about that. Do you see e-commerce as an accelerating risk for the J&J businesses or do you think that your brands are frankly more durable?

And then also about the 20% margins, you got there dramatically faster than you ever expected. So strategically from here, is the focus to get to 25% margins or reinvestment? And then I had a quick follow-up.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Sure, a couple things. E-commerce is not a risk, it's a real obvious trend in the industry. We're well-positioned and getting better positioned. Our brands are iconic in nature. They do still have quite an appeal to a mass audience, and you see us continuing to advertise, for example, with NEUTROGENA and AVEENO and TYLENOL. So we think those brands still hold up well in more classic marketing, although we're very present in e-commerce. And products like Vogue and others that we're acquiring in the Consumer space specialty brands fit really well in the e-commerce strategy.

With respect to the second part of your question, could you just repeat that again, please?

Q - David Ryan Lewis {BIO 15161699 <GO>}

I'm sorry, margins.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Oh, margins.

Q - David Ryan Lewis {BIO 15161699 <GO>}

Margins, Dominic, 20%.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yes.

Q - David Ryan Lewis {BIO 15161699 <GO>}

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You got there guicker.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Yeah. Well, a couple things. Obviously, we're on a long plan to improve the margins in this business, but I think as Alex often mentions, first things first. So now that the business has worked through the issues that it had in the OTC business, although it's still under a consent decree, I just want to remind you, we are focused on cost improvement programs and, while at the same time, investing.

So there's no particular focus or goal to get to one particular pre-tax operating margin number. We expect it to be competitive with the industry, which is now is, but we're obviously going to take the opportunity to invest when we can. Especially, as I mentioned, we're launching new products this year. So we're going to make sure we invest behind those launches and make sure they do exceptionally well right out of the gate.

A - Joseph Wolk {BIO 19812977 <GO>}

Great. Thank you, David, and thanks for everyone for their questions and apologies to those we couldn't get to today.

I'll now turn it back over to Dominic for some closing comments.

A - Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Joe. As I noted earlier, we're confident in our guidance for 2017 and we're optimistic for the future. I would like to take this moment to recognize and thank all of our associates around the world for their important contributions and dedication to the success of Johnson & Johnson.

Thank you for your time this morning. I look forward to updating you on our progress throughout the year, and I hope to see you all at our Pharmaceutical Business Review Meeting on May 17. Thanks, and have a great day.

Operator

Thank you, ladies and gentlemen. And this concludes today's Johnson & Johnson's first quarter 2017 earnings conference call. You may now disconnect, and have a wonderful day.

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