Q4 2016 Earnings Call

Company Participants

- Alex Gorsky, Chairman & Chief Executive Officer
- Dominic J. Caruso, Vice President, Finance and Chief Financial Officer
- Joseph Wolk, Vice President-Investor Relations

Other Participants

- Danielle J. Antalffy, Analyst
- David Ryan Lewis, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Joshua Jennings, Analyst
- Lawrence Biegelsen, Analyst
- Matt Miksic, Analyst
- Michael Weinstein, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning and welcome to the Johnson & Johnson's Fourth Quarter 2016 Earnings Conference Call. All participants will be in a 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>}

Good morning. I am Joe Wolk, Vice President of Investor Relations for Johnson & Johnson and it is my pleasure to welcome you to our review of business results for the fourth quarter and full year of 2016. Also on the call today are Alex Gorsky, Chairman of the Board of Directors and Chief Executive Officer; and Dominic Caruso, Executive Vice President and Chief Financial Officer. Thank you for joining us today.

We are very pleased with our 2016 results as they demonstrate our track record of consistent sustainable growth, exceeding financial expectation and making progress on our long-term strategic drivers such as advancing our pharmaceutical pipeline, implementing new commercial models in our medical device segment and enhancing market leadership for many of our iconic consumer brand. As we enter 2017, we are confident in our ability to continue producing solid results while also delivering innovation that will have an enduring impact on patients, caregivers and customers.

A few logistics before we get into the details. This review is being made available via webcast, accessible through the Investor Relations section of the Johnson & Johnson website at investor.jnj.com where you can also find additional materials including today's presentation and accompanying schedules. In terms of the agenda for today's discussion, after I review results for the corporation and the three business segments, Alex will comment on our 2016 performance, share his perspectives on current dynamics in healthcare and discuss key growth drivers for the company. Dominic will then provide remarks on the income statement and insights on our guidance for 2017. The remaining time will be available to answer to your questions. We anticipate the call will last about 90 minutes.

Before we begin, please be aware that some of the statements made today during this review are or may be considered forward-looking statements. Please refer to the Investor Relations section on our website for the company's SEC filings, in particular our 10-K that identify certain factors that could cause the company's actual results to differ materially from those projected in any forward-looking statements made today.

The company does not undertake to update any forward-looking statements as a result of new information or future event. We will also make reference to certain non-GAAP financial measures which are not replacement for GAAP financial measures. Again, please refer to our press release and website for tables reconciling non-GAAP to comparable GAAP measures.

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.

Now on to our results for the fourth quarter of 2016. Worldwide sales were $18.1 billion for the fourth quarter of 2016, up 1.7% versus the fourth quarter of 2015. On an operational basis, sales were up 2.3% as currency had a negative impact of 0.6%. In the U.S., sales were up 2.6%. In regions outside the U.S., our operational growth was 1.9% as the effective currency exchange rate negatively impacted our reported OUS results by 1.3 points.

You may remember that during last year's fourth quarter call, we informed you that our 2015 fiscal year included an additional week, resulting in a few additional shipping days. Calculated off the 2015 base, these additional days negatively impacted growth in the fourth quarter 2016 by 480 basis points and the full year 2016 by 130 basis points.

Excluding the net impact of acquisition, divestitures, hepatitis C, Venezuela and the additional shipping days in 2015, operational sales growth was 7.6% worldwide, 9.5% in the U.S. and 5.6% outside the U.S. I will provide you the same reference for each segment.

For the full year 2016, consolidated sales were $71.9 billion, an increase of 2.6% compared to the same period a year ago. Operationally, full year sales grew 3.9% with currency having a negative impact of 1.3%.Excluding the net impact of acquisition, divestitures, hepatitis C, Venezuela and the additional shipping days in 2015, operational sales growth was 7.4% worldwide, 8.9% in the U.S. and 5.7% outside the US.

Turning now to earnings. For the quarter, net earnings were $3.8 billion and diluted earnings per share were $1.38 versus $1.15 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were $4.4 billion and adjusted diluted earnings per share were $1.58, representing increases of 7.9% and 9.7% respectively compared to the same period in 2015. On an operational basis, adjusted diluted earnings per share grew 10.4%.

Regarding the full year, 2016 net earnings were $16.5 billion and diluted earnings per share were $5.93. 2016 adjusted net earnings were $18.8 billion and adjusted earnings per share were $6.73, up 7.6% and 8.5% respectively versus full year 2015 results. On an operational basis, adjusted diluted earnings per share grew 9.4%.

Please note, with respect to the extra days in 2015 as we stated last year, we did incur additional operating costs, and as such, the bottom line impact was negligible. Dominic will provide further detail regarding earnings in his remarks.

Beginning with consumer, I'll now comment on quarterly business segment sales performance, highlighting items that build upon the slide you have in front of you. Unless otherwise stated, percentages quoted represent operational sales changes in comparison to the fourth quarter of 2015, and therefore exclude the impact of currency translation.

While not part of the prepared remarks for today's call, we have provided additional commentary on our website for full year 2016 sales by segment to assist you in updating your models.

Worldwide consumer segment sales totaled $3.4 billion, growing 4.9%. Excluding the impact of acquisitions, divestitures, Venezuela and the 2015 additional shipping days, adjusted sales growth was 7.6% worldwide.

Operational growth was driven by global beauty and OTC. Despite global consumer category slowdown, we did continue to see strong consumptions for many of our products. The beauty franchise, previously reported as skincare, includes the acquisitions of Vogue, NeoStrata and La Lumiere Light Mask which in total contributed sales of $105 million or 12 points of growth for the franchise. The Neutrogena brand grew approximately 20% in the U.S.

Also in the U.S., higher levels of retail stocking occurred in the quarter as we introduced new products and our beauty products continued to gain share, accounting for approximately 8 points of growth.

The OTC market growth rate was down compared to the same period a year ago. Instances of adult cold and flu and total allergy were estimated to be down in the range of

4% to 5%. However, like many of our consumer franchises, our TYLENOL and ZYRTEC brands continue to gain market share. Analgesic adult share is currently 14.3% and pediatric share is 49.8%, up approximately 1 point and 4 points respectively from Q4 2015. You may remember, in our third quarter call, we commented on lower inventory levels impacting growth which we felt was temporary given our share gains.

In the fourth quarter, we did see a replenishment of that inventory to match the higher demand as well as some seasonal build. This represented approximately 8 points in the U.S. OTC growth rate for the quarter. It is worth noting that the impact of demonetization in India and Article 94 regulation in China collectively represented a negative impact of approximately $50 million or 150 basis points on worldwide consumer growth. The impact from demonetization mostly impacted the Baby Care franchise while Article 94 primarily impacted the OTC business.

Moving now to our pharmaceutical segment. Worldwide sales of $8.2 billion grew 2.6%. Excluding the net impact of acquisitions, divestitures, hepatitis C, Venezuela and the 2015 additional shipping days, adjusted sales growth was 9.9% worldwide. Oncology and immunology were the primary contributors to operational growth.

In oncology, DARZALEX continued its strong growth trajectory with $200 million in sales for the quarter, and in its first full year on the market, reached sales of $572 million. DARZALEX maintains its leadership in line four multiple myeloma and we are seeing early signs of strong adoption for lines two and three following the recent approvals.

IMBRUVICA in the U.S, across all lines of therapy, gained approximately 7 points of market share and the CLL market, based on third quarter data, is estimated to have grown better than 20%. Outside the U.S, we are seeing strong penetration in the G5 Countries. Worldwide ZYTIGA growth was down versus the fourth quarter of 2015 due to competition in the EMEA region as well as a higher utilization of Patient Assistance Foundation in the U.S.

In immunology, the U.S. market is estimated to have grown approximately 11%. STELARA in the U.S. gained 3.6 points of market share in psoriasis versus the fourth quarter of 2015. And during the quarter, we received approval for the Crohn's disease indication in the E.U. to add to the U.S. approval we received in September.

SIMPONI and SIMPONI ARIA benefited in quarterly year-on-year comparisons by approximately four points from an inventory burn that occurred in the fourth quarter of 2015. REMICADE export business continues to see the impact of biosimilar competition. Regarding the at-risk biosimilar launch of INFLECTRA in the U.S, we have not observed any significant impact to-date.

I'll conclude the pharmaceutical segment by commenting to some other key brands. INVOKANA, INVOKAMET sales were flat worldwide driven by continued uptake outside the U.S. and modest declines in U.S. share. XARELTO growth was driven by continued total prescription market share gains with the U.S. now at 18%, up nearly 2 points from a year ago. Warfarin still makes up 53% of the market but that is down from 61% in the fourth quarter of 2015. Our long-acting injectable portfolio achieved strong results in all major regions due to increasing market share.

I'll now review the medical device segment results. Worldwide medical device sales were $6.4 billion, growing 0.6%. Excluding the net impact of acquisitions, divestitures, Venezuela and the 2015 additional shipping days, adjusted sales growth was 4.7% worldwide. Operational growth was driven by our priority platforms which, as a reminder, includes electrophysiology, endocutters, energy, knees and trauma. Combined, that set of businesses grew approximately 4%. When you adjust for the additional shipping days in Q4 2015, our priority platforms grew approximately 8%.

Electrophysiology grew 10% worldwide as atrial fibrillation procedures are estimated to have grown 15% in the U.S. and we see strong adoption of our newer OUS product offerings in ablation and advanced catheters. This business has grown double-digits 28 out of the last 29 quarters.

Within the advanced surgery category, endocutters growth was primarily driven by an uptake of new products in Europe and the Asia Pacific region, specifically China and Japan. The energy business benefited in quarterly year-on-year comparisons by approximately 7 points due to the business disruption we experienced on HARMONIC ACE 7+ Shears in Q4 2015.

Within orthopedics, knee growth was driven by continued uptake of ATTUNE outside the U.S. ATTUNE continues to gain volume in the U.S. Trauma, which now includes sales from the acquisition of BioMedical, grew due to the TFNA nailing system uptake and the U.S. market increasing approximately 5% based on our estimates.

Pricing pressure continued across the major categories in orthopedics but was partially offset by favorable mix. We are routinely asked in this forum about net price, so let me provide that to you now. For the quarter, net price in hips was negative 2.4%, knees negative 2%, trauma positive 3.2%, and spine positive 2%.

Lastly, within the medical device segment, strong Vision Care results were driven by the introduction of new products such as ACUVUE VITA and new offerings in the beauty lens category as well as trade inventory build which accounted for approximately 3 points of growth.

That concludes the segment highlights for Johnson & Johnson's fourth quarter 2016. For your reference, here's a slide summarizing notable developments that occurred in the fourth quarter.

It is now my pleasure to turn the call over to Alex Gorsky. Alex?

Alex Gorsky {BIO 16239711 <GO>}

Thank you, Joe, and thanks to all of you for joining us on the line today. We're really pleased to be here, sharing the strong results we delivered for 2016. Not only did we meet our financial commitments to our investors and shareholders, we also delivered on the commitments and responsibilities defined in Our Credo.

As all of you know, we have several important responsibilities outlined in Our Credo. It compels us to meet our first responsibility to the doctors and nurses, mothers and fathers, and all others who use our products; to our employees, our communities, and the world we live in; and it compels us to make a sound profit, experiment with new ideas and develop innovative programs. When we do all of this, our shareholders should realize a fair return.

In fact, we delivered a very fair return this year. Our total shareholder return for 2016 was a strong 15.3%, significantly exceeding our competitor composite as well as exceeding most major indices. And not only is that true for 2016, but I'm very proud to say it's also the case over the last 3-, 5-, 10- and 20-year periods. Our strong shareholder return for 2016 is indicative of the strength of our businesses and the improved strategic focus and execution that our leaders and teams have delivered over the past several years.

Our pharmaceutical business continued to deliver strong growth while also increasing investment to further develop our incredibly strong pipeline of innovative new medicines. Our medical device business refocused and accelerated our pace of innovation and developed novel commercial models to meet the evolving needs of today's healthcare systems. And our consumer business continued gaining share across most of our major categories and significantly improved margins with the goal of returning to benchmark profitability.

Our strong record of total shareholder returns is the result of our approach to managing for the long-term, our relentless drive for innovation, our disciplined portfolio management and our capital allocation strategy, all of which are regularly discussed as part of our ongoing strategic planning with our board of directors.

We believe that sustaining investments in innovation is the most important aspect of our strategy. In 2016, we invested more than $9 billion in R&D and submitted 250 NDAs, BLAs, PMAs, 510(k)s and CE marks for approval and received 243 product approvals in major markets in addition to a number of new product launches in our consumer businesses. We expect to continue this rate of investment and accelerate our submissions and approvals in the future.

Now another important part of that strategy is value-creating acquisitions and collaborations. In the last year, we closed several acquisitions of significant size, including Vogue International in the consumer beauty space, and we look forward to closing on our acquisition of Abbott Medical Optics in the vision care space during the first quarter. In total, we completed 13 acquisitions and license of various size, 67 innovation deals and made 21 new investments from our Johnson & Johnson Development Corporation during 2016.

And as we've previously announced, we're currently in exclusive negotiations with Actelion for a potential transaction. While we won't be commenting any further on that today, regardless of whether an agreement is reached with Actelion, we will continue to look for additional opportunities to create value for our shareholders.

As our portfolio evolves through acquisitions like these, we're also constantly evaluating each of our existing businesses to determine whether they continue to fit our criteria for value creation. As a result, from time to time, it makes sense to undertake a process to consider whether a different operating structure or different ownership for a business might be value enhancing, or whether a business might be a better fit in another company's portfolio.

This process also ensures that we continue to invest in the most promising areas of our portfolio where we believe we can make a significant difference for patients and consumers and create greater value for our shareholders.

In 2016, we divested eight businesses from our portfolio, the most significant being the divestiture of our Noramco business in pharmaceuticals. As you saw in our release this morning, we're currently evaluating strategic options for our consumer medical device diabetes franchise including LifeScan, Animas and Calibra.

We're assessing a wide range of options including strategic partnerships and joint ventures and have not set a definitive timeline to complete this review. I'd also note that there is no guarantee that this process will result in any transaction.

As we undertake this review, we remain focused on best positioning these businesses in their respective markets and meeting the changing needs of our customers and patients. Given our broad base in human health care, Johnson & Johnson remains fully committed to the prevention and detection of diabetes and will continue to serve those impacted by diabetes through innovative products, services and solutions from our medical device, pharmaceuticals and health and wellness businesses.

This includes important leadership and innovation in areas such as bariatric surgery and through medicine such as INVOKANA and INVOKAMET. We will continue investing in this important area across all of our business segments. All of this is consistent with our capital allocation priorities which we discussed before.

After funding our internal growth initiatives, our estimated free cash flow for 2016 was $15.5 billion. Our first priority for that cash is delivering a competitive dividend to our shareholders. And in 2016, we paid $8.6 billion in dividends which have increased for 54 consecutive years.

After meeting our dividend goals, we target value-creating acquisitions with $5 billion invested in M&A and major licensing deals this year. And finally, we consider other prudent ways to return value to shareholders such as share repurchase programs. As you know, we completed the majority of our $10 billion share repurchase program in 2016.

Historically, approximately 70% of our free cash flow deployed over the last 10 years has been returned to shareholders in the form of dividends or share repurchases.

As the world's largest and most broadly-based health care company, we understand the important role we play in leading responsibly and representing our industry with integrity. Our industry has a track record of producing advancements in healthcare that have saved and improved people's lives and people depend on us to continue making new discoveries.

As I think back on how far we've come, the investments we've made in innovation and healthcare have yielded some amazing returns. The average life expectancy continues to rise and diseases such as HIV that were once considered a death sentence are now treatable. Surgeries that once required extended hospital stays now can be done through an outpatient procedure.

Cures and treatments reaching the market today are not only improving quality of life for many patients, extending life for others and contributing to the productivity of our society, but they are also helping to reduce caregiver burden, disability and healthcare spending in other parts of the system such as hospitalizations.

Healthcare affects each one of us in a deeply personal way whether it's our own health or the health of a loved one, but it also accounts for 18% of our GDP. Pharmaceutical spending, as one component, accounts for about 14% of the overall healthcare spending in the U.S. Considering that, I think it's important to be clear on how we view our responsibility to the patients and stakeholders impacted by our products.

We believe that investing in innovation to create differentiated products that ultimately help people live longer, healthier and happier lives is our first responsibility. Our process to then set the prices for those products includes extensive research and collecting diverse stakeholder input in order to ensure that they are both accessible and representative of the outcomes and value they ultimately deliver.

We have maintained a responsible approach to pharmaceutical pricing, generally limiting aggregate annual price increases to single-digit percentages below those of our competitive set. Furthermore, in our pharmaceutical business, we invest more in R&D than we do in sales and marketing. And cumulatively since 2010, we've invested more incremental dollars in R&D than we have realized from U.S. net price increases.

Moving forward, we plan to take the next step in our proud legacy of leadership in transparency and responsible pricing. Later this quarter, we will consolidate and expand upon our disclosures with the release of our first U.S. pharmaceuticals transparency report. This annual report will highlight existing disclosures of Johnson & Johnson's clinical trial data and compassionate use as well as Janssen's transfer of value to U.S. healthcare providers in support for patient access.

Additionally, it'll include expanded disclosures on U.S. pricing and value as well as R&D and sales and marketing expenses. We recognize that this is one step towards demonstrating how serious we are about responsible pricing. In the long-term, we know it will take all parts of the healthcare system working together to address the challenges we are facing. We look forward to continuing our work with government officials, our customers and other stakeholders to ensure we are doing our part to provide differentiated value-based and affordable healthcare to people around the world.

We also recognize we are uniquely positioned to provide leadership on the health and wellness issues that we understand better than anyone else. We know many of you may be curious or anxious about the impact of various changes both here in the U.S. and globally that could impact our business. As you may know, yesterday, I had the honor of meeting with the president and the new administration. And we had a productive conversation about accelerating growth in jobs in the United States.

We look forward to continuing that dialogue. And while it's still too early to speculate about the impact that changes to existing U.S. health policy or potential changes for the U.S. tax code. I'd like to provide our perspective about the changes we will advocate for and hope to see in the near future.

First, in regards to healthcare reform, we're glad that healthcare has been and continues to be a significant part of the dialogue in Washington as well as around the world. We look forward to continuing to work with lawmakers and politicians on both sides of the aisle to find solutions that improve the health of our society. And in fact, we were very pleased with the bipartisan support and ultimate passing of the 21st Century Cures Act in late 2016.

This legislation was a significant investment in innovation, signaling its importance to all stakeholders. We hope lawmakers take the same cooperative spirit, putting patients first as we move through debate about the future of our healthcare system.

Now, while we won't speculate about what may be included in potential new healthcare legislation in the U.S., I would like to offer a summary of the components that we are encouraging lawmakers to consider in any new or reformed healthcare law.

First, we are advocating for important elements like increased access, coverage of pre-existing conditions and coverage of young people on their parents health plan to continue in the future.

Second, we believe that any ACA replacement must support a competitive market for individual health insurance. We will continue to advocate for models that encourage innovation and value, continuing the move towards value based care and payment for improved patient outcomes.

Finally, we support reforms that emphasize wellness and intercepting disease before it happens. Preventive care, more latitude for employer wellness programs and incentives for healthy behaviors are great ways to embody this focus.

Outside the U.S., healthcare systems are evolving as well. And we will continue to be a champion for improving patient outcomes and investing in healthy societies. We know that when government invests in healthcare, they see a return on that investment in worker productivity, economic growth and stability. In addition to advocating for all these healthcare priorities as a U.S. based multinational company. We also are advocating for the modernization of the U.S. tax code.

As both sides in the aisle in Washington have noted, the U.S. tax code for business is outdated and in many cases makes the U.S. a more costly place to do business, leaving U.S. workers and the U.S. economy at a disadvantage. We are very encouraged by the proposals currently in discussion and will support business tax policy that is competitive with most developed countries and encourages innovation and growth. This includes a system based on territorial taxation in line with most economically developed nations.

We also believe there should be incentives for innovation such as research and development and the cash currently held abroad should be allowed to be brought back into the U.S. at a more competitive tax rate. Regardless of the outcome of these discussions, we will continue to engage with global leaders and continue to be a leading voice, advocating for the stakeholders in Our Credo.

As the healthcare landscape continues to evolve, so too does our business. But despite these changing dynamics, at an enterprise level, we remain committed to our long-term growth objectives.

As we have said many times, our objective is to grow our sales organically at a faster rate than the market and grow our earnings faster than sales. That, coupled with value creating M&A and our strong dividend yield, is the basis for our strong long-term total shareholder returns.

In the near-term, we are focused on meeting our financial and quality commitments. In terms of financial performance, we expect each of our three business segments to grow and contribute to our sales and income growth in 2017. And in keeping with Our Credo commitment that everything we do must be of high quality, in 2016, we continued to elevate our quality standards with measurable progress.

In our pharmaceutical business, our priority is to drive continued growth while delivering on our near-term pipeline. We will do this by focusing on our five therapeutic areas of high unmet medical need, our robust innovation engine and strong commercial capabilities. For 2017, we expect our key catalyst for growth will include continued strong performance of our in-line products, increasing penetration in markets such as anticoagulants, psoriasis and long-acting antipsychotics.

Capitalizing on the early launch success from key products such as DARZALEX, IMBRUVICA and STELARA for Crohn's disease and anticipated regulatory approval for two new immunology products, guselkumab and sirukumab each with greater than $1 billion in sales potential. Further, we will continue to vigorously defend our patents on

REMICADE while remaining competitive against at-risk biosimilar entries given our long track record of efficacy and safety.

For those of you following our remarks on the webcast, you can see the many key events we have highlighted in our pharmaceutical pipeline for 2017, including the potential approval of several line extensions, planned regulatory submissions in both the U.S. and EU as well as the presentation of key clinical data. We are confident in our industry leading pharmaceutical pipeline and will continue working toward our goal of filing 10 new products by 2019 each with at least $1 billion in potential sales as well as filing an additional 40-line extensions by 2019, 10 of which have more than $500 million in potential sales.

Our near-term priority in medical devices is to accelerate growth through innovation, portfolio management and new business models. We are driving growth in priority platforms, sustaining leadership in our core platforms, implementing novel commercial models and seeking expansion opportunities in large growing markets with significant unmet needs.

Our goal is to return to above market growth by the second half of this year and we plan to drive that growth through continued progress on the restructuring initiative in our hospital medical device businesses which I'll remind everyone is on track to achieve savings of $800 million to $1 billion with the majority realized by 2018. More than doubling the number of new product launches in 2016 with more than 12 major launches.

Accelerating the impact from strategic acquisitions made in 2016 including BME in the foot and ankle space, our new expandable cage from Interventional Spine, Coherex Medical in the atrial fibrillation space and NeuWave Medical in energy. And as I mentioned, we plan to close the acquisition of AMO this quarter.

And finally, incorporating a suite of holistic insights-driven capabilities to help health systems navigate value-based care through the CareAdvantage and Orthopedic Episode of Care partnerships which we announced earlier this month. And in our consumer segment in the near-term, our priority is to enhance our leadership and priority categories and continue to improve profitability to benchmark levels by focusing on critical geographies and iconic megabrands.

Our plans for consumer growth in 2017 include continuing to grow faster than the market and gaining market share across our megabrands, bringing innovation to the market and launching key science-based new products, accelerating the growth from recent acquisitions in our beauty franchise including Vogue International, Light Therapy in our NEUTROGENA business and NeoStrata in dermal cosmetics. And finally, we will continue to utilize supply chain and SG&A efficiencies to ensure operating margins are at benchmark levels.

All of these compelling strategies and strong results would not be possible without our talented, diverse and dedicated employees around the world. Today, we employ approximately 127,000 global employees with approximately 40,000 jobs here in the U.S.

Our purpose-driven, Credo-based culture puts people first and this is certainly true in the way we think about our employees.

We believe employers have an opportunity and responsibility as well as an incentive to ensure their employees are healthy and engaged. Our goal is to lead by example by cultivating the world's healthiest workforce, from programs that encourage healthy eating, movement and resilience to ensuring the financial health of our employees through competitive compensation programs as well as providing important benefits to support healthy families.

We believe these programs help us to achieve our goals of attracting, developing and retaining the very best talent to deliver the best outcomes, positioning us to deliver another 130 years of strong growth and shareholder returns.

In total, we are proud of the results we've delivered over the past several years, and we will continue working to achieve and exceed your expectations for us in 2017 and beyond. I'm very confident that with our robust pipelines and investments in innovation, our improved efficiency and productivity and value driven leaders and employees united by Our Credo, we will continue to deliver strong and consistent growth.

I'll now turn it over to Dominic who'll provide additional details about our results and guidance for 2017.

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Alex, and good morning, everyone. We understand that there has been some audio difficulties this morning, and we apologize for that. And hopefully, that issue has now been resolved. As you've heard from Alex, we're very pleased with our 2016 performance. We believe we've managed our business well and that we have transparently shared information to help you understand our plans and expectations.

We ended the year at the top end of our most recent operational guidance range for sales and the negative impact of currency resulted in sales slightly below consensus on a reported basis. With respect to adjusted earnings, we also finished above our operational guidance and at the high end of our reported EPS guidance despite the negative impact of currency and exceeded consensus estimates for earnings as published by First Call.

Turning to the next slide, you can see our condensed consolidated statement of earnings for the full year 2016. On a reported sales basis, $71.9 billion represented an increase of 2.6% which on an operational or constant currency basis grew 3.9%.

As we told you this time last year, we expected to accelerate our underlying growth from 2015 to 2016, excluding any impact of acquisitions and divestitures, hepatitis C sales and the impact of Venezuela as well as the additional shipping days in 2015 which we previously discussed. On that basis, we grew sales in 2015 at 5.5%. We have exceeded that level of growth for the full year 2016 at 7.4%.

Our earnings adjusted operational EPS growth in our 2016 guidance was expected to range between 5.3% and 7.7%. As reported this morning, our EPS of $6.73 reflects reported growth of 8.5% and operational growth of 9.4%, exceeding both our original guidance and the updated guidance range we gave in October, driven by significant improvement in our adjusted pre-tax operating margin.

Our guidance from January included a more than 200-basis point increase in our 2016 adjusted pre-tax operating margin. For full year 2016, we exceeded our projections, achieving a 330-basis improvement while continuing to invest in our business.

As you may remember, when we provided guidance this time last year, 2015's earnings had been impacted by significant divestiture gains. As we told you at that time, not all of those gains were reflected in income, most were used to reinvest in our business which lowered our pre-tax operating margin for 2015.

So naturally, in 2016 without that impact, our margins improved. And in addition, through margin improvement programs in our supply chain, our consumer business and our enterprise standards and productivity initiative, we were able to further exceed our guidance. These factors have resulted in very strong adjusted pre-tax operating margin for the enterprise.

Now let's take a few moments to talk about certain items on the statement of earnings for the quarter. Turning to the next slide, you can see our condensed consolidated statement of earnings for the fourth quarter of 2016.

On a reported sales for the fourth quarter basis, they grew at 1.7%. That represents 2.3% on an operational basis. And excluding the impact of acquisitions, divestitures, hep C sales and the impact of Venezuela as well as the impact in the quarter associated with the extra shipping days, our 2014 fourth quarter operational growth was a strong 7.6%.

Please now direct your attention to the box section of the schedule where we have provided earnings adjusted to exclude special items and intangible asset amortization expense. Adjusted net earnings were $4.4 billion in the quarter, up 7.9% compared to fourth quarter 2015. And adjusted earnings per share of $1.58 versus $1.44 a year ago are up 9.7%. And adjusted EPS results exceeded the mean of the analyst estimates as published by First Call. Excluding the net impact of translational currency, our operational adjusted EPS was $1.59 and up a strong 10.4% for the fourth quarter.

In the quarter, we incurred intangible amortization expense of $252 million on an after-tax basis and after-tax special charges of $295 million which included cost of approximately $251 million related to the restructuring that we previously announced of our medical device business.

Now let's take a few moments to talk about other items on the statement of earnings. Cost of goods sold was 130 basis points lower than the same period last year due to cost improvement programs. Selling, marketing and administrative expenses were 29.3% of sales. This is a 380-basis point improvement from last year as we saw the benefits of many of the programs designed to lower the level of certain cost while we continue to invest to drive growth in our key brands.

Our investment in research and development as a percent of sales was 14.6% in the quarter and 150 basis points lower than the prior year. This is mostly due to the timing of milestone payments. Interest expense net of interest income was lower, reflecting higher earnings on our investments.

Other income and expense was a net loss of $20 million in the quarter compared to a net gain of approximately $1.2 billion in the same period last year. Of course, this is the line item that includes several special items in both years. Excluding those special items, other income and expense was a net gain of approximately $200 million in 2016 compared to a net gain of approximately $1.3 billion in the prior year period.

The total gain for the year was lower than our guidance as not all of our planned activities were executed in 2016 which I will discuss further in my guidance for 2017.

The adjusted fourth quarter effective tax rate for 2016 was 14.5%. This lower tax rate offset the impact of currency on the quarter and the lower than expected other income. The adjusted full year effective tax rate for 2016 was 17.6% which was slightly below our guidance due to the mix of our business within our international affiliates. It was also lower than prior year also due to the mix of business and the adoption of a new accounting standard in the second quarter of 2016 related to the tax benefit on share-based compensation.

Turning to the next slide, I will now review adjusted income before tax by segment. Full year 2016 adjusted income before tax for the enterprise improved from 31.4% of sales in 2015 to 31.7% of sales in 2016.

Looking at the adjusted pre-tax income by segment, medical devices at 32.2% is lower than the previous year, primarily due to the Cordis gain which we recorded in 2015. Pharmaceutical margins were flat but still remained significantly above their benchmark. Consumer margins improved by 560 basis points versus 2015, approaching benchmark levels while still making important investments for future growth as we return our iconic consumer brands to the market.

Now I will provide some guidance for you to consider as you refine your models for 2017. Before I discuss sales and earnings, I will give you some guidance on items we know may be difficult for you to forecast.

I'd like to first address our cash position. At the end of the quarter, we had approximately $15 billion of net cash which consists of approximately $42 billion of cash and marketable securities and approximately $27 billion of debt. As Alex said earlier, regardless of any potential transaction with Actelion, we are always looking for the right opportunities to deploy that capital to create greater value for our shareholders. And due to our strong balance sheet, we have the financial strength and flexibility to execute on all of our capital allocation priorities simultaneously.

Also as Alex noted, we have now completed approximately 75% of our $10 billion share repurchase program. We expect to complete the program during the first half of 2017. Although we're continuing to evaluate external value creating opportunities in line with our capital allocation priorities, for purposes of your models, assuming no major acquisitions or other major uses of cash except for the completion of our share repurchase program, we suggest you consider modeling 2017 net interest expense of $500 million to $600 million.

Regarding other income and expense, which is the account where we record royalty income as well as gains and losses arising from litigation, investments by our development corp as well as divestitures, asset sales and write-offs, we would be comfortable with your models for 2017 reflecting other income and expense excluding special items as a net gain ranging from approximately $1.1 billion to $1.3 billion. This is a higher level than 2016 as certain activities were not completed in 2016 as expected. As we move forward, a portion of any gains will be reinvested in the business as we have done in previous years.

In regards to adjusted pre-tax operating margins, because we did not have the same level of divestitures in 2016 as in 2015 and subsequently did not have the additional investments in our business, we delivered significant improvement in 2016. While we wouldn't expect the same level of improvement in our adjusted pre-tax operating margins in 2017, not including any impact of acquisition and divestitures, we would expect to maintain to slightly improve our adjusted pre-tax operating margin in 2017 as we continue with the key margin improving initiatives in our business.

And now a word on taxes. While we remain optimistic about the U.S. corporate tax reform proposals, our guidance today does not include any assumptions about the current proposals. At this time, we would suggest that your models reflect an effective tax rate for 2017 excluding special items of approximately 19% to 20%.

Now turning to guidance on sales and earnings. Our sales guidance for 2017 includes the impact of Abbott Medical Optics which we expect will close before the end of the first quarter as well as REMICADE, the impact of any REMICADE biosimilars which we consider to be at risk due to the ongoing patent litigation as we have previously discussed. However, 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 of operations. This is the way we manage our business and it reflects the underlying performance of our business. We will also provide an estimate of our sales and adjusted EPS results for 2017 with the impact that exchange rates could have on the translation of those results.

For full year 2017, we would be comfortable with your models reflecting an operational sales increase of 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 2015 on an underlying basis excluding any acquisitions and divestitures is expected to reflect growth of 3% to 3.5%. Although we are not predicting the impact of currency movements, using the euro at $1.07, our guidance for sales growth would decrease by approximately 1%. Of course, we will update this estimate as we progress through the year. Thus, under this scenario, we would expect reported sales to reflect a change in the range of 3% to 4% for a total expected level of reported sales of approximately $74.1 billion to $74.8 billion.

And now turning to earnings. A continuing factor in our earnings guidance for 2017 is the impact of currency movements on transactions which, although hedged, are still expected to be negative. We expect transaction currency impacts to negatively impact our gross margin by approximately 20 basis points to 30 basis points in 2017 as compared to 2016. We'd be comfortable with adjusted EPS guidance in the range of $7.05 to $7.20 per share on a constant currency basis, reflecting operational or constant currency growth of approximately 5% to 7%.

Again, we're not predicting the impact of currency movements but to give you an idea of the potential impact on EPS, with the euro at $1.07, our reported adjusted EPS would be negatively impacted by approximately $0.12 per share. Therefore, our reported adjusted EPS would range from $6.93 to $7.08 per share. At this early stage in the year, we would be comfortable with your models reflecting the midpoint of this range. As we look at the published models that support the consensus EPS estimates currently, it appears that many of those models have not yet been updated for the negative impact of currency movement.

So, in summary, as you update your models for the guidance I just provided, I would like to make a few key points. We expect our operational sales growth to range between 4% and 5% and our underlying growth which excludes any impact of acquisition and divestitures to be approximately 3% to 3.5%. With regards to expected EPS growth, on an operational constant currency adjusted basis, our guidance is strong in the range of 5% to 7%, consistent with our objective to grow earnings faster than sales on a constant currency basis. Also for 2017, we expect to maintain or slightly improve on our adjusted pre-tax operating margins based on the guidance I just provided.

As we move into 2017, we are confident in the strength of our business. As we execute on our growth plans and near-term priorities that Alex laid out for you this morning, we are well positioned with a strong balance sheet to deliver solid results while continuing to invest in innovation which will ensure our future growth and success.

Finally, before I turn it over to Joe for Q&A, just a reminder to please save the date for our pharmaceutical business review on Wednesday, May 17.

Thank you. And, Joe, now to you for the Q&A.

Joseph Wolk {BIO 19812977 <GO>}

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

Q&A

Operator

Yes. Your first question comes from Matt Miksic with UBS. Please proceed with your question.

A - Joseph Wolk {BIO 19812977 <GO>}

Good morning, Matt.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks so much for taking our questions. So, Alex, I had one for you. You made some comments on tax policy, important issue I think for investors, everyone is kind of wondering how this new administration is going to go. And given that you'd met with them recently, a couple of quick points if you can shed any light for us. One, I mean repatriation seems like something that has broad appeal and may be something that could happen relatively quickly.

But when we think about the investments that a lot of companies have made and tax optimization strategies, these include obviously things like overseas manufacturing assets, et cetera, how would you want to see reforms put in place or phased into place? What, if anything, can you read into where the new administration and Congress is headed in potentially putting that process in place or should we worry as I think some investors might that this could be sort of a change that would click into place in 2017 or in 2018?

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Matt, thank you very much for your question. And look, just a quick comment first. I want to say how really pleased I am with the performance overall of the company, not only in Q4 but also for the full year 2016, and frankly, how excited we are and confident in our prospects for 2017. I mean, if you look across the different businesses, pharma, medical device, consumer, the announced strategies that we've actually had in place now for the past several years, I think our performance has been quite consistent with that. We're ending the year on a strong share note across all of our major franchises and we've been able to do that while also investing for the future.

You consider more than $9 billion invested in R&D. If you take a look at the other very strategic investments that we've made in acquisitions this past year in our consumer, our medical device, continued licensing, options in our pharmaceutical business, and then you compound that with some of the efficiencies and the continued path that we're on to making sure that we're as effective and as efficient as we can be in our business, it really delivered those results.

And again, we think the prospects for 2017 are promising. But as it relates to tax policy, look, I would say that the major themes that we've been able to ascertain from our ongoing discussions with the new administration as well as other stakeholders is they are clearly focused on growing the economy and growing high quality jobs, particularly here in the United States. And we believe that any of the potential changes – we stated openly that there are many aspects of the blueprint that we think would be very favorable. I think net-net, any time we can get more flexibility by moving to things like a territorial system outside the United States to be able to invest back here in the United States and other areas, we think that's a net positive.

Clearly, we are being very clear with the need to have an adequate transition. To your point, given some of the investments that have been made in previous tax constructs as well as manufacturing footprints. But so far, I remain very confident in the discussions that we've had. That ultimately, we will make changes to the overall tax system that will be a stimulus for growth and that ultimately will help Johnson & Johnson and many other companies grow at an even faster rate going forward.

Q - Matt Miksic {BIO 6990080 <GO>}

That's great. And congrats, as you point out, on the solid performance, particularly adjusting for shipping days. Thinking about the portfolio, if I could ask a follow-up just on if you could update us on your thoughts on your preference for investment, I think the talk in the news with Actelion and thoughts about other assets. If you could just run through maybe how do you think about putting capital to work in pharma? I think you mentioned in the past partnerships and in-licensing being a preference. How do you think about putting assets to work and capital to work rather in devices and maybe how you think differently about those two types of investments potentially.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Matt. Thanks for the follow-up. Look, I think overall our strategy and our outlook around putting capital to work in M&As has actually stayed pretty consistent through the past several years. And that is, one, we want to make sure that something is strategically right, that it fits with our capabilities. Two, that financially it's a sound investment. I think we demonstrated a lot of discipline and a lot of thoughtfulness about the way that we put the capital to work over the past few years. Next, we need to just make sure operationally that it can be done and that our ability to execute on those deals ultimately produces the kind of outcome for customers, produces the kind of value that we think is important.

Generally, and I think we've been consistent with this over the past few years, about 50% of our growth comes from external innovation. We think that's a very good cadence. And we've been able to do that, by the way, without compromising our internal innovation. I mean if you take a look at our freshness index of about 25% of our sales coming from products that have been launched over the past five years, our continued increased innovation across our portfolio, and another comment that I'd like to make is also on what areas where we don't believe we should participate, where we don't feel that ultimately we're helping patients or consumers to a greater degree, or that we feel that there's a very strong technology path forward. Many of these are very strong businesses but perhaps they're better in someone else's portfolio than ours. I think we've shown a good discipline about that over the past few years.

As I look across our broader portfolio, we would love to find the next IMBRUVICA, the next DARZALEX. I think we've shown a great ability particularly with our very strong scientific underpinning of being able to identify new opportunities, new mechanisms. We apply the clinical regulatory development expertise. And then, of course, our sales, marketing, reimbursement teams have done a great job of making those new molecules frankly blockbusters. When you think about the fact now that in our pharma portfolio alone, we've got 11 brands that are over $1 billion, 10 growing at a very strong rate, and when you compound that with what we've done around line extensions, we would like that.

We also said, however, that there are other areas of significant unmet medical need where we do feel that either our clinical or regulatory expertise, our global footprint, our sales, marketing, reimbursement capabilities could increase the growth rate, we would also consider those. And I think that's been our guiding strategy for pharma. In medical devices, look, over the past several years, we've divested some businesses but we've also, particularly this past year, I'm proud of the investments that we made in areas like extremities. We've made investments in spine. And we've also made some – obviously what we did in Vision Care and in cardiovascular, we're excited about that and we'll continue, I think, that progression to look at portfolio opportunities and devices.

And with our consumer business, I'm very proud of the progress that that team has made over the last three years for their – look, mission number one was to make sure that our over-the-counter business, our quality issues were remediated. We've done that. I think the team has done really a remarkable job of meeting all the FDA requirements. And by the way, we did that while reinvesting right here in Pennsylvania in the United States at a plant in Fort Washington that we now feel is world class and really will set the standard around OTC production going forward.

Now that we made that progress, we, of course, made the investment in areas like Vogue and other portions of that portfolio that we think will be generating growth in 2017 and 2018 and beyond. So I think at a macro level, that's the way we look at it. If I dig down each one of the franchises, that's my description as well, Matt.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Matt. Michelle, next question please?

Operator

Thank you. Your next question comes from Mike Weinstein with JPMorgan. Please proceed with your question.

Q - Michael Weinstein {BIO 20602373 <GO>}

Thank you. Can you hear me okay?

A - Joseph Wolk {BIO 19812977 <GO>}

Yes, Mike.

A - Alex Gorsky {BIO 16239711 <GO>}

Hi, Mike.

A - Joseph Wolk {BIO 19812977 <GO>}

Mike, just speak up a little bit.

A - Alex Gorsky {BIO 16239711 <GO>}

If you could please.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay. Perfect. Well, first off, guys, since the audio was off for probably 8 to 10 minutes, you may want to send around the transcript just to cover some of the sections that never made it across to everybody.

A - Alex Gorsky {BIO 16239711 <GO>}

Thank you.

A - Joseph Wolk {BIO 19812977 <GO>}

We will.

Q - Michael Weinstein {BIO 20602373 <GO>}

Yeah, let me just touch on a couple of items, and maybe if I can do this first, Dominic, could you just comment on a couple pieces of the guidance. The organic top line outlook for 2017 was pretty close to where we're at but probably a little bit below the Street. Can you just talk about any puts and takes you want the Street to be thinking about, particularly in the pharma business relative to competition, be it REMICADE or the generic composition for CONCERTA? And then second, down the P&L, Dominic, could you just comment on the other income guidance which is a lot higher than, I think, people were expecting? It looks like you're assuming some sales there. So is there anything there that we should be aware of? And then on the tax rate line, your tax rate is a good deal higher than it was in 2016. So if you could comment on that as well. Thanks.

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

Sure, Mike. Well, just on the top line, of course, we always give you constant currency guidance first. So I think it's important, and when I look at the various models that are out there today that have not yet been updated and I try to peel back the impact of currency, it's pretty clear that our guidance and Street expectations, if they were all adjusted for the same currency rates, would be pretty much in line. So I think the Street has a pretty good sense of where we're headed in 2017.

The major factors in pharma, for example, obviously, we've included the impact of a REMICADE biosimilar. I think many of you have also done that in your models. We will not see significant competition for other products like ZYTIGA and the like that could go generic by the end of the year, but we don't think we'll see any impact there. You mentioned CONCERTA. We will see an impact there. We've already seen some impact there.

And overall, I would say I would characterize the three businesses as pharma – even without the impact of REMICADE biosimilars, the growth rate is going to be slower than it was in 2016 just naturally as those products have been in the market for a while now. They've achieved pretty good share. They still have room to grow, but the rate at which they grow looks like it will be a little slower in 2017 than in 2016. Medical devices and consumer we think will accelerate the growth in 2017 over 2016.

With respect to other income, I mentioned that we had not completed everything that we had expected to complete in 2016. So, therefore, our actual other income line for 2016 was lower than our guidance. So, naturally, we have some carryover into 2017.

I want to emphasize, though, that since we're in the early stage of the evaluations of diabetes business that, that line does not include any impact there because there's no assurance that any transaction would get done in that regard.

Nothing in particular that I would call out there. It's just that our normal review of the portfolio and looking at various aspects of the business we think are either better in someone else's hands or we can get more value for our shareholders through a divestiture. And then of course, we'll reinvest as appropriately in the business and our guidance considers that as well.

The tax rate is higher in 2017 than we ended in 2016. The impact of share-based compensation was greater in 2016 when we first implemented it than we expect it will be in 2017. It could change throughout the year, and obviously, we'll continue to update you.

And then as we look at the mix of the business, international jurisdictions versus domestic jurisdictions, and when you think of a situation where we have more divestiture income than prior year, those divestitures are usually taxed at the U.S. rate. So that adds to the effective tax rate for the year versus the prior year.

So, hopefully, that's helpful, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

It is, Dominic. Let me ask one follow-up on – and got two parts here. So, Alex, could you just talk about the decision relative to the diabetes business? Obviously, given the importance of diabetes in the category, not an easy decision to consider other alternatives for the business. And Dominic, can you talk about the profitability of that business, and I'm asking in part because, if you do end up acquiring Actelion or some other transaction that would be accretive to earnings, if you end up not having the diabetes business, I just want to think about the offset. Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, thanks, Mike. Look, it's always a difficult decision when you look at your portfolio. And as I would frequently describe it, it's a little bit like your children. You love all of them. Just from time to time, we're trying to make decisions that we think ultimately are in the best long-term interest of our customers, stakeholders and our shareholders. And we think diabetes is clearly an area of a lot of unmet medical need. We're very proud of the history and track record we have in blood glucose monitoring as well as insulin pumps and some of the things we've been able to do. We're also very proud of, frankly, the performance that we generated over the past few years with products like INVOKANA, the progress that we've made in areas like bariatric surgery that can have a huge difference in the metabolic space.

That being said, we do feel that based upon the broader market dynamics, particularly things such as pricing in certain areas, has led us to the point where we say the right thing for us to do is to consider strategic options for these three particular areas of this business. I want to be clear. We still are very interested in diabetes and we've got a lot of, we think, very important, very promising trials coming out for INVOKANA this year, in fact. And it's a space where we'll continue to work with our medical device group, but we think, at this point in time, it's important for us to look hard at these businesses and make sure ultimately that we're making the right investments for the future.

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

And, Mike, regarding profitability, as you know, you follow the industry closely. The diabetes pricing over the last several years has been challenging. And although I think our team has done a nice job of adjusting the cost structure there, the level of profitability in that business has declined. We don't give you specific franchise profitability, but it's been challenging to generate strong profits in the business where there's significant price decline year-after-year. And without commenting on whether or not Actelion would or would not get completed, that transaction, should it get completed, would be accretive to both top line and bottom line and more so – more than offset any impact of diabetes.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Mike. Michelle, next question please?

Operator

Your next question comes from David Lewis with Morgan Stanley.

A - Joseph Wolk {BIO 19812977 <GO>}

Good morning, David.

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

Good morning. A couple of quick questions and maybe some strategic ones. I guess just, Dominic, following up on a prior question here on REMICADE, I think the consensus view into this year was that REMICADE was something like a 1% hit to the top line. Is that still a decent place to be for 2017?

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

We don't give guidance by product, David, as you know, but I previously commented when you think of the fact that Merck had experienced two years of a biosimilar in Europe and they retained 70% market share after two years, so it's reasonable to assume 10% to 15% perhaps market share erosion in the first year. Of course, in Europe, it's much more dramatic because of the impact of the healthcare system there. So I think if generally consensus is in that range that you mentioned, that's a pretty reasonable range.

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

Okay. And maybe just two more strategic questions. I guess, Alex, first for you. I know diabetes is going to be a topic this morning. But I guess pruning devices shouldn't really be a surprise for investors but I guess I was struck by this notion of you're getting bigger in one of your big consumer medical device franchises which is ophthalmology and then try to get smaller in one of your other consumer device franchises which is diabetes. I mean is it – should we be thinking about these two businesses the same way that you think of them as sort of two consumer assets and you want to get bigger in one and then smaller in the other?

A - Alex Gorsky {BIO 16239711 <GO>}

David, thanks for your question. The way that I would frame it is, we're very excited about the opportunities that we have going forward in Vision Care. We've looked over the past several years, and first of all, I want to commend the Vision Care franchise for the work that they've done over the last two and three years in contact lenses. If you look at the growth rates, I mean we ended up at a double-digit growth rate in Q4 by that team. And they've introduced more than five new product launches. The execution in the field with customers has been outstanding, and frankly, when you think about the broader capabilities that we have in our surgical space and the potential to marry those up with our Vision Care business, and of course when AMO became available, we just thought that that was a very good match strategically and from an operational stand point. And Vision Care, just on a incidence basis, as we look at an aging population and things of that nature, we think that there's a lot of dynamics that would suggest we're going to see strong continued growth. And we think we can be, frankly, the very best eye care company in the world as we continue to evolve that portfolio and move ahead.

Diabetes, look, as I said earlier, I'm incredibly proud of the work of all of our Johnson & Johnson associates and what they've done. We have people and scientists and people in the field that have spent their careers building that franchise. If you take a look at our actual volume share, we've maintained a strong position. That being said, there are other dynamics within that market that make it more challenging as it – and particularly in comparison to other areas in our portfolio. So I want to highlight the fact that we're still very early days in this and we are taking a look at a range of options. But we also, as I mentioned earlier, remain very committed in the diabetes space through many of our other areas such as bariatric surgery, such as INVOKANA that continued in ongoing development programs that we have around that. So that's the way that we think about it.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, David.

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

That's very helpful, Alex. Let me just...

A - Joseph Wolk {BIO 19812977 <GO>}

Michelle, next question please.

Operator

Your next question comes from Jami Rubin with Goldman Sachs. Please proceed with your question.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Just a couple for you, Alex. You met with Donald – with President Trump yesterday. I saw you on the front page of the Wall Street Journal. Just wondering like you commented on tax policy, healthcare policy generally, repatriation, what do you think our new president is thinking in terms of drug pricing? Obviously, he has come out with some very provocative comments about removing the non-interference clause. The industry has certainly been fighting that for years. There are reasons to believe that that may never happen. But what do you think the end goal is here? Because drug pricing, the whole drug pricing debate has been a major overhang over the sector, biopharma stocks, for the past year-and-a-half. What do you think the end game is? Is he just trying to be provocative to change behavior or is the industry really willing to give something up? How do you think this all plays out? That would be very helpful.

And then my follow-up question is just on capital allocation and M&A. Clearly, the pharma business has been a key driver of your growth for the past, say, five years. Most of the earnings beats has come from the pharma business. This quarter, the pharma business came in a bit lower. As you acknowledged, growth will slow in 2017 versus 2016 as a number of your key growth drivers has slowed down and faced competition. We all see the news around Actelion and I think the initial reaction is, okay, that's nice but that's sort of a small bolt-on deal, doesn't really change the company. Would you consider M&A that is more transformative to the company? Is that something that you would consider or would you be prepared today to rule something out like that? I mean and what I'm thinking of here is a transaction that would have a much bigger impact on the company in terms of sales growth, in terms of earnings growth, in terms of reshaping the portfolio, et cetera, et cetera. Thanks very much.

A - Alex Gorsky {BIO 16239711 <GO>}

No, thank you very much for the question, Jami. Look, first of all, that healthcare, specifically, was not a significant topic of discussion that we had yesterday. It really focused more on overall economic growth, and as we mentioned earlier, what are things around tax, regulatory and other policies? And that those were really the major drivers of the conversation. Clearly, the administration will be looking at healthcare. And I think what's really important in all those conversations, that I'm sure will be coming, Jami, is that we look at healthcare in total. And the way that I would frame it is, look, I believe healthcare, for all the reasons that we talked about earlier, is a growth industry going into the future. And while – and we know the drivers that demand in aging population, increasing middle class around the world, new technology that we're introducing but clearly that is going to put strain on the systems.

And what we've continued to emphasize is, number one, the important role that pharmaceuticals play in overall healthcare. We mentioned in the comments that pharmaceuticals make up between 10% and 14% over all of healthcare spend. If you look at a lot of studies, it would suggest that 75% of the improvements that we've seen in things like mortality, in improvements in things like cardiovascular disease, cancer, HIV are really due to pharmaceuticals. And so we want to make sure that we continue to innovate. And by the way, I believe a lot of the technology and innovation that we're seeing right now truly has the potential to transform many diseases and move more towards disease interception, cures, than what we've seen in the previous 20 years. And so I think it's important to keep that perspective.

Two, I think it's incumbent upon us as an industry to price responsibly. As you heard in the comments that I made earlier, we have attempted to do that. We believe that that has in fact been our practice. We announced some other additional steps that we're taking regarding transparency. We think that's important for the industry to do. And we certainly do not want a few bad actors, I believe, to color overall what is an incredibly important contribution the pharmaceutical industry makes to overall healthcare. And so that's what we'll be working, obviously, with our other trade partners, directly ourselves, to maintain that. And again, I remain confident in the long run, the most important thing we can do is continue to bring innovative products to market that make a big difference for patients and consumers. And that's what we're going to be focused on doing.

Regarding capital allocation, as you mentioned, we're always looking at a range of options. And I think that what you see is that our model that we've used, and I mentioned earlier the approach that we've taken in pharma, that tends to be bolt-on or early licensing opportunities, I would argue has been very successful. And I think if you look at the number of launches, the number of billion dollar products that we've been able to create during that timeframe, the difference that we made for a lot of patients shows that it is no surprise, as Joaquin will sometimes say, but in fact it's rooted in a lot of strong capabilities. And we would expect to continue that going forward.

We look at a range of opportunities. And while I think we've been very clear about our five therapeutic areas where we want to focus because we do think we have strong capabilities there, it's not to the point of being dogmatic. We challenge ourselves. We do look at large opportunities. We look at very significant transformational changes to our portfolio. We have broad discussions about that with the board.

What I would highlight, Jami, is that I think the large transactions by their very nature tend to be more challenging. They tend to be more than initiatives that are focused on growth and innovation as the majority of ours have been. They tend to focus on cost cutting and synergies. Operationally, they're just more challenging. And so for all those reasons, we've found it to be much more successful to take the earlier stage, the smaller stage companies and add our capabilities so that ultimately we have a good strategic and a good financial outcome for the company and for our shareholders.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Jami. Michelle, next question, please?

Operator

Your next question comes from Larry Biegelsen with Wells Fargo.

A - Joseph Wolk {BIO 19812977 <GO>}

Hi, Larry.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. One for Dominic, one for Alex. Let me just ask a little bit more on the top line guidance for 2017. The delta between the 2016 organic sales result of 7.4% and the organic growth guidance of 3% to 3.5% is a bit greater than we expected, Dominic, based on your previous comments I think on the Q3 call. It feels like something may have changed since the Q3 call. Is that fair? And then I had one follow-up for Alex.

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

Yeah, I don't think anything has dramatically changed. I mean we're not calling out any particular impact to REMICADE. And I think you're all familiar with the fact that we are going to see some slower growth throughout many of the pharma brands that have done exceptionally well up to this point. I'll just remind you that we had a very significant impact with hepatitis C not too many years ago, and we did call that out because that was very significant. The impact to REMICADE biosimilars is nowhere near that level of impact. So I don't think anything's changed dramatically, Larry. Just sort of pace of growth in each of the businesses as we look into 2017 is still going to be good, but as I said, pharma, just a bit slower than it was in 2016.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

All right. Thank you. And, Alex, if you divest the diabetes business, it will represent the third major device divestiture since you became CEO. So my question is, are you done making major divestitures in the device business? And we all see what you're doing with ortho, surgery and vision care with the AMO acquisition, building breadth and scale. But cardio, although it's been a very strong performer, it is relatively narrowly focused. So how are you thinking about that business now? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, Larry, thanks a lot. Look, you're absolutely right. The three primary drivers of our strategy and, we believe, of the growth going forward in our current portfolio, our orthopedics group, our surgery group and our vision care group. And I think if you look at the underlying health of each one of those franchises, we're really pleased with the fourth quarter and the full year results in 2016.

If we take a look at surgery, for example, you see EP growing at about 14%. We see some of the other – things like endo/mec, biosurgery, all growing at very strong rates. Hips and knees we think came in and we're holding gaining share in many of the areas. And vision care, frankly, had an incredibly strong quarter and we think it's well positioned for growth in spite of even new competition with better launches in 2017. So we think that those franchises are very well positioned. As we look to the future in cardiology, we're very proud of the success that we've had with our EP business.

As I mentioned earlier, when you see EP, you probably have about 32, 33 consecutive quarters now I believe of double-digit growth. We've had a constant cadence of new innovation. We have done some small tuck-in acquisitions through the year to augment that franchise but we realize longer-term and we've been very open with it that we'll continue to look at the cardiovascular space because we do think there's a lot of unmet need but it's one that we'll have to continue to evaluate strategically, financially to see exactly what is that best path forward.

And so the only other statement I would make, Larry, to yours is I want to highlight it is early days regarding our decision in diabetes. We'll look at a range of options. Again, I want to openly state the hard work that that team has been doing in a very difficult and challenging marketplace and we'll keep you informed as we go through that decision process.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Larry. Michelle, next question, please?

Operator

Your next question comes from Glenn Novarro with RBC Capital Markets. Please state your question.

A - Joseph Wolk {BIO 19812977 <GO>}

Hi, Glenn.

Q - Glenn John Novarro {BIO 2430199 <GO>}

Good morning, everyone. For Alex or Dominic, can you can comment on device utilization in the fourth quarter? We've already seen several companies positively preannounce the upside a few weeks ago, particularly in ortho and spine. And, Dominic, I remember on the third quarter call in October, you gave color on monthly trends saying September was stronger than July and August. So I wonder if you could provide similar color on the fourth quarter trend.

And then as a follow-up, I'm just wondering if we're starting to see greater seasonality in 3Q on the downside and I'm wondering if we're starting to see greater seasonality to the upside in the fourth quarter as individuals work through their deductibles and plan more surgeries in the fourth quarter? Thanks.

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

Yeah, Glenn, well, we don't have all the data for the fourth quarter in yet, but the projections that we looked at that are published do show a improvement in fourth quarter utilization over third quarter utilization. And as I said during the third quarter call, we did see a slowdown. It looked like it was in the summer months. And as September rolled around, it picked back up again. We don't have specific details by month in the fourth quarter yet that's reliable yet to comment on. But overall, fourth quarter utilization does look better than we saw in third quarter.

I wouldn't say it's dramatically improved. I mean we're still in very low single-digit year-over-year uptick in utilization. With respect to seasonality, we do see a phenomenon in that now. As you know, more surgeons are actually employees of hospital systems in the U.S. that, during what would be considered normal holiday periods, such as summer months or holidays, typical holidays, that we do see less procedure volume because it appears that there's more vacation time, et cetera, taken by the profession than was previously the case when they were independent and running their own business, so to speak, as opposed to being employees of a larger institution. So we are seeing that kind of seasonality.

And you're right. Sometimes you see an uptick when people try to fulfill or postpone, I should say, their procedures to later in the year so they can get their procedures in and have it be – have already achieved their deductible and other matters and then not have to pay for the expensive surgery upfront. So we're seeing that dynamic as well. So I think this is going to change over time and it's beginning to change now as we see the dynamics in the market.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, Glenn, Alex here. I would really recommend that as we look at the overall device market and given some of the changes that Dominic brought up, be it – especially in the United States, where physicians are employed, holidays, seasonality, things like that are changing, it's very important in the device space to take a longer-term perspective. And I realize in the past that you can see certain quarter-to-quarter variations. I think we will going forward, but if I step back overall and look at what's – as the markets continue to develop on an annualized basis, I think we remain very confident in some of the underlying trends. But I think it is important to take kind of a longer-term view.

A - Joseph Wolk {BIO 19812977 <GO>}

Thank you, Glenn. Next question, Michelle?

Operator

Your next question comes from Danielle Antalffy with Leerink Partners.

Q - Danielle J. Antalffy {BIO 16104603 <GO>}

Hi. Good morning, guys. Thanks so much for taking the questions. Just, Alex, if I could ask on a high level, following up on some of the earlier questions, pharma has been a driver of outperformance over the last year-plus, and the device business has been a relative underperformer, although clearly seems to be stabilizing to improving here. But just thinking about the sort of mix of the businesses going forward, considering the competition you have coming from pharma, you expect pharma to slow, you expect devices to return to above market growth going forward. Does this lend more – does this make devices more important relative to pharma going forward? Or how do we think about how you're sort of allocating capital between the businesses and even from a capital allocation perspective which was asked earlier? Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Danielle. Look, we still think there's great opportunity in each one of these sectors. And let me just start with the pharmaceutical. In 2017, Dominic, took you through some of the rationale regarding our guidance, but make no doubt about it, we still remain very bullish on the core fundamentals of our business. If you look at products like STELARA and SIMPONI growing in excess of 20% this past quarter. We got the additional Crohn's indication with STELARA that we think in and of itself could be a very significant opportunity going forward.

If you think about the potential products that we have guselkumab, sirukumab in the near-term and you compound that with new information that we're certainly hoping for with INVOKANA. And you top that off with the future pipeline of the 10 compounds between now and 2019, 2020 that we'll be launching, we're quite excited about that portfolio. And so while we'll always be looking for opportunities to add on to it, if we look at that core performance, again, we think it's been quite strong.

What we see in the medical devices, a continued acceleration. I mentioned some of the growth rates earlier around EP, endo/mec, biosurgery, let alone some of our core ortho and Vision Care areas. If you compound that with some of the investments that we made, things like AMO with things like in extremities, in cardiology as well as in spine, we think that's also going to help us accelerate growth even as we head into 2017. And we think the underlying fundamentals of that business have continued to improve over the past year and consumer certainly the same case. We ended the quarter in areas such as beauty, OTC, wound care quite strong. And when you add that on to the several billion dollars worth of investments that we made with Vogue but also in other areas, we think that franchise is positioned for increased growth prospects as we head into 2016 and beyond. And then on top of that, look, we're going to continue to look for the kind of deals that I had outlined earlier that we think make strategic financial sense, and that ultimately, we can execute on.

A - Joseph Wolk {BIO 19812977 <GO>}

Thanks, Danielle. Michelle, we have time for one more question please.

Operator

Thank you. Your next question comes from Josh Jennings with Cowen & Company.

A - Joseph Wolk {BIO 19812977 <GO>}

Good morning, Josh.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi, good morning.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Josh.

Q - Joshua Jennings {BIO 16451037 <GO>}

Thanks for taking the questions. I was hoping, to start, we might be able to get a little history lesson, Alex and Dominic, about whether you see implementation met to Johnson & Johnson for the pharma and device businesses. I know it's hard to predict what's going to happen moving forward, but what potentially – how the impact could be for the repeal of the ACA?

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

Yeah, Josh, we had commented on this before. We did not see any significant impact, uptick, in the business as a result of the implementation of the Affordable Care Act. Certainly, there was not much of an impact at all in the pharma business, in our device business because of the nature of the type of device products we have. We did not see much of an impact. So, therefore, any change going in the opposite direction we don't think will be negative. We did see an impact in terms of the cost associated with the Affordable Care Act. And as we've said before, we've incurred approximately $1.4 billion between the pharmaceutical fee, increased rebates, et cetera, even excluding the currently postponed medical device tax.

So we'll have to see when new legislation is announced whether or not these fees and costs associated with the Affordable Care Act remain or if they're altered in any way. But those have already been incorporated in our business. We've adjusted our cost structure accordingly and we have them fully baked into our 2017 guidance as continuing as they currently are.

A - Joseph Wolk {BIO 19812977 <GO>}

Thanks for the question, Josh. Before I turn the call over to Alex for some closing remarks, again, I want to apologize for any audio outage you may have encountered today. We will post the comments from Alex and I from earlier in the call in the Investor Relations section of our website following the close of this discussion to ensure that everyone has access to any content that may have been missed.

Alex?

A - Alex Gorsky {BIO 16239711 <GO>}

So, look, thank you all for joining the call this morning. We really do appreciate your participation and questions. And in closing, I'd just say that – and reiterate our confidence in the strength of our businesses and our optimism for 2017. We look forward to updating you on our progress with delivering on our robust pipeline and commercial success in pharmaceuticals, accelerating our growth in medical devices and capturing share gains in efficiencies and consumer as we move through the year. Hope you have a great day, everybody. Thank you very much.

Operator

Thank you. This concludes today's Johnson & Johnson's Fourth Quarter 2016 Earnings Conference Call. You may now disconnect.
