Q4 2017 Earnings Call

Company Participants

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

Other Participants

- Bob Hopkins, Analyst
- Danielle J. Antalffy, Analyst
- David Ryan Lewis, Analyst
- Geoff Meacham, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Jeffrey Holford, Analyst
- Joanne Karen Wuensch, Analyst
- Larry Biegelsen, Analyst
- Michael Weinstein, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning and welcome to Johnson & Johnson's fourth 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 J. Wolk {BIO 19812977 <GO>}

Hello, I'm Joe Wolk, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for the fourth quarter and full-year of 2017. Joining me on today's call 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 your interest in Johnson & Johnson. We are very pleased with our 2017 fourth quarter and full-year results. Once again the performance illustrates a track record of consistent growth exceeding financial expectations and making progress on our long-term strategies.

As we guided this time last year, sales for the business accelerated in the second half of 2017 based largely on the strength of our Pharmaceuticals segment and improving performance in Medical Devices. 2017 also marked a year in which we complemented our existing portfolio with significant acquisitions and many collaborative agreements.

These are some of the factors that contributed not only to our superior total shareholder return for 2017 but the more than 225% returns since the end of 2011 exceeding major indices as well as our competitor composite over that span. As we enter 2018, we are confident that our Pharmaceutical business will remain strong and anticipate our Consumer and Medical Device segments will continue to improve, resulting in solid financial performance while delivering innovation that will have an enduring impact on patients, caregivers and consumers.

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.

Please note that today's presentation includes forward-looking statements. We encourage you to review this cautionary statement regarding such statements included in today's presentation as well as the company's Form 10-K, which identifies certain factors that may 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 non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures are also available at investor.jnj.com.

Several 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.

In terms of today's agenda, I will begin with a review of the results for the corporation and three business segments. Alex will then reflect upon our 2017 performance and share his perspectives on healthcare and Johnson & Johnson's drivers for growth in 2018. Dominic will conclude by providing insights on the income statement and our guidance for 2018. The remaining time will be available for your questions. We anticipate the webcast will last 90 minutes.

Now on to our results, worldwide sales were $20.2 billion for the fourth quarter of 2017, up 11.5% versus the fourth quarter of 2016. On an operational basis, sales increased 9.4%, as currency had a positive impact of 2.1%. In the U.S., sales were up 9.8%. In regions outside the U.S., our operational growth was 9%, as currency favorably impacted our reported OUS results by 4.5 points.

Excluding the net impact of acquisitions and divestitures, operational sales growth was 4.2% worldwide, 4.1% in the U.S., and 4.3% outside the U.S. For the full year 2017, consolidated sales were $76.5 billion, an increase of 6.3% compared to the full year of 2016. Operationally, full-year sales grew 6%, with currency having a positive impact of 0.3%. Excluding the net impact of acquisitions and divestitures, operational sales growth was 2.4% worldwide, 1.6% in the U.S. and 3.3% outside the U.S.

Turning now to earnings, for the quarter, there was a net loss of $10.7 billion, and diluted earnings per share was a loss of $3.99 versus earnings of $1.38 a year ago. As noted in this morning's press release, the company did record a provisional charge of $13.6 billion for recently enacted tax legislation, which is treated as a special item. In response to a request many of you had after our third quarter call and to facilitate a transparent understanding of special items, we have included on our website a schedule that details special items labeled net income and diluted EPS GAAP to non-GAAP reconciliation.

Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were $4.8 billion and adjusted diluted earnings per share were $1.74, representing increases of 9.5% and 10.1% respectively, compared to the fourth quarter of 2016. On an operational basis, adjusted diluted earnings per share grew 5.7%.

Regarding the full year, 2017 net earnings were $1.3 billion and diluted earnings per share were $0.47. 2017 adjusted net earnings were $20 billion and adjusted earnings per share were $7.30, up 6.8% and 8.5% respectively versus the full-year 2016 results. On an operational basis, adjusted diluted earnings per share grew 7.6%. Dominic will provide additional details about earnings in his remarks.

Beginning with Consumer, I will now comment on quarterly business segment sales performance, highlighting items that build upon the slides you have in front of you. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the fourth quarter of 2016, 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 the full-year 2017 sales by segment to assist you in updating your models. Worldwide Consumer segment sales totaled $3.5 billion, growing 0.4%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 0.2% worldwide. The beauty franchise grew 2.4%, driven by U.S. share gains in body and hair care attributable to new products Maui Moisture and OGx within our Vogue portfolio and gains in e-commerce. This growth was partially offset by increased trade promotion spending for NEUTROGENA products.

Over-the-counter medicines grew globally 2.6% in the fourth quarter of 2017. Growth of 6% outside the U.S. was driven by strong performance in upper respiratory, primarily driven by TYLENOL and BENADRYL in the Asia-Pacific region and the RHINOCORT acquisition. The decline of 3% in the U.S. is largely due to the fourth quarter 2016 restocking we commented to last year regarding retailer inventory reductions earlier that

year and some minor supply disruption we faced following Hurricane Maria out of the Puerto Rico facility, which has now been fully remedied.

Concluding the Consumer segment, baby care, down 2.4%, continues to be impacted by new entrants to the market. As communicated in the past, despite remaining the market leader, we are actively working on re-launching these brands in 2018, and you will hear more details regarding this at our May 16 Business Review Day featuring our Consumer and Medical Device segments.

Moving now to our Pharmaceutical segment, worldwide sales of $9.7 billion grew 15.5%. Excluding the net impact of acquisitions and divestitures, adjusted sales growth was 7.6% worldwide, an acceleration of growth over the third quarter of 2017.

The therapeutic area with the strongest growth was in oncology at 36%. In oncology, DARZALEX grew 82% versus the fourth quarter of 2016 and surpassed $1 billion in sales for the year. DARZALEX continues to increase U.S. market share in lines 2 and 3 and experienced market growth in the line 4-plus setting. OUS sales were driven by strong uptake in the EMEA and LatAm regions.

IMBRUVICA grew 46% worldwide, driven largely by higher market share and market growth across multiple indications in the U.S. and strong uptake outside the U.S. in the EMEA and ASPAC regions. In the U.S., based on third quarter data across all lines of therapy, IMBRUVICA gained approximately 5.5 points of market share. And the CLL market, based on third quarter data, grew approximately 14%.

Worldwide ZYTIGA growth was also significant, led by U.S. growth of 61% versus the fourth quarter of 2016. Clinical data from the LATITUDE study continued to drive both market growth and market share. The total metastatic castration-resistant prostate cancer market is estimated to have grown 25% in the quarter, and market share for ZYTIGA at 37% is 4 points higher than the same period last year.

In immunology, the U.S. market is estimated to have grown approximately 9%. STELARA in the U.S. gained 2 points of market share in total immunology and 11 points in the Crohn's disease market versus the fourth quarter of 2016. Approximately one-third of STELARA's fourth quarter sales are in the newer Crohn's disease indication.

One other note on STELARA, growth for the quarter was negatively impacted by approximately 10 points in the U.S. related to additional rebates associated with prior quarters in 2017. As we discussed in the past, actual rebate claims do experience a time lag, and original estimates for prior quarters required an adjustment due to the rapid utilization uptake we are experiencing with STELARA for the Crohn's indication.

REMICADE in the U.S. declined more than 8% as we continue to compete in the face of biosimilar entries. While this is more of a decline than the modest levels of erosion experienced during the first three quarters of 2017, demand was relatively stable and the erosion was primarily driven by negative price. REMICADE U.S. export and international businesses declined, as erosion from biosimilar competition persists in key markets.

To conclude immunology, we are very pleased with the uptake of TREMFYA, launched for moderately severe to severe psoriasis, in the third quarter of 2017. Sales totaled $47 million in the fourth quarter and the product is already the new-to-brand share leader when accounting for both IMS claims data and internal data on samples.

In neuroscience, the paliperidone long-acting products performed well, with higher market share driven by increased new patient starts and strong persistency for INVEGA SUSTENNA and TRINZA in the U.S. and TREVICTA outside the U.S. My comments regarding results for the pulmonary hypertension assets acquired from Actelion in mid-2017 are on a pro forma basis. This therapeutic area grew 3% globally, 12% in the U.S. and declining 8% outside the U.S.

Strong demand for UPTRAVI, which also benefited from a wholesaler inventory build, and OPSUMIT was partially offset by two items: first, the expected decline of TRACLEER outside the U.S. due to generics; and second, the transition of patient assistance foundations.

Within the cardiovascular metabolic therapeutic area, INVOKANA declined 34% in the U.S. Similar to prior quarters, the primary driver of the decline is increasing discounts. There was also a loss in share of approximately 1 point. XARELTO's growth of almost 19% was the result of increasing total prescription market share, up almost 2.5 points versus one year ago. Warfarin continues to decline in favor of branded products.

I'll now review the Medical Devices segment. Worldwide Medical Devices sales were $7 billion, growing 6.5%. Excluding the net impact of acquisitions and divestitures, adjusted sales growth was 2% worldwide. Operational growth was driven by continued strong performance in Vision Care and Cardiovascular as well as improving growth in Surgery. However, Orthopaedics performance was below where we aspire to be and we continue to decline in Diabetes Care.

Strong Vision Care results were driven by contact lenses which grew 6% globally in the fourth quarter as the ACUVUE OASYS 1-DAY portfolio and new variants of the ACUVUE DEFINE had strong adoption. On a pro forma basis, the Vision Surgical business grew approximately 5% driven by the continued uptake of TECNIS Symfony in the cataract, IOL category. Underlying demand for cataract business approached double digits for the quarter.

Electrophysiology within Cardiovascular grew almost 20% worldwide which is the ninth consecutive year of double-digit growth for that business. Atrial fibrillation procedures are estimated to have grown approximately 13% worldwide. Our newer product offerings in ablation and advanced catheters are responsible for modest share gains.

Within the Advanced Surgery, endocutters grew globally 14% primarily driven by strength outside the U.S. from uptake of new products in Europe and Asia-Pacific. We are also experiencing some benefit to the fourth quarter OUS growth from a competitor's supply disruption.

Biosurgery grew approximately 8% worldwide largely due to performance in topical absorbable hemostasis products. In General Surgery, suture growth was more than 4.5%. Barbed sutures are experiencing strong adoption and new World Health Organization guidelines recommending our Plus Suture product drove performance in China, India and Japan.

Specialty surgery declined 4.3% as the infection prevention and aesthetics businesses underperformed versus the competition.

Within orthopaedics, we are disappointed with the year-on-year declines in the knee and spine businesses as we continue working to improve portfolio offerings in faster growing segments of those markets. Hip growth of above 2% appears to be slightly ahead of our projected market growth for the fourth quarter.

Pricing pressure continued across the major categories in Orthopaedics but was largely offset by favorable mix. For the quarter, U.S. price inclusive of mix was negative 3% in hips. U.S. price inclusive of mix for spine, trauma and knees were all positive at 3.9%, 1.4% and 0.8%, respectively.

We are often asked about utilization in the U.S. hospital setting, so let me conclude the Medical Devices segment providing that information. For the third quarter, we saw a slight decline in hospital admissions of about 0.5%. Surgical procedures were down approximately 3%, and lab procedures were up about 2%. Our preliminary estimates for the fourth quarter indicate the same rates for surgery and lab procedures with admissions improving to flat.

That concludes the segment sales highlights for Johnson & Johnson's fourth quarter 2017. For your reference, here is a slide summarizing notable developments occurring in the fourth quarter, including the agreement with Legend Biotech for a CAR T-cell therapy candidate for the treatment of multiple myeloma.

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

Alex Gorsky {BIO 16239711 <GO>}

Thank you, Joe, and thanks to all of you for joining us today.

We're pleased to be here sharing the strong results we delivered for 2017. Not only did we exceed the financial performance metrics we set at the beginning of last year, resulting in superior returns for our shareholders, but we also delivered on the commitments and responsibilities defined in our credo.

Total shareholder return for 2017 was more than 24%, which is exceptional, exceeding our competitor composite as well as exceeding most major indices. And not only is that true for 2017, but I'm proud to say that it's also been the case for the last 3, 5, 10 and 20-year periods.

Our shareholder return for 2017 is indicative of the strength of our business as well as the strategic focus and execution that our leaders and teams have delivered over the past several years. Our Pharmaceutical business has been an industry leader in all performance measures, including R&D productivity and continues to deliver strong top-line growth while simultaneously increasing investment to further develop our incredibly strong pipeline of innovative new medicines.

Our Medical Devices business continues to refine and accelerate its pace of innovation while also implementing novel commercial models to meet evolving marketplace demands.

In our Consumer business, despite a global category slowdown in 2017 we maintained our 2016 share gains in many major categories and improved adjusted income before tax margins further, while also investing in our products via traditional platforms and newer digital vehicles.

As you have heard me say before, while we are pleased with our recent performance, we are not satisfied. Going forward, we are committed to meeting the full potential of both the Medical Devices and Consumer businesses. Our track record of strong shareholder returns is also 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 2017, we achieved record levels of investment, we invested $10.5 billion in research and development and $35 billion in M&A, which resulted in a number of value creating acquisitions and collaborations, including Actelion, the company's largest acquisition to date, which added a sixth therapeutic area to our Pharmaceutical business, and Medical Optics, which continues to fuel growth and establish leadership in the eye health space.

In total, we completed 16 acquisitions and licenses of various sizes, 60 innovation deals and made 21 new investments from our Johnson & Johnson Development Corporation during 2017.

In 2018, we will continue to enhance our status as a preferred partner being agnostic to where the best science and technology resides and aggressively pursuing transformational innovation. We understand that ideas come from everywhere and that collaboration is a critical step in unlocking new treatments for patients and solutions for our consumers and customers.

A great example of this is our collaboration with Legend Biotech, a company in China that we are partnering with to develop a truly breakthrough investigational CAR T anti-cancer therapy for multiple myeloma, which remains an incurable disease for many patients. CAR T-cells are an innovative approach to eradicating cancer cells by harnessing the power of a patient's own immune system. We're excited to combine our expertise in multiple

myeloma with the emerging biotech industry we are seeing in China and we are hopeful that by applying shared knowledge and expertise, we can work on building regimens aiming for a cure.

We kicked off 2018 with our announcement of 15 new collaborations to drive the development of novel solutions that can impact healthcare. They focus on addressing areas of unmet need and include exciting new areas such as the use of AI to detect signs of Alzheimer's disease earlier, identifying throat cancers through a simple saliva tests and harnessing the microbiome to treat sleep disorders.

As our portfolio evolves through innovation, acquisitions and growth initiatives, we also regularly evaluate each of our existing businesses to determine if they still fit our strategy and our criteria for value creation.

As a result and as you've seen us do, when it makes sense we undertake a process to consider if different ownership for a business might be value enhancing or if 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 2017, we announced that we are evaluating our strategic options for businesses. In addition to continuing this work, we executed four divestitures in 2017, including the Codman Neurosurgery business. Although we made these strategic divestitures, we strengthened our commitment to stroke treatment as evidenced by the launch of CERENOVUS. This portfolio includes aneurysm coils, vascular reconstruction devices and other technologies used in the endovascular treatment of cerebral aneurysms and stroke, a market we see growing faster than the average in medical devices.

Our activity reflects our capital allocation priorities which have remained consistent and we believe proven. After funding our internal growth initiatives, R&D and SG&A, our estimated free cash flow for 2017 was $17.8 billion. Our next priority in our capital allocation strategy is delivering a competitive dividend to our shareholders and in 2017 we paid $8.9 billion in dividends, which has increased for the last 55 consecutive years.

After meeting our dividend goals, we target value creating M&A and major licensing deals. And finally, we consider other prudent ways to return value to shareholders, such as share repurchase programs and given our financial strength, we have the demonstrated ability to do all of these things simultaneously.

Over long periods of time more than half of our free cash flow has been returned to shareholders. As the world's largest and most broadly-based healthcare company, we understand the important role we play in leading responsibly and representing our industry with integrity. As I think back on how far we've come, the investments we made in healthcare innovation have yielded some amazing returns.

We are in the final stages of creating the first vaccine for HIV/AIDS and we are driving toward the end of the vertical transmission of AIDS in Africa. We are winning the fight against drug-resistant tuberculosis. We are enabling important breakthroughs against pulmonary arterial hypertension. We are advancing spinal care for patients who suffer from debilitating disc disease with our interventional spine technology.

We enabled enhanced ability and mobility and knee replacements via novel joint reconstruction technology. We offer the convenience and ability to utilize acne care treatment technology at home. We are enabling consumers to digitally scan their skin via smart phone app and receive analysis that provides personalized skincare advice and product recommendations. We are delivering e-commerce vision care solutions that enable consumers to manage their eye care online.

Clearly, we have a track record of producing advancements in healthcare that have saved and improved people's lives for over a century. And people depend on us to continue making new discoveries. We recognize this and we also recognize that we must find new solutions faster than ever before.

I believe that to drive the change in the healthcare space that people want and need, we must have a sense of urgency. This requires us to actually re-imagine Johnson & Johnson as a 132-year-old startup, one that embraces and acts on the best ideas, that is nimble and fast, that leverages technology to drive life changing and lifesaving innovation, and one that focuses on being competitive always via transformative products, quality services and transparent pricing, all with the consumer top of mind.

It's an incredibly exciting time to be in the business of healthcare. Cures and treatments reaching the market today are not only improving the 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 and healthcare spending in other parts of the system such as hospitalizations.

Healthcare is a monumental part of each and every one of our lives. It affects all of us in a deeply personal way, whether it's our own health or the health of a loved one. And healthcare is equally important and significant from an economic standpoint. It accounts for 18% of U.S. GDP. Pharmaceutical spending, as one widely-discussed component, accounts for about 14% of the overall healthcare spending in the U.S.

As such it's important to be clear on how we view our responsibility to the patients and stakeholders served by our products. We believe that investing in innovation to focus on unmet medical needs that create differentiated products to ultimately help people live longer, healthier and happier lives is our first responsibility.

We believe a more value-based healthcare system has tremendous potential to improve the health of populations, increase access to care and limit costs. We are working with others in the healthcare system to transform the way healthcare is paid for, so everyone involved is held accountable for the value they deliver. At the same time, we are taking steps in today's system to advance a more value-based approach.

We have entered into a number of value-based contracts and we continue to explore new opportunities such as outcome-based contracts, which are tied to clinical endpoints as well as contracts that share risk with managed care organizations and contracts tied to offset other healthcare expenditures.

We are also committed to responsible pricing. When we price a new medicine, we consider the value to patients and society, the importance of maintaining affordable access to medicines for people who need them and the importance of preserving our ability to develop future groundbreaking cures and treatments.

As our 2016 Janssen U.S. Transparency Report demonstrated, we have maintained a responsible approach to pharmaceutical pricing, generally limiting our aggregate annual price increase to single-digit percentages, below those of our competitive set.

For 2017, the net price for pharmaceuticals in the U.S. is negative, a topic you'll see more details on when we issue our 2017 U.S. Transparency Report later this quarter. Transparency is just one of the ways we can demonstrate how serious we are about responsible pricing. We look forward to continuing our work with government officials, our customers and other stakeholders to ensure we continue to provide differentiated, value-based and affordable healthcare to people around the world.

Healthcare reform is a major public platform, and we remain proactively engaged in this discussion. To be clear: we support bipartisan steps that will expand the access to affordable healthcare and improve long-term sustainability of the U.S. healthcare system, while fostering a competitive market and incentivizing R&D investments behind new treatments, innovations and cures. From our view, there are several areas for possible bipartisan agreement, some of which include: the continued funding of cost-sharing reduction payments, strengthening the insurance risk pool, and allowing state flexibility.

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 around the world. We know that when governments invest in healthcare, they see return on that investment in the form of worker productivity, economic growth and stability. We are pleased with the final passage of legislation to modernize the tax code for American businesses, which can further jumpstart the economy and fuel job creation. And that's good for all Americans.

Some of the elements included in the package are provisions that will allow companies like Johnson & Johnson to have greater flexibility in how we can use overseas earnings to invest for the future. Improving the abilities of companies like ours to bring these resources into the U.S. and elsewhere fuels growth and ultimately strengthens the company overall. Changes to corporate tax rates will help improve the overall competitiveness of U.S. companies. The tax modernization effort moves the U.S. closer to a territorial system, and we believe that is good for the economy.

Finally, in terms of direct benefit to Johnson & Johnson, we believe as the world's largest healthcare provider, one of the most meaningful deployments of the benefits from the

most recently enacted tax legislation is to invest in innovation to address significant, unmet healthcare needs for society. And we plan to do just that, by making increased investments in innovation with the intent to have those substantially made in the U.S. while benefiting the globe. In just a few minutes, you'll hear more details from Dominic on the new U.S. tax legislation and the direct impact on Johnson & Johnson.

As the healthcare system 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. In the near-term, we are focused on meeting our financial and quality commitments, keeping Our Credo obligations that everything we do must be of high quality. Quality is paramount across Johnson & Johnson, and it's worth noting the great progress we've experienced with our supply chain over the last few years; improving quality, optimizing costs and leveraging capabilities globally that enable further innovation in all parts of our business and help us operate from a position of strength.

In terms of our financial performance, we expect each of our three business segments to continue to grow and contribute to our sales and income growth in 2018. We recognize the importance of innovation in all that we do, and innovation will continue to be at the heart of our efforts to meet the needs of patients and consumers. We are well-positioned to continue to lead the way, leveraging both internal and external resources to execute our strategies. And our commitment to innovation is highlighted by the fact that Johnson & Johnson ranks among the top 5 companies in the U.S. and the top 10 companies globally for R&D investment across all industries. We have not only demonstrated our commitment to driving innovation from an investment perspective, we've also demonstrated solid productivity that has resulted in positive patient and consumer outcomes, as exemplified by our Pharma business.

In our Pharmaceutical business, our priorities remain fairly consistent with what we stated in recent years. We will drive continued growth while delivering on our near-term pipeline. We will do this by focusing on our six therapeutic areas of high unmet medical need, our robust innovation engine, and strong commercial capabilities.

For 2018, we expect our key catalysts for growth will include: expanding the profile on key life-saving and life-changing products such as DARZALEX, IMBRUVICA, and STELARA; enabling a best-in-class uptake of TREMFYA, which was approved last July in the U.S. and last November in the EU; the continued contribution of Actelion sales; securing regulatory approval for apalutamide in the U.S.; submitting NMEs and line extensions, which include esketamine, erdafitinib, and apalutamide in the EU, six significant line extensions, including OPSUMIT and CTEPH.

We are on track with launching the products in our Pharmaceutical pipeline. In 2017, TREMFYA was approved for psoriasis. In 2018, we expect approval for apalutamide, and we'll file for the approval of esketamine in treatment-resistant depression. In addition, we expect to file for the approval of seven more products by 2021 for a total of 10, like we told you last May, each with more than $1 billion peak revenue potential.

Although we've had particularly strong performance in Pharmaceuticals, we realize that we have more work to do in further accelerating the Medical Devices and Consumer businesses. Our near-term priority in Medical Devices is to accelerate growth through innovation, portfolio management, and new business models. We continue to strengthen the foundation and simplify operations. We're also reshaping our business and portfolio in anticipation of and in response to dramatic changes the industry and our customers are experiencing, which include aging populations, increasing chronic diseases, health system consolidation, alternative sources for healthcare, and increasing expectations of patients related to pricing, products, and efficiency.

2017 was a transition year. We stabilized and invested in the commercial organization, improved quality, execution, and competitiveness, filled many critical portfolio gaps, and built new platforms, services, and digital solutions.

Our goal is to continue the top line acceleration we saw in the second half of 2017 through 2018, and we plan to drive that growth by: building world-class commercial capabilities across the portfolio; globalizing our operational footprint and talent; developing robotics and digital surgery solutions for Orthopaedics, Surgery, and Interventional; maximizing new market growth opportunities in platforms such as stroke and in care delivery locations beyond the hospital; delivering a forward-looking pipeline to meet consumers' eye health needs across their lifetime and building a premium surgical channel with superior intraocular lenses' and offering competitive capital equipment platforms in both cataracts and refractive.

While we're pleased with the progress we made in our Medical Devices business, we know there's still a great deal of work ahead of us to ensure that we are poised to consistently deliver value in 2018 and beyond.

And in our Consumer segment in the near term, we will concentrate on enhancing our leadership in priority categories by focusing on critical geographies and our iconic mega-brands.

Our plans for Consumer growth in 2018 include: broadening the scope of our innovation model with breakthrough global platforms such as a light-based pain therapy device; continuing steady growth in AVEENO Baby; rapidly expanding e-commerce and scaling Perfect Store; building our portfolio through insight-led innovation that delivers superior science and differentiated products that are professionally endorsed; and relaunching the Baby franchise with new formulations in new packaging to meet the purchasing preferences of millennial parents.

I am confident about the strategies that our Consumer business is putting in place, but I also recognize that to drive value and lead in the market, we will have to stay focused, continue to evolve our capabilities, and deliver solutions that drive growth.

These compelling strategies and strong results would not be possible without our talented, diverse, and dedicated employees around the world. Today we employ

approximately 134,000 global employees, with more than 43,000 jobs right 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 best, healthiest, and most engaged 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 achieve our goals of attracting, developing, and retaining the best talent to deliver the best outcomes, positioning us to deliver another 132 years of strong and continued growth and shareholder returns.

I'm also pleased to share another important accomplishment that was recently announced on this front. Johnson & Johnson has once again made the Fortune Most Admired Companies list for 2018. I say with great pride that we are ranked in the top 20 and we are the number one pharmaceutical company worldwide on the list.

We are proud of the results we delivered, not just in 2017, but over the past several years and we will continue working to earn your confidence by meeting and exceeding your expectations of us in 2018 and beyond.

And I'm equally pleased and proud to share that we celebrate the 75th anniversary of the Johnson & Johnson Credo this year. Our Credo dates back to 1943, authored by Robert Wood Johnson II, the son of one of the founding Johnson brothers, right before Johnson & Johnson became a public company.

At that moment, J&J's moral compass as a company was formally documented, and that has sustained us for the last 75 years. Our credo is part of our DNA. We live in the responsibilities that outlines each and every day, which enables us to deliver shareholder value, at the same time strive to change the trajectory of Health for Humanity.

So, as I travel around the world, meeting with our employees, customers, partners, government officials, and world leaders, I am constantly reminded of the astounding pace of change we are experiencing in healthcare, as well as the ongoing technological, cultural, political, and social demands that influence the decisions we make in this space. And I truly believe that no company is better positioned to lead profound change during this dynamic era than Johnson & Johnson.

I am both humbled and honored to have led this company for the last six years. And while I'm proud of our history, I know we will do even more to deliver life-enhancing products and services of the highest quality to people around the world in 2018 and beyond.

I look forward to addressing your questions during the upcoming Q&A, but I'll now turn it over to Dominic, who will provide additional details about our fourth quarter results and guidance for 2018. Dominic?

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Alex, and good morning, everyone.

As you've heard from both Joe and Alex, we are very pleased with our 2017 performance. Our full-year performance reflects the acceleration of sales growth in the second half of 2017, as we expected, largely driven by the organic growth in the Pharmaceuticals segment. In addition, we are very pleased with the performance from all of our acquisitions, including Actelion and Medical Optics, which have been integrated seamlessly and are performing at or above our expectations.

We ended the year at the top end of our most recent guidance with sales at 6% operational growth for the year. With respect to adjusted earnings, we finished at the top end of our EPS guidance range, with EPS at $7.30 per share. Overall, both sales and EPS exceeded consensus estimates.

Turning to the next slide, you can see our consolidated condensed statement of earnings for the full year 2017. Our guidance from October included an expectation that we would maintain to slightly decline our pre-tax operating margins on an adjusted basis. In looking at your models, it appears that they reflected that expectation. During the fourth quarter, we significantly increased our investment in research and development, which essentially was offset by a higher level of divestiture gains in other income and a lower tax rate as compared to your models, as I will discuss in just a few minutes.

Therefore, for the full year, you will see pre-tax operating margin at 25% versus 29.4% the prior year, but this is on a GAAP basis. Excluding the impact of special items, our pre-tax operating margin declined 140 basis points on an adjusted basis as compared to the prior year.

Now, let's take a few moments to talk about certain items on the statement of earnings for the quarter. Our reported sales for the fourth quarter grew 11.5%, 9.4% on an operational basis. And excluding the impact of acquisitions/divestitures, our adjusted fourth quarter 2017 operational growth rate was 4.2%, an acceleration from the third quarter.

Please now direct your attention to the boxed section of the schedule, where we have provided earnings adjusted to exclude special items and intangible asset amortization expense.

Adjusted net earnings were $4.8 billion in the quarter, up 9.5% compared to 2016. And adjusted diluted earnings per share of $1.74 versus $1.58 a year ago are up 10.1% and exceeded the mean of analyst estimates. Excluding the net impact of translational currency, our operational adjusted diluted EPS was $1.67 or up 5.7% for the fourth quarter.

In the quarter, we incurred intangible amortization expense of approximately $900 million on an after-tax basis and an after-tax net charge for special items of approximately $14.6 billion. The largest component of special items this quarter reflects $13.6 billion, a

provisional amount for recently enacted tax legislation. The U.S. impact is a provisional $13 billion.

As you know, Johnson & Johnson has long advocated for the modernization of the business tax code and, overall, we are very pleased with the new U.S. tax legislation, particularly the lower tax rate and the ability to access our cash previously retained overseas now at a reasonable rate. The legislation requires a transition tax on previously unremitted foreign earnings, even if no longer in the form of cash, to be paid over an eight-year period, with the heavier weighting toward the latter years. This amount is provisional as we anticipate further guidance from the SEC and the IRS. The remaining after-tax special items included $500 million for litigation charges, $300 million for in-process research and development and $200 million for ongoing restructuring charges.

Now, let's take a few moments to talk about the other items on the statement of earnings. Cost of goods sold was 540 basis points higher than the same period last year. This is due primarily to the amortization of intangible assets and inventory step-up charges related to recent acquisitions. Excluding this impact, cost of goods sold was 80 basis points higher than the prior year, due primarily to the mix of products sold.

Selling, marketing and administrative expenses were 29.8% of sales. This is 50 basis points higher than last year as we invested behind the launch of new products.

Our investment in research and development, as a percent of sales, was 18% in the quarter, 340 basis points higher than the prior year, which is mostly related to our collaborative agreements with Idorsia, the R&D spinout of Actelion and Legend Biotech regarding exciting new therapies we are developing. These higher levels of investments late in the year were offset by higher other income and a lower tax rate in the quarter. Interest expense net of interest income was higher than fourth quarter 2016, reflecting higher levels of debt and lower levels of cash.

Other income and expense was a net gain of $9 million in the quarter compared to a net loss of $20 million in the same period last year. Of course, this line item includes several special items in both years. Excluding those special items, other income and expense was a net gain of $848 million compared to a net gain of $220 million in the prior-year period, reflecting gains from divestitures at a slightly higher level than our guidance for the year, which we re-deployed to R&D and selling and marketing expenses, as I said earlier.

The adjusted fourth quarter effective tax rate for 2017 was 9%. The adjusted full-year effective tax rate for 2017 was 17.2%, which was below our guidance in October. This lower effective tax rate for the year was lower than our guidance primarily as a result of the increased investment in R&D, which I noted earlier. This was incurred at the then higher U.S. tax rate. It was also lower than guidance due to international earnings mix and lower tax jurisdictions and higher tax benefits related to share-based compensation which we saw in the fourth quarter. Excluding the impact of these previously unplanned items, our normalized annual effective tax rate in 2017 would have been between 19% and 19.5%.

Turning to the next slide, I will now review adjusted income before tax by segment. Full-year 2017 adjusted income before tax for the enterprise was 31.7% of sales in both 2017 and 2016.

Looking at the adjusted pre-tax income by segment, Medical Devices at 32.7% is higher than the previous year by 50 basis points, primarily due to the divestiture gains, but partially offset by investments in new product launches.

Consumer margins improved by 40 basis points versus 2016, while still making important investments for future growth. We continue to see improvement in our Consumer margins as we've previously discussed.

Pharmaceutical margins were slightly lower by 30 basis points due to R&D investments that I mentioned previously.

Now, I'll provide some guidance for you to consider as you refine your models for 2018. Before I discuss sales and earnings, I will first give you some guidance on items we know may be difficult for you to forecast. I would like to first address our cash and debt position. At the end of the quarter, we had $16.2 billion of net debt, which consists of $18.4 billion of cash and marketable securities and approximately $34.6 billion of debt.

We are always looking for the right opportunities to deploy our capital to create greater value for shareholders, following our disciplined capital allocation strategy.

Although we're continuously evaluating external value creating opportunities in line with this strategy, for purposes of your models assuming no major acquisitions or other major uses of cash, we suggest you consider modeling 2018 net interest expense of between $700 million and $800 million, reflecting higher levels of new debt incurred in 2017 and lower levels of cash due to the major acquisitions in 2017. This also reflects an offset for repatriated cash which avoids further debt issuances.

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 corporation, divestitures, asset sales and write-offs, we would be comfortable with your models for 2018 reflecting other income and expense excluding special items as a net gain ranging from approximately $1.7 billion to $2 billion.

As is commonly the case, forecasted gains assume various transactions to which we typically don't comment on for obvious reasons. However, as you know, we actively evaluate and manage our portfolio with the intention of redeploying those gains toward investment opportunities that fund long term growth.

With regard to pre-tax operating margins and not including the impact of any special items, we expect to improve margins in 2018 by approximately 100 basis points, as we continue key margin improving initiatives in our business. We also expect, as a result of

the lower tax rate on U.S. earnings, that we will see increased investment in R&D in 2008 (sic) [2018], which would mitigate any further operating margin improvement.

And now a word on taxes, as I noted earlier, we are pleased by the final passage of the U.S. Tax Cuts and Jobs Act, new legislation to modernize the U.S. tax code for business, which we believe will further jumpstart the economy, fuel jobs and investment and level the playing field between U.S. and foreign-headquartered companies.

Our guidance today includes the impact of the new U.S. tax legislation, although some provisions of the new legislation are subject to interpretation and may be clarified by treasury in the near future. The impact of the new tax legislation on our 2018 rate may differ from the company's current estimate due to, among other things, guidance that may be issued clarifying the mechanics of some of the rules and interpretations and assumptions the company has made in developing this estimated impact.

At this time, we would suggest your models reflect an effective tax rate for 2018 excluding special items of approximately 16.5% to 18%. This reflects approximately 1.5 percentage points to 2.5 percentage points positive impact on our normalized tax rate as a result of new U.S. tax legislation.

As always, we look forward to improving upon this rate throughout the year as certain provisions for implementing the legislation become clarified.

Turning now to guidance on sales and earnings, our sales guidance for 2018 includes the impact of generics for PROCRIT and TRACLEER, as well as REMICADE biosimilars, which we still consider to be at risk due to ongoing patent litigation, as we've previously discussed.

However, we do not anticipate any impact from generic competition this year for ZYTIGA, RISPERDAL CONSTA, PREZISTA and INVEGA SUSTENNA. Regarding ZYTIGA, we disagree with the Patent and Trademark Office ruling last week on the IPR, which contradicts their earlier decision to grant the patent. We believe the '483 (sic) ['438] patent is valid and we'll continue vigorously to defend it.

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 it reflects the underlying performance of our business. Of course, we will also provide an estimate for our sales and adjusted EPS results for 2018 with the impact that exchange rates could have on the translation of those results.

For the full-year of 2018, we would be comfortable with your models reflecting an operational sales increase of between 3.5% and 4.5% for the year. This would result in sales for 2018 on a constant currency basis of approximately $79 billion to $80 billion.

Our operational sales guidance for 2018 on an underlying basis, which excludes acquisitions and divestitures, is expected to reflect growth of between 2.5% and 3.5%,

which is an acceleration from 2017.

Although we're not predicting the impact of currency movements, using the euro rate last week at $1.22, our guidance for sales growth would increase by approximately 200 basis points. Of course, we will update this estimate as we progress throughout the year. Plus, under this scenario, we would expect reported sales to reflect an increase in the range of 5.5%, to 6.5% for a total expected level of reported sales of approximately $80.5 billion to $81.5 billion.

And now, turning to earnings. Considering all the factors I just noted, we would be comfortable with adjusted EPS guidance in a range of $7.80 to $8.00 per share on a constant currency basis, reflecting operational constant currency growth of approximately 7% to 9.5%. 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 $1.22, our reported adjusted EPS would be positively impacted by approximately $0.20 per share.

Therefore, our reported adjusted EPS would range from between $8 and $8.20 per share. At this early stage in the year, we would be comfortable with your models reflecting the midpoint of this range.

So, in summary, as you update your models for the guidance that I just provided, I'd like to make a few key points. We expect our operational sales growth to range between 3.5% and 4.5% and our underlying growth, excluding acquisition and divestitures, at approximately 2.5% to 3.5%, which is an acceleration from 2017. With regard to expected EPS growth on an operational adjusted basis, our guidance is strong in the range of 7% to 9.5%, consistent with our objective to grow earnings faster than sales on a constant currency basis.

Also, for 2018, we expect to improve our pre-tax operating margins by approximately 100 basis points based on the guidance I just provided, while also increasing our investment in R&D for future growth.

While we are pleased with our performance in 2017, we also recognize that there are still areas within our business where we continue to be particularly focused on improving our performance. Additionally, we're very pleased with the passage of the new tax legislation and its positive impact on our ability to access our earnings outside the U.S., and allowing us the ability to increase our investment in innovation, a substantial portion of which we intend to deploy in the United States.

As we execute on our growth platforms and near-term priorities that Alex shared with 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 the Q&A portion, just a reminder to please save the date for our Consumer and Medical Device business review on May 16.

Thank you. And, Joe, now back to you.

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Alex and Dominic. We will now move on to the Q&A portion of the webcast. Rob, can you please provide instructions for those on the line wishing to ask a question?

Q&A

Operator

Your first question comes from the line of David Lewis with Morgan Stanley.

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

Good morning. Just a couple of questions from me. Dominic, just thinking about revenue guidance, of course, for 2018, can you just give us a general sense of the pieces, based in your qualitative commentary, my sense is, Consumer is relatively flattish for 2017, Devices gets a little better, and the Pharmaceutical business is something around the 6% range. So, clear acceleration. Just want to understand sort of those mixed pieces. And within Pharma, can we expect that REMICADE and ZYTIGA, can you just give us some expectations around those businesses for Pharma? And I had a quick one for Alex.

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

Sure, David. Well, as you know, we don't provide specific segment sales guidance, but I think it's fair to point out that we saw acceleration in the back half of 2018 across mostly the entire business, and we expect that that will continue through 2018, and we have lots of new product launches, as you know, and new product approvals in the Pharma business which should help accelerate growth.

With regards to REMICADE and ZYTIGA, again, we don't give specific guidance on individual products either. But with REMICADE, as you know, we saw far less of an impact in 2017 than we had expected. The product is now been on the market for over a year, and we do have an additional biosimilar market entrant. So, we would expect that the acceleration of that biosimilar impact to REMICADE, we'll see more of that in 2018 than we saw in 2017, but I can't give you a very specific member.

And with respect to ZYTIGA, as I said in my opening comments about sales guidance, we do not expect to see generic competition for ZYTIGA in 2018.

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

Okay, very helpful. And then, Alex, just a quick strategic question for you. I know it's a bit of a cliché. Everyone expected increased M&A activity in life sciences post tax reform, and yet that's sort of what we're seeing here in the last few days. How does tax reform kind of impact your views from a corporate perspective on both the size and activity of M&A and

the level of reinvestments back into the U.S. or broader reinvestment versus the money you will give back to shareholders? Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey. Thank you, David. Look, overall, what I would say is that, our strategy around M&A will likely stay quite consistent with what we talked about before, and it really starts with unmet medical need, what do we see there to be significant opportunities to improve care for patients, what do we see as being value creating, and what do we see as being something that we can execute with a high degree of effectiveness and efficiency.

Now, regarding tax reform, what we said from the very beginning is, one of the major reasons in addition to lowering the rate is just frankly the flexibility that it provides us, and we think it actually helps make us more competitive, particularly on an international level if we happen to be in a competitive situation with other companies, because now we have greater flexibility on how we can access that cash.

So, we think, net-net, it's a positive for us. As you heard Dominic mention earlier, regarding the more immediate tax reform impact, we think that the wise thing to do is to invest a good portion of that back into R&D. If you look over the past several years, the output, the productivity particularly in our Pharmaceutical pipeline, but also in others, of our investments in R&D, we think of them at the high end, and we think ultimately doing that will have the greatest impact on our business, will help us get out to better serve underserved needs around the globe. And that's why we're heading in that direction.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, David, next question, Rob?

Operator

Your next question is from the line of Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning, guys. Thanks for taking the question. So, on ZYTIGA, your assumptions for 2018 were clear, but I guess, Dominic, my question for you is, if we do see generic ZYTIGA earlier in the year or in 2018, what's your ability to offset that on the EPS line? And I have one follow-up question for Alex.

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

Well, as you know, Larry, we provide a range of guidance for both sales and earnings. And obviously we'll have to see what happens with ZYTIGA in the ultimate upcoming District Court case and others, but we're pretty confident that the range we provided could absorb any impact from ZYTIGA.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful. And then, Alex, 2017 seemed like kind of a watershed year for robotics in the Medical Device space, and they're starting to have some impact on your businesses in the Orthopaedic area and in the Surgical area. So, how are you addressing this? And how quickly can you launch your surgical robot in the U.S.? And are you satisfied with that timeline, given what we're seeing here? Thanks for taking the questions.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. Larry, as you know, several years ago, we entered into the agreement with Google and Verb and Verily in really creating our significant approach in robotics. What I would say is that, we're excited about that opportunity. In fact, just a few weeks ago, when we were out there for the conference, I got a chance to visit, see the prototype. I would say, overall, that it's on track, and we're continuing to make refinements in it.

Clearly, we think the area of robotics is going to have an impact on surgery, and that's why we want to make sure that we've got a system that is different from those that's currently offered, that we think takes it beyond simply assisting in the surgery to actually helping to improve the outcome of the surgery, something that's more modular, something that frankly is more economical, and that's our goal. So overall, the project remains on track with our timelines, and we're excited about it.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thanks for the question, Larry. Rob, next question, please.

Operator

Your next question comes from Mike Weinstein with JPMorgan.

Q - Michael Weinstein {BIO 20602373 <GO>}

Good morning, guys. I'm going to try and follow up with a couple items on the 2018 guidance. So the top line 2.5% to 3.5% organic would be a little below what you reported this quarter and this one, Dominic, for you to spend a minute just to shed a little light on the differential of how you see the 2018 top line outlook versus what you saw this quarter and as well really the second half of 2017.

Second, the other income guidance of $1.7 billion to $2 billion of gains, that seems to imply an asset sale beyond what you've already disclosed to the Street, recognizing that the business that you've commented on but you haven't executed on yet is the residual diabetes business. So, is there something that you haven't yet disclosed to the Street that's contemplated in that guidance? And then I'll follow up, thanks.

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

Let me take the second question first, Mike. As I mentioned in my comments, we're always constantly looking at our business and making the determination whether the business is sometimes better in someone else's hands or we can get better value for our shareholders through a divestiture. So we have considered other assets in that regard. We

haven't disclosed what those assets are for obvious reasons, and we'll obviously continue to update our estimates as we move forward with those potential transactions.

A very important point to point out though is that it's also true that whatever gains we experience, we'll look to obviously redeploy them back in the business, which has been our history now for several years, and we think that's the right way to approach these things.

With respect to the operational guidance, excluding acquisitions and divestitures, on a organic basis we did about 2.4% for 2017, and I mentioned 2.5% to 3.5% for all of 2018. The fourth quarter of 2017 was higher than that, as you pointed out. And I think this just has to do with the ramp of products, particularly in the Pharmaceutical business, which are continuing to grow, but they're obviously continuing to grow now off of a higher base. So we took that into consideration in our estimate.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay, and just one follow-up here, Dominic and Alex. The opportunity that you have with tax reform, there's two pieces to it, but you have immediately access to your previously trapped $16 billion in OUS cash. Are you assuming that you're going to use a portion of that cash to immediately pay down U.S. debt?

And, Dominic, now that you have access to your global cash flows going forward, are you thinking any differently about ongoing buybacks or your dividend relative to how you were prior? Thanks.

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

Mike, one thing to point out is that you're right, we have $16 billion of cash. Not all of it is readily repatriated back to the U.S., but not because of the U.S. tax code, but because of individual country-by-country restrictions. So I would say that, what we've already estimated is that roughly in the neighborhood of $12 billion of that will come back immediately. We'll immediately use that to fund U.S. operations, because as you have pointed out before in your reports, in the U.S. we have a shortfall of cash needs versus cash generation, and that's why we were borrowing in the past. So we'll no longer need to borrow for U.S. purposes, and then the balance of that will immediately pay down debt.

As far as any change to our capital allocation strategy as a result of having more readily access to the cash, as Alex pointed out, I think our strategy remains the same. We have a very disciplined approach to this. It starts with investing in our business, which we intend to increment, as I mentioned earlier and as Alex mentioned. And then obviously the dividend after that remains our top priority, and we think we're already at a very healthy dividend at 50% of our cash flow being paid out to shareholders. So we'll evaluate our opportunities on a case-by-case basis and make the best decision that we think promotes the long-term growth and benefit for our shareholders.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Just one point of clarification. So it's clear we would pay down maturing debt this year. We looked at potentially other options, but there's a penalty associated with longer-term debt. Thanks for the question, Mike. Next question, please, Rob?

Operator

Your next question comes from Joanne Wuensch with BMO.

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

Good morning and thank you for taking the question. Can we shift a little bit over to Medical Devices? Specifically two questions, one big picture. You talked about 2017 being a transition year. How can we think about 2018?

And then my second question really has to do with the Orthopaedic business. What's really going on in the spine business and in your knee franchise? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure. Joanne, thank you very much for the question. Why don't I take both of those? Look, I think big picture what we see going on in our Medical Device business is that 2017 was a year of transition. And what we're pleased about is the fact that we saw an increase in the number of launches. In fact, I think we ended up having 16 launches, most of them in the back end of the year. We saw improved execution, given some of the reorganizations that had occurred earlier. And frankly, we think that's also what produced some of the improvement in results sequentially. If you look at fourth quarter, where particularly in the Hospital Medical Devices division, you saw a performance of about 3.4%.

Now I think what's also important to highlight is this is a business where we've got businesses such as EP, which is growing at about 19%. We saw EndoMech growing at a very healthy rate as well, around 14%. We saw areas such as energy and biosurgery growing at about 8%. And of course, we saw our Vision Care business growing at the core at about 6% with the contact lens and about 5% with the surgery business.

So overall, those businesses are actually performing quite well. Of course, offsetting that has been the performance of our diabetes business and some of our specialty surgery areas, as Joe outlined earlier.

So overall, we remain very confident in these businesses. But clearly, we've taken a lot of action regarding innovation. We've taken a lot of action regarding pruning the portfolio, and we've taken some action as well to improve execution in the field that we think overall will result in an accelerated growth rate in 2018.

If we dig down a little bit deeper regarding Orthopaedics, what we would say is spine, we've had a delay in some of the product launches that we had in this area. If you recall back, over the last several years, this is the area likely most impacted by the integration along with Synthes that resulted in the most disruption. We've seen an overall slowdown in this marketplace due to reimbursement issues. But clearly, we're focused on continuing

to launch new innovation and work our way through some of the disruption that we saw earlier.

We do have product launches planned for the back end of this year, including an interspace cage as well as some additional plates and screws, as well as visioning devices that we think will improve performance. So again, we think there remains a lot of unmet medical need there in an area where we can clearly improve our performance.

Regarding knees, we're in the midst now of launching the ATTUNE revision, which we think will be an important addition to the ATTUNE platform, and we expect that will result in an increased uptake in 2018.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thanks for the question, Joanne. Rob, next question, please.

Operator

Yes, your next question comes from Jeff Holford with Jefferies.

Q - Jeffrey Holford {BIO 4872636 <GO>}

Hi, thanks very much for taking the questions. So I know there's a bit of confusion still out there on the Q4 EBT margins that came in. I wondered, maybe, Dominic, you can just speak to that very quickly in terms of can we expect a more normal pattern of spend in 2018 in terms of how the margins will play out for 2018? I know you've guided to the 100 basis points pre-tax increase. That's helpful. But you are speaking to higher R&D. So, how can we think about COGS and SG&A on more of an adjusted basis?

And then another quick follow-up would just be, were there any one-offs for either ZYTIGA or IMBRUVICA? IMBRUVICA seemed a little light. Obviously, ZYTIGA was very impressive in the quarter. Thank you.

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

Sure, Jeff, a couple things. We had announced several years ago that we were embarking on a number of cost-saving efficiency initiatives which we refer to as our Enterprise Standards and Productivity, and that particular program actually culminates or reaches its peak in 2018. So we're going to see much better year-over-year cost improvement as a result of that program in 2018 versus 2017, or 2017 versus 2016. You remember that our Medical Device restructuring program was also going to achieve its peak savings by 2018. So there are positive developments in the 2018 margin.

We will in fact increase our investment in R&D, as both Alex and I mentioned. That's a bit of a headwind on overall margin improvement, but we feel confident that, at about 100 basis points improvement, which we'll see that throughout 2018.

As far as how it meters by quarter, that all depends because we – as I mentioned earlier to an earlier question, we tend to redeploy, reinvest the gains from various divestitures back into the business and make incremental investments accordingly. So, that sometimes they may not be ratably distributed throughout the whole year.

And, Joe, do you have a comment on the ZYTIGA question?

A - Joseph J. Wolk {BIO 19812977 <GO>}

Sure. For ZYTIGA and IMBRUVICA. So, with ZYTIGA, nothing unique in those results, Jeff. It's really being driven by the LATITUDE data where we're seeing an increase, not only in the market growth, but then obviously, as I mentioned earlier, almost 5 points a share for ZYTIGA in terms of comparisons to the prior year.

With respect to IMBRUVICA, that's a good observation on your part. So, we've been growing roughly 50% to 55% in the first three quarters. This quarter was about 38%, but that's all attributable to increased investment with us and our partner, feeling good about the recent indications that we received and putting investment behind those. So, if you normalize for that, you'd be up around 51%.

Thanks for the question, Jeff. Next question, Rob?

Operator

Your next question comes from Glenn Novarro with RBC.

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

Hi. Good afternoon – good morning, guys. Alex, a question for you. There's been a major debate on whether Amazon will start disturbing drugs and/or distribute devices and supplies. Is this having any impact on how you guys are starting to think about how you distribute drugs and devices? I'm just curious of your thoughts because we're getting a lot of questions from investors on these topics. Thanks.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Glenn. Thank you for the question. And look, we're always considering what could be the impact of new entrants, new competitors, or disruptions in any of our channels. To be clear, we're already a partner with Amazon, particularly in our Consumer segment, where we sell directly through Amazon as well as through the e-commerce channels of some of our major retailers that we work with as well as our own.

We're watching closely in areas such as the Medical Device space and the Pharmaceutical space and we'll respond accordingly. I think ultimately it's going to depend on their ability to meet all the regulatory requirements to make sure that customers are getting good transparency around pricing and service levels and we'll respond accordingly.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Great. Next question, please?

Operator

Your next question comes from Geoff Meacham with Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys. Good morning and thanks for the question. Just have a few. First one, across the Immunology categories, IMS is pointing a pretty good growth on derm for the aggregate J&J portfolio, but it looks like GIS had a couple of tough quarters. Is this more of a mix issue? And what is the path to getting share back?

And then second question for Alex, big picture, when you look at the Pharma segment, oncology has been consistently the fastest growing franchise, but when you think about organic R&D or external biz dev, is there a focus on shoring up underperforming therapeutic areas or do you guys look more holistically at investments in Pharma? Thanks.

A - Joseph J. Wolk {BIO 19812977 <GO>}

So Geoff let me maybe address the first question with respect to immunology and our performance there. If you look at it, we're very pleased with the uptake for Crohn's in STELARA. You compare it to the fourth quarter of last year, we're up about 11 points. Now some of that has come at the expense of REMICADE, but only about 5 points of that. So overall, we're very pleased with our performance in the GI space for immunology.

A - Alex Gorsky {BIO 16239711 <GO>}

Geoff, in regarding to the second one, look, we're always looking for opportunity to cross all of our therapeutic areas, the 6 in Pharma, but also all of our other major platforms in both Medical Devices as well as Consumer. For example, in 2017, we completed about 16 acquisitions. I think we did almost 60 different innovation deals and about over 20 investments from JJDC. And, again, that represents a very diverse cross section across all of our areas. And clearly, when we see a gap in our portfolio that's not meeting customer needs, and a good example of that is over the past several years in trauma with the extremity area, or where we see new technology such as stroke that allows us to address an area where there's a lot of unmet medical need and a great new approach. So, yeah, we're constantly looking across all those different platforms.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thanks for the questions, Geoff. Next question please, Rob.

Operator

Your next question is from Jami Rubin from Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. I have a few. First, really for you, Dominic and Alex, now with tax reform finally approved and part of law, should we expect that your capital allocation activities or strategy will accelerate this year? You obviously have one of the strongest balance sheets in the industry. So does this mean that we should expect activity from you guys to pick up? And along those lines, I'm just curious your thoughts on some of the recent deals that have been announced. Two major trades in the biotech area, seems to be a disconnect between corporate acquirers' views on value versus investors.

And, Alex, just want to get your sense on that. I think it was you or Dominic who said at a conference back in September that companies were going to wait for tax reform to do deals, but then deals – they will again end up having to chase deals at much higher prices. So I'm just wondering what your views are on that?

And then secondly on ZYTIGA, I know you're going to defend that vigorously but, Dominic, can you walk through the steps, when would be the earliest that generics can enter the market? And then lastly, Dominic, normally you provide a preliminary number for free cash flow in your year-end slides, I didn't see it this time. Thanks very much.

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

Okay. Hi, Jami. Good morning. Just a couple thoughts on capital allocation and recent deals and Alex will comment on that as well. So with respect to capital allocation, both Alex and I have described this approach very consistently for years and we do have a certain capital allocation priority that we go through with dividends at the top, after we've appropriately invested in our business. And value creating M&A is the second priority.

Now value creating M&A depends on what value you pay for the asset and whether you're going to generate cash flows in excess of that value, which includes a premium. And if that deal is not value creating for our shareholders, we're not interested in pursuing it. Even though you see more activity in the early part of this year, I just want to remind you that we were extremely active last year doing in excess of $35 billion of acquisitions last year, obviously in advance of corporate tax reform.

With respect to ZYTIGA, one way to think about this is that the current 30-month stay under the Hatch-Waxman law expires in October 2018 and the recent IPR ruling against the ZYTIGA patent does not in any way impact that 30-month stay, meaning that the 30-month stay is not lifted, it's still in existence. Of course, during that time period, we will go into district court and have hearings on the patent. And should we succeed with those hearings then of course the 30-month stay wouldn't have any difference because the patent extends beyond this year and into 2027.

Also, with respect to free cash flow, Jami, and then I'll turn it over to Alex for any other comments on recent deals, we don't typically provide a free cash flow estimate in our guidance. Although I can tell you that we had very strong free cash flow in 2017 at $17.8 billion and typically, our free cash flow growth approximates our earnings growth because our businesses do a great job of managing their receivables, payables and capital deployment. So a good rule of thumb is free cash flow generally grows at the same rate as our earnings growth. Alex?

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Jami. Thank you very much for the question. Look, I would pick up where Dominic left off. If you look over the past year, we did make over $35 billion worth of investment ahead of this, which we thought was the right thing to do. We do that really based upon unmet medical need, either franchise or is the technology complementary to something that we have that we're already doing? Or is it an area where we feel that our R&D, clinical, regulatory development skills, our commercial and reimbursement skills frankly can make a difference and ultimately is this value creating?

We said quite consistently over the past few years and I think we've acted in a way that we would prefer earlier stage investments. And we think across all of our different categories we've demonstrated that whether it's the next ZYTIGA or IMBRUVICA or the next NEUTROGENA or the next Biosense Webster, when we can get a great new technology or innovation or science that we can then ramp up through clinical development or regulatory skills and then launch and create $1 billion platforms and major breakthroughs for patients that's our preferred model.

And look, we – at the same time, we do watch competitive moves and what's going on in different categories, which we'll continue to do this year. But we feel confident in the strength of our pipeline, as we've talked about. Again, whether it's in Pharma, with the very high number of line extensions or products we expect to launch over the next several years, or in our Medical Device space or in Consumer. We think we've got a nice balanced approach between internal and external R&D at about 50% each of them.

And ultimately, we've also got the flexibility to move depending on what opportunities present themselves. Because, frankly, of the way that we've been able to manage our balance sheet, because of our overall strong position, should an opportunity present itself, we can – we always have the prerogative to engage at that point in time. So thanks a lot and I expect that's the way we will navigate our way through 2018 and beyond.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Next question, please, Rob.

Operator

Your next question comes from Bob Hopkins with Bank of America Merrill Lynch.

Q - Bob Hopkins {BIO 2150525 <GO>}

Hi. Thanks and good morning, and thanks for taking the questions, just two quick ones for me, one on Consumer and one on Devices. I'll just lay them out there to make it easy. So first on Consumer, just a pretty straightforward question, some of the issues impacting that business in 2017 were market-related. So I guess my question is will those market issues be cleared up in 2018 and could the combination of better market growth and changes in baby care and other initiatives allow you to get back to historical growth rates for Consumer in 2018? That's my Consumer question.

The Device question I wanted to ask is that 2017 is a year where there's a bunch of strategic moves made, both in terms of divestitures and M&A. Now here we're starting 2018 and you're once again emphasizing portfolio management in Devices as a core strategy. And I'm just curious, is that emphasis on portfolio management – are you referencing there the decision you will make this year on diabetes? Or is there the potential for other, kind of, portfolio management moves in Devices in 2018? Thank you very much.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. Thank you, Bob. Let me start. I would say yes, we do expect our Consumer business to grow at a faster rate in 2018 than we saw in 2017. And you're correct in that we think some of the market forces, i.e. the shift to e-commerce, shifts in some cases to more natural brands, digital types of brands, have been more secular in nature and have affected all of the large FMCG companies.

That being said, we're not just sitting back. We're making aggressive moves in areas such as e-commerce investments in that shift. As I've mentioned before, we're taking the innovation model at a company like Vogue, which has continued to do very well as part of Johnson & Johnson, and we're trying to export that to other areas in our Consumer innovation to be faster, more agile, even more flexible.

And so we think that combination combined with – in some cases, just improved execution, particularly in areas like our baby line that's going to be going through a major relaunch through the course of 2018, is going to result in improved performance. And by the way, we still have some core areas such as NEUTROGENA, AVEENO, LISTERINE, OTC that we remain very confident in. These are great brands with great science behind them that have also got great consumer loyalty as well as attention.

Now – if I switch now to Devices, I believe we've been pretty consistent in saying that portfolio management can and should be and has been an integral part of our strategy. And so for 2018, yes, part of that we've mentioned that we're actively looking at strategic options for diabetes but there are also other areas where if they have not met our criteria in terms of us feeling as though we've got the right competitive position, the right technology going forward, or it's not complementary to one of our existing platforms that it's not that it's a bad business or a bad technology but perhaps it's better situated in someone else's hands. That – we would continue that in 2018 as well.

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

Yeah, and, Bob, one thing to hopefully not to read into too much because you asked the question in light of the perspective of Devices, when we do this portfolio management, it's across all three of our major businesses. And so we have plans in 2018 for all three of the businesses where assets are being evaluated and we may make decisions with respect to those assets. So it's not limited to Devices.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thanks for the questions, Bob. Next question, please, Rob.

Operator

Your next question is from the line of Vamil Divan from Credit Suisse.

Q - Vamil K. Divan {BIO 15748296 <GO>}

Hi. Great, thanks for taking my question. So one just on REMICADE in the U.S. I know you mentioned most of impact is on the price side as opposed to volume. But could you just give us a sense exactly how much of the overall (1:30:16) spend market volume is still with the brand and how much is going to either of the biosimilars?

And then second, maybe just a pipeline one that we haven't really talked much about was on esketamine. I think it's an important data point for you guys. Can you just give us a sense of when we should expect that data? And then obviously there are some unusual features of that product in terms of the administration of safety and maybe a schedule of product. What do you think if you can just frame your expectation on what would be sort of considered good data as we await the results?

A - Joseph J. Wolk {BIO 19812977 <GO>}

Yeah. So, Vamil, with respect to REMICADE in the U.S. specifically, I would say the volume is still up around the high 90%, so all of the change that you saw in the quarter of about 9% down was associated with price declines.

With respect to data for esketamine, so there is a couple of different presentations. There's, as you know, four, five trials with respect to that program. I would say the first long-term safety data to be released is likely going to be the MCL-3002 study. That's also considered important for short-term efficacy as well as the safety. We would expect that possibly at several events in the second quarter of this year.

Thanks for the question. Next question, please, Rob. And I think this is probably going to be our last one.

Operator

Your next question is from Danielle Antalffy from Leerink Partners.

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

Hey. Good morning, guys. Thanks so much for squeezing me in. I appreciate it. Just a quick question following up on ZYTIGA. Dominic, totally understand you aren't assuming any generic competition. Appreciate your answer that you think that you can offset that. But I was wondering if you could give a little bit more color there, where you think you're being, I don't want to say overly conservative, but more conservative, where you could see upside to potentially offset some headwinds that maybe aren't being considered in guidance?

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

Yes. Thanks, Danielle. Well, what I said to answer the question earlier was that obviously we have to wait and see what happens with the district court decision which happens later this quarter. But in the end, should ZYTIGA generics come to market which, of course, we're not expecting we intend to defend the patent vigorously, I said that our range of sales and earnings guidance should be sufficiently wide to absorb that impact. I think we're going to look at upside in all of our businesses going forward, but I think the range we provided should be sufficient to offset any impact of a negative ZYTIGA decision.

A - Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Danielle, and thanks to everyone for the questions posed today and your continued interest in our company. Apologies to those who we couldn't get to due to time, but don't hesitate to reach out to the Investor Relations team as needed.

I will now turn the call back to Alex for some closing remarks.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey. Thank you, everyone, for joining us this morning. We're proud to share our results for 2017, our strong results, and we're even more excited about lining up with you and discussing the prospects for 2018 which we're very excited about as well. So thanks for your continued belief and support and commitment to Johnson & Johnson. We look forward to updating you as we move our way through the year. In particular, at the May meeting we'll be reviewing our Medical Device and Consumer businesses. And again, thank you very much, and we'll look forward to continued updates over the course of the year.

Operator

Thank you. This concludes today's Johnson & Johnson's fourth quarter 2017 earnings conference call. You may now disconnect.
