Q4 2018 Earnings Call

Company Participants

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

Other Participants

- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- David Ryan Lewis, Analyst
- Geoff Meacham, Senior Analyst - Biotech & Pharma
- Glenn John Novarro, Analyst
- Joanne Karen Wuensch, Analyst
- Larry Biegelsen, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning, and welcome to Johnson & Johnson's Fourth Quarter 2018 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 over to Johnson & Johnson. You may begin.

Chris DelOrefice {BIO 20730104 <GO>}

Hello. This is Chris DelOrefice, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for fourth quarter and full year of 2018. Joining me on today's call are Alex Gorsky, Chairman of the Board of Directors and Chief Executive Officer; and Joe Wolk, Executive Vice President, Chief Financial Officer. Thank you for your interest in Johnson & Johnson.

We are very pleased with our 2018 fourth quarter and full year results. Once again, our performance illustrates a track record of consistent growth exceeding financial expectations and making progress on our long-term strategies. Sales for the business accelerated versus 2017 on both an operational and adjusted basis. Consistent with the guidance we provided at the beginning of the year, this acceleration was driven by the continued strength of our Pharmaceutical segment, delivering on our objective of restoring Consumer growth to above market levels and improving performance in Medical Devices. 2018 also marked another year of disciplined portfolio management, including the completion of key divestitures while also advancing our portfolio with strategic acquisitions and collaborative agreements that we believe will fortify long-term performance.

As we enter 2019, we are confident in the strength of our business. We believe our Pharmaceutical business will deliver growth while absorbing significant impacts from biosimilar and generic competition. We expect Consumer to maintain above-market growth and we anticipate our Medical Devices segment will continue to improve. We plan to deliver innovation that will have an enduring impact on patients, caregivers and consumers while also delivering solid financial performance.

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 associated 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 2017 Form 10-K and most recently filed Form 10-Q, along with reconciliations of the 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 its three business segments. Alex will then reflect upon our 2018 performance and share his perspectives on health care and Johnson & Johnson's performance drivers in 2019. Joe will conclude by providing insights on the P&L, cash and guidance for 2019. The remaining time will be available for your questions. We anticipate the webcast will last 90 minutes.

Now I'm pleased to share our results for the quarter. Worldwide sales were $20.4 billion for the fourth quarter of 2018, up 1% versus the fourth quarter of 2017. On an operational basis, sales increased 3.3% as currency had a negative impact of 2.3%. In the U.S. sales were up 1.5%. In regions outside the U.S. our operational growth was 5.1%, as currency negatively impacted our reported OUS results by 4.7 points (sic) [4.7%]. Excluding the net impact of acquisitions and divestitures, operational sales growth was 5.3% worldwide, 2.6% in the U.S., and 8.3% outside the U.S.

For the full year 2018, consolidated sales were $81.6 billion, an increase of 6.7% compared to the full year of 2017. Operationally, full year sales grew 6.3%, with currency having a positive impact of 0.4%.

Operational sales growth was strong in both the U.S., increasing 5.1%, and in regions outside the U.S., increasing 7.7%, with currency positively impacting our reported OUS results by 0.8 points (sic) [0.8%]. Excluding the net impact of acquisitions and divestitures, operational sales growth was 5.5% worldwide, 3.4% in the U.S., and 7.8% outside the U.S.

Turning now to earnings, for the quarter, net earnings were $3 billion; and diluted earnings per share was $1.12, versus diluted earnings per share of negative $3.99 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were $5.4 billion and adjusted diluted earnings per share was $1.97, representing increases of 12.5% and 13.2%, respectively, compared to the fourth quarter of 2017. On an operational basis, adjusted diluted earnings per share grew 16.1%.

Regarding the full year, 2018 net earnings were $15.3 billion and diluted earnings per share was $5.61. 2018 adjusted net earnings were $22.3 billion and adjusted earnings per share was $8.18, up 11.4% and 12.1%, respectively, versus full year 2017 results. On an operational basis, adjusted diluted earnings per share grew 10.4%. Joe will provide additional details about earnings in his remarks.

Beginning with Consumer, I will now comment on business segment sales performance for the fourth quarter, 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 2017 and therefore exclude the impact of currency translation. While not part of the prepared remarks for today's call, we've provided additional commentary on our website for the full year 2018 sales by segment, to assist you in updating your models.

Worldwide Consumer segment sales totaled $3.5 billion, growing above the market at 3.3%. Excluding the net impact of acquisitions and divestitures, such as the divestiture of COMPEED in the wound care franchise and NIZORAL in the beauty franchise, offset by the acquisition of Zarbee's portfolio of naturally-based products in our OTC business, adjusted operational sales growth was 3.8%. Consumer continues to grow share in the e-commerce channel, outpacing category growth rates with strong double-digit growth across all regions.

The beauty franchise continues to deliver strong performance growing 2.5% or 4.5%, adjusted for the impact of the NIZORAL divestiture. U.S. growth was driven by strength in AVEENO and NEUTROGENA due to new products and market growth. OUS growth was primarily driven by the continued market expansion of the Vogue portfolio, including OGX and Maui Moisture brands in EMEA and Latin America. Additionally, NEUTROGENA continues to perform strong in Asia fueled by new products, including our Hydro Boost platform. Over-the-counter medicines grew globally 6.4%, or 3.7% when adjusting for the impact of the Zarbee's acquisition.

In the U.S., OTC share growth is well outpacing the category with 13 brands gaining share, driving growth of over 13%. TYLENOL, in particular, showed solid growth, driven by strong consumption in addition to benefiting from seasonal and other retail stocking dynamics. OUS performance declined 2%, driven by declining sales of upper respiratory brands in Russia due to a soft cough, cold and flu season, partially offset by strong growth in our smoking cessation business in Canada.

Oral Care grew 4.4% globally, with strong growth in the U.S. driven by the performance of innovative new launches, including LISTERINE READY! TABS and strong growth outside the U.S., primarily in China.

Concluding the Consumer segment, Baby Care grew 2.1% globally. Recent performance trends of the Johnson's Baby relaunch continue to be positive, with U.S. consumption data up 7 points since the launch. The U.S., however, experienced net sales declines in the quarter driven by lower BabyCenter media sales, coupled with declines in DESITIN due to trade promotion spending shifts in prior-year comparables. Sales growth outside the U.S. was led by strong AVEENO Baby growth, primarily in China.

Moving on to our Pharmaceutical segment, worldwide sales of $10.2 billion grew 7.2%, with double-digit growth in seven key products, resulting in continued above-market performance. Sales increased in the U.S. by 2.8% and outside the U.S. by 13.7%. U.S. sales growth slowed in the fourth quarter primarily due to the impact of generic competition for ZYTIGA, which had about a 100 basis point impact on U.S. growth, along with some increased discounts primarily in XARELTO.

Sales growth was led by the Oncology therapeutic area with worldwide growth of 25%. DARZALEX continued its strong performance, growing about 60% globally. U.S. grew 34% and continues to benefit from strong market growth and a 6 point increase in U.S. market share across all lines of therapy based on third quarter data. Outside the U.S., DARZALEX is experiencing increased penetration and share gains in the 31 EMEA countries where it is commercially available, as well as in Latin America and the Asia Pacific region.

IMBRUVICA grew about 39% globally, driven largely by market share gains and strong market growth across multiple indications in the U.S. and strong uptake outside the U.S. in the European and Asia Pacific markets. In the U.S., based on third quarter data across all lines of therapy, IMBRUVICA gained approximately 4 points of market share and is the new patient and total patient share leader in chronic lymphocytic leukemia.

Worldwide ZYTIGA growth slowed to about 6%, with 27% growth outside the U.S., which was partially offset by declines of about 13% in the U.S. due to generic competition. Strong sales growth in Europe and Asia were driven by market growth and share gains, primarily from the expanded indication in metastatic high-risk castration-sensitive prostate cancer based on the LATITUDE clinical trial.

In nonmetastatic castration-resistant prostate cancer, we continue to be pleased with the launch progress of ERLEADA, with the penetration of prescribers split evenly among urology and oncology practices. We also just received approval in the EU for nonmetastatic castration-resistant prostate cancer.

In Immunology, we delivered global sales growth of just under 10%, driven by continued strong performance in STELARA of 35%, offset by continued erosion of REMICADE of 15% due to increased discounts and modest share loss to biosimilars. REMICADE has maintained approximately 93% of the infliximab volume share. We remain very pleased with the uptake of STELARA in Crohn's disease, where market share has increased by approximately 8 points in the U.S. compared to the fourth quarter of 2017.

Lastly, sales for our newly launched treatment for psoriasis, TREMFYA, totaled $175 million globally. TREMFYA's experiencing strong demand with over 28,000 patients on therapy and achieved a 6.6% share of the psoriasis market in the U.S., which is up 1 point from the third quarter.

In Neuroscience, our paliperidone long-acting portfolio performed well, growing almost 12% with higher market share, driven by increased new patient starts and strong persistency. We did experience declining sales of about 13% in our cardiovascular, metabolism and other product portfolio, primarily driven by declines in XARELTO and INVOKANA. XARELTO continues to increase TRx share growth. However, this growth was offset by increased discounts and higher Medicare donut hole utilization.

We remain excited by the potential to significantly increase XARELTO's treatable patient population by approximately 13 million patients in the U.S., supported by the U.S. FDA's recent approval of XARELTO's new 2.5 milligram vascular dose for the CAD and PAD indication. Initial customer response has been positive, and we are confident in the value this indication will provide to patients.

Our total pulmonary hypertension portfolio grew by double-digits, increasing by about 11%. We realized strong growth in both OPSUMIT and UPTRAVI growing by about 22% and 40% respectively on a global basis. Both benefited from further market penetration and increased share. As expected, TRACLEER is declining due to increased use of OPSUMIT as well as generic competition in Europe.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were $6.7 billion declining 2.2%. Excluding the net impact of acquisitions and divestitures, primarily the divestiture of LifeScan, adjusted sales growth was 3.3% worldwide and accelerated versus the third quarter. The adjusted operational growth was driven by continued strong performance in Interventional Solutions, Advanced Surgery, General Surgery and Vision.

Orthopaedics continues to lag market growth with operational sales growth of 0.5% globally but continued its fourth straight quarter of sequential improvement due to strengthening fundamentals, including the uptake of new launches.

Interventional Solutions grew over 12% globally, with continued strength in our electrophysiology business which grew more than 14% worldwide, fueled by our market leadership position from newer product offerings in ablation and advanced catheters contributing to atrial fibrillation procedure market growth. This represents 10 consecutive years of double-digit growth. Additionally, we realized strong growth in our CERENOVUS business with double-digit growth in all regions, driven by new product innovation including EMBOTRAP for the treatment of ischemic stroke.

Strong Vision results were driven by contact lenses which grew over 4% globally, on the strength of the astigmatism and daily disposable lenses in the OASYS family. Growth outside the U.S. of about 7% was strong, with penetration and emerging markets being a large contributor. The U.S. continues to experience high consumption of approximately 7%, however, sales were basically flat due to year-over-year inventory dynamics. Contact lenses have now grown at or above the market for three consecutive years.

In Orthopaedics, hips grew 2% which we expect to represent performance in line with the market, driven by our leadership position in the anterior approach and continued strong demand for the primary stem ACTIS.

Trauma growth increased versus the prior quarter to just over 2% globally, driven by improved market growth. We continue to see strong adoption of newer innovation such as our TFNA femoral nail and experienced strong growth in Asia led by China and India. Spine delivered adjusted operational growth of about 1%. However, this growth was aided by onetime pricing related true-ups worth about 250 basis points. Adjusting for this, our performance was consistent with third quarter growth. We continue to see stabilization of performance driven by new products such as the CONCORDE LIFT expandable cage and the VIPER PRIME system for minimally invasive surgery.

Knees grew 0.2% in the quarter. As previously disclosed, our third quarter 2018 results were aided by the onetime impact of 2017 price legislation in India that contributed about 280 basis points to growth in the third quarter of 2018. When adjusting for this, our Knee portfolio showed strong sequential improvement, primarily outside of the U.S. due to strong performance in Asia. We continue to see strong uptake of the ATTUNE Revision system.

Pricing pressure continue to impact all categories in Orthopaedics. For the quarter, U.S. pure price was negative across all platforms by approximately negative 4.5% in Spine, excluding the onetime pricing true-up I mentioned earlier, negative 3.5% in Hips, negative 2.5% in Knees, and negative 2% in Trauma.

We were very pleased with the results for the Surgery business. The Advanced Surgery performance of 5.7% growth globally was led by biosurgery with growth of over 9%, along with strong performance in energy at 5.5%. Biosurgery strength was driven by strong demand, aided by new innovation such as SURGICEL Powder. Endocutters also grew at over 3%, despite high-growth comparables from Q4 2017 that were partially driven by a competitor's supply disruption last year.

In General Surgery, wound closure grew over 7%, with growth in all regions as barbed and Plus sutures are experiencing strong adoption. Additionally, the U.S. market benefited from customers adopting innovative technologies with associated price premiums. As expected, selling days did not have a material impact on our global growth rates in the fourth quarter.

As a final comment regarding the U.S. hospital setting, let me provide utilization trends. For the third quarter of 2018, we saw an increase in hospital admissions and surgical procedures, with both increasing about 1.5%. Lab procedures were also up about 1%. Our preliminary estimates for the fourth quarter indicate a slight declining trend in both hospital admissions and surgical procedures growth to 1%, and lab procedures growth consistent with the third quarter at approximately 1%.

That concludes the segment sales highlights for Johnson & Johnson's fourth quarter 2018. For your reference, here is a slide summarizing notable developments occurring in the fourth quarter, some of which were mentioned in my comments.

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

Alex Gorsky {BIO 16239711 <GO>}

Thank you, Chris, and thanks to all of you for joining us today. We're pleased to be highlighting the strong results we delivered in 2018. Given the focused execution of our performance-driven strategy, I'm proud to share that we exceeded the financial performance metrics we set at the beginning of last year. And we also delivered on the commitments and responsibilities to our patients, employees and communities as defined in Our Credo.

Now, as you've heard me mention throughout 2018, we have been celebrating the 75th anniversary of Our Credo. Introduced in 1943 by General Robert Wood Johnson, Our Credo has been the blueprint for shaping the caring role that Johnson & Johnson plays in society. Although Our Credo is etched in stone, it is a living document that on a few select occasions we have evolved to keep pace with the world in which we live.

To that end, in anticipation of the 75th anniversary, we introduced some enhancements to Our Credo responsibilities that were inspired by feedback from more than 2,000 of our diverse Johnson & Johnson employees, representing all regions, sectors and functions. These enhancements explicitly put the patient first and at the center of our focus, reflect the needs of a changing world and a new generation of employees, underscore our commitment to diversity and inclusion and solidify our commitment to improving the health of humanity.

Our Credo remains as relevant today as when it was first introduced 75 years ago, and I'm excited and confident that together, we will propel Johnson & Johnson forward to shape the next 75 years and beyond of health care. With that long-term mindset, we remain focused on leveraging our broad-based capabilities to continue to drive the next generation of growth across our entire portfolio, both in markets where we have greater opportunity to compete as well as in the markets where we lead, which include our 26 platforms that each deliver $1 billion or more in sales annually.

In Consumer, we improved operational performance and delivered above-market growth in 2018, while also making investments for the future, which I'll discuss in greater detail shortly. Key drivers were the development and rollout of innovative new products, the continued geographic expansion across the evolving consumer channels and the strong sales performance of our most popular brands such as NEUTROGENA, AVEENO, TYLENOL, MOTRIN and LISTERINE, as well as strong performance in newer brands such as OGX. Additionally, our global Johnson's Baby relaunch is off to a strong start, and we will continue to launch into other markets in 2019.

In Pharmaceuticals, our strong track record of success continued throughout 2018. We achieved above-market performance even in the face of biosimilar competition for REMICADE, which was driven by double-digit growth in 10 key products, including STELARA, DARZALEX, IMBRUVICA, INVEGA SUSTENNA and OPSUMIT, to name a few.

And at the same time, we continue to invest in and advance our robust pipeline which translates to better outcomes and treatment options for patients fighting cancer, HIV, pulmonary arterial hypertension, cardiovascular disease, schizophrenia and diseases of the immune system. In fact, we were just recently ranked among the top three companies worldwide, working to expand access to medicines by the 2018 Access to Medicines Index.

In Medical Devices, consistent sales momentum throughout the year was fueled by Interventional Solutions, Advanced Surgery and Vision. We promised improved performance starting in 2018 and our team is delivering on this promise by improving our cadence of innovation coupled with continued portfolio optimization as we completed the divestiture of LifeScan and completed more than 30 acquisitions or strategic partnerships that we expect will further augment our future growth.

We know we still have more work to do and we are committed to continuing to build upon this momentum and return to above market growth in 2020.

Now when I think about value creation, I'm proud to highlight that 2018 marked our 35th consecutive year of adjusted operational earnings growth for Johnson & Johnson of approximately 10%. This robust performance is indicative of the strength of our broad-based business and these results reflect our ongoing commitment to manage for the long term our relentless drive for innovation, our strategic portfolio management and our discipline capital allocation strategy, all of which are regularly discussed with our Board of Directors as part of our ongoing strategic planning.

As you've heard me say before, while we're pleased with our 2018 performance, it's important to remember that we are never satisfied. Looking ahead, we are committed to advancing the innovation pipeline in our Pharmaceutical business, broadening the reach of our Consumer business and meeting the full potential of our Medical Devices business.

I want to emphasize that our number one priority is to drive superior performance across all our businesses. To ensure this, we benchmark, track and hold every one of our Johnson & Johnson leaders accountable for key metrics that focus on innovation, execution, customer satisfaction, financial performance, portfolio management, quality, long-term value creation, and importantly, Credo values and leadership.

We believe that sustaining our investment in innovation is a key aspect of our strategy. We achieved record levels of investment, investing approximately $11 billion in R&D. And across all industries, we are one of the top 10 companies that invest at the highest levels in innovation and R&D.

We remain committed to being a strategic partner of choice, evidenced by the over $1 billion we invested in 2018 across a number of value-creating acquisitions and collaborations, which include Zarbee's, Orthotaxy, our collaboration with Arrowhead in hepatitis B, and most recently, our agreement with argenx for the treatment of acute myeloid leukemia, high-risk myelodysplastic syndrome and other hematological malignancies which closed last week.

In total, we signed 13 acquisitions and licenses of various sizes, including our acquisition of the company that markets the Dr.Ci:Labo line of skincare products which we closed last week. We also signed 74 innovation deals and we made 29 new investments from our Johnson & Johnson Development Corporation during 2018.

Additionally, I'm pleased to share that last week we announced that in collaboration with Apple Inc., Johnson & Johnson will conduct a research study to analyze whether a new heart health program, using an app from Johnson & Johnson in combination with the Apple Watch's irregular rhythm notifications and electrocardiogram app, can accelerate the diagnosis and improve health outcomes of the 33 million people worldwide living with atrial fibrillation or AFib.

Now this is a condition that can lead to stroke and other potentially devastating complications. In fact, in the U.S. alone, AFib is responsible for approximately 130,000 deaths and 750,000 hospitalizations every year. We are very optimistic about the potential of this wearable technology, which could aid in the earlier detection and prevention of a frequent cause of stroke. And based upon the insights generated through this research program, in the future, we may be able to develop new ways to detect other health conditions earlier that also exhibit measurable physiological symptoms.

Now moving forward, we will continue to enhance our status as a preferred partner, be agnostic to where the best science and technology resides and aggressively pursue transformational innovation internally and through our innovation ecosystem across our innovation centers, JLABS and JJDC and various strategic partnerships.

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 have seen us do, we undertake a process to consider 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 2018, we executed six divestitures including LifeScan in October, and we also accepted a binding offer to divest our ASP business which we expect to close in the first half of 2019.

Now I'm sure we've all come to accept the change we are seeing across the health care industry and around the world is the new normal. It's constant and it's rapid. Challenges and opportunities arise with breathtaking speed, and we are committed to thriving in this environment. We feel strongly that our broad base in health care provides a distinct competitive advantage.

By being positioned across three vital aspects of health care: pharmaceuticals, consumer and medical devices, we have a unique insight into challenges and opportunities as they emerge and are better positioned, I believe, than any other organization to meet the needs of patients and consumers around the world, and to address the challenges and opportunities that the world and economy present.

Our broad base, well, it's not just our heritage, it's a strategic choice, grounded and proven in the long-term performance and our understanding of the industry's present and future. 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. We work with many organizations with similar aspirations, such as the Business Roundtable, THE CEO FORCE FOR GOOD, and the Embankment Project for Inclusive Capitalism.

When we look at the current marketplace, business landscape and our external environment, we are often asked about the potential impacts to our business and industries. To this end, throughout the course of 2018, we engaged with global leaders, government officials, business partners and customers in countries around the world on a variety of topics that not only impact current access to quality health care but that will also drive the quality of health care for the future. I'd like to share our perspective on a few of those key topics today.

Now regarding overall health care costs and drug pricing in the United States, the cost of health care is one of the most pressing issues facing our country today, and we greatly recognize the importance of quality and accessible health care and medication as central to every individual's quality to life. We share the administration's goals of reducing health care costs while improving the quality and efficiency of care.

In our effort to offer solutions that help achieve these goals, we responded to several administration proposals, offering insights on ways to expand value-based care and value-based arrangements. We understand why there is such a passionate dialogue on health care costs and drug pricing. There is likely nothing more personal or important to every individual than quality and accessible health care.

We also recognize that people are facing higher out-of-pocket costs when they seek medical care from a hospital, a doctor's office or some other alternative health care provider, and especially when they go to the pharmacy to get medication.

But it's important to note medicines represent 14% of the total health care costs in the U.S., and medical devices represent 6% of the total health care costs in the United States. The remaining 80% is accounted for by areas outside of our industry. Additionally, we can all agree that the value derived from innovative medicines has been and continues to be significant in addressing health issues today and reducing morbidity rates in the future.

Furthermore, medicines have contributed greatly to extending life expectancy. For example, back in the 1980s, the life expectancy of an HIV patient was just six months. Today, we are close to providing patients a near-normal life expectancy. People are now surviving 30 to 40 years after diagnosis. While HIV patients still need to take medication every day, we can keep them healthy for the rest of their lives.

We are also working with various partners in the health care system to transform the way health care is paid for, so everyone involved is held accountable and rewarded for the value they deliver. Now there are a few key priorities that we focus on when participating in the health care cost and drug pricing dialogue, and they include a system that rewards innovation. We believe companies have an obligation to continually help improve the standard of health care by investing in science and technology to develop new solutions and new products. Additionally, we want to see a personalized and value-based health care system which keeps the patient at the center and is held accountable for the overall outcome.

Next, a system that values transparency. Transparency benefits all participants in the health care system, and I'm really proud that our Pharmaceutical business has taken such a strong leadership stance on increasing transparency in the industry. Last year, we issued our second annual report on transparency, which showed that the net price of our medicines in the U.S. decreased in 2017.

We are preparing to issue our 2018 transparency report in the next couple of months, but I can already tell you that in 2018 our net prices declined between 6% and 8% and we look forward to providing more information when the report is released.

These results demonstrate our commitment to responsible business practices that put patients first, including how we invest our resources, price our medicines, and help people who need our medicines get access to them.

Third, as we continue to engage in dialogue and develop proposals to contain health care costs, stakeholders need to be extremely careful and cognizant about avoiding unintended consequences which may increase patients' costs further and/or decrease patient's access to affordable and quality health care.

We know this continues to be a very important issue, and it's our responsibility to help lead and identify solutions. And we will continue to unite around efforts that address some of the most critical health and consumer needs of people around the world. We will continue to seek opportunities to work with the administration and others who share our commitment to developing a more results-based health system.

Turning to the topic of global trade. As a global health care company, Johnson & Johnson relies on free trade in open markets to bring its products to patients and consumers around the world. We are hopeful that an agreement can be reached with China that addresses concerns and creates a long-term framework for partnership in the future.

We'll continue to work with government officials across the globe because fair and equitable trade is in everyone's best interests, not just for companies, but for the consumer. We'll also continue to monitor developments closely on this front, as we expect this to be an issue in motion for some time.

Lastly, regarding our global view. We are committed to being a leader in the global health care space to help drive the change that people around the world want and need to see. We recognize that through collaboration and viable strategies, which are developed in conjunction with the health care industry, governments, community leaders and other health care professionals, that we can successfully solve issues and seek solutions that advance health for humanity.

And despite any challenges that lie ahead, we remain optimistic about the future of the health care industry based upon the strategic plans we have in place, the innovative technology and solutions we leverage every day, and the talented people across Johnson & Johnson who remain committed to delivering lifesaving and life-changing solutions to our patients and consumers everywhere.

Now, before I move on to talk about our long-term objectives and 2019 outlook, I do think it's important to reiterate that the quality and safety of our products are top priority. As it relates to our baby powder, which has been a trusted product for over 100 years, we remain committed to ensuring that facts about talc are understood and we will continue to defend the safety of our product.

We have a legacy of working hard to earn our customers' trusts and working equally hard to keep it. We will continue to focus on meeting the needs of the patients and consumers around the world who've come to depend on us and put their trust in us each and every day.

As I've consistently shared with you, our long-term objectives remain focused on growing our sales organically at a faster rate than the market and growing our earnings faster than sales. Now that, coupled with value-creating M&A and our strong dividend yield, is the basis for our strong, long-term total shareholder returns.

And in keeping with Our Credo commitment that everything we do must be of high quality, quality and safety remain paramount across Johnson & Johnson; and this enables us to operate from a position of strength. This is important for all stakeholders, especially the value that is experienced by every patient and consumer we touch.

And as the health care landscape continues to evolve and change, so does our business and business strategies. In response to these changing dynamics, at an enterprise level, we remain committed to our near-term priorities which are consistent with our long-term growth objectives.

With regard to our 2019 outlook, we remain focused on bringing innovative solutions to patients and consumers globally, as well as driving strong growth while anticipating biosimilar and generic impact with some of our pharmaceutical products in the near term, which we expect will impact sales by approximately $3 billion.

To address this impact, we have deliberately and actively managed our portfolio for the last few years and especially throughout 2018. As I've already mentioned, we regularly make portfolio management decisions that give us the flexibility to invest in innovation, pursue M&A deals, divest, and withstand the impact of patent erosion.

Our robust long-term strategy has enabled us to make the investments necessary to not only withstand this impact, but to grow at competitive rates in 2019. Additionally, we are continuing to progress our current robust pipeline of differentiated and novel products.

So even in the face of these short-term pressures, we remain confident that our marketed portfolio and near-term pipeline across our Pharmaceutical business will be one of our key growth drivers into the future. Additionally, we expect to deliver on our financial, quality and innovation commitments, as well as to continue to optimize our portfolio.

Now, let me provide some greater detail and deeper insights regarding each of our business segments. As I just mentioned in Pharmaceuticals, we expect to drive the growth of our in-market products and successfully launch new products and line extensions while replenishing our pipeline to support sustained, long-term, above-market growth.

With an industry-leading pipeline and established commercial excellence, our Pharmaceutical businesses delivered outstanding and sustained performance for the past several years, growing operationally in 2018 at approximately 12%, inclusive of the impact of negative net price driven by the successful launches and growth in many blockbuster medicines.

Pharmaceuticals has been an industry leader in all performance measures, including R&D productivity and commercial capabilities. Our key catalysts for growth include: reaching more patients; continuing to penetrate and secure new indications for life-changing products such as DARZALEX, IMBRUVICA and STELARA; driving best-in-class uptake of the successful new product launches such as TREMFYA and ERLEADA; and securing regulatory approvals for esketamine and erdafitinib, which are two promising new therapeutics with the potential for more than $1 billion of peak revenue.

In 2018, fueled by iconic brands and unparalleled consumer insights, our Consumer business achieved above-market growth. Moving forward, we'll concentrate on enhancing our leadership in priority categories by focusing on critical geographies and our mega brands.

We'll also continue to look to expand in the fast-growing natural category, as evident by the acquisition of Zarbee's in OTC; and the premium beauty category with our recent acquisition of the company that markets the Dr.Ci:Labo line of skincare products.

I am confident that we have the strategies in place to allow us to move with the agility needed to address new market needs with an omni-channel approach from the large box retailers to the e-commerce channels to better serve our consumers.

In Consumer, we expect to continue to grow slightly above market, advance our e-commerce and digital capabilities, and deliver innovation to win both globally and locally while expanding margins.

Our key catalysts for growth focus on: continuing to build upon the early success of the Johnson's Baby brand relaunch; broadening the scope of our innovation model to accelerate growth of our beloved brands to more consumers around the world, wherever and however they shop; and enduring brand portfolio strength through sustained innovation, delivering differentiated products that are professionally endorsed and science-based. That's our history and that will be our future.

In Medical Devices, we expect to accelerate growth through improved execution and enhance the flow and value of innovation which includes the progression of digital surgery platforms. And as we capitalize on our comprehensive portfolio and an accelerated growth strategy, we expect to deliver on our commitment to improve performance as we did in 2018, where we improved operational growth, excluding acquisitions and divestitures, by 1.1% as compared to 2017.

Additionally, we delivered on our commitment to improve our cadence of innovation by exceeding our goal and delivering 21 major product launches in 2018. Still, we fully recognize that our progress has not been uniform across the entire portfolio. There are areas where we must and we will improve, specifically in Orthopaedics. We demonstrated positive progress throughout 2018 in our Knees and Spine businesses, and we believe this sets us up well for 2019 and beyond. In Medical Devices, we will continue to accelerate growth through innovation, strategic partnerships, portfolio management and new business models.

Our key catalysts for growth in Medical Devices include: fueling growth from top platforms such as electrophysiology, Advanced Surgery and Vision; continuing to increase our cadence of innovation by launching 20 to 25 major new products across our Orthopaedics, Surgery, Interventional and Vision portfolios, such as ATTUNE Cementless, ECHELON next-gen Powered Stapler, the VIZIGO steerable sheath, and ACUVUE OASYS with Transitions Light Intelligent Technology; and by maximizing new market growth opportunities such as stroke and sites of care beyond the hospital; and simplifying operations while relentlessly focusing on execution.

We will do this while progressing our efforts in digital surgery, including robotics, which is a critical element to our future success, not just in the near term, but as we look to the next decade and beyond.

Throughout Johnson & Johnson's history, we have proudly and passionately strived to create and maintain a strong, consistent and sustainable business and this is evidenced by 35 consecutive years of adjusted operational earnings growth, 56 consecutive years of dividend returns and increases, being one of only two companies that hold a AAA credit rating and being among the Standard & Poor's top 10 market cap companies.

There are also many notable annual recognitions on major publication lists including Fortune, DiversityInc, TIME Magazine and Working Mother where we are one of the most admired, respected, diverse and best places to work. These strong results and compelling recognitions would not be possible without our talented, diverse and dedicated employees around the world. Today we employ approximately 135,000 global employees with more than 44,000 jobs here in the U.S. Those numbers continue to grow as we extend our capabilities and our reach.

And we are all united around a shared commitment and a common purpose that inspires a world without disease. This is evident in the tireless efforts and relentless passion that drives our ambition to reach the next frontier of cancer care, continue to combat Ebola, bring healthy vision to people everywhere and create a world free from tuberculosis, just to name a few areas of focus.

Our purpose-driven credo-based culture puts patients and people first, and this is certainly true in the way we think about our employees and work to consistently cultivate the world's best, healthiest and most engaged workforce. I believe this is critical for operating a healthy business. It also positions us very well to deliver another 133 years of quality health care that is within the reach of everyone, everywhere, and it enables us to continue to drive growth and strong shareholder returns.

We are proud of the results we've delivered, not just in 2018 but over the past several years, and we will continue working to achieve and exceed your expectations of us in 2019 and beyond. We have a unique mission. We must lead as stewards of Our Credo and as leaders in health care around the world.

It's not just to deliver great results and shareholder value, it's also to deliver the best medicines and solutions to our patients and consumers around the world. It's about the lives that we touch, the hopes that we raise and the progress of healing, ultimately, advancing health for humanity.

Lastly, I'm honored to have led this company for almost seven years now and I believe that no company is better positioned to lead the profound change during this dynamic era than Johnson & Johnson. I'm proud of our history and could not be more excited about our future. I look forward to addressing your questions during the upcoming Q&A. But I'll now turn it over to Joe who will provide additional details about our fourth quarter results and guidance for 2019. Thank you. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Alex. Good morning, everyone. As Alex and Chris mentioned, we are pleased with our performance in 2018, which exhibited the strength of our portfolio and disciplined management of our business. In fact, our adjusted operational sales growth of 5.5% was the highest since 2014, and our adjusted EPS growth was the highest in over 10 years.

We ended the year exceeding the consensus estimates from the latest analyst models for both revenue and earnings per share. Our results were also at the higher end or exceeded the ranges that we provided in October for the full year guidance.

Since Chris already provided a detailed overview of sales for the quarter and Alex has provided an overall business update, I'll provide commentary on the P&L, cash and guidance for 2019. I will start by sharing highlights regarding the full year 2018 statement of earnings.

Please direct your attention to the boxed section at the bottom of the schedule. You will see we have provided our earnings adjusted to exclude intangible amortization expense and special items. Our adjusted operational EPS growth in our latest guidance for 2018 was in the range of 9.3% to 10%. As reported this morning, our adjusted EPS of $8.18 reflects reported growth of 12.1% and operational growth of 10.4%, again, at the upper end of our estimate range for reported EPS and exceeding our operational guidance from October, driven by our strong sales results and margin improvement.

Regarding adjusted pre-tax operating margins, our latest guidance commented to at least a 150 basis point improvement versus 2017. For the full year, we exceeded those projections, achieving a 210 basis point improvement while we continue to invest in our business. This improvement is attributable to sales growth and leveraging our scale for productivity, coupled with improved cost of goods sold due to mix and volume.

Moving to the next slide. These improvements are reflected in our full year 2018 adjusted income before tax for the enterprise, which improved 100 basis points versus 2017. Looking at the adjusted pre-tax income by segment, Medical Devices at 29.5% is lower than the previous year, primarily due to reduced divestiture gains as well as investments targeted to improve sales growth. Pharmaceutical margins improved by 320 basis points to 42%, driven by improved cost of goods and leveraging SG&A as well as the timing of milestones in R&D. Consumer margins slightly improved to 20.5%.

Now a few words about certain items on the statement of earnings for the quarter. Turning to our consolidated statement of earnings for the fourth quarter of 2018, please direct your attention to the boxed section towards the bottom of the schedule where we provide our adjusted earnings, which excludes intangible amortization expense and special items of $2.3 billion on an after-tax basis, primarily driven by intangible amortization of $1 billion and litigation expense of $1.1 billion.

Excluding the impact of those items, our adjusted earnings per share is $1.97, an increase of 13.2% versus the fourth quarter of 2017. Adjusted EPS on a constant currency basis was $2.02, up 16.1% versus the fourth quarter of 2017.

I will now highlight a few items that have changed on the GAAP statement of earnings compared to last year. Gross profit margin for the quarter improved by 190 basis points to 65.9%, primarily driven by the impact of inventory step up for Actelion and favorable mix. Our investment in research and development as a percent to sales was 15.8%, which is lower than the fourth quarter of 2017, primarily due to lower milestone payments in 2018.

As a reminder, during the fourth quarter of 2017, we entered into strategic licenses with Legend for a CAR-T asset and exercised our option with Idorsia for a compound to treat patients with resistant hypertension. However, it is worth noting that for the full year, we continue to prioritize funding for innovation, increasing our annual investment in R&D to $10.8 billion.

Other income and expense was a net expense of $978 million in the quarter compared to net income of $53 million in the fourth quarter of 2017. Excluding special items recorded in this line, other income and expense was relatively flat, with a net gain of $777 million in 2018 compared to a net gain of $892 million in the prior-year period, primarily reflecting divestiture gains.

Regarding taxes in the quarter. Our tax rate of 2.6% includes adjustments related to the Tax Cuts and Jobs Act that will be further highlighted in the tax footnote in our upcoming 10-K.

A few words on cash. At the end of 2018, we had approximately $11 billion of net debt which consists of approximately $20 billion of cash and marketable securities and approximately $31 billion of debt. We estimate that the free cash flow generated for 2018 was $18.6 billion, which was an improvement over 2017 of approximately $800 million.

As announced on December 17, the Johnson & Johnson Board of Directors authorized the repurchase of up to $5 billion of the company's common stock. This authorization was based on our continued strong performance, the confidence we have in our business going forward and the conviction the Board of Directors and management team have that the company's shares are an attractive investment opportunity. Through year end, we completed approximately 20% of the authorized amount.

Let's now focus on the company's guidance for 2019 for you to consider for your models. As Alex mentioned our 2019 focus is on continuing to deliver growth even in the face of biosimilar and generics impact. As you think about our performance for the upcoming year, let me provide some general qualitative themes that factor into our quantitative thinking. Items that are moving in a positive direction, or tailwinds, include factors that you have consistently heard from us that exist across our businesses. It starts with the breadth of our portfolio and the strength behind our 26 $1 billion or better platforms.

We also expect that the Consumer segment, relying on innovation and improved go-to-market models, will continue the strength we delivered in the second half of 2018 and expect to grow slightly above the market in 2019. Additionally, we believe that improved execution and new product introductions will enable the Medical Devices segment to continue to improve growth, advancing our goal to be above market in 2020.

In Pharmaceuticals, we anticipate recently launched products, such as ERLEADA and TREMFYA, to continue performing well, as will products like DARZALEX, IMBRUVICA and STELARA with continued uptake and new indications added to their approved labels. And finally, we are excited about the potential approvals and launches for NMEs, such as esketamine for treatment-resistant depression, and erdafitinib for bladder cancer.

As with any business, there are some offsets or headwinds for us to also consider. Most notably, we anticipate continued biosimilar competition for REMICADE and PROCRIT and generic competition related to VELCADE, TRACLEER and ZYTIGA in the U.S. Pricing pressure is expected to persist and a stronger U.S. dollar will likely result in a negative impact on reported results in 2019.

This next slide illustrates how these qualitative factors are reflected in our guidance. Consistent with past practice, our guidance is based on a constant currency basis reflecting our results from operations. This is the way we manage our business to provide the best understanding of our underlying performance. Despite the headwinds of generic and biosimilar competition of approximately $3 billion, we will continue to grow. This implies the balance of our portfolio will grow organically at about 6.5% in 2019. Netting these two factors, we would expect to be in the range of 2% to 3% for adjusted operational sales growth, or $83.2 billion to $84 billion in sales.

Next, considering the negative impact of net acquisitions and divestitures of about 2%, we are comfortable with your models reflecting operational sales growth in the range of 0% to 1%, or $81.6 billion to $82.4 billion. Again, we do not predict the impact of currency movements, but utilizing the euro spot rate relative to the U.S. dollar as of last week at $1.14, the estimated negative impact of foreign currency translation would be approximately 1.5% and result in an estimated reported sales decline of minus 1.5% to minus 0.5% compared to 2018, or $80.4 billion, to $81.2 billion.

This slide recaps all line items we provide for our full year 2019 guidance. Since I have discussed sales guidance, I will now focus on the remaining components of our P&L guidance including EPS. For 2019, we are expecting adjusted pre-tax operating margin to slightly improve while still prioritizing investment in our business for the long term.

Although we are continuously evaluating external value-creating opportunities in line with our capital allocation strategy, for purposes of your models and assuming no major acquisitions or other major uses of cash other than the current share repurchase program, we are comfortable with you modelling net interest expense between $100 million and $200 million, lower than 2018 due to expected lower levels of debt and higher anticipated interest income than the prior year.

As you are aware, other income and expense is the line on the P&L where we record low royalty income as well as gains and losses related to items such as litigation, investments by our Johnson & Johnson Development Corporation, divestitures, asset sales and write-offs. We would be comfortable with your models for 2019 reflecting net other income and expense, excluding special items as net income ranging from $2 billion to $2.3 billion. We recognize that this is higher than 2018, and we intend to deploy a portion of this income into investments across the enterprise to fortify our existing internal pipelines as well as to obtain external sources of innovation to bolster long-term growth, which we do as part of our continual portfolio management strategy.

For reference, this level of other income is consistent with levels we had experienced in 2017 and 2015. In the subsequent years of 2016 and 2018, we reduced other income by significant levels and still delivered strong financial results that produced adjusted earnings growth.

Moving on to taxes. Our effective tax rate guidance for 2019, excluding special items, is approximately 17% to 18%. This guidance takes into account our latest assumptions regarding income mix as well as other onetime favorable items in 2018 that we are not planning to reoccur. Considering all these factors, we are comfortable with adjusted EPS guidance in a range of $8.65 to $8.80 per share on a constant currency basis, reflecting operational or constant currency growth of approximately 5.7% to 7.6%.

While not predicting the impact of currency movements but to provide some insight on the potential impact on EPS using recent exchange rates, our reported adjusted EPS would be negatively impacted by approximately $0.15 per share. Therefore, our reported adjusted EPS would range from $8.50 to $8.65 per share, reflecting growth of approximately 4.9% or $8.58 per share at the midpoint.

We often get asked about first half/second half dynamics or quarterly nuances. We do not provide quarterly guidance, but there are a few factors to consider in your modeling. The first half of 2018 was the Pharmaceutical segment's stronger half which did not include the impact of ZYTIGA U.S. generic entries. We would also expect a higher level of R&D investment earlier in the year, anticipating the closing of the recently announced argenx deal. Towards the end of the year, we will obviously lap the U.S. ZYTIGA generics entry late in the fourth quarter. Lastly, based on today's spot rates, currency will have a more negative impact in the first half of 2019.

That concludes our financial summary. I trust you see the broad-based strength of our business in the 2018 results and in the guidance we've provided for 2019. While there are some headwinds this year, we are confident in our ability to grow operational sales and EPS in spite of those headwinds, which will position us extremely well not just for 2019 but for years beyond.

I am pleased to turn the call back to Chris to initiate the Q&A portion of the call. Thank you.

Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Joe. Before we moved to the Q&A portion of the webcast, please remember to mark your calendars for our Pharmaceutical Business Review, which is scheduled for Wednesday, May 15.

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

Sure. Your first question comes from Chris Schott with JPMorgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much for the questions. I guess my first one was just on a little bit more on your assumption for net U.S. pharma pricing in 2019. I think you mentioned 6% to 8% erosion in 2018. Just talk a little bit about how we should think about dynamics as we think about this year.

And then my second question was specifically on XARELTO and just a little bit more about the 4Q performance. It's a little bit more what's happening with net price for the product. And as we think about 2019 for that product, how are you thinking about kind of balancing, I guess, competitive dynamics in the core indications, the step-up in the donut hole against the recent label expansions, trying to get my hands around some of the pushes and pulls on that product, specifically. Thank you.

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

Hey. Good morning, Chris. Thanks for the question. With respect to net U.S. pharma pricing, what Alex referred to was obviously the experience we had in 2018, which was greater than 6% as we see it right now. We'll provide some more details in our transparency report which should be out in about four to six weeks.

In terms of going forward, we do expect it to be elevated levels. What I would say is it's a great testament to just the strength of the innovative portfolio that we have in the Pharmaceuticals segment. We grew about 8% for the year and that is in the face of net price decreases of greater than 6%. We don't predict obviously for competitive reasons what they might look like going forward, but we do plan for continued price decreases on a net basis into the future.

With respect to XARELTO, yeah, I think what you saw in the quarter was some of those pricing dynamics. There was some catch up with respect to donut hole provisions to a modest level, some inventory adjustments in terms of the pipeline out there. We are growing our volume. We are gaining prescription share, so we feel good about the brand. And as we move into 2019, we would expect the CAD/PAD indications to be a differentiating factor moving forward to expand not only market share for the brand but also the market itself as it's going to reach a broader base of patients.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Chris. Rob, next question.

Operator

Yes. The next question comes from Danielle Antalffy with Leerink Partners.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey. Good morning, guys. Thanks so much for taking the question. Just hoping you could give a little bit more color on the Medical Device business and what you're seeing from a utilization perspective more broadly. Did you see a seasonal uptick in Q4 and generally in 2018? And what you're expecting for 2019 for that business, considering all the moving parts as it relates to the economy, is it slowing? Where are we today with that? And also if you could comment on emerging markets. Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Danielle. Alex here. Thank you for your question. First of all, look, we were overall pleased with the continued improved performance that we saw, particularly across our Hospital Medical Devices group. If you look at the Q4 performance for them, it was about 3.6%, which was one of their strongest quarters. And what we saw was really strong growth being driven by Interventional Solutions at over 14%; our launch with CERENOVUS was almost a 20% growth. We saw really good performance in biosurgicals, up 9%, energy up about 5%, and wound closure was up over 7%.

We did see as well some modest improvement across the Orthopaedics group, particularly in Trauma. That was up almost 2.5%; Hips around 2%; and as mentioned earlier, also in our Spine business. So regarding volume themselves, we see – of course, we don't have line of sight yet to all the Q4 data, but it'll be our expectation that we would see continued slight improved trends coming out of Q3 overall. And we continue to see very strong performance in emerging markets and in BRIC.

For the year, we had about 10% growth across all of our BRIC markets. And by the way, that was consistent across each one of our sectors. China, in particularly – remain particularly strong. In our Medical Device group, we are very pleased both in Hospital Medical Devices, but also in our Vision Care business as well.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Thanks for that, Alex.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Alex. And, Danielle, just to build on the procedures. In 3Q, we did see procedure increases, admission, surgical procedures increasing about 1.5%, lab procedures were about 1% and we see that being relatively consistent. We didn't see any major seasonal dynamics in any one particular area. So thank you for your question.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Understood.

A - Chris DelOrefice {BIO 20730104 <GO>}

Rob, next question, please.

Operator

Your next question is from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Hey. Good morning. Thanks for taking the questions. Joe, one on the guidance and one product-related question. So, Joe, the 2019 adjusted operational growth of 2% to 3% was a little below what we expected based on your public comments in Q4. So I want to understand the components. It sounds like you expect Consumer to accelerate or at least stay consistent with 2018 in 2019 and you expect Med Tech (sic) [Devices] to accelerate versus 2018.

So the implication is that Pharma's going to be about 2% at the midpoint in 2019, which is slightly below the market growth of, I think, 3% to 4% you said you could achieve in 2019 during your public comments in Q4. So is my math directionally accurate and did something change since Q4?

And then, I'll just throw the product question in here. There were some changes to the leadership at Verb. Can you talk about the progress you're making with the surgical robot and Orthotaxy and remind us when you expect to launch? Is it, I believe you said, 2020 for both in the past? Thanks for taking the questions, guys.

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

Sure, Larry. Good morning, and thanks for the question. So no, I don't think anything's fundamentally changed. And although we don't provide guidance by segment, qualitatively I can say you're directionally correct, we do expect that we have turned the corner in our Consumer business. If you look at the first half growth of about 1.5%, the second half growth of about 5%, we feel really good about the innovative products we have in premium skincare. The relaunch of our Baby franchise, as Chris noted in his prepared remarks, is off to a great start.

In Medical Devices, we are expecting to see what we've seen throughout 2018, and that's improved quarterly upticks with respect to growth, getting us on that path to what we articulated at Analyst Day in May of being at or above the market in 2020.

With Pharmaceuticals, again, I just really think it speaks to the tremendous strength and health of this business. If you think about a $3 billion to $3.5 billion headwind with respect to generic and biosimilar competition, and we're still talking about growth. Most companies would be talking about contraction and the dialogue would be, when are you going to get back to growth. It really speaks to the health of the business.

And whether it's 2% or 3%, Larry, I think once these anniversary, we feel very confident about 2019, but it really portends very strongly for the future outlook of our company longer term. You take those out, the base portfolio of Pharmaceuticals is still growing up to 2x to 3x the market, which it has done historically.

And I can also say it is a testament to the strength of the broad-based nature of Johnson & Johnson. This is not a statement we could've made a decade ago. So I feel good that we're talking about growth despite a $3 billion to $3.5 billion headwind. I'll turn it over to Alex to talk a little bit about our Surgical platform.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Larry. Thanks for the question. Before I talk about Verb though, I'd just like to complement some of the comments that Joe made because we remain extremely excited about our business prospects as we head in 2019. And to put a bit of an exclamation point on Joe's comments, if you look at the underlying strength of our Pharma business, growing in excess of like almost 6%, 7%, if we pull ZYTIGA out of it, the number of additional indications that we're going to have across our Oncology and Immunology platforms, the new product launches with both esketamine as well as erdafitinib that we're expecting this year, again, we think that sets us up not only for very strong performance in the face of significant headwinds in 2019, but also even more accelerated growth in 2020 and beyond.

So we remain very confident and optimistic in those opportunities. And I think consistent with what you've seen happen with us in past years, you'll see that play out as we go through the year. And we'll continue to provide updates as we deliver.

Regarding Verb, look, we were just out there and I had an opportunity to visit, but myself, Ashley as well as Paul Stoffels, other members of the leadership team. And I think based upon our latest update, we feel, frankly, even more confident in the progress that we're seeing in this platform.

That includes, yes, the robotics what I'd call the front-end, but also the great work that's taking place on the back-end on the system part of it that really represents a transition in robotics into digital surgery. And the progress that that team has made I think over the last 12 months has been very strong. We believe we continue to be on track going forward.

And as I've mentioned several times, look, you're going to see continued news about our robotics platform over the course of 2020 and beyond. But what's so important about this is we're taking an outlook that digital surgery will be an important dynamic for the next 5, 10 and 15 years. And what we want to make sure is that we get out in a timely manner, but that we're also out in a manner that ensures we're competitive and ensures, ultimately, that we're making an even bigger difference in this area as we go forward.

And the other aspect of it, which I think you mentioned, is the fact that having options and platforms in general surgery, minimally invasive surgery, but also Orthopaedics as well, we think is an additional benefit, ultimately, to the platform that we'll be rolling out.

And look, regarding changes in the management team, what I would say is there have been changes in the management team, which we would expect as we begin to transition from a very early start-up mode into a prepare-for-launch mode. And what we have done actually over the course of the last three to six months is bring in additional leadership into Verb that we feel have got the kind of capabilities, the backgrounds and the experiences to ensure that we're successful as we roll out this launch.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Larry. Rob, next question, please.

Operator

Your next question comes from David Lewis with Morgan Stanley.

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

Good morning. Just one for Joe, and then a follow-up for Alex. Joe, just want to focus on margins for 2019. By our math, it looks like, at the midpoint, around 50, 60 basis points of margin expansion. Obviously, you're down from the significant expansion from 2018, but obviously you had these Pharmaceutical headwinds that you've talked about. Can you help us sort of parse out the margin impact either from currency or from the Pharmaceutical headwinds in 2019? Or any color you can give us on sort of the underlying margin performance in 2019 as it compares to 2018?

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

Yeah. So, David, I think that's an astute observation on your part that it isn't the margin expansion that we had in 2018. But again, given that our Pharmaceutical segment enjoys the best margins across all of our businesses and that growth is going to be moderated somewhat in 2019, I think it's a reasonable expectation. We want to continue like we always have to invest for the long-term. So 2019 and delivering on these results are very important, but we also want to make sure we're well-positioned for two to five years out as well. And so, we're going to take that opportunity to do that.

In terms of segment performance, you already have a Pharmaceuticals sector that's best-in-class in terms of their overall margins. Medical Device is still at the top of the peer set as well. We want to continue to invest there to make sure we do accelerate and deliver on those plans to grow at or above market in 2020.

And then, in Consumer, I would say that's probably our biggest opportunity for margin improvement. We lag the peer set by a little bit there from the midpoint perspective. So we are looking at additional measures. In addition to just being an $80 billion company with the infrastructure, we'll look at some of the complementary services such as finance, human resources, information technology to make sure we're being not just effective there, but efficient as well.

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

Okay. Very helpful. And then I have just two strategic questions for you. Your position on talc has been very clear, I just wondered if you could help us understand, do you expect any impact derivative to talc on the Consumer franchise? And will it impact your strategic activity from an M&A perspective? And then somewhat related to that, I noticed that the Medical Device business moved down on your priority list last year versus this year, just help us understand the underlying driver of that. Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Okay, David. Thanks a lot. Just one comment before I answer those questions, I want to pick up on Joe's former comment. I think what's really important about the way that we're managing the business, particularly in 2019, is to both ensure that we're continuing to invest in areas, frankly, that we think are important to our growth going forward, while simultaneously managing our P&L in our business, we believe, in a very appropriate way.

And so when it comes to additional deal opportunities, for example, the argenx deal with our Pharmaceutical group, we think that's a great investment. I think if you look at the track record of that group and the way that they've been able to perform, especially on those deals where we identify compounds like the CD70 very early and then create multibillion-dollar platforms, reaching many, many patients with significant unmet need, we think that's a good investment for the future.

And the same thing in our Medical Device group. Our Medical Device group has, as Joe mentioned, been at the top of their peer group but when it comes to investments in things like digital, in certain cases, David, as you well know, frankly, we need to improve our performance in other areas, so we have invested additional funds in areas as it relates to just straight out execution in the field, both in the United States as well as abroad in places like China. So we will continue to do that to make sure that we deliver in 2019, but as important, maybe even more, that we deliver in 2020, 2021, 2022 and beyond.

Now as it relates to the other issue regarding the impact on talc, what I would say is it does not have an impact on our long-run strategic look at our Consumer business. And we still believe that there are a lot of good growth opportunities. I think we demonstrated that in Q4 with the investment that we announced with Dr.Ci:Labo. There are many exciting areas, particularly in areas like premium beauty, naturals and by the way, the early signs around Zarbee's in our OTC group are very positive. So, we think that those are positives.

We're obviously watching the Baby relaunch very closely. As Chris mentioned in his earlier comments, the Johnson's Baby portion of our business was up 7%. And the negative results in Q4 overall for Baby are really related to some things, as he mentioned, regarding DESITIN and some other activities in Q4 of last year, but we're not seeing that in the core Baby performance.

And what I would say overall in Medical Device, there is not a change in its ranking in terms of strategic importance. It remains a critical brand for us. As you know, we have over 12 platforms of $1 billion and over 70% of those we're number one or number two in the marketplace. I went through earlier areas that we were particularly pleased to see like EP, like biosurgery, like wound closure, energy, some areas in Ortho having positive signs back as well as our Vision Care business. But we realize that there's others that we've got to advance even faster, including robotics, and others that we need to continue to turn around such as a spine, sport, shoulders and other pockets of our business. But we're confident in the leadership, in the plans that we have for that business.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, David. Appreciate the questions. Rob, next question, please.

Operator

Your next question comes from the line of Joanne Wuensch with BMO capital markets.

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

Good morning, everybody, and thanks for taking the question. Actually, I have two of them. One of the things you repeatedly have talked about is improving your Orthopaedic franchise. You just rambled off spine, sport, shoulders, and other pockets of the business. We have AAOS coming up. Could you please give us an idea of how you're approaching improving some of those and how we would expect or what we should expect at AAOS?

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Joanne. Thank you very much for the question. Look, there's a number of reasons why we believe we're going to see improving performance across this platform. Number one, it starts with our knee platform and the continued launch of ATTUNE Revision as well as Cementless. We have several additional platforms that we're rolling out that we think will reinforce the profile, not only here in North America but, as Chris mentioned earlier, we're seeing very good uptake with ATTUNE on a worldwide basis. And we also have some additional instrument sets that are being launched. And as you know, the cementless section of that market is growing faster and so we remain confident that those launches are going to help reinforce that platform.

In spine, we continue to focus on areas such as severe deformity, degeneration, as well as others. We have a number of new launches that we have coming out including the interbody cage, biomaterials is an area that's of interest to us as well. In Hips we continue to see strong performance. We have a few additional launches that we'll be announcing, and you'll be seeing more, particularly as it relates to the anterior approach. And as I mentioned, look, we still have some work to do in sports, shoulders and those areas, but we're also confident that, overall, with the 20 to 25 launches that we'll have taking place in the course of 2018, many of those in this space are frankly that were done in the back end of 2018 as we head into 2019, will enable us to continue that momentum.

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

Joanne. I might add, too, that if you look a little bit longer term out, we also are looking forward to the addition of robotic digital capabilities there with our Orthotaxy platform in Orthopaedics.

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

Thank you. And then I wanted to spend a moment on the heart health program with the Apple Watches. Can you think about or talk about how you plan on rolling that out, not just across AF but across other applications? Ultimately, I'm trying to get my head around, are people who wear the watch going to walk in and say, hey, I have X, Y and Z, are physicians going to be handing this out? How do you see this moving into a commercialization stage and over what timeframe? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Joanne. Thank you very much. Look, we're very excited about the partnership that we have with Apple in this area. And we think it does represent what we've been talking about for a while is that next step in introducing digital adaptation, almost consumer level, and how does that augment what we currently have across our Pharmaceutical, Medical Device as well as our Consumer area.

I think it's safe to say that it's still early days, but here's an opportunity to better detect patients who either have the potential for AFib or who are experiencing AFib. And then of course longer term, how they respond to various treatments as well as other support programs that are helping to ensure compliance as well as broader wellness programs as well.

So we think this, again, is going to be a great first step for us. We really appreciate the commitment and the time, the resources and the prioritization that Apple has placed on this and the way that our teams have worked together. But look, we think that this is likely the first of many steps that you'll see not only in our Pharma space but again our Device as well as Consumer space in the years to come.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Joanne. Rob, next question, please.

Operator

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

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

Hi. Good morning, everyone. Joe, I was wondering if you can give us a little bit more color on the sales and EPS cadence for 2019. So for example, you're talking about reported sales for the full year in the range of down 1.5%, to down 0.5%. Should we be thinking in the first half down 2% or 3% and then positive growth as we enter the fourth quarter? And then EPS at the midpoint of your range is plus 5%. Should we be thinking flattish growth, EPS growth in the first half, and then high single in the fourth quarter?

And then just lastly, tying into all of this, a lot of our companies are telling us the FX hit in the first quarter will be around 5% and maybe even 2% or 3% in the second quarter. Is that consistent with how you're viewing the FX impact in the first half of the year? Thanks.

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

Yeah, so, Glenn, thanks for the question. Good morning. We don't provide quarterly guidance. But what I would say is from a FX perspective, if you think about it, in the first two quarters of last year, I would think the average – let's use the euro spot rate – was about $1.20 to $1.22. Today, we're standing at something a little bit less than $1.14. So you would expect to see a more pronounced effect in terms of reported results in the first half of the year.

In terms of EPS, I wouldn't think it would be as stark as flat to high single-digits, flat in the first half, high single-digits in the second half, as you mentioned. I think it'd be a little bit more calibrated; again, a little bit softer in the first half but then a little bit stronger in the second half as that spot rate, assuming today's rate holds, is pretty consistent.

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

Okay. Great. Thanks, Joe.

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

You're welcome, Glenn.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Glenn. Operator, next question.

Operator

Next question is from the line of Vamil Divan with Credit Suisse.

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

Great. Thanks so much for taking my questions. So one, if you can maybe just provide a little more detail on that other income and expense line, I believe you mentioned it should provide $2 billion to $3 billion (sic) [$2.3 billion] of income for the year. That's a little bit more than what we were estimating, so just a little more color on what you're already incorporating in there at the start of the year. And then again, and maybe a little bit of a sense of the quarterly breakdown would be very helpful, given it's a fairly large number.

And then on the Pharma side, just one question, you mentioned esketamine and erdafitinib are both in front of the FDA. I know they both had Breakthrough Therapy designation. I'm just wondering if you've seen any impact, given the government shutdown, on your interactions with the FDA over the past month, or is there any sense that these reviews might take a little bit longer than you were previously estimating. Thanks so much.

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

Great. Thanks, Vamil. Thanks for the question. So with respect to other income, it's $2 billion to $2.3 billion is what we've guided at this point in time. That is the account in which we capture royalty income, gains from equity investments we hold through Johnson & Johnson Development Corp. as well as any gains we might have related to divestitures.

I would expect that would be more of a first half dynamic with respect to some of the divestitures that we have planned. The most notable one would be our sterilization products business, which should happen late first quarter or early second quarter. Again, that's just one component of the overall number.

I will remind folks, too, that we have seen these levels in 2015 and 2017, and then the subsequent years, we're very cognizant of managing that. So we take the opportunity when we have other income that's at elevated levels to invest again in the long term, making sure that we're well positioned across all of our segments to influence health care in a positive way, which should result in a better return for shareholders.

With respect to the government shutdown, I would say, yes, esketamine and erdafitinib have Breakthrough designation. Certainly with esketamine being a little bit more near term, the PDUFA date has not changed as of yet, so it's March 4. What we did receive information on recently was a delay of an ad board meeting. So we don't think that will impact the PDUFA date but we are monitoring the situation closely.

Obviously, the FDA through their designation of Breakthrough status for the drug realizes the importance that this has for patients who suffer from treatment-resistant depression who really haven't had a new mechanism of action in better than a couple decades now. So we hope that that level of energy on both sides will carry through. We certainly hope both sides come together to reopen the government and end the partial shutdown, but we're monitoring it very closely.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Vamil. Rob, next question, please.

Operator

The next question is from Geoff Meacham with Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Morning, guys. Thanks for the question. I just had a few quick ones. Joe, on the Pharma segment, J&J has previously used a number of novel contracting approaches and this includes REMICADE and ZYTIGA. Are there opportunities for the broader portfolio on 2019 and, specifically, how you're thinking about the payer approach this year to ERLEADA with generic ZYTIGA now in the market? And I have one follow-up for Alex.

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

Yeah. Thanks for the question, Geoff. I would say we're looking for contracts that make sense. As you know, we've got a very, I would say, best in class strategic customer group within our Pharmaceutical unit. We want to make sure that payers understand the value that our medications bring based on outcomes. So we'll continue to change our contracting with the landscape and want to influence how a payment occurs.

Again, we do have some outcomes-based pilots out there that are across a number of therapeutic areas. We think that's a way that could potentially be a long-term solution. We certainly understand the conversation around pharmaceutical pricing but, again, I'll reiterate what I said earlier with respect to just our strong Pharmaceutical performance. We've got products that make a difference in patients' lives. It is better for the health care system overall, less costly, to utilize those therapeutics. And our 8% growth this year was delivered even though we were able to decrease net price 6%.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay. And just as a follow up to that, Joe or Alex, you guys have been very transparent on drug pricing. How viable do you think the Part B OUS reference pricing proposal really is? And do you feel like your assumptions on pricing across the portfolio for, say, later stage products is conservative enough?

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, Geoff, thanks for the question. Look, we're obviously engaged with the administration and a lot of different groups right now in the issue of pharmaceutical pricing. We understand that it's important and it's critical for all of us to do things in a responsible way in this area.

We do think that there are some changes around Part B and especially Part D as it relates to out-of-pocket costs that can and should be addressed to alleviate some of the current pressure in the system. Regarding the reference pricing, we do have some concerns with reference pricing overall. At the same time, what I would say is, we regularly track the pricing of our products on a global level and we can tell you, when you take a look at net pricing overall, we think that we're actually quite competitive.

But again, we are concerned about unintended consequences around access and innovation as it relates to some of the proposals. But I think it's still early days and look, we'll continue to work with the government and others to ultimately get the right outcome that ensures that we're going to continue to get a number of great breakthrough therapies at responsible prices and in a transparent and open way.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

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

A - Alex Gorsky {BIO 16239711 <GO>}

I just want to thank all of you again for your continued support and confidence in Johnson & Johnson. We're pleased with the performance that we were able to generate over the course of 2018 and we believe that we delivered on all of our priority commitments, but we're even more excited about 2019 for all the reasons that we just outlined and enumerated. So on behalf of the entire leadership team, thank you very much and I'll look forward to engaging with all of you in the coming weeks and months.

Operator

Thank you. This concludes today's Johnson & Johnson's Fourth Quarter 2018 Earnings Conference Call. You may now disconnect.