

Q3 2018 Earnings Call

Company Participants

- Ashley A. McEvoy, Executive Vice President, Worldwide Chairman, Medical Devices
- Chris DelOrefice, Vice President of Investor Relations
- Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals
- Jorge S. Mesquita, Executive Vice President & Worldwide Chairman, Consumer
- Joseph J. Wolk, Executive Vice President & Chief Financial Officer

Other Participants

- Amit Hazan, Analyst
- Bob Hopkins, Managing Director
- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- David Ryan Lewis, Analyst
- Geoff Meacham, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Jayson T. Bedford, Analyst
- Joanne Karen Wuensch, Analyst
- Larry Biegelsen, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning and welcome to Johnson & Johnson's Third 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 and it is my pleasure to welcome you to the investor conference call to review Johnson & Johnson's business results for the third quarter of 2018. I am pleased to be joined for a discussion today by Joe Wolk, Executive Vice President and Chief Financial Officer, who will provide

commentary on the quarter's financial performance, along with an update on our guidance for 2018. Additionally, I'm pleased to be joined by the leaders of our business segments, who will participate in our Q&A session.

Joining me today in New Brunswick are: Jorge Mesquita, Executive Vice President and Worldwide Chairman, Consumer; Jennifer Talbert, Executive Vice President and Worldwide Chairman, Pharmaceuticals. We also have via phone Ashley McEvoy, Executive Vice President and Worldwide Chairman, Medical Devices.

Thank you for your interest in Johnson & Johnson and joining us on today's call. Our strong third quarter results included areas of strength across all segments of our business. Consumer's operational growth accelerated across all franchises and all major regions in our portfolio and also benefited from the relaunch of our iconic JOHNSON's baby brand in the U.S.

Our Pharmaceutical business demonstrated strong above-market growth, fueled by multiple innovative products. We continue to successfully navigate overall market dynamics and are confident in our proven business model to enable us to deliver sustainable growth. Medical Devices continues to enhance market-leading positions in many key platforms and delivered improved performance across more platforms than prior quarters to deliver on our goal of above-market performance in 2020.

Specifically, adjusted for acquisitions and divestitures, we saw another quarter of improved growth in Hospital Medical Devices, with almost a full point improvement versus the second quarter of 2018. As an enterprise, we continue to exceed near-term financial expectations, while managing the business for the long term to benefit patients, customers and shareholders.

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. There you can also find additional materials including today's presentation and associated schedules. Please note that this morning's presentation includes forward-looking statements. We include you to review this cautionary statement regarding commentary included in today's discussion as well as the company's Form 10-K, which identifies certain factors that could cause the company's actual results to differ materially from those projected. Our SEC filings, including our 2017 Form 10-K, along with reconciliations of non-GAAP financial measures utilized for today's discussion to the most directly comparable GAAP measure, are all available at investor.jnj.com. A number of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships. We anticipate today's webcast to last approximately 75 minutes.

Now, I'm pleased to share our results for the quarter. Worldwide sales were \$20.3 billion for the third quarter of 2018, a 3.6% increase versus the third quarter of 2017. On an operational basis, sales were up 5.5% as currency had a negative impact of 1.9%. In the U.S., sales were up 3.6%. In regions outside the U.S., our operational growth was 7.5%, with the effect of currency exchange rates reducing our reported O.U.S. results by four

points. Excluding the net impact of acquisitions and divestitures, operational sales growth was 6.1% worldwide, 3.9% in the U.S. and 8.5% outside the U.S. I will provide the same reference for each segment.

With respect to earnings for the quarter, net earnings were \$3.9 billion and diluted earnings per share were \$1.44 versus \$1.37 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the quarter were \$5.6 billion and adjusted diluted earnings per share were \$2.05, representing increases of 7.3% and 7.9% respectively compared to the same period in 2017. On an operational basis, adjusted diluted earnings per share grew 9.5%. Joe will discuss earnings further in his remarks.

Beginning with Consumer, I'll now comment on quarterly sales performance by business segment, highlighting items that build upon the slides that will be presented. Unless otherwise stated, percentages referenced represent operational sales change in comparison to the third quarter of 2017 or, in other words, results that exclude the impact of currency translation.

Worldwide Consumer sales totaled \$3.4 billion, growing 4.9%. Excluding the net impact of acquisitions and divestitures, mainly the divestiture of the Compeed business in the Wound Care/Other franchise outside the U.S., total adjusted operational sales growth was 6.1% worldwide. Performance in the quarter was positively impacted by the restocking of retail inventory to support the relaunch of our JOHNSON's baby portfolio in the U.S. that we highlighted last quarter. Excluding this impact, our adjusted operational growth was approximately 5.4%, representing above-market growth for our Consumer segment this quarter. Beauty led the Consumer segment performance, growing 6.5% or just above 8% when adjusting for divestitures, primarily Nizoral. The U.S. realized strong category consumption and growth, including continued strong performance in e-commerce. The NEUTROGENA brand delivered strong results, primarily reflecting growth in facial moisturizing and share gains in sun protection. Additionally, the OGX and MAUI MOISTURE brands delivered strong performance, growing share globally.

Results outside the U.S. were also driven by the Asia-Pacific region, where DR. CI LABO and NEUTROGENA brands had strong uptake. OTC also delivered strong results, growing 6.8% or slightly above 6% adjusting for acquisitions and divestitures, mainly our recent acquisition of Zarbee's.

In the U.S., we grew overall category market share by 0.6 points versus prior year, with strong consumption across many key categories such as upper respiratory, including ZYRTEC for allergy relief, IMODIUM for digestive health and TYLENOL and MOTRIN in analgesics. We also delivered strong growth outside of the U.S. across our portfolio, led by performance in antismoking aids, driven by new product innovation.

As previously referenced, we successfully relaunched our JOHNSON's baby product line and achieved growth of 4.3% this quarter. Excluding the benefit of the retail inventory restocking, the business was essentially flat versus prior year. While it is early, we are excited about the progress of the relaunch as we realized strong consumption in the month of September.

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Moving on to our Pharmaceutical segment. Worldwide Pharmaceutical sales of \$10.3 billion grew 8.2%, with double-digit growth in nine key products, resulting in continued above-market performance. The segment was led by performance of the Oncology portfolio, growing about 39% globally. DARZALEX continued its strong performance, growing globally by approximately 60%. In the U.S., market growth and strong launch uptake of the one prior line indication is resulting in share gains.

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, where it gained approval late last year. This strong broad-based volume growth was partially offset by a onetime adjustment outside the U.S. related to accruals for retroactive reimbursement matters which negatively impacted worldwide DARZALEX growth by 16 points.

IMBRUVICA grew approximately 40% globally, with growth in the U.S. of 45%. Based on second quarter data, IMBRUVICA gained approximately 3 points of market share versus prior year across all lines of therapy, largely driven by share in line one chronic lymphocytic leukemia or CLL. The CLL line one market is estimated to have grown approximately 14% in the same period.

ZYTIGA grew approximately 45% due to continued strong 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 non-metastatic 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.

In Immunology, we delivered global sales growth of 5%, driven by continued strong performance in STELARA of 17% and SIMPONI/SIMPONI ARIA of approximately 15%, offset by continued erosion of REMICADE of 15% due to competition from 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 approximately seven points compared to the third quarter of 2017.

Lastly, sales of our newly launched treatment for psoriasis, TREMFYA, totaled \$171 million globally. TREMFYA is experiencing strong demand with over 25,000 patients on therapy and achieved a 5.8% share of the psoriasis market in the U.S.

In Neuroscience, our paliperidone palmitate long-acting injectable portfolio delivered strong global growth of approximately 18%, driven by new patient starts and persistency. We did experience negative growth in our Cardiovascular, Metabolism and Other product portfolio, primarily driven by declines in INVOKANA.

Additionally, XARELTO declined by 3.6%, with continued share growth being offset by increased rebates, including approximately six points of the negative impact from prior quarter adjustments. Excluding these adjustments, XARELTO's underlying growth would have been approximately 2.5%.

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Subsequent to the quarter, the U.S. FDA approved XARELTO for a new 2.5 milligram vascular dose, making XARELTO the first and only Factor Xa inhibitor to reduce the risk of major cardiovascular events, such as CV death, myocardial infarction or stroke in people with chronic, coronary or peripheral artery disease. This indication significantly increases XARELTO's treatable patient population by approximately 13 million patients in the U.S.

In pulmonary hypertension, we realized strong growth in both OPSUMIT and UPTRAVI. OPSUMIT grew globally approximately 21% with similar growth both inside and outside the U.S. and UPTRAVI grew 38% globally, both driven by further market penetration and increased share. As expected, TRACLEER is declining as generics entered the European market during the second half of last year.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were \$6.6 billion, growing 1.7%. Excluding the net impact of acquisitions and divestitures, primarily the divestiture of Codman Neuroscience, adjusted operational sales growth was 2.9% worldwide. This growth represents an acceleration versus the first half of 2018.

We continue to strengthen our market-leading positions in our Electrophysiology and Vision businesses, while also improving performance in Spine and Knees in our Orthopaedics portfolio. Growth was partially offset by declines in our Diabetes Care business.

Subsequent to the quarter, we announced the completion of the divestiture of our LifeScan business, which is consistent with our approach to strategic portfolio optimization.

Interventional Solutions grew 19.4% globally, with continued strength in our Electrophysiology business, which grew more than 23% worldwide, fueled by our market leadership position in the space from newer product offerings in ablation and advanced catheters, contributing to atrial fibrillation procedural market growth. This represents the highest growth we've realized in any quarter over the last nine-plus years of double-digit growth. Additionally, we realized strong double-digit growth in our CERENOVUS business, fueled by new product innovation, including the launch of EMBOTRAP for the treatment of ischemic stroke.

Moving to our Vision business, the Contact Lens business continued to grow above market at 6.2% worldwide on the strength of the astigmatism and daily disposable lenses in the OASYS family. In Vision Surgical, worldwide growth of 4.1% was driven by international intraocular lens growth in cataracts.

In Orthopaedics, excluding the impact of acquisitions and divestitures, primarily the divestitures of Codman Neuroscience and Prodisc in Spine, performance was flat to third quarter 2017.

In Hips, we grew market share, leveraging our leadership position in the anterior approach and continue to see strong demand for the primary stem, ACTIS. Trauma was

flat due to lower market growth, along with continued pricing pressure in the U.S. market. As the clear market leader in this segment, we continue to see strong adoption of newer innovation such as our TFNA femoral nail.

Performance improved in both Spine and Knees, although we are committed to doing better. Spine performance improved for the third straight quarter, driven by new products such as the CONCORDE LIFT Expandable Interbody Implant and the VIPER PRIME System for minimally invasive surgery.

Our performance in Knees accelerated to approximately 1% growth due to the continued strong uptake of the ATTUNE Revision System and aided by the onetime impact of price legislation in India in 2017. Pricing pressure continued to impact all categories in Orthopaedics. For the quarter, U.S. pure price was negative across all platforms by approximately negative 6% in Spine, 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 group. The Advanced Surgery performance was strong, led by double-digit growth outside the U.S. On a worldwide basis, Endocutters grew 10% and Energy grew 4.5% as new products are experiencing strong demand, especially outside the U.S. Biosurgery grew over 9%, driven by strong demand, fueled by new innovation such as SURGICEL Powder. In General Surgery, Wound Closure grew 3.5%, with growth in all regions, as barbed and plus sutures are experiencing strong adoption.

Selling days had a negligible impact on Medical Devices in Q3. And, as previously communicated, we don't expect a material impact globally for the remainder of this year, but there could be some variances by region.

As a final comment regarding the U.S. hospital setting, let me provide utilization trends. For the second quarter of 2018, we saw an increase in hospital admissions of about 1.5%. Surgical procedures were up approximately 1% and lab procedures were up about 2%. Our preliminary estimates for the third quarter indicate a modest decline in hospital admissions growth to 1%, with surgical procedures and lab procedures growth consistent with the second quarter at approximately 1% and 2%, respectively.

That concludes the sales highlights for Johnson & Johnson's 2018 third quarter. For your reference, this slide summarizes notable developments that occurred in the third quarter, some of which were mentioned in my comments.

It is now my pleasure to turn the call over to Joe Wolk, who will provide further insights on Johnson & Johnson's quarterly financial results.

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Chris. It is great to have you in the Investor Relations role. Good morning, everyone. As Chris mentioned, we are very pleased with our strong third quarter results, a product of the effort and contributions made by our Johnson & Johnson colleagues

around the world. Our performance reflects the progress we're making against the robust strategies and plans that we have put in place across all three segments and that we've been sharing with you throughout 2018.

I'd also like to welcome Ashley, Jorge and Jennifer to today's call. These are performance-based leaders who embody Our Credo-based culture. We all look forward to answering your questions about our business later in the call.

Since Chris already provided many details on sales, I'll provide only a brief few comments on revenue before focusing the discussion on cash, the income statement and guidance for the remainder of 2018.

In Consumer, we're very encouraged by the third quarter results, which are consistent with our plan to deliver above-market performance in the year that we shared at Analyst Day. Over-the-counter medicines and beauty continued to thrive and we are very pleased with the early positive feedback related to our JOHNSON's baby relaunch. We launched in the United States, China and India during the quarter and we plan to continue the full global rollout into 2019.

Our Medical Devices performance is also consistent with our Analyst Day plans. The third quarter reflected accelerated strength in already strong franchises, such as Electrophysiology, Biosurgery and Endocutters and improvement in areas that underperformed in recent quarters, most notably Spine and Knees. The third quarter is a positive step toward our goal of returning to above-market performance by 2020.

In Pharmaceuticals, we continue to be an industry leader across many performance measures, including sales growth, R&D productivity and commercial capabilities. While we'll face tougher comparisons in the Pharmaceutical segment through the remainder of this year, as well as biosimilar and generic competition, we are confident in the strength of our business. Our growth, as in prior quarters, is the result of our approach to innovation and delivering transformational products. Our growth continues to be driven by volume rather than price.

Being broadly based in healthcare allows us to continue to seek opportunities where we can uniquely drive value through our cross-segment collaboration and external partnering. One example is in the managed care setting, where we are combining our patient and provider insights, our behavioural science expertise and our human-centered design methods to enable a health insurance customer and a retail customer to collectively deliver a better experience for a priority patient population. This kind of collaboration is indicative of how we live into Our Credo and our commitment to ensure that good health is within reach for everyone, everywhere. We will continue to use our broad base to provide new solutions in healthcare and meet the needs of patients and consumers globally.

Starting with cash, I will now highlight other key financial activity for this quarter. At the end of the quarter, we had approximately \$12 billion of net debt, which consists of approximately \$19 billion of cash and marketable securities and approximately \$31 billion

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of debt. Regarding our consolidated statement of earnings for the third quarter of 2018, please direct your attention to the boxed section of the schedule. As referenced in the table of non-GAAP measures, the 2018 third quarter net earnings are adjusted to exclude intangible asset amortization expense and special items of \$1.7 billion on an after-tax basis, driven by intangible amortization of \$1 billion and an in-process R&D charge of \$900 million, which is primarily related to the partial write-down of Alios BioPharma, as noted in this morning's press release.

Excluding the impact of those items, our adjusted earnings per share is \$2.05, exceeding the mean of analyst estimates and an increase of 7.9% versus the third quarter of 2017. Adjusted EPS on a constant currency basis was \$2.08, up 9.5% versus the third quarter of 2017.

I'd like to now highlight a few noteworthy items that have changed in the statement of earnings compared to the same quarter last year. Gross profit margin for the quarter improved by 280 basis points, primarily driven by favourable business mix, as well as the impact of the Actelion inventory step-up charge recorded in 2017. Our investment in research and development as a percent of sales was 12.3%, which is lower than the third quarter of 2017, primarily due to the timing of investments. Other income and expense was a net expense of \$3 million in the quarter compared to a net gain of \$297 million in the same period last year. Excluding special items recorded in this line, other income and expense was lower, with a net gain of \$32 million in 2018 compared to a net gain of \$578 million in the prior-year period, primarily due to the sale of the Consumer Compeed business in the third quarter of last year.

Excluding special items, the effective tax rate was 17.6% compared to 20.8% in the same period last year. This rate is consistent with our expectations as a component of the full year effective tax rate. The lower rate compared to the third quarter of last year is the result of the Tax Cuts and Jobs Act. We anticipate the U.S. Treasury will issue further regulatory guidance later this year, specifically related to foreign tax credits and expense allocation against international income. Our tax rate guidance, which I will provide shortly, reflects these anticipated developments.

Let's now look at adjusted income before tax by segment. In the third quarter of 2018, our adjusted income before tax for the enterprise declined 20 basis points versus the third quarter of 2017. Looking at the adjusted pre-tax income by segment, Medical Devices at 27.1% is lower than the previous year, primarily due to investments in the business. Pharmaceutical margins improved by 380 basis points to 44.8%, driven by favorable product mix and timing of research and development spend. Consumer margins declined to 17.1%, due to a prior year divestiture gain previously mentioned, partially offset by investment spend.

Turning to guidance for you to consider as you update your models. Our sales guidance for 2018 continues to include erosion due to the biosimilar competition impacting REMICADE, continued generic competition for CONCERTA and VELCADE and the expected generic and biosimilar competition to TRACLEER and PROCRT later this year. Our guidance is based on a constant currency basis, reflecting our results from operations. This is consistent with past guidance practice and the way we manage our

business to provide the best understanding of our underlying performance. We will also provide an estimate of our sales and EPS results for 2018, with the impact that current exchange rates could have on the translation of those results.

For the full year 2018, we are comfortable with your models, reflecting operational sales of 5.5% to 6.0% for the year, an increase over the guidance we provided in July. This growth would result in sales for 2018 on a constant currency basis of approximately \$80.6 billion to \$81 billion. We expect that operational sales growth, excluding the impact of acquisitions and divestitures, will be between 4.5% and 5.0% for the year, also an increase to our previous guidance.

Although we are not predicting the impact of currency movements, utilizing the euro spot rate relative to the U.S. dollar as of last week at \$1.15, the positive impact of foreign currency translation would be approximately 0.5%. This rate is below previous guidance, which assumed a spot rate of \$1.17 and results in a 30 basis point reduction in growth compared to that previous guidance. Therefore, under this scenario, we expect reported sales growth in the range of 6.0% to 6.5% or approximately \$81.0 billion to \$81.4 billion. Again, this is higher than our previous guidance due to our operational strength.

Our adjusted pre-tax operating margin guidance remains relatively unchanged. Although year-to-date performance suggests even greater improvement, we expect investments in the fourth quarter will result in the full-year pre-tax operating margin improvement of at least 150 basis points. For purposes of your models, assuming no major acquisitions or other major uses of cash, I suggest you consider modeling net interest expense between \$450 million and \$500 million. This is lower than previous guidance, as we benefit from an increase in interest income from higher rates.

Regarding other income and expense. We would be comfortable with your 2018 models, reflecting net other income and expense, excluding special items as a net gain, ranging from approximately \$1.5 billion to \$1.7 billion, which is consistent with our previous guidance. As a reminder, this is the account where we record royalty income as well as gains and losses arising from such items as litigation, investments by our Development Corporation, divestitures, asset sales and write-offs. This would include the gain associated with the divestiture of the LifeScan business announced subsequent to the quarter, but does not include the divestiture of our Advanced Sterilization Products business, which we expect to close in 2019.

Moving on to taxes. Our effective tax rate guidance for 2019, excluding special items, is approximately 17.5% to 18.0%, reflecting a tightening of the previous range. Considering all these factors, we are comfortable with adjusted EPS guidance in the range of \$7.98 to \$8.03 per share on a constant currency basis, reflecting operational or constant currency growth of approximately 9% to 10%, which is higher than our previous guidance, again, reflecting the strength of our business.

We are not predicting the impact of currency movements. But to give you an idea of the potential impact on EPS using recent exchange rates, our reported adjusted EPS would be positively impacted by approximately \$0.15 per share. Therefore, our reported

adjusted EPS would range from \$8.13 to \$8.18 per share, reflecting growth of approximately 11.8% at the midpoint, which is also higher than our previous guidance.

That concludes our financial summary. I will now turn the call back over to Chris for the Q&A portion of the call, where, again, I'm very pleased to be joined by Ashley, Jorge and Jennifer. Chris?

Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Joe. We will now move on to our Q&A portion of today's discussion. Rob, can you please provide instructions for those on the line wishing to ask a question?

Q&A

Operator

Sure. Your first question is coming from David Lewis with Morgan Stanley.

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

Good morning. Maybe a few questions. Because we have so many people on the call this morning, I'll be quick. Joe, I just want to start with financial for you and then one for Jennifer and one for Ashley. So, Joe, just the guidance you gave here for the year, I'm just sort of doing some net math here. It seems like margins for the fourth quarter are somewhere around the mid-20s, which is consistent with your historical spending into the fourth quarter. Just want to get a sanity check on that. And as we think about next year on other income, is it reasonable to expect other income levels in 2019 similar to 2018? And I have two quick follow-ups.

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

Yeah, so good morning, David. Good to hear from you. I would say with our margins for the fourth quarter, I would stand by the guidance that we just gave. You might have noticed the slight tweak in language, we've gone from approximately 150 basis points to at least 150 basis points, so we'll plan to invest in the fourth quarter much as you've seen in previous years.

With respect to other income and expense, I prefer to hold off till January when we give you 2019 guidance. I think it's fair to say that we've commented in the past for quite some time now that when we do see a lessening of other income on that line, we will adjust accordingly with our operating margins.

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

Okay. Very clear. And then to ask my two questions here together. First, for Jennifer. Just your growth ex-ZYTIGA this quarter was around, I think, 6%. Is that a good way to think about 2019 Pharma growth? And could you just give us an update on where you're coming out on, whether the fourth quarter implies any impact from ZYTIGA?

And then just, Ashley, and congrats, by the way, to both of you on the new positions. But the Ortho basically was stable overall, but the U.S. knee franchise obviously remains under pressure. Can you just give us a sense of how much of this is ATTUNE perception issues versus robotics and what's the pathway to recovery in U.S. knees? Thanks so much.

A - Jennifer Taubert {BIO 20108880 <GO>}

Great. Let me start in there - good morning, David. First of all, we're really pleased with our third quarter performance for the Pharmaceutical sector. So, the 8.2% operational growth, which is above the market, and growth coming that's broadly based across the portfolio with nine key brands achieving double-digit growth and very strong performance as we look across the globe.

As you noted, if we actually remove ZYTIGA from that mix, our growth was 6.6% operationally, so really, really strong performance. And so, I think what ZYTIGA shows and demonstrates, while we're pleased with ZYTIGA, we're absolutely not dependent on it. As Joe indicated, we're not providing any guidance right now for 2019. And in previous sessions, we have discussed sort of the process and the legal challenges that are underway. Right now, we're in the process of waiting for a court ruling on ZYTIGA and our stay ends at the end of October; October 28, I believe. So, we're not going to make any speculations or predictions on that, but we're very, very pleased with the Pharm performance overall and very, very broadly based throughout the portfolio.

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

Ashley, do you want to...

A - Ashley A. McEvoy {BIO 20108895 <GO>}

David, good morning. Sure. No, I think for Knees, with quarter three, I think you saw a little bit of a stabilization in quarter three in North America versus quarter two. We expect that to improve as we continue the rollout of our ATTUNE Revision, which has gotten a very healthy uptick. And as we launch the cementless program in 2019 and then progress our Digital Surgery offering in Orthotaxy following in 2020, obviously, coupled with very strong commercial excellence. Thanks for the question.

Operator

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

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. So just, Joe, a couple follow-ups on David's questions earlier. So I know you're not giving 2019 guidance until January, but maybe you can help us think about some of the headwinds and tailwinds we should be thinking about; some of the ones that people are interested in. Specifically, our currency, we estimate it's about a 100 basis point headwind right now; and REMICADE erosion, how that might compare in 2019 to 2018. And I had one follow-up.

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

Sure, Larry. Good morning. Good to speak with you. I think probably the best way for me to comment on currency is to say that we provide guidance on our operational performance and then just an estimate based on what the current spot rates are at the time. This year, it was much less of a tailwind than we thought when we were speaking with the investment community back in January. We thought it would translate into about \$1.5 billion of additional revenue reported. It's only turning out to be about 25% of that, but we've been able to take up guidance based on just the solid operational strength of our underlying business. So I won't comment because it's just much too speculative as to what next year may hold with respect to a strengthening dollar.

And your second question with respect to REMICADE...

Q - Larry Biegelsen {BIO 7539249 <GO>}

Just on REMICADE.

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

I wouldn't expect any kind of step change. I think what you've seen this year is roughly 18% in the U.S. with biosimilar erosion. We continue to compete there. Most of that erosion is related to price, and we're going to continue to do that because we know that that's what patients and healthcare providers actually see as a product of most comfort. So based on the safety and efficacy that we've demonstrated for a number of years across all indications, we feel pretty strong that it still has a very strong place in the market. And the good news, as we said before biosimilars launch is the immunology portfolio with the expansion of the STELARA label as well as the introduction of TREMFYA, continues to grow in spite of REMICADE's erosion.

Q - Larry Biegelsen {BIO 7539249 <GO>}

And, Joe, you grew organically about 6% year to date, including about 6% in Q3. Can you walk us through what your guidance assumes for organic growth in Q4? I'm getting to about 2% at the midpoint and I'm wondering why you're assuming such a deceleration. Could you just help us bridge that? Thanks for taking the questions.

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

Sure thing, Larry. I know I can count on you for a math question. So let me give you some things to think about. Obviously, we don't provide quarterly guidance, but I realize we've got three quarters into the year; so it becomes somewhat of a plug. But let me give you the qualitative things to consider as you model Q4, which we think are somewhat temporary or fleeting in nature. We do expect Medical Devices to continue that modest improvement quarter on quarter, strengthening in areas where we're already strong and then improving some of those areas that have underperformed in recent quarters.

We do think we've turned the corner with Consumer. We want to see more data points with that. But the growth that belies this quarter of 6% adjusted operational, there's a slight, I would say, downward revision for that, given some of the baby stocking. But

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you're still into the mid-5% range. We think that's going to continue because it's underpinned by the baby franchise being rolled out across the globe. We're seeing strong receptivity for those products here in the U.S., China and India. And then OTCs and beauty/skincare continued to perform at 6% levels.

With Pharmaceutical, you have some unique adjustments. I would say there's going to be some new generic and biosimilar entries with respect to TRACLEER and PROCRIT that we anticipate and is in our thinking for guidance in the fourth quarter. We'll see continued erosion that wasn't around fourth quarter of last year with respect to CONCERTA and VELCADE. We do have much higher comps with respect to Pharmaceutical business as you know and the second half of 2017 is really when that business reaccelerated its strength.

And then lastly, there is a gross-to-net accrual that we'll be making related to 2019 activity. As we get ready for the new year, we have inventory out at wholesalers and we accrue on those rebates. And just given the size of our business and some of the contracts that we see coming through, we think that's going to be a little bit of an impact in the fourth quarter here.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for taking the questions.

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

Thanks, Larry.

Operator

Your next question comes from Jami Rubin with Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Joe, just sort of a big picture strategic question, J&J seems to be stuck in a pattern of Pharma outperforming, but MD&D underperforming, and while you are starting to see evidence of improvement in certain pockets of that business, I think relative to your peer group, J&J's business has been a pretty visible underperformer.

I'm just wondering - and this is sort of a narrative that we've seen for many, many years now - are you satisfied with that narrative? And if not, what would it take to jump-start that narrative? And what would it take to jump-start the MD&D business? Will it require a large-scale transformative deal, which I think you've somewhat alluded to or is it more likely that you would stick to tuck-in deals?

Is that the right way to look at it? Or do we just need to be patient and wait for new products to reach the market so that - I think your guidance is that this business would start to grow in line or better than the market by 2020, just wondering if you could address that?

And then I have a follow-up question for the Pharma business. Just if you exclude REMICADE, I'm just curious if prices or rebates have changed much in the Immunology franchise, just given how crowded that space has become. Thanks very much.

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

Well, thanks for the question, Jami. What I'll do is I'll kick off the answer and then maybe kick it over to Ashley to talk a little bit more about the plans for going forward in Medical Devices. But I would say comparing us to the peer group in Med Devices can be a little bit misleading. I don't know that anybody's got the breadth or scale that we have when you just look at the level of revenue. There's maybe one other competitor that's notable, and we outperform them.

That being said, we are not satisfied with the performance in Medical Devices. We're seeing improvements. Whether that's going to take a transformational deal or a tuck-in deal, we're looking at all of them across all segments of our businesses. We want to make sure it's a good strategic fit and that we can create value not just for the company, but for shareholders going forward.

Ashley, maybe you can comment on a few things that will continue this upward momentum that we started in Medical Devices?

A - Ashley A. McEvoy {BIO 20108895 <GO>}

Yeah, Jami, thanks for the question. I guess I would offer - I'd ground this on kind of where we come from and then clearly where we aim to be, and what we're fortunate to be is in a very strong position with number two in med tech and we have half of our platforms growing above the market and we've got very competitive profitability and very competitive free cash flow.

So with I like to say, a very strong purpose of what we do every day of helping people. So with that at our back, clearly we are very focused on flipping each of those platforms that we're dissatisfied and have been underperforming the market. And our strategy to achieve this has really been through accelerating innovation. You've heard us speak, around 15 to 20 new products, and many of those are having very strong traction in the marketplace. I use examples like some of the spine innovations have been enabling some of that spine performance. I expect some of the innovations in the ATTUNE Revision and getting cementless will help us with Knees. I expect some of the innovations that we're launching in Energy and in Endocutters, particularly around like the ECHELON FLEX, will help us.

We've also been doing a lot of different M&A deals. We've done about 26 deals this year: 5 of them have been acquisitions; 10 equity investments; 2 of them are divestitures, 1 which will hit quarter four, which is Diabetes, the other one will be ASP, which is early 2019; and then several other co-promotes. So I think we are very focused on accelerating those platforms that are in fact growing above the market, relying on that strength, feeding the ones that are underperforming through innovation, M&A and commercial

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excellence. And obviously, we're always looking at transformative M&A, but we haven't modeled on in any of that.

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

Great. Thank you, Ashley. And, Jennifer, maybe you can address Jami's question regarding pricing in Pharmaceutical, ex REMICADE?

A - Jennifer Taubert {BIO 20108880 <GO>}

Yeah, and I believe Jami's question also was fairly focused in on Immunology as well.

A - Ashley A. McEvoy {BIO 20108895 <GO>}

Correct, correct, right.

A - Jennifer Taubert {BIO 20108880 <GO>}

So we definitely are seeing continued pressure on pricing in Immunology as both the payers are working to extract greater rebates and discounts and also as there's increasing competition in the key categories.

However, that being said, I think given our strategy with being a transformational medical innovator, the types of products that we're bringing forward, the data that we're bringing forward, and the types of analytics and things that we're doing in partnering with customers, I think we're really well positioned to continue to compete and to be able to succeed in the market.

If you take a look at our products ex REMICADE in the Immunology category, we've got very robust growth. Taking a look at STELARA, with that growth being led by our Crohn's indication, TREMFYA, which is really making significant inroads in psoriasis and also SIMPONI and SIMPONI ARIA. And so, if you even if include REMICADE, we're continuing to grow. Outside of that with the others, we've got very robust growth.

So going back, our growth really has been driven largely by volume and expanding our reach and reaching greater number of patients, and I continue to believe that that's how we'll be deriving our growth going forward. So, yeah, market is heating up in terms of discounts and rebates, but I think that we're well positioned to be able to continue to compete successfully.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you.

Operator

Your next question comes from Chris Schott with JPMorgan.

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Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much. Just two here, maybe first another one on drug pricing. I guess, as we look out to 2019 – and now you have a bit more clarity on some of your contracting – should we expect any major shifts in price dynamics for your Pharma business next year based on these conversations or should we think about really a similar dynamic that we saw in 2018? My second question was on DARZALEX. I know sales were maybe a bit below expectations. I think you mentioned some ex-U.S. price adjustments impacting results. So can you just elaborate a little bit more on the trends we're seeing with the product and what specifically is happening ex-U.S. on pricing? Thank you.

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. So on the pricing front overall, I think as we look into 2019 and what we're seeing in the contracts, I think that we're going to see continued evolution in some of the categories where there are very high level of competitors. But it'll be an evolution in pricing, not a revolution or a step change. But it definitely continues to be an area of focus for the payers in that heavily contracted category.

If we take a look at DARZALEX, so DARZALEX had very strong performance, with 60% growth worldwide, sales nearly \$500 million. And it was very strong, both based in the U.S. and ex-U.S. What you're referring to and what we had mentioned relating to ex-U.S. is that we did have a onetime adjustment related to accruals for retroactive reimbursement and that negatively impacted the DARZALEX worldwide growth by 16 points. This is just a normal adjustment as we negotiate with governments to get reimbursement in some of the ex-U.S. markets and we see this as a normal course of business and, really, a onetime adjustment, but DARZALEX overall demonstrating very, very strong growth and another strong quarter.

Q - Chris Schott {BIO 6299911 <GO>}

Thank you.

Operator

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

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

Hi. Good morning. Two questions for Jennifer on the pipeline. Two key drivers over the next couple years: ERLEADA, which was just launched and then esketamine, which you're hoping to launch in 2019. So Jennifer, on esketamine, I just wanted to get your sense of confidence in FDA approval. And the reason I'm asking is you did five Phase 3s. Three were positive. I think two missed their primary endpoints, but nonetheless very good safety data. So what's your confidence in approval? And do you think we may need an FDA panel for esketamine? And then on ERLEADA, I know you're not giving the actual sales numbers, but when we track IMS data, ERLEADA is off to a slightly slower start than we would have expected. So maybe talk about your expectations for ERLEADA as well. Thanks.

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A - Jennifer Taubert {BIO 20108880 <GO>}

So for esketamine, we're really excited about esketamine's potential for treatment-resistant depression and also, hopefully, in the future, major depressive disorder for those patients who are at imminent risk of suicidality. Both of those products or programs, excuse me, have FDA breakthrough designation, which represents the significant unmet medical need. We are really confident in the totality of our data across the esketamine program and what we have filed both with the U.S. authorities as well as the EMEA authorities. It's really difficult in these types of trials to prove success, as you know, as you take a look across the industry. And we believe that across the totality of our data, we've got a very, very robust program and robust data and are hopeful and optimistic for approval.

In terms of an FDA panel, I don't know if we have heard back from the agency yet if we will have one or not. They are typically standard for first-in-class or new mechanisms, so I think our team is going to anticipate and prepare for one. And as soon as - I don't know if we have the actual answer on that, but that would not be unusual in any respect. I think the default is everyone gets a panel unless the agency says no on that.

And the other question was on ERLEADA. So we have launched ERLEADA in the U.S. I believe we're not yet reporting sales on that in terms of numbers. We're pleased with the uptake. As you know, with ERLEADA, this is in the pre-metastatic setting; so it's in the earlier course of disease. Both urologists and oncologists prescribe for it. There is very strong both awareness and receptivity to the profile, the data and the label and so there's very strong interest in prescribing.

But you don't - we didn't anticipate and you wouldn't anticipate to see the same type of uptake that you would in a later line of therapy. You really need to look at this as more of a chronic type of therapy with a chronic uptake ramp. But what we've seen to date in terms of that provider and patient receptivity and uptake, we have been very pleased with for ERLEADA. And we're also looking forward to data hopefully coming soon or early in 2019 in combination with ZYTIGA, the ASIS (51:26) data as well.

Operator

Your next question comes from the line of Joanne Wuensch with BMO Capital Markets.

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

Good morning, and thank you very much for taking the questions. In no particular order, Vision Care, up 6.2%, growing faster than the market. Could you please discuss if there was any stocking or onetime items in that? And how do you see Johnson & Johnson going forward in terms of product pipeline? If I can just continue quickly, Orthopaedic pricing was a little bit worse sequentially, about 50 basis points. Is that just normal gyrations or is there anything that we need to think about on that? And then a follow-up to David's question. How much do you think the lack of a robot in your Orthopaedic franchise is holding that back? Thank you.

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A - Ashley A. McEvoy {BIO 20108895 <GO>}

So, Joanne, I guess I'll start with your first question related to Vision. So Chris mentioned the performance in Vision and it really continues. In Contact Lens; it's like the 13th quarter that we've outperformed the market. Underlying growth in Contact Lenses remains around 7%, very consistent with the first half. I don't expect, to Chris's earlier point, a lot of additional selling days or any unique stocking events in Q3.

As it relates to the pipeline, I think that they have a healthy cadence. We mentioned the global rollout of OASYS 1-Day for Astigmatism. We are preparing for the light management launch of a contact lens which automatically adjusts from outdoor light to indoor light and also preparing within the next 24 months for our allergy lens. So I think there's a healthy cadence there in Vision. I believe your question on Orthopaedics, if you could repeat, Joanne, your question on Orthopaedics?

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

Of course. Thank you for taking my speed questions. It looks like pricing is about 50 basis points worse across the board this quarter versus last quarter, and I just didn't know if I should read anything into that.

A - Ashley A. McEvoy {BIO 20108895 <GO>}

No, I think what we referenced earlier with Chris, it's - Spine is a little bit softer than some of the other joint businesses. Hips and Knees are pretty consistent at that 2% to 3% and I - we don't anticipate significant shifts in upcoming quarters. I do think it's a good news that our Orthopaedics business, I would use the word, stabilized in quarter three and the mix improved with Hips performing up 2.4%. We had our Cranio-Maxillofacial growing 2.4%. You heard Chris mention that our Knees were up one point, and then Spine continued to improve versus prior quarters. Spine was down around 7.5% in quarter one. It was down about 3.2% in quarter two and down about 1.4% in quarter three. So clearly progress, but still work to be done in Orthopaedics.

And I believe your last question was related to robots. And I guess what I would offer is, we have the good fortune to enjoy really very strong market-leading position in open surgery, which is about 50% of all surgeries are conducted, as well as minimally-invasive laparoscopic surgery. And we intend to have offerings in digital surgery as well as offerings in endoluminal surgery. And we really think that having contribution in all four of those segments will enable a future of surgery that J&J can really add a lot of value.

So, clearly, robotics are having an impact in today's market, the penetrations are still low, although growing and I envision Johnson & Johnson have a very competitive offering in the foreseeable future related to digital surgery.

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

Thank you so much.

Operator

Our next question comes from Danielle Antalffy with Leerink Partners. Please go ahead with your question.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey. Good morning, guys. Thanks so much for taking the question. I guess this question is for Ashley. Just wanted to follow up on a comment you made earlier regarding transformative M&A. Just curious what you would define as transformative M&A within the Device business and one follow-up to that. Obviously, transformative M&A would - I mean, presumably, that would be a large deal. So, in the meantime, it feels like the Device business, while you guys have certainly been turning the business around, is still below market growth. You highlighted a number of drivers as it relates to new product launches, but it feels like it's going a little bit slower than maybe some people would expect. Are there smaller tuck-in deals that can be done between now and any sort of transformative deal that could accelerate you guys back to in line with market growth? Thank you so much.

A - Ashley A. McEvoy {BIO 20108895 <GO>}

Joe, I'll turn it to you first and then I'm happy to complement with some commentary.

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

Sure. So, thanks for the question, Danielle. With respect to transformative deals or tuck-in deals, again, we look at all scale of deals. Last year alone in Medical Devices, we invested slightly over \$1 billion with the 30 tuck-in deals and you're seeing some of that improve the performance within the Medical Device segment right now. So, again, it's going to come back to those core principles of making sure it's a strategic fit and then creating value for shareholders.

A - Ashley A. McEvoy {BIO 20108895 <GO>}

I would just complement that, Danielle, with just saying, again, historically, 50% of our innovation has come from inorganic versus organic and that blend will continue. As Joe mentioned, even in 2018, we've already done 26 deals. Some of those acquisitions, some of those equities, some of those co-promotes, so it really has to do with the strategic fit and the value creation in each of the platforms that we compete in.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Thank you very much.

Operator

Next question comes from Jayson Bedford with Raymond James.

Q - Jayson T. Bedford {BIO 5141602 <GO>}

Good morning, and thanks for taking the questions. Just a couple quickies. First, on Devices, maybe for Ashley. The 23% growth in Biosense Webster is a notable step-up. You

mentioned contribution from new products, but you also talked about strong procedure growth. So, I'm just wondering have you seen any pickup in market growth from the CABANA results last spring?

A - Ashley A. McEvoy {BIO 20108895 <GO>}

Thank you, Jayson. Yeah, we did enjoy 23% growth in quarter three. I think it's been a very strong combination of market procedures continuing to increase, as well as a very strong focus on commercial execution and market creation on ablation, as well as very balanced geographic growth. We enjoyed in our Biosense Webster business, growth of 34% in Asia and 11% in EMEA, as well as 20% in North America, again, combination of core performance, as well as some of the new products taking effect.

Q - Jayson T. Bedford {BIO 5141602 <GO>}

Okay. Thank you. And just...

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

The CABANA data, I would say that's - it maybe had a slight impact in terms of overall procedural market growth, but nothing that the team called out as a significant driver.

Q - Jayson T. Bedford {BIO 5141602 <GO>}

Okay. So, there's clearly some share capture here in your view.

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

Next question, please.

Operator

Yes, sir. The next question is from Amit Hazan with Citi.

Q - Amit Hazan {BIO 6327168 <GO>}

Hello. Thanks. Hey. Good morning, guys. Just maybe start with the utilization stats that you guys give. The U.S. surgical procedures are now up for a second straight quarter in a row after, I think, like seven straight down quarters, so I'm just wondering if you guys could take a stab at trying to explain what might be happening with underlying surgical procedures in the U.S.

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

Thanks, Amit for the...

A - Ashley A. McEvoy {BIO 20108895 <GO>}

I think we...

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

...question. Go ahead, Ashley.

A - Ashley A. McEvoy {BIO 20108895 <GO>}

Go ahead, Joe.

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

So, I mean, I think when we look at a strong economy across the globe is really where our strength has been. If you look, we're actually growing outside the U.S. stronger 2X times what we've grown here in the U.S., but a strong economy does tend to lend itself to better coverage and better healthcare, so that is helping underpin some of the procedural growth that we're seeing.

Q - Amit Hazan {BIO 6327168 <GO>}

Okay. And then specifically though with regard to your Surgery business, the U.S. Advanced piece in the U.S., it was obviously a good number this quarter, but you're actually still trending at about 2% growth for the year versus about 6% for the past few years. So maybe just some color for you guys on why you're having slower growth in Advanced this year and it's kind of a similar trend in U.S. General as well?

A - Ashley A. McEvoy {BIO 20108895 <GO>}

I think, Amit – this is Ashley speaking – a couple things. One, in our Ethicon Surgical business, clearly we enjoy many market-leading positions, and I'll come back to the mix. What I'm pleased to see is that our Endocutter business is up 10% in quarter three; our Biosurgery up 9%. Consistent growth in our wound closure, where we enjoy market-leading really driven by some innovation on barbed sutures and a lot of evidence generation strategy related to the antimicrobial effect for infection reduction. We are seeing challenges clearly in reprocessing and robotics in some of our Energy and Endomechanical business. O.U.S., our Energy business is performing quite well, but we are experiencing some challenges in the U.S. related to robotics and some reprocessing. I do expect that when the advancement of our robotic offering and digital surgery in the forthcoming years, that will help ameliorate that. We've also dialed up the innovation agenda and our Endomechanical and Energy business to really stronger compete in the handheld market.

Q - Amit Hazan {BIO 6327168 <GO>}

Thanks very much, guys.

Operator

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

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

Hi. Great. Thanks for taking my questions. So just a couple of – maybe just one to follow up on some of the comments around drug pricing. There was a – we've seen a lot from the administration. Yesterday, obviously the proposal came out around needing to include pricing in some of the TV ads and I'm just curious if you can maybe provide your perspective on this issue and just do you think this is something that would be useful or not useful? And maybe more broadly, any other sort of broader changes that you think might be implemented by the administration and things sort of played out here over the last several months.

And then second is just on DARZALEX, I appreciate the comments you made about the quarter. I'm just curious about the MAIA study. And I think it was previously listed as a potential clinical presentation this year. It's not on the key events slide now, and I just – I'm assuming you're still going to get that internally. And just the color people are asking is if you can clarify exactly when you expect that data and should we expect some sort of topline press release when you receive it? And then maybe again generally how important that data is to the longer-term outlook for that product? Thanks.

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. So as it relates yesterday to the administration's proposal as well as – hopefully you saw as well that Pharma put forward some new principles that the Pharma members will be adhering to, we really believe that patients should have access to the information that is helpful and that they can use to make the best decisions regarding their health. And so this does include greater transparency around healthcare costs.

And so we've been a leader in transparency to date. That's why we provide information about how we price our medicines and how we invest our resources in our annual U.S. Transparency Report. So we are absolutely working in partnership with Pharma. Around Pharma's announcement yesterday and what we can do on DTC pricing, this has been done in line with what we learned from customers and patients and what they think is actually going to be helpful, which is not only information on list pricing, but also putting that information into the right context. So what that actually means for them since list price is really just a starting point.

So for patients, what is their likely out-of-pocket cost going to be? What type of financial assistance is available in addition to information like the list price? So we're going to respond to the agency's proposal. There are 60 days. We're going to go ahead and respond to that and provide our input. In the meantime, go ahead and implement what we're executing and what we're doing in line with Pharma on that.

Again, I think anything that is helpful and useful to patients and helps put all the information in context is going to be really good for them. I think we just need to be careful of things such as list price alone is not the full extent of the information, and we would worry about patients not going to their doctor to seek care, not going in for their appropriate treatments. So we believe we're doing the right thing with the Pharma proposal and we'll just have to wait and see what happens with Secretary Azar's proposal that he announced yesterday.

A - Chris DelOrefice {BIO 20730104 <GO>}

Yes. And regarding DARZALEX, it's a 2019 filing. It's an event-driven – so that's all we're sharing at this point in time.

A - Jennifer Taubert {BIO 20108880 <GO>}

And we're very optimistic about that data and we think it'll be an important further catalyst for DARZALEX, is that data will be the regimen that is most commonly used in the United States. So we already have that frontline data in use with VELCADE, ex-U.S., as well as approved in the U.S. We think the data, including REVLIMID, is going to be really important going forward for the U.S. market.

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

Okay. Thanks so much.

Operator

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

Q - Bob Hopkins {BIO 6184955 <GO>}

Oh, thank you very much, and good morning. Joe, if okay, I wanted to ask you a quick question on emerging markets. Obviously, emerging markets have been in the press quite a bit lately, both in terms of the volatility of currency and emerging market economies. So I'm just curious, can you give us a sense in the – in your third calendar quarter kind of what happened to your businesses in emerging markets? Maybe some flavor by division if okay, just in terms of did anything really change in terms of underlying demand or the growth rates that you achieved in emerging markets in your three big divisions? Thank you.

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

Yeah, thanks for the question, Bob. So in our emerging markets, we saw very healthy growth. In total, it's about – on an operational basis, almost 13%, and it was pretty uniform across the board. I would say BRICs specifically was very strong, with 15% or better growth in Brazil, Russia and China. Maybe I can turn it over to Jorge because we did see some particular strength out of our Consumer business and maybe just talk about the Consumer results at large in the third quarter. Obviously, that was a significant step change for us, performing what we believe is going to be twice the market. And Jorge, maybe if you can share a few of those thoughts?

A - Jorge S. Mesquita {BIO 1871463 <GO>}

Sure. Thanks, Joe. Yes, we feel very good about our results in the third quarter, growing overalls north of 6% organically. And, as Joe mentioned, the emerging markets, where it contributed to this growth, growing above 10% across the key geographies. Particularly, we saw a very strong performance in the BRIC markets and we continue to expect that over time the emerging world will continue to grow at twice the rate of overall – of our business at a global level.

Underpinning our performance was a significant improvement in our Baby Care business. We're very pleased with the early results coming out of our restage here in the United States. And, as Joe mentioned, we're now going to roll that out across the world, starting with India and China and we expect to complete the global rollout across the emerging world into 2019. So we are - despite the occasional volatility in some punctual markets, I think overall we're bullish on the outlook for the emerging world as we go forward.

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

Great. Thanks, Jorge.

Q - Bob Hopkins {BIO 6184955 <GO>}

Yeah, that's super helpful. Maybe just, Joe, one quick follow-up on that, so it sounds like underlying demand is very strong across the board, especially, as you mentioned, Consumer. But given the volatility in emerging market currencies, maybe just qualitatively or quantitatively as you look forward, is that a meaningful headwind to reported EPS as we look forward, given the volatility? Or is that something that's in your mind very manageable relative to all the different moving pieces that are involved with the J&J income statement?

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

Yeah, Bob, it's a good question. I would think it should be a manageable headwind and obviously it's going to depend on how much currencies fluctuate. But we're not overly tied to currencies in emerging markets, so it should be manageable.

Q - Bob Hopkins {BIO 6184955 <GO>}

Terrific. Thanks for taking the questions.

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

I just want to take a moment here to follow up maybe on Jennifer's comments with respect to Secretary Azar's proposal and just be very clear that we support the administration's spirit of transparency and getting more information out there. I think the position of pharma right now is we want to make sure that we provide that information in a way that's meaningful and provides clarity to patients. Having list price on DTC ads could be somewhat confusing and actually act as a deterrent to good responsible healthcare, and we just want to make sure that that doesn't play out that way. But certainly looking to digest the proposal and put it into practice the best way possible, that's meaningful for patients and the healthcare system.

Operator

Your next question comes from Geoff Meacham with Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Morning, guys. Thanks for the questions, just had a few for Jennifer and maybe Joe, too. To revisit the 2019 question, I know you guys haven't given a formal view, but just given the headwinds on Pharma organic growth from ZYTIGA and the other LOEs, if you're not above market growth, does that change strategic priorities, either your attitude towards deals or investments across different therapeutic categories? And I have one follow-up.

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

Yeah, so, Geoff, maybe the first thing is to clarify the question in that we currently believe we are the holder of a strong patent and we plan to defend those rights. We're looking forward to the judge's decision later this month. But, as Jennifer indicated, our growth, even without ZYTIGA, was very strong. There are some potentially generic headwinds on the horizon. Should that, for some reason, put us below market, which is not something that other companies face given the breadth of our portfolio, we've got 12 brands in Pharmaceuticals that deliver better than \$1 billion in revenue. We can absorb that. So, we're not in a situation where we're going to take a year or two off from growth and anything that's at market is probably only temporary, because we've got good confidence in our pipeline going forward.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay. That's helpful, Joe. And then, a few product-specific questions for Pharma, for DARZALEX, how has the duration of therapy been tracking? And how do you guys see the refractory myeloma space evolving when you look at the cell therapies for BCMA? And then on XARELTO, just want to get a sense for the feedback from the field following MARINER and COMMANDER since ESC, just trying to put these data in context of the overall brand. Thanks.

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. I can start off on the XARELTO piece. So, we just got approval last week for CAD and PAD and the team is actually out launching it as we speak, so product is in the market and the teams are out in the market launching and bringing XARELTO and the 2.5-milligram dose to patients. And so, we're really excited about the opportunity to expand XARELTO as the first Factor Xa inhibitor in the CAD/PAD space, which expands the opportunity by, I think, 13 million additional patients in the U.S. alone and the data is quite striking in that indication, 24% reduction in CV death, stroke and heart attack. So we're really very optimistic about this launch for XARELTO.

As it relates to MARINER and the data that we have across the medically-ill space, we are working with the agency on that and do believe that there's a good path forward in that space for XARELTO. So, probably can't say any more than that on that right now, but we will be continuing to pursue that with the FDA going forward. So, we believe there's good reasons for future growth in XARELTO, as well as continued growth and share gains in both the AFib and DVT prevention and treatment space.

And the other question was on sort of CAR T and DARZALEX?

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

Around DARZALEX and CAR T and how they might play together?

A - Jennifer Taubert {BIO 20108880 <GO>}

Yeah, so, we actually think that they're complementary in the multiple myeloma space and so we're very excited about CAR T. We've dosed our first patient already, which is a very, very fast timeline versus when we did that deal with Legend. I think if you take a look at the unmet medical need, in multiple myeloma, there is - it still remains significant need, and so I think having both DARZALEX as well as what we've got with the BCMA, CAR T together will be a nice portfolio for patients, which will allow us to continue to grow.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay. Great. Thank you.

A - Chris DelOrefice {BIO 20730104 <GO>}

So great. So that concludes today's Q&A portion. Thanks to everyone who asked a question today and apologies to those who we could not get to due to time. Please don't hesitate to reach out to the Investor Relations team as is needed with any follow ups.

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

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

Great. Thanks, Chris. Thank you, Ashley, Jorge, Jennifer for sharing your insights on our business and delivering with your team's very strong results for the third quarter. I hope it is clear to you in the investment community that our business is very strong and we look forward to living into the new guidance that we have articulated earlier today for 2018. Thanks for your interest in Johnson & Johnson and we look forward to speaking with you soon. Have a good day.

Operator

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

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