Q3 2019 Earnings Call

Company Participants

- Ashley McEvoy, Executive Vice President, Worldwide Chairman, Medical Devices
- Chris DelOrefice, Vice President of Investor Relations
- Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals
- Joseph J. Wolk, Executive Vice President and Chief Financial Officer
- Thibaut Mongon, Executive Vice President, Worldwide Chairman, Consumer

Other Participants

- Bob Hopkins, Analyst
- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- David Lewis, Analyst
- Jayson Bedford, Analyst
- Joshua Jennings, Analyst
- Kristen Stewart, Analyst
- Lawrence Biegelsen, Analyst
- Matt Miksic, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning. Welcome to Johnson & Johnson's Third Quarter 2019 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. (Operator Instructions).

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

Chris DelOrefice {BIO 20730104 <GO>}

Good morning. This is Chris DelOrefice, Vice President of Investor Relations for Johnson & Johnson. Welcome to our Company's review of business results for the third quarter of 2019. Joining me on today's call is Joe Wolk, Executive Vice President, Chief Financial Officer. Additionally, during our Q&A session, Joe and I are pleased to be joined by Ashley McEvoy, Executive Vice President, Worldwide Chairman, Medical Devices; Thibaut

Mongon, Executive Vice President, Worldwide Chairman, Consumer; and Jennifer Taubert, Executive Vice President, Worldwide Chairman Pharmaceuticals.

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 2018 Form 10-K and our most recent 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.

Moving to today's agenda, Joe will first provide some perspective on our overall results for the third quarter. I will then review the sales and P&L results for the corporation and the three business segments. Joe will conclude by providing insights about our cash position, capital allocation deployment and our updated guidance for 2019, along with some considerations for the balance of this year and initial high level thoughts for next year. The remaining time will be available for your questions. We anticipate the webcast will last about 75 minutes.

I'm now pleased to turn the call over to Joe Wolk.

Joseph J. Wolk {BIO 19812977 <GO>}

Great, Chris. Good morning, everyone. Thank you for your interest in Johnson & Johnson. As you might suspect, we're very pleased to discuss our strong third quarter results. Our performance positions us well to exceed the 2019 outlook we provided at the start of the year, providing us with a solid foundation for the future.

During the quarter, we delivered strong revenue and earnings growth, while also making investments that advance our innovative pipeline across all three segments. We remain committed to advancing solutions that enhance the lives of patients, consumers, employees and communities, while also delivering value to our shareholders.

In a moment, Chris will provide details on our results. But before he does, let me offer some general observations and context about the performance in the third quarter.

While there are many headlines surrounding our Company as well as the industry, we continue to deliver lifesaving and life-enhancing products to patients and consumers,

which translates into solid financial performance. We must recognize that businesses in the US are working in a very litigious environment. But the fundamentals of Johnson & Johnson's business are strong. We remain confident in our ability to navigate challenges and deliver results, focused on our mission, as we have done for 133 years.

For the quarter, our Pharmaceutical business, even in the face of significant generic and biosimilar competition, once again delivered above market performance across a broad base of therapeutic areas, led by double digit growth in 10 key products. We are particularly pleased by the progress in the quarter of regulatory approvals and submissions, notably the FDA's approval of ERLEADA, for the treatment of metastatic castration-sensitive prostate cancer, based on the TITAN data. And the approval of STELARA in ulcerative colitis in the EU, additional indications for both of those products.

In our Consumer Health business, third quarter performance reflects continued strength in areas we prioritized earlier this year, beauty and over-the-counter medicines. These businesses are fueled by new product innovations and recent acquisitions in large markets experiencing higher growth, which positions the Consumer business to grow competitively with the market, while also improving the profitability of this segment.

Our Medical Device business continues to accelerate growth. We had some tailwinds that Chris will outline, but the adjusted operational sales growth was the best quarterly growth we posted since 2015. Interventional solutions delivered yet another quarter of double-digit growth. Surgery improved, and orthopedics progress continues. We successfully executed multiple launches in the quarter, and we believe we are well positioned to continue the momentum.

Let me turn the discussion back to Chris for details on the third quarter sales drivers and notable line items in our P&L, I will return prior to the Q&A to provide comments on our cash position and guidance.

Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Joe. Worldwide sales were $20.7 billion for the third quarter of 2019, an increase of 1.9% versus the third quarter of 2018. Operational sales growth, which excludes the effect of translational currency, increased 3.2%, as currency had a negative impact of 1.3 points. In the US, sales increased 1.2%. In regions outside the US, our reported growth was 2.6%. Operational sales growth outside the US was 5.4%, with currency negatively impacting our reported OUS results by 2.8 points. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 5.2% worldwide, 3.4% in the US, and 7.3% outside the US.

Turning now to earnings; for the quarter, net earnings were $4.8 billion, and diluted earnings per share was $1.81 versus diluted earnings per share of $1.44 a year ago. Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were $5.7 billion and adjusted diluted earnings per share was $2.12, representing increases of 1.5% and 3.4% respectively compared to the third quarter of 2018. On an operational basis, adjusted diluted earnings per share grew 5.9%.

Beginning with Consumer Health; I will now comment on business segment sales performance for the third quarter, highlighting items that build upon the slide you have in front of you. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the third quarter of 2018, and therefore, exclude the impact of currency translation.

Worldwide Consumer segment sales totaled $3.5 billion, growing at 3.3%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 1.3%, with strong growth in the US of 2.4%, due primarily to strong performance in our beauty and OTC franchises.

Growth outside of the US was 0.6%. On a year-to-date basis, consumer grew double-digits across all regions in the e-commerce channel. The beauty franchise grew 8.1% or 2% adjusted to exclude the impact of the acquisition of Dr.Ci:Labo and the RoC divestiture.

Our priority brands, Neutrogena and Aveeno delivered strong performance results, due to share growth combined with timing of promotions in our club channel in the US. Share growth in Neutrogena was realized in the facial moisturizing treatment, cleansing and sun protection categories and Aveeno share gains were due to the hair product line relaunch.

Over-the-counter medicines grew 6.5% globally or just over 5%, when adjusted to exclude the impact of the Zarbee's acquisition, which continues to perform well. In the US, OTC adjusted operational sales growth was just over 5% and is growing share. Adult TYLENOL was the core contributor to sales growth, and continues to drive significant share growth driven by rapid release gel, and TYLENOL arthritis products.

ZYRTEC continued to grow market share. However, sales declined due to lapping 2018 retail stocking, due to a competitor supply disruption. Concluding the Consumer segment, Baby Care declined 9.8% globally or negative 8% when adjusted to exclude the impact of the BabyCenter divestiture. This decline was primarily due to lapping retail stocking, associated with the Johnson's Baby relaunch, most notably in the US. Excluding the relaunch comparisons, US Baby was flat.

Moving on to our Pharmaceutical segment; worldwide Pharmaceutical sales of $10.9 billion grew 6.4%, enabled by double-digit growth in 10 key products. Sales grew in the US by 4% and increased outside the US by 10%. Generic competition for ZYTIGA negatively impact our worldwide and US growth by about 350 and 560 basis points respectively.

Our strong portfolio of products and commercial capabilities has enabled us to deliver global growth at above market levels, despite significant biosimilar and generic headwinds. Our immunology portfolio delivered global sales growth of just over 10%, driven by strong double-digit performance in STELARA, TREMFYA and SIMPONI, SIMPONI ARIA.

Sales growth was partially offset by continued erosion of REMICADE of almost 17%, due to increased discounts and modest share loss in the US to alternative mechanisms of action

and biosimilars. STELARA growth of almost 31% was primarily from the Crohn's Disease indication, where market share has increased by over 6 points in the US, compared to the third quarter of 2018. TREMFYA grew over 70% and achieved an 8.1% share of the psoriasis market in the US, which is up about 2.5 points from the third quarter 2018. Additionally, we filed an application to the US FDA, seeking approval of TREMFYA, for treatment of adults with active psoriatic arthritis.

Our oncology therapeutic area, delivered another strong quarter, with worldwide growth at almost 9%. DARZALEX continued its strong performance, growing about 57% globally, or about 42%, when adjusting for the impact of a favorable comparison to the prior year one time reimbursement adjustment outside the US. The US grew just over 26%, and continues to benefit from strong market growth, and about a 3.5-point increase in US market share across all lines of therapy. The continued strong growth outside the US is driven by increased penetration and share gains across the 41 EMEA countries, where it is commercially available, as well as Latin America and the Asia-Pacific region.

Of note, we received regulatory approval for DARZALEX combination regimen for newly diagnosed transplant eligible patients with multiple myeloma in the US. IMBRUVICA grew 33.5% globally, driven largely by market share gains and strong market growth, primarily in the CLL indication in the US, along with strong uptake outside the US in the European, Asia Pacific and Latin America markets.

In the US, based on second quarter data across all indications and lines of therapy, IMBRUVICA gained approximately 2.5 points of market share and continues to be the new patient and total patient share leader in chronic lymphocytic leukaemia, which gained above 8.5 points of market share in line one therapy. Worldwide ZYTIGA growth declined by about 21%, with declines of almost 56% in the US, due to generic competition, which was partially offset by continued strong growth of about 21% outside the US.

In non-metastatic castration-resistant prostate cancer, we continue to be pleased with the launch progress of ERLEADA, which gained almost three points of market share in the US. As Joe highlighted, during the quarter, we received approval in the US for treatment of patients with metastatic castration-sensitive prostate cancer. We are also pleased with the launch progress in EMEA, where ERLEADA is now available in eight countries.

In neuroscience, our Paliperidone long-acting portfolio performed well, growing 15%, with higher market share driven by increased new patient starts and strong persistency. In addition, we continue to progress the launch of SPRAVATO. Patient demand is strong, and the unmet need remains very high. To date, over 2,000 sites have been certified in the REMS program to become a SPRAVATO treatment center, and more than 500 of these are actively treating patients, with treatment resistant depression. We are encouraged by the continued progression of treatment centers being certified and treating patients.

During the quarter, we filed an sNDA in the US, for a second indication for the rapid reduction of depressive symptoms in adults with major depressive disorder, who have active suicidal ideation with intent. In infectious diseases, our portfolio grew 3.6%, led by

strong growth of SYMTUZA and JULUCA for HIV, partially offset by cannibalization and increased generic competition in other products.

In our cardiovascular, metabolism and other product portfolio, we did experience declining sales of 4.8%, primarily driven by declines in INVOKANA and biosimilar competition for PROCRIT. XARELTO was flat, with volume increases offset by rebates, primarily due to increase in the legislative rate for the doughnut hole from 50% to 70%, along with higher Medicare and doughnut hole utilization. And just yesterday, we were pleased to announce the US approval of an additional indication for XARELTO for the treatment of VTE in a medically ill population.

Our total pulmonary hypertension portfolio grew by 0.5%, with strong performance in both OPSUMIT and UPTRAVI, growing by about 13% and 24% respectively on a global basis. Both benefited from further market penetration and increased share. This growth was offset by TRACLEER, which was negatively impacted by the recent generic entry in the US, as well as continued generic competition outside of the US.

I'll now turn your attention to the Medical Devices segment. Worldwide medical devices sales were $6.4 billion, declining 2%, excluding the net impact of acquisitions and divestitures, primarily the divestitures of LifeScan and ASP, adjusted operational sales growth was 5.3% worldwide. Growth in the quarter was aided by one-time items, contributing about 80 basis points to growth, largely related to forward buying ahead of the consumption tax change in Japan, primarily impacting our Vision business. We expect the majority of this to sell-through in Q4, with the remainder occurring in Q1 2020.

Interventional solutions grew over 14% globally, led by continued strength in our electrophysiology business, achieving about 15% growth worldwide, continuing its trend of double-digit growth. Growth was strong in all regions, driven by our newer product offerings in ablation and advanced catheters, contributing to atrial fibrillation procedure market growth.

During the quarter, we were pleased to share the results of the Atrial Fibrillation Progression Trial, known as ATTEST, which show that patients treated with catheter ablation, are almost 10 times less likely to develop persistent atrial fibrillation, than patients on standard antiarrhythmic drugs at three years after study initiation.

Additionally our Cerenovus business delivered a fifth straight quarter of double-digit growth, driven by new product innovation, including EMBOTRAP for the treatment of ischemic stroke, as well as strong market growth. Vision growth of 6.1% was driven by contact lenses, which grew 7.6% globally, led by daily disposables in the Oasys family. As I mentioned earlier, total Vision sales were aided by a forward buy in Japan, in advance of a consumption tax increase worth approximately 300 basis points globally. In surgical vision, we launched our TECNIS Synergy Intraocular lens, a continuous range of vision intraocular lens.

Orthopedics growth continues to improve with significant acceleration in the quarter, delivering growth of 2.3%, its largest quarterly growth since 2016. This progress reflects

the continued execution of our innovation and commercial strategies, aimed to improve performance.

Hips grew 2.9%, driven by our leadership position in the anterior approach, continued strong demand for our primary stem ACTIS, and the concise surgical automated system. Trauma growth of 4.7% globally was driven by market growth, supported by strong adoption of newer innovation, such as our Femoral neck system and Recon Nails. Sales growth was also aided by a one-time rebate reserve adjustment in the US, worth almost 90 basis points globally.

Adjusting for this item, as the market leader in trauma, we are driving growth and expect our performance to represent growth in line with the overall global market.

Spine declined less than 3% with the US being the primary driver of decline. While we continue to see stabilization of performance, driven by new products, such as the VIPER PRIME system for minimally invasive surgery, and our newly launched conduit interbody platform with EIT cellular titanium 3D printed technology to treat degenerative spine disease, we lost share in the quarter.

Knees growth was 2.3% in the quarter, with declines in the US, offset by strong double-digit growth of 10.8% outside the US. OUS. results are expected to represent above market performance, led by new innovation including ATTUNE Revision and S+. The US market continues to realize positive uptake from the ATTUNE Revision system, and this quarter we launched the ATTUNE cementless knee in the US and other select markets around the world.

Pricing pressure continued to impact all categories in orthopedics, but did show modest improvement compared to Q2. However, US pure price was negative across all platforms for the quarter. Spine, hips and trauma all declined approximately 2%, with knees declining about 1%.

Moving to the results for the surgery business, advanced surgery delivered global growth of over 5%, led by strong performance in energy of 8%, primarily driven by share gains and new products in the Asia Pacific region. Biosurgery grew approximately 5%, with growth in all regions, particularly the Asia Pacific region.

We were pleased to have brought SURGIFLO back to the market in the US at the end of July, with that one month of being off the market in the quarter impacting global growth by about 100 basis points. Wound closure grew almost 5%, driven by share gains in conventional and barbed sutures and continued strong market growth in China. Timing of purchases in the veterinary channel favorably impacted global growth by almost 100 basis points. Additionally, we launched the industry's first powered circular stapler for colorectal, gastric and thoracic surgery, a key innovation for us in our general surgery franchise. As expected, selling days had a minor positive impact on our global growth rates in the third quarter, and we do not expect a significant impact in Q4.

I would now provide some commentary on our earnings for the quarter. Regarding our consolidated statement of earnings for the third quarter of 2019, please direct your attention to the box section of the schedule. As referenced in the table of non-GAAP measures, the 2019 third quarter net earnings are adjusted to exclude intangible asset amortization expense and special items of $0.8 billion on an after-tax basis, primarily driven by intangible amortization of $1 billion.

Excluding the impact of those items, our adjusted earnings per share is $2.12, an increase of 3.4% versus the third quarter 2018. Adjusted EPS on a constant currency basis was $2.17, up 5.9% versus third quarter 2018.

I'd like to now highlight a few noteworthy items that have changed on the statement of earnings compared to the same quarter last year. Cost of products sold delevered slightly, primarily driven by negative impact of currency in the Pharmaceuticals business. Selling, marketing and administrative margins for the quarter improved, as a result of favorable segment mix, plan prioritization in the consumer and medical devices businesses, as well as expense leveraging in the Pharmaceuticals business.

We continue to invest in R&D at competitive levels, and our investment in research and development this quarter as a percent of sales was 12.5%, which is higher than the third quarter 2018 by 20 basis points. This increase was primarily driven by higher investment in our Medical Devices business, related to robotics, digital programs, and key growth platforms.

The change recorded in the other income and expense line was primarily driven by a contingent liability reversal in the third quarter of 2018. Net interest expense was lower by $109 million, primarily driven by the positive effect of net investment hedging arrangements, and lower interest expense, due to a lower average debt balance.

Regarding taxes in the quarter; our effective tax rate was 14.4% compared to the third quarter of 2018 tax rate of 11.1%. As a reminder, regarding the third quarter of 2018, the Company recorded a favorable financial impact of approximately 9% related to US tax reform. The current quarter includes an estimated tax benefit for the transition provisions of Swiss tax reform, partially offset by an adjustment to existing tax reserve positions, negatively impacting the effective tax rate. We encourage you to reference our 10-Q for further details on this and other specific tax matters.

Excluding special items, the effective tax rate was 20.3% compared to 17.6% in the same period last year. The increase was driven by the adjustment to tax reserve positions previously noted.

Now looking at adjusted income before tax, in the third quarter of 2019, our adjusted income before tax for the Enterprise as a percent of sales increased from 33.3% to 34.3% in 2019, primarily driven by improvement in selling, marketing and administrative margins for the quarter as previously noted.

The following are the main drivers of adjusted income before tax by segment. The decrease in Pharmaceutical margins by 180 basis points, was primarily driven by the negative impact of currency in cost of goods sold. Consumer margins improved by 450 basis points, primarily due to planned optimization of selling and marketing expenses.

Medical Devices improved by 220 basis points due to investment optimization in selling, marketing and administrative expenses and other income items, which were partially offset by R&D investment in robotics and digital surgery solutions.

That concludes the sales and P&L highlights for Johnson & Johnson's third quarter 2019. For your reference, here is a slide summarizing notable developments occurring in the third quarter, some of which were mentioned in my comments.

I will now turn the call back to Joe.

Joseph J. Wolk {BIO 19812977 <GO>}

Thanks Chris. With respect to cash at the end of the third quarter, we had approximately $11 billion of net debt, consisting of approximately $18 billion of cash and marketable securities and approximately $29 billion of debt. We estimate our year-to-date free cash flow to be approximately $14.5 billion. We acted upon all four tenets of our capital allocation strategy, which are designed to and continue to drive shareholder value.

Some of the highlights include, investing $2.6 billion in research and development in the quarter. Investing in our business to deliver transformative healthcare solutions remains a top priority at Johnson & Johnson. As in previous years, we expect to experience even higher levels of investment during the fourth quarter.

Some tangible examples of where this investment will be directed will be progressing our future digital surgery offerings, and R&D activity related to CAR-T, cusatuzumab, DARZALEX subcutaneous formulation, and line extensions within the immunology portfolio, such as STELARA in lupus.

At the same time, we continue to evaluate strategic transactions, that will further enhance our broad-based business and drive value creation, having invested nearly $6 billion this year. We also used cash in the quarter to complete the authorized $5 billion share repurchase program announced just last December, the $1.2 billion in the third quarter.

I will now provide updates to our guidance for 2019. We continue to see strong results across our enterprise. As such, we are increasing sales guidance and are now comfortable with your models reflecting operational sales growth of 2.5% to 3.0% for the year. This growth would result in sales for 2019 on a constant currency basis of approximately $83.7 billion to $84.2 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.

Both metrics are up over 200 basis points at the respective midpoints from the original guidance we provided in January, and over 100 basis points from the guidance we

provided last July.

Although we are not predicting the impact of currency movements, utilizing the euro spot rate relative to the US dollar as of last week at 1.10, the negative impact of foreign currency translation is slightly worse than our last guide by 20 basis points, and is estimated to negatively impacted reported sales by approximately 2.3 points. Under this scenario, we expect reported sales growth in the range of 0.2% to 0.7% or approximately $81.8 billion to $82.3 billion .

Moving to items impacting earnings; net interest expense is now expected to be net interest income of $50 million to $100 million. For other income and expenses, we are tightening the range to $2.75 billion to $2.85 billion. 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.

Our effective tax rate guidance for 2019 is now estimated to be approximately 18.0% to 18.5%, reflecting the higher end and a tightening of the previous guidance range.

Given those updates, we are now comfortable with the adjusted EPS guidance in the range of $8.84 to $8.89 per share on a constant currency basis. This reflects operational or constant currency growth of approximately 8.1% to 8.7%, which is higher than our prior guidance and reflective of our solid performance this year. Again, 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 negatively impacted by approximately $0.22 per share versus prior guidance of negative $0.20.

Accounting for that, our reported adjusted EPS would range from $8.62 to $8.67 per share, reflecting growth of approximately 5.7% at the midpoint, which is also higher than our previous guidance. While we do not provide quarterly guidance and are not providing guidance for next year just yet, I will provide a few comments for you to consider looking ahead, both for the fourth quarter as well as for 2020, to better inform your modeling.

One notable item for the fourth quarter of this year, you may recall that in the fourth quarter of 2018, we had an elevated level of adjusted other income of approximately $800 million, primarily due to the LifeScan divestiture. There is nothing similarly planned for the fourth quarter of this year. Looking beyond the fourth quarter, we are still in the process of finalizing our 2020 plans. But allow me to provide some context from line items where we have some preliminary insights.

Qualitatively for sales, we expect our Pharmaceutical business to continue to deliver growth above market. Our Medical Device business is anticipated to continue sales momentum, and we remain focused on optimizing our consumer portfolio for competitive growth, while improving profitability. In terms of items on the P&L, again, robust plans are still being developed by our leaders, but we will continue to balance improved operating efficiency with investing for sustainable long-term success.

For other income and expense at this early stage, we expect at this time to record approximately half the level of income, just provided in our current 2019 guidance range. We continue to prefer investment in R&D to progress our robust pipeline of assets. This includes continued investment in our digital surgery portfolio, which was bolstered by the acquisition of Auris that we completed in the second quarter of 2019.

For the effective tax rate, based on current legislation, we anticipate the range being relatively similar to the 2019 full year tax guidance I provided earlier, 18.0% to 18.5%. And while we don't forecast currency fluctuations based on current exchange rates, we expect currency to continue to be a headwind, although less than this year's impact.

That concludes our financial summary. I am pleased to be joined on today's call by Ashley, Thibaut and Jennifer to help me address your questions. Before we open up the call for Q&A, I would like to thank our Johnson & Johnson associates around the world for their continued hard work and dedication. We celebrated the 75th anniversary of our initial public offering at the New York Stock Exchange in September, a significant milestone made possible by their tremendous efforts and those who proceeded them.

I will now turn the call back over to Chris to begin the Q&A portion.

Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Joe. We will now move to the Q&A portion of the webcast. As a reminder, I would encourage you to take advantage of Ashley, Thibaut and Jennifer being on today's call, by directing questions to them about their areas of expertise.

Operator, can you please provide instructions for those on the line wishing to ask a question?

Questions And Answers

Operator

(Operator Instructions). Your first question comes from David Lewis with Morgan Stanley.

Q - David Lewis {BIO 15161699 <GO>}

Good morning, and thanks for the questions. Maybe just Joe, one for you and then one for Ashley. Joe, this is a greater level of financial disclosure we typically get heading into 2020. So thank you in advance. Just doing some quick math here, it does sound like you're basically suggesting for 2020 outlook, by not providing official guidance, Top line should accelerate into next year, and you're pretty comfortable with that kind of relative type of leverage J&J has done historically, which is sort of a earnings growth rate kind of in the 1.5 ratio at earnings relative to sales. Is that a decent way of thinking about 2020?

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

Yeah, so David, thanks for the comments. Certainly glad that you find some of the outlook commentary helpful to you. I do want to emphasize though what I said in the prepared remarks in that its -- our teams are still working through their plans for 2020. We want to see the momentum that we've seen through this year carry on through.

With respect to top line, I would say if you recall back in January, we were a little bit more conservative with this year's outlook, given some of the ability to hold on to brands that were facing exclusivity risk, ZYTIGA, PROCRIT, TRACLEER. We performed a little bit better. So we do expect to be above market, but just not as pronounced as we would have thought in the beginning of this year for 2020. But we're feeling very good about the momentum.

With respect to the income ratio to sales growth ratio, I'd say that's a little bit early to comment on. I would expect to see some moderating, more back towards -- around sales growth. This year if you look at it, let's just take adjusted -- to adjusted. So accounting for divestitures and acquisitions impact. It's a 1.8 ratio. That's a little bit higher than we typically run at and then obviously we're going to digest a pretty significant hit on the other income line.

So again, the team is working through the plans. We do have ambitious goals for next year. And what I would say is, stay tuned, is probably the best direction I can give you at this point in time.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Maybe just two quick follow-ups, Joe. The first is for you on the repo -- you completed the repo this quarter. Just given the operational performance of J&J and the Company's historical discount, what are you thinking now with the share repo completed going forward? And then Ashley, just real quickly, can you just talk a little bit about the US market dynamics within Vision? Two specific dynamics. You talked about pressure in the surgical business, to what extent is that IOL dynamics in the marketplace versus the LASIK franchise? That'd be super helpful. Thanks so much.

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

So David, with respect to the share repurchase, we are pleased to have the $5 billion Board authorized program completed. It continues to be one of the four pillars within our capital allocation strategy. I would say in terms of pecking order, as you know, having covered us for years, it's probably the least of our preferred options. Although it is still an option, simply because it doesn't provide us capabilities going forward.

But we'll continue to evaluate that along with the dividend increase, the investment in R&D, as well as opportunistic acquisitions that make sense from a value creation standpoint, but also a really good strategic fit that expand our portfolio.

A - Ashley McEvoy {BIO 20108895 <GO>}

And thank you, David for the question on Vision. But before I get to that, I have to first acknowledge kind of the strong quarter for Medical Device in quarter three growing 5.3%. And as Chris had mentioned, we did experience some forward buying and the Japan

consumption. So if you take that out, we're looking at around 4.5% growth, which is the strongest that we've had in four years.

So as you know, we've been on this journey since 2017 to really enhance our performance year-over-year. And when we look at '17, we exited 1.5% growth on revenue and '18 we exited 2.6%. And in 2019 to date we're tracking to a little bit north of 4%. So as I always say, I don't think our growth is going to be linear, but I do think that we've turned the corner, and that really is due to -- predominantly in the near term, the strategic choices that we're making to strengthen our competitiveness. And it's really about this very strong seasoned leadership team. They have got five quarters underneath them, and a very, very strong focus on execution. So I think this is starting to have an effect.

So to your question on Vision, Vision had a good quarter. I would say contact lenses in particular had a very healthy quarter, really driven by very strong growth in the United States of around 6%. In surgery, we had very strong outside of US performance double digit. The US surgical business is challenged really due to two front. Number one, some competitive inroads and we are working to strengthen our commercial execution. In US, we strengthened that leadership team, revisited our programs and we also are accelerating some innovations. We expect to have three meaningful innovations in premium IOLs and monofocal IOLs over the next 18 months.

And to your earlier point, yes, we do believe that we've seen some softening in the LASIK market in the United States. Thanks for the question. David.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thank you, David. Appreciate the question. Rob, next question please.

Operator

Your next question is from Chris Schott with JPMorgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks very much. Just two questions here. Maybe first, can you talk about TREMFYA dynamics, particularly relative to SKYRIZI? The product obviously -- TREMFYA obviously ramping nicely. I know there is some investor concern though that, that ramp could be impacted by a strong launch from your competitors. So just how you think about price and volume for that business going forward?

The second question was on liabilities. It seems like kind of these -- liabilities have somewhat dominated the narrative for the J&J story this year. What do you think the Company can do to address that overhang, and what's the Company's approach towards settlement? Because it seems like right now the mix of opioids, talc and some others have overshadowed, what seem to be very strong underlying fundamentals of the Company. Thank you.

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

So Jennifer, why don't you address Chris's question around TREMFYA, maybe you can give him some Pharmaceutical perspective, and then I'll take up the litigation matters

A - Jennifer Taubert {BIO 20108880 <GO>}

Hi Chris and good morning everyone. First off, it was a really strong quarter for the Pharmaceutical Group, and I just wanted to highlight a couple of key points. The first being, sales of $10.9 billion, 6.5% operational growth. This was our sixth consecutive quarter with sales above $10 billion, and if you take a look at our growth excluding ZYTIGA, it was 10% and also with very strong contribution from the US and the international markets, where actually we had 10% growth outside of the US as well.

Our growth was broadly based with 10 of our key brands growing at double-digit rates, which more than offset the erosion due to biosimilars in generics. Overall, our immunology business was up 10%, our oncology business, up 9%, and Neuroscience, up 8%. A few notable call-outs, STELARA had 31% growth, DARZALEX had 57%, IMBRUVICA 33% growth, TREMFYA, which I'll come back to, 70% growth, INVEGA is down at 15% and ERLEADA, 95% growth, So very strong performance across our base of business and across our key growth drivers.

Additionally, it was a really nice quarter for the progression of our pipeline, and we had a number of significant approvals, as well as filings that are worth calling out. Most recently as of last Friday, we got approval for XARELTO to help prevent VTE in acutely medically ill patients. We got approval for INVOKANA for the treatment of diabetic kidney disease. DARZALEX, we got approval for the combination regimen in newly diagnosed transplant eligible patients, and for ERLEADA, we got approval for treatment of metastatic castration-sensitive prostate cancer, which expands our opportunity for that product, so that it's not only in the non-metastatic space, but into the metastatic space as well.

We also had a number of regulatory submissions and two breakthrough designations that were granted. So strong performance for our key growth drivers, and good reasons for optimism on our pipeline progression as well.

In terms of TREMFYA; our TREMFYA business grew 70% versus the third quarter, and in addition, we filed an application for use in active psoriatic arthritis in August. And so to date, we're really pleased with the launch progress and the trajectory. Based on the strength of the profile of the product that we've got, coupled with very strong longevity data that we have, we believe that we've got a really competitive offering, that IL-23 is the right mechanism for psoriasis and other areas that we're exploring, and also, that we've got a very, very strong package to drive continued growth.

I think in these settings before, we've discussed the strength of the package that we have with superiority data versus three separate mechanisms. So approval versus -- in our label, superiority data versus Humira as an anti-TNF, versus STELARA non-responders with IL-12/23 mechanism. And then our most recent data versus Cosentyx, which is an IL-17 and PASI 90 at week 48. And now we actually have four years of data that further demonstrates the therapeutic longevity of the asset, and that's going to be presented next week.

So when you take a look at it, we believe we've got a real competitive profile versus the IL-17. We've also got a competitive profile versus the other IL-23s, and we don't see that they're bringing anything to the market that is any different. In fact, based on the strength of our data, plus now our four year data and the strength of the access that we have in the market, we think that we're going to continue to compete very, very well in what was arguably be a very competitive space.

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

Thanks Jennifer. Chris, with respect to your second question on litigation more broadly and what can the company do, so I think it's important, without going into too deep of a litany about the cases that are out there, there's three I'd say headline grabbers that folks have taken notice of. And it is important for me to just give a brief summary of the position on each, because they are unique in their own right.

With respect to the RISPERDAL judgment that you heard last week, first of all, let's make sure people understand the benefits of RISPERDAL, what it provides for psychosis. It's for decades now been on WHO's list of most preferred medicines and the judgment itself, based on US Supreme Court precedent, would suggest it's very egregious. So we don't expect that to stand. We will appeal, certainly the amount and you can expect that to come down, should precedent hold.

With respect to opioids, you've seen two divergent paths there for us. So in Oklahoma, we thought that based on the theory of law in which was brought under in public nuisance, as well as the facts that underlie that case, where even the Attorney General of the states said many times during the court proceedings, this is not about Johnson & Johnson, it's about that there is an opioid crisis, where we have less than 1% market share. That's not just for the State of Oklahoma, but across the country.

When those facts were ignored and we couldn't find a reasonable settlement approach, we decided to pursue with that case and we are currently appealing that case and have made motions to do that.

In Ohio, you saw something different. We saw a reasonable amount in proportion to other companies that were involved as defendants. We were particularly pleased to see that the funds were going to victims of opioid addiction. And so for many reasons there, we thought the best path for all stakeholders was settlement, and that's something that we will always kind of take into account in terms of what is the best solution for all stakeholders, including investors who obviously want certainty.

Lastly was talc, this to me is probably the poster child for how big a business plaintiff's attorneys have made this type of approach. If you think about the outstanding cases, product liability cases in the US courts just today, about 50% are related to life sciences or against life science companies, when products have never been safer and have never been more effective.

The plaintiff's bar in total has spent over $400 million this year alone in advertising on TV, trying to drum up the numbers in class action suits. It's become a $36 billion industry. And what you may not realize, you'll see the headlines, certainly when verdicts are ruled

against us, and I will remind everyone that there is currently not any case that's been fully adjudicated that stands in judgment against us.

But last week alone, there were three decisions that were in favor of the company, and you don't see headlines on that. So in that case, we're going to continue to defend a product that we know to be safe, that we know does not cause cancer, and that's not just the opinions of Johnson & Johnson scientists, that's the opinion of respected institutions like the National Cancer Institute, the FDA and numerous prestigious universities.

So we'll continue to evaluate each situation for its unique merits. But what I can't underscore enough is, we've got a small great legal team working on these matters. As today's results hopefully demonstrate to all of you on the phone and anybody who's reading the press release, is that we continue to be focused as an organization of 135,000 associates, trying to bring better solutions, better innovation to healthcare. That will eventually win out. We're very strong in our conviction around that and have for 133 years. We know how to navigate these matters, and we're going to stay focused at the task at hand.

With that last point, it may be good. Sometimes we get a question, especially as it relates to talc, if there's been any overhang on the business. And for that I'd like to turn it over to Thibaut, maybe just to give some quick commentary with respect to the consumer business and whether he's seeing any impact from it.

A - Thibaut Mongon {BIO 20973347 <GO>}

Sure. Good morning everyone. The short answer is no. We do not see any significant effect across the consumer business. As Joe just referenced, our employees around the world in the consumer sector are hyper-focused on delivering personal health in a very differentiated way, with very strong brands that are rooted in science and endorsed by professionals in Q3.

As Chris highlighted earlier, we delivered solid growth in our key priority areas that we declared at the beginning of the year. You heard about 5.2% growth in OTC, 2% in beauty, strong performance by brands like TYLENOL, Neutrogena, Aveeno. Full perspective in to ground view, the baby franchise represents only 12% approximately of our revenues, and approximately 80% of those sales outside the United States, where there is less of an impact from the US events.

So you see the performance of the business. In the US, we continue to gain share. In beauty and OTC we are outperforming the market. We are well positioned in segments that are growing 2% to 2.5% in the markets and segments where we compete. You also saw that we increased our adjusted IBT [ph] significantly this year, 210 basis points, so far year-to-date at 22.4%. So we are focused on executing our strategy.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thanks Thibaut. Chris, thanks for the question, Rob, next question please.

Operator

Your next question is from Larry Biegelsen with Wells Fargo.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good morning, thanks for taking the question. One for China, -- one on China and one on MedTech for Ashley. So first on China, Joe, any color on what you're seeing across divisions there and your expectations going forward? Obviously there has been some concern about the environment in China, and just remind us of how much China accounts for as a percent of total J&J sales, and I just had one follow-up for Ashley.

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

Yeah sure, Larry. Good to speak with you. So China continues to perform extremely well for us. So if you look -- if I strip out significant divestitures of LifeScan and ASP, our overall growth was about 15%. I would say Medical Devices, which we know is the number one company for medical devices in China, we were up around 19%, 14% in Pharmaceuticals and about 5% in consumer. So very healthy across the board.

We have not seen any impacts on tariffs and we don't know of any that are pending around healthcare. So we've been fortunate in that way. We continue to monitor it. The business overall was $1 billion for the quarter. So that's I think a high watermark for that business, as it continues to go fairly strong in terms of growth levels.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

That's very helpful Joe. And Ashley, European surgery business has been growing outside the US nicely. But has been soft in the US. So my question is, what turned that around in the US, and will these recent trends continue, until you launch your surgical robot. Thanks for taking the question.

A - Ashley McEvoy {BIO 20108895 <GO>}

Thanks Larry. I mean before I kind of get specifically into kind of the surgery business, I do think it's helpful to share -- I had talked at the last quarter, some of our hotspots and how do we address some of those, and then will we look at some of the areas that are really on fire. As Joe mentioned in China, like our Asia business continues to perform double digit, and we actually performed high single-digit, if not double-digit, in all of our franchises in orthopedics, in surgery, as well as in interventional. And as I talked last time, really, the US is our largest market, how do we continue to accelerate growth there.

So I am pleased to see that year-to-date, that business is up around 2.2%, and this time last year, that number was a little bit south of 1%. And I mean, when I look at our global orthopedics business where we are, we do command the world-leading position in orthopedics, we've accelerated that revenue in 2019. So year-to-date, that business is up around 1%, really fueled by very strong quarter. In quarter three, up of around 2.3%, which is our strongest quarter since 2016, which is a growth acceleration versus a year ago, where that number was about down 1%.

So if I turn my attention to surgery, I would say our energy business has a very strong performance, really double-digit growth OUS. In the US, we will be challenged until we

get our digital surgery offerings out there. And then similarly for endocutters; endocutters globally had a softer quarter versus the second quarter, really due to some phasing between quarter two and quarter three, and due to a very healthy comp last year, where we grew 10% in endocutters.

Similarly, we're seeing very strong performance outside of the United States, high single-digit. But we are challenged versus the robotic penetration happening in the United States.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Thank you.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thank you, Larry. Appreciate the question. Rob, next question please.

Operator

Next question is from Danielle Antalffy with SVB Leerink.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning guys. Thanks so much for taking the question. I appreciate all the commentary on Medical Devices, love to see the growth this quarter. Ashley, just a quick question for you, as we think about that 4.5% growth, you talked about ex some one timers. How should we think about the sustainability of this? I know there's probably going to be volatility quarter-to-quarter, but just wanted to make sure this level of growth isn't going to fall off for any sort of reason.

So I am wondering if you could talk about this, as we look out over the next four to six quarters, the sustainability of that 4% to 5% growth level, or are there any headwinds at any particular quarter coming up that we should be thinking about?

A - Ashley McEvoy {BIO 20108895 <GO>}

So thanks for the question. Danielle, and listen, it's really good to see number four, and we're pleased with quarter three, and we're pleased with really kind of the year-over-the-year enhancement. So I feel confident in that continued year-over-year progression. I don't anticipate us having a perfect linear line every quarter-to-quarter. The market is just -- we will have to adapt to the market. But I really think that we're going to accomplish that. What you're seeing is really the benefit of strength in commercial execution.

But I would say what I'm equally bullish on, is really the innovation agenda. And when I look at 2019, I think we benefited from some really novel innovations in our circular powered, circular stapler for complex oncology cases. We had a first-in on -- in contact lens with a light adaptive lens. We are launching our cementless, which is a high-growing segment in knees in quarter three. In quarter four, we'll have some news in spine, related to our Symfony launch for our complex posterior cervical and deformity.

So I really think that those are going to have an effect, but equally important is really when I look at the innovations coming out over the next, let's say 18 months. And we're going to have a first-in-kind, smart micro catheter in our electrophysiology business under QDOT, which is going to deliver about two to three times the amount of energy, and take the procedure from four hours to two hours.

We're going to have another novel innovation in Vision, related to the first ever drug-eluting contact lens for allergy. More premium intraocular lens coming, and we're going to have some digital surgery robots in our orthopedics business really beginning with the filing in 2020, let alone all the digital surgery offerings that we have with Monarch in the future with Verb And Eye [ph] platform. So thanks for the question.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks Danielle. Appreciate the question, Rob, next question please.

Operator

Next question is from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question. Just as we think about margins, obviously posted a really strong quarter. It looks like consumer and MedTech were the key drivers of the improvement. Just wondering if that level is sustainable here, or if there is room for further improvement in each of these segments, as we look into 2020. And then on DARZALEX looking ahead into 2020, is it reasonable to assume that year-over-year growth in the US should inflect positively next year, given the front line label? Thanks.

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

Maybe Thibaut and Ashley, if you'd like to address your levels of investment with respect to your businesses. And then Jennifer you can handle the DARZALEX question.

A - Thibaut Mongon {BIO 20973347 <GO>}

Sure, I can start with consumer, Terence. On -- as you saw, we are very focused on improving our profitability level. I just talked about the sequential improvement we are seeing this year. As I look at 2020, we expect to see moderate acceleration in the topline, with market growing around 3% and we remain focused on driving our productivity agenda. So that's the agenda for 2020.

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

Yeah, I think the best way to characterize it relative to this year, Terence, is that this year was the bigger lift in terms of profit improvement -- profitability margins improving for the consumer unit. So you will still see continued improvement, as Thibaut mentioned, but not to the same degree you probably saw in 2019.

A - Ashley McEvoy {BIO 20108895 <GO>}

And just to build, Terence, this is Ashley, on the kind of the investments and what the expectations are, I think we're seeing very strong performance in Asia. We've made continued investment in Asia, and continued investment in China. We command a leadership position in China and we command leadership position in emerging markets, and it's really nice to see emerging markets up 10% and China up 19%. And we will continue to make those very, very select investments.

And then in areas like commercial infrastructure around having a world class sales force and world-class professional education. I think we're seeing the investments that we made, particularly in new deployment models in the United States, having an effect.

And then clearly in innovation, both in digital surgery, through the Auris acquisition, and what we're continuing to do with our Verb and Orthotaxy, and some robotic programs in spine. And as you know, we've invested about $12 billion in M&A since 2017 in Medical Devices to make sure that we're playing in the most attractive spaces.

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

And to be fair Terence, it's a little bit of a tough question for our business leaders to answer at this point in time. As I mentioned at the outset, we're still developing our plans for 2020. And for us, when we go through those plannings, we're really looking at what investment opportunities are available to us, in terms of fortifying not just the short term, but the long term. What's going to make us truly competitively advantaged two, three, five years down the road.

So that's why it's a little bit difficult to answer. But we're always looking to make sure that we've got over sustained periods of time, sales growth that exceeds the market in the respective segments, and then profit a little bit better growth than sales growth.

A - Jennifer Taubert {BIO 20108880 <GO>}

Hi Terence. Our oncology business had another strong quarter and DARZALEX was really one of the key drivers of that, with 57% growth versus the third quarter of last year. As you noted, we've got a great opportunity to make strides in the front line setting. Right now DARZALEX is a leader in line 2 plus. However, at the end of June, we gained approval in the front line setting for transplant in eligible patients, in combination with REVLIMID and at the end of the third quarter we gained approval in front line for the transplant eligible patients in combination with Velcade and Thalidomide, based on our CASSIOPEIA data.

And so we're really looking to continue to expand DARZALEX across the various lines of therapy and in various combinations to really be the backbone of therapy. Importantly for us, and I believe the key growth driver for the future, we filed our subcu formulation, which is going to take us from a several hour infusion on this product, down to under five minutes. And so we think that's going to be an important catalyst for growth, particularly in the outpatient settings, and the more community settings. And we're also importantly studying DARZALEX in amyloidosis, smoldering myeloma. So we think that there is both near-term, short-term growth, as well as continued long-term growth potential on this asset.

So based on the strength of the performance to-date, the additional data that we're seeing and the opportunities that we have in the front line setting and growth potential, coupled with the subcu formulation that's coming up, we believe that there is very good reasons for a very strong, continued growth for DARZALEX going forward.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks Terence. Appreciate the question. Rob, next question please.

Operator

Your next question is from Kristen Stewart with Barclays.

Q - Kristen Stewart {BIO 15155691 <GO>}

Hey everyone. Thanks for taking the question. Just wanted to I guess clarify just some of the timing around the digital surgery platforms. I think Ashley you mentioned filing for Orthotaxy in 2020. Just wanted to get some clarification there, and then also any updates on progress with Monarch and then timing around Verb, and I think you might have a Medical Device Day next year, just wondering what we should expect with that, and just kind of Verb and thoughts with Medtronic I guess showcasing their platform too?

A - Ashley McEvoy {BIO 20108895 <GO>}

Thank you, Kristen for the question. So listen, I couldn't be more bullish around how J&J is going to create value in the space, and really kind of the goal that we're trying to achieve is really to make medical interventions smarter, less invasive, more personalized, quite frankly to change the standard of care, not just for the next 10 years, but the 20 years and 30 years on.

So it really starts with, as you know, a very strong footprint that we actually have today in -- as a world leader in open surgery and a world leader in minimally invasive laparoscopic surgery. I'm very pleased to share that Monarch is off to a great start, as a first in, endoluminal surgery. We've conducted over a thousand bronchoscopes using the Monarch system.

You'll see in the chest, at the end of October, we will be sharing our post-market surveillance data, and so stay tuned for that. We have a very healthy pipeline with Monarch, for not just lung biopsies, but potentially lung treatment via ablation, and potential treatment via oncolytic viruses. So that program is well on its way. We also are looking at applications of Monarch in endourology for the treatment of kidney stones, and we also are assessing the potential application of Morcart [ph] in GI endoscopy.

So very encouraged with Monarch. Equally encouraged with the acquisition of Auris as well as Verb. We brought in a new leader to head our Verb program, Kurt Azarbarzin. He's got over 30 years' experience in minimally invasive surgery robotics. It's pretty fun to watch Kurt and the community of Dr. Fred Moll, again one of the founders of Intuitive, Peter Shen, he's grown up on Ethicon Instrumentation and then Andy Conrad from Verily, kind of put those thought leaders together with over 30 different key opinion leaders from

around the world, who've been really assessing how we can create value with all of these assets over the next several years.

So I am encouraged to say both programs have conducted -- and I mean both programs both the Auris eye platform and Verb have conducted end-to-end procedures in multiple different indications in general surgery. We've gotten very good feedback from over 30 plus surgeons, and we're going to take the absolute best of all of those, as we in parallel, advance both of those programs.

Equally pleased to see Dr. Fred Moll engage with our orthopedics team. We plan to file our orthopedics program for filing, middle of 2020. And so when I take a step back, I really see us having a healthy cadence of news starting last year, with the launch of Monarch, every single year having meaningful news. We are completing our assessment, Kristen, as you had mentioned around the eye platform and Verb and how do we create the most amount of value. Right now, we're not changing any timelines until that assessment is complete. So stay tuned.

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

Great, thanks, Ashley. And maybe just another update to Ashley's point on the progress of the Monarch platform; while it's early and limited revenue today, we're very pleased with the progress of the placement of systems. Two times the amount year-to-date versus where we were in 2018. So that continues to progress well from an adoption standpoint in the marketplace.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Kristen. Rob, next question please.

Operator

Your next question is from Josh Jennings with Cowen & Company.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi, good morning, congratulations on a strong quarter. I was hoping to start off around on the Pharma business. Just wanted an update on the generic/biosimilar headwind, you guys have called out kind of a $3 billion number for 2019. And is there anyway you can help us think about where that headwind will sit, as we head into 2020?

And then the second question, another pharma question just on XARELTO. Congrats on the line extension. Any help there, just in terms of how you would perceive launching into this new indication. Are there any pricing considerations you need to undertake and can XARELTO return to growth? It has been a blockbuster, that's been relatively anchored over the last number of quarters? Thanks a lot.

A - Jennifer Taubert {BIO 20108880 <GO>}

Hi Josh. It's Jennifer. So as we take a look at this year, first, on your question regarding sort of biosimilar and generic impact. We think we're seeing about $2 billion of incremental

impact from biosims and generics. This is a little bit less than what we had anticipated this year. However, the number of generic approvals and the erosion rates are starting to catch up. And so we think as we enter into next year, we'll work through the rest of that. So part of it -- a little bit of it's going to carry over into -- to 2020, and then we'll be working through and be done with that.

As it relates to XARELTO, we are very excited about the new indication. This is actually the eighth indication for XARELTO and that product really remains unmatched in the oral space, in terms of the number of indications. So the asset has indications in AFib, VTE prevention and treatment, and then also in CAD, PAD.

So how to think about the acute medically ill indication. First of all, it broadens XARELTO's base of indications across these three areas, and that's really unmatched. And so that can help from a formulary and from a payer perspective. And then within the market, there is over 7 million Americans that are hospitalized each year with acute medical illnesses and so these patients are at increased risk of clots for up to three months post discharge.

So currently they are treated in hospital, with a product like Lovenox, but because of the complications and the difficulties with injections, they typically go untreated, once they leave the hospital.

What we now know from our studies and our data, is that it's much better for these patients to actually be treated for about 31 to 39 days, following their medical illness. And so this is a -- we believe that patients will start on XARELTO in hospital, when they're there with the acute medical illness, and then our goal is a transition out of hospital with a script and continue on oral medication for that 31 to 39 days.

Now you may have the question, how do we go about doing this? The good news is, XARELTO 10 milligram, which is the right dose for this indication, is already available on hospital formularies. That's the dose that we've had in the market now for a number of years, for post knee and hip surgery. So we do have very broad availability in hospitals, formulary access and also payer access for this.

We've also got teams that are already deployed to hospitals across the other range of indication sets. So in our typical way, we do next day launches. So the team's already out in the markets, getting ready and working on this indication, as well as continuing to drive uptake in the paradigm-changing CAD, PAD indication, and fighting out for a competitive share in both AFib, as well as the other VTE treatment and prevention indication.

So we feel very good that we reached flat this year. That's obviously not where we want to be, but we are moving forward and getting past some of the donut hole and rebate issues, and we do believe there is an opportunity for growth for this asset as we take a look, and completing the year and going forward.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thanks, Josh. Appreciate the question, Rob, next question please.

Operator

Next question is from Matt Miksic with Credit Suisse.

Q - Matt Miksic {BIO 6990080 <GO>}

Hi, thanks for taking the question. So just two follow-ups, if I could, one on the digital surgery side, Ashley, appreciate the color on the strategy across the major business lines. The one that I wanted to ask about, was just spine. You have a partnership with Brainlab, and that continues to progress. You have a pretty solid set of new products that you mentioned are going to drive improving growth in spine. But just if you could, what amount of the competitive pressure there is coming from this sort of increase in robots in that space, and how do you think about that strategically? And then just one follow-up for Joe, if I could?

A - Ashley McEvoy {BIO 20108895 <GO>}

Sure. Thank you, Matt. So spine, we're number two in the world in spine. We have been challenged. Our revenue performance has been challenged, and really what we've been working on is, one to give very dedicated focus to -- if I'll call it like the top six markets in spine, that are really going to be the growth contributors and stabilizing those. From a leadership point of view, from a commercial execution point of view, from a clinical acumen of how we engage with spine surgeons and then rebuilding the spine portfolio. And so, I think we are starting to see the fruit of that on stabilization. And we mentioned some of -- Chris had mentioned some of the innovations around VIPER PRIME, around CONDUIT Interbody cages, around Symfony which is going out quarter four.

And so clearly digital surgery is also going to be important that we launch that. To date, that has had a very minimal effect. As you know and you referenced, we do have a strategic partnership with Brainlab, which is offering us an end-to-end navigation solution, and we actually in quarter three entered into a co-marketing distribution and R&D agreement with Tinavi, who is the market leader in orthopedics, robotics in China. And actually is the only robotic [ph] technology approved for spine in China. So clearly, we feel like we have to have a digital surgery offering as well in spine.

Q - Matt Miksic {BIO 6990080 <GO>}

That's helpful. And the question for Joe, if I could. Just I understand from your comments on the call that you're working through the plan for next year, and it's still not a full outlook for next year. But just if you could help us understand perhaps the puts and takes and how you think about spending, as you've mentioned balancing near-term to long-term? Again some of the year-over-year challenges you may have elsewhere in the P&L, that would be super helpful, just to maybe walk us through R&D and SG&A and any potential flex or opportunities you have in gross margin just at a high level, Joe, would be super helpful?

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

Yeah so, appreciate the question. Matt, I think I'm going to be respectful to the teams on letting them finalize their plans. What I would say, in terms of puts and takes, I feel very good about the top line growth. We need to see where the net of all the incremental

generic and biosimilar erosions will eventually land, as we go through the fourth quarter here, that will give us a pretty good insight, as you saw with Medical Devices. We expect to be around the markets, so 4% to 5% is where we see that market overall.

As you know, some of that is influenced by some of the higher segments, where we yet don't have a, I'd say, a pronounced presence, but working our way towards that. But again, Ashley and the team have their line of sight and continued acceleration there. Maybe as a step back for the overall pharma market, we see about 4% growth for next year. And then in consumer, you've heard from Thibaut, that we expect to be competitive with the market, which we anticipate will be around 3%, but the focus there has been on prioritization to skin health and self-care and improving the profitability profile.

We're going to continue to invest in R&D, that's been a bias of ours for a number of years. You can see that when we issue our P&Ls, that there is a disproportionate share, and that's where we grow as a percent of sales more often than not. And we're going to continue to look for those opportunities to advance the pipeline.

I was really thrilled with the press release today, not simply because of the financial results, although, I was very pleased with those. I would say it was the 15 items that were listed across our businesses of notable advancements in our pipeline. And that really just bodes well for the future. So Matt, I appreciate the question, I apologize, I can't give you a little bit more detailed guidance today. But stay tuned for our report out in January, and we'll be pretty specific then.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks Matt. I appreciate it. Rob, next question please.

Operator

And your next question is from Bob Hopkins with Bank of America.

Q - Bob Hopkins {BIO 2150525 <GO>}

Thanks very much for taking the question. Just two really quick ones, given the strength in medical devices. I was wondering if you could comment on two quick things. One, you had very strong growth in hips and knees outside the United States. I was wondering if you could just elaborate on what drove that incremental growth. Was it market share, was it market strength?

And then just one last one on Verb, I was just wondering, when you think you'll be able to be in a position to provide us with a more detailed update on the timelines for filing and approval. And I ask in part, because your comments on endocutters, and in part because one of the other large competitors has now provided pretty specific timelines. So just those two quick device questions. Thank you.

A - Ashley McEvoy {BIO 20108895 <GO>}

Sure, thanks Bob. I think I'm pleased with the performance that we've had in hips, around 3%. We have a strong portfolio in hips and we're really leading the way on the anterior approach. We actually just completed a new acquisition of JointPoint, which is going to help us with kind of an intra-operative software program, to enable a more digitally oriented procedure in hips. I'd say hips is pretty balanced between OUS and US.

Knees, I am encouraged. This is the first quarter in several quarters that we actually posted growth in knees of around 2%, really fueled by OUS performance. The US I'll come back to that. ATTUNE is performing well in the US, we've seen a pivot and start in primary and revision in ATTUNE. We're working off some legacy transition in some of our legacy knee brands in Sigma.

Really what's enabling knees, is just a couple of things. One, strength in commercial execution in our top six markets. It's also about innovation. We have a very strong foundation in our ATTUNE knee platform that we've invested over 10 years in bringing to market. It's performing very well from an efficacy and safety point of view. We now have a full portfolio in the ATTUNE Revision, both fixed bearing and rotating platform and we've also launched our cementless in quarter three. And then you could add to that, Bob, you can see in next year when we'll have cementless in fixed bearing, and we'll have our digital surgery offering in knees, I feel pretty confident that our joint platform will start to get back to the market performance.

As it relates to Verb, we have been progressing Verb in all of the milestones to bring this to market. We have been preparing for kind of validation studies. We've been in active discussions with all regulatory authorities, both in the United States as well as in Europe. As I mentioned, we brought in a new CEO of Verb, Kurt Azarbarzin, about 60 days ago. So we've been letting him get underneath the hood of what needs more focus, what needs acceleration.

Very pleased with, again, the customer feedback from Verb. What we've done is, we've brought in the combination of Auris, their leaders with Dr. Fred Moll and Kurt and Verily, our partner, Verily are creating kind of this connected OR of the future, and we're in the middle of assessing how do we really optimize all of these assets to make a difference in healthcare systems. So we're still in the middle of that, and I expect to have that completed before the end of the year. Right now, we're holding to the timelines, but I expect probably in quarter one with some updates, we will keep you posted. Thanks for the question, Bob.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thanks, Ashley. Rob, we have time for one last question, and then after that I will turn it over to Joe Wolk for some closing remarks.

Operator

Thank you. Your next question comes from Jayson Bedford from Raymond James.

Q - Jayson Bedford {BIO 5141602 <GO>}

Hi, good morning. I'll keep it to one question and thanks for squeezing me in. Just maybe for Thibaut, and I apologize if I missed this earlier, but your International Consumer business seems to have lagged year-to-date about 1% growth. Can you give us a little detail on why the international growth has been a little slower, and then you've alluded to a bit of a pickup in market growth next year in consumer. What are the big factors driving the better growth? Thanks.

A - Thibaut Mongon {BIO 20973347 <GO>}

Yeah, thank you for the question. Regarding as you said, we had a very strong quarter in the US a bit softer outside of the US. A number of factors internal and external. Externally, we see some softness in some emerging markets, Latin America, especially, and we are rolling out of baby -- on new Johnson's Baby brand around the world. The rollout will be completed by the end of this year and this has an impact on our shipments outside of the US. In the US, we have already completed this rollout last year, as we just talked about.

Regarding next year, we anticipate a modest acceleration in the markets and geographies in which we compete, from 2% to 2.5% this year to 3% next year. And as Joe just mentioned, we are finalizing our plans to grow competitively in these markets, while continuing to work on our profitability agenda. So we can improve our profitability, and at the same time, invest behind growth opportunities we see in our priority areas.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great, thank you, Jayson. Appreciate the question. Joe, final comments from you?

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

Sure. Well, first let me thank all of you on the webcast today for your time and your continued interest in Johnson & Johnson. Ashley, Thibaut, Jennifer, Chris and I were certainly proud to discuss the quarterly results, and also engage in discussing the overall health of our business. What you hopefully saw from today's press release, and the discussion that we're about to conclude, is that you have a focused organization here on delivering transformational innovation for the betterment of healthcare and much broader society. We manage through any challenges that we face to deliver those results, not just over one year or five years, but many, many years, many, many decades, and hopefully you saw that on display today.

So again, thank you for your time and we look forward to the next encounter.

Operator

Thank you. This concludes today's Johnson & Johnson's third quarter 2019 earnings conference call. You may now disconnect.