Q3 2017 Earnings Call

Company Participants

- Dominic J. Caruso, Executive Vice President, Chief Financial Officer
- Joaquin Duato, Executive Vice President & Worldwide Chairman, Pharmaceuticals
- Jorge S. Mesquita, Executive Vice President, Worldwide Chairman, Consumer
- Joseph J. Wolk, Vice President-Investor Relations
- Sandra E. Peterson, Group Worldwide Chair

Other Participants

- David Ryan Lewis, Analyst
- Geoff Meacham, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Jeffrey Holford, Analyst
- Joshua Jennings, Analyst
- Larry Biegelsen, Analyst
- Matt Miksic, Analyst
- Michael Weinstein, Analyst
- Robert Hopkins, Analyst
- Tony Butler, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning and welcome to Johnson & Johnson's third quarter 2017 earnings conference call. All participants will be a listen-only mode until the question-and-answer session in the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time.

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

Joseph J. Wolk {BIO 19812977 <GO>}

Hello and thank you for joining us to review Johnson & Johnson's business results for the third quarter of 2017. I am Joe Wolk, Vice President of Investor Relations.

I would like to provide a few logistics for today's call. 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 find additional materials, including today's presentation and accompanying schedules. We anticipate today's webcast to last approximately 75 minutes.

Please note that today's presentation includes forward-looking statements. We encourage you to review this cautionary statement regarding such statements included in today's presentation as well as the company's Form 10-K, which identifies certain factors that may cause the company's actual results to differ materially from those projected.

Our SEC filings, including our 2016 Form 10-K along with reconciliations of 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. I am very pleased to be joined by a few members from our executive committee, Dominic Caruso, Executive Vice President and Chief Financial Officer, will provide some prepared remarks prior to the Q&A portion of the call. You will not only have the opportunity to post questions to Dominic during that time, but also to each of our segment leaders. Accompanying Dominic and I on today's call are Joaquin Duato, Executive Vice President, Worldwide Chairman, Pharmaceuticals; Jorge Mesquita, Executive Vice President Worldwide Chairman, Consumer; and Sandi Peterson, Executive Vice President, Worldwide Group Chair.

We are very pleased with our strong results. As highlighted in this morning's press release and accompanying materials, the third quarter demonstrated an acceleration of organic sales growth and continued robust adjusted earnings per share. The anticipated acceleration of sales performance was most pronounced in the Pharmaceuticals segment, where key major brands are penetrating new markets and gaining share.

The Consumer segment returned to growth in the face of relatively soft global categories and worldwide Medical Devices growth was relatively stable to second quarter levels.

Sales performance in the quarter reflects the contribution from recent acquisitions as well as the strength of new products across all three segments.

Now onto the details related to this quarter's results. Worldwide sales were $19.7 billion for the third quarter of 2017, up 10.3% versus the third quarter of 2016. On an operational basis, sales were up 9.5% as currency had a positive impact of 0.8%. In the U.S., operational sales growth was 9.7% and regions outside the U.S. achieved operational growth of 9.3%. The effective currency exchange rates positively impacted reported OUS sales by 1.6 points.

Excluding the net impact of acquisitions and divestitures, operational sales growth for the enterprise was 3.8% worldwide.

Net earnings for the quarter were $3.8 billion and diluted earnings per share were $1.37 versus $1.53 a year ago. Excluding after-tax amortization expense and special items for both periods, adjusted net earnings for the quarter were $5.2 billion and adjusted diluted earnings per share were $1.90, representing increases of 11.2% and 13.1%, respectively, compared to the third quarter of 2016.

On an operational basis, adjusted diluted earnings per share grew 10.1%. Dominic will provide additional commentary on earnings in his remarks.

I'll now summarize segment sales performance for the quarter, with the intent of building upon the slides being presented. Unless otherwise stated, percentages quoted represent operational sales change in comparison to the third quarter of 2016, and thus, exclude the impact of currency translation.

Beginning with the Consumer segment. Worldwide sales grew 1.6% to $3.4 billion. Excluding the net impact of acquisitions and divestitures, operational sales increased 1.1% worldwide. Operational growth in the segment was driven by the beauty and OTC franchises, each growing 4.4%. The results in beauty were driven by strong OUS performance in the Vogue and NEUTROGENA brands. Additionally, the Dr.Ci:Labo brand in Asia-Pacific is experiencing good uptake. Franchise growth excluding acquisitions was 2.1%. The worldwide beauty market is estimated to have grown approximately 3% in the quarter and was modestly up in the U.S.

In our OTC business, adult and children's TYLENOL continue to gain market share with adult TYLENOL benefiting from strong sales of the rapid release formulation.

Concluding the Consumer segment, baby care continues to be impacted by the new entrants to the market. However, we remain the market leader. As previously communicated, we are actively working on relaunching these brands in 2018.

Regarding our Pharmaceuticals segment, worldwide sales grew 14.6% to $9.7 billion. Excluding the net impact of acquisitions and divestitures, operational adjusted sales grew 6.7%, a clear acceleration of the growth over the first half of 2017.

The strongest therapeutic area of growth was in oncology, growing 24% overall. DARZALEX continues its robust performance, with rapid uptake in the one prior line setting. DARZALEX growth in EMEA drove results outside the U.S., where the product has now been launched in 25 countries.

IMBRUVICA continues to gain market share globally. As you are aware, data lags for this product. But based on second quarter data, IMBRUVICA is now above 50% market share in the U.S. across all approved indications.

ZYTIGA growth in the U.S. was driven largely by a growing market, which we estimate at approximately 13%, and a slightly higher share both versus the prior year and sequentially.

In immunology, the U.S. market is estimated to have grown approximately 7%. STELARA in the U.S. gained 1.8 points of market share in the total immunology market versus the third quarter of 2016, driven mostly by strong adoption for the newer Crohn's disease indication. STELARA market share for Crohn's of the U.S. is now estimated to be approximately 10%.

REMICADE in the U.S. declined a little more than 1%, as it continues to compete in the face of biosimilar entries. REMICADE U.S. export and international combined declined 23%. While we continue to experience erosion from biosimilar competition in Europe, approximately, two-thirds of this decline was attributable to the timing of shipments with our partner Merck.

Within the cardiovascular metabolic therapeutic area, XARELTO's growth of 20% was primarily the result of increasing total prescription market share, up almost 2.5 points versus one year ago. Warfarin continues to decline in favor of branded products.

INVOKANA/INVOKAMET sales in the U.S. declined. As we commented to in recent quarters, the primary driver of this decline is increasing discounts for the brand in managed care contracting and higher utilization in the Medicaid channel. There was also a loss in share of approximately 1 point.

This is the first full quarter we are reporting pulmonary hypertension product results. On a pro-forma basis, this therapeutic area grew 9% globally, 16% in the U.S. and 1% outside the U.S. Worldwide pro-forma growth of better than 17% in OPSUMIT was driven by further market penetration and share gains. UPTRAVI, up more than 70% and still largely a U.S. product, is experiencing strong launch demand. TRACLEER was down about 14%, which is expected as business converged to OPSUMIT.

To conclude the review of Pharmaceuticals, I would like to provide additional context on a few of our late-stage compounds that were mentioned in today's press release. A New Drug Application for apalutamide was submitted to the FDA for men with non-metastatic castration-resistant prostate cancer. The filing was based on Phase III data from the SPARTAN trial, which met its primary endpoint. We plan to present the study results at a major medical meeting in 2018.

Regarding talacotuzumab, based on a recommendation from the Independent Data Monitoring Committee, we have discontinued treatment with talacotuzumab in AML 2002, as the Phase III results did not demonstrate a positive benefit/risk ratio. We continue to assess the data to determine next steps in the clinical development program.

Lastly, we've made the decision to withdraw the applications we had filed globally for sirukumab in rheumatoid arthritis. We are continuing to study sirukumab in major depressive disorder currently in Phase II.

I will now turn to our Medical Devices segment. Worldwide Medical Devices sales were $6.6 billion, growing 6.6%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 1.2% worldwide.

The Vision Care business continues to exhibit strength. Contact lenses grew 5.3% worldwide, as new products, namely OASYS 1-Day and OASYS 1-Day for Astigmatism, continue to be well received in the market. Within the contact lens/other line, there is $27 million associated with the recently acquired consumer eye health products. The Vision Surgical business on a pro-forma basis grew approximately 10%, driven by the cataract business in the U.S., where strong adoption of the IOL TECNIS Symfony lens continues.

We did experience a modest negative impact in our Hospital Medical Device businesses from weather-related events during the quarter. Based on a very preliminary analysis, we estimate that impact to have been a modest 30 basis points to overall total Medical Device growth. Dominic will discuss this impact in the outlook of our future supply continuity in a few minutes.

We routinely reference general selling days. On a worldwide basis, selling day impact this quarter was negligible.

Within Hospital Medical Devices, electrophysiology grew approximately 14% worldwide, largely in line with atrial fibrillation procedure growth. The advanced surgery category grew 3.9% or 2.2% excluding the Megadyne acquisition. Energy is facing competitive pressures from reprocessing alternatives. Growth was largely generated by 13% OUS biosurgery performance, with strength in the Middle East and Asia-Pacific markets. Endocutters grew 6% outside the U.S., driven by ECHELON performance in China.

Within general surgery, worldwide sutures grew approximately 5%, behind strong growth of traditional and barbed sutures in China. The decline in specialty surgery was driven by share loss in the aesthetics and infection protection businesses. The decline in the orthopedics business versus the third quarter of 2016 was largely the result of share loss in U.S. spine, but we are working to expand our product offerings in faster-growing segments.

Performance in knees outside the U.S. was negatively impacted by new legislation in India, which is lowering the pricing of implants. That impact was approximately $10 million in the quarter. But since the legislation is retroactive to the beginning of the year, the third quarter represents three quarters worth of negative impact.

Trauma grew 3.1%, driven by solid growth in the U.S. market and strength in the Asia-Pacific and Latin America regions.

Hips round out the orthopedic portfolio, and that platform grew 1.5% globally, as strength in the U.S. was driven by continued adoption of CORAIL. Pure pricing pressure continued across most orthopedic categories, but favorable mix helped offset the erosion. For the quarter, U.S. price net of mix was negative 2.4% in hips. Spine and trauma net of mix were positive 2.1% and 1.2% respectively. Knee price net of mix was flat.

That concludes the segment sales highlights for Johnson & Johnson's third quarter of 2017. For your reference, here's a slide summarizing notable developments that occurred during the quarter.

I am now pleased to turn the call over to Dominic Caruso. Dominic?

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Joe, and good morning, everyone.

We were very pleased with our strong third quarter results. The performance highlights the many areas of strength in our business that have given us the confidence to state throughout the year that we would accelerate sales growth in the second half of 2017. That was exactly what we delivered in the third quarter.

We experienced organic growth acceleration, most significantly in the Pharmaceuticals segment, as oncology and immunology products continue to grow at robust levels. The Consumer segment, which declined modestly in the first half of 2017, grew in the third quarter, while Medical Devices was relatively stable, but as Joe noted, experienced some minor negative impact to growth due to hurricanes in Texas, Florida, and Puerto Rico.

In addition, we were very pleased with the performance from our recent acquisitions, Actelion and Medical Optics, which will continue to fuel our growth. And so overall sales beat analyst estimates by approximately 2% or $350 million, and adjusted earnings beat analyst estimates by $0.10 per share.

I know for many of you, there are questions regarding the impact of the unprecedented storms that occurred in the quarter. I want to take a moment to acknowledge the courage and resilience of all those who have been directly impacted by these storms. It's really been incredible. The response of the global business community has also been impressive, and I'm especially proud of the role Johnson & Johnson has played. Our desire to improve lives is a foundational element in our credo, and it is times like these when the character of our people who have been working on the ground side-by-side with relief organizations in a united effort to help their communities really shine through.

In terms of sales, the limited impact we experienced in the third quarter is not the result of any supply disruption, but rather lost surgery days in those areas affected by the storms. It remains to be seen whether volumes associated with those lost surgeries will be recouped in future quarters. However, in terms of future supply, we are very well-positioned.

We have six manufacturing sites on the island of Puerto Rico, and considering the magnitude of the storm, our facilities fared well. All of our sites are open with reliable generator power, operating in various stages of capacity, while the work continues to ramp up to full operations in Puerto Rico.

To ensure critical patient needs are met, we are closely monitoring inventories across our global manufacturing network, prioritizing production of the essential products and have already begun shipping newly-manufactured goods from the island.

While we cannot rule out the potential for intermittent shortages of certain product formats, many of our products have dual production sites and backup supply outside of Puerto Rico to help meet demand. Based on what we know today, we do not foresee any material impact to future results.

I will now turn to our consolidated statement of earnings for the third quarter of 2017. As you heard, our operational sales growth this quarter was 9.5%; and excluding the impact of acquisitions and divestitures, operational growth was 3.8%.

If you will direct your attention to the box section of the schedule, you will see we have provided our earnings adjusted to exclude intangible amortization expense and special items. As referenced in the table of non-GAAP measures, the 2017 third quarter net earnings were adjusted to exclude intangible amortization expense and special items of $1.4 billion on an after-tax basis, which consisted primarily of the following: intangible amortization expense of approximately $933 million, primarily from the recent acquisition of Actelion; litigation expenses of approximately $100 million; acquisition-related cost of approximately $280 million; and a charge for the continuing restructuring of our Hospital Medical Device business of approximately $140 million. Our adjusted earnings per share is, therefore, $1.90, up 13%. And adjusted EPS on a constant currency basis was $1.85 or up 10% over the prior year.

Now, let's take a few moments to talk about the other items in the statement of earnings. Cost of goods sold increased by 430 basis points, primarily due to the inclusion of the amortization expense and charges for inventory step-up from our recent acquisitions. Excluding the impact of these types of expenses in both periods, cost of goods sold was 27.8% or 120 basis points lower than the prior year, mostly due to favorable product mix.

Selling, marketing and administrative expenses were up 70 basis points as compared to the second quarter of 2017, largely due to the investment of new products in our Consumer segment. Our investment in research and development as a percent of sales was 13.1%, up 90 basis points compared to the prior year as we continue to advance our robust pipeline of pharmaceutical products.

And interest expense, net of interest income, was a net expense of $155 million, slightly higher than last year. Other income and expense was a net gain, $236 million in the quarter, compared to a net gain of $54 million in the same period last year. Excluding the special items that are recorded in this line, other income and expense was a net gain of $517 million compared to a net gain of $220 million in the prior-year period, reflecting completion of certain asset sales, which were included in our annual guidance. I'll provide an update on this activity during my guidance comments.

Excluding special items, the effective tax rate was 20.8% compared to 19.7% in the same period last year. This rate is consistent with our expectations as a component of the full-year effective tax rate. I'll also provide an update on tax during my guidance comments.

Turning to the next slide. I will now review adjusted income before tax by segment. In the third quarter of 2017, our adjusted income before tax for the enterprise improved 80 basis

points versus the third quarter of 2016, driven by favorability in the other income and expense line, partially offset by the additional investments I mentioned earlier.

Looking at the adjusted pre-tax income by segment, Medical Devices at 30.1% is lower than the prior year, primarily due to higher investment spend to support new product launches. Pharmaceutical margins improved 110 basis points to 41%, driven by favorable product mix. Consumer margins improved to 28%, primarily due to the divestiture gains, partially offset by increased advertising and promotional spending.

Now I will provide some guidance for you to consider as you refine your models for 2017. At the end of the quarter, we had $19 billion of net debt, which consisted of approximately $16 billion of cash and marketable securities and approximately $35 billion of total debt. Therefore, for purposes of your models and assuming no other significant uses of cash, I suggest you consider modeling net interest expense of between $600 million and $700 million, which is consistent with our previous guidance.

Regarding other income and expense, 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. As you know, one of our business priorities is to actively manage our portfolio to maximize value creation with the intention of redeploying most of those gains back into the business to enhance our long-term growth prospects.

Consistent with our previous guidance, we are still comfortable with your models for 2017, reflecting net other income and expense, excluding special items as a net gain, ranging from approximately $1.6 billion to $1.8 billion. This includes the gain associated with the sale of the Codman Neurosurgery business, which we closed subsequent to the third quarter.

Regarding pre-tax operating margin, we expect that investment levels will increase, and therefore, we maintain our guidance that we will be flat to slightly decreased from 2016 levels. This is, of course, offset by the divestiture gains I just mentioned.

Now a word on taxes. As the Chief Financial Officer of one of the largest U.S.-based multinational companies, I'm often asked these days about my perspective on tax reform. In fact, it is a topic I've been actively engaged in for more than 10 years with legislators as well as my peers across many industries.

While our guidance today does not include any assumptions about potential tax reform measures, there are some points I'd like to share as I do believe we now have momentum to attain meaningful and impactful business tax reform in the very near future.

First, we commend our leaders in Washington for taking steps to address business tax reform, and we see the united framework as a thoughtful approach to jump-starting the U.S. economy, fueling U.S. jobs and U.S. investment, one that will improve the ability of U.S. multinational companies to compete more effectively. The current tax system has not

kept pace with modern innovation-driven global economy, which results in an increasingly difficult business environment for U.S.-based companies that do compete globally.

To level the playing field with other industrialized countries, tax reform should include three fundamental elements: a lower corporate income tax rate, in line with other industrialized countries; the adoption of a modern, globally competitive international tax system, allowing U.S. companies to manage their cash without tax penalty; and, of course, greater incentives for innovation in the U.S.

The framework addresses each of these elements, and while clarity and additional detail is still needed on some elements, it is important that Washington and the business community unite now behind a tax reform bill that will have a positive impact on domestic jobs and on economic growth.

Having said all that and still remaining optimistic that something on this front can get done, we are not assuming reform in our 2017 guidance. Excluding special items, our guidance is 19% to 19.5% as an effective tax rate and this is a slight tightening of the range from our previous guidance.

Now turning to sales and earnings, our sales guidance for 2017 does not anticipate any impact from generic competition this year for ZYTIGA, RISPERDAL CONSTA, PROCRIT, PREZISTA or INVEGA SUSTENNA.

As we've done for several years, our guidance will be based first on a constant-currency basis, reflecting our results from operations. This is the way we manage our business and provides a good understanding of the underlying performance of our business. We will, of course, also provide an estimate of our sales and EPS results for 2017 with the impact that current exchange rates could have on the translation of those results.

As I mentioned earlier, we expect to maintain the acceleration of our underlying sales growth for the balance of the year and our major acquisitions of Actelion and Medical Optics completed earlier this year remain on track.

As this is in line with our previous expectations, we are maintaining our operational sales guidance for the year in the range of 5.5% to 6%. This translates to sales for 2017 of approximately $75.9 billion to $76.2 billion on a constant-currency basis.

We are not predicting the impact of currency movements, but to give you an idea of the impact on sales, if currency exchange rates were to remain where they were as of last week, with the euro, for example, at $1.18, for the balance of the year, our sales growth rate would increase by 60 basis points versus our previous guidance. Thus, under this scenario, we expect reported sales growth in the range of 6% to 6.5% for a total expected level of reported sales of approximately $76.2 billion to $76.5 billion, which is higher than our previous guidance.

And now turning to earnings, as I noted earlier, we plan to continue to invest in our growth opportunities, and those plans are already in place. In the fourth quarter, as we did in the third quarter, we will see an elevated level of R&D investment as well as additional investments in marketing programs behind the launches of several new products. Therefore, we continue to expect that our pre-tax operating margins will decline somewhat from the prior year, consistent with our previous guidance.

We expect adjusted EPS to be in the range of between $7.22 and $7.27 per share on a constant-currency basis, reflecting an operational or constant-currency growth rate of between 7% and 8%. This is a tightening of the range and an increase of about $0.02 over the July adjusted EPS guidance. If currency exchange rates for all of 2017 were to remain where they were as of last week that our reported adjusted EPS would be favorably impacted by $0.03 due to currency movements, and this is an improvement from the negative impact of $0.05 in our previous guidance. Therefore, we would be comfortable with our reported adjusted EPS ranging from $7.25 to $7.30 per share, an increase of $0.10 from our prior guidance and a growth rate of between 7.7% and 8.4%.

So in closing, we are extremely pleased with the sales and earnings performance in the third quarter and our higher EPS guidance for 2017.

In summary, we're maintaining our operational sales growth of 5.5% to 6% for the year. Consistent with our goal of growing earnings faster than sales, our guidance for operational adjusted EPS growth remains strong in the range of 7% to 8%, and our businesses continue to invest for the long term, while also delivering on near-term priorities.

So now, I'd like to turn things back to Joe to begin the Q&A portion of the call, where I'm delighted to be joined by Joaquin, Jorge and Sandi to address your questions. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Dominic. So let's move into the Q&A session. Rob, can you please provide instructions for those on the line willing to ask a question?

Q&A

Operator

Thank you. Your first question comes from the line of Mike Weinstein with JPMorgan.

Q - Michael Weinstein {BIO 20602373 <GO>}

Good morning. Can you hear me okay?

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

Yes, we can.

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

Yeah. Yeah. Hi, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

Perfect. Thanks, Dominic. So, Dominic, first item, I just want to clarify for people, because it appears to be there's a fair amount of confusion out there. The margins that you reported this morning, the kind of headliner on adjusted margins this morning, that doesn't back out the amortization cost, and so those numbers that the people are looking at are not apples-to-apples. The ones you gave on your comments were more apples-to-apples for gross margins and operating margins, correct?

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

That's correct. When I'm commenting on our results, I'm doing so by excluding the special items, the most impactful impact of amortization expense, just so we can have an apples-to-apples comparison, because of the significant acquisitions we did this year. And that's right, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

Okay. Perfect. A couple of items I wanted you to touch on. One was can you give us an update on ZYTIGA and what's happening from what you can see with the IPR decision and the trial? And then, second, could you spend a minute on STELARA? Because if we look at the Pharma outperformance this quarter, and, in part, the overall acceleration in Pharma from first half to second half, one of the big stories is STELARA's acceleration over the last several months driven by the Crohn's launch. So can you talk a little bit about how that launch is going and maybe the outlook for STELARA going forward, because relative to consensus, STELARA was the big outperformer this quarter? Thanks.

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

Hey, Mike, let me turn that question over to Joaquin, who's here, as you know, runs our Pharmaceutical business. So Joaquin?

A - Joaquin Duato {BIO 17056015 <GO>}

Hi, Mike, and good morning to all of you. Before I go to STELARA, let me give you a couple of thoughts and reflections on how the quarter went. I think when we met in May 2017 on the occasion of the Pharmaceutical R&D Review Day, we anticipated that the performance of the Pharmaceutical group was going to accelerate during the second half of the year, and that's precisely what you're seeing today. You're seeing the Pharmaceutical group moving from low single-digit growth in the first half of the year to 6.7% in this third quarter, so clear acceleration of the sales of the Pharmaceutical group.

They are driven by a number of factors. One is the momentum that our key brands are gaining, mainly driven by market share gains. And one example of that that I will talk about is STELARA. As you mentioned, that posted very impressive 43% gain in the U.S. in the quarter.

The second is positive news on our pipeline. During this period, we have launched TREMFYA, which has been very well accepted by physicians. We have already 900 physicians prescribing TREMFYA, about 3,000 patients. And as we speak, TREMFYA, it's already leading a new-to-brand share when compared to the new therapies, when compared to the anti-IL-17.

And then the third one is that we completed the acquisition of Actelion and we are now in our first 100 days post-integration. You've seen the results of Actelion there, very much aligned with the expectations, positive growth and share gains both in UPTRAVI and OPSUMIT. So the combination of these three factors is driving the 6.7% adjusted growth and the 14.6% of total Pharmaceutical growth. This is very aligned on what we discussed in our Pharmaceutical Review Day.

When it comes to STELARA, the growth is driven by two factors: first, share gains in the psoriasis market, where STELARA is the leading brand in new-to-brand share in psoriasis; and second, very impressive gains also in the Crohn's disease market, where we continue to gain share. So the combination of our continuous growth and sustained growth in psoriasis plus the launch in Crohn's disease is driving this growth in STELARA that you are seeing today.

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

And, Mike, with respect to the ZYTIGA patent, so I think as you're well aware, there are two avenues that are being pursued there. The first was with respect to the court, so the New Jersey court had set a preliminary trial date for October of this year. However, during a status conference as recently as a few weeks ago in September, there was a schedule of pretrial activity. So we don't anticipate that a new trial date will be set until early next year. With respect to the second avenue in the U.S. Patent and Trademark Office, we have not yet received a decision. We understand that it's the U.S. PTO's right and permission to extend deadlines on that. So we will await word, just like everyone else. Next question, please.

Operator

Yes, your next question comes from the line of Matt Miksic with UBS.

Q - Matt Miksic {BIO 6990080 <GO>}

Hi, good morning. Thanks for taking our questions. So I had one on Pharma, and if I could, just one follow-up on Devices. So first and I guess for Joaquin since we have you here, obviously very impressive results across the core franchises, excluding Actelion. I'd love to get your thoughts on – Mike mentioned STELARA, but how some of the other pieces fit together over the next 12 months, specifically new indications, line extensions for key drugs like XARELTO and dara, and some of the other recent filings like apalutamide and how they fit together against the potential increase of biosimilar pressure.

And the reason I mention the next 12 months is because I think investors are interested in seeing how you'll maintain and extend the CAH Actelion franchise and then fit these other

pieces together to sustain your growth going forward. And then I had just one follow-up.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. Thank you for the question, and let me start with the drivers of the growth that we are having and we are seeing in the third quarter and in the second half of the year that you're going to continue to see over the next year.

Let me start with XARELTO that posted very impressive growth in this quarter of 20%, mainly driven by share gains that we believe will be sustained into next year. You remember that we already shared the data of our COMPASS study and we are planning to file this new indication by the end of the year. And that will, together with the existing share gains that we have in our markets, drive the growth of XARELTO in 2018. XARELTO had the highest share gain in the quarter in the last four years, mainly driven because we are starting to put a bigger dent on warfarin. So that's an important driver for us moving forward.

If we continue with oncology, both IMBRUVICA and DARZALEX continue to have impressive share gains. IMBRUVICA, as Joe commented, has already 50% share across line of therapies. And DARZALEX is gaining share both in third-line and second-line multiple myeloma with around 20% and 40% respectively. And we plan to file our first-line study, our ALCYONE study, by the end of the year. So that's going to be another positive driver moving into next year as we continue to gain share in different line of therapies. If you recall too, this past quarter we had the approval of the combination with Pomalyst in second-line multiple myeloma. So both IMBRUVICA and DARZALEX will remain important drivers of our growth into 2018.

The other driver that sometimes goes unrecognized but is having an important contribution is our long-acting franchise that in the quarter posted 15% growth, and we see that continue to gain share in the antipsychotic market as long-acting therapies remain relatively underutilized as compared to the potential of it. So those are going to be some of the most important drivers moving into 2018.

Then two important updates on our pipeline, it's the filing of apalutamide that we just completed and that is going to enable us to have a medicine that is going to have an indication in patients that have prostate cancer without metastasis. It would be a very important new indication for apalutamide and a great option for prostate cancers. We will continue to progress with TREMFYA in psoriasis. And also in 2018, we are planning the filing of esketamine, which we believe would be a very important option for the treatment of treatment-resistant depression. So those are the drivers that will continue to enable our market growth in 2018.

Q - Matt Miksic {BIO 6990080 <GO>}

That's great, thank you. And then, if I could, just a couple of things I think investors are curious about in Devices. One – and either Joe or Dominic on the U.S. knee market, worldwide down. Obviously, there was some international pricing you mentioned. But any color on what you're seeing here in Q3? And then in spine, the pressure, you talked about

portfolio gaps. Anything, being your position in the market as one of the leaders, comments you had on just the color of that market would be helpful. Thanks.

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

Sure, Matt, so just a little bit of commentary on knees. It was a little bit softer than what we had experienced in recent quarters. But I would say it's not the 4% that was reported as down. You have some pricing issues, specifically in India with some legislation where we actually booked the charges for three quarters, not just the one quarter since it was retroactive back to the beginning of the year. You also had some weather-related impact, albeit modest. So you're getting closer to a negative 1% to flat versus the minus 4% that we reported. Maybe for some qualitative commentary with respect to knees and spine, I'll turn it over to Sandi.

A - Sandra E. Peterson {BIO 14010554 <GO>}

Hi, Matt. Thanks for your question. So just a couple of general comments and then I'll specifically answer your questions about knees and spine in particular. As you know, I've just recently in the last few months taken over responsibility for Medical Devices. And I think in the quarter, you will see that we have some clear areas where we're doing very well like EP, wound closure, biosurgery, and some parts of our orthopedics portfolio. But there are some places in the portfolio where the full impact of some of our new product launches and some of our acquisitions have not fully taken hold yet.

And as I've said to others before, we've also spent a lot of time over the last quarter talking about how do we ensure commercial execution on the ground in a much more robust way in some of these markets. And I think we're beginning to see the positive impact of that with a lot of our businesses and some account wins that will start having some positive impact for us as we kind of continue through the fourth quarter.

Joe's comments about knees are absolutely spot on. We also – I think there's a little bit of the impact about elective surgeries in parts of the U.S. where we know a large percentage of the volume happens in that Southeast part of the U.S. that clearly had some minor impact on the business also in the quarter. We – also in Europe, which impacted our business, both our spine and knee business, we had a very unusual one-time impact on our ordering and distribution system that impacted about a week's worth of sales particularly in orthopedics. So we're catching up from that, but it clearly had an impact in both spine and knees in Europe as well as the U.S.

And then the last thing I would say is, our Tibial Tray, our cementless program as well we have just completed our first ATTUNE revision case in the U.S. and we are still in the soft rollout of that. But that clearly is going to have a very positive impact on our knee business in particular in the U.S. But as it goes global outside of the U.S., we'll start seeing the positive impact of that on our knee business as we move forward.

So I guess, I would characterize the quarter as a few one-off things that had an impact on the business. But, generally speaking, the platform is doing very well, and will start gaining more momentum as we move forward.

As it relates to our spine business, if you break it apart and look at the performance overall, obviously, we're not satisfied with the performance of that business. We have had portfolio gaps in that business for a while. We're starting to get through those and starting to launch some new things in the business. But if you look at the business from a regional standpoint, the Asian business and Latin American business had a good quarter and we have things work to do in the U.S. and North America. But you should start seeing some more positive momentum in our spine business as we go into next year, and in general, I think spine procedures have been down in the industry overall over the last couple of quarters, and that clearly there's a macroeconomic impact on spine. So thank you, Matt.

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

Great. Next question please, Rob?

Operator

Your next question will be coming from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thank you for taking the question. One for Jorge, one for Dominic. So on consumer, obviously, everyone's seen the news that Pfizer is exploring strategic alternatives for its Consumer Health business. What's the implication, if any, for your Consumer franchise? J&J has been reshaping its Consumer portfolio in recent years. Are you interested in a large deal in Consumer? Or do you prefer to continue to do smaller deals in your current categories? And as I said, I have one follow-up for Dominic.

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

So good morning and thank you for your question. Well, as you know, we have a very disciplined and systemic approach to evaluating potential acquisitions, and our focus primarily is always on value creation. And that's the overriding criteria that we use to establish whether or not we have an interest in a particular asset. So as assets become available, we systemically evaluate them, but our focus is always can we create value for Johnson & Johnson regardless of the scale of the asset.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful. And, Dominic, I wanted to ask about the puts and takes for 2018. I know you're not giving guidance yet until the Q4 call, but anything on the top line that you would call out versus 2017? But I'm more curious about EPS and how we should be thinking about the incremental Actelion accretion in 2018. It's probably about an increment of $0.30 or so. And I'm curious if that we should expect to see that on top of your normal 6% to 8% operational EPS growth or you'll reinvest some of it. Thanks for taking the questions.

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

Larry, look, I think we previously described the first full year of accretion for Actelion to be $0.35 to $0.40 a share. We said that this year's accretion was going to be about $0.07 a

share. So you're right. I mean, you get to a place that's just under $0.30 of potential additional EPS accretion from that acquisition.

As we always do, we're evaluating all our plans right now in determining where is the best place to invest, what the businesses have in terms of launches of new products, and what they have in terms of their own momentum, and we want to continue to invest behind new product launches. So it's too early to give you an expectation of how much of the accretion from Actelion will fall through versus how much will be invested. But suffice it to say, we generally, as you know, grow our sales, we aim to grow our sales faster than categories we compete in, and we aim to grow our earnings at a rate faster than sales. So we'll continue to do that and we'll give you a clearer picture of that as we set our plans for 2018 when we talk in January.

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

Thank you, Larry. Next question, Rob?

Operator

Your next question comes from Jeff Holford with Jefferies.

Q - Jeffrey Holford {BIO 4872636 <GO>}

Hi. Thanks for taking me very much. Just wondering if you can just give us a little bit more color on DARZALEX. I guess, unless you talk about in the U.S., so you'll have better information hopefully. Just your market share in the lines of therapy that you're in and what kind of duration of therapy you think you're going to get to in those lines. Thanks very much.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. So as far as DARZALEX, as I commented, our market share in third-line plus is north of 40% in the U.S. already. And in second-line, depending on the sort, it's generally north of 20% and it continues to grow.

Q - Jeffrey Holford {BIO 4872636 <GO>}

And just as a quick...

A - Joaquin Duato {BIO 17056015 <GO>}

The trends that we are seeing in the market are very positive, particularly after the approval in one prior line and the data we represented in one prior line, and also, as I commented earlier, we already finished the study in first-line in combination with VMP and we are planning to file before the end of the year. So all is positive on that side.

Importantly, we are also working, as you guys know, in developing a subcu formulation. And we are going to start our Phase III study with the subcu formulation this year. So increasingly, we see daratumumab, DARZALEX becoming a backbone therapy in the

treatment of multiple myeloma. And that's the feedback that we are getting from customers.

Q - Jeffrey Holford {BIO 4872636 <GO>}

And then just one quick follow-up, if I can, on Actelion. Dominic, I think, has talked a couple of times about how accretion from this deal can be delivered pretty quickly. I'm just wondering for 2018, do you think you'll give us some kind of update on the level of accretion that really will drop through from this in 2018 and whether there's any potential upside to the $0.35 to $0.40 that you've previously talked to? Thank you.

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

Yeah, Jeff, when we talk in January, we'll obviously point out the impact of Actelion and actually all of our acquisitions on growth. So we'll give you an estimate of organic growth, and therefore, you'll be able to see the impact of acquisitions. And on the bottom line, we'll talk about the impact it has to our overall earnings picture and also any major investments we plan to make.

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

Thank you, Jeff. Next question, please, Rob?

Operator

Your next question comes from David Lewis with Morgan Stanley.

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

Good morning. Just a couple of questions. Maybe just a, Jorge, starting with you, and maybe a couple for Joaquin. Just, Jorge, just strategically, since you got to the company, you really saw some very impressive improvements in the Consumer franchise earlier last year, and that has slowed in the near term. There are a lot of strategic questions investors have about the impact of Amazon on the broader Consumer business, the impact to millennials on brands.

Other than just making some of the investments you've talked about, is there a change in the strategic focus for this business for you based on some of these sort of macro pressures? Or is it just continuing to do the prior plan? So strategically, how well do you think you're positioned now versus when you first joined J&J?

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

Thanks very much for the question, Dave, and it's a very good one. There's no doubt that the broader CPG industry is seeing a change in the competitive landscape and there is a fundamental shift here enabled by digital technologies. And we see the rise of a lot of small companies that are now competing with the large established companies in this field.

But in the face of it, I am very confident that our strategies are absolutely the right one for us to continue with what we've had for a number of years, which is a strong sustained line of market share growth.

We have to make some adjustments in terms of the operational focus of those strategies. In particular, we have to drive accelerated growth on the online channel. And we're doing just that. We are growing we estimate at this point at twice the rate of the broader online channel with our e-commerce capabilities. We are investing very heavily in leadership, in systems, in capabilities, in general, and sales fundamentals online so that we drive our share of e-commerce to match our off-line share.

So there are some adjustments we're making, but overall, the broad strategic focus that we've had and has driven our results for the last few years remains very much in place and we feel we're very well-positioned.

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

Okay, that's Very helpful. And then, Joaquin, just two questions for me on Pharma. First, just is ZYTIGA's strength this quarter, how much does that have to do with the Patient Assistance program's disconnects in the earlier part of the year resolving, and how should we think about that franchise growth going forward?

And the second question was just on talacotuzumab, you talked about this at the Analyst Day, potential multi-billion-dollar opportunity. Can you just give us a little more detail, was this a safety issue, efficacy issue, and what's the future path going forward for talacotuzumab? Thanks so much.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. Thank you for the question. And ZYTIGA's strength, it's been mainly driven in the U.S. by the combination of market growth and share gains. So that's the reason we have had this ZYTIGA strength in the U.S.

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

Joaquin, if I could just interject, the Patient Assistance Foundation still hasn't anniversaried yet. We'd expect that in the fourth quarter. So that was actually about a 4 to 5-point headwind to growth of this quarter. Again, these are independent organizations. So it's hard to predict what may happen. But we didn't see the incremental lift from the sequential quarter from Q2, but it is still a significant comparator when you compare it to last year's Q3.

A - Joaquin Duato {BIO 17056015 <GO>}

So that's the source of the strength of ZYTIGA is the market is growing and also we continue to gain share. On price overall, including the effect of the third-party foundations continues to be a negative for ZYTIGA. What has been new recently is the presentation of the LATITUDE data, which was very well received by the customers and by patients with

very significant results in increasing overall survival and radiographic progression-free survival in patients that were metastatic, but yet hormone-naïve.

So this is the first time that a medicine is tested in this indication. And we are filing in this indication, in the U.S. and in Europe, and as a matter of fact, in Europe, we received a positive opinion for this CHMP recently. So that is the major driver of ZYTIGA. Growth is higher; market penetration combined with share gains across the board.

Regarding talacotuzumab, as Joe commented, we discontinued talacotuzumab based on recommendation of the IDMC in AML based on the safety/risk benefit ratio. And we are now evaluating that data and using those learnings to see which other indications we may pursue in the future. So it's still premature to comment on what else we would be doing with talacotuzumab.

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

Thank you, David. Next question please, Rob?

Operator

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

Q - Robert Hopkins {BIO 2150525 <GO>}

Hi. Thanks for taking the questions. Just one clarifying question and then one question for Sandi. First just to clarify, the impact of the hurricanes on the Medical Device growth you said was 30 basis points. Was that global or U.S.? And was it more pronounced in certain areas of hospital med-tech versus others?

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

Yeah. I would say, Bob, the best way to classify that, it's a very preliminary analysis. We looked at some ZIP Codes to see what particular metropolitan areas might have been hit that were in direct line of the storm. But it's mostly – would be a U.S. phenomenon obviously, because it was related to surgery days and not anything to do with supply disruption.

Q - Robert Hopkins {BIO 2150525 <GO>}

But the 30-basis-point was the impact on worldwide hospital med-tech growth, not U.S.

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

Correct. Yes.

Q - Robert Hopkins {BIO 2150525 <GO>}

Okay. And then the bigger picture question for Sandi. Just on the outlook for pricing in hospital med-tech because we've been noticing that whether it's China or Australia or India, it just feels like governments in these countries are sort of taking a hard harder line

around med-tech pricing and it could be something that impacts growth going forward. So I was just curious to get your views on how big of a concern is this for you as you look at the hospital med-tech business growth outlook outside the United States?

A - Sandra E. Peterson {BIO 14010554 <GO>}

So thanks for the question. Our sense of it is it's – in some of these markets, it's an episodic thing that happens and it's not that unusual over time. But I think what we're also finding, I guess, the punch line is we're concerned about it, but not terribly concerned about it because we have been able to go and work with many of these governments and hospital systems to find ways to provide incremental value to them beyond the physical product alone. And that's a way for us to actually be able to deal with some of these questions about pricing.

Now, obviously, the situation in India, this one-time price impact on knees clearly has an impact on the marketplace in that regard. And I think that's sort of a much more extreme example of what we've seen in other marketplaces, which were a lot more moderated. And we have the opportunity in some cases to have broader conversations with them. And it's part of why we have changed our business strategy to really show up as an integrated business talking to them about a number of different things beyond purely the physical product going forward. And so that's how we believe we're going to address this question when it arises and OUS markets.

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

Hey, Bob, maybe just to pick up on that point for the benefit of those on the call. If you look at our price contribution to the enterprise results, it was actually about negative 2%. And it was a slight positive price impact in Consumer, slightly negative in Medical Devices. And where we actually saw some price decline or price erosion was about 3% in the Pharmaceuticals sector, and that translates to about 2% down for the entire enterprise. So it speaks to the strength of Pharma that it really came from volume, market share-related types of improvements. Rob, next question, please?

Operator

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

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

Hi. Good morning, guys. Thanks for taking the question, another question for Sandi. J&J has been reshaping its Device portfolio for several years now, selling diagnostics, selling cardio. I know you're strategically looking at diabetes. So I was hoping you'd give us an update beyond what you said on Animas most recently.

And then as you look at the portfolio, and I know you've only been there a short time, but are there other areas that when you analyze the portfolio that may be divested? And then, as you look at the portfolio, are there areas that you see that may be helped through M&A? So long question and then I had a follow-up on utilization in the U.S. Thanks.

A - Sandra E. Peterson {BIO 14010554 <GO>}

Thanks, Glenn. So I'll start with you have seen the actions we've taken regarding our portfolio, but I think the most important thing is all of the actions we've taken to invest in the platforms that we believe have significant growth, and we've been doing this both in terms of acquisitions, strategic partnerships, and investing in R&D.

So if you look at our – as you know, we've made a significant bet in our neurovascular business, where stroke is a huge unmet need, and it's only growing. And so we now have a business due to some things we did internally as well as a couple of acquisitions in the last 12 months. So you should see us over time build that business the way that we have built the EP business. So it's an important growth driver for us as a company.

Obviously, in our core orthopedics businesses, we have been making acquisitions, small tuck-in acquisitions plus investing in technology as well as innovation, and you'll see us continue to drive that. The most obvious significant one in the last year is all of the investments we've been making in vision to broaden our portfolio in Vision Care. So we did three acquisitions this year to broaden the depth and breadth of our vision portfolio.

So I think you should think about this as a combination of where do we see growth in the business, whether it's in core surgery, whether it's in orthopedics, whether it's in Vision Care or what we call now interventional, you should expect to see us continuing to make those investments. And over time, if we make choices about other parts of our portfolio, we'll let you know when we make those choices.

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

Okay, so no update on diabetes other than the announcement on Animas. Is that correct?

A - Sandra E. Peterson {BIO 14010554 <GO>}

Right.

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

Okay. And then just my...

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

Glenn, I think your question was on utilization?

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

Yeah, Joe. If I look at your U.S. surgery business, I look at your U.S. orthopedic business, it did come in lighter than we expected. And it looks like in the third quarter there was a step-down to slightly negative growth versus positive growth in the first half. So I was wondering if you can provide any commentary on what you're seeing in the U.S. with respect to utilization. Is there any impact from fewer signups with ACA? Is there impact occurring because of high-deductible plans being purchased? So any color as to why we saw some weakness in either your business or utilization in the third quarter. Thank you.

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

What we're seeing, Glenn, is – and again, this is very preliminary for the third quarter, but pretty much on par with hospital admissions being down maybe 50 basis points to 100 basis points. Surgical procedures from our lens looks to be down about 2.5%. And then lab procedures are remaining flat sequentially, up about 2%. Thanks for the questions, Glenn. Next question please, Rob?

Operator

Your next question comes from Geoff Meacham with Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, guys. Thanks for the question. I just have a few quick ones for Pharma. On INVOKANA, it looks like the quarter performance was a little weak. I wanted to get your perspective from the field now that it's been a few months since the CANVAS presentation at ADA. How much of the sequential drop would you attribute to pricing, and what does that look like going forward?

And then, on apalutamide, I just want to get the J&J perspective on the cost/benefit, the profile, how it stacks against ZYTIGA. Obviously, down the road you'll be competing against the generics. So that's obviously a different sort of sales cycle on that. And then maybe bigger picture on prostate, you guys have had good data in pre-metastatic as has Xtandi. I just want to get your perspective on the tipping point really for broader urologist adoption. Thanks, guys.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the questions, and let me start with INVOKANA. INVOKANA first continues to be the leader in prescriptions in the SGLT2 category, so it's still the leader in the SGLT2 category. When it comes to this quarter, we saw a decline. The decline was mainly, mainly driven by price. And also we saw some share impact since we included the black-box warning in our label. So it was a combination of mainly price and some share declines due to the black-box warning.

As we move forward, we see opportunities with INVOKANA. The first one is we just filed our MACE indication based on the COMPASS data, and that's going to be important for us moving into 2018. And the second one, we continue to progress with our CREDENCE study in patients with diabetic nephropathy in order to evaluate how the kidney function progresses. So those are two elements that make us confident of the future of INVOKANA moving into 2018.

Regarding apalutamide, we are super-excited at being able to continue our leadership in prostate cancer with apalutamide. It's been great that we have been able to file recently for this indication. As you commented, it's going to be the first time that these agents are indicated in patients that have no metastasis.

To your question of ZYTIGA, I think you are aware that in metastatic prostate cancer, what we are analyzing, it's a combination of apalutamide and ZYTIGA compared to ZYTIGA. So that would be transformational if we are able to demonstrate that superiority. That's how we see the market moving forward. And as you are also aware, we have a license for niraparib, a PARP inhibitor in the area of prostate cancer that we are studying now that we plan to file in this indication in 2018 that eventually we will combine with our antiandrogen agent.

So we have a full line of products in the area of prostate cancer, from the non-metastatic to the metastatic indications, combining apalutamide, ZYTIGA, and eventually niraparib. So we feel very confident about the options that we are bringing to those patients. And also, we feel very confident about how competitive our offering is, which has been demonstrated by the share gains that you have seen in this quarter and about our speed in being able to complete the apalutamide trials and file for that.

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

Great, thanks for the question, Geoff. Rob, next question, please?

Operator

The next question is from Jami Rubin with Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Joaquin, maybe you could just follow up on the question related to INVOKANA. What are you seeing with the SGLT2 class? Are you losing share to Jardiance because of the amputation warning? And you talked about price, but how should we think about this franchise going forward? INVOKANA was one of those drugs that had such a spectacular launch. It was strong and now it's in negative territory, down 20% this quarter. How should we think about the growth of this franchise going forward? Would you anticipate price continues to be a thorn, or is this more of a step-down and a rebalancing, a rebasing, and would you expect to see the SGLT2 class start to take some share? And then I have a couple follow-up questions for Dominic. Thanks.

A - Joaquin Duato {BIO 17056015 <GO>}

So to your first question, yes, we are losing share to the other SGLT2 agents since we introduced the box warning in our label. We remain the leader of the category but we are losing share, particularly in new patients. Certainly, the price has been even a bigger driver in the step decline that you have seen this quarter.

Our belief in INVOKANA moving forward is based on the very positive data that we have submitted in MACE and the overall risk reduction that we see in utilizing INVOKANA, and also in the study that we are conducting, the CREDENCE one, in patients with diabetic nephropathy, evaluating their renal function. So overall, we see the SGLT2 category and INVOKANA bringing important benefits, and we continue to see INVOKANA as an important brand for us moving into 2018.

Q - Jami Rubin {BIO 1527982 <GO>}

Okay, thank you. And, Dominic, just a couple of P&L questions. I think you had said that currency has now swung from minus $0.05 to plus $0.03, so that's an 8 percentage point (sic) [$0.08] benefit. So should we assume that most of the top line and bottom line guidance increases – not all but most, the majority is related to FX? And then secondly, on the other income line, that's aligned – I know you're going to give us guidance in 2018, but it's very hard for us to analyze because it fluctuates so much depending on asset sales.

Going back in my model, this is a line item that was more into sort of the $500 million, $600 million range, and now it's $1.7 billion – $1.8 billion. There was a year where it was $2 billion. Can you just give us kind of the big picture view in terms of how we should think about this line going forward because obviously it's become a driver to earnings? Thanks.

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

Hi, Jami. So first of all, on the FX question, you're correct that the increase in our guidance is partly due to, of course, a different outlook on FX on both top and bottom line. So I think that's an accurate assessment.

With respect to other income, here's a good way to think about it. We have consistently talked about the fact that we intend to actively manage our portfolios. We've been doing that over the last several years. And in doing that, we will make a determination whether the asset is better in our hands or better in someone else's hands.

And once those decisions are made, we do include in our overall guidance for the year our expectation on this other income line, which is difficult for anyone to forecast. And that's why we give you our expectation. And you can see that we're pretty much in line with the expectation we gave you from the beginning of the year with respect to the asset sales that we think would occur this year, and therefore, be part of our overall expectation from the very beginning. We're executing on those.

The way to think about this is we don't expect that our work in evaluating the portfolio is going to diminish. We're going to continue to do that. We're going to make sure that assets are better either in our hands or in someone else's hands.

And when you look at the other income line in your model and you see it increase, please take also a look at pre-tax operating margin, which is after COGS and SG&A and R&D, and you can see that that margin at the same time decreases, which goes to the point that I made earlier that when we do this it's a portfolio decision. So we're increasing our investment in R&D, SG&A, et cetera, at the same time that we're recognizing these gains.

So they're not really drivers of earnings. They're really drivers of investment in the portfolio, and so take a look at that. And as I said earlier, we expect to complete this group of asset sales this year in our guidance, but I said earlier when we talked last quarter that I would not expect that this line item would drop off significantly in 2018. And, therefore, that allows us to keep our investment levels up high going into 2018 as well.

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

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

Operator

Your next question is coming from Josh Jennings with Cowen and Company.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi. Good morning, and thank you. I just had two quick questions for Joaquin. First on just REMICADE, the biosimilar readiness plan you installed has been effective. You've been highly successful in contracting in 2017. But I just wanted to get your input on if anything changes within the REMICADE defense strategy, the second biosimilar market in 2018 in terms of continuing to secure wins with your innovative contracting model? And I just have one follow-up.

A - Joaquin Duato {BIO 17056015 <GO>}

So thank you for the question, and the important thing here is to understand the dynamics on the REMICADE and in the immunology biologics market overall. The key factor for REMICADE being successful is the fact that physicians and patients have a high confidence in trusting REMICADE based on more than 2 million patients treated and 16 indications. There's no other medicine as established, as experienced as REMICADE is.

And the second factor, which is important to recognize is that these medicines are not interchangeable. And sometimes this element is lost in the debate. These medicines are not designated as interchangeable by the FDA. So in other words, they are not like generics, and they are not the same. They are biosimilars but not the same.

So having said that, what we are seeing in the marketplace that the physicians are very reluctant to switch a stable patient for REMICADE into other medicines. And that is normal, because in many of the indications that REMICADE is used in, particularly in the most frequent one in gastroenterology, these biosimilars do not have any data to show for. So the most important factor in the success of REMICADE is the physician and the patient experience and the body of data that supports using REMICADE and the lack of interchangeability.

Now we continue to compete vigorously in price and we continue to drive reductions, of course, for the overall system based on that. And as a matter of fact, the price of REMICADE has decreased year-over-year when you look at the net price. So when we move into 2018, we're going to continue to work along the same lines of making sure that physicians have the option to continue to use REMICADE and making sure that they are aware of the body of data and the experience that they have had during the last years in which they have been able to have this therapeutic option.

So that's really the base of our 2018 plan, making sure that physicians have the option to prescribe REMICADE and making sure that patients that are stable that can benefit from REMICADE can remain in REMICADE.

Q - Joshua Jennings {BIO 16451037 <GO>}

Thanks for that. And just a quick one on XARELTO. The COMPASS trial, it's still early days post-data, but any preliminary thoughts on how to maximize the capitalization on the coronary and peripheral artery disease opportunities? Thanks a lot.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question. As I said, XARELTO has had a terrific share gains during this quarter. It is highest share gain in the last four years. And that – while we are very pleased with the COMPASS results has nothing to do with the COMPASS results because as you know, COMPASS population, either the coronary and peripheral arterial vascular disease is a different one. And XARELTO will be used in a different dose. So all that you're seeing in XARELTO today is driven by our existing indications, particularly atrial fibrillation and VTE treatment and prophylaxis.

So moving into 2018, we are filing this year for the COMPASS data, as I commented. So we see significant opportunities in COMPASS. It's 6 million to 7 million patients that can be treated – is the total population. And we believe that the profile of XERELTA based on the data of the COMPASS trial is going to be extremely competitive. And that's going to be one of the drivers. This is only one of the studies that are included in our EXPLORER program that contains multiple indications in the studies in congestive heart failure, acute coronary syndrome, medically ill patients that would continue to drive the growth of XARELTO in 2018 and after 2018.

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

Thanks for the questions, Josh. Rob, it looks like we've got time for one more question.

Operator

Yes, your next question comes from the line of Tony Butler with Guggenheim Partners.

Q - Tony Butler {BIO 1504193 <GO>}

Thanks very much. Immunology section for J&J has been a tremendous grower, even since you date back to the acquisition of Centocor in the 1990s. But one of the things that you've recently done is that you've backed out sirukumab in RA. So I'm curious, outside of the products you have on the market today, is there anything to backfill into RA that you have in the portfolio?

And number two, within immunology, can you comment on how guselkumab has been received with payers? And if I may, a third. In – for IMBRUVICA for GVHD, Joaquin, would you say that that's a large market opportunity for you? And if so, how large? Thanks very much.

A - Joaquin Duato {BIO 17056015 <GO>}

Okay. So we – let's say, it's important for me to remind that when it comes to discussion of sirukumab or talacotuzumab, those were setbacks. But our outlook of continue to drive

above-market growth through 2021 remains more surely than before, based on the growth of our existing brands and the progress that we have had with several key elements of our pipeline like TREMFYA, apalutamide and esketamine. So that's an important thing for me to remind.

When it comes to immunology, we are the company with more assets in this category. We have four approved sets, REMICADE, SIMPONI, STELARA, and recently TREMFYA. Are we disappointed with sirukumab? We are, because we stand behind sirukumab and the value it has as an anti-IL-6. Now the additional data request that we were having from the Complete Response Letter would have delayed the introduction of sirukumab significantly. And based on the competition that exists there with all the anti-IL-6, we thought the best thing for us is to focus on other priorities.

TREMFYA, it's been very well received by physicians and by patients. As a matter of fact, as I commented, we already have 900 physicians prescribing TREMFYA in 3,000 patients, and as we speak, it's the leading in new-to-brand share in psoriasis when you consider new therapies anti-IL-17.

What about the payers? Look, this is a very competitive market in this category, and we feel confident that we have appropriate access moving into 2018. We'll be negotiating that access in this part of the year, and when the formularies come for 2018, we feel good that patients that want to use TREMFYA or physicians that want to use TREMFYA will be able to use it and will be able to prescribe it.

So overall, as we discussed, we see that even in immunology, even considering the erosion that we're going to have with REMICADE, we are going to continue to post positive growth in immunology based on the strength of STELARA and on the strength of TREMFYA moving forward.

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

Great. So that concludes the Q&A portion of today's call. Thanks to everyone for the questions and continued interest in Johnson & Johnson, and apologies for those questions we weren't able to address today.

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

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

Thanks, Joe. And as I noted earlier, we're very, very pleased with our strong third quarter performance. And I'm also glad you had the opportunity to hear directly from our business leaders, Sandi, Jorge and Joaquin, who are doing a terrific job in leading our strong businesses and delivering very, very strong results. We owe our strong performance, and therefore, our thanks to the very talented colleagues we have around the world who continue to bring innovative solutions to patients and consumers.

So thank you for your time today. I look forward to updating you on our full-year results in January. Have a great day.

Operator

Thank you. This concludes today's Johnson & Johnson's Third Quarter 2017 Earnings Conference Call. You may now disconnect.