Q2 2017 Earnings Call

Company Participants

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

Other Participants

- Damien Conover, Analyst
- Danielle J. Antalffy, Analyst
- David Ryan Lewis, Analyst
- Frederick Allen Wise, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Larry Biegelsen, Analyst
- Matt Miksic, Analyst
- Michael Weinstein, Analyst
- Robert Hopkins, Analyst
- Tony Butler, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

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

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

Joseph J. Wolk {BIO 19812977 <GO>}

Hello, this is Joe Wolk, Vice President of Investor Relations. Welcome to the review of Johnson & Johnson's business results for the second quarter of 2017. I am pleased to be accompanied on the webcast by Alex Gorsky, Chairman and Chief Executive Officer; and Dominic Caruso, Executive Vice President and Chief Financial Officer. Thank you for joining us today.

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As you've likely already seen in today's press release and accompanying materials, our results for the second quarter reflected strong adjusted earnings per share growth. Sales performance in the quarter highlights the strength of new products across all three segments as well as the positive contribution from recent acquisitions. Although there were some anticipated nonoperational offsets to reported sales growth in the quarter, which we'll address during the call, we believe the business is poised to accelerate sales growth in the second half of 2017.

A few logistics before we get into the details. This review is being made available via webcast accessible through the Investor Relations section of Johnson & Johnson's website at investor.jnj.com. There you can find additional materials including today's presentation and accompanying schedules.

Please note that this morning's presentation includes forward-looking statements. We encourage you to review the cautionary statement regarding such statements included in today's presentation as well as the company's Form 10-K, which identifies certain factors that could cause the company's actual results to differ materially from those projected. Our SEC filings including our 2016 Form 10-K along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measure are available at investor.jnj.com.

A number of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships. After remarks from Alex and Dominic, we will open up the discussion to address questions you may have regarding the performance in the quarter or the outlook for the balance of 2017. We anticipate today's webcast to last approximately 90 minutes.

Now on to recap the quarter's results. Worldwide sales were \$18.8 billion for the second quarter of 2017, up 1.9% versus the second quarter of 2016. On an operational basis, sales were up 2.9% as currency had a negative impact of 1%.

In the U.S., operational sales growth was 1.6% and regions outside the U.S. achieved operational growth of 4.4%. The effective currency exchange rates negatively impacted our reported OUS sales by 2.1 points. Excluding the net impact of acquisitions and divestitures, operational sales growth was 0.5% worldwide. I will provide this same reference for each segment.

With respect to earnings for the quarter, net earnings were \$3.8 billion, and diluted earnings per share were \$1.40 versus \$1.43 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were \$5 billion and adjusted diluted earnings per share were \$1.83, representing increases of 3.1% and 5.2%, respectively, compared to the second quarter of 2016. On an operational basis, adjusted diluted earnings per share grew 6.9%. Dominic will provide further detail regarding earnings in his remarks.

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Beginning with Consumer, I'll now comment on segment sales performance for the quarter, with the intent of building upon the slides being presented. Unless otherwise stated, percentages quoted exclude the impact of currency translation and, therefore, represent operational sales change in comparison to the second quarter of 2016. Worldwide Consumer segment sales grew 2.3% to \$3.5 billion. Excluding the net impact of acquisitions and divestitures, total adjusted operational sales declined 0.8% worldwide.

Similar to the first quarter of 2017, although to a lesser extent, sales performance across some of our Consumer franchises were negatively impacted by category slowdown. Additionally, there were a few distinct items that impeded Worldwide Consumer segment sales growth collectively by more than 1.5% worldwide.

For example, in India, the implementation of a national goods and services tax resulted in some market disruption, which negatively impacted growth by approximately 0.5 point. You may also recall in last year's second quarter, we commented to an inventory build in preparation for an IT systems conversion. This negatively impacted sales growth comparisons by a little more than 0.5 point in the current quarter.

Switching to specific platforms, the beauty franchise includes acquisitions, which contributed approximately 12 points of growth, the most impactful being Vogue. Worldwide Vogue sales totaled \$94 million for the quarter, and on a pro-forma basis is estimated to have grown high single digits. The worldwide beauty market is estimated to have grown approximately 2.5 points in the quarter.

NEUTROGENA grew 3.4%, bolstered by strong performance of sun protection products.

The OTC franchise grew 2.1%. Adult and children's TYLENOL market share continued to gain, with adult TYLENOL benefiting from the strong uptake of the Rapid Release launch. ZYRTEC grew over 17% worldwide. However, approximately two-thirds of that growth was the result of inventory restocking at distributors in the U.S. attributable to later allergy season.

Concluding the Consumer segment, oral care sales were impacted by the market contracting versus the second quarter of 2016 by approximately 1%. Worldwide market share was slightly up from the first quarter, but flat to the second quarter of 2016.

Regarding our Pharmaceutical segment, worldwide sales grew 1% to \$8.6 billion. Excluding the net impact of acquisitions and divestitures, operational adjusted sales growth was 0.5%. As we discussed in the second quarter of 2016 and reiterated on the first quarter call earlier this year, favorable prior-period price adjustments, or gross-to-net, contributed approximately \$340 million to the second quarter 2016 results in the U.S. This is a comparative headwind for the second quarter 2017 growth rate of approximately 4 points, which, when added, would take the worldwide Pharmaceutical growth to approximately 5%. While these adjustments occurred across the entire U.S. Pharmaceutical portfolio, the most pronounced impacts occurred in REMICADE, PROCRIT, STELARA, and SIMPONI.

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In oncology, DARZALEX continued its strong performance as the brand continues to experience strong adoption across all lines of therapy, with share leadership in line four-plus and strong uptake in lines two and three, pursuant to the approvals of those indications late last year. OUS strength was evident in many Euro countries, most notably Germany and France.

IMBRUVICA continues to gain share across all indications globally. And based on first quarter data, the CLL market in the U.S. is estimated to have grown approximately 20%. Negative ZYTIGA growth in the U.S. was largely the result of higher utilization of independent patient assistance foundations, a dynamic that has carried over from the prior two quarters.

In immunology, the U.S. market is estimated to have grown approximately 8%. STELARA in the U.S. gained 1.4 points of market share in the total immunology market versus the second quarter of 2016, driven by the strong adoption for the newer Crohn's disease indication. REMICADE in the U.S., after considering the 2016 prior-period price adjustment mentioned earlier, declined a little more than 5%, which is below the 10% to 15% we projected earlier in the year for 2017. SIMPONI/SIMPONI ARIA in the U.S., when accounting for the 2016 prior-period price adjustment also referenced earlier, grew approximately 4%

In neuroscience, our paliperidone palmitate long-acting injectable portfolio achieved strong results in all major regions due to increasing market share for TRINZA and SUSTENNA. CONCERTA in the U.S. experienced negative impact from the reentry of generic competition late last year.

Within the cardiovascular metabolic therapeutic area, XARELTO's total prescription market share was up more than 2 points versus one year ago, as warfarin continues to decline in favor of branded products. Similar to last quarter, for preferred access positions, we are experiencing higher discounting in managed care and government channels. A favorable return reserve adjustment in the second quarter of 2016 impacted comparative growth for the second quarter of 2017 by approximately 3 points.

INVOKANA/INVOKAMET sales in the U.S. declined due to increasing discounts for managed care contracting and higher utilization in the Medicaid channel.

Finally, the pulmonary hypertension products reflect the sales in the quarter since the Actelion acquisition closed on June 16. Many of you have asked for historical data prior to Johnson & Johnson's ownership of these assets to reflect in your financial models. So at this time, we have provided an unaudited schedule of sales for this business on our website.

I'll now turn to the Medical Devices segment. Worldwide Medical Devices sales were \$6.7 billion, growing 5.9%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 1.1% worldwide.

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The Vision Care business was strong on all fronts. Contact lenses grew above market at approximately 7% worldwide, as new products, namely OASYS 1-Day and variants of the DEFINE lens, continue to be well-received in the market. There is \$25 million under the label of other, reflecting the inclusion of the recently acquired consumer eye health products from Abbott. That transaction closed February 27, so this is the first full quarter we are reporting for that as well as the vision surgical business. To help put the surgical performance into context, on a pro forma basis, worldwide surgical grew more than 10% based on cataract lens strength.

Our Hospital Medical Devices business had approximately one-half less selling day OUS as compared to the same period a year ago, negatively impacting worldwide growth by approximately 80 basis points. For those in the audience who are updating their models, the impact of selling days for the balance of the year will be nominal.

Within Hospital Medical Device platforms, electrophysiology grew approximately 15% worldwide as atrial fibrillation procedures continue to grow, estimated at 13% for the quarter. Strong adoption of newer product offerings such as SMARTTOUCH Sensing Force in ablation and advanced catheters continued.

Within the Advanced Surgery category, endocutters and energy grew 3% and 4% respectively. Endocutter growth was driven by performance in EMEA and China, while energy growth includes 480 basis points of growth from the Megadyne acquisition.

Biosurgicals growth of 5% was the result of strength in China across all platforms and growth of the U.S. market. The decline in Specialty Surgery business was driven by share loss in the aesthetics and infection protection businesses.

Within orthopaedics, growth in hips was driven by continued uptake of the primary stem platform, partially offset by competitive pressures in the Asia-Pacific region. Knee performance was driven by growth in the U.S. market and the continued uptake of ATTUNE, partially offset by declines in ASPAC related to competitor pressure and pricing.

Trauma, including sales from the acquisition of BioMedical Enterprises, which positively impacted growth by 20 basis points, grew approximately 2%, driven by the continued uptake of TFNA, solid growth in the U.S. market, and strength in EMEA, particularly UK, Germany, and Italy. Finally, continued share loss in our spine business was principally due to portfolio gaps and was partially offset by strength in sports medicine and power tools.

Pricing pressure continued across the major categories in orthopaedics, but was partially offset by favorable mix in knees, trauma, and spine. For the quarter, price net of mix in hips was negative 2.6%, knees positive 0.3%, positive 2% in trauma, and negative 2.3% in spine.

That concludes the segment sales highlights for Johnson & Johnson's 2017 second quarter. For your reference, here is a slide summarizing the many notable events that occurred during the second quarter. I am now pleased to turn the call over to Alex Gorsky.

Alex Gorsky {BIO 16239711 <GO>}

Thank you, Joe, and thank you all for joining our call and webcast today. I'm pleased to be here to discuss our performance for the first half of 2017 as well as to update you on our outlook and expectations for the remainder of the year.

There have been a number of significant events in the first half of the year, including completing the acquisitions of our new surgical vision business as well as Actelion. A few weeks ago, we also shared with you our pharmaceutical R&D strategy and pipeline of transformational medicines at our business review meeting.

These events all illustrate how we continue to invest for strong, long-term, sustainable growth. And as Joe outlined for you this morning, we are very pleased with the earnings per share results we've delivered, which exceeded your consensus estimates, and our businesses have largely continued to deliver sales results in line with expectations.

Dominic will take you through a bit more detail in a few minutes regarding how our performance and outlook will impact our guidance moving forward, but we're optimistic that the investments we made and strategies we put in place can continue to build the momentum we need to accelerate our growth in the second half of the year.

First and most importantly, I'm proud of how the commitment to Our Credo continues to be upheld by our more than 130,000 employees around the world. You can find many examples of how we're living into Our Credo in our recently released Health for Humanity Report. Holding ourself accountable to the important responsibilities highlighted in Our Credo unites us and guides us in achieving our mission. As we look at the external environment and potential impacts on our business, there are a few topics that I'm often asked to comment on that have been areas of interest in recent weeks.

First, in terms of our interactions with the U.S. administration, we're pleased that senior officials are continuing to listen to business leaders when considering the impacts of legislation, and we'll continue to participate in these conversations as well as those with other world leaders to make sure our voices are heard on these vital issues. In fact, I'm here in Washington, D.C. today meeting with U.S. and global leaders, driving forward discussions on the important issues impacting healthcare today.

On the topic of healthcare reform, we continue to support initiatives that expand access to affordable healthcare and improve long-term sustainability of the U.S. healthcare system. We've been monitoring the ongoing development of the AHCA with great interests and think that as our political leaders bring the new healthcare bill through Congress, it is important that they consider how these efforts will ensure stability within the system while enhancing the competitive market and fostering continued innovation for new treatments and cures.

In terms of the potential executive order on pharmaceutical pricing, we understand the concern about the cost of healthcare and believe we have a responsibility to ensure our products are both accessible and representative of the outcomes and value they deliver.

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We recognize the important role pharmaceutical drugs play in improving healthcare outcomes. We know these medicines represent only about 15% of overall healthcare spending, yet they also represent a critical component of effectiveness and efficiency in the healthcare system.

As we note in our 2017 Janssen U.S. Transparency Report, we've maintained a responsible approach to pharmaceutical pricing, generally limiting our aggregate annual price increase to single-digit percentages below those of our competitive set. We'll continue working with all our stakeholders to ensure a sustainable future for America's healthcare ecosystem.

Finally, while we remain optimistic that there are opportunities for modernization of the corporate tax code in the near future, we'll continue to monitor any developments or progress as Congress prioritizes this among other pressing needs. As we've said before, we believe fundamental elements of our current tax system are outdated and disadvantage U.S. companies against our international competitors, who have reduced tax rates, domestic-only taxation and have incentives for innovation and investments.

We look forward to continuing our work with government officials, our customers, and other stakeholders to ensure we're doing our part to provide differentiated, value-based and accessible healthcare to people around the world. Regardless of the outcome of these discussions, we will continue to engage with global leaders and be a leading voice advocating for the stakeholders in Our Credo.

As we evaluate how we are and will be positioned in the markets in which we compete, we continue to actively manage our portfolio of businesses. We see external innovation and acquisitions and licensing deals as equally important to our growth strategy as our internal innovation programs. While we continue to make progress on our rich pipelines across our three business segments in the first half of this year, we have also closed eight acquisitions and licensing deals including Actelion and AMO. And as we announced in January, we're continuing to work on strategic options for a Medical Device diabetes franchise.

As we evaluate each of our businesses, we always want to ensure they are a good strategic fit, that they are addressing unmet patient needs, and that they are contributing to our overall growth and financial strength. One of those investments that we expect to augment our future growth is our acquisition of Actelion. We're excited to expand our already-strong portfolio with leading differentiated in-market medicines, including OPSUMIT, UPTRAVI and TRACLEER, and promising late-stage products that will help patients suffering from pulmonary arterial hypertension [PAH] and other serious illnesses.

We see great opportunities with this business, starting with the treatment of the disease itself, addressing PAH earlier, producing better outcomes and expanding into new patient populations. For the existing medications, we want to explore how combination therapies can improve patient outcomes. For the business itself, we want to expand its global footprint. When you look at the clinical development, regulatory and commercial skills in

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our Janssen organization, we believe there are significant opportunities to create value for both the Actelion business and Johnson & Johnson.

Beyond the value we will deliver to patients and the growth we'll realize in our business, we're very excited to welcome the talented employees from Actelion. They are a great cultural fit with the Johnson & Johnson Family of Companies as they value innovation, patient centricity, collaboration and the very best science. We feel the Actelion business has already been and will continue to be a great addition to our Pharmaceutical portfolio.

Across our Pharmaceuticals business, we continue to deliver life-saving and life-changing therapies to patients around the world with an incredible pipeline of more than 10 new blockbuster products to launch or file for regulatory approval in the next five years, each with greater than \$1 billion in peak year sales potential.

We hope you were all able to either join us in person or on our webcast for our Pharmaceutical business review in May. And if you weren't able to attend live, I encourage you to review the replay available on our website. Our strong and talented Janssen leadership team outlined our strategy for growth and innovation in Pharmaceuticals, and provided great insight into our robust pipeline.

I'm not only proud of the impactful cures and treatments our Pharmaceutical business is delivering to patients around the world, but our R&D investments are projected to deliver more value than ever before. And the potential value of our pipeline is greater than it has ever been.

As we look at the near-term opportunities in this business, in addition to Actelion, we're continuing to increase our penetration in markets such as anticoagulants, psoriasis and long-acting antipsychotics. We'll continue to build on the recent launch successes of DARZALEX, IMBRUVICA, and line extensions such as STELARA for Crohn's disease. And with the early approval of TREMFYA, as we've just announced last week, and the anticipated regulatory approval for sirukumab later this year, we look forward to further expanding our immunology portfolio.

These two medicines represent important enhancements to our immunology portfolio, adding to our leading in-market brands like STELARA and SIMPONI, as well as REMICADE. Physicians have a strong preference for REMICADE versus biosimilars, and we enjoy a strong access position in the U.S. We'll continue to compete in the market and defend our IP against biosimilars to launch at-risk in the U.S. Overall, we expect our immunology business will continue to grow in 2017, and we expect to maintain our leadership in this segment.

In our Medical Device business, in the second quarter, we continue have areas of above market growth like electrophysiology and Vision Care for both contact lens and surgical businesses based on our internal estimates, areas where we're growing with the market like biosurgery, wound closure and hips. And there are also areas where we know we still need to do better, as is the case with spine, ENT, and our aesthetics products.

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We are continuing to actively manage our portfolio, focusing on transitioning our business to higher growth areas with large unmet needs, as you've seen through many of our recent acquisitions and strategic partnerships across our Medical Device portfolio, including our surgical Vision Care business, interventional spine, Megadyne in energy, Torax Medical in general surgery, and Neuravi in the neurovascular category.

Through the work we put in to restructure and focus in our Hospital Medical Device business, we're on track to accelerate our number of major product launches with new products like our THERMOCOOL SMARTTOUCH SF catheter. We're going to market with novel commercial models such as our recently announced CareAdvantage collaboration with Medical University of South Carolina to reduce infection risks, and we're filling key portfolio gaps that we expect will provide growth in 2017 and beyond.

As the most comprehensive medical devices company in the world, we remain confident that we are well positioned to serve a market that continues to consolidate by providing a simplified customer experience, progressive contracting and innovative solutions, and developing innovations and capabilities and improved patient outcomes, and deliver value to the healthcare market.

In our Consumer business, we have a world-class portfolio of iconic megabrands that are professionally endorsed, and we continue to believe we're playing in large structurally attractive markets despite some recent lagging category growth that Dominic will comment on later. As with Medical Devices, there are areas that are performing well like beauty and OTC, where we continue to see strong results. We know we have work to do in other areas such as our baby franchise where, as we've previously discussed, we're working to revitalize and relaunch key products.

We're also leveraging our scale and global footprint with a strong portfolio of local brands in emerging markets which will serve as an entry point for further expansion across our enterprise. Additionally, we expect to further accelerate our growth through our recent acquisitions in the beauty franchise, OGX and NeoStrata, and the light therapy products now in our NEUTROGENA business. And we expect some of these products that are new to our portfolio, along with some of our recently launched innovations such as NEUTROGENA Hydra Boost and TYLENOL Rapid Release to drive growth in the second half of this year.

Overall, we continue to make very good progress on all of our near-term priorities, as well as continue to invest and advance our long-term growth drivers. Our shareholder return for the first six months of the year of 16.3% continues our trend of topping most major indices over the last 3, 5, 10 and 20 years. And for all the reasons you've just heard me share about the opportunities across each of our businesses, we are well positioned to accelerate our growth to the end of 2017 and beyond.

And now, Dominic Caruso will share a little more insight on our results for this quarter and provide some additional commentary about our guidance for the remainder of the year. Dominic?

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Alex, and good morning, everyone. I'll begin my remarks with a few comments on second quarter results, which will be followed by comments regarding some changes to our guidance for you to consider as you update your models.

We are very pleased with our adjusted earnings per share growth of 5.2% for the second quarter, which exceeded the mean of the analyst estimates on first call. Overall, sales results and our operating performance were largely in line with your estimates. We continue to expect an acceleration in our sales and earnings growth in the second half of the year, which I will provide further insights into later in my remarks. And, of course, we are extremely pleased to have closed the acquisition of Actelion, and I'd like to add my welcome to the Actelion employees joining Johnson & Johnson.

I will now turn to our consolidated statement of earnings for the second quarter of 2017. As Joe described, our operational sales growth this quarter was 2.9%, and excluding the impact of acquisition and divestitures, it was 0.5%. As many of you have modeled and as we've discussed previously, this quarter's results were impacted by prior-period positive adjustments we recorded in the second quarter of 2016 for reserves set aside for discounts and rebates to various payers such as Managed Medicaid. Adjusting for that and excluding acquisitions and divestitures, operational growth was 2.4%.

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 second quarter net earnings were adjusted to exclude intangible asset amortization expense and special items of \$1.2 billion on an after-tax basis, which consisted primarily of the following: intangible asset amortization expense of approximately \$375 million; litigation expenses of approximately \$350 million; Actelion acquisition-related cost of approximately \$200 million; an impairment charge of approximately \$125 million related to the previously disclosed process of seeking strategic alternatives for our diabetes business; and a charge for the continuing restructuring of our Hospital Medical Device business of approximately \$100 million. Our adjusted earnings per share is, therefore, \$1.83. Adjusted EPS on a constant currency basis was \$1.86 or up 6.9% over the prior year.

Now, let's take a few moments to talk about the other items on the statement of earnings. Cost of goods sold increased by 200 basis points, primarily due to the inclusion of amortization expense from our recent acquisitions. Excluding the impact of amortization expense for both periods, cost of goods sold was 27.9% or 60 basis points higher than the prior year, mostly due to transactional currency and product mix. Selling, marketing and administrative expenses were flat as compared to the second quarter of 2016. Our investment in research and development as a percent of sales was 12.1%, consistent with the prior year. Interest expense, net of interest income, was a net expense of \$122 million, which was slightly higher than last year.

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Other income and expense was a net expense of \$588 million in the second quarter compared to a net expense of \$557 million in the same period last year. Excluding special items recorded in this line, other income and expense was a net gain of \$373 million compared to a net gain of \$119 million in the prior-year period, reflecting completion of certain asset sales which were included in our annual guidance. I will provide an update on this activity during my guidance comments.

Excluding special items, the effective tax rate was 20.2% compared to 19.2% in the same period last year. This rate is consistent with our expectations as a component of the full-year effective tax rate.

Turning to the next slide, I will now review adjusted income before tax by segment. In the second quarter of 2017, our adjusted income before tax for the enterprise improved 80 basis points versus the second quarter of 2016, driven by favorability and other income and expense.

Looking at the adjusted pre-tax income by segment, Medical Devices at 30.4% is higher than the previous year, primarily due to SG&A cost efficiencies. Pharmaceutical margins improved by 40 basis points to 44.5%, driven by favorability of other income items. And Consumer margins improved to 20.5%, primarily due to SG&A cost efficiencies, as well as some other income. Now, I will provide some guidance for you to consider as you refine your models for 2017.

As expected, with the close of Actelion in June, at the end of the second quarter, we had approximately \$22 billion of net debt, which consisted of approximately \$13 billion of cash and marketable securities, and approximately \$35 billion of debt. Also of note, we have now completed our \$10 billion stock repurchase program. 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, 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. Our ongoing reviews suggest we currently have more opportunity to divest some nonstrategic businesses, which will result in higher other income gains.

While some of this may result in higher EPS, as we have done many times before, most recently in 2015, we intend to redeploy most of those gains back into the business to enhance our long-term growth prospects. Considering this, we would be 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, an increase over our previous guidance.

In regard to pre-tax operating margin, you may recall at the start of the year, we guided that this would remain flat to slightly improved. As we expect investment levels to further

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increase in the second half of the year, we now expect that we will maintain or possibly see a slight decrease in our adjusted pre-tax operating margin for the full year. This of course is offset by the higher divestiture gains I just mentioned.

And now a word on taxes, our guidance today does not include any assumptions about potential tax reform measures. Our effective tax rate guidance for 2017, excluding special items, is 19% to 20%, consistent with 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, and 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 we believe this provides a good understanding of the underlying performance of our business. We will 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 continue to expect an acceleration of our operational sales growth in the second half of the year. Across the enterprise, the second half acquisitions in 2016 as well as the major acquisitions of Actelion and Medical Optics completed earlier this year all remain on track to slightly ahead of our original projections. Despite some moving parts, our outlook for Pharmaceuticals remains optimistic as to a back-half acceleration, especially when considering easier year-over-year comparisons in the third and fourth quarters. Also, we expect that the positive factors of the earlier launch of TREMFYA and a more moderate erosion of the U.S. REMICADE business versus original projections will help offset the higher discounting we are experiencing.

In Hospital Medical Devices, our restructuring initiatives continue to progress. And as we stated previously, we expect that the contribution from new products will accelerate in the back half of this year. And in Vision Care, our strong growth is expected to continue.

In Consumer, as you heard from Alex and Joe, although slightly improved in the second quarter, the broader market continued to experience lagging category growth. We still expect new product launches in Consumer to have a meaningful positive impact on second-half growth, and we will increase investment to support these launches. However, these new product offerings are likely launching into weaker markets. So naturally, that positive impact will be mitigated to some extent. The impact from the weaker macroeconomic dynamics in Consumer is now estimated to continue through the balance of the year, longer than we had previously expected.

Considering all of this, we are updating our operational sales guidance for the year. Previously, we guided to a range of 5.8% to 6.8%. Our new operational sales guidance is now 5.5% to 6%. This translates to sales for 2017 of approximately \$75.9 billion to \$76.2 billion on a constant currency basis.

Although we are not predicting the impact of currency movements, using the euro as of last week at a blended rate of \$1.11, the negative impact of foreign currency translation

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would be approximately 10 basis points, a much lower negative impact than our previous guidance. Thus, under this scenario, we expect reported sales growth in the range of 5.4% to 5.9%, for a total expected level of reported sales of approximately \$75.8 billion to \$76.1 billion, which is higher than our previous guidance.

Now, turning to earnings, we expect adjusted EPS to be in the range between \$7.17 to \$7.27 per share on a constant currency basis, reflecting an operational or constant currency growth rate of 7% to 8%, a midpoint increase of \$0.03 over our April adjusted EPS guidance. If currency exchange rates for all of 2017 were to remain where they were as of last week, then our reported adjusted EPS will be negatively impacted by \$0.05 due to currency movements. This is a smaller negative impact than our previous guidance. Therefore, we would be comfortable with our reported adjusted EPS ranging from \$7.12 to \$7.22 per share or a growth rate of between 6% and 7%.

In closing, we remain optimistic that we will see accelerated growth in the second half of 2017. And in summary, we are expecting operational sales growth of 5.5% to 6% for the year. Our operational adjusted EPS growth and our guidance remain strong, in the range of 7% to 8%, consistent with our goal of growing earnings faster than sales. And our businesses are continuing to invest while also delivering on our near-term priorities.

Now, I'd like to turn things back to Joe to open up the Q&A portion of the call. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Great. Thank you, Dominic. We will now move into our Q&A session. Manny, can you please provide instructions for those on the line wishing to ask a question?

Q&A

Bloomberg Transcript

Operator

And with that, the first question comes from Glenn Novarro of RBC Capital Markets. Please go ahead.

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

Hi. Good morning, guys.

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

Good morning, Glenn.

Q - Glenn John Novarro (BIO 2430199 <GO>)

Thanks for taking the question.

A - Alex Gorsky {BIO 16239711 <GO>}

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Good morning, Glenn.

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

Let me start on the pharmaceutical side. So we continue to see pricing pressure in XARELTO and INVOKANA, and we understand both drugs are in competitive categories. But is there a light at the end of the tunnel? Do these two drugs face less pricing pressure in the back end of the year? So that's specifically on those two drugs.

And then more broadly, Alex, maybe talk about what you're seeing in terms of pricing pressure across the franchises. Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Glenn. Thank you very much for your question. I'm assuming that you're talking about the Pharmaceutical business. Is that correct?

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

That is correct, yes. Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

I think it's two very different stories between XARELTO and INVOKANA. And while there's always a secular backdrop here, I think the pricing pressure in many of these areas in the Pharma business, in the case of INVOKANA, of course, we've seen a significant impact based upon the relabeling issue. And even prior to that, we had seen a lot, obviously, of competitive pressure around pricing. And just given the incidence of Type 2 diabetes and the pressure on systems, we feel the competition, frankly, exemplified that.

If you look at XARELTO, however, we continue to be encouraged by the ongoing stream of really positive data, our very strong managed care account management capabilities, and so we feel optimistic about the future with XARELTO. And while there will undoubtedly be pricing pressure, we think that by continuing to differentiate the brand with strong clinical information, strong value information, as well as, frankly, execution in the field, that we'll be well positioned going forward.

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

And then, Alex, can you just broadly talk about pricing in general across the Pharmaceutical franchise? Because it looks like some of your differentiated drugs such as IMBRUVICA and DARZALEX are holding up a lot better in terms of pricing than maybe some of your more GP mainstream oriented drugs.

A - Alex Gorsky {BIO 16239711 <GO>}

Glenn, in general, we would say is that in the specialty areas, particularly in areas, whether it's IMBRUVICA, whether it's DARZALEX, where you're literally adding months, years of life to patients and really making significant differences in terms of outcomes, we are seeing less pricing pressure versus the categories where you have very large patient populations,

very large incidence, used more in a primary care setting. And so we definitely see that in both cases. We think that our account management and our reimbursement teams globally are doing a very good job of making sure that stakeholders, particularly payers, understand not only the benefits, but frankly, the difference in overall outcomes and economic value that the drugs represent. But I think overall, those have been our major observations.

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

Hey, Glenn. I might add as well, with the more competitive dynamic in some of the primary care drugs, you do have elevated discount levels that raise the statutory rebates as well. So things like Medicaid, the rebates are going to be a little bit greater in those areas. And then under the Affordable Care Act, you had a few states opt in to expand their Medicaid. I think was Louisiana, Indiana, and Pennsylvania. So that's having a minor impact as well.

A - Alex Gorsky {BIO 16239711 <GO>}

Definitely, yeah.

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

Those are recent opt-ins, right?

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

That's correct.

Operator

Thank you. The next question is from Mike Weinstein of JPMorgan. Please go ahead.

Q - Michael Weinstein {BIO 20602373 <GO>}

Good morning, everybody.

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

Hi, Mike.

Sloomberg Transcript

A - Alex Gorsky {BIO 16239711 <GO>}

Good morning, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

I'm going to try and sneak in a couple here. So let me touch on a few. So number one, I was hoping you could comment on STELARA. It's probably one of the top products that the Street seems to have a debate on, on the outlook going forward. And I think the expectation is that psoriasis use has declined while Crohn's sees uptake. In this quarter, STELARA particularly exceeded the Street's expectations. with some of your commentary

Sloomberg Transcript

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pointing to a strong Crohn's launch. So can you talk about the outlook for STELARA, and how potentially you size the Crohn's opportunity and how you view it going forward?

The second question is hoping you could give us an update on the ZYTIGA IPR decision? This is for the 438 patent. I think originally, you were expecting that we would hear something by the end of May. We haven't, so we'd like your expectation as when we could hear something. And then last one. Hoping you could give us an update on the diabetes business and where that process stands. Thanks.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Mike. Thank you very much, and you did sneak in three there. But let me start with the first one. Look, we remain very positive about the overall opportunity in psoriasis. It just starts with the patient population, the unmet medical need. We believe that only about 25% to 30% of the patients in that category are actually on some of the newer agents. So that in and of itself represents a significant opportunity. We know that there are shifts from one therapy to another. And then when you really look at the strong data that we have - and, by the way, we're really excited with the recent approval just last week of TREMFYA as well; that, that gives us a big opportunity.

And as we've been talking about now for quite some time, we really are trying to look at our immunology portfolio, not just a product-by-product accounting, so to speak. And with that, we think with TREMFYA - STELARA, certainly, we saw rapid uptake in psoriasis; now in Crohn's. But if we look at the data with TREMFYA, particularly competitively, what we have versus HUMIRA, we think that represents a very significant opportunity going forward.

While at the same time, you take a drug like STELARA in Crohn's, again, high prevalence, a lot of unmet medical need, very strong data, that's going to allow us to continue to grow STELARA, we think, at a very significant rate going forward. So it does represent, again, a portfolio approach, and we think that's why we're especially well prepared to manage through the REMICADE biosimilars, but also continue to expand our overall immunology portfolio. I'm going to let Joe pick up on ZYTIGA, and then I'll come back for diabetes.

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

Okay. Mike, with ZYTIGA, you're absolutely correct. We were expecting to hear from the PTO at the end of May. We had not received word and there's been no notification since that point in time, and they're not obligated to do so. So we're awaiting word just as you are.

A - Alex Gorsky {BIO 16239711 <GO>}

And, Mike, as we talk about type 2 diabetes, look, obviously an area where there's a lot of unmet medical need, but the same time, an area where there's a lot of competition among the SGLT2s, let alone other therapeutic options in that category. There's still a lot of good news about the CANVAS trial when you really look into the data. At the same time, the recent labeling change has also impacted, along with just the overall competitive environment. So this remains an area where we're very interested. We want to

make sure the patients continue to have options, as well as physicians, but we also recognize the competitive nature of the category.

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

Hey, Mike. I might just add that you may be referring to the diabetes medical device franchise as well. And there, you saw we took an impairment charge, this is largely related to the Animas pump business, not the overall blood glucose monitoring business, which is, of course, the larger portion of the business. And our efforts to review various strategic alternatives are still progressing, moving along just fine, but nothing to report on that front yet.

Operator

Thank you. The next question is from Jami Rubin of Goldman Sachs. Please, go ahead.

Q - Jami Rubin {BIO 1527982 <GO>}

Hi. Can you hear me all right? Because there's a really bad echo. I hope I'm not echoing.

A - Alex Gorsky {BIO 16239711 <GO>}

No. We hear you fine.

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

We can hear you fine, Jami.

Q - Jami Rubin {BIO 1527982 <GO>}

Okay, great. Great, good, thank you. So I just wanted to get some clarification on the guidance raise and the revenue raise, and try to better understand where that's coming from. It seems, based on our math – and, Dominic, I want you to correct me if we're wrong – that the additional \$500 million or so, \$500 million to \$600 million sale in asset sales is adding \$0.15 to your EPS. But then, when I look at your previous guidance, it looks like you are only raising the guidance by \$0.10. So what is happening? What is the offset to that \$0.05?

And then, secondly, on revenues, FX will be less of a hit than what you anticipated, adding \$600 million in benefit. But from taking the midpoint of your previous guidance, that was only about \$200 million. So, again, what is explaining the difference? Why are revenues going up more just given your confidence in a stronger back half in a less-challenging FX environment? Thanks very much.

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

Sure, Jami. So let me take it in the order of EPS and other income first, and then revenue. So in the area of other income and expense, you're right, we did raise that guidance roughly \$500 million. We don't expect all of that to flow to the bottom line because as we commented in my earlier remarks, we expect, as we always have done in the past

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whenever we have portfolio shifts, to reinvest some of those gains back into the business with respect to new product launches, R&D investments, and the like.

So you may recall that we also commented that our operating profit margin, instead of maintaining or slightly improving, would maintain or slightly decline. So the vast majority of the other income raise was going to be reinvested in product launches and R&D and, therefore, operating profit margin before other income and expense would decline, so that's the offset.

You had rightly so commented on a \$0.10 raise in EPS. A little over 65% of that is currency related, so it just saw what we saw, benefits to revenue from currency, we'll see benefits to EPS from currency, and the balance is operating performance, some of which from the OI&E line and none from the tax line. So, hopefully, that explains or reconciles for you that distinction.

And then, with revenue, yes, currency will have a more favorable impact of roughly \$600 million due to a less negative impact of currency, but we did tighten up our range on operational or constant currency sales a little bit, lowered that midpoint just a bit, and we talked about earlier, what we see in the back half of the year, although acceleration will take place across all three businesses.

In the Consumer business, we're seeing some much weaker markets and some macroeconomic conditions, particularly in China and India. So, we've adjusted our expectations. Although they will increase revenues in the back half, Consumer is going to face some lingering market deceleration versus the prior year. So, hopefully, that reconciles those two points for you as well.

Q - Jami Rubin {BIO 1527982 <GO>}

It does. Can I just follow up with REMICADE?

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

Sure.

Q - Jami Rubin {BIO 1527982 <GO>}

On REMICADE, you've only had one competitor on the market. There will be another biosimilar to enter later this year. What are you seeing in terms of market share from INFLECTRA and the pricing dynamic? And how do you expect that to change with the second biosimilar entering the market later in the year?

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

Okay. Well, let me tell you what we're seeing so far, is that you saw REMICADE was down about 14%, but the significant impact to that was this prior-period adjustment issue for rebate reserves that we discussed. So excluding that, REMICADE's only down about 5%. That 5% down has some impact of price, some minor impact of share erosion, and we see some conversion of REMICADE in Crohn's disease to STELARA in Crohn's disease, part of

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Mike Weinstein's earlier question of why STELARA is doing so well as a conversion over from REMICADE patients in Crohn's.

So, roughly, 5% decline is much lower than, I think, us and any of you had expected for erosion of REMICADE, which we all targeted to be somewhere between 10% and 15%. So, we haven't seen much impact now. We don't know when the new biosimilar from Samsung will launch. It may launch later this year, and in terms of what impact that might have, I think that all depends on the degree to which they discount that product and significance of which they discount that product. But I would say largely, for this year, we have our contracting in place with all the managed care organizations, so we feel pretty good that REMICADE erosion overall, even with the entrance of a new biosimilar, will be less than we previously expected.

Next question?

Operator

Thank you. The next question is from Matt Miksic of UBS. Please, go ahead.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks. Good morning. Thanks for taking our question, and I would say we are getting a pretty strong echo here from our end. Anyway, so just a follow-up, if I could, on the Pharma business, and then I have one additional follow-up on device trends. But first, on Pharma, we'd be interested in any additional color you could share on some of the key drivers and forthcoming drivers here in the back half. For example, you've seen very strong first half in DARZALEX. Maybe where are we, what inning are we in maybe in terms of some of the extended indications? What kind of ramp might we expect towards this \$1 billion TREMFYA opportunity, and any transitional adjustments to the Actelion PAH business, the sorts of odds and ends for us to consider as we put together our back-half estimates? And I would mention one follow-up for devices, if I could.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Matt. This is Alex. Look, we remain very optimistic about Pharma in the second half of the year. And we continue to see really strong uptake, both with DARZALEX and the various multiple myeloma indications, earlier utilization, IMBRUVICA in lymphoma. Again, with all the different data sets that we have going out, we continue to see very nice uptake there. We mentioned earlier, the strong performance of STELARA, I think up over 23% for the quarter, a lot of that in Crohn's. The other area that we've been really pleased with that is showing growth, I believe, at around 13%, 14% is our long-acting antipsychotics, TRINZA in particular. We've continued to see uptake go well there.

The Actelion integration thus far has gone very well under the leadership of both Paul and Joaquin. Our teams are working, I think, very smoothly together. And as alluded to earlier, Actelion overall is meeting and/or slightly exceeding some of our expectations. We're certainly putting a big premium on minimizing or eliminating any disruption and, in fact, looking for ways to grow these areas appropriately, but an even higher growth rate, as we indicated earlier in some of my comments. And then when you compound that with the

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launch of TREMFYA in our immunology group, it - and the lapping of some of the earlier PPAs that we were talking about, I think gives us confidence in the back end.

And then, of course, if we go one step further out, and you combine that with some of the new data sets that we expect in the back end of the year and as we head into early 2018 around esketamine and the TRANSFORM data; apalutamide in prostate cancer; a continuing stream of data with DARZALEX as first line, multiple myeloma; IMBRUVICA, first line in DLBCL; and then the COMPASS data with XARELTO, we think that, again, all of these will be reinforcing the great profiles of these compounds and provide even additional sources for growth.

Q - Matt Miksic {BIO 6990080 <GO>}

That's very helpful, Alex. Thanks. And then on devices, understanding that you're addressing some of the competitive gaps, as you mentioned, that you have in spine, and that's a different kind of business. There's a lot of competitors there, I know you're one of the market leaders. If we look at ortho and general surgery, it seems like the trends into $\Omega 2$ here were on the margin just slightly more favorable potentially. And I'd love to get just your thoughts qualitatively on the tone of those businesses, the trends in price, or are there any qualitative comments you'd make just on what you see here sequentially from $\Omega 1$ to $\Omega 2$?

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, Matt. Thanks. Look, we think the core businesses in our ortho were - excuse me, in our broader Hospital Medical Device group, we think, continue to show good performance. And we mentioned earlier, EP was up around 14%, the launch of the SMARTTOUCH catheter continues to go very well.

Our Vision Care business in particular showed really strong growth. And again, even with the transition, the acquisition with AMO, you're seeing over 7.5% growth in our contact lens business, which, when you think about the job that that team has done, Ashley McEvoy and the rest of her group over the past several years, competitively, the launching of new products, the OASYS astig lens that is in the launch phase as we speak and now augmented with the surgical business, and Tom Frinzi and his team are doing a really nice job on coming on board. I just had a chance to visit those businesses. They're doing particularly well.

If we look across surgery, even in wound closure, we saw growth of about 3%. Energy and endo-mac are in the 3%, 4%, 5% range. You have to keep in mind that we did have an impact from selling days. Where we don't anticipate that we're seeing major share shifts, we're seeing some movement. But overall, I think we are quite confident. We do have some areas that, frankly, we need to do a better job in such as aesthetics and ENT that we mentioned. Spine, certainly, we're focusing a lot. We are more optimistic at the back end of the year based upon some additional VIPER line extensions that we're coming out with, as well as an expandable cage.

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And if you look at core orthopaedics such as hips and knees, particularly at the U.S. business, we saw hip growth at over 5% in the U.S. business. And if you also add on for our selling days, we think we're doing very well, gaining share of the ACTIS stem. Along with the anterior approach, it creates a nice opportunity. The ATTUNE Knee rollout, again, if we adjust for selling days, we're seeing good performance. We're going to have some additional launches in the back end of the year for that platform.

And sports also put in a really good quarter as well based upon some more recent introductions. So - and we think trauma, overall, we're in line. The TFNA launch continues to go well. So we certainly have areas where we should and we need to do better, but we've also got a lot of core platforms in that group that are performing with a very solid performance overall.

Operator

Thank you. The next question is from Larry Biegelsen of Wells Fargo. Please, go ahead.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning, guys.

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

Good morning.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks for taking my question.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Larry.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Dominic, I wanted to understand the guidance and the acceleration in the second half of this year a little bit better. On the last call, in the first call, you had an organic underlying sales growth of 3% to 3.5% in 2017. Based on my math, it looks like that's about 2.7% today based on the reduction you talked about earlier. That would imply by my math about 4.5% growth in the second half versus about 2.3% in the first half if you adjust for the PPA. Hopefully, you can follow along with me, but I'm trying to understand that.

And in Pharma, Dominic, it looks like the first half grew about 4.5% once you adjust for the gross to net adjustments. Are you expecting that type of growth in the second half? In other words, the acceleration is more just about moving past the gross to net adjustments, or could you actually do better than the 4.5% kind of underlying in the first half? And I just have one quick follow-up for you, Dominic.

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

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Sure. Well, Larry, I think your math is pretty straight on. I mean, if you exclude acquisition, divestitures and this purchase price adjustment that we've spoken to at length, first half was about 2.4%, and on a similar analysis for the full year, underlying growth might be about 3.2-ish. So 4% back half of the year versus 2.4% first half of the year. All three of our business segments are expected to accelerate growth. Pharma will benefit not only from the easier comps from the first half to second half, but obviously, we talked about the things that Alex mentioned earlier with lower erosion for REMICADE, uptick from the launch of TREMFYA, better performance in STELARA as well as XARELTO, despite some setbacks in pricing for INVOKANA. So overall, we think Pharma will continue to accelerate.

And Medical Devices and Consumer are expected to accelerate as well, primarily driven off the fact that most of the launches in both of those businesses are planned for the second half of the year. We've already seen some launch, of course, in the Vision Care business, but in the base Hospital Medical Device business, a number of new launches as well as easier comps because of no impact of a lower selling day in the back half. In Consumer, as I mentioned earlier, although they will accelerate new product launches we're excited about, the markets there are somewhat softer, and some economic trends in China and India are impacting our expectations there, so somewhat muted for the back half versus our previous expectations. But overall, the acceleration to about 4% growth for the second half of the year excluding acquisition, divestitures, and this purchase price adjustment is about right.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's helpful. And, Dominic, just for the record, that 3.2%, you said that the old guidance was 3% to 3.5% underlying sales excluding acquisitions. That has to be lower today.

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

It is lower today. And the 3.2%, I was using your analysis, which excluded this purchase price adjustment. So you're right, the 3% and 3.5% is now lower, maybe 2.5% to 3%. But adjusted for this purchase price adjustment, it exceeds 3%, so I was just trying to keep apples and apples straight.

Operator

Thank you. The next question is from David Lewis of Morgan Stanley. Please go ahead.

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

Good morning.

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

Good morning.

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

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Alex, I wanted to start with a strategic question for you, and then maybe a quick follow-up. So it starts out with Consumer. There were general concerns out there in the consumer industry about brand risk, whether it be Amazon or millennials. How are you feeling about the durability of key Consumer franchises? And I'd note that Consumer still remains the smallest piece of corporate profit. Do you still think that's the appropriate mix? And I had a quick follow-up.

A - Alex Gorsky {BIO 16239711 <GO>}

Look, we still remain very bullish long term on the brands that we currently have. And a lot of it, David, gets to the fact that our brands are rooted in science. And I think a key differentiator for our OTCs, but as well as our beauty franchise, oral care, is the strong science that we have behind all these different areas. And then that of course helps translate into very strong brand images. And while we have seen some recent slowdowns in some of the markets, as Dominic mentioned earlier, we think at the end of the day, we're still going to need products to fill all these channels. And having great innovation and innovative products is going to be essential.

As far as our overall mix, as we said in the past, look, we don't have a particular algorithm. We look at opportunities as they present themselves in each way. We're in each different sector. We think we made some pretty significant investments last year in Consumer with Vogue. I just had a chance to go down and visit that group. And again, when you look at the rate, the pace of their innovation and our ability now to globalize that platform, we're quite excited about it, and to expand it into other areas outside of hair care. So we still think Consumer represents a very solid opportunity going forward.

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

Okay. that's very helpful. Maybe I'll just stick with strategic there for a second. Hey, Dominic, you mentioned further assets - maybe it was Alex, further opportunities for asset divestiture to drive other income. And then, Alex, in your commentary in devices, I sensed you specified certain markets that you haven't talked about before. So maybe just help us understand, two markets stuck out for me. What's the strategic commitment to the aesthetics business? That seems like an undersized business for J&J. We could go either way. And then you mentioned ENT in this call, which I thought was interesting. Is that an area where you could be interested in expanding through acquisition? Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Thanks, David. Look, if you look over the past few years, I think our aesthetic business had done a very nice job of actually improving their performance. There's recently been a broader dynamic with some of the side effects seen that have tempered the growth in that market. So it's one that we're going to continue to watch very closely.

ENT has been one, frankly, of competitiveness, but our team has done a nice job of addressing that. We're in the midst of some launches as we speak, and so we'll be watching that obviously closely in the back half of this year and as we head into early 2018.

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

Great, Next question, Manny.

Operator

Thank you. The next question is from Vamil Divan of Credit Suisse. Please go ahead.

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

Great, thanks so much for taking my questions. So one, just following up on the earlier question around pricing, can you just break out how much of your U.S. growth this quarter was driven by price versus how much came from volume?

And then my second question relates to the COMPASS data which you mentioned is one of the key events for the second half of the year. I think we're just trying to get a better sense - of the investors trying to get a sense of how to think about the potential impact there, given that there's three arms in that study. We know, obviously, it stopped early, how to think about as we see the results in a few weeks here, how much more important is it that you see a benefit from the group with XARELTO-only versus the group where XARELTO is added on therapy? And if you could maybe just give us color how you think about that. Thank you.

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

Sure. So, Vamil, with respect to price, if you look at our entire business, it's a little bit I guess messy because of the prior-period price adjustments, but let's take those out of the mix for this discussion. If you look, our domestic form price was down about 2% overall, and on the entire business was down about 1% overall. Worldwide price was similar to that as well, so a little bit better volume than price this particular quarter.

And then with respect to COMPASS, what I would say there is largely around the patient population, the expansion of the entire EXPLORER program. So with CAD and PAD, we obviously have the chance to expand the market by about 10 million to 12 million patients here in the U.S. What we're currently indicated for is about 7 million to 8 million patients, so you can see significant opportunity. And if you take the entire EXPLORER program, it has the potential to be 30 million to 35 million additional patients.

So it's a matter of market expansion. We don't believe that our competition has anywhere near as robust a clinical development program as we do for all of those indications that we're seeking. And so we seem to be in pretty good position. We continue to take share from warfarin, so we were up, as we said in the earlier comments, more than 2% in terms of total market share versus this time last year.

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

Okay, all right. Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

You're welcome.

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

Next question, Manny?

Operator

Thank you. The next question is from Tony Butler of Guggenheim Partners. Please go ahead.

Q - Tony Butler {BIO 1504193 <GO>}

Yes, thanks very much. Alex, you alluded to the fact that you were in Washington, and I'm just asking. Do you need to take a more defensive posture while you're there having meetings, or is it one of an offensive nature? And then I have one follow-up.

A - Alex Gorsky {BIO 16239711 <GO>}

Thanks, Tony. No, look, what we're spending a lot of time doing is making sure that we're educating lawmakers with facts regarding the overall healthcare system as well as obviously, the important role of the pharmaceuticals, medical devices, as well as consumers ultimately play.

And you heard in my earlier remarks as it relates to pharma. It's making sure that we understand that it is about 15% of healthcare. We think it's a really important - an important part of healthcare when you look at overall benefits, making sure that they understand the intricacies of the system. As you've heard in earlier comments, it is complex. And so we think it's very important to be constantly taking them through the data, the information, so that ultimately we can have the most informed and sound policy decisions.

Q - Tony Butler {BIO 1504193 <GO>}

Thanks very much for that. And then, Joe or Dominic, just two brief product-related questions. One, for INVOKANA, I recognize the relabeling effect and managed Medicaid rebates. But did you find that the total category did grow despite those effects because sometimes they can bleed to the entire category?

And second, does your full-year earnings guidance, Dominic, include the opt-in R&D expense that would be included for Idorsia from Actelion? Thanks very much.

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

Sure, Tony. Let me take the second question. Yes, consistent with our previous guidance update, which we provided last quarter to include Actelion, we've maintained the assumption in that guidance and now in this new updated guidance that we would exercise our option with respect to an Idorsia product that we have the rights to. We're optimistic to see those results and discuss those results with the FDA. And that option is not exercisable until we complete those particular steps but, of course, we're expecting

that we will complete those steps in a favorable manner. So our guidance does in fact include that extra R&D expense associated with opting in on the particular product. Joe?

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

And, Tony, with respect to INVOKANA, this market, the way we define it, it excludes metformin; by our projections, it grew about 3.5% in the quarter.

Operator

Thank you. The next question is from Danielle Antalffy of Leerink Partners. Please go ahead.

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

Hi, good morning, guys. Thanks so much for taking the question. I just had a higher-level question for you, Alex or Dominic. If we just think about you're calling for growth acceleration in the second half of the year, but as we move into 2018, how do we think about the sustainability of that growth acceleration profile, particularly since you should have increasing competition on the REMICADE side of things?

And I believe it's 2018 that ZYTIGA goes off patent so please remind me if that's the case. Is there something within the underlying growth trends in some of the other businesses that could sustain this growth acceleration trajectory? Or how should we be thinking about that?

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

Yeah. Danielle, thanks for the question. So, obviously we expect that the growth acceleration in the back half of 2017 will create some momentum going into 2018 of course, right? Because the majority of that growth acceleration in both Hospital Medical Devices and Consumer have to do with new product launches and we expect that they'll - that momentum will carry over into 2018.

You're right, there's some puts and takes with respect to some competition as well as patent expiration issues like ZYTIGA, which you just mentioned, but remember, the overall Pharm portfolio remains strong.

Joe talked about the COMPASS data with XARELTO and IMBRUVICA, and DARZALEX continuing to move upward in an upward trend in gaining share with more data, and obviously the entire immunology portfolio now is bolstered by the earlier launch of guselkumab or TREMFYA and so that's exciting and able to propel growth further. So, we expect it – although there may be some puts and takes and we're not prepared to talk about guidance now for 2018, we expect the momentum to continue.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. Danielle, what I would add to that are a of couple things. One is I think it really starts with the unmet need that exists among our core platforms. So, if you look at penetration

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rates in areas for example, in our Pharmaceutical group in areas like psoriasis, Crohn's disease, you're seeing treatment rates of only 20% to 30%. If you take a look at even treatment with next-generation anticoagulants, you're only around 50%. If you look at antipsychotics, long-acting antipsychotics, there too you're looking at in the vicinity much smaller, below 20%. So we think that there's just a lot of unserved need in each of those categories that's going to allow for growth.

Secondly, when you look at the data stream that we have coming out across all of these platforms, again whether it's XARELTO, whether it's the continued launch uptake of TRINZA, the great data for STELARA in Crohn's disease, the TREMFYA launch, we think that's going to add momentum. And then you compound that with the Actelion acquisition, and the reasons why we believe that we can reach more patients and generate additional growth, it gives us a lot of confidence in our Pharma group for growth potential going forward.

And there certainly will be the events that you mentioned, but underlying that's why we're going to be launching 10 new brands between now and 2021. We think have \$1 billion potential, several of them with over \$3 billion and \$4 billion potential, a long list of other line extensions, I think 50, 10 of which we think have about \$0.5 billion potential in our and so, that's our Pharma group.

In our Medical Device group, we mentioned more than 12 launches that we have in the back end of the year combined with some of the other work that we've done around making us more effective, more efficient. And then you compound that with some of the acquisitions that we've done really in each of our major platforms over the last 12 months and project that going forward, things like AMO, things like the expandable cage and spine, Megadyne that I mentioned earlier.

We think that also provides us a very solid opportunity for growth going forward. And then of course in Consumer, we're very excited about the Vogue acquisition, about NeoStrata, combined with - we're very confident that we will see positive trends going forward. So again, overall, we think that direct to 2017 and 2018, while we're not providing any guidance, represents a great opportunity for J&J.

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

Thanks, Danielle. Next question.

Operator

Yes. The next question is from Rick Wise of Stifel. Please go ahead.

Q - Frederick Allen Wise {BIO 1490589 <GO>}

Hey. Good morning, Alex. Hi, Dominic.

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

Hi, Rick.

Q - Frederick Allen Wise {BIO 1490589 <GO>}

Just talking about the device pipeline, Alex. One thing you haven't talked about much lately is the robotic program. Can you update us on where you are? I think there's a working prototype of the system in December. What's next? What events are – is this all on track from your point of view? And just if you'd update us there, I'd appreciate it. Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. The short answer on that, Rick, is we are quite excited about our computerized surgery program. Everything up to this point in time is on track. We're continuing to make really good progress. We had outlined earlier our reasons for excitement. We think that there is an opportunity there not to just actually improve the surgery, itself; bring data to bear in the operating room, having much more flexibility and modularity in the system that we would introduce. And of course, we think that also offers a great opportunity for the rest of our surgical care business as part of the – an entire system and offering.

So it's on track. And - but what I would tell you is stay tuned. We're obviously not going to provide too much information on that right now, given the competitive environment. But we still remain very committed to that program.

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

And, Rick, the working prototype was already available at the end of last year. And in fact, I know Alex actually tried it out. So...

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah.

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

So we're not behind there, we're actually on track with that working prototype.

Operator

Thank you. The next question is from Bob Hopkins of Bank of America Merrill Lynch. Please go ahead.

Q - Robert Hopkins {BIO 2150525 <GO>}

Hi. Thanks very much for taking the question. It's just two quick ones. First Alex, I'd love to get your perspective on emerging market growth and the outlook for J&J's emerging market growth going forward. And may be specifically, could you just comment on what EM growth was this quarter for you guys? And were there any stand-outs like there were last quarter where devices I think grew almost close to 10%?

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A - Alex Gorsky {BIO 16239711 <GO>}

Yes. Thanks a lot, Bob. Overall, if we look at emerging markets' performance for this quarter, we saw a growth of around 4%. Sequentially, it was little bit slower but again, it was a couple things. One, we mentioned earlier Consumer, we had issues with the demonetization and some lingering policy issues as it related to our Consumer business. We saw some competitive issues in China. But overall for example, our Medical Device business was up over 10%. So we saw strong – and that's in China – excuse me – total emerging markets, we saw that kind of growth.

We've got to get through some of these policy issues in India related to demonetization. There's some in the way that OTC and pharma drugs are being distributed that we've got to get through in China. The other markets can be impacted, frankly, their economies to a certain degree by how reliant they are on petroleum. But overall, for the next several years we think emerging markets and particularly BRIC represent a significant opportunity. Other than those things that I just mentioned, I don't think we've seen significant issues that would affect our outlook.

Q - Robert Hopkins {BIO 2150525 <GO>}

Great. And then just as a follow up. You mentioned earlier about the changing guidance on - related to potential divestitures and an incremental \$500 million gains. I was just wondering if there was any more color there. Are these potential divestitures several smaller deals? Is it one bigger one? Is it more Device, more Consumer, more Pharma? Just any more color on those and what you expect would be helpful. Thank you.

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

Yeah, Bob. Let me provide as much color as I can without obviously jeopardizing potential value we expect to get from these additional divestitures. So they're - none of any major consequence. So the ones that are of major consequence which haven't yet closed; for example, the Codman neurosurgery business, that's still on track to close this year. That was in our original guidance. That's one of the most significant of the group but not an additional divestiture, although we hope that that'll actually close at a bit higher value than we previously estimated.

The rest are across multiple businesses. I would call them smaller brands. I would call them not of any major consequence and we'll have to see whether we can get the right value for those assets before we actually execute on them, but that's our plan for the remaining part of this year. But not anymore detail, and I'm sure you can appreciate that.

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

Thanks, Bob. I think we have time for one more question. Manny?

Operator

Yes. The final question is from Damien Conover of Morningstar. Please go ahead.

Date: 2017-07-18

Q - Damien Conover {BIO 15414079 <GO>}

Great, good morning and thanks for taking the questions. I just had a question on ZYTIGA, and I just want to follow up on the higher utilization by the independent patient assistance foundations. I know it started in the first quarter. It's continued into the second quarter here. I'm just wondering if you could give us an update on why that is continuing. And why is prostate cancer one of the focus points for these particular groups?

And then a second question, I was wondering if you could also give us an update on your outlook for the amortization expense for the rest of the year. I know it's going to be increasing with the closure of the Actelion deal. Thank you.

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

So thanks for the question, Damien. With respect to the patient assistance foundations, as we stated previously, those are independent foundations, so they really do operate distinct from Johnson & Johnson. So our insights and data around that is very, very limited.

What I can say with respect to ZYTIGA is it actually goes back to probably the fourth quarter of last year, where we saw a significant bump up, and we've got some statistics that suggest our prescriptions for ZYTIGA last year this time that ran through the foundation were about 4% of total prescriptions. Now, they're up to about 15%, but the good news is we've seen a leveling off. So in the last couple of quarters, where we've commented to this impact, it's been around that 13%, 14%, 15% level.

So we think there's a leveling off. As to why these are more utilized than maybe some other foundations, that's probably related to some funding that went dark for some other foundations, but, again, that's pure speculation on our part, because these patient foundation assistance programs are run independently from Johnson & Johnson.

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

So, Damien, earlier I gave you some after-tax impacts of intangible amortization expense that are in this year's earnings, or adjusted from this year's earnings to arrive at our adjusted earnings. The pre-tax number so far, just for the second quarter, was \$480 million, and the pre-tax number in the same quarter of last year was \$326 million.

The largest impact of that increase is, obviously, the AMO acquisition, because, of course, we had a full quarter's worth of amortization there, and only a couple of weeks' worth of amortization of Actelion. So, going forward, the Actelion acquisition will add substantially to the amortization expense, but as you know our practice, consistent with all those in our industry is to exclude that from our adjusted earnings, because it's obviously a noncash impact. So, hopefully, that helps you model it going forward.

Q - Damien Conover {BIO 15414079 <GO>}

Great, thank you.

A - Joseph J. Wolk (BIO 19812977 <GO>)

Great. So that concludes the question-and-answer session. Thanks for your questions, as well as your continued interest in Johnson & Johnson.

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

A - Alex Gorsky {BIO 16239711 <GO>}

Well, thank you, everyone, for making time to be on the call this morning, and I want to end where we began with a few thank yous. First of all, I really thank all the associates of Johnson & Johnson for their ongoing commitment to Our Credo, to being competitive, and ultimately to producing the results that we just had a chance to review with you this morning. And, also, a big thank you to all of you for your continued trust and confidence in Johnson & Johnson. We look forward to updating you at upcoming calls as we work our way through 2017.

And with that, I'll close the call, and look forward to speaking with you all of you again soon. Thank you.

Operator

Thank you. Ladies and gentlemen, this concludes today's Johnson & Johnson's second quarter 2017 earnings conference call. You may now disconnect, and have a wonderful day.

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