

Q1 2018 Earnings Call

Company Participants

- Dominic J. Caruso, Executive Vice President & Chief Financial Officer
- Joaquin Duato, Executive Vice President & Worldwide Chairman-Pharmaceuticals
- Joseph J. Wolk, Vice President-Investor Relations

Other Participants

- Danielle Antalffy, Analyst
- David Ryan Lewis, Analyst
- Geoff Meacham, Analyst
- Glenn John Novarro, Analyst
- Jami Rubin, Analyst
- Joshua Jennings, Analyst
- Larry Biegelsen, Analyst
- Michael Weinstein, Analyst
- Robert Hopkins, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good morning. Welcome to Johnson & Johnson's first quarter 2018 earnings conference call. All participants will be in listen-only mode until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time.

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

Joseph J. Wolk {BIO 19812977 <GO>}

Hello. This is Joe Wolk, Vice President of Investor Relations, and it is my pleasure to welcome you to the investor conference call reviewing Johnson & Johnson's business results for the first quarter of 2018. Accompanying me on today's call are Dominic Caruso, Executive Vice President and Chief Financial Officer, who will provide commentary on the quarter's financial performance; and Joaquin Duato, Executive Vice President and Worldwide Company Group Chairman of Pharmaceuticals, who will participate in the Q&A portion. Thank you for joining us and your interest in Johnson & Johnson.

Our strong first quarter results are an extension of the momentum we established in the second half of 2017. Pharmaceuticals again grew well above the market, Consumer's

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growth maintained its acceleration, and Medical Device has platforms that are enhancing market-leading positions, as well as areas where we are executing plans to improve performance that are not meeting our objectives, as mentioned during our call in January. We continue to exceed financial expectations, while managing the business for the long term to benefit patients, customers, and shareholders.

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

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

Our SEC filings, including our 2017 Form 10-K, along with reconciliations of non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures, are all available at investor.jnj.com.

A number of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships. We anticipate today's webcast to last approximately 60 minutes.

Now onto the results. Worldwide sales were \$20 billion for the first quarter of 2018, a 12.6% increase versus the first quarter of 2017. On an operational basis, sales were up 8.4%, as currency had a positive impact of 4.2%. In the U.S., sales were up 6.1%. In regions outside the U.S., our operational growth was 10.9%, with the effective currency exchange rates benefiting our reported OUS results by 9 points. Excluding the net impact of acquisitions and divestitures, operational sales growth was 4.3% worldwide, increasing 1.3% in the U.S. and 7.6% outside the U.S. I will provide the same reference for each segment.

With respect to earnings for the quarter, net earnings were \$4.4 billion and diluted earnings per share were \$1.60 versus \$1.61 a year ago. Excluding amortization expense and special items for both periods, adjusted net earnings for the current quarter were \$5.6 billion and adjusted diluted earnings per share were \$2.06, representing increases of 11.8% and 12.6%, respectively, compared to the same period in 2017. On an operational basis, adjusted diluted earnings per share grew 5.5%. Dominic will provide further earnings details in his remarks.

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

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Worldwide Consumer segment sales totaled \$3.4 billion, growing operationally 1.3%. Excluding the net impact of acquisitions and divestitures, mainly the divestiture of the COMPEED business in Wound Care/Other franchise outside the U.S., total adjusted operational sales growth was 2% worldwide.

The Beauty franchise led segment performance, growing 7.1% operationally. Growth in the quarter was aided by a seasonal inventory build of approximately \$20 million related to sun protection products. In the U.S., we are seeing robust growth in the e-commerce channel for the NEUTROGENA and AVEENO brands. Results outside the U.S. were driven by the Asia-Pacific region, where Dr. Ci Labo and NEUTROGENA brands had strong uptake. Worldwide and U.S. market shares remained relatively flat compared to the same period of 2017 and the worldwide Beauty market is estimated to have grown approximately 4%.

OTC grew 0.9%, but that understates the true performance of the franchise. In the U.S., strong consumption in both adult and children's TYLENOL and children's MOTRIN, was offset by a negative comparison to the first quarter of 2017 when pipeline was built for the launch of the rapid release and chewable children's TYLENOL, negatively impacting worldwide OTC operational growth in the first quarter of 2018 by an estimated 3 points.

Oral Care results reflect a market-leading, but relatively flat share in a market growing modestly at 1%. The divestitures of the REACH and REMBRANDT brands negatively impacted worldwide growth by approximately 1.5 points.

As previously referenced, Baby Care results are not where we want them to be and we have the franchise restage planned for later this year. Our Business Review Day on May 16 highlighting both the Consumer and Medical Device businesses will share more details about JOHNSON's Baby restage.

Moving onto our Pharmaceutical segment, worldwide sales of \$9.8 billion grew 15.1%. Excluding the net impact of the Actelion acquisition, operational adjusted sales growth was 7.5% worldwide. The segment was led by the Oncology portfolio, which grew globally 37%.

DARZALEX continued its strong performance, growing globally better than 60%. In the U.S., market growth and the strong launch uptake of the one prior line indication is resulting in share gains. Outside the U.S., DARZALEX is experiencing increased penetration in the 29 EMEA countries it is now commercially available in, and growth in the Asia-Pacific region was driven by the products recent approval in Japan last November.

IMBRUVICA in the U.S. gained approximately 3 points of market share versus prior year across all lines of therapy based on the fourth quarter data, largely driven by share in Line 1 chronic lymphocytic leukemia, or CLL. The CLL market is estimated to have grown almost 15%.

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ZYTIGA had another strong quarter, growing 54%. In February, the FDA approved ZYTIGA for patients with metastatic high-risk castration-sensitive prostate cancer based on the LATITUDE clinical trial. This was a driver for ZYTIGA's first quarter performance resulting in market and share expansion. During the quarter, we expanded our presence in the treatment of prostate cancer with the U.S. approval of ERLEADA, a next-generation androgen receptor inhibitor to treat pre-metastatic patients. We also filed for EU approval in February.

In Immunology, the U.S. market is estimated to have grown approximately 12%. We remain very pleased with the uptake of STELARA in Crohn's disease, as more than 20,000 Crohn's patients have been treated with STELARA since that indication launched late in 2016. Market share has improved 11 points in Crohn's disease compared to the first quarter of 2017.

REMICADE in the U.S. was down 22%, negatively impacted by a prior period pricing adjustment related to a major payer's delayed submission of rebate claims. We don't anticipate significant adjustments will be required in future quarters. Excluding this adjustment, REMICADE's decline would have been closer to 16%, largely driven by price erosion, as REMICADE has retained better than 95% of its volume share.

Lastly in Immunology, sales for our newly-launched treatment for psoriasis, TREMFYA, totaled \$72 million. New-to-brand share, including first dose sampling program volume, is outpacing the leading competitors.

In Neuroscience, our paliperidone palmitate long-acting injectable portfolio grew steadily in all regions with increasing market share, particularly in Europe. CONCERTA in the U.S. is experiencing negative price due to generic competition.

Results for the Actelion pulmonary hypertension assets acquired in mid-2017 are commented to here on a pro forma basis. OPSUMIT grew globally 7%, which was comprised of 4% in the U.S. and 11% outside the U.S. UPTRAVI continues to experience strong demand, with 37% growth in the U.S. As expected, TRACLEER is declining, as generics entered the European market during the second half of last year. The dynamic we noted in the fourth quarter results impacting all three brands was an increased level of patients on assistance programs in the U.S., although that was less of a negative factor as the quarter progressed.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were \$6.8 billion, growing 3.2%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 1.1% worldwide.

Beginning this quarter within the Medical Devices segment, we are reporting revenue for the Neurovascular platform in combination with the Cardiovascular platform under the label of Interventional Solutions. This change better reflects our business structure, given the recent divestiture of Codman Neurosurgery and the creation of the CERENOVUS Neurovascular business unit, which includes the Codman Neurovascular business as well as the recent acquisitions of Neuravi and Pulsar Vascular. Both the Codman Neurosurgery

and CERENOVUS revenues were previously reported within the Orthopaedics platform under the Spine & Other category. Please reference the supplemental sales schedule on our website for additional details.

Within Interventional Solutions, electrophysiology grew approximately 15% worldwide, as the atrial fibrillation procedure market continues to grow and we improve upon our market leadership in this space with newer product offerings in ablation and advanced catheters.

In Orthopaedics, although selling days did negatively impact growth by approximately 1 point, we are disappointed with the performance and are actively implementing plans to address challenges we face in this segment. In trauma, we are experiencing good volume for some of our newer products, like the TFNA femoral nail, and in hips we continue to see strong demand for the primary stem ACTIS anterior approach. However, we are losing share in spine as newer competitive entries are being better received in the market, as well as in knees, where we believe new offerings throughout 2018, such as the ATTUNE Revision System, ATTUNE S+, and cementless are expected to improve performance.

We were pleased to announce during the first quarter the acquisition of Orthotaxy, which we believe will provide next-generation robotic-assisted orthopedic surgery, which will be on display at our May 16 Analyst Day. Pricing pressure impacted all categories in Orthopaedics. For the quarter, U.S. pure price was negative 4% in spine, negative 3% in hips, and negative 2% in both trauma and knees.

Within the Surgery group, the Advanced Surgery category was strong, particularly outside the U.S. On a worldwide basis, endocutters grew 7%, as new products are experiencing strong demand. And biosurgery grew 5%, driven by topical absorbable hemostat and BIOSEAL. Growth in energy was just shy of 3%, as strength outside the U.S. was partially offset by the U.S. market dynamics of a shift to advanced bipolar products and reprocessed products.

As a final comment regarding the U.S. hospital setting, let me provide utilization trends. For the fourth quarter of 2017, we saw a slight increase in hospital admissions of about 1.5%. Surgical procedures were down approximately 50 basis points and lab procedures were up about 3%. Our preliminary estimates for the first quarter indicate modest declines across all those rates, with admissions growth at 1%, surgical procedures down approximately 1%, and lab procedures up an estimated 2%.

To conclude the Medical Devices segment, Vision Care. As a reminder, the acquisition of the Vision Surgical business closed February 27, 2017. Excluding the one month of sales in 2017 for that acquisition and other smaller acquisitions, the Vision Care business grew approximately 9%. The contact lens business grew a very healthy 11% worldwide on the strength of ACUVUE OASYS and ACUVUE Moist lines, but also benefited in the quarter from one of our larger customers scaling up a new distribution center. This was worth about 3 points. In Vision Surgical, worldwide growth of 5% on a pro forma basis was driven by intraocular lenses in cataracts.

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

It is now my pleasure to turn the call over to Dominic Caruso, who will provide his insights on Johnson & Johnson's quarterly results for the 46th consecutive time. As most of you on the call know, on March 20 Dominic announced plans for his retirement later this year. While Dominic will still be at investor events in the coming months and opportunities for more proper sendoffs will occur, I would be remiss if I didn't acknowledge on this call his many contributions to Johnson & Johnson and its employees, the healthcare industry and, quite frankly, industry in its broadest sense.

I have personally learned a great deal from Dominic and benefited from his leadership, a sentiment that I know many, many folks share. Dominic, on behalf of everyone that has had the privilege to know and work with you at Johnson & Johnson, thank you for your years of effort and dedication and the wisdom you were gracious enough to share.

Dominic J. Caruso {BIO 1423936 <GO>}

Thanks, Joe, and good morning, everyone.

We carried last year's momentum into 2018 and we're off to a strong start this year. We're very pleased with the results generated in the first quarter, with underlying operational sales growth consistent with quarter four of 2017. Both our sales and earnings were above analyst estimates, and we continue to make very good progress on our near-term priorities as well as our long-term growth drivers, which we discussed during our call with you in January. And we remain confident in the strength of our business.

In our Pharmaceutical business, our strong performance from 2017 continued into the first quarter, with underlying operational growth at 7.5%. First quarter underlying operational sales growth for Consumer increased 2%, which is an acceleration over the fourth quarter of 2017. As with Pharmaceutical and Consumer, in Medical Devices we are also above consensus. We continue to have areas of strength behind new products in our Vision business, continued growth within electrophysiology, as well as our Advanced Surgery business, particularly with the endcutters and biosurgery platforms, and in our trauma business. We remain focused on making improvements across our Medical Devices businesses, and we will discuss this in greater detail on May 16 at our Consumer and Medical Device Business Review Day.

Additionally, as part of our ongoing portfolio management, we announced a binding offer from Platinum Equity, a private investment firm, to acquire our LifeScan business for approximately \$2.1 billion, subject to customary closing adjustments.

As noted in this morning's press release, we announced that we plan to implement a series of actions across our global supply chain that are intended to focus our resources and increase investments in critical capabilities, technologies, and solutions necessary to manufacture and supply our product portfolio. This will enable us to better meet patient

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and customer needs, make us more agile in the rapidly evolving healthcare landscape, and drive business growth. We expect our supply chain actions will include expanding our use of strategic collaborations and bolstering our initiatives to reduce complexity, improve cost competitiveness, enhance capabilities, and optimize our network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized.

In total, we expect these actions to generate approximately \$600 million to \$800 million in annual pre-tax cost savings that will be substantially delivered by 2022. Further, we expect to record pre-tax restructuring charges of approximately \$1.9 billion to \$2.3 billion over the four to five-year period of this activity, which we will treat as special items.

And as we discussed in January, the new U.S. tax legislation creates greater flexibility and opportunity to capitalize on our investments in innovation and R&D. In fact, we intend to invest more than \$30 billion in the U.S., with capital investments in R&D between 2018 and 2021 representing an increase over the prior four years of more than 15%.

Since Joe walked you through the sales results for each segment, I would like to add some overall commentary on those results, our operating performance, and what we expect for the balance of the year. I will now turn to our consolidated statement of earnings for the first quarter of 2018. As we've mentioned, our operational sales growth this quarter was 8.4%. And, excluding the impact of acquisitions and divestitures, growth was 4.3%.

If you will direct your attention to the box section of the schedule, you will see we have provided our adjusted earnings to exclude intangible amortization expense and special items. As referenced in the table of non-GAAP measures, the 2018 first quarter net earnings were adjusted to exclude intangible amortization expense and special items of \$1.3 billion on an after-tax basis, which consisted primarily of the following.

Intangible asset amortization expense of approximately \$1 billion, a charge for the continuing restructuring of our Hospital Medical Device businesses of approximately \$100 million, Actelion acquisition-related costs of approximately \$100 million, and a refinement of tax legislation and other costs of approximately \$100 million. Our adjusted earnings per share is, therefore, \$2.06, exceeding the mean of the analysts' estimates. This is an increase in adjusted EPS of 12.6% versus the prior year. Adjusted EPS on a constant currency basis was \$1.93, up 5.5% over the prior year.

Now let's take a moment to talk about the other items on the statement of earnings. Cost of goods sold, excluding the impact of intangible amortization and acquisition-related costs, actually decreased by 140 basis points, primarily due to favorable product mix. Selling, marketing, and administrative expenses were 26.3% of sales, or 50 basis points lower as compared to the first quarter of 2017, due to lower cost relative to sales growth in the Pharmaceutical business, partially offset by investments in recent acquisitions and new product launches in the Medical Devices business.

Our investment in research and development as a percent of sales was 12%, which was a 16% increase versus the prior year as we continue to advance our promising product pipelines. Interest expense net of interest income was higher than last year due to higher average debt levels and lower average balances of cash and cash equivalents.

Other income and expense was a net expense of \$60 million in the quarter compared to a net gain of \$219 million in the same period last year. Excluding the special items recorded in this line, current year was a net gain of approximately \$77 million compared to a net gain of \$320 million in the same period last year. The prior year had higher level of gains from our investment portfolio.

Excluding special items, the effective tax rate was 17.8% compared to 17.5% in the same period last year. This rate is consistent with our expectations as a component of the full-year effective tax rate. The 17.8% rate for the first quarter is a result of current interpretation of certain provisions of the Tax Cuts and Jobs Act related to foreign tax credits and expense allocations. We expect the Treasury to issue updated guidance later this year. This expected update is reflected in our guidance, which I will provide later.

Turning to the next slide, I will now review adjusted income before tax by segment. In the first quarter of 2018, our adjusted income before tax margin for the enterprise was relatively flat versus the first quarter of 2017, driven by higher levels of operating profit, offset by lower levels of other income and expense.

Looking at the adjusted pre-tax income by segment, Medical Devices at 29.3% is lower than the previous year, primarily due to investments in recent acquisitions and new product launches. Pharmaceutical margins improved from the prior year by 150 basis points to 46.5%, primarily driven by favorable product mix and cost of products sold and slower increases in expenses relative to the increase in sales. Consumer margins declined by 220 basis points to 18% due to an increase in brand marketing expenses supporting the launch of new products.

Now, I will provide some guidance for you to consider as you refine your models for 2018. At the end of the quarter, we had approximately \$17 billion of net debt, which consists of approximately \$15 billion of cash and marketable securities and approximately \$32 billion of debt. For purposes of your models and assuming no major acquisitions or other major uses of cash, I suggest you consider modeling net interest expense between \$600 million and \$700 million. This is slightly lower than previous guidance due to changes in average debt levels and changes in rates.

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 or investments by our development corporation, divestitures, asset sales, and write-offs. We would be comfortable with your models for 2018 reflecting net other income and expense, excluding special items, as a net gain ranging from approximately \$1.5 billion to \$1.7 billion, which is lower than our previous guidance due to the anticipated timing of the activities recorded in this account.

This lower level of earnings contribution from these activities will be fully offset by the stronger performance in our business, as reflected in our first quarter results. In fact, we now expect pre-tax operating margin improvement of approximately 150 basis points as compared to 100 basis points in our previous guidance.

And now for a word on taxes, our effective tax rate guidance for 2018, excluding special items, is approximately 16.5% to 18%, and that's no change from our prior guidance.

Now turning to sales and earnings, our sales guidance for 2018 includes the impact of generics for PROCIT and TRACLEER, as well as REMICADE biosimilars. However, we do not anticipate any impact from generic competition this year for ZYTIGA, RISPERDAL CONSTA, 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 2018 with the impact that current exchange rates could have on the translation of those results.

So for the full-year 2018, we would be comfortable with your models reflecting an operational sales increase of 4% to 5% for the year. This would result in sales for 2018 on a constant currency basis of approximately \$79.5 billion to \$80.3 billion. This is higher than our January guidance based on strong Q1 performance. We now expect that operational sales growth, excluding the impact of acquisition and divestitures, will be between 3% and 4% for the year, which is also higher than our previous estimate.

And although we're not predicting the impact of currency movements, using the euro as an example, which last week was at \$1.23, the positive impact of foreign currency translation would still be approximately 2%. Thus, under this scenario, we expect reported sales to reflect a change in the range of 6% to 7%, or a total expected level of reported sales of approximately \$81 billion to \$81.8 billion, which is higher than our previous guidance.

And now turning to earnings, considering all the factors I just noted, we would be comfortable with adjusted EPS guidance in the range of \$7.80 to \$8 per share on a constant currency basis, reflecting operational or constant currency growth of approximately 6.8% to 9.6%, which is consistent with our previous guidance. And again, we're not predicting the impact of currency movements, but just to give you an idea of the potential impact on EPS with the euro at \$1.23, our reported EPS would be positively impacted by approximately \$0.20 per share. Therefore, our reported adjusted EPS would range from between \$8 and \$8.20 per share, reflecting growth of approximately 11% at the midpoint of that range, and this is consistent with our previous guidance. While it's still early in the year, we would be comfortable with your models reflecting the midpoint of this range.

So in summary, as you update your models for the guidance I just provided, I'd like to make a few key points. We expect our operational sales growth to range between 4% and 5%, and our underlying growth, excluding the impact of acquisitions and divestitures, to be approximately 3% to 4%, which is an acceleration from 2017.

With regard to expected EPS growth on an operational adjusted basis, our guidance is strong in the range of 6.8% to 9.6%, consistent with our objective of growing earnings faster than sales on a constant currency basis. While we expect a lower level of other income, as I noted earlier, we now expect to improve our pre-tax operating margins by approximately 150 basis points.

Now, before I turn things back to Joe to open up the Q&A portion of the call, I'd like to make a few brief comments regarding my retirement and the great news that Joe will assume the role of Executive Vice President and Chief Financial Officer for Johnson & Johnson on July 1.

Joe has been with Johnson & Johnson for the past 19 years and has served on my Finance Leadership team reporting to me and we've worked together for many, many years. Joe is a strong, collaborative, Credo-based leader who has a long track record of success, most recently in his current role and, as you know him, the head of our Investor Relations group. I'm confident that Johnson & Johnson will be in great hands and we can expect significant contributions under Joe's financial leadership.

Now, regarding my retirement, let me start by saying that having been a CFO for almost 12 years and part of Johnson & Johnson for a total of 19 years, I have tremendous pride, respect, and appreciation for my Johnson & Johnson colleagues, the healthcare industry, our patients and consumers, partners, financial community, media, and all the entities that I've had the privilege to work with during my tenure. I'm also very appreciative of the phenomenal experiences that I've been afforded and the positive impact, both internal and external, that this role and its responsibilities has enabled me to make.

Some of the J&J successes that I'm very proud to have been associated with in partnership with my finance team and J&J colleagues include a consistent capital allocation strategy, where after investing in our business at competitive levels, we allocate capital first by paying dividends to our shareholders, then deploying capital for value creating acquisitions, and finally using any excess cash to further return capital to shareholders, such as through share repurchases.

We've exceeded our competitor composite, as well as most major indices, for total shareholder returns over the last, 3-, 5-, 10- and 20-year periods, and we've returned 2 times more value to shareholders than compared to our closest competitor over the last five years. And we're only one of seven mega cap companies to increase its market cap by more than \$175 billion over the last 5.5 years.

Finally, I'm proud to be associated with an incredible legacy of exceptional financial performance, as reflected in our 34 consecutive years of adjusted earnings increases and our incredible 55 consecutive years of increasing our dividend to shareholders. And I

know that the key to our success as an enterprise, and therefore to my success, has always been our credo, our purpose, and our people, as we've all united around a singular focus of changing the trajectory of health for humanity, a bold, but inspiring purpose.

I've been inspired every day since I began my career journey at Johnson & Johnson back in 1999, when I joined this great company as a result of the Centocor acquisition. I quickly realized that I had joined a fantastic organization of incredibly dedicated, remarkably intelligent, and really passionate people.

As Alex Gorsky often says, our work in healthcare is not a job, it's a calling. Alex Gorsky, our CEO, is truly an inspirational, committed, and passionate leader. He has set a high standard for excellence and execution, and I want to sincerely thank Alex for his unwavering support through the years and for being my manager, colleague, partner, and my very good friend.

I also want to acknowledge the incredible management committee that I've had the pleasure to work with for many years. They are a group of passionate and expiring leaders. I'm also very pleased to have one very important member here with us today, Joaquin Duato, and I'd like to recognize and thank Joaquin for his bold and visionary leadership, which has been integral in our Pharmaceutical business delivering outstanding and sustained performance and growth.

My time here at Johnson & Johnson has been, without a doubt, a humbling and amazing experience for almost two decades, and I've had the honor of working alongside people doing important and outstanding things that positively impact this world. I've enjoyed every minute of my stewardship of Johnson & Johnson's business as CFO and working with all of you. Thank you for your engagement, exchanges, and partnership. And although Joe assumes his new role in July, I'll still be around for another couple months so we can work to closely ensure a seamless transition. And you'll hear from me again, along with Alex, at our May 16 Medical Devices and Consumer Business Review Day, and I'm looking forward to seeing and talking personally with you then.

Let me now turn things back over to Joe to open up the Q&A portion of the call. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Great. Thank you, Dominic. That takes us to the Q&A portion of today's discussion. As a reminder, Joaquin is available with Dominic to address your questions. Rob, can you please provide instructions for those wishing to ask a question?

Q&A

Operator

Yes. Thank you. Please limit your questions to one question and one follow-up. Your first question comes from Mike Weinstein with JPMorgan.

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

Good morning, Mike.

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

Hi, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

Good morning. Thank you. And, Dominic, a personal note just to thank you for our relationship over the years, your stewardship of J&J. And I think you've set a high bar for everyone in the industry, so thank you for that.

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

Thank you, Mike.

Q - Michael Weinstein {BIO 20602373 <GO>}

Dominic, let me ask you a couple of items. So if we go back to the fourth quarter, everybody kind of walked away a bit concerned about top line deceleration in the Pharmaceutical business. This quarter you posted a better-than-expected performance. Can you just give us your thoughts on the outlook for the Pharmaceutical business this year today in April versus where you were in January? And it certainly looks like some of that upside is being driven by ZYTIGA, which people are, obviously, still thinking about the life of that product. So can you give us any update on your latest thoughts on ZYTIGA generic competition timing? Thanks.

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

Sure, Mike. Well, we did have growth in the first quarter for Pharma reasonably consistent with fourth quarter growth at nearly 7.5%, and we did see a couple factors that we were tracking. One was the continued erosion of REMICADE, which in the first quarter was a little higher than we expected. But that has to do with an adjustment, as Joe mentioned, with one of our payers delayed in requesting a true-up of the rebates. So we don't expect that that particular phenomenon is going to continue throughout the balance of the year, so the normalized erosion, 16%, is then therefore pretty consistent with what we expected.

ZYTIGA did very well in the quarter. It started to do well last year as a result of the LATITUDE data. It continued. I think that's a product that's continuing to improve patients' lives. Physicians are impressed with the data. And I'm happy to report, obviously, that we just launched ERLEADA as a follow-up. As I said, we don't expect that we'll see generic competition for ZYTIGA this year, so we have it in our plans to continue to grow. Much of our guidance increase is related to the stronger performance of Pharma. So, as you know, we don't give very specific guidance by sector, but I could tell you that the Pharm business is driving most of our upbeat outlook for the remainder of the year.

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

Go ahead, Mike.

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Q - Michael Weinstein {BIO 20602373 <GO>}

Sorry. Either Joe or Dominic, you commented about the Orthopaedics business disappointment this quarter. How much of that do you think was J&J? And do you have a view on whether the market within the U.S. was particularly weak this quarter just looking at your knee and hip results?

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

So, Mike, it's a great question. I think if you look at knees and hips, hips we feel is still very well received in the marketplace. The ACTIS stem, from everything we hear, is qualitatively very strong. We do think that there was a selling day impact of roughly 1 point in Orthopaedics impacting the U.S. And there's, I'll say, qualitative or anecdotal suggestions that a rough flu season also impacted surgeries this quarter.

With knees, we think we'll improve performance as we go throughout the year as we come up with the ATTUNE Revision entering that in the marketplace, ATTUNE S+, as well as cementless offerings. So I'd say it's a mixed bag. The market was a little bit softer due to some ancillary factors, but there's also some product performance that we can do as the year progresses.

Operator

Your next question comes from Jami Rubin with Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Can you all hear me?

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

Yes. Hi, Jami.

Q - Jami Rubin {BIO 1527982 <GO>}

Okay, I guess you can. Hi. Dominic, I too want to extend my congratulations, and it has been an absolute pleasure to work with you. I think you're an incredible class act. You and I have had some fun discussions over the years. You've always been extremely respectful, and I will always be grateful to that. So congratulations on your retirement, and I'm sure you're going to go ahead and do continued great things. And, Joe, congratulations to you too. It's going to be fun to work with you.

Anyway, on to the question, I'm wondering, Dominic, if you can provide a little bit more color around the comments related to supply chain actions in an effort to reduce complexity and improve cost savings. Can you give more specific color around that? And you talked about \$30 billion in additional investments over the next five years or so. Will the cost-cutting initiatives, the \$600 million to \$800 million annual savings, offset the additional increases in investments? Will that fund the additional increases of investments? If you can, just provide a little bit more color around that.

And then, Joaquin, a question for you on Actelion, obviously, something we've been following closely. The trends, certainly OPSUMIT and UPTRAVI, do appear to be a little bit below our expectations, and I know that you were really excited about this opportunity in growing and expanding the market. Just in light of the recent acquisition, can you give us a state of play where you are with these assets? When should we start to see a bigger acceleration? Just wondering how you're performing relative to your own internal expectations. Thanks very much.

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

Sure, let me take the supply chain question, Jami. So just to give you a little bit of perspective on it, so as you know, we have a wide-ranging and complex supply chain due to the various businesses and technologies that are required to produce our products.

And, looking forward into the future, we need more of some newer technologies, like biologics, like an investment in CAR-T, for example, and we need less of the technologies that are related to some of the older parts of the portfolio. So we need to advance our manufacturing footprint to have more capacity with new technologies, less capacity with older technologies. We're going to do that from a position of strength, so that we're ready when our plans materialize and our strategies to continue to launch new products that have these new technologies embedded in them, and we want to be ready for that.

In terms of the cost savings, we mentioned about \$600 million to \$800 million. That will be gradual over a period of time. We won't get to that level of \$600 million to \$800 million until we're near the end of the program, which is about 2022. And some of those cost savings will, in fact, help us offset things like pricing pressure or help us offset other investments in the company.

In the aggregate, the \$30 billion in additional both capital investment and R&D over the next four-year period I think is a good number for us, regardless of these cost savings. We're committed to make these investments in the U.S. for some of the technologies that we just talked about and particularly additional R&D investment right here in the U.S. So I think they're good numbers to plan for the future.

Joaquin?

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you, Jami, for the question. Let me start by setting a couple of headlines on the quarter of the Pharmaceutical group. It was another strong quarter with above-market growth, 15.1% growth and 7.5% when you exclude the Actelion acquisition. And one of the important factors of this growth is that it was global, both in the U.S. and international, and it was broadly based, with eight of our key products growing double digit.

Importantly, also we made significant progress in our recently launched products and also in our pipeline. TREMFYA with \$72 million of sales in the quarter and 17% new-to-brand share in psoriasis in December is outpacing the anti-IL-17 class competitors. ERLEADA was also approved in February, and we are seeing good uptake of ERLEADA, with 80% of the

prescriptions coming from urologists. And I'm also looking forward to the anticipated filing of esketamine in the second half of 2018, and you are going to see more data on this promising medicine in a few weeks at the APA meeting.

Finally, let me get into your question about Actelion, and the answer is Actelion is delivering as expected. We knew about the TRACLEER generics outside of the U.S., and we also expect to have TRACLEER generics in the U.S. later this year. However, both OPSUMIT and UPTRAVI are posting a strong demand growth, and we anticipate that this performance is going to improve for both OPSUMIT and UPTRAVI during the year moving forward.

So let me give you some details on OPSUMIT. OPSUMIT has new-to-brand share on the ERA category in the U.S. of 48% and in Europe of 60%, demonstrating that even in the face of TRACLEER generics, OPSUMIT is the preferred agent. We have 91% Part D coverage and 97% in commercial, showing that we have broad access in the U.S. So we are pleased about the progression of OPSUMIT and we anticipate that we are going to continue to progress moving forward.

And when it comes to UPTRAVI, the new-to-brand share in the prostacyclin category is also 66%, and we continue to make progress with it and are working in educating physicians about the data of the study, the GRIPHON study indicating that earlier use of prostacyclins could have benefits. So we see positively the results so far and we anticipate that they are going to improve as the year progresses.

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

Thank you, Jami. Next question, Rob.

Operator

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

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

Hi, good morning. And, Dominic, you will be missed and best of luck in retirement and spending more time with your grandkids, and I hope to be able to say goodbye to you in person next month. So, best of luck.

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

Thanks very much

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

Yeah. And I just had two questions for Joaquin on the Pharma side. The first has to do with pharmaceutical pricing. Some of the drugs, XARELTO, ZYTIGA and REMICADE, they differed from our expectations based on our analysis of IMS data, which suggests there's pricing going on. So I'm wondering if you can help us with REMICADE pricing, with ZYTIGA pricing, which again ZYTIGA came in much better, so I'm assuming some of that

was pricing. And then XARELTO, which came in lighter, so I'm assuming there's more discounting in the market. So if you can touch on those three drugs.

And then just more specifically about pricing for the rest of the year, particularly in light of next week President Trump, I think, is going to talk more broadly about his views on pharmaceutical pricing in the U.S. And then I just had a quick follow-up on STELARA and TREMFYA. Thanks.

A - Joaquin Duato {BIO 17056015 <GO>}

So thank you for the questions, Glenn. Let me start with the general one on pharmaceutical pricing overall. As you mentioned, we expect that there's going to be an announcement on pricing by President Trump, and that announcement will resemble the drug pricing policies, including in the President's budget and the Council of Economic Advisers report. Those policies were generally seeking to increase competition and to reduce out-of-pocket costs for patients, while recognizing the value of innovation. We also understand that the announcement will include a request for information from the public on drug price issues, and we are looking forward to participate there.

Going into our pricing in the U.S., and to your question on how do we see pricing trends for us in the U.S., we see that if you exclude REMICADE and the onetime adjustment that was referred by Joe earlier, we see a continuation of the trends that we have seen in the previous quarters. So we don't see a big change from what you saw in previous quarters.

Specifically, in your question of ZYTIGA, the increase of ZYTIGA is generally demand and share driven. With the approval of LATITUDE, we have seen a very significant growth of ZYTIGA in the U.S. and ex-U.S., with 53% growth year-over-year, 75% in the U.S. and 37% ex-U.S. As a reminder, 55% of the sales of ZYTIGA are realized outside of the U.S., so the demand on ZYTIGA is very much share and market driven.

When it comes to XARELTO, there is two factors that have influenced XARELTO performance this quarter. The first thing I have to say is that it grew 13% and it also gained share when you look year-over-year. So we gained 1.6 points of share in the anticoagulant market. When we look at the comparison with the previous quarter, there are two factors that influenced then.

The first one is that we had an inventory build at the end of the fourth quarter due to Hurricane Maria supply issues that we have burned in the first quarter. And the second one is that, as it happens every - beginning of the year every first quarter of the year, the new access agreements kick in and that also impacted our first quarter sequential comparison. So in general, as I said, if we exclude the REMICADE situation, we see the pricing environment overall being similar to the trends we experienced in the previous quarters.

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

Great.

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

Thanks for the question, Glenn.

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

Thank you.

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

Next question, Rob.

Operator

Your next question comes from Geoff Meacham with Barclays.

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

Geoff?

Operator

Mr. Meacham, your line is open. Go ahead with your question.

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

Why don't we move on to the next question, Rob, and then we can put Geoff back in.

Operator

Yes, your next question is coming from Josh Jennings with Cowen & Company.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi. Thanks for taking the questions and I'll be brief. Dominic, you will be missed and it's sad to see you go, and congratulations, Joe, on the new seat.

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

Thank you.

Q - Joshua Jennings {BIO 16451037 <GO>}

I was hoping to just start off with a question on guidance for Dominic. Just on the pre-tax operating margin guidance increase, so I think 150 basis points from approximately 100, I believe, on the fourth quarter call. 1Q pre-tax operating margin performance was flattish. Were there some one-timers in 1Q, or can you just help us, outside of the bump in the top line, you also have a reduction in other income? So what are some of the drivers that are leading to that increased outlook, improved outlook, for the operating margin performance for the rest of the year?

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

Sure. Sure. Well, we saw very good cost of goods sold performance in the first quarter. It was down 140 basis points, has to do with the mix of the products sold, but also the great work that's done in our supply chain to be more efficient in manufacturing. We also have, as you saw, relatively a slower increase in the rate of selling and marketing expenses in relation to the rate of sales increase, so we're still investing there. But we're, obviously, leveraging the business in terms of productivity. That's particularly pronounced in our Pharmaceutical business.

And then the other income and expense line, we have a lower expectation now simply due to the timing. There's a number of activities that we undertake. Each year we, obviously, look to further enhance our portfolio by exiting some lower growth categories or brands or products and entering new ones. And they're always difficult to predict, Josh, and we just think that some of them will move over into 2019. We're still on track with many of them, but we'll probably see some more in 2019 than in 2018. And so we decided it'd be prudent to just lower that expectation, again, completely offset by the stronger performance in the business and improved pre-tax operating margin, as I just mentioned.

Q - Joshua Jennings {BIO 16451037 <GO>}

Great. And I was hoping to just follow-up with a high-level question on the Medical Devices business. I understand we're going to get a lot of details next month, but just in terms of thinking about the executive team's patience with that business unit, I mean, it seems as if the recent strategy has been to prune lower growth, lower margin business units with some tuck-ins. Is that how we should think about the strategy going forward is continuing with internal R&D and continued pruning? Thanks a lot for taking the questions.

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

Yeah. Well, Josh, just to put it in perspective, I mean, there are areas within the Medical Devices business that are really very strong, right? So our Vision business is doing exceptionally well, electrophysiology is doing exceptionally well, endocutter is doing well, our trauma business is back on track. And so having said that, we do have the areas where we need to improve and we'll improve in those areas through a number of factors, as we've always done at Johnson & Johnson over the years, a good mix of internal innovation and acquisitions and new technologies.

So I don't think that's ever been an issue for us. We've always been able to do that. And we'll, obviously, talk more about it on May 16 when you'll get to hear from the leaders of the business who are responsible for their business, both on what's happened in the market and with our products, and the enthusiasm they have for the launch of new products and new areas that we're getting into. So, I look forward to joining you for that and we'll hear a lot more about that then.

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

Thank you, Josh. Next question, Rob.

Operator

Your next question is coming from the line of Geoff Meacham with Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys. Can you hear me?

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

Yeah, yeah. Hi, Geoff.

Q - Geoff Meacham {BIO 21252662 <GO>}

Perfect. Good morning. Thanks for the question. Let me also offer up congrats to both Dominic and to Joe.

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

...Geoff.

Q - Geoff Meacham {BIO 21252662 <GO>}

Just had a few on the Pharma segment. So, Joaquin, when you look at the DARZALEX trajectory, the growth has, obviously, been quite good. But how do you think about where adoption trends could go into first-line myeloma? And then in this market, how disruptive could the BCMA class do you think could be to the myeloma market?

And then a follow-up more broadly for Dominic, now that you have the Actelion deal fully integrated, I want to get your perspective on attitudes towards Pharma growth going forward. Are you comfortable with the level today? Do you feel like a bolt-on would be helpful to tick up growth, or is the pipeline kind of set for more of an inflection looking out, say, 12 to 24 months?

A - Joaquin Duato {BIO 17056015 <GO>}

Okay. So thanks for the question. Thank you for asking about DARZALEX. That, as you've seen, is achieving a very rapid uptake with adoption both in the hospital and in the clinic. To-date, in the U.S. we have had already 21,000 patients treated with DARZALEX and as you have seen, we are posting a strong growth with 64% in the quarter. Largely, this is due to our increasing share in Line 2, in which we had in the first quarter 24% of new-to-brand, so really a very positive result.

What is going to be the next growth driver? As you mentioned, it's going to be first-line. We are expecting the approval of our first-line indication in the U.S. in this first half of the year, and that is the study that we are comparing with VMP. And then we also are expecting the data reads of our additional first-line studies, the one with REVLIMID and the one in transplant eligible later this year. So that body of data in first-line, it's going to be the driver of future growth of DARZALEX.

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What is interesting to see is that in every single study that we have done with DARZALEX, we have added DARZALEX to different combos, DARZALEX has always in every single one, including the ALCYONE one, has always been able to double the PFS and to triple the MRD, showing the synergistic effect that DARZALEX had in every treatment regimen. So we are very positive about how DARZALEX is doing and we believe that, as you mentioned, the next wave of growth with DARZALEX is going to come with adoption in first-line subsequent to the approval that we'll have in this first half of the year.

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

And, Geoff, I think undoubtedly our strategy in Pharm has been very successful for a long period of time, which includes a good mix of internal and external development. And quite frankly, picking the right products and collaborating with others in some very important areas, like in oncology. So, good examples are IMBRUVICA and DARZALEX as two really good examples. And we'll continue to do that. We just announced a collaboration with Bristol-Myers Squibb on a new anticoagulant mechanism of action of Factor XIa. So that has been the hallmark of our success in Pharma, and I think that will continue.

The pipeline is very strong, with now - we're now eight more products we intend to file between now and 2021 each having \$1 billion potential. Having said that, there may be times when there's an opportunity to do a great deal in Pharma, like we did with Actelion. And that depends on the right price with the right partner at the right time. And we think that - if that we think that generates value for our shareholders, we'll do that. But I would say we have a very, very good, solid pipeline already, and our collaboration strategy has proved to be remarkable, and I think that will continue as the primary way of growing the Pharma business.

A - Joaquin Duato {BIO 17056015 <GO>}

Yeah. If we look even further, Geoff, the other important event with DARZALEX, other than first-line approval, it's going to be the SubQ formulation. We have now four ongoing Phase 3 studies with the SubQ formulation, and we expect the filing before 2021. So that would create another opportunity for DARZALEX to improve patient convenience and to continue to grow adoption.

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

Thanks for the questions, Geoff. Next question, Rob.

Operator

Your next question comes from David Lewis with Morgan Stanley.

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

Hello, David.

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

Good morning. Dominic, we're running out of superlatives to describe your tenure, so I'll just say congratulations, and I hope Joe has big feet.

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

(59:50).

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

So, Dominic, one for you, and then just one for Joaquin here. So we think about the first quarter, Dominic, as it relates to basically the guidance, is first quarter a decent proxy for the year as it relates to growth? So basically, if Pharma gets better this year, Consumer gets a little better, and Devices is more flattish?

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

I think the way to think about the first quarter, there's a few things that will not continue. For example, in the first quarter we had some timing of tenders in Europe, so you see the very strong Pharma performance in Europe that has a lot to do with the timing of tenders in Europe, and that, obviously, doesn't continue in every quarter. We also had this particular adjustment that we talked about that was negative in the first quarter, a catch-up on rebates for one of the major payers. And we do expect that we'll see an acceleration of TRACLEER and PROCrit generic erosion going into the balance of the year.

At the same time, we expect that Medical Devices will continue to accelerate, as well as Consumer. So overall, we had some puts and takes in the first quarter. We've increased our overall guidance about 0.5 point from the previous expectations, and we'll update you more, obviously, as we see second quarter results. But overall I think we're in great shape and I'm pretty confident we're going to deliver on a good solid year this year, as we did last year.

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

Okay, that's very helpful, and then two follow-ups for me on Pharma. The first is just on REMICADE. You talked about that being one-time. But is that 16% adjusted number decline, is that a good way to think about the balance of the year?

And then for Joaquin on esketamine, obviously a key product launch back half of this year, it hasn't come up much on the call. I know we'll see data here in the second quarter. Can you just talk about the size of that commercial opportunity and how you think your confidence in that commercial ramp, just given the unique dynamics of this market? Thanks so much.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question. On REMICADE, I think that the 15% - 16% that you quoted is a good way to think about the erosion moving forward this year.

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Related with esketamine, we are very excited about esketamine. It's been a long time that we don't have a new mechanism of action in the treatment of treatment-resistant depression. As you know, esketamine uniquely has two Breakthrough designations; one in treatment-resistant depression, the other one in suicidal ideation. And we are looking forward to be able to file in the second half of this year, and you're going to see more data of one of the Phase 3 studies at the upcoming APA.

So what is the medical need here? You know how many people use antidepressants and you know how many people that are using antidepressants is not getting the right response. So you are talking about millions of patients in this case. It's one of the categories more used in all the pharmaceutical market. So the commercial and patient opportunity is very, very significant, and I think it's one that has been underestimated generally.

This is going to be uniquely if we are able to demonstrate that in the Phase 3 studies, which are going to be the most important thing to look after, it's going to be the first time that a new medicine is able to demonstrate efficacy on top of an active medication. So that has been never demonstrated. So it would be the first time that any medicine is able to demonstrate efficacy on top of an active medication. So we believe that it has very significant opportunity.

It also builds on our expertise in CNS. Remember that we are the leading company in schizophrenia with our long-acting therapy franchise, which by the way posted double-digit growth this quarter. We have a strong equity in the psychiatry community, and we have a very good understanding of how to manage site-of-care issues based on our experience in REMICADE and in others, helping physicians to be able to appropriately administer the medicine at the site of care.

So we are very confident on esketamine. We are very confident also in our capability in being able to translate good clinical data, a potential approval into patient access through our ability to manage site of care and market access for this product.

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

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

Operator

Your next question comes from Danielle Antalffy with Leerink Partners.

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

Good morning Danielle.

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

Hi Danielle.

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Q - Danielle Antalffy {BIO 16104603 <GO>}

Hi. Good morning, guys. Thanks so much for taking the question. And, Dominic, thank you so much for all you've done over the years. And I'm very grateful for the relationship that we've developed. Joe, I'm excited for you and to work with you going forward even more. So I just wanted to ask a question as it relates to the commentary about the incremental \$30 billion now with tax reform and how to think about the approach you guys are going to take between incremental investment in organic R&D versus inorganic capital deployment. Does that change the strategy at all or potentially make you get more aggressive on the inorganic front?

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

Danielle, just to clarify, so \$30 billion invested in R&D and capital investments in the U.S., which is a 15% increase over the prior four-year period. And in terms of the mix, I think we will continue to look for productivity from our incredible efforts in R&D, particularly in the Pharma business, where we invest at the higher rates in the industry in R&D., so I think we'll continue to maintain that.

We'll continue to do, as I said earlier to an earlier question, collaborate and bring on bolt-on products in Pharma as well as across Medical Devices. But look, 50% of our growth over long periods of time has come from acquisition, have come from external-enabled growth, and I don't think that will change going forward. It's just a matter of the right asset at the right price that will create value for our shareholders. So I don't see a major shift in our strategy in that regard.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Thanks so much.

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

Thanks for the question, Danielle. Next question, Rob.

Operator

Your next question is from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for fitting me in. Dominic, congratulations on your retirement. It truly was a pleasure working with you. And, Joe, congratulations on your new role.

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

Thanks, Larry.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Two quick questions; one financial, one Pharma. So, Dominic, you guided to \$1.5 billion to \$1.7 billion of other income in 2018. Does this become a headwind to EPS growth next

year, or do you expect that to remain at an elevated level via additional divestitures? I think in the past, Dominic, you've said that that line underlying other income excluding one-time items is about \$500 million to \$600 million. Is that still the case? Basically how do you want us to think about that line going forward?

And I'll just quickly fit in the Pharma question. It's a quick one. Joaquin, on the COMPASS trial, do you expect an FDA panel? Is it possible still to get an accelerated review? And how are you thinking about that impacting XARELTO growth? Thanks for taking the questions, guys.

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

Sure, Larry, this \$1.5 billion to \$1.7 billion is lower than our previous guidance, as you know, and that's because of timing primarily, so some of the activities are going to shift into 2019. So that gives us "a head start" on that line, if you will, for 2019. And we're going to continue to look at optimizing our portfolio. When we do that, we have these gains, and we typically use some of those gains to invest back in the business. So you see a much higher level of R&D investment if you compare it to any prior period when the OI&E line is lower in prior periods. So it's not always just driving earnings. In fact, it's basically a portfolio decision. We're investing in new products with the gains that we get from divesting products. I think that will be the case going forward.

I think the \$500 million to \$600 million that I mentioned earlier is still a good underlying number for that line. And as I mentioned, we're seeing improvements in our pre-tax operating margin, and we expect that will continue to grow as the Consumer business ramps back up and the Medical Devices business improves, and obviously, the continued strength of Pharma. So even if that line is a little bit lower going forward, we have the higher pre-tax operating margin, which will drive our earnings growth.

As you know, Larry, we generally look to grow our sales at a pace that's faster than the markets we compete in, but then we also look to grow our earnings at a pace that's slightly faster than the rate of growth in sales, and I think we'll continue to do that through the right mix on the P&L.

A - Joaquin Duato {BIO 17056015 <GO>}

So thank you for the question on XARELTO, Larry. We are very also excited about COMPASS and the COMPASS result. As you recall, we presented the COMPASS results at the ESC in August last year and the results were impressive with 24% risk reduction in MACE. We file in December and we are anticipating a potential approval in the fourth quarter of this year.

Regarding an advisory committee, I cannot comment on that. We don't know. So what is the market opportunity and the relevance and significance of COMPASS? As we have discussed with you in the past, this is a population of about 10 million potential patients. You know that the dose would be lower, 2.5 milligram in combination with aspirin, and it's a new treatment paradigm. So we are very excited about being able to bring this new therapeutic option here.

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It's also important from a competitive perspective. We are the only new oral anticoagulant that has this broad development program called EXPLORER that contains a reduction in MACE for CAD/PAD patients, but also other indications that I will comment, and that will enable us to do a couple of important things.

First, have a new growth driver for XARELTO in addition of the existing set of indications. Second, differentiate ourselves from the competition and in that case, gain share in the particular anticoagulant market. And third, as we will be the only one to have this indication with a differentiated dose, also have a stronger position vis-à-vis the payers. So we think it's a very significant opportunity for us.

And as I said, this is only part of multiple Phase 3 indication seeking studies that we have in XARELTO. So COMPASS is one, but if I can refresh your memory there, you know that we also have the MARINER, the COMMANDER studies that we'll read this year, respectively, in medical ill patients and congestive heart failure that also represent a very significant opportunity to upgrade the standard of care of anticoagulation in these patients.

So overall, the EXPLORER program that is going to start with the COMPASS study, it's going to be a growth driver for XARELTO that is going to put us in a much better position moving forward from a competitive perspective.

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

Thanks for the questions, Larry. Rob, I think we've got time for one more.

Operator

Yes, that will be from the line of Bob Hopkins with Bank of America.

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

Good morning, Bob.

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

Hi, Bob.

Q - Robert Hopkins {BIO 2150525 <GO>}

Hey. Good morning. Good morning. And also let me offer my congratulations to both Dominic and Joe. Those statistics were, obviously, very impressive. Since the Device and Consumer Day is coming up, I thought I'd ask two quick device questions. One, on the Ortho sort of pure pricing numbers that you provided in the prepared remarks, I was just curious are those U.S. numbers. And they did seem a little worse. Is there something going on with pure price that's worth calling out?

That was the first question, and I'll just rattle off the second one. I was curious at the upcoming Analyst Day how much detail you might be willing to provide or are going to

provide on the surgical robotics JV. Will we get a lot of specifics in terms of timelines and seeing the device, or is it too early to be specific? Thank you very much.

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

So, Bob, with respect to the price, that was U.S. only and we provided this quarter pure price. In the past we put it in with mix, but then we found out that you and your peers would simply ask for it on the follow-up call, so we thought it was just a little bit more clear. In terms of overall pure price trends, we haven't seen any deviation from what's consistently been in place for the past few quarters.

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

And at the upcoming Medical Devices and Consumer Day, we will have a dedicated portion of the program on surgical robotics. We'll talk about the current status of the venture that we have through Verb with Verily. We'll give you as much as we can a description of the current state of the robot. We'll show you some aspects of it, of course. We want to be careful as to the competitive issues that that could raise, but I think you'll get a good understanding of where we are, how it works, how it's different. And we'll also talk about Orthotaxy, the new knee robotic technology that we just acquired, Bob. So that will be a dedicated portion of the session to bring everyone up to date.

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

Great. So thanks, Bob, for the question and to everyone who asked a question today, and apologies to those who we could not get to due to time. But certainly, don't hesitate to reach out to the Investor Relations team as you need to, to follow-up. I will now turn the call back to Dominic for some closing remarks.

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

Thanks, Joe, and I want to sincerely thank all of you here in the room with me and listening on the phone for the tremendous support and partnership you've given me and Johnson & Johnson each and every quarter. It's hard to believe this is the 46th quarter that I've done this, so it's been a pleasure.

I also want to take one more opportunity to express my confidence in our guidance for this year, the overall success of our business, and I'm very optimistic about the future of Johnson & Johnson. I look forward to seeing you all on May 16 at our Consumer and Medical Devices Business Review Day. Thanks for joining us today, and have a great day.

Operator

Thank you. This concludes today's Johnson & Johnson's first quarter 2018 earnings conference call. You may now disconnect.

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