

Q2 2019 Earnings Call

Company Participants

- Chris DelOrefice, Vice President, Investor Relations
- Dr. Paul Stoffels, Vice Chairman of the Executive Committee and Chief Scientific Officer
- Joaquin Duato, Vice Chairman of the Executive Committee
- Joseph J. Wolk, Executive Vice President & Chief Financial Officer
- Joseph J. Wolk, Executive Vice President & Chief Financial Officer
- Paul Stoffels, M.D. Vice Chairman of the Executive Committee & Chief Scientific Officer

Other Participants

- Bob Hopkins
- Christopher Schott
- Danielle Antalffy
- David Lewis
- Joanne Wuensch
- Kristen Stewart
- Larry Biegelsen
- Matthew Miksic
- Terrence Flynn

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's Second Quarter 2019 Earnings Conference Call. All participants will be in listen-only mode until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time. (Operator Instructions).

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

Chris DelOrefice {BIO 20730104 <GO>}

Good morning. This is Chris DelOrefice, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for the second quarter of 2019.

Joining me on today's call is Joe Wolk, Executive Vice President, Chief Financial Officer. Additionally, during our Q&A session, Joe and I will be joined by Joaquin Duato, Vice

Chairman of the Executive Committee and Dr. Paul Stoffels, Vice Chairman of the Executive Committee and Chief Scientific Officer. This is a great opportunity for you to engage with our Vice Chairman and not only obtain insights into the drivers of our current performance related to their areas of expertise, but also hear their perspective on our approach to innovation and building differentiated capabilities that we expect to enable continued strong performance over time. A few logistics before we get into the details.

This review is being made available via webcast, accessible through the Investor Relations section of the Johnson & Johnson website at investor.jnj.com, where you can also find additional materials, including today's presentation and associated schedules. Please note that today's presentation includes forward-looking statements. We encourage you to review this cautionary statement regarding such statements included in today's presentation as well as the Company's Form 10-K which identifies certain factors that may cause the company's actual results to differ materially from those projected. Our SEC filings, including our 2018 Form 10-K, and our most recent 10-Q along with reconciliations of non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures are also available at investor.jnj.com.

Several of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships. Regarding today's agenda, Joe will first provide some perspective on our overall results for the second quarter. I will then review the sales and P&L results for the corporation and the three business segments. Joe will conclude by providing insights on our cash position, capital allocation deployment, and our updated guidance for 2019, along with some considerations for the balance of the year. The remaining time will be available for your questions. We anticipate the webcast will last about 75 minutes.

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

Joseph J Wolk {BIO 19812977 <GO>}

Great, Chris. Good morning, everyone. Thank you for your interest in Johnson & Johnson, I'm pleased to discuss with you our solid results for the second quarter and how our performance during the first half of 2019, positions us well for the rest of the year and beyond. During the quarter, we continued to deliver growth across the three segments of our broad-based business while also optimizing our portfolio and making progress against long-term strategies.

Revenue and earnings per share were in line with our expectations. As expected, we did experience sales deceleration from the first quarter primarily due to the impact of generic and biosimilar competition in our Pharmaceutical business. Income in the first half of 2019 provides us the opportunity to continue investing to fortify accelerate and potentially add to our pipelines across all three segments. We are committed to driving solid financial and operational performance for our shareholders while also delivering on our responsibilities to patients, employees and communities as outlined in Our Credo.

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Chris will provide additional franchise and product detail, but let me provide some high-level framing. Our Pharmaceutical business continues to deliver strong growth across our oncology, pulmonary hypertension and immunology portfolios. We are particularly pleased with the success of DARZALEX, STELARA, IMBRUVICA and the INVEGA portfolio. As highlighted during our May Pharmaceutical business review, our performance demonstrates our ability to consistently obtain approval for new products and line extensions. Once again, our performance was driven by volume of transformational medicines that address high unmet medical need rather than price.

In our consumer segment, we accelerated growth in the second quarter in our stronghold beauty lines of NEUTROGENA and AVEENO. We are also pleased with the contributions from newly acquired businesses, Dr.Ci Labo and Zarbee's. This growth more than offset the one-time impacts related to seasonality and inventory levels we mentioned during our first quarter call. We expect to deliver competitive growth relative to the market for the year.

In our Medical Devices segment, we did incur some isolated supply disruptions in the quarter which Chris will outline, and the impact limited growth by one point. Accounting for that, we grew above 4% in line with last quarter and we are on track towards our goal of exceeding last year's performance. We continue to enhance our leadership positions in platforms such as electrophysiology, energy and endocutters. Orthopedics grew modestly during the quarter, in line with Q1 led by hips and trauma. That being said, we remain intense on improving our performance in Orthopedics and the segment at large.

Turning to earnings. Earnings per share was favorably impacted by a significant gain recorded in other income, specifically the approximately \$2 billion pre-tax gain related to the sale of the Advanced Sterilization Products business. We closed this transaction in early April and as mentioned during the first quarter call, this gain comprises a large majority of our other income guidance for the full year 2019. Other income for 2019 is on par with levels experienced in 2015 and consistent with past practice, we intend to utilize these gains to invest in opportunities that increase shareholder value and better position the business for long-term success.

I'll now turn the call back to Chris to discuss second quarter sales drivers as well as highlight notable line items in our P&L before I return with some comments regarding our cash position capital allocation priorities and guidance.

Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Joe. Worldwide sales were \$20.6 billion for the second quarter of 2019, a decrease of 1.3% versus the second quarter of 2018. Operational sales growth, which excludes the effect of translational currency, increased to 1.6% as currency had a negative impact of 2.9 points.

In the US, sales decreased 2.2%. In regions outside the US, our reported growth declined by 0.3%. Operational sales growth outside the US was 5.5%, with currency negatively impacting our reported OUS results by 5.8 points. Excluding the net impact of

acquisitions and divestitures, adjusted operational sales growth was 3.7% worldwide, flat in the US and 7.6% outside the US.

Turning now to earnings, for the quarter, net earnings were \$5.6 billion, and diluted earnings per share was \$2.08 versus diluted earnings per share of \$1.45 a year ago. Excluding the after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were \$7 billion and adjusted diluted earnings per share was \$2.58, representing increases of 21.5% and 22.9%, respectively, compared to the second quarter of 2018.

On an operational basis, adjusted diluted earnings per share grew 25.2%. Beginning with consumer, I will now comment on business segment sales performance for the second quarter, highlighting items that build upon the slides you have in front of you. Unless otherwise stated percentages quoted represent the operational sales change in comparison to the second quarter of 2018, and therefore exclude the impact of currency translation.

Worldwide consumer segment sales totaled \$3.5 billion, growing at 4.6%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 2.3% with strong growth in the US of 4.4%, due primarily to strong performance in our Beauty franchise. Growth outside the US was 0.7%. Consumer continues to grow share in the e-commerce channel, outpacing category growth rates in that channel with strong double-digit growth across all regions.

The Beauty franchise grew 10.7% or about 5% adjusted to exclude the impact of the acquisition of Dr.Ci Labo and the NIZORAL and RoC divestitures. Our priority brands NEUTROGENA and AVEENO delivered strong performance results due to share growth combined with strong sales in our club and e-commerce channels in the US. Share growth in NEUTROGENA was realized in the facial moisturizing treatment and sun protection categories. AVEENO was further aided by retail stocking for the hair products launch OGX and MAUI MOISTURE brands continued to experience solid growth, primarily resulting from new market expansions.

Over-the-counter medicines grew 2.8% globally or 1% when adjusted to exclude the impact of the Zarbee's acquisition which continues to perform well. In the US, OTC adjusted operational sales growth was just over 2% and is growing share, however, the US was negatively impacted by retail inventory factors. ZYRTEC was a core contributor to sales growth and grew market share.

Additionally, children's MOTRIN and TYLENOL in pediatric analgesics delivered strong sales and share growth. Adult TYLENOL also continues to drive significant share growth with consumption well outpacing the category, realizing double-digit consumption growth driven by rapid release gel and TYLENOL arthritis products. However, TYLENOL sales declined slightly this quarter, as this consumption was more than offset by the lapping of the supply disruption associated with Hurricane Maria and the sell-through of 2018 elevated retail inventory levels that occurred in response to seasonal and other retailer stocking dynamics.

Concluding the consumer segment, Baby Care grew 2.2% globally. Growth was primarily due to lapping retail destocking and other events associated with the Johnson's Baby relaunch in the US. The Johnson's relaunch is stabilizing performance in all markets where it has been relaunched.

Moving on to our Pharmaceutical segment. Worldwide Pharmaceutical sales of \$10.5 billion grew 4.4%, enabled by double-digit growth in nine key products. Sales were aided by one-time favorable pricing adjustments outside the US, worth almost 100 basis points worldwide primarily driven by DARZALEX. Sales declined in the US by 2% and increased outside the US by 12.9%. Generic competition for ZYTIGA negatively impacted our worldwide and US growth by about 300 and 500 basis points respectively. Our strong portfolio of products and commercial capabilities has enabled us to deliver global growth at competitive levels despite significant biosimilar and generic headwinds.

Our oncology therapeutic area delivered another strong quarter, with worldwide growth of 14.1%. DARZALEX continued its strong performance growing about 57% globally or about 41% when removing the impact of a favorable one-time adjustment related to the completion of pricing and reimbursement discussions in certain European countries. The US grew 24% and continues to benefit from strong market growth and about a three point increase in US market share across all lines of therapy.

The continued strong double-digit growth outside the US is driven by increased penetration and share gains across the 40 EMEA countries where it is commercially available as well as in Latin America and the Asia-Pacific region. Of note, just last week, we filed a regulatory submission for the subcutaneous formulation of DARZALEX for multiple myeloma in the US.

IMBRUVICA grew over 39% globally, driven largely by market share gains and strong market growth across multiple indications in the US along with strong uptake outside the US, in the European and Asia-Pacific markets. In the US, based on first quarter data across all indications and lines of therapy, IMBRUVICA gained approximately three points of market share and continues to be the new patient and total patient share leader in chronic lymphocytic leukemia which gained almost eight points of market share in line one therapy.

Worldwide ZYTIGA growth declined by about 20% with declines of 59% in the US driven by generic competition which was partially offset by growth of about 25% outside the US. Strong sales growth in Europe and Asia were driven by market growth and share gains primarily from the expanded indication in metastatic high-risk castration sensitive prostate cancer based on the LATITUDE clinical trial.

In non-metastatic castration resistant prostate cancer, we continue to be pleased with the launch progress of ERLEADA, which gained almost four points of market share in the US with the penetration of prescribers split, almost evenly among urology and oncology practices. We are also pleased with the early launch progress in EMEA, where ERLEADA is now available in five countries.

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During the quarter, we filed regulatory submissions in the US and Europe for metastatic castration sensitive prostate cancer. Further we are pleased with the early launch progress of BALVERSA, for the treatment of adults with locally or advanced metastatic urothelial cancer.

Our immunology portfolio delivered global sales growth of just under 6% driven by continued strong performance in STELARA with growth of 18% primarily from the Crohn's disease indication. We remain very pleased with the uptake of STELARA in Crohn's disease where market share has increased by over 6 points in the US compared to the second quarter of 2018. Sales growth was partially offset by continued erosion of REMICADE of 15% due to increased discounts and modest share loss in the US to alternative mechanisms of action and biosimilars.

Lastly TREMFYA totaled \$235 million globally and is experiencing strong demand with over 35,000 patients on therapy. TREMFYA achieved a 7.6% share of the psoriasis market in the US, which is up 3 points from the second quarter of 2018. In infectious diseases, our portfolio grew 5.4%, led by strong growth of SYMTUZA and JULUCA for HIV, partially offset by cannibalization and increased market competition in other products.

In neuroscience, our paliperidone, long-acting portfolio performed well, growing about 16% with higher market share driven by increased new patient starts and strong persistency. In addition, we are pleased with the launch performance of SPRAVATO for treatment-resistant depression. There are more than 1,600 sites certified with the REMS program and new treatment centers are being added daily.

In our cardiovascular, metabolism and other product portfolio, we did experience declining sales of 14.7%, primarily driven by declines in XARELTO, INVOKANA and biosimilar competition for PROCIT. XARELTO continues to increase TRx share, however, the share uptake was offset by the increase in the legislative rate for the donut hole from 50% to 70%, along with higher Medicare and donut hole utilization resulting in an overall decline in XARELTO of 19% this quarter.

We've seen a positive response to XARELTO's new 2.5-milligram vascular dose for the CAD and PAD indication. And while we expect the penetration of this expanded patient population to occur over time, we are confident in the value this indication provides to patients. Our total pulmonary hypertension portfolio grew by 6% with strong performance in both OPSUMIT and UPTRAVI growing by about 15% and 19%, respectively on a global basis. Both benefited from further market penetration and an increased share. This growth was partially offset by TRACLEER, which was negatively impacted by the recent generic entry in the US as well as continued generic competition outside of the US.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were \$6.5 billion declining 4.1%. Excluding the net impact of acquisitions and divestitures, primarily the divestitures of LifeScan and ASP, adjusted operational sales growth was 3.2% worldwide. As Joe mentioned, we did have some isolated supply challenges in the quarter that negatively impacted growth by about a 100 basis points worldwide. Adjusting for this, Medical Devices would have delivered growth of just over

4%, consistent with the first quarter and representative of the continued progress being need to improve performance in this segment.

Interventional solutions grew about 16% globally led by continued strength in our electrophysiology business, achieving more than 16% growth worldwide, continuing its trend of double-digit growth. Growth was strong in all regions driven by our newer product offerings in ablation and advanced catheters, contributing to atrial fibrillation procedural market growth. Additionally, we delivered a fourth straight quarter of double-digit growth in our Cerenovus business, driven by new product innovation including EMBOTRAP for the treatment of ischemic stroke as well as strong market growth.

Vision growth of 1.5% was driven by contact lenses which grew almost 3% globally, led by daily disposables and astigmatism lenses in the OASYS family. Our contact lenses business remained strong with year-to-date growth of just under 5% in both the US and OUS. Orthopedics growth remained consistent versus Q1 of 2019 with growth of 0.6% or 0.9% when adjusting for acquisitions divestitures and selling days.

We continue to make progress to improve growth in this franchise and we remain committed to executing our innovation and commercial plans that aim to improve performance. Hips grew 3.3%, which we expect to represent above market performance globally driven by our leadership position in the anterior approach and continued strong demand for our primary STEM ACTIS which is now our number one selling STEM in the U.S. Additionally, our KINCISE Surgical Impactor designed to replace the handheld mallet is enabling hip procedures in the U.S.

Trauma growth of 1.7% globally was driven by market growth supported by strong adoption of newer innovation such as our Femoral Recon Nails. The U.S. growth rate of 3.3% is expected to be in line with the market and accelerated for the third consecutive quarter. Growth outside the US was flat when adjusting for selling days and was also impacted by over one point due to timing of a tender shifting to the second half.

Spine declined over 2% with the US being the primary driver of the decline. OUS growth was flat when adjusting for acquisitions, divestitures and selling days while we continue to see some stabilization of performance driven by new products such as the Viper Prime System for minimally invasive surgery and EXPEDIUM VERSE, our all-in-one pedicle screw system for deformity. We continue to pursue opportunities to further improve growth, including new innovation such as the Symphony system we plan to launch in the second half in complex cervical.

Knees declined by less than 1% in the quarter with the US being the driver of the decline offsetting strong growth of over 5% outside the US that is expected to represent above market performance led by new innovation, including ATTUNE revision and S+. The US market is realizing positive uptake from the ATTUNE revision system, but we continue to have portfolio gaps, which we are addressing to enhance performance, including the expected full commercial launch of our cementless offering later this year.

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Pricing pressure continued to impact all categories in Orthopedics, but was relatively stable overall compared to Q1. For the quarter US pure price was negative across all platforms. Spine pure price declined approximately 4% with Hips, Trauma and Knees all down about 2%.

Turning to the results for the surgery business, Advanced Surgery delivered global growth of just over 6% led by strong performance in both energy and endocutters, primarily driven by share gains and new products in the Asia-Pacific region. Biosurgery declined by over 2% due to a stop shipment of SURGIFLO 3 in the which impacted the global biosurgery growth by 11 points. We will continue to work with the FDA to ensure this important technology for patients is available again in the US market as soon as possible. Wound closure grew approximately 3% as conventional and barbed sutures gained share. Across total general surgery, worldwide growth was negatively impacted by 250 basis points due to a field action on our intraluminal staplers. Corrective actions were taken in the quarter and we began distributing to customers in June.

Selling days had a minor negative impact on our global growth rates in the second quarter, and we do not expect a significant impact in any subsequent quarter in 2019. As a final comment on Medical Devices based on feedback we received from the analyst community, we will no longer be providing utilization trends during this call. These estimates were based on limited external data and provide a low correlation to our actual market performance in the segments we compete. As a final update on utilization, we did want to provide you the latest figures for Q1 since we shared estimates last quarter. Hospital Admissions, Surgical Procedures and Lab Procedures all increased by approximately 1.5%, 1% and 1.5%, respectively.

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I would now provide some commentary on our earnings for the quarter. Regarding our consolidated statement of earnings for the second quarter of 2019, please direct your attention to the box section of the schedule. As referenced in the table of non-GAAP measures the 2019 second quarter net earnings are adjusted to exclude intangible asset amortization expense and special items of \$1.3 billion on an after-tax basis, primarily driven by intangible amortization of \$1 billion. Excluding the impact of those items, our adjusted earnings per share is \$2.58, an increase of 22.9% versus the second quarter of 2018. Adjusted EPS on a constant currency basis was \$2.63, up 25.2% versus second quarter 2018.

I'd like to now highlight a few noteworthy items that have changed on the statement of earnings compared to the same quarter last year. Cost of products sold deleveraged slightly primarily driven by product mix, which was offset by improvement in selling marketing and administrative margins for the quarter as a result of leverage in our Pharmaceutical and Consumer businesses. We continue to invest in R&D at competitive levels and our investment in research and development this quarter as a percent of sales was 13%, which is higher than the second quarter of 2018 by 30 basis points. This increase was primarily driven by higher investment in our Medical Devices business, to support the development of our digital surgery platforms, including robotics.

The increased levels of income recorded in the other income and expense line was primarily driven by the gain on the ASP divestiture. Net interest expense was lower by

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\$132 million primarily driven by the positive effect of net investment hedging arrangements and certain cross currency swaps. Regarding taxes in the quarter, our effective tax rate of 20.4% was in line with the second quarter 2018 of 20.5%. We encourage you to reference our 10-Q for further details on specific tax matters. Excluding special items the effective tax rate was 19.3% compared to 18.5% in the same period last year. The second quarter of 2019 includes the tax impact on the gain of the ASP divestiture.

Now looking at adjusted income before tax. In the second quarter of 2019, our adjusted income before tax for the enterprise increased from 33.7% to 41.9% in 2019, primarily driven by the gain on the divestiture of ASP. The following are the main drivers of adjusted income before tax by segment; the decrease in Pharmaceutical margins by 160 basis points was primarily driven by product mix and lower other income; consumer margins also decreased by 480 basis points, because of lower divestiture gains that were partially offset by leveraging in selling and marketing expenses; Medical Devices increased from 27.8% to 57.5% in 2019 due to the gain on the ASP divestiture partially offset by investments in digital surgery.

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

I would now turn the call back to Joe.

Joseph J Wolk {BIO 19812977 <GO>}

Thanks, Chris. With respect to cash at the end of the second quarter, we had approximately \$14 billion of net debt consisting of approximately \$15 billion of cash and marketable securities and approximately \$29 billion of debt. These levels are similar to the first quarter. We simultaneously executed across all four tenets of our capital allocation strategy which are designed and have proven historically to drive shareholder value.

Reinvestment in our business remains a top priority at Johnson & Johnson. We invested \$2.7 billion in research and development in the quarter, which as Chris mentioned, represents a 30 basis point increase relative to net trade sales from the second quarter of 2018.

Regarding investment in inorganic opportunities, we closed the acquisition of Auris Health and we continue to evaluate potential opportunities to further enhance our portfolio. We also used cash in the quarter to continue returning value to shareholders. As announced in April, we increased our dividend for the 57th consecutive year to \$0.95 per share, distributing \$2.5 billion to shareholders in the quarter. We also acted on our authorized \$5 billion share repurchase program in the quarter deploying \$2 billion for that purpose. We are now slightly above 75% complete with the authorized program.

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I will now provide a few comments on the updates to our guidance for 2019. Our results for the first half of the year have given us additional confidence in our sales performance for the full year. As a result, we are increasing our guidance for operational sales growth by 50 basis points to a range of 1.0% to 2.0%. We are also increasing and tightening our operational sales growth adjusted for acquisitions and divestiture guidance to a range of 3.2% to 3.7%. The estimated impact of translational currency of 200 basis points has remained the same as our last update, although we are not predicting the impact of future currency movements.

Regarding adjusted pre-tax operating margin, we now expect adjusted pre-tax operating margin for the year to slightly decline, as we are planning for investment in innovation that adds to solidifies and accelerates our pipelines. One really good example of this is our recent acquisition of Auris Health, which I just mentioned. Our opportunities to invest in digital surgery capabilities coupled with other strategic investments in support of acquisitions such as Dr.Ci Labo, are estimated to equate to about \$0.10 of dilution; however, we have absorbed impacts like this in our current guidance.

For net interest expense, we are lowering the range to between 0 and \$100 million due to the favorability that Chris described in his earlier remarks. We are increasing our expectations for other income, the account where we record royalty income as well as gains and losses arising from items such as litigation, investments by our development corporation, divestitures, asset sales and write-offs. We've more certainty given that we are halfway through the year and having closed the Advanced Sterilization Products transaction, we are comfortable increasing and tightening the range to approximately \$2.7 billion to \$2.9 billion, increasing the midpoint by \$200 million compared to our prior guidance. Regarding our effective tax rate, we are increasing our effective tax rate guidance to a range of 17.5% to 18.5%, which includes the updated impact to tax associated with the Advanced Sterilization Products divestiture gain.

Taking all these factors into consideration we are maintaining our full year adjusted EPS guidance for 2019. The operational EPS guidance represents strong growth of over 7% at the midpoint, which is approximately 2 times our adjusted operational sales growth, while simultaneously increasing investment levels to fortify our confidence in the long-term prospects of our business.

We do not provide quarterly guidance, however, to better inform your modeling, I'll provide a few qualitative factors to consider near-term. We expect the largest impacts from generics and biosimilars for the year in our Pharmaceutical business to occur in the third quarter, this is primarily driven by expected US ZYTIGA accelerated erosion as well as the comparison to the highest growth quarter in 2018. Also US TRACLEER and US PROCRIT as well as VELCADE outside the US, expect accelerating erosion driven largely by generic entries in new markets and additional competitors. Also in the third quarter of 2018, we had the favorable impact of the US Baby the pipeline replenishment due to the relaunch which will not repeat. Lastly, as I mentioned, we are taking the opportunity to incrementally invest the higher level of divestiture gains. Most notably, we plan to increase investment in our pipelines and therefore we would expect our R&D spending to be higher in the second half of the year.

Before I hand the call back to Chris to begin the Q&A, let me take a moment to thank Joaquin and Paul for being part of this call today as well as our 135,000 global associates for their hard work and dedication, without whom our continued success would not be possible.

Chris, let's begin the Q&A portion.

Questions And Answers

Operator

(Question And Answer)

A - Chris DelOrefice {BIO 20730104 <GO>}

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

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

Operator

(Operator Instructions) Please limit your questions to one question and one follow-up. Your first question comes from Chris Schott with JP Morgan.

Q - Christopher Schott {BIO 6299911 <GO>}

Great. Thanks very much for the questions. I guess my first question was just on the EPS guidance. You've steadily raised top-line growth this year but we haven't seen your earnings move that much higher, I know you talked about some investments, but can you just elaborate a little bit more in this dynamic? So specifically is this mostly kind of R&D going into the device business or is it across your franchises? And should we think about this as a sustained higher level of investment or more of a, kind of onetime step up this year? My second question just quickly was on XARELTO. Can you just elaborate a little bit more on the dynamics that are resulting in this kind of sharp decline we saw in the quarter. I guess, the heart of this is, are we seeing Part D dynamics that are worse than you anticipated for that franchise? Thanks so much.

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

Hey, Chris, this is Joe Wolk. Thanks for your question and good morning. With respect to the EPS, I'll address that and then I'll turn it over to Joaquin to address the XARELTO question. With EPS, we are looking at the back half as investing more heavily in R&D as we've consistently done for a number of years now. When we have the opportunity to divest a business where we recognize an appreciable gain, we always look to turn that back into the business whether it's for our current pipelines to fortify or solidify those as

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well as to add onto our pipelines. The investment is spread, I would say primarily across Medical Devices and Pharmaceuticals at this point. That's the plan. If you think about what I said in some of my prepared remarks with Auris and the acquisition there, that was an additional investment that would have been dilutive of about \$0.10. We've absorbed that. And so that's, kind of some of the examples that I could give you. Earlier in the year you may recall, we also did a deal with Argenx for CD70. We're going to look to continue to do things like that inorganically as well as within our own pipelines to see what we can accelerate and bring to the market a little bit early for patients. Joaquin, would you like to take XARELTO question?

A - Joaquin Duato {BIO 17056015 <GO>}

Yes, thank you. Thank you for the question. First, this was a strong quarter for the Pharmaceutical group, with operational growth of 4.4% and very robust volume growth of 7.8%, and specially very robust and strong OUS growth with 12.9%. So very positive quarter for the Pharmaceutical group with nine products achieving double-digit growth. Specifically, when you look at the underlying growth that is when do you exclude US ZYTIGA, our growth was 7.6%. So that is a good position for us moving into the rest of the year, and especially moving into 2020 when we anniversary the US loss of exclusivity.

Moving to XARELTO. The first thing that we continued to see XARELTO as a very important driver, both growth for the Pharmaceutical group. The decline that you see in the quarter as was explained already is related to higher cost for patient access due to channel mix changes, particularly more sales in PH, ASP, PAD and Part D and also higher standard rebates in the donut hole. We expect that we will be able to come back to positive territory, once we anniversary these factors. Where is the growth going to come from once we do that? It's going to come first through continued volume and share growth in VTE and in AFib. Second, we will continue to reach more patients through our CA-PAD indication, which is tracking align with cardiovascular drugs launches like Entresto and Brilinta. And finally we continue our indication expansion through new indications such as BD prevention in medically ill patients that we filed in the fourth quarter of 2018.

So overall we continue to see XARELTO as a growth driver for the Pharmaceutical group. We expect to be in positive territory, once we anniversary those factors and we will leverage the fact that XARELTO has the most complete set of indications the largest safety data generating clinical trials particularly in higher risk patients and the most real-world living experience with more than 6 million patients treated in the U.S.

A - Chris DelOrefice {BIO 20730104 <GO>}

Chris thanks for the questions. I guess one just short build on Joe's commentary, just as a reminder, in Q1, we took our adjusted ops guidance up \$0.05 that was offset by currency and another acquisition investment, I think is a good example is Dr.Ci Labo as well that we've covered the dilutive impact there. Next question, please.

Operator

The next question is from David Lewis with Morgan Stanley.

Q - David Lewis {BIO 15161699 <GO>}

Good morning. Thanks for taking the question. Maybe Joe just a quick financial one for you and then I'll focus on Pharma. So Joe, just considering your commentary on spending, your other income very strong in first half of the year, as expected. But as you look into 2020, that's obviously a headwind. In prior annual periods, you used SG&A as a factor to offset any other income headwinds. So are you comfortable as you headed in next year that supply chain reduction, somebody easing on exclusivity issues still creates an opportunity for levered earnings in 2020?

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

Yes. So David, thanks for the question. Good morning. I think that's a great question. We - one, we get off with respect to the level of other income that we've had. You'll notice that today's guidance reflects pretty similar to what we experienced in 2015, and when we went into 2016, we didn't skip a beat in terms of improving our operating margins, we were able to leverage SG&A as well as to have a healthier top-line. That is the outlook we're not providing guidance, obviously for 2020 on today's call, but that is certainly the outlook and the expectation for our business moving into next year. So maybe to parlay some of the answer for Chris' question,

is this a new level or not? We've challenged the teams to look for value creating opportunities and we're planning for high levels of investment. Should those not materialize, obviously we would come back and revise guidance accordingly. But right now, we think we serve patients as well as shareholders best by looking for those opportunities. When we don't have those divestitures gains, there may be a need to scale back. We also appreciate our commitment with respect to earnings expectations as well. But we will manage for the long term.

Q - David Lewis {BIO 15161699 <GO>}

All right, Joe, very helpful. And maybe for Joaquin, a quick question on Pharma, maybe a two-part question. But many of the balance for J&J is the headwinds versus some of the pipeline tailwinds. In the next quarter or so, we are really going to see the full effect of ZYTIGA, we've already seen the effect of REMICADE. So it does feel like in the next quarter or so Joaquin, the Pharmaceutical business does should begin to accelerate and that acceleration should be sustained into 2020. And is that how you see the business here in the next quarter or so? And then secondarily, if you could just give us an update on where we stood with the ESKETAMINE launch in terms of center ads and how that launch is tracking relative to the expectations? Thanks so much.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question David. As I said -- I referred before, we see a strong underlying growth in the Pharmaceutical group of 7.6% in the second quarter as we saw strong some underlying growth in the first quarter. So as we anniversary in particular US ZYTIGA LOE, you're going to see the underlying growth coming to the forefront. And that predicts for a positive 2020. The drivers of this growth are on one hand slower ZYTIGA erosion that we had anticipated, but most importantly what you are seeing is a strong performance of our core brands, as I said before we had nine brands growing double-digit in the second

quarter. So that is how we see it similar to you see it, too. When it goes to SPRAVATO we are working to be sure that we make it available for centers, physicians or patients. SPRAVATO was approved earlier in March. And we are excited about the therapeutic app that is going to fill in treatment-resistant depression. We've created a model that is addressing all the areas to ensure appropriate use and distribution. We have a controlled distribution model. We have a REMS certification program and also it's a medicine that is self-administered but under physician administration with an observation period.

So far we have already 1,600 centers that have been certified and we continue to have great interest from the Psychiatric community and the patient community in this treatment alternative. So we remain very positive about the opportunities for SPRAVATO. Overall, we are very positive about the opportunities that our pipeline have and the opportunity that we will be afforded in the coming years for continuing reaching more patients. And perhaps this may be a good opportunity for Paul to discuss, what are the opportunities that we have in the pipeline in the short term.

A - Dr. Paul Stoffels

I can add something there Joaquin. We expect at the moment a pipeline of 14 medicines which can exceed \$1 billion by 2023 and reaching millions of patients. And there is a significant opportunity there to increase growth to new indications, increase penetration and share but also of new formulations as we have seen with DARZALEX subcu.

In addition, we expect 40 line extensions with more than 10 having the potential to exceed \$500 million. And at the same time going forward, we are integrated -- we are integrating disease areas and pathways and leveraging new technologies cell therapy, gene therapy, data science and you will also see the first vaccines, and with that continue to seek also the best science, internal or external. Our R&D portfolio is not one which comes together by chance. It's very well designed the way we do this. We focus on differentiated medicines and vaccines, years of life, quality of life is their first metric before the business comes, sourcing selective and agnostic early mid and late stage. And then we apply excellence in development with time, quality and differentiation as the main drivers.

And with that, we have been able in the collaborative space to become a partner of choice. We had a Pharma R&D review. You can go back to the website and have a review there. The materials are still on there for all the details. But let me highlight a few of the very transformational products we have in the pipeline. We have the CAR-T which we licensed from legend in 2017, now advancing fast. We took it over, started a Phase I last year and now we are entering into Phase 2b and with the data generated, we expect to file in the range of 2021. And the ongoing study in China has continued to perform very well, and that gives us lots of confidence, where at the moment, three years in 88% of patients achieved an overall response rate and 74% achieved a complete response. So more data will be presented by the end of the year.

The new -- also new in our pipeline is cusatuzumab, the anti-CD70, which was talked will start earlier, which we acquired from Argenx. Again investigational product for AML and that is a CD70 antibody. And there we anticipate starting a Phase II later in the year. We

also acquired three very interesting gene therapy products which represents a new platform for us in retinal disease. And there the first for us, is a first entry into gene therapy and positioned to be first in market with best-in-class assets.

And last but not least, let me introduce also a new space for us with the vaccine portfolio, where we are entering with an RSV vaccine now in late-stage development in older adults. But also as we announced this week, we're going to progress with an HIV vaccine, which is already ongoing in Africa since two years where we did the Phase IIb. And now we start with a study in the US, Latin America and in Europe, where we will test the HIV vaccine in high-risk MSM and transgenders. And hopefully with that, getting just a few highlights to you on the pipeline. We continue to build on our current pipeline with significant line extensions further expansion as well as, as I just was telling building on the new pipeline going for the future.

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

Great. Thanks, David. Appreciate the questions. Operator next question, please.

Operator

Your next question is from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning, gentlemen, thanks for taking the question, apologies to Paul and Joaquin, I had two for Joe. So Joe, first, the fundamentals of J&J have been good, but the Talc and Opioid litigation have been overhangs for the stock. How do you move past those two issues? What are the milestones we should be looking for? And what are your messages to investors? And I have one follow-up.

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

Sure. So thanks for the question Larry. Good to speak with you. So let me take those separately. With respect to Talc. As you know, and as we've said many times on this call and many other forums that we've known for decades and it's been validated by many other agencies that are highly respected that the product is safe. We also know that the company acted responsibly, so we'll continue to pursue defense the company's actions as well as the product going forward. The next major event I'd say starts in a few weeks here July 22 to be specific, related to multi-district litigation known as a Daubert hearings here in the state of New Jersey. That is not a ruling per se, it's a determination of evidentiary standards, so what evidence the plaintiffs need to present, what would be acceptable. And it covers about 85% of the outstanding cases.

So we're obviously preparing very thoroughly for that. Again, when folks have a chance to really look at the facts in these cases, they see that the product is safe that the company acted responsibly. As you know and as we've also said many times that even when a verdict goes against us originally, we often prevail on appeal. So we'll continue to fight that one. With respect to the Oklahoma and the Opioids litigation. A similar dynamic in that? The facts simply just don't align to what the state is claiming. And so what do I mean

by that? The facts specifically are that based on Oklahoma's own Medicaid reimbursement records, not just for a period of time, but for the last 20 years less than 1% of the reimbursement occurred for Johnson & Johnson's products. Johnson & Johnson's products were designed to prevent abuse. Even the state's attorneys in this case have said multiple times, as I understand it, throughout the proceedings, that this is not about Johnson & Johnson's products, it's about the Opioid epidemic. We agree that there's an epidemic with Opioid addiction. However, it's going to be multiple factorial in terms of the solution set, and it's going to require, many sophisticated parties to make sure that we've got the right remedies in place for people who suffer from that.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Thanks. Joe. And just to more quickly follow up. Just vision has been a bright spot for devices with both contact lenses and surgical growing above average. But this quarter was soft in both areas. Why was that? And what turns those around? Thanks for taking the question.

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

Great, thank you. Good observation Larry. So I would say vision has been very strong for us. We have for a number of years now a great cadence of innovation. I think it's really turned around, that business from where it was earlier this decade. Our latest innovation is around transition lenses, which is being very well received in the marketplace. The contact lens performance and the underlying demand continues to be strong. I would say there were some inventory adjustments that were required. We thought it was going to be more of a hard Brexit, which impacted some of the first quarter levels of inventory. So we're comfortable on the contact lens side. On the surgical side we're seeing a little bit softness specifically in the US. Outside the US is still fairly strong with some of the IOL lenses and the innovation that we introduced here about a year, one and half years ago. In the US, cataract and refractory are both a little bit softer from a market perspective. And we have to improve the innovation cadence there as we move into 2020.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks, Larry. Operator, next question?

Operator

Your next question is from Kristen Stewart with Barclays.

Q - Kristen Stewart {BIO 15155691 <GO>}

Hi, thanks for taking my question. Just one from me, just on the area of digital surgery and robotics, I was wondering if you could just provide us with an update on where you stand across the various business units in those efforts, specifically with the Verb products what your kind of current thinking is around the opportunities with Auris and then also Orthotaxy? Thanks so much.

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

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Great. Thanks for the question Kristen. Nice to speak with you. So I'll start but I'll probably turn it over to Paul as well to talk about each of the specific platforms. But maybe it's appropriate at the outset just to take a step back to provide kind of an update to our overall digital surgery strategy, inclusive of the robotic enabled surgery for endoluminal Orthopedics as well as general surgery. So as I mentioned earlier on the call, we real pleased with the Auris Health acquisition. It's off to a great start. Not only did we get some great products there and some great technology, but we secured one of the pioneers with respect to robotic surgery in Dr.Fred Moll and his team. So they're currently looking at and assessing all of our platforms. We think it's prudent of us to utilize that expertise to look at not just what we're doing for the Monarch Platform and lung cancer and bronchoscopies, but also to take a look at Orthotaxy and as well as our partnership with Verily to see how we can make sure that it's not a matter of coming to market fast but coming to market best. And so we want to make sure that we've got a differentiated product one that competes with the current product offerings that are out in the marketplace for the next three, five, ten years down the road. So that's how we're approaching it. Our time lines have not changed with Orthotaxy specifically. We're still progressing towards a 2020 mid-year regulatory submission. We feel that, that very much on track. As you know, with the acquisition of Auris, we are on the market with their Monarch Platform and we continue to make great advancements with the verily partnership.

But Paul, maybe I can turn it over to you to talk about some of the finer points and what the technology can offer.

A - Dr.Paul Stoffels

Thank you, Joe. Let me start with Auris which as Joe said, is off to a great start. It's a great acquisition. The Monarch Platform is currently on the market for the diagnosis of lung cancer. And that is part of a broader lung cancer initiative in the company where we both look at early diagnosis as well as early intervention. And with an existing marketed platform that accelerates activity in that space very much. But furthermore the possibilities of the -- in endourology, we're probably targeting a 90% stone free in a single treatment is within reach as well as a very significant opportunity in GI endoscopy gives us a very strong start in the robotic space with the Monarch Platform.

The Eye Platform from Auris is a very attractive space, which has more reach more different positioning possible and almost covering all of the different interventions. So that's where we are aiming for finally. If we look into Orthotaxy, we continue to receive great feedback about that platform especially about its smaller footprint the fact that it is an imageless system and the surgeon's freedom to move within the cutting plane defined by the robot. So and that results in an overall ease of use, which is greatly appreciated by the surgeons.

Finishing up with verb, as Joe expressed the confidence in the platform and the value proposition, we recently successfully completed a series of end-to-end procedures engaging a group of global KOLs across a subset of target specialties including general and with hernia colorectal and bariatrics, endourologic and gynecologic and thoracic surgery, and we continue to believe our system will address the current limitations of robotic surgeries, such as access and reach the footprint and cost and the workflow and

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advanced instrumentations to such a much better outcome. I was personally able to operate one of the instruments in the lab and it's a really very impressive new robotic surgical tool. And also overall the surgeons, their feedback continues to be very positive on the product. So overall, a very good start, hard work for us and lots of developments to be done, but on a very good path.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Paul. Thanks, Kristen for the question. Operator next question, pleas?

Operator

Yes, the next question is from the line of Terence Flynn with Goldman Sachs.

Q - Terrence Flynn {BIO 18060829 <GO>}

Hi, thanks for taking my questions. Was wondering on the R&D spend you mentioned on the pharma side, it sounds like that ramp is mainly external opportunities, but I was wondering if there's any internal programs that you're going to be ramping spend on if you could to be any more specific there. And then on DARZALEX, any insight you can provide on average treatment duration now and how you see this evolving over time? And then any initial thoughts on how you're thinking about pricing the subcus formulation? Thank you.

A - Joaquin Duato {BIO 17056015 <GO>}

Let me start with DARZALEX, I'm telling you that we are very pleased with the provision of DARZALEX. We had a very strong growth in the quarter with 57%, 41% when you neutralize for the one-time price effect. So we are pleased with the progression -- with operation of DARZALEX and the strong growth that we are having across all lines of therapy. Particularly, recently, we've had two important events. One is the approval of the frontline indication in transplant-ineligible patients in the combination with REVLIMID which was much anticipated and that will give us together with the filing of the also frontline indication in transplant eligible will give us three indications in frontline. So to your question on the duration. As we move into earlier lines, the duration of the treatment increases. When it comes to the Subcu that we filed earlier this week, we think this is a very important opportunity for DARZALEX overall. Keep in mind that we're going to be able to reduce the infusion time from eight hours that we have today to five minutes. So that's going to give significant advantages in terms of adoption of DARZALEX. In particular, in earlier lines and particularly when you think that 50% of the use of DARZALEX today in the U.S. is in oncology clinics in outpatient patients. So we think that this combination is going to make DARZALEX easier to use for Physicians, more convenient to patients that if you add to that, the number of studies in which we are showing very, very strong results in frontline, will portend for a very positive continue adoption of DARZALEX that we see one of the major drivers of the growth of the Pharmaceutical group.

A - Paul Stoffels {BIO 16443573 <GO>}

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With regard to the spending internal or external. Once we bring in an asset internally, we consider it all as internal spending. The external spending we do is on milestones. And that has been an upfront and that has been an very effective way to create value for us. We do lot of acquisitions, but we invest a lot in external innovation through -- in early stages through collaborations, through our J labs and also through our venture capital and then through acquisitions. But once we acquire a product, it becomes part of a portfolio and we continue to drive the success of that.

We have a significant number of internal derived opportunities. Let's say at the moment in the range of 50-50, 60-40 of problems -- products coming from our own portfolio as products which we brought in. And we invest also something like 50-50 in new products but also as Joaquin was saying in line extensions. Line extensions are great opportunities to have derisked products and get additional indications and additional access to patients which grow products faster. And that's why you see us doing on good assets, very extensive development very fast, so that indication after indication, we can bring to the market. That grows our product. Look at DARZALEX, IMBRUVICA, now ERLEADA, just to name a few the next generation of TRINZA with the 6-month. So we build on derisked products also as well as on new platforms as I indicated earlier with gene therapy, cell therapy and the new assets which we brought in.

A - Joaquin Duato {BIO 17056015 <GO>}

Another area, Terence, where we are making significant investments is in data sciences. We are trying to embed data sciences in everything we do across R&D to both accelerate discovery and early development and also to improve late development. For example, we are using data sciences to better understand disease expression and progression and also to be more effective molecular invention. Now we have models to accelerate molecular design of NMEs for high-priority targets across all our therapeutic areas. In late development, we are also using data sciences to do a step change in the efficiency in which we run clinical trials and also to create synthetic control arms and better stratify patients. So we are embedding, as I said data sciences and making significant investments to be bilingual both in science and in data science.

Q - Terrence Flynn {BIO 18060829 <GO>}

Great, thank you, Paul, Joaquin.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks Terrence for your question. Appreciate it. Operator, next question?

Operator

Next question is from the line of Joanne Wuensch, with BMO Capital markets.

Q - Joanne Wuensch {BIO 2379289 <GO>}

Good morning everybody and thank you for taking the question. I have a specific question and then a big picture one. Specifically, you talked about 100 basis points of

supply issues in Medical Devices. I was curious if you could share which devices were impacted and if that's been fully resolved at this stage.

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

Joanne, thanks for the questions. So there were two that were mentioned and obviously, our first priority patient safety. One has been remediated and the product is actually back on the market and that's related to our circular staplers. So there was a product -- a manufacturing lot that we pulled off the market. Again it's been remediated and everything is back in order. The second was during a routine FDA inspection through a third-party manufacturer, which is manufacturing a surgical flow for us. They went through the regulatory filing identified a change in the manufacturing process. So they were just seeking more information. We're working fully with the FDA and expect that to be resolved shortly.

Q - Joanne Wuensch {BIO 2379289 <GO>}

Thank you. Then my big picture question has to do with sort of the lay of the land in healthcare and how you're looking at patient volumes and pricing and then according with that, how are tariffs impacting the business? Thank you.

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

Okay. I'll start, and maybe I'll turn it over to Joaquin or Paul to give you some further insights. But with respect to tariffs first, I would say that we've had modest impact on our business nothing that's noteworthy. If you look specifically where most of the rhetoric and dialogue has occurred, it's been around China. Our business in China across all three of our segments has been very strong, high double-digit growth, mid-teen are higher across all three segments. So we really haven't seen that impact. With respect to pricing. The Pharmaceutical results again, I think, we would all agree are very strong. And that is in the face of net prices declining by 6%, similar to what we saw in 2018. So in the U.S., strong growth. We've got generic and biosimilar erosion and we've got about a 6% price headwind. Yet the transformational portfolio continues to deliver for patients as well as for our business results. I don't know, Joaquin, if you want to add anything around the pricing dynamic.

A - Joaquin Duato {BIO 17056015 <GO>}

Pricing, we see continued price erosion, which is a dynamic that we have seen in the U.S. Market for the last couple of years, which we, as we have commented earlier more than offset with our volume growth. And overall, we don't see that trend changing. What we think is that in that context, we are positioned most favorably than the rest of the companies because of three reasons. One is the diversification of our portfolio. We had in 2018, 11 medicines of more than \$1 billion. So we are present across many therapeutic areas also with a payer mix which is very similar to the overall market. In other words, we don't over index in any particular payer. The second thing is that we have a very robust volume growth. And this volume growth which is driven by the share that we are gaining and the penetration through new indications more than offsets that price erosion. And finally, we have a strong presence OUS. 45% of our sales are OUS, and in this quarter for example, our sales OUS grew 12.9%. So overall, we do believe that if we are able to

continue to do what we do exceptionally well, which is bringing new breakthrough medicines to patients, we are very well positioned in this context of price erosion.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you. Thanks, Joanne for your questions. Next question, please.

Operator

Next question is from Danielle Antalffy with SVB Leerink.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning, guys, thanks so much for taking the question. Just a high-level question on devices. I mean based on our math on a comp adjusted basis, you saw another quarter of growth acceleration. And just wondering if you could comment on, are we past the trough now in devices? And how much of the healthy growth this quarter was J&J specific versus perhaps a sort of uplift in the various different market growth rates?

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

Yes. So a great question, Danielle. And yes, we do think that the trough is behind us with respect to Medical Devices. Ashley McEvoy and her team are doing a great job in terms of ensuring that across all of four platforms, so eye health, cardiovascular, Interventional and Orthopedics that we've got solid plans for execution and improved performance going forward coupled with stronger innovation. So I would say that I don't have a full estimate as to what other competitors' challenges may have added to ours. We got a ballpark estimate, but I would say it was probably offset by the supply disruptions that we referenced earlier. So you get back to that normalized level of let's call it 3% to 4%.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Great. That's helpful. And then just a higher-level comment on the other income upside that you're going to be reinvesting to follow up on an earlier question. When you do need to scale back spend given potentially lower other income as we're looking 2020 and beyond, what are the levers that you can pull to do that? And in which businesses is it easiest to sort of scale back without giving up anything on the top line?

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

So we're currently looking to improve the operating margin profile within our consumer unit, a great job by Thibaut Mongon, Joaquin, in terms of really centering and focusing our investment prioritizing that towards our strongholds of beauty, skincare as well as over-the-counter medicines. And we are projected to have strong improvement in that, margin profile for this year and then going forward. I would say the same with Medical Devices. Once you have an improving top-line that should help the rest of the P&L. And Ashley is going about her business that way and making the right structural changes. And then lastly, in Pharmaceuticals, we are already at the top of the peer set with respect to operating margin performance. But as that top-line improves and we anniversary some of

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the challenges that I mentioned earlier, that should also bode well for some, I would say incremental improvement.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks, Danielle. Appreciate the questions. Next question please?

Operator

Next question is from Matt Miksic with Credit Suisse.

Q - Matthew Miksic

Thanks for taking the questions. Just one follow-up on Pharma, and in kind of a bigger picture question on Medical Devices. So you talked a little bit about the XARELTO launch for CAD and PAD maybe taking some time. If you could elaborate maybe on what some of the challenges there or steps that have to kind of take place to start gaining momentum on that front? And then I just have one follow-up.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question Matt. Certainly, the difference with the launches that we had in other indications like AFib and VTE is that the use of novel oral anticoagulants in CAD-PAD is novel. So we are establishing a new standard of care there. So far, it was either aspirin, the one medicine used. So establishing a new standard of care takes longer than when you are comparing to an existing standard of care. So we think that the progression will continue to be, like a chronic medication steady but constantly growing. And as I said, we are exceeding the launch align metrics of BRILINTA and we are similar to ENTRESTO. At this point, just to give you an idea of the extension of the use of XARELTO in CAD-PAD, we have 8,500 prescribers already. So we see a steady climb, and we are confident that it will become a very important driver of growth for XARELTO.

Q - Matthew Miksic

That's helpful. Thank you. And maybe just on Medical Devices broadly. I think one of the questions we get often is just the steps that J&J can take to turn the growth up in this division. Of course, you have bright spots like Biosense Webster and CERENOVUS and others in the quarter, which you talked about. But I wonder if I can ask just what -- robotic surgery is obviously an area where you've invested continue to invest. But Joe, maybe if you could sketch out the areas of med devices where you feel like there are sort of disruptive opportunities or areas where J&J can enter, expand, invest and sort of make an impact on this division.

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

Sure Matt. So again, I -- we are seeing improved growth rates from what we were experiencing 12 to 24 months ago. We're continuing on that right cadence I believe. If I look at opportunities as to where we're playing, you mentioned digital surgery that will be a growth driver going forward. I think interventional space specifically around our CERENOVUS unit and stroke, it's a small unit that we don't report out on but we grew

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about 25% in the quarter. We think that has tremendous opportunity. We do know that eye health and contact lenses specifically will be a growth driver for us based on the cadence of innovation we've got coming through there. And we all have improved performance with Orthopedics. We obviously had some challenges last year with respect to knee performance. As we launch with Orthotaxy at some point late next year or early in '21 as well as bring cementless options to the marketplace, I think we'll be in very good shape where you'll see this unit performing at or above market.

Q - Matthew Miksic

And any things on areas outside the company that you think about in terms of investing, not just in your businesses but externally, like Auris?

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

Yes. We're always looking, Matt, across all three of our segments to fortify the portfolio that we have today. There's one or two areas that we're not currently in, but we're going to make sure that, one, we can create value and that asset in our hands; and that we're compensating shareholders for the risk that we're bearing on their behalf. So we don't just -- simply look at the cost to capital. There would be some risk opportunity associated with that opportunity that we'll make sure that we compensate for. So I guess that's a long way of saying we're going to make sure that we pay the right value. We're not in a position where we need to do something. We will do something when it makes sense to do it from a strategic as well as a financial perspective.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Matt. Appreciate the questions. Operator, we have time for one last question.

Operator

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

Q - Bob Hopkins {BIO 2150525 <GO>}

Thanks very much, I appreciate it and good morning. I'll be quick. Just two, and I'll mention them both upfront. First, on the pharma side. At the beginning of the year, you guys gave guidance on the headwind from generics and biosimilars of roughly \$3 billion to \$3.5 billion. Can you just give an update on kind of where you stand with that number today? And then secondly, just a quick clarification on the talc litigation. Are you guys reserving for that currently or no? Thank you.

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

Let me take the talc question quickly. So we did incur a charge in our earnings for the quarter of \$190 million. That is related to defense cost only. That does not contemplate settlement or any liability payments. So again, we think we're on very firm ground with respect to the facts supporting our case. And as I've mentioned on appeal when we don't win in original verdicts, we prevail on appeal, so that's the only charge that you will see in there for the quarter Bob.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you, Bob. As I said before, our growth this year is mainly driven by the strength of our core franchises. We have nine medicines growing double-digit and we see all across our franchises very strong growth. We commented on DARZALEX with 57%, but also IMBRUVICA, 39% STELARA, 18% TREMFYA doing very well. So overall very positive growth in our core franchises. At the same time we have seen less generic erosion than anticipated mainly due to two factors. One, it's related to lower generic erosion in Zytiga that we anticipated and we think that is going to increase as the year goes on. And also a delay in the introduction of a TRACLEER generic. So we see now our headwind from an LOE perspective between \$2.5 billion to \$3 billion.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Bob and thanks to everyone for your questions and your continued interest in our company. Apologies to those, we couldn't get to because of time, but don't hesitate to reach out to the Investor Relations team as needed.

I will now turn the call back to Joe for some brief closing remarks.

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

Thanks, Chris. And thanks to everyone on the call for your interest as well as your time. As you can see in today's results, not just for the quarter but for the first half, we are well set up for both near and long-term success. We continue to manage our portfolio to benefit patients, healthcare systems and shareholders, and we will continue to invest for impact. As we anniversary some of the LOE challenges in Pharmaceuticals and continue our upward momentum in our consumer health and medical device segments, we feel the business is poised for even greater success going forward. So again, thanks for your time and enjoy the rest of your day.

Operator

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

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