Q2 2020 Earnings Call

Company Participants

- Alex Gorsky, Chairman of the Board of Directors and Chief Executive Officer
- Chris DelOrefice, Vice President, Investor Relations
- Joaquin Duato, Vice Chairman of the Executive Committee
- Joseph J. Wolk, Executive Vice President, Chief Financial Officer
- Paul Stoffels, Vice Chairman of the Executive Committee and Chief Scientific Officer

Other Participants

- Bob Hopkins, Analyst
- Chris Schott, Analyst
- David Lewis, Analyst
- Kristen Stewart, Analyst
- Lawrence Biegelsen, Analyst
- Louise Chen, Analyst
- Matt Miksic, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's Second Quarter 2020 Earnings Conference Call. All participants will be in a listen-only mode until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time. (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 2020. I hope everyone is healthy and continues to remain safe during these times.

Joining me on the call today to address Johnson & Johnson's response to the global coronavirus pandemic along with our second quarter results are Dr. Paul Stoffels, Vice Chairman of the Executive Committee and Chief Scientific Officer; and Joe Wolk, Executive Vice President, Chief Financial Officer. During the Q&A portion of the call, Alex

Gorsky, Chairman of the Board of Directors and Chief Executive Officer; and Joaquin Duato, Vice Chairman of the Executive Committee will also join Paul, Joe, and myself.

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 the cautionary statement included in today's presentation, which identifies certain factors that may cause the Company's actual results to differ materially from those projected. In particular there are significant uncertainty about the duration and contemplated impact of the COVID-19 pandemic. This means the results could change at any time and the contemplated impact of COVID-19 on the Company's business results and outlook is the best estimate based on the information available as of today's date.

Our SEC filings, including our 2019 Form 10-K and subsequent Form 10-Qs along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures are also available at investor.jnj.com.

Several of the products and compounds discussed today are being developed in collaboration with strategic partners or licenced from other companies. This slide acknowledges those relationships.

Moving to today's agenda. I will cover consolidated and segment sales information along with some operational highlights from the P&L results for the corporation and the three business segments. Next, Paul will provide an update on our vaccine platform including our efforts to develop and manufacture a COVID-19 vaccine. Finally, Joe will conclude by providing insights on our cash position and how we think about our capital allocation during this time. He will then provide an update on our full year guidance. The remaining time will be available for your questions. We anticipate the webcast will last about 75 minutes.

Worldwide sales were $18.3 billion for the second quarter of 2020, a decrease of 10.8% versus the second quarter of 2019. Operational sales growth, which excludes the effect of translational currency decreased 9% as currency had a negative impact of 1.8 points. In the US, sales decreased 8.3%. In regions outside the US are reported decline was 13.4%, however, operational sales declined outside the US was 9.6% with currency negatively impacting our reported OUS results by 3.8 points.

Excluding the net impact of acquisitions and divestitures, adjusted operational sales decline was 8.8% worldwide, 8.1% in the US and 9.4% outside the US. Results were negatively impacted by the COVID-19 pandemic. However, we did see improvement throughout the quarter as countries and states began to reopen. China, for example, returned to growth in the second quarter, led by a strong rebound of our Medical Devices segment.

Turning now to earnings. For the quarter, net earnings were $3.6 billion and diluted earnings per share was $1.36 versus diluted earnings per share of $2.08 a year ago.

Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were $4.4 billion and adjusted diluted earnings per share was $1.67, representing decreases of 36% and 35.3% respectively, compared to the second quarter of 2019. On an operational basis, adjusted diluted earnings per share declined 34.5%.

Beginning with Consumer Health, 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 2019. And therefore exclude the impact of currency translation.

I will also be providing additional insights using our best estimates on the impacts of COVID-19 to our performance in the areas where it had the largest influence. Worldwide Consumer Health sales totaled $3.3 billion declining 3.6% with operational growth in the US of 1.3% and the decline outside the US of 7.4%.

Our Consumer Health segment realized a negative estimated impact associated with COVID-19 of about 700 basis points. This impact was the result of consumers stocking products during the first quarter and lower consumption due to government lockdowns during the second quarter.

Our year-to-date growth was 3.6% and normalizes for some of the timing of consumer stocking that occurred in the first quarter. Excluding the negative impact of COVID-19, our Consumer Health segment delivered solid performance, with continued strong performance in our US, OTC and oral care businesses. Over-the-counter medicines grew globally almost 11% with about 30% growth in the US and a 5% decline outside the US.

In the US, we estimate about two-thirds of the growth was due to the COVID-19 pandemic as we continue to see strong demand and share gains for Adult TYLENOL. Additional brands driving growth include US PEPCID, due to share gains from a competitive withdrawal from the market and continued strong performance of ZARBEE'S NATURALS. Outside the US, declines were primarily driven by COVID-19 restrictions, most notably in China, partially offset by an increase in anti-smoking consumption.

Our oral care franchise was positively impacted by COVID-19 as the franchise grew 6.3% from strong demand of Adult LISTERINE, primarily in the U.S. across multiple channels. Growth outside of the US was also driven by Asia Pacific from promotional activities and new product launches of Adult LISTERINE.

The skin health and beauty franchise declined 14.3% and was the franchise that was most negatively impacted by COVID-19 due to changes in consumers', skin health and beauty routines. The US declined by 19.2% from reduced consumption of sun care, cosmetics and facial care products, impacting the NEUTROGENA and AVEENO brands. Outside the US,

our skin health and beauty franchise declined by 8.2%, primarily from the COVID-19 impact in Asia Pacific and SKU rationalization initiatives in EMEA.

And in our remaining Consumer Health franchises, Baby Care, Women's Health and Wound Care/Other, all declined primarily due to with COVID-19.

Global Baby Care declined 11.6% when adjusted to exclude the impact of the Baby Center divestiture. The US grew when you exclude the impact of the Baby Center divestiture primarily due to increased COVID-19 demand. The COVID-19 increased demand in the US was more than offset by the negative impact of COVID-19 outside the US, primarily in Asia Pacific.

The slower performance outside the US was also negatively impacted by the SKU rationalization program and lapping of Johnson's restage launch in EMEA. Globally, we continue to see strong growth in AVEENO baby.

Moving on to the Pharmaceutical segment. Worldwide pharmaceutical sales of $10.8 billion grew 3.9% enabled by growth across all regions and in all key therapeutic areas, except for the cardiovascular, metabolism and other therapeutic area due primarily to biosimilar competition on PROCRIT. We realized double-digit growth in eight key products. Sales grew in the US by 5.8% and outside the US by 1.4%.

Our growth in the quarter was negatively impacted by COVID-19 driven by delayed diagnosis and slower new patient starts due to office closures and access to physician-administered drugs as well as the phasing impact of stocking in the first quarter.

The products most impacted by COVID-19 were DARZALEX, IMBRUVICA, STELARA, TREMFYA, INVEGA SUSTENNA and our pulmonary hypertension portfolio and we estimate the impact on these products to be worth roughly 300 basis points to 350 basis points to our worldwide pharmaceutical growth. Despite this impact, global operational growth for first half of the year is strong at 7%, which remains above expected market growth. While not significant in total, our second quarter results did include favorable prior period pricing adjustments in the US to XARELTO and INVOKANA, partially offset by a negative adjustment to STELARA.

Our oncology portfolio delivered another strong quarter with worldwide growth of 5.7%. Our prior year results included a favorable one-time adjustment for DARZALEX, related to the completion of pricing and reimbursement discussions in certain European countries. Excluding this impact growth for the total oncology portfolio was about 9% for the quarter or 15% on a year-to-date basis.

DARZALEX continued its strong performance, growing 18.8% globally. Excluding the previously mentioned one-time adjustment, worldwide growth was about 33% and excluding the negative impact of COVID-19, we estimate the DARZALEX growth would have been more in line with previous quarters.

The US grew 32.9% with strong growth across all lines of therapy, driven by the new front-line indications for multiple myeloma. During the quarter, we launched a subcutaneous formulation in the US and Europe, an innovative fixed-dose formulation, which can be administered in three to five minutes and offers a clinically meaningful reduction in infusion and administration related reactions. We are pleased with the uptake of this new product and the benefit it provides to our patients and healthcare providers.

IMBRUVICA grew 17% globally, driven largely by market share gains and strong market growth, primarily in the chronic lymphocytic leukemia indication in the US, along with strong uptake outside the US, while negatively impacted by delayed diagnosis and the reversal of Q1 stocking related to COVID-19 in the quarter, IMBRUVICA growth year-to-date is strong at over 25% as IMBRUVICA remains the best in class BTK inhibitor and is the new and total patient share leader in CLL line 1, CLL line 2 plus and MCL line 2 plus.

ERLEADA continued its strong launch trajectory with sales more than doubling versus prior year. During the quarter, we presented results at the Annual ASCO Conference from the final analysis of the pivotal Phase 3 SPARTAN study demonstrating that ERLEADA significantly improved overall survival in patients with non-metastatic castration-resistant prostate cancer. Slightly offsetting these results were declines in ZYTIGA and VELCADE, primarily due to generic competition.

Moving now to immunology. Globally sales grew 3% in the second quarter, driven by strong double-digit performance of STELARA and TREMFYA. Internationally sales grew double-digits at 11%, offsetting a slight decline in the US of under 1%. Second quarter growth for our immunology portfolio as well as the overall market was impacted by COVID-19 related delayed diagnosis, access and the impact of first quarter stocking. Year-to-date immunology growth is 7.9% worldwide and US growth is 5.1%.

STELARA growth of about 10% was driven by continued share gains in Crohn's disease with about a 7 point share increase in the US and growth from the recently approved ulcerative colitis indication.

STELARA growth was negatively impacted by a prior period price adjustment impacting growth by over 250 basis points globally, and was negatively impacted by COVID-19. On a year-to-date basis, STELARA growth remained strong at about 20% globally.

TREMFYA, the first in class market leading IL-23 inhibitor therapy grew 46% globally and achieved roughly a 10% share of the psoriasis market in the US, which is up about 3 points from the second quarter of 2019. We are excited to share that TREMFYA received FDA approval earlier this week for adult patients with active psoriatic arthritis.

Sales growth was partially offset by continued erosion of REMICADE of about 14% from share loss due to alternative mechanisms of action and biosimilars. In neuroscience, our Paliperidone long-acting portfolio performed well growing almost 9% led by double-digit US growth of 13.8% due to market growth in the US, along with share gains for INVEGA SUSTENNA and INVEGA TRINZA.

We continue to progress the launch of SPRAVATO, where the unmet need remains high. In infectious diseases. Our portfolio grew 4.7% led by strong growth of SYMTUZA and JULUCA for HIV, partially offset by cannibalization and increased generic competition in other products.

Our total pulmonary hypertension portfolio posted double-digit growth of 15% driven by strong growth of OPSUMIT and UPTRAVI of 17.6% and 39.5% respectively, driven by increased market penetration and share growth.

I'll now turn your attention to the Medical Devices segment. Worldwide medical devices sales were $4.3 billion, declining by 32.7% due to the negative impact of COVID-19, restricting elective procedures across all regions. Sales declined in the US by 39.6% and declined 26.4% outside the US. Given the negative impact of COVID-19 across all platforms, my commentary will focus on key trends in each platform. As expected, our Q2 results included one additional selling day versus prior year positively impacting results by about 50 basis points.

We expect a minor benefit in Q3 from selling days. Interventional Solutions declined by 20.5% globally with the US decline of 30.5% and then OUS decline of 10.9%. Interventional Solutions saw improvement throughout the quarter, returning to growth in June at almost 3%.

China had a particularly strong recovery growing double-digits in the quarter. The US returned to growth in June, led by electrophysiology performance. Procedures in electrophysiology over the last two weeks of the month averaged 91% of pre-COVID levels across the US with the northeast part of the country recovering at the slowest rate, primarily due to the New York City metro area.

Orthopedics declined by 33.9% in the quarter due to market declines from restrictions on deferrable procedures and reductions in general activity such as travel and recreation, the negatively impacted trauma. The US saw the largest recovery of all regions with June declining less than 8% versus prior year as US hips grew high-single digits and US Trauma was flat. Knees and Spine also showed improvement globally throughout the quarter with June declines of around 21% and 15%, respectively. For the quarter, US pure price improved slightly versus previous quarters across all platforms.

Moving to the results for the surgery business. Advanced Surgery declined by 22.9% with worldwide energy and endocutters, declining about 27% for the quarter, and less than 20% in the month of June. Biosurgery declined less than 13% in Q2 as results were positively impacted by almost 9 points, due to the recovery from the SURGIFLO stop shipment in Q2 2019. Biosurgery returned to growth in the month of June, led by the US and Asia Pacific.

General surgery declined 39.5%. In addition to the negative impact of COVID-19, global sales were negatively impacted by 10 points, due to an unfavorable prior period pricing adjustment in the US. The impact was primarily related to COVID-19 providing enhanced insight into the level and mix of inventory in our distributor channel, resulting in the need

to increase our reserves. Wound closure declined almost 28% for the quarter with June declining 17%.

Vision declined by 39.3% in total, with contact lenses declining 33.6% and surgical declining 55.2%. Contact lenses was negatively impacted by COVID-19, which resulted in less new wearers entering the category, due to the shutdown of optical stores and lower consumption for existing wearers as people spend more time at home.

The e-commerce channel, which primarily serves existing wearers, is estimated to have a slight decline versus the second quarter of prior year representing significant outperformance compared to other channels. Contact lens performance is recovering overall as geography start to open back up with June declining approximately 26% versus prior year.

I will now provide some commentary on our earnings for the quarter. Regarding our consolidated statement of earnings for the second quarter of 2020, please direct your attention to the boxed section at the bottom of the schedule, you will see, we have provided our earnings, adjusted to exclude intangible amortization expense and special items. As reported this morning, our adjusted EPS of $1.67 reflects a reported decline of 35.3% and an operational decline of 34.5%.

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 primarily driven by COVID-19 period costs and fixed cost deleveraging in the Medical Devices business. Selling, marketing and administrative margins declined, driven by the negative impact of Medical Device sales, partially offset by favorable segment mix, expense leveraging in the Pharmaceutical business and optimized brand marketing expenditures in the Consumer Health business.

We continue to invest in research and development at competitive levels, investing 14.8% of sales this quarter. This was higher than the second quarter 2019 by 180 basis points, driven by the negative COVID-19 impact on medical device sales and segment mix.

The other income and expense line showed net expense of $24 million in the second quarter of 2020 compared to the net income of $1.7 billion last year. This was primarily driven by the ASP divestiture gain of $2 billion in the second quarter of 2019.

Regarding taxes in the quarter, our effective tax rate declined from 20.4% in the second quarter of 2019 to 8% in the second quarter of 2020 as a result of recording additional adjustments to the transitional provision of Swiss tax which benefited the rate by approximately 7.5 points. We expect no further adjustments to the transitional provisions of Swiss tax reform and encourage you to reference our 10-Q for further details on this and other specific tax matters. Excluding special items, the effective tax rate was 16.7% versus 19.3% in the same period last year, primarily driven by Swiss tax reform adjustments.

Let's now look at adjusted income before tax by segment. In the second quarter of 2020, adjusted income before tax for the enterprise declined versus the second quarter of 2019 to 29.1%.

Looking at the adjusted pretax income by segment, Pharmaceutical margins improved by 250 basis points to 44.1%, primarily driven by favorable product mix and selling and marketing expense leveraging. Medical Devices declined to 1.2%, driven by COVID-19 impacts on the business including significant sales declines coupled with continued overhead cost and idle manufacturing expenses.

Additionally, 2019 results included the gain of approximately $2 billion related to the divestiture of the ASP business. Consumer margins improved by 310 basis points to 24% driven by planned prioritization and optimization of brand marketing expenses.

That concludes the sales and P&L highlights for Johnson & Johnson's second quarter 2020. I'm now pleased to turn the call over to Paul.

Paul Stoffels {BIO 16443573 <GO>}

Thank you, Chris, and good morning, everyone. I'm pleased to provide an update on our vaccine program, particularly our progress on the development of a COVID-19 vaccine. As you know, we announced our lead COVID-19 vaccine candidate on March 30th, and since then, we have made significant progress. We have seen strong pre-clinical data so far, which we have published in the Journal Science in May. These data validated the pre-clinical vaccine challenge model and showed that prototype DNA vaccines were able to create strong immunity.

Based on these data and interactions with regulatory authorities, we were able to accelerate the clinical development program of our COVID-19 vaccine candidate. Since then, we have initiated a study of a final Ad26 vaccine candidate in non-human primate challenge model. These results will be published in a major Scientific Journal in the coming weeks. Based on this total package of results, we are very comfortable moving forward with Phase 1/2a studies later this month. This represents an acceleration of our timeline from our original date of September to the end of July.

These studies will establish both the safety and immunogenicity of our vaccine candidate as well as evaluate the single-dose and the booster dose regimen. The trials will be conducted in more than 1,000 healthy adults aged 18 to 55 years, as well as adults aged 65 years and older. The study sites are located in the US and Belgium. We are also planning for a Phase 2 study in the Netherlands, Spain and Germany and plan to conduct a Phase 1 study in Japan.

We anticipate the initiation of the trial on July 22 in Belgium and the following week in the US. We are also in discussions with the National Institute of Health with the objective to start the Phase 3 clinical trial, ahead of its original schedule, potentially in late September to evaluate the effectiveness of our vaccine. We are using epidemiology data to predict and plan where our study should take place.

We also announced that in parallel with the clinical development, we are working to expand our global manufacturing capacity to be able to deliver more than 1 billion doses of our COVID-19 vaccine by the end of 2021. We have made excellent progress on this front as well.

In addition to building out our internal manufacturing capabilities, we entered into collaborations with Emergent BioSolutions and Catalent Biologics and others to support commercial manufacturing of the vaccine.

As you have heard me say previously, our COVID-19 vaccine program is leveraging Janssen adenovector technology that provides the ability to rapidly develop new vaccine candidates. The same technology was used to construct our HIV, RSP and Zika vaccine candidates, and to develop our Ebola vaccine regimen, we just received marketing authorization from the European Commission for the prevention of Ebola virus disease.

The EMA approval is the culmination of work that become in response to the West Africa Ebola epidemic in 2014. Achieving major regulatory approval in this time frame is a tremendous accomplishment. The approval marks the first major regulatory approval of a vaccine developed by Janssen, confirming the potential of adenovector technology. To date, more than 80,000 people have been vaccinated using this vaccine technology.

As we have previously shared, we are also working on an HIV vaccine and are pleased to report that we have reached an important milestone. Earlier this month, our Imbokodo trial, taking place across sub-Saharan Africa, reached an important milestone with all people having completed all study vaccination despite difficult COVID-19 circumstances, as we expect the outcomes of this study in the next two years. Together with our partners at the NIH and the Gates Foundation, we now have the most advanced HIV candidate in clinical development.

These recent milestones strengthened our confidence in our vaccine technology. The work we are doing today to help address the COVID-19 pandemic, built on more than 130 years of Johnson & Johnson's leadership in public health. We believe we have a responsibility to step in and invest in solutions for global public health crisis and are proud to be contributing to the global response to COVID-19.

Our efforts to expedite the development of a COVID-19 vaccine and to identify potential treatments are enhanced by multiple collaborations with government, academia, health authorities and other worldwide and we are working with them to ensure the broadest possible access to people around the world. Thank you.

Joe, I will now turn it over to you.

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Paul. Not only for that encouraging update but to you and your team for leading the rapid and responsible advancement of our COVID-19 vaccine candidate. It is one of many actions that illustrate how Johnson & Johnson is deploying our range of

capabilities to tackle the COVID-19 pandemic as we aspire to do across healthcare for patients and consumers who count on us each and every day.

Good morning, everyone, and thank you for joining us today. I hope you and those close to you continue to be safe and healthy. While the second quarter was strong relative to expectations, the main message my colleagues and I want you to take away from today's call is that the long-term fundamentals of Johnson & Johnson's business remained strong and our expectations of where the business is heading have not changed. An indicator of that strength is our balance sheet, so let me briefly touch upon our cash position and capital allocation thoughts before getting into guidance commentary.

We ended the quarter in a net debt position of $11 billion made up of cash and cash equivalents of $19 billion and debt of $30 billion. We did issue commercial paper in the quarter for additional liquidity at favorable interest rates commensurate with our financial strength. Our long-term capital allocation strategy remains intact. We'll continue to prioritize investing in innovation, returning capital to shareholders by paying dividends and increasing them annually as we have done for 58 years and then capitalizing on strategic acquisition opportunities that fortify our existing portfolio, whilst simultaneously compensating shareholders for the risk we bear on their behalf.

Earlier Chris provided specific commentary related to COVID-19 impacts that our business experienced in the second quarter. I will now provide some industry context regarding the COVID-19 pandemic and what that may mean to our business going forward.

With respect to the healthcare industry, we are encouraged to see many procedures starting to return versus what we saw in the back half of the first quarter across the globe. For example, according to IQVIA, office visits are down approximately 10% to 15% as of late June compared to the earlier stages of the pandemic in mid-April, when office visits were down almost 70%. So still down but showing improvement. This is an indicator for our Pharmaceutical and Medical Device segments.

Johnson & Johnson is developing programs to alleviate patient concerns related to elective surgeries and procedures as well as helping the overall industry, treat patients with new public education materials and resources that increase patient confidence and inspire people to prioritize their health.

In consumer, based on US Nielsen data, we saw the categories we compete in decline in April by 10%. However, June data suggest those categories declined, but with an improving trend falling just 2% to 3%.

With that high level backdrop, I will now update you on how we are thinking about performance for the balance of 2020. Our objective with guidance as always is to transparently provide information that is useful for you identifying key assumptions and highlighting factors less clear that may influence our current full year outlook. Similar to our guidance update in April, it is important to caveat that the impact of the pandemic is very fluid and likely to continue evolving over the coming weeks and months. As such, our

perspective relies upon numerous internal and external sources to help inform financial projections related to our near-term outlook.

What does that include? Our assumptions consider external expert assessments related to the macro impact of COVID-19 and potential negative consequences it may have on the overall healthcare system, on the number of insured individuals and evolving consumer and patient spending in addition to the frame of mind related to healthcare behavior when it comes to, for instance, elective procedures and office visits.

We are also relying on numerous conversations that Alex, Ashley and our Medical Device leaders are having with hospital system administrators and surgeons related to capacity, the preparedness for potential spikes of the virus, the improvements that have been implemented to treat COVID-19 patients and the economics of their institutions.

Lastly, we will review extensive analytics on our business that account for individual weekly hospital trends. Taking these quantitative and qualitative factors into account, let's delve into our updated 2020 guidance beginning with our Pharmaceutical business.

Our expectations for our Pharmaceutical business remain unchanged. In Q2, we did experience reduced patient interactions with healthcare providers, which impacted new patient starts and lower activity for physician-administered drugs. But we are seeing improvement in recent weeks for those areas. You may recall, Q1 was very strong with a modest piece of that strength attributable to pharmacy providers offering longer prescription durations which slightly impacted Q2 results negatively. All in all, the strength of our Pharmaceutical portfolio that addresses significant patient need, gives us confidence to expect above-market growth in 2020 once again.

Regarding our Consumer Health segment, here too we see no changes to the expectations we had at the beginning of the year. We are off to a fast start in over-the-counter medicines and oral care with those franchises growing year-to-date, 2 to 3 times versus what we grew in 2019, reflecting some increased COVID-19 demand.

As Chris shared, that growth is partially offset by results in other categories, namely skin health beauty, primarily due to COVID-19. We are proceeding as planned with the SKU rationalization program, mentioned in January to improve future operating margins.

Shifting to Medical Devices, changes from the guidance we offered in April are driven by what we have learned since then, and similar to the first quarter, these assumptions are the most ambiguous at this time. As expected, the Medical Device industry continues to experience near term negative impacts, while elective procedures are deferred and hospital resources are redeployed to address COVID-19. We assume the most significant negative impact to Medical Devices would occur in the second quarter, that is still our expectation.

In April, based on data available at the time, we assumed a weighted average decline across all markets and all procedures in the second quarter of 40% to 60% versus our original expectations to start the year. As you can see on this slide, total Medical Devices

performed better than that assumption as economies around the world began opening sooner than anticipated, but was still down approximately 35% in the quarter.

Importantly, we are encouraged by the improvement we saw in each month in the second quarter with the month of June being down the least at approximately 25% versus our original expectations. Not surprisingly, urgent procedures declined at a lesser rate than procedures considered deferrable.

As we think about the remainder of 2020, the ramp of the recovery is the most difficult variable to estimate. When we provided guidance in April, we expected the impact of COVID-19 in Medical Devices to linger throughout Q2 and Q3 with a recovery in Q4. However, as just noted, we experienced a faster recovery than anticipated. And thus the backlog of patients we originally predicted in Q4 as a result of pent-up demand is now presumed to occur earlier in the year.

Additionally given China was the first country impacted and Japan and Korea were seeing early success in containing the virus, we bucketed these three markets together when providing guidance in April. As you can see, China has been the first market to recover and returned to double-digit growth versus prior year in Q2.

However, Japan and Korea saw new cases arise early in the quarter and implemented restrictions resulting in declines, consistent with the rest of total Medical Devices.

Similarly, the bucket of countries we defined as major markets saw some countries like Germany outperforming our overall Medical Devices business, whereas other markets such as the US declined 40% versus our original expectations to start the year.

Clearly, the countries bucketed together in our April framework are performing differently from each other and therefore are no longer the best representation of how our business will perform going forward.

Additionally, the dynamics within a country can be very different across communities. Our evolving detailed procedural model allows us to forecast at a granular level within each country. As such, we are not relying on the previous regionally-based buckets and instead of providing our expectations for Q3 and Q4 for total Medical Devices to provide visibility to the impact in a simplified manner.

In Q3, we now expect a decline of 10% to 25% versus our original expectations to start the year, a smaller decline than we incorporated in our April guidance.

In Q4, we are now assuming a decline of 15% to 0%, consistent with my remarks from a moment ago was a pent-up demand we were anticipating largely occurs throughout quarters, two and three. Considering all these factors, we estimate a negative operational sales impact of approximately $3.8 billion to approximately $5.3 billion to the Medical Devices forecast below our original January guidance. While there are many moving

parts, the impact in Medical Devices is the sole change to our prior operational sales guidance for the enterprise.

Now we often get asked about a second wave of COVID. Our thinking continues to be that if that occurs, it should not have the same level of global impact that's been experienced in the last four months. This assumption is based on opinion shared by various experts as they believe, as do we, that if this occurs, the world is much better prepared. How so? Testing is more readily available, remarkably over 700,000 tests now occur daily in the US alone. There is adequate supply of necessary medical equipment, isolation and other preventative measures are being implemented quickly with more precision, treatment protocols continue to improve and there may be therapeutic options available. Finally, a portion of the population will have developed antibodies.

While one death is too many, with a rapidly declining death rate related to the virus, the healthcare system is much better positioned than when the virus first appeared. Therefore while we actively monitor the rising case rate, our premise is that procedures and doctor visits will be largely permissible in the second half of this year.

So let's summarize our Medical Devices outlook, we still estimate the most significant negative impact occurred in Q2. But the impact of both Q2 and Q3 is now expected to be less than what we were anticipating in April. This upside is partially offset in Q4 compared to our April guidance as that predicted bolus of patients is now assumed to have occurred earlier in the year.

We are seeing signs of recovery and while the next few months and quarters contain uncertainty, the long-term underlying fundamentals remain solid, and most importantly, we continue to see tremendous potential over the long term to serve our patients and customers.

Given all of these factors, we would be comfortable with your models reflecting the following. Adjusted operational sales of minus 0.8% to positive 1.0%, incorporating the latest range of negative Medical Device operational sales impact of approximately $4 billion to approximately $5 billion versus January guidance.

Moving onto operational sales, our guidance is $81 billion to $82.5 billion or minus 1.3% to a positive 0.5%. As you know, we do not predict the impact of currency movements, but utilizing the euro spot rate relative to the US dollar as of last week at $1.13, there is an estimated negative impact of foreign currency translation of approximately 130 basis points versus the negative 200 basis points provided in our April guidance, resulting in an estimated reported sales growth between minus 2.6% to minus 0.8%, compared to 2019 or $79.9 billion to $81.4 billion.

We are maintaining our expectation for operating margins with a decline year-over-year of 100 basis points, as well as April guidance ranges of net other income and net interest expense. Our effective tax rate guidance for 2020 is now estimated to be 16.5% to 17.5%, tighter than the previous range. Given those updates, we are comfortable with adjusted

earnings per share guidance ranging from $7.85 to $8.05 on a constant currency basis. This reflects an operational or constant currency decline of 9.6% to 7.3%.

While not predicting currency movements, but to provide some insights on the potential impact on EPS, our reported adjusted EPS would be negatively impacted by approximately $0.10 per share versus our April guidance impact of a negative $0.15.

Accounting for that we would be comfortable with your models reflecting reported adjusted EPS ranging from $7.75 to $7.95, a range of minus 10.7% to minus 8.4%.

I know many of you are interested in our thoughts beyond 2020. So I thought I would say a few words on very early thinking on select topics for next year. In our Pharmaceutical business, we don't anticipate new biosimilar or generic competitors and expect another year of above-market performance, largely driven by increased penetration and new indications across our existing diversified portfolio, led by key products such as DARZALEX, IMBRUVICA, TREMFYA, STELARA and ERLEADA.

In our Consumer Health business, we will continue to focus on delivering solid growth in our core strongholds of OTC and skin health and continued expansion of the e-commerce channel.

In Medical Devices, based on what we know today, we expect procedures to be largely permissible throughout the year and given COVID-19's impact on 2020, we expect to deliver robust double-digit operational sales growth.

Regarding the P&L for 2021, while not providing guidance at this very early stage, I will share that we are expecting other income and expense to be consistent with the guidance I just shared for 2020. In addition, while we continue to manage our portfolio with rigor, emphasizing platforms where we can optimize our success, we are planning to treat future significant divestiture gains as a special item going forward.

We would expect to improve operating margins from this year's level, given higher sales, as well as realizing benefits from our SKU rationalization initiative in Consumer Health.

And finally as a reminder, when comparing revenue next year versus this year, our 2020 fiscal calendar has the benefit of an additional two to three shipping days associated with a 53rd week. Robust plans are being developed and will be finalized as we move throughout 2020. We anticipate strong EPS growth in 2021 on an operational basis given some of the dynamics at play in 2020 and commit to providing updates as appropriate on future earnings calls.

Let me conclude prepared remarks with our key developments in the quarter. As we look at our pipeline, we have been able to advance a majority of our portfolio despite COVID-19, but I'd like to highlight a few items. Beginning with the Pharmaceutical pipeline. In addition to the progress Paul referenced on the development of our COVID-19 vaccine candidate, we had a number of approvals in the second quarter included on this slide,

several ahead of their PDUFA dates. Most notable, are TREMFYA for active psoriatic arthritis in the US, DARZALEX, subcutaneous formulation in the US and EU, IMBRUVICA front line in CLL combo with rituximab in the US and the Ebola vaccine in the EU.

We updated our filing timelines slightly for BCMA CAR-T. We remain on track to initiate the US regulatory application by year-end 2020 and have updated timing of the EU submission to early 2021, which accounts for comprehensive manufacturing and commercial plans. You will also note that we are no longer following the niraparib in line 3 metastatic castration-resistant prostate cancer. The data from the Phase 2 GALAHAD study did demonstrate a highly competitive efficacy and safety profile for niraparib, which supported FDA breakthrough therapy designation.

However, recent approvals of other agents in this class have removed the path to gain accelerated approval for niraparib based on the single-arm study. Considering this development, we will not be moving forward with regulatory submissions with GALAHAD but niraparib remains an important part of our prostate cancer pipeline with $1 billion-plus revenue potential.

Turning to Medical Devices, we continue to advance our innovation agenda with some notable achievements in the quarter, such as US FDA breakthrough designation for Monarch enabled new ablation technology, CE Mark for HELIOSTAR, our single-shot balloon catheter and CE Mark for QDOT, a microcatheter enabling better lesion [ph] treatment just to highlight a few.

We also continue to advance digital surgery offerings. Since launch, there have been over 3,200 lung biopsies completed using the Monarch system. We will also expand the system with multi-specialty applications with endourology next in line for US approval for the treatment of kidney stones, a market that is almost twice the size of the one we are in today.

We continue to make great progress towards a second half 2020 US regulatory submission for our orthopedic robotic solution as part of our VELYS Digital surgery platform, first in knees coming out of our acquisition of Orthotaxy.

In general surgery, we will incorporate elements from the general surgery robotic platforms of both Verb and Auris, which we believe enhances our value proposition and increases our ability to create a differentiated platform for surgeons. We continue to have ongoing conversations with regulatory authorities around the world and based on these conversations, we will not be following a 510K regulatory pathway in the US. After analyzing time to market compared to overall value proposition, our goal is to initiate first in human studies with our robotic solution in the second half of 2022. We continue to be very excited about the overall program, and that our continued investment here will offer a differentiated and competitive product to the market with better outcomes for patients. The new timelines are based on what we know today, reflecting a world that is very different than what it was just a few short months ago.

One item occurring after the second quarter close and not listed on this slide was Johnson & Johnson Development Corporation sale of the equity position in Idorsia. As part of the Actelion acquisition in 2017, you may recall that we employed an innovative deal structure resulting in the formation of a new company, which is now established. We remain very excited about our ongoing partnership with Idorsia on assets like Ponesimod and aprocitentan.

Before I hand the call back to Chris, I want to express our sincere gratitude to 132,000 associates around the world. Johnson & Johnson's strong foundation begins with their tireless effort and unwavering dedication to elevating the standards of healthcare. In a tumultuous year, they remain focused on credo [ph] values and meeting commitments to patients, doctors and nurses, employees, parents and children, communities and shareholders. Without them, our current and future success would not be possible.

Chris, back to you, to begin the Q&A portion.

Chris DelOrefice {BIO 20730104 <GO>}

Thank you, Joe. We will now move to the Q&A portion of the webcast. Operator, can you please provide instructions for those on the line wishing to ask a question.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from Chris Schott with JP Morgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much for the questions and all the color today. Just two from me. Can you maybe first talk about -- I know you addressed the potential for a second wave, but any early read in terms of what you're seeing in some of the regions in the US that are seeing a rapid increase in COVID cases, are those states still seeing a recovery in procedure volumes? Are you starting to see some slowdown in volumes in some of those regions?

And then my second question was on the vision business and just elaborate on some of the trends and how are you thinking about recovery there. It seems like that's one of the segments of the market that might be seeing a bit of a lagging recovery versus some of your other device businesses and just interested in how you're thinking about that franchise over the coming quarters? Thanks so much.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Chris, this is Alex. Can you hear me okay on the audio?

Q - Chris Schott {BIO 6299911 <GO>}

Yes.

A - Alex Gorsky {BIO 16239711 <GO>}

Okay, Chris. First of all, thank you very much for the question. And look, before I start off answering directly to your question, I just want to continue to acknowledge the great work of our colleagues across Johnson & Johnson as we just shared with you in the second quarter. And while we are going to be reviewing a lot of statistics and a lot of facts and a lot of figures on the call today. I also think it's always important to acknowledge the direct impact the COVID-19 has had on patients, has had on family and friends, for all of us in some way. And also, I'd be remiss if I didn't do a shout out for the frontline healthcare workers, the doctors, the surgeons, the nurses, the assistants, who have been showing up for the last five months dealing with just an unprecedented pandemic, learning real-time and adjusting as necessary, literally working 24/7. And finally, our own J&J workers nearly one-third of our workforce who have continued to show up to ensure that we can have supply of our products as well as continue the important research and the development, not only on our vaccine but on so many other therapeutics devices and consumer products for patients and consumers around the world.

So Chris, as I've reached out and been able to connect with CEOs of hospital systems across the United States, but also more broadly with other administrators around the world, as we've taken a look at the data, clearly, we believe that the virus spread has accelerated, particularly in the South, the Southeast, the Southwest and Far West. What we're -- but they are seeing in the hospital right now is clearly a resurgence over the previous rates, similar to Joe's earlier comments, the general sentiment is that they are better prepared in the hospitals. But it's important to note that in certain counties, certain cities and localities, be it Dade in Florida, Miami, Palm Beach, areas around Dallas -- excuse me, Houston, San Antonio, San Diego, Los Angeles, that -- the rates are increasing at a very significant rate.

I think the general sentiment is that they are better prepared in terms of the kind of equipment that they have on hand. Testing still depends on where you are while testing rates have increased dramatically, there are still -- there are still remains spot-ages [ph] in particular areas and other areas where hospitals have ramped up to run laboratory capabilities combined with others. They think that they're getting the results in a reasonable period of time. And of course, they've got better protocols in place in terms of understanding whether it's treating with Dexamethasone, Anticoagulants and other approaches, that are leading to better outcomes.

I think the things that we're -- they're continuing to watch very closely is the exact incidence rate and how that unfolds in the coming weeks and months with weekends going to be critical. I mean, thus far as we alluded to the death rates and hospitalization rates have not -- while increasing, have not been the same as we saw very early, but the next few weeks are going to be critical, and obviously we're going to have to watch that very closely

And I think something else that the hospitals are keeping a close hand along are the staffing, because in many cases just as they were beginning to ramp back up with elective

procedures and bring staffing back on, now they're having too many cases reallocated based upon the surge that they're saying take place.

I think the other important factor is they learned a lot about re-opening up their surgical suites and also how to create additional space for ICU and CCU patients. They've seen some of the detrimental effect of these delayed procedures. Therefore, they as much as possible want to try to continue ensuring the patients can get access to those procedures, even while managing the pandemic.

But again, depending on where they are, there have been some areas where they shutdown elective procedures and they're managing it based upon the caseload they're seeing. So that's a -- that's an overall response -- if I back up just one more step, if we look at the data through the end of June, I think Chris alluded to this in his remarks as well as Joe, across the United States in the majority of the surgical categories that we're operating in, we're seeing about a return to 85% to 90% of what we did pre-COVID baseline periods. But obviously, we're going to watch that closely as we watch the numbers in the areas I mentioned increase at least as of late and in the coming weeks. Thank you.

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

Hey, Chris. This is Joe. Maybe just to pick up with respect to your questions around Vision Care, specifically, so contact lenses was down a little bit over 30% in the quarter. Clearly, the impact of COVID-19 as there's just simply less new wearers entering the category, due to a shutdown of optical stores, but also lower consumption for existing wearers as people saw adopt shelter-in-place measures and stay at home. The e-commerce channel, which primarily serves existing wearers was also down when you compare to the second quarter of last year, but we are seeing an improved performance.

So if you look at June, contact lenses was down almost 25% versus the prior year. So you're seeing that same quarterly improvement throughout -- the monthly improvement throughout the quarter with respect to contact lenses.

In terms of vision surgical, I would say that's probably one of the most deferrable procedures out there. And so as we start to see, elective procedures become more prevalent, we would expect that to return as well.

A - Chris DelOrefice {BIO 20730104 <GO>}

Yeah, Chris, I would just add on Vision Care. I think when you think of our contact lens business going forward, we've had consistent strong performance there, with at or above market performance levels the past four years and have had a very strong cadence of innovation 2019 TRANSITIONS LIGHT INTELLIGENT technology. 2020, we're excited about our ACUVUE fair vision, first anti-allergy contact lens and then did receive FDA breakthrough device designation on our myopia control lens. So, it's a franchise that we feel very strong about going into the future.

Thanks for the questions. Operator, next question, please.

Operator

Your next question is from David Lewis with Morgan Stanley.

Q - David Lewis {BIO 15161699 <GO>}

Good morning, thanks for taking the questions. Maybe one for Paul on vaccines and a quick commentary on recovery for Joe. Yeah, Paul, just to start off on vaccines for a second here Just two quick ones. Our sense is the FDA wanted hundreds of exposures before allowing Phase 2 trials. So I guess what's your confidence you're going to have the data needed to start those Phase 3 trials later this year? And then a lot of investors are focused on sort of femoral versus cellular immunity. I just wonder if you could talk to the durability of neutralizing antibodies and whether we should expect a CDA response. And frankly, does that matter in your view. And then a quick recovery counter for Joe?

A - Paul Stoffels {BIO 16443573 <GO>}

Yeah. Well, first on the experience to start a clinical trial, we have developed vaccine platform over the last six, seven years and we have now more than 80,000 people who have been vaccinated by our platform, and that is in RSV, in Zika, in HIV and Ebola and that gives very good comfort that we have a safe platform. In addition to that, we have been able in RSV and Zika to use a high dose at 1.10, 11 [ph] for those who know what that means, is that -- is a highest dose you can administer but with almost no fever. So we will be able to administer a very high single dose, which will be enabled in our Zika and in our RSV to elicit a very strong neutralizing antibodies -- antibody response as well as the cellular immunity response with one single dose. Whether we need to boost durability, we have learned that in Ebola, we've learned that in others [ph] that maybe yes, but not immediately. We are going to test a booster dose as we start, but we think more that we will have to boost one year or two years after the single high dose. So we're going to learn fast and with a single dose Phase 1 study, we should be able to start mid-September with the experience we have and that's in full discussion with the regulatory authorities around the world.

A - Chris DelOrefice {BIO 20730104 <GO>}

David, your second point. Are you there on your question of recovery? Operator, are you there?

Operator

Yes. I'm here.

A - Chris DelOrefice {BIO 20730104 <GO>}

Let's move on to our next question, we can always back to David, if need be.

Operator

Sure. Your next question comes from Larry Biegelsen with Wells Fargo.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good morning, thanks for taking the question, I'll ask one recovery, one vaccine question as well. And just on the recovery, thanks so much for the data, Alex. Just when you talk about the end of June, 85% to 95% of pre-COVID levels and the spike in cases in the south, are you seeing other parts of the world offset that and so, in other words, you're still seeing improvements in trends through mid-July?

And then second, for Paul, when are we going to see the initial human clinical data and you didn't mention when you expect availability of the vaccine. I think your prior comments, where maybe early 2021. Are you still going to seek EUA approval based on the Phase 1/2 trial or do you think you'll need the Phase 3 data for approval? Thanks for taking the questions.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure. Larry, let me respond the first and then I'll ask Paul obviously to cover the second. Look the data we are citing, we're trying to provide the most up-to-date information we had which basically goes with the data through the latter part of June. I think for the first couple of days in July. And if we look across the world, we see basically most of the -- majority of countries up over 85% and what I mean by that is, if we're tracking their weekly recovery rate and we compare that to pre-COVID period and we adjust for that over a several week period, those numbers are in the -- I would say north of 80% to 85% range.

The one outlier to that is that UK, UK is still below 50%, and again, we're clearly developing the ability to track this not only on a country and on a region basis, but in the United States on a -- literally on a state, a county and city and individual hospital basis. And again, there are differences at each one of those levels, but at a -- overall country level, if we take about the top 12 markets around the world, I'd say the overwhelming majority of them are north of 85% with the outlier being the UK.

A - Chris DelOrefice {BIO 20730104 <GO>}

Yeah. Larry, I think on that one. China is a good example where we continue to see very good progress and momentum with double-digit growth in recent times here in Q2.

A - Paul Stoffels {BIO 16443573 <GO>}

On your vaccine questions, Larry. First I want to also add to it that neutralizing antibodies and T-cell immunity is important for -- not just for the response, but also for durability. Our initial data on the Phase 1 will be available second half of September, which they will become the basis for our Phase 3 study, and that will start mid to end September. That's the goal. With the large number of people included and the simple design with a single dose, we could have data before the year-end or at the latest early next year and availability of a vaccine will be starting early next year. We will have some dosages before the year-end, which will be used for clinical trials and maybe for other reasons, but the larger quantity will start first quarter of next year. And then in the year, we will deliver up to 1 billion dosage of our vaccine. And all of that is in place. We have the manufacturing sites, we have the filling sites, we have everything what's needed to deliver that 1 billion vaccines and more next year.

A - Chris DelOrefice {BIO 20730104 <GO>}

Larry, thanks for the questions. Rob, next question, please.

Operator

The next question is from the line of Kristen Stewart with Barclays.

Q - Kristen Stewart {BIO 15155691 <GO>}

Hi. Thanks, guys. Thanks for taking the question and thanks for all you guys are doing to fight COVID. I just had a question and following-up just on the robotics platform. I was wondering, if you could just provide a little bit more details, it sounded to me that you were redesigning if I heard you right the programs integrate the two systems. Could you just provide a little bit more details on that and just the timing. I just want to make sure I understood the comments in the prepared remarks. Thanks again.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Kristen, this is Alex. First of all, I just want to restate our excitement about the overall digital space, and when we look at the potential of this market currently being less than 5% penetrated and understandably that's indicative of some markets in the United States at well over 50% for certain procedures. But on a global basis, we think that there is just tremendous growth opportunity. Two, if you just look at the acceleration of technology that we're also seeing and clearly that's a -- then the driving force behind our investment, both in Auris but also our partnership with Verb and Verily and as we brought those different capabilities, those different technologies together, I think it's actually reinforced the potential and the possibilities that we see in surgery for the future.

And I also think it's important to note that we continue to see really good uptake with our Monarch system. We are going to expand the system with multiple specialty applications with endourology next in line for US approval for the treatment of kidney stones and that market in and itself is about twice the size of where we are today. We're making good progress, even with -- as our teams deal with the COVID-19 situation on the general surgery robotic platforms and that's for both Verb and Auris. We think that it clearly enhances not only the capabilities, but our value proposition and our ability long term to really create and launch a differentiated platform.

As Joe, I believe, Chris may have alluded to earlier in their points, we continue to have ongoing conversations with regulatory authorities around the world. We will not be following a 510K regulatory pathway for the US and after analyzing time to market compared to the overall value proposition, look, our goal is to initiate first in human studies with our robotic solution in the second half of 2022. And again, we think there is significant potential. We continue to be impressed by the technology advancements we're seeing with both the Verb and Verily and the Auris combination. Our teams are making very good progress as we speak, and we'll be providing more information as well as on our digital and we'll be providing you some further updates regarding a more focused digital review in the coming months. So stay tuned. But I think we're as excited as ever about the possibility and the potential in this market.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Kristen. I appreciate the question. Rob, next question, please.

Operator

Next question is coming from Matt Miksic with Credit Suisse.

Q - Matt Miksic {BIO 6990080 <GO>}

Hey, good morning. Thanks for taking the question. So just one clarification on the recovery side [ph] that emphasizes there's one topic. But, but it sounds like the fourth quarter expectations came down as you're describing a little bit just on the backlog not being as strong given the strength and recovery that we saw in June. And are your assumptions for the back half and for Q3, Q4 are based on sort of the transacting June and Alex, as you pointed out, we need to watch carefully over the next several weeks. Is that sort of the set up for the back half and then maybe if that does -- if we pause here at all in the next month or two, is it fair to say that I guess, we're looking at making up those, that -- is the backlog go back up? And then sort of brings up Q4, Q1 is that the right sort of way to think about the flow of procedures? And I have one follow-up for Paul on vaccines?

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

So, Matt, this is Joe. Thanks for the question. You're thinking about it appropriately. So we took down the fourth quarter simply because that pent-up demand or that backlog that we thought would occur from a deferment of procedures in Q2 and Q3 when we issued guidance in April is quite frankly not occurring. That's a good thing for certainly patients, but for the healthcare system that -- there is not some unintended unintended consequences with the deferral of very, very important procedures. The model going forward is based on the best information we had coming out of June. So yes, it would reflect that. And I think that's probably a fair assumption or premise to say that, if we had a slowdown here as cases rise in select areas, that slowdown would probably be compensated with an improvement to the outlook for Q4, possibly Q1 depending on how long elective procedures are not permitted.

Again, I do want to emphasize that collectively, as a society, as a healthcare system at large, we're much better prepared and when there are isolation measures that are put in place, it's much more selective than maybe the universal approach we were looking at back at the end of March or early April. So I think it would be less of an impact, but I don't think it's unfair to think that impact if negative would come back in a positive way at some point later in the future.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Matt. This is Alex. I think -- I think one other factor that we're going to have to watch closely is also what's happening more broadly with the economy, unemployment and insurance rate and coverage, as we had in the Q4. And I think again the next few weeks and the next couple of months will be very important in determining that. But that's another factor that we're -- that we're watching. Of course, that's not the case outside the

United States. It's over -- about [ph] 50% of our business, but in the US, that's something -- that's another figure that we're going to have to watch closely.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks. And then a follow-up. That's super helpful color on -- for Paul on vaccines. Just it sounds like the immunogenicity is on track as you're moving it to first in human studies. I guess, it may be too early to answer this question. But any color or thoughts at this point on what level of protection this antibody creation can give us at this point or what do we know and what do you expect to learn maybe over the next several months in terms of actual protection?

A - Paul Stoffels {BIO 16443573 <GO>}

Well, in non-human primates in animal models, you can get to a high level of protection. So we -- it's difficult to extrapolate to humans. But typically, we have a good correlation between animal models and in all of our experiments with RSV, HIV, Ebola and Zika. So we should expect significantly above 50% what the barriers for the FDA. I think you should expect 70%, 80% in that range at least and that is also the statistics, which will go into the studies.

So let's -- let's hope we reach that, because that could create -- herd [ph] immunity and we could hopefully get a stop -- put a stop to the disease. So let's -- let's hope for a very good neutralizing antibody level protecting people at a very high level. So.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks Matt. I appreciate the questions. Rob, next question please.

Operator

Next question is from Bob Hopkins with Bank of America.

Q - Bob Hopkins {BIO 2150525 <GO>}

Thanks for taking the question. I'll just ask one as a follow-up on the guidance, and thank you for providing that. So just on the fourth quarter guidance for devices, it sounds like the reduction from previous commentary is really just a function as you said of better trends in deferred procedures here in Q2 and Q3. I'm curious, does that Q4 guidance that you provided of minus 15% to 0%? Does that assume a slowdown from current trends due to the spread of COVID in the US over the last couple of weeks? Or are you assuming that your kind of current trends continue? Just want to get a sense for whether you assume in that 0% to 15% that things get worse, as we go forward or not?

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

Yeah. So Bob, I would say that it probably looks at trends the way they were occurring more at the end of June, that's the best date, official data that we had. So we rely on certainly the IHME model, but also studies that are being done and analytics from UCLA, MIT and various other sources. As Alex mentioned, the outreach that he's had personally

that Ashley has had personally and other Medical Device leaders in our Company to the customers themselves to understand what's going on in the ground is probably the most insightful qualitative analysis we put into our modeling and that's been extremely helpful.

So I would say it's largely based on the trends that we saw at the end of June. And again, I do want to caution folks that while we are seeing a rise in cases. It is in very select communities in very select states. So again, it's not that same universal approach and to the -- the size of the business in Medical Devices, it would have a relatively minor impact and our thinking should one of those areas slow down versus what the dynamic was at the end of March and early April.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks Bob. I appreciate the question. Rob, next question please.

Operator

Your next question is from Louise Chen with Cantor Fitzgerald.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions here. So my first question is just on this new to brand prescription pickup. How much of an improvement have you seen or are there any metrics that you can provide here and how will it unfold throughout the rest of the year in your mind?

And then second question is, how should we think about how much of your increase in your 2020 financial guidance was already captured or incorporated into the second quarter '20 be? Thank you.

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

Joaquin, maybe you want to answer the new to brand

A - Joaquin Duato {BIO 17056015 <GO>}

Yeah. Thank you. Let me take the new to brand data. Overall what we have seen in both prescriptions and new-to-brand is that they are still below pre-COVID levels, about 9% in overall prescriptions and about 30% in new-to-brand. I'm talking about market now in general. But what we are seeing it -- during the quarter, a constant improvement, so the trends are still improving and we are seeing particularly positive trends in oncology, where diagnostics visits and IV drug administrations have already returned to the pre-pandemic levels.

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

Thanks, Joaquin, and Louise with respect to your question about how much has already been captured with the second quarter results, I think if you just look purely at the numbers, a lot of the guidance uptake was dependent upon at least for top line on the results of the second quarter specifically in Medical Devices. From our April guidance, we

kind of knocked out the worst-case scenario if you will. And we also saw a little bit of improvement with currency translation as well.

With respect to earnings in the bottom line, as you know, I think coming into the call at least as of Monday's data, it suggests that we beat by roughly $0.20 per share on the bottom line. We've taken our guidance up operationally $0.10. As we're going to continue to look and challenge our teams for a good solid investments for the balance of this year that fortify 2021 and beyond. And that's kind of how we're thinking of this going forward.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. I would also add that with respect of our own brands, what we are seeing both in immunology and oncology is that we continue to gain share both in total TRxs and in new-to-brand. For example, when you look at the STELARA in chronic disease, our year-over-year share gain has been 6.8 points. And when you look at our actual share in overall chronic disease is 16% and our new-to-brand share is 17.7%. So when you look at our share trends both in immunology and oncology in total TRxs and in new-to-brand share, in both cases, we see share gains.

A - Chris DelOrefice {BIO 20730104 <GO>}

Thanks, Louise. Appreciate the question. We have time for one more question, Rob could you introduce the next question, please.

Operator

Sure. Your next question comes from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question. Appreciate the early insights on 2021, but just I might have missed it. But any thoughts on how we should think about margins, maybe relative. I know this year is kind of an outlier but relative to prior years. And then would welcome your latest perspective on any impact you're seeing with respect to payer mix from elevated unemployment and how this might impact 2021. I know Alex, you touched on this a little bit, but maybe anything you're seeing at this point and how you're thinking about that right now? Thank you.

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

So Terence I'll answer in terms of operating margin first before turning it over to Joaquin for some of the payer mix. In terms of margins, this is right -- you're absolutely right, this is a year that's a little bit abnormal to say the least. So we would expect margin improvement off of this year. I would point to a number of initiatives that we had already in place that should continue to yield better margins, specifically in our consumer unit, where we did have a SKU rationalization program, which should be fully executed by the end of this year, that will help improve margins. And then some broader supply chain initiatives that we had with respect to our partnership with Jabil, largely in our Medical Device unit. So we wouldn't anticipate that there would be margin improvement. We're still going to look to prioritize investment in R&D. I think it was a very strong sign for the

Company that our level of R&D investment in the second quarter of this year was actually slightly higher than what it was last year despite the work from home dynamic. We continue to progress our pipeline across all three of our businesses.

A - Joaquin Duato {BIO 17056015 <GO>}

So regarding our payer mix, just for background, our payer mix now, it's about 50% commercial and about 43% Medicare and Medicaid. Medicare being 37%, Medicaid 6%, so a very well-diversified payer mix. At this point, we have not seen any major changes in our payer mix yet. So we have not seen those changes. Depending as Alex referred before on the economic recovery and the resulting unemployment rate, we could expect in the second half of the year an increase in Medicaid, health exchanges and also uninsured numbers, which will also create affordability programs. But again, at this point we have not seen changes in our payer mix yet.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks Joaquin, appreciate it. Terence, thank you and as always, thanks to everyone for your questions and your continued interest. If we weren't able to get to your question at this time, obviously, please reach out to the Investor Relations team. And then I'll just turn it over to Alex now just for final comment.

A - Alex Gorsky {BIO 16239711 <GO>}

Well, thank you, Chris. And look, let me end where we started and thank all of you for your ongoing support and also thank all of our colleagues at Johnson & Johnson. We've been working around the clock over the past several quarters to ensure that we can continue to serve all of our credo stakeholders, the patients, the doctors, the surgeons, mothers and fathers that depend on us, that -- ensuring that our employees have got a safe environment, the communities where we serve and ultimately to you, our shareholders.

Hopefully, you also agree that the transparency and the strength of our results in the second quarter reinforce. I think the core philosophy of Johnson & Johnson, and that in -- whether it'd be in good times or challenging times like these, that our strategy, our business model and our value system will ensure that we're able to navigate through in a way that's best for everyone. So thank you. Well, we're committed to keeping you updated on the progress that we're making in our various programs and as we get more information. And thank you very much, everyone. Stay healthy and stay safe. Bye for now.

Operator

Thank you. This concludes today's Johnson & Johnson Second Quarter 2020 earnings conference call. You may now disconnect.
