Q1 2020 Earnings Call

Company Participants

- Alex Gorsky, Chairman and Chief Executive Officer
- Christopher 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 & Chief Scientific Officer

Other Participants

- Chris Schott, Analyst
- David Lewis, Analyst
- Joanne Wuensch, Analyst
- Larry Biegelsen, Analyst
- Louise Chen, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning. Welcome to Johnson & Johnson's First Quarter 2020 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. (Operator Instructions)

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

Christopher 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 first quarter of 2020. I hope everyone is healthy and remaining safe during these times. With safety in mind, we are utilizing a more virtual approach and exercising social distancing while conducting this call.

Joining me on the call today to address Johnson & Johnson's response to the coronavirus global pandemic along with our first quarter results are Alex Gorsky, Chairman of the Board of Directors and Chief Executive Officer; 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, Joaquin Duato, Vice Chairman of the Executive Committee will also join Alex, Paul, Joe and myself.

Date: 2020-04-14

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. We would like to draw your attention to the fact that there are slight changes to the sales reporting for the Medical Devices and Pharmaceutical businesses, which I will comment too as I review the segment commentary. Additionally, those changes are noted and reconciliations are available on the website.

We appreciate you joining us on the call today. In order for us to provide insights related to the COVID-19 pandemic and to allow for ample time for Q&A, the call will last around 90 minutes. 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 is significant uncertainty about the duration and contemplated impact of the COVID-19 pandemic. This means that results could change at any time and the contemplated impact of COVID-19 on the company's business results and outlook is a best estimate based on the information available as of today's date.

Our SEC filings, including our 2019 Form 10-K, along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures are also available at investor.jnj.com. Several of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships.

Moving to today's agenda. Alex will start with his perspectives related to the COVID-19 pandemic and J&J's response. Paul will then update you on our efforts to develop a vaccine for the COVID-19 virus, along with J&J's therapeutic development efforts. Next, I will cover consolidated and segment sales information, along with some operational highlights from the P&L with the estimated COVID-19 impact framed where applicable. Joe will conclude by providing insights on the status of our operations, including actions we are taking to maintain business continuity how we think about our capital allocation during this time and will provide an update on our full year guidance. The remaining time will be available for your questions.

I'm now pleased to turn the call over to Alex Gorsky.

Alex Gorsky {BIO 16239711 <GO>}

Thank you, Chris, and thanks to all of you for joining us today. I also want to thank Joaquin Duato and Dr. Paul Stoffels for joining our first quarter webcast as the Vice Chairs of Johnson & Johnson and given the leadership role they are playing as we mobilized our efforts and resources across the company to address COVID-19. I thought it would be helpful to have both of them available to answer potential questions in conveying key information. Paul will also share a more detailed perspective in his prepared commentary which will follow my remarks.

Bloomberg Transcript

Date: 2020-04-14

Clearly, COVID-19 is at the forefront of everyone's mind, which is why we plan to spend a fair amount of time during the earnings webcast discussing this unprecedented global pandemic, the profound impact that's having on global public health, and our unwavering commitment to create and deliver value to all of our stakeholders. Johnson & Johnson was built for times like this and our strong first quarter results are just one reflection of our sustainable business model.

Our Johnson & Johnson colleagues remain focused on delivering on the commitments and responsibilities to our patients, doctors, nurses, employees, parents, children, communities and shareholders as defined in our credo. As we announced this morning, we increased our quarterly dividend by 6.3% to \$1.01, which is another reflection of our stability and further underscores our commitment to delivering value to our shareholders. This marks the 58th consecutive year of dividend increases for Johnson & Johnson, and we believe that taking this action is the right thing to do for our shareholders at this time, and importantly, a strong example of the confidence we have in our business now and in the future.

Given Chris and Joe will discuss our first quarter performance and outlook in greater detail, I'd like to take just a few minutes to highlight four pillars of strength that reinforce why Johnson & Johnson is built for times like this. These pillars serve as the foundation of our resiliency and response to the current COVID-19 crisis, and provides a dynamic foundation for Johnson & Johnson to continue to build a stronger, healthier and successful future for all of our stakeholders. And we recognize the challenges that individuals, companies in the world are facing right now, but as we look forward, we are confident that together we will win this fight against the COVID-19 pandemic, and we are maintaining a long-term view of optimism.

The first pillar is our longstanding belief in driving both performance and purpose with equal commitment. Across Johnson & Johnson, we operate with the believe there is a tightly linked connection between our company's purpose, which is to advance health for humanity and our financial performance, which has helped us deliver lifesaving medicines and lifesaving products, as well as invest in support communities around the world. We recognize the challenges that families and their loved ones are facing in these volatile and unpredictable times, and this is exactly why across our enterprise we've been working so hard to help those in need and to accelerate our collective efforts towards ending this pandemic.

Some examples of note include, we are applying all of our capabilities to support nurses, doctors, midwives, and community health workers. Recently, it was announced that Johnson & Johnson family of companies, and the Johnson & Johnson Foundation are increasing our previous \$250 million commitment over 10 years by an additional \$50 million for immediate COVID-19 response. This contribution will primarily focus on supporting front line health workers who are truly modern day heroes and the backbone of the health care system. We are also working diligently to convert manufacturing lines in several facilities around the world for products most in need during the pandemic, so we can continue to provide important medicines and products to patients.

The second pillar I want to highlight is our strategic advantage of being the most broadly based healthcare company in the industry. Leading across the Pharmaceutical, Consumer and Medical Devices segments, provides us with the unique and powerful perspective that enables us to see more, reach more, learn more, and do more across the full spectrum of health, as well as throughout every age and stage of our patients and consumers lives.

In fact, in our Pharmaceutical business, we are thrilled to have identified a lead candidate for a potential vaccine. In Consumer, Tylenol is one of our most iconic and trusted brands by consumers and healthcare professionals for reducing fever, and we have increased production running our Tylenol manufacturing plant 24/7 to maximize supply. We've also refocused our manufacturing lines to make our easiest to produce pills, which are the White Tylenol caplets, so we can increase production and throughput. In Medical Devices, we are experiencing a near-term negative impact, and expect this to continue while elective procedures are deferred and hospital resources are redeployed to address patients impacted by this pandemic. That said, Medical Devices has historically been a strong market and we believe the underlying fundamentals of the market remain intact. We continue to see tremendous potential over the long-term to serve our patients and customers.

And at this time and in this time of need, we are utilizing our supply chain delivery in 3D printing expertise and collaboration with Prisma Health to manufacture and distribute the VESper, Ventilator Expansion Splitter device, which addresses the acute ventilator shortage during the COVID-19 pandemic, and at no cost to healthcare providers. Additionally, we continue to support and share product availability to healthcare workers, hospital systems, and surgeons, in critical need areas such as trauma, stroke, and other lifesaving surgeries that cannot be deferred.

The third pillar is our unparalleled scientific expertise. Innovation is integral to our ability to deliver breakthrough healthcare solutions at a remarkable and ambitious work that we have underway to eradicate COVID-19 is a true testament to this fact. Based on 134 years of experience, we know that the power of our science, the scale of our business, and the dedication of our employees is critical in driving innovative solutions that can change people's lives the better and change the face of healthcare.

In collaboration with scientists from various external institutions, we have been able to identify a lead COVID-19 vaccine candidate. We will leverage the scientific expertise of our internal teams with a decade of work spend developing vaccines for HIV, Zika and Ebola, to apply the ground breaking science and scalable manufacturing platform that we already have in place. This is monumental and is much needed. We are accelerating timelines and plan to begin production at risk imminently, and we are committed to bringing in affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

The fourth and last pillar is the world class talent, capabilities, and dedication, of our 130,000 colleagues worldwide. We always take actions in employee tactics to support our Johnson & Johnson colleagues, both professionally and personally to ensure they are safe

and well equipped, and today is no different. We are ensuring employees are able to play their part in helping to fight the COVID-19 outbreak at home and at work.

Some examples include: we've implemented significantly enhanced standardizing procedures and appropriate distancing to ensure we maintain safe, clean, and well functioning facilities across our manufacturing, distribution centers, and research and development sites. We're rolling out a one-time award of \$1,000 per essential employee, with cost of living adjustments globally, whose presence is required on site to recognize the extraordinary work these employees are doing to advance our science and ensure supply of our most essential products and medicines. We're providing 100% of base salary and benefits through April 30th to employees who were primary caregivers and are unable to work remotely due to COVID-related family care responsibilities, underlying health issues, connectivity issues or other unique circumstances, and we're granting up to 14 weeks of paid leave to employees around the world of medical training who volunteer or who are called to serve the communities in diagnosing, treating and providing health support related to COVID-19.

And underpinning each of these four pillars is Our Credo. Our Credo has been a source of both inspiration and confidence for me and my Johnson & Johnson colleagues, especially in times like these. For more than 75 years, Our Credo has been the moral compass that guides our business decisions and is the blueprint that outlines how we operate and care for the world. Guided by Our Credo and in yielding sense of purpose, we have created a powerful legacy of improving the health and well-being of people worldwide, while delivering sustainable long-term value to all of our stakeholders. We have a century plus history of leading in times of great challenge. We've done it before and we can do it again. This is what the world expects of us and this is what we are all committed to and prepared to do.

Now as the world continues to face the significant and urgent public health prices, I want to emphasize that across Johnson & Johnson we are leveraging our broad base size and scale to think, lead, and operate with the same level of incredible urgency, relying on the same courage, conviction and core strains that set us apart and empower us to make a positive impact on society and healthcare. I am both proud and amazed with the level of dedication that I've witnessed from every Johnson & Johnson business, function team, and person over the last several weeks.

Now, we certainly don't have all the answers a day. We will find the ones needed to ensure our success for tomorrow, and we won't take shortcuts that compromise our standards or values as we move with speed and determination. As I said earlier, Johnson & Johnson is built for times like this. We take a long-term strategic view, which means we're in this for the long haul, delivering value to all of our stakeholders.

I look forward to addressing your questions during the upcoming Q&A, but I'll now turn it over to Paul, who will provide an update on the progress we're making with the COVID-19 vaccine development. Thank you. Paul?

Paul Stoffels {BIO 16443573 <GO>}

Thank you, Alex. I am pleased to provide an update on a multi-pronged approach to addressing COVID-19, including developing a vaccine and screening of compound libraries to identify potential new treatments to address this pandemic. In addition, we are exploring immuno-modulators to protect against Acute Respiratory Distress Syndrome or ARDS in COVID-19. While we focus today on finding potential new treatments, ultimately a vaccine is key to eradicating the ongoing threat of the pandemic.

Since 2011, Johnson & Johnson has invested heavily to build state-of-the-art vaccine capabilities, which we used to develop and manufacture our Ebola, Zika, RSV and HIV vaccine candidates. We are bringing to bear those same capabilities to rapidly accelerate our efforts towards the potential COVID-19 vaccine. We are pleased to see that there are many approaches to vaccines for COVID-19, which show the importance of ongoing research in industry over the past several decades. Our COVID-19 vaccine program leverages Janssen's adeno vector and Per.C6 technologies that provide the ability to rapidly develop new vaccine candidates and upscale production of the optimal vaccine candidate.

Based on the WHO criteria for key attributes for prioritizing vaccine platforms, here on the right, the attributes of our platform put us in a leadership position. First, adeno 26 viral vector platform induces potent and long lasting humoral and cellular immune responses in humans. Further, this approach has a very low to no risk on the respiratory disease enhancement, based on the immune responses observed across our programs. This is in line with the observation that targeted pre-clinical models used in context of the RSV vaccine development have shown that this platform is not associated with enhanced respiratory disease. Our platform has a proven safety profile. More than 50,000 people have been vaccinated and we have demonstrated that it's well tolerated.

Our PER.C6 cell line offers a high yielding vaccine manufacturing platform and is scalable and fully industrialized, providing us the ability to make hundreds of millions of vaccines per year. Capacity in our Leiden based vaccines launch facility is as high as 300 million doses per year. Finally, we have 2 to 8 Celsius stability data on our vaccine, making it compatible with standard vaccine distribution channels and therefore will not require new infrastructure to get it to the people who need it. We begun working on a vaccine candidate in early January as soon as the coronavirus sequence became first available.

As you can see in the infographic on the right, to make vaccine candidates, we insert a piece of the spike protein into the genome of a non-replicating and therefore non-infective adenovirus, a type of common cold virus. The research teams at the Janssen, in collaboration with BIDMC at Harvard Medical School constructed and tested multiple vaccine candidates. The vaccine constructs were tested then to identify those with most promise in producing an immune response in pre-clinical testing. Based on this work, Johnson & Johnson announced on March 30th that we have identified a lead COVID-19 vaccine candidate, along with two backups. In order for any vaccine to be manufactured to GMP in large quantities, it is necessary to first produce a master seed bank, which is then progenitive of all future large scale vaccination batches. All three candidates are now entering pre-master seed production. Final selection of start of master seed production is expected in June 2020.

As we have already announced, we are expanding our global manufacturing capacity in parallel, including the establishment of a new US vaccine manufacturing capability. We are also in discussions with other potential partners to expand manufacturing capacity in Europe and Asia, and look forward to making those announcements in the coming weeks. We plan to begin production at risk imminently, and our goal is to enable the supply of more than 1 billion doses of the vaccine globally.

We are on track to start Phase 1 clinical trials in early September in the US and Europe, with clinical data on safety and immunogenicity expected to be available by the end of the year. This could allow vaccine availability for emergency use authorization as early as early 2021. We are confident in this vaccine candidate, because we have now seen good data in animal models. While we are moving with extreme speed, we are absolutely committed to making sure that our vaccine follows all guidelines with regard to good manufacturing practices and quality controls. We are not cutting any corners when it comes to safety. We are able to achieve the speed, because we are doing several processes in parallel, many at risk rather than in sequence.

In addition to our work on vaccines, we are screening compound libraries, including compounds from Janssen and other pharmaceutical companies to identify potential treatments against COVID-19 and exploring immuno modulators to protect against ARDS. The antiviral screening efforts are being conducted in partnership with the Rega Institute at the University of Leuven in Belgium.

As I mentioned, we have been able to reach this point as a result of multiple collaborations. As you also saw in the March 30th announcement, as part of our new partnership with BARDA, we have together committed more than 1 billion of investment to co-fund vaccine research development clinical testing and accelerated manufacturing. If a vaccine is approved, we will work with relevant healthcare authorities to ensure that our products are accessible wherever needed. We are committed to bringing an affordable vaccine to the public on a not-for-profit basis for emergency pandemic use.

In conclusion, I want to note that COVID-19 is one of the most severe global health challenges we have seen in our lifetimes, but at the same time we have unprecedented science and technology available today to help us mount a fast and effective response. Johnson & Johnson is committed to harnessing the latest tools, sharing knowledge and resources, and fueling global collaborations to help the world win the fight against COVID-19, and be even better prepared for possible future pandemics.

Now I will turn it over to Chris to discuss our results for the quarter. Thank you.

Christopher DelOrefice {BIO 20730104 <GO>}

Thank you, Paul. Now I will provide our Q1 results. Worldwide sales were \$20.7 billion for the first quarter of 2020, an increase of 3.3% versus the first quarter of 2019. Operational sales growth, which excludes the effect of translational currency, increased 4.8%, as currency had a negative impact of 1.5 points. In the US, sales increased 5.6%. In regions outside the US, our reported growth was 1%, however operational sales growth outside the US was 4%, with currency negatively impacting our reported OUS results by 3 points.

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Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 5.6% worldwide, 6.7% in the US, and 4.5% outside the US. These global sales results include an estimated net impact of COVID-19, which negatively impacted worldwide sales by about 80 basis points. This includes a negative impact to our Medical Device business segment across all regions, with Asia Pacific and the US regions seeing the most prominent impact. Partially offsetting this was a net positive sales lift in our Consumer Health and Pharmaceutical business segments, as communities prepare to ensure they have the necessary access to health care products and medicines.

Turning now to earnings. For the quarter, net earnings were \$5.8 billion and diluted earnings per share was \$2.17 versus diluted earnings per share of \$1.39 a year ago. Excluding after tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were \$6.2 billion and adjusted diluted earnings per share was \$2.30, representing increases of 8.7% and 9.5% respectively compared to the first quarter of 2019. On an operational basis, adjusted diluted earnings per share grew 10.5%.

Beginning with Consumer Health, I will now comment on business segment sales performance for the first 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 first quarter of 2019, and therefore exclude the impact of currency translation. Additionally, I will be providing additional insights using our best estimates on the contribution of COVID-19 to our performance in the areas where this had the largest impact.

Worldwide Consumer Health sales totaled \$3.6 billion, growing 11.3%, with operational growth in the US of 21% and growth outside the US of 3.9%. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 11%. Our Consumer Health segment realized a net positive impact of nearly 700 basis points associated with consumers, ensuring they have access to products during the COVID-19 pandemic. We do expect some of this benefit to reverse over the subsequent quarters this year. This benefit was mostly realized in our over-the-counter medicines franchise. The benefit was also most prominent in the US, with a small benefit outside the US, primarily in Europe, offset by declines in Asia-Pacific in mostly the skin health/beauty and baby franchises.

Excluding some one-time items and the net benefit of COVID-19, our Consumer Health segment delivered solid performance. We continued strong performance in the US and priority areas within our OTC and skin health/beauty franchises. Over-the-counter medicines grew globally, almost 26% operationally, with about 36% growth in the US and 17% outside the US. COVID-19 contributed about 17 points to the global growth.

In the US, we estimated COVID-19 contributed about 24 points to growth. And excluding that impact, our growth was strong, enabled by share increases in multiple products such as Adult Tylenol, PEPCID, ZYRTEC and ZARBEE'S. US performance was also aided by a stronger allergy season. Additionally, there were some favorable one-time benefits resulting from competitive dynamics. COVID-19 contributed about 10 points to growth outside the US. Excluding that, growth was strong, driven by an elevated cough and cold season in key markets like Russia.

The skin health/beauty franchise grew 3.5% or just under 2% when adjusted to exclude the impact of acquisitions and divestitures, driven primarily by the acquisition of Dr. Ci Labo. This franchise experienced a net negative impact due to COVID-19 by slightly over 100 basis points, with the largest negative impact in Asia-Pacific, especially in China, partially offset by a favorable benefit in the US. The US operational growth of just over 12% benefited by about 450 basis points from COVID-19.

Additionally, our core business in the US remains competitive, with strong performance in NEUTROGENA facial care. The US also benefited from some timing of promotional orders. And then, our remaining Consumer Health franchises are oral care, women's health, and wound care other franchises, all reported strong growth, primarily driven by COVID-19. And excluding the favorable impact of COVID-19, each of these franchises delivered solid performance.

Baby care declined 4.9% globally or negative 2.7% when adjusted to exclude the impact of the Baby Center divestiture. The majority of this decline was primarily due to the execution of SKU rationalization actions, primarily in EMEA, and a smaller net negative COVID-19 impact, partially offset by solid growth in AVEENO baby globally.

Moving on to the Pharmaceutical segment. Worldwide Pharmaceutical sales of \$11.1 billion grew 10.1%, enabled by double-digit growth in nine key products. Sales grew in the US by 8.6%, and increased outside the US by 12%. Global growth was aided by over 200 basis points of one-time items, including about 100 basis points of impact from favorable prior period pricing adjustments in the US, with REMICADE being the largest product impacted, and about 100 basis points of net favorable estimated impact from COVID-19, resulting from health care providers and wholesalers ensuring there is access to essential medicines. This benefit occurred across our portfolio, with favorable benefits in the US and Europe, offsetting downside in the Asia-Pacific region, and mostly China. Incremental COVID-19 demand primarily impacted IMBRUVICA, XARELTO, STELARA, the pulmonary hypertension portfolio, and HIV products. Our strong portfolio of products and commercial capabilities has enabled us to continue to deliver global growth at above market levels.

Our oncology portfolio delivered another strong quarter with worldwide growth of almost 22%. DARZALEX continued its strong performance, growing over 51% globally. The US grew almost 32% with strong growth across all lines of therapy, driven by the new front line indications for multiple myeloma. The continued strong growth outside the US is driven by increased penetration and share gains. IMBRUVICA grew over 34% 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. In the US, based on fourth quarter data, IMBRUVICA gained almost 8 points of market share in CLL Line one therapy.

We continue to be pleased with the launch progress of ERLEADA. As part of the sales reporting change as I mentioned earlier, we are now disclosing our leader sales separately, which were \$143 million globally, and more than doubled versus last year, driven by continued share growth in the US and continued launch progress in EMEA with availability in 18 countries.

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Our immunology therapeutic area delivered double-digit global sales growth of 13.1%, driven by strong double-digit performance of STELARA and TREMFYA. Sales growth was partially offset by continued erosion of REMICADE due to increased discounts and modest share loss in the US. STELARA growth of over 30% was primarily driven by the Crohn's disease indication, where market share increased by over 7 points in the US versus the first quarter of 2019. TREMFYA grew over 37% and achieved a 9% share of the psoriasis market in the US, which is up 2.5 points from the first quarter of 2019. In neuroscience, our paliperidone long-acting portfolio performed well, growing almost 13% with higher market share driven by increased new patient starts and strong persistency.

In addition, we continue to progress the launch of SPRAVATO, where the unmet need remains high, patient demand continues to build, with new patient starts steadily increasing with over 5,000 patients treated today. In infectious diseases, our portfolio grew 11%, led by strong growth of SYMTUZA and JULUCA for HIV, partially offset by cannibalization and increased generic competition in other products. In our cardiovascular metabolism and other product portfolio, we did experience declining sales of 13.1%, primarily driven by declines in INVOKANA and biosimilar competition for PROCRIT. XARELTO also declined by 2.7%, with volume increases offset by increased rebates, including channel mix dynamics.

In our total pulmonary hypertension portfolio, sales increased 14.7%, driven by strong growth of OPSUMIT and UPTRAVI of about 29% and 27% respectively, driven by increased market penetration and share growth. This portfolio growth was net of declining sales in TRACLEER, as a result of continued generic competition. Note, as part of the sales reporting changes I referenced, TRACLEER is now included under other pulmonary hypertension.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were \$5.9 billion, declining by 6.9%. Excluding the net impact of acquisitions and divestitures, primarily the divestiture of ASP, adjusted operational sales declined by 4.8% worldwide. Our global medical device portfolio realized a significant impact on sales, estimated to be worth 750 basis points to 800 basis points as a result of procedures being deferred due to the COVID-19 pandemic, which were partially offset by stocking, primarily in Asia-Pacific, in anticipation of procedures ramping back up. Approximately 50% of the net impact occurred in Asia-Pacific, about 30% was in the US, and the remaining balance was primarily in Europe. I will provide further contact shortly about how this impacted each platform.

Additionally, one-time items negatively impacted growth this quarter by about 90 basis points, primarily related to there being fewer selling days in this period. Adjusting for these one-time impacts and the estimated impact of COVID-19, our adjusted operational sales growth reflects continued strong underlying fundamentals, consistent with our full year 2019 adjusted results. Interventional Solutions grew 0.4% globally, with US growth of 6.6%, offset by declining sales outside the US of 5.1%. COVID-19 had a net negative impact to our global growth rate by about an estimated 14.5 points, reducing US growth by over 8 points and OUS growth by about 20 points. Growth excluding the impact of COVID-19 was led by continued strength in our electrophysiology business, driven by our newer

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product offerings in ablation and advanced catheters, contributing to atrial fibrillation procedural market growth.

Vision declined by 4%. The estimated net impact of COVID-19 de-growth is around 550 basis points. Additionally, results in the quarter were negatively impacted by both the final bleed down of the Japan consumption tax forward buy that occurred in Q3 2019, along with an unfavorable prior year comparison due to an inventory forward buy related to BREXIT uncertainty, which were worth over 200 basis points in total. While contact lens has realized a slight decline, when you adjust for the aforementioned items, the business delivered another quarter of competitive growth globally versus the market led by continued strong performance of daily disposables in the ACUVUE OASYS family.

In surgical vision, sales declined 15.9%, with the primary driver of the decline driven by COVID-19 which impacted results by an estimated 12 points. The business excluding COVID-19 saw continued strong OUS growth in the cataract business due to strong performance in Asia-Pacific, which was more than offset by a decline in the US, primarily due to competitive pressures.

Orthopedics declined by 6.5% in the quarter. The COVID-19 pandemic impacted growth in this franchise by about an estimated 750 basis points, with the US market realizing the largest dollar impact at just over 40% of the total, and the balance of the negative impact split relatively evenly between Asia-Pacific and Europe. Total orthopedics growth adjusting for this impact was relatively consistent with our prior quarter performance, reflecting the continued execution of our innovation and commercial strategies aimed to improve performance.

Hips declined by 5.6%. We estimated COVID-19 negatively impacted growth by about 9.5 points. Excluding this impact, hips continue to deliver competitive performance, driven by our leadership position in the anterior approach, continued strong demand for our primary stem ACTIS and enabling technologies such as the KINCISE Surgical Automated System and the VELYS Hip Navigation system that came from the Joint Point acquisition.

Knees declined by 6.1%. Adjusting for the estimated COVID-19 impact of about 11 points, knees underlying fundamentals continue to improve and deliver solid performance in both the US and OUS, driven by new innovation, such as ATTUNE Revision, ATTUNE S+ and the ATTUNE Cementless rotating platform, which launched later in 2019. Trauma declined by 3.5%. COVID-19 negatively impacted results by an estimated 400 basis points. Additionally, performance was impacted by overall market softness as a result of a mild winter season leading to lower procedures, as well as competitive pressures.

Spine declined 10.6%. However, adjusting for COVID-19's estimated impact of over 750 basis points, spine's underlying performance remain consistent with recent results. While we lost share in the quarter, we continue to see positive uptake of newer products such as CONDUIT and VIPER PRIME. We are also pleased with the roll out of our newly launched SYMPHONY surgical system for use in posterior cervical spine procedures.

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Pricing pressure continued in orthopedics. US pure price in spine, hips and knees eroded versus Q4 2019, declining about 5%, 2% and 1% respectively. Pricing trauma improved compared to Q4 and was essentially flat.

Moving to the results for the surgery business. As I noted earlier, we made some minor adjustments to how we report our Medical Devices sales, and you will see that we moved the platforms previously under specialty surgery to general surgery, now that we've closed the divestiture of the ASP business, which was the majority of the specialty surgery sales.

Advanced Surgery declined by 1.4%, but was significantly impacted by COVID-19, which we estimate was almost an 800 basis points impact. COVID-19 primarily impacted OUS results, particularly in endocutters and energy, with an estimated negative impact to global growth of about 900 basis points to each platform. Excluding this negative impact, performance was strong, led by energy. Both energy and endocutters performed well outside the US, driven by share gains and new products, primarily in Asia, and were partially offset by competitive pressure in the US.

Biosurgery had an estimated negative impact of over 550 basis points, driven by COVID-19. However, underlying fundamentals excluding this negative impact remain strong, with growth balanced between the US and OUS. US performance in biosurgery was driven by continued uptake of SURGIFLO, after last year's stop shipment, coupled with new products such as VISTASEAL. OUS performance continues to be led by market and share performance in the Asia-Pacific region. We also continue to see great uptake of our Monarch system for the diagnosis of lung cancer. Q1 procedures grew 150% compared to the prior year, and almost 2,700 procedures have been performed since launch.

Wound closure declined over 7% in the quarter with COVID-19 negatively impacting results by an estimated 800 basis points. Growth excluding COVID-19 was driven by continued strong market growth, as well as share gains in conventional and barbed sutures in China.

I would now provide some commentary on our earnings for the quarter. Regarding our consolidated statement of earnings. For the first 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 \$2.30 reflects reported growth of 9.5% and operational growth of 10.5%. 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 as a result of product mix and the establishment of inventory reserves associated with the COVID-19 impact in the Medical Devices business. Selling, marketing and administrative margins for the quarter improved, driven by leveraging in the Pharmaceutical and Consumer Health businesses, and favorable segment mix, partially offset by deleveraging in the Medical Devices business, resulting from the COVID-19 impact on sales. We continue to invest in research and development in competitive levels, investing 12.5% of sales this quarter. This was lower than the first quarter 2019 by 180 basis points, driven by timing of Pharmaceutical

milestone payments, partially offset by increased investment in robotics and digital solutions in the Medical Devices business.

The other income and expense line show net income of \$679 million in the first quarter of 2020 compared to net income of \$22 million last year. This was primarily driven by a contingent consideration reversal of approximately \$1 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition, partially offset by higher unrealized losses on securities.

Regarding taxes in the quarter, our effective tax rate declined from 15.2% in the first quarter of 2019 to 11% in the first quarter of 2020 as a result of additional favorable impacts from Swiss Tax Reform and the reversal of the Auris contingent liability. We 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 15% versus 17.6% in the same period last year, driven by certain tax costs incurred in the first quarter of 2019 that were not repeated in 2020.

Let's now look at adjusted income before tax by segment. In the first quarter of 2020, adjusted income before tax for the enterprise improved 70 basis points versus the first quarter of 2019 to 35%. Looking at the adjusted pre-tax income by segment, Pharmaceutical margins improved by 360 basis points to 45.3%, primarily driven by timing of R&D milestone payments. Medical Devices declined by 540 basis points to 24.2% due to COVID-19 impacts on the business including incremental inventory reserves and deleveraging in selling and marketing, in addition to continued increased investment in robotics and digital solutions. Consumer margins declined slightly by 50 basis points to 24.5%, driven by a one-time gain in 2019 related to the company's previously held equity investment in Dr. Ci Labo, which was partially offset by leveraging selling, marketing and administrative margins in the current quarter.

That concludes the sales and P&L highlights for Johnson & Johnson's first quarter 2020. For your reference, this slide summarizes notable developments occurring in the first quarter. Of note, we submitted new drug applications to the FDA and EMA for Ponesimod for the treatment of adult patients with relapsing multiple sclerosis.

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

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Chris, and good morning everyone. We appreciate that you decided to join the call today, and like others on this call who spoke before me, I hope you and those close to you are safe and healthy.

Let me state right upfront. The fundamentals of Johnson & Johnson's business are strong, and our expectations of where the business is heading have not changed. Combatting the current crisis is anything but usual. However, many aspects of Johnson & Johnson continue to operate with a business as usual focus, such as advancing, breakthrough innovation, fostering, consumer and patient access, and being financially disciplined. We are motivated by never stopping when it comes to taking care of you, our stakeholders,

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and we can have a profound positive impact, because we are built to lead, built to last, and quite frankly, built for times like this.

My central focus in today's prepared remarks is two-fold. First, I will share with you our ongoing business continuity plans. It is important, particularly in times of challenge that you understand the steps we have put in place recently and over a number of years to ensure reliable supply of the important products we provide. Second, I will outline how we are thinking about the impact of the COVID-19 crisis and what that will have on our near-term financial performance in the context of changes from the guidance we issued in January. I trust at the end of my remarks and at the end of this call, the obvious conclusion is that Johnson & Johnson is strong in a financial position to meet its obligation to all stakeholders and poised for many years of success. The fundamentals of our business are intact.

As Alex mentioned earlier, as the most broadly based global company in the healthcare industry, we have established a sustainable and resilient business model, with flexibility designed into our research, manufacturing and commercial capabilities. We have robust active business continuity plans across our network, which have been instrumental in preparing us for events like COVID-19.

Some steps we have taken recently include: leveraging our global manufacturing footprint and dual sourced capabilities while closely monitoring and maintaining critical inventory at major distribution centers to address high-risk areas and ensure adequate and effective distribution; working closely with suppliers, distributors, local governments and regulators to gain better insights to address their concerns; through our commercial organizations, supporting healthcare providers in the safest way possible by moving to virtual connections to serve as a resource for physicians, where needed we directly engage to support them in areas like trauma surgeries, ensuring we follow all health protocols to keep everyone safe. Within clinical operations, our first priority is always to protect the health and well-being of participants currently enrolled in our clinical trials.

Our next priority is to complete these trials in a manner to fully satisfy regulatory requirements. This pandemic does not change these priorities. As a result of these efforts, we are able to meet the majority of patient and consumer needs. Given the unprecedented nature of current events, I'd like to provide insights on a few topics that we typically don't detail, but are likely top of mind these days for most.

From a liquidity standpoint, we are very well positioned. We ended the first quarter with cash and marketable securities of \$18 billion, generating approximately \$3 billion of free cash flow in the quarter, consistent with first quarter of the previous two years. Coupled with our AAA credit rating, we are able to access the capital markets if needed and would anticipate securing the most competitive credit spreads available. A strong balance sheet has been a hallmark of Johnson & Johnson, and is most valued in times of macro economic distress. We are able to use this strength to benefit many constituents.

Some recent examples include, partnering with BARDA to jointly invest approximately \$1 billion to not only develop and deliver a vaccine for the novel Coronavirus but potentially

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in record time. We are complementing the efforts of communities and healthcare heroes through numerous donations and other activities which Alex highlighted. We are supporting small and diverse suppliers and customers, offering financial flexibility at a time when they need it most and we responsibly increased our dividend to shareholders.

Our capital allocation priorities are clear and remain unchanged. We continue to invest in our business with a bias towards innovation that delivers meaningful products and services to address unmet needs or commercial capabilities that generate greater access to healthy living for more people. It is investing in innovation, particularly in times of uncertainty, that will not just bridge the next few months but the next several years.

After investing at or above competitive levels in our business, we look to allocate capital to our shareholders in the form of dividends. We know that many of our shareholders prioritize that aspect when investing in Johnson & Johnson. Alex announced earlier in the call that for the 58th straight year we re increasing our dividend. While certainly notable from a historical standpoint, this announcement is important and that it underscores our confidence and optimism for the future. We intend to continue generating strong cash flows and be financially well-positioned.

Our next priority is to invest our capital in value creating M&A, pursuing transactions that bolster our portfolio or enhance our pipeline, while targeting returns that compensate shareholders for the risk we are bearing on their behalf. The current crisis does not reduce our desire to do these transactions. In fact, given our financial strength, we may be in a better position to fund opportunities that will augment sustainable long-term growth.

While a second quarter event, a good example of this in practice is our recently signed pre-clinical research collaboration with Fate Therapeutics to develop and commercialize off-the-shelf allogeneic cell therapies for up to four tumor-associated antigens, which we believe has the potential to significantly change the current cell therapy paradigm in the treatment of several distinct cancer types.

Finally, within our capital allocation paradigm, as you saw the past few years, we also simultaneously allocate capital to share repurchase programs. We do not have an active program at this time and have no plans to announce a new program as we feel other capital allocation priorities take precedence at this time. Given it is often a question, let me offer a few remarks related to ongoing litigation.

With respect to opioids, as announced last October, we reached an agreement in principle to settle the litigations. The State Attorney General's are engaged and there continues to be cooperation working towards broad participation by the states, cities and counties involved in this litigation. Regarding talc, as we have previously stated, multiple sources of independent science and third party testing supports the safety of our products. We await the Daubert hearing outcomes from Judge Wolfson in the Federal District Court of New Jersey.

Okay. Let's move to our guidance for 2020. We know some companies in our peer set have pulled their guidance. We also know that some sell side models have not been

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updated. We understand that may have been an option for us as well. But in uncertain times, we look forward to offering you as much transparency incredible insight into our view of our business. We have decided to provide updated guidance given what we know today with the objective of finding that right balance between bolstering your confidence in Johnson & Johnson, while not providing false assurances. Things will change in the coming days, weeks and months, but at least you will have the benefit of our perspective to consider among the numerous sources you rely upon to make financial sense of the near-term outlook.

During the next few minutes, I will touch upon each part of our business with greater emphasis on Medical Devices. That segment is currently projected to experience the most significant impact. Let me start, however, by sharing a few assumptions that apply across our entire business. Our guidance attempts to account for the macroeconomic impact of COVID-19, and the potential impact it will have on the overall healthcare system capturing the potential negative impact on the number of insured individuals and how people may prioritize disposable income in the near term.

Second, utilizing the experience in earlier affected markets as a reference. Our estimates of the COVID-19 impact assume the relative shape of the COVID-19 curve as being more of an acute shorter term impact rather than a prolonged impact. For our largest market, the US, this assumption is consistent with the estimated mid-April peak assumed by the Institute of Health Metrics and Evaluation or IHME. The IHME also predicts mid to late April peaks for several European countries.

Third, taking into account recent statements by Dr. Fauci and other scientifically accomplished sources, our estimates do not assume the virus returns in the fall with the same intensity currently experienced. What do I mean by that? As the experts have noted in various forums, if the virus does return, the world should be much better prepared to test, identify and isolate it. There may also be therapeutic options available. So our premise is that elective procedures and doctor visits will largely be permissible in the second half of this year.

Finally, we assume a recovery for procedures that begins in the third quarter and improves further in the fourth quarter. We do anticipate some disruption to the economy and have considered it on a smaller scale. Coming out of the second quarter, we assume an improving global economy, with lower unemployment, better insurance coverage, and higher procedure capacity than what has been or will be experienced at peak.

Let's delve into the segments. The story for Pharmaceuticals is fairly straightforward. Our results in the first quarter confirm the strength of our Pharmaceutical business and we expect it to be resilient. We provide valuable solutions in critical disease states with high unmet need and we largely expect patients will continue to receive and seek treatment. Quite frankly, it is important that they do so to avoid unintended health consequences related to COVID-19 beyond the pandemic itself.

With that said, based on what we have seen to date, we do expect a small level of disruption associated with delayed diagnosis and new patient starts. This is driven by two

factors. First, data from IQVIA suggests that office visits have recently declined by 30% and that interaction is not being entirely offset by the escalating use of telehealth services. We also know that benefit inquiries have declined, suggesting new patient activity has slowed. The second factor is related to physician administered drugs. For example, some infusion centers are being repurposed as COVID-19 treatment centers, and there are staggered infusion times with fewer chairs to comply with social distancing practices. The extent in duration of those two factors comprise the largest variable in our Pharmaceuticals outlook. However, the net of it all is that we remain confident in delivering the Pharmaceutical expectation we had in our guidance at the start of the year and anticipate the business to grow above the market again.

Looking slightly ahead to next year, we also remain confident in the progression of our pipeline, which should fuel growth beyond 2020. We are partnering with health authorities on the status of our 2020 projected regulatory filings and approvals, and have not received notification from regulatory authorities regarding any delays for our major submissions. We continue to progress our plans, prepared to work through any implications related to COVID-19. At this time, our major filings and approvals planned in 2020 are on track.

Let's transition to Consumer Health. As you heard, the first quarter was very strong for this segment as our essential products are in high demand across the globe. We operate in key categories such as over-the-counter medicines that should continue to perform well as consumers look to self-managed conditions such as fever and pain. However, the first quarter surge was partially due to pantry loading that will not continue for the full year. Access to necessary consumer products across most of our portfolio will continue, but perhaps differently. There will be some impact in certain categories as a result of reduced store traffic and social distancing behaviors that are not likely to be fully offset by higher ecommerce activity, so we expect some category softness in franchises such as skin health, most notably sun care products. With that said, we think the upside opportunities at least offset the downside risks and are therefore projecting that here too, our full year assumption in January remains intact for the segment. We continue to expect growth above the market in the US, while executing the SKU rationalization program mostly focused outside the US.

So let's move on to Medical Devices, which is at the core of our guidance change and remains the most uncertain. When I referenced at the outset of this section that some companies have withdrawn guidance, it has been primarily in the Medical Device segment. So that is a good indication of where the uncertainty exists. Consistent with what we experienced in the first quarter, we expect our Medical Device business to be negatively impacted as many procedures continue to be deferred and hospital resources are diverted to address the pandemic. We are assuming the most significant negative impact occurs in the second quarter, a lingering impact, but signs of stabilization in the third quarter and then some recovery in the fourth quarter.

To determine the impact, we started by reviewing external data, including surveys, expert panels, epidemiology, data and capacity constraints. We then reviewed our own internal data at the procedural level and weekly sales results at the country level compared to reported cases of coronavirus. Given China was the first country impacted by this

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pandemic and is believed to be further along in the COVID-19 curve than the rest of the world, we modeled this first.

Then, given the success that Japan and Korea appear to have had thus far containing the virus, we decided to bucket all three of these Asia-Pacific markets together, which represents approximately 20% of our Medical Devices revenue. We then looked at the remaining seven countries in our top 10 markets. The United States, Italy, France, Germany, the United Kingdom, Spain and Russia, which collectively make up approximately 60% of our Medical Devices revenue. The remaining rest of the world markets outside of our top 10 countries therefore account for 20% of our Medical Devices revenue.

As you know, we have a broad portfolio in Medical Devices. As this slide depicts, approximately one-third of our Medical Device business supports urgent procedures that aren't candidates for deferral, in other words, non-elective, such as events that address trauma, stroke, and critical surgeries associated with cancer.

Based on this procedural classification data and the geographic split I outlined, we developed a range of scenarios to inform the low end and the high end of our estimates. In those key Asia-Pacific markets, we assume that elective procedures will declined 20% to 60% during the second quarter based on trends we are currently observing in those countries. Elective procedures could be down less than this if recovery occurs earlier and ramps back up quickly, but given how much is still unknown, we felt this was an appropriate view at this time.

We do see stabilization occurring earlier in these countries compared to the rest of the world and expect to start seeing deferred procedures being made up primarily throughout the second half of this year. Using similar methodologies for the other remaining major markets, we assume deferred procedures declined 65% to 85% in the second quarter, and declined 20% to 60% in the third quarter versus our prior guidance. We see stabilization in the fourth quarter with these countries starting to recover deferred procedures. The rest of the world assumptions are consistent with these seven countries.

You can also see that we are assuming declines in urgent procedures as well. Individuals are spending less time outdoors, engage in physical activity, which we expect to impact procedures, even urgent ones, particularly in a market like trauma. In terms of recovery, if hospitals everywhere were doing procedures 24 hours a day including weekends, they could only increase capacity by about 30%. So we looked at that as the highest possible increase in capacity, which we view as unlikely.

We believe hospital systems will have capacity to make up deferred procedures from earlier in the year, but we suspect it could take time for patients to get comfortable, scheduling an elective procedure, hospitals and surgeons may still be recovering from peak COVID-19 impacts, and there will be economic challenges we discussed earlier, namely a potential impact to the number of insured patients and changing prioritization of income in the near term. Those factors lead us to a sooner recovery in a range of 0% to 15%.

These assumptions are our best estimates at this time. And again, we are not assuming a recurrence or significant mutation of COVID-19. Similarly, we are not assuming potential aggressive recovery measures that maybe implemented sooner by hospitals who are experiencing or will experience a minimal COVID-19 impact yet are faced with managing unexpected financial challenges resulting from being underutilized. As a result of all these factors, we estimate a negative operational sales impact of approximately \$4 billion to approximately \$7 billion to the Medical Devices forecast below our prior guidance. While there are many moving parts, the impact in Medical device is the sole change to our prior operational sales guidance for the enterprise.

So let's summarize this for you. Given all the factors I've described, we would be comfortable with new models reflecting the following. Adjusted operational sales of minus 3% to plus zero 0.5%, incorporating the range of the Medical Device operational sales negative impact of approximately \$4 billion to approximately \$7 billion. Moving to operational sales, our guidance is \$79.2 billion to \$82.2 billion or minus 3.5% to 0%. 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 \$1.09, there is an estimated negative impact of foreign currency translation of approximately 200 basis points versus the negative 50 basis points provided in our January guidance, resulting in an estimated reported sales growth between minus 5.5% to minus 2.0% compared to 2019 or \$77.5 billion to \$80.5 billion.

Moving to items impacting earnings. Regarding adjusted pre-tax operating margin, we now expect adjusted pre-tax operating margin for the year to decline about 100 basis points due to higher manufacturing cost related to COVID-19 sales impact, which is partially offset by spending reductions of approximately \$2 billion, Net interest expense is now expected to be in the range of \$50 million to \$150 million of expense due to lower rates on interest income earned. We are lowering our expectations for net other income.

As mentioned earlier, our financial strength may present us with near-term opportunities to execute transactions that enhance our current or future portfolio. There is another element to that strength. We are not dependent on selling assets to achieve our long-term objectives. Given the current market conditions and to ensure we create appropriate returns, we are assuming previously planned divestitures will be deferred until such time we can secure commensurate value for these very solid businesses. This decision results in us reducing our previously guided other income by \$700 million to a range of \$800 million to \$1 billion.

Our effective tax rate guidance for 2020 is now estimated to be approximately 16.5% to 18.0% wider than the previous range, given the variability associated with the sequence and pace of economic recovery across the major regions. Given those updates, we are now comfortable with adjusted EPS guidance in the range of \$7.65 to \$8.05 on a constant currency basis. This reflects an operational or constant currency decline of 11.9% to 7.3%.

Again, while not predicting currency movements, but to provide some insight on the potential impact on EPS. Using exchange rates from last week, our reported adjusted EPS would be negatively impacted by approximately \$0.15 per share versus our prior guidance impact of negative \$0.05. Accounting for that, we would be comfortable with your models

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reflecting reported adjusted EPS ranging from \$7.50 to \$7.90, a range of minus 13.6% to minus 9.0% based on what we know today.

A quick illustration of our EPS guidance change from January is presented here. The biggest impacts are obviously from the estimated decline in Medical Device sales and what we believe is a prudent decision to delay some previously planned divestitures. We also have some earnings impact associated with Johnson & Johnson's multi-faceted leadership to combat COVID-19. From vaccine development, employee well-being, and addressing healthcare worker needs, totaling close to \$0.25 billion.

To help partially offset these items, we are reducing spend by approximately \$2.3 billion on a pre-tax basis. But let me be clear, this is largely a reduction aligned to expenses that we believe will naturally be lower. We are not reducing important programs, initiatives or practices that best serve all stakeholders for the long-term. Our investors convey to us that they want us to continue managing for results 2, 5 and 10 years into the future. We do not provide quarterly guidance, but there are two items worth noting for you to consider as you update your models for Q2. The first is likely apparent, we expect the greatest COVID-19 impact on sales to occur in the second quarter. Second, for comparative purposes, recall that in the second quarter of 2019, we recorded a significant divestiture gain as other income. Today's revised guidance is a clear indication that a gain of that size will not occur in the second quarter of 2020.

Before I hand the call back to Chris to begin the Q&A, let me thank many on the phone listening today. We appreciate the insights you have shared to enhance our thought process, and well a 100% precision is not the order of the day, we hope you found the explanation of our guidance updates useful. I also want to thank our Johnson & Johnson associates around the world for the extraordinary effort and dedication they have displayed these past few months. I am humbled by the magnificent leadership stories I hear on a daily basis. They serve as an inspiration. Our performance of the first quarter highlights the resiliency of our business during challenging times and showcases the commitment of our employees to advance solutions that enhance the lives of patients and consumers seeking better health.

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

Christopher 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

Yes. Thank you. (Operator Instructions) Your first question comes from David Lewis, Morgan Stanley.

Q - David Lewis {BIO 15161699 <GO>}

Good morning, and thanks for all the significant work you're doing on behalf of patients in the system, as well as the very significant guidance that Joe just provided. Just a couple of quick questions from me. The first, for Paul, just -- you talked extensively about the vaccine program, and I know your goal is to produce 1 billion doses and you're ramping production throughout the year. So just first question is, by the first quarter of '21, where do you think production capacity will be and how could that scale through 2021 relative to that 1 billion doses? And I had a quick follow-up for Joe.

A - Paul Stoffels {BIO 16443573 <GO>}

Yeah, production capacity would be ready to go at 600 million to 900 million in the first quarter, going up to a 1 billion in the course of the year, north of 1 billion by the end of the year. So -- and that's on an annual basis. So we'll have four manufacturing sites going on one by one, bringing the whole capacity up to 1 billion in the course of the year.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Very helpful, Paul. And then Joe, just your detailed guidance on Medical Device is very much appreciated. On Consumer and Pharma, obviously we saw in the first quarter some hoarding benefiting Consumer in the OTC franchises and probably some stocking benefiting Pharma. So those businesses for the year, I appreciate you're stable. Can you give us any help first to second quarter, how we should be thinking about the relative trends of those businesses. Should we expect them to be below trend in second quarter versus first and then pop back up in the third quarter just based on the stocking and hoarding benefits? Thanks so much.

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

Great. Sure, David. Thanks for the questions. I would say you could probably expect that in our Consumer unit. You saw significant stocking across the globe. Probably as Chris referenced, it was about 7 points of additional growth for the Consumer franchise. We were off to a good start, but then you saw the benefit of pantry loading. I would say inform remains to be seen. As you know, we don't give quarterly guidance. It was only worth about one point of growth in the quarter as some PDMs moved from 30-day refill cycles to 90 days. I would imagine that activity will still continue, but we have to see how that plays out a little bit further into the second quarter here when you have stay at home protocols.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Thanks so much.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Thanks, David. Appreciate the question. Rob, next question please.

Operator

Our next question is from Chris Schott with JP Morgan.

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Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much. And again, I appreciate all the color on the COVID dynamics. Very helpful, given all the uncertainty out there. So just my two questions here was, one, can you just elaborate on the sensitivity of your business to elevated unemployment levels. As we look past some of the near-term shutdowns, I guess, we're in an environment where we have double-digit unemployment in the near term and maybe still rates are elevated as we look out in 2021. What does that do to the business as we think about things starting to normalize?

My second question was a question about China. And just -- you just shared a little bit about what you're seeing with the business as the economy begins to reopen there? And are there any learnings we've found from China that could be helpful as we think about recoveries elsewhere in the world from what you've seen today? Thanks so much.

A - Christopher DelOrefice {BIO 20730104 <GO>}

So, Chris, let me take the first question with respect to how we factored unemployment into our modeling specifically around the Medical Device business and maybe I'll turn it over to Alex to provide some commentary around what our team is telling us with respect to getting back to things in China.

With respect to unemployment, we look back at the financial crisis of 2008, 2009, try to draw inferences from GDP growth and what that meant relative to elective procedures and procedures in general. So we'll have to see how that kind of plays out relative to the 2008, 2009 financial crisis. The team has done a nice job relying on many of the reports and surveys that you in the sell side have conducted to make some assessments, but we'll really have to see how it plays out and that's why we've widened our range much more than we have traditionally. I think at the outset of the year, we had about \$800 million range on our overall enterprise sales guidance. Here you can see, it's about \$3 billion of a range and it's exclusively tied to Medical Devices. So more to come on that front, but we believe we've got at least a fairly sizable element of that already baked in.

Alex, can I turn it over to you for some thoughts on China?

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Chris. Thank you very much for the message. And look, maybe before I answer that, I just want to make a couple of comments. First of all, once again, acknowledging the tremendous impact that this is having on citizens around the world, let alone patients and consumers. This is likely one of the most significant events that any of us ever experienced in a very personal way. And I think making sure that throughout this, particularly as the world's largest healthcare products company that we remain just incredibly focused on serving them is our number one priority.

I think secondly, it's really acknowledging healthcare workers. I'm privileged to have a number of family members, frankly, who were out there on the front line and making a difference every day. And when you see what they're doing and literally going into battle

and preparing for the worst, hoping for the best, working 24/7, without them, I couldn't imagine the situation we would be.

And then, last but not least, is the work of our employees. I'm incredibly inspired. You heard earlier the great progress, the strong progress that we've made on our vaccine program. And while Paul reviewed that perhaps in 10 minutes, what I think is really important to keep into perspective is that the work that he's talking about accomplishing literally in 6 to 12 months would usually take between 5 and 7 years. And to do that in a way where there's a relentless focus on safety, on efficacy, on affordability but also while accelerating those time lines to do everything we can to be touching, as you heard in those numbers, up to 1 billion people with vaccines in the course of 2021 is just a huge undertaking, and we've got people working 24/7 every day of the week right now to really make that possible.

As it relates to China, Chris, I think that there too it's important to acknowledge the work of our team member. When we first saw this starting to break in late December, early January, we immediately assembled the team, and they began taking actions very quickly, obviously to ensure the safety of our employees, but also to ensure the integrity of our supply chain and being able to support the healthcare infrastructure within China.

And what we've seen over the past several weeks, I would say, it's a gradual return on the business. It's important to remember that in our case, in addition to the economic statistics that I think many other people can share, given the number of associates that we have on the ground that are literally visiting hospitals, even in some more of the remote areas, we're confident that we're starting to see, what I would call, a re-entry into procedures depending on where you are, that can range from 50% to as high to 60% or 70% as of today, and there is still are areas that are at the low end of that spectrum.

We've also heard some comments recently about some concern about a follow-up way, our resurgence, and they're responding accordingly. But I think overall, we are starting to see a return to a more normal rate of surgical procedures. And frankly, just the provision of healthcare services vis-a-vis our Pharmaceutical business and in our Consumer business as well. We have more than 50% of our employees back to work following very specific protocols and directions to ensure their safety, but we are confident that as we proceed in the coming months that we'll see a more return to normal continuing. Thank you.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Thanks, Chris. Appreciate the question. Rob, next question please.

Operator

Your next question is from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. Thanks for all the very helpful color. One question on Medical Devices in the recovery there, and one on the vaccine. First on devices, Joe, can you share with us your preliminary thoughts on, believe it or not, 2021,

just the postpone procedures, I heard your comments about the capacity and little catch up assumed for Q4. Just qualitatively, should we think about a lower base in 2020 and normalized growth in 2021 or how should we think about those postponed procedures potentially coming back next year? And I have one follow-up.

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

Sure, Larry. Thanks for the question. As you might imagine, while we hope 2021 looks a lot like we thought it was going to look like, maybe three months ago. We really have to let that play out. We did see and put into our modeling anywhere from normal level of procedures in the fourth quarter to a recruitment, if you will, of plus 15%, but it's really going to depend on the pandemic itself, what's the health priorities, how are patients and consumers feeling about going to the hospital for these procedures.

So I believe from what we've heard from hospital CEOs that they would like to get back in the business of elective surgeries, many of you have saw recent announcements, Mayo Clinic, most recently with respect to just only 25% utilization in their elective suites, that is putting financial strain on major hospital systems. And we want to make sure that when we return to normal that there's good quality healthcare still in place. So I'll defer I think would be a little bit irresponsible for me at this point in time to comment on 2021, the hope and the optimism is whenever the pandemic abates, we will be at or above expectations that we all once had.

A - Alex Gorsky {BIO 16239711 <GO>}

Larry?

Q - Larry Biegelsen {BIO 7539249 <GO>}

Yes, Alex.

A - Alex Gorsky {BIO 16239711 <GO>}

Larry, just one other comment on that, but I think it might be some important perspective. As Joe said, and as I'm sure you can appreciate, over the past several weeks, we have done our best to be in very close touch with hospital CEOs, with physicians who are working in systems around the country. And we are currently seeing, I think is a -- and this is consistent with what you've seen in some recent press articles where -- look there are clearly areas where it is in terms of a reluctant case of patient care in areas like New York, areas like Northern New Jersey, other hotspots such as New Orleans, Detroit, and there are also other areas in the Midwest where you might say there are hot zones.

Outside of that, however, and very consistent with Joe's comments, what you see in many cases are hospitals that are well under 50% of their capacity that have also increased some of their investments two to threefold, sometimes more, and appropriately so, preparing for the absolute worst case in the pandemic. But at the same time, they've lost a very significant portion of their income, seeing the cost increase putting potential financial stress on them.

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And so -- and we are also hearing a consistent theme of making sure that, as they think about returning, ensuring that we can get consumer and patient confidence back up through the right kind of testing programs, the right kind of protocols in the hospital in place, to make sure that we can get health care professionals, that is physicians and nurses, the kind of assurance that they're going to need to get back to a more normal state of working, as well as in some case, given the amount of work they've been doing, make sure that they've got this kind of backup resources in place to be able to do that is going to be very, very important as those healthcare systems work with governors, and frankly even where with Congress, making sure that CARES 3 and CARES 4 are accounting for this significant strain on hospitals around the country. So I hope that's helpful.

Q - Larry Biegelsen {BIO 7539249 <GO>}

That's super helpful. Chris, if I could just get one in on the vaccine for Paul. My understanding is, Moderna is targeting four times the base immunity. Paul, what's your understanding of the base immunity in effective COVID-19 patients? What level do you think you need for the effective vaccine? What are you targeting? Thank you for taking the questions.

A - Paul Stoffels {BIO 16443573 <GO>}

Well, I can't -- difficult to give a scientific answer for that because I don't think that's tested yet. But what we learned in -- from Zika, from Ebola, and other vaccines is that we get a strong humoral but also a cellular immunity with one injection. Especially in Zika we saw that. So we think that it can get to very high levels of protection with one single vaccine and that will give us an ability to then protect for longer terms, eventually boosting one year later, we think would be sufficient, but we are going to study that in large-scale studies in Phase 1 and that will start early September.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Thanks Larry. Appreciate the questions. Rob, next question please.

Operator

Your next question is from Joanne Wuensch with Citi.

Q - Joanne Wuensch {BIO 2379289 <GO>}

Good morning, and thank you for all the work that you're doing during this time and for all the information from modeling. It's really appreciated. I have two questions. The first one has to do with, as we think about procedures coming back in Medical Devices in your conversations with hospitals and physicians, and also experience during other economic downturns, which types of procedures generally come back first and recognizing this is a different lay of the land, but also I just want to think about ortho versus vision care versus surgical or anything that you can add there?

And I'll say my second question now, which is in your conversation with the FDA, what are you seeing or expecting to see in terms of clinical trial enrollment and FDA product approvals? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Okay. Hey, Joanne. This is Alex. Thank you for the first one. Look, what we're staying in the first case, and again, referring to my earlier comments is, I think that there is a keen sense among hospital executives and physicians of the need to try to return to a more normal state of surgery. As we see, our system to be able to work their way through this curve in the virus and that's being driven by the way for -- also a broad recognition that many of the procedures that are currently being delayed, will have an healthcare impact on these patients. And we also know, for example, that the -- the more of a significant hit the economy takes, we will likely lead to greater rates of uninsurance or under insurance and those studies were demonstrated in a poor economy, healthcare outcomes are poor. So these are not only economic issues but these are actually healthcare issues driving their desire to get back to work.

Also similar to Joe's point. I think every system is trying to decide what does that pace look like as they have to return to operating suites. Even some of their ambulatory surgery centers back to more elective procedures, that's not going to happen overnight. That's going to take some time for them to reestablish the system. I think there is clear recognition of that.

And then regarding the specific procedures, look, we would expect obvious areas such as oncology and general surgery to come back sooner. We would expect there to be also certain areas in orthopedics. While elective, they can have a significant impact on mobility and overall standard of living to come back in next. And then look, we think the longer-term procedures, perhaps cataract surgery and areas of like that, could be what I'd call a third tier. We also believe that the EP, the electrophysiology business would be one that we would also see a faster return too. I mean, there is some concerning data actually regarding the cardiovascular effects of COVID-19, and how that could manifest itself in some of these conditions. But at a high level. I think that's the way we're thinking about it today.

Paul or Joaquin, did you want to discuss the impact on clinical timelines?

A - Joaquin Duato {BIO 17056015 <GO>}

Yeah. Thank you, Alex. (Multiple Speakers) Go ahead, Paul.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Go ahead, Paul. Why don't you go?

A - Paul Stoffels {BIO 16443573 <GO>}

Yeah. On -- first on the regulatory, there are not -- at the moment, we have not got any information for regulatory authorities that the current issues on review timelines on our current submissions have changed. So that is -- that's going like planned. For our anticipated filings in 2020, we progress as planned. And at the moment, for the submissions that are fully recruited, our target, they will stay -- stay unchanged. And then maybe for the submissions that are continuing to recruit patients, we will evaluate in the next few weeks. Clinical trials, we do our best -- utmost best to keep going with minimal

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delays as we changing sides and to less impacted areas, as well as have different ways of reaching patients and working with the investigators. Alex?

A - Alex Gorsky {BIO 16239711 <GO>}

And Joanne and others, just one comment that I would like to make, more at the global level here too is, to acknowledge the great work that the FDA and frankly European authorities and others are making and partnering in an appropriate way to this pandemic. Our sense is that they have been extremely collaborative in helping to ensure that our ongoing clinical trials, the patient care is not interrupted, they're working with us on how can we make again appropriate adjustments along the way. So we've been really pleased by the partnering that we've been able to have with them, and I just think it's really important to acknowledge given all the other dynamics that are taking place right now that they're making that a priority.

Joaquin?

A - Joaquin Duato {BIO 17056015 <GO>}

Yeah, I would also add that this is going to be a particularly strong year for the pharmaceutical group in terms of approvals and submissions. In terms of approvals, in the second half of the year, we're expecting four key line extension approvals, one being DARZALEX subcu that we expect in the second quarter, very important for us and very important driver for DARZALEX. We also are expecting TREMFYA in psoriatic arthritis. It's going to give us the opportunity to be the only IL 23 with both psoriasis and psoriatic arthritis. We are expecting SPRAVATO in major depressive disorder with suicidal intend. And finally, we are also expecting IMBRUVICA in frontline CLL in combo with Rituximab. So four major line extension approvals in the second half of the year.

Additionally, this is going to be a very strong year for Johnson & Johnson in submissions. We submitted in the first quarter Ponesimod, a new NME for multiple sclerosis, and we plan to have three additional submissions also during the second half of the year. One is our BCMA CAR-T in relapsed/refractory multiple myeloma that has breakthrough resignation. The other one, niraparib in metastatic castration-resistant prostate cancer that also had breakthrough explanation. And finally, our latest one is our bispecific EGFR-cMet in non-small cell lung cancer that will be also submitted at the end of this year. That also has breakthrough designation. So very strong year from a filing and approvals perspective for the pharmaceutical group.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thanks Joanne. I appreciate the question. Operator, we have time for two more questions. I would ask folks to keep their questions to just one.

Operator

Thank you. Our next question is from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, good morning. Thanks for taking the question and thanks for all the work the company is doing on the COVID front. Would you be able to share any high-level perspective on what framework for reopening the country looks like and maybe what are the leading indicators that you're watching here to understand if you will need to potentially adjust your guidance again? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah, Terence. Thank you very much. And look, I'd also like to acknowledge the great work that I think our teams have done in trying to provide you with a very thoughtful, balanced and fact-based projection on what we're seeing in each of our markets. And again, it's been extremely rigorous using a number of quantitative as well as qualitative sources to -and hopefully the kind of transparency that you're -- you're hearing and you're saying on this call is indicative of the way we're trying to proceed to ensure that you've got as much information as possible to help understand what we're dealing with.

It's difficult to predict overall, but I would tell you that there are many efforts here in the United States, certainly with organizations like the Business Roundtable. There are others taking place on a global basis. And obviously, I think everyone believe the vision start with the science and the data on what we're seeing in terms of disease progression, particularly in some of the hotspots and what you're seeing in Italy and Spain, watching the ongoing issue in China, with an emphasis on what could happen in a round two or round three, as well as what we're seeing here in the United States, be it in New York City, Northern New Jersey, but also relative to other places. Frankly, we're seeing some guite encouraging signs such as California and other areas.

So understanding the data in terms of what is the rate of new patient infections versus the rate, for example, of discharges or deaths that are taking place, we think is an important factor. Next, it's also the availability of some of the testing kits available, both the front end with antigen testing, but at the back end with antibody testing. We're really encouraged by some of the work that we're seeing in the diagnostics area and the way the companies who stepped up to try to accelerate availability. Clearly, there were some challenges early on and there likely continue to be some challenges that the more that we can ensure the kind of capacity that's necessary with kids, with reagents, with swabs in these new testing procedures. We think that, again, that's going to give citizens and others a lot more confidence.

I think, third is going to be, we'll likely to be in a state where it will be a combination of testing and protocols for some time. Even as we return to work understanding that the workplace that our lives will be a bit different, but understanding that we can -- we can use that data and sometimes maybe even by new tracking devices in conjunction with the test kits, along with these protocols to form what I'd call a progressive or more gradual reentry, again, ensuring that we continue to build confidence, we continue to watch the data and we do that by the way while we're developing hopefully a therapeutic that would give us an opportunity to intervene in this disease in the coming months as you know.

The biopharmaceutical industry has invested billions of dollars over the past decade -several decades and it's not only Johnson & Johnson, other companies are doing tremendous work, working with regulators to see what can be done to accelerate that.

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And then, if we can have one or several of those in combination perhaps, later in the summer or certainly as we head into the fall, and then if we can get success with the vaccine, and again, we're certainly proud of the work that we're doing that Paul mentioned, but also by the other companies. This would give us a very comprehensive approach as soon as we head into the back end of 2020 and early 2021 that -- this is a disease that can be managed and one that will have a much better understanding and hopefully be able to put behind us at the right point in time.

A - Christopher DelOrefice {BIO 20730104 <GO>}

So do you want to comment on leading indicators related to guidance?

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

Yeah, I would think it really dovetails to what Alex outlined there in terms of returning to work, opening up the economy. We're going to look for those same telltale signs, how safe is the environment at large with respect to people's comfort level to going back being in social settings, going to hospitals to get procedures that they would might otherwise deferred during the time like this. So we'll continue to watch those on each weekly basis and the volume that comes through our major markets.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thanks, Terence. Appreciate the question. Rob, last question please.

Operator

The last question is from Louise Chen with Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thanks for taking my questions here. So first question I have for you is, could you provide more color on your variable cost structure and what's in that \$2.3 billion decline in spend for this year? And then secondly, how should we think about cash flow for 2020 and 2021 in light of your new guidance? Thank you.

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

Thanks for the questions, Louise. So with respect to what's in the \$2.3 billion that I referenced in my prepared remarks, those are expenses that we expect to naturally fall out as a result of the social distancing or stay at home measures, the work from home measures that have been instituted across the globe. So think of those in categories such as travel, company meetings, there will be some project delays naturally when people aren't on site to execute them. I want to be very clear though. We are not rushing to judgment and cutting valuable scientific programs, valuable initiatives within our commercial capabilities or programs that benefit our employees to manage our P&L in the short term.

As you heard me say, we think we're very well positioned for the long term. You heard from Paul, Alex, and Joaquin that our clinical trials for our major submissions this year continue to be on track. We are not looking to disrupt this. So we talk to investors

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regularly. They want us managing for 2, 5, 10 years out with a long-term perspective. And so that's what we're living into. We think that's appropriate given with the guidance we provided today and should the need arise we will look to course correct as appropriate.

With respect to our cash flow, clearly, we'll have a little bit of a hit to our original projections. But as a reminder, we are a strong generator of cash flow. Last year, we had an all-time high of about \$20 billion in cash flow. We were still up very well into the teens this year in all of our projections. We'll see how it plays out relative to this guidance, but was very well positioned with \$18 billion of cash and access to credit markets should we need them on a short-term basis, but we feel very comfortable with the position not just forgetting through 2020, but then being very strong into 2021.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thanks Louise. Appreciate the question. Thanks to everyone for your questions and your continued interest in our company. Apologies. I know we weren't able to get to a lot of you, but certainly the Investor Relations team is happy to engage with you in more detailed discussions and we appreciate your time on the call today. We'd hope you find this information valuable. And I'll now turn the call over to Alex just for some final comments.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, thank you once again everybody for your time and the work that you're doing. And I want to end where we started by once again acknowledging the significant impact this is having on citizens, on patients, on consumers around the world. We also believe that this demonstrates the importance of healthcare in everyone's lives. The impact that it has in a very personal way, on people, on families, but also the impact that it has on countries, on economies, on almost every aspect of our lives.

And what I can absolutely commit to you is that, when we say that Johnson & Johnson were built for time like these, it's out of humility, knowing the important role that we play in ensuring healthcare is available and accessible in a way where we can truly make a difference for billions of people around the world. So thank you very much and we look forward to our upcoming discussions and updates in the coming weeks and months. Bye everybody. Stay safe and stay healthy.

Operator

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

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