Q1 2021 Earnings Call

Company Participants

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

Other Participants

- Bob Hopkins, Analyst
- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- Joanne Wuensch, Analyst
- Joshua Jennings, Analyst
- Larry Biegelsen, Analyst
- Louise Chen, Analyst
- Matt Miksic, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's First Quarter 2021 Earnings Conference Call. All participants will be in listen-only mode until the question-and-answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time. (Operator Instructions)

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

Chris DelOrefice {BIO 20730104 <GO>}

Good morning. This is Chris DelOrefice, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for the first quarter and our updated financial outlook for 2021.

Joining me on today's call is Joe Wolk, Executive Vice President, Chief Financial Officer. Also joining Joe and myself during the Q&A portion of the call will be Alex Gorsky, Chairman of the Board of Directors and Chief Executive Officer; Joaquin Duato, Vice

Chairman of the Executive Committee; and Dr. Paul Stoffels, Vice Chairman of the Executive Committee and Chief Scientific Officer. 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.j&j.com where you can also find additional materials including today's presentation and associated schedules.

Please note that today's presentation includes forward-looking statements. We encourage you to review the cautionary statement included in today's presentation, which identifies certain risks and factors that may cause the company's actual results to differ materially from those projected. In particular there is uncertainty about the duration and contemplated impact of the COVID-19 pandemic. This means that the 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.

A further description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2020 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.j&j.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 I will review first quarter sales and P&L results for the corporation and the three business segments. Joe will provide insights about our cash position, capital allocation deployment and will spend some time on 2021 qualitative commentary and will outline our updated guidance for 2021. The remaining time will be available for your questions. We anticipate the webcast will last up to 75 minutes.

Now let's move to the first quarter results. Worldwide sales were $22.3 billion for the first quarter of 2021, an increase of 7.9% versus the first quarter of 2020. Operational sales growth, which excludes the effect of translational currency increased 5.5% as currency had a positive impact of 2.4 points. In the US, sales increased 3.9%. In regions outside the US, our reported growth was 12.2%. Operational sales growth outside the US was 7.3% with currency positively impacting our reported OUS results by 4.9 points.

Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 6% worldwide, 3.9% in the US and 8.2% outside the US.

Turning now to earnings. For the quarter net earnings were $6.2 billion and diluted earnings per share was $2.32 versus diluted earnings per share of $2.17 a year ago. Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were $6.9 billion and adjusted diluted earnings per share was $2.59 representing increases of 12.5% and 12.6% respectively compared to the first quarter of 2020. On an operational basis, adjusted diluted earnings per share increased 8.3%.

I will now comment on business segment sales performance 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 2020, and therefore exclude the impact of currency translation.

Beginning with Consumer Health, Worldwide Consumer Health sales totaled $3.5 billion, and declined 3.3% with declines in the US of 7.4%, a modest growth of 0.5% outside of the US. The Consumer Health results reflect negative comparisons due to prior year pantry loading and increased COVID-19 demand particularly in over-the-counter medicines.

Excluding the prior year COVID-19 comparison the Consumer Health segment grew low single digits in the quarter. Over-the-counter medicines declined 14.8%. Globally results were negatively impacted by the prior-year comparisons that previously mentioned coupled with continued impacts of social distancing restrictions, resulting in lower cough, cold and flu incidences partially offsetting declines were US share gains primarily in TYLENOL, ZYRTEC and PEPCID as well as strong performance of NICORETTE outside the US.

The skin health, beauty franchise grew by 2.8% driven by strong performance outside the US for NEUTROGENA and AVEENO due to new product innovations and strength in e-commerce. Results were partially offset by US COVID-19 related market contraction in makeup removal wipes. Consumers continue to focus on products related to personal health and hygiene including oral care, which grew 4.5% from continued growth of LISTERINE mouthwash due to category growth and strong promotions, partially offset by divestitures.

Worldwide growth excluding divestitures was approximately 8%. Additionally, the Baby Care franchise grew by 9.5% as a result of strength in Janssen's outside the US, primarily in the Latin America and Asia Pacific regions across all categories, coupled with the AVEENO baby growth in e-commerce globally.

Moving on to our Pharmaceutical segment. Worldwide Pharmaceutical sales of $12.2 billion grew 7.1% with strength in both the US increasing by 6.4% and OUS with sales increasing by 7.9%. Sales in the quarter included a small contribution in the US from Janssen's COVID-19 vaccine following its emergency use authorization in February.

Our strong portfolio of products and commercial capabilities continues to enable us to deliver strong adjusted operational growth at above market levels with seven key products realizing double-digit growth in the first quarter. Our immunology therapeutic area delivered global sales growth of 5.5% driven by strong double-digit performance of STELARA and TREMFYA offset by continued declines in REMICADE due to biosimilar competition. STELARA continue to show strength in all regions growing at 15.4% driven by increased market growth and share gains.

US share increased roughly 4 points in Crohn's disease, and nearly 10 points in ulcerative colitis. STELARA growth was partially offset by an unfavorable comparison to a prior

period pricing adjustment in Q1 2020 and an unfavorable comparison to increased sales in Q1, 2020 resulting from COVID-19 related longer script durations in the US and Europe.

TREMFYA grew 37.8% with strong double-digit growth in both the US and OUS driven by share gains in psoriasis of 2.7 points in the US continued global expansion into new markets and continued penetration into the psoriatic arthritis indication that was approved in 2020. Our oncology portfolio delivered another strong quarter with worldwide growth of 14.6%. DARZALEX continued its strong performance growing 42.2% driven by share growth across all lines of therapy and increased penetration of the subcutaneous formulation in the US and EU.

DARZALEX continues to penetrate the front line setting aided by recently approved line extensions to penetrate new patient populations posting nearly 3 points of share growth in line one in the US this quarter. ERLEADA continued its global momentum with growth of 79.7% in the quarter, driven by market share and penetration gains, especially in the metastatic indication.

IMBRUVICA grew 5.6% globally with increased volume growth driven by our market leading share and increased persistency as patients extend the duration of therapy. However, this was partially offset by the market contraction due to temporary COVID-19 impacts on new patient starts. Growth was also negatively impacted by one-time items, including the increased demand in Q1 of 2020 related to longer-term script durations in anticipation of pandemic related restrictions and higher levels of clinical trial volume in the same quarter last year.

Excluding the impact of these one-time events global growth for IMBRUVICA would have been double digits. In neuroscience, our paliperidone long-acting portfolio grew 6.9% driven by market and share growth due to increased new patient starts and strong persistency. Cardiovascular/Metabolism/Other declined 4.1% this quarter, driven by continued biosimilar competition for PROCRIT and competitive pressures in INVOKANA which was partially offset by growth of 11.7% in XARELTO driven by continued demand and a one-time favorable prior period pricing adjustment in the current quarter, which contributed over half of XARELTO's growth in the quarter.

Lastly, our total pulmonary hypertension portfolio achieved strong growth of 13.7% with OPSUMIT growth of 13.5% and UPTRAVI growth of 20.9% both driven by market penetration and share gains.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were $6.6 billion growing 8%. Growth versus prior year was primarily driven by market recovery from procedures impacted by COVID-19 along with continued momentum driven by commercial initiatives and our recently launched new products that are further enhancing our competitiveness across several areas of the business.

Additionally, selling days positively impacted worldwide growth by 190 basis points. We expect the full-year impact from selling days excluding the impact of the 53rd week in 2020 will be minimal, while recovery dynamics continue to vary across procedure type

and geography, our results reflect continued momentum with nine of our 11 priority platforms delivering global growth in Q1 with six of these delivering double-digit worldwide growth.

As you consider regional dynamics, Asia Pacific was the first region to be impacted by COVID-19 and experienced the most significant sales declines in the first quarter last year. Asia-Pacific realized strong market recovery primarily in China against this low sales base from the prior year. So that coupled with our commercial efforts to expand into Tier 2 and Tier 3 hospitals in China resulted in strong double-digit growth in this region.

COVID-19 remains a dynamic variable in the US. However, the market has been resilient and continues to recover resulting in growth of 5.4% in the US. Sales declined in Europe and Latin America where there continues to be a higher level of COVID-19 related mobility restrictions and procedure deferrals.

Looking at results for each of our platforms. Interventional Solutions delivered another quarter of strong double-digit growth. Electrophysiology grew 25.7% in the quarter, primarily driven by recovery in the market coupled with the strength of our broad based portfolio focus on commercial execution and introduction of new products such as an update to our CARTO 3 System and the CARTO PRIME mapping module, which further enhanced our market position globally. These new product introduction support improved mapping capabilities and reduce ablation time storing atrial fibrillation procedures.

Worldwide orthopedics grew 1.2% versus the prior year with continued COVID-19 impacts on procedure recovery. Worldwide trauma delivered growth of 9.5% reflecting market recovery and success of our newer product introductions that continue to support our market leading position in trauma such as the most comprehensive Cannulated Compression Headless Screw system on the market and the RIA 2 System designed for long bone grafts.

Hips return to worldwide growth this quarter, increasing 3.2% driven by market recovery and our continued leadership position in the anterior approach and demand for the active stem aided by our other enabling technologies in hip navigation.

Knees declined 9.9% globally, primarily due to slower market recovery in these more deferrable procedures in addition to some softness stemming from business mix dynamics. We are on track for commercialization of our VELYS robotic assisted solution for total knee procedures in the US. We believe the combination of this launch along with our differentiated VELYS Digital Solutions and ATTUNE knee platform including cementless offerings will enhance our portfolio and support improved performance as procedures continue to recover.

Spine declined 0.6%, reflecting the continued impact of COVID-19 on this market coupled with some one-time stocking reductions in China resulting from the consolidation to a national distribution model worth about 250 basis points globally. The decline was partially offset by success of recently launched products such as SYMPHONY, CONDUIT

and FIBERGRAFT, as well as partnerships, which further enhance our offerings such as the X-pack expandable cage.

Advanced Surgery grew 14.3% versus prior year with double-digit growth globally in Endocutters, Biosurgery and Energy primarily from robust growth in Asia, driven by market recovery and mortgage share gains due to new product launches, globalization of our portfolio including Biosurgeries, SURGIFLO plus Thrombin launch in Japan and commercial investments to expand our coverage in China.

In general surgery wound closure grew 12% globally with growth of 6.6% in the US, and 15.7% OUS results were driven by a recovery in the markets as well as continued strength of our market leading suture portfolio including the STRATAFIX barbed suture family.

US contact lens growth of 7.2% reflects the strength of our commercial execution and our market leading ACUVUE portfolio, including the recent launch of ACUVUE Oasis Multifocal lenses which were designed to provide clear vision at all distances. Channel inventory increases related to continued COVID-19 volatility and support of this new product launch contributed about 400 basis points to growth.

Growth outside the US of 0.9% reflects slower market recovery in Japan and Europe. Global surgical vision grew 11.2% due to a combination of recovery in both cataract and refractive procedures as well as continued strength of recent product introductions including TECNIS TORIC II and early success of TECNIS EYHANCE driving improved share momentum in both the US and OUS markets.

Now, regarding our consolidated statement of earnings for the first quarter of 2021. Please direct your attention to the boxed section 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 $2.59 reflects a reported increase of 12.6% and an operational increase of 8.3%.

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 product sold improved versus 2020 as a percent of sales due to favorable product mix in the pharmaceutical business and favorable volume and mix in the Medical Devices business. Additionally, the first quarter 2020 Medical Devices results included the establishment of a COVID-19 inventory reserve which did not repeat in 2021. Selling, marketing and administrative margins improved due to leveraging in the Medical Devices business resulting from the recovery of sales from the prior year's negative COVID-19 impact.

We continue to invest in research and development at competitive levels investing 14.2% of sales this quarter. This was higher than the first quarter of 2020 by 170 basis points, driven by portfolio progression in the pharmaceutical business. The other income and expense line showed net income of $882 million in the first quarter of 2021 compared to

net income of $679 million in the first quarter of 2020 primarily due to higher acquisition, integration and divestiture-related activity.

However, as a reminder, we treat significant divestiture gains as a special item and these gains are therefore excluded from adjusted earnings. Regarding taxes in the quarter, our effective tax rate increased from 11% in the first quarter of 2020 to 16.6% in the first quarter of 2021. This increase was driven primarily by the impact of one-time items in 2020 that did not repeat. Excluding special items the effective tax rate was 16.5% versus 15% in the same period last year.

I encourage you to review our 10-Q for further details on specific tax matters. Let's now look at adjusted income before tax by segment. In the first quarter of 2021, our adjusted income before tax for the enterprise as a percentage of sales increased from 35% to 37.1%. The following are the main drivers of change to the adjusted income before tax by segment. Medical Devices margin improved by 640 basis points, driven by inventory reserves recorded in 2020 associated with the impact of COVID-19 which did not repeat in the current quarter, and overall expense leveraging in 2021 resulting from the Medical Devices sales recovery.

Consumer health margins improved by 150 basis points, primarily driven by supply chain efficiencies including the benefit from our SKU rationalization program.

Pharmaceutical margins improved by 30 basis points, primarily driven by favorable product mix, partially offset by increased investment in research and development.

That concludes the sales and P&L highlights for Johnson & Johnson's first quarter. I'm now pleased to turn the call over to Joe Wolk.

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Chris. Good morning, everyone, and thanks for joining us today. When we spoke with you this time last year, we updated our full-year 2020 outlook with perhaps the highest level of uncertainty Johnson & Johnson had ever faced much like every other company in every other industry. COVID-19 cases were on the rise, worldwide lockdowns were in effect and most were adapting to new ways of working while maintaining productivity. No one knew how long the pandemic would last and demand forecasts were ambiguous at best.

However, what was crystal clear what we did know was that the resilience of our business, the strength of our financial position and an unrelenting long-term focus to develop and deliver our life saving medicines and products to patients and customers around the globe would likely lead to a better future. We are stronger as a business than before the pandemic and our first quarter 2021 results give us even more confidence in our ability to continue delivering compelling performance in the future.

Let me begin with our cash position and capital allocation priorities. We ended the first quarter of 2021 with approximately $9 billion of net debt, consisting of approximately $25

billion of cash and marketable securities and approximately $34 billion of debt. While our capital allocation priorities remain intact, the past year has reinforced the importance of managing our business for the long-term through a disciplined approach, and a focus on investments for innovation to further enhance our competitive positioning.

In addition to disproportionately invest in competitively in our R&D pipelines, we continue to evaluate and capitalize on acquisition opportunities when appropriate to create value over the long term. Paying our dividend and increasing it annually remains a key priority. Earlier this morning we announced that the Board of Directors approved an increase of the quarterly dividend for the 59th consecutive year by 5%. The dividend increase to $1.06 per share per quarter reflects our recent performance, strong financial position and confidence in the future of Johnson & Johnson.

An indication that our capital deployment is fortifying the foundation for our future is in part illustrated on this next slide which details pipeline developments that have occurred since our last call. I'll highlight a few starting with our Pharmaceutical business. First we received US approval and a positive opinion from the CHMP in the EU for PONVORY in multiple sclerosis. Our first NME approval this year.

In addition, we completed our BLA filing for Cilta-cel, a BCMA CAR-T for the treatment of multiple myeloma and we anticipate US approval later this year. As you know we are rigorous in focusing on differentiated transformational medical innovation despite showing proof of concept in initial phases of the study, we decided to discontinue the phase II development of Tesnatilimab an Anti-NKG2D monoclonal antibody for Crohn's disease based on insufficient efficacy in the trial.

Within our Medical Devices portfolio, the FDA granted approval for TECNIS EYHANCE a next generation intraocular lens. This represents the first significant innovation in monofocal technology in over 20 years. Johnson & Johnson's vision also announced a collaboration with Menicon to deliver therapeutic contact lenses that manage the progression of myopia in children.

We expect commercialization of this product by the end of 2021 under the brand name ACUVUE ability, pending health authority approval. We are excited to accelerate our entry into this growing an important space for patients while we continue to advance our myopia pipeline. As Chris commented too earlier, we are pleased by the first quarter results.

I'll now provide some insight into how we are thinking about the remainder of 2021. So, let's start simply with we remain confident in our business. Our Pharmaceutical segment is on track with our expectations and in 2021, we expect to deliver a 10th consecutive year of operational above market growth.

Importantly, this growth is volume driven not dependent on price. You may have noticed that we issued our 5th annual Janssen US transparency report last week. While I am admittedly biased, this is a very informative read and you'll not only see the average price

for our products declined by nearly 6% in 2020, but how more than $29 billion of rebates and discounts were allocated.

In consumer health prior-year comparisons will be choppy by quarter throughout this year due to the COVID-19 pantry loading and demand surges experienced in 2020. However, we continue to expect to grow with the market for the year in those areas in which we compete driven by our strong iconic brands that consumers rely on every day. We will also continue to focus on maintaining our enhanced margin profile, driven by our SKU rationalization and investment optimization programs.

In Medical Devices, better execution, new innovative offerings and market recovery led to growth in the first quarter. However, market variables such as patient willingness to seek care, insurance coverage and unemployment rates along with the easing of mobility restrictions will influence the rate of recovery as we progress through the year. Despite those uncertain dynamics, we remain confident in the full-year outlook we had in January.

Let me say a few words related to our COVID-19 vaccine. Our goal has always been to bring our scientific capabilities and resources to develop a safe, effective vaccine that would complement other measures to end the global pandemic. To ensure broad access, we announced early on that we would supply the vaccine on a not-for-profit basis during the crisis period. Given the not-for-profit commitment as previously stated, we never anticipated COVID-19 vaccine revenue would have a significant upside impact 2021 adjusted EPS, already projected to grow at 18%, or 1.8 times greater than sales growth.

Paul will say a few words at the conclusion of my remarks on our COVID-19 vaccine. Regarding vaccine financials please note that we commit to providing timely updates to actual results and guidance as warranted. Considering the qualitative factors I just referenced here is what we expect for the full year 2021.

Starting with sales. On an adjusted operational basis, we are increasing our guidance and tightening our range to reflect the ongoing confidence in the business to a range of growth to 8.7% to 9.9%. This adjusted operational sales growth is on a constant currency basis consistent with how we manage our business performance.

We are maintaining our estimate for the net impact of acquisitions and divestitures of approximately 50 basis points resulting in operational sales of $89.3 billion to $90.3 billion, or 8.2% to 9.4%. While we don't offer predictions on currency movement utilizing the euro spot rate relative to the US dollar as of last week at 1.19 results in a still favorable, but to a lesser degree currency impact of $1.3 billion or a year-over-year increase of 150 basis points resulting in estimated reported sales in the range of $90.6 billion to $91.6 billion, an increase of 9.7% to 10.9% or 10.3% at that midpoint versus 2020.

Regarding the balance of the P&L, we are maintaining the guidance we offered in January for all other items for which we routinely provide guidance. We are however comfortable tightening our range by raising the lower end, resulting in increasing the midpoint of our adjusted operational EPS by $0.03. Therefore, our new adjusted earnings per share guidance range is $9.30 to $9.45 on a constant currency basis, while not predicting

currency movements, but to provide some direction on the impact of currency fluctuations on our reported adjusted EPS the estimated benefit is now $0.12 versus $0.15 for the full year.

Accounting for that we would be comfortable with your models reflecting reported adjusted EPS ranging from $9.42 to $9.57 or a midpoint of $9.50 to a range of 17.3% to 19.2%. We don't provide quarterly guidance, but do appreciate that you find value in us providing some qualitative considerations to keep in mind as you update your models.

This slide looks rather similar to what we shared in January with the most noteworthy call out being the negative impact of COVID-19 experienced in the second quarter of 2020 particularly in Medical Devices. It is reasonable to infer that the second quarter of 2021 should have highly favorable comparisons in Medical Devices.

Let me close our prepared remarks by acknowledging the Johnson & Johnson colleagues and all they have overcome, but more importantly accomplished over the last year. Driven by our credo their unrelenting dedication to continue meeting our commitments to all stakeholders has been inspiring. On behalf of the entire executive team to all 135,000 employees around the world. Thank you.

Paul, Chris and I are pleased to be joined by Alex and Joaquin to address your questions. But before we begin the Q&A, let me turn the call over to Paul.

Paul Stoffels {BIO 16443573 <GO>}

Thank you, Joe. And I'm pleased to provide an update on our COVID-19 vaccine, and our efforts to address the ongoing pandemic which today has taken the lives of more than 3 million people globally. From the very beginning, we have worked to develop and deliver a Single-shot easy transportable COVID-19 vaccine to help protect the health of people everywhere and reach communities in needs globally.

We are committed to equitable access and to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for the emerging pandemic use. In last quarter we announced results from our multi-country Phase III ENSEMBLE study that demonstrated the vaccine was 85% effective in preventing severe disease across all regions studied and showed protection against COVID-19 related to hospitalization and deaths beginning day 28 after vaccination.

The vaccine has demonstrated protection across all countries studied and with multiple variance of the virus, including the B1.351 variant. Based on the robust data we submitted to health authorities, we received emergency use authorization from the US Food and Drug Administration, a conditional marketing authorization from the European Medicines Agency and the emergency use listing from the World Health Organization.

We began US distribution in March with plans to begin shipping to Europe in April. In addition, given the threat of variance, we collaborated with the South African Medical Research Council on the Sisonke study an open label Phase 3B vaccine implementation

study among 500,000 frontline healthcare workers in South Africa, where the B1.351 variant has become dominant and where there is limited supportive care of, or wide availability of COVID vaccines. This variant now makes up more than 60% of cases across this African continent and has been detected in more than 60 countries globally.

A Single-shot vaccine with demonstrated protection against COVID-19 related hospitalization and death can be critical tool for fighting the global pandemic particularly with protection across countries with different variants. Last Tuesday, the US Centers of Disease Control and Prevention Advisory Committee on Immunization Practices, or ACIP review to reports of an extremely rare disorder involving blood clots in combination with low platelets observed in a small number of individuals following vaccination with the Johnson & Johnson COVID-19 vaccine.

Out of an abundance of caution, the CDC and FDA recommended a pause in the use of our vaccine in the US. ACIP will reconvene this Friday and we look forward to their review and the outcome of the meeting. Johnson & Johnson made the decision to proactively delay the rollout of our vaccine in Europe and boost vaccinations in all COVID-19 vaccine clinical trials while the updated guidance for investigators and participants.

On the safety and well-being of the people who use our product is our number one priority, and we strongly support awareness of the signs and symptoms of this extremely rare event to ensure the correct diagnosis, appropriate treatment and expedited report by healthcare professionals.

We continue to believe in the positive benefit risk profile of our vaccine and in view of the raise raging pandemic that continues to devastate communities around the world, continue to collaborate with medical experts and global health authorities, including the CDC, FDA, EMA the WHO and the South African Health Products Regulatory Authority, SAHPRA as we work towards continuing vaccination to end the global pandemic.

We welcome the recent recommendation of SAHPRA to lift the poles in the investigator-led to collaborative Sisonke study, provided that specific conditions are met. SAHPRA based this decision on a review of the availability -- available safety data from Sisonke study, as well as adverse event reports in the United States. We look forward to partnering with the South African Ministry of Health to resume vaccinations of healthcare workers in South Africa soon.

We are looking forward to the outcome of from today's meeting of the European Medicines Agency, Pharmacovigilance Risk Assessment Committeem, the PRAC as this called and so looking forward to working with AMAG to ensure appropriate awareness of this extremely rare event and guidance on diagnosis and treatment of this condition.

Johnson & Johnson stands ready to resume shipment of its COVID-19 vaccine in Europe. In addition, we will work with member states to resume vaccinations in all the Janssen COVID-19 vaccine clinical trials in Europe. We remain committed to supplying 200 million doses of our COVID-19 vaccine to the European Union plus Norway and Iceland.

Moving on to manufacturing. The quality and safety of our COVID-19 vaccine is paramount. In April 3 we announced we would increase our oversight of drug substance manufacturing at the Emergent BioSolutions' Bayview facility. Since then, we have worked closely with the US government and with the FDA, including during the ongoing FDA inspection at Emergent Bayview. We will work closely with Emergent and the FDA to address any inspection findings.

Our goal remains ensuring all drug substance for our COVID-19 vaccine meets our high-quality standards and securing emergency use authorization for the drug substance manufactured at Emergent Bayview. We remain committed to delivering 100 million Single shot doses of our COVID-19 vaccine to the US government and helping to bring an end to this global pandemic.

In conclusion, I want to note that COVID-19 is the most severe global health challenge we have seen in our lifetimes. Johnson & Johnson is committed 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 start the Q&A.

Chris DelOrefice {BIO 20730104 <GO>}

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

Questions And Answers

Operator

Yes. (Operator Instructions) Your first question comes from Chris Schott with JP Morgan. Please proceed with your question.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much, and I appreciate all the color on the business dynamics here. I just had two questions centered around the vaccine. I guess first, how do you see this causing risk issue being addressed? Is this going to be just some sort of safety warning to physicians, or do you think there's going to be a way to identify certain populations with this might not be an appropriate vaccine? And maybe tied to that, how are you thinking about addressing public safety perceptions given what seems to be a very rare side effect, if in fact even linked your once vaccinations resume?

I going to slip another quick one on vaccines. And I just want make sure I'm clear as well. On the guidance for 2021 are there vaccine sales beyond Q1 reflected in that guidance? Or just given some of the uncertainty is that not included in the updated guidance? Thanks so much.

A - Paul Stoffels {BIO 16443573 <GO>}

Yeah. Let me take the first question. We are working very closely both with FDA CDC as well the EMA and the PRAC on addressing your first question on risk and whether there will be guidance, and we will work closely if that comes out in the course of the week to implement that the globally, but also restore the confidence in the vaccine. This is extremely rare event. We hope by making people aware, as well as putting clear diagnostic and therapeutic guidelines in place that we can restore the confidence in our vaccine.

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

And Chris, with respect to financial guidance there is nothing in our future outlook with respect to that at this point in time. So we will, when it's warranted certainly provide updates. Right now we're just commenting to what was actually experienced in the first quarter. Thanks for your question.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

Operator

Your next question comes from Larry Biegelsen with Wells Fargo. Please proceed with your question.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning, thanks for taking the question. Just two quick ones for me. Joe, can you talk a little bit, your medical device sales came in better than our expectations. Can you talk a little bit about what you're seeing in the end markets with regard to the recovery?

And can you also secondly, talk about the quarterly EPS phasing.Why didn't you raise EPS guidance more despite the beat Q1 EPS is usually about 24%, 25% of full year EPS whereas the guidance implies Q1, EPS is about 27% using that mid point. So, why not raise the guidance more? Thanks for taking my questions, guys.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey, Larry. Thank you very much for your question. This is Alex. Why don't I go first? And look before I respond directly to your question, I just want to give a special shout out to all of our front-line heroes especially the 50,000 plus or minus associated to Johnson & Johnson, who have been consistently going to work, putting on their mask on the supply-room floor, on the shop floor manufacturing and really enabling us to continue to serve patients and consumers around the world, throughout this pandemic.

Two, a very special recognition to the doctors, the scientists, the engineers who have not only been working diligently on our approach to COVID-19, but also to keep our ongoing innovation portfolio on track and we're very thankful to them. And last but not least, all of our associates who really worked in a very agile, flexible and dedicated way throughout this period.

I think our results overall today demonstrate that in spite of a lot of variability, unpredictability that Johnson & Johnson remains a very consistent and in fact stronger performer today than we were even a year ago. If you look at our competitive position, whether it's market share on all of our major $28 billion plus platforms, if you look at our pipeline progress and development, we clearly have continued to make progress in spite of a lot of other dynamics.

So, getting specifically to your question on medical device marketplace we would say is, we're seeing continued improvement through the first quarter. If we look at the last couple of weeks of March in the United States most of the major systems are somewhere in the range of 90% to 105% of their performance back in 2019. If we look across Europe, of course, there is a bit more variability. Markets in Italy, for example, have lagged given the outbreak of COVID -19. In the UK where you've seen other markets return more in the 90% to 100% range. Although we have continued to see month to month, and even week to week progression across those major markets.

As was alluded to in the earlier comments, we would expect that to begin to change in a pretty significant way in the second quarter, not only as we see more vaccinations, but of course the year-on-year comparisons. And again, what I'd like to highlight is the strong performance across almost all of our medical device platforms. If you take a look at vision surgery, up 11%. If you take a look at our EP business up 26%. Our surgery business as well up into double digits across whether it was Energy, Biosurgery or Endomechanical. Orthopedics, particularly large joints we saw lag slightly but we know that these are more elective procedures. We feel we remain competitive and we're quite excited about our VELYS launch, as well as our fixed bearing cementless options as well.

So we remain confident and actually quite optimistic for our ongoing improvement in performance in our medical device sector as we head through the remainder of the year.

Joe, I'll hand it over to you for the question on EPS raising.

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

Sure. Thanks, Larry. Thanks for the question. And as usual, you have all the numbers at the ready there. So, I think I got them all down but I think the real short story is that I would say on 10% sales growth we're going to grow earnings, about 18%. And so, given the early nature of the year we challenged our leadership teams in each of our segments and across our functions to see what we can invest today to benefit the future.

So I'd much rather hold back a nickel today and hopes of giving $0.10 or $0.15 next year, the year after. And that's really how we're looking at it. As we have many great opportunities and hopefully you noticed in our P&L the increase in R&D investment year-over-year by $600 million. You saw the same trend last year for the full year.

We're going to look to seize those opportunities given we already started the year with very strong expectations. If some of those opportunities don't come to fruition, we'll certainly be happy to revise guidance upward later on this year. But right now we thought that was the best course of action to solidify the long-term.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

Operator

Your next question comes from Joanne Wuensch with Citi. Please proceed with your question.

Q - Joanne Wuensch {BIO 2379289 <GO>}

Good morning, and thank you for taking the questions. I want to focus on two areas. The first one is in Vision Care. And I'm trying to parse through, how much of the delivery is easy comp share loss and/or gain and just recovery in elective procedures? And then I want to sort of put the second one on the table, which is --it sounds like orthopedics particularly is lagging. If you'll review on when that may recover? And just more broadly speaking is there a pattern to segment recovery that you anticipate throughout the year? Thank you.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey Joanne. This is Alex. Thank you very much for your question. Look in Vision Care overall, we think our performance was solid. We have seen the contact lens business and the surgery business be significantly impacted with the course of 2020 we have seen gradual improvement in the back end of last year as we started out the first part of this year.

We think our Vision Care or contact lens business is in very good shape. We think our share position is stable to increasing, and we think we've seen a definitely an improving position in our Vision Surgery business. Part of that being comps, but also part of it due to new innovation launches that were mentioned earlier in Chris's and Joe's comments and we believe that our lineup for new lenses, whether it's our anti-allergy lens or multifocal and contact lenses or in the improvement that we're seeing in our surgery business will continue to bear out in stronger performance and in share gains through the year.

Regarding orthopedics, as noted in our comments, we saw very strong performance for example in our trauma business growing in excess of 9%. We saw good rollout in our hip business at about 3.5%. And as I mentioned in my comments knees, which we think are perhaps the most elective of the procedures in terms of being able to delay we're lagging somewhat, but the indicators are that we would expect and based upon some of the surgical planning reports that we saw especially through the end of first quarter that it looks as though performance for second quarter and third quarter should be on good trends and we would expect that to improve as patients gain confidence to go back into the hospitals.

And we see systems work their way through backlogs. And as of course, in our business being global as we see Europe come more back online as well following vaccinations as we move through the second and third quarters. Thank you.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

Operator

Your next question comes from Bob Hopkins with Bank of America. Please proceed with your question.

Q - Bob Hopkins {BIO 2150525 <GO>}

Okay. Thank you, and good morning. Joe, I was wondering if you could comment on how your 2021 EPS guidance might look if you exclude the impact of COVID reserve release and the spending on the vaccine? Just wanted to kind of maybe get a sense for EPS for the true underlying business? And I'll just state -- the second topic I'd love you to comment on, as well as just wanted to get your latest thinking on the potential to the shift to more of a for-profit model as we potentially exit the Emergent phase. I realize it might be a little early to talk about that, but just wanted to get your latest thinking on the potential to shift to more -- to shift post the Emergent phase of this pandemic. Thank you very much.

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

Thanks for the questions, Bob. With respect to the impact of I'd say COVID-19 vaccine investing in the quarter, it was -- let's call it between $0.05 and $0.10 for the quarter. I'm not overly concerned about that, because as you heard from Paul, we are going through the rigor of these scientific reviews. It appears that there is a very path forward that we'll find out about here in the next couple of days, and we're going to do all we can to make sure that important solution to address the global pandemic it gets back into the marketplace.

So we think we'll recover that even in the not-for-profit model. With respect to pricing and dynamics, I think you're probably correct in your initial assessment that it's a bit early, but let me turn it over to Joaquin to give you some thoughts that we have on that topic.

A - Joaquin Duato {BIO 17056015 <GO>}

Thanks for the question. Our focus from the beginning in this pandemic was to be a partner in addressing this humanitarian crisis. And as a consequence, in order to make sure that we facilitate access globally, we decided to go with a non-profit model. Our focus now remains to be able to be a participant in addressing this pandemic, and once this pandemic is over there will be time to discuss different options.

But today, our focus is to address this pandemic and be an important partner in making an impact globally in stopping COVID-19.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

Operator

Your next question comes from Josh Jennings with Cowen. Please proceed with your question.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi, good morning. Thanks for taking the questions. I had a follow-up to Bob's question just on the vaccine and just how revenues and expenses flow through the P&L. Just wanted to make sure are sanity check the 100 million doses by mid-year in the US 100 million more by the end of 2021, 200 million doses in Europe for instance. Are those guaranteed contracts? And just in terms of the risk-sharing model and the non-profit model just want to make sure that you're downside is protected in terms of expenses going forward that are already incurred? And where those contracts sit?

A - Alex Gorsky {BIO 16239711 <GO>}

Yeah. Thanks for the follow-up, Josh. Yeah as you can imagine, it is very fluid, but there is nothing in the guidance today that should give analysts or investors concern about any downside with respect to this. Again we're hope -- we're cautiously hopeful that there is a very viable path forward. We'll learn a lot more in the next couple of days through the regulators, let the process play out. But investors should feel very comfortable with our EPS guidance to protect against any downside that may be envisioned, although I don't see that is likely at this point.

A - Chris DelOrefice {BIO 20730104 <GO>}

Yeah, I mean maybe just want to add on as it relates to Bob's question and, Josh, your question too. I mean, just keep in mind when you look at our underlying performance, -- is a segment which was less impacted topline strong above market and we continue to improve margins there as well. And you did see margin improvement as well in consumer. So while there certainly many impacts from COVID year-over-year, I think when you really look underneath the underlying results their strength, both on the top line and bottom line that's factored when you look at this year.

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

That's a good point, Chris. And I think this is going to be a choppy year. So we have to look selectively at year-on-year comps. And if you just look at let's call what was a normal quarter at least as we know it back in the first quarter of 2019 you look at our respective businesses. You have consumer is up about 8% this quarter versus first quarter of 2019.

So again that suggest of the strong underlying business. Pharmaceuticals is up about 17.5%, and Medical Devices is approaching 4% on that same comparison. But I would say that's a very strong 4% when you consider we still have as you heard in our commentary many delayed procedures or paused elective procedures in the marketplace which simply didn't exist in the first quarter of 2019.

So across all three parts of our business I think there is a real good take away there that the business is healthy and strong you couple that with the investment, we continue to

make in R&D at elevated levels, I would hope folks feel really good about not just our performance of today, but our future performance on the horizon.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you. Thanks, Josh. Rob, next question please.

Operator

Next question comes from Louise Chen of Cantor Fitzgerald. Please proceed with your question.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions. So, my first question was do you have any thoughts on potential corporate tax increases in the US as well as potential drug pricing reform? And then second question is on (inaudible) I know you're expecting approval this year, where do you expect it to fit into the treatment paradigm if it is approved? And do you expect CAR -Ts to gain wider usage over time? Thank you.

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

Great. Louise, thanks for the questions. I will address tax reform as best I can obviously that's a fluid situation. Then I'll turn it over to walk Joaquin and Paul for your other questions.

With respect to tax reform we've shared a lot of rhetoric about a race to a bottom. I don't know why folks are anxious to have a race to the top in terms of rates either. And I can give you one example in one industry and that's Johnson & Johnson where when tax reform was passed in 2017 we committed to increasing our investment in the US by 15% over the upcoming four years versus the preceding four years. We are on track to actually invest about 25% more in the US over that four-year period and that's more than $30 billion.

Now what does that mean in terms of the US economy? It means more jobs. I mean, as Johnson & Johnson employees 3,000 more people today than we did before the passage of the 2017 Act. So, I think when you look at where the US sits with respect to OECD countries, right now we're at the middle of the pack, maybe even skewing a little bit towards the bottom in terms of competitiveness. If we were to raise rates even to 25%, and you include tax from states we become the highest rated developed country in the world with respect to tax rates.

So, I think it's something that we need a little more fact based dialog on and making sure that we remain competitive that the US becomes a source of innovation across all industries and we don't afford the innovation and competitive spirit that has been successful over the recent times. Even in addressing many of the concerned and solutions with respect to COVID-19 we've seen in the past year where many US based companies have stepped up.

Joaquin let me turn it to you address the other items.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. So with regards to pricing reforms in the US that was your question, Louise. So we continue to expect that there will be pressure to do something to reduce patient out of pocket costs. And in that context, the industry could potentially be seen again as a pay for in another budget reconciliation package for AC reform or infrastructure legislation. We believe that the negotiations in that regard could be collaborative and that the overall value that innovation its bringing to society as highlighted by our contributions in COVID-19 will be understood. So, that's the way we see it.

Now, we think that the most important thing in any price bill, or any price reform is to be sure that patients experience an reduction in an out of pocket cost and Johnson & Johnson will be a constructive partner in that regard. We think that also that patient cost sharing should be based on the net price of medicines and in that sense, we continue to support that type of reform.

I also want to take a step back and look at our pharmaceutical business in the context of pricing reform. I believe that the type of portfolio and growth that we have placed out very well in this situation. Our growth has been based on volume. Our net price declined in 2025.7%[ph] and this is the fourth consecutive year that we have net price declines and we are able and ready to growth in that environment based on having a very broad based portfolio with 11 products of more than $1 billion and R&D based model that allow us to have a very differentiated pipeline. In 2020, we invested $9.6 billion in R&D, which is about two times what we invest in sales and marketing.

So we believe that these negotiations could be collaborative and that in that context the Johnson & Johnson pharmaceutical business is especially well positioned based on our ability to drive growth based on volume and in our very broadly diversified portfolio.

So about our BCMA CAR-T that we file in the first quarter of 2020, that was an important milestone in our pipeline. Our initial indication, it's going to be for patients with multiple myeloma that have progressed on available established therapies. Over time we see BCMA CAR-T, and our BCMA CAR-T specifically progressing into earlier lines of therapy. You could see a moment in which patients may have BCMA CAR-T as after lines therapy in an intend to build regimens that are curative. Paul? Yeah. From the beginning the selective BCMA CAR T-based on its double binding and that has yielded a superior profile with -- in the high '90s overall response rates as well as very high MRD negativity rates and lasting effect. And so we think this CAR-T is very strongly positioned in the market and hope to get approval in the second half of the year.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Paul. Thanks, Louise. Appreciate the question. Rob, next question please.

Operator

Next question comes from Danielle Antalffy with SVB Leerink. Please proceed with your question.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning, everyone. Thank you so much for taking the question. I have two questions. One is really on the devices. And I think Joe you alluded to this when you were talking about growth comparisons to 2019. But, there was still a COVID impact in Q1, and I guess I'm just trying to get a sense of how Q1 sort of shaped up as you work through the month. Did you see a strong recovery in March in the device side of things? And do you feel like, and this might be an ambiguous and kind of difficult question to truly answer, but I guess, do you feel like the worst is behind us even regardless of how vaccinations continue to rollout? And what variants might do? And then I have one vaccine follow up.

A - Alex Gorsky {BIO 16239711 <GO>}

Hey Danielle, this is Alex. Thanks a lot for your question. We do there expect to see improving trends in our Medical Device arena. If we take a look at the first quarter, there was some irregularity just based upon what we are seeing with the virus and on a global basis in January versus February, March. But overall, it's clear to us that we're seeing improving trends. And as Joe alluded to in his earlier comments, we would expect that just given year-on-year comps, plus what we're seeing underlying both in the United States and Europe in terms of procedure scheduling, confidence in returning to the hospitals and overall surgical volumes we would expect those to improve through second, third quarter of this year.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Okay, that's helpful. And then on the vaccine side of things as it relates to manufacturing, and what are the alternatives for the volumes that were supposed to be manufactured out of Emergent, if in a worst-case scenario Emergent is prevented from being able to produce for the next few months?

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you, Danielle. Look, as Paul said our goal remains ensuring that all the acceptance for our COVID-19 vaccine meets our high quality standards and at the same time that we secure emergency use authorization for the drug substance manufacturer at the Emergant Bayview facility. At this time as we continuing discussions with the FDA, it is premature to speculate on any potential impact that this may have on our timing of our vaccine deliveries.

So we will expect to work with the FDA to work this inspection this to close this inspection this week and then we will work with the FDA, and Emergent to address those inspections findings. But at this time, it would be premature to speculate on any potential impact that this could have on our delivery timing.

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

Great, thanks. And then just real quick to build on Alex's comments. Maybe just to give you a little bit of color. We're obviously looking at procedures closely, surgical procedures imaging as well. Diagnostics is actually outpacing surgical procedures, it accelerated through the quarter. It's almost in line with where we were pre-pandemic. So that's a positive sign although the situation of course remains fluid, and then many important procedures such as colorectal, again sequentially improved through the quarter and actually grew year-over-year.

So again, we're seeing positive signs across, and I think you saw that in our results in pockets of our business as advanced surgery for example, growing over 14%. So, we're continuing to look at everything. The situation remains fluid, but there is definitely positive signs of the trends that we're seeing.

Thanks, Danielle. Rob, next question please.

Operator

The next question comes from Matt Miksic with Credit Suisse. Please proceed with your question.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks so much. So, I've got one to utilization-related question and procedure trends and a follow-up for Alex if I could on digital strategy. And so first devices up 8.8% stronger than we was expecting. The mix also a bit stronger than expected on the advanced surgery and maybe a little bit slower, as it has come up in Q&A here than expected and Knees as you mentioned Alex is couple of times is being more deferrable. The question is, should we read through this as a bit of a shift to higher acuity procedures at least within your portfolio? And then maybe how should we see the recent rise in hospitalizations potentially affecting the trajectory of recovery over these procedures over the next months and quarters? And then as I mentioned I've one follow-up on digital.

A - Alex Gorsky {BIO 16239711 <GO>}

Sure, Matt. Thanks a lot for the question. Look Matt overall, I wouldn't read too much into just these recent results regarding a significant shift overall in our portfolio. I mean, we remain very committed and optimistic about the underlying unmet need and demand across our surgical portfolio, our orthopedics portfolio and our Vision Care portfolio. But as we alluded to earlier, there are some procedures that in terms of your ability to differ and how elective they truly are that may have near-term impact on timing.

So look overall, if we look at our underlying trends not only versus 2020, but as was noted earlier also versus 2019 we're seeing growth rates consistent overall with what we see for this market. We think this market has the opportunity to grow at about the 5% range over the long term, and we've been very explicit in our goal to grow at, or faster than the markets where we compete. That's number one.

Number two we're actually very excited about some of the opportunities that we have for launches. I think in total, we have more than 21 major launches lined up in our Medical Device business for this year. We mentioned specifically in the Knees area VELYS as well as our ATTUNE cementless fixed bearing, which we think will offer us a real competitive opportunity to generate additional growth in that area. The QDOT MICRO is another great add-on in our EP business that is already growing in excess of 20%.

And if you look across our Endo Mech or Energy business here too we've got really nice add-on innovations as well as throughout our Vision Care portfolio. And of course longer term, the significant opportunity that we see in digital surgery that team has continued to make very solid progress and we're excited about the long-term prospects there as well.

So overall, we see a lot of opportunity across our Medical Device portfolio.

Q - Matt Miksic {BIO 6990080 <GO>}

That's great. And maybe just a segue on your second point there about digital. You mentioned robotic knee systems on track. Monarch obviously leading the market in robotic assisted lung and Ottava is sort of tracking through clinicals and validation. The question is what else you've built out this portfolio of artificial in some artificial intelligence robotic surgery applications and technology. What are the white spaces, where else do you see investments within digital?

A - Alex Gorsky {BIO 16239711 <GO>}

Sure. Look we believe that we're in the very, very early innings of digital, Matt. First of all, if we just look at the overall penetration rate of digital surgery, it's about 10% in the United States. It's just a couple of percent on a global basis. And so we think if you consider the overall trends of how technology can be utilized in some of these procedures, if you take a look at our global footprint, we think we will be well positioned there in the long term.

As you mentioned, our team has continued to make good progress. We said from the very beginning look, we're building this for the decades. We're not just building this for the next quarter. And we're optimistic about the progress of that team has been making to ensure that we've got a platform that one can truly make a difference for patients and surgery, the two that's differentiated. And three that also allows us to integrate not only the robotics aspect, but also the digital component that we think long-term can truly help show very significant differences in surgical outcomes.

And also just to give you one example of an application. We've mentioned this before but in Johnson & Johnson right now, I think this exemplifies the unique nature of our diverse portfolio. Several years ago we embarked on something that we call the lung cancer initiative. As we know unfortunately lung cancer continues to kill more people than just about any other type of cancer.

And we know that all too often patients are diagnosed far too late in the process, and we are quite excited about an early application with Monarch, where we're not only able to go out and potentially do a diagnostic procedure through bronchoscope to identify for

example lung nodules, but we're working right now on how can we deliver oncolytic agents, viruses and other immune type agents locally. And how could we really think about the treatment paradigm being shifted in the way that we fundamentally think about lung cancer by combining pharma, medical device, some of these technologies and very new unique and innovative ways.

So there's still much more work to be done, but we're very excited about some of the early prospects that we've seen thus far. And again, I think it exemplifies kind of our unique position to bring these different clinical development, discovery, as well as regulatory capabilities and eventually commercial together.

A - Chris DelOrefice {BIO 20730104 <GO>}

Great. Thanks, Matt. I appreciate the question. Rob, will take our last question now.

Operator

Yes. The question comes from the line of Terence Flynn of Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, good morning. Thanks for taking the questions. Recently, there has been some new post-marketing data reported for (inaudible) and the FDA pushed out the PDUFA dates of several JAK inhibitors. You guys are developing a pan-JAK inhibitor for IBD. Would just love your latest perspective on the risk benefit profile of the category here and next steps and your development program? And then just as a follow-up just wanted to confirm that you're on track to supply a billion doses of your COVID-19 vaccine this year? Thank you.

A - Joaquin Duato {BIO 17056015 <GO>}

So, thank you for the question on immunology. Look, I'm not going to comment on the safety of the oral JAK inhibitors. What I can tell you is that we have a very strong and robust pipeline in immunology driven by our three existing assets SIMPONI, STELARA and TREMFYA. STELARA and TREMFYA had very strong quarters with close to 40% growth in TREMFYA and 15% in STELARA. In STELARA we continue to grow share in GI both in Crohn's disease and ulcerative colitis. And TREMFYA is the first and only IL-23 that does have both indications PSA and PSO, and it continue to gain share in both areas.

Moving forward, we are excited about our possibilities in immunology with our rollout agents as you mentioned, one we have two in Phase 2. One of them is pan-JAK oral that we think could be important. We'll have to see the data and broadly in immunology we also are excited about the possibilities of nipocalimab which is our FcRn antibody in pathways that are how to antibody mediated with very rare diseases that could create a pipeline in a product.

So for us, immunology remains a core area of growth and focus and we believe we are in a very strong position to continue to drive growth, in the coming years, but even beyond 2025 too.

A - Paul Stoffels {BIO 16443573 <GO>}

Maybe Terence just to pile on to what Joaquin outlined there with the strength of our pipeline. So in Pharmaceutical specifically, we're looking at 10 new filings that will be new products or indications in 2021, 13 in 2022 and 26 in 2023,. So you can see that R&D investment incrementally paying off. With respect to your second question regarding supply, I want to be respectful of the process by which the regulators are going through. We are remediating what we need to remediate. We think that will lend itself to a positive outcome and should put us in a position to meet all of our contractual commitments as they stand today, but let's be respectful of the process and let that play out. We're going to do all we can and provide that effort. As you know, and as you've heard in the press we do have some of our best personnel on-site at Emergent. So they're benefiting from our expertise, and we should know more in the next couple of days.

A - Chris DelOrefice {BIO 20730104 <GO>}

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

I'll now turn the call back to Alex just for some brief closing remarks.

A - Alex Gorsky {BIO 16239711 <GO>}

Well, let me end where I began. First of all by thanking all of you for your insightful questions and your ongoing support. Two, and also by thanking all of our associates of Johnson & Johnson, almost 140,000 who have been working 24/7 particularly over the last 15 months during this pandemic period. We appreciate your ongoing interest in your support and look forward to updating you at our next quarterly call.

Thank you very much, and have a great day.

Operator

Thank you. This concludes Johnson & Johnson's first quarter 2021 earnings conference call. You may now disconnect.
