Q3 2020 Earnings Call

Company Participants

- Ashley McEvoy, Executive Vice President, Worldwide Chairman, Medical Devices
- Christopher DelOrefice, Vice President of Investor Relations
- Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals
- Joseph J. Wolk, Executive Vice President & Chief Financial Officer
- Mathai Mammen, Global Head of Janssen Research and Development
- Thibaut Mongon, Executive Vice President, Worldwide Chairman, Consumer Health

Other Participants

- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- David Lewis, Analyst
- Josh Jennings, Analyst
- Larry Biegelsen, Analyst
- Louise Chen, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's Third 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 third quarter of 2020. I hope everyone is healthy and continues to remain safe during these times.

Joining me on today's call is Joe Wolk, Executive Vice President, Chief Financial Officer. During the Q&A portion of the call, we will be joined by Jennifer Taubert; Executive Vice President and Worldwide Chairman, Pharmaceuticals; Ashley McEvoy, Executive Vice President and Worldwide Chairman, Medical Devices; Thibaut Mongon, Executive Vice President and Worldwide Chairman, Consumer Health; and Mathai Mammen, Global Head of Janssen Research and Development.

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

Please note that today's presentation includes forward-looking statements. We encourage you to review the cautionary statement included in today's presentation, which identifies certain risks and 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 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.

For further description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2019 Form 10-K and subsequent Form 10-Qs, along with a reconciliation 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. I will cover consolidated and segment sales information, along with some operational highlights from the P&L results for the corporation and the three business segments. My comments on the segments will be shared at a high level to allow more time for Q&A. Joe will provide high level commentary about our enterprise performance, including J&J's response to COVID-19, followed by insights into our capital allocation priorities, as well as some key pipeline updates. He will then conclude with our 2020 guidance and qualitative expectations as we position for a strong start to 2021. The remaining time will be available for your questions. We anticipate the webcast will last about 75 minutes.

Worldwide sales were $21.1 billion for the third quarter of 2020, reflecting a reported growth of 1.7% versus the third quarter of 2019. Operational sales growth, which excludes the effect of translational currency, also increased 1.7%, as currency had no impact in the quarter. In the US, sales increased 2.7%, while in regions outside the US, our reported and operational increase was 0.6%.

Excluding the net impact of acquisitions and divestitures, adjusted operational sales increase was 2% worldwide, 2.8% in the US and 1.1% outside the US. Results were negatively impacted by the COVID-19 pandemic. However, we did see improvement throughout the quarter with procedure volume recovering faster than expected, as well as positive trends in scripts and physician office visits.

Turning now to earnings. For the quarter, net earnings were $3.6 billion and diluted earnings per share was $1.33 versus diluted earnings per share of $0.66 a year ago. Excluding after-tax intangible asset amortization expense and special items for both

periods, adjusted net earnings for the quarter were $5.9 billion and adjusted diluted earnings per share was $2.20, representing increases of 3.5% and 3.8% respectively compared to the third quarter of 2019. On an operational basis, adjusted diluted earnings per share increased 2.4%.

Beginning with Consumer Health, I would now comment on business segment sales performance for the third 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 third quarter of 2019 and therefore exclude the impact of currency translation.

Worldwide Consumer Health sales totaled $3.5 billion and grew 3%, with growth in the US of 11.6% and a decline outside the US of 2.7%. Consumer Health delivered strong performance in our US OTC, oral care, and wound care businesses, partially offset by the negative impact of COVID-19 outside the US, primarily in our OTC and skin health/beauty businesses. We are making good progress, executing our SKU rationalization program which as expected negatively impacted sales results in mostly OUS markets. However, this was mostly offset by some sales related true-ups in Latin America.

Additionally, e-Commerce sales continue to drive growth across most brands. Over-the-counter medicines grew globally by 4% on strong US sales of Tylenol in analgesics due to share growth, an increased demand driven by COVID-19, Pepcid in digestive health due to a competitive withdrawal, and Zyrtec in allergy due to share gains, incremental distribution and strong in-season marketing plans. Growth was also driven by increased retailer stocking across multiple brands in preparation for a potential upcoming cold and flu season. This strong performance was partially offset outside the US, by the impact of COVID-19 consumption declines in China in pain and in cough, cold and digestive health in other regions. Our OTC business is growing above the market, gaining 0.7 points of share on a year-to-date basis.

The skin health and beauty franchise returned to growth of 0.9% on strong performance of OGX due to share gains coupled with increased retailer stocking across multiple brands and a reduction in Sun Care returns due to a rebound in category growth. This growth was partially offset by competitive pressures in the US and a negative impact of COVID-19 in Asia Pacific and Latin America. As consumers continue to focus on products related to personal health and hygiene, oral care grew by 10.8% on continued growth of Listerine mouthwash due to new product launches in Asia Pacific and increased demand globally related to COVID-19. Wound care grew 13.5%, primarily due to strong sales of Band-Aid brand adhesive bandages and Neosporin.

Moving onto the Pharmaceutical segment. Worldwide Pharmaceutical sales of $11.4 billion grew 4.6%, enabled by growth across all regions. The business realized double digit growth in seven key products, with oncology as the main catalyst. Sales grew in the US by 1.5%, and outside the US by 8.8%. Our growth was negatively impacted by COVID-19, driven by continued delays in diagnosis and slower new patient starts.

The products most impacted were Stelara, Tremfya, Invega Sustenna and our pulmonary hypertension portfolio. The estimated impact of these products was worth roughly 200 basis points on Worldwide Pharmaceuticals growth in the quarter, which was an improvement from Q2, as office visit and script trends continue to improve. Year-to-date global operational growth is strong at roughly 6%, which remains above expected market growth for 2020.

Our oncology portfolio delivered another strong quarter with worldwide growth of 12.4%. Darzalex continue to show momentum in all regions growing 43.4%, led by share uptake in lines one and two with US line 1 share of 2 points versus the prior year. Additionally, the US and European markets exhibited increasing adoption of the subcutaneous formulation launched in the second quarter as feedback continues to be very positive on the ease, and reduce time to administer the new formulation, especially during this pandemic period. Also, we continue to advance the Darzalex innovation pipeline with the US filing for amyloidosis.

Imbruvica grew 11.2% globally, driven largely by increased penetration and share gains in Europe. US saw strong underlying double-digit growth and continued leadership and share growth in CLL line one up 1.9 points. US growth was negatively impacted by two comparisons to the prior year: a one-time returns reserve adjustment, and higher inventory levels in 2019. On a global basis, these adjustments were worth over 500 basis points.

ERLEADA continued its strong growth momentum contributing just over 200 million in the quarter, with sales more than doubling versus prior year, with strong share growth, especially in the metastatic indication. Slightly offsetting these results were declines in Zytiga and Velcade, primarily due to generic competition.

Moving now to immunology. Globally, sales grew 1.9% in the third quarter, driven by double-digit growth in Stelara and Tremfya, partially offset by continued erosion in Remicade due to biosimilar competition. Internationally, sales grew at 8.4%, offsetting a slight decline in the US of under 1%. Third quarter growth for our immunology portfolio as well as the overall market was impacted by COVID-19-related delayed diagnosis. Year-to-date, immunology growth is 5.7%.

Stelara growth of 14% was driven by continued global uptake and share gains in Crohn's disease with about a 5 point share increase in the US and growth from the recently approved ulcerative colitis indication despite the negative impacts to the immunology market created by COVID-19. On a year-to-date basis, Stelara growth remained strong at about 18% globally.

Tremfya, the first-in-class market leading IL-23 inhibitor grew 12.2% in the quarter, driven by growth of roughly 50% outside the US, due to continued strength of new launches in Europe and Asia. US sales were flat in the quarter. US delivered strong share gains up nearly 3 points. However, growth was negatively impacted by COVID-19, along with an unfavorable prior period pricing adjustment and further investments in rebates offered to

enhance access. On a year-to-date basis, global growth for Tremfya remained strong at 30.3%

Our total pulmonary hypertension portfolio posted double-digit growth of 13.9%, driven by strong growth of Opsumit and Uptravi of 12.3% and 23.2% respectively, driven by increased market penetration and share growth.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales were $6.2 billion, declining 3.9%. Excluding the net impact of acquisitions and divestitures, primarily the divestiture of ASP, adjusted operational sales decline was 3.3% worldwide. The medical device market continued to be impacted by the COVID-19 pandemic in Q3, but procedures began to resume more widely across the globe and we are reporting significant improvement in sales versus the 32.5% adjusted operational decline in Q2 and 20.1% decline in June.

There were some variability by platform and across markets, but overall, we saw a more stable results in total across each month this quarter, with September declining in line with the total quarter decline of 3.3%. The sequential improvement compared to Q2 occurred across all segments of our business, with the recovery occurring the quickest in the US and China, two of our largest geographies. The US returned to growth in the quarter. China grew almost 17% adjusting for the ASP divestiture, despite the negative impact from the sell-through of product stocking that occurred in the first quarter to ensure there was product available to support the expected market recovery in subsequent quarters. We expect most of this product stocking to be depleted in Q4.

Most other OUS markets experienced significant improvements compared to Q2. However, the state of procedure recovery has varied by market due to factors, such as the structure of different healthcare systems and localized decisions regarding COVID-19 restrictions. Consistent with what we shared in the prior quarter, the impact of results related to selling days was immaterial for this quarter. As a reminder, we will have extra selling days in the fourth quarter as a result of the 53rd week.

Interventional solutions return to double-digit growth this quarter across both the US and OUS regions, delivering 12.4% growth globally. The US and China were the primary drivers, with newer product offerings in both electrophysiology and Cerenovus positively contributing to both market and share growth for the quarter. Additionally, we received approval from the USFDA for a Thermocool SmartTouch SF Ablation Catheter for the treatment of persistent atrial fibrillation, making it the only radio frequency catheter on the US market with this indication.

Worldwide orthopedics declined 3.1% versus prior year, with the US returning to growth for the quarter. Hips grew 1.9% globally, led by strong US growth of 8.7%. This reflects both market recovery, as well as strength from our leadership position in the US in the anterior approach and related demand for products like the ACTIS total hip system and enabling technologies. Sales outside the US declined by 8.4% due to COVID-19, as well as product stocking reductions in China worth over 250 basis points.

Worldwide trauma returned to growth in Q3, delivering 0.7% growth globally. US growth of 4.2% for the quarter reflects COVID-19-related procedural recovery, as well as continued strength of our newer products such as the femoral neck systems and cannulated compression screws. OUS declines reflect slower procedure volumes due to COVID-19. We continue to see stabilization of our spine business, with recent launches of Symphony, Conduit and Fibergraft. Global results for this platform were flat versus prior year.

The new market accelerated versus Q2 performance but is recovering slower than the other segments of orthopedics. The US recovery was better than other markets, declining about 2%, primarily driven by COVID-19. Performance was aided by the continued success of products like ATTUNE Revision and Cementless. While improving from a Q2 decline of 55.3%, Q3 OUS sales decline of 26.4% reflects slower market recovery, especially in revision procedures where we have higher penetration in primary. Performance was also negatively impacted by a comparison to strong double-digit adjusted growth in the third quarter of 2019. Pricing continues to be a factor in orthopedics. For the quarter, US price returned to more historic levels, down low-single digits.

Moving to the results for the surgery business. Advanced surgery showed significant improvement versus Q2, but still declined by 1.2% due to the impact of COVID-19. Worldwide energy and endocutters declined about 7% and 3% respectively. We continue to experience competitive pressures in the US. However, relative to the market, both platforms performed well outside the US, especially in China, due to the strength of new products. Global biosurgery increased over 5%, reflecting share gains from new products and the return of Surgiflo plus thrombin to the US market after the supply disruption in the prior year. Last year supply disruption impacted biosurgery growth by about 400 basis points in the quarter.

Global wound closure declined less than 5% in line with the market recovery with continued competitive growth in both the US and China. The vision business declined 9.5% globally. US contact lens growth of about 13% was largely driven by product stocking worth about 11 points, which is expected to return to more normalized levels in Q4. OUS contact lens improved versus the prior quarter. The decline of 18% was negatively impacted by a prior year pre-buy in advance of consumption tax increase in Japan worth about 5 points.

We continue to advance our contact lens pipeline with the world's first and only drug releasing contact lens for patients with allergic eye itch, having received approval from Health Canada for ACUVUE Theravision. Surgical vision declined 16.4% globally due to the continued impact of COVID-19 on procedures and competitive pressures in the US.

I will now provide some commentary on our earnings for the quarter. Regarding our consolidated statement of earnings for the third quarter of 2020, please direct your attention to the boxed section at the bottom of the schedule. You will see that we have provided our earnings adjusted to exclude intangible amortization expense and special items. As reported this morning, our adjusted EPS of $2.20 reflects a reported increase of 3.8%, and an operational increase of 2.4%.

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 remain flat versus 2019 as a percent of sales as COVID-19-related fixed cost deleveraging in the Medical Devices business was offset by favorable mix in the Pharmaceutical and Consumer businesses. Selling, marketing and administrative margins for the quarter improved as a result of favorable segment mix and expense leveraging in the Pharmaceuticals business, partially offset by the negative COVID-19 impact on Medical Devices sales and increased brand marketing expense investments in the Consumer business.

We continue to invest in research and development at competitive levels, investing 13.5% of sales this quarter. This was higher than the third quarter of 2019 by 100 basis points, driven by portfolio progression, including the COVID-19 vaccine in the Pharmaceutical business, increased investment in robotics and digital platforms, and negative COVID-19 impact on Medical Devices sales.

The other income and expense line showed net expense of $1.2 billion in the third quarter of 2020 compared to a net expense of $4.2 billion last year. 2019 includes $4 billion related to the initial agreement in principle to settle opioid litigation and we recorded an additional $1 billion in the third quarter of 2020 based on continued negotiations of an all-in settlement amount for the state, local and tribal governments opioid litigation claims for a cumulative total of $5 billion.

Regarding taxes in the quarter, our effective tax rate increased from a 6.4% benefit in the third quarter of 2019 to 19.2% in the third quarter of 2020. As a reminder, the third quarter 2019 tax rate was significantly affected by the aforementioned $4 billion agreement in principle. I encourage you to review our 10-Q for further details on specific tax matters. Excluding special items, the effective tax rate was 19% versus 20.3% in the same period last year.

Let's now look at adjusted income before tax by segment. In the third quarter of 2020, adjusted income before tax for the enterprise increased by 0.1% versus the third quarter of 2019 to 34.4%. Looking at the adjusted pretax income by segment, Pharmaceutical margins improved by 340 basis points to 46.4%, primarily driven by favorable product mix and selling and marketing expense leveraging. Medical Devices declined to 21.6%, driven by COVID-19 impacts on the business, including sales declines and fixed costs deleveraging. Consumer Health margins improved by 280 basis points to 24.4%, driven by favorable product mix, inclusive of progressing our SKU rationalization program. That concludes the sales and P&L highlights for Johnson & Johnson's third quarter 2020.

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

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Chris. Good morning, everyone, and thanks to all of you for joining us today. 2020 has proven to be an eventful year, with uncertainty sparking rapid change across many industries, particularly in healthcare. I'm honored to represent Johnson & Johnson management to acknowledge the tremendous resilience and the willingness of our colleagues across the globe to tackle the many challenges being encountered. Like in

prior quarters and for that matter prior years, their strength, character and perseverance is the driving force behind our solid performance this quarter, while solidifying the foundation for long-term success across Johnson & Johnson's businesses.

Our team continues to be hard at work pursuing a vaccine candidate to help combat the COVID-19 pandemic, and we are proud of the progress that has been made thus far. On September 23, we announced that the first participants were dosed in our pivotal multi-country Phase 3 trial Ensemble, which will evaluate a single dose of our COVID-19 vaccine candidate in up to 60,000 people worldwide, including representation from high-risk populations and underrepresented communities. This follows positive interim results from our Phase 1/2a study, which showed the safety profile and immunogenicity after a single vaccination with our candidate supported further development. These findings demonstrated that a single dose resulted in immunogenicity in all age groups with similar responses including older adults.

A single dose of a safe and effective vaccine could offer a significant advantage during a global pandemic. We also appreciate that a two-dose regimen may have the potential for enhanced durability in some participants. Therefore, we plan to run a Phase 3 clinical trial with a two-dose regimen beginning later this year. Simultaneously, we have scaled up manufacturing capacity, and are on track to meet our goal of providing over 1 billion doses of a vaccine per year. We have committed to the public to provide the vaccine once approved on a not-for-profit basis for emergency pandemic use.

As we continue to progress our vaccine clinical program, we are committed to the highest ethical standards, sound scientific principles, pursuit of diversity and inclusion, and transparent communication of our processes and results. Let me be unequivocal here, we have not encountered any undue pressure and we will maintain the rigorous requirements of research, development and manufacturing to bring a safe and effective COVID-19 vaccine to the public as we do for all our products. Mathai Mammen will provide a few words on the COVID-19 vaccine candidate at the conclusion of my remarks.

Now let's take a deeper look into our results and outlook. Each of our business segments performed well in the third quarter despite COVID-19 related headwinds. We believe our Pharmaceutical segment once again outperformed the market, recovery in our Medical Device business was faster than anticipated, and in Consumer, our strategy focused on science-based products led to solid growth. While COVID dynamics continue to make the outlook fluid and perhaps not linear, we are encouraged by this progress and believe that we will continue to see improvement through the end of the year.

As Chris mentioned in his remarks with respect to the additional accrual for opioid litigation, the amount accrued this quarter is intended to bring a comprehensive resolution to the overall opioid litigation with states, cities, counties and tribal governments for a final amount and provide certainty for involved parties and critical assistance for families and communities in need.

Regarding our cash position. We ended the third quarter with approximately $7 billion of net debt, consisting of approximately $31 billion of cash and marketable securities, and

approximately $38 billion of debt. Our balance sheet remain strong. We estimate free cash flow through the first three quarters to be more than $13 billion. In August, the company completed a $7.5 billion debt offering. We were able to secure historically low rates benefiting from the current low interest rate environment and our strong credit rating. Subsequent to the quarter, approximately $6.5 billion was used to fund our recently closed acquisition of Momenta Pharmaceuticals.

Our capital allocation strategy remains intact, committed to managing our entire business and portfolio with a long-term mindset. While all aspects of our COVID-19 vaccine program are a top priority, we continue to invest in innovation in key areas of our pipeline across all parts of our business. With respect to M&A, we continue to evaluate potential strategic opportunities that complement the robust R&D portfolio across our broad-based business, while driving long-term value for our stakeholders.

As I just noted earlier this month, we closed the Momenta Pharmaceuticals' transaction, bolstering our pipeline with novel therapeutics being developed for immune-mediated diseases. We are particularly excited by the lead asset, nipocalimab, a potentially best-in-class anti-FcRn antibody. The science behind nipocalimab is advancing research in rare auto antibody driven diseases, with significant unmet need with current Phase II and Phase III studies in warm autoimmune hemolytic anemia, hemolytic diseases of the fetus and newborn in myasthenia gravis. We plan to build on this foundation with additional indications planned in serious dermatological, rheumatic, neurologic and hematologic diseases. Many of these auto antibody diseases have no adequate standard of care today.

Finally, on capital allocation, our dividend remains a top priority, and during the quarter, we distributed $2.7 billion to shareholders in line with the 6.3% increase we announced in April. We continue to make progress advancing key pipeline assets that are expected to deliver long-term growth. Beyond what Chris mentioned in his remarks, there are few other pipeline items worth highlighting.

In our Pharmaceutical segment, we continue to advance our innovative pipeline. During the third quarter, we received FDA approval for a second indication of Spravato in major depressive disorder, with acute suicidal ideation or behavior. We did make a strategic decision to discontinue development of Pimodivir, an investigational treatment for influenza A. Based on recent results from pre-planned interim analysis that sound Pimodivir in combination with the standard of care, did not demonstrate added benefit in hospitalized patients.

As we head into the fourth quarter, we look forward to additional planned submissions. Most notably, our US filing of our BCMA CAR-T in multiple myeloma, as well as the US filing for amivantamab, a non-small cell lung cancer.

Regarding digital robotic surgery in our Medical Device business, we made a significant step for our orthopedic solution, submitting a 510(k) premarket notification to the US FDA in September for our Velys robotic-assisted solutions for total knee arthroplasty. This is another important milestone in our digital surgery program, complementing the commercial success we have seen with Monarch.

As you may recall, we planned a full Medical Device Business Review back in May, and then hope we could provide that in-person event sometime this year. However, given the ongoing limitations for in-person events, we decided to provide a shorter limited scope virtual update on our Medical Device business featuring all of our digital surgery solutions. We scheduled this for Thursday, November 19, and we'll provide additional event details in the coming weeks.

So let's now turn to our full year 2020 guidance and key updates. As I noted, based on our third quarter results across the enterprise and the continued progress we saw in procedure volumes, we are confident to increase our guidance. To provide you a little more insights regarding our Medical Devices business, as you can see from our results, we exceeded our expectations as the market recovery was even stronger than anticipated as hospital and surgeons continue to work through the pent-up demand resulting from restrictions on procedures earlier in the year.

Moving to the fourth quarter, we are expecting continued procedure stabilization slightly ahead of our assumptions communicated last quarter. We are updating our range to be flat to down 10% versus flat to down 15% provided last quarter. As a reminder, this range is compared with our original estimates to start the year when we were expecting to continue our positive sales momentum prior to the pandemic. This updated range reflects continued improvement with fourth quarter sales expectations around 2019 levels. This forecast reflects our latest thinking based on what we know today and is consistent with our efforts throughout the year to provide transparency around our assumptions.

Taking the qualitative factors related to each of our segments into account and based on recent developments, we are making the following adjustments to our 2020 guidance. Adjusted operational sales growth of 0.5% to 1.5%. Moving onto operational sales, our guidance is $82 billion to $82.8 billion or flat to growth of 1% versus 2019. 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 $1.17, there is an estimated negative impact of foreign currency translation of approximately 100 basis points versus the negative 130 basis points provided in our July guidance or an improvement of 30 basis points, resulting in an estimated reported sales change between minus 1% to flat compared to 2019 or $81.2 billion to $82 billion.

We are expecting our operating margins to be in line with our previous guidance of approximately 100 basis points decline, with planned investments across all of our business segments in the fourth quarter. We are tightening our other income guidance to $800 million to $900 million versus our previous guidance of $800 million to $1 billion. We are tightening the range of net interest expense, now expected to be net interest expense of $100 million to $150 million. We are also tightening the range of our effective tax rate guidance for 2020 estimated at 17.0% to 17.5%.

Given those updates, we are comfortable with adjusted earnings per share guidance ranging from $7.95 to $8.05 on a constant currency basis. While not predicting currency movements, but to provide some insights on the potential impact on EPS, our reported adjusted EPS would be positively impacted by approximately $0.10 per share versus our July guidance and now reflects no translational currency impact for the full year.

Accounting for that, we will be comfortable with your models reflecting reported adjusted EPS ranging from $7.95 to $8.05 or a range of minus 8.4% to minus 7.3%. In case you're now doing a double take, yes, that is the same range I just provided for constant currency, so essentially on income, we are estimating no year-on-year impact from currency.

While not providing guidance related to 2021 at this time, I'd like to provide some early perspectives on how we are thinking about next year for consideration in your financial modeling. We anticipate our Pharmaceutical segment to remain strong, continuing to reach more patients with best-in-class products in areas of high unmet need. As such, we expect to continue delivering solid volume driven above market growth in 2021.

In Consumer Health, we expect to grow competitively with the market, driven by priority areas and enhanced strength in e-commerce. We expect that continued SKU rationalization and 2020 COVID-related sales comparisons primarily in OTC can be a headwind in the first half of 2021. With respect to margins, we have demonstrated a steady cadence of margin improvement.

Our previously announced SKU rationalization will result in margin improvement, but given the tremendous progress the team has made in recent years to reach benchmark levels, the improvement will not be as significant as we've experienced the last two years.

In our Medical Devices segment, we anticipate a continued increase in procedures associated with pandemic recovery. We continue to believe in the strong underlying fundamentals in the medical device market such as aging demographics in unmet need, coupled with hospital systems that have successfully navigated the pandemic.

As I said on our second quarter earnings call, hospitals are much better prepared for any potential COVID resurgence and that become even more efficient in the allocation of resources to meet the needs of all patients. While we certainly continue to watch closely as the rest of 2020 plays out, we remain optimistic heading into 2021, and as you might expect, anticipate to deliver robust double-digit sales growth.

Moving on to a few comments related to the 2021 P&L. Consistent with sales, we also anticipate strong comparative year-over-year earnings per share. This in part due to the 2020 dynamics, but also in part due to the strength of our businesses. At this time, we anticipate that operating margin will be more in the range of where we ended 2019. For R&D, we will continue to invest for the long-term and anticipate that level of spend to be in the same range of approximately 14% of sales, consistent with prior years.

Lastly, it's important to note that we are committed to the incremental investment necessary to advance our pipeline inclusive of the negative impact to EPS related to the Momenta acquisition. And that in 2021, the impact to EPS is approximately dilution of $0.10 to $0.15 as we disclosed at the deal signing.

We remain confident in our strength heading into 2021 and optimistic in our long-term outlook. I want to thank the business leaders joining our call today, Jennifer, Ashley, Thibaut and Mathai to engage in the Q&A session. In fact, I'm going to take the liberty of

kicking off this portion of the webcast with the topics that we are often asked that being the impact of COVID-19, not only this year, but what we anticipate for 2021 by requesting each of these leaders to provide a few brief comments on their respective businesses, and then we'll have Mathai address the state of our vaccine candidate development.

Jennifer, let's start with you.

Jennifer Taubert {BIO 20108880 <GO>}

Thank you, Joe, and good morning everyone. It's really nice to have the opportunity to speak with you today. I'd like to start by acknowledging all those who have been and continue to be impacted by COVID-19. I sincerely hope that you and those closest to you remain healthy and safe. I'm really proud of the Pharmaceuticals Group performance in the third quarter. We know that illnesses don't hit pause just because there is a global pandemic. So whether battling cancer, facing mental health challenges or living with an autoimmune disease, patients rely on our transformational medicines every single day.

As you heard from Chris, our Pharmaceuticals business grew 4.6% operationally in the third quarter, and we delivered our 10th consecutive quarter with sales that exceeded $10 billion, and our second quarter with sales exceeding $11 billion. Seven of our key brands grew at double-digit rates, including our oncology brands leader Darzalex and Imbruvica, our immunology brands Stelara and Tremfya, and our pulmonary hypertension brands Opsumit and Uptravi. And despite the pressures that COVID-19 has placed on our business, our growth year-to-date is roughly 6%, definitely above market growth.

During the third quarter, we kept a relentless focus on innovation and on delivering for our patients and customers around the world. So we worked really hard to maximize the value of our industry-leading portfolio of marketed medicines. We delivered on our pipeline of transformational medicines and we advanced our next wave of innovation.

In Q3, we continued the very successful launch of Darzalex FasPro, which is our subcutaneous formulation of Darzalex to treat multiple myeloma. And we received approvals of Spravato, a major depressive disorder with acute suicidal ideation or behavior. And we filed Uptravi IV for pulmonary arterial hypertension and Darzalex for light chain amyloidosis.

And on October 1st, we closed our acquisition of Momenta Pharmaceuticals, which provides a significant opportunity to drive long-term growth through expansion into in leadership and auto antibody driven diseases. 2020 has been an unprecedented year and we've adapted our business to meet the new challenges that have been posed by the COVID-19 pandemic. We quickly transition to scaling omni-channel capabilities to engage with healthcare providers, we enable patients to both start and stay on therapy using virtual tools, and we deployed a number of technologies to help keep our clinical trials on track.

And despite some negative impact related to COVID-19 in the quarter, we also saw encouraging signs of recovery in our market performance across multiple metrics. The fundamentals of our business remain strong and we feel confident in our ability to grow

above the market on a full year basis in 2020, and also our expectations of where our businesses heading remain unchanged and we continue to plan for another strong year of above market growth in 2021.

So again, it's a pleasure to have this opportunity to connect with you today, and I look forward to any questions. But first, let me go ahead and turn it over to Ashley McEvoy. Ashley?

Ashley McEvoy {BIO 20108895 <GO>}

Thank you, Jennifer. Well, listen, clearly the MedTech market has been disrupted by this once in a generation event. And I too would like to start by acknowledging that this recovery would not be possible without the heroic efforts of healthcare workers around the world. Their selfless dedication to patient care has just been amazing. And I must give a shout out to our J&J (Technical Difficulty) since day one in Wuhan has been partnering with our customers, covering cases, managing both COVID-19 patients, as well as helping to stand back up other important medical procedures.

So as Jennifer mentioned, COVID has really been an accelerant for shifts within the MedTech industry, really creating a lot of new creative solutions related to digital patient engagement, virtual surgeon training, a shift in sites of care and continued evolution in our business models. We risen to this challenge and rethinking how we engage with our customers. To name a couple of examples, we partnered with an education partner advances in surgery, where we virtually trained over 1 million surgeons in 150 different countries on COVID-19 protocols, as well as ways to safely stand back up medical procedures. We've incorporated remote clinical case support to assist and connect customers around the world. And most recently, in September, we launched resources to educate patients about the importance of routine medical visit and the implications of deferring treatment with My Health Can't Wait campaign.

During the pandemic, we meaningfully advanced our innovation agenda. We continue to increase the overall value of our new product pipeline, and are shifting to more substantial and transformational innovation. In quarter three, we received FDA approval for the indication to treat persistent atrial fibrillation in our Biosense Webster business. We were granted approval from Health Canada for a first of its kind drug-eluting contact lens for allergy sufferers. We submitted our FDA filing for our upcoming Velys robotic-assisted knee replacement program. We received FDA clearance for our Dual Mobility Hip, a high-growth segment. And lastly, we begun a rollout of an entire revamp of our Ethicon Endo-cutter Echelon platform from budgeted [ph] to Powered Circular Stapler to improve stapling mechanisms all to reduce leaks and improve outcomes.

So as we've been talking about MedTech, really we've been on this three-year improvement journey, and we are demonstrating progress with growth year-over-year from 1.5% in 2017 to 3.9% in 2019. While COVID temporarily interrupted its progression, our results this quarter demonstrate that in addition to the overall market recovery, the strategic choices we've made to strengthen our competitiveness and our relentless focus on customers and patients are working. It's good to see our largest market, the United States, go positive, up 1% growth, our second largest market China will deliver 17% growth

and platforms like Biosense Webster and Cerenovus grew double digit and hips, trauma and biosurgery -- where all posted low to mid-single digit growth.

So looking forward, there are still going to be factors like patient willingness and affordability of medical care, which will continue to drive some level of uncertainty in the near term. However, when I look at the end state markets overall in MedTech, I continue to believe optimistic as there is still new rules of unmet clinical need to be met. So knowing what we know today with the impact of COVID and what it had on 2020, I expect that we're going to deliver robust double-digit operational growth in 2021.

Thanks for your time. Looking forward to the questions. And now I'm going to turn it over to Thibaut.

Thibaut Mongon {BIO 20973347 <GO>}

Thank you, Ashley, and good morning to all of you on the call. As you heard from Chris, this quarter, again, we have seen that our consumer brand have been very resilient during this unprecedented time. Our Consumer Health sector grew a solid 3% operationally in the quarter, delivering a 3.4% operational growth on a year-to-date basis, while continuing to expand our margins. And this is a testament to the strength of our strategy of offering differentiated science based brands focused on personal health and endorsed by professionals.

So in today's environment, consumers globally have a heightened interest in personal health and hygiene, and it's driving high demand for efficacious trusted solutions backed by science like those offered by Johnson & Johnson. And an example of that preference would be -- is a tremendous growth we have seen in our over-the-counter medicines business, driven by brands like Tylenol, Zyrtec, Pepcid and Zarbee's or like being [ph] in our oral care franchise with Listerine mouthwash.

In other parts of our business like skin health and beauty, results have been more nuanced. We have seen a negative impact of COVID-19 in categories like sun care and make up removers, while seeing increased demand for body wash, body lotions or premium hair care. So for 2021, we expect both headwinds and tailwinds as we saw this year, but we strongly believe that our strategy, our capabilities and our focus on execution position us very well for continued performance.

We are prepared to see ongoing fluctuation in consumer demand related to the pandemic, potential pantry loading behaviors or lower incidence of conditions like cold and flu. However, even with this uncertainties in mind, we expect to see continued strong growth in e-commerce and continued demand for our leading brands, which efficacy is backed by science resulting our Consumer Health business to continue to grow competitively with the market in 2021.

And with this, let me hand over to Mathai Mammen.

Mathai Mammen {BIO 16105905 <GO>}

Thank you, Thibaut. Let me now give you a brief update on our COVID-19 vaccine. First, a reminder of a bit of background. On the heels of some really promising Phase 1 and 2a data, we initiated a single dose Phase 3 study called Ensemble a few weeks ago on September 21 in the United States, and we're in the process of opening numerous sites globally. Our vaccine as a reminder is based on Ad26. This is a human adenovirus and contain the variance of the SARS-CoV-2 spike protein. Our vaccine was shown to elicit a robust immune response in humans as demonstrated by the presence of neutralizing antibodies in T-cells.

I'd like to now elaborate on the statement we posted on our website yesterday regarding a temporary pause in further dosing in our COVID vaccine clinical trial. First, some context. It's not at all unusual for unexpected illnesses that occur in large studies over their duration. In some cases, they're called serious adverse events or SAEs and may have something or that they wish to do with the drug or vaccine being investigated. However, as a company that always put safety first, we take each and every case seriously.

In certain cases when we need more information, we call the enrollment and dosing of additional participants as we take the time to gather more information. We have a very defined and well thought through process at J&J that follows high standards of scientific, medical and ethical practice, and we followed all of that to the (inaudible).

First, preliminary information is sent to an independent Data and Safety Monitoring Board or DSMB. DSMBs, as you know, a very commonly called trials in the pharmaceutical industry. This Board is comprised of outside experts who evaluate the information and then make a recommendation to us. In our case here, we were informed of an unexpected illness on Sunday evening, October 11, and we followed our process exactly and quickly and posted a statement on our website the following day on Monday, October 12, pausing enrollment. The DSMB was inquired immediately on Sunday and they requested additional information. We are now awaiting further medical information and evaluations which we will then forward to the DSMB for their independent recommendation. We're absolutely committed to providing transparent updates throughout our vaccine development program, and we will update you when we learn more.

And finally, I would be remiss if I didn't express great enthusiasm for the R&D portfolio at Janssen. I'm very excited about all the really tremendous progress we've made against the programs in our portfolio in spite of COVID-19. We continue to make deep investments and terrific progress on currently marketed product to extend them further and against new molecular entities.

Highlights were already mentioned that include Darzalex FasPro for AL amyloidosis progress as we continue to build on Tremfya, amivantamab, our CD3 redirector franchise, BCMA CAR-T, RPGR gene therapy, and many others. So happy to address any of that in the Q&A.

I hand it now back to Chris DelOrefice. Chris?

Christopher DelOrefice {BIO 20730104 <GO>}

Terrific. Thank you, Mathai, and thank you, Jennifer, Ashley and Thibaut. Rob, let's now move to questions from the investment community. Can you please provide instructions for those on the line wishing to ask a question?

Questions And Answers

Operator

Sure. (Operator Instructions) And your first question comes from David Lewis with Morgan Stanley.

Q - David Lewis {BIO 15161699 <GO>}

Good morning. Thanks for taking the question. Mathai, maybe I'll start with you just as we finished with you. Is there a realistic time frame for us to learn if the adverse event was in the treatment or placebo arm? Any sense right now if the AE [ph] was neurological in nature?

A - Mathai Mammen {BIO 16105905 <GO>}

So we know very little information right now. We've given information that we do know to the DSMB, and they've asked a number of specific questions. We don't know whether -- they haven't informed us. They have the right to unblind. We are still blinded. So we don't know treatment arm, vaccine arm [ph]. We know very little at this point, and it will be a few days at minimum for the right set of information to be gathered and valuated.

Q - David Lewis {BIO 15161699 <GO>}

Okay. Very helpful. And I'll just ask my other two questions right upfront, maybe one for Ashley and one for Joe? Ashley, just thinking about the NTD [ph] commentary for September which suggested improvement, but some are resting the improvement in the month of September. As I think about the guidance range at the top end, you basically get to do the top end of your range for the fourth quarter to show improvement in the fourth quarter. So, what is your confidence in delivering the top end of the range and what are some of the factors in the fourth quarter that could impact the ability to show sequential improvement?

And then for Joe, just quickly on Pharma, thanks for the outlook for '21. Pharma has accelerated the entire year on both a reported underlying basis, obviously above market next year. Can Pharma accelerate in '21? Thanks so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

So thanks for the question, David. Maybe I'll start with really -- obviously, we ended Q3 down 3%. As Joe mentioned, our expectations for quarter four, they are really in line with the range communicated in July. We've tightened a bit of it to make it from flat to down 10%. And just as a reminder, this is a guide versus what we originally communicated in the beginning of the year in January of our plan. So if you look at this, it means that our range for quarter four could be consistent with the results we delivered in quarter three, a kind of one bookend to then delivery in some modest growth versus 2019 last year.

And things that we're considering -- I do think that we're confident in how hospitals are managing through the surgeons. We are paying close attention to patient sentiment and affordability. And at J&J, I believe, Chris mentioned, we did have -- we are bleeding through some inventory that we procured shrewdly in the beginning of the year for China, and we will be also adjusting from, as Chris mentioned, coming off of last year the Japan consumption tax. So those are two things to consider, one from this year and one from last year.

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

And David, with respect to Pharmaceuticals, I do think that we could see acceleration. So the in-line portfolio continues to perform extremely well as we've seen. We're getting nice uptake in some of our larger products, notably Stelara in UC which was recently an approval we acquired. Tremfya for PsA. I would also point to some of the filings that we anticipate here in the near term with respect to the CAR-T BCMA, as well as of anti-mAB for non-small cell lung cancer potentially on the horizon and part of the mix in 2021.

I will also point out that while this quarter was strong, we still have some impact in all three segments related to COVID-19 dynamics. So there's probably two to three points of growth that hampered the third quarter reported results. As you can imagine, there's still a segment of the population that's a little bit cautious about going out in public, having their normal office visits. So I would anticipate that should come back as therapeutics, as vaccines, as people know more about the virus itself. So it wouldn't be beyond our expectation to think that. Jennifer and her team could do even better in 2021.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Thanks, Dave. Appreciate the question. Rob, next question please?

Operator

Your next question comes from Chris Schott with JP Morgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much for the questions. The first one was just a bit of a clarification on the 2021 operating margin dynamics. I just want to make sure I understood what levels you're referring to with results in line with 2019 margins, specifically, is that including or excluding the ASP gain last year? And as I think about '21 margins, would you characterize those as normalized margins for J&J or these still margins that are going to be depressed as we're facing some COVID disruptions?

My second question was just on Pharma pricing and how you're thinking about that for '21. I guess, specifically, as we think about higher unemployment rates in adverse payer mix, is there any expectation we should be thinking about pricing different in '21 versus what we're seeing in 2020? Thanks so much.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Chris, thanks for the questions. I'll take the first question around margins, and then I'll turn it over to Jennifer to give some thoughts with respect to an outlook to the extent we can provide pharmaceutical pricing.

So with margins, in my commentary, I referenced we should be around 2019 operating margin levels, that would exclude other income. So it would exclude the ASP divestiture gain that you've referenced. Our operating margin for 2019 was 31.3%. We expect to get back to that level. We're going to continue to invest in our pipeline. We recalled too that in our projections for 2021, we're looking at the Momenta transaction which was dilutive by as much as $0.15. So that's part of the mix.

But I would say, Chris that probably best labeled if I was to label them as normal operating margins, we expect to grow our bottom line slightly faster than our top line in most years. And so, I think, we will continue to look to do that with respect to the portfolio at our investment capacity, but not compromising the long-term in any point in time.

A - Jennifer Taubert {BIO 20108880 <GO>}

And -- hi Chris, this is Jennifer. I can jump in on the pricing one. So whether it's based on unemployment trends or whether it's based on healthcare reform, we do see that there is going to be continued pressure on pricing across the pharma industry. I think an important reminder is that for us, our growth is all based on volume, not price. So we think relative to our competitive set that we are very well positioned for this future environment.

We work very, very hard to develop robust value propositions and to be able to get appropriate value for our products in the market and we'll continue to do so, but whether it's through healthcare reform efforts, which actually we think could ultimately have a positive if it can help lower patient out of pocket costs or through other channel mix and dynamics. We do think that there will be continued pressure there.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Chris. Appreciate the questions. Rob, next question please?

Operator

Your next question comes from Larry Biegelsen with Wells Fargo.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. One for Ashley, one for Jennifer. To Ashley, I appreciate the commentary about 2021, you expect double-digit growth. My question is, can you grow in 2021 over 2019 levels in the device business?

And for Jennifer, you have the Sustenna bench trial starting this week. Can you offer any thoughts on that? Do you still believe it will be very difficult for a generic company to manufacture a generic version of Sustenna even if you lose that litigation? Thanks for taking the questions guys.

A - Ashley McEvoy {BIO 20108895 <GO>}

Thank you, Larry. So for 2021, we do anticipate as I mentioned double-digit growth versus 2020, and we do anticipate growth in 2021 relative to where we exited 2019.

A - Jennifer Taubert {BIO 20108880 <GO>}

And then if we talk about Invega Sustenna, we are very confident in our IP positions around our long-acting injectable portfolio, whether we're talking about Invega Sustenna, whether we're talking about Invega Trinza. Those products bring significant benefit to patients with schizophrenia. And so, Larry as you noted, we do have a bench trial that starting, but that we feel good in our position there and that those assets are going to continue to be able to deliver not only for patients with schizophrenia, but also for Janssen and for Johnson & Johnson.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Thanks, Larry. I appreciate the questions. Rob, next question please?

Operator

Thanks. Your next question comes from Josh Jennings with Cowen & Company.

Q - Josh Jennings {BIO 16451037 <GO>}

Hi. Good morning. Thanks for taking the questions. First question for Ashley. I was hoping -- just thanks for the 2021 outlook on the Medical Devices franchise. But I was hoping if you could help us think through the risk of the Affordable Care Act being repealed by the Trump administration? And then secondarily, if unemployment levels stay where they are, what type of headwinds you expect in 2021 and whether those have been baked into that 2021 outlook?

And then I was also hoping for Jennifer to ask about the immunology franchise just by revenue, it's the largest business in pharma. It seems like you're bulking it through the Momenta acquisition, but I wanted to ask about any updates you can provide on the outlook for Remicade declines with the premise being just if that anchor can get lighter, declines can be tempered, that would be a positive for that immunology franchise in 2021 and beyond? But any help you can give on the outlook for Remicade from here? Thanks for taking the questions.

A - Ashley McEvoy {BIO 20108895 <GO>}

Well, thank you, Josh. I think your question was about the ACA. In our business for J&J Med Device, we have about 60% of our payer mix is public, clearly a big chunk of that is Medicare, and then the smaller amount in Medicaid, and about 40% private. So we do anticipate Medicaid increasing this amount and we do anticipate, given employment and some of the economic challenges that that private amount may decrease a bit. But we factor those into our consideration when you look at 2021.

And then I think your second question was really around patient sentiment, and I would tell you that that fast evolving data that we look at weekly and monthly, and we are always looking to, how do we replenish that funnel and we factor those considerations into our assumptions into 2021.

A - Jennifer Taubert {BIO 20108880 <GO>}

Yeah, and then, it is Jennifer. I'll jump in on the immunology front. So immunology, as you know, is our largest business for the Janssen franchise and continues to deliver very, very strong growth. And both Stelara and Tremfya delivered very solid quarters. Stelara is showing very significant gains globally in both Crohn's disease and in the Ulcerative Colitis launch. And very importantly, just this week, we have five-year long-term remission data in Crohn's disease that is actually being presented publicly, which we think is another great catalyst and demonstration of the significant benefits that STELARA offers to patients in the GI space.

From a Tremfya perspective, we've got very strong growth and competitiveness as we continue to launch into not only psoriasis, but now also psoriatic arthritis, which we think is going to be a great catalyst, not only for psoriatic arthritis, but also for the psoriasis business. And right now with Tremfya, we're the only IL-23 that has that psoriatic arthritis indication. And hopefully as you know, we're also studying it for GI applications and our Crohn's Phase II data. It was actually presented this week as well at the United European Gastroenterology Week. So using our IL-23 pathway strategy, we're not only developing Tremfya for psoriasis and psoriatic arthritis, but also taking it into the GI space, where we believe that we're going to be able to benefit even more patients, because there's still so much unmet medical need there.

Now you referenced Momenta, and we were really excited to both, announce that deal and to close that deal in a very short time frame. And that acquisition is going to give us the opportunity to enter into the auto antibody space, where we believe for nipocalimab we've got as many as 10 or more indications that we're going to be able to go into to really transform auto antibody related diseases, and just about all of these are very underserved. In many cases, we will be able to be first-in-class and we believe best-in-class, and we think this is going to be a really significant catalyst for us.

We've also got a number of other assets in the immunology portfolio. The one we brought in, bermekimab from XBiotech. We've got other novel mechanisms that are being developed in GI applications, and we'll look forward to really unveiling the true breadth of our immunology pipeline when we have our Analyst Day in 2021.

But so -- let me come back to your question on Remicade. Remicade, I think we can anticipated -- anticipate continued relatively similar declines going forward as that product is very, very late in its life cycle. But please know, across the breadth of our immunology portfolio, we have got a ton of strength there and are really planning on continuing -- having that be one of our leading franchises for the Janssen business globally.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Josh. Appreciate it. Rob, next question please?

Operator

Thanks. Next question is from Danielle Antalffy with SVB Leerink.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning guys. Thank you so much for taking the question. Ashley, this is a question for you. And I guess, I'm curious, you gave a lot of color, I appreciate that. So I just want to get a little bit deeper. And I'm wondering if you guys could characterize what you're seeing from a backlog work down versus new patients entering the system if there is a way to sort of even qualitatively characterize that.

And then the second part of the question for you Ashley, I'll just ask it now. As we think about the referral funnel refill within devices, and maybe this is even an appropriate question for pharma and diagnosis, where do you see the areas that are most susceptible should we see some hiccups in the referral funnel reselling? Thank you so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

So thank you Danielle. When we look at, again, I have to give a huge acknowledgment to our customer, and quite frankly, around the world that how they really figured out how to manage people with COVID, as well as manage patients who don't have COVID. And when we look at our top 10 markets, we see about a 95% recovery to date in the past four weeks. And really obviously with China leading the way, but we also saw positive in areas like Germany and areas like Russia. In the United States, it is around 95% and -- which is remarkable, if you think about it that we're in October.

And then, we look at the top 10 IDNs, which are really -- many of those are present in more hotter spots for COVID. There are around 92% recovered. And clearly, some hospitals are well above 100%, and some are a little softer than that. And so I think it really demonstrates to us that they have really learned how to manage both patient populations quite well.

And when we go forward, we did see in quarter three, a significant kind of clearing out of the patient backlog. We think when we go into quarter four, there's a little bit more to go. What we're paying attention to is really the diagnosis, Danielle, to say, let me give you an example, colorectal surgery. Those colorectal surgeries in the United States are down about 10% to 12% from a procedure point of view versus pre-COVID baseline. But the diagnosis, the colonoscopy is down about 20% to 30%. Now that's improving because that used to be down 50%. So, we're looking at MRIs for joint and spine surgeries and when we start to see that number improve, I think it shows that the new patient funnel is starting to replenish at a pace we hope to have.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Jennifer, you're on mute.

A - Jennifer Taubert {BIO 20108880 <GO>}

No. Can you hear me now Chris?

A - Christopher DelOrefice {BIO 20730104 <GO>}

Yeah. Perfect, thank you.

A - Jennifer Taubert {BIO 20108880 <GO>}

So when we look on the pharma side, so we continue to see improving new-to-brand trends. For some of the assets, they are still a little bit below pre-COVID levels as patients are just getting back in for the diagnosis and the workups and everything to ultimately get diagnosed and then treated. But as we take a look at total demand, most of our brands and as we're looking across the market, are really back to and above pre-COVID levels. And where dental is seeing stability and some growth in that area.

I think while new-to-brand has still been a bit depressed, what we're seeing is higher rates of refills, higher rates of persistency and lower rates of switch. And so they sort of compensate for each other. And so we've been really pleased with the recovery that we've seen. We think that our customers as well are really adapting and figuring out how to use a combination of both telehealth as well as in-person visits depending upon the actual patient and potential diagnosis and we see very positive trends going forward. And should there be any type of second wave, we think that they're going to be much better able to handle that in the second wave than what we saw originally.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thanks, Danielle. I appreciate it. Rob, next question please.

Operator

Thanks. Next question is from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the questions. I was just wondering on the COVID vaccine, if you can remind us of what you're hoping to show on the efficacy profile. And then second part of that question is what steps both you and the industry can take to encourage broad utilization of a vaccine, if successful?

And then my second question relates to your EGFR-MET antibody, some pretty compelling Phase I data at ESMO this year. You mentioned this asset a couple of times in your remarks, but maybe you could just expand on the development program here for lung cancer and also other tumors, such as head and neck and colorectal and remind us of how you're thinking about both the near-term opportunity as well as the longer term opportunity? Thank you.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Mathai, do you want to address the vaccine question and start with the pipeline?

A - Mathai Mammen {BIO 16105905 <GO>}

Sure. So in terms of the vaccine overall, like as soon as we overcome this temporary pause, our plan is to continue to (Technical Difficulty) person study that we're on route to. And the vaccine efficacy, specifically was your question, all statistical analysis, plans, assume something, and we've assumed a 70% vaccine efficacy for this trial. But of course, based on the Phase I/IIa data, we're very bullish on that or better efficacy. So if we happen to see better efficacy than that, what will happen is the events will -- as they come in, we'll show a greater imbalance between placebo and vaccine, and we have a chance to finish even faster. And so that's how it will manifest. We just assumed something for the moment, but that doesn't actually dictate how the study is conducted.

Jennifer, do you want to take the broader vaccine question or we can come back to amivantamab?

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. So couple of points. So I mean, first, our industry is demonstrating really heroic and historic leadership during this public health crisis. And between everything that the R&D teams and manufacturing teams are doing around the clock to help bring forward new vaccines and new treatments as well as what the commercial teams are doing to be prepared to both be able to supply these products in the marketplace, but also make sure that there's going to be a receptive audience and demand, people actually wanting to get these vaccines once they get to market. There's a lot of work that's underway there now.

What I can say is, as an industry group, we really have come together. And in working with our local industry associations, be they bio or pharma in the US, be it IFPMA, ex-US, there's a lot of work that's underway to help develop and build vaccine confidence across the board by different types of audiences. So everything for making sure that providers, physicians, nurses, pharmacists, people who would be involved in the administration have accurate information and information that they can use with their patients because they're viewed so positively to broad campaigns, to even very targeted local campaigns to get at specific minority populations who otherwise might not be as receptive. All of this work is currently underway.

And I think you can look forward to many types of different campaigns to enroll, all of the appropriate folks at the appropriate time once we have greater line of sight into when these products will actually be able to reach the market. But safe to say, everybody realizes that vaccine confidence is really, really key. And there's a lot of great work that's being done. And more to come on that as we're able to start unveiling it as the products get closer to the market and emergency use authorization.

A - Mathai Mammen {BIO 16105905 <GO>}

Thanks, Jennifer. Maybe I can take the question on the EGFR C-MET antibody amivantamab. It is indeed really exciting project for us. You asked about near term and long term. First on the antibody itself, it's a really interesting antibody. It's unique to us. And it incorporates both an EGFR (inaudible) and the C-MET (inaudible). And C-MET is a common resistance mechanism for EGFR therapy. So, it hits both the primary mutations and the resistance methods at the same time. The near-term plan is to go forward with an

exon 20 EGFR tumors, non-small cell lung cancers. There is really no good options for patients with exon 20 signatures. But that's how we will begin, but our eyes are on the larger EGFR mutation market and patients in non-small lung cancer. So with time, we plan on exploring multiple lines of therapy and eventually all EGFR containing tumors.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Great. Thank you, Terence. Appreciate the questions. Rob, last question please.

Operator

It comes from Louise Chen with Cantor Fitzgerald.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my question here. So, I wanted to ask you on the FDA. Have you seen any change in their appetite for risk. We've seen a recent speed of complete response letters, not sure if that's just a timing issue or if they've truly changed your thinking there? And then just a follow-up question here on the vaccine, how any potential changes to your vaccine program impact the manufacturing process you've already started? And how many patients have you dosed thus far? Thank you.

A - Christopher DelOrefice {BIO 20730104 <GO>}

Mathai, with the vaccine and then Jennifer and/or Mathai weighing on the FDA. Actually Mathai, why don't you start with the vaccine?

A - Mathai Mammen {BIO 16105905 <GO>}

Yeah, vaccine question. So this interaction right now we're having with regulators in DSMB doesn't change our manufacturing process or plans at all. And we're well underway with our program right now, and we're looking forward to getting going. Overall plans are to complete recruitment of the 50,000 [ph] subjects in two or three months, and that's -- that remains on track.

A - Jennifer Taubert {BIO 20108880 <GO>}

Yeah. And in terms of our working with the agency, we've had a really good track record over the past few months, really, during the height of COVID and continuing to submit files, have them accepted and really importantly, get approvals, not only on time but actually ahead of time. So as an example, our Darzalex FasPro formulation, our subcu form for multiple myeloma was actually approved ahead of schedule. We had an Imbruvica new indication. As you know, we've got 11 indications now for Imbruvica. And we had one of the new ones there approved ahead of time.

I mentioned Tremfya PsA in that approval. And I could go on and list others, but we continue to have very productive conversations with the FDA and continue to have our products moving through the pipeline as anticipated and in some cases, even faster than planned.

A - Ashley McEvoy {BIO 20108895 <GO>}

Yeah, just to complement what Jennifer mentioned, this is Ashley, Louise, I would just echo that from a med tech point of view. You heard us share around the new indication in our PMA for persistent AFib. But recently, in the past couple of months, we were granted a breakthrough designation for the slowing down the progression of myopia in our vision business. That's moving forward nicely, and we were granted a breakthrough designation that's moving forward nicely on the combination of our Monarch and Illuminal diagnostic, coupled with our new wave ablation technology for lung nodules. But from a notion of regulatory approvals and engagement as well as audits, I couldn't be more encouraged.

A - Christopher DelOrefice {BIO 20730104 <GO>}

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

And I'll now turn the call over to Joe for some brief closing remarks.

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

Great. Thank you, Chris, and thank you, again, everyone, for joining today's call to discuss our third quarter results and your very thoughtful questions. I'd also like to take a moment to just thank the Johnson & Johnson associates around the world for their unrelenting commitment to deliver for patients and all of our stakeholders around the world.

Don't forget to mark your calendars to join us for our virtual medical device update on Thursday, November 19th. Best wishes for continued safety and health and know that we will responsibly provide relevant transparent updates as warranted. Bye for now.

Operator

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