Q3 2021 Earnings Call

Company Participants

- Ashley McEvoy, Executive Vice President, Worldwide Chairman, Medical Devices
- Jennifer McIntyre, Senior Director, Investor Relations
- Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals
- Joseph J. Wolk, Executive Vice President, Chief Financial Officer
- Sarah Wood, Senior Director Investor Relations
- Thibaut Mongon, Executive Vice President, Worldwide Chairman, Consumer Health

Other Participants

- Chris Schott
- Danielle Antalffy
- Josh Jennings
- Larry Biegelsen
- Louise Chen
- Matt Miksic
- Matthew Harrison

Presentation

Operator

Good morning. Welcome to Johnson & Johnson's Third 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 you have any objections, you may disconnect at this time. (Operator Instructions)

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

Sarah Wood {BIO 21778714 <GO>}

Good morning. This is Sarah Wood, Senior Director, Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for the third quarter and our updated financial outlook for 2021. On today's call is Joe Wolk, Executive Vice President, Chief Financial Officer. And during the Q&A portion of the call, Joe will be joined by Ashley McEvoy, Executive Vice President and Worldwide Chair, Medical Devices; Thibaut Mongon, Executive Vice President Vice President and Worldwide Chair Consumer Health; and Jennifer Taubert, Executive Vice President and Worldwide Chair Pharmaceuticals.

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 uncertainty about the duration and contemplated impact of the COVID-19 pandemic and other marketplace dynamics.

This means that results could change at any time, and the contemplated impact of COVID-19 on the company's business results and outlook is a best estimate based on the information available as of today's date. A further description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2020 Form 10-K and subsequent Form 10-Qs, along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures. These materials 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 review the third-quarter sales and P&L results for the corporation and the three segments. Joe will provide some additional business and financial commentary before providing an overview of our cash position and capital allocation and then conclude with updated guidance on 2021 results. The remaining time will be available for your questions. We anticipate the webcast will last up to 60 minutes.

Now, let's move to the third quarter results. Worldwide sales were $23.3 billion for the third quarter of 2021, an increase of 10.7% versus the third quarter of 2020. Operational sales growth, which excludes the effect of translational currency increased 9.9% as currency had a positive impact of 0.8 points. In the U.S., sales increased 7.9%. In regions outside the U.S., our reported growth was 13.8%, operational sales growth outside the U.S. was 12.1% with currency positively impacting our reported OUS results by 1.7 points. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 10.6% worldwide, 8% in the U.S. and 13.5% outside the U.S.

Turning now to earnings. For the quarter, net earnings were $3.7 billion and diluted earnings per share was $1.37 versus diluted earnings per share of $1.33 a year ago, excluding after tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were $7 billion and adjusted diluted earnings per share was $2.60, representing increases of 18.7% and 18.2%, respectively, compared to the third quarter of 2020. On an operational basis, adjusted diluted earnings per share increased 16.4%.

I will now comment on business segments sales performance, highlighting items that build upon the slide you have in front of you. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the third quarter of 2020, and therefore, exclude the impact of currency translation. Beginning with Consumer Health. Worldwide Consumer Health sales of $3.7 billion increased 4.1% with growth of

4.5% in the U.S. and growth of 3.7% outside of the U.S. Excluding the impact of divestitures, worldwide growth was 5.7%. Although there is variability across the franchises due to the impact of COVID-19, the overall portfolio is performing well. When comparing to 2019, the Consumer Health business grew approximately 8% operationally in the quarter. Over-the-counter medicines saw strong growth of 18.2% globally, due to share gains in the U.S. along with an increase of pediatric fever incidences and demand for vaccination symptom relief that drove increased sales of TYLENOL and MOTRIN globally.

Additionally, category recovery increased demand for cough, cold, flu and digestive health brands such as Imodium. Sales outside the U.S. benefited from prior year comparisons, specifically prior year reduction and consumption in China. Our skin health/beauty franchise declined by 3% globally, largely due to the 330 basis point impact of the divestiture of Sedona; the salon based portion of Dr.Ci Labo in Asia-Pacific. Excluding this impact, the franchise experienced modest growth driven by strong performance in AVEENO and NEUTROGENA facial moisturizing and body care driven by COVID-19 market recovery and e-commerce growth, partially offset by external supply constraints and lost sales from the Sun aerosol recall. Oral care declined 4.5% globally, largely due to the impact of divestitures worth approximately 300 basis points.

Excluding this impact, the franchise declined due to external supply constraints for Listerine in the U.S. and negative comparisons to prior year COVID-19 related impacts in EMEA, partially offset by strong performance in Asia-Pacific, driven by strong promotions and brand building behind Listerine's strong fighting ability. The Baby Care franchise declined 1.2% globally, resulting from Asia-Pacific COVID-19 lockdowns and competitive pressure, mostly offset by strong AVEENO performance along with category and e-commerce growth in the U.S. Our Women's Health franchise grew 0.8% globally, primarily due to lapping prior year COVID-19 impacts. And finally, our wound care franchise declined 4.8% globally, driven by unfavorable comparisons to prior year's stocking in the U.S. and competitive pressure in Asia-Pacific.

Moving on to our Pharmaceutical segment. Worldwide pharmaceutical sales of $13 billion increased 13.2% with growth of 12.2% in the U.S. and growth of 14.6% outside of the U.S. Excluding the net impact of acquisitions and divestitures, worldwide growth was 13.8%. Additionally, as a reminder, for comparison purposes, Q3 of 2020 was negatively impacted by access-related constraints due to COVID-19 resulting in a decrease of roughly 200 basis points in total across key brands. Our strong portfolio of products and commercial capabilities continue to enable us to deliver adjusted operational growth at above market levels. The immunology portfolio delivered strong global sales growth of 11.7% driven by double-digit performance of STELARA and TREMFYA offset by declines in REMICADE due to biosimilar competition.

STELARA continued to show strength in all regions, growing at 21.7% driven by market growth and share gains of roughly 4 points in Crohn's disease and nearly 7 points in ulcerative colitis in the U.S. TREMFYA was up 63.5% with strong double digit growth worldwide due to continued positive share growth and additional penetration into the psoriatic arthritis indication. U.S. share increased over 2 points in psoriasis and over 3 points in psoriatic arthritis. Oncology also delivered another strong quarter with global sales growth of 16.5%. DARZALEX continued its double-digit performance with 42.9%

growth in the quarter, driven by share gains, increased penetration of the subcutaneous formulation in the U.S. and EU and continued launches globally. DARZALEX grew share across all lines of therapy with nearly 5 points of share growth in the U.S. this quarter, as an example.

ERLEADA also continued its global uptake, with growth of 65.8% in the quarter driven by global market share gains which increased in the U.S. alone, by nearly two points across all indications, led by the metastatic indication. IMBRUVICA grew 2.5% globally due to the brand's market-leading share position, but was partially offset by modest share losses in the U.S., and a market that remains constrained due to temporary COVID-19 impact on new patient starts. In addition, growth was negatively impacted by a prior period adjustment in the U.S. that was worth nearly 350 basis points on worldwide IMBRUVICA growth. Neuroscience grew 4.6% globally driven by paliperidone long-acting portfolio, posting market and share growth due to increased new patient starts and strong persistency in the U.S. The cardiovascular, metabolism and other business declined 12.4% globally due to competitive pressures in INVOKANA and biosimilar competition for PROCRIT. Pulmonary hypertension achieved strong growth of 16.1%, driven by OPSUMIT growth of 17.1% and UPTRAVI grows of 18.8%, both driven by market penetration and share gains. And lastly, global sales in the quarter included a $502 million contribution from the COVID-19 vaccine, bringing the year-to-date total to $766 million. Through the first nine months of the year, revenue has been recorded at a not-for-profit price of $7.50.

I'll now turn your attention to the Medical Devices segment. Worldwide Medical Devices sales of $6.6 billion increased 7% with growth of 0.8% in the U.S. and growth of 13.3% outside of the U.S. Excluding the impact of divestitures, worldwide growth was 7.6%. In the Medical Devices segment, we have seen mixed marketplace recovery as the COVID-19 delta variant and related factors impacted our sales across most of the categories in which we participate within the quarter. With certain procedures, such as spine and knees within orthopedics, deemed to be more elective in nature, continuing to lag in terms of recovery. The Interventional Solutions franchise delivered another quarter of worldwide double-digit growth at 13.2%, driven by market recovery, success of new products in both electrophysiology and neurovascular and strong commercial execution. Worldwide surgery grew 10.2% primarily driven by recovering procedure volumes and market expansion in Asia-Pacific. Advanced surgery grew 12.6% globally, driven by the positive impact of procedure recovery, new product introductions and China Tier 2 and 3 hospital market expansion across endocutters, biosurgicals and energy, partially offset by continued competitive pressure in endocutters and energy in the U.S. Building on the MONARCH robotic milestone communicated last quarter, we reached another significant commercial achievement, now enabling over 10,000 bronchoscopy procedures.

General surgery grew 8.1% globally. Wound closure is the largest contributor with growth driven by procedure recovery, China Tier 2 and 3 hospital market expansion and continued competitive growth in both traditional and barb suture markets. The worldwide orthopedics franchise declined 0.3% with U.S. declines of 4.5% reflecting the impact of COVID-19 on procedures within the quarter partially offset by 6.8% OUS growth. Trauma grew 3.7% globally, 5.3% increase in the U.S. and a 0.9% increase outside the U.S. Results reflect global market recovery dynamics and the success of recent product introductions like our Cannulated Compression Headless Screws, Advanced Nailing Systems and FIBULINK. Hips grew 2.3% globally, driven by recovery and procedures, primarily outside

the U.S. and continued leadership in the anterior approach, supported by our robust portfolio of new products, such as ACTIS femoral stem, PINNACLE Dual Mobility and VELYS Hip navigation.

In Q3, we introduced new image guidance capability for VELYS Hip navigation, which supports surgeons who prefer the posterior approach, in addition to the anterior approach. Knees grew 2.1% this quarter, reflecting recovery of procedures, especially in markets outside of the U.S. Growth in the U.S. outpatient surgery channel and continued momentum from recently launched products, including the VELYS robotic-assisted solution, and our knee portfolio. Results in the quarter also benefited from the timing of international tender orders worth approximately 350 basis points of global growth.

Lastly, within orthopedics, spine declined 11% globally, driven primarily by a deceleration and procedure volume related to COVID-19. The worldwide vision franchise, grew 10% this quarter, primarily driven by market recovery, commercial initiatives and new products driving enhance competitiveness. Contact lens global growth of 6.4% reflects continued positive momentum for our market leading ACUVUE portfolio, success of commercial initiatives and recently launched products such as ACUVUE OASYS Multifocal and ACUVUE Define Fresh. The decline of 4.3% in the U.S. includes a negative impact of prior your stocking worth about 10 points. Surgical vision delivered global growth of 22.1%, driven by market recovery across all regions and success of recently launched products continuing to enhance competitiveness, including TECNIS Eyhance and TECNIS Synergy.

Now regarding our consolidated statement of earnings for the third quarter of 2021, I'd like to highlight a few noteworthy items that have changed compared to the same quarter of last year. Cost of products sold improved by 200 basis points, driven by recovery from prior year COVID-19 related impacts and favorable enterprise mix from gross in pharmaceuticals. We continue to invest strategically in research and development at competitive levels investing 14.7% of sales this quarter. The $3.4 billion investment was 20.5% increased versus the prior year due to portfolio progression. In process research and development, reflects a partial impairment expense of $900 million for assets associated with the acquisition of Auris. The other income and expense line changed from a net expense of $1.2 billion in the third quarter of 2020 to net expensive of $1.9 billion in the third quarter of 2021 primarily due to an increase in litigation related charges. Joe will provide more details on both the IP R&D and litigation related charges.

Regarding taxes in the quarter on a GAAP basis. Our effective tax rate was 4.7% in the third quarter of 2021 compared to 19.2% in the third quarter of 2020 mostly driven by driven by unfavorable tax reserves in positions from the prior year, which did not reoccur, along with lower income and higher tax jurisdictions driven by one time current quarter, special items. Excluding special items, the effective tax rate was 13.5% versus 19% in the same period last year. I encourage you to review our upcoming third quarter 10-Q filing for additional details on specific tax matters. Lastly, I'll direct your attention to the boxed section of the slide, where we have also provided our income before tax, net earnings, and earnings per share, adjusted to exclude the impact of intangible amortization expense and special items.

Now let's look at adjusted income before tax by segment. In the third quarter of 2021, our adjusted income before tax for the as a percentage of sales remained fairly consistent to the prior year, with some changes between our three segments, pharmaceutical margins declined from 46.4% to 43.9%, driven by research and development investment to enable portfolio progression. Medical Devices margin improved from 21.6% to 25.5% driven by recovery from prior year COVID-19 related impacts and overall expense leveraging resulting from sales recovery. Finally, consumer health margins declined from 24.4% to 23.3% driven by a 2020 one-time item and increased brand marketing expenses partially offset by COGS improvement.

That concludes the sales and earnings portion of the Johnson & Johnson third quarter results. I'm now pleased to turn the call over to Joe Wolk.

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Sarah, and good morning, everyone. We appreciate you joining us to discuss our third quarter results, which reflect a continued strength in our pharmaceutical and consumer health businesses and solid growth in medical devices despite COVID-19 variability across geographies. How do we see the current medical device landscape? In the U.S., surgical procedures across most specialties in which we compete decelerated in late July and August with the highest impacts consistently in those procedures deemed to be more elective, such as knees and spine. Globally, new cases of COVID-19 and hospitalizations related to the Delta variant have gradually declined in recent weeks and we are encouraged by more positive procedure trends in many Western European markets, where restrictions are beginning to ease. Some hotspots still remain in parts of the U.S., the UK, Eastern Europe, and Southeast Asia. And the growing impact from reduced medical staffing or constraining procedure volumes. We continue to believe these variables are more short-term in nature and the medical devices market remains attractive as the long-term factors leading to the need for medical and surgical intervention have not changed due to COVID-19.

The segment leaders on the call will provide more insights into each of their businesses during the Q&A, but let me briefly touch upon some pipeline updates for the quarter. We continue to advance our strong pipeline of innovative medicines and products. This progress is supported by our commitment to investments in R&D that have increased $1.9 billion or 23% on a year-to-date basis. In the quarter, we've received U.S. approval for INVEGA HAFYERA the first and only twice yearly treatment for adults with schizophrenia. And we announced the start of a Phase 3 study of our Investigational RSV Vaccine in older adults. Subsequent to the quarter, the FDA granted orphan drug designation for nipocalimab in chronic inflammatory demyelinating polyneuropathy or CIDP, a rare neurological disorder of the peripheral nerves characterized by gradually increasing sensory loss and weaknesses associated with loss of reflexes. This represents nipocalimab's fourth orphan drug designation. We also anticipate U.S. approval for our BCMA CAR-T later this year, which will represent a third new product approval in 2021. However, we are stopping further investigation in the Fontan palliated population of Macitentan 10 milligram in pulmonary hypertension, as results from the Roboto Phase 3 trial did not yield sufficient clinical benefit.

Regarding our COVID-19 vaccine, we are pleased that on Friday, the FDA's, vaccines, and related biological products advisory committee voted unanimously to recommend emergency use authorization for a booster dose of the Johnson and Johnson COVID-19 vaccine for adults aged 18 and older, at least two months following initial single-shot vaccine. The recommendation is based on the totality of evidence with clinical and real-world data showing that while a single-shot offers strong and lasting protection, a booster increases protection, particularly against symptomatic COVID-19. We are very excited to share more about the entirety of our robust pharmaceutical pipeline and long-term growth outlook at our business review on November 18.

In our medical device business, we built upon a record number of 17 significant product introductions in the first half of 2021 by introducing the INHANCE Shoulder System in the third quarter. A first-to-market fully integrated Shoulder Arthroplasty System designed to treat a broad range of cases in hospital or outpatient settings, where economic value and operational efficiency are important considerations. We also announce results from a real-world study showing that the ECHELON CIRCULAR Powered Stapler is Associated with a major reduction in serious complications following colorectal surgery, when compared with manual staplers, reinforcing clinical evidence as a meaningful differentiator in product selection.

Let's transition to financial starting with commentary on special items for the quarter. Other income and expense in the third quarter includes a $2.1 billion charge of litigation expenses, primarily driven by an incremental $1.4 billion charge associated with the recently announced qualified settlement fund for current and future talc claims. The qualified settlement fund is intended to facilitate a final equitable resolution of all talc litigation in a structured manner through established bankruptcy law precedent. Additionally, there is another $800 million legal expense in the quarter, representing final resolution of outstanding claims related to Risperdal.

Another special item worth noting is on the in-process research and development line. We have a broad offering across the digital robotic surgery landscape, and continue to make meaningful progress in advancing differentiated solutions across our portfolio. We are very pleased with the adoption of our MONARCH platform for lung bronchoscopy and are well on our way to expanding MONARCH indications, including initiating a clinical trial exploring the potential for localized drug delivery for the treatment of lung cancer and submitting an application to the FDA for MONARCH to be used in the treatment of kidney stones.

Our VELYS robotic-assisted solution for total knee replacement is commercialized in the U.S., has received several OUS approvals and we are experiencing higher utilization on the system's place to date than we projected. We continue to be committed to the development of a general surgery offering with Ottava. But as Sarah mentioned, we've recorded a partial in-process R&D charge for $900 million in the third quarter. The accounting for this charge contemplates a first in-human delay of approximately two years from our earlier projections of the second half of 2022, reflecting technical development challenges and COVID-19 related disruptions, including supply chain constraints being experienced broadly across all industries. Clearly, we realize the importance that a differentiated digital robotic platform can have for patient outcomes and the market. We

continue to invest in and be committed to the platform and we'll provide updates to the external community as warranted.

Let's transition to a few comments on our cash position. We continue to generate strong free cash flow with $15 billion a year-to-date. We ended the third quarter with $31 billion dollars of cash in marketable securities and approximately $34 billion of debt, resulting in $3 billion of net debt. Our financial position and balance sheet remains strong and we are well positioned to continue to deploy capital in a strategic value creating way consistent with our priorities, that will benefit stakeholders over the long term.

Moving to our full year 2021 guidance. Given where we are in the year, our current assumptions around continued recovery in medical device markets and confidence in the business, we are tightening our adjusted operational sales range to 12.9% to 13.5%. This adjusted operational sales growth is on a constant currency basis, consistent with how we assess our business performance. This guidance also incorporates the estimated a $2.5 billion of COVID-19 vaccine sales consistent with our July guidance. We are maintaining our estimate for the net impact of acquisitions and divestitures of approximately 50 basis points, resulting in an operational sales range of range of 12.4% to 13.0% or $92.8 billion to $93.3 billion for a midpoint of 12.7% or $93.1 billion. 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 1.16 there's an estimated positive impact of foreign currency translation of approximately 150 basis points, consistent with our July guidance resulting in estimated reported sales growth between 13.9% and 14.5% compared to 2020 or $94.1 billion to $94.6 billion.

Moving to other items of the P&L. Consistent with our previous guidance, you can expect our operating margins to be nearly a 200 basis point improvement over last year. Given year-to-date trends, we are modestly increasing and tightening our other income estimate to be a range of $900 million to $950 million. Regarding interest expense again based on our year-to-date experience, we are also tightening the range of our estimate to $100 million to $150 million. And finally, we are lowering our effective tax rate estimate to arrange a 14.5% to 15.5% based on the occurrence of certain one-time favorable tax positions and settlements both in the U.S. and abroad. Considering those updates, we are comfortable with adjusted earnings per share guidance ranging from $9.65 to $9.70 on a constant currency basis, a guidance increase of at the midpoint. We're not predicting currency movements, but to write some insights on the potential impact on EPS. Our reported adjusted EPS would be positively impacted by approximately $0.12 per share. Accounting for that, we would be comfortable with your models, reflecting reported adjusted EPS ranging from $9.77 to $9.82, an increase versus 2020 of 22% at the midpoint.

Consistent with what we shared before, given the not-for-profit nature of the vaccine, there is no significant EPS contribution in 2021 and therefore, the EPS guidance I provided is inclusive of the vaccine revenue. As always, none of our achievements are possible without the hard work of our world-class team of employees around the globe, whose dedication ensures that we that we deliver for all our stakeholders. We continue to make significant strides towards our mission of improving human health and well-being of everyone everywhere and I am grateful for their efforts and commitment.

I'd like to close my prepared remarks by briefly commenting on the CEO transition that was announced earlier in the third quarter. First, I want to acknowledge Alex for his leadership and contributions to Johnson & Johnson during his tenure. It has been my pleasure to work alongside him, particularly over the last three years and to observe and to learn from him both professionally and personally. I'm also pleased to congratulate Joaquin on his new role starting this January. I know firsthand, that he shares the same commitment to patients, employees and society that Alex considers core. Joaquin similarly values innovation that underscores our strategy for long-term success. Both gentlemen will be featured at the previously mentioned, November 18th, Analyst Day sharing their thoughts on our business and plans for the future. I am pleased our worldwide Chairs Ashley McEvoy, Thibaut Mongon and Jennifer Taubert are here with me today to address your questions. Jen McIntyre from our Investor Relations team, will facilitate the Q&A portion of the call.

So I will now turn it over to her, to begin to Q&A. Jen?

Jennifer McIntyre {BIO 19316283 <GO>}

Thank you, Joe. Good morning, everyone. Rob, can you please provide instructions for those on the line wishing to ask a question?

Questions And Answers

Operator

(Question And Answer)

Sure. (Operator Instructions) Your first question comes from Chris Schott with JPMorgan. Please proceed with your question.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much for the questions. I guess, just first, can you just quantify or elaborate on the impact that the Delta variant had on 3Q results in your guidance. I guess, just trying to get to was the impact you saw in the third quarter, basically in line with what you had contemplated in guidance? Or did we have upside elsewhere in the portfolio that offset some of those slowdowns that you mentioned that hit part of the businesses?

And then just kind of maybe building on that, as we think about 2022 and I know you're not giving guidance yet. But is there more in the way of COVID recovery that can aid growth next year, as we think about the portfolio as a whole. So, I guess just trying to get to basically as pharma growth sustainable these levels. And should we think about still device growth may be above historic levels as we kind of get COVID more in the rearview mirror a bit? Thanks so much.

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

Yes Chris. So, this is Joe Wolk. Let me answer some of it quantitatively and then maybe I'll hand it over to Ashley and Jennifer to discuss their outlook for their particular segments.

In terms of the guidance for the balance of the year, as it relates to where we ended the third quarter. If you look at what I guess has been labeled early morning here is a miss I would say, I think about it in two categories. The vaccine quite frankly and as you saw we did not change the full-year guidance. So, that is simply timing we expect that to be fulfilled in the fourth quarter and we're still very much committed to the $2.5 billion of revenue and the supply that is correlated to that.

With respect to medical devices, I think we're very pleased that we had above 7% growth in the quarter, given the different dynamics of Delta variant and hospital shortages, and we do anticipate that those procedures will be recovered. It's hard to say, whether they'll be recovered in the fourth quarter or early next year. So, that could provide some tailwind as you think about 2022.

But let me turn it over first to Ashley to comment on medical devices and then to Jennifer to discuss pharmaceuticals.

A - Ashley McEvoy {BIO 20108895 <GO>}

Sure. Thanks Joe. And thanks for the question, Chris. I would -- when I look at quarter three, as we've shared procedures across most categories in which we participated decelerate through the quarter primarily due to obviously the Delta. So, if I take you a little bit around the world, Asia-Pacific and aggregate continues to operate above pre-COVID levels. However, COVID does continue to be a challenge with like mobility restrictions being reinstated or remaining in places like Japan, Australia, Southeast Asia. China, clearly a setting a new pace for the world.

When we look in the United States, we saw procedure trends decelerate in quarter three. You'll recall on our quarter two call, we were feeling pretty good around 5% growth procedures in May. We saw a stabilization in June, and July. In August, we saw the numbers of procedures dip around mid-single digit and we saw that continued into the early part of September. We are starting to see qualitatively recover from hospital systems, the past four weeks, when we look at early indicators of really filling the patient funnel, we look at diagnostic procedures and the past four weeks we're seeing diagnostic procedures in the United States flat relative to pre-COVID numbers.

And as we talked about, we do expect some micro surges in areas like the North West as well as the Midwest. And then in May around it out, we are encouraged the countries are beginning to ease the strict mobility restrictions and are really starting to resume procedures, given the vaccine deployment accelerations, the decreasing rates of new cases and hospitalizations and overall procedure volumes are gradually improving like Spain, Italy, Germany are all above pre-COVID. The UK where I was just there two weeks ago, clearly below 2019, long waiting lists, really working to go, make progress on that patient funnel. I'll turn it to Jennifer for any other commentary.

A - Jennifer Taubert {BIO 20108880 <GO>}

Thanks Ashley. And hi Chris. Yes, so we've got a real positive outlook on the pharmaceutical business. I think if you take a look at our third quarter results, we had clear double-digit growth across a number of our key brands, including DARZALEX and ERLEADA in oncology, TREMFYA and STELARA in immunology and OPSUMIT and

UPTRAVI in pulmonary hypertension. Those areas we have seen strong recovery. And we believe that the trajectory on those assets is really going to continue. So, continued trajectory in '21 and into '22.

The area part of the market, where we're still seeing a bit of a slower recovery, but we're starting to see it take that is really in chronic lymphocytic leukemia and mantle cell lymphoma the market where IMBRUVICA, is right now from IMBRUVICA we just achieved double-digit growth ex-US, but in the U.S. it's actually been a little bit lower than that. And so I think that's one that as you take a look and we move into 2022, we're anticipating to see some positive recovery there. But really strong results in 3Q and we anticipate continued strong trajectory through the rest of the year and into '22.

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

Great. Thanks, Ashley and Jennifer. And Chris, I know you asked about medical devices and pharmaceuticals, but to be complete Thibaut, I know you had great success in the quarter 6%, almost 9%, when you compare it to Q3 of 2019, maybe give a little bit of an outlook as to what you're seeing for the balance of the year and into next?

A - Thibaut Mongon {BIO 20973347 <GO>}

Yes, Joe. As you just said, the consumer segment continues to experience very strong momentum. So, we're very pleased with how the portfolio continues to perform around the world. Clearly, this quarter the star is our OTC segment growing double-digit, with continued strong demand for therapeutic brands in analgesics, but also digestive health, continued demand in smoking cessation as well. So, across all categories and around the world, continued strong demand for our products.

As we get into Q4 and into 2022, we expect our portfolio of brands to continue to be very well positioned in the markets and categories in which we compete. Our brand -- many of our brands are iconic and we would expect continued growth for these brand around the world.

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

Great. Thanks, Thibaut. And back to you.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thank you for your question, Chris. Rob, next question, please.

Operator

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

Q - Josh Jennings {BIO 16451037 <GO>}

Hi. Good morning. Thanks so much for taking the questions. I wanted to just circle on the announcements around the top litigation and the process that change is undergoing. Is there any way -- I know, you're not going to talk about deeply about the strategy, but just thinking about milestones for this process and any way you can help us understand, when

this strategy will be fully cleared and in play? And I guess stamp of approval by the bankruptcy court or how should we thinking about this process through the rest of this year and in the 2022?

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

Yeah. Thanks for the question, Josh. Let me start this response by underscoring just our conviction in the safety based on decades of science that these products are safe. What we've done is acknowledge that there's an established process that allows companies facing abusive towards systems to resolve claims in an efficient and equitable manner. We initiated this process specifically for our cosmetic talc claims both current and future.

And while we believe the case is lack merit, and by the way, an overwhelming number of courts, juries and judges, who have opined on this to full adjudication ultimately agree with us. We did establish a $2 billion qualified settlement fund. But as you note in your question Josh, it's really the bankruptcy courts that will ultimately decide. This is not plaintiffs' attorneys, it's not Johnson & Johnson. But we do know that based on prior experience precedent, that claimants are far better off and clarity and resolution is in the best interest of all stakeholders. So, we'll continue to monitor the process, but it will really behold into how the Bankruptcy Court decides to proceed in their timeline.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks, Josh. Rob, next question, please.

Operator

Next question comes from the line of Larry Biegelsen with Wells Fargo. Please proceed with your question.

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. Just one for Ashley. Just Ashley, it looks like Q3 growth in devices relative to 2019 was about 4%. Could you confirm that? And what are your expectations for Q4 relative to that metric relative to Q4 2019 after adjusting for one last week? I think people are trying to understand, if Q4 growth could be better than Q3 on an underlying basis versus 2019. And how are you thinking about the staffing shortages and supply constraints, I think Joe alluded to an inflation. How are you thinking about those factors that people are concerned about in the device industry? Thanks for taking the question.

A - Ashley McEvoy {BIO 20108895 <GO>}

Thanks for the question, Larry. And, before I get to quarter four, let me just give a quick frame for quarter three, just going to add a macro level. First is really the market, and while COVID-19 has temporarily disrupted, the medtech markets. We absolutely believe that the underlying foundation of these end state markets continue to remain attractive really due to, what we say oodles of clinical unmet need, and quite frankly, the overall state of the technology on the s-curve.

Quick refresh is outstanding and our competitiveness as the second largest medtech company with 11 platforms, delivering at least $1 billion in annual sales. We are very much focused on competitiveness and innovation. In quarter two, almost all of our priority platforms held our gain share, some notables include continuing to enhance our global market position in electrophysiology, biosurgery, gaining share in hips, seen the impact of recent innovation in surgical vision, now seeing several sequential quarters of share gains and even seen stabilization in needs year-to-date. So, this is really about our focus on commercial effectiveness and our ability to deliver innovation. As Joe mentioned earlier in 2021, we had 17 new product launches year-to-date. And this is a significant amount over last year.

So, year-to-date through 2021, Larry, we are tracking to 5% growth versus 2019. We did achieve 4% growth in quarter three, obviously that's an improvement of how we exited 2019 the full year.

And then last, I would just say, you've heard us talk a lot about digital surgery. We're absolutely committed to leading in the future of surgery and making it our medical innovation smarter, less invasive and more personalized. Joe talked a little bit about our Monarch reaching 10,000 patients this year has a very rich pipeline. VELYS Knees is now approved in five countries. Our smart digital tools continue to scale. And lastly Ottawa, our soft tissue offering, you heard us share we're experiencing a temporary setback in its development.

Transformational innovation is all kinds of fun, I will tell you, it's highly complex. But sometimes we do experience technical challenges, but we are absolutely committed to resolving our challenges, continuing to invest and bringing to market a competitive differentiate offering as soon as possible.

When we look at quarter four, we do expect to see continued improvement. We do expect hospitals are going to have to continue to manage through labor shortages, I don't expect that to get better in quarter four nor in 2022, but they've been quite masterful and how to manage patient close. We are, when I talk to hospital systems over the past three weeks in particular, in the United States, they are ramping up again and resuming elective procedures. We're keeping our eye on vaccination rates, patient sentiments, the cold weather, but we do we are planning for a strong recovery in quarter four versus how we exited quarter three.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks for your question Larry. Rob, next question please.

Operator

Next question is from Louise Chen with Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my question. So, I wanted to ask you about some of the management changes that were announced. And how we should think about what could change or

what could stay the same under a new CEO and CSO? And then any anticipated changes to business mix between pharma, med device and consumer as a result of new leadership? Thank you.

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

Thanks Louise for the question. I'll try to address that one. What I would say is, first-off I probably repeat the words I had both to congratulate Alex as well as Joaquin. Alex, clearly on a stellar career, a great run as his tenure as CEO, and he'll be a very active Executive Chairman. I suspect it's not as if he's riding completely off into the sunset.

Joaquin values the same principles that have made Johnson & Johnson successful. That's investing in innovation and making sure that we've got differentiated products and solutions to improve the standard of healthcare across the globe.

The nice thing about the transition is, I don't expect any significant bumps. They've worked together for a number of years. The strategies that they have talked about and that you'll probably see in the early part of Joaquin's tenure have been contemplated with Alex in mind and they've collaborated as Chair and Vice Chair over a number of years. So, I would expect as the organization does a very smooth transition.

With respect to CSO, we have not had a chance to acknowledge just really the impact that Paul has had on the scientific community, not just here at Johnson & Johnson, but across the globe. He was a pioneer in infectious diseases, when nobody had an answer for HID. Paul emerged as clearly a leader there. And then just most recently his notable leadership on the COVID-19 vaccine again here at JNJ, but also on the global stage.

I think the probably the greatest testament to Paul's legacy is the fact that our R&D investment this year is 23% higher through nine months than what it was last year. And last year was a record setting year in terms of what we've invested in innovation. We've got a great team of scientists that Paul has assembled over the years, across all of our therapeutic areas, across all of our franchises. And I just look forward to the success that they will continue to carry on that Paul has really, I guess, cement it, in terms of how we approach our business.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Louise, thanks for your question. Rob, next question, please.

Operator

Next question is from Matthew Harrison with Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good morning. Thanks for taking the question. I guess, I was hoping you could focus a little bit on the upcoming BCMA CAR-T launch. And just talk a little bit about how you think about your capacity to supply that market and your preparations for that launch? Thanks.

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. Hi, its Jennifer. So, we are really looking forward to our upcoming PDUFA date in the fourth quarter for our BCMA CAR-T. This is going to be our first entry into cell therapy. And so, the team -- the total team from R&D to supply chain, to commercial, has been really, really invested in this asset over the past couple of years, preparing to launch. I think, on the results that you've all seen and they're really deep and durable responses that have been proven through our clinical programs, really highlight that this is going to be a really meaningful and transformational asset for patients.

As we have been planning the launch, we're really taking a thoughtful approach to scaling our global manufacturing, making sure that we're learning from those who come before us. And that we're really going to plan to deliver an optimal patient experience and a patient treatment or provider treatment center experience as well as we scale up. So, the team has been working very heavily on this and we're gearing up for what we believe will be a very successful launch for patients, hopefully later this year.

I also want to call out the very strong partnership that we have with Legend Biotech, where we've been attached at the hip throughout and we're so excited to be working in partnership with them to be bringing that to market. So, I'm looking forward to a good launch later this year.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks, Jennifer. Matt, thanks for your question. Rob, next question, please.

Operator

Your next question comes from Matt Miksic with Credit Suisse.

Q - Matt Miksic {BIO 6990080 <GO>}

Hi, thanks so much for taking the questions. So, I've one for Ashley, just on the knee business in the U.S. and one quick follow-up, if I could on COVID vaccines. So, Ashley, I think one of the things that was mentioned was, sort of continued growth and expansion in around the knee business, if I'm not mistaken in ASCs, and obviously the VELYS launch. If you could talk maybe it's a ASC, I guess, in knees or something that we see regional fluctuation around the U.S. is to uptake some areas stronger than others and love to get your sense of how that's progressing, where it's stronger and why, and how you see that playing out? And as I mentioned one follow-up for on vaccines.

A - Ashley McEvoy {BIO 20108895 <GO>}

Yes, thank you for the question, Matt. As Sarah shared, in quarter three, KINCISE grew 2% versus 2020 and a lot of that was due to really two folds, one is the state of innovation. So, the VELYS knee robot is obviously getting some nice traction. As Joe shared earlier, the utilization rates are very encouraging from hospital systems that have adopted this new technology that coupled with a very proven differentiated to knee implant with a revision offering as well as the cement lists rotating platform have all really help shore up, I would say our portfolio in knees.

And then you mentioned the channel and we are seeing really healthy growth in the ASC channel. We continue to be encouraged by our market share gains, predominantly in joint in ASCs. And really, we started to pull away what we call an advanced case management, which is really how you simplify the pre-op planning in ASCs and that new advanced case management service is starting to really take effect. And we expect to have these new sites to care start to really improve. Not just and take hold, not just in the U.S., but even in the areas of Europe and really moving joints to more of a day surgery. Thank you for the question.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks, Ashley. Matt you want to ask your vaccine follow-up?

Q - Matt Miksic {BIO 6990080 <GO>}

Yeah, just we hadn't touched on it on this call. But the sort of pivot to commercial would love to get your sense of how we should think about timing and the sort of catalysts for that product becoming a commercial product, whether next year or the year after?

A - Ashley McEvoy {BIO 20108895 <GO>}

Yeah, so hi. So, we're obviously proud of the role that our vaccines playing and really helping address the global COVID pandemic throughout the world, and hopefully, you saw last week that the FDA Advisory Panel Unanimously Recommended booster for our COVID vaccine. We are in the process right now of continuing under emergency use authorization to rollout our vaccine across the globe both in developed markets as well as developing markets.

I think as the pandemic, as we continue to work through and fulfill our existing contracts that we have throughout the globe and as we move into more of a booster market in later '22, potentially into 2023, we'd be looking at moving into a more of a commercial market. I know, our R&D team is gearing up and getting ready to file for full approval. I think we want to be moving into a full approval market for that switch over to commercial.

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

Hey, Matt, this is Joe. Just thanks for raising the point, because I do think that underscores in that question, just the strength of our core business, right? So, vaccines in and of itself this year's not-for-profit, as Jennifer said, will rely on the science and the data to guide us how we proceed commercially. But you should all consider that as upside to our base plan. We're so proud of the results that we've been able to accomplish the investment in R&D and just the strength of the portfolio, not just this year, but how it really sets up for the balance of this decade. I think is something that people should take away from the call.

I always smile a little bit whenever there's vaccine news, because it seems to be overly pronounced impact on our stock, good or bad. And it always just makes me chuckle a little bit because of the strength of our business is really in our pharmaceutical medical device and consumer strength these days.

A - Jennifer Taubert {BIO 20108880 <GO>}

And if I can jump in as well, and just put in a commercial for our upcoming pharmaceutical business review on November 18th, we're really looking forward to having a comprehensive overview of the business plug in our robust pipeline, featuring our therapeutic area leaders and also really outlining our long-term growth outlook. So, we're real excited.

I think at that meeting, we're planning for a great day and we'll be highlighting a number, not only our key therapeutic areas and delving deep into pipelines, but also having a chance to feature a number of the key assets that folks, I know how really, really interested in learning more about.

So, everything from CARVIC-T or BCMA CAR-T to nipocalimab that we got through our Momenta acquisition last year. Our new treatment for lung cancer and what we hope will be expanding into a much broader market, RYBREVANT plus Lazertinib. Our retina portfolio also things like our RSV vaccine and our TARIS drug delivery platform for bladder cancer and I could go on and on. But nonetheless, we're really planning for a very exciting day on November 18th and look forward to having you all join us.

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

It was a 60 second spot, Jennifer. She was going to tell you about the rates on that one.

A - Jennifer Taubert {BIO 20108880 <GO>}

We're really looking forward to a great day. I couldn't pass this opportunity not highlighted.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks Matt for your question. Rob, last question, please.

Operator

Your last question comes from Danielle Antalffy with SVB Leerink.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning, everyone. Thank you so much for taking the questions. I just had a quick question a follow-up to Ashley on the medical device business. And I'm just curious, it feels like now there might be a little bit more uncertainty around the pace of recovery. I just want to be sure I'm getting that message correct? And you did mention that you didn't expect the hospital labor shortages to necessarily improve, as we go through Q4. So, I was just curious about how to reconcile that with the strong recovery? Thanks so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

Yes, Thanks for the question, Danielle. I think we're planning for quarter four is, I think, we'll still continue to see micro surges in cases, there always be little hotspots. Hospitals are still going to experience some labor challenges. We don't see that getting better in the near-term immediately. I will qualify that though to say that they have been quite frankly masters at understanding how to manage patient flow and procedure flow.

When we look at diagnostic agnostic and routine screenings and surgical procedures, we expect the trends will continue to recover globally similar to the trends we saw on quarter two, where surgical procedures grew low single-digit above 2019 baselines. As we referenced there are more procedural backlogs and the highly-elective procedures like knees and spine. And we expect those to recover, although maybe not as in terms of hospital capacity at levels significantly above 2019 in the near-term.

But I would just say, going into November, relative to where we were entering November last year, we are encouraged to look at the worldwide case data to look at the worldwide hospitalization data and the freeing up of mobility restrictions. So, we are encouraged by quarter-over-quarter performance from 2021 Q4 versus last year, you'll recall, we ended around 1.5% medical device did in revenue versus 2019. So, we are anticipating a healthier recovery.

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

And Danielle, maybe just to clarify too. It's a recovery, no matter what, it's just the intensity of the recovery. So, I would not expect based on what we know today any backward step with respect to medical devices performance going forward across the industry.

A - Jennifer McIntyre {BIO 19316283 <GO>}

Thanks, Danielle for your question, and thanks to everyone for your questions and your continued interest in our company. Our apologies to those we couldn't get to you today because of time, but please don't hesitate to reach out to Investor Relations as needed.

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

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

Great. Thanks, Jen. So, I hope you take away from the third quarter results, as well as this call, just how broad our financial strength is, setting us up a very well to close out 2021, but more importantly 2022 and beyond. We certainly do look forward to seeing many of you in New Brunswick on November 18th, where Jennifer, Mathai and the number of the pharmaceutical leaders will be featuring our product portfolio, and just how optimistic we are about the future.

With that, I'll close the call and wish everyone have a great day.

Operator

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