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OVERVIEW:

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PRESENTATION

Operator

Good morning, and welcome to Johnson & Johnson's Third Quarter 2023 Earnings Conference Call. (Operator Instructions) This call is being recorded. (Operator Instructions)

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

Jessica Moore - *Johnson & Johnson - VP of IR*

Good morning. This is Jessica Moore, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of the 2023 third quarter business results and full year financial outlook.

A few logistics before we get into the details. As a reminder, you can find additional materials, including today's presentation and associated schedules, on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com.

Please note that this presentation contains forward-looking statements regarding, among other things, the company's future operating and financial performance, market position and business strategy. You are cautioned not to rely on these forward-looking statements, which are based on current

expectations of future events using the information available as of the date of this recording and are subject to certain risks and uncertainties that may cause the company's actual results to differ materially from those projected. A description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2022 Form 10-K, which is available at investor.jnj.com and on the SEC's website.

Additionally, 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 start by reviewing the third quarter sales and P&L results for the corporation and highlights related to our two businesses. Joe Wolk, our CFO, will then provide additional business and financial commentary before sharing an overview of our cash position, capital allocation priorities and updated guidance for 2023.

The remaining time will be available for your questions. Joaquin Duato, our Chairman and CEO; John Reed; and Ahmet Tezel, our Innovative Medicine and MedTech R&D leaders; as well as Erik Haas, our VP of Litigation, will be joining us for Q&A. To ensure we provide enough time to address your questions, we anticipate the webcast will last approximately 60 minutes.

As a reminder, on August 23, 2023, Johnson & Johnson announced the final results of the exchange offer and completion of the separation of Kenvue Inc. Unless otherwise stated, the financial results and guidance highlighted today reflect the continuing operations of Johnson & Johnson. We will report the Consumer Health financial results as discontinued operations. Additionally, going forward, the Pharmaceuticals segment will be referred to as Innovative Medicine.

Starting with Q3 2023 sales results. Worldwide sales were \$21.4 billion for the third quarter of 2023, an increase of 6.8% versus the third quarter of 2022. Operational sales growth, which excludes the effect of translational currency, increased 6.4% as currency had a positive impact of 0.4 points. In the U.S., sales increased 11.1%. In regions outside the U.S., our reported growth was 1.6%. Operational sales growth outside the U.S. was 0.7%, with currency positively impacting our reported OUS results by 0.9 points.

It is important to note that operational sales in Europe were negatively impacted by the COVID-19 vaccine and loss of exclusivity of ZYTIGA. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 4.9% worldwide, 8.9% in the U.S. and 0.3% outside the U.S.

Turning now to earnings. For the quarter, net earnings were \$4.3 billion, and diluted earnings per share was \$1.69 versus diluted earnings per share of \$1.62 a year ago. Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were \$6.8 billion and adjusted diluted earnings per share was \$2.66, representing increases of 14.1% and 19.3%, respectively, compared to the third quarter of 2022. On an operational basis, adjusted diluted earnings per share increased 13.9%.

I will now comment on business sales performance. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the third quarter of 2022, and therefore exclude the impact of currency translation.

Beginning with Innovative Medicine. Worldwide Innovative Medicine sales of \$13.9 billion increased 5.1% with growth of 10.9% in the U.S. and a decline of 2.3% outside of the U.S. Operational sales growth increased 4.3% as currency had a positive impact of 0.8 points. Excluding COVID-19 vaccine sales, worldwide operational sales growth was 8.2% with growth of 10.9% in the U.S. and growth of 4.3% outside of the U.S. Sales outside the U.S., excluding the COVID-19 vaccine, were negatively impacted by approximately 500 basis points due to the loss of exclusivity of ZYTIGA in Europe.

Innovative Medicine growth was driven by our key brands and continued uptake from our recently launched products, with 11 assets delivering double-digit growth. We continue to drive strong sales growth for both DARZALEX and ERLEADA with increases of 20.7% and 27%, respectively, due to continued share gains and market growth. Within Immunology, we saw growth in STELARA and TREMFYA with increases of 15.8% and 21.5%, respectively. This growth was predominantly driven by favorable patient mix and market growth.

Turning to newly launched products. We continue to make progress on our launches of CARVYKTI and SPRAVATO. We are also encouraged by the early success of our launches of TECVAYLI and TALVEY, sales of which are driving the growth in other oncology. We expect to begin disclosing TECVAYLI sales in Q1 2024.

Total Innovative Medicine sales growth was partially offset by the loss of exclusive of ZYTIGA and REMICADE, along with a decrease in IMBRUVICA sales due to competitive pressures.

I'll now turn your attention to MedTech. Worldwide MedTech sales of \$7.5 billion increased to 10% with growth of 11.6% in the U.S. and 8.3% outside of the U.S. Operational sales growth increased 10.4% as currency had a negative impact of 0.4 points. Abiomed contributed 4.6% to operational growth. Excluding the impact of acquisition and divestitures, worldwide adjusted operational sales growth was 6%. On a pro forma basis, utilizing sales in the prior year from Abiomed as a stand-alone company, MedTech's growth for the quarter would be 6.4%.

MedTech was negatively impacted across all platforms by international sanctions in Russia worth approximately 60 basis points and volume-based procurement in China, primarily in 5 MedTech platforms: Spine, trauma, endcutters, energy and electrophysiology. As communicated last quarter, we saw the return to more normalized seasonality with moderate deceleration in the third quarter.

The Interventional Solutions franchise delivered operational growth of 48.1%, which includes \$311 million related to Abiomed. This reflects growth in Abiomed patient procedures in the high teens and continued strong adoption of Impella 5.5 technology in surgery. Electrophysiology is a major contributor to this growth with a double-digit increase of 20.3%. This reflects strong growth in all regions, including Europe, driven by our global market-leading portfolio, including the most recently launched QDOT RF ablation and OPTRELL mapping catheters.

Operational growth of 3.2% in Surgery was driven primarily by procedure recovery and strength of our biosurgery and wound closure portfolios. Growth was partially offset by the impacts of volume-based procurement in China and supply challenges.

Global growth of 5.4% in Vision was driven by price actions in contact lenses and other as well as strength of new products, including ACUVUE OASYS 1-Day family of products in contact lenses and TECNIS Eyehance, our monofocal interocular lens in surgical vision. Growth of contact lenses was partially offset by strategic portfolio choices and supply challenges, although these continue to improve. Global Vision growth was negatively impacted by 100 basis points due to the Blink divestiture.

Orthopedics operational growth of 2.6% reflects procedure growth; success of recently launched products, such as the global expansion of our VELYS digital solutions; and expansion in ambulatory surgical centers; partly offset by the impacts of volume-based procurement in China in spine and trauma.

Now turning to our consolidated statement of earnings for the third quarter of 2023. I'd like to highlight a few noteworthy items that have changed compared to the same quarter of last year. Cost of products sold margin was flat due to favorable patient mix and lower COVID-19 vaccine supply network-related exit costs in the Innovative Medicine business, partially offset by commodity inflation, unfavorable product mix and restructuring related to excess inventory costs in the MedTech business.

Selling, marketing and administrative margins deleveraged 40 basis points, driven by increased expenses across enterprise. We continue to invest strategically in research and development at competitive levels, investing \$3.4 billion or 16.2% of sales this quarter. R&D was leveraged by 120 basis points, primarily driven by portfolio prioritization, partially offset by higher milestone payments in the Innovative Medicine business. Additionally, IP R&D impairments were \$206 million in the third quarter of 2023.

Interest income was \$182 million in the third quarter of 2023 as compared to \$99 million of income in the third quarter of 2022. The increase in income was driven by higher interest rates earned on cash balances, partially offset by higher interest rates on debt balances.

The other income and expense line was an expense of \$499 million in the third quarter of 2023 compared to an expense of \$226 million in the third quarter of 2022. This was primarily driven by higher unrealized mark-to-market losses on public securities, partially offset by the lower COVID-19 vaccine-related exit costs and lower litigation expense.

Restructuring in the third quarter was \$158 million, primarily related to the Innovative Medicine restructuring program announced in the first quarter.

Regarding taxes in the quarter. Our effective tax rate was 17.4% versus 16.7% in the same period last year. This increase was primarily driven by a non-deductible, non-recurring pretax charge that occurred in the current quarter. Excluding special items, the effective tax rate was 15.6% versus 15.9% in the same period last year.

As a result of the completion of the exchange offer, Johnson & Johnson is presenting the Consumer Health business financial results as discontinuing operations, including a gain of approximately \$21 billion. I encourage you to review our upcoming third quarter 10-Q filing for additional details on specific tax and separation-related matters.

Lastly, I'll direct your attention to the box 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 2023, our adjusted income before tax for the enterprise as a percentage of sales increased from 35.3% to 37.6%, primarily driven by favorable patient mix in Innovative Medicine, partially offset by unfavorable product mix and commodity inflation in MedTech. Innovative Medicine margins improved from 41.4% to 45.4%, primarily driven by favorable patient mix and R&D portfolio prioritization. MedTech margins declined from 25% to 24.7%, primarily driven by commodity inflation and unfavorable product mix, partially offset by a divestiture gain.

This 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. Joe?

Joseph J. Wolk - *Johnson & Johnson - Executive VP & CFO*

Thank you, Jessica, and thanks, everyone, for joining us today. This quarter's call marks a new era for Johnson & Johnson with a sharpened focus on Innovative Medicine and MedTech. What has remained consistent is our credo and our commitment to patients. We are privileged to build upon our 137-year legacy of tackling the world's most complex health care challenges and helping patients with serious unmet health needs around the world. As we look forward, we are well positioned to grow our business and innovate across the spectrum of health care. We are excited about what's ahead and what we can achieve in the future.

Before we dive into our performance, I want to briefly touch upon other items important to our business. The first is a brief recap of the Kenvue separation which was formally completed during the quarter. The transaction was executed within our targeted time frame and under budget while generating significant cash and value for our shareholders.

Through this separation, we raised \$13.2 billion in cash proceeds through the Kenvue debt offering and IPO. We reduced Johnson & Johnson's outstanding share count by 191 million shares or approximately 7% without the use of cash and in a tax-free manner. We maintained our current quarterly dividend per share, and we retained approximately 180 million shares of Kenvue stock that provides cash proceeds for future flexibility. We will see the full impact to EPS of the share reduction in 2024.

Another item warranting comment is the Inflation Reduction Act. We continue to believe the IRA's price-setting provisions are damaging to innovation and will prevent the delivery of transformative therapies and cures to patients. As we await adjudication of legal proceedings initiated by us and others, we did submit all requested information in compliance with CMS' drug price-setting scheme to continue supporting patients' access to our medicines that help them stay healthy and live longer.

Moving to segment highlights in the quarter. As Jessica previously shared, our teams delivered strong results in the third quarter while continuing to advance our pipeline to enhance future growth.

Within the Innovative Medicine business, two important regulatory milestones were announced during the quarter. Specifically, we received the European Commission approval for a reduced biweekly dosing frequency for TECVAYLI for eligible patients with relapsed and refractory multiple myeloma, and U.S. FDA and European Commission approval of TALVEY, a first-in-class bispecific therapy for the treatment of patients with heavily pretreated multiple myeloma.

Regarding clinical data, we are excited to have an unprecedented seven late-breaking abstracts, including three featured in the Presidential Symposium being presented at the European Society of Medical Oncology meeting this weekend. Highlights will include the results from all three Phase III studies of RYBREVANT in lung cancer, including MARIPOSA, MARIPOSA-2 and PAPILLON.

Additionally, updated data from the SunRISe-1 study of TAR-200 in non-muscle-invasive bladder cancer will be shared, as well as the first-ever data of TAR-210 in patients with FGFR mutations.

We also look forward to presenting Phase II data for nipocalimab in rheumatoid arthritis at the American College of Rheumatology Annual meeting in November and have already launched a Phase II combination study in RA.

Lastly, we plan to initiate multiple clinical development programs for our targeted oral peptide JNJ-2113. This includes the initiation of the ANTHEM Phase IIb study in ulcerative colitis, which will begin this month; and the Phase III clinical program titled ICONIC, for adults with moderate to severe plaque psoriasis, expected to begin in November.

Moving to MedTech. Notable highlights in the quarter include significant advancements in electrophysiology across our cardiac ablation platform. We received FDA clearance for multiple atrial fibrillation ablation products in our portfolio to be used in a workflow without fluoroscopy. This FDA indication is unique to Johnson & Johnson and is a significant advancement where caregivers and patients are not exposed to harmful fluoroscopy-related radiation during their cardiac ablation procedures. It also allows for the removal of heavy lead protective equipment that may lead to orthopedic complications for care teams.

In pulse field ablation, we have completed our clinical trial in Europe and submitted for CE Mark for our VARIPULSE catheter. We expect the completion for our U.S. VARIPULSE study to occur in the fourth quarter. We are also simultaneously advancing clinical studies for two additional pulse field ablation catheters, the STSF dual energy catheter capable of delivering both PF and RF energy through the same device; and OMNYPULSE, a large-tip focal catheter.

Beyond electrophysiology, we have completed enrollment in the Abiomed Impella ECP clinical study, a landmark pivotal trial designed to demonstrate the safety and efficacy of the Impella ECP during high-risk PCI procedures. Impella ECP is the world's smallest heart pump and the only heart pump compatible with small-bore access and closure techniques.

While not a clinical advancement, we have also taken steps in the quarter to improve MedTech's future margin profile, implementing a restructuring program designed to simplify and focus the operations of our Orthopedic business. As part of this 2-year program, we expect to exit certain markets and product lines across that business. We anticipate some short-term modest revenue disruption in Orthopedics of approximately \$250 million in total over the next 2 years, given the market and product line exits, but believe these actions will improve our ability to meet demand, resulting in accelerated growth and enhanced profitability. The program is expected to be completed by the end of 2025 with total program costs estimated to be between \$700 million and \$800 million.

Let's now turn to cash and capital allocation. We ended the third quarter with approximately \$24 billion of cash and marketable securities and approximately \$30 billion of debt for a net debt position of \$6 billion. Free cash flow year-to-date through the third quarter was approximately \$12 billion, up from the \$5 billion we reported year-to-date in the second quarter of 2023.

Our capital allocation priorities remain unchanged. We will continue to execute a strategic and disciplined approach, utilizing our strong credit profile and robust free cash flow generation to prioritize continued investment in our business, increasing dividends on an annual basis, executing strategic business development initiatives for inorganic growth and executing share repurchases when appropriate.

Moving on to our 2023 guidance update. Based on the strong results delivered in the quarter and the first 9 months of this year, balanced with planned investments in the fourth quarter, we are raising the ranges for full year sales and EPS guidance. We now expect operational sales growth for the full year 2023 to be in the range of 8.5% to 9.0% or up \$600 million at the midpoint in the range of \$84.4 billion to \$84.8 billion on a constant currency basis, and adjusted operational sales growth in the range of 7.2% to 7.7%.

Just a reminder, our sales guidance continues to exclude any COVID-19 vaccine revenue. While we do not speculate on future currency movements, utilizing the euro spot rate as of last week at \$1.06, we now anticipate an incremental negative currency impact of \$400 million, resulting in a full year impact of negative 1% or \$800 million.

Looking across the P&L. Adjusted pretax operating margin is still expected to improve by approximately 50 basis points versus prior year, driven by stronger margin profile and business mix. Net other income is also being maintained, ranging from \$1.7 billion to \$1.9 billion. Due to higher interest rates earned on our cash, we now expect net interest income in the range of \$300 million to \$400 million. And finally, based on current tax law, our estimate for the effective tax rate for 2023 will be between 15.0% and 15.5%.

These revised estimates translate to an increase in our adjusted operational earnings per share guidance by \$0.10 at the midpoint. Our new range is \$10.02 and to \$10.08, or 12.5% growth at the midpoint; and adjusted reported earnings per share in the range of \$10.07 to \$10.13, or 13% growth at the midpoint.

Since January, we've been able to increase our guidance throughout the year for a cumulative impact of \$3 billion on operational sales and \$0.25 on adjusted operational earnings per share, which includes absorbing \$0.10 for our licensing deal with Cellular Biomedicine Group announced in the second quarter of 2023.

Now I appreciate that many of you are turning your attention to 2024, and our team is actively finalizing our plans for next year. With that context, allow me to provide some preliminary perspectives for you to consider.

For Innovative Medicine, we remain confident in our ability to deliver growth from key brands and anticipate continued progress from our newly launched products, all while advancing our robust pipeline with many exciting data readouts, filings and approvals ahead of us. This includes data presentation and regulatory submissions for TREMFYA in IBD, presenting data from our Phase III study of nipocalimab in myasthenia gravis and readouts from two Phase III ERLEADA trials in early stage prostate cancer. We do not expect entry of STELARA biosimilars in the United States during 2024. However, as a reminder, STELARA does have a composition of matter patent expiry in mid-2024 in Europe.

For MedTech, we expect our commercial capabilities and continued adoption of recently launched products across all MedTech businesses will continue to drive our growth and improve competitiveness while continuing to advance our pipeline programs, including innovation in pulse field ablation, Abiomed and surgical robotics. We expect procedures in 2024 to remain consistent with elevated 2023 levels.

With respect to tax. As you may be aware, the European Union member states are in the process of enacting the EU's Pillar Two directive, which generally provides for a 15% minimum tax rate as established by the OECD Pillar Two framework. The first EU effective date for certain aspects of the law is January 1, 2024. As a result, we currently estimated up to a 1% tax rate increase in 2024. In addition, the U.S. Treasury's current perspective on Pillar Two will be harmful as it relates to the treatment of U.S. incentives for innovation and will result in U.S.-based multinational companies paying more tax revenue to foreign governments.

Regarding share count given the Kenvue separation. The full benefit of the approximately 191 million net share reduction in Johnson & Johnson shares outstanding from the exchange offer will be reflected in our 2024 financials.

And finally, while we don't speculate on future currency impact, utilizing the current euro spot rate would yield an approximate \$0.15 negative currency impact on 2024 full year adjusted earnings per share.

We are pleased with our strong performance during the first 9 months of this year and have positive momentum as we move into 2024. We look forward to sharing more about the strength of our business, promise of our Innovative Medicine and MedTech pipelines and the long-term strategy

of Johnson & Johnson at our upcoming Enterprise Business Review on December 5 at the New York Stock Exchange. More information, including an overview of the day's schedule, will be shared shortly. We hope you will be able to join us either in person or on the available webcast.

I want to conclude my remarks by thanking our teams around the world for their continued hard work and unwavering commitment to excellence on behalf of our patients. We are confident that our strategy will position us to deliver long-term growth and create significant value for our shareholders.

With that, it's my pleasure to turn to Kevin and begin the Q&A portion of the call.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is coming from David Risinger from Leerink Partners.

David Reed Risinger - *Leerink Partners LLC, Research Division - Senior MD*

Congrats on the strong financial performance. So my question is on benchmarking MARIPOSA results, please. Could you share your thoughts on key considerations, including AstraZeneca's recent FLAURA2 results, which included a 9-month PFS benefit?

John C. Reed - *Johnson & Johnson - EVP of Pharmaceuticals, R&D*

John Reed here. It's great to join the call. This is my first time as a newcomer to J&J. And before I answer your question, David, I would just like to say I have to tell you, I'm really enjoying being a new member of the J&J team. I've really been impressed with the culture inspired by our credo, with the caliber of our talent, our people here at J&J, and with the really strong performance of the pipeline.

We've already launched two NMEs this year, AKEEGA for prostate cancer and TALVEY for myeloma, continuing our tradition bringing new therapies in those agents. And we're positioned to deliver an average of more than two NMEs per year between now and the close of the decade, 2030. So the pipeline is very robust, and it's exciting to be here and to be a part of it.

So on to your question. The data will be presented at ESMO in a Presidential session, so we're embargoed until then. Abstracts will be available on Wednesday. I can only say that the RYBREVANT-lazertinib combo did perform well head-to-head against osimertinib. Our regimen is a chemo-free option for patients, which we think is important, and we'll present those data at ESMO.

Operator

Next question today coming from Matt Miksic from Barclays.

Matthew Stephan Miksic - *Barclays Bank PLC, Research Division - Research Analyst*

I think most folks may look at the orthopedic results in medical devices as maybe being a little bit softer than expected, and I know that's not everything by a long shot for J&J. But given expectations were for continued strength heading into Q3, if you could talk maybe a little bit about your comment on more traditional seasonality and thoughts on the sustainability of that strength, as well as the sort of divestiture and realignment plan, Joe, that you described.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

So thank you for the question. And yes, I mean, our results in Orthopedics were 2.6% growth overall. And part of it, as you mentioned, is driven by seasonality. As we have commented, we are in a journey of improvement in Orthopedics. We want to be #1 and #2 in every segment we compete. And that is a place where we are not there yet, but we are very confident that we are going to continue to make improvements by investing and by growing in the highest-growth segments.

We have made improvements in our portfolio. For example, on the Knee side, we have a complete portfolio now. On the revision side, on the cementless side, we are launching now our VELYS Orthopedics total knee surgery replacement in Europe. And we already have about 30,000 procedures that have been performed with our VELYS robotic system.

Overall, we are increasing our penetration also in the ASCs, which is a fast-growing segment. And we see our performance continue to improve in the U.S. and globally. In this particular quarter, we also had some impact due to the impact of volume-based procurement in China and also because of the impact of the Russia sanctions that was mentioned already in the prepared remarks.

So overall, in Orthopedics, we are determined to continue our journey of improvement. We are focusing in having the right portfolio. We have a very strong team in the field. And as Joe has announced, and Joe can comment that we have a plan to be able to continue to improve our margins in Orthopedics.

Joseph J. Wolk - *Johnson & Johnson - Executive VP & CFO*

Yes. Just very quickly, Matt. Thanks for the question. With respect to the restructuring program that we announced specifically in Orthopedics, we're looking to exit those less-profitable markets and product lines. So we'll have some, clearly, inventory write-downs as a result of that over the next 2 years. There will be some modest revenue disruption. But we actually do think these actions not only accelerate growth going forward, but will improve profitability.

Operator

Your next question is from Chris Shibutani from Goldman Sachs.

Chris Shibutani - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

Can you provide us with some insight into updates on the talc litigation process?

And then secondly, if you could just comment, Joe, you used the word voracious last time with your appetite for business development opportunities. How does that word stand, still, in terms of your appetite on the forward?

Joseph J. Wolk - *Johnson & Johnson - Executive VP & CFO*

So Erik, why don't I turn it over to you to discuss the talc litigation matter? And then I'll come back and answer Chris' second question.

Erik Haas - *Johnson & Johnson - Worldwide Vice President, Litigation*

Great. Thanks, Joe. The short answer is that we continue to pursue the four-pronged strategy that we communicated back in July. So let me quickly summarize those four prongs and highlight the salient development and perhaps anticipate some follow-up questions about talc.

So the first prong, we are pursuing the appeal to the Supreme Court of the United States of the July ruling by the New Jersey Bankruptcy Court that dismissed LTL's bankruptcy case. Notably, our appeal recently was joined by counsel representing the vast majority of the talc claimants. Also thereafter, the bankruptcy court certified the case for a direct appeal to the Third Circuit, bypassing the District Court because the bankruptcy court found that the appeal raises matters of significant public interest, the resolution of which would materially advance the progress of the case, and we fully agree with that assessment.

On the merit, the appeal challenges both the validity as well as the application of the novel standard that was imposed by the Third Circuit that requires a showing of "immediate financial distress" to proceed with the bankruptcy case. That immediate financial distress requirement, which the Third Circuit did not specifically define, is nowhere in the Bankruptcy Code and is contrary to the standards that are employed by other circuits. Moreover, under any reasonable interpretation of that standard, we believe the record has fully established that LTL faced immediate financial distress due to the large volume of talc claims that were asserted against it.

In terms of timing. The Third Circuit could rule at any moment whether it will take the direct appeal or not. If it does, we expect briefing to take place over the next couple of months with a decision in the early 2024 time frame. And because we do anticipate the Third Circuit will summarily affirm the application of its standards, we will immediately thereafter request the Supreme Court to resolve the circuit split and decide if the Third Circuit's novel approach is an appropriate standard for deciding a motion to dismiss. We do not think it is. We hope to squeeze the served petition to the Supreme Court into the first term in 2024. But if not, we will raise it in the second term.

The second prong of our strategy involves working with the counsel representing the vast majority of the talc claimants, more than we had previously that were along with us, along with the -- and in addition to the future claims representatives. And together with the counsel and the future claims representatives, we're pursuing a consensual resolution of the talc claims through another bankruptcy. And that is exactly what the bankruptcy court, the New Jersey Bankruptcy Court, urged and strongly recommended that we do in its decision that actually dismissed the case. And the New Jersey Court made those recommendations having found that LTL had made remarkable progress towards an equitable and efficient resolution to date. So we are continuing on in that process.

In terms of timing on the second prong. The consensual resolution is on the same trajectory as the initial bankruptcy plan with a vote expected in the next 6 months to determine whether the requisite supermajority of claimants support the plan.

Third. While those negotiations are proceeding, we will continue to vigorously defend the meritless talc claims in the tort system. As you may have seen just this last week, we had a significant favorable ruling in that regard with the New Jersey's Appellate Court in the Barden case, reversing a \$223 million verdict against the company.

The appellate court reversed because it determines the opinions of the leading plaintiff's experts were unsound, were unscientific and were unsubstantiated. And it is that baseless nature of those expert opinions why we have prevailed in the vast majority of the cases that have been tried to date.

In terms of timing of the litigation. There are two additional mesothelioma cases that we expect will be tried this year, with more to come in 2024. As with the Barden case, it's important to keep in mind that the ultimate resolution of those matters often is determined at the appellate level, not at the trial level, which is the place and which occur in the forms that the plaintiff lawyers choose.

Finally, we will aggressively challenge the abuses of the judicial system by the mass tort claims bar and its experts, with our own affirmative litigation. We mentioned last time that we brought two actions against the plaintiff's bar's lead experts for defaming our talc products with publications premised on knowingly false propositions. And those are moving forward. They've been fully briefed with respect to the initial case motions. And in terms of timing, we expect ruling shortly from the Federal District Court in New Jersey whether those matters may proceed to the discovery phase.

So that's a quick summary. I'd be happy to answer any follow-up questions you may have regarding the strategy.

Joseph J. Wolk - *Johnson & Johnson - Executive VP & CFO*

Great. Thank you, Erik. Chris, regarding your second question. If J&J had a nickel for every time voracious was quoted back to me since the second quarter earnings, we probably could have taken up guidance even a little bit more. And while that's often associated with wanting or devouring great quantities, I think it's really the second definition in Webster's, where having a very eager approach to an activity is the construct in which I meant that term in the second quarter.

So we -- I could have said that 5 years ago, 10 years ago. My predecessors could have said that. We routinely, almost weekly, meet on new opportunities that may complement our existing portfolio or our future pipeline in both MedTech and Innovative Medicines, and the current moment is no different. In fact, we're in a very good position, given the low levels of net debt, the cash we were able to raise, to fulfill one of our capital allocation priorities, which you're probably very, very familiar with at this point in time.

But we're not going to compromise our principles in making sure that it's a strategic fit. So it fits into the scientific expertise, the commercial capabilities or the global reach that will add value to that asset in our hands versus someone else. And we're going to make sure that we're disciplined in that approach financially by ensuring that we have a return that's commensurate with the risk that we're bearing on behalf of shareholders.

So we'd much rather have an okay deal pass us by than make a bad deal. And that's kind of the principles that we'll live into. There's no deal that's too big, given our credit rating as well as our financial strength and annual cash flow generation. But as you know, we've had great success doing smaller earlier-stage deals as well.

We're agnostic with respect to whether it be -- the next one being MedTech or Innovative Medicines. We are simply looking for the best qualified deal that meets both strategic and financial parameters. So hopefully, that answers your question.

Operator

Our next question is coming from Geoff Meacham from Bank of America.

Geoffrey Christopher Meacham - *BofA Securities, Research Division - MD*

I'll stick with one. So on CARVYKTI, can you talk about the commercial backdrop just with respect to new centers or prescribers? And related on manufacturing, you guys have any update on the vector constraints and maybe when that could be relieved?

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Thank you, Geoff. And as you have seen in the progression quarter-over-quarter of CARVYKTI, we continue to have, on one hand, strong demand; and on the other hand, progress in our manufacturing. We're also very encouraged by the data that came out with CARTITUDE-4 that eventually, we make CARVYKTI also a medicine in earlier lines of therapy.

So when it comes to our manufacturing progress, I'm going to let John explain what are we doing in order to be able to supply the strong demand that we are seeing in CARVYKTI today. Overall, what you can expect, Geoff, is that we -- you will continue to see quarter-over-quarter improvement in 2023 into also 2024.

John C. Reed - *Johnson & Johnson - EVP of Pharmaceuticals, R&D*

Yes, to follow-up on Joaquin's comments. We've been progressively adding more and more capacity. That's included at our original launch site in New Jersey, but we're close to having an additional manufacturing site up and rolling in Europe in Belgium, and also have recently increased our capacity by using some excess capacity that Novartis had to further bolster the number of slots that we can accommodate.

One of the traditionally rate-limiting components of the therapy has been the lentivirus component. And there, we've made really outstanding progress in-house mastering that technology, increasing the scale at our factory in Switzerland. And we're in the process -- we're building, and I think it will be available [in 2025] (corrected by company after the call), another factory in the Netherlands to support the lentivirus component, which has sometimes been one of the rate-limiting aspects.

So altogether, the capacity continues to ramp up, and we continue to perfect the technology, I would say. Same thing with the number of centers that are qualified to administer the therapy, and we're also making progress on a number of countries where CARVYKTI will be available. So very excited, obviously, about the momentum with that. Really best-in-class CAR therapy.

The CARTITUDE-4 data, as you know showed unprecedented progression-free survival benefit, a hazard ratio of 0.26, overall response rate of 99%, 86% complete response. Very durable for a one-and-done therapy that was well tolerated. The Grade 3 or above cytokine release syndrome was only 1.1%. So this is really, I think, now emerging as the preferred second-line therapy. And we hope to do more, such as bringing to front line as a possible alternative to stem cell transplant.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

And Geoff, to your point, in multiple myeloma new product launches, we are also very encouraged by the launch of TECVAYLI and also the recent approval of TALVEY. The progression of these medicines is exceeding our internal expectations. And we already have about 2,000 health care professionals in the U.S. that are REMS-certified to be able to administer TECVAYLI and TALVEY. So very encouraging progress in these two medicines in multiple myeloma. And we expect to be able to break out TECVAYLI sales beginning in 2024.

Operator

Your next question is coming from Josh Jennings from TD Cowen.

Joshua Thomas Jennings - *TD Cowen, Research Division - MD & Senior Research Analyst*

Was hoping to ask on STELARA and the biosimilar competition in the U.S. now expected in 2025. That's not new news. But wanted to check in on how beneficial is the extra year for the Innovative Medicine business' defense strategy? I guess, focusing on just the potential for TREMFYA to take share from STELARA in psoriasis and psoriatic arthritis and inflammatory bowel disease indications. And does timing shift provide more confidence in the potential hit to constant currency revenue target set for 2025 for the pharma unit?

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Thank you for the question. Certainly, we have always been very confident in being able to hit our \$57 billion target in 2025 for pharma. As I have explained before, there are a number of factors there are. The first one and most important is the growth that we're having in our key assets: TREMFYA; ERLEADA; UPTRAVI; our long-acting injectables; and especially DARZALEX, which continue to have a tremendous trajectory gaining share in first line. We are encouraged, as I just commented, by the launches of CARVYKTI; the progression of SPRAVATO; and also the recent launches, too, also in multiple myeloma of TECVAYLI and TALVEY.

And looking into 2024, the remainder of the year, and also into 2025, we have some very exciting news in our pipeline. Some of them have been already commented. For example, the first chemo-free regimen as first-line in EGFR-mutated non-small lung cancer. We will be presenting the data of MARIPOSA in -- at ESMO, and that potentially will be a filing and an approval in [2024] (corrected by company after the call). This would be a new standard of therapy in this line of therapy in this very important need for patients.

We also continue to be encouraged by the progress in our TARIS drug delivery platform. You are also going to see data being presented at ESMO. Very important for us, in two existing products, we will be presenting data on TREMFYA in IBD, both in Crohn's and in ulcerative colitis, for a potential

approval later in 2024. That's going to be a very significant growth driver for TREMFYA. Take into consideration that in the STELARA case, IBD represents 75% of the sales.

So we still have a lot of growth in front of us with TREMFYA as we do also in ERLEADA, in which we will present data in localized high-risk prostate cancer. We're also going to be able to present some data of nipocalimab in myasthenia gravis, end of this year. So all in all, very good news for our pipeline in 2024 and 2025.

Certainly, the entrance of the biosimilars in 2025 in the U.S. is another factor that builds our confidence that we are going to be able to meet the \$57 billion.

For me, the most important thing now is to look forward and to think about the growth profile of our Innovative Medicine group into the second half of the decade. We have a number of growth drivers that are already there that I've described, but also the strength of our pipeline, both in immunology, in oncology and in neuroscience, profiles us as a strong company that has a strong growth profile into the second half of the decade. And that's part of what we will be looking forward to discussing with you in our upcoming enterprise business review, focusing on what is going to be the growth profile in the second half of the decade.

Operator

Next question is coming from Chris Schott from JPMorgan.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Maybe, Joe, just a little bit more color on 2024. I appreciate the details you provided, seems like a year of another healthy top line growth. But can you just give us some directional color on margins next year? I know there are some dis-synergies with Kenvue this year. I'm just trying to get a sense of how you think about margin progression here as you kind of balance some of these, kind of the pipeline opportunities and some of these top line growth initiatives, versus kind of dropping that to the bottom line. So just any directional color would be appreciated.

Joseph J. Wolk - *Johnson & Johnson - Executive VP & CFO*

Yes. Sure, Chris. Thanks for the question. So first off, we're very pleased with the margin progress that we've been able to make in 2023. I think we started the year to -- roughly flat to now improving by 50 basis points. A lot of that has really gone -- is directly attributable to the efforts of many people in the organization who really took the opportunity to look at our infrastructure as a two-segment company versus a three-segment company.

So the dis-synergies that we warned about and talked about early on in the Kenvue separation process really haven't come to manifest. In fact, as we look out to 2024, we see minimal to almost no impact from dis-synergies from the separation. We are in the process of finalizing our business plans for 2024. I'd like to get a little bit better assessment of how the clinical development pipeline is shaping up, what the investments are required there.

But we're a larger company. We take the opportunity to look each and every year at efficiencies. So we're not in a position to give you margin guidance right now, but I would expect that something similar to where we started this year would not be a bad starting point for next year. Again, it's going to depend on the investments that the R&D teams from both MedTech and Innovative Medicines can bring forth. And we'll obviously look to accelerate bringing some of these great products to patients sooner if we have that opportunity.

Operator

Your next question is coming from Larry Biegelsen from Wells Fargo.

Lawrence H. Biegelsen - Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst

Joe, just -- could you just clarify what you meant by flat procedures in '24 in MedTech? Are you assuming -- does that mean flat in MedTech growth? And just for my question, can you talk about what you're seeing with bariatrics? For GLP-1, this is. And how you're thinking about the potential impact of GLP-1s across your device business, long term, especially in cardio and ortho?

Joseph J. Wolk - Johnson & Johnson - Executive VP & CFO

So I'll give the second half of that question to Joaquin, but thanks for the clarifying question with respect to market growth. We are not suggesting flat market -- or flat market in MedTech next year. What we do is -- are foreseeing right now, based on what we know today, is the elevated levels, the market overall being 5% to 7% versus what traditionally has been maybe 4% to 6%. We see that same 5% to 7% next year.

Joaquin?

Joaquin Duato - Johnson & Johnson - CEO & Chairman

Thank you, Larry. And taking a step back, we see the evolution of our MedTech business in a very positive way. One of our key goals for us is to be a top-tier grower in MedTech. When I look at the results of MedTech this year, we are delivering on that. Our growth in the quarter pro forma was 6.4% when you compare with Abiomed as a stand-alone company. And when you look at our pro forma growth year-to-date in MedTech, it's 7.9%.

So very pleased with the performance of our MedTech business. And we have expectations to continue our progression into 2024, in part fueled by the procedural growth that we see and also by our continued improvement in our execution and the launch of new products. Some of them we can discuss later. For example, we will be launching our first PFA catheter in Europe into 2024.

When it comes to GLP-1s, it's good for patients to have new options for treatment, especially in obesity, which, at times, has been a stigmatized disease in which patients were not looking for treatment due to the stigmatization of that. Certainly, as you commented, we're seeing some impact in our bariatric business in the short term as some patients are reconsidering surgery, expecting to get treatment.

But overall, when we talk to surgeons, bariatric surgeons, what they see is a complementary role of surgery and GLP-1s and many of them comment on the fact that they could see a tailwind for bariatric surgery down the road given this complementary nature, the increased awareness about obesity, more patients seeking treatment. And many of the patients, about 30% of them, are not going to be tolerating these medications, so they would be another funnel for our bariatric business.

In the rest of our MedTech business, at this point, we continue to see robust procedure increase, and we don't anticipate that changing in the foreseeable future.

Operator

Next question is coming from Terence Flynn from Morgan Stanley.

Terence C. Flynn - Morgan Stanley, Research Division - Equity Analyst

I was just wondering if you could elaborate a little bit more, John, on nipocalimab in RA. I know we're going to see the full data here at ACR. But is this a drug that you see potentially working in a broad population? Or is there a biomarker subset, group, that's more likely to respond? And then how are you thinking about Phase III plans here in this indication?

John C. Reed - *Johnson & Johnson - EVP of Pharmaceuticals, R&D*

Yes. Thanks for the question, and we look forward to sharing those data at the ACR in November in San Diego. The -- we're looking at nipo as either a monotherapy, combined with a precision medicine strategy, or as a combination for a broad population where we aim to combine with an anti-TNF agent. And we see those two mechanisms as being very complementary, reducing the levels of autoantibodies with nipo, and then inhibiting inflammatory mechanisms with the TNF. That so-called DAISY study, the Phase II, is underway now, and we'll test that combination.

So that, in general, has been the way we're looking at RA, not only for nipo, but other agents in our pipeline, where we see the future being monotherapies that are targeted in a precision medicine way or broad therapies that are combos that can bring together synergistic mechanisms in a safe way.

We're excited to be launching the DAISY program to look at that combo. And we're hoping that, that will bring deeper, more durable remissions for patients as we bring those new mechanisms together.

Operator

Next question is coming from Joanne Wuensch from Citibank.

Joanne Karen Wuensch - *Citigroup Inc., Research Division - MD*

Is it possible to give us a little bit more detail on a couple of things? You mentioned headwinds from VBP. And I'm just curious if there's, a, a way to quantify it? And b, a way to say if it's at least better or worse or the same as it has been in the last couple of quarters?

And then similarly in other aspects of China, we've been hearing a lot about anti-corruption policies, et cetera. If you could comment on that, that would be great.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Thank you, Joanne. And first, let me say that China for us is a key market and a market in which we are delivering growth now, and we are going to continue to deliver strong growth into 2024. So it's a key growth driver for us.

So on one hand, certainly, VBP represents a headwind in price. And on the other hand, it also represents an opportunity as you can expand quality products, medical technologies into more patients. So there are a number of MedTech platforms now currently undergoing VBP headwinds, electrophysiology, spine, trauma, endocutters and energy. And these effects will last during 2023 and part of 2024. We have already anniversary our large joints VBP, so at this point, we have about 80% of our platforms that have been already affected by VBP. Again, as we look into 2024, we expect to continue to deliver a strong growth in China and China remaining a key part of our growth.

When it comes to question that you were asking in anti-corruption side, we have a strong culture of compliance in our business. And at this point, we may see some limitations related to physician and surgeon access, but we are not seeing any material impact in any part of our business due to that, and we'll continue to monitor the situation. Overall, as I said, we continue to see China as a key driver of our growth and also as a key source of innovation moving into the future.

Operator

Your next question is coming from Vamil Divan from Guggenheim Securities.

Vamil Kishore Divan - *Guggenheim Securities, LLC, Research Division - Research Analyst*

Great. I just want to maybe dive a little deeper on the immunology side. Appreciate some of the comments you made there already. But for the quarter, the performance was very strong for several of your products there. So I'm just curious if there were any sort of onetime items there that we should be aware of. It sounded like it was a lot about patient mix and market growth that you guys were commenting on. I'm curious if you can just highlight any major stocking or sort of onetime pricing adjustments that we should take into account as we look at future quarters.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Thank you. We are very pleased with the performance of our immunology business. Especially, we're pleased with the performance of TREMFYA with 25.1% growth in the quarter, which shows our ability to drive growth there. As I said before, TREMFYA currently is now indicated in psoriatic arthritis and psoriasis. As an analog, in the case of STELARA, that represents about 25% of the sales.

So with the upcoming readouts, filing and potential approvals of ulcerative colitis and Crohn's disease, we expect to have significant growth in TREMFYA. We talk about TREMFYA as a \$5 billion product earlier in our Analyst Day in 2021. Now you can see clearly that we're going not only to meet that, but to clearly exceed that benchmark for TREMFYA.

So when it comes to STELARA, we had also a very robust growth of close to 16%. In that case, there is a prior period adjustment in the quarter a year ago that represents about 600 basis points. So you should take that into consideration when you think about the STELARA growth.

We are very pleased overall, as I said, with our immunology portfolio. Overall, our immunology portfolio in the quarter grew 12.4%, which is very strong considering that we also have headwinds there of REMICADE biosimilars.

And we remain very excited about the immunology portfolio as a key driver for J&J. Our Innovative Medicines are going to be bringing significant improvements in IBD with TREMFYA, as I recall. But also staying there, we have our targeted oral peptide which is going to be presenting some data soon, that we already presented data in psoriasis. And also, we have the combination of guselkumab and golimumab in IBD, which has presented also groundbreaking results.

So very encouraged about our immunology portfolio and the ability to drive growth in the second half of the decade. More to be seen in our EBR later in the year.

Operator

Your next question is coming from Danielle Antalffy from UBS.

Danielle Joy Antalffy - *UBS Investment Bank, Research Division - Analyst*

Ahmet, I wanted to actually bring you into the conversation here and ask about some of the innovation in MedTech. And specifically, you guys have an Ottawa Day coming up. And just curious what you can say about, a, what we get to see? Obviously, appreciating you're not going to totally open the kimono and front-run the day. But b, and probably most importantly, sort of where you see Ottawa ultimately fitting into the robotics landscape and helping contribute to a continued move higher in robotics penetration?

Ahmet Tezel - *Johnson & Johnson - Company Group Chairman and Global Head of J&J MedTech Innovation and R&D*

So first of all, thank you for the question. Similar to John, this is my first call as well. So really excited to be here, equally excited to be leading a team of talented scientists, engineers and physicians as we do smarter, less invasive and more personalized solutions for our patients.

So with respect to Ottawa, we have made great progress on the platform. The team is really focused on combining a really differentiated architecture, based on its software and hardware, together with our best-in-class instruments. And we believe that combination of a differentiated architecture with instruments is going to enable us to have high value from day 1.

Now we will have more updates on Ottawa next month, as you mentioned. And at that time, we will provide a lot more detail. But the one point I'll make is that, even today, robotic-assisted surgery penetration is in single digits. So there's still a lot of growth left in that segment. And we're really excited because Ottawa brings a lot of differentiation. So we're very excited that we can make a big kind of path. We can open our path and growth there in that segment as well.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Danielle, if I may interject here on Ottawa. I've been in touch with multiple surgeons around the world. And one common comment that I find is that they all want, they all are rooting for Johnson & Johnson to come into the robotic surgical space. They want to have the service and the support that they have accustomed during decades with our Ethicon business, and they also want to be able to utilize the advanced instruments with whom they have grown. So what I see in the surgical space is that the surgeons want to have alternatives, and they are all looking forward to having Johnson & Johnson play an important role in robotic surgery.

Jessica Moore - *Johnson & Johnson - VP of IR*

Thank you, Danielle. We have time for one last question.

Operator

Our final question today is coming from Louise Chen from Cantor Fitzgerald.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - MD & Senior Research Analyst*

I wanted to ask you on the FLAURA2 results, if they impacted at all your thinking on your market opportunity for MARIPOSA? And why or why not?

John C. Reed - *Johnson & Johnson - EVP of Pharmaceuticals, R&D*

No, I don't think it influences because it's really important to pay attention not only to progression-free survival, but also overall survival as well as the PFS to the survival on the second line of therapy.

Unfortunately, with today's therapies, almost all lung cancer patients will eventually relapse, they will need a second line therapy. And we think chemo was best reserved for that circumstance, where the patient now has failed the frontline targeted therapies.

So I would really say, pay attention to overall survival, pay attention to that progression-free survival, too, endpoint because these are going to be, I think, really things that matter in terms of what the long-term outcome is for patients with EGF receptor mutant lung cancer.

The -- we believe, based on the data we'll present in the Presidential session at ESMO, that the combination of RYBREVANT, our bispecific antibody, the first bispecific ever approved for a solid tumor indication, incidentally, fully human; as well as the third-generation small molecule oral EGF receptor, lazertinib, which is brain-penetrant. In our mind, we believe that, that will become the new frontline standard of care for EGF receptor mutant lung cancer and offer patients durable remissions that are achieved in a chemo-free regimen.

Jessica Moore - *Johnson & Johnson - VP of IR*

Thank you, and thanks to everyone for your questions and your continued interest in our company. We apologize to those that we couldn't get to because of time, but don't hesitate to reach out to the Investor Relations team with any remaining questions you may have.

I will now turn the call back to Joaquin for some brief closing remarks.

Joaquin Duato - *Johnson & Johnson - CEO & Chairman*

Thank you, Jess, and thank you to all of you for joining us today. I'm proud to present today the company's performance. This is the first quarter that we report as a new J&J, focused in health care innovation, in MedTech and in Pharmaceuticals. And I believe this new J&J has a better foundation to continue to drive growth for the next decades.

We are achieving strong results in 2023 with our 7.5% adjusted operational growth in the quarter. It's the second quarter in a row that we have a beat and a raise of our guidance. And we continue to believe that we're going to have a very strong finish into 2023, and that reads well for a strong 2024, too.

We have a dedicated team, both in Innovative Medicines and in MedTech. And we think we are very well positioned, as I said, to carry the momentum that you are seeing in 2023 into 2024.

Finally, we are looking forward to engaging all of you at our Enterprise Business Review on December 5. Thank you very much and enjoy the rest of your day.

Operator

Thank you. This concludes today's Johnson & Johnson's Third Quarter 2023 Earnings Conference Call. You may now disconnect.

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