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JNJ.N - Q3 2024 Johnson & Johnson Earnings Call

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## OVERVIEW:

Company Summary

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**Joaquin Duato** *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

**Joseph Wolk** *Johnson & Johnson - Chief Financial Officer, Executive Vice President*

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

**Tim Schmid** *Johnson & Johnson - Executive Vice President, Worldwide Chairman of MedTech*

**Jennifer Taubert** *Johnson & Johnson - Executive Vice President, Worldwide Chairman, Innovative Medicine*

**John Reed** *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

## CONFERENCE CALL PARTICIPANTS

**Chris Schott** *JPMorgan - Analyst*

**Larry Biegelsen** *Wells Fargo Securities, LLC - Analyst*

**Louise Chen** *Cantor Fitzgerald - Analyst*

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## PRESENTATION

### Operator

Good morning, and welcome to Johnson & Johnson's third-quarter 2024 earnings conference call. (Operator Instructions)

This call is being recorded. If anyone has any objections, you may disconnect at this time. (Operator Instructions) I will now turn the conference call over to Johnson & Johnson. You may begin.

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**Jessica Moore** - *Johnson & Johnson - Vice President - Investor Relations*

Hello, everyone. This is Jessica Moore, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of the third-quarter results and our full-year financial outlook for 2024. 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](http://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 the 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 2023 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, Joaquin Duato, our Chairman and CEO, will kick us off with opening remarks and highlight key catalysts within the segments. I will review the third-quarter sales and P&L results for the enterprise, as well as highlights related to our two businesses.

Joe Wolk, our CFO, will then provide an overview of our pipeline advancements, cash position, capital allocation priorities, and guidance for 2024, as well as qualitative considerations for 2025. Jennifer Taubert, John Reed, and Tim Schmid, our innovative medicine and MedTech leaders, 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. I will now turn the call over to Joaquin.

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**Joaquin Duato** - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Thank you, Jess, and hello, everyone. As you will hear, we delivered strong results in the third quarter with 6.3% operational sales growth. Our performance once again reflects the unique breadth of our business and our commitment to delivering the next wave of healthcare innovation to patients around the world. It also reflects the work we have done to shift our pipeline and portfolio to high-innovation and high-growth markets.

That work continues, which you saw, with the recently completed acquisitions of Shockwave and V-Wave in MedTech; and Ambrx, Proteologix, and the NM26 bispecific antibody in innovative medicine. And we are pleased with the progress we are making.

In innovative medicine, we reported a second consecutive quarter of sales exceeding \$14 billion, with 11 key brands growing double digits. DARZALEX became the first product in our portfolio to reach \$3 billion in sales in a single quarter. And as you will hear, our pipeline of high-innovation, high-growth potential assets is advancing rapidly, with five major US and EC approvals in the quarter.

This includes FDA approval of RYBREVANT plus LAZCLUZE as first-line treatment for EGFR-mutated advanced lung cancer, a transformational step forward for patients; and FDA approval of TREMFYA for active ulcerative colitis, which represents a significant opportunity for Johnson & Johnson, given 75% of STELARA sales today come from inflammatory bowel disease.

And with filings and reviews underway for many of our innovative medicines that have the potential to generate \$5 billion in peak-year sales, we are increasingly confident in our near- and long-term growth trajectory.

In MedTech, you can see the impact of our portfolio shift to high-innovation, high-growth markets, particularly in cardiovascular. With the recent acquisitions of Shockwave and Abiomed, we are now category leaders in four of the largest and highest-growth cardiovascular intervention MedTech markets, which in Q3 translated to another quarter of double-digit growth across the cardiovascular portfolio.

And with the full market launch of Shockwave E8 peripheral IVL catheter, we are seeing an immediate impact of the Shockwave acquisition. In vision, growth is accelerating, and we expect that to continue with the recent full market release of TECNIS Odyssey in the US and ACUVUE OASYS MAX one-day contact lenses.

We are also excited about the future of our surgery business. As you will recall, in November 2023, we committed to submitting the OTTAVA robotic surgical system for an investigational device exemption or IDE to the US FDA in the second half of 2024 to initiate clinical trials. I'm pleased to announce that we have met that milestone with the IDE application submitted in Q3.

Looking across the enterprise, our high-innovation, high-growth strategy is working. And our progress this quarter speaks to the strength of our commercial and innovation capabilities. We have increased adjusted operational EPS guidance pre-M&A for the third quarter in a row.

We have invested \$18 billion in high-innovation, high-growth M&A this year. And based on this quarter's results, we are confident in our expectations for 2025 through the end of the decade and beyond. And with that, I will turn the call back to Jess.

**Jessica Moore** - Johnson & Johnson - Vice President - Investor Relations

Thank you, Joaquin. Moving to our financial results for the quarter. Unless otherwise stated, the financial results and guidance highlighted today reflect the continuing operations of Johnson & Johnson. Furthermore, the percentages quoted represent operational results and therefore, exclude the impact of currency translation.

Worldwide sales were \$22.5 billion for the third quarter of 2024. Sales increased 6.3%, with growth of 7.6% in the US and 4.6% outside of the US. Acquisitions and divestitures positively impacted worldwide growth by 90 basis points.

Turning now to earnings. For the quarter, net earnings were \$2.7 billion. And diluted earnings per share was \$1.11 versus diluted earnings per share of \$1.69 a year ago. Results in the quarter were impacted by the updated talc litigation settlement proposal as well as acquired IPR&D expense associated with the NM26 bispecific antibody.

Excluding after-tax and tangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were \$5.9 billion, and adjusted diluted earnings per share was \$2.42, representing decreases of 13.3% and 9%, respectively, compared to the third quarter of 2023. Results were impacted by the acquired IPR&D expense of \$1.25 billion or approximately 1,900 basis points associated with the NM26 bispecific antibody.

I will now comment on business sales performance in the quarter, beginning with innovative medicine. Worldwide sales of \$14.6 billion increased 6.3%, with growth of 7.5% in the US and 4.4% outside of the US. Innovative medicine growth was driven by our key brands and continued uptake from recently launched products, with 11 assets delivering double-digit growth.

Results across the portfolio continue to be positively impacted by price increases associated with Argentina hyperinflation, consistent with market practice. We continue to drive strong sales growth across our multiple myeloma portfolio.

DARZALEX growth was 22.9%, primarily driven by share gains of 4 points across all lines of therapy, with 7.7 points of growth in the frontline setting, as well as market growth. CARVYKTI achieved sales of \$286 million, with growth of 87.6%, driven by share gains, continued capacity expansion, and manufacturing efficiencies. This reflects sequential growth of 53.2%, aligned with our expectations of accelerating growth in the back half of the year.

TECVAYLI sales were \$135 million in the quarter with growth of 21.4%, reflecting a strong launch in the relapsed refractory setting. Demand remained strong, while sequential growth was flat due to continued adoption of longer duration dosing intervals.

Finally, within our multiple myeloma portfolio, TALVEY continued its launch trajectory with another quarter of strong growth. We anticipate disclosing TALVEY sales in the first quarter of 2025, which are currently reported in other oncology. ERLEADA continues to deliver strong growth of 26.3%, primarily driven by share gains in metastatic castrate-sensitive prostate cancer and favorable inventory dynamics.

RYBREVANT, our bispecific antibody for non-small cell lung cancer, contributed to growth in other oncology, as we expand approved indications. We also anticipate disclosing RYBREVANT sales in the first quarter of 2025.

Within immunology, we saw sales growth in TREMFYA of 14.3%, driven by strong market growth and share gains in Pso and PsA, partially offset by unfavorable patient mix. STELARA declined 5.7%, driven by unfavorable net patient mix and share loss, partially offset by market growth. As a reminder, biosimilar competition has entered Europe as of July, and we anticipate US biosimilar entry in January 2025.

In neuroscience, SPRAVATO growth of 55.3% continues to be driven by increased physician and patient confidence. In pulmonary hypertension, OPSUMIT and UPTRAVI grew 17.4% and 15.2%, respectively, driven by market growth, share gains, and patient mix. As mentioned last quarter, REMICADE and SIMPONI realized limited sales in Europe, as we prepare for the return of distribution rights in Q4.

I'll now turn your attention to MedTech. Worldwide sales of \$7.9 billion increased 6.4% with growth in the US of 7.8% and 5% outside of the US. Acquisitions and divestitures had a net positive impact of 270 basis points on worldwide growth, 360 basis points in the US, and 180 basis points outside of the US. Overall, MedTech growth was driven by commercial execution and strength of new product introductions, partially offset by continued headwinds in Asia-Pacific, specifically in China.

In cardiovascular, electrophysiology delivered double-digit growth of 10.7%. Performance was driven by global procedure growth, new product uptake, and commercial execution, partially offset by competitive PFA ablation catheter uptake in the US, as well as prior-year trade inventory dynamics and VBP in China.

Abiomed delivered growth of 16.3%, driven by strong growth in all regions and continued adoption of Impella 5.5 and Impella RP technology. Cardiovascular results also included \$229 million associated with the acquisition of Shockwave.

Contact lenses and other performance improved to 4.7%, driven by continued strategic price actions, strong performance in ACUVUE OASYS one-day family of products, a one-time benefit from a change in US contract shipping terms worth approximately 150 basis points, as well as lapping prior-year impacts from Russia's sanctions.

Surgical vision grew 1.9%, driven by TECNIS PureSee and TECNIS Eyhance, partially offset by China VBP and softness in the US. Surgery declined 0.7%, with the Acclarent divestiture negatively impacting results by approximately 110 basis points.

Performance was driven primarily by competitive pressures in energy and endcutters, as well as VBP and the anti-corruption campaign in China. This was partially offset by commercial execution, strength of new products across wound closure and biosurgery, and continued price increases associated with Argentina hyperinflation, consistent with market practice.

Orthopedics growth of 1.3% was primarily driven by success of recent product launches and commercial execution, partially offset by competitive pressures, impacts of China VBP, and revenue disruption from the previously announced orthopedics transformation.

Now turning to our consolidated statement of earnings for the third quarter of 2024. I'd like to highlight a few noteworthy items that have changed compared to the same quarter of last year. We continue to invest strategically in research and development at competitive levels, investing nearly \$5 billion or 22% of sales, which includes a \$1.25 billion payment to secure the global rights to NM26 bispecific antibody. Even when excluding this investment, R&D, as a percent of sales, increased 30 basis points.

Selling, marketing, and administrative expense as a percent of sales would leverage 100 basis points, driven by the realization of optimization efforts following the Kenvue separation. Interest income was \$99 million as compared to \$182 million of income last year, driven by a higher net debt position primarily related to the financing impacts of the Shockwave acquisition.

Other income and expense was a net expense of \$1.8 billion, compared to an expense of \$0.5 billion in the prior year. The increase in expense was driven by a \$1.75 billion dollar charge related to the talc litigation settlement proposal, partially offset by prior-year higher unrealized mark-to-market losses on public securities, as well as the monetization of royalty rights.

Regarding taxes in the quarter, our effective tax rate was 19.3% versus 17.4% in the same period last year. This increase was primarily driven by the tax treatment of the NM26 bispecific antibody acquisition and OECD Pillar II. Excluding special items, the effective tax rate was 19.3% versus 15.6% in the same period last year. I encourage you to review our upcoming third-quarter 10-Q filing for additional details on specific tax-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. Innovative medicine margin declined from 45.4% to 37.9%, primarily driven by the \$1.25 billion acquired IPR&D expense to secure the global rights for NM26 bispecific antibody, partially offset by the monetization of royalty rights. MedTech margin declined from 24.7% to 24.1%, driven by increased R&D investment and lapping of a prior-year divestiture gain, partially offset by supply chain efficiencies.

As a result, adjusted income before tax for the enterprise, as a percentage of sales, decreased from 37.6% to 32.4%, with acquired IPR&D expense impacting results by 560 basis points. Starting in 2025, aligned with recent FASB reporting disclosure requirements, we will begin providing additional P&L details by segment.

This concludes the sales and earnings portion of the call. I'm now pleased to turn it over to Joe.

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**Joseph Wolk** - *Johnson & Johnson - Chief Financial Officer, Executive Vice President*

Thank you, Jessica. In the third quarter, Johnson & Johnson delivered results that illustrate not only the breadth of the business, but our ability to consistently beat financial expectations. Innovative medicine continued to build on strong first-half revenue momentum. We are advancing our pharmaceutical pipeline, achieving significant clinical and regulatory milestones across key therapeutic areas.

Our MedTech business, with the addition of Shockwave, delivered operational growth of 6.4% in the quarter, but did experience headwinds in the Asia-Pacific region. We continue to fortify our future, advancing the OTTAVA robotic surgery system to IDE, expanding VELYS use, and launching new intraocular lenses.

Due to dynamics in the Asia-Pacific region, specifically in China, we are taking a responsibly conservative approach by assuming no material improvement in that part of the business for the remainder of this year. And as such, we expect MedTech adjusted operational sales growth for the full-year 2024 to be closer to 5% versus the 6% we referenced last quarter.

The strength of a diversified business enables us to more than offset volatility in one part of our business, but yet be in a position to once again increase 2024 guidance for the enterprise. Before diving into the results, I'll take a moment to touch on some enterprise-wide updates from the quarter.

We are making progress towards resolving talc litigation. Our prepackaged bankruptcy plan received overwhelming support from the current claimants of roughly 83%, as well as the future claimants' representative.

As announced last Thursday, the case will be heard in the Texas Bankruptcy Court. And while we remain committed to bringing this matter to a resolution, it would be premature to speculate on timing. In addition to the pipeline highlights Joaquin mentioned, there are some additional notable advancements throughout the quarter.

In oncology, we received US and EU regulatory approval for RYBREVANT in combination with chemotherapy as a second-line treatment for adults with advanced EGFR-mutated non-small cell lung cancer. With FDA priority review underway for a subcutaneous formulation of RYBREVANT, along with data supporting a treatment regimen to reduce adverse events, we are building a best-in-class EGFR portfolio. We also presented Phase I data for RYBREVANT with chemotherapy in metastatic colorectal cancer patients, extending the asset's potential beyond lung cancer.

In multiple myeloma, we advanced our leadership position with FDA approval and filing of two DARZALEX FASPRO quad base regimens for newly diagnosed patients. With CARVYKTI, we announced three-year follow-up data showing significantly extended overall survival, and gained approval for commercial production at our Ghent facility, further expanding supply capacity.

Finally, in oncology, we added to the growing evidence base for our TARIS platform, with positive Phase IIb data in patients with high-risk, non-muscle-invasive bladder cancer, and positive interim to Phase IIb data in patients with muscle-invasive bladder cancer.

In neuroscience, we submitted to the US and European regulatory bodies for what would be the first global approval of nivalimab for the treatment of people living with generalized myasthenia gravis. For the remainder of the year, we expect approval of TREMFYA sub-Q for Crohn's disease; and data readouts on JNJ-2113, our targeted oral peptide for psoriasis and ulcerative colitis; JNJ-4804, our co-antibody therapeutic for inflammatory bowel disease; Aticaprant for adjunctive major depressive disorder; and nivalimab for rheumatoid arthritis.

In MedTech, we completed enrollment of the Omny-IRE clinical trial to evaluate safety and effectiveness in mapping and treating symptomatic paroxysmal atrial fibrillation during standard ablation procedures. Also, in cardiovascular, we are preparing for the anticipated approval of VARIPULSE in the US and the submission of Impella ECP for regulatory approval.

In orthopedics, we launched several exciting new products in the US, including our VELYS spine robot and VOLT plating system. The plentiful pipeline progress across our businesses will ensure continued success.

Let's now turn to cash and capital allocation. Free cash flow year to date was approximately \$14 billion, compared to \$12 billion last year, which included eight months' contribution from the consumer health business. We ended the third quarter with \$20 billion of cash and marketable securities, and \$36 billion of debt for a net debt position of approximately \$16 billion.

Our capital allocation priorities remain unchanged. Our strong balance sheet enables us to strategically invest to grow our business while simultaneously returning capital to our shareholders. Innovation remains core to our strategy.

During the quarter, we invested nearly \$5 billion in research and development. This is an increase over 2023 levels, even after excluding acquired in-process R&D expense. Thus far in 2024, Johnson & Johnson has deployed approximately \$18 billion for strategic acquisitions and licensing agreements, which includes the recent acquisition of V-Wave, another innovative treatment in heart failure, which closed last week.

Turning to our full-year 2024 guidance, excluding the impact from acquisitions and divestitures, we are increasing our adjusted operational sales guidance. We now expect growth in the range of 5.7% to 6.2% with a midpoint of 6%. We are also increasing operational sales growth by \$200 million to a range of 6.3% to 6.8% with a midpoint of \$89.6 billion or 6.6%.

As you know, we don't speculate on future currency movements. For today's call, we are utilizing a euro spot rate relative to the US dollar of 1.10, slightly above last quarter's guidance. This results in an estimated incremental positive foreign currency impact of \$200 million, reducing our previous full-year negative impact to \$1 billion. As such, we expect reported sales growth between 5.1% to 5.6% with a midpoint of \$88.6 billion or 5.4%.

Regarding the rest of the P&L, with the addition of the V-Wave transaction, we now anticipate our 2024 adjusted pre-tax operating margin to decline by approximately 200 basis points. Excluding the impact of asset acquisition accounting, and related R&D investment, we would be on track to improve operating margins by 50 basis points, which is consistent with what we guided to at the beginning of the year.

As we strive to advance and accelerate our pipeline, you can anticipate elevated levels of investment in the fourth quarter. Net interest income is now projected to be between \$450 million and \$550 million, \$150 million greater than our previous guidance.

Other income is anticipated to be in the range of \$1.9 billion to \$2.1 billion, an increase versus previous guidance, driven by the one-time monetization of royalty rights Jessica referenced that will be utilized for that higher Q4 investment I referenced a moment ago. Our effective tax rate, consistent with previous guidance, is expected to be between 17.5% and 18.5% for the full year.

Similar to last quarter, we have provided an EPS bridge to outline the impact from acquisition activity throughout the year. Before the impact of the V-Wave acquisition, our outlook for adjusted operational EPS performance is once again increasing.

As the schedule reflects, we are expecting an incremental \$0.10 per share increase on our operational performance for a total increase of \$0.18 per share for the year. On this basis, when excluding acquisition activity throughout the year, EPS growth is 9.2%.



To account for the completion of the V-Wave transaction, as previously disclosed, our adjusted operational EPS guidance now includes dilution of \$0.24 per share in the fourth quarter and \$0.06 per share in 2025. Combined, this yields an updated 2024 adjusted operational EPS guidance of \$9.91 at the midpoint of the range, basically flat year on year despite absorbing approximately \$0.92 of acquisition activity.

While not predicting the impact of currency movements, utilizing the recent exchange rates just referenced, a reported adjusted earnings per share for the year now estimates a full-year positive impact of \$0.02 per share. As such, we expect reported adjusted earnings per share of \$9.93 at the midpoint.

We are still finalizing our plans for next year, but let me provide you some preliminary qualitative commentary to inform your modeling for 2025. For innovative medicine, we remain very confident in our ability to deliver growth despite a significant LOE resulting in sales above the \$57 billion commitment we stated in 2021.

This will be driven by our in-market brands and continued progress from our recently launched products, including TREMFYA in IBD and RYBREVANT in non-small cell lung cancer. Regarding the STELARA LOE, we are planning for biosimilar entries in the US in January, assuming that Humira's erosion curve is a relatively good proxy for your models.

We continue to expect a negative impact associated with the Part D redesign. In our pipeline, we anticipate data readouts across all our priority platforms, anticipated approvals of TREMFYA sub-Q in Crohn's disease, RYBREVANT sub-Q for lung cancer, and nipocalimab in generalized myasthenia gravis, as well as potential filings for TARIS in bladder cancer and aticaprant in major depressive disorder.

As a reminder, TREMFYA, RYBREVANT, and TARIS continue to be the three largest underappreciated assets in terms of our revenue projections versus what analysts are estimating for the back half of this decade. For MedTech, we continue to expect to deliver on our long-term objective identified at last year's enterprise business review of growing operational sales in the upper end of the 2022 to 2027 weighted average market growth rate of 5% to 7%.

We also expect continued adoption of newer products across all MedTech businesses, such as VARIPULSE in electrophysiology, VELYS-enabling technology across orthopedics, Odyssey and PureSee in surgical vision, and contributions from our Abiomed and Shockwave integrations.

Specific to volume-based pricing in China, we expect continued impacts from the rollout of the 2024 tenders in orthopedic sports and intraocular lenses, and anticipate VBP to continue expanding across provinces and products.

Moving to the rest of the P&L, when thinking about operating margin, there are pluses and minuses. Tailwinds include an anticipated reduction of acquired IPR&D expense year over year, continued focus on MedTech margin improvement, and continued OpEx optimization benefits post separation. Working against us is unfavorable product mix driven by STELARA biosimilar entrance and Part D redesign.

With a brief look at your models last week, the consensus margin does not appear unreasonable. And we'll provide further clarity in January once we complete our 2025 plan. We do not expect to maintain the heightened levels of interest income due to a reduction in interest rates and impact from debt experienced in 2024 related to acquisition activity.

Regarding other income and expense, we expect lower net other income due to the non-recurring nature of the monetization of royalty rights experienced in Q3, a lower benefit related to employee benefit programs based on discount rate assumptions, as well as income lost on the Kenvue dividend.

Lastly, based on what we know today, under current tax law, we anticipate our 2025 tax rate to be slightly lower than our anticipated 2024 tax rate. To wrap up prior to Q&A, we are pleased with our underlying 2024 performance that simultaneously fortified a strong foundation for continued success heading into 2025.

With that, I'll now turn over to Kevin to open the call for your questions.



## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Chris Schott, JPMorgan.

### Chris Schott - JPMorgan - Analyst

Great. Thanks so much for the question. Maybe just one on talc here. I know there's still limited comments, but it seems as though the company's obviously made some advancements here into getting this behind the organization.

Maybe just -- can you help us a little bit in terms of, from your perspective, next key steps to watch from here? And what is J&J's overall level of confidence that you have a path to resolve this in the relative near term for the story? Thanks so much.

### Joaquin Duato - Johnson & Johnson - Chairman of the Board, Chief Executive Officer

Yeah, thank you, Chris. And as you have heard me before, our intention with respect to the talc litigation is to bring a responsible, final, and comprehensive resolution to these claims, and we are making meaningful progress to do just that.

We have filed our prepackaged reorganization plan with the support of 83% of the claimants, and also, we have a decision of the court to keep the filing in Houston. So as I said, we are making progress in this resolution that I refer. As far as next steps, Erik?

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

Hi, thanks, Chris. This is Erik Haas, Head of Worldwide Litigation. Judge Lopez last week on Thursday, after ruling that the case properly and appropriately should remain in Texas, ordered the parties to meet and confer and agree to a schedule for the expeditious resolution of the case.

And by that, it means setting forth the schedule to get through to the confirmation procedure addressing any ancillary motions, whether the motions to dismiss or issues relating to the votes. And the parties are in that process. We contemplate putting forth a schedule that resolve those issues through the end of the year for a confirmation hearing sometime at the beginning of next year. So that's the schedule we're on.

### Operator

Larry Biegelsen, Wells Fargo.

### Larry Biegelsen - Wells Fargo Securities, LLC - Analyst

Good morning. Thanks for taking the question. Tim, on MedTech, maybe help us understand the impact of the one-time items in Q3, such as the ortho, SKU rationalization, how you're thinking about the impact from hurricanes in Q4. What gives you confidence you can deliver the high end of that 5% to 7% next year? Thanks for taking the question.

### Tim Schmid - Johnson & Johnson - Executive Vice President, Worldwide Chairman of MedTech

Larry, thank you for the question. We're proud of the 6.4% operational growth for the quarter, 5.7% for full year. And I think the results really talk to the success of our deliberate move into higher-growth, higher-margin categories, especially in the cardiovascular space.

You'll recall and you'll see that from our results, almost \$300 million is being added from the Shockwave acquisition which continues to perform to expectations as does Abiomed. And we've also added to the portfolio with the acquisition of Laminar in the fourth quarter of last year, and then more recently the announced closure of the acquisition of V-Wave, which once again takes us into even more exciting high-growth, high-margin opportunities within cardiovascular.

Specifically to orthopedics, we believe this is going to be another solid year for orthopedics, 3.2% growth for the year. We did have a slightly softer third quarter, which was a result, to your point, of the restructure within orthopedics.

And as we look to the full year, we expect a return to significantly better performance, especially in orthopedics, which typically has a stronger fourth quarter. And we are seeing tremendous performance specifically within the hips and knees categories, growing 6% and 7%. And I think that's really been enabled by the success of our enabling technologies in VELYS in knees, which also, by the way, we've added the indication of the UNI-Knee, as well as our KINCISE and hip navigation systems within hips.

I'd also add to the orthopedics performance, we are significantly addressing portfolio gaps within our trauma portfolio with the launch of TriLEAP, VirtuGuide, and VOLT in the back half of the year. I think you know our spine portfolio has been challenged, and we're addressing that with the launch of TELIGEN, our new trial to thoracolumbar system, and the new spine robot, which we just received approval for.

As relates to the hurricanes, we did see the impact certainly of Hurricane Helene in the final weeks of the third quarter and continue to see the impact of Milton over the last coming days, especially in the areas most impacted by those storms.

I do think the watch out that we all need to watch carefully is certainly the impact of the recently announced IV saline shortages, which if they do persist, could potentially impact surgical procedures across our portfolio. Thank you, Larry.

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**Operator**

Louise Chen, Cantor Fitzgerald.

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**Louise Chen - Cantor Fitzgerald - Analyst**

Hi, thank you for taking my question here. I wanted to ask you how you see TREMFYA, JNJ-2113, and some of your other pipeline products coming together to replace sales loss to STELARA, and then take share from entrenched competitors. Thank you.

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**Jennifer Taubert - Johnson & Johnson - Executive Vice President, Worldwide Chairman, Innovative Medicine**

Hi, Louise. It's Jennifer. And good morning, everyone. And I wanted to start off by having a chance to really recognize and thank all my innovative medicine colleagues around the world for a fabulous quarter in the third quarter.

We really continue to deliver against our strategy with 11 key brands, having double-digit growth, and achieving a few really notable milestones, notably the TREMFYA approval and launch in ulcerative colitis, also RYBREVANT plus LAZCLUZE in first-line non-small-cell lung cancer. And we also completed the acquisition of NM26, which is a Phase II-ready asset for atopic dermatitis.

So as we take a look at the immunology portfolio, we're really excited about TREMFYA and what we see as the prospects ahead. I just mentioned that we got approval during the quarter for that product in ulcerative colitis. We believe we truly have a winning proposition for that asset in IBD.

And it's off to a really nice start with a really strong reception amongst the medical community. And we see that product having a lot of strength because it's the only dual active IL-23. So it blocks both IL-23 and the CD64 receptor cells. It really sets what we believe is a new bar in terms of efficacy with the highest rate of endoscopic normalization.

And we've got really rigorous head-to-head data versus STELARA, showing superiority in Crohn's disease. And we think that we've got unrivaled flexibility in what will ultimately be a sub-Q both induction and maintenance dose for TREMFYA.

So TREMFYA was [\$1 billion] (corrected by the company after the call) in sales for the quarter, and that was really on psoriasis and psoriatic arthritis alone. When we take a look going forward and what we had seen with STELARA in terms of the strength in IBD and the potential, we think that TREMFYA definitely is an asset that is of STELARA size or bigger and better. So a lot of exciting opportunity for us ahead.

For 2113, we're really excited about our oral asset that we're developing. And I'll let John Reed -- my colleague, John Reed, actually talk about why we're so excited about it and some of the data -- upcoming data there.

But we do think that being able to have that advanced efficacy and known safety profile in a simple oral tablet is not only going to be great for the existing biologics appropriate patients. But we think it gives us a great market expansion opportunity moving into earlier lines of therapy as well. John?

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**John Reed** - Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development

Yeah. Thanks. The 2113 is really moving along nicely. As you know, this is our targeted oral peptide, very exquisite, elegantly designed molecule that binds to and blocks the IL-23 receptor and is orally bioavailable with a once-daily dosing.

The psoriasis indication is fully enrolled now for Phase III studies, which are quite broad, and include head-to-heads against TYK2 inhibitors, as well as both adult and adolescent patients, as well as a study in patients that have disease affecting hard-to-treat areas, scalp and other parts of the anatomy that can be very difficult to clear, typically. So we're really looking quite comprehensively there and the data will be rolling out in the next few months. So we look forward to sharing those at the appropriate time.

In inflammatory bowel disease, we're in a signal-seeking Phase 2 study in ulcerative colitis, where we're exploring different doses before moving into more advanced studies, given that the IL-23 pathway is well-validated inflammatory bowel disease. Thanks to STELARA and TREMFYA, we're quite confident that those studies will come through for us. But we'll wait for those data later this year to see how that oral medication is faring there.

The other thing I'll maybe mention, just in case it's not on your radar, is we also have a co-antibody approach -- we call it 4804 -- where guselkumab and golimumab, TREMFYA and our TNF inhibitor, are combined for patients who tend to be on the more refractory side. And we're in the middle of inflammatory bowel disease studies there that we'll read out next year.

So I'm really excited about that antibody combination as well. So all together, the immunology portfolio is really quite robust, particularly in inflammatory bowel disease and the areas of dermatology where we've had traditional strengths.

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**Jennifer Taubert** - Johnson & Johnson - Executive Vice President, Worldwide Chairman, Innovative Medicine

We really do think that we've got a winning portfolio for inflammatory bowel diseases. And maybe just one addition, because I know we've had questions on this in the past, on 2113. We're going to be developing that really across the spectrum, so both ulcerative colitis as well as Crohn's disease. So we're starting off in ulcerative colitis, but absolutely have plans to develop it in Crohn's as well.

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**Operator**

Terence Flynn, Morgan Stanley.

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**Terence Flynn** - *Morgan Stanley & Co. LLC - Analyst*

Great. Thanks so much for taking the question. Maybe just on the multiple myeloma portfolio, obviously, very nice growth in CARVYKTI this quarter. I know you spoke to some of the drivers, but just was wondering if you can elaborate on what you're seeing in the second-line setting at this point.

And then as you look at TECVAYLI through the rest of this year into next year, what's it going to take to really see an acceleration in growth in this product? Or do we have to wait until we get to earlier lines of treatment here to see growth again in that franchise? Thank you.

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**Jennifer Taubert** - *Johnson & Johnson - Executive Vice President, Worldwide Chairman, Innovative Medicine*

Hi, Terence. Thanks so much for the question on multiple myeloma. And I won't go into a lot of detail on DARZALEX, but it's worth noting that we had \$3 billion in sales, more than 20% growth, and that DARZALEX really continues to perform quite strongly for us, as we continue to grow on share, particularly in frontline, in both transplant-eligible and ineligible patients.

I really appreciate the question on CARVYKTI. So \$286 million in sales, 88% growth year over year, and 53% quarter over quarter. And we're really seeing that continued growth for a number of reasons. So first, we're seeing very strong demand based on the CARTITUDE-4 approval for that second-line and beyond patients.

In addition, overall survival data was just presented for CARVYKTI in this line, which is very, very significant and further adds to the importance of this medicine for patients with multiple myeloma. And the other aspect is we continue to progress really nicely with our continued capacity expansion, in terms of number of slots per day, in Raritan. We gained approval for our Ghent manufacturing site, in Europe, for commercial production that is now underway and able to serve patients. And our CMO in the United States, as well, is producing on the clinical end, so all the way around from performance of the product, from new data, as well as continued capacity expansion, we continue to see very strong performance for CARVYKTI. And as we discussed before, I don't know that we will see that as a complete, exact, linear growth curve quarter to quarter, simply because the capacity expansion works in a bit more of a stair-step fashion.

But as we have discussed, second quarter for us being definitely more robust than the first half that's playing through, and I think if you think about that going forward, that makes a lot of sense. We're over [4,000] (corrected by the company after the call) patients now with CARVYKTI, and it is the most successful CAR-T launch for across -- throughout the industry across all CAR-Ts.

Then last, you asked about TECVAYLI and talquetamab. So if we take a look at -- we'll start off basically with TECVAYLI. Tec sales were \$135 million and 21% growth for the quarter, but it was flat sequentially. We're seeing really nice uptake in the market in terms of new patients. But there's also a dynamic where physicians are treating with longer treatment durations.

So we do think that there's a lot of continued growth and expansion for the product. It's performing very well for patients and not only in its current lines of therapy, but we're also taking a look and studying it in combinations, whether with DARZALEX, whether with TALVEY and so we do believe that there's a lot of growth potential there.

For TALVEY, we're not reporting out the sales yet. I think we'll start on that probably next year. But both Tal and Tec, we continue to expand not only with the academic community, but also out into the community setting. And so we think there's a lot of growth ahead.

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**John Reed** - *Johnson & Johnson - Executive Vice President - Innovative Medicine, Research and Development*

Maybe just a couple things to highlight as well. With Tec, that is not only the first-in-class BCMA-targeting T-cell engager, but the data really show it also is best in class relative to other molecules of that type.

The deepest complete response rates are approaching 50%, about half of patients. Duration of response is nearly two years, and very low discontinuation rates, less than 5%, showing that the weight-adjusted dosing, where we can really optimize for the patients, is really playing out there.

I'm very excited about the early data we're seeing when we combine Tec with DARZALEX, where we're seeing really high response rates in patients who have been multiply treated and now in Phase III studies in patients with one to three prior lines.

And in similar story with Tal, that is a B cell preserving target, as you note. So there are fewer risks of severe infections with Tal. And it has shown in the late line the highest overall response rates of any T-cell engager bispecific for myeloma.

So we think there's a lot of upside opportunity there. And again, the data in combo with Dara are really impressive. So we're marching along with that combination and where we can have the benefits of both the T-cell engager together with the CD38 class. And really, only J&J is positioned to do that.

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### Operator

Danielle Antalffy, UBS.

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### Danielle Antalffy - UBS - Analyst

Hey, good morning, everyone. Thanks so much for taking the question. Just a quick question on the EP business. I mean, obviously, that's very topical. You hadn't really seen much of a slowdown. I appreciate Q3 was probably arguably the first quarter where we had a more -- a full quarter of PFA launching.

I guess, I'm just curious about what you think the underlying market is growing and where PFA is versus RF. And also, as we look ahead to 2025 and VARIPULSE, how that changes dynamics for J&J's EP business. Thanks so much.

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### Tim Schmid - Johnson & Johnson - Executive Vice President, Worldwide Chairman of MedTech

Thank you, Danielle. And as you said, it is a really exciting time to be in electrophysiology. And we couldn't be more proud of the significant leadership position we've held in this category for more than 20 years. And just to put our performance in context, our EP business is a \$5 billion business, which grew 11% in the third quarter and 17% year to date.

We are actively progressing our launch of VARIPULSE in EMEA and in Japan, where we still are executing against our soft launches. We've had over 800 successful cases. We shared the data from our admIRE study at the recent HRS meeting, showing 85% primary effectiveness in that portfolio and that product. And we believe we've got a product that really will hunt.

As it relates to the US, you're right. We're seeing continued competition, especially in the ablation space, given that we don't currently have a PFA product. But having spent a lot of time in EP labs over the last couple weeks, I can tell you that we are incredibly excited for the availability of VARIPULSE, which we expect to have approval sometime later this quarter or in Q1 of next year.

We are still, by the way, mapping the majority of those cases, Danielle. That's what most people don't see, is that while we may not have that product in the portfolio, we are mapping more than 50% of competitive cases. In fact, we've updated our market-leading CARTO software to actually reflect better visualization for competitive products.

And what we've seen in the market -- and I can't give you specific data -- but a significant increase in procedures on the time it's taking EPs to perform ablation procedures with PFA. And by the way, today, we're benefiting from the volume increase from PFA even though we don't have that catheter.

And so that combination of the 5,500 installed base of CARTO system's best-in-class mapping and highly trained mappers, we believe, is a significant advantage and positions us extremely well when PFA comes to market.

I will also say that similar to RF, which, by the way, we still believe has a play within the portfolio, we have the best-in-class RF catheter with QDOT, 86% primary effectiveness. The winning strategy in RF has been a full portfolio and similarly in PFA.

Beyond our first launch with VARIPULSE, you will see a full portfolio of focal -- large-focal, single-shot, and dual-energy catheters. By the way, we already applied for CE marking for our dual-energy catheter. And so we're confident in our leadership position in EP and our sources of differentiation for the future. Thank you, Danielle.

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## Operator

Shagun Singh, RBC Capital Markets.

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## Shagun Singh - RBC Capital Markets Wealth Management - Analyst

Great. Thank you so much. I was hoping you could elaborate on the dynamics that you're seeing in the Asia-Pacific region in MedTech, specifically China. Could you quantify the headwinds? When do you expect it to normalize? And you did talk about China VBP and that it's expanded into additional provinces and products, so could you just elaborate on the impact there and how we should think about it in '25? Thank you.

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## Tim Schmid - Johnson & Johnson - Executive Vice President, Worldwide Chairman of MedTech

Thank you, Shagun. And yes, we've had a myriad of issues hitting us in the Asia-Pacific region of late. And let me just highlight a couple, and I'll certainly get to your question on China.

Firstly, you may know that in February of this year in Korea, the government initiated -- or at least, a strike was initiated among the healthcare professional community. Unfortunately, we don't see any end in sight to that. And so that's certainly has been a headwind.

We're seeing macroeconomic pressures in Japan, and then more importantly, to your question, the ongoing impact to volume-based procurement, which has also been exacerbated by the anti-corruption campaign.

And by the way, while we believe this is absolutely the right thing to do and we support it for the long term, it is impacting procedures and the engagement by healthcare professionals with companies like ours, especially on premium products.

We have a leadership position. We have the largest MedTech company in China. And given the high leadership positions, we are seeing a disproportionate impact from VBP. We have five major categories impacted through tenders in 2023, in electrophysiology, trauma, spine, endocutters, and energy and more recently, the IOLs and sports in our orthopedics business.

We do believe that this will be a headwind through the remainder of '24 and into '25. That said, we are absolutely confident that China continues and will continue to be an important part of our portfolio even with the impact of VBP. We believe we can deliver tremendous growth and returns for our shareholders, and I think this really talks to the strength of our global portfolio across MedTech.

The fact that we can offset headwinds in one geography with better performance in places like Europe and the US. Please rest assured that we also believe that this part of the world, especially in Asia-Pacific, will continue to be a growth opportunity.

And let me tell you why; 60% of the world's patients live in that part of the world. And we're proud of the fact that we've been in many of these markets for many, many years and expect to continue to do so.

The final point I'll make is -- let's remember -- while this is a headwind for MedTech, this is not material to Johnson & Johnson. When we look at our global sales across Johnson & Johnson, [is about 5%] (corrected by the company after the call) of our business is in China. Thank you again.

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**Operator**

Vamil Divan, Guggenheim Securities.

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**Vamil Divan** - *Guggenheim Securities LLC - Analyst*

Thanks for taking my question. I have a question on the immunology side just on TREMFYA and STELARA. You mentioned the US sales for both those products were a little bit lighter than we were expecting, and you mentioned this unfavorable patient mix impacting the quarter.

So I'm just curious if you can you just going a little more detail on what you're seeing for those products in the US specifically and this patient mix issues this quarter. So I'm just curious if you can just go into a little more detail on what you're seeing for those products in the US specifically. And is this patient mix issue sort of this quarter? Is it adjustments from prior quarters? And is there something specific to the Johnson & Johnson? Or is it maybe something broader to the immunology market? Thank you.

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**Jessica Moore** - *Johnson & Johnson - Vice President - Investor Relations*

Yeah, Vamil. If you talk about with patient mix, this would be something that is specific to some of the true-ups that we do. As you are all aware, we end up having to make an assessment on our gross to net reduction. And as we get final bills in, there always are some true-ups. Sometimes, they're for the positive. Sometimes, it is a negative reduction.

So when we refer to patient mix, this is different patients coming through different channels, as well as some of the accounting true-ups for the final payments that we make. And then I will hand it over to Jennifer to specifically talk about the performance and the commercial perspective of TREMFYA and STELARA in the US.

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**Jennifer Taubert** - *Johnson & Johnson - Executive Vice President, Worldwide Chairman, Innovative Medicine*

And I think -- so if we take a look for TREMFYA outside the US, really nice growth of 27%. In the US, it was a little over 9% specifically for that patient mix issue that Jess just spoke about. We do think that the prospects are very strong for continued TREMFYA growth based on what I articulated before around on the launches in ulcerative colitis and the upcoming launches that we're planning for in Crohn's disease as well.

I think on for STELARA, we did see a decline and that, again, sort of similar patient mix piece in the US. And also, we've noted the decline ex-US, particularly in EMEA, due to biosimilar competition. We know that STELARA is near at its end of life and really, that TREMFYA and across the rest of our portfolio, we've got a very robust stable of products with pretty significant growth.

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**Jessica Moore** - *Johnson & Johnson - Vice President - Investor Relations*

Thank you, Vamil. Kevin, we have time for one last question.

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**Operator**

Jayson Bedford, Raymond James.

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**Jayson Bedford** - *Raymond James - Analyst*

Good morning. Maybe just a question for either Tim or Joe. Appreciate the color on MedTech, but the 5% bogey (inaudible) for the year still implies a decent acceleration in 4Q off a tougher comp. What gets better in 4Q?



And then just a quick clarification. The IV solutions dynamic from Helene, are you seeing an impact on volumes outside of Western North Carolina and Florida? Thanks.

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**Tim Schmid** - *Johnson & Johnson - Executive Vice President, Worldwide Chairman of MedTech*

Jayson, thank you for the question, and let me hit the last one first. No, we have seen the majority of the impact in the areas impacted by that storm. As I mentioned earlier, I think the watch out is any potential impact from additional shortage of IV fluid, which may impact elective procedures. And certainly, we're continuing to monitor that very carefully.

As Joe mentioned, we expect now on the back of the headwinds we mentioned earlier in Asia-Pacific to deliver adjusted operational growth of around 5% and north of 6% on an operational basis for the year. We believe that the momentum we're carrying into the fourth quarter, especially in our cardiovascular businesses with our winning portfolio in electrophysiology, strong double-digit growth in Shockwave, Abiomed. I mean, those are, as you can see from the performance, absolute home runs.

The other important dynamic here is that, as we signaled in the first and second quarter, we expected to see improvement within our vision business, which typically has delivered solid mid-single-digit growth. We had a tremendous third quarter, which really gives us confidence in even stronger force. This was delivered by much better performances, especially in our contact lens business.

In fact, here in the US, our most important market, double-digit growth for contact lenses in the quarter. And this just really has been delivered from a stabilization of our distributor inventory in the US, the fact that we're able to get back to taking new wearer share now that we have unconstrained supply, especially within our astigmatism portfolio. And so we do believe that vision has a very strong quarter ahead.

And then finally, across the portfolio, we're benefiting from tremendous new product launches, both within cardiovascular, the E8 peripheral catheter within Shockwave, continued performance within Abiomed with our broad portfolio of pumps and then within our surgery business, as well as orthopedics, as I mentioned earlier, tremendous new products to add differentiation to the portfolio.

And typically, that fourth quarter also is a stronger one for us. So once again, very confident in our performance at around 5% on an adjusted basis and north of 6% operationally. Thank you.

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**Jessica Moore** - *Johnson & Johnson - Vice President - Investor Relations*

Thank you, Jayson, and thanks to everyone for your questions and your continued interest in our company. We apologize to those we couldn't get to because of time. But don't hesitate to reach out to the Investor Relations team with any remaining questions that you may have. I would now turn the call over to Joaquin for some brief closing remarks.

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**Joaquin Duato** - *Johnson & Johnson - Chairman of the Board, Chief Executive Officer*

Thank you, everyone, for joining the call today. As you have heard, we delivered strong results in the third quarter. Our high-innovation and high-growth portfolio and pipelines are advancing rapidly. And we are increasingly confident in our expectations for 2025 and beyond.

Enjoy the rest of your day.

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**Operator**

Thank you. This concludes today's Johnson & Johnson's third-quarter 2024 earnings conference call. You may now disconnect.

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