Speaker 4 (0s)
Good morning and welcome to Johnson & Johnson.

Speaker 1 (1s)
Johnson's third quarter 2025 earnings conference call.

Speaker 4 (5s)
All participants will be in the listen-only mode until the question and answer session of the conference. This call is being recorded. If anyone has any objections, you may disconnect at this time.

Speaker 1 (16s)
If you experience technical difficulties during the conference, you may press Star 0 to reach the operator.

Speaker 4 (22s)
I will now turn the conference call.

Speaker 1 (23s)
Over to Johnson & Johnson.

Speaker 4 (25s)
You may begin.

Speaker 1 (28s)
Hello everyone, this is Darren Snellgrove, Vice President of Investor Relations for Johnson & Johnson. Welcome to our 2025 third quarter review of business results and updated financial outlook. First, a few logistics. As a reminder, today's presentation and associated schedules are available 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 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 2024 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 discuss our business performance and growth drivers.

Speaker 1 (2m 5s)
I will then review the third quarter sales and P&L results. Joe Wolk, our CFO, will then close by sharing an overview of our cash position and capital allocation priorities, followed by additional details on our intended separation of the orthopedics business. He will also provide an update on 2025 guidance, key milestones and qualitative considerations for 2026. Jennifer Taubert, Executive Vice President, Worldwide Chairman, Innovative Medicine, John Reed, Executive Vice President, Innovative Medicine Research and Development, and Tim Schmid, Executive Vice President, Worldwide Chairman, MedTech, 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. With that, I will now turn the call over to Joaquin.

Speaker 2
2m 59s

Thank you, Darren, and hello everyone. We are looking forward to sharing our very strong third quarter results with you. They are a clear sign Johnson & Johnson is in a powerful new era of growth. The success of our portfolio and pipeline is proof that our relentless focus on innovation is doing more than fueling progress, it is accelerating it. In the third quarter, we delivered operational sales growth of 5.4% across our business. In Innovative Medicine, we reported 5.3% operational sales growth and a second consecutive quarter of sales of more than $15 billion. Some were not convinced we could grow through the loss of exclusivity of Stelara, but we were confident and we have now unequivocally answered that question. How did we accomplish that when other companies have failed? In Q3, we did it by delivering double-digit growth across 11 brands including Darzalex, Carvykti, Talvey, Tecvayli, Erleada, Rybrevant, Pluvicto, Caplyta, Spravato, Symponi, Remicade, and remarkable growth of 40% in Tremfya. In MedTech, operational sales growth was even stronger, accelerating to 5.6% with improvements across all businesses. As you have seen from this morning's news, we have announced the planned separation of our orthopedics business. This decision further sharpens our focus as a healthcare innovation leader and accelerates the shift of our MedTech portfolio to areas of greatest unmet need and higher growth, which includes cardiovascular and robotic surgery.

Speaker 2
4m 58s

I will touch more on this later, but one thing is clear, Johnson & Johnson's momentum is strong and our achievements are multiplying. I will now focus on the progress we are making across our six priority areas: oncology, immunology, neuroscience, cardiovascular surgery, and vision. These are areas where we have deep expertise and clear leadership positions. First, oncology, where Q3 operational sales grew nearly 20%. You have heard me say before that we are much more than a one-shot company and our expertise in blood cancers and solid tumors in our oncology portfolio is a great example. Take multiple myeloma, where our competitiveness is unrivaled. No other company has the expertise or success in multiple myeloma that we do. We have treatments in every line of therapy and Darzalex is the gold standard with more than 50% market share across all lines of therapy. Q3 operational sales of Darzalex grew by 20% and its potential continues to build with the approval this quarter in Europe as a treatment for high risk smoldering multiple myeloma as well as promising new studies of Darzalex Faspro in combination with teclistamab. I also want to say a word about Carvykti, our CAR-T treatment for multiple myeloma.

Speaker 2
6m 32s

We have now treated more than 8,500 patients globally, making Carvykti the most successful CAR-T launch ever. With operational sales growing by more than 80% this quarter, we are increasingly confident in Carvykti's $5 billion peak year sales potential. Turning to solid tumors, we were thrilled to receive FDA approval for our bladder cancer treatment Inlexa last month. Inlexa highlights what is unique about Johnson & Johnson. Building on our unmatched capabilities in both Innovative Medicine and MedTech, it is the first and only drug releasing system to provide sustained local delivery of a cancer treatment directly into the bladder. It is transformative for patients and it is transformative for doctors. It will also contribute significantly to future growth with a targeted release platform projected to be another blockbuster treatment with at least $5 billion in annual peak year sales. Sourced through an early stage deal, Inlexa is also an example of our outstanding business development model. In fact, in the last 18 months alone we have completed more than 60 deals of this kind and in lung cancer we recently published results in the New England Journal of Medicine for riviprant plus lazertinib showing a statistically significant reduction in the risk of death compared to osimertinib.

Speaker 2
8m 12s

We are now seeing the potential for patients to live significantly longer than anyone thought possible. The combination of riviprant plus lazertinib is another of our $5 billion peak year sales assets. Next I want to talk about Immunology, where we have been leaders for 25 years. From Remicade to Simponi and Stelara to Tremfya, some of our biggest blockbusters have come from our immunology portfolio. We have long talked about Tremfya as the next big innovation to follow the success of Stelara. Based on this quarter's performance, it looks like it could be both bigger and better. Having delivered operational sales growth of 40% driven by new indications in inflammatory bowel disease, Tremfya is the only IL-23 inhibitor to offer a fully subcutaneous regimen across ulcerative colitis and Crohn's disease. Even prior to the launch of our subcutaneous formulation, Tremfya was capturing approximately half of all new patient starts for IL-23 ulcerative colitis treatments in the U.S., which we achieved within one year from launch. We are confident Tremfya will become a more than $10 billion asset, and in typical J&J fashion, we are deep in development of our next immunology innovation, icatrekibart, initially for moderate to severe plaque psoriasis.

Speaker 2
9m 52s

Historically, the most effective immunology treatments have been injectables. As the first oral peptide to selectively block the IL-23 receptor, icatrekibart has the potential to revolutionize the treatment of plaque psoriasis with a once-a-day pill. We submitted icatrekibart for plaque psoriasis to the FDA in July. This is just the beginning, as we have already presented data from our phase 2 trials in ulcerative colitis. Let's now turn to neuroscience. With Spravato operational sales growing an impressive 61% in Q3, Spravato remains the only approved standalone therapy for treatment-resistant depression, a major depressive disorder with suicidal ideation. Through Q3, we have now treated more than 180,000 patients, and I could not be prouder of the impact this team is having. Our leadership in neuropsychiatry was also strengthened by this year's acquisition of Intra-Cellular Therapies. With FDA approval for Caplyta in major depressive disorder anticipated soon, Caplyta is already FDA approved for the treatment of schizophrenia as well as depressive episodes associated with bipolar disorder 1 and 2. We project Caplyta to reach $5 billion annually. Now let's turn to MedTech, starting with our cardiovascular portfolio. In Q3, cardiovascular operational sales increased by approximately 12% as we fortify our leadership in the fastest growing cardiovascular intervention segments.

Speaker 2
11m 44s

With operational sales growth of over 20%, Shockwave's unique intravascular lithotripsy technology is helping treat more atherosclerotic cardiovascular patients than ever before. In fact, in the last quarter, Shockwave supported their 1 millionth patient, and with the recent European approval of the Javelin peripheral intravascular lithotripsy catheter, we expect strong momentum moving forward. We anticipate Shockwave becoming our 13th billion dollar MedTech platform by year end. In electrophysiology, we are industry leaders, and with the strength of our mapping technology that continues in Q3, we again delivered close to 10% operational sales growth, and our position was further strengthened with real world data showing Varipulse achieved 99.7% acute effectiveness in nearly 800 patients with strong safety and no incidence of stroke. Our Abiomed business also continues to perform strongly with more than 15% operational sales growth in the quarter. Our success reflects the impact that our Impella CP heart pump is having on the lives of patients, which you could see in the long term survival data that was published in the New England Journal of Medicine this quarter. In the 10-year DANGER Shock study, routine use of Impella CP in patients who have had a heart attack with cardiogenic shock reduced mortality by 16.3% compared to the standard of care, with patients gaining an average of 600 additional days alive.

Speaker 2
13m 31s

It is a perfect example of what we mean when we say Johnson & Johnson is delivering groundbreaking innovation in surgery. We are making progress on multiple fronts. Our surgical technologies are used in most operating rooms globally, and in Q3 we delivered more than 9% growth in biosurgery and almost 7% in wound closure, driven by accelerating adoption of our latest innovations. We also continue to make positive progress with OTAVA as we anticipate FDA de novo submission in early 2026. Now to Vision, where we grew more than 6% last quarter. Our TECNIS intraocular lenses are the fastest growing in the markets. What we have launched is fueling our 13.8% operational sales growth in surgical vision, and after launching the world's first multifocal contact lens for people with astigmatism in the U.S. last quarter, we brought this latest member of the ACUVUE OASYS MAX 1-Day family to Europe and Korea in Q3, further strengthening our momentum. Finally, to this morning's Orthopaedics news. As you know, the healthcare industry continues to evolve rapidly, and we are constantly evaluating our overall business and portfolio to ensure Johnson & Johnson remains best positioned to truly lead where healthcare is going. We continue to invest at industry leading levels in our pipeline and portfolio while making disciplined decisions to exit businesses that we believe will be better able to thrive outside of Johnson & Johnson.

Speaker 2
15m 16s

For our orthopedics business, the planned separation creates new opportunities. Operating as DePuy Synthes and led by Namal Nawana, it would be the largest, most comprehensive orthopedics company with leading market share positions across major categories and addressing a more than $50 billion and growing market opportunity. We expect DePuy Synthes to benefit from a more focused business model with greater flexibility to extend its market leadership, invest in its commercial capabilities, and capitalize on profitable growth opportunities. Following the completion of the planned separation, Johnson & Johnson will retain a leadership position in our six core growth areas across innovative medicine and MedTech for oncology, immunology, neuroscience, cardiovascular surgery, and vision, and be able to place even greater focus in our investment towards higher growth areas where we can meaningfully extend and improve lives. We are positioning each business to win and deliver for our stakeholders as we move forward in the separation process. We will provide additional information as appropriate, and Joe will share more details shortly. As I said at the start of the call, we are in a new era of accelerated growth at Johnson & Johnson. This is more than just another strong quarter. It is proof that our momentum is building and that our impact is accelerating.

Speaker 2
16m 50s

Thank you very much, and I will now turn the call back over to Darren.

Speaker 1
16m 56s

Thank you, Joaquin. Moving to our financial results, unless otherwise stated, the percentages quoted represent operational results and therefore exclude the impact of currency translation. Starting with Q3 2025 sales results, worldwide sales were $24 billion for the quarter. Sales increased 5.4% despite an approximate 640 basis point headwind from Stelara. Growth in the U.S. was 6.2% and 4.4% outside of the U.S. Acquisitions and divestitures had a net positive impact on worldwide growth of 100 basis points, primarily driven by the Intra-Cellular acquisition. Turning now to earnings for the quarter, net earnings were $5.2 billion with diluted earnings per share of $2.12 versus diluted earnings per share of $1.11 a year ago. Adjusted net earnings for the quarter were $6.8 billion with adjusted diluted earnings per share of $2.00, both representing an increase of 15.7% compared to the third quarter of 2024. As a reminder, results in the third quarter of 2024 were impacted by the acquired IPR&D expense of $1.25 billion associated with the NM26 bispecific antibody. I will now comment on business sales performance in the quarter, focusing on the six key areas where meaningful innovation is driving our performance and fueling long-term growth, beginning with Innovative Medicine where our results demonstrate the depth of our expertise across oncology, immunology, and neuroscience.

Speaker 1
18m 46s

Worldwide sales of $15.6 billion increased 5.3% despite an approximate 1,070 basis point headwind from Stelara, illustrating the continued strength of our key brands and new launches. Growth in the U.S. was 6% and 4.3% outside of the U.S. Acquisitions and divestitures had a net positive impact of 160 basis points on worldwide growth due to the Intra-Cellular acquisition. In oncology, starting with multiple myeloma, Darzalex growth was 19.9%, primarily driven by continued strong share gains of approximately 5.7 points across all lines of therapy, with nearly 9 points in the frontline setting as well as market growth. Carvykti achieved sales of $524 million with growth of 81.4% driven by share gains and site expansion. This reflects continued strong sequential growth of 18.5% as our expansion outside the U.S. progresses. Tecvayli and Talvey growth was 29.9% and 59.1% respectively, bolstered by continued expansion into the community setting. In prostate cancer, Erleada delivered strong growth of 15.3% due to market growth and continued share gains, partially offset by the impact of Part D redesign. In lung cancer, Rivipansel plus Lasclus delivered sales of $198 million and growth over 100% driven by continued strong launch uptake. We continue to see share gains in both first and second lines of therapy.

Speaker 1
20m 37s

Within Immunology, Tremfya delivered very strong growth of 40.1%. We continue to see share gains across all indications with particularly robust momentum from our IBD launch. Stelara declined by 42% driven by the impact of biosimilar competition and Part D redesign, which is in line with our expectations. In neuroscience, Spravato grew an impressive 60.8% driven by continued strong demand from physicians and patients. Caplyta, which was acquired in Q2 as part of the Intra-Cellular Therapies acquisition, delivered sales of $240 million and reflects healthy sequential growth of 13.4%. Now moving to MedTech, worldwide sales of $8.4 billion increased 5.6% with growth of 6.6% in the U.S. and 4.5% outside the U.S. driven by strong performance in our three focus areas, cardiovascular surgery and vision. Acquisitions and divestitures had a net negative impact of 10 basis points on worldwide growth. In cardiovascular, electrophysiology delivered growth of 9.7% versus prior year driven by procedure growth, commercial execution, Varipulse and other new products and strength in competitive mapping. Abiomed delivered growth of 15.6% with continued strong adoption of Impella technology and Shockwave increased 20.9% driven by double-digit growth globally in both coronary and peripheral. Surgery grew 3.3% despite divestitures negatively impacting results by approximately 50 basis points.

Speaker 1
22m 26s

Performance was primarily driven by technology penetration in wound closure, the strength of the portfolio and commercial execution in biosurgery as well as a one-time reserve adjustment in the quarter. Growth was partially offset by competitive pressures in energy and the negative impact of China VBP. Across the portfolio in vision, contact lenses and other products grew 3.5% driven by market growth, strong performance in the ACUVUE OASYS 1-Day family of contact lenses. This includes the recent launches of OASYS MAX 1-Day multifocal for astigmatism and MAX 1-Day for astigmatism as well as continued strategic price actions. Surgical Vision had another strong quarter with growth of 13.8% driven by new product. Product innovations such as TECNIS PureSee, Odyssey and Eyhance, robust demand and strong commercial execution. These results further solidify our leadership positions in vision. As Joaquin noted, we have today announced our intent to separate the orthopaedic business. Orthopaedic growth this quarter is gaining momentum and increased to 2.4%. Importantly, hips and knees returned to growth this quarter, delivering 5.1% and 5.6% growth respectively. Now turning to our consolidated statement of earnings for the third quarter of 2025, I'd like to highlight a few noteworthy items that have changed compared to the same quarter a year ago.

Speaker 1
24m 6s

Cost of products sold leveraged by 60 basis points, driven by a reduction in amortization expense and favorable currency in the Innovative Medicine business, as well as the non-recurring fair value inventory step up related to Shockwave in 2024. This was partially offset by unfavorable product mix in Innovative Medicine along with MedTech macroeconomic factors. Selling, marketing, and administrative expenses deleveraged by 40 basis points, driven by increased investment in the recent Intra-Cellular acquisition for Caplyta and promotional spend across the Innovative Medicine business, partially offset by expense leveraging in MedTech. Research and development expenses leveraged by 670 basis points, primarily driven by the expense of $1.25 billion to secure the global rights to the NM26 bispecific antibody recorded in 2024. We continued our strong investment in research and development with $3.7 billion, approximately 15% of sales in Q3. Interest income and expense was a net expense of $18 million as compared to $99 million of income in the third quarter of 2024, primarily driven by a higher average debt balance and a lower average cash balance. Other income and expense was net income of $0.5 billion compared to an expense of $1.8 billion in the prior year, primarily driven by a TALC litigation charge in 2024 and higher gains on the sales of securities in 2025, partially offset by the monetization of royalty rights recorded in 2024.

Speaker 1
26m 0s

Regarding taxes in the quarter, our effective tax rate was 31.2% compared to 19.3% in the same period last year. The increase is primarily driven by the one-time $1 billion remeasurement of deferred tax balances, which are required to reflect the changes in statutory tax rates associated with the enactment of the One Big Beautiful Bill Act in the third quarter. More information can be found in the company's Form 10-Q. Lastly, I'll direct your attention to the box section of the slide where we have also provided the company's 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 for the quarter. Innovative Medicine margin improved from 37.9% to 44.3% primarily driven by the one-time expense of $1.25 billion to secure the global rights of the NM26 bispecific antibody recorded in 2024, partially offset by increased investment in commercial spend in 2025 and the non-recurring monetization of royalty rights in 2024. MedTech margin declined from 24.1% to 21% driven by macroeconomic factors in cost of products sold, partially offset by expense leveraging in SMA. This concludes the sales and earnings portion of the call, and I will now turn the call over to Joe.

Speaker 1
27m 41s

Thanks.

Speaker 4
27m 42s

Hello everyone and thank you for joining us today. In the third quarter, we sustained momentum across our in-market portfolio, delivering upon the heightened financial expectations we guided to last quarter. In Innovative Medicine, we continue to grow through the STELARA loss of exclusivity as.

Speaker 2
27m 59s

We said we would.

Speaker 4
28m 0s

The progression of our pipeline, evidenced by significant regulatory milestones, adds further depth to our three focus areas of oncology, immunology, and neuroscience. We are well positioned for the balance of the decade. In MedTech, we improved adjusted operational sales across key areas of the business. As Joaquin mentioned, we are sharpening our focus on high-growth, high-margin markets where we can improve patient outcomes, as this morning's announcement regarding the DePuy Synthes business indicates. In a moment, I will build upon Joaquin's comments regarding that announcement. The foundation we have set, combined with the progression of our pipeline, strongly positions the company for accelerated growth. It also reinforces our conviction to deliver on the upper end of our long-term growth targets. Let me provide a brief update on the Daubert motions pending in the talc litigation. As you are aware, this is the judicial process by which the court will reexamine the junk science that the mass tort plaintiff's bar concocts to fuel baseless claims against Johnson & Johnson as well as many American businesses. We look forward to and expect to secure favorable rulings on the Daubert motions, which should be rendered by the first quarter of 2026. Now turning to cash and capital allocation, we generated $14 billion in free cash flow through the first nine months of the year.

Speaker 4
29m 25s

We ended the third quarter with approximately $19 billion in cash and marketable securities and $46 billion of debt for a net debt position of $27 billion versus the $32 billion of net debt reported in the second quarter. We continue to utilize our free cash flow generation and strong balance sheet to invest in innovation and return capital directly to shareholders. We are often asked about our appetite for acquisitions to meet financial targets. I can be very clear on this. We rely on a thoughtful, long-term approach to growing through any loss of exclusivity and won't carelessly deploy capital on transactions out of desperation. Our current portfolio and pipeline have momentum, and with the Stelara loss of exclusivity increasingly in the rearview mirror, we do not need to rely on large transactions to drive our growth. We intend to remain disciplined, opportunistically pursuing strategic, high-value opportunities that utilize our expertise and capabilities that deliver an appropriate return for the risk that we bear on behalf of shareholders. Regarding the planned separation of our orthopedics business, as Joaquin noted, the separation is expected to enhance the strategic and operational focus of each company and drive value for our shareholders and other stakeholders.

Speaker 4
30m 43s

Given that we are early in the process, there are limited details available, but we are committed to providing you with information on a timely basis. While we will of course communicate material developments, we don't expect to have anything newsworthy to convey until mid next year. What can we say at this moment? First, the separation will further strengthen our overall MedTech business and increase Johnson & Johnson's top line growth and margins. To give that some directional context, if we just look at normalized year to date 2025 results, MedTech's top line revenue growth and operating margin would both improve by at least 75 basis points. Next, we are targeting completion of the separation within 18 to 24 months, subject to the satisfaction of certain conditions given it is the most resource intensive and likely longest duration. We are prioritizing and have begun the separation assuming a spinoff with the intention for that to qualify as a tax free separation for U.S. Federal income tax purposes. However, we will consider other avenues that optimize shareholder value. We do not expect any change to the Johnson & Johnson dividend and are mindful of any impact from stranded costs that are typically present in these types of transactions.

Speaker 4
32m 3s

Finally, following the separation, we would expect DePuy Synthes to have a strong capital structure that would allow the orthopedics business to build on its long history of innovation and extend leadership positions through enhanced organic investment and strategic growth. Accretive M&A as we pursue this separation, the orthopedics unit will operate in alignment with the business current strategy, continuing to make investments in growth, margin improvement and innovation. Turning now to full year guidance for 2025, we are increasing operational sales guidance for the full year by approximately $300 million, resulting in operational sales growth for the full year in the range of 4.8% to 5.3%. With a midpoint of $93.2 billion or 5.1% excluding the impact from acquisitions and divestitures. Our adjusted operational sales growth is now expected to be in the range of 4.0% compared to 2024. As a reminder, we started the year guiding to a midpoint for 2.5% for adjusted operational sales. As you know, we don't speculate on future currency movements and last quarter we utilized the Euro spot rate relative to the U.S. dollar of 1.17. The U.S. dollar has stayed relatively flat to the Euro spot rate and as a result we now expect reported sales growth between 5.4% to 5.9% with a midpoint of $90 billion or 5.7%.

Speaker 4
33m 39s

Turning to other notable items on the P&L, we are reiterating our operating margin guide of an approximate 300 basis point improvement for the full year. Assuming what we know today as it relates to tariffs for net interest expense, we are now projecting between $0 and $50 million, an improvement from the previous guidance primarily driven by higher cash balances. We are expecting a higher effective tax rate to be in the range of 17.5% to 18% for the full year, with the increase largely due to the recently enacted One Big Beautiful Bill Act. We feel strongly that U.S. tax policy has enabled Johnson & Johnson to increase our manufacturing footprint in the U.S. We have more manufacturing facilities in the United States than in any other country and we remain committed to investing $55 billion in U.S.-based innovation and manufacturing over the next four years. In March we broke ground at our Wilson, North Carolina facility and in August we announced a $2 billion commitment to further increase our presence in North Carolina with a more than 160,000 square foot dedicated manufacturing facility at Fujifilm's new biopharmaceutical manufacturing site in Holly Springs. Our overall U.S. investment plans also include three additional new advanced manufacturing facilities as well as the expansion of several existing sites.

Speaker 4
35m 4s

Turning to earnings per share, you may recall we started the year guiding to adjusted EPS of $10.60. Today we stand much higher even after including dilution of $0.25 from the Intra-Cellular acquisition. Today we are reaffirming our elevated July earnings per share outlook, which also absorbs a higher annual effective tax rate and fourth quarter investments that will further position the business for success. As such, our expected adjusted earnings per share guidance remains $10.85 or 8.7% at the midpoint, with a range of $10.80 to $10.90. Our adjusted operational earnings per share guidance is $10.68 or 7% at the midpoint. Looking beyond our financial commitments for the year, we are on track to add to the already impressive number of milestones that we achieved across our pipeline in 2025. In Innovative Medicine, we anticipate U.S. FDA approval for subcutaneous Riviprant for non-small cell lung cancer as well as for Caplyta, an adjunctive major depressive disorder. We recently filed for a label expansion on Tremfya in psoriatic arthritis and plan to present data for Riviprant in head and neck cancer at ESMO in the coming week. In MedTech, we continue to make progress with our clinical trial for our OTAVA robotic surgical system in our cardiovascular portfolio.

Speaker 4
36m 34s

We are planning regulatory submissions for the Dual Energy ThermoCool SmartTouch SF catheter for cardiac arrhythmia in the U.S. and envision we will continue to roll out ACUVUE OASYS MAX for astigmatism. As we are close to year end and with the strong caveat that we are still finalizing plans for next year and macro factors can change quickly, let me provide some preliminary thoughts to inform your modeling for 2026. For Innovative Medicine, we remain very confident in our ability to deliver accelerated growth despite Stelara loss of exclusivity. This will be driven by our in-market brands and continued progress from our recently launched products including Tremfya in inflammatory bowel disease, Riviprant plus LAS clues in non-small cell lung cancer, and Inlexa in bladder cancer. We currently anticipate a 2026 approval for icatrekibart in psoriasis. In MedTech, we continue to expect accelerated growth off this year's levels driven by focus on higher growth markets as well as the continued adoption of newer products across all MedTech platforms. We also anticipate the launch of Shockwave C2+ AERO Coronary IVL Catheter, the TECNIS PureSee intraocular lens in the U.S. as well as regulatory submission for the OTAVA robotic surgical. Again, while early, I like the way 2026 is shaping up.

Speaker 4
38m 2s

In fact, based on my last look at your 2026 models, it appears the current revenue consensus of 4.6% growth in your models for 2026 is lower than we project, which we believe in total will exceed 5%. Similarly, with the expectation that adjusted earnings per share is commensurate with sales growth, there appears to be some upside to the current adjusted earnings per share consensus of $11.39, perhaps as much as $0.05. This commentary considers investments we will be making behind many of the new product launches I just highlighted, but you can also expect some margin improvement. It also reflects our understanding of the present legislative landscape, tariffs, foreign exchange rates, and procedural volumes. We look forward to sharing further details regarding our official guide for 2026 during our Q4 earnings call in January. In summary, the strength of our business model, with a focus on where we can have the greatest impact for patients, will enable Johnson & Johnson to deliver against our strategic objectives and financial commitments. We are as confident as we have been in recent memory about the future. I'd like to end my remarks by thanking our colleagues around the world for their continued hard work and steadfast dedication that serve our patients and who make these financial results possible and sustainable.

Speaker 4
39m 25s

With that, we are happy to take your questions. Kevin, will you please open the call for Q&A?

Speaker 1
39m 32s

Certainly.

Speaker 4
39m 32s

Ladies and gentlemen, if you'd like to ask a question at this time, please.

Speaker 1
39m 36s

Press Star then one on your telephone keypad. If you'd like to withdraw your question, please press Star then two.

Speaker 4
39m 43s

We ask that you please limit yourselves.

Speaker 1
39m 45s

To one question only. Our first question is coming from Alex Hammond from Wolfe Research. Your line is now.

Speaker 5
39m 53s

Good morning and thanks for taking the question on the orthopedic spin out. I'd be interested to understand the why now, and also could we expect similar separations for other divisions in the future? As a quick follow up, how should we think about the long term guidance in light of the separation? Could we expect Johnson & Johnson to revisit these forecasts in the near term?

Speaker 2
40m 12s

Thank you, Alex. Let me take the first question. Why now? Why the orthopedic separation? It's been a hallmark of Johnson & Johnson to be a good steward of our capital and to make decisions in our portfolio to prioritize where we think breakthrough innovation can come through. That's exactly what we are doing. We're moving Johnson & Johnson into high growth markets with significant medical need, and at the same time, we have the foresight to recognize when a standalone company could be better and could be in a better position to drive growth, innovation, and better margins. That's exactly what we are doing with our orthopedic separation. We are fueling the innovation within Johnson & Johnson, focus on our six priority areas, continue to invest as we are doing in cardiovascular with the acquisitions of Abiomed, Shockwave, and also in pharmaceuticals with the acquisition of Intra-Cellular, and creating a standalone company that is going to be a champion within the context of the orthopedics sector. Orthopedics is a growing market, $50 billion market. It's fueled by the aging of the population, and we have commanding market shares in the most important segments of the orthopedics business. The company is going to be called DePuy Synthes.

Speaker 2
41m 30s

It's going to be led by Namal Nawana, who is an industry veteran. I have no doubt that they are going to be better positioned to succeed, to drive innovation, to drive growth, and to become what they are, the largest orthopedics company in the world. Overall, this is a clear move to be able to manage our portfolio, to position Johnson & Johnson to be able to deliver breakthrough innovation, and the results that you are seeing so far with a very, very strong quarter. I want to underline this is not only a very strong quarter, it's also an indication, a signal that Johnson & Johnson is in an accelerated cycle of growth, which we expect is going to last the balance of the decade. Moving in the right direction. I'm sure investors are going to be happy to see that Johnson & Johnson is an active portfolio manager.

Speaker 4
42m 21s

Yes, Alex, maybe just to build on Joaquin's comments. Thanks for the question. There were two other parts that I thought I heard from you. This is not a precursor to anything else. We look at what we have now in the clarity of our portfolio. Three strong strong-holds in innovative medicine serving unmet needs with transformational innovation that elevates the standard of care in oncology, neuroscience, and immunology. Likewise, now in MedTech where we have market-leading positions, cutting-edge technology that is improving care for patients in surgery, eye health, and cardiovascular. We are going to be real pleased with the portfolio and we think Orthopaedics is set up for success going forward based on their profile and their ability to compete against other singularly focused orthopedics companies with respect to guidance revisions. As we mentioned in the scripted commentary, this will take 18 to 24 months. Anything we say about 2026 will likely include the orthopedics business in our outlooks. We would expect maybe some material developments middle of next year, but we commit to keeping this audience particularly advised on a timely basis should anything material unfold. Thank you. Next question today is coming from Daniela Antalpi from UBS.

Speaker 4
43m 40s

Your line is now live.

Speaker 5
43m 43s

Hey, good afternoon, guys. Thanks so much for taking the question. Just a question on Joe, your commentary around potential margins post the Ortho Spin 75 bps. I don't want to get too greedy, but that feels a little light to me. Just curious about why, you know, given the mix of the business, it's high growth cardiovascular surgery, which I think should be relatively high margin, and vision feels like maybe it could be a little bit more than that. Just want to make sure I understand the puts and takes to that 75 bps number. Appreciating that's just, you know, a very early target.

Speaker 4
44m 20s

Yeah, thanks, Danielle. That's an insightful question and I think it really depends on the time period by which you're measuring. If we were just to take 2025, you're absolutely right, it would be probably closer to 100 bps both on top and bottom or margin improvement. What I would say is we looked out a couple years given this will take a couple years to go through the process. As Abiomed, Shockwave, and the other businesses have higher growth profiles, margin improvements, initiatives that are already underway under Tim's leadership, it will have a more muted impact as it goes forward. I think on today's math, you're probably closer to being right. It's okay. I don't consider it greedy. Tim might, but I don't. I think as you look out a little bit further with some of the stronger profile businesses, from a financial perspective, it'll have more of a muted impact. Yes.

Speaker 2
45m 14s

Daniel, maybe just building on Joe's.

Speaker 4
45m 17s

Comments, as I'm sure there'll be a lot of questions on this topic, and we'd like to try and get them out of the way so we can.

Speaker 2
45m 21s

Focus on the broader business.

Speaker 4
45m 23s

I wanted to highlight why this makes sense for Johnson & Johnson MedTech, as you've heard from Joaquin.

Speaker 2
45m 29s

Joe, this is all about our commitment.

Speaker 4
45m 30s

To continuous portfolio optimization and value creation.

Speaker 2
45m 34s

As you know, we've been on a journey over the last several years to really aggressively move our portfolio.

Speaker 4
45m 40s
Into higher growth markets. Adding attractive assets such as Abiomed and Shockwave in high growth markets like cardiovascular are good examples of the bold.

Speaker 2
45m 49s
Moves we already made in. Now this decision to separate Ortho is.

Speaker 4
45m 53s
The next major step in that direction.

Speaker 2
45m 54s
Ortho is a great business, frankly.

Speaker 4
45m 57s
One that participates, as you know, in lower growth markets.

Speaker 2
46m 0s
This is all about shrinking to grow faster for MedTech. Last time I looked.

Speaker 4
46m 5s
You're not rewarding size, but really rather.

Speaker 2
46m 7s
Best-in-class performance.

Speaker 4
46m 8s
That is the path that we're on. As you already have heard, we expect the separation would increase our top line growth and margins following the completion. This allows us in MedTech really to focus on the businesses that will remain, which is our priorities of cardiovascular surgery and vision.

Speaker 2
46m 27s
Thank you. I want to reiterate, as I told you day one when I became CEO, that I am fully focused, determined to make our MedTech sector the best-in-class MedTech group in the industry. That is a total priority for me, is a priority for Johnson & Johnson, and we are fully committed to deliver on that. We are on track to become the best MedTech sector in the industry.

Speaker 4
46m 55s
Thank you.

Speaker 1
46m 56s
Our next question today is coming from.

Speaker 4
46m 57s
Chris Schott from J.P. Morgan. Your line is now live.

Speaker 1
47m 0s
Great.

Speaker 4
47m 1s
Thanks so much.

Speaker 1
47m 2s
Maybe just a question for Joaquin. There seems like there might be a framework for MFM agreements with the administration that's emerging across the space, focused on.

Speaker 4
47m 11s
New launches in Medicaid.

Speaker 1
47m 12s
Can you just talk about how you're thinking about MFN tariffs, et cetera, and Johnson & Johnson's approach to some of these kind.

Speaker 4
47m 20s
Of policy dynamics that are floating around out there. Thanks so much.

Speaker 2
47m 23s

Thank you for the question. We've been talking with this administration with an open dialogue since day one, even before day one. We are always looking, as we have done as Johnson & Johnson, for common ground to build in the administration priorities that are similar to ours. Priorities like making sure that American patients have access to innovation in an affordable and timely way. Priorities like making sure that foreign entities do not free ride on American innovation. Making sure that we are able to maintain the overall leadership that this country has in life sciences. Finally, making sure that we continue to invest in manufacturing in this country to build good middle class jobs. We are delivering on that. We announced our plan to invest $55 billion in the U.S. in the next four years, which essentially is going to make it so that all our advanced medicines that are used in the U.S. are going to be manufactured in the U.S. As far as the discussions, those are ongoing, I don't have anything to share today, but I am optimistic that we are going to land in a place which is going to create common ground between the administration and ourselves.

Speaker 2
48m 36s

Thank you.

Speaker 1
48m 36s

Our next question today is coming from Larry Biegelsen from Wells Fargo.

Speaker 4
48m 39s

Your line is now live. Good morning.

Speaker 1
48m 42s

Thanks for taking the question, Joe.

Speaker 4
48m 44s

You talked about the accelerating sales growth in both Innovative Medicine and MedTech. Next year is the 5%+ I heard you say earlier on a reported.

Speaker 1
48m 53s

Or adjusted operational basis.

Speaker 4
48m 56s

I think FX is a tailwind. How are you thinking about the extra week next year?

Speaker 1
49m 0s

I'm trying to understand if.

Speaker 4
49m 1s

Growth will accelerate next year.

Speaker 1
49m 3s

Adjusted operational basis excluding the extra week and the same for EPS. Is that on a reported or operational basis?

Speaker 4
49m 11s

Thank you. Yeah, Larry, very simply, since consensus is based on reported for both top line as well as EPS, that was the comparator I used. There is a slight tailwind, as you mentioned, for FX. I assume, and I know, Larry, you and your team are very astute at capturing the FX impact. I would assume that's already baked into the 4.6% top line growth that I saw consensus have for 2026, similarly with the earnings. It is a lift, I would say across the board, but on a basis by which the analysts, yourself included, look at it. Thank you.

Speaker 1
49m 51s

Our next question today is coming from.

Speaker 4
49m 53s

Asad Haider from Goldman Sachs, line is now live.

Speaker 2
49m 57s

Great, thanks for taking the question.

Speaker 4
49m 58s

Just a big picture question.

Speaker 2
50m 0s
You'll be exiting this year in a clear position of strength where a number of headwinds from the Stelara LOE are.

Speaker 4
50m 5s
Fading into the background. The base business is strong, and you've got new product cycle momentum accelerating through.

Speaker 2
50m 11s
The innovative medicines portfolio and you're also.

Speaker 4
50m 13s
Seeing a second half improvement in MedTech.

Speaker 2
50m 15s
In that context and with the.

Speaker 4
50m 17s
Announcement of this morning to spin off.

Speaker 2
50m 20s
Can you just maybe double click a little bit more on how you're.

Speaker 4
50m 22s
Going to be balancing capital allocation priorities to sustain acceleration in Innovative Medicine.

Speaker 2
50m 28s
Push MedTech sustainably towards the 5% to 7% ERB targets. Related in the Innovative Medicines.

Speaker 4
50m 35s
Business, the sales growth acceleration in 2026.

Speaker 2
50m 38s
Like you said, Joe, that's not getting modeled by consensus.

Speaker 4
50m 41s
What are the biggest disconnect there?

Speaker 2
50m 42s
That you're able to highlight today specifically for next year?

Speaker 4
50m 45s
Thank you.

Speaker 2
50m 48s
First look, we are in a favorable position as far as capital allocation means we have a number of important opportunities to invest within our pipeline and portfolio. That is our number one priority. Now as far as capital allocation, we're in the middle of the launch and Tim and Jennifer will be discussing that of major, major blockbuster products. On the Innovative Medicine side, we're launching Tremfya in inflammatory bowel disease, Riviprant and Lazertinib in lung cancer, Inlexa in localized bladder cancer. We continue with the growth of Carvykti and Spravato and we just filed for icatrekibart in plaque psoriasis. We have a wealth of opportunities to drive significant growth in our pharmaceutical business that Jennifer will describe. Just to give you an idea of the strength of our pharmaceutical business, excluding Stelara, our pharmaceutical business in the third quarter grew a whopping 16%. That's a very big business. More than $50 billion business growing at 16%. We have multiple opportunities to drive capital allocation in the pharmaceutical business as well as in our pipeline there. We're working on bispecific for prostate cancer, trispecific for multiple myeloma. A wealth of opportunities to drive capital allocation on the MedTech side. We're in the middle of major things in the MedTech side.

Speaker 2
52m 17s

On one hand, we are committed to remain leaders in the electrophysiology segment. With the launch of Varipulse, our dual energy company, we continue to work in improvements in our CARTO system and we are determined to invest there to remain the leaders as we have been. We are working to expand our heart pumps. You guys all know about the New England Journal of Medicine publication showing the DANSH study in patients with acute myocardial infarction that had cardiogenic shock that showed a 600 days improvement over a 10 year period. Impressive breakthrough innovation there. We have a lot of opportunities in Shockwave with the Javelin peripheral catheter and the AERIO system in coronary that we are launching. If I move into the second priority, which is our robotic surgery expansion, we are about to file with the FDA in the first half of the year our Ottava soft tissue robotic system. We are also determined to be a major player in robotics. Always telling you we are determined to be a major player in robotics. We continue to have opportunities for capital allocation in both businesses, and our priority now is to be able to fuel the growth in our portfolio and our pipeline.

Speaker 2
53m 34s

As Joe mentioned before, we are in a position, just to be clear, that we do not need large M&A to deliver in the high end of our growth targets. Let me repeat that: we do not need large M&A to deliver in the high end of our growth targets. We are going to be looking at opportunities as we always do, but we are in a position in which our number one capital priority is going to be to fuel our pipeline and our portfolio.

Speaker 4
53m 59s

Yeah, I think the only thing I would add to that is just the number of smaller deals we do that don't make headlines on the day of the transaction. I think 60 over the last two years. Those lead to products like Inlexa, which we acquired in 2019 for a couple hundred million dollars. Through really passion for their craft as well as passion for meeting patients' unmet needs, Doctors Chris Cootie and Dr. Charles Drake and their teams were able to find a bladder cancer treatment that is revolutionary. Nothing's been new in the last few decades with respect to not only ease for the patient, but also ease for the administrating physician. It's deals like that. We look at next year's product for icatrekibart where we're expecting again a couple hundred million dollar investment will turn out to be a billion dollar platform for us because that's where our competitive advantage lies, is the scientific expertise that we're able to recognize early on, bringing forth a layer that is most expansive, most complete and in record time.

Speaker 5
55m 7s

Thanks and good morning everybody. I'd love to double down on the fact that it really was a great quarter in 3Q and those numbers that for 90% of our business we actually grew 16%. That's really driven by 11 key brands that grew double digits, brands like Darzalex, Erleada, Spravato, Carvykti and so on, as well as the strength that we're seeing in our new launches. Most notable there is Tremfya in Crohn's disease and ulcerative colitis with 40% growth, that is 4, 0. We've got a lot of strength in the business right now. Those growth drivers that are growing double digits are not only now and just this year. These really are our growth drivers throughout the rest of the decade as well as the pipeline assets that are coming in and the great growth that we're seeing and most notably Tremfya. If we take a look versus your models in the areas where we are even more bullish, a few areas to note. First is Tremfya. We think that there's a lot of strength with Tremfya. Already we're seeing in ulcerative colitis about 50% share of the IL-23s. This was actually before we got the subcutaneous induction dose which we just got approval for.

Speaker 5
56m 28s

We're seeing really, really strong uptake there. I think things bode real well for Tremfya. As a reminder, for Stelara, about 75% of Stelara sales were in Crohn's and ulcerative colitis. In IBD, we think that that's entirely likely or may even be stronger for Tremfya. We think that there's a lot of growth opportunity there. We believe Spravato, there is a bit of a disconnect. We are more bullish there as well as we continue to expand into new treatment centers. As we continue to expand globally, that product is offering so much value for patients with treatment-resistant depression. I'll throw in Riviprant last quarter for non-small cell lung cancer. We're anxiously anticipating our launch of the subcutaneous dosage form. We think that there is a lot of runway there as a $5 billion plus asset. We're also anticipating new data coming out in head and neck cancer and also colorectal cancer. Great growth. Joaquin and Joe mentioned Inlexa, formerly known as Tarisu, and we just got approval and are in the process of launching for bladder cancer. This is one of our billion plus assets. Last but not least, icatrekibart, which we have filed and are also in the midst of showing new data both in psoriasis as well as in ulcerative colitis.

Speaker 5
57m 57s

When we take a look at the business both now as well as these future growth drivers, we've got a lot of bullishness there and those are really the major areas for disconnect.

Speaker 4
58m 6s

Asad, maybe just building on Jennifer and Joaquin's comments for MedTech, a couple of.

Speaker 2
58m 11s

Things that I'd really highlight. Joaquin mentioned our continued confidence and commitment.

Speaker 4
58m 15s

To winning over the long term. In electrophysiology, we had a standout quarter, and what really marked it was our continued improvement, especially here in the U.S. Which will continue to be the largest.

Speaker 4
58m 26s

The most attractive market. We saw a doubling of our growth rate in this quarter, and we continue.

Speaker 2
58m 31s

To build momentum in vision, which we haven't touched on, also, which had a standout.

Speaker 4
58m 35s

Quarter, 62 point growth, 14% growth in the IOL category with significant share gains against our major competitors there. Surgery, our largest business, you know around 3.3% growth but really bolstered by strong performance in wound closure at 7% and biosurgery. That launch of OTAVA next year is going to really bolster our performance there. I think also what made us more proud and excited about this quarter versus last is that we had performance across the board. Ortho back to growth with significant improvements in spine, knees, trauma and broader. Thank you.

Speaker 1
59m 12s

Thanks, Tim. Just before we take the next question, we will actually run a little bit longer than the 60 minutes we planned, given the announcement that we had leading to longer script remarks. Next question, please.

Speaker 4
59m 25s

Thank you.

Speaker 1
59m 25s

Next question is coming from Shagun Singh from RBC.

Speaker 4
59m 28s

Your line is now live. Great.

Speaker 5
59m 30s

Thank you so much. Joaquin and Joe, congratulations on all the operational progress at Johnson & Johnson. I think a key message that I'm hearing is the acceleration in sales growth. In your prepared comments, you did indicate the higher end of the 5 to 7%. I guess my question is, a lot of your businesses are growing very impressively in the double digits. What gets you to exceed those levels? As we think about 2026, why is 5% a good number? Given that you have easy comps, could you do better and what would drive that? Thank you for taking the question.

Speaker 4
1h 0m

Yeah, Chagun, thanks for the recognition. It's a great job by the entire Johnson & Johnson team across the globe. I think towards the 5 to 7%, obviously we made that commitment back in 2023. We've seen significant progress with our portfolio. We've added some activity acquisitions that fortify that number. We are striving for something better than that. Don't misconstrue our ambitions here. What I would say for next year specifically, we are still going to face significant erosion with respect to Stelara. There will be additional discounting in the Innovative Medicine portfolio and we will still have the orthopedics business. We will continue to make progress with electrophysiology going back to market leadership with the PFA platform. There are things that we will obviously look to improve upon those numbers. When I glimpsed at your models for 2026, I did see a clear disconnect and I'll provide more details when it comes to January. We feel very confident in not just how we're going to conclude 2025, not just the backdrop for 2026, but really the balance of the decade. As Joaquin has said, both on media interviews as well as on today's call, this is a new era of growth, accelerated growth for Johnson & Johnson.

Speaker 4
1h 1m

We feel very good about not just our in-market portfolio, but all the new products within our pipeline that will come to launch over the next one to two years. Thank you. Next question is coming from Terrence Flynn from Morgan Stanley. Your line is now live. Great, thanks for taking the questions.

Speaker 1
1h 1m

Congrats on all the progress.

Speaker 4
1h 1m

This one's for John.

Speaker 3
1h 1m

I know at our healthcare conference you Talked about some upcoming data you're going to have for your anti-Tau antibody which is in phase two. Just was wondering if you could help frame that data for us, what you're.

Speaker 4
1h 2m

Hoping to see you there.

Speaker 1
1h 2m

Could that trial actually be used to support an accelerated approval, or will you need a phase three? Thank you.

Speaker 3
1h 2m

Hey, thanks, Terrence. We expect to have the data on the phase two study in house within this year and would then be in a position to share those at a medical congress sometime first half of next year. The endpoints in that study include, first and foremost, cognitive endpoints that are traditionally used for regulatory approvals for medicines in terms of looking for effects and efficacy in Alzheimer's. In addition, we'll also have important neuroimaging data looking at tau spread using PET imaging. That'll be an important piece of the data as well. Based on the quality of those data, that will be a decision-making point for us in terms of go, no go. We have designed our antibody to attack a specific epitope in tau that's differentiated from what some others have exploited and feel confident in the ability to prevent the spread of tau based on the preclinical data. Of course, the data will be the data, as we say, when we get the clinical results. We'll be eagerly awaiting those results and look forward to communicating in the fullness of time.

Speaker 4
1h 3m
Thank you.

Speaker 2
1h 3m
Next question today is coming from Jason.

Speaker 4
1h 3m
Bedford from Raymond James. Line is now live.

Speaker 1
1h 3m
Good morning and congrats on the progress. Maybe just a quick one for Joe or Tim. Just trying to gauge the underlying growth in MedTech. It looks like there was a reserve adjustment that helped MedTech growth perhaps offset.

Speaker 4
1h 3m
By this go-to-market change in Energy.

Speaker 1
1h 4m
Is there a way to quantify the net impact of these adjustments as it relates to the 5.7% adjusted operational growth in MedTech?

Speaker 2
1h 4m
Yeah, I'm happy to take one.

Speaker 4
1h 4m
We do not believe that the one you're referring to has any significant materiality and shouldn't impact.

Speaker 2
1h 4m
We would say moderate to certainly not.

Speaker 4
1h 4m
Material from an overall performance perspective.

Speaker 1
1h 4m
Next question is coming from Vamil Devan from Guggenheim Securities.

Speaker 4
1h 4m
Your line is now live. Great, thanks so much for taking my questions. So I mean Inlexa had really a two part question. One is sort of the near term uptake. Just curious if you can comment on sort of what initial feedback is from doctors and if this is this buy and build model. Just curious if you're seeing doctors already sort of step in and purchase the product or are they waiting for the permanent J code. The second is more of a longer term question on this, just what should we expect in terms of updates both clinical data wise or regulatory wise in the next, say, 12 to 18 months to just expand the addressable population here to other patients with bladder cancer and also outside the U.S. I think people are getting excited about the outlook for this product. I know before you've mentioned that there's a big disconnect between your internal expectations and what consensus is. I think that suggests you guys think this will be a $2 billion plus product by 2028. Just trying to get a sense of how you expect to build from the initial launch to that level. Thanks. Sure.

Speaker 5
1h 5m

Thanks so much for the question. Yes, we did just get approval for Inlexa and the teams are out in full launch mode. We have a lot of confidence that this is one of our $5 billion plus assets for Johnson & Johnson. The receptivity has been very strong. We like to say that this product was really designed by urologists for urologists and really is addressing a high unmet need. There hasn't been much advances in the way of bladder cancer for a very, very long time. In the initial launch, it's in BCG-unresponsive high-risk non-muscle invasive bladder cancer. We've been able to demonstrate the highest complete response rates without a need for re-induction, and over half of responders are still cancer free at one year. These are really transformational results. The product was designed to seamlessly fit into urology practice and be, relatively speaking, easy on the patient compared to other therapies and, like I said, seamlessly work into practice. So far, the response from clinicians has been very positive. For our Executive Committee, we actually had one of our top investigators come and spend time with us last week and show us on models their demonstration and talk about why he's so excited about it, both as a clinician as well as for his patients.

Speaker 5
1h 7m

We've already had a number of insertions based on the high level of unmet need. As you note, we're also anticipating the J code for reimbursement come April of next year. We think that will be an important catalyst for uptake, as is normal and common in routine buy and bill type program. We're excited about that. John, maybe you want to talk a little bit particularly about SUNRISE-3 and what's coming as well as TAR-210.

Speaker 3
1h 7m

Yeah, thank you so much for the question. We have a broad development program underway with several phase three studies to address the non-muscle invasive bladder cancer population, high risk. That's about half of all the non-muscle invasive bladder cancer patients. Our studies include both the patients who are BCG experienced. In the first approval, that was for BCG non-responsive. We also have studies in BCG relapsed, and we also have head-to-head frontline studies against BCG, really covering a broad landscape there. Just to remember that there are about 600,000 patients every year who are newly diagnosed with bladder cancer. 75% of those have the non-muscle invasive localized, and then another 20% have localized, but it is muscle invasive there too. We're also doing studies, and in fact at the ESMO conference in a couple days, we'll present data where in the neoadjuvant context we've used Inlexa in combination with our PD-1 antibody, citralumab, and we'll report the data there showing that we're able to render a much higher percentage of patients completely free of any evidence of disease that you can find histologically or by other methods, what's called pathological complete response, and therefore voting for better outcomes for these patients who already have muscle invasive disease and are having surgery to remove their bladder as a result of that risk.

Speaker 3
1h 9m

Really see a broad opportunity for Inlexa, particularly in the non-muscle invasive across all lines of therapy in that high risk non-muscle invasive, which is about half of all those patients, as well as in some populations of patients with the muscle invasive as well. I would just give a shout out that you know, that's not going to be a one trick pony for us. We have TAR210 coming rapidly on the heels. This is a next generation device that releases instead of a chemotherapy, a targeted therapy or ertifitinib drug that inhibits receptor tyrosine kinase that is commonly mutated in bladder cancers. It's actually the most common genetic mutation that occurs in bladder cancers. There we've seen response rates, complete response rates north of 90%. Our next generation device for that releases the medicine at a steady rate not just for three weeks like Inlexa, but for three months. More to come. Really excited about this platform for addressing the great unmet need of bladder cancer.

Speaker 4
1h 10m

Thank you. Next question is coming from Matt Nixic from Barclays. Your line is now live.

Speaker 2
1h 10m
Hey, thanks so much. Just a couple of follow ups.

Speaker 4
1h 10m
One on just the sequential strength in.

Speaker 1
1h 10m
The quarter, a little bit unusual for a summer quarter.

Speaker 2
1h 10m
How much of that do you? feel like is these speaking of MedTech mostly here, even though pharma was pretty strong also, just the sequential improvements.

Speaker 4
1h 10m
Do you think the market feels stronger, or was this predominantly user leaning back?

Speaker 1
1h 11m
Into competition in some of your core MedTech markets? Just a follow up on.

Speaker 4
1h 11m
All the discussion about the spin, just if we should think of holding onto.

Speaker 1
1h 11m
MedTech, concentrating on the key businesses that you mentioned, this also opens the door to sort of, I guess, loosen up the capital structure and balance sheet in.

Speaker 4
1h 11m
Such a way to start adding to some of those areas as you get.

Speaker 1
1h 11m
Closer to or through this spin.

Speaker 4
1h 11m
Thanks so much, Matt.

Speaker 2
1h 11m
Thank you for the question. Let me take the first one.

Speaker 4
1h 11m
What was really attractive about this quarter and built on the tremendous performance in the second quarter was the solid performances across all businesses. Where you saw that sequential improvement, if you'll recall, our ortho business struggled in the first and second quarter. We saw a nice improvement in Q2, Q3. We returned that business to growth with tremendous performances in categories like hips with 5.1%, knees, 5.6%, strong performance in trauma and actually returning to growth in spine.

Speaker 2
1h 12m
Ortho was a major contributor to that performance. Of course, we had continued.

Speaker 4
1h 12m
Tremendous performances in our fastest growing category in cardiovascular, solid performances in surgery.

Speaker 2
1h 12m
Acceleration within vision, as I mentioned.

Speaker 4
1h 12m
Earlier, driven by our performance primarily in the intraocular space. Thank you.

Speaker 2
1h 12m
Overall, as we discussed at the beginning of this call, our focus and priority within MedTech is around our three areas, which are vision, cardiovascular, in which we already have acquired a number of companies, and also robotic surgery, where we are focusing on being able to support our Ottava soft tissue robotic system to the FDA in the first half of 2026. We will continue to look for opportunities there in order to enhance our portfolio and be able to make our MedTech group the best MedTech group in the industry, which is a clear goal for me and for Johnson & Johnson.

Speaker 1
1h 13m
Thanks, Matt. We have time for one last question. Certainly.

Speaker 2
1h 13m
Our final question today is coming from.

Speaker 4
1h 13m
David Reisinger from Lyriq. Your line is now live.

Speaker 1
1h 13m
Yes, thanks very much, and congrats on the performance.

Speaker 4
1h 13m
My question is on icatrekibart.

Speaker 1
1h 13m
I'm curious about how you plan to position it relative to Tremfya given the.

Speaker 4
1h 13m
Similar indications.

Speaker 1
1h 13m
For the two therapies.

Speaker 4
1h 13m
Thank you very much.

Speaker 5
1h 13m
Great, thanks. Good morning. We are really excited about the opportunity for icatrekibart and see this as one of our next big, you know, $5 billion plus brands. Why are we excited about it? We believe it's really going to set the new standard of care in the treatment of plaque psoriasis, and that will be the first indication. You know, unprecedented combination of complete skin clearance and a favorable safety profile. With the simplicity of an oral pill, we're really, really confident in what we've seen. Not only are we studying it versus other orals, we're actually studying it head to head versus Stelara, and no oral agents have been able to really compete with that combination of both biologic-like efficacy and that known safety profile. We're really bullish. If you take a look at the market, despite today's treatments, there's still less than 30% of eligible patients who have moderate to severe psoriasis who are receiving advanced treatments. We think there is a significant market expansion opportunity to be able to bring patients into advanced therapies into that frontline setting. We think there's a big opportunity there. As we move closer to the launches, with the way the profile is differentiating, there will be a unique and distinct position for icatrekibart and also a distinct and unique position for Tremfya that will allow us to have both really continued significant growth on both assets, particularly given the high level of unmet need in the market.

Speaker 5
1h 15m
More to come on that. I'm not going to give away everything on the positioning, but we think that there are really distinct places that they're going to play. Icatrekibart is going to be a really significant asset for us, and you can see how well Tremfya is doing with the 40% growth that we achieved this quarter.

Speaker 3
1h 15m
David, keep your eyes open. We have more publications coming out on our icatrekibart data. Two back to back papers in press at the New England Journal of Medicine describing the placebo-controlled studies, and then a paper in press at The Lancet showing our head to head against the leading TYK2 inhibitor in psoriasis. Exciting times for that really novel targeted oral peptide for the autoimmune diseases where the IL-23 class plays.

Speaker 1
1h 16m
Thanks David, and thanks to everyone for your questions and interest in Johnson & Johnson. Please reach out to the Investor Relations team with any remaining questions you have. I will now turn the call over to Joaquin for some brief closing remarks.

Speaker 2
1h 16m

Thank you all of you for joining the call today. As you heard, we have had a very strong third quarter. We have sharpened focus around our six priority areas of oncology, immunology, neuroscience, cardiovascular surgery, and vision. We are in a period of accelerated growth with innovation and pioneering treatments that are going to transform lives. Thank you for your interest in Johnson & Johnson and enjoy the rest of your day.

Speaker 4
1h 16m

Thank you. This concludes today's Johnson & Johnson's third.

Speaker 1
1h 17m

Quarter 2025 earnings conference call.

Speaker 4
1h 17m

You may now disconnect.