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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Good morning, and welcome to Johnson & Johnson's Fourth Quarter 2023 Earnings Conference Call. (Operator Instructions) This call is being recorded. If anyone has any objections, you may disconnect at this time. (Operator Instructions) I would now like to turn the conference call over to Johnson & Johnson. You may begin.

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

Good morning. This is Jessica Moore, Vice President of Investor Relations for Johnson & Johnson. Welcome to our company's review of business results for the fourth quarter and full year 2023 and our financial outlook for 2024. Joining me on today's call are Joaquin Duato, Chairman and Chief Executive Officer; and Joe Wolk, Executive Vice President, Chief Financial Officer.

As a reminder, you can find additional materials, including today's presentation and associated schedules, on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com.

Please note that this presentation contains forward-looking statements regarding, among other things, the company's future operating and financial performance, market position and business strategy. You are cautioned not to rely on these forward-looking statements, which are based on current expectations of future events using the information available as of the date of this recording and are subject to certain risks and uncertainties that may cause the company's actual results to differ materially from those projected. A description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2022 Form 10-K, which is available at investor.jnj.com and on the SEC's website. Additionally, several of

the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships.

Moving to today's agenda. Joaquin will open with a few comments on our 2023 performance and key milestones as well as highlights from our Enterprise Business Review. I will then review the fourth quarter sales and P&L results as well as full year 2023 results for the enterprise. Joe will then close by sharing an overview of our cash position, capital allocation priorities and guidance for 2024. The remaining time will be available for your questions. To ensure we provide enough time to address your questions, we anticipate the webcast will last a little over 60 minutes.

I am now pleased to turn the call over to Joaquin.

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

Thank you, Jess, and good morning, everyone. 2023 was a remarkable year for Johnson & Johnson. In becoming a two-sector company focused on Innovative Medicine and MedTech, we strengthened our position as an innovation powerhouse.

With breakthrough science and transformative technology, we innovate across the entire patient pathway in ways no other company can. And as we shared at our Enterprise Business Review, we have a stronger growth and margin profile and are more focused and agile than ever before, which is what you see with today's results.

I'm particularly proud of our Q4 results with Innovative Medicine operational sales, excluding the COVID-19 vaccine, growing by 9.5%, and MedTech adjusted operational sales growing by an impressive 9.1%. For the full year, we delivered strong and sustained performance with 9% operational sales growth, excluding the COVID-19 vaccine, and 10.8% adjusted operational earnings per share growth. These results reflect the breadth and competitiveness of our portfolio. And when I look at the milestones we achieved in 2023 and the promise of our pipeline, I have confidence in our guidance for 2024 and beyond. So let's take a deeper look at the business and what we achieved last year.

Starting with Innovative Medicine for the full year, we delivered above-market operational sales growth of 7.2%, excluding the COVID-19 vaccine. Our Innovative Medicine business continues to be fueled by growth from key brands and the acceleration of sales of new products. Our multiple myeloma portfolio is a good example with significant contribution from recently launched products, including CARVYKTI, TECVAYLI and TALVEY.

Turning to clinical trials, key results from the year included positive Phase III readouts for more than 10 of our in-line and pipeline medicines, including CARVYKTI in one to three prior lines of therapy in multiple myeloma; DARZALEX in frontline multiple myeloma transplant-eligible patients; RYBREVANT in combination with chemotherapy and RYBREVANT plus lazertinib in nonsmall cell lung cancer; and finally, TREMFYA monotherapy in Ulcerative Colitis.

In addition, we saw positive Phase I and Phase II readouts for nipocalimab and TAR-200 and TAR-210. And we initiated our Phase III clinical development programs for milvexian and our targeted oral peptide JNJ-2113. Beyond that, we received FDA breakthrough designation for TAR-200 for the treatment of bladder cancer and fast track designations for milvexian in atrial fibrillation, stroke and acute coronary syndrome. And with 19 U.S. and EU filings across our Innovative Medicine business in 2023, we have high expectations for the year ahead. Our recent announcement of a definitive agreement to acquire Ambrx to develop next-generation Antibody Drug Conjugates further strengthens our Oncology pipeline.

Now moving to MedTech. In 2023, we delivered full year operational sales growth of 12.4% and full year adjusted operational sales growth of 7.8%. For the first time, our MedTech team delivered more than $30 billion in sales as we continue to build a best-in-class business. We are accelerating growth through commercial execution, differentiated innovation and moving into higher-growth markets - as you saw with our successful integration of Abiomed and our recent acquisition of Laminar, which is focused on eliminating the left atrial appendage in patients with nonvalvular atrial fibrillation.

And at the same time, we are making strong progress in our pipeline, including advancing our OTTAVA surgical robot, MONARCH approval in China for bronchoscopy and continued market expansion for VELYS, our robotic-assisted solution for total knee replacement with CE Mark approval in 2023.

In electrophysiology, we have a lot of momentum in our Pulsed Field Ablation portfolio. We announced regulatory approval a few weeks ago for the VARIPULSE PFA platform in Japan and have submitted for CE Mark approval in the EU. The TRUPULSE generator has received approval in the EU. And we received the first and only approval from the U.S. FDA for a zero fluoroscopy workflow for cardiac ablation.

And in the fourth quarter, findings from our QDOT MICRO Catheter Q-FFICIECY study showed that very high power, short duration ablations improved quality of life and reduced health care utilization for atrial fibrillation patients. In Vision, we are driving strong performance across our TECNIS IOLs and OASYS 1-Day family of contact lenses, including our most premium lens, ACUVUE OASYS MAX 1-Day, which has proven superiority in comfort and clarity than the competition.

Turning to Abiomed. We recently completed our Impella ECP pivotal clinical trial. In Q4, we also enrolled our first patient in the ABIOMED RECOVER IV randomized, controlled trial. As we look ahead, I have never been more excited about the future of our business. At our Enterprise Business Review, we shared that we expect our Innovative Medicine business to grow 5% to 7% from 2025 to 2030 with our industry-leading pipeline and portfolio delivering more than 10 assets that have the potential to generate over $5 billion in peak year sales by 2030.

We also expect a further 15 assets to have the potential for $1 to $5 billion in peak year sales. In 2024, we expect data readouts for many of these assets, including Phase III trials for TREMFYA in IBD, ERLEADA in heavy stage prostate cancer, our targeted oral peptide, JNJ-2113 in psoriasis, nipocalimab in myasthenia gravis as well as aticaprant and seltorexant in major depressive disorder.

We also expect Phase II readouts for our combination therapy, guselkumab and golimumab, JNJ-4804 in psoriatic arthritis, nipocalimab in Sjogren's disease and TAR-200 in non-muscle invasive bladder cancer.

In MedTech, we shared that we expect to grow at the upper range of our markets, which are anticipated to grow by 5% to 7% between 2022 and 2027. And that by 2027, we expect 1/3 of our revenue to be generated by new products.

In 2024, we see strong progress towards these goals in electrophysiology that includes the full U.S. market release of QDOT MIRCO CATHETER. And we are expecting CE Mark approval for our pulse field ablation catheter VARIPULSE in Europe in the first half of 2024. We plan to submit an investigational device exemption to the FDA for OTTAVA in the second half of 2024.

And in Abiomed, we expect U.S. commercial launch of IMPELLA RP Flex with SmartAssist and an IMPELLA ECP submission in 2024. As you can see, our pipeline is advancing. Our business is transforming.

Before I turn the call to Jess and Joe, I want to thank our teams around the world for everything they do help our patients. We have entered 2024 from a position of strength, and I'm confident in our ability to lead the next wave of health innovation.

With that, I'll turn the call over to Jess.

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

Thanks, Joaquin. Unless otherwise stated, the financial results and guidance highlighted reflects the continuing operations of Johnson & Johnson. We will report the Consumer Health financial results as discontinued operations. Furthermore, the percentages quoted represent operational results and therefore, exclude the impact of currency translation.

Starting with Q4 2023 sales results. Worldwide sales were $21.4 billion for the fourth quarter of 2023. Sales increased 7.2%, with 11% in the U.S. and 2.7% outside of the U.S. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 5.7% worldwide, 8.8% in the U.S. and 2.1% outside the U.S. It is important to note that sales in Europe were negatively impacted by the COVID-19 vaccine and loss of exclusivity of ZYTIGA by approximately 1,500 basis points operationally.

Turning now to earnings. For the quarter, net earnings were $4.1 billion, and diluted earnings per share was $1.70 versus diluted earnings per share of $1.22 a year ago. Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the

quarter were $5.6 billion. And the diluted earnings per share was $2.29, representing increases of 2.4% and 11.7%, respectively, compared to the fourth quarter of 2022. On an operational basis, adjusted diluted earnings per share increased 11.2%.

For the full year 2023, sales were $85.2 billion. Sales grew 7.4%, with 10.6% in the U.S. and 3.8% outside of the U.S. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 5.9% worldwide, 8.2% in the U.S. and 3.4% outside the U.S. Sales in Europe were negatively impacted by the COVID-19 vaccine and loss of exclusivity of ZYTIGA by approximately 1,000 basis points operationally.

Net earnings for the full year 2023 were $13.3 billion and diluted earnings per share was $5.20 versus diluted earnings per share of $6.14 a year ago. Full year 2023 adjusted net earnings were $25.4 billion, and adjusted diluted earnings per share was $9.92, representing increases of 6.8% and 11.1%, respectively, versus full year 2022. On an operational basis, adjusted diluted earnings per share increased by 10.8%.

I will now comment on business sales performance in the quarter. Beginning with Innovative Medicine. Worldwide Innovative Medicine sales of $13.7 billion increased 4% with growth of 9.5% in the U.S. and a decline of 3.1% outside of the U.S. Excluding COVID-19 vaccine sales, worldwide and U.S. sales growth was 9.5%, and growth outside of the U.S. was 9.4%. Sales outside the U.S., excluding the COVID-19 vaccine, were negatively impacted by approximately 120 basis points due to the loss of exclusivity of ZYTIGA in Europe.

Innovative Medicine growth was driven by our key brands and continued uptake from recently launched products, with 9 assets delivering double-digit growth. We continue to drive strong sales growth for both DARZALEX and ERLEADA, with increases of 22.2% and 19%, respectively.

Within immunology, we saw sales growth in both STELARA and TREMFYA, with increases of 14.5% and 20.5%, respectively. This growth was driven by market growth and share gains as well as favorable patient mix in TREMFYA. Growth of 17.4% in pulmonary hypertension was driven by favorable patient mix, share gains and market growth.

Turning to newly launched products. We continue to make progress on our launches of CARVYKTI and SPRAVATO. We are also encouraged by the early success of our launches of TECVAYLI and TALVEY, sales of which are driving the growth in Other Oncology. As a reminder, we expect to begin disclosing TECVAYLI sales in Q1 2024. Total Innovative Medicine sales growth was partially offset by unfavorable patient mix in XARELTO, a decrease in IMBRUVICA sales due to competitive pressures and a loss of exclusivity of ZYTIGA, REMICADE and Prezista.

I'll now turn your attention to MedTech. Worldwide MedTech sales of $7.7 billion increased 13.4% with Abiomed contributing 4.5% to growth. Growth in the U.S. was 14.1% and 12.8% outside of the U.S. Excluding the impact of acquisitions and divestitures, worldwide adjusted operational sales growth was 9.1%.

MedTech was negatively impacted by international sanctions in Russia worth approximately 50 basis points, primarily in Advanced Surgery and Vision. Electrophysiology delivered double-digit growth of 25.2% with strong growth in all regions, including Europe. This growth was driven by our global market-leading portfolio, including the most recently launched QDOT RF ablation and OCTARAY catheters.

Abiomed contributed $340 million in sales within the quarter driven by continued strong adoption of Impella 5.5 technology. Growth of 6.4% in surgery was driven primarily by procedure recovery and strength of our Biosurgery and Wound Closure portfolios. Growth was partially offset by volume-based procurement in China, primarily in Endocutters.

Orthopaedics growth of 5% reflects procedure growth, success of recently launched products such as the global expansion of our VELYS digital solutions and expansion in ambulatory surgical centers as well as lapping of prior year China VBP price concessions in Spine.

Growth of 6.6% in Vision was driven by price actions in contact lenses as well as strength of new products including ACUVUE OASYS 1-Day family of products and contact lenses and TECNIS Eyehance, our monofocal intraocular lens and surgical vision. Growth of contact lenses was partially offset by U.S. stocking dynamics. Global Vision growth was negatively impacted by 100 basis points due to the Blink divestiture in Q3.

Now turning to our consolidated statement of earnings for the fourth quarter of 2023. I'd like to highlight a few noteworthy items that have changed compared to the same quarter of last year. Cost of products sold margin deleveraged by 130 basis points due to commodity inflation and unfavorable

product mix in MedTech, partially offset by favorable patient mix and lower COVID-19 vaccine supply network-related exit cost in Innovative Medicine. We continue to invest strategically in Research and Development at competitive levels, investing$4.5 billion or 20.9% of sales this quarter. We invested $3.4 billion or 24.5% of sales in Innovative Medicine with the increase in investment being driven by higher milestones, partially off by portfolio prioritization.

In MedTech, R&D investment was $1.1 billion or 14.6% of sales with the increase in investment primarily driven by the Laminar acquisition. Interest income was $212 million in the fourth quarter of 2023 as compared to $77 million of income in the fourth quarter of 2022. The increase in income was driven by higher interest rates earned on cash balances and a lower average debt balance. The Other Income and Expense line was income of $421 million in the fourth quarter of 2023 compared to an expense of $795 million in the fourth quarter of 2022. This was primarily driven by higher unrealized gains on securities and lower COVID-19 vaccine-related exit costs.

Regarding taxes in the quarter, our effective tax rate was 14.4% versus 16% in the same period last year. This decrease was primarily driven by the net decrease of tax liabilities, including the settlement of the 2013 through 2016 U.S. tax audit. Excluding special items, the effective tax rate was 10.8% versus 16.2% in the same period last year. I encourage you to review our upcoming 2023 10-K filing for additional details on specific tax-related matters.

Lastly, I will direct your attention to the box section of the slide, where we have also provided our income before tax, net earnings and earnings per share adjusted to exclude the impact of intangible amortization expense and special items.

Now let's look at adjusted income before tax by segment. In the fourth quarter of 2023, our adjusted income before tax for the enterprise as a percentage of sales decreased from 32.5% to 29.2%. Innovative Medicine margins declined from 37.7% to 37.4%, primarily driven by higher R&D milestones, partially offset by favorable patient mix and leveraging and selling and marketing expense.

MedTech margins declined from 24.5% to 15.5%, primarily driven by in-process research and development expense from the Laminar acquisition, commodity inflation and unfavorable product mix, partially offset by selling and marketing expense leverage. This concludes the sale and earnings portion of the call.

I'm now pleased to turn it over to Joe.

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

Thank you, Jessica, and thanks, everyone, for joining us today. As Joaquin and Jessica commented, 2023 was a strong year for Johnson & Johnson evidenced by notable top and bottom line performance beats relative to what we guided to 2023 at this time last year.

We are particularly proud of the innovation we advanced to strengthen our development pipelines, the continued expansion of our portfolio and investments made for future success. All of this provides us with a strong foundation as we enter 2024.

Thus far during the call, you've heard about sales and income performance in 2023. So now let's dive into some detail on capital allocation highlights. We generated free cash flow of more than $18 billion in 2023. At the end of the year, we had approximately $23 billion of cash and marketable securities and approximately $29 billion of debt for a net debt position of $6 billion. We maintained a healthy balance sheet and robust credit rating, underscoring the strength of Johnson & Johnson's financial position, which enables us to strategically invest and deploy capital to unlock value.

To that end, we executed against all of our capital allocation priorities in 2023. For starters, we invested more than $15 billion in research and development, or 17.7% of sales, an all-time high for the company as we remain one of the top investors in R&D across all industries. Jessica provided R&D investment by business segment, information we will continue to provide on a quarterly basis moving forward.

As far as dividends, 2023 marked the 61st consecutive year in which we increased our dividend. We know this use of capital is a priority for our investors, and we plan to continue to increase our dividend annually. We also deployed, announced or committed over $3 billion in strategic

value-creating inorganic growth opportunities in the last 12 months. This amount includes the recent Ambrx and Laminar transactions as well as more than 50 smaller early-stage licensing deals and partnerships that complement our current Innovative Medicine and MedTech pipelines.

Finally, share repurchases. In early 2023, we completed the $5 billion share repurchase program initiated in late 2022 and in combination with our dividend, returned over $14 billion to shareholders last year. Through the Kenvue separation, we further reduced the Johnson & Johnson's outstanding share count by 191 million shares, or approximately 7%, without the use of cash and in a tax-free manner. Looking ahead to 2024, Johnson & Johnson's robust free cash flow generation should continue to solidify our already strong financial foundation and fuel further investment leading to growth for our business or returns to shareholders.

Now turning to our full year 2024 guidance. Today, we are confirming the 2024 guidance for those items previewed at our Enterprise Business Review in early December while filling in some of the details. We expect operational sales growth for the full year to be in the range of 5% to 6% or $88.2 billion to $89 billion. As a reminder, our sales guidance continues to exclude any impact from COVID-19 vaccine sales.

In Innovative Medicine, we expect 2024 to deliver a 13th consecutive year of above-market growth, driven by market share gains from key brands such as DARZALEX, TREMFYA and ERLEADA, as well as continued adoption of recently launched newer products such as CARVYKTI, TECVAYLI, TALVEY and SPRAVATO. In MedTech, we remain focused on executing our key value drivers: first, advancing our differentiated pipeline such as programs in pulse field ablation, Abiomed and surgical robotics, further shifting our portfolio into high-growth markets. Second, expanding our reach and scale around the world. And third, building operational resilience across our portfolio.

We don't speculate on future currency movements. But utilizing the euro spot rate relative to the U.S. dollar as of last week at $1.09 as well as other major currencies, we estimate there would be a slight unfavorable impact of $400 million or a negative 0.5% on reported sales growth for the year.

Turning to other items on our P&L. We expect our 2024 adjusted pretax operating margin to improve by approximately 50 basis points, driven primarily by a continuation of efficiency programs across the organization. We expect this to be partially offset by anticipated STELARA biosimilar entrants in Europe in the second half of this year and some lingering inflation impact in MedTech inventory that will flow through 2024's P&L. This margin improvement encompasses dilution of additional investment associated with our planned acquisition of Ambrx, which will be treated as a business combination. Now we do acknowledge that the 50 basis point improvement simply gets us back to what your models expected, given the elevated Q4 2023 R&D investment for new pipeline assets.

Regarding other income and expense. We anticipate income to be $1.2 billion to $1.4 billion for 2024. This is less than the 2023 amount, driven by the impact of actuarial assumptions on certain employee benefit programs such as lower discount rates. We are comfortable with new modeling net interest income between $450 million and $550 million, consistent with 2023 levels.

Finally, we are projecting an effective tax rate for 2024 in the range of 16% to 17% based on current tax laws and anticipated geographic income mix across our businesses. This tax rate takes into account an increase of approximately 1.5% or 150 basis points relative to the recently enacted Pillar 2 legislation. We continue to believe the U.S. Treasury's current perspective on Pillar 2 is harmful, reducing U.S. incentives for innovation and resulting in U.S. based multinational companies paying more tax revenue to foreign governments.

Our full year share count calculation for adjusted earnings per share in 2024 will include the remaining benefit equal to approximately 120 million shares from the approximately 191 million net share reduction in outstanding J&J shares following the Kenvue exchange offer. Given all these factors, we expect adjusted operational earnings per share to grow 7.4% at the midpoint for a range of $10.55 to $10.75. Based on the Euro spot rate of 1.09 from last week, we do not estimate any currency impact on earnings per share.

I'll now provide some qualitative considerations on quarterly phasing for your models. We expect Innovative Medicine sales growth to be slightly stronger in the first half of the year compared to the second half, given the anticipated entry of STELARA biosimilars in Europe towards the middle of the year. This headwind will be partially offset by continued uptake from our recently launched products.

We project MedTech operational sales growth to be relatively consistent throughout the year, expecting procedures in 2024 to remain above pre-COVID levels. The first half of the year will continue to have modest impact from Russia sanctions as our licenses are approved. We anticipate

China VBP pricing for surgical IOLs and orthopedic sports to begin in 2024 with impacts from 2023 VBP in Electrophysiology, Endocutters, Energy, Spine and Trauma to begin to anniversary throughout 2024.

Regarding EPS phasing. It is important to highlight that the first half of the year will benefit from the full 191 million net share reduction following the Kenvue exchange offer, with only a partial comparative benefit in the third quarter versus Q3 2023, and the fourth quarter being neutral versus Q4 2023. So based on the foundation strengthened in 2023 and numerous catalysts that Joaquin outlined across our business in 2024, we are confident in our ability to achieve both near and long-term financial targets.

I'd like to close by thanking our colleagues for their dedication and commitment to benefit patients around the world. It is their effort that enables Johnson & Johnson to deliver innovative therapies and solutions that address serious unmet medical needs and creates long-term sustainable value for shareholders.

With that, I am now pleased to turn the call over to Kevin to begin the Q&A portion of the call.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question today is coming from Joanne Wuensch from Citi.

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

With my one question, I'm curious why you're looking for 2024 procedure volumes to remain above pre-COVID levels and your expectations for how long that will last?

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

Thank you, Joanne, and good morning, everyone. First, let me remark the strong close of our MedTech business in 2023. We delivered annually more than $30 billion in sales, which is our all time high in our company history with adjusted operational growth in the fourth quarter of 9.1. So very strong results across the board in electrophysiology, in heart recovery, in surgery, in orthopedics and in vision. So when we think about our results in 2023, we think it's going to be aligned with our competitor composite for the year but ahead of our competitor composite in the fourth quarter. Now certainly, COVID-19 impacts have stabilized globally. While we continue to see some challenges, macro challenges from the point of view of inflation, hospital staffing and the like, there is a bolus of patients coming out into the market after COVID-19, which has made 2023 market growth faster than historical averages.

And we see that trend continuing into a good part of 2024. And therefore, being a tailwind into 2024. There's a lot of factors playing into that. But overall, we see the amended procedures continuing into, at least, the first half of 2024. Now we also have a number of tailwinds on our side, other than the procedures that make me optimistic about 2024. We have the trajectory of Abiomed in heart recovery, which is very strong with the adoption of Impella 5.5. We filed already for our Impella ECP, which is the smaller version of Impella CP.

In orthopedics, we continue to move into higher-growth markets with the expansion of our VELYS Robotic-Assisted Solution. We obtained CE Mark in Europe. In surgery, we continue to launch innovations across our surgery business with the ENSEAL X1 Curved Jaw Tissue Sealer in energy and ECHELON 3000 as a Stapler. And we continue to see good expansion of our Plus Sutures, too. In our Vision business, we are expanding our TECNIS family into the premium segment of IOLs. And finally, and I know this is an area of interest to you - in electrophysiology, we continue to expand our PFA portfolio of catheters.

We obtained approval for our VARIPULSE, loop catheter, PFA loop catheter in Japan at the beginning of this year. And we continue to roll out the global launch of QDOT Micro, our newest radiofrequency ablation catheter. So overall, a number of catalysts and tailwinds into our MedTech business into 2024. As we discussed in our enterprise business review, we continue to see our MedTech business growing at the upper end of our markets and becoming a best-in-class competitor in MedTech.

Operator

Next question is coming from Terence Flynn from Morgan Stanley.

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

Great. Maybe 2 parts for me on CARVYKTI. I noticed an ODAC panel was just announced to review the CARTITUDE-4 data. I was just wondering if you can talk about the focus of that upcoming meeting and your confidence in an on-time label expansion for CARTITUDE-4. And then the second part of the question is I know in manufacturing, you've been ramping up in Belgium. And I believe that facility is now up and running. So how should we think about supply for 2024 broadly for CARVYKTI?

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

Thank you, Terence. So, with more than 2,000 patients treated, CARVYKTI, it's already the fastest launched CAR-T in the market overall. And we are pleased to continue to see quarter-over-quarter sequential growth in CARVYKTI. And overall, we remain confident in 2 things, both the risk benefit of CARVYKTI in the indication that it is being studied, and at the same on the potential of CARVYKTI to be a $5 billion-plus asset at peak year sales. Regarding the ODAC that you commented to. We are very confident on the data of our Phase III CARTITUDE-4 study that supports the efficacy and safety of CARVYKTI in 1 to 3 prior lines in the treatment of patients with relapsed/refractory multiple myeloma.

We presented the results at ASCO, as you know. And we also published those results in the New England Journal of Medicine. And we very much look forward to reviewing the updated survival and safety data with the FDA ODAC in the future. We are committed to work with the FDA in the continued development of CARVYKTI. And we continue to have the focus on bringing this immunotherapy to multiple myeloma patients in earlier lines of therapy. We are working with the FDA towards a PDUFA date for our CARTITUDE-4 indication on April 5 and with EMEA towards an anticipated CHMP opinion in the first quarter of 2024. So overall, we feel confident about the risk-benefit profile in this indication and about the future of CARVYKTI.

Regarding your manufacturing question. We've done a significant progress in our manufacturing capacity, which is a major driver in the continuous growth of CARVYKTI. On the cell processing side, we have doubled our cell processing capacity in our Raritan facility since 2023. We are making progress to your point, Terence, in our European cell processing facilities. We are already manufacturing the first batches of CARVYKTI for clinical use this month in January. And we also have contracted additional capacity, external capacity to scale up production and increase our ability moving forward, that will start mid this year.

On the other hand, we have also made significant progress in the internalization and scale-up of our lentivirus production. We have increased capacity in Switzerland, in our Switzerland site. And at the same time, we continue to progress with new U.S. capacity and addition sites in the Netherlands to produce our lentivirus. Late December, we received approval to expand our lentivirus capacity from 20-liter tanks to 50-liter tanks of lentivirus production in our U.S. facility. So overall, we feel good that we are progressing with CARVYKTI, that we will continue to deliver quarter-over-quarter growth in 2024. And we are working towards building this $5 billion-plus product and continue to transform the treatment paradigm in multiple myeloma, as we have discussed in the past, moving from treating-to-progression to treating-to-cure as we move CARVYKTI into earlier lines of therapy.

Operator

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

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

Congrats to a nice finish to the year here. Joe or Joaquin, I'd love to hear just a general update on your M&A appetite and expand on your recent comments about Abiomed being a gateway in cardiovascular devices, which you, Joaquin, commented on earlier this month.

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

Yes. So Larry, let me start, and then I can turn it over to Joaquin. So we are very well positioned to continue to entertain many types of deals. As you know, we have the parameters of making sure that they are a strategic fit so that we've got scientific expertise and insights. A familiarity with the space has proven to be our most successful platforms.

We want to make sure that we're earning a fair return to compensate shareholders for the risk that we're bearing on their behalf. It was only 13 months ago, we were able to deploy $17 billion in capital for Abiomed. We're very pleased with that acquisition. Not only has it beat our internal deal models, but it also is performing better than what the Street had called for that business prior to the announcement of the acquisition. So it's been a really nice fit.

What I would say is we also deployed or announced, as I said in my prepared remarks, over $3 billion in capital for more than 50 smaller licensing partnerships or deals. And while those may have not made headlines, they usually are headlines when they become products for patients. And so that when you think about our history of DARZALEX, IMBRUVICA, CARVYKTI for one, that's kind of our track record. Our appetite is still, I would say, interested in moving into spaces that complement our existing portfolio, whether that be for the near or long term.

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

Thank you. Let me say we are agnostic to sector and agnostic to size. And as Joe commented, our preference is clearly to be in areas in which we have internal capabilities and know-how and also to go into products that represent a significant progress from the point of view of improving the current standard of care and that are first-in-class and best-in-class.

To illustrate that, the 2 deals that we completed this year, Laminar and Ambrx would be in that direction. So for example, Laminar is a deal in an area we know well, which is atrial fibrillation, and we believe could be first-in-class to be a device that can eliminate the left atrial appendage. When it comes to Ambrx, it's a deal in an area that we have a strong legacy like prostate cancer with a number of products marketed already. And this could be a first-in-class antibody drug conjugate, in order to address a significant medical need in metastatic castration-resistant prostate cancer in patients that have failed under gene therapy.

So very much so and in that context, we continue to see also opportunities when it comes to Innovative Medicines in neuroscience and in immunology. And when it comes to MedTech, to your point, in other cardiology areas based on the strength that we have now with Biosense Webster and Abiomed, and not excluding also the potential for other areas like robotic surgery or segments of orthopedics that are growing faster and also areas of vision. So overall, that's our approach. We try to put this strategic, scientific and to Joe's point, scientific lens, in order to be able to deliver value for patients and also value for our shareholders.

Operator

Next question is coming from Chris Schott from JPMorgan.

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

Joe, a question for you. How should we think about gross margins in 2024 and beyond? I know you've talked about operating margins, but it did seem like adjusted gross margins came down in 4Q. And I'm just wondering if that's a one-off result or a longer-term trend when you think about kind of the cadence of your P&L over the next few years.

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

Chris, thanks for the question. I think as you look at that specifically for the fourth quarter, what you have in our operating margins is obviously the Laminar transaction that was part of that mix. So on our slide that details IBT, you likely saw a quarterly reduction in MedTech, specifically of about 9 points, about 2 points for the full year. I would say 2/3 of that is represented by the Laminar transaction. You also then have, I would say, in the fourth quarter specific some mix as orthopedics performed probably a little bit better than it had in previous quarters. And then you have the inflationary impact, obviously, with higher levels of inventory on our balance sheet that flow through the P&L, that is occurring throughout 2023. And we expect it to occur throughout at least the first half of 2024. We're not seeing any incremental inflation in, I'll call it, current activity. So it's not being additive to inventory, but it's also not subsiding either. So we're kind of at a new, I'd say water level, if you will, that should be going forward but not hurting the P&L as we look out beyond the second half of 2024.

Operator

Next question is coming from Shagun Singh from RBC Capital Markets.

Shagun Singh Chadha - *RBC Capital Markets, Research Division - Research Analyst*

I was just wondering if we could get your latest thoughts on the potential impact of Novo's osteoarthritis data on orthopedic utilization, given the focus on WOMAC or pain scores. I believe the presentation could be here soon. Just curious to hear your thoughts and also what kind of scores could or may not have a potential impact.

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

So overall, look, osteoarthritis is a contributor to knee surgery. Sometimes I'm asked about osteoarthritis in the context of the GLP-1s, and weight is not a factor in osteoarthritis. We continue to look at this data, and it's early for us to give you an answer there. Now what we can tell you is that we continue to see an increased volume of procedures in orthopedics based on coming out of COVID. And we don't see any change in that neither in the hips or in the knee area or in any of the segments that we compete. So we are optimistic about our orthopedics trajectory. Specifically we are optimistic about how we are progressing with our VELYS Robotic System for total knee replacement. We have already have 30,000 procedures with very positive feedback from the surgeons, especially in the ambulatory surgical centers.

We are working to submit our 510(k) for our VELYS unique knee application. And we are seeing a strong recovery also in our hip business with a combination of new products like ACTIS, KINCISE and VELYS hip navigation. So we feel good about our orthopedics business as we continue to see global procedure recovery in most markets. We continue to succeed with our new products, and we also lapped part of the headwind that we had in China during this year. So very positive outlook moving forward for our orthopedics business.

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

It's also important to maybe provide us a reminder what we commented to last quarter, and that's that we're looking very hard at improving the profitability of the orthopedics unit. So being very selective as to what geographies we play in and what SKUs are actually going to be offered. So not only will you see some of the strength in the top line, as Joaquin outlined, but you should see an improved margin profile for that business as well.

Operator

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

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

So just maybe an area we don't spend as much time on is on the respiratory side, PAH. But just sort of a 2-part question, but that franchise of yours continues to sort of outperform expectations. So curious if you can talk about sort of what's driving success there. There's also an area where you don't have a lot of sort of longer-term investment. So going back to sort of the business development question, I'm just curious in your interest in sort of PAH or respiratory more generally as an area, further focus given your key franchises are going to be going away but you do have the infrastructure there already.

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

So first, let me underline the great results of our PAH franchise in 2023. We had growth in the high teens driven by improved patient mix, market growth coming out of COVID, too. This was an area that was heavily impacted by COVID as pulmonologists were working on COVID and not diagnosing new patients. So overall, it's been a very positive trajectory of our PAH business, and we remain confident about the short-term future of this business into 2024.

We are working towards the combination of macitentan, OPSUMIT with Tadalafil, which the trademark would be OPSYNVI. And that would be another option for patients there to enhance compliance. And in my talks with physicians treating pulmonary hypertension, they seem very positive about it, and we expect an approval of that combination in 2024. So that's the outlook for our pulmonary franchise. Are we looking at other areas there? We are looking at the space and see if there are potential opportunities to be able to improve the standard of care. And we continue to look to see how we can continue to extend the success of our pulmonary franchise into the future. But overall, we're very happy with the trajectory of our pulmonary franchise in 2023. And we expect a similar trajectory as macitentan, OPSUMIT and UPTRAVI become standard of care clearly established in this area.

Operator

Your next question today is coming from Louise Chen from Cantor Fitzgerald.

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

I just wanted to ask you with respect to your oncology franchise. Do you have any thoughts on CAR-Ts for autoimmune disease at all? And then secondly, radiopharmaceutical?

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

So thank you, Louise. And we have a strong oncology franchise in different areas. I commented that here in prostate cancer with ERLEADA that I discussed before. We'll see data in high-risk localized prostate cancer in 2024 with the addition of Ambrx now, an antibody drug conjugate in this area. We are very, very excited about RYBREVANT and the combination of RYBREVANT plus lazertinib. We have Phase III studies completed. We have filed all the 3 indications, and we expect approval of that in 2024.

So we are very excited about RYBREVANT and the combination of RYBREVANT plus lazertinib in EGFR-mutated nonsmall cell lung cancer in first line. Moving into bladder cancer, you also will see data with TARIS-200, and TARIS-210 in nonmuscle invasive localized bladder cancer. And we received FDA breakthrough designation for TARIS-200 in 2023. And then we continue our progress in our multiple myeloma franchise. We talk

about CARVYKTI, but it's important to recognize how well TECVAYLI and TALVEY, our 2 bispecific antibodies, are performing in the marketplace and the continued growth of DARZALEX with the impressive per sales data that we presented in first-line in newly diagnosed transplant-eligible multiple myeloma patients.

So we are looking at CAR-T in autoimmune diseases to your question, yes. But it's early data. As you know, we did a deal earlier in 2023 to partner 2 CAR-Ts, a CD19 and a CD19/CD20 BiCAR. So we are looking at that, and it's early data. It looks promising. We are interested in radiopharmaceuticals. We believe that the avenue that we are doing with antibody drug conjugates, it's an important therapeutic option. And when it comes to radiopharmaceuticals, we did a deal earlier this year with Nanobiotix for a radio enhancer that they've been developing for head and neck cancer.

We expanded our rights at the end of the year. And this could be another avenue to be there for us in which we could combine our expertise in medical technology and pharmaceuticals. And we plan to do a broader development plan of our radio enhancer, and we'll provide you more information about it as we continue to move. So overall, we are very pleased with the progress that we see in our oncology franchise, both in solid tumors and in hematology. And it remains a core strength of our Innovative Medicine group.

Operator

Next question is coming from Matt Miksic from Barclays.

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

I wanted to follow up on some of the comments you made about MedTech trends and margins. And I think you mentioned some of the headwinds there were patient mix. Would love to get an idea of maybe kind of in the middle of the P&L and the operating line, in terms of margin progression throughout the year. Which ones of those of your business lines there are kind of more reflecting that negative mix that you described and how that progresses during the year?

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

Yes, Matt, I apologize, but it was a little bit tough to hear your question entirely. I think it was around margins, specifically in MedTech and how that may progress through the year. So as I stated earlier, I would say that the margin profile is going to be impacted by inflationary pressures that were incurred really in 2022, sit on our balance sheet as inventory and then kind of flow through the P&L throughout the corresponding 2023 and probably a good piece of 2024.

That being said, Tim and the team are doing magnificent work in terms of finding efficiencies across the business. I highlighted one of the earlier ones with respect to orthopedics. But we're, quite frankly, doing that across the entire MedTech portfolio at this point in time, looking for opportunities whether it be aided by artificial intelligence or just infrastructure overall as to how we can further improve the MedTech profitability profile. Right now, we stand a little bit above the middle of the pack in terms of our peer set on margin. And we're looking to get towards the upper end of that peer set.

Operator

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

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

Great. I just wanted to ask you about the XARELTO patient mix that you guys called out. Just help us with kind of current dynamics and maybe looking forward whether this trend you expect to continue.

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

Yes, Geoff, I can answer that one. So specifically on XARELTO in the quarter. We would say there's 2 items. It's patient mix, but there is also a onetime entry. Moving forward in 2024, we do expect that there will be a decline but not to the extent that you saw in Q4.

Operator

Your next question is coming from Danielle Antalffy from UBS.

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

Joe, sorry to harp on the MedTech margin side of things. I appreciate everything you're saying for going forward. But just as we look at Q4 specifically, even adding back Laminar, we're still getting to sort of down 400 basis points year-over-year in the quarter. And I was just hoping maybe you could bridge us a little bit more. Is there any component of that is sort of price increases taken in late '22 into '23 rolling off? Or anything that you would highlight there.

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

No, Danielle. I think it's really the inflationary impact. So out of the 9% drop that you saw in Q4, 5 points are really Laminar. The balance of 4 points, I would chalk up to the inflationary impact that I spoke of earlier and then the mix component, whereby orthopedics, which is our lowest margin portfolio within the MedTech portfolio overall, performed a little bit better.

So there's really nothing magical behind it other than the explanations that were already given on the call. Again, we are looking at cost improvement initiatives, specifically in orthopedics, but across the entire portfolio as we move through 2024. But there's nothing that happened in Q4 that has us concerned about our outlook or calls around margin profile or EPS for the balance of this upcoming year.

Operator

Our next question is coming from David Risinger from Leerink Partners.

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

So notwithstanding the recently announced Ambrx acquisition, in recent years, J&J has executed more MedTech M&A than pharma M&A. And I don't mean to belabor the point. I know that you got some specific therapeutic area questions. But could you just comment at a high level on what has held J&J back in pharma M&A in recent years? And whether we should expect greater cash deployment to accelerate long-term pharma revenue growth going forward?

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

So thank you, David. M&A and external innovation has been a core of our pharma portfolio growth and transformation. As I said initially, we are agnostic to sector. In the case of pharma, our preferred mode has been trying to go to assets that were around proof-of-concept. So generally speaking, from a size perspective, it's been about deals that have been either of a smaller size or have been different modalities like licenses or partnerships.

Just last year, we completed overall, at Johnson & Johnson, more than 50 deals. The thing is that the headlines are only made by the ones that are M&A. So we've done multiple deals on our pharmaceutical side in order to be able to enhance our existing portfolio. And our bias is to go for

transactions that are going to enable us to create more value by leveraging our clinical development strength, our manufacturing capabilities, and our commercial reach.

So hence, why the majority of the deals that you see in our pharmaceutical side are at an earlier stage. Are we looking broader than that? Yes, we are. But mainly, we find more opportunities to create value at an earlier stage. For example, this year, we did a number of deals that went less publicized. We did, as I commented before, a deal with CBMG now called AbelZeta, in CAR-T with CD19 and CD20, which we believe could be a best-in-class CAR-T in this area that could launch in this decade or at the end of the year. We also did another deal in antibody drug conjugates with a Korean company called LegoChem, which was underreported.

But we continue to work in identifying deals in our pharmaceutical space that enables us to be able to put all our capabilities to work on the clinical development side, in manufacturing and in commercial. And that's been the source of very significant value creation in products that all of you know, like DARZALEX or CARVYKTI, that come from that type of approach of going earlier on into the development process.

Operator

Our final question today is coming from Rick Wise from Stifel.

Frederick Allen Wise - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Equity Research Analyst*

Maybe you could expand a little bit more on your electrophysiology comments. You had an extraordinary quarter. I'm guessing the new products helped. Maybe you could give us a little more color on maybe quantify the negative impact from China VBP. And looking ahead, we've got one PFA device approved in the U.S. Another one seemingly coming in the next month or 3 maybe. How should we think about the EP franchise as we look ahead to '24? What are you incorporating in your thinking?

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

So thank you for the question. Great and strong results of our EP franchise in 2023. And you should think about our EP franchise in 2024 as also a strong year, another year of growth, strong growth for our EP franchise. If I look at to your point that the drivers of growth in 2023, it was across the board. I mean it was in Asia Pacific, in the U.S. and EMEA. It was driven by the procedure recovery but also by the new product performance and a slight offset of value-based procurement in China.

The new products that we introduced this year are the engine generator, our mapping catheters, OCTARAY and OPTRELL. And also, importantly, our QDOT MICRO Catheter in radiofrequency ablation that has efficacy results higher than any PFA catheter. And that together with our strong commercial execution and broad clinical support across the board has driven these results in electrophysiology that in the fourth quarter was 25% growth globally, 22% growth in the U.S. and 29% outside of the U.S. So very strong results.

So we have a strong leadership in electrophysiology and 20 years of understanding this field. And when it comes to our strategy in cardiac ablation, we have multiple strategies, but one core strategy is our CARTO mapping system. That is a fundamental pillar of our strategy in cardiac ablation that supports procedural efficiency and very importantly, now low to zero fluoroscopy workflow.

For the electrophysiologist, it's very important to know where they are and what they are doing to the heart anatomy. Otherwise, they are flying blind if they don't have a mapping system. And the CARTO system, it's providing the electrophysiologist real-time feedback and very important parameters like tissue proximity, contact force measurement and ablation indexes that give them an idea of how durable the lesion is going to be and what are going to be the outcomes of the procedures. So that's key for us to be able to have a workflow that enables the type of progress that electrophysiologists have been already used to with radio frequency ablation. And hence, our suite of catheters is going to be from Day 1, fully integrated in our mapping system.

We have 5,000 CARTO systems already deployed globally and an extensive network of mappers to support the electrophysiologist. When it comes to our catheters, we are developing a full portfolio of options. You commented on VARIPULSE, our multi-electrode catheter that was approved in Japan. We are developing a focal and a large focal catheter and also a single shot one. So electrophysiologists are going to be able to choose the catheter that is more appropriate for their anatomy and for the workflow that they are selecting. We have 5 clinical trials active, 3 of them have completed. And we have submitted our VARIPULSE catheter for CE Mark, and we plan to submit the VARIPULSE catheter to the U.S. FDA in 2024.

Ultimately, PFA is an important option, but RF is also here to stay. That's why we believe that having the workflow and the procedure efficiency that CARTO gives you plus the option of having a catheter, like our dual energy catheter that would enable electrophysiologists to simply change depending on the anatomy of the lesion from PFA to RFA, it's going to be important for the future. And it's going to help them adopting PFA as this is the most widely used catheter in the world. So very positive about our growth in 2024 based on the strength that we have in this area. I'm positive about the outlook of our ablation business moving forward.

As we have commented in multiple occasions, atrial fibrillation is an area that is still undertreated. And the outcomes of radio frequency ablation and most likely, the outcomes of PFA have shown significant improvement even compared to medical therapy. So very positive about the outlook and the strength of our atrial fibrillation business.

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

Thank you, Rick, 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 you may have. I will now turn the call back over to Joaquin for some brief closing remarks.

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

Thank you, Jess. The strong performance we delivered in '23 gives me great confidence in the trajectory of our business. As I said earlier, we are entering 2024 from a position of strength, and we have multiple catalysts for growth. No other company is as well positioned as Johnson & Johnson to lead the next wave of health care innovation. And we look forward to sharing our progress in the year ahead. Thank you.

Operator

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