Q4 2022 Earnings Call

Company Participants

- Jessica Moore, Vice President, Investor Relations
- Joaquin Duato, Chief Executive Officer
- Joseph J. Wolk, Executive Vice President, Chief Financial Officer

Other Participants

- Chris Schott
- Chris Shibutani
- David Risinger
- Lawrence Biegelsen
- Louise Chen
- Matt Miksic
- Terence Flynn
- Trung Huynh

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's Fourth Quarter 2022 Earnings Conference Call. All participants will be in a 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. (Operator Instructions)

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

Jessica Moore {BIO 22511603 <GO>}

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 of 2022, and our financial outlook for 2023. Joining me on today's call are Joaquin Duato, Chairman of the Board and Chief Executive Officer; and Joe Wolk, Executive Vice President, Chief Financial Officer.

A few logistics before we get into the details, as a reminder, you can find additional material including today's presentation and associated schedules on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com. Please note that today's meeting may include forward-looking statements related to among other things, the company's future financial performance, product development, market position and

business strategy and the anticipated separation of the company's Consumer Health business.

You're cautioned not to rely on these statements which are based on current expectations of future events using the information available as of today's date and are subject to certain risks and uncertainties that may cause the company's actual results to differ materially from those projected.

In particular, there is significant uncertainty about the duration and contemplated impact of the COVID-19 pandemic. A further description of these risks, uncertainties and other factors can be found in our SEC filings including our 2021 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 highlighting his first year as CEO and his priorities for 2023. I will then review the fourth quarter sales and P&L results for the corporation and highlights related to the three segments, as well as full year 2022 results for the enterprise. Joe will then close with additional business commentary before sharing an overview of our cash position, our capital allocation priorities and our guidance for 2023. The remaining time will be available for your questions. We anticipate the webcast will last approximately 75 minutes.

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

Joaquin Duato {BIO 17056015 <GO>}

Thanks, Jess. Good morning, everyone. I'm pleased to be here today to review our 2022 results and highlight my priorities for the business. I'm excited for the future of Johnson & Johnson. For over 135 years people have counted on Johnson & Johnson to be at the forefront of health care innovation. This remains as true today as the day we were founded, and I'm honored to continue this legacy.

In 2022, despite macroeconomic challenges, we delivered full year operational growth of over 6%. This is the result of the dedication and focus of our employees around the world as well as the breadth and diversification of our business. There were many business achievements last year, let me share some highlights. Our pharmaceutical team achieved its 11th consecutive year of above-market adjusted operational sales growth, excluding the COVID-19 vaccine delivering nearly 7% growth, as we continue to advance our innovation pipeline.

I'm particularly excited about the progress made across our multiple myeloma portfolio. This includes the launches of CARVYKTI, our first cell therapy and TECVAYLI, our BCMA CD3 bispecific antibody along with the recent filing of Talquetamab, our GPRC5D CD3 bispecific. In MedTech, we generated above 6% full year operational growth anticipating our second consecutive year, outperforming our competitive composite.

In terms of innovation, we accelerated the cadence of new product launches and significantly enhanced the quality of our MedTech pipeline, including more than doubling the number of programs with over $100 million of net present value potential. Notably, we completed the acquisition of Abiomed, which positions us as the global leader in heart recovery and immediately enhances MedTech revenue growth, this transaction will become accretive to earnings in 2024.

Finally, we made significant progress towards the separation of Kenvue. We have begun operating our consumer business, as a company within a company and we filed our Form S-1 with the SEC giving us the option to pursue an IPO as a potential step in the separation. Looking ahead, while we expect some of the headwinds that impacted 2022 to continue, we have proven that Johnson & Johnson is resilient in times of macroeconomic challenges. In this environment, our approach to 2023 can be best described as prudent and our priorities for the year are clear and remain consistent.

First, we are finalizing our plans for Johnson & Johnson to operate as a two sector company dedicated to competitive performance both in Pharmaceutical and MedTech, this change will enable us to become simpler, faster and more focused. In Pharmaceutical, we will continue delivering top-line growth annually while driving towards $60 billion in revenue by 2025.

We believe we will be able to achieve our market growth in 2023 for the 12th consecutive year, even in the face of the STELARA loss of exclusivity and macroeconomic challenges. Growth will be driven primarily by our existing portfolio including DARZALEX, TREMFYA, ERLEADA, INVEGA SUSTENNA and UPTRAVI and also continued uptake from new launches including SPRAVATO, CARVYKTI and TECVAYLI.

In MedTech with the acquisition of Abiomed, we now have 12 platforms with over $1 billion in annual sales. We expect to continue to build on 2022's momentum. We will do this by maximizing the commercial opportunity for recently launched innovations, continuing to advance the Abiomed pipeline and prioritizing investment in higher growth segments of our markets.

This will be a transformational year for Johnson & Johnson which brings me to my next priority, completing the successful creation of a new Consumer Health Company, Kenvue. We remain on track to complete the separation in 2023 as indicated in our initial announcement in November of 2021. As we look forward, our track record gives us the confidence that we can grow ahead of our peers and cement the foundation for long-term success.

Following 2021, a year where we substantially increased R&D investment, we continued our commitment to organic innovation. We invested nearly $15 billion in R&D during 2022, also we increased our dividend for the 60th consecutive year, we instituted a share repurchase and we deployed over $17 billion in M&A including the acquisition of Abiomed. Very few companies have the capability and the balance sheet to take such significant actions concurrently, especially in a year like 2022. I'm confident that we are well-positioned for 2023 and beyond.

In closing, I am energized about what is to come, as the largest and most diversified health care products company in the world, we will continue to use our scale and breadth to drive innovations, deliver for patients and shape the future of health care around the world.

Now, let me turn it back to Jess.

Jessica Moore {BIO 22511603 <GO>}

Thanks, Joaquin. Starting with Q4 2022 sales results. Worldwide sales were $23.7 billion for the fourth quarter of 2022, a decrease of 4.4% versus the fourth quarter of 2021. Operational sales growth which excludes the effect of translational currency increased 0.9% as currency had a negative impact of 5.3 points. In the U.S., sales increased 2.9%. In regions outside the U.S., our reported sales declined 11.5%.

Operational sales outside the U.S. declined 1.1% with currency negatively impacting our reported OUS results by 10.4 points. Excluding sales from the COVID-19 vaccine, operational sales growth was 4.6% worldwide, 4.7% in the U.S. and 4.4% outside the U.S. As you will find in our supplemental sales schedules, acquisitions and divestitures had an immaterial impact on our results in the quarter.

Turning now to earnings, for the quarter, net earnings were $3.5 billion and diluted earnings per share was $1.33 versus diluted earnings per share of $1.77 one year ago. Excluding after-tax intangible asset amortization, expense and special items for both periods, adjusted net earnings for the quarter were $6.2 billion and adjusted diluted earnings per share was $2.35, representing increases of 9.5% and 10.3%, respectively, compared to the fourth quarter of 2021. On an operational basis adjusted diluted earnings per share increased 15.5%.

For the full year 2022, consolidated sales were $94.9 billion, an increase of 1.3% compared to the full year of 2021. Operationally, full year sales grew 6.1% with currency having a negative impact of 4.8 points. Sales growth in the U.S. was 3%. In regions outside the U.S. our reported year-over-year sales declined 0.6%. Operational sales growth outside the U.S. grew by 9.1% with currency negatively impacting our reported OUS results by 9.7 points. As you will find in our supplemental sales schedules, acquisition and divestitures as well as sales from our COVID-19 vaccines had an immaterial impact on our results for the full year.

Net earnings for the full year 2022 were $17.9 billion and diluted earnings per share was $6.73 versus diluted earnings per share of $7.81 a year ago. 2022 adjusted net earnings were $27 billion and adjusted diluted earnings per share was $10.15, representing increases of 3.2% and 3.6%, respectively, versus full year 2021.

On an operational basis, adjusted diluted earnings per share increased by 9.2%. While not part of our prepared remarks for today's call, we have provided additional information and back-up for our full year 2022 sales by segment, consolidated statement of earnings and adjusted income before tax by segment, which can be downloaded from our website.

I will now comment on business segment sales performance highlights for the quarter. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the fourth quarter of 2021 and therefore, exclude the impact of currency translation. Beginning with Consumer Health, worldwide Consumer Health sales of $3.8 billion increased 1% with an increase of 10.9% in the U.S. and a decline of 5.8% outside the U.S. Excluding translational currency, worldwide operational sales growth increased 6.4% and outside the U.S. operational sales growth increased 3.2%.

Results were primarily driven by strategic price increases, growth in OTC due to a strong cough, cold and flu season, and growth in NEUTROGENA, as well as strong new product introductions in Asia-Pacific and Latin America. NEUTROGENA growth contributed to the second consecutive quarter of 5% operational growth for Skin Health/Beauty. Growth across the portfolio was partially offset by continued although reduced supply constraints in the U.S., COVID-19 impacts in China, portfolio simplification and the suspension of personal care products sales in Russia.

Moving on to our Pharmaceutical segment, worldwide Pharmaceutical sales of $13.2 billion decreased 7.4% with declines of 0.6% in the U.S. and 14.9% outside of the U.S. Excluding translational currency, worldwide operational sales declined 2.5% and outside the U.S. operational sales declined 4.5%.

Excluding the COVID-19 vaccine sales, worldwide operational sales growth increased 3.9%. U.S. operational sales growth increased 2.4% and outside the U.S. operational sales growth increased 6%. Pharmaceutical growth excluding the COVID-19 vaccine was driven by our key brands and continued uptake in our recently launched products enabling us to continue to deliver above-market adjusted operational sales growth for the 11th consecutive year including seven assets with double-digit growth.

Growth was driven by DARZALEX, ERLEADA, STELARA and TREMFYA and was partially offset by REMICADE and ZYTIGA due to loss of exclusivity along with a decrease in IMBRUVICA sales. Within our Oncology business, DARZALEX and ERLEADA continue to drive strong sales growth, with increases of 33.9% and 48.6%, respectively.

ZYTIGA sales declined 43.6% worldwide predominantly due to loss of exclusivity in Europe in September. IMBRUVICA sales declined 12.3% worldwide, due to competitive pressures and a suppressed CLL market due to COVID-19, despite competitive pressures IMBRUVICA maintains its market leadership position worldwide.

In our Immunology business, STELARA grew 6.2% driven by market growth and share gains in Crohn's disease and ulcerative colitis with gains of 4 points and 5.4 points in the U.S. respectively, as well as a favorable prior period adjustment impacting worldwide results by approximately 460 basis points. Results in the quarter were partially offset by unfavorable patient mix and rebating in the U.S. as well as austerity measures in Europe and shipment timing in Asia-Pacific.

TREMFYA grew 12.5% driven by share gains in psoriasis and psoriatic arthritis, with gains of 1.4 points and 2.9 points in the U.S., respectively, along with market growth. Q4 growth

was partially offset by a net unfavorable prior period adjustment impacting worldwide results by approximately 1,150 basis points, unfavorable patient mix and a challenging prior year comparison. Beginning in Q1 2023, we anticipate that CARVYKTI currently reported in other oncology and SPRAVATO currently reported in Other Neuroscience will meet the threshold to be separately disclosed.

I'll now turn your attention to the MedTech segment. Worldwide MedTech sales of $6.8 billion decreased by 1.2% with growth of 7.1% in the U.S. and a decline of 8.6% outside of the U.S. Excluding translational currency, worldwide operational sales growth increased 4.9% and outside the U.S. operational sales growth increased 2.9%, excluding the impact of acquisition and divestitures, worldwide adjusted operational sales growth was 4.4%.

Q4 growth was driven by commercial execution, strong new product introduction performance as well as COVID-19 procedure recovery in many parts of the world, partially offsetting growth in the quarter was the impact of volume-based procurement, COVID resurgence in China as well as supply constraints predominantly in Vision. Strong growth continued in the U.S. with dollar sales sequentially improving each quarter throughout 2022.

OUS performance was adversely impacted by dynamics related to COVID-19 especially given our strong position in China. The Interventional Solutions franchise delivered another quarter of worldwide double-digit growth at 15.1% driven primarily by strong new product introductions performance, commercial executions and continued market growth in electrophysiology. Abiomed sales are also reported in Interventional Solutions and financial results were reflected as of December '22, the date the acquisition closed.

Contact lens global growth of 7.7% reflects strong performance of our ACUVUE OASYS 1-Day family of products, including the recent launch of ACUVUE OASYS MAX 1-Day, strong commercial execution and market appropriate price actions, growth was tempered by continued supply challenges. In the Orthopaedics franchise digital and enabling technologies reported in spine, sports and other continued to accelerate and drive pull through sales in areas like hips and knees. For additional context, selling days had approximately a 60 basis points positive impact on results in the quarter.

Now, turning to our consolidated statement of earnings for the fourth quarter of 2022, I'd like to highlight a few noteworthy items that have changed compared to the same quarter of last year. Cost of products sold deleveraged by 70 basis points primarily driven by onetime COVID-19 vaccine manufacturing related cost, unfavorable currency impact in the Pharmaceutical business, inflationary pressures as well as unfavorable mix with the enterprise with a lower portion of sales coming from the Pharmaceutical business.

Selling, marketing and administrative margins leveraged by 150 basis points. This represents a 9% reduction versus the prior year driven by phasing with higher spend earlier in the year, as well as proactive management of cost given the current inflationary environment. We continue to invest strategically in research and development at competitive levels, investing 16.2% of sales this quarter. The $3.8 billion invested was an 18.6% reduction versus the prior year, driven primarily by phasing with higher spend

earlier in the year. Interest income was favorable to prior year by just over $100 million driven by higher rates of interest earned on cash balances.

The other income and expense line was an expense of $1.2 billion in the fourth quarter of 2022 compared to an expense of $9 million in the fourth quarter of 2021. This was primarily driven by onetime COVID-19 vaccine manufacturing-related exit costs, higher consumer health separation-related costs, higher costs related to the Abiomed acquisition and lower gains on securities.

As we announced in Q2 2022, we continue to have commitments and obligations related to the COVID-19 vaccine, including external manufacturing network exit cost and required clinical trial expenses, associated with the company's modification of its COVID-19 vaccine research program and manufacturing capacity to levels that meet all remaining customer contractual requirements.

Regarding taxes in the quarter, our effective tax rate was 16.2% versus 2.1% in the same period last year. The increase was primarily driven by more income in higher tax jurisdictions versus the prior year. Additionally, the company benefited from onetime tax items in the fourth quarter of 2021 that did not repeat in the current year. Excluding special items, the effective tax rate was 16.2% versus 10.4% in the same period last year. I encourage you to review our upcoming 2022 10-K filing for additional details on specific tax matters.

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

Now let's look at adjusted income before tax by segment. In the fourth quarter of 2022, our adjusted income before tax for the enterprise as a percentage of sales increased from 25.6% to 31.3%. Pharmaceutical margins improved from 33.9% to 38.2%, primarily driven by SG&A and R&D phasing, with higher spend earlier in the year, partially offset by the negative impact of currency and cost of products sold.

MedTech margins improved from 18.1% to 25.3%, primarily driven by SG&A and R&D phasing, with higher spend earlier in the year, favorable portfolio mix and supply chain efficiencies, partially offset by inflationary pressures.

Finally, Consumer Health margins improved from 18.6% to 22%, driven by brand marketing phasing with higher spend earlier in the year and supply chain efficiencies, partially offset by inflationary pressures.

This concludes the sales and earnings portion of the Johnson & Johnson fourth quarter and full year 2022 results. I'm now pleased to turn the call over to Joe Wolk. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Jess, and thanks, everyone, for joining us today. As Jess shared, we reported solid results with competitive growth across our business segments in 2022. While macroeconomic challenges and lingering COVID-19-related impacts tempered our fourth quarter sales growth, we prioritized our top investments, while managing costs to yield slightly better margin performance than guided in October to meet our earnings expectations. The business is resilient, and we should be positioned well entering 2023.

We are particularly proud of the advancements in our pipeline and portfolio to solidify the long-term, including the launch of TECVAYLI, the filing of Talquetamab in the U.S. and Europe, FDA clearance for our TELIGEN Digital Spine Solution, the closing of the Abiomed acquisition and the tremendous progress made on separating our Consumer Health business.

Let's delve into the financials, beginning with our 2022 year-end cash position and execution against our capital allocation priorities. We generated free cash flow for the year of approximately $17 billion. And at the end of 2022, we had approximately $24 billion of cash and marketable securities and approximately $40 billion of debt or a net debt position of $16 billion. Despite macroeconomic uncertainty, we had a strong year deploying capital against all of our capital allocation priorities. These priorities remain unchanged.

This past year, we invested more than 15% of sales for a total of nearly $15 billion in research and development. This investment has enabled the advancement of important programs, including strengthening our MedTech pipeline and progression of our multiple myeloma portfolio, which Joaquin referenced.

Investment in R&D remains a top priority to support long-term growth and value creation. Our second priority is our commitment to dividends. 2022 marked the 60th consecutive year in which we increased our annual dividend. We know investors value our dividend and as a part of the Consumer Health separation, we intend, at a minimum, to maintain that dividend. As you can appreciate, we will need more clarity on the type of separation to determine how that is best achieved.

Our third priority is strategic acquisitions, which is intended to complement our organic activities. In 2022, we closed the acquisition of Abiomed, strengthening MedTech's presence in higher growth segments, as well as more than 100 smaller early-stage acquisitions, licensing deals and partnerships.

Finally, our Board authorized a $5 billion share repurchase program in the third quarter. And as of the end of the year, we've completed approximately 50% of that program. In combination with our dividend, we returned over $14 billion to shareholders in 2022.

I'll now provide our full year 2023 guidance. As we are still in the process of the Kenvue separation, our guidance represents the current Johnson & Johnson businesses, inclusive of Pharmaceuticals, MedTech and Consumer Health segments. We expect operational sales growth for the full year 2023 in the range of 4.5% to 5.5% or $96.9 billion to $97.9 billion. This guidance is provided on a constant currency basis, reflecting how we manage

business performance. We estimate a favorable impact from net acquisitions and divestitures associated primarily with the Abiomed acquisition, and thus, are comfortable with your models reflecting adjusted operational sales growth in the range of 3.5% to 4.5%.

Our sales guidance continues to exclude contribution from the COVID-19 vaccine, which as your models already correctly anticipate will decline in 2023. As you know, 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 $1.08 as well as other currencies, we estimate there would be no impact from foreign currency translation on reported sales for the year.

Regarding other items on our P&L, we expect 2023 adjusted pretax operating margin to be flat driven by continued inflationary pressures and cost of goods sold, offset by continued operating expense leverage. Regarding other income and expense, the line on the P&L where we record royalty income, the return on assets and actuarial costs associated with certain employee benefit programs as well as gains and losses related to items such as investments by Johnson & Johnson Development Corp., litigation and balance sheet write-offs.

On an adjusted basis, we expect this to be $1.9 billion, $2.1 billion for 2023. The majority of this income is associated with our employee benefits programs aligned with accounting disclosure requirements. Rising interest rates, return on assets and program actions the team has implemented to derisk the plans have lowered our projected future benefit obligations. And based on current trends, we expect this benefit to continue through the next couple of years.

We are comfortable with you modeling net interest expense between $250 million and $350 million. These figures include increased financing charges versus 2022, associated with the Abiomed acquisition. Finally, we are projecting an effective tax rate for 2023 in the range of 15.5% to 16.5% based on current tax laws and anticipated geographic income mix across our businesses.

Considering all these factors, we are guiding adjusted earnings per share in the range of $10.40 to $10.60 on a constant currency basis, reflecting operational or constant currency growth of approximately 2.5% to 4.5% or 3.5% at the midpoint.

While not predicting the impact of currency movements assuming recent exchange rates I previously referenced, our reported adjusted operational earnings per share for the year would be favorably impacted by approximately $0.05 per share, resulting in adjusted reported earnings per share in a range of $10.45 to $10.65 or $10.55 at the midpoint, growth of 4% versus the prior year.

While we do not provide guidance by segment or on a quarterly basis, I'd like to provide some qualitative considerations for your modeling. Some segment remarks starting with Pharmaceuticals. We expect to again deliver above-market growth in 2023, driven by key assets such as DARZALEX, ERLEADA, TREMFYA, INVEGA SUSTENNA and UPTRAVI as well as continued uptake of recently launched products, such as CARVYKTI, SPRAVATO and

TECVAYLI. This growth is despite lower pharmaceutical market growth than experienced in recent years and considers the STELARA loss of exclusivity, which we anticipate occurring in late 2023 in the U.S.

While we continue to expect volume growth for STELARA in the U.S. up to the LOE date, we expect this growth to be offset by pricing pressure. Further, we continue to expect a 2023 impact from other post-LOE products as well as potential increased austerity measures across Europe.

In MedTech, we expect continued competitive growth fueled by market recovery and continued commercial uptake of recently launched products. We anticipate a relatively stable recovery in procedure volumes with health care staffing constraints remaining the most significant limitation on the pace of recovery.

Specific to China, we anticipate continued pressure into 2023 related to the easing of the zero COVID policies as well as impacts from volume-based procurement. As we've said, we're excited about the Abiomed acquisition, which accelerates our sales growth in 2023.

In Consumer Health, we anticipate continued growth in line with the markets that we compete in. We also expect to continue to utilize strategic price increases across the portfolio to minimize the impact of ongoing inflationary pressures within the supply chain. Regarding quarterly phasing, it's best summed up with a general theme that we expect the second half to be stronger than the first half and likely the second quarter is stronger than the first quarter. We are assuming the following to support these statements.

In Pharmaceuticals, the first half of the year will be impacted by continued declines from LOE products in Europe that impacted Q4 2022 results, namely ZYTIGA and INVEGA SUSTENNA as well as continued pricing pressure. Also, we expect the ramp of new product launches will occur more prominently in the second half of the year.

In MedTech, we expect second half operational sales growth to be higher than the first half of the year as we anticipate ongoing procedure recovery to improve as the year progresses. We also believe that some of the COVID impact felt in China in Q4 will carry over into early 2023. And similar to Pharmaceuticals, uptake of new product launches is assumed to be more pronounced in the second half. Given we are in the registration process, regulations limit what we can currently discuss around the planned Consumer Health Company.

On the P&L, we also anticipate operating margin to be better in the second half than the first half. This is attributable to inventory built in 2022 at higher costs driven by inflation that will flow through the P&L in the first half of 2023 and a second half that accounts for cost leverage driven by mitigation efforts and higher sales reflected in the comments I just made.

And finally, while we don't speculate on future currency movements, utilizing the euro spot rate relative to the U.S. dollar as of last week at $1.08 as well as other currencies,

foreign exchange would have a negative impact on our results in the first half of the year, but potentially a favorable impact in the second half.

Turning to key events in 2023. As mentioned, we are limited in the information we can provide around the planned Consumer Health separation. We publicly filed a Form S-1 on January 4th with the Securities and Exchange Commission, giving us the option to pursue an initial public offering as a potential first step in the planned separation, and we have started to operate Kenvue as a company within a company.

Consistent with our initial announcement in November of 2021, we continue to expect to complete separation in 2023. And we expect that any interim steps, such as an IPO, would be consistent with that timing subject to market conditions.

We are estimating $1.8 billion to $2.1 billion in after-tax Kenvue standup costs, with $1.2 billion having already been incurred through the end of 2022. These estimates are in line with industry average for transactions such as this one, given Johnson & Johnson's market cap.

In terms of dissynergies to be incurred following the completion of the separation, we are estimating between $500 million and $750 million of annual after-tax impact. We are already executing on plans to address these dissynergies and expect to have them fully mitigated by the end 2024.

As we separate new Johnson & Johnson, we'll also continue to reevaluate the level of ongoing financial information provided based on discussions with investors. While our financials will become simpler as we move from a three-segment company to a two-segment company, we will continue to look for ways to enhance our disclosures, such as providing quarterly R&D by segment and a patent expiry table in our Form 10-K.

We also expect 2023 to be an important year of scientific innovations and readouts across our segments. In our Pharmaceutical business, some examples include the potential approval of Talquetamab, our GPRC5D CD3 bispecific antibody in relapsed/refractory multiple myeloma. Potential clinical data from CARTITUDE-4, a trial studying CARVYKTI, our BCMA CAR-T in patients with one to three lines of prior therapy.

The potential for an interim analysis of the MARIPOSA study of RYBREVANT plus lazertinib in frontline non-small cell lung cancer with EGFR mutations versus Tagrisso as well as potential clinical data from the PAPILLON study in frontline non-small cell lung cancer in combination with chemotherapy. Early clinical data from the Phase 2 SunRISe-1 study of TAR-200, our drug-eluting device in non-muscle invasive bladder cancer.

Starting Phase 3 clinical program for milvexian, a factor XI anticoagulant in partnership with Bristol-Myers Squibb. Potential Phase 2 clinical data from nipocalimab, our FcRn antagonist in rheumatoid arthritis and hemolytic disease of the fetus and newborn. Potential Phase 3 clinical data from TREMFYA in Crohn's disease and ulcerative colitis. And finally TREMFYA, our IL-23 inhibitor was recently added to the National Reimbursement Drug List in China, which will take effect later this year.

In MedTech, we look forward to providing information on significant innovation programs across the business including expansion of our digital solutions in orthopedics, our digital robotic solution Ottava, our pulsed-field ablation solutions for cardiac ablation and advancements in our pipeline and clinical studies for heart recovery associated with Abiomed.

Overall, our approach to 2023 financial guidance should be viewed as responsibly cautious given the many external uncertainties. We are focused on delivering competitive growth for the new Johnson & Johnson, while also completing a successful Consumer Health separation. We are confident that our current plans position us for long-term growth and value creation for shareholders.

That concludes our prepared remarks, I am now pleased to open the line for your questions. Kevin, will you please provide the listeners with instructions, if they'd like to ask a question.

Questions And Answers

Operator

(Question And Answer)

(Operator Instructions) Our first question today is coming from Terence Flynn from Morgan Stanley. Your line is now live.

Q - Terence Flynn {BIO 15030404 <GO>}

Great. Thanks so much. I appreciate the time this morning. Maybe a two-part question for me. I guess, Joe, first on the guidance, you mentioned it should be viewed as responsibly cautious. Just wondering any areas you'd call out in terms of conservatism as we think about the year? And then on the pipeline side, obviously, myeloma -- sorry, excuse me, myeloma an important area for you guys. Just wondering if you can confirm the timing of the CARTITUDE-4 study and what you're hoping to see from that readout? Thank you.

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

Good morning, Terence, I'll handle the first question, and then I'll kick the question of CARTITUDE over to Joaquin. With respect to guidance, I would say, just given all the macroeconomic uncertainty, geopolitical uncertainty, we thought this was the right approach at this point in time to come out with guidance in the ranges that we did. I wouldn't classify it as conservative per se. What I would say in terms of our outlook for the P&L, is that we're assuming a lot of carryover, quite frankly, of the inflationary impact that we had in 2022.

As you can imagine, the way the accounting would work, we built inventory at higher cost in 2022. That's set on the balance sheet at year-end and will flow through mostly the first half of 2023. If there's any element of conservatism, I would say, it probably resides in the fact that we're not assuming any deflationary relief as we go throughout the year. So we

do think these costs will be at a higher level for some time. But as you saw with our fourth quarter results and really the outlook for 2023, we're doing everything we can responsibly to prioritize our top investments for the long term as well as manage costs in the interim.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. And with respect to CARTITUDE-4 and CARVYKTI, our multiple myeloma portfolio turns is the most important driver of growth for our pharmaceutical group moving forward. It's about DARZALEX continued progression in first line. CARVYKTI, our best-in-class BCMA cell therapy. The recently approved TECVYLI, our BCMA CD3 bispecific. And also, we are excited about the filing of Talquetamab, our GPRC5D CD3 bispecific.

So all in all, this portfolio enables us to do something very significant, which is changing the treatment paradigm from treating to progression to treating to cure. And we'll see these medicines being used in combination and in different sequences in order to achieve these treating to cure.

Specifically, what you mentioned, CARTITUDE-4, which is the study that evaluates CARVYKTI in patients who have received one or three prior lines of therapy, it's very important in achieving that goal. CARTITUDE-4 is an event-driven study, and we look forward to have some results of CARTITUDE-4 in 2023. We cannot give you the specific timing because it's an event-driven study, and it will be very important in our ambition to move CARVYKTI into earlier lines of therapy.

Operator

Thank you. Next question today is coming from David Risinger from SVB Securities. Your line is now live.

Q - David Risinger {BIO 1504228 <GO>}

Yes. Thanks very much. So first of all, congratulations on the performance. I was hoping that you could please discuss the longer-term prospects for the pharmaceutical business. In the past, J&J has targeted $60 billion in pharmaceutical revenue in 2025. I'm wondering if that's still the target? And if so, what you believe consensus is under modeling because consensus is projecting sales below the $60 billion figure for 2025? Thank you.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question and turning to what you mentioned our 2025 targets. We continue to work towards accomplishing our previously stated goals of on one hand, delivering growth every single year in our pharmaceutical group through 2025 despite of the loss of exclusivity of STELARA. At the same time, continue to advance our differentiated pipeline and achieving $60 billion in revenue by 2025. So we continue to work towards these goals.

As we have discussed multiple times, the growth by 2025 is going to be driven mainly through the strength of our currently marketed portfolio as well as new indications of

these marketed portfolio. Some examples, continuous growth of DARZALEX in first line, TREMFYA, which is gaining share both in psoriatic arthritis and in psoriasis, and we expect a readout of our IBD studies in ulcerative colitis and Crohn's disease in 2023, where we'll provide a significant additional leg of growth for TREMFYA, ERLEADA, which is now in different indications in metastatic and non-metastatic prostate cancer will have some readouts of studies in high-risk localized prostate cancer in 2023, providing an additional leg of growth, our INVEGA SUSTENNA franchise in the U.S. as well as our pulmonary arterial hypertension franchise with UPTRAVI and OPSUMIT that has been affected by COVID-19, but that we expect that will continue to deliver growth. So that is the mainstay of our growth prospects towards 2025. And I will go later about the disconnect.

Then connected with that, we are also excited about our new product launches, specifically growth of SPRAVATO, growth in CARVYKTI that I just mentioned before and also TECVAYLI, which we got the approval very recently. And as I commented, the filing of Talquetamab, everything in multiple myeloma.

At the same time, we continue to make significant progress in some of the key products in our pipeline. Some of them we commented that were opportunities of more than $5 billion. Example of them, Milvexian, our oral anticoagulant, the combination of Libervant plus lazertinib in non-small cell lung cancer, our TARIS platform in bladder cancer, and finally, nipocalimab in auto antibody-mediated diseases. So those are the key drivers of our growth moving into 2025.

If I think about the main disconnect between our forecast and the Street forecast, it's our multiple myeloma portfolio. As I commented earlier, we see our multiple myeloma portfolio helping treat into cure rather than cannibalizing each other. And as a matter of fact, some of the studies that we have now in place show that ambition of combining our therapies.

I mentioned CARTITUDE-4, moving CARVYKTI into earlier lines of therapy. TECVAYLI and Talquetamab, our two bispecific antibodies are being studied in combination with one another, and TECVAYLI or Talquetamab are also being studied in combination with DARZALEX. So I see that as the major source of disconnect with the Street.

Then further to that, I continue to see disconnects in SPRAVATO, our treatment for treatment-resistant depression. Significant disconnects also in ERLEADA because of the indications in high-risk patients with localized prostate cancer that will read in 2023. We see a disconnect, as I commented in our pulmonary arterial hypertension franchise with UPTRAVI and OPSUMIT, which have been impacted by the pandemic, but we see strong growth moving forward.

And then finally in the expectations for XARELTO loss of exclusivity, which we see that in the back half of this decade. So those are elements that I have reflected as disconnect. So as I said, we continue to drive towards our 2025 goal of $60 billion and posting growth every year. I think, it's a reflection of the strength of our current portfolio and how well we are executing in our pipeline.

Operator

Thank you. Next question today is coming from Larry Biegelsen from Wells Fargo. Your line is now live.

Q - Lawrence Biegelsen {BIO 7539249 <GO>}

Good morning. Thanks for taking the question. Just a two part one for me. Joe, can you provide a little more color on the cadence of operational sales growth in pharma and devices? How much lower do you expect the first half to be versus the second half? And what are you assuming for market growth in each of the segments in '23?

And Joaquin just a follow-up to David's question there on the $60 billion. It implies a 6% CAGR between 2022 and 2025. How do you -- how should we think about the ramp to $60 billion? At 6%, do you expect to be more back-end loaded. Thanks for taking the questions.

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

Good morning, Larry. So let me start by -- as you know, we don't provide guidance by quarter, but let me talk a little bit about market growth. With respect to MedTech, we anticipate pretty much what we typically see in any given year of 4% to 6%. As some of my earlier comments in the prepared remarks reflect, we anticipate that there will be a little bit of, I'll call it carryover from some of the COVID surges that we saw in the Asia-Pacific region in the fourth quarter. But other than that, a normal cadence of steady procedure recovery.

The biggest challenge that hospital administrators are facing right now is really the staffing concern, but they've done a wonderful job in getting some sense of normalcy to that.

With respect to Pharmaceuticals, again, we enjoyed our 11th consecutive year of above-market growth. We anticipate 2023 will be a 12th year, but it is off of a lower base. If you happen to see some of the IQVIA data from last week, they're calling global and actually U.S. growth somewhere in that 2.5% to 4% range, depending on what region you're looking at. So while we will beat the market, we think it will be a lower number just by the dynamic of the market overall. And that's kind of how we're thinking of it.

In terms of some of the cadence, maybe to elaborate on the comments that I had prepared earlier, we will see some of that generic erosion that we experienced in the fourth quarter in Europe with the long-acting injectables as well as ZYTIGA having a much more pronounced impact in the first and second quarter, bleeding over from the fourth quarter. And pricing measures likely will be consistent throughout the year.

So hopefully, that helps give you a better sense of how we're looking at it. But again, the general theme of second half stronger than first half and probably second quarter stronger than first quarter seems to hold intact based on top line as well as bottom line performance given our expectations.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. And regarding to your question, Larry, as we have discussed and commented, we see above market growth in 2023 for our pharmaceutical group, which would be the 12th consecutive year of our market growth. And we continue to see positive growth in 2024 despite the loss of exclusivity in STELARA. And then we would see again pick up our growth above market in 2025. That's the sequence that we will see.

Certainly, the actual growth rate will be impacted by the FX and we don't anticipate and we don't project FX. And when we were establishing our $60 billion goal, we were thinking about the FX at the moment. We don't change the $60 billion because we don't know what the FX would be by 2025. But for purposes of you understanding how we see that, we see above market growth in 2023. We see positive growth in 2024, and then we see a pickup of growth, a significant one, in 2025 above market.

Operator

Thank you. Next question today is coming from Chris Schott from JPMorgan. Your line is now live.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much. Just one question and one quick clarification. I guess on operating margins, and this is a question maybe beyond '23. I'm just trying to think through the balance of, I guess, on one hand, some of the inflation headwinds potentially decreasing as you work through some of this inventory, I guess balanced against the STELARA LOE and some of the dissynergies from the spin. So I guess, as something kind of bigger picture about operating margins, is 2023 a decent proxy going forward? Or could we see either modest erosion in margins or expansion? Or is it too early to call? I'm trying to just get some sense of how that plays out?

And then my second question, which is just maybe a clarification on some of the immunology comments you made regarding 4Q. I think you mentioned unfavorable mix and rebate dynamics as headwinds. Should we expect those dynamics to continue in 2023? And I guess, are they getting worse? Or is this more just a continuation of what you've seen in the last few years that rebates are just kind of like gradually going up for that franchise as a whole? Thanks so much.

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

Great. Good morning, Chris, I'll tackle the operating margin question, and then I'll turn it over to Joaquin for some of the immunology references. So with respect to operating margin, I think, while we don't give multiyear guidance, I think this year does portend to have a considerable achievement in terms of managing cost by the organization in addition to inflationary pressures, and again, that's not combated with an assumption that we'll see deflationary relief.

We also have the dissynergies that come along with the Consumer separation itself. As the comments indicated, we plan to address all of those, and we've already started in mid-

2022 to mitigate some of those. They'll be fully mitigated by 2024. So I would think just looking out now qualitatively, '23 and '24 may look similar because you've got some different dynamics playing out, and we'll certainly have to see how inflation plays out over the course of this year.

And then getting back on a more normal cadence, I would say, you would expect from Johnson & Johnson, you know that we like to grow income a little bit faster than sales growth. And you do that by improving your margin profile. We have $60 billion of resources in a given year. So we've got a responsibility, we think, to continue looking at our prioritization, and our processes and technology to make sure that we are being not only as effective as we can be, but also as efficient as we can be.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you. And Chris, regarding the dynamics in the immunology market, overall, what we see is that the patient mix is changing, putting more pressure in our overall net price by having a higher participation of some channels we had lower priced. We see those situations continuing into 2023, but not getting worse. Simply the situation that we are now will continue into 2023, but will stabilize from where we are.

Operator

Thank you. Our next question is coming from that Matt Miksic from Barclays. Your line is now live.

Q - Matt Miksic {BIO 6990080 <GO>}

Hi. Thanks so much for taking the question. So I have just one on -- a follow-up on guidance. Joe, if you could talk a little bit about following up on some of the conservatism and maybe the bright spots, the China assumptions that you've made for procedure disruption and maybe VBP? If you could give us a sense of how long into '23 you expect that to go? And then what you assume for the STELARA LOE?

And then on this sort of or that's the conservative side, on the bright spots, I think you just kind of covered, I guess, the ortho trends. I understand you aim at this mid-single-digit range for performance, but you had a very, very strong back half in the U.S. And I'm just wondering does that kind of strength in ortho and the spine, for example, which is kind of well above sort of historical ranges. Does that kind of continue into '23? Or are we assuming that we're going to get some comp challenges there? Or how -- what sort of elements are contemplated in your guidance, that would be helpful? Thanks.

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

Sure. Good morning, Matt. First of all, I guess let me follow up to Terence's question with respect to how he positioned the conservatism. I probably did miss an opportunity to speak about some of the things that maybe could go better on our behalf. And some of that could be a quicker rebound in China, whether that be in both MedTech or Pharmaceuticals.

Right now, we're assuming there is some carryover effect from the COVID surges we saw in the fourth quarter. The teams on the ground seem to indicate that it's still persistent, but if that rebounded a little bit quicker.

I think also looking at the multiple myeloma portfolio, and the performance of CARVYKTI or TECVAYLI could be significant and opportunities or pockets for upside. We're obviously excited by the Abiomed acquisition and what that could possibly mean and bringing the capabilities of Johnson & Johnson, both in terms of scale and reach, presents some opportunity that maybe isn't in the current projections. So there are some opportunities for outperformance. Right now, we like where the number is at with respect to that.

China and VBP specifically, I would say that is a dynamic that's not really a new phenomenon for us. We had won a number of tenders at the end of 2021 that were persistent throughout 2022, and we continue to win tenders. And we think over time, that the volume and the opportunity to help many more patients, will be persistent with that. So we are -- it's part of the guidance that we see today that we've offered today, but it's not really much more pronounced in terms of the impact it has on the business versus what we've experienced already.

Operator

Thank you. Next question today is coming from Trung Huynh from Credit Suisse. Your line is now live.

Q - Trung Huynh {BIO 19379786 <GO>}

Hi guys. Thanks for the question, Trung Huynh from Credit Suisse. Just a question on STELARA erosion expectations. So I was hoping you can give us some thoughts about the cadence of biosimilar products that are going to be coming along this year. None are approved yet. But can we expect the first company to enter with exclusivity for six months, something we've seen with HUMIRA, and then the rest coming in '24? Or should we expect all the players to come at once? So any color on this patent answer would be helpful. Thanks.

A - Joaquin Duato {BIO 17056015 <GO>}

Thank you for the question. And it's difficult for us to comment on some of your topics there. There's no approved biosimilars at this time, and we are going to continue to monitor the situation. As we have commented, we expect the erosion curve of STELARA to be likely steeper than that of REMICADE, given the evolution of the biosimilar market and the fact that STELARA is a self-administered product as well as potentially to your point, potentially interchangeability in the label. So that's how we see the STELARA loss of exclusivity.

In 2023, when we think about the STELARA in the U.S., we see the sales of STELARA flat to declining, obviously, given the price pressures that will be offset also by continuous volume growth that we see in STELARA. So that's the perspective that we have for STELARA in 2023.

Overall, we have a very strong immunology franchise. I commented on TREMFYA before, the continuous progression in psoriasis and psoriatic arthritis, the readout of our ulcerative colitis and Crohn's disease studies, which is exciting. And also, in 2023, we may have some data from our Phase 2 study of our oral IL-23, which we think it's a very exciting underappreciated opportunity in our pipeline, too.

Operator

Thank you. Next question today is coming from Chris Shibutani from Goldman Sachs. Your line is now live.

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you very much. The multiple myeloma franchise, obviously, very central to your objective for 2025. Between the CAR-T sort of gradual launch that you have based upon supply and the bispecifics, can you talk about what that interplay has been since the approval and launch, and what you're expecting through the year in 2023? Thank you.

A - Joaquin Duato {BIO 17056015 <GO>}

So as far as the demand for CARVYKTI, we see very strong demand for CARVYKTI and also for TECVAYLI. There's a significant need for new therapies in this relapsed/refractory patient population. So the demand for the products, the physicians and patient adoption has been really strong. So that is really encouraging and portents the unmet medical need for these type of patients.

With CARVYKTI, we continue to scale our production capacity and expand our network of providers, and we are doing that in a phased approach. With TECVAYLI, we are off to a successful start and the early indications for this of the self-option are very, very positive, too, connected with the high unmet medical need that we see there.

Moving into 2023. Key elements of that would be, from a data perspective, they're reading CARTITUDE-4, which would give us the opportunity to move CARVYKTI into earlier lines of therapy. Also the filing of Talquetamab, which will give us another line of therapy, because some of the studies of Talquetamab are done in patients who have failed BCMA, either cell therapy or bispecifics and the continued data that we'll continue to provide to guide how to use this incredible portfolio in multiple myeloma.

Operator

Thank you. Next question --

A - Jessica Moore {BIO 22511603 <GO>}

Sorry. Sorry, Kevin, we have time for one last question.

Operator

Perfect. Our final question today is coming from Louise Chen from Cantor Fitzgerald. Your line is now live.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thank you for taking my question here. So I wanted to ask you about the timing of data readouts first half or second half and your expectations for a few products. First one is nipocalimab in rheumatoid arthritis. And then your oral IL-23. I saw that a trial was finished and what your next steps are here and when you might have some data?

And then lastly, just on your RYBREVANT and lazertinib, are you still expecting a potential interim readout for lung cancer here? Thank you.

A - Joaquin Duato {BIO 17056015 <GO>}

So regarding the main data readouts that you could expect in 2023, I mean, I commented already on CARTITUDE-4, which is a key one for us. Again, this is an event-driven study, so it's difficult for us to give you an exact time, Louise. Importantly, we have the potential for an interim analysis on the MARIPOSA study, which is the study of RYBREVANT plus lazertinib in frontline non-small cell lung cancer with EGFR mutations in this study versus Tagrisso. And this is an important study for us.

And also, we have the potential clinical data from the PAPILLON study, which is in frontline non-small cell lung cancer in combination with chemotherapy. So those are important ones in non-small cell lung cancer.

And then staying in oncology, we also have the data for the -- from the Phase 2 SunRISe-1 study of our TAR-200 platform, our drug-eluting device in non-muscle invasive bladder cancer. And we continue to work on our high-risk localized prostate cancer with ERLEADA. So that's key elements in our oncology side.

As far as nipocalimab, we are expecting data from our Phase 3 studies in RA, in rheumatoid arthritis, which I know has created significant attention from you and also in hemolytic disease of the fetus and the newborn. It will be towards the later part of the year. That's when you can expect those data to come up. And then keeping with important data reads next year, we'll also have the data reads in our two IBD studies, ulcerative colitis and Crohn's disease with TREMFYA.

Finally, important progress in our pipeline is that we will be starting our Phase 3 clinical program with Milvexian, our factor XI anticoagulant with our partners at Bristol-Myers Squibb. So I would say a very important year for us in terms of data reads that will also include our Phase 2 study of our oral IL-23. It's difficult for us to give you an exact time line, but we fully expect that to happen in 2023. So many important data reads for us that will showcase the good execution that we're having in our pipeline.

A - Jessica Moore {BIO 22511603 <GO>}

Thank you, Louise, and thanks to everyone for your questions and your continued interest in our company. We apologize to those that we couldn't get to because of time, but don't

hesitate to reach out to the Investor Relations team with any questions that you may have.

I would now like to turn it over to Joaquin for some brief closing remarks.

A - Joaquin Duato {BIO 17056015 <GO>}

So thank you, everyone, for your questions and interests in Johnson & Johnson. While we have highlighted some of the challenges that we have in the macro environment, we think that 2023 it's going to be another exciting year for innovation, for patients and you can rely on us on delivering strong financial performance for both the near and the long term. Thank you very much.

Operator

Thank you. This concludes today's Johnson & Johnson's Fourth Quarter 2022 Earnings Conference Call. You may now disconnect.