Q1 2023 Earnings Call

Company Participants

- Andrew White, Assistant General Counsel; Practice Group Lead Product Liability Litigation
- Ashley McEvoy, Executive Vice President, Worldwide Chairman, MedTech
- Jessica Moore, Vice President, Investor Relations
- Joseph J. Wolk, Executive Vice President, Chief Financial Officer

Other Participants

- Chris Schott, Analyst
- Danielle Antalffy, Analyst
- Geoff Meacham, Analyst
- Joshua Jennings, Analyst
- Larry Biegelsen, Analyst
- Louise Chen, Analyst
- Matt Miksic, Analyst
- Terence Flynn, Analyst

Presentation

Operator

Good morning, and welcome to Johnson & Johnson's First Quarter 2023 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 will now 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 the 2023 first quarter business results and full year financial outlook. Joining me on today's call are Joe Wolk, Executive Vice President, Chief Financial Officer; and Ashley McEvoy, Executive Vice President, Worldwide Chairman of MedTech. Unfortunately, Jennifer Taubert, Executive Vice President, Worldwide Chairman of Pharmaceuticals is not feeling well and is unable to join us today.

A few logistics before we get into the details. As a reminder, you can find additional materials, including today's presentation and associated schedules on the Investor Relations section of the Johnson & Johnson website at investor.jnj.com. Please note that today's meeting contains forward-looking statements regarding among other things the company's future operating and financial performance, product development, market position, and business strategy, and the anticipated separation of the company's Consumer Health business. 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 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. A description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2022 Form 10-K, which is available at investor.jnj.com and on the SEC's website. Additionally, several of the products and compounds discussed today are being developed in collaboration with strategic partners or licensed from other companies. This slide acknowledges those relationships.

Moving to today's agenda. I will review the first quarter sales and P&L results for the corporation and highlights related to the three segments. Joe will then provide additional business and financial commentary before sharing an overview of our cash position, capital allocation priorities, and updated guidance for 2023. The remaining time will be available for your questions. We anticipate the webcast will last approximately 60 minutes.

Now let's turn to our first quarter results. Worldwide sales were $24.7 billion for the first quarter of 2023, an increase of 5.6% versus the first quarter of 2022. Operational sales, which excludes the effect of translational currency increased 9% as currency had a negative impact of 3.4 points. In the US, sales increased 9.7%. In regions outside the US, our reported sales increased 1.8%. Operational sales outside the US increased 8.3% with currency negatively impacting our reported OUS results by 6.5 points. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 7.6% worldwide, 7.4% in the US, and 7.9% outside the US, with all three segments growing sequentially over the fourth quarter.

Turning now to earnings. For the quarter, net loss was $68 million and basic loss per share was $0.03 versus diluted earnings per share of $1.93 one year ago, primarily driven by the $6.9 billion charge related to the talc settlement proposal. Excluding after tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were $7.1 billion, and adjusted diluted earnings per share was $2.68, representing a decrease of 0.9% and an increase of 0.4% respectively, compared to the first quarter of 2022. On an operational basis adjusted diluted earnings per share increased 3%.

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 first quarter of 2022, and therefore exclude the impact of currency translation. Beginning with Consumer Health. Worldwide Consumer Health sales of $3.9 billion increased 7.4%, with an increase of 11.4% in the US and an increase of 4.4% outside the US. Worldwide operational sales increased 11.3% and outside the US operational sales increased 11.3%. Results were primarily driven by global strategic price increases across all

franchises. Volume growth in OTC was due to an exceptionally strong cough, cold and flu season most pronounced in Europe coupled with one-time retailer restocking, primarily in the US related to low inventory levels due to triple domec [ph] demand. Skin Health/Beauty delivered double-digit growth, driven by price actions lapping prior year supply constraints and current quarter restocking, as well as strong Neutrogena and Aveeno e-commerce and club channel performance, and new product innovations.

Moving on to our Pharmaceutical segment. Worldwide Pharmaceutical sales of $13.4 billion increased 4.2% with growth of 5.9% in the US and 2.4% outside of the US. Worldwide operational sales increased 7.2% and outside the US operational sales increased 8.6%. Excluding the COVID-19 vaccine sales, worldwide operational sales increased 4.9%, US operational sales increased 7.1% and outside the US operational sales increased 2.4%. Pharmaceutical growth excluding the COVID-19 vaccine was driven by our key brands and continued uptake in our recently launched products with eight assets delivering double-digit growth. We continued to drive strong sales growth for both DARZALEX and ERLEADA with increases of 25.7% and 40.3% respectively. STELARA grew 9.6%, driven by market growth and share gains in Crohn's disease and ulcerative colitis, with gains of 2.2 points and 4.8 points in the US respectively, partially offset by unfavorable patient mix and price. TREMFYA grew 11%, driven by market growth and share gains in psoriasis and psoriatic arthritis, with gains of 0.9 points and 2.1 points in the US, respectively, partially offset by unfavorable patient mix.

Turning to newly launched products. We are excited to disclose CARVYKTI and SPRAVATO sales for the first time this quarter. We continue to make progress on our thoughtful and safe launch of CARVYKTI and continued to expand access and reimbursement for SPRAVATO. Also we are encouraged by the early success of our launch of TECVAYLI, sales of which are included in other oncology. This sales growth was partially offset by the loss of exclusivity in REMICADE and ZYTIGA, along with a decrease in IMBRUVICA sales due to competitive pressures. IMBRUVICA maintains its market leadership position worldwide.

I will now turn your attention to the MedTech segment. Worldwide MedTech sales of $7.5 billion increased by 7.3% with growth of 16.6% in the US and a decline of 0.6% outside of the US. Worldwide operational sales increased 11% and outside the US operational sales increased 6.2%. Abiomed contributed 4.6% to operational growth. Excluding the impact of acquisition and divestitures, worldwide adjusted operational sales growth was 6.4%. Sales in the first quarter accelerated sequentially from Q4 for all four MedTech businesses, driven by global procedure growth, continued uptake of recently launched products, and commercial execution. As anticipated, in China, procedure volumes improved as the quarter progressed. Partially offsetting growth in the quarter was the impact of volume based procurement in China as well as supply constraints. The Interventional Solutions franchise delivered operational growth of 41.9%, which includes $324 million related to Abiomed. We are excited about the progress of the integration, to which Joe will provide additional context.

Excluding the impact of the acquisition, this franchise delivered another quarter of double-digit worldwide growth at 12.3%. As we continue to increase our reporting transparency, beginning this quarter, we are providing visibility to Electrophysiology sales. Electrophysiology continued to deliver double-digit sales growth in all regions with the

exception of Asia-Pacific, which reflects impacts related to volume-based procurement in China. Orthopedics operational growth of 5.1% reflects the strong procedure recovery and success of recently launched products, especially digital and enabling technologies driving pull-through sales in areas like hips and knees. Growth was partially offset by the impacts of volume based procurement in China primarily in hips and spine. Global growth of 9.3% in contact lens and other reflects continued penetration of our ACUVUE OASYS 1-Day family of products, including the recent launch of ACUVUE OASYS MAX 1-Day, strong commercial execution, and strategic price actions. Growth in contact lens and US surgical vision was tempered by continued supply challenges.

Now turning to our consolidated statement of earnings for the first 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 deleveraged by 150 basis points driven by one-time COVID-19 vaccine manufacturing exit-related costs in the Pharmaceutical business and commodity inflation and acquisition-related items in the MedTech business. Selling, marketing, and administrative margins leveraged by 60 basis points, driven by proactive management of costs given the current inflationary environment. We continue to invest strategically in research and development at competitive levels, investing 14.4% of sales this quarter. The $3.6 billion invested was a 2.9% increase versus the prior year. The other income and expense line was an expense of $7.2 billion in the first quarter of 2023 compared to net income of $100 million in the first quarter of 2022. The increase in expense was the result of the $6.9 billion charge related to the talc settlement proposal recorded in the first quarter of 2023 as previously disclosed.

Regarding taxes in the quarter, our effective tax rate was 90.8% versus 12.2% in the same period last year, primarily driven by the $6.9 billion accrual for the talc settlement proposal. Excluding special items, the effective tax rate was 16.5% versus 13.3% in the same period last year. I encourage you to review our upcoming first quarter 10-Q filing for additional details on specific tax matters. Lastly, I'll direct your attention to the boxed 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 the adjusted income before tax by segment. In the first quarter of 2023, our adjusted income before tax for the enterprise, as a percentage of sales, decreased from 35.1% to 34.2%. Pharmaceutical margins declined from 44.1% to 43.2%, driven primarily by mix, partially offset by proactive management of costs. MedTech margins remained flat at 27%, driven primarily by inflationary impacts, offset by proactive management of costs. Finally, Consumer Health margins improved from 22.1% to 22.3%, driven primarily by strategic price actions, partially offset by input cost inflation.

This concludes the sales and earnings portion of the Johnson & Johnson first quarter 2023 results. I am now pleased to turn the call over to Joe Wolk. Joe?

Joseph J. Wolk {BIO 19812977 <GO>}

Thank you, Jess, and thank you all for joining today's call. We are pleased to report another quarter of strong operational performance across our business. The results reflect

the strength and versatility of Johnson & Johnson, and our commitment to improving healthcare outcomes around the world.

2023 has many important catalysts that can drive meaningful near and long-term value for Johnson & Johnson's shareholders. We remained focused on the successful separation of our Consumer Health business Kenvue, which will position both companies to be more agile, focused and competitive. We are also expecting a number of pipeline advancements that will provide increased confidence in our Pharmaceutical and MedTech businesses. Our Pharmaceutical segment delivered a strong first quarter. Growth from our Pharmaceutical business continues to be driven by key assets in our existing portfolio, including DARZALEX to TREMFYA, ERLEADA, INVEGA SUSTENNA, and UPTRAVI as well as uptake from new launches, such as SPRAVATO, CARVYKTI and TECVAYLI.

2023 is an important year of scientific innovation for our Pharmaceutical business. And in Q1, we announced that CARVYKTI, our BCMA cell therapy met its primary endpoint in the CARTITUDE-4 study, a Phase 3 trial in multiple myeloma patients who have received one to three prior lines of therapy. We look forward to presenting these results in an upcoming major medical meeting. Additionally, our partners at Protagonist Therapeutics announced positive topline results from the Phase 2b FRONTIER 1 study of our oral IL-23 in patients with moderate to severe plaque psoriasis. We look forward to sharing this data and future development plans at an upcoming medical meeting.

Finally, as we continually review our portfolio to prioritize the most transformational assets for ongoing investment and an assessment of the RSV vaccine landscape, the company made the decision to discontinue its Investigational RSV adult vaccine program. This decision is part of a broader effort to make strategic choices for our pipeline and R&D investments to focus on medicines with the greatest potential benefit to patients.

Looking at the rest of the year, we expect important data from key pipeline assets such as Nipocalimab and TREMFYA as well as the potential approval of Talquetamab. Importantly, I want to mention two additional highlights. First, the MARIPOSA study of RYBREVANT plus lazertinib in frontline non-small cell lung cancer remains on-track with the potential for final analysis later this year. We are also excited to present data from the SunRISe-1 study of TAR-200 in muscle-invasive bladder cancer at the American Urological Association's Annual Meeting this month, which demonstrated a promising complete response and safety profile.

Regarding our Pharmaceutical business, I'd like to reiterate some comments I recently made at the Cowen Investor Conference in March, related to the strengthening of the US dollar and the impact on the 2025 Pharmaceutical sales goal the team put forth during the 2021 Investor Day. While we don't speculate on currency, based on the current rates, the 2025 sales target of $60 billion is approximately $57 billion on a constant-currency basis. In 2022 alone, FX had a negative impact of roughly $3 billion in Pharmaceuticals. While that is the math, qualitatively, since 2021, a number of things have changed in our portfolio. On the plus side, we've seen acceleration of some current and potential upcoming launches like TECVAYLI and Talquetamab. But to be balanced we've also experienced competitive pressure on IMBRUVICA above what was anticipated in 2021.

So many push and pulls, but we are striving to obtain our operational goals. We are confident in our ability to exceed 2025 estimates the Street has out there today of approximately $54 billion. MedTech delivered a strong quarter of sales growth. We continued to advance key pipeline programs. For example, within our Electrophysiology business, we reached a few milestones this quarter related to our Pulsed Field Ablation pipeline programs, including the European clinical study inspIRE, which achieved early success by meeting both primary safety and efficacy endpoints. Additionally, we announced completion of the first procedures in the European SmartfIRE clinical study, evaluating the safety and effectiveness of our investigational dual-energy catheter, which combines both pulsed field and radio frequency ablation capabilities.

As you know, we continue to prioritize investment in high-growth areas. As demonstrated by our acquisition of Abiomed, which closed this past December. With Abiomed, MedTech now has 12 platforms with over $1 billion in annual sales. While it is still early days, we are pleased with the integration and performance of Abiomed. Patient utilization of Abiomed technologies grew mid-to-high teens in both Europe and the United States and over 30% in Japan. We continue to see strong adoption of newer technologies such as Impella 5.5 and we achieved record quarterly enrollment in both the STEMI DTU and PROTECT IV pivotal trials as we continue to advance efforts in pursuit of Class One guidelines. For perspective, operational sales growth compared to the same quarter last year reported by Abiomed as a standalone company was 22%.

In orthopedics, just this month, we obtained CE Mark for the VELYS Robotic assisted solution, positioning us to expand our international footprint with this differentiated solution in total knee. Finally, the MedTech team is excited by the progress being made in regards to the Ottava general surgery robotic solution. And we remain on track to share more information in the second half of this year. Our Consumer Health business delivered double-digit first quarter sales growth driven by strategic price actions, strong demand, and some stock replenishment. We will remain on track to complete the separation of this business in 2023, assuming accommodative market conditions. Since the start of the year, we have been operating our Consumer Health business as a company within a company, and continue to update our Form S1 filing with the Securities and Exchange Commission, giving us the opportunity to pursue an initial public offering as a potential first step in the separation. Standup cost and stranded costs remain consistent with what we have stated previously, with an active program well underway to reduce the stranded costs.

Turning to notable enterprise events. I'd like to briefly touch on LTLs' refiling for bankruptcy on April 4th, neither LTLs' original filing nor this refiling is an acknowledgment of wrongdoing, nor an indication that the company has changed its long-standing position that its talcum powder products are safe. Our goal continues to be for an equitable and efficient resolution of the cosmetic talc litigation against the company, and we believe this refiling represents progress towards that goal. As a reminder, LTLs' bankruptcy filing will not have an impact upon the Kenvue separation and the talc liabilities in the United States and Canada will remain with Johnson & Johnson. As part of the refiling we have proposed a reorganization plan that has significant support from claimants and includes payment of $8.9 billion in present value over a 25-year period. LTL will continue to work through the process set forth by the bankruptcy court and expects to present the reorganization plan to the court in mid May.

Our capital allocation priorities remain consistent. And in 2022, we successfully executed against all pillars. R&D investment remains our number one priority and driver of long-term growth and value creation. We know the value our investors place on our dividend and we were pleased to announce this morning that our Board of Directors has authorized a 5.3% increase, marking our 61st consecutive year of dividend increases. In addition, we continuously evaluate strategic business development opportunities that enable Johnson & Johnson to create value for patients, customers and shareholders.

Our final priority is share repurchase programs when appropriate. In fact, this past quarter, we completed the $5 billion share repurchase program announced late last year. We are confident in our strong financial position, including our AAA-rated balance sheet and our ability to deploy capital across all strategic priorities. We believe this strength differentiates Johnson & Johnson and enables us to pull the appropriate levers to set us up for long-term success.

Moving on to our full year 2023 guidance for the enterprise. Based on our strong start to the year, we are pleased to raise our guidance. We now expect operational sales growth for the full year 2023, up 1 percentage point in the range of 5.5% to 6.5% or up $1 billion in a range of $97.9 billion to $98.9 billion on a constant-currency basis. And adjusted operational sales growth up 1 percentage point in the range of 4.5% to 5.5%. Our sales guidance continues to exclude contribution from the COVID-19 vaccine. As you know we don't speculate on future currency movements. Last quarter, we noted that we utilized the euro spot rate relative to the US dollar at $1.08. The euro spot rate as of late last week was $1.10. We continue to estimate there would be minimal impact from foreign currency translation on reported sales for the year as the dollar has strengthened versus other select currencies.

We are maintaining the guidance we provided in January for our adjusted pretax operating margin, other income and expense, interest expense, and tax-rate. We are also increasing our adjusted earnings per share guidance by $0.05 per share and tightening the range to $10.50 to $10.60 or $10.55 at the midpoint on a constant-currency basis, reflecting operational or constant-currency growth of approximately 3.5% to 4.5%, or 4% at the midpoint. While not predicting the impact of currency movements, assuming recent exchange rates, I previously referenced, our reported adjusted earnings per share for the year would be favorably impacted by approximately $0.05 per share. This favorable currency impact coupled with our strong operational outlook results in an increase to our reported adjusted earnings per share for the year, by $0.10 per share and tightening the range to $10.60 to $10.70 or $10.65 at the midpoint, reflecting growth of approximately 4.5% to 5.5% or 5% at the midpoint.

While we do not provide guidance by segment or on a quarterly basis, I'd like to provide some qualitative considerations for your modeling. In Pharmaceuticals, we maintain our expectation of delivering above-market growth in 2023, driven by key assets and continued uptake of our newly launched products. This growth considers the potential composition of matter patent expiry of STELARA, which we currently assume will occur in late 2023 in the United States. Further, we continue to expect 2023 impact from other post LOE products including REMICADE, ZYTIGA, and XEPLION, as well as increased austerity measures across Europe.

Regarding our COVID-19 vaccine, we do not anticipate material sales beyond that, which were recorded in the first quarter as our contractual commitments are complete. In MedTech, we expect continued competitive growth fueled by increased procedures, and commercial uptake of recently launched products. We anticipate relatively stable procedure volumes and healthcare staffing levels for the remainder of the year with normal seasonality. Regarding quarterly phasing, given the strength of our first quarter results, we now expect relatively consistent performance throughout the year from our Pharmaceutical and MedTech businesses. When modeling Consumer Health growth rates in 2023, it is important to take into consideration prior year comparisons as well as the robust cough, cold and flu season and the one-time restocking that occurred in the first quarter. As a reminder, the first half of 2022 was impacted by supply constraints.

A few brief announcements before we take your questions. Continuing our efforts to increase our transparency and assist with your modeling, we are planning to post a patent table, including US pharmaceutical patents to our investor website in the quarter. In addition, please mark your calendars for December 5th as we will be hosting an Enterprise Business Review at the New York Stock Exchange, focused on the new Johnson & Johnson highlighting both our Pharmaceutical and MedTech businesses. We will provide additional details about the event in the coming months.

Before we turn to your questions, let me state how proud we are regarding our team's continued hard work and unwavering commitment. Our sights are set on the future, focused on delivering competitive growth for the new Johnson & Johnson. We are confident that our current plans position us for near-term success, long-term growth and value creation for our shareholders. I'll now turn the discussion to the Q&A portion of the call. Kevin, can you please provide instructions for those wishing to ask a question?

Questions And Answers

Operator

Certainly. (Operator Instructions). Our first question is coming from Chris Schott from JPMorgan. Your line is now live.

Q - Chris Schott {BIO 6299911 <GO>}

Great, thanks so much. Just having a two-parter on the Pharma side. First on the $57 billion target for Pharma. I think your comments are very clear in terms of your confidence of exceeding consensus of $54 billion. Are you still confident though in that $57 billion target as we think about kind of the pushes and pulls that you just outlined there? And then maybe just a specific question on RYBREVANT. Just want to make sure the comments correctly there. I think you mentioned there is a final analysis of MARIPOSA later this year. Does that mean the interim has passed at this point. I mean just put some context of what you think you need to show in that study to dislodge share from Tagrisso? Thank you.

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

Great. Thanks, Chris. Appreciate the questions. So first, with respect to the $57 billion. I wanted to make sure that I was clear on the record since I had the opportunity to do that

about a month ago that everybody understood the message around the math component of it. We feel very good about our pipeline, we're continuing to work towards some really good data that came out this quarter around multiple myeloma, MARIPOSA, which we'll talk about in a minute. We continue to see some uptake of some of our newer products. And the goal is still that for us. But you'll have a much better and much more informed and probably timely update once we hit the December 5th meeting at the New York Stock Exchange, so stay posted on that. What I do feel comfortable though, is that we're moving certainly in the right direction. I wanted to take out the unclarity that maybe was created by currency, and the dramatic movements that occurred over the last 18 months.

So for MARIPOSA, I would say, the study of RYBREVANT and lazertinib in frontline non-small cell lung cancer versus Tagrisso remains very much on track, it's an event-driven trial. So there is the potential for final analysis later this year, which is actually two quarters ahead than what we had originally expected -- was originally expected to be second quarter of 2024. The accrual to the study, we can say is very rapid as there was tremendous interest and the interim analysis was specified in the protocol with a significantly limited follow-up and supported the continuation of the study. We were blinded to that interim analysis. And as far as what we need to show, I think we're just going to let the science dictate, let the trial results come out. But we feel pretty comfortable where we're at now, and pleased with how quickly the trial enrolled.

Operator

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

Q - Matt Miksic {BIO 6990080 <GO>}

Great. Thanks so much. I have, if I could, just one question on knees, and a quick follow-up, kind of a general strategy question on STELARA and Pharma, if I could. So, on knees, in the US, obviously very strong growth. And just wondering if you could -- and I think expectations have been strong throughout Q1. I just was wondering if you could maybe give a little bit of color as to what's driving that strength, how much of that is maybe the robot? How much of that is, I don't know, other product launches. And then one quick follow-up on Pharma, if I may.

A - Jessica Moore {BIO 22511603 <GO>}

Matt, now thank you for the question. And before I turn it to Joe on STELARA, it's really nice to see 12% growth in the US for knees, we haven't seen that in a while. But before I get into specifically knees, maybe just a quick frame on like the quarter. Obviously first the industry, I think continues to remain strong and growing, procedures are well in recovery mode. It's awesome to see at 11% operational performance and 6.4 adjusted ops for the first quarter. It was our first quarter with Abiomed. So if you look at them, like prior periods as a standalone of 22% growth. But I think when I look at all of the math, if you will, for the quarter, what I'm most pleased about is really the balanced growth. And we had our BWI business up 13%, our Global Vision up 8%, and our US business, our largest market, growing north of 8%, really fueled by ortho performance, up 6%, as well as surgery up 6%.

And you hear us talk about these 12 $1 billion platforms, but six of those grew double-digit in the United States in the quarter. EMEA was strong and Asia was a little bit softer again

by China, obviously Jan and Feb was a bit softer. We were encouraged, with March, procedures recovered in March. But I would call it three specific innovations and then I'll go deeper into knees. One is our Pulsed Field Ablation. So we're very pleased with the data that -- and AFib that it's promising, we have four clinical trials ongoing, two out of the four, we've completed enrollment and we shared the data from the inspIRE trial where we met the primary endpoint for both safety and efficacy.

Our Abiomed, as we've talked about, we're about 90 days, they continue to advance the innovation pipeline, they're in clinic in four clinical trials to expand new products and to expand indications to get Class One designation. And last, I would say, Matt, we are in all things, robotics. So let's talk about VELYS, we just received CE Mark positioning it for expansion to more global markets, right now we're in five. But I'm pleased to say that it's now the fastest-growing knee robotic system in the United States. We've completed over 20,000 procedures. And we're taking a systems approach to our business in hips to shoulders and to spine. Our MONARCH platform is the first and only multi-specialty flexible robotic solution with FDA clearance in bronchoscopy as well as endourology. We've completed 25,000 procedures, and are in clinic right now combining the MONARCH endoluminal navigation with ablation treatment technology of NeuWave. And just recently, in February, we were the first patient received robotic-assisted removal of kidney stone, we're trying to get a higher kidney stone clearance rate than the standard-of-care.

And last, as we talked about our team in Ottava is really progressing significantly really looking forward to the back half of the year update with the team. So VELYS is really a combination of having access to cementless both on fixed bearing and rotating platform. Revision, our new introduction of the Medial Stabilized Knees. And most importantly, not just coupled with the robotic system of VELYS, but coupled with the most modern knee implant in the world. Thank you.

Q - Matt Miksic {BIO 6990080 <GO>}

That was a fantastic overview. And thanks for that and congrats on all the innovation and the significant change in momentum across all those businesses. Just as a quick question I guess I had on Pharma was, I mean, it's a big question, and I think it's on a lot of investors minds is, you turned into the end of the year and you think about STELARA and you think about sort of the actions that you expect to take whether organic in the pipeline that you have and as it comes through and some of these new products launch and get bigger and then strategic. If you could maybe give a sense of what are your goals over the next 12, 18 months as you sort of weather that LOE and what sort of mix of actions should we expect you to take to kind of manage through that? Thanks.

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

Sure, thanks, Matt, for the question. There is a lot to maybe unpack possibly there. But let me first start with our base assumption in the guidance, which has the underlying assumption that in the US, STELARA will lose exclusivity in the late third quarter, early fourth quarter of this year. And that's kind of the assumption that we're going on. What I would say is that somewhat fluid. At this point there are currently no biosimilars approved. In terms of our planning, we are expecting --despite learning a lot over the last few years with REMICADE, we're expecting a steeper erosion curve than what was experienced

there because this is a self-administered subcutaneous product. There'll be multiple competitors on the market at some point and they may have the affordability of interchangeability. But we may remain committed to growing through the patent expiration, one of the great things about our portfolio, whether we're talking within pharmaceuticals or across the broader business, we've got 30 products or platforms that generate over $1 billion in annual revenue. So we're not dependent on one product the way others may have.

In terms of unpacking your question maybe a little bit further, I got the sense you were heading towards M&A. Certainly we always remain vigilant and look at a number of opportunities, making sure there is strategic fit before we act. If there's strategic fit, then we're going to look to deploy capital in a way that returns to shareholders to compensate them quite frankly for the risk that we're bearing on their behalf. But we're not going to do anything out of desperation based on the breadth of our product portfolio. We are lucky and that we've got a strong balance sheet to do whatever we'd like. But we want to make sure it makes good strategic and financial sense.

So that's probably the best way to answer that. I know, Jennifer and the team are very committed to growing through the loss of STELARA, whenever that may occur. And the pipeline data that we're generating now as well as really the early success we're having in some of these newer products, I think positions us well to meet those goals.

Operator

Thank you. Next 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 for taking the questions. Maybe a two part one for me as well. Thanks for the update on the talc litigation, Joe. I was just wondering if you could comment at all about any additional progress towards that 75% threshold. Specifically the denominator and kind of where that's shaking out. And then on the oral IL-23 program there, just wondering if you can confirm if you're going to advance into Phase 3 and where that drug might be positioned ultimately in the treatment paradigm based on the data you guys have seen thus far? Thank you.

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

Great, thanks for the question, Terence. Let me start with the second one first. With respect to the oral IL-23 where our partners at Protagonist announced some very encouraging data out of the Phase 2 FRONTIER 1 study. So we do plan to present data from various preclinical and clinical studies on this compound at medical conferences beginning in the second quarter of this year. We believe this could be very much an important and under-appreciated asset within our immunology portfolio.

With respect to the litigation, we thought this could come up as a question. So we're very pleased to have Andrew White, our Assistant General Counsel here with us today. But let me say a little -- maybe a couple of qualitative things from my seat, and then we can have

Andrew, either clean it up or give you some more specifics. But it is important to note that these cases, and we stand by the safety of the product. There is decades of independent research conducted by reputable government agencies, patient advocacy groups as well as academic institutions that support the safety of cosmetic talc. Furthermore, it was only two years ago in a (inaudible) hearing where the judge really restricted the use of many of the claims, supposedly scientific claims that were being made by the plaintiffs attorneys in this case, and many pundits even classified it as junk science at that point.

Here we have the support of 60,000 to 70,000 claimants that would vote for the proposal as it's currently presented. But curiously, we've got a small number of plaintiffs attorneys who don't even want to give their claimants the right to vote. So we're simply asking that they get the right to vote. Now from my Chair, as CFO, it is unfortunate that we've got to put dollars towards, quite frankly, baseless scientific claims. However, litigation is inherently costly when it's protracted. And it's also inherently uncertain and what proposal really aims to bring certainty in a very efficient manner for all really involved, something that would otherwise take probably decades to resolve.

So, let me turn it over to Andrew in terms of maybe any specifics that you can add.

A - Andrew White {BIO 15839252 <GO>}

Yeah, good morning, Terence, and thanks Joe. As Joe mentioned, we are very confident in the position that we stand today in terms of support for the plan. We have well over 60,000 that have expressed a desire to vote for this plan. And the expectation is that we will move forward with a reorganization plan to present to the court within the next 30 days. And hope to quickly move to a vote. And we believe once we put that plan out for a vote we'll gain even more support from a small, but I would say, vocal minority of attorneys. So we believe we're going to reach that 75% threshold. And look forward to getting that plant out to a vote.

Q - Terence Flynn {BIO 15030404 <GO>}

Thank you, Andrew.

Operator

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

Q - Larry Biegelsen {BIO 7539249 <GO>}

Good morning, thanks for taking the question. Joe, two for you on the guidance. I heard you on CNBC this morning and you said you turned from cautious in January to optimistic now about 2023. So I was curious about two things, one on the guidance, you previously expected second half to be better than the first half in MedTech and Pharma because of the growth drivers you outlined on the Q4 call. So what changed there? Why do you expect growth to be more stable through the year?

And second, Joe, on the margins. Q1 was up about 60 basis points year-over-year in Q1 on the operating margin, but you expect -- and you expect gross margins to improve through

2023, as inflation wanes. So why would the operating margin be flat for the full year? Thanks for taking the questions.

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

Yeah, thanks, Larry. Well, first I do want to correct the record a little bit on here, responsibly was in front of both cautious as well as optimistic. So we've moved from responsibly cautious to responsibly optimistic. Why do I say that? It's because we did see some dynamics within our P&L, the team's great ability to really manage our resources effectively with the backdrop of really a company separation that could lend itself to some stranded costs. We're managing those extremely well. There is still inflation within the P&L. I don't think we should say that it's now behind us. We have a good data point with respect to where we landed Q1, very pleased with the first quarter results and the strength of that. And why we may be moved from a little bit more of a consistent approach throughout the year versus a stronger second half from a first half is really around the first quarter results. So in terms of pharmaceutical pricing, it was still unfavorable, as you might expect, with respect to Pharmaceutical, but not as unfavorable as we anticipated.

And then maybe Ashley, can talk here too. When we came out in January, there was -- the pandemic was kind of full blown in the Asia-Pacific region. And we did see a very positive data point in March with respect to China, specifically. I don't know, Ashley, anything to add there?

A - Ashley McEvoy {BIO 20108895 <GO>}

Yeah, no, Larry, what I would share is, you know, I would say that procedures are trending well above all pre-COVID levels. It was up until December with the exception of China. China in December, January, and February were well below pre-COVID levels and January trending like down 50%. So I am encouraged to see in March that they're back up, they're back up a little bit ahead of pre-COVID levels. And so that's why we're kind of rebalancing the year. I think that we're going to have more stability throughout the balance to go year versus earlier thinking that we will be having a stronger second half versus first half.

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

Yeah, and Larry with respect to operating margins, it's still very early in the year, it's still only April. If we have the opportunity to manage these macroeconomic headwinds that we entered the year with and then maybe provide the flexibility for further investment for great opportunities down the road that fortify the future, we'll certainly look to do that. You guys know us well enough that if we don't find those meaningful opportunities, we'll probably have the opportunity to take up guidance down the road. But my first preference would be to deploy that in investment opportunities that secure both MedTech and Pharmaceuticals for the future.

Operator

Thank you. Next 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. So I had a Pharmaceutical question for you, you've built a really strong oncology franchise and what are some unique approaches you think you can take to create combos and regimens that might not be available to other companies and are there any additional areas in oncology that you would like to be involved in that you were not now currently involved in? Thank you.

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

Yeah, thanks for the question, Louise. So, I think we're always looking at combinations, the one that's most prolific at this point now is certainly the one for non-small cell lung cancer, which really impacts about 20% of lung cancer that's diagnosed today with a certain mutation. We're very much looking-forward to the data that may read out later this year with respect to that. In terms of new areas, I know that the teams are looking very much, I would say, some of the new areas that we're coming into now would be some of the bispecific antibodies with respect to multiple myeloma, rounding out that portfolio. We know how, I want to say, almost personalized that disease is. And having multiple options for treatments and maybe even someday potentially cures certainly lends itself with the multiple options that we have.

We're going to be focused on multiple myeloma obviously, prostate cancer, lung cancer, we're very excited about some of the data that could read out on what I'll call the MedTech Pharma combo of -- for bladder cancer and with the TARIS device with the drug-eluting BALVERSA. So there's a multiple place within oncology, which is now our biggest franchise with immunology in terms of sales contribution to the Pharmaceutical success.

A - Jessica Moore {BIO 22511603 <GO>}

The only aspect that I'd add Louise is, as you know, our multiple myeloma platform is extremely strong and we're looking at multiple clinical trials about not cannibalizing those products, but rather looking at combination treatments, as well as sequences of those products between TECVAYLI, DARZALEX, CARVYKTI, and then hopefully our soon-to-be approved Talquetamab.

Operator

Thank you. Next question is coming from Josh Jennings from TD Cowen. Your line is now live.

Q - Joshua Jennings {BIO 16451037 <GO>}

Hi, good morning. Thanks for taking the questions. Had a question for Ashley just on the VARIPULSE PFA platform. I was hoping to just get an update on commercial timelines, anything you can share just in terms of CE Mark and then FDA approvals. And then maybe digging a little bit deeper just helping us understand, I mean our expectation is that, VARIPULSE will be third to market in the United States. But what percentage of Biosense Webster's revenues are levered to the ablation catheter segment within the EP industry? And then what drives your optimism that VARIPULSE will maintain -- be able to maintain Biosense's leadership position in the ablation catheter segment? Thanks for taking the questions.

A - Ashley McEvoy {BIO 20108895 <GO>}

Yeah, thank you, Josh. Listen, it's a really important space and we always say, at J&J we're always trying to intercept disease before it advances. And this is one example of managing atrial fibrillation, which is the leading cause of cardiac arrhythmia and unmanaged that could lead to a stroke. So what gives us confidence that we can lead and compete and have a source of differentiation, I would say, kind of the following, I'd say, one, we have a 20-year track record of being a world leader in cardiac ablation. We have 5,000 plus installed base. We do see the promise of PFA. We are actively engaged in four clinical trials. Two of those trials have completed enrollment, the European and the inspIRE as well as the US, we've shared data in February in the International Afib Symposium that we met the primary endpoint.

And I would tell you, our approach is really what's differentiated, Josh. We're kind of leveraging the deep expertise and the insights into the various ablation strategies. So we have a portfolio of PFA catheters, which are fully integrated into the (inaudible) sensory system and it's powered by kind of our true pulse generator. So we really underscore the importance of how important mapping is in Vision to know where operators are and what they're doing in the heart anatomy. And kind of the bottom line for us is, we actually think access to radio-frequency, which has like 20-plus years of safety and efficacy, coupled with the newer generation of PFA is really going to be the winning combo for electrophysiologists. It's really why we are in clinic right now with the dual-energy solution, because we think it could offer the relative safety of the PFA. And really the proven durability of radio frequency. So we're not issuing specific timelines. But you can know that we've completed enrollment in two of those four clinical trials.

Operator

Thank you. Next question is coming from Geoff Meacham from Bank of America. Your line is now live.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning everyone, and thanks for the question. Have two related ones in Pharma. So on IMBRUVICA, how do you guys view the impact from the indication withdrawal. And is there a risk of other non-CLL indications like follicular being pulled? And then related to your hematology business, do you guys have a status update on CARVYKTI supply after what was this quarter a really good quarter? Thank you.

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

Yeah, thanks for the question, Geoff. See, with respect to IMBRUVICA, I would say that, we're not expecting any more withdrawals at this point. It is obviously based on our performance, encountering competitive pressures. But it's really the competition that's been the biggest driver in terms of the performance that we're not seeing there quite frankly. But it's -- the withdrawal is a very small part of our business to begin with, but we don't anticipate other withdrawals at this point.

With respect to your second question and supply on CARVYKTI, I would say that, you probably did read the announcement recently that we did sign on for additional capacity

to scale up some production and increase availability moving forward. The manufacturing is ramping up to supply markets, we have really tremendous demand given some of the data that supports this the CARVYKTI, the CARTI [ph] for Johnson & Johnson. And we're committed to doing everything we can to accelerate our manufacturing abilities to meet that demand. We work in our facility and again continues to progress, and it will serve as an important part of our supply chain network for not just this, but other shelf therapies in the future.

A - Jessica Moore {BIO 22511603 <GO>}

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

Operator

Thank you. Our final question today is coming from Danielle Antalffy from UBS. Your line is now live.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hey, good morning everyone. Thanks so much for taking the question. And it's good to be back talking to you all. Ashley, just a quick question for you on orthopedics number, a very good quarter. I was just wondering, I know this is really hard to parse out, but what is -- from your sense, what is backlog work down versus real underlying growth and/or more specific to J&J share gain, anything you can say on how to think about what's happening in the orthopedics market right now in the US? Thanks so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

No, thank you, Danielle. It's great to hear your voice. Listen, it's really a combination of both, procedures are accelerating, particularly like even as recently as March in China, as an example. US working through some of the backlogs. So I do think that the market is in our favor. But at the same time, I have to give huge acknowledgment to the orthopedics team who has really built a very differentiated portfolio, and they are now participating in the fastest growing segments within the orthopedics category. So if the category is going three to four, they're competing in categories -- in areas that are high single digit. And what are those areas, it's all things robotics, it's around new sites of care like ASCs, it's around extremities and very pleased with our recent acquisition of CrossRoads of foot and ankle. It's what we talked about around Revision Knees and Cementless Knees. Those are really the faster growing segments in orthopedics. And we are well-positioned to take advantage of that demand. Thank you for the question.

A - Jessica Moore {BIO 22511603 <GO>}

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

Operator

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