Q1 2022 Earnings Call

Company Participants

- Ashley McEvoy, Executive Vice President, Worldwide Chairman, MedTech
- Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals
- Jessica Moore, Vice President, Investor Relations
- Joseph J. Wolk, Executive Vice President and Chief Financial Officer
- Thibaut Mongon, Executive Vice President, Worldwide Chairman, Consumer Health

Other Participants

- Chris Schott, Analyst
- Chris Shibutani, Analyst
- Danielle Antalffy, Analyst
- Geoff Meacham, Analyst
- Joanne Wuensch, Analyst
- Josh 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 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.

Joseph J. Wolk {BIO 19812977 <GO>}

Good morning. This is Joe Wolk, Executive Vice President and Chief Financial Officer of Johnson & Johnson. Thank you for joining us today to discuss our Company's First Quarter 2022 Financial Results and Full Year 2022 Outlook. While many things have changed in the world since our last call much has stayed the same for Johnson & Johnson.

We continue to deliver reliable growth and generate meaningful free cash flow enabling us to invest and advance our pipeline, increase our dividend for the 60th consecutive year and continue to make a positive impact across the landscape of healthcare. It is however important to take a few moments to recognize the current events that are impacting the world we're living in.

Today, while we're also managing through the global pandemic as evidenced by the current surge of cases in China, we also acknowledge the increasing hardship brought on by the war in Ukraine. We remain focused on the safety of our employees and their families, guided by our credo and grounded in our purpose. Our hearts are with all those affected by these crises and hope for a rapid resolution to both.

Now, I'd like to turn the program over to Jessica Moore, Vice President, Investor Relations, to take you through our Q1 results.

Jessica Moore {BIO 16638328 <GO>}

Thank you, Joe. A few logistics before we get into the details. This review is being made available via webcast accessible through the Investor Relations section of the Johnson & Johnson website at investor.jnj.com, where you can also find additional materials including today's presentation and associated schedules.

Please note that today's presentation includes forward-looking statements regarding among other things, our future operating and financial performance and the anticipated separation of the Company's Consumer Health business. We encourage you to review the cautionary statement included in today's presentation, which identifies certain risks and factors 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 and other marketplace dynamics. This means that results could change at anytime and the contemplated impact of COVID-19 on the Company's business results and outlook is a best estimate based on the information available as of today's date.

A further description of these risks, uncertainties and other factors can be found in our SEC filings, including our 2021 Form 10-K, along with reconciliations of the non-GAAP financial measures utilized for today's discussion to the most comparable GAAP measures. These materials are also available at investor.jnj.com. 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 the three segments. Following, Joe will provide additional business and financial commentary before sharing an overview of our cash position, our capital allocation priorities and updated guidance for 2022. The remaining time will be available for your questions. During the Q&A portion of the call, Joe will be joined by Ashley McEvoy, Executive Vice President and Worldwide Chair, MedTech; Thibaut Mongon, Executive Vice President and Worldwide Chair, Consumer Health; and Jennifer Taubert, Executive Vice President and Worldwide Chair, Pharmaceuticals.

We have heard your feedback and are implementing a few enhancements this quarter. First, we are now providing select earlier phase clinical trial information on our pharmaceutical pipeline to streamline your data collection efforts from clinicaltrials.gov. Second, rather than sharing detailed business performance commentary on each part of the business, I will summarize significant business drivers leaving more time for Q&A. You can find additional detailed segment commentary in our earnings presentation. We anticipate the webcast will last up to 60 minutes.

Now let's move to the first quarter results. Worldwide sales were $23.4 billion for the first quarter of 2022, an increase of 5% versus the first quarter of 2021. Operational sales growth, which excludes the effect of translational currency, increased 7.7% as currency had a negative impact of 2.7 points. In the U.S., sales increased 2.7%. In regions outside the U.S., our reported growth was 7.2%. Operational sales growth outside the U.S. was 12.6% with currency negatively impacting our reported OUS results by 5.4% points. Excluding the net impact of acquisition and divestitures, adjusted operational sales growth was 7.9% worldwide, 2.8% in the U.S. and 12.9% outside the U.S.

Turning now to earnings. For the quarter net earnings were $5.1 billion and diluted earnings per share was $1.93 versus diluted earnings per share of $2.32 a year ago. 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 $2.67, representing increases of 3% and 3.1% respectively compared to the first quarter of 2021. On an operational basis, adjusted diluted earnings per share increased 6.2%.

I will now comment on business segment sales performance highlights. Unless otherwise stated percentages quoted represent the operational sales change in comparison to the first quarter of 2021 and therefore exclude the impact of currency translation. Beginning in 2022 certain over-the-counter products previously reported under the Pharmaceutical segment have been re-classed to consumer health. These products represent roughly $100 million of sales per quarter. Please refer to the supplemental sales schedules for prior year restatements. Also as stated in our 2021 10-K effective January our Medical Devices segment is now referred to as MedTech.

Beginning with Consumer Health. Worldwide Consumer Health sales of $3.6 billion increased 0.8% with the decline of 3.4% in the U.S. and growth of 4.1% outside the U.S. Excluding the impact of acquisitions and divestitures worldwide growth was 1.6%. Consumer Health was negatively impacted by industry wide external supply constraints, primarily due to ingredients and packaging availability as well as labor shortages largely reflected in our skin health and beauty business, worth approximately 280 basis points worldwide, and 500 basis points in the U.S. Adjusting for these constraints, Consumer Health delivered solid results, primarily due to above market growth in OTC driven by increased TYLENOL, MOTRIN and upper respiratory product sales.

Moving on to our Pharmaceutical segment. Worldwide Pharmaceutical sales of $12.9 billion increased 9.3% with growth of 2.9% in the U.S. and 16.7% outside of the U.S. Base pharmaceutical growth was driven by our broad portfolio of products, paired with strong commercial execution, enabling us to deliver above market adjusted operational sales

growth including six assets with double-digit growth in the quarter. Base business growth was due to strength from DARZALEX, TREMFYA, STELARA, ERLEADA and our paliperidone long-acting portfolio. Growth was partially offset by LOE pressures from both REMICADE and ZYTIGA, along with decrease in IMBRUVICA and XARELTO sales.

Darzalex continues to drive very strong operational growth with sales increases of 40.3% driven by subcutaneous formulation penetration and meaningful share gains across all lines of therapy and in all regions. IMBRUVICA sales declined 3.9% worldwide, due to increased competition from novel oral agents, particularly in the U.S. IMBRUVICA maintains its market leadership position worldwide and continues to drive growth outside of the U.S. despite ongoing competitive pressures.

XARELTO sales declined 13.8% in the U.S. driven largely by a net unfavorable prior period price adjustment and increased cost for patient access, partially offset by continued demand and market growth. The COVID-19 vaccine also contributed approximately $500 million to sales in the quarter. Given these results, we remain confident in our ability to deliver our 11th consecutive year of above market adjusted operational sales growth in 2022.

I will now turn your attention to the MedTech segment. Worldwide MedTech sales of $7 billion increased 8.5% with growth of 5.6% in the U.S. and growth of 11.1% outside the U.S. Excluding the impact of acquisitions and divestitures worldwide growth was 8.6%. We see strong performance in Q1, driven by market recovery, focused commercial strategies and differentiated new products driving enhanced or sustained market share across most of the 11 priority platforms. We continue to monitor potential impacts on elective procedures, driven by COVID-19 resurgences across various markets.

Before highlighting the financial performance for the segment, I'd like to share a few notable first quarter MedTech events that demonstrate our stated aspirations of entering higher growth market segments and continuing to build upon digital technologies across the portfolio. Two acquisitions were closed in the quarter, CrossRoads Extremity with a differentiated portfolio of bunion and hammertoes solutions in the fast growing elective foot and ankle market. And CUPTIMIZE which will be a new addition to the VELYS Digital Surgery Platform of Connected Technologies. The CUPTIMIZE solution is designed to give surgeons an easy to use tool to better understand and address the impact of abnormal motion between the spine and pelvis and some patients who require total hip arthroplasty and may help reduce the risk of dislocation related to pelvic tilt.

I am also pleased to share that Fast Company selected Johnson & Johnson MedTech as one of its Top 10 World's Most Innovative Health Companies of 2022 recognizing MedTech success and commitment to delivering breakthrough scientific innovation and re-imagining health in an increasingly digital world. The interventional solutions franchise delivered another quarter of worldwide double-digit growth at 17.4% with double-digit growth in both the U.S. and OUS regions, driven primarily by success of new products and electrophysiology commercial execution and continued market recovery.

Worldwide surgery grew 5% driven by strong performance and wound closure and biosurgery where we continue to gain market share. MONARCH enabled procedures now exceed 14,000 since launch providing continued evidence of the adoption of MONARCH technology and patient treatment regimens. The worldwide orthopedics franchise grew 5.6% reflecting COVID-19 recovery continued penetration in the U.S. ambulatory surgery center channel or ASCs and penetration of new product launches such as enhancements to VELYS Hip Navigation, VELYS Robotic Assisted Solution and ATTUNE Cementless knee system. Partially offsetting this growth with softness in spine procedures in the U.S.

The worldwide vision franchise continued its double-digit growth, growing 13.9% this quarter. Contact lenses global growth of 10.6% reflects continued positive momentum for our market-leading ACUVUE portfolio success of commercial initiatives and recently launched products such as ACUVUE OASYS Multifocal and ACUVUE DEFINE Fresh.

Surgical vision delivered global growth of 23.8% with both the U.S. and OUS posting growth above 20% fueled by market recovery and share momentum due to the success of recently launched products including TECNIS EYHANCE and TECNIS SYNERGY. As a reminder, additional sales commentary for all of our segments can be found on the slides.

Now turning to our consolidated statement of earnings for the first 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 driven by unfavorable mix in the MedTech business and commodity inflation and the Consumer Health business.

Sales, marketing and administrative deleveraged by 110 basis points, driven by higher brand marketing expenses and consumer health and timing of brand marketing expenses in the Pharmaceutical segment. We continue to invest strategically in research and development at competitive levels, investing 14.8% of sales this quarter. The $3.5 billion investment was an 8.9% increase versus the prior year, primarily due to portfolio progression in pharmaceutical and MedTech.

In-process research and development reflects an impairment expense of $610 million for certain indications associated with bermekimab. The investigational compound acquired from XBiotech Inc, as disclosed in our previous SEC filings. This impairment was driven by the termination of development of bermekimab for atopic dermatitis based on the efficacy data. The other income and expense line was net income of $102 million in the first quarter of 2022 compared to net income of $882 million in the first quarter of 2021. This decrease was the result of lapping prior year gains on the divestiture of Doxil, Caelyx and Evra in 2021. Higher unrealized losses on securities in Consumer Health separation costs. This was partially offset by favorable returns associated with our employee benefit plans. Regarding taxes in the quarter our effective tax rate was 12.2% versus 16.6% in the same period last year. The decreased tax rate was primarily driven by lower U.S. income due to higher unrealized losses on securities and the impairment of bermekimab IPR&D compared to prior year divestiture gains. Excluding special items, the effective tax rate was 13.3% versus 16.5% 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 will direct your attention to the box section of the slide, where we have also provided our income before tax, net earnings and earnings per share adjusted to exclude the impact of intangible amortization expense and special items.

Now let's look at adjusted income before tax by segment. In the first quarter of 2022, our adjusted income before tax for the enterprise, as a percentage of sales decreased from 37.1% to 35.1% due to product mix, commodity inflation, increased brand marketing expense, portfolio progression in R&D and comparisons to gains from prior year divestitures.

Pharmaceutical margin declined from 45.5% to 44.1%, primarily driven by timing of brand marketing expenses and general portfolio progression in R&D. MedTech margins declined from 30.6% to 27% driven by unfavorable product mix.

Finally, Consumer Health margins declined from 26.8% to 22.1% due to commodity inflation and higher brand marketing expenses. This concludes the sales and earnings portion of the Johnson & Johnson first quarter results.

I'm now pleased to turn the call back over to Joe Wolk.

Joseph J. Wolk {BIO 19812977 <GO>}

As Jess just mentioned, Johnson & Johnson posted solid performance for the quarter, continuing to invest in the business for the long-term success while overcoming multiple macroeconomic headwinds, including inflationary pressures and higher input costs. These external challenges include limited availability and rising prices of certain commodities, as well as increased costs for labor, energy and transportation. These impacts are pervasive across the enterprise, but most notable in Consumer Health. We expect these pressures will continue to some degree throughout the remainder of 2022. However, mitigation efforts are underway including cost improvement initiatives, strategic price increases and contract negotiations with external supply partners. We are committed to sustaining supply of the products, medicines and treatments that consumers and patients want and need.

Turning to our segments and notable events in the quarter. MedTech led our enterprise performance with nearly 9% adjusted operational sales growth. We continue to drive this business forward and are increasing the value of our pipeline through innovation, internally and externally. We were pleased to see a steady uptick in surgical procedures this quarter, with the easing of COVID restrictions in many parts of the world. But we recognize that the situation is fluid, which requires monitoring.

Building on more than 20 major new product launches in 2021, MedTech announced the addition of two new innovations to our ATTUNE Knee portfolio. The ATTUNE Cementless fixed bearing knee with AFFIXIUM 3DP technology and the ATTUNE Medial Stabilized Knee System.

In our pharmaceutical business, we continue to deliver above-market growth driven by volume as evidenced by our recently published 2021 Janssen U.S. transparency report, which reflects our fifth consecutive year of price decreases across the portfolio despite inflationary pressure. We also continue to advance our pharmaceutical pipeline. This quarter we received FDA approval for CARVYKTI a CAR-T therapy for the treatment of multiple myeloma developed together with our partner Legend Biotech. We are partnering with clinics, utilizing a phased approach to begin patient dosing and the feedback to date has been positive. We also filed Teclistamab, our BCMA CD3 bispecific antibody seeking EMA approval. And we also received priority review from the FDA, potentially expanding our multiple myeloma portfolio further.

In our Consumer Health business, we remain focused on delivering on our 2022 performance objectives, continuing to achieve above market growth in our over-the-counter medicines business while navigating industry-wide supply constraints that have primarily impacted our skin health beauty business. We continue to be excited about the activity related to the announcement we made in November on the creation of two new industry leading companies, the new Johnson & Johnson and the new Consumer Health company.

For the new Johnson & Johnson, the portfolio will remain well diversified with 25 brands delivering over $1 billion in sales annually, holding market-leading positions across key therapeutic areas and franchises. The financial hallmarks of Johnson & Johnson will remain the same, including a well-defined capital allocation strategy, a disciplined approach to inorganic growth and a strong balance sheet while also creating opportunities to sharpen focus on execution and clinically differentiated innovation.

The new Consumer Health company will also have a strong financial profile and be better positioned to drive incremental growth, realizing increased potential in new markets through a more agile operating model. The Company will continue to deliver science backed innovation and enhanced digital consumer-centric solutions. The Consumer Health separation team is making substantial progress related to our efforts in establishing the new independent company.

As previously mentioned, we cannot disclose new financial information specific to Consumer Health, in order to preserve optionality on the various separation pathways. Our timelines remain unchanged. We anticipate announcing key executive leadership appointments for the new Consumer Health company in the coming months, with plans to provide the new company name and headquarters location around the middle of this year. In the second half of 2022, we plan to provide the updated path forward and applicable financial information such as refined standup cost estimates and potential short-term dissynergies.

Finally, consistent with previous communications, we expect to execute the separation in 2023. You have our ongoing commitment adhering to the regulatory framework to provide transparent updates for material decisions on a timely basis.

Turning now to cash and capital allocation. We generated free cash flow for the quarter of nearly $3.4 billion. At the end of the first quarter we had approximately $30 billion of cash and marketable securities and approximately $33 billion of debt -- for a net debt position of approximately $3 billion. Our capital allocation priorities remain unchanged. Internal innovation remains critical to our future growth and a top priority. In the first quarter, we increased R&D investment by approximately 9% compared to the first quarter of 2021. We also continued to evaluate opportunities to complement the current portfolio with acquisitions that build upon our capabilities, address portfolio gaps or play in higher growth markets while yielding solid financial returns.

As I mentioned earlier, we were pleased to announce today that our Board of Directors approved an increase in our quarterly dividend for the 60th consecutive year from $1.06 per share to $1.13 per share, an increase of 6.6%.

Moving to full year 2022 guidance and key considerations. I'll start with comments on our COVID-19 vaccine and foreign exchange impacts, essentially the only items with updates from our January guidance. As market demand for all COVID-19 vaccines is currently challenged by global supply surplus and vaccine hesitancy in developing markets, we have made the decision to suspend guidance for sales of our COVID-19 vaccine. This will enable investors to focus on the performance of our core businesses, which drive the current and future value for investors.

We are maintaining the total adjusted operational earnings per share guidance we provided in January, absorbing if need -- the modest income impact from the COVID-19 vaccine. Regarding foreign exchange, as you know we don't offer guidance or predictions on currency movements. But to give you a sense of the impact, currency may have on potential full year reported results, utilizing the euro spot rate relative to the U.S. dollar as of last week at $1.08. There is an incremental unfavorable currency impact of $1.1 billion on reported sales and an unfavorable $0.25 for reported adjusted earnings per share versus the calculation related to January's guidance.

The full year unfavorable impact is now projected to be $2.5 billion on reported sales and $0.45 on reported adjusted earnings per share. All other line items for which we provide guidance remain the same as communicated in January. To reiterate we are maintaining our adjusted operational earnings per share guidance. We don't provide quarterly guidance, but do understand that you find value in us providing some qualitative considerations as you update your models.

In Consumer Health, we expect supply constraints to continue throughout the year but not to the same extent in the second half. As a result we anticipate that the back half performance will improve over the first half. For MedTech while the first quarter demonstrated faster recovery than we anticipated our full year expectations remain fairly intact. We anticipate continued market recovery and uptake from recently launched products and are monitoring the ever-changing COVID dynamics, particularly the surge in cases in China. Similar to Consumer Health, we expect the second half to be stronger than the first half. As a reminder with respect to growth rates the second quarter was a strongest quarter for MedTech in 2021.

The expectations for the pharmaceutical base business remain the same. We anticipate delivering another year of above market adjusted operational sales growth with relatively consistent growth throughout the remainder of the year. In summary, Johnson & Johnson had a solid start to the year despite managing macroeconomic headwinds and we remain confident in our business.

I would like to recognize the continued efforts of our 144,000 global colleagues focused on delivering our innovative healthcare solutions to our credo stakeholders. Their unwavering dedication and support continue to inspire and on behalf of the executive team I'd like to extend our gratitude.

I'm now pleased to welcome to the call, Ashley McEvoy, Thibaut Mongon and Jennifer Taubert, our Worldwide Chairs to address your questions.

Kevin, can you please provide instructions and open the line for Q&A?

Questions And Answers

Operator

(Operator Instructions) Our first 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. So many different places to go, but Joe, I'll start with the M&A, there are comments on the tape stating that you are eager to deploy cash to M&A, especially for devices. So maybe for you or Ashley could you add more color to your thinking there and the types of opportunities to consider? You've talked about reaching the top of the peer set in devices, that would seem to require a relatively large deal or a series of small to medium-sized deals to move the needle. Is that a fair way to think about it? Thanks for taking the question.

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

Yes. So Larry, I'll start and then I'll turn it over to Ashley for some thought specific on medical devices. Before I answer, Larry, I do want to compliment you and your team for the foreign exchange report that you guys issued back, I think it was on April 13. I was just -- it's a tough topic to really grasp and you guys did a fantastic job in assessing what it meant for the medical device industry. It was really a fantastic report so well done.

With respect to cash as you heard us in January, we are reaching our lowest levels of net debt and we will remain very active. You could talk to Thibaut, Jennifer and Ashley, with respect to ideas that they are bringing forth. We continue to have the same principles that we've had historically, want to make sure there is a strategic fit. And by that I simply mean, we've got capabilities, we've got scientific expertise perhaps it's just our scale that adds more value to that asset than where it currently resides. And then we want to make sure that we compensate risk -- compensate shareholders for the risk that we're bearing on

their behalf when we do so. I would not get overly locked into size, Johnson & Johnson quite frankly has been built through a number of smaller acquisitions and really the outliers of these larger acquisitions. But we look at really the strategic merit and then the financial value creation and don't get locked into saying something is too small or too big, with respect to adding to our already dynamic internal portfolio and pipeline.

Ashley, I don't know, you want to comment on that?

A - Ashley McEvoy {BIO 20108895 <GO>}

Larry, maybe, before I get to M&A, just kind of some macro thoughts on MedTech in the quarter. I'm pleased with the results of the quarter, we saw positive signs of the market recovery, clearly while COVID has not disappeared health systems around the world are becoming increasingly more resistance with each passing wave. And as we know, the world is a lot more equipped to manage the pandemic and quite frankly so is Johnson & Johnson. So encouraged to see in quarter one, that we continue to maintain our path to above market performance. We referenced to that this is kind of a growth at scale if you will, -- 11, $1 billion platforms really most of them growing or maintaining share. And we saw robust sales growth across all four of our franchises and all four of our regions.

Some standouts encouraging to see both vision surgery and vision care, both double-digit performance and growing market share really fueled by innovation in ACUVUE and TECNIS. We are the world leader in electrophysiology, still a category that has significant under-penetration. We've had 11 consecutive years of double-digit performance and really significantly enhanced our share gain. We're the world leader in biosurgery, the business was up almost 10%, really driven by a clinically differentiated portfolio. And then finally and enthusiastically, I say, we had strong performance in joints, really by penetrating some new sites of care like ASCs both with hips and knees.

So when I look forward, I'm encouraged by the organic agenda that we see in innovation like with the likes of the FDA approval on ACUVUE THERAVISION, the first drug-eluting contact lens. As Joe mentioned earlier around really shoring up high-growth segments in knees with the two in fixed bearing and then really with CERENOVUS the launch of Emboguard, the balloon catheter. So continue to advance robotics and digital surgery, you'll hear us talk about MONARCH 14,000 cases with a big pipeline of new indications and then VELYS completing over 2,000 cases.

So when I think about the future of M&A, Larry, we're going to continue to do tuck-ins and to really digitize the patient experience. You heard us talk about CUPTIMIZE as an example around really adding a precise delivery to hit navigation to improve outcomes, you're going to see us continue to penetrate faster growing segments, like what we have in neurovascular as an example, 90% of our capital deployment has been to $1 billion or more. But we do intend to make sure that we are well positioned to be in a highest growth end state markets.

Operator

Thank you. Our next question today is coming from Chris Schott from J.P. Morgan. Your line is now live.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much. Maybe, Ashley just following up on some of your MedTech comments. Can you just specifically comment on China, in terms of the impact you're currently seeing to the business and your outlook for that market? Specifically, given some of the lockdowns that we're seeing there. And then my kind of core question was just on IMBRUVICA. It seems like prescriptions here are really starting to see some erosion. I'm trying to understand the dynamics you're expecting going forward. So is this especially maybe the U.S. market, are you expecting this erosion continues? Or do you see dynamics in place that we could start to see some of those prescription trends start to stabilize a bit? Thanks so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

Yeah. Sure, Chris. So first, we have -- I would say a very strong and healthy business in China, where the world -- we are number one in MedTech in China. We have a very diversified portfolio from surgery to orthopedics to interventional as well as vision. We did experience an impact probably in the March timeframe, due to the recent surge of the virus is happening and the lockdowns particularly in Shanghai and other regions, we do anticipate that to continue in April and through the month of May. But like we've seen, I think China might come down a bit faster when it comes back faster too. We've very strong leadership there and there are a lot of patients that need care.

I'll turn it to Jennifer, maybe to talk about your second question.

A - Jennifer Taubert {BIO 20108880 <GO>}

Great. Thanks a lot. Hi Chris, and hello everybody. Few comments on the Pharmaceutical business, and then I'll get to the question on IMBRUVICA. First for our farm business, I was really proud that we delivered $12.9 billion in worldwide sales would definitely above market adjusted operational growth of 9.3%. And this is our sixth quarter where we achieve worldwide sales exceeding $12 billion. And as I look across the globe, the growth was really broadly based across our portfolio and the regions, with particularly strong growth in EMEA, Asia Pac and Latin America.

During the course of the quarter, we really continue to maximize the value of our key brands. So strong double-digit growth across six of them, including DARZALEX, ERLEADA, TREMFYA, Invega Sustenna, Spravato, and Edurant. And we also had a number of important milestones, the first being the FDA approval of CARVYKTI, which is our first cell therapy for patients with relapsed or refractory multiple myeloma. The Teclistamab filing in the EU with mentioned, the FDA approved expanded label indications for CABENUVA, to be administered every two months for the treatment of HIV in virologically suppressed adults and adolescents. And we present a great new data on TREMFYA in our approved indications of psoriasis and psoriatic arthritis, as well as from our Phase 2 studies where we're evaluating the product in Crohn's disease and also in UC.

So, if we take a look at IMBRUVICA more specifically, IMBRUVICA sales did decline for the quarter 3.9% and this really was a U.S. story. Outside the U.S., our sales actually grew 4.5%. In the U.S. performance was impacted by both competitive factors with a number of new

competitors in the market as well as market softness. We haven't seen that market fully rebound to the pre-COVID levels yet.

As we take a look at IMBRUVICA -- IMBRUVICA has really changed the standard of care for adults with CLL and other B-cell malignancies. And it is the only BTKi, that's demonstrated overall survival and a high rate of progression-free survival at five years, with up to eight years of safety follow-up. So we remain really confident in the efficacy and safety profile of the product. It's the market share leader and continues to be the most comprehensively studied in prescribed BTKi with over 250,000 patients worldwide. So we continue to work to develop the asset, we do see further growth opportunities through the introduction of new indications and new combination therapies, as we take a look at IMBRUVICA plus venetoclax that we're working to develop and we filed in the EU. We're also taking a look at first-line MCL and really trying to bring that forward. So I think you can anticipate there will -- continue to be strong competition in that market. We continue to believe in and invest in IMBRUVICA.

Operator

Thank you. Our next question is coming from Joanne Wuensch from Citi. Your line is now live.

Q - Joanne Wuensch {BIO 2379289 <GO>}

Good morning, and thank you for taking the question. I'd like to spend a little bit of time talking about the middle of the income statement. Look, all of the multiple headwinds on those factors, how do you think about managing it? What are the levers to pull and how do you think about raising prices in this environment for each of your key divisions?

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

Yeah. Good morning, Joanne, thanks for the question. With respect to operating margins overall, which is really I think at the heart of your question. In the front -- the first quarter, I should say, we do tend to adapt a little bit more of an aggressive approach to advertising and promotion and hopes of getting the full-year benefit of that promotion to the top line lift throughout the year.

And I would say on R&D, it's also a little bit front-end loaded this year, simply from the standpoint of the progression of our pharmaceutical pipeline as well as digital robotic surgery. So in pharmaceuticals think about nipocalimab, our RSV vaccine. Those had very nice progression to Teclistamab, maybe moving a little bit faster than we anticipated, as well as being able to launch CARVYKTI.

There was a healthy amount of inflation built into our P&L in the January guidance. What I think our teams have seen in the -- let's say the first four months of this year is an uptick in that inflationary impact, little about 10% or 15%. So still very manageable. Again, as you heard in some of the prepared remarks, we anticipate that inflationary pressure as well as commodity scarcity will subside a little bit in the second quarter. And then hopefully more pronounced in the second half of this year. If it doesn't, it's certainly something that will keep our attention. And we have the resources to adjust accordingly to make sure that we

not only meet the needs of long-term value creation, but also meet short-term performance expectations.

So we all think it's very manageable at this point in time, but it's something that we're not taking for granted. We're being very active with cost initiative programs as we look to separate the two companies, we are looking at ways to streamline technology processes, things that will lead to leverage on the P&L.

Operator

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

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you. Good morning, appreciate the opportunity. Perhaps directed at the Pharmaceutical segment for Jennifer. Two products I'd like to focus on, one being STELARA and the other on XARELTO. With STELARA, could you perhaps elaborate a little bit more in terms of some of the underlying dynamics across the various indications, i.e., the derm versus perhaps the IBD in terms of what the growth trends and outlook you are seeing and you expect there?

And then for XARELTO, part of your commentary in the prepared segment discussed and mentioned about patient access. Could you just elaborate a little bit further on how that was an impact on the commercial dynamics? Thank you.

A - Jennifer Taubert {BIO 20108880 <GO>}

Sure. Hi, thanks for the question. So let me start-off with STELARA. So STELARA sales were $2.29 billion in the first quarter and that was 9% growth and we continue to see a lot of strength in STELARA. On ex-U.S. the product had nearly 18% growth. In the U.S. what we saw was growth around 3.6%. And what this really was due to -- we saw an impact in the U.S. due to the Omicron variant and the impact that it actually had on staffing resources, that particularly impacted a number of areas where you had more resource-intensive delivery of care and GI offices was definitely one.

As we take a look at Crohn's disease and all sort of colitis, our share positions remain strong and with very strong positive momentum we actually gained over five share points in CD and six share points in all sort of colitis. So really strong growth and momentum. And with in psoriasis is anticipated with TREMFYA and the very strong growth there in psoriasis and psoriatic arthritis and we expected the STELARA sales there to start tailing-off and that's in line with our expectations. So we continue to have a very strong, a very positive outlook for STELARA going through the rest of the year in CD and in Crohn's -- Crohn's and ulcerative colitis where we've really been realizing the growth. And likewise, when you take a look at TREMFYA we saw 44.5% growth in psoriasis and psoriatic arthritis in the quarter. So together really, really nice performance there.

Question on XARELTO, so XARELTO in the U.S., we did see sales decline that was largely driven by a net unfavorable prior period adjustment and most of this had actually been a

positive adjustment that took place in 2021. So when you do the comparables it was negative. And so that was really due to the vast majority of that. With XARELTO, we continue to see really nice share gains and growth at a prescription level, across the indications whether we're talking about CAD and PAD, really the newest indication set, but also across AFib and VTE. And so it really was around the net unfavorable PPA and a little bit of channel mix as well with some of the mix shifting into 340B and Medicaid in some of the lower price channels.

Operator

Thank you. Your next question today is coming from Louise Chen from Cantor Fitzgerald. Your line is now live.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my question. So I wanted to ask you about CARVYKTI and what gives you confidence in your ability to meet some of the manufacturing complexity associated with CARVYKTI? And how much capacity do you think you'll be able to bring online this year, both in the U.S. and potentially globally as well? Thank you.

A - Jennifer Taubert {BIO 20108880 <GO>}

Thanks for the question. So we're real proud about our approval and our launch to date on CARVYKTI. What I can say is that it is going well and it is on track with our expectations. We're real pleased, as you know, this is a customized therapy where the supply chain is literally built around each patient. We've got about a four to five-week period that goes from the collection of the cells, the processing and manufacturing and the return shipment of the final product and then ultimately the infusion back into the patient at the treatment center.

As we've mentioned before, we really are taking a thoughtful and a phased approach to scaling this launch to ensure a predictable and a reliable experience for the patients and for the treatment centers. We really tried to learn from the other launches in the market in this area. And so far we're off to a really good start there and have been very pleased with the feedback that we're getting back from our customers. So we have activated our initial round of treatment centers and we did this based on folks who were very well experienced from our clinical trials and also very broadly dispersed throughout the U.S. and to help ensure patient access.

We are working through all of the orders and the slots that we have and actually have product now that's been shipped back, has been manufactured and shipped back to the patients for infusion into the patients. So we're going to continue on a planned and thoughtful, responsible approach to this scaling both in the United States, as well as we do -- as we scale outside the U.S. I mean, throughout the world as well.

Now we discussed before around lentivirus because there is an industry wide shortage of lentivirus, that is something that we are also working and investing in to scale all of our internal capabilities to be able to meet the demand, both now in our initial launches and the relapsed refractory setting as well as our ultimate goal to be able to move into first line

setting here. And so we would have a internal control on that as well. So hope this answers your question.

Operator

Thank you. Our next question is coming from Josh Jennings from Cowen. Your line is now live.

Q - Josh Jennings {BIO 16451037 <GO>}

Hi, good morning. Thanks a lot for taking the question. Joe, since Joaquin made some public commentary on his commitment to support Ashley and her team to drive revenue growth acceleration in the mega devices unit. Maybe your focus has been on M&A opportunities, but how should be thinking about the level of internal best investment to fuel growth of the devices franchise? You don't break out the percentage of R&D spend allocated to devices but one data point we do have is from the '19 Pharma Day when you relate at $8.4 billion of the $11 billion in R&D expense from '18 went to pharma initiatives, so that's north of 75%. But just I mean had that stepped up, just the level of investments in the devices business over the last couple of years and what that step-up even further? And just to be clear, Ashley did not plant this question with our team.

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

I'm going to check the transcript on that, Josh, just to be sure. But listen, I think what you would hear if Joaquin was sitting here is that, he supports all the businesses with respect to innovation. We realize that our calling card is innovation. And we're going to have growth across all of our franchises. When we have products that, that matter that are differentiated that are beyond the current standard of care and meeting consumer needs as well. I actually want to credit Ashley and her team for the way they've managed their P&L, they've been conscious about moving more of their investment into R&D. You saw a record number of 20-plus new product launches last year that are considered meaningful. We're going to be very close to probably a very similar number this year. And so that portfolio has taken very much the same approach that I would say pharmaceuticals did almost a decade ago when the focus is very well understood and where we want to play because we've got a strategic or competitive advantage will be capitalized upon.

I don't know, Ashley, if you want to add anything more, but I think that certainly there is continued support, but a lot of the credit goes to Ashley and her team in terms of managing their levels of investment throughout the P&L.

A - Ashley McEvoy {BIO 20108895 <GO>}

Thanks, Joe. I mean, Josh, I would say that we are investing at a competitive level and I'm really pleased with the state of execution. We have in our pipeline right now 27 $100 million plus ENPV projects that number three years ago was six. So they continue to focus the pipeline on medium to higher growth segments and really execute. And we're off to a good start in 2022.

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

I would maybe underscore too is that gives us the confidence to go out and add in inorganic opportunities when the opportunity presents itself using the criteria of strategic fit, as well as financial value creation. So a stronger internal pipeline that gets hopefully success out in the acquisition markets.

A - Jessica Moore {BIO 16638328 <GO>}

Just to reference our 10-K, we do provide the break out of R&D by segment on an annual basis for reference.

Operator

Thank you. Your 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. Jennifer, I was just wondering if you could elaborate a little bit more on the COVID recovery in the Pharma segment, I know you touched on staffing issues on the gastric (Technical Difficulty).

A - Jennifer Taubert {BIO 20108880 <GO>}

Yeah. So I understand Terry's comment really was around the U.S., and what we're seeing in terms of COVID. So as we exited last year really in the December timeframe and entered this year into really January and February, we did see over Omicron variant impact the U.S. business. And what we saw there really -- that's already mentioned before, we did see staffing shortages because so many people got sick, people weren't able to go into work. And so in the higher more intensive resource settings and some of the markets we did see slowdown in terms of delayed visits and new patient starts. What we are seeing now is we're in looking towards the end of March and in early April, we are seeing nice recovery there. And so this really hopefully was something really just at the end of last year and the beginning of this year and it does look to be more specific to the U.S. than to any of the other markets.

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

Thanks, Jennifer. Thibaut, maybe give some insight to on the consumer segment and how COVID's impacting, obviously it was much more tumultuous I'd say in 2020 and 2021, but what are you seeing relative to the early start of this year?

A - Thibaut Mongon {BIO 20973347 <GO>}

Look, clearly, we continue to see the impact of COVID on the life of our consumers and that has an impact --the differentiated impact by category. We are looking at China very specifically right now to see how the situation evolves there. What I would say that COVID has really shifted consumer behavior to digital space and digital solutions. And so and we see it in the continued growth of our e-commerce channel representing more and more of our business. So that's what makes well more resilient, this ability to count on multiple channels is something that is serving us well in the COVID environment. Having said that, we need to continue to monitor how the situation evolves around the world.

Q - Terence Flynn {BIO 15030404 <GO>}

Thank you.

Operator

Thank you. Our next question today is coming from Matt Miksic from Credit Suisse. Your line is now live.

Q - Matt Miksic {BIO 6990080 <GO>}

Thanks. Thanks so much for taking the question. So maybe for Ashley, I was hoping you could provide a little bit more color on med devices in Q1 and this trajectory exiting March. You had pretty impressive growth across the Board, so congrats on that. But investors are often trying to just figure out the difference between in-patient segments like orthopedics or cardio and surgery and how those are recovering potentially at different rates in the U.S. and what you might be seeing there? As well as, any color you can provide on how say, Europe and Japan overseas developed markets compared with the recovery trends we've seen in the U.S.? Thanks.

A - Ashley McEvoy {BIO 20108895 <GO>}

Thanks, Matt for the question. It's April 2022, we're still talking about this. So just huge acknowledgment for our healthcare workers who are still battling through this. But I would tell you, EMEA really bounced back nicely in quarter one, it was pretty broad-based within EMEA. I would say, Asia, with the exception of China recently also bounced back. And then U.S. really gained momentum. I always look at two data points in the U.S. as an example. I look at, like how our diagnostic procedure is performing in the U.S.? And then how are surgical procedures performing and probably at our trough when Omicron was hitting in the U.S. in January, we had about flat diagnostic procedures and we were looking at surgical procedures down near double digit down 10%. Encouragingly as we exited March, we started to see diagnostic procedures tick-up to high single-digit and start to see a flattening of surgical procedures. I expect in the month of April in the U.S. to see it go north of 2019 levels, really driven by cardio -- cardiac ablation, bariatrics and colorectal surgery.

Operator

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

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, good morning. Thanks so much for the question. I just had a couple -- Jennifer in the Myeloma market we'll see REVLIMID generic soon. And I realize that combinations with DARZALEX are our standard of care. But what are your expectations for broader market disruption going forward either from a pricing or share perspective?

And then a quick follow-up on the M&A front for Joe, when you think about the P&L or cash flow impact from the consumer separation to what degree does this inform or impact

plans for a larger scale BD or M&A for either MedTech or Pharma? Thank you.

A - Jennifer Taubert {BIO 20108880 <GO>}

So thanks for the opportunity to talk about our multiple Myeloma portfolio. And in response to your question, so as we take a look at the myeloma market, despite the advances to date in therapies, there is still so much unmet need there, given the underlying heterogeneity of the disease. And so it's really important that there are treatment choices and what we're really trying to do is to have a strong portfolio of highly affected -- highly effective treatments and actually ultimately shoot for a cure.

And so as we take a look at the market with DARZALEX -- in DARZALEX FASPRO right now, we're really seeing this is a foundational therapy for multiple myeloma. And so irrespective of ethers and LOE and those types of things, as you noted, it's a lot of combination therapy and things like that, that does not fundamentally change the opportunity for DARZALEX and FASPRO.

What I'm also really excited about is, then you add in CARVYKTI, that was recently approved as we mentioned for triple refractory multiple myeloma. And we really think that this will ultimately become a preferred treatment for patients with relapsed-refractory multiple myeloma. We also mentioned Teclistamab -- in the filing of Teclistamab and this really is the first ever BCMA CD3 bispecific. And we think that, this is going to be a great off the shelf option, and for patients who really are triple class exposed and who are really not eligible for CARVYKTI or don't have access.

And then in the future, we are not stopping there. We're also working on Talquetamab and this would be the first and potentially best-in-class GPRC5D bispecific, that we think could be potentially sequenced and combined to help transform outcomes. And so as we take a look at our portfolio, we really think that these assets are additive and complementary versus something where they would be cannibalizing each other. And we really think that these are the important advances that are going to really help transform multiple myeloma in the future and going forward versus any of the older therapies.

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

And Geoff, with respect to cash flow and M&A, I think I'll answer that in two parts. I think short-term, we certainly have the credit rating to warrant more firepower, should we need it. As you have observed, our cash flow generation over the last couple of years has ticked up to new levels north of $20 billion or around $20 billion from when we were just maybe $17 billion few years ago. As the consumer company separates, I think that's going to be actually liberating for both sides. We still have opportunities to improve our cash flow with inventory management and receivables. But as we move to a higher growth segment, we think were be able to generate similar cash flow with a higher level of sales growth, managing the P&L appropriately. So I've got every confidence that we'll be able to do small, medium and large-scale acquisitions should the right opportunity present itself.

I also think it's liberating for the Consumer Health segment, because they'll be able to focus their cash flow generation to value creating opportunities through their particular lens being fit for purpose in a digitized environment that Thibaut spoke to. So whether it's

near-term or long term, I think we're in a very good position to utilize today's cash and hopefully that which should we generate tomorrow.

Kevin, maybe we've got time for one more question.

Operator

Certainly. Our final question today is coming from Danielle Antalffy from SVB Leerink. Your line is now live.

Q - Danielle Antalffy {BIO 16104603 <GO>}

Hi, good morning everyone. Thanks so much for squeezing me in. This is a question for Ashley, and is the commentary around the ASC penetration. And I'm just curious Ashley is that site of care becomes increasingly important? Where you guys think you are relative to the market from a penetration perspective and where you think you can grow, how meaningful of growth driver will your recent success in the ASC be over the next few years? Thanks so much.

A - Ashley McEvoy {BIO 20108895 <GO>}

Well, thank you, Danielle, I appreciate the question and hope you're well. We in U.S. into the ASCs, I think it still relatively low penetration, I would tell from a macro U.S. less than 20%, but I think it's the fastest growing as we know. In a COVID environment we've seen the model evolve to create a safe, more patient friendly experience that addresses a patient sentiment of not wanting to go into a hospital setting. Certain procedures have gone there early sooner than later, I'd say hips or migrating there and knees, less spine per se, less complicated, obviously trauma case is still happening in the hospital setting. We've done a lot of work recently to modify our business model to make it a capital-efficient flow. If you will an inventory management on the personalization of care using digital assets to kind of make your pre-op and your post-op experience less full of friction. And we're taking a lot of that experience in the U.S. ASCs to really what we're doing in China in the tier two and the tier three cities as well as we deliver care.

So I'm optimistic that this channel will continue to evolve. I do think that we've increased our competitiveness there and we're making sure that we really have a sustainable business model going forward. Thank you.

A - Jessica Moore {BIO 16638328 <GO>}

Thank you, Danielle, and thanks to everyone for your questions and your continued interest in our Company. We apologize to those who we couldn't get to because of time, but don't hesitate to reach out to the Investor Relations team as needed.

I will now turn the call back to Joe for some brief closing remarks.

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

Great. Thanks, Jess, and as Jess alluded to, we certainly do appreciate your questions and the chance to interact with you. I'd like to remind everybody, as we close that we do have

the opportunity to engage with shareholders at next week's Annual Meeting on April 28. Also beyond the look out for an update on our commitments to ESG, on June 8 we will be issuing our health for humanity report which is an in-depth review on the progress we are making on our 2025 goals.

Thank you for your time and your interest in Johnson & Johnson. Have a great day.

Operator

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