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JNJ.N - Q2 2023 Johnson & Johnson Earnings Call

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OVERVIEW:

Company reported diluted earnings per share of \$1.96, cash and marketable securities of \$29 billion, debt of \$46 billion, net debt of \$17 billion, Free cash flow of \$5.4 billion, sales of \$57 billion.

CORPORATE PARTICIPANTS

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PRESENTATION

Operator

Good morning, and welcome to Johnson & Johnson's Second Quarter 2023 Earnings Conference Call. (Operator Instructions) This call is being recorded. If anyone has any objections, you may disconnect at this time. (Operator Instructions)

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

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

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

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 risk 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 website.

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

Moving to today's agenda. Joaquin will open with a few comments highlighting business performance achievements in the quarter and outlook for the remainder of the year. I will then review the second quarter sales and P&L results for the corporation and highlights related to the 3 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. Finally, Erik will provide comments regarding the talc litigation. The remaining time will be available for your questions. To ensure we provide enough time to address your questions, we anticipate the webcast will last approximately 75 minutes.

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

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

Thank you, Jess, and good morning, everyone. This was a strong quarter for Johnson & Johnson with market-leading performance, important advances across our innovative Pharmaceutical and MedTech pipelines and a successful initial public offering of Kenvue. We delivered solid sales and earnings growth for the second quarter of 2023, reporting operational sales of 7.5% and adjusted operational EPS growth of 9.7%. These strong results contributed to our confidence in raising our expectations for this year.

You may have seen this morning the announcement that we intend to split off Kenvue shares through an exchange offer as the next step in the separation of Kenvue. Joe will provide additional information later in the call.

We're excited about entering a new era for Johnson & Johnson, one built around science, innovation and technology and strategically focused on Pharmaceutical and MedTech while maintaining our position as the world's largest, most diversified health care products company with 25 platforms over \$1 billion in annual sales. And on today's call, I would like to share recent highlights and achievements from across the business that have contributed to our year-to-date results as well as upcoming catalysts that give me great confidence in our near- and long-term future performance.

Starting with MedTech. For the second quarter of 2023, we generated 14.7% operational and 9.9% adjusted operational growth, which excludes the impact of the Abiomed acquisition. On a pro forma basis, using sales publicly reported by Abiomed prior to our acquisition, MedTech grew 10.2%. These strong results continue to show that our efforts to improve the growth of the MedTech business are working.

Q2 highlights in electrophysiology include the publication of clinical data supporting the safety and effectiveness of QDOT, our newest ablation catheter for atrial fibrillation. In fact, this study demonstrated a clinical success rate of 86% as well as achieving shorter procedure and fluoroscopy times than ablation with conventional catheters.

I'm also happy to share that this month, we completed enrollment in the third clinical study evaluating our pulsed field ablation solutions. The SmartFIRE study evaluates our dual-energy catheter, which enables physicians to instantly switch energy source, whether radio frequency or pulsed field, based on patient needs.

The Abiomed integration continues to deliver against planned milestones and is on track across all areas and regions with no disruption to commercial activities or pipeline progression. Second quarter sales of \$331 million, compared to Abiomed's publicly reported sales in the same period last year as a standalone company, reflects approximately 20% growth.

We also continue to see strong enrollment in the ongoing pivotal clinical trials, which aim to expand the use of our products into new patient populations. We anticipate that heart recovery will become a significant multiyear growth platform for Johnson & Johnson.

In Orthopaedics, the VELYS Robotic-Assisted Solution is poised for further acceleration, having recently received CE and CA Mark international approvals.

In Surgery, we are pleased with our progression on Ottawa, our next-generation soft tissue surgical robotic system. And we look forward to providing an investor update later in the year.

In Vision, we recently launched products, such as ACUVUE OASYS MAX and TECNIS Eyhance. And we are performing very well across both contact lenses and surgical vision.

Now turning to Pharmaceuticals. In the second quarter of the year, we delivered above-market operational growth of 6.2%, excluding the COVID-19 vaccine. Of note, our multiple myeloma portfolio has grown more than 30% year-on-year, which includes the acceleration of our newly launched products, CARVYKTI and TECVAYLI. These new launches, along with SPRAVATO, are performing very well and are expected to be important contributors to achieving our 2025 sales target.

We also achieved important regulatory and operational milestones, including multiple readouts from our pipeline. A few things I'm particularly excited by include, first, the receipt of fast-track designation from the U.S. FDA for all 3 prospective indications for milvexian, our Factor XI oral anticoagulant in partnership with Bristol-Myers Squibb, which has the potential to treat a broader set of patients, such as those who currently have limited therapeutic options due to bleeding risk.

Second, recent submission of a supplemental BLA for CARVYKTI to the FDA and European Commission, supported by data from the CARTITUDE-4 study, seeking approval for a new earlier indication in treating relapsed or refractory multiple myeloma.

Third, the presentation of initial TAR-200 data from the SunRISe-1 study in bladder cancer at the American Urological Association Meeting.

And finally, we announced positive top line results from the Phase III PAPILLON study evaluating RYBREVANT in combination with chemotherapy in patients with newly diagnosed lung cancer with exon 20 insertion mutations. This is the first of several ongoing pivotal Phase III studies to read out for RYBREVANT-based regimens in EGFR-mutated lung cancer.

In addition, I want to highlight the Phase II study data that we presented earlier this month at the World Congress of Dermatology for JNJ-2113, our novel oral IL-23 receptor antagonist peptide in psoriasis. The finding suggests that JNJ-2113 has broad potential across the spectrum of IL-23-mediated diseases, including inflammatory bowel disease. We are already advancing into Phase III in moderate to severe plaque psoriasis and initiating a Phase IIb in ulcerative colitis. And we will continue to assess additional opportunities. We are very excited about the potential of this asset and believe it represents a \$1 billion-plus commercial opportunity.

We also continue to defend the intellectual property associated with our medicines, including STELARA. In fact, we have reached settlements regarding our STELARA IP with both Amgen and Alvotech. We expect Amgen to launch in the U.S. on January 1, 2025, and Alvotech to launch in the U.S. on February 21, 2025.

In all, our Pharmaceutical business delivered very strong results. Our pipeline is progressing well, and we continue to be confident in meeting our 2025 sales target of \$57 billion. We are excited to enter the back half of the year from a position of strength, and we have high expectations as we evolve to a 2-sector Johnson & Johnson with a higher growth profile.

I am now pleased to turn the call over to Jess to review our financial results in more detail. Jess?

Jessica Moore - Johnson & Johnson - VP of IR

Thanks, Joaquin. As a reminder, on May 8, 2023, Kenvue Inc. closed its initial public offering. Johnson & Johnson continues to own 89.6% of total outstanding shares of Kenvue's common stock and remains the majority shareholder. Therefore, the following financial results continue to include the Consumer Health business, with the 10.4% of Consumer Health net earnings no longer attributed to Johnson & Johnson being adjusted for in other income and expense from the date of the IPO through the end of the quarter.

Starting with Q2 2023 sales results. Worldwide sales were \$25.5 billion for the second quarter of 2023, an increase of 6.3% versus the second quarter of 2022. Operational sales growth, which excludes the effect of translational currency, increased 7.5% as currency had a negative impact of 1.2 points.

In the U.S., sales increased 10.2%. In regions outside the U.S., our reported growth was 2.2%. Operational sales growth outside the U.S. was 4.7% with currency negatively impacting our reported OUS results by 2.5 points. Operational sales in Europe were negatively impacted by the COVID-19 vaccine and loss of exclusivity of ZYTIGA. Excluding the net impact of acquisitions and divestitures, adjusted operational sales growth was 6.2% worldwide, 8% in the U.S. and 4.4% outside the U.S.

Turning now to earnings. For the quarter, net earnings were \$5.1 billion, and diluted earnings per share was \$1.96 versus diluted earnings per share of \$1.80 a year ago. Excluding after-tax intangible asset amortization expense and special items for both periods, adjusted net earnings for the quarter were \$7.4 billion, and adjusted diluted earnings per share was \$2.80, representing increases of 6.5% and 8.1%, respectively, compared to the second quarter of 2022. On an operational basis, adjusted diluted earnings per share increased 9.7%.

I will now comment on business segment sales performance highlights. Unless otherwise stated, percentages quoted represent the operational sales change in comparison to the second quarter of 2022 and therefore exclude the impact of currency translation.

Beginning with the Pharmaceutical segment. Worldwide Pharmaceutical sales of \$13.7 billion increased 3.1% with growth of 9.2% in the U.S. and a decline of 4% outside the U.S. Operational sales growth increased 3.8% as currency had a negative impact of 0.7 points. Excluding COVID-19 vaccine sales, worldwide operational sales growth was 6.2% with growth of 9.9% in the U.S. and growth of 1.5% outside the U.S. Sales outside the U.S., excluding the COVID-19 vaccine, were negatively impacted by approximately 500 basis points due to the loss of exclusivity of ZYTIGA in Europe.

Pharmaceutical growth was driven by our key brands and continued uptake in our recently launched products, with 9 assets delivering double-digit growth. We continue to drive strong sales growth for both DARZALEX and ERLEADA, with increases of 23.4% and 26.9%, respectively. STELARA grew 8%, driven by market growth and IBD share gains in the U.S., partially offset by unfavorable patient mix and increased rebates. TREMFYA grew 18.9%, driven by market growth and share gains in the U.S., partially offset by unfavorable patient mix. Growth of 16.5% in pulmonary hypertension was driven by favorable patient mix, share gains in the U.S. and market growth.

Turning to newly launched products. We continue to make progress on our launch of CARVYKTI and continue to expand access and reimbursement for SPRAVATO. We are also encouraged by the early success of our launch of TECVAYLI, sales of which are included in other oncology.

Total Pharmaceutical 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 \$7.8 billion increased 12.9% with growth of 14.6% in the U.S. and 11.3% outside of the U.S. Operational sales growth increased 14.7% as currency had a negative impact of 1.8 points. Abiomed contributed 4.8% to operational growth. Excluding the impact of acquisitions and divestitures, worldwide adjusted operational sales growth was 9.9%.

Sales in the second quarter accelerated sequentially from Q1 for all MedTech businesses, driven by global procedure growth, recovery in China, continued uptake of recently launched products and commercial execution. 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 56.9%, which includes \$331 million related to Abiomed. Electrophysiology is a major contributor to the growth with a double-digit increase of 25.9%. This reflects strong growth in all regions, including Europe, driven by our comprehensive portfolio, including the most recently launched QDOT RS Catheter.

Orthopaedics operational growth of 5.7% reflects strong procedure recovery, success of recently launched products, such as the INHANCE shoulder portfolio as well as global expansion of our digital solutions, such as VELYS Robotic-Assisted Solution. Growth was partially offset by the impact of volume-based procurement in China and continued supply challenges primarily in hips.

Operational growth of 8.4% in Surgery was driven primarily by procedure recovery and strength of our biosurgery and wound closure portfolios. Growth was partially offset by the impacts of volume-based procurement in China and supply challenges.

Global growth of 6.9% in Vision was driven by price actions in contact lenses and other as well as strength of new products, including ACUVUE OASYS 1-Day family of products and contact lenses; and TECNIS Eyhance, our monofocal intraocular lens in surgical vision. Growth of contact lenses was partially offset by strategic portfolio choices and supply challenges, although these continue to improve.

Moving to the Consumer Health segment. Worldwide Consumer Health sales of \$4 billion increased 5.4% with growth of 6% in the U.S. and 5% outside the U.S. Operational sales growth increased 7.7% as currency had a negative impact of 2.3 points. Sales in the second quarter accelerated sequentially from Q1 for all Consumer Health franchises primarily driven by strategic price increases and growth in OTC globally due to strong pain performance and cold, cough and flu season. Excluding the impact of strategic portfolio decisions and sales of personal care products in Russia, volume across all consumer franchises was relatively flat on strong price actions. For more detailed information, please visit investors.kenvue.com.

Now turning to our consolidated statement of earnings for the second 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 leveraged by 80 basis points, primarily driven by favorable patient mix and lower COVID-19 vaccine supply network-related costs in the Pharmaceutical business, partially offset by commodity inflation in the Consumer and MedTech businesses.

Selling, marketing and administrative margins deleveraged 20 basis points, driven by incremental costs to support the standalone Consumer Health business, partially offset by proactive management of costs.

We continue to invest strategically in research and development at competitive levels, investing 15% of sales this quarter. The \$3.8 billion invested was a 3.4% increase versus the prior year.

The other income and expense line was income of \$60 million in the second quarter of 2023 compared to an expense of \$273 million in the second quarter of 2022. This was primarily driven by favorable litigation settlements, lower litigation expense and lower unrealized losses on securities; partially offset by higher COVID-19 vaccine manufacturing exit-related costs; and as previously mentioned, the 10.4% of Consumer Health earnings that are no longer attributable to Johnson & Johnson, which resulted in a \$37 million reduction in consolidated earnings.

Regarding taxes in the quarter. Our effective tax rate was 23.9% versus 17.6% in the same period last year. This increase was primarily driven by 2023 tax costs incurred as part of the planned separation of the Consumer Health business due to the internal reorganization of certain international subsidiaries. Excluding special items, the effective tax rate was 16.6% versus 15.4% in the same period last year. I encourage you to review our upcoming second 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 adjusted income before tax by segment. In the second quarter of 2023, our adjusted income before tax for the enterprise as a percentage of sales increased from 34% to 34.6%, primarily driven by favorable product and patient mix, partially offset by unfavorable segment mix and commodity inflation.

Pharmaceutical margins improved from 42% to 42.7%, primarily driven by favorable patient mix; sales, marketing and administrative expense leverage and R&D portfolio prioritization; partially offset by higher milestone payments.

MedTech margins improved from 26.5% to 28.6%, driven by favorable intellectual property-related litigation settlements and cost management initiatives, partially offset by commodity inflation.

Finally, Consumer Health margins declined from 25.9% to 23.5% due to incremental cost to support the standalone Consumer Health business, foreign exchange impacts and commodity inflation, partially offset by supply chain efficiencies.

It is important to highlight that the adjusted income before tax for the Consumer Health business as reported by Johnson & Johnson differs from the financial results reported by Kenvue Inc. this morning. The difference is primarily driven by incremental costs required to run Kenvue as an independent company. Additional differences also exist on an after-tax basis due to the application of different tax rates.

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

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

Thank you, Jessica, and thanks, everyone, for joining us today. As previously shared, we reported particularly strong results across all segments for the second quarter and the first half of 2023.

During the second quarter, adjusted operational sales growth by Pharmaceuticals, excluding COVID-19 revenue, accelerated 6.2% over the first quarter of 2023. Similarly, on a sequential basis, MedTech operational sales increased 4.5% over an already strong first quarter.

During the first half of the year, we executed against our long-term business strategy and achieved key clinical and regulatory milestones. These advancements provide a strong foundation for long-term growth and are a testament to the hard work and dedication of our talented colleagues around the world.

We also made considerable progress toward the separation of Kenvue. On May 8, as partial consideration for the transfer of the Consumer Health business, Kenvue paid \$13.2 billion to Johnson & Johnson from the net proceeds of the initial public offering and debt financing transactions in connection with the separation.

Today, we were pleased to announce an update on our next step toward the separation of Kenvue. Subject to market conditions, our intention is to split off Kenvue shares through an exchange offer as our next step in the separation. As part of the proposed exchange offer, Johnson & Johnson shareholders will have the choice to exchange all, some or none of their shares of Johnson & Johnson common stock for shares of Kenvue common stock subject to the terms of an offer.

We believe a split-off is the most advantageous form of separation for Johnson & Johnson, Kenvue and our shareholders. Specifically, an exchange offer provides Johnson & Johnson the potential opportunity to acquire a large number of outstanding shares of Johnson & Johnson common stock at one time in a tax-free manner for U.S. federal income tax purposes without reducing overall cash or future financial flexibility. Further, following the completion of the exchange offer, Kenvue would most likely have a shareholder base that would have made the election to own its shares.

The exact timing of our decision to launch an exchange offer will, as stated earlier, depend on market conditions. But the launch of the tender could occur as early as the coming days. Offer terms for the exchange, inclusive of applicable discounts, as well as the duration of the exchange tender period, would be set upon launch.

We understand that you may have questions on this process. At this point, there are no additional details about the contemplated split-off to share, but we are committed to providing timely updates as appropriate.

Let's now turn to cash and capital allocation. We ended the second quarter with approximately \$29 billion of cash and marketable securities and approximately \$46 billion of debt for a net debt position of \$17 billion, inclusive of approximately \$7 billion of Kenvue net debt.

Free cash flow through the second quarter was approximately \$5.4 billion compared to \$8.1 billion in the prior year. The second quarter reflects elevated tax payments of approximately \$2 billion related to TCJA and past audit-related matters.

Our capital allocation priorities remain unchanged, with continued investment in our business being the highest priority to drive new and better solutions for patients, followed by dividends increasing on an annual basis, adding strategic opportunities for inorganic growth and share repurchases when attractive.

Our R&D investment in the first half of 2023 was \$7.4 billion or approximately 15% of sales. This includes external investments, such as our recently announced partnership with Cellular Biomedicine Group on 2 next-generation CAR-Ts for the treatment of B-cell malignancies, further broadening our cell therapy portfolio.

In April, we announced our 61st consecutive year of dividend increases. And in combination with the completion of our \$5 billion share repurchase program authorized by the Board in September of 2022 and completed earlier this year, we returned \$8.5 billion to shareholders in the first half of 2023.

Let's discuss our outlook for the balance of 2023. Before I get into the specifics of guidance, in light of the potential Kenvue split-off transaction, I will remind you that our updated full year guidance today continues to include results from the Consumer Health business, given Johnson & Johnson remains the majority shareholder of Kenvue.

I suspect you already know this, but it would not be accurate to subtract any guidance provided separately by Kenvue from total Johnson & Johnson guidance and assume that the resulting total reflects guidance for the new Johnson & Johnson. When Johnson & Johnson is no longer the majority shareholder of Kenvue, we will provide timely updated new Johnson & Johnson guidance that will reflect, among other things, the removal of Consumer Health's current contribution to Johnson & Johnson's performance as well as any updates to Johnson & Johnson's outstanding share count.

So with that context, moving on to our full year guidance. Based on the strong results delivered in the quarter, like we did in April, we are again raising full year operational sales and EPS guidance despite some strategic items not accretive to EPS as detailed on this schedule. Specifically, the lost income related to the approximate 10% noncontrolling interest in Kenvue and the acquired in-process research and development costs related to our investment in Cellular Biomedicine Group.

We now expect operational sales growth for the full year 2023 to be in the range of 7% to 8% or up \$1.4 billion in the range of \$99.3 billion to \$100.3 billion on a constant currency basis, and adjusted operational sales growth in the range of 6% to 7%.

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 U.S. dollar at \$1.10. The euro spot rate as of mid-last week remains at \$1.10. However, the U.S. dollar has strengthened versus other select currencies, such as the won and the yen. As such, we now estimate a negative impact of foreign currency translation of approximately 500 basis points, resulting in estimated reported sales growth between 6.5% to 7.5% compared to 2022 with a midpoint of \$99.3 billion.

Regarding other lines on the P&L. We now anticipate a slight improvement to our adjusted pretax operating margin driven by expense management. We have reduced our other income estimate to be in the range of \$1.6 billion to \$1.8 billion, primarily related to the company's 10.4% noncontrolling interest in Kenvue.

Regarding interest income and expense. We now anticipate a reduction of net interest expense to the range of \$150 million to \$250 million due to interest income on the net proceeds linked to the Kenvue separation.

And finally, based on current tax law, we are maintaining our effective tax rate estimate in the range of 15.5% to 16.5%.

These changes result in us increasing our adjusted operational earnings per share guidance by \$0.10 per share to a range of \$10.60 to \$10.70 or \$10.65 at the midpoint on a constant currency basis, constant currency growth of 5% 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 assumes no additional foreign exchange impact. As such, our reported adjusted earnings per share for the year increases by \$0.10 per share to a range of \$10.70 to \$10.80 or \$10.75 at the midpoint, reflecting growth of 6% at the midpoint.

While we do not provide guidance by segment or on a quarterly basis, let me offer some qualitative considerations to support your modeling. In MedTech, we continue to anticipate stable procedure volumes and health care staffing levels in the back half of the year with normal seasonality. We expect continued competitive performance attributable to commercial execution, recently launched products and improvement in supply. Headwinds from volume-based procurement in China as well as potential impacts from international sanctions in Russia are expected to be higher in the second half than the first half of the year.

In Pharmaceuticals, we continue to expect to deliver our 12th consecutive year of above-market growth in 2023, driven by key assets and continued uptick of our newly launched products. We expect continued strong growth in the back half of the year slightly higher than the first half.

When modeling Consumer Health growth rates in 2023, it's important to take into consideration prior year comparisons with lapping price increases in the back half of the year.

Given the strong momentum in our Pharmaceutical business and the upcoming clinical milestones mentioned earlier, we remain very confident in our ability to meet our 2025 Pharmaceutical sales target of \$57 billion.

Looking ahead, we have many important catalysts for the remainder of the year that can drive meaningful near- and long-term value. Beyond the separation, in the near term, we are continuing to drive performance in MedTech, with better commercial execution and recently launched innovative products being a significant factor in driving the continued higher growth trajectory across the MedTech business.

Many of the solutions mentioned are early in their commercialization, which means there is still significant opportunity ahead. For example, in electrophysiology, we are excited to begin the commercialization of the QDOT microcatheter in the U.S. during the second half of this year. In Orthopaedics, the VELYS Robotic-Assisted Solution recently received regulatory approvals in Europe, and we plan to launch it in key European countries by the end of this year. And in Vision, we are seeing the benefits of our recently launched innovations, such as ACUVUE OASYS MAX 1-Day multifocal, which is driving Johnson & Johnson's market share growth in the large and growing presbyopia market. We look forward to continued growth from this and other recent Vision launches.

Related to our Pharmaceutical business. We are excited about upcoming advancements in our pipeline with a number of important regulatory and clinical milestones for our key future assets, including on the regulatory front, there is expected approval of talquetamab in relapsed or refractory multiple myeloma.

Clinically, we expect Phase III data for TREMFYA for Crohn's disease and ulcerative colitis, the results of the MARIPOSA study of RYBREVANT plus lazertinib in frontline non-small cell lung cancer with the opportunity to potentially present that data at an upcoming major medical meeting, Phase I data for TAR-210 in non-muscle invasive bladder cancer and Phase II data for nipocalimab in rheumatoid arthritis.

A couple of other items to highlight. In case you missed them, we recently published our Health for Humanity Report, our U.S. Pharmaceutical Pricing Transparency Report and our U.S. Patent Table, all of which can be found on our website.

Also a reminder that we will be hosting an enterprise business review featuring both Pharmaceutical and MedTech at the New York Stock Exchange on December 5.

I'll conclude my prepared remarks by reiterating that we have had a strong first half of the year both financially and operationally, and we expect to continue to build upon that momentum in the second half of this year.

With that, I will now turn the call over to Erik Haas.

Erik Haas - *Johnson & Johnson - Worldwide Vice President of Litigation*

Thank you, Joe. On Tuesday, July 18 in the case of Valdez v Johnson & Johnson, a jury in Alameda County, California ruled in favor of the plaintiff on his talc product liability claims. We intend to pursue an appeal based on the erroneous rulings by the trial judge that prevented us from sharing with the jury critical facts that demonstrate that plaintiff's exceedingly rare form of mesothelioma was not caused by baby powder.

Without the benefit of that evidence, the jury rendered a verdict that is irreconcilable with the decades of independent scientific evaluations confirming Johnson's Baby Powder is safe, does not contain asbestos and does not cause cancer. The research, clinical evidence in over 40 years of studies by independent medical experts around the world continue to support the safety of our cosmetic talc.

The verdict award will not be paid while the bankruptcy proceeding continues, and this decision has absolutely no impact on that process, which has the support of lawyers representing the majority of claimants. We remain focused on all claimants having the opportunity to vote and decide for themselves on our plan to compensate them in a timely and efficient manner.

Looking ahead with respect to the bankruptcy refiling by LTL. The bankruptcy judge is expected to rule by August 2 on the motion to dismiss hearing that took place in the last week of June. In addition, a hearing on the motion for LTL's proposed reorganization plan and voting procedures process and the path forward is scheduled for August 22.

As we previously stated, Johnson & Johnson stands by its position that its talcum products are safe, as confirmed through decades of numerous independent scientific tests and studies.

I would now like to hand the call back over to Jess.

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

Thanks, Erik. This concludes the prepared remarks section of our call. I will now turn the discussion over 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

(Operator Instructions) Our first question is coming from Larry Biegelsen from Wells Fargo.

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

Congratulations on another strong quarter here. For Erik, if Judge Kaplan dismisses the bankruptcy proposal, what's the backup settlement in mind that would proceed outside of bankruptcy that could ring-fence the cost?

And Joe or Joaquin, in MedTech, how are you thinking about the sustainability of the first half strength where you grew 8% organic? Do you still expect the MedTech market to grow 5% to 7% this year? With J&J in that range, it seems conservative.

Erik Haas - *Johnson & Johnson - Worldwide Vice President of Litigation*

Larry, it's Erik. Thanks for the question. If Judge Kaplan dismisses the bankruptcy, we will be back in the tort system. And in that scenario, we intend to fight the claims aggressively.

And indeed, based upon the indicated decades of scientific support for the safety of our talc products, the fact that our talc products do not contain asbestos and the fact that our talc products do not cause cancer, we feel very confident in our ability to continue to prevail in the vast majority of claims as we have done in the past in the tort system.

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

Thank you, Larry, and thank you for complimenting us on the results on the first quarter and also on the MedTech ones. When it comes to the MedTech results, the growth in the first half of the year was north of 8%. So this is a continuation of the sustained improvement in our performance that we have had in the last couple of years in which we have grown at or above our competitive composite.

When we think about the dynamics that are driving our growth, which are multiple, one is the recovery in the overall market procedures, which is helping; our improved commercial execution; and then especially, the cadence and flow of new product launches that we are having in the market, we see our trajectory in MedTech in the first half of the year continuing in the second half of the year. So we expect a similar trajectory for MedTech in the second half of the year.

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

Yes, Larry, maybe I might just add to Joaquin's comments. The only thing that is limiting the growth, I would say in the back half of the year, is China volume-based pricing as well as some international sanctions in Russia. But those are already incorporated into our outlook for the balance of 2023. So we feel we have those well in hand. If there's a little bit of abatement on either of those fronts, it portends well for the future.

Operator

Next question is coming from Vamil Divan from Guggenheim Securities.

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

So maybe just one on the guidance commentary. So I appreciate what you said around the Kenvue and Cellular Biomedicine dynamics. But I'm curious about STELARA. Because you have the 2 settlements now, I don't think there's any chance for having a biosimilar enter this year. And I think before, you had expected that. So I'm curious what your expectations are now in terms of biosimilar entry before Amgen. And how does that impact sort of your guidance expectation for this year? And if you want to comment on sort of next year or sort of how it might impact 2025 with the \$57 billion there.

And then one also, the other one if I could, just on MARIPOSA. We've been getting a lot of questions just sort of what's changed there. I know before, the study is supposed to end next year. We obviously heard about the interim on your last earnings call. But then in the last few weeks, it sounds like there's a chance we'll get the data sooner this year and you may even be able to present it. So kind of what's changed from April to now to give you a sense that the data may come a little bit earlier and give you a chance to present it this year?

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

Thanks for the questions, Vamil. I'll start with STELARA and then see if Erik can add anything from a legal perspective, and then we'll hand it over to Joaquin for your question on the MARIPOSA study.

With respect to STELARA, this year, there won't be a significant impact. As you can imagine, most of that business was contracted for the full year about this time last year. So there really wasn't any material impact. And our current assumption, based on some of the agreements you read about, similar to what we've said previously, is that we wouldn't expect anything before January 1, 2025.

I don't know, Erik, from a legal perspective, anything to add?

Erik Haas - *Johnson & Johnson - Worldwide Vice President of Litigation*

Yes. Thanks, Joe. From a litigation perspective, I could say that no other biosimilar is better positioned in our view than Amgen or Alvotect would be. So we would not anticipate any other biosimilar having the opportunity or ability to enter the market before those 2.

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

Thank you. And with respect to MARIPOSA, nothing has changed. This is an event-driven study with a final analysis expected, as we said, by the end of 2023 with a potential to be presented at a major medical meeting in 2023. We remain excited about the potential of RYBREVANT in combination with lazertinib to become a new standard of care in first-line nonsmall cell lung cancer with EGFR mutations. And we are looking forward to be able to present these results in due time in a medical meeting potentially this year.

Operator

Your next question today is coming from Joanne Wuensch from Citibank.

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

I'm trying to think about 2 things as I look forward to -- given the strength in the first half of the year in MedTech, does this create, in your opinion, a new base from which we grow from? Or are we going to be writing about difficult comps next year?

And second of all, with Kenvue's split-off by within days or by the end of this year, I anticipate, how do we think about different investments in the MedTech and Pharmaceutical franchises, either through pure R&D internally or externally?

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

So as I commented in the earlier question, we are pleased with the strength of our MedTech business in the first half of the year with 8% growth. This is driven by market growth, which we believe it's also slightly elevated this year due to the clearing of the COVID-19 backlog; and at the same time, as I commented, to our improved commercial execution and the introduction of new products.

Of note, of our 12 \$1 billion platforms in MedTech, all of them have grown during the first half of the year. And we are being quite successful in introducing some important new products in all segments of our business.

For example, if I start with electrophysiology, that grew north of 25% in the quarter. We have introduced a new mapping catheter, OCTARAY; and also a new treatment catheter, QDOT. Which as you know, Joanne, we presented results about QDOT, so we increased efficacy and procedure efficiency, too.

If we move into Vision, we are in the middle of the launch of ACUVUE OASYS MAX, which is doing well; and also the launch of our TECNIS Eyhance, the first monofocal intraocular lens, which is progressing also very well.

Moving into Orthopaedics. The good news is that we have received CE Mark and CA Mark for our Robotic-Assisted System, VELYS. And we continue to have an enhanced portfolio of knees and hips with our cementless knees, the medial stabilized, and in the area of hips with Hip Navigation and the recent addition of CUPTIMIZE. And we see our market position there also progressing. And moving forward, we will continue to see good evolution also in Orthopaedics.

Finally, in Surgery, we continue to enhance our endocutter and our energy portfolio with the launch of ENSEAL jaw, curved; and also with the launch of ECHELON 3000 in the stapler side.

So overall, good reception of our new products. That portend well for a continuation of growth, as I said before, in the second half of the year.

And we look forward also to the different readouts of our PFA pipeline, which as we have announced, we have completed the enrollment of our dual-energy catheter, which is going to be offering the physicians the comfort of a catheter that fits the most widely used with the option of having both radio frequency and PFA to adapt to every patient anatomy.

And then on the robotic side, we will provide you more updates on our progress on Ottawa, our soft tissue robotics system, before the end of the year, as we committed. And we have also good news on our MONARCH system that has already started with the first patient treated in removal of kidney stone.

So overall, good progress during the year. Clearly, our MedTech business is doing well, delivering competitive growth. And we have good news in innovation as the year moves forward.

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

And Joanne, with respect to your second question and completing the Consumer Health separation. Our capital allocation priorities aren't changing. So we're going to continue to invest organically in our own pipeline.

You saw that we pretty much have kept our percent to sales, which leads across industries as a top 10 investor in R&D on an annual basis. We prioritize that. We realize that, that is underpinning our future success, as we have demonstrated. The dividends and the share repurchases that we've done this year has already returned a significant amount back to shareholders. And then we'll always be on the hunt for real good strategic opportunities that fit with either the clinical or science expertise we have or commercial capabilities that we can offer that drive more value out of a potential asset in our hands than where it currently resides. So we are looking feverishly as we always do across both MedTech and Pharm.

Operator

Your next question is coming from Chris Schott from JPMorgan.

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

Just the first one is, would love just some additional views on the \$57 billion pharma target by 2025. It seems like between the pipeline progress we've seen this year and the STELARA settlements, you've had some clear positive updates over the past few months. And I'm just wondering, just level of confidence in that target, and has that increased as we've gone through this year?

And then my second question was just for Erik on talc. Is there any update in terms of the number of plaintiffs where you have an agreement on the settlement terms relative to where we stood with the comments in April? And just where you stand right now relative to that 75% threshold you ultimately need.

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

Thank you, Chris. And let me start with your first question. We have always been confident on the fact that we will reach our \$57 billion target by 2025, as we announced back in 2021. And certainly, what we are seeing now increases and reinforces and enhances our confidence.

On one hand, you're seeing the progression of our Pharmaceutical portfolio and our existing products with excellent results in DARZALEX, TREMFYA and ERLEADA, also in our pulmonary hypertension franchise and in our long-acting injectable anti-psychotic franchise, which are key products in this period.

We are very pleased with the trajectory of our new product launches, including CARVYKTI, TECVAYLI and SPRAVATO. If I focus on CARVYKTI, you see a clear improvement quarter-over-quarter in CARVYKTI, which reflects improvements in supply.

In TECVAYLI, you see also a clear improvement. Of note, when we look at the TECVAYLI launch, align data with DARZALEX in the addressable patient population, TECVAYLI, it's having a faster introduction.

And finally, SPRAVATO, which is doing well. And now we see SPRAVATO as a \$1 billion-plus product, and you're seeing the results this quarter also reaching close to \$170 million.

If we look at our pipeline and the products of the pipeline that are going to impact this period, we are expecting the PDUFA date of talquetamab, our GPRC5D CD3 bispecific antibody, which is going to give another option in the treatment of multiple myeloma.

And we continue to progress and execute well in some of the key products in our pipeline. I commented on RYBREVENT and the combination of lazertinib, as you know. We received fast track designation for the 3 key indications of milvexian, our Factor XI oral anticoagulant that we are working in collaboration with Bristol-Myers Squibb. We presented very positive data about TAR-200 in non-muscle invasive bladder cancer in meeting in the American Urological Association. And we also -- when it comes to CARVYKTI, we were very pleased to show the data on CARTITUDE-4. We are filing the BLA now, both in Europe and in the U.S. And we are expecting to show you some data on nipocalimab in rheumatoid arthritis. We also have already presented in hemolytic disease of the fetus, of the newborn.

So in every angle of the products that we highlighted as the core products of our pipeline, we are executing well. Plus we recently presented in the World Congress of Dermatology our data in our oral IL-23 receptor antagonist peptide, which shows great efficacy in psoriasis. And we have announced plans to continue developing into psoriasis and also a Phase II study in ulcerative colitis.

So overall, when I look at the picture for 2025, we have increased confidence based on our portfolio, in our new product launches and how we are executing on our pipeline.

But now I would like to look even beyond 2025 if you allow me, Chris, because 2025 is very close. It's only 3 years from now. So what I think you are seeing with this renewal of our portfolio is a very strong position for Johnson & Johnson in Pharmaceuticals beyond 2025. And that's something that we need to highlight, and I think it's important for everybody to recognize. This is going to put us in a great position beyond 2025.

Erik Haas - *Johnson & Johnson - Worldwide Vice President of Litigation*

Turning to the question with respect to the number of claimants. Good and important question. The most recent update comes from the hearing on the motions to dismiss that finished on June 30. And I would refer you to the post-trial findings of fact and conclusions in law that were filed last night that really detailed the evidentiary record that was elicited during the hearing.

Based upon that testimony that was elicited and the evidence that went in, we are now looking at approximately 60,000 claimants in support or lawyers who represent 60,000 claimants in support of the plan, and lawyers who represent about 40,000 claimants in opposition.

So the numbers right now show that the vast majority of claimants support the proposed plan. Based upon the testimony during that hearing from the lawyers that support those claimants, we are confident that, that support will not waver. And we do anticipate that additional support will be coming forward.

Operator

Our next question is coming from Trung Huynh from Credit Suisse.

Trung Chuong Huynh - *Crédit Suisse AG, Research Division - Research Analyst*

Just 2, if I may. So just on -- thanks for your thoughts on the talc outcome. Should we just expect any more similar suits like the one in Alameda in the near future?

And then secondly, do you know -- just a clarification on MARIPOSA, if another interim passed for MARIPOSA?

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

So let me start with the MARIPOSA. No. I mean, we are -- as we communicated, we are moving into a final analysis by the end of the year, potentially presenting the data at the end of the year.

Erik Haas - *Johnson & Johnson - Worldwide Vice President of Litigation*

And with respect to the talc suits, we don't anticipate additional individual actions to go up for it outside the bankruptcy. Judge Kaplan lifted the stay only with respect to that one particular case, the Valdez case. Indeed, subsequent to that, he denied a request from the same counsel to lift the stay on another case. So currently, I would not anticipate any other case to go forward in advance of a ruling on the motion to dismiss.

Operator

Next question is coming from Terence Flynn from Morgan Stanley.

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

Congrats on the quarter. I had 2. I was wondering, Joaquin, we've talked a lot about the myeloma market evolution over the last decade or so. J&J has been a leader there. This is a \$20 billion market. You obviously have a number of different options now for patients, including TECVAYLI most recently and talquetamab with upcoming PDUFA date. So I guess my question is just, top down, what prevents you from capturing a majority share of that \$20 billion market?

And then, Joe, a question for you on margins post-Kenvue. Any early idea you can give us in terms of how that structure could evolve post the full separation?

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

Yes. So thank you for the question. And the answer is nothing prevents us from doing that. As a matter of fact, our aspiration in myeloma is that, with the portfolio that we have today with DARZALEX, TECVAYLI, talquetamab and CARVYKTI, we would be in a position to have 3 out of every 4 patients starting in Janssen containing regimen by the end of this decade. So that's our aspiration in myeloma. Our aspiration is that there is a Janssen regimen for every line of therapy and a Janssen treatment for every patient irrespective of their characteristics. And that's the way we are planning our development.

Certainly, DARZALEX being a backbone of therapy, first line, and also in combination with multiple agents; and then sequencing into CARVYKTI and talquetamab and TECVAYLI, which we are studying in combination with DARZALEX and also in combination among each other and sequencing among them.

So ultimately, our goal when it comes to multiple myeloma is to be able to sequence our medicines, combine them in a way that we are changing the treatment paradigm from treating to progression to treating to cure. And that is a big, big, big plus in our portfolio. And as I have commented often, multiple myeloma is the core of our Pharmaceutical franchise and the #1 growth driver that is going to be for 2025 and beyond.

There's more factors that give us optimism about the business potential of this area, is that as we combine and as we seek those treatments, the treatment duration itself is going to be significantly increased. So we overall foresee great patient and growth opportunity as we look to combine all these modalities, as I said, in order to be able to convert multiple myeloma into a chronic disease.

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

And Terence, thanks for the question regarding margins. And specifically, I think you're getting at the heart of the potential deleverage that could occur with the separation once Kenvue is on its own entirely.

You may recall a couple of quarters ago on one of these calls, we said that there was potentially \$500 million to \$750 million of deleverage in SG&A. We embarked on an initiative -- and I guess the benchmarks would suggest companies usually take about 2 to 3 years to get those costs out of their system.

Last summer, we really embarked on a project to eliminate those costs in a much faster cadence. And I would say of that \$500 million to \$750 million, there's a small fraction that may remain, and we're still working to eliminate that. So you should expect, as you're modeling, no deleveraging or very, very little deleveraging from the Kenvue separation.

Operator

Your next question today is coming from Danielle Antalffy from UBS.

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

Just a follow up on some of the capital allocation commentary. Joe, I appreciate what you're saying that things haven't changed. But I'm just curious, now that you guys have integrated Abiomed, you're seeing some success there, how your appetite -- for specifically within medical devices and MedTech, how your appetite for potentially larger deals may have changed?

And are there any specific areas you would call out within cardiology now that you do have Abiomed, or just with -- throughout medical devices, as areas of interest or where you feel underscaled and you might benefit from building out there?

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

Yes. And I know you directed the question to me, and I'll answer with one word. I would say our appetite is pretty voracious at this point. But I'll leave it to Joaquin with respect to the size of the deals. I don't think -- it unequivocally doesn't change, whether it's big or small, it has to be a really good strategic fit utilizing the expertise and capabilities that we have and has to provide financial value.

Joaquin, maybe you want to comment on any specific areas that are of interest.

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

Yes. Thank you, Danielle. And before I go there, let me say that the Abiomed integration is progressing really well. The growth of Abiomed, it's been 20% on the quarter. and we continue to move forward with the enrollment in the key PMA studies, PROTECT and STEMI DTU, as well as the

Impella ECP. So everything is moving well according to plan in the Abiomed integration. And we are increasingly convinced that this is going to be a key component of our MedTech strategy in becoming a leader in heart recovery.

So when it comes to M&A, look, we continue to look for opportunities. And our #1 criteria in looking for opportunities is the medical innovation, how they improve patient care, how do we see the science behind the product? So we are agnostic in that sense to MedTech and Pharmaceuticals. It's all about identifying areas that are going to have a significant impact in patient care.

When it comes to MedTech, certainly, as we have commented, we are continuing to look forward for opportunities to grow into areas that are close to where we are today. Vision, Cardiovascular obviously, Surgery too, and also opportunities in certain high-growth segments of Orthopaedics. And we normally will continue to look for these opportunities, trying to have a good return on capital as well as things that are close to our existing expertise.

When it comes to pharma, our history in tuck-ins, in license and collaboration has been very successful. As a matter of fact, external innovation represents about 50% of our pipeline. And while we will continue to look for opportunities like we have done now with Cellular Biomedicines and the agreement that we have too in CAR-T, we are not averse to other transactions of larger size. Evidently, both in MedTech and in pharma, we are very disciplined with our capital allocation. And all our transactions will have to clear certain financial milestones for us to be able to move on. But M&A and also licensing acquisition collaborations remains a key factor in our growth moving forward.

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

We have time for one more question.

Operator

Our final question today is coming from Louise Chen from Cantor Fitzgerald.

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

Congratulations on the quarter. So I wanted to ask you where your latest thoughts on IRA are and the potential impact to the drug industry and also to J&J.

And second question was just on CARVYKTI. Just curious how you expect to expand into earlier lines of treatment and then more widely into the community.

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

Yes. So let me start with the IRA. Obviously, we remain very concerned about the government price-setting environment that the IRA creates, which we believe creates a significant disincentive to innovation without addressing the core problem, which is patient access. So it is a significant concern for us. And that's one of the reasons, as Erik commented earlier, that we have filed a lawsuit versus the IRA. So that's important for us.

Then when it comes to the actual business impact, I think it's still early to be able to calculate it, given the fact that many of the rules and procedures are still in flux. So it would be too much to be able to try to anticipate that.

In our case, when we look at Johnson & Johnson, relatively speaking towards the industry, based on our diversification between MedTech and pharma and also the diversification of our pharma portfolio, we feel that we are well positioned competitively to continue to grow well beyond the second half of this decade. So we remain concerned. But at the same time, we think we are prepared to be able to manage successfully any situation coming from that relative to other industry players.

The second question was about CARVYKTI. As I commented earlier, we are working to improve CARVYKTI supply, which is very important. You've seen that improvement in our sales in the second quarter. We are working in different ways. One is we are increasing capacity. We have internalized the production of lentivirus now. And also, we are in the process of increasing the number of slots internally. And also, we have reached agreements with other companies like Novartis to continue to increase capacity. So we are going to be in the trajectory of increasing capacity gradually in order to be able to eventually meet demand that exists in CARVYKTI.

As far as reaching to other patient populations, the CARVYKTI 4, it's already been filed. And it's moving CARVYKTI into earlier lines of therapy, and we are also working in first line with CARVYKTI 5 and CARVYKTI -- excuse me, with CARTITUDE-5 and CARTITUDE-6. So we are clearly intending to move CARVYKTI through CARTITUDE-4, CARTITUDE-5 and CARTITUDE-6 into earlier lines of therapy. And we are increasingly convinced of the potential of CARVYKTI to be one of our more than \$5 billion assets that we announced back in 2021.

Jessica Moore - Johnson & Johnson - VP of IR

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

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

Joaquin Duato - Johnson & Johnson - CEO & Chairman

Thank you, Jess, and thank you to all of you for joining this call today. I'm extremely proud of the performance that we have achieved in the first half of 2023. We are entering the back half of the year from a position of strength with numerous catalysts, including the fact that we are going to be a 2-sector company focused on Pharmaceutical and MedTech research, development and innovation.

We look forward to having future engagements with you to update you on our continued progress. Thank you very much, and enjoy the rest of your day.

Operator

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

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