

# Otsuka Holdings Co Ltd

## The 3<sup>rd</sup> Medium-Term Management Plan FY 2019 - 2023

### Q&A

May 30, 2019

**Q1:** How will you ensure that management focused on capital costs spreads throughout the Group?  
While seeking to lower capital costs requires prioritizing time, it takes a long period of time to implement Otsuka's value creation model, and it is not easy to change the corporate culture, so how will you go about doing this?

**A1:** We will continue with our plans and strategies for each business company, as well as our assessment of these plans and strategies, and plan to build up this awareness through general initiatives.  
In addition, in considering investments and returns, we have in-depth discussions with operating companies on the underlying strategies, and expect that the quality of management will improve through such means. However, in some cases, we have to be patient in the short term if there are long-term chances consistent with our strategy.

**Q2:** You mentioned that Otsuka Holdings is considering making extra returns to shareholders, but what situations would this be offered in? Is there a benchmark?  
In addition, if these extra returns are provided, would the Company prioritize higher dividends or share buyback?

**A2:** The period covered by our 3rd Medium-Term Management Plan is the growth period for the new products we invested in during the 2nd medium-term plan. We expect substantial returns, but the outlook is uncertain. Revenue from *JYNARQUE* is currently strong, and if we build up cash flow, we can consider making additional shareholder returns. At this point, stable dividends are our top priority.  
We will make a decision on whether we will increase dividends or buy back shares based on conditions at that point.

**Q3:** What is the policy for investing SG&A costs into new drugs?

**A3:** Our overall SG&A ratio has fallen slightly from constant levels, but our policy is to change the breakdown, lower the S&GA ratio for already launched products and prioritize growth investments in new drugs.

**Q4:** Do you expect to maintain or further raise the profit ratio in the Nutraceutical Business?

**A4:** During this medium-term management plan, we plan to expand topline, and make investments as necessary. From a mid- to long-term perspective, we may need to be patient during this plan's period. We expect that, rather than maintaining the profit ratio at the same level, we will be able to gradually increase it in the second half of the period. However, we will not put too much weight on raising the profit ratio and intend to make investments expediently.

**Q5:** Do you have strategies and policies tailored to specific regions? Which regions will see higher sales revenue?

**A5:** The Nutraceutical Business has different products and strategies depending on the region, and we plan to boost sales revenue uniformly, primarily in Japan, North America and Asia. Expanding into new areas requires initial investments.

In the Pharmaceutical Business, we plan to increase sales revenue primarily in North America and Asia.

**Q6:** While revenue in the Pharmaceutical Business is increasing significantly, your forecasts do not show significant improvements in the profit margin. Why is that?

**A6:** Business profit before R&D investment in the 3rd Medium-Term Management Plan is expected to be higher than in our initial forecast for the final year of the 2nd Medium-Term Management Plan. Business momentum has been increasing.

**Q7:** With a management approach focused on lowering capital costs, what is the role of profitability in the Consumer Products Business and Other Businesses, and its role in the business overall?

**A7:** When we adopted IFRS, we determined that reporting the investment profit/losses of all companies that had introduced the equity method as operating income was the best policy. The Consumer Products Business, particularly the water business, contributes to equity-method economy, and it is generating income overall.

Moreover, Otsuka Foods and Otsuka Pharmaceuticals have a long history of collaborating on product development, and some of the products developed at Otsuka Foods' research labs are sold by Otsuka Pharmaceuticals as products in the Nutraceutical segment. Going forward, we expect such interaction and contributions on the technology front in our global expansion.

**Q8:** R&D expenses for 2023 are high; what are the factors behind this? Will the late-stage clinical trials for the compounds in the current pipeline have been finished by then?

**A8:** As you have pointed out, many trials currently in Phase 3 will have been completed in 2023. At the same time, new clinical trials will begin, such as ones for VIS649. In the psychiatry and neurology fields, we need to add new indications for *Rexulti* to include PTSD and others. In the oncology area, we have many early stage assets in the pipeline during this Management Plan period, particularly from Taiho Pharmaceutical. If we make steady progress in developing these assets, we continue to need a certain level of R&D investment. If R&D expense seems to increase too much, we will prioritize our programs and control them cautiously.

**Q9:** Profitability in the Pharmaceutical Business is not expected to improve during the 3rd Medium-Term Management Plan since home grown products will make little contribution to profit through 2023, but will this improve from the 4th medium-term plan period? What about the balance with R&D expenses?

**A9:** We expect contributions from the ongoing growth of the current drivers that we invested in during the 2nd Medium-Term Management Plan and growth of new products to be launched during the 3rd Medium-Term Management Plan. We do expect profitability to improve in the 4th Medium-Term Management Plan.

On the other hand, in Japan, the contracts for *SPRYCEL* and *E Keppra* will be terminated during the 3rd Medium-Term Management Plan, and we forecast lower revenue in the Pharmaceutical Business. To make up for this negative growth, we will have to make strategic investments such as in-licensing deals.

**Q10:** The forecasts for the Nutraceutical Business look aggressive. N&S is currently struggling on the earnings front, so are these forecasts feasible? Also, are you thinking of acquiring brands in order to achieve these forecasts?

**A10:** It is easy to predict sales revenue for pharmaceuticals based on the number of target patients population, but Nutraceutical (NC) products are not as simple as pharmaceuticals. A wide range of factors intersect, making predictions difficult. However, once NC products become established brands in the market and repeat customers increase, we can expect stable growth.

Nutraceutical business has a different business model and market context than the Pharmaceutical business, but we hope to focus on the market environment and move ahead while taking into account the products' and regions' attributes and the timeframe.

**Q11:** Business income in fiscal 2023 is expected to be 200 billion yen, about the same as in the last fiscal year of the 2nd Medium-Term Management Plan, but isn't this a conservative forecast, including sales revenue from mainstay products?

**A11:** We want to make cautious forecasts based on current conditions. Moreover, there are uncertainties around the scale of R&D investments. We will make revisions to our sales and profit forecasts as necessary while monitoring conditions.

**Q12:** If profit increases more than expected, will you allocate the increment to R&D investment? Will you secure it as business profit?

**A12:** That will depend on conditions.

**Q13:** What is the overall trend of the SG&A ratio in the Pharmaceutical Business when including investments in new products, co-promotion fees and one-off factors?

**A13:** If global sales revenue from *Abilify Maintena* and *Rexulti* grow, co-promotion fees will increase. Moreover, if acquired or in-licensed products are launched, the amortization of intangible assets (marketing rights) also increases. In such a case, we would like to lower SG&A costs for existing products and keep a balance.

**Q14:** My understanding was that *Rexulti LAI* is under development as *Abilify Maintena*'s successor, but it is not included in the list of "main projects to be filed during the period." What is the status of its development at present?

**A14:** As for *Rexulti LAI*, we are currently optimizing the formulations for intramuscular and subcutaneous injections. Since this we would not be ready to file for approval during the 3rd Medium-Term Management Plan, we do not include it on the list.

**Q15:** You use ROE as a KPI, but if we assume that the factors on the shareholders' equity side will not change significantly, am I right in thinking that you expect to achieve the ROE target by expanding net income? Would it not be achieved if you make growth investments such as M&A?

In addition, ROE of 8% is low compared to the global standard. How do you plan to improve this?

**A15:** As you pointed out, ROE of 8% is low, but the ROE was extremely low in 2018 due to extraordinary factors. Given this situation, we plan to return it to at least 8% or higher during the period covered by the 3rd Medium-Term Management Plan. In order to raise returns, we want to optimize costs while increasing sales revenues in our businesses and enhance corporate value.

In the final year of our 1st Medium-Term Management Plan, ROE was almost 11% due to *Abilify's* contribution to revenue.

In the 2nd Medium-Term Management Plan, we aimed for ROE of 8–10%, but the penetration of generic drugs and lower drug prices in Japan, impairment losses and the impact of *Abilify's* generic status in Europe, as well as higher R&D expenses, all pressured profits more than expected, so that ultimately, ROE was just 4.7%.

However, total sales revenue from our three global products (*Abilify Maintena*, *Rexulti*, *Samsca/JYNARQUE*) grew to about 250 billion yen. Also, the acquisition of ReCor Medical Inc., which develops renal denervation devices, resulted in valuation gains and had other positive effects as well.

We want to achieve an ROE of at least 8% in the period of the 3rd Medium-Term Management Plan, taking into consideration the growth of our core products and the diversification of products. Business has both investment periods and harvest periods, but we recognize that a minimum ROE of 8% or more is necessary in any phase.

**Q16:** What is the breakdown of the 90 billion yen in increased sales due to new products in the Pharmaceutical business?

**A16:** We do not disclose targets for each of our mainstay products, but by therapeutic area, we expect the psychiatry and neurology area to account for about 40% of sales, the oncology area for about 30%, and the cardiovascular and renal area for about 30%.

We have priced in AVP-786, fremanezumab, digital medicine, and *Selincro* in the psychiatry and neurology area, SGI-110, ASTX727 and TAS-120 in the oncology area, and vadadustat and renal denervation device in the cardiovascular and renal field.

**Q17:** What are the development plans for TAS-116?

**A17:** At present, we are developing it for GIST (gastrointestinal stromal tumors). GIST is a rare cancer, and in Japan we estimate that it affects 1-2 per 100,000 people. Given TAS-116's mechanism of action, we believe that we can expand its indications to other types of cancer as well. We aim to get approval for its use with GIST first, and then select target tumor types based in the MOA to expand its indications.

**Q18:** Is the 250 billion yen in capital expenditure a finalized figure?

Also, you explained that total operating cash flow during the 3rd Medium-Term Management Plan will be a maximum of 800 billion yen, but this is not enough for the total 950 billion in strategic investments and shareholder returns. What is the thinking on debt financing?

In addition, if the total operating cash flow target is not met, will you reduce shareholders' returns rather than growth investments?

**A18:** We make about 50 billion yen a year in capital investment, so we have estimated about 250 billion yen over five years. If our cash flow falls short, we will raise the money by means that are optimal at that point in light of economic conditions, whether that is bank loans or market financing.

We will make growth investments within a certain range in light of ROIC target. Our growth investments will not reach the point that we have to reduce shareholder returns. We plan to secure stable shareholder returns and then put the balance into growth investments.