Otsuka Holdings Co., Ltd.

FY2020 Q2 Financial Results Announcement
August 8, 2020 (Friday)

Contents

△ FY2020 Q2 Consolidated Financial Results
  Executive Director, CFO
  Yuko Makino

△ Progress of 3rd Medium-Term Management Plan
  President and Representative Director, CEO
  Tatsuo Higuchi

△ Pharmaceutical Development Update
  Vice President, Director of Corporate Planning Department
  Tomohiro Emura, Ph.D.
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FY2020 Q2
Consolidated Financial Results
(Six Months Ended June 30, 2020)

Executive Director, CFO
Yuko Makino
Otsuka Holdings Co., Ltd.
I would like to explain the consolidated business performance for the 2nd quarter of FY2020.
First of all, I will explain the financial highlights for the second quarter of fiscal 2020.

The Group's business activities have been affected to a certain extent by the global spread of COVID-19. However, even in such a situation, consolidated revenue increased by 3.6% year on year to 695.4 billion yen.

In the pharmaceutical business, our four global products grew by 26.2%, driving consolidated performance. On the other hand, revenues of intravenous solutions and some other businesses have been declining due to factors such as the suppression of patient visits to hospitals. The nutraceutical business was affected by a decrease in the opportunities for consumers to go out, but we were able to secure 96% of the sales year on year despite the impact of COVID-19, which was attributable to growth in our Nature Made, Daiya products, and EQUELLE products. As a result, business profit increased substantially by 16.7% year on year, and by the first half of the year we had increased profit by 10 billion yen compared to the initial plan.

For the full-year forecast of consolidated results, I will explain this later. We have upwardly revised the business profit by 5 billion yen against the initial plan. By promoting the growth of our 4 global products and further cost reduction, we aim for a business profit of 200 billion yen or more.
Next, I will outline the consolidated results.

As explained earlier, revenues from our 4 global products in the pharmaceutical segment increased. On the other hand, the nutraceutical business suffered negative results due to the impact of the new coronavirus infection. However, robust growth of Nature Made and the 3 nurture brands led to a consolidated revenue increase of 3.6%, year on year with an achievement rate of 99.3%, virtually in line with the initial plan.

Business profit before R&D expenses, an important performance indicator, rose 12.9% from the previous year, with an achievement rate of 107.8%, thereby meeting the initial plan as revenue did.

As business profit was up by 16.7% year on year, with an achievement rate of 109.6%, we secured revenue and profit increases despite the impact of COVID-19.
This compares the business profit this year to last year.

As was explained earlier, the 4 global products, our home grown assets in the pharmaceutical segment, contributed to a revenue increase of 16.3 billion yen.

Business profit increased by 16.7% to 113.9 billion yen.

For your reference, upward and downward factors by business segment are shown in the appendix.
This shows revenue and business profit by segment.

Our pharmaceutical segment saw robust growth both in revenue and business profit by 7.6% and 20.9%, respectively, driving the consolidated revenue and profit increases.

In addition, revenue declines in the nutraceutical, consumer, and other businesses were kept at single-digit levels thanks to reduced SG&A expenses from cost efficiency initiatives, and, as a result, business profit in each business segment was maintained at a level similar to the previous year despite the impact of COVID-19.

Next, let me explain specifics of our pharmaceutical and nutraceutical segments.
First, the revenue of the pharmaceutical segment.

Sales of the 4 global products were up by 26.2% year on year to 218.5 billion yen, continuing to make its significant contribution to the overall revenue increase.

On the other hand, as the number of operations and hospital bed utilization rates decreased due to the spread of COVID-19, intravenous solution sales were impacted. Diagnostics were also impacted by the early end to the influenza season. As a result, revenue from other products decreased.

As a result, revenue grew by 7.6% to 471.8 billion yen.
This shows a summary of the nutraceutical segment revenue.

In the functional beverages category, Pocari Sweat and Oronamin C drink sales decreased as consumer activity declined due to the spread of COVID-19.

In the functional food category, N&S reported decrease in revenue due to the impact of the lockdown and going-out restrictions in Europe, while sales of Daiya Foods brands increased due to expanded demand in North America.

In the vitamin and supplement business, revenue increased, mainly for products such as vitamins, in response to an increase in health management awareness.

Overall, revenue of nutraceutical segment was down by 4.0% year on year to 158.8 billion yen.
This last slide shows the consolidated performance forecast for FY2020.

The full-year plan has been revised considering the impact of COVID-19.

Revenue is now planned at 1.41 trillion yen, a decrease of 35 billion based on the first-half results. In the pharmaceutical segment, the impact of COVID-19 is uncertain, so we have not made any changes to our initial plan. Gross profit is expected to decrease by 15 billion yen, but the full-year business profit is expected to increase by 5 billion yen to 200 billion yen in the revised plan.

Annual dividend is planned to be 100 yen per share as set at the beginning of the fiscal year.

Please refer to the reference materials for the status of each segment related to this revision.

This has been the consolidated financial results for the 2nd quarter of FY2020.
Progress of 3rd Medium-Term Management Plan

President and Representative Director, CEO
Tatsuo Higuchi
Otsuka Holdings Co., Ltd.
I will explain the progress of the 3rd mid-term management plan, focusing mainly on an update of our pharmaceutical business and nutraceutical business.
This is a summary of our plan for FY2020.

Currently, we are steadily promoting our businesses toward realizing sustainable growth.

People’s lives have had to change significantly due to the impact of COVID-19. We must adapt to new lifestyles, that is, a new normal, and it has become harder to see the future.

In this environment, people's sense of values greatly fluctuates, and especially the importance of health is recognized again.

Based on the concept of total health care, the Otsuka Group has been promoting corporate activities encompassing maintenance and promotion of health and the diagnosis and treatment of diseases. Now in this era of the new normal, Otsuka is reassured that its philosophy of total healthcare is the correct approach.

Now is the time to demonstrate the true value of Otsuka and see the growing awareness of health in the new normal as an opportunity, and we will continue to move toward the realization of sustainable growth.

Under the unchanging corporate philosophy, the Otsuka Group will continue to work to contribute to a new society that can be achieved by our own total healthcare company.
I will now explain the initiatives for the post-cora era.

So far, we have been promoting various new initiatives in each value chain in order to deliver unique products and services that contribute to people's health around the world.

In the pharmaceutical business, we are strengthening our systems including new initiatives for the digitalization of operations and structure to support the start and continuation of treatment for patients. In the nutraceutical business, we are creating consumption opportunities by highlighting our product functionality in response to increasing health awareness, stimulating domestic demand by leveraging brand characteristics, and supporting the promotion of people's health rooted in each area.

By accelerating these conventional efforts under new normal era, we will contribute to the health of people around the world by creating new values in the form of innovative and high-quality products and services.
Now, I will illustrate our pharmaceutical business in detail.
In the outline of our strategy for the pharmaceutical business explained in the 3rd mid-term plan, we are promoting our businesses with the themes of value maximization of existing businesses and new value creation.
This is an update on our 4 global products.

During the 3rd mid-term period, the sales of these products are expected to increase by about ¥ 200 billion in 5 years.

Although COVID-19 has had some impact on our business activities, we have been making good strides with our initial targets by already achieving around 53% of our FY2020 sales target of ¥415.0 billion. We have confirmed an improved trend for new prescriptions of Abilify Maintena and Rexulti and that prescriptions for Lonsurf are also increasing given the background that home treatment and the use of oral anticancer agents are recommended by academic societies amid the spread of COVID-19.

In the second half of this year, we will pursue our business aiming to advance various initiatives for adapting to the new normal and maintain the momentum of our 4 global products so as to exceed the plan.
This shows how the *Jynarque* business in the US has been progressing.

Sales in the first half of FY2020 reached US$312 million, an increase of about 80% year on year.

Looking at the cumulative new patients, the number of new patient receiving treatment has slowed slightly due to the impact of COVID-19. However, we have seen an increase in sales due to a higher-than-expected number of patients who continue with treatment.

Moreover, even in this situation, there are still patients who are waiting to start treatment.

*Jynarque* is the only treatment available for ADPKD.

We believe our mission as a pharmaceutical company is to make preparations for delivering treatments smoothly, even under the new normal. We will therefore work to further enhance our systems for starting therapy and providing ongoing support.
We have made many achievements in 2020 that will lead to realizing sustainable growth. I will introduce them now.

In our three core therapeutic areas, psychiatry & neurology, oncology, and cardiovascular & renal systems, we have made many achievements towards maximization of existing business values and creation of new values. We have also had many achievements in strengthening our pipeline in Japan, which is a key investment area under the 3rd mid-term plan. In our in-house drug discovery and research, we have also successfully advanced many promising new compounds to the clinical phase.

Furthermore, to materialize Otsuka’s original perspectives and ideas, we will capture opportunities to use unique technologies in collaboration with partners, while continuing our efforts to develop new treatments that leverage Otsuka’s distinctive capabilities.
I would like to introduce INQOVI, which was approved in the US and Canada for the indications of myelodysplastic syndrome (MDS), and chronic myelomonocytic leukemia (CMML) in July 2020.

INQOVI is the world’s first oral DNA methylation inhibitor that has been approved by the FDA.

Amid the increasing need for oral formulations as also indicated in guidelines, we aim to contribute to patients by providing new treatment options that can reduce their burden, such as daily visits to medical institutions as required with conventional intravenous administration.

Furthermore, as part of our lifecycle management strategy, clinical trials for treatment naive AML, low-risk MDS, and combination therapy with ASTX660 are ongoing. We are also making preparations for other new clinical development programs, and will contribute to the health of many patients through initiatives that maximize product value.
This shows completion timeline of major P-3 programs.

Around early September, we plan to announce the P-3 topline results of vadadustat for anemia associated with chronic kidney disease in the non-dialysis stage, as Akebia Therapeutics disclosed in a press release the other day. We are jointly developing vadadustat with Akebia Therapeutics.

In addition, there are numerous programs with great potential to realize sustainable growth. We will make sure to take steady steps to advance them toward successful outcomes.
I will now give you updates on our nutraceutical business.
This is the outline of our nutraceutical business strategy.

Similar to our pharma business, our main themes are value maximization of existing businesses and new value creation. I will now explain our progress to date.
This graph shows the quarter to quarter growth in sales of Nature Made and Daiya products in the North American market. Amid an increase in health awareness centered on prevention due to the impact of COVID-19, we have had a highly positive response to our nutraceutical brands, and more and more consumers are choosing Nature Made and Daiya products. We have been able to achieve this based on various measures such as the initially planned new product launch, promotion activities, and enhancement of our production system.

We have been promoting corporate management with an emphasis on diversity, as I have explained. By operating diverse businesses even within the nutraceutical business, we have been able to realize the ability to respond even to the current unforeseen situation, and we believe this will also lead to stable business activities over the medium and long term.
Now I would like to present some information about the plant-based alternatives market in the US.

According to outside data sources, in 2019, the US plant-based alternatives market reached the US$5 billion mark, and it is continuing to grow rapidly. In addition, in a comparison over the same period, the sales at Daiya grew at an even faster pace than the market.

More recently there are reports that amid the spread of COVID-19, consumers have been choosing more plant-based alternatives than animal-based foods. Looking ahead, with further market growth expected in this environment, we will continue to carry out aggressive marketing activities using Daiya’s core product, cheese, as a growth driver, aiming to cement the company’s position as a category leader in plant-based foods.
Summary

- **Summary of 3rd MTM plan**
  - Accelerated initiatives to contribute to people’s health under the new normal

- **Pharmaceutical business**
  - Numerous achievements toward realizing sustainable growth and creating new value

- **Nutraceutical business**
  - The expansion of coronavirus infection has raised awareness of health, particularly in prevention, and the NC brand has been highly appraised

This is the summary of my presentation today.

We appreciate your continued support.
Pharmaceutical Development Update

Vice President, Director of Corporate Planning Department
Tomohiro Emura, Ph.D.
Otsuka Holdings Co., Ltd.
These are the 3 agenda items today.

- **Key development progress in Q2/2020**
  - Approval
  - Phase transition

- **Topics**
  - futibatinib/TAS-120 (Oncology)
  - difamilast/OPA-15406 (Other areas)

- **Key projects scheduled for P-3 & NDA submission**
  - Progress with initial FY2020 plan
This table summarizes the key development progress as of the end of June 2020.

Centanafadine has obtained positive results in a Phase-3 study for adults with attention deficit hyperactivity disorder (ADHD).

In subsequent events, on July 7, ASTX 727, (product name: INQOVI), received regulatory approval in the US and Canada for the indications of myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML).

For fremanezumab, we filed a new drug application in Japan on July 29, seeking approval for the indication of migraine.

Tolvaptan received regulatory approval in Japan for the additional indication of hyponatremia due to syndrome of inappropriate antidiuretic of hormone secretion (SIADH).
OPC-64005 started a P-2 trial for major depressive disorder (MDD) in April this year.

Futibatinib started a P-2 trial for breast cancer in the US and Europe.

TAS1440 started a P-1 trial for relapsed/refractory acute myeloid leukemia (AML) in the US.

TAS-119 has been out-licensed to VITRAC Therapeutics.

OPC-64005 was being developed for ADHD in the US, but has been discontinued for strategic reasons. Developments for TAS-118 and OPS-2071 in Japan have also been discontinued for strategic reasons.
The first topic is futibatinib (TAS-120).

Futibatinib is a fibroblast growth factor receptor (FGFR) inhibitor under development by Taiho Pharmaceutical. It is highly selective and has an irreversible inhibitory effect through covalent bonding.

At ASCO, the largest oncology conference held from the end of May to the beginning of June 2020, we announced the interim results of the P-2 trial in patients with FGFR2 fusion and gene rearrangement positive intrahepatic cholangiocarcinoma.

The objective response rate is 37.3%, the disease control rate is 82.1%, and the progression-free survival period is 7.2 months. We are currently preparing for a P-3 trial.

Intrahepatic cholangiocarcinoma has an extremely poor prognosis with a five-year survival rate of 8%. We will continue working on development to contribute to improved treatment results.
Next topic is difamilast.

Difamilast is a topical product that inhibits phosphodiesterase 4 (PDE4), an enzyme that degrades cyclic Adenosine Monophosphate (cAMP), and shows anti-inflammatory effect due to suppressing production of cytokines and chemical mediators by increasing concentration of cAMP through PDE4 inhibition. Difamilast potentially improves symptoms of atopic dermatitis by anti-inflammatory effects.

There are a lot of patients with atopic dermatitis in children and adults. Diagnosed patients with atopic dermatitis in Japan are approx. 4.34 million.

We conducted P-3 trials of adult and pediatric patients with atopic dermatitis. Difamilast demonstrated statistically significant improvements vs. vehicle for primary endpoints in P-3 trials of adult and pediatric patients. Detailed results of the trials will be announced at an academic conferences with further analysis. No major adverse reactions were observed.

Drugs with sufficient effects and highly safety for the treatment of atopic dermatitis are required. Difamilast is expected to be a new treatment option for adult and pediatric patients with atopic dermatitis.
This last slide shows major projects planned for NDA submission and projects scheduled to advance to P-3 in FY2020.

Due to the discontinuation of TAS-118 development program, regulatory filing is now planned for 4 projects. There are 3 projects left that are expected to migrate to P-3.

For your reference, major development pipeline by therapeutic area is shown in the appendix.

I would like to conclude my presentation on the pharmaceutical development updates.