

Consolidated Financial Results for the Third Quarter of Fiscal Year 2017

1. Revenue

Revenue totaled ¥200.6 billion, which was an increase of ¥11.7 billion (6.2%) from the corresponding period of the previous fiscal year (year-on-year).

Sales of long-term listed products decreased due to the impact of competitive products and generic drug use promotion policies. Sales of OPDIVO Intravenous Infusion for malignant tumors, our core product, decreased by ¥13.6 billion (-16.5%) year-on-year to ¥69.0 billion due to the influence of 50% cut in the price of the drug from February 2017, while the use has been expanded for renal cell carcinoma, head and neck cancer approved in the previous fiscal year, and gastric cancer approved in September 2017.

With respect to other main products, the sales of ORENCIA Subcutaneous Injection for rheumatoid arthritis, FORXIGA Tablets for type-2 diabetes, KYPROLIS for Intravenous Infusion for relapsed or refractory multiple myeloma and PARSABIV Intravenous Injection for Dialysis were steadily increasing.

Royalty and Other Revenue increased by ¥18.9 billion (86.7%) year-on-year to ¥40.6 billion, mainly due to the rise in OPDIVO-related royalty from Bristol-Myers Squibb.

2. Operating profit

Operating profit was ¥52.2 billion, a decrease of ¥1.1 billion (-2.1%) year-on-year.

Cost of sales was ¥50.2 billion, almost the same amount as the corresponding period of the previous fiscal year.

Research and development (R&D) costs increased by ¥9.4 billion (24.1%) year-on-year to ¥48.4 billion due to an increase of OPDIVO-related expenses.

Selling, general, and administrative expenses increased by ¥4.3 billion (9.6%) year-on-year to ¥49.5 billion, mainly due to the rise in operating costs.

3. Profit for the quarter (attributable to owners of the parent company)

Profit for the quarter decreased by ¥1.0 billion (-2.4%) year-on-year to ¥41.4 billion.

Consolidated Financial Forecasts for the Fiscal Year 2017

Consolidated financial forecasts for the fiscal year ending March 31, 2018, which were announced on November 6, 2017, have been revised.

Regarding revenue, sales of our key product OPDIVO is expected to exceed the previously announced forecast due to expansion of use for renal cell carcinoma, head and neck cancer approved in the previous fiscal year, and gastric cancer approved in September 2017.

In addition, we recognized a part of received upfront payment from Bristol Myers Squibb along with the out-licensing of ONO-4578 as revenue in the third quarter.

With respect to expenses, although cost of sales is expected to increase due to the rise in product sales, research and development costs and selling, general, and administrative expenses remain unchanged.

Revisions of consolidated financial forecasts are as follows;

Revenue has been revised upward by ¥6.0 billion from ¥254.0 billion to ¥260.0 billion.

Operating profit has been revised upward by ¥4.5 billion from ¥50.0 billion to ¥54.5 billion.

Profit for the quarter (attributable to owners of the parent company) has been revised upward by ¥3.5 billion from ¥39.5 billion to ¥43.0 billion

As for the year-end dividend, we plan to make it ¥20 yen per share, and there is no change in the current situation.

Sales of key products for the Third Quarter of Fiscal Year 2017

OPDIVO Intravenous Infusion:

Although the cumulative sales of OPDIVO Intravenous Infusion for malignant tumors for April – December 2017 decreased by ¥13.6 billion (-16.5%) year-on-year to ¥69.0 billion, it was about 70% increase on a quantity basis.

The number of newly prescribed patients in non-small cell lung cancer has been declining due to the impact of the competitive product KEYTRUDA[®] (melanoma, non-small cell lung cancer) launched in February 2017 and the optimal use promotion guidelines. Nonetheless, it still maintains a high market share in the non-small cell lung cancer area, and the number of newly prescribed patients has been increasing in the area of renal cell carcinoma and head and neck cancer, which estimated numbers of patients to be used for April – December were approximately 1,700 in renal cell carcinoma, and about 1,900 in head and neck cancer.

Regarding gastric cancer, the estimated number of patients treated with OPDIVO was about 2,000 at the end of December (about 900 patients from the approval date to the end of October, about 600 in November and December, respectively). It was exceeding 2,300, which was predicted as the number for this term, at the time of approval in September 2017.

Although there are uncertainties about future prospects, we estimate positive and negative factors for each cancer; the forecast of the sales of OPDIVO has been revised upward to ¥89.0 billion, including the impact of drug price cut.

GLACTIV Tablets:

Sales of GLACTIV Tablets for type-2 diabetes decreased by ¥0.4 billion (-1.6%) year-on-year to ¥22.3 billion, which was slightly lower than the full-year target of ¥29.5 billion (0.4% up year-on-year), and the progress against the full-year target was 75.6%.

The DPP4 inhibitor market has been on a 3.3% increase over the same period last year (drug price base). While the competition among diabetes medicines including DPP4 inhibitor combination agent and SGLT2 inhibitor is intensifying as a whole, we are working towards the full-year target of ¥29.5 billion.

ORENCIA Subcutaneous Injection:

Sales of ORENCIA Subcutaneous Injection for rheumatoid arthritis was steadily increasing by ¥2.2 billion (25.6%) year-on-year to ¥10.9 billion.

In accordance with the number of cases prescribed for patients as 1st bio has been increasing, the reputation of the drug has improved more than ever. As a result, the sales has been steadily increasing towards its full-year target of ¥14.5 billion, which is up by ¥2.9 billion (25%) year-on-year.

RECALBON Tablets:

Sales of RECALBON Tablets for osteoporosis decreased by ¥0.2 billion (-1.9%) year-on-year to ¥8.5 billion which was almost as estimated.

While the competition in the osteoporosis area is increasingly intensifying, there is no change to the full year forecast of ¥11.0 billion, down by ¥ 0.3 billion (-2.6%) year-on-year.

The sales breakdown of the products was ¥8.3 billion for 50 mg Tablet and ¥0.2 billion for 1 mg Tablet.

FORXIGA Tablets:

Sales of FORXIGA Tablets increased by ¥2.7 billion (47.0%) year-on-year to ¥8.5 billion. In light of the steady growth than expected, we revised our full-year forecast from ¥10.0 billion to ¥11.0 billion which increased by ¥3.2 billion (40.9%) year-on-year, at the end of the second quarter. The current sales trend is also good against the revised target.

RIVASTACH Patch:

Sales of RIVASTACH Patch for Alzheimer's disease increased by ¥0.2 billion (3.2%) year-on-year to ¥7.0 billion. Although the progress has been delayed against the full-year target of ¥10.0 billion, an increase of ¥ 1.1 billion (12.9%) year-on-year, we aim to achieve full-year targets by expanding the number of newly prescribed patients.

EMEND Capsules and PROEMEND for Intravenous Injection:

The combined sales of EMEND Capsules and PROEMEND for Intravenous Injection for chemotherapy-induced nausea and vomiting increased by ¥0.2 billion (2.4%) year-on-year to ¥7.8 billion. There is no change in the full-year target of ¥10.0 billion, an increase of ¥ 0.1 billion (1.2%) year-on-year, as it has been steady progress.

KYPROLIS for Intravenous Infusion:

Sales of KYPROLIS for Intravenous Infusion for relapsed or refractory multiple myeloma increased by ¥3.4 billion (325.7%) year-on-year to ¥4.5 billion. There is no change in the full-year target of ¥6.0 billion, an increase of ¥ 4.0 billion year-on-year, as it has progressed as estimated.

ONOACT Intravenous Infusion:

Sales of ONOACT Intravenous Infusion for tachyarrhythmia remained increased by ¥0.2 billion (3.5%) year-on-year to ¥4.6 billion. There is no change in the full-year target of ¥6.0 billion, an increase of ¥ 0.3 billion (4.8%) year-on-year, as it has progressed as estimated.

PARSABIV Intravenous Injection for Dialysis:

Sales of PARSABIV Intravenous Injection for Dialysis launched in February 2017 for secondary hyperparathyroidism in patients on hemodialysis was ¥2.5 billion, which has progressed steadily against the full-year target of ¥ 3.0 billion.

We have already acquired more than 76% accounts of all dialysis facilities and the drug is adopted in facilities covering 83% of patients in the dialysis market.

As of the end of December, the number of prescription cases exceeded 22,000(including 8000 new cases), and the market share was over 25%.

Switching from existing drugs and prescription for new patients have been expanding.

Long-term listed products:

Sales of long-term listed products including OPALMON Tablets for peripheral circulatory disorder decreased by about 20%, due to the impact of generic drugs.

