Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2020 (IFRS)

November 12, 2019

Company name: Nichi-Iko Pharmaceutical Co., Ltd. Stock exchange listings:

Tokyo Stock Exchange

Securities code: 4541 (URL https://www.nichiiko.co.jp/)

Representative: Yuichi Tamura

President and CEO

Contact: Shuji Ishida Tel: 076-432-2121

Senior Operating Officer, Head of

Administrative Division

Scheduled date of filing of quarterly report:

Scheduled date of commencement of dividend payment:

November 13, 2019

December 6, 2019

Presentation of supplementary materials on quarterly financial results: Yes Holding of quarterly financial presentation meeting: Yes

(Note that all amounts have been rounded down to the nearest one million yen.)

1. Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2020 (From April 1, 2019 to September 30, 2019)

(1) Consolidated Results of Operations (cumulative)

(Percentage figures represent changes from the same period of the previous fiscal year)

| | Revenue | Core operating profit | Operating profit | Profit before tax | Profit | Profit attributable to owners of parent |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|------------------------------|--|
| Second quarter of fiscal year ending March 31, 2020 | ¥91,519 million (11.1%) | ¥3,917 million (-20.7%) | ¥3,777 million (-20.0%) | ¥4,544 million (-20.7%) | ¥2,940 million (-36.4%) | ¥3,006 million (-34.9%) |
| Second quarter of fiscal year ended March 31, 2019 | ¥82,346 million (-0.9%) | ¥4,939 million (-%) | ¥4,720 million (75.1%) | ¥5,727 million (119.1%) | ¥4,620 million (88.8%) | ¥4,620 million (88.8%) |

| | Total comprehensive income | Basic earnings per share | Diluted earnings per share |
|--|--------------------------------|--------------------------|----------------------------------|
| Second quarter of fiscal year ending March 31, 2020 | ¥72 million (-99.3%) | ¥47.14 | ¥46.90 |
| Second quarter of fiscal year ended March 31, 2019 | ¥10,342 million (130.8%) | ¥80.93 | ¥79.79 |

(2) Consolidated Financial Position

| | Total assets | Total equity | Equity attributable to owners of parent | Ratio of total equity attributable to owners of the parent to total assets | Equity attributable to owners of parent per share |
|--|---------------------|---------------------|---|---|---|
| Second quarter of fiscal year ending March 31, 2020 | ¥316,789 million | ¥116,132 million | ¥115,359 million | 36.4% | ¥1,806.75 |
| Fiscal year ended March 31, 2019 | ¥306,838 million | ¥116,323 million | ¥116,323 million | 37.9% | ¥1,825.00 |

2. Dividends

| | | Annual dividends per share | | | | |
|--|---------------|----------------------------|---------------|----------|--------|--|
| | First quarter | Second quarter | Third quarter | Year-end | Total | |
| Fiscal year ended March 31, 2019 | ¥- | ¥15.00 | ¥- | ¥15.00 | ¥30.00 | |
| Fiscal year ending March 31, 2020 | ¥- | ¥15.00 | | | | |
| Fiscal year ending March 31, 2020 (forecast) | | | ¥- | ¥15.00 | ¥30.00 | |

(Note)

Revisions to recently announced dividends forecast: None

3. Forecast of Consolidated Financial Results for the Fiscal Year Ending March 31, 2020 (From April 1, 2019 to March 31, 2020)

(Percentage figures represent changes from the same period of the previous fiscal year)

| | Revenue | Core operating profit | Operating profit | Profit attributable to owners of parent | Basic earnings per share |
|--------|--------------------------------|-------------------------|-----------------------|---|-----------------------------|
| Annual | ¥194,000 million (16.5%) | ¥8,500 million (-36.2%) | ¥8,500 million (3.4%) | ¥6,000 million (-12.6%) | ¥93.99 |

(Note)

Revisions to recently announced forecast of financial results: Yes

For details, please refer to "(3) Explanation of Forecast of Consolidated Financial Results and Other Forward-looking Statements" in "1. Qualitative Information on Financial Results for the Quarter under Review" on page 5 of the Attachment.

*Notes

- (1) Changes in significant subsidiaries during the consolidated cumulative quarter under review (changes in specified subsidiaries resulting in change in scope of consolidation): No
- (2) Changes in accounting policies and changes in accounting estimates

(i) Changes in accounting policies required by IFRS: Yes

(ii) Changes in accounting policies due to other reasons: No

(iii) Changes in accounting estimates: No

- (3) Total number of issued shares (common stock)
 - (i) Total number of issued shares as of the end of the period (including treasury shares):

As of September 30, 2019 65,162,652 shares As of March 31, 2019 65,162,652 shares

(ii) Number of treasury shares as of the end of the period:

As of September 30, 2019 1,313,489 shares As of March 31, 2019 1,423,511 shares

(iii) Average number of shares during the period (cumulative quarter):

Second quarter of fiscal year ending March 31, 2020 63,785,258 shares Second quarter of fiscal year ended March 31, 2019 57,088,597 shares

(Note)

Number of treasury shares as of the end of the period includes shares held by the Employee Shareholding Incentive Plan.

- * Quarterly financial results reports are exempt from quarterly reviews conducted by certified public accountants or an audit corporation.
- * Explanation on the appropriate usage of forecast of financial results, and other specific matters

(Considerations on forward-looking statements)

The forward-looking statements including forecast of financial results contained in these materials are based on the information currently available to the Company and certain assumptions which are regarded as legitimate. As such, they do not constitute the Company's guarantee that such results would be achieved. Actual business and other results may differ substantially from the forecasts provided in these materials as a result of various factors.

(How to obtain supplementary materials for financial results)

Supplementary materials for financial results will be provided on the website of the Company on Tuesday, November 12, 2019.

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1. Qualitative Information on Financial Results for the Quarter under Review

(1) Explanation on Operating Results

In the cumulative second quarter under review, although the Japanese economy was on a trend of moderate recovery due to improvements in the employment and income environment, the future of the economy remains unclear due to heightened uncertainty about the global economy such as the evident impact of trade friction between the United States and China on exports and production.

In the generic drug industry, the usage rate of generic drugs is steadily increasing toward the government's target of "an 80% usage rate of generic drugs." Meanwhile, a revision of drug prices was implemented in October 2019 to coincide with the consumption tax hike. Furthermore, the revisions of drug prices that had generally been made once every two years in the past are scheduled to be implemented every year from April 2020 onward, and the earning environment is expected to become increasingly harsh in the generic drug industry.

Under such conditions, the Company formulated the 8th Medium-term Management Plan "Nexus ∞ " (from the fiscal year ending March 31, 2020 until the fiscal year ending March 31, 2022) in May 2019, and has been pursuing the four core strategies of "Continue our deeper pursuit of business arenas (where to play)," "Relentless efforts for operational excellence," "Drive for global standard of quality and competitive edge" and "Be the most trusted life science company driven by our ESG activities" in order to evolve into a global comprehensive generic pharmaceutical company.

| (in millions of yen) | Second quarter of fiscal year ended March 31, 2019 | Second quarter of fiscal year ending March 31, 2020 | Change |
|---|--|---|----------|
| Revenue | 82,346 | 91,519 | +9,173 |
| Core operating profit | 4,939 | 3,917 | -1,022 |
| Profit before tax | 5,727 | 4,544 | -1,183 |
| Profit attributable to owners of parent | 4,620 | 3,006 | -1,613 |
| Diluted earnings per share | ¥79.79 | ¥46.90 | - ¥32.89 |

^{*} The Group has adopted "core operating profit" as an indicator representing ordinary profitability. "Core operating profit" is calculated by deducting gains and losses caused by extraordinary factors from operating profit.

Although revenue decreased in the Sagent Group, revenue on a consolidated basis increased by 9,173 million yen year-on-year mainly due to an increase in sales resulting from making Elmed Co., Ltd. (hereinafter referred to as "Elmed") a consolidated subsidiary.

Although gross profit increased due to increased revenue in the Nichi-Iko Group, this was outweighed by the decrease in gross profit caused by increased selling, general and administrative expenses due to the integration of Elmed and the decrease in revenue in the Sagent Group. As a result, core operating profit decreased by 1,022 million yen year-on-year.

Profit before tax decreased by 1,183 million yen year-on-year due to factors such as foreign exchange gains and losses changing significantly from a gain of 443 million yen in the previous fiscal year to a loss of 364 million yen in the current fiscal year, and the absence of the investment gain on equity method of 997 million yen recorded in the previous fiscal year, despite gains on sale due to the partial sale of shares of Aprogen Inc., which is an equity method affiliate.

Profit attributable to owners of parent decreased by 1,613 million yen year-on-year reflecting the above factors.

The Company has changed to the following reportable segments from the first quarter, and the figures of the same period of the previous fiscal year have been reclassified for year-on-year comparison to reflect that change. The two segments are the "Nichi-Iko Group" and the "Sagent Group," with the "Sagent Group" being made up of Sagent Pharmaceuticals, Inc. (hereinafter referred to as "Sagent") and its consolidated subsidiaries, and the "Nichi-Iko Group" being made up of companies excluding the "Sagent Group."

The results by segment are as follows. Note that "core operating profit" is used for segment profit.

| (in millions of yen) | Nichi-Iko Group | | | Sagent Group | | |
|-----------------------|--|---|---------|--|---|--------|
| | Second quarter of fiscal year ended March 31, 2019 | Second quarter of fiscal year ending March 31, 2020 | Change | Second quarter of fiscal year ended March 31, 2019 | Second quarter of fiscal year ending March 31, 2020 | Change |
| Revenue | 63,853 | 76,851 | +12,998 | 18,493 | 14,668 | -3,824 |
| Core operating profit | 4,455 | 4,664 | +208 | 483 | -747 | -1,230 |

(i) Nichi-Iko Group

In the Nichi-Iko Group, we have continued to expand the product line-up through the added-value products of Elmed, which became a consolidated subsidiary in April 2019, and launching newly listed 5 products with 10 strengths in June 2019. In August 2019, a comprehensive partnership agreement was concluded with the municipality of Namerikawa, Toyama and a comprehensive partnership agreement on the streamlining of medical expenses and other issues was concluded with Matsudo, Chiba, with efforts being made to resolve issues in society and the community as a company involved with health and life. In September 2019, a comprehensive partnership agreement on the generic pharmaceutical business in China was concluded with Eisai Co., Ltd., making progress in the preparations to enter into the Chinese market, which is the second largest pharmaceutical market in the world.

The results in the Nichi-Iko Group during the cumulative second quarter of the current fiscal year showed segment profit of 4,664 million yen (an increase of 208 million yen year-on-year) due to the increase in revenue and resulting increase in gross profit arising as a result of making Elmed a consolidated subsidiary, despite an increase in selling, general and administrative expenses caused mainly by the integration of Elmed.

(ii) Sagent Group

In the Sagent Group, the Montreal Plant of Sagent's subsidiary Omega Laboratories Limited became the Group's second FDA-approved plant in September 2019, following Sagent's Raleigh Plant, as we made an effort to expand the Company's production capacity for the United States, become more cost competitive, strengthen stable supply capability, and maintain global-standard quality. Furthermore, we have continued to work toward application for approval of Infliximab BS in the United States with the aim of its prompt release on the market.

The results in the Sagent Group during the cumulative second quarter of the current fiscal year showed a segment loss of 747 million yen (a decrease of 1,230 million yen year-on-year in segment profit), mainly due to the impact of delays in the supply from contract manufacturers for certain products.

(2) Explanation on Financial Position

(i) Assets, Liabilities and Equity

Assets on a consolidated basis at the end of the second quarter of the current fiscal year increased by 9,950 million yen from the previous fiscal year-end to 316,789 million yen. This was mainly attributable to the following factors:

- Due to the additional acquisition of shares of Elmed, which used to be an equity method affiliate, to make it a consolidated subsidiary, cash and cash equivalents decreased by 5,832 million yen, trade and other receivables increased by 11,339 million yen, inventories increased by 5,832 million yen, and investments accounted for using equity method decreased by 5,863 million yen.
- Cash and cash equivalents increased by 3,200 million yen due to the partial sale of shares of Aprogen Inc., which is an equity method affiliate.

Liabilities on a consolidated basis increased by 10,142 million yen from the previous fiscal yearend to 200,657 million yen. This was mainly attributable to the following factors:

• Trade and other payables increased by 10,051 million yen due to making Elmed a consolidated subsidiary.

Equity on a consolidated basis decreased by 191 million yen from the previous fiscal year-end to 116,132 million yen. This was mainly attributable to the following factors:

- Retained earnings increased by 3,006 million yen due to recording profit attributable to owners of parent.
- Foreign currency translation adjustment decreased by 2,097 million yen due to appreciation of the yen against the dollar since the previous fiscal year-end.

(ii) Cash Flows

At the end of the second quarter of the current fiscal year, cash and cash equivalents on a consolidated basis decreased by 7,684 million yen from the previous fiscal year-end to 34,408 million yen.

Details of cash flows from each of the three activities for the cumulative second quarter of the current fiscal year are described below.

(Cash flows from operating activities)

Net cash provided by operating activities during the cumulative second quarter of the current fiscal year amounted to income over expenditure by 11,732 million yen. The main outflows included inventories increasing by 3,434 million yen as a result of factors such as making Elmed a consolidated subsidiary. In terms of inflows, there were trade and other receivables decreasing by 7,177 million yen, depreciation and amortization of 5,498 million yen, and profit before tax of 4,544 million yen.

(Cash flows from investing activities)

Net cash used in investing activities during the cumulative second quarter of the current fiscal year amounted to expenditure over income by 13,370 million yen. This was due to an inflow of 3,200 million yen due to the proceeds from sale of investments accounted for using equity method as a result of the partial sale of shares of Aprogen Inc., which is an equity method affiliate, and outflows including 6,341 million yen for the payments for acquisition of subsidiaries as a result of the acquisition of 66.6% of the shares issued by Elmed, 3,923 million yen in expenditure due to the purchase of property, plant and equipment and 6,318 million yen in purchase of intangible assets.

(Cash flows from financing activities)

Net cash used in financing activities during the cumulative second quarter of the current fiscal year amounted to expenditure over income by 6,120 million yen. The main outflows were 4,288 million yen in repayments of long-term borrowings, 957 million yen in dividends paid and 772 million yen in repayments of lease obligations.

(3) Explanation of Forecast of Consolidated Financial Results and Other Forward-looking Statements

The forecast of consolidated financial results for the fiscal year ending March 31, 2020 that was announced on May 13, 2019 has been revised as follows based on the results during the cumulative second quarter of the current fiscal year and the outlook for future results.

Revisions to the forecast of consolidated financial results for the fiscal year ending March 31, 2020 (from April 1, 2019 to March 31, 2020)

| | Revenue | Core operating profit | Operating profit | Profit attributable to owners of parent | Basic earnings per share |
|---|---------------------|-----------------------------|-------------------|---|--------------------------------|
| Previous forecast (A) | ¥201,000 million | ¥8,500 million | ¥8,500 million | ¥7,000 million | ¥109.70 |
| Revised forecast (B) | ¥194,000 million | ¥8,500 million | ¥8,500 million | ¥6,000 million | ¥93.99 |
| Change in amount (B-A) | -¥7,000 million | - | - | -¥1,000 million | |
| Change (%) | -3.5% | - | - | -14.3% | |
| (Reference) Actual results for the fiscal year ended March 31, 2019 | ¥166,592 million | ¥13,320 million | ¥8,223 million | ¥6,864 million | ¥115.46 |

Although the revenue from the third quarter onward is expected to be in line with the initial forecast, given that the results of the cumulative second quarter fell short of the initial forecast, the full-year revenue is expected to be lower than that in the previous forecast.

The forecast for core operating profit and operating profit remains unchanged from the previous forecast because although results during the cumulative second quarter exceeded the initial forecast, the selling, general and administrative expenses not utilized by the second quarter are expected to be utilized by the end of the fiscal year.

Profit attributable to owners of parent is expected to fall below the previous forecast due to foreign exchange losses caused by the appreciation of the yen exceeding the initial forecast.

The forecast of financial results was made based on information available to the Company at this point, and actual business and other results may differ from the forecast values provided in these materials as a result of various factors in the future.

2. Condensed Quarterly Consolidated Financial Statements and Primary Notes

(1) Condensed Quarterly Consolidated Statement of Financial Position

| | | (in millions of yen) |
|---|---|--|
| | Fiscal year ended March 31, 2019 (as of March 31, 2019) | Second quarter of fiscal year ending March 31, 2020 (as of September 30, 2019) |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | 42,093 | 34,408 |
| Trade and other receivables | 30,035 | 34,083 |
| Inventories | 66,783 | 75,922 |
| Income taxes receivable | 72 | - |
| Other financial assets | 447 | 425 |
| Other current assets | 3,290 | 3,292 |
| Subtotal | 142,722 | 148,132 |
| Assets held for sale | | 1,430 |
| Total current assets | 142,722 | 149,563 |
| Non-current assets | | |
| Property, plant and equipment | 55,710 | 58,483 |
| Goodwill | 42,892 | 44,172 |
| Intangible assets | 46,721 | 56,615 |
| Investments accounted for using equity method | 12,993 | 3,154 |
| Other financial assets | 5,724 | 4,689 |
| Deferred tax assets | 9 | 11 |
| Other non-current assets | 64 | 98 |
| Total non-current assets | 164,115 | 167,226 |
| Total assets | 306,838 | 316,789 |
| | | |

| Liabilities 44,172 54,698 Current liabilities 37,435 37,119 Other financial liabilities 956 1,653 Income taxes payable 74 518 Refund liabilities 2,196 2,199 Contract liabilities 116 116 Other current liabilities 6,884 8,216 Total current liabilities 91,837 104,522 Non-current liabilities 91,837 104,522 Non-current liabilities 1,589 2,399 Retirement benefit liability 173 407 Provisions 57 81 Refund liabilities 75 121 Contract liabilities 75 121 Contract liabilities 3,329 4,274 Other non-current liabilities 1,847 1,450 Total non-current liabilities 98,677 96,135 Total liabilities 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 <td< th=""><th></th><th>Fiscal year ended March 31, 2019 (as of March 31, 2019)</th><th>(in millions of yen) Second quarter of fiscal year ending March 31, 2020 (as of September 30, 2019)</th></td<> | | Fiscal year ended March 31, 2019 (as of March 31, 2019) | (in millions of yen) Second quarter of fiscal year ending March 31, 2020 (as of September 30, 2019) |
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| Contract liabilities 865 806 Deferred tax liabilities 3,329 4,274 Other non-current liabilities 1,847 1,450 Total non-current liabilities 98,677 96,135 Total liabilities 190,514 200,657 Equity Share capital 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | | | |
| Deferred tax liabilities 3,329 4,274 Other non-current liabilities 1,847 1,450 Total non-current liabilities 98,677 96,135 Total liabilities 190,514 200,657 Equity Share capital 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | | | |
| Other non-current liabilities 1,847 1,450 Total non-current liabilities 98,677 96,135 Total liabilities 190,514 200,657 Equity 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | | 865 | 806 |
| Total non-current liabilities 98,677 96,135 Total liabilities 190,514 200,657 Equity 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Deferred tax liabilities | · · · · · · · · · · · · · · · · · · · | 4,274 |
| Total liabilities 190,514 200,657 Equity 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Other non-current liabilities | 1,847 | 1,450 |
| Equity 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Total non-current liabilities | 98,677 | 96,135 |
| Share capital 23,360 23,360 Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Total liabilities | 190,514 | 200,657 |
| Capital surplus 21,896 21,866 Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Equity | | |
| Other equity instruments 9,918 9,918 Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Share capital | 23,360 | 23,360 |
| Treasury shares (2,893) (2,706) Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Capital surplus | 21,896 | 21,866 |
| Retained earnings 55,016 56,873 Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Other equity instruments | 9,918 | 9,918 |
| Other components of equity 9,025 6,047 Total equity attributable to owners of parent 116,323 115,359 | Treasury shares | (2,893) | (2,706) |
| Total equity attributable to owners of parent 116,323 115,359 | Retained earnings | 55,016 | 56,873 |
| | Other components of equity | 9,025 | 6,047 |
| Non-controlling interests 0 773 | Total equity attributable to owners of parent | 116,323 | 115,359 |
| | Non-controlling interests | 0 | 773 |
| Total equity 116,323 116,132 | Total equity | 116,323 | 116,132 |
| Total liabilities and equity 306,838 316,789 | Total liabilities and equity | 306,838 | 316,789 |

(2) Condensed Quarterly Consolidated Statement of Income and Condensed Quarterly Consolidated Statement of Comprehensive Income

(Condensed Quarterly Consolidated Statement of Income)

| | | (in millions of yen) |
|---|---|---|
| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
| Revenue | 82,346 | 91,519 |
| Cost of sales | 64,166 | 72,509 |
| Gross profit | 18,179 | 19,009 |
| Selling, general and administrative expenses | 11,615 | 12,980 |
| Research and development expenses | 1,915 | 2,100 |
| Other operating income | 273 | 168 |
| Other operating expenses | 202 | 318 |
| Operating profit | 4,720 | 3,777 |
| Finance income | 484 | 44 |
| Finance costs | 474 | 789 |
| Share of profit (loss) of investments accounted for using equity method | 997 | (31) |
| Other income | - | 2,166 |
| Other expenses | - | 624 |
| Profit before tax | 5,727 | 4,544 |
| Income tax expense | 1,107 | 1,604 |
| Profit | 4,620 | 2,940 |
| Profit attributable to: | | |
| Owners of parent | 4,620 | 3,006 |
| Non-controlling interests | (0) | (66) |
| Profit | 4,620 | 2,940 |
| Earnings per share | | |
| Basic earnings per share (Yen) | 80.93 | 47.14 |
| Diluted earnings per share (Yen) | 79.79 | 46.90 |

(Condensed Quarterly Consolidated Statement of Comprehensive Income)

| | | (in millions of yen) |
|--|--|---|
| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
| Profit | 4,620 | 2,940 |
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss | | |
| Financial assets measured at fair value through other comprehensive income | 665 | (690) |
| Share of other comprehensive income of investments accounted for using equity method | (109) | (80) |
| Total of items that will not be reclassified to profit or loss | 555 | (770) |
| Items that may be reclassified to profit or loss | | |
| Exchange differences on translation of foreign operations | 5,070 | (1,981) |
| Share of other comprehensive income of investments accounted for using equity method | 96 | (115) |
| Total of items that may be reclassified to profit or loss | 5,167 | (2,097) |
| Other comprehensive income (net of tax) | 5,722 | (2,867) |
| Comprehensive income | 10,342 | 72 |
| Comprehensive income attributable to: | | |
| Owners of parent | 10,343 | 137 |
| Non-controlling interests | (0) | (65) |
| Comprehensive income | 10,342 | 72 |

(3) Condensed Quarterly Consolidated Statement of Changes in Equity

Second Quarter of Previous Fiscal Year (from April 1, 2018 to September 30, 2018)

(in millions of yen)

| | Equity attributable to owners of parent | | | | | | |
|---|---|--------------------|--------------------------|--------------------|-------------------|--|---|
| - | | | | | | | ponents of uity |
| | Share capital | Capital surplus | Other equity instruments | Treasury shares | Retained earnings | Exchange differences on translation of foreign operations | Financial assets measured at fair value through other comprehen- sive income |
| Balance as of April 1, 2018 | 19,976 | 18,827 | - | (9,046) | 51,912 | 3,448 | 2,165 |
| Changes in accounting policies | | | | | (480) | | |
| Restated balance Profit (loss) | 19,976 | 18,827 | - | (9,046) | 51,431 4,620 | 3,448 | 2,165 |
| Other comprehensive income | | | | | | 5,167 | 565 |
| Total comprehensive income | - | - | - | - | 4,620 | 5,167 | 565 |
| Purchase of treasury shares | | | | (0) | | | |
| Disposal of treasury shares | | (1,996) | | 6,044 | | | |
| Transfer of loss on disposal of treasury shares | | 1,681 | | | (1,681) | | |
| Forfeiture of share acquisition rights | | | | | 13 | | |
| Dividends | | | | | (846) | | |
| Share-based payment transactions | | | | | | | |
| Transfer from other components of equity | | | | | (10) | | |
| Total transactions with owners | - | (315) | - | 6,043 | (2,524) | - | - |
| Balance as of September 30, 2018 | 19,976 | 18,511 | - | (3,002) | 53,527 | 8,615 | 2,731 |

Equity attributable to owners of parent

| | Other components of equity | | | | Non- | |
|---|--|-------|--------|---------|--------------------------|---------|
| | Remeasure- ments of defined benefit plans | Other | Total | Total | controlling interests | Total |
| Balance as of April 1, 2018 | - | 258 | 5,872 | 87,542 | 0 | 87,542 |
| Changes in accounting policies | | | | (480) | | (480) |
| Restated balance | - | 258 | 5,872 | 87,062 | 0 | 87,062 |
| Profit (loss) | | | | 4,620 | (0) | 4,620 |
| Other comprehensive income | (10) | | 5,722 | 5,722 | (0) | 5,722 |
| Total comprehensive income | (10) | - | 5,722 | 10,343 | (0) | 10,342 |
| Purchase of treasury shares | | | | (0) | | (0) |
| Disposal of treasury shares | | (3) | (3) | 4,043 | | 4,043 |
| Transfer of loss on disposal of treasury shares | | | | - | | - |
| Forfeiture of share acquisition rights | | (13) | (13) | - | | - |
| Dividends | | | | (846) | | (846) |
| Share-based payment transactions | | 44 | 44 | 44 | | 44 |
| Transfer from other components of equity | 10 | | 10 | - | | - |
| Total transactions with owners | 10 | 27 | 37 | 3,240 | - | 3,240 |
| Balance as of September 30, 2018 | - | 285 | 11,633 | 100,646 | 0 | 100,646 |

(Note

The amount of dividends does not include the amount of dividends to the Employee Shareholding Incentive Plan.

Second Quarter of Current Fiscal Year (from April 1, 2019 to September 30, 2019)

(in millions of ven)

| | | | F ' "1 | . 11 . | C . | (in mil | lions of yen) |
|--|------------------|--------------------|--------------------------------|--------------------|----------------------|--|--|
| _ | | | Equity attribu | itable to own | ers of parent | Other com | ponents of |
| | | | | | | equ | • |
| _ | Share capital | Capital surplus | Other equity instruments | Treasury shares | Retained earnings | Exchange differences on translation of foreign operations | Financial assets measured at fair value through other comprehen- sive income |
| Balance as of April 1, 2019 | 23,360 | 21,896 | 9,918 | (2,893) | 55,016 | 6,367 | 2,371 |
| Changes in accounting policies | | | | | (49) | | |
| Restated balance Profit (loss) | 23,360 | 21,896 | 9,918 | (2,893) | 54,967 3,006 | 6,367 | 2,371 |
| Other comprehensive income | | | | | | (2,097) | (770) |
| Total comprehensive income | - | - | - | - | 3,006 | (2,097) | (770) |
| Direct issuance expenses due to issuance of new shares | | (5) | | | | | |
| Distributions to owners of other equity instruments | | | | | (243) | | |
| Disposal of treasury shares | | (38) | | 187 | | | |
| Transfer of loss on disposal of treasury shares | | 8 | | | (8) | | |
| Dividends | | | | | (956) | | |
| Share-based payment transactions | | | | | | | |
| Equity transactions with non-controlling interests and other | | | | | | | |
| Transfer to capital surplus from retained earnings | | 5 | | | (5) | | |
| Transfer from other components of equity | | | | | 113 | | (114) |
| Total transactions with owners | - | (29) | - | 187 | (1,100) | - | (114) |
| Balance as of September 30, 2019 | 23,360 | 21,866 | 9,918 | (2,706) | 56,873 | 4,269 | 1,487 |

| Equity | attributa | ble to | owners | of | parent |
|--------|-----------|--------|--------|----|--------|
|--------|-----------|--------|--------|----|--------|

| Remeasurements of defined benefit plans Other defined benefit plans Total Total controlling interests Total interests Total interests Total controlling interests Total interests Total interests Total interests Total congress in accounting policies 285 9,025 116,323 0 116,323 Changes in accounting policies - 285 9,025 116,274 0 116,274 Profit (loss) - 285 9,025 116,274 0 116,274 Profit (loss) - 2,868 0.2,868 0 0,2,867 Other comprehensive income (0) - 2,868 137 (65) 72 Total comprehensive income (0) - 2,868 137 (65) 72 Direct issuance expenses due to issuance of new shares - (0) - (2,868) 137 (65) 72 Disposal of treasury shares - (37) (37) 111 111 111 Transfer of loss on disposal of treasury shares - (956) (| | Other components of equity | | | Non- | | | |
|--|---------------------------|----------------------------|-------|---------|---------|-------------|---------|--|
| Changes in accounting policies Case Ca | | ments of defined | Other | Total | Total | controlling | Total | |
| Restated balance - 285 9,025 116,274 0 116,274 Profit (loss) 3,006 (66) 2,940 Other comprehensive income (0) 2,868) (2,868) 0 (2,867) Total comprehensive income (0) - (2,868) 137 (65) 72 Direct issuance expenses due to issuance of new shares Distributions to owners of other equity instruments Disposal of treasury shares Dividends (37) (37) 111 111 Transfer of loss on disposal of treasury shares Dividends (956) (956) Share-based payment transactions with non-controlling interests and other Transfer for capital surplus from retained earnings Transfer from other components of equity Total transactions 0 4 (109) (1,052) 838 (213) | | - | 285 | 9,025 | 116,323 | 0 | 116,323 | |
| Profit (loss) | | | | | (49) | | (49) | |
| Other comprehensive income (0) (2,868) (2,868) 0 (2,867) Total comprehensive income (0) - (2,868) 137 (65) 72 Direct issuance expenses due to issuance of new shares (5) (5) (5) Distributions to owners of other equity instruments (243) (243) (243) Disposal of treasury shares (37) (37) 111 111 Transfer of loss on disposal of treasury shares - - - Dividends (956) (956) (956) Share-based payment transactions 41 41 41 41 41 Equity transactions with non-controlling interests and other - 838 838 Transfer to capital surplus from retained earnings - - - - Total transactions with owners 0 (113) - - - Total transactions with owners 0 4 (109) (1,052) 838 (213) | Restated balance | - | 285 | 9,025 | 116,274 | 0 | 116,274 | |
| Total comprehensive (0) | Profit (loss) | | | | 3,006 | (66) | 2,940 | |
| Direct issuance Company Compan | _ | (0) | | (2,868) | (2,868) | 0 | (2,867) | |
| Expenses due to (5) | _ | (0) | - | (2,868) | 137 | (65) | 72 | |
| Cada | expenses due to | | | | (5) | | (5) | |
| Transfer of loss on disposal of treasury shares Components of equity Components of September Components of Septemb | of other equity | | | | (243) | | (243) | |
| disposal of treasury shares Dividends Share-based payment transactions Equity transactions with non-controlling interests and other Transfer to capital surplus from retained earnings Transfer from other components of equity Total transactions with owners Balance as of September - 289 6 047 115 359 773 116 132 | | | (37) | (37) | 111 | | 111 | |
| Share-based payment transactions Equity transactions with non-controlling interests and other Transfer to capital surplus from retained earnings Transfer from other components of equity Total transactions with owners Balance as of September 41 41 41 41 41 41 41 5389 838 838 (213) | disposal of treasury | | | | - | | - | |
| transactions Equity transactions with non-controlling interests and other Transfer to capital surplus from retained earnings Transfer from other components of equity Total transactions with owners Balance as of September 41 41 41 41 41 41 41 41 41 41 41 41 41 4 | Dividends | | | | (956) | | (956) | |
| non-controlling interests and other Transfer to capital surplus from retained earnings Transfer from other components of equity Total transactions with owners Balance as of September - 838 838 - 838 - 838 (113) | 2 2 | | 41 | 41 | 41 | | 41 | |
| surplus from retained earnings Transfer from other components of equity Total transactions with owners Balance as of September - 289 6 047 115 359 773 116 132 | non-controlling interests | | | | - | 838 | 838 | |
| components of equity 0 (113) - - Total transactions with owners 0 4 (109) (1,052) 838 (213) Balance as of September 289 6.047 115.359 773 116.132 | surplus from retained | | | | - | | - | |
| with owners 0 4 (109) (1,052) 838 (213) Balance as of September 289 6.047 115.359 773 116.132 | | 0 | | (113) | - | | - | |
| | | 0 | 4 | (109) | (1,052) | 838 | (213) | |
| | | - | 289 | 6,047 | 115,359 | 773 | 116,132 | |

(Note)

The amount of dividends does not include the amount of dividends to the Employee Shareholding Incentive Plan.

(4) Condensed Quarterly Consolidated Statement of Cash Flows

| | | (in millions of yen) |
|---|---|---|
| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
| Cash flows from operating activities | | |
| Profit before tax | 5,727 | 4,544 |
| Depreciation and amortization | 4,601 | 5,498 |
| Impairment losses (reversal of impairment losses) | 111 | 0 |
| Interest and dividend income | (40) | (44) |
| Interest expenses | 345 | 294 |
| Share of loss (profit) of investments accounted for using equity method | (997) | 31 |
| Loss (gain) on sale of investments in associates | - | (1,762) |
| Decrease (increase) in trade and other receivables | 5,859 | 7,177 |
| Decrease (increase) in inventories | 6,556 | (3,434) |
| Increase (decrease) in trade and other payables | (7,933) | 47 |
| Increase (decrease) in provisions | (506) | (100) |
| Other | (108) | (216) |
| Subtotal | 13,615 | 12,036 |
| Dividends received | 59 | 86 |
| Interest received | 16 | 4 |
| Interest paid | (340) | (293) |
| Income taxes paid | (1,294) | (331) |
| Income taxes refund | 7 | 229 |
| Net cash provided by (used in) operating activities | 12,064 | 11,732 |
| Cash flows from investing activities | | |
| Purchase of property, plant and equipment | (5,066) | (3,923) |
| Purchase of intangible assets | (3,853) | (6,318) |
| Purchase of investments | (994) | (4) |
| Purchase of investments accounted for using equity method | (3,400) | - |
| Proceeds from sale of investments accounted for using equity method | - | 3,200 |
| Collection of loans receivable | 598 | 71 |
| Proceeds from reversal of international interests | 999 | - |
| Payments for acquisition of subsidiaries | - | (6,341) |
| Other | (68) | (54) |
| Net cash provided by (used in) investing activities | (11,785) | (13,370) |

| | | (in millions of yen) |
|--|--|---|
| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
| Cash flows from financing activities | | |
| Net increase (decrease) in short-term borrowings | 91 | 55 |
| Proceeds from long-term borrowings | 5,000 | - |
| Repayments of long-term borrowings | (3,918) | (4,288) |
| Proceeds from sale of treasury shares | 4,031 | 106 |
| Repayments of finance lease obligations | (469) | - |
| Repayments of lease obligations | - | (772) |
| Dividends paid | (847) | (957) |
| Distributions to owners of other equity instruments | - | (243) |
| Other | 40 | (19) |
| Net cash provided by (used in) financing activities | 3,927 | (6,120) |
| Effect of exchange rate changes on cash and cash equivalents | (128) | 73 |
| Net increase (decrease) in cash and cash equivalents | 4,077 | (7,684) |
| Cash and cash equivalents at beginning of period | 18,529 | 42,093 |
| Cash and cash equivalents at end of period | 22,606 | 34,408 |

(5) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes on premise of going concern)

Not applicable.

(Changes in significant subsidiaries during the consolidated cumulative quarter under review)

Not applicable.

There were no changes in specified subsidiaries, but the Company acquired additional shares of Elmed Eisai Co., Ltd. and made it a consolidated subsidiary of the Company in the first quarter of the current fiscal year. The trade name of Elmed Eisai Co., Ltd. was also changed to Elmed Co., Ltd. on the same day.

(Changes in accounting policies)

The significant accounting policies applied to the Condensed Quarterly Consolidated Financial Statements are the same as the accounting policies applied to the consolidated financial statements for the previous fiscal year with the exception of the changes in the accounting policies listed below. Income tax expense for the cumulative second quarter of the current fiscal year is calculated based on the estimated annual effective tax rate.

The following standards are applied from the first quarter of the current fiscal year.

The Group has applied IFRS 16 "Leases" (issued in January 2016) from the first quarter of the current fiscal year. The new standard replaces IAS 17 "Leases." The new accounting policies by the application of IFRS 16 are as follows.

The Group determines whether a contract contains a lease at the inception of the contract. Lease liabilities are measured at the present value of the total accrued lease payments at the commencement date of the lease by discounting them at the lessee's incremental borrowing rate. The right-of-use asset is initially measured at the initial measurement amount of lease liabilities adjusted by the initial direct cost and other costs such as prepaid lease payments, and adding the cost of restoration obligations required by the lease contract.

A right-of-use asset is depreciated by using the straight-line method over the shorter period of either from the commencement date to the end of the lease term or the end of the useful life of the right-of-use asset. When measuring lease liabilities, these are measured at the present value of accrued lease payments.

The Group has included right-of-use assets under "property, plant and equipment" and lease liabilities under "other financial liabilities" on the consolidated statement of financial position.

In the application of IFRS 16, the Group has adopted the method where the cumulative effect of applying this standard is recognized as an adjustment of retained earnings at the date of initial application, which is allowed as the transition approach. Due to the adoption of this method, there are no restatements of comparative information.

In transitioning to IFRS 16, the Group has elected the practical expedient provided in paragraph C3 of IFRS 16 and followed the assessment of whether a contract contains a lease in accordance with IAS 17 "Leases" ("IAS 17") and IFRIC 4 "Determining whether an Arrangement Contains a Lease."

The Group recognized lease liabilities on the date of initial application of IFRS 16 for leases previously classified as operating leases under IAS 17. The lease liabilities are initially measured at the present value of the total accrued lease payments at the commencement date by discounting them at the lessee's incremental borrowing rate. The weighted average lessee's incremental borrowing rate applied to lease liabilities recognized in the consolidated statement of financial position at the date of initial application is 0.40%.

Furthermore, right-of-use assets are measured using one of the following methods.

- The carrying amount calculated by assuming that IFRS 16 was applied from the commencement date of the lease. However, lessee's incremental borrowing rate on the date of initial application is used as the discount rate.
- Same amount as the lease liabilities. However, this is the amount adjusted by any prepaid or accrued lease payments.

The following is the reconciliation of operating lease contracts disclosed under IAS 17 as of the previous fiscal year-end and lease liabilities at the date of initial application recognized in the consolidated statement of financial position.

(in millions of yen)

| Operating lease contracts disclosed as of March 31, 2019 | 295 |
|--|-------|
| Lease contracts discounted at the incremental borrowing rate as of April 1, 2019 | 295 |
| Finance lease contracts disclosed as of March 31, 2019 | 2,524 |
| Cancelable operating lease contracts | 1,451 |
| Lease liabilities as of April 1, 2019 | 4,271 |

As a result of application of IFRS 16, compared to if the previous accounting standards are applied, right-of-use assets increased by 1,617 million yen, lease liabilities increased by 1,746 million yen and retained earnings decreased by 49 million yen at the beginning of the first quarter of the current fiscal year.

When applying IFRS 16, the Group used the following practical expedients:

- Initial direct costs are excluded from the measurement of right-of-use assets at the date of initial application.
- Ex-post assessment is used, such as in determining the lease term, if the contract contains options to extend or terminate the lease.
- This is dependent on the assessment of whether a lease is disadvantageous by applying IAS 37 "Provisions, Contingent Liabilities and Contingent Assets" immediately prior to the initial application as a substitute for implementing an impairment review.

(Segment information)

(1) Reportable segments

The Group's reportable segments are components of the business units of the Group for which discrete financial statements are available and evaluated regularly by the Board of Directors in determining the allocation of management resources and assessing the segment's performance.

The Group has established the 8th Medium-term Management Plan "Nexus ∞" starting this fiscal year and with the fiscal year ending March 31, 2022 as the final year. It aims to maximize synergies in three areas (therapeutic area/region, cost and people) under the theme of "Going Beyond with Infinite Power to Connect," seeking to further evolve into a global comprehensive generic pharmaceutical company by pursuing the four core strategies of "Continue our deeper pursuit of business arenas (where to play)," "Relentless efforts for operational excellence," "Drive for global standard of quality and competitive edge" and "Be the most trusted life science company driven by our ESG activities," and one of the targets is to achieve 60.0 billion yen in overseas sales in the fiscal year ending March 31, 2022. In order to clearly indicate progress in these efforts, the Group's reportable segments have been changed from the single segment of the pharmaceutical business to the "Nichi-Iko Group" and the "Sagent Group" making up the pharmaceutical business. The "Sagent Group" is made up of Sagent Pharmaceuticals, Inc. and its consolidated subsidiaries. The "Nichi-Iko Group" is made up of companies excluding the "Sagent Group."

Revenue, profit and loss of the reportable segments are as follows.

Second Quarter of Previous Fiscal Year (from April 1, 2018 to September 30, 2018)

(in millions of yen)

| (in initial of join) | | | | | |
|-------------------------|--------------------|-----------------|--------|------------|--------------|
| | Reportable segment | | | | |
| | Nichi-Iko Group | Sagent Group | Total | Adjustment | Consolidated |
| Revenue | | - | | | |
| External revenue | 63,853 | 18,493 | 82,346 | - | 82,346 |
| Inter-segment revenue | - | - | - | - | - |
| Total | 63,853 | 18,493 | 82,346 | - | 82,346 |
| Segment profit (loss) | | | | | |
| (Core operating profit) | 4,455 | 483 | 4,939 | - | 4,939 |
| (Note) | | | | | |

(Note)

Core operating profit is calculated by deducting gains and losses caused by extraordinary factors from operating profit.

Second Quarter of Current Fiscal Year (from April 1, 2019 to September 30, 2019)

(in millions of yen)

| | Reportable segment | | | | | |
|--|--------------------|-----------------|--------|------------|--------------|--|
| | Nichi-Iko Group | Sagent Group | Total | Adjustment | Consolidated | |
| Revenue | | | | | | |
| External revenue | 76,851 | 14,668 | 91,519 | - | 91,519 | |
| Inter-segment revenue | - | - | - | - | - | |
| Total | 76,851 | 14,668 | 91,519 | - | 91,519 | |
| Segment profit (loss) (Core operating profit) (Note) | 4,664 | (747) | 3,917 | - | 3,917 | |

(Note)

Core operating profit is calculated by deducting gains and losses caused by extraordinary factors from operating profit.

Adjustments from segment profit to profit before tax are as follows.

(in millions of yen)

| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
|---|---|---|
| Segment profit | 4,939 | 3,917 |
| Integration-related expenses | 107 | 138 |
| Other | 111 | 0 |
| Operating profit | 4,720 | 3,777 |
| Finance income | 484 | 44 |
| Finance costs | 474 | 789 |
| Share of profit (loss) of investments accounted for using equity method | 997 | (31) |
| Other income | - | 2,166 |
| Other expenses | - | 624 |
| Profit before tax | 5,727 | 4,544 |

(2) Information about products and services

Revenue from each product and service is as follows.

(in millions of yen)

| | | (III IIIIIII e I j vii) |
|-------------------------------------|---|---|
| | Second quarter of previous fiscal year (from April 1, 2018 to September 30, 2018) | Second quarter of current fiscal year (from April 1, 2019 to September 30, 2019) |
| Treatments for circulatory system | 12,925 | 17,431 |
| Treatments for blood and body fluid | 13,576 | 13,906 |
| Antibiotics | 12,111 | 9,799 |
| Treatments for nervous system | 6,259 | 8,695 |
| Treatments for digestive system | 7,389 | 8,361 |
| Treatments for allergies | 4,573 | 6,740 |
| Chemotherapeutics | 6,721 | 6,431 |
| Others | 18,789 | 20,152 |
| Total | 82,346 | 91,519 |

(3) Information by geographical area

Revenue by geographical area is shown below.

(in millions of yen)

| | | 3 / |
|---------------|---|--|
| | Second quarter of previous fiscal year (from April 1, 2018 to | Second quarter of current fiscal year (from April 1, 2019 to |
| | September 30, 2018) | September 30, 2019) |
| Japan | 63,782 | 76,686 |
| United States | 16,638 | 12,786 |
| Others | 1,925 | 2,046 |
| Total | 82,346 | 91,519 |

(Note)

Revenue is based on the location of the destination of sales.