Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending December 31, 2019 [IFRS]

August 8, 2019

Company name	: **Otsuka Holdings Company Limited**
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
URL	: https://www.otsuka.com/en/
Representative	: Tatsuo Higuchi President and Representative Director, CEO
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Scheduled date of quarterly securities report submission	: August 9, 2019
Scheduled date of dividend payment commencement	: September 2, 2019
Supplementary materials for quarterly financial results	: Yes
Earnings announcement for quarterly financial results	: Yes (for institutional investors, analysts and the press)

(Figures are rounded down to the nearest million yen unless otherwise stated)

1. Consolidated Financial Results for the Second Quarter of FY2019 (January 1, 2019 to June 30, 2019)

(1) Consolidated Operating Results (cumulative)

(% change from the same period of the previous fiscal year)

	Revenue		Business profit		Operating profit		Profit for the period		Profit attributable to owners of the Company		Total comprehensive income for the period	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2019 Q2	671,131	8.5	97,651	40.1	96,524	22.9	70,190	6.6	67,763	5.4	44,886	73.5
FY2018 Q2	618,325	3.9	69,696	–	78,542	58.7	65,816	51.8	64,302	51.6	25,864	(21.4)

(Reference) Profit before taxes FY2019 Q2 ¥93,421 million (15.2%)
FY2018 Q2 ¥81,083 million (67.4%)

(Note 1) Business profit is an indicator of earnings power and calculated as follows:
Revenue – Cost of sales – Selling, general and administrative expenses ± Equity in earnings affiliates – Research and development expenses.

(Note 2) The provisional accounting treatment for business combinations was finalized at the end of FY2018, which is reflected in the financial results of FY2018 Q2.

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY2019 Q2	125.03	123.53
FY2018 Q2	118.67	117.90

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity attributable to owners of the Company per share
	Million yen	Million yen	Million yen	%	Yen
As of June 30, 2019	2,610,656	1,748,854	1,721,542	65.9	3,174.68
As of December 31, 2018	2,476,634	1,732,266	1,704,499	68.8	3,145.71

2. Dividends

	Annual dividend per share				
	First quarter	Second quarter	Third quarter	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
FY2018	–	50.00	–	50.00	100.00
FY2019	–	50.00			
FY2019 (forecast)			–	50.00	100.00

(Note) Revisions to dividends forecast most recently announced: None

3. Forecasts of Consolidated Financial Results for FY2019 (January 1, 2019 to December 31, 2019)

(% change from the same period of the previous fiscal year)

	Revenue		Business profit		Operating profit		Profit		Profit attributable to owners of the Company		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2019	1,400,000	8.4	175,000	44.8	174,000	60.7	128,000	49.9	125,000	51.5	230.58

(Reference) Profit before taxes ¥170,000 million (55.3%)
(Note) Revisions to financial forecast most recently announced: Yes

4. Others

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies due to other reasons: None
3) Changes in accounting estimates: None

(3) Number of shares issued and outstanding (common stock)
1) Number of shares issued and outstanding as of the end of the reporting period (including treasury shares):
June 30, 2019 557,835,617 shares
December 31, 2018 557,835,617 shares
2) Number of shares of treasury shares as of the end of the reporting period:
June 30, 2019 15,564,037 shares
December 31, 2018 15,987,217 shares
3) Average number of shares outstanding during the reporting period:
Six months ended June 30, 2019 541,935,060 shares
Six months ended June 30, 2018 541,848,721 shares

***** These consolidated financial results are not subject to quarterly reviews.

*** Note to ensure appropriate use of forecasts, and other comments in particular**

Forecasts and other forward-looking statements included in this report are based on information currently available and certain assumptions that the Company deems reasonable. Actual performance and other results may differ significantly due to various factors. Please refer to “1. Qualitative Information (3) Forecast for Consolidated Performance” on page 10 for information regarding the forecast of consolidated financial results.

The Company plans to hold a meeting for institutional investors, analysts and the press on August 8, 2019. Presentation materials and the webcast of the meeting will be available on the Company’s website promptly after the meeting.

Attachment Index

1. Qualitative Information

(1) Consolidated Operating Results

The forward-looking statements in this report were prepared based on information available as of June 30, 2019.

Starting from FY2019, the Group adopted IFRS 16 "Leases" (hereinafter "IFRS 16"). The impact of the adoption is stated in "(6) Notes to Condensed Interim Consolidated Financial Statements (Changes in Accounting Policies)" in "2. Condensed Interim Consolidated Financial Statements and Major Notes".

Summary of Operating Results for the First Half of FY2019

From FY2019, the Group adopted "Business profit" as an indicator of earnings power, which is calculated by excluding "Impairment loss" and "Other income and expenses" from "Operating profit".

In addition, the provisional accounting treatment for the acquisition of ReCor Medical Inc. in FY2018 Q2 was finalized as of the end of FY2018. Therefore, the following comparative table presents numerical values that reflect retroactive adjustments to the purchase price allocation due to the finalization of the provisional accounting treatment.

(Millions of yen)

	Actual results of the first half of FY 2018	Actual results of the first half of FY 2019	Change	% Change
Revenue	618,325	671,131	52,806	8.5%
Business profit before R&D expenses	157,003	197,670	40,667	25.9%
Business profit	69,696	97,651	27,955	40.1%
Operating profit	78,542	96,524	17,981	22.9%
Profit before taxes	81,083	93,421	12,338	15.2%
Profit for the period	65,816	70,190	4,374	6.6%
Profit attributable to owners of the Company	64,302	67,763	3,460	5.4%

R&D expenses	87,306	100,019	12,712	14.6%
Impairment loss	11,467	377	(11,089)	(96.7)%

For the first half of FY2019 (from January 1 to June 30, 2019), the Group recorded revenue of ¥671,131 million (up 8.5% over the comparable prior year period) with the increase primarily attributable to sales growth of the four global pharmaceutical products (*ABILIFY MAINTENA, REXULTI/RXULTI, Samsca/JINARC/JYNARQUE,* and *LONSURF*). Business profit before research and development expenses was ¥197,670 million (up 25.9%). On the other hand, the Group recorded research and development expenses of ¥100,019 million (up 14.6%) due to the increase of development expenses for AVP-786, ultrasound renal denervation devices, centanafadine, *REXULTI*, TAS-120, and products developed by Visterra Inc., which resulted in business profit of ¥97,651 million (up 40.1%).

The Group also recorded operating profit of ¥96,524 million (up 22.9%), profit for the period of ¥70,190 million (up 6.6%) and profit attributable to owners of the Company of ¥67,763 million (up 5.4%).

The impairment loss in the first half of FY2019 was ¥377 million (down 96.7%).

Results by business segment are as follows:

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	438,560	165,433	16,189	70,123	(19,175)	671,131
Business profit	84,917	21,725	4,318	5,924	(19,234)	97,651

Reference (Q2 FY2018)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Revenue	389,166	162,711	16,243	69,080	(18,876)	618,325
Business profit	57,238	19,685	5,522	5,886	(18,636)	69,696

1) Pharmaceuticals

Revenue for the first half of FY2019 (from January 1 to June 30, 2019) totaled ¥438,560 million (up 12.7% over the comparable prior year period), with business profit of ¥84,917 million (up 48.4%).

Main products

● Four global products

The Company positions the long acting antipsychotic agent *ABILIFY MAINTENA*, the antipsychotic agent *REXULTI*[*1]/*RXULTI*[*2], the V_2-receptor antagonist *Samsca/JINARC*[*3]/*JYNARQUE*[*4], and the anti-cancer agent *LONSURF* as its four global products. The sales of those products totaled ¥173,138 million (up 36.6%).

*1: Brand name for the antipsychotic agent in the U.S.
*2: Brand name for the antipsychotic agent in Europe
*3: Brand name for ADPKD treatment in multiple regions outside Japan
*4: Brand name for ADPKD treatment in the U.S.

● Antipsychotic agent *ABILIFY MAINTENA*

Sales of *ABILIFY MAINTENA* ¥48,605 million (up 17.0%) reflecting the contribution of expanding prescriptions as a treatment for bipolar disorder, an indication was approved in the U.S. in 2017, in addition to promotion of the product's efficacy as a treatment for schizophrenia in global markets and growing awareness of the drug's ease of use.

● Antipsychotic agent *REXULTI/RXULTI*

Antipsychotic agent *REXULTI* has been highly evaluated in the U.S. for its efficacy and safety as a new treatment option for adjunctive therapy in major depressive disorder and a treatment for schizophrenia, and its sales have increased smoothly. In Japan, where the agent is sold for the treatment of schizophrenia, the number of prescriptions has sharply increased since the limit on the number of prescription days was removed in May 2019. *RXULTI* was launched sequentially in several European countries from April 2019. As a result, sales of *REXULTI/RXULTI* were ¥40,928 million (up 33.6%).

● V_2-receptor antagonist *Samsca*

In Japan, high recommendation in various guidelines contributed to expanding its prescriptions for the treatments of cardiac edema and hepatic edema. The number of prescriptions also increased as a treatment for autosomal dominant polycystic kidney disease ("ADPKD"), an intractable kidney disease, due to efforts to raise awareness of the disease as well as promote appropriate use of *Samsca* pursuant to the treatment guidelines. As a result, overall sales totaled ¥42,676 million (up 20.5%).

● V_2-receptor antagonist *JINARC/JYNARQUE*

Sales for this agent began in the U.S. under the brand name *JYNARQUE* in May 2018, as a treatment for ADPKD. Prescriptions have since increased smoothly in the country as efforts to raise awareness of the disease and provide information about clinical data helped more people recognize the disease and the product. In addition, the number of patient users has been increasing in European markets. As a result, overall sales totaled ¥24,241 million (up 569.9%), marking a significant revenue increase.

● Anti-cancer agent *LONSURF*

In the U.S., enhanced activities to promote the product as a therapy for unresectable advanced or recurrent colorectal cancer contributed to an increase in sales. In addition, approval was granted in February 2019 for the treatment of additional indications of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy. In Europe, sales decreased due to the timing of shipments to Servier, our licensing partner, but the number of countries where the product is available has increased smoothly and prescriptions have expanded. The number of prescriptions has also increased steadily in Japan. As a result, overall sales totaled ¥16,686 million (up 7.3%).

● Other mainstay products

Sales of antiallergic agent *Bilanoa* increased significantly (sales of ¥6,586 million, up 120.5%), as the product has been highly evaluated by medical specialists and patients as a new treatment option for pollen allergies. Increases in sales of antiepileptic drug *E Keppra* (sales of ¥21,991 million, up 17.7%) and anti-cancer agent *Abraxane* (sales of ¥13,738 million, up 17.8%) and other factors also contributed to increases in revenue for the period under review.

2) Nutraceuticals

Revenue for the period under review totaled ¥165,433 million (up 1.7%), with business profit of ¥21,725 million (up 10.4%).

Main products

The Company positions *POCARI SWEAT*, *Nature Made* and the Nutrition & Santé SAS brand as its three major brands. The sales of those brands totaled ¥100,567 million (down 1.4%). Total sales of its three nurture brands, the Daiya Foods Inc. brand, *EQUELLE* and *BODY MAINTÉ*, were ¥9,981 million (up 25.3%).

● Three major brands

POCARI SWEAT, an electrolyte supplement drink, gained the largest share in the Japanese sports drink market*1 during the period between January and June 2019, as consumer confidence in the brand had been established due to our communication activities to stress the importance of hydration in dry conditions or after perspiration and the usefulness of the product as a measure to prevent heatstroke. In overseas markets, mainly in Asia, sales volume increased, particularly in Indonesia. This was the result of increased product recognition mainly due to educational and promotional activities catered to the features and needs in each market, including the promotion of the importance of hydration and replenishment of electrolytes (ions). As a result, total sales of the *POCARI SWEAT* brand increased compared with the prior year period.

Sales of *Nature Made*, supplements manufactured and sold mainly in the U.S. by Pharmavite LLC, were flat compared with the prior year period. Due to high quality of the brand and the active educational and promotional activities, nine products were selected in June among top 2019 picks among U.S. pharmacists*2, following the brand's selection in 2018.

At Nutrition & Santé SAS, which operates in over 40 countries, mainly in Europe, sales of sugar-free products steadily increased, but overall sales decreased compared with the prior year period, affected by intensified competition in the nutrition food market and the impact of foreign exchange rates.

● Three nurture brands

Sales of the plant-based foods of the Daiya Foods Inc. brand increased compared with the prior year period due to the growth of cheese alternatives and new products launched during the second half of 2018 in North America.

Sales of *EQUELLE*, a food and supplement brand containing equol, made from lactic acid fermented soy, sharply increased compared with the prior year period due to increased recognition of the product through the wide ranging spread of information on the product and women's health.

As for *BODY MAINTÉ*, a protective beverage brand containing lactic-acid bacteria B240*3 (a strain licensed to Otsuka Pharmaceutical Co., Ltd.), we proceeded with its market entry by launching *BODY MAINTÉ CONDITIONING DRINK* nationwide in October 2018, in addition to *BODY MAINTÉ Jelly*, a conditioning nutritional food.

*1: INTAGE SRI (12/31/2018 to 06/23/2019)
*2: 2019 U.S. News & World Report-Pharmacy Times Survey: The selected products are letter vitamins (A, B, C, D and E), coenzyme Q10, omega-3 / fish oil, flaxseed oil, herbal supplement, mood health supplement, diabetic multivitamin, garlic supplement and cholesterol management (fish oil).
*3: *Lactobacillus pentosus ONRICb0240*：Strain isolated by Tokyo University of Agriculture, for which Otsuka Pharmaceutical has confirmed efficacy.

3) Consumer products

Sales volume for mineral water products increased, with main contributors being mainstay brand *CRYSTAL GEYSER*'s direct shipping to consumers and its 700-milliliter bottles, the largest size for personal use, which can be attributed to the success of proactive communication marketing activities for expanding the brand's user base, mainly targeting young people. Sales volume of *MATCH*, a carbonated electrolyte drink containing vitamins, slightly decreased in reaction to the previous year's revamping of *Berry MATCH*, a product flavored with mixed berries. However, we launched jelly-type product *Match Jelly* in April 2019 and its sales smoothly expanded in the market. As a result, revenue for the period under review totaled ¥16,189 million (down 0.3%). Business profit was ¥4,318 million (down 21.8%) mainly due to a decrease in share of profit from investment accounted for using the equity method.

4) Others

Sales in the specialty chemical business for the period under review decreased compared with the prior year period due to a fall in shipments of brake friction materials. Sales in the fine chemical business increased compared with the prior year period mainly due to revenue from an active pharmaceutical ingredient-related business supplying cefixime to overseas licensees, which was acquired in June 2019.

In the transportation and warehousing business, sales increased compared to the prior year period mainly due to the growth in handling volume of the Group products and increase in new customers spurred by the "common distribution platform" in line with external customers.

As a result, revenue for the period under review totaled ¥70,123 million (up 1.5%), with business profit of ¥5,924 million (up 0.6%).

* Please refer to the Supplement Documents (Factbook) for sales by product and other information.
https://www.otsuka.com/en/ir/library/earnings.php

<u>Research and Development Activities for the First Half of FY2019</u>

Research and development expenses for the period under review totaled ¥100,019 million.

The primary areas of research and development as well as the status of new product development by business segment were as follows:

<u>Pharmaceuticals</u>

The Group conducts research and development with a primary focus on the areas of the psychiatry and neurology and oncology. The Group also conducts research and development focusing on fields that are yet to be fully addressed such as cardiovascular and renal system, etc.

Pharmaceutical business's research and development expenses for the period under review were ¥95,016 million.

Pharmaceutical business's research and development activities carried out during the period under review are summarized below.

Category	*Brand Name,* (Generic Name), Development Code	Status
Psychiatry and neurology	*REXULTI/RXULTI* (brexpiprazole) OPC-34712	<China> ・Phase III trial for the treatment for schizophrenia was initiated in May 2019.
	(deuterium-modified dextromethorphan, quinidine) AVP-786	<U.S.> ・Phase II/III trial for the treatment of negative symptoms of schizophrenia was initiated in March 2019.
	(centanafadine) EB-1020	<U.S.> ・Phase III trials for the treatment of attention deficit hyperactivity disorder (ADHD) were initiated in February 2019.
	Selincro (nalmefene) Lu AA36143	<Japan> ・Approval was granted in January 2019 for the reduction of alcohol consumption in patients with alcohol dependence.
	Lu AF20513	<Europe> ・Development in the Group was halted in line with development strategy.
Oncology	*LONSURF* (trifluridine, tipiracil) TAS-102	<U.S.> ・Approval was granted in February 2019 for the additional indications of gastric cancer.
	ASTX727	<Japan> ・Phase I trial for the treatment of myelodysplastic syndrome was initiated in March 2019.
	TAS0313	<Japan> ・Phase II trial for the treatment of urothelial cancer was initiated in January 2019.
	(canerpaturev) TBI-1401	<Japan> ・An application for the indication of melanoma was filed in March 2019 by Takara Bio Inc.
	(fosnetupitant) Pro-NETU	<Japan> ・Phase III trial for the treatment of nausea and vomiting related to the administration of anti-cancer agents was initiated in February 2019.
Cardiovascular and renal system	OPC-61815	<Japan> ・Phase III trial for the treatment of cardiac edema was initiated in January 2019.
Other categories	(difamilast) OPA-15406	<Japan> ・Phase III trial for the treatment of atopic dermatitis was initiated in April 2019.

Category	*Brand Name*, (Generic Name), Development Code	Status
Other categories	*WT1 mRNA Assay Kit II 'Otsuka'* ODK-1003-CN	<China> ・Approval was granted as a diagnostic agent for myelodysplastic syndrome and in-vitro diagnostic agent in March 2019.

Nutraceuticals

In the nutraceutical business, the Group draws on its knowledge in the pharmaceutical business to constantly conduct research and development of world-class products centering on functional foods and beverages that support the maintenance and improvement of day-to-day well-being. In February 2019, *SOYJOY Crispy Sakura* as a special seasonal flavor limited to springtime was launched from the *SOYJOY* brand of soy snack bars which deliver a convenient way to consume the nutrition of whole soybeans. Moreover, in March of this year, *UL•OS Medicated Skin Breezy Lotion* (classified as a quasi-drug), formulated with moisturizing ingredient AMP[*1] and effective whitening ingredient tranexamic acid for prevention of discoloration[*2] was launched from the *UL•OS* total skincare brand for middle-aged men.

*1 Moisturizing ingredient AMP: Adenosine monophosphate
*2 Prevention of discoloration: Inhibits melanin formation to prevent dark spots and freckles

Nutraceutical business's research and development expenses for the period under review were ¥2,713 million.

Consumer products

In the consumer products business, the Group is engaged in the research and development of original and unique products in the field of food and beverage that are part of everyone's daily life.

Consumer products business's research and development expenses for the period under review were ¥287 million.

Others

In others business, the Group is primarily engaged in the research and development of specialty chemical products and fine chemicals.

Others business's research and development expenses for the consumer products business for the period under review were ¥2,001 million.

(2) Consolidated Financial Position

1) Assets, Liabilities, and Equity

(Millions of yen)

	As of December 31, 2018	As of June 30, 2019	Change
Current assets	933,102	1,037,415	104,312
Non-current assets	1,543,532	1,573,240	29,708
Total assets	2,476,634	2,610,656	134,021
Current liabilities	427,502	445,036	17,534
Non-current liabilities	316,865	416,765	99,899
Total liabilities	744,368	861,802	117,434
Total equity	1,732,266	1,748,854	16,587

Assets

Total assets as of June 30, 2019 were ¥2,610,656 million, an increase of ¥134,021 million compared to ¥2,476,634 million at the end of the previous fiscal year. Current assets increased by ¥104,312 million, and non-current assets increased by ¥29,708 million.

(Current Assets)

Total current assets as of June 30, 2019 were ¥1,037,415 million, an increase of ¥104,312 million compared to ¥933,102 million at the end of the previous fiscal year. This was mainly due to increases in cash and cash equivalents by ¥90,179 million, trade and other receivables by ¥13,886 million, and inventories by ¥11,742 million, partially offset by a decrease in other financial assets by ¥11,962 million. For the first half of FY2019, cash and cash equivalents increased as a result of the issuance of ¥80,000 million of unsecured domestic straight bonds in March 2019 to appropriate funds for repayment of borrowings and working capital, while other financial assets such as time deposits and certificates of deposit decreased. Trade and other receivables and inventories increased mainly as a result of the expansion in revenue of four global pharmaceutical products.

(Non-current Assets)

Total non-current assets as of June 30, 2019 were ¥1,573,240 million, an increase of ¥29,708 million compared to ¥1,543,532 million at the end of the previous fiscal year. This was mainly due to an increase in property, plant and equipment by ¥56,497 million, while there were decreases in goodwill by ¥7,472 million and intangible assets by ¥14,538 million. The decrease in goodwill was due to exchange rate fluctuations, while the decrease in intangible assets was due to amortization and exchange rate fluctuations. The increase in property, plant and equipment was a result of the adoption of IFRS 16 and investment in Tokushima Mima and Matsushige pharmaceutical production facilities.

Liabilities

(Current Liabilities)

Total current liabilities as of June 30, 2019 were ¥445,036 million, an increase of ¥17,534 million compared to ¥427,502 million at the end of the previous fiscal year. This was mainly due to increases in trade and other payables by ¥3,198 million and lease liabilities by ¥12,603 million. The increase in lease liabilities was mainly caused by the adoption of IFRS 16.

(Non-current Liabilities)

Total non-current liabilities as of June 30, 2019 were ¥416,765 million, an increase of ¥99,899 million compared to ¥316,865 million at the end of the previous fiscal year. This was mainly due to increases in bonds and borrowings by ¥61,402 million and lease liabilities by ¥44,664 million. The increase in bonds and borrowings was mainly due to the issuance of bonds of ¥80,000 million, partially offset by the repayment of borrowings associated with the acquisition of Avanir Pharmaceuticals, Inc. The increase in lease liabilities was due to the adoption of IFRS 16.

Equity

Total equity as of June 30, 2019 was ¥1,748,854 million, an increase of ¥16,587 million compared to ¥1,732,266 million at the end of the previous fiscal year. This was mainly due to an increase in retained earnings by ¥40,789 million as a result of profit attributable to owners of the Company of ¥67,763 million net of ¥27,092 million in dividend payments. Additionally, there was a decrease in other components of equity by ¥24,694 million as a result of market revaluations and exchange rate fluctuations.

2) Cash Flows

Cash and cash equivalents as of June 30, 2019 was ¥375,202 million, an increase of ¥90,179 million compared to the end of previous fiscal year. For the first half of FY2019, net cash provided by operating activities was ¥94,849 million, while net cash used in investing activities was ¥(27,332) million as a result of investment in Tokushima Mima and Matsushige pharmaceutical production facilities. Net cash provided by financing activities was ¥26,449 million as a result of the issuance of ¥80,000 million in bonds, partially offset by dividend payments of ¥50 per share to shareholders (¥(27,092) million in total) and repayments of non-current borrowings of ¥20,936 million. Thus, the total cash inflows from operating and financing activities exceeded investing cash outflows, and cash and cash equivalents increased by ¥90,179 million compared to the end of the previous fiscal year.

The total amounts of bonds and borrowings as of June 30, 2019 were ¥266,736 million, which is exceeded by total cash and cash equivalents. Therefore, the Group maintains its own financial soundness.

The following provides detail around cash flow movement in the first half of FY2019:

Cash Flows from Operating Activities

Net cash flows provided by operating activities were ¥94,849 million. Main operating activities for the period included ¥93,421 million in profit before taxes, adjusted for ¥36,707 million in depreciation and amortization expenses, ¥(12,241) million increase in trade and other receivables, ¥(13,511) million increase in inventories, ¥7,267 million increase in trade and other payables and ¥(16,285) million in income taxes paid. The net impact of these transactions represent an increase of ¥47,995 million compared to the prior year period, driven primarily by an increase in profit before taxes by ¥23,121 million on more robust Group performance, after adjusting for non-cash factors such as impairment losses for centanafadine and valuation gains for acquisition of ReCor Medical, Inc. in FY2018 Q2. In addition, the cash impact of movement in trade and other receivables, inventories, and trade and other payables was ¥9,082 million favorable to the comparable period in the prior year. Depreciation and amortization expenses for right-of-use assets associated with lease contracts previously classified as operating leases under IAS 17 "Leases" increased in accordance with the application of IFRS 16, while repayments of the related lease liabilities were recognized as a reduction of cash flows from financing activities.

Cash Flows from Investing Activities

Net cash flows used in investing activities were ¥(27,332) million. Main investing activities included ¥(24,739) million in payments for acquisition of property, plant and equipment, ¥(7,680) million payments for acquisition of intangible assets, ¥30,092 million in proceeds from sales and redemption of investments, ¥(38,908) million in payments for acquisition of investments, and ¥16,475 million in decrease in time deposits. The net impact of these transactions represent an increase of ¥24,147 million over the comparable prior year period, driven primarily by cash inflows of ¥16,475 million in time deposits in the first half of FY2019 compared to cash outflows of ¥(2,411) million in the comparable prior year period.

Cash Flows from Financing Activities

Net cash flows provided by financing activities were ¥26,449 million. Main financing activities included ¥80,000 million in proceeds from issuance of bonds, ¥(20,936) million in repayments of non-current borrowings, ¥(8,244) million in payments of lease liabilities and ¥(28,236) million in dividends paid. The net impact of these transactions represent an increase of

¥58,581 million compared to the prior year period, driven primarily by ¥80,000 million in proceeds from the issuance of unsecured domestic straight bonds in March 2019, net of ¥(7,198) million increase in repayments of lease liabilities in accordance with the application of IFRS 16 and a decrease short term financing of ¥(12,357) million, as no short-term borrowing was utilized in the first half of FY2019.

(3) Forecast for Consolidated Performance

On the basis of the consolidated performance in the first half of FY2019, the consolidated financial results forecast was amended from those announced on February 13 and May 14, 2019 as follows:

Amendments to the consolidated financial results forecast for FY2019 (January 1, 2019 to December 31, 2019)

(Millions of yen)

	Previous forecast (A)	Revised forecast (B)	Amount of change (B - A)	Change (%)	(Reference) Consolidated results of FY2018
Revenue	1,390,000	1,400,000	10,000	0.7	1,291,981
Business profit (disclosed on May 14, 2019)	148,000	175,000	27,000	18.2	120,892
Operating profit	150,000	174,000	24,000	16.0	108,304
Profit before taxes	147,500	170,000	22,500	15.3	109,497
Profit for the year	113,000	128,000	15,000	13.3	85,395
Profit attributable to owners of the Company	110,000	125,000	15,000	13.6	82,492
Basic earnings per share (Yen)	203.01	230.58			152.24

R&D expenses	225,000	220,000	(5,000)	(2.2)	192,931

(Note) Forecast exchange rates are as follows:

	Previous forecast	Revised forecast
USD	110 yen	109 yen
EUR	130 yen	123 yen

Business profit, operating profit, profit before taxes, profit for the year, and profit attributable to owners of the Company are expected to be higher than the previous forecast. This was driven by robust sales of the four global products (*ABILIFY MAINTENA, REXULTI/RXULTI, Samsca/JINARC/JYNARQUE,* and *LONSURF*) in our pharmaceutical business, especially *JYNARQUE* in the U.S., and revisions to projected R&D expenses.

2. Condensed Interim Consolidated Financial Statements and Major Notes

(1) Condensed Interim Consolidated Statements of Financial Position

(Millions of yen)

	As of December 31, 2018	As of June 30, 2019
Assets		
Current assets		
Cash and cash equivalents	285,022	375,202
Trade and other receivables	378,520	392,407
Inventories	157,128	168,871
Income taxes receivable	9,226	2,439
Other financial assets	66,614	54,651
Other current assets	36,573	42,989
Subtotal	933,085	1,036,562
Assets held for sale	16	852
Total current assets	933,102	1,037,415
Non-current assets		
Property, plant and equipment	393,572	450,070
Goodwill	284,097	276,624
Intangible assets	483,942	469,404
Investments in associates	189,633	187,694
Other financial assets	155,153	152,321
Deferred tax assets	28,428	26,381
Other non-current assets	8,704	10,744
Total non-current assets	1,543,532	1,573,240
Total assets	2,476,634	2,610,656

(Millions of yen)

	As of December 31, 2018	As of June 30, 2019
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	170,854	174,052
Bonds and borrowings	65,912	65,361
Lease liabilities	1,894	14,498
Other financial liabilities	2,307	2,340
Income taxes payable	7,211	7,955
Contract liabilities	10,809	11,295
Other current liabilities	168,511	169,532
Total current liabilities	427,502	445,036
Non-current liabilities		
Bonds and borrowings	139,973	201,375
Lease liabilities	6,159	50,824
Other financial liabilities	16,666	17,580
Net defined benefit liabilities	18,337	19,104
Provisions	619	971
Contract liabilities	87,245	81,885
Deferred tax liabilities	35,564	33,846
Other non-current liabilities	12,300	11,176
Total non-current liabilities	316,865	416,765
Total liabilities	744,368	861,802
Equity		
Equity attributable to owners of the Company		
Share capital	81,690	81,690
Capital surplus	505,894	505,591
Treasury shares	(47,268)	(46,017)
Retained earnings	1,229,360	1,270,149
Other components of equity	(65,177)	(89,871)
Total equity attributable to owners of the Company	1,704,499	1,721,542
Non-controlling interests	27,766	27,311
Total equity	1,732,266	1,748,854
Total liabilities and equity	2,476,634	2,610,656

(2) Condensed Interim Consolidated Statements of Income

(Millions of yen)

	FY2018 (From January 1, 2018 to June 30, 2018)	FY2019 (From January 1, 2019 to June 30, 2019)
Revenue	618,325	671,131
Cost of sales	(211,495)	(216,858)
Gross profit	406,830	454,273
Selling, general and administrative expenses	(259,558)	(265,197)
Equity in earnings of affiliates	9,731	8,594
Research and development expenses	(87,306)	(100,019)
Impairment loss	(11,467)	(377)
Other income	21,194	3,049
Other expenses	(881)	(3,799)
Operating profit	78,542	96,524
Finance income	7,518	2,429
Finance costs	(4,977)	(5,532)
Profit before taxes	81,083	93,421
Income tax expenses	(15,266)	(23,230)
Profit for the period	65,816	70,190
Attributable to:		
Owners of the Company	64,302	67,763
Non-controlling interests	1,513	2,427
Earnings per share:		
Basic earnings per share (Yen)	118.67	125.03
Diluted earnings per share (Yen)	117.90	123.53

(3) Condensed Interim Consolidated Statements of Comprehensive Income

(Millions of yen)

	FY2018 (From January 1, 2018 to June 30, 2018)	FY2019 (From January 1, 2019 to June 30, 2019)
Profit for the period	65,816	70,190
Other comprehensive income		
Components that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	1	(8)
Financial assets measured at fair value through other comprehensive income	(7,669)	3,020
Share of other comprehensive income of associates	(9)	(30)
Subtotal	(7,677)	2,981
Components that may be reclassified to profit or loss		
Foreign currency translation reserve	(25,812)	(22,133)
Cash flow hedges	9	(1)
Share of other comprehensive income of associates	(6,471)	(6,150)
Subtotal	(32,274)	(28,286)
Total other comprehensive income	(39,951)	(25,304)
Comprehensive income	25,864	44,886
Attributable to:		
Owners of the Company	25,667	43,209
Non-controlling interests	197	1,677
Comprehensive income	25,864	44,886

(4) Condensed Interim Consolidated Statements of Changes in Equity
FY2018 (From January 1, 2018 to June 30, 2018)

(Millions of yen)

	Equity attributable to owners of the Company					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasurements of defined benefit plans	Financial assets measured at fair value through other comprehensive income
Balance as of January 1, 2018	81,690	505,620	(47,267)	1,266,399	–	42,915
Changes in accounting policies	–	–	–	(70,242)	–	–
Restated balance	81,690	505,620	(47,267)	1,196,157	–	42,915
Profit for the period	–	–	–	64,302	–	–
Other comprehensive income	–	–	–	–	47	(7,627)
Comprehensive income	–	–	–	64,302	47	(7,627)
Purchase of treasury shares	–	–	(0)	–	–	–
Dividends	–	–	–	(27,092)	–	–
Changes in ownership interests in subsidiaries that do not result in loss of control	–	400	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	47	(47)	–
Total transactions with owners, etc.	–	400	(0)	(27,045)	(47)	–
Balance as of June 30, 2018	81,690	506,020	(47,267)	1,233,415	–	35,288

	Equity attributable to owners of the Company					
	Other components of equity					
	Foreign currency translation reserve	Cash flow hedges	Total	Total	Non-controlling interests	Total equity
Balance as of January 1, 2018	(56,072)	(8)	(13,165)	1,793,278	28,671	1,821,950
Changes in accounting policies	–	–	–	(70,242)	–	(70,242)
Restated balance	(56,072)	(8)	(13,165)	1,723,036	28,671	1,751,707
Profit for the period	–	–	–	64,302	1,513	65,816
Other comprehensive income	(31,065)	9	(38,635)	(38,635)	(1,316)	(39,951)
Comprehensive income	(31,065)	9	(38,635)	25,667	197	25,864
Purchase of treasury shares	–	–	–	(0)	–	(0)
Dividends	–	–	–	(27,092)	(1,049)	(28,141)
Changes in ownership interests in subsidiaries that do not result in loss of control	39	–	39	440	(653)	(212)
Transfer from other components of equity to retained earnings	–	–	(47)	–	–	–
Total transactions with owners, etc.	39	–	(8)	(26,653)	(1,702)	(28,355)
Balance as of June 30, 2018	(87,098)	0	(51,809)	1,722,050	27,166	1,749,216

FY2019 (From January 1, 2019 to June 30, 2019)

(Millions of yen)

	Equity attributable to owners of the Company					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Remeasure-ments of defined benefit plans	Financial assets measured at fair value through other comprehensive income
Balance as of January 1, 2019	81,690	505,894	(47,268)	1,229,360	–	23,344
Changes in accounting policies	–	–	–	(23)	–	–
Restated balance	81,690	505,894	(47,268)	1,229,337	–	23,344
Profit for the period	–	–	–	67,763	–	–
Other comprehensive income	–	–	–	–	(24)	3,038
Comprehensive income	–	–	–	67,763	(24)	3,038
Purchase of treasury shares	–	–	(0)	–	–	–
Dividends	–	–	–	(27,092)	–	–
Share-based payment transaction	–	(885)	1,005	–	–	–
Exercise of stock options	–	(245)	245	–	–	–
Changes in ownership interests in subsidiaries that do not result in loss of control	–	828	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	140	24	(164)
Total transactions with owners, etc.	–	(302)	1,251	(26,951)	24	(164)
Balance as of June 30, 2019	81,690	505,591	(46,017)	1,270,149	–	26,218

	Equity attributable to owners of the Company					
	Other components of equity					
	Foreign currency translation reserve	Cash flow hedges	Total	Total	Non-controlling interests	Total equity
Balance as of January 1, 2019	(88,521)	0	(65,177)	1,704,499	27,766	1,732,266
Changes in accounting policies	–	–	–	(23)	–	(23)
Restated balance	(88,521)	0	(65,177)	1,704,476	27,766	1,732,243
Profit for the period	–	–	–	67,763	2,427	70,190
Other comprehensive income	(27,567)	(1)	(24,554)	(24,554)	(750)	(25,304)
Comprehensive income	(27,567)	(1)	(24,554)	43,209	1,677	44,886
Purchase of treasury shares	–	–	–	(0)	–	(0)
Dividends	–	–	–	(27,092)	(1,303)	(28,396)
Share-based payment transaction	–	–	–	120	–	120
Exercise of stock options	–	–	–	0	–	0
Changes in ownership interests in subsidiaries that do not result in loss of control	–	–	–	828	(828)	–
Transfer from other components of equity to retained earnings	–	–	(140)	–	–	–
Total transactions with owners, etc.	–	–	(140)	(26,144)	(2,132)	(28,276)
Balance as of June 30, 2019	(116,089)	(0)	(89,871)	1,721,542	27,311	1,748,854

(5) Condensed Interim Consolidated Statements of Cash Flows

(Millions of yen)

	FY2018 (From January 1, 2018 to June 30, 2018)	FY2019 (From January 1, 2019 to June 30, 2019)
Cash flows from operating activities		
Profit before taxes	81,083	93,421
Depreciation and amortization expenses	29,749	36,707
Impairment loss and reversal of impairment loss	11,467	377
Equity in earnings of affiliates	(9,731)	(8,594)
Finance income	(7,518)	(2,429)
Finance costs	4,977	5,532
Decrease (increase) in inventories	(19,729)	(13,511)
Decrease (increase) in trade and other receivables	(9,123)	(12,241)
Increase (decrease) in trade and other payables	1,285	7,267
Other	(36,104)	2,150
Subtotal	46,356	108,679
Interest and dividends received	4,206	4,659
Interest paid	(1,407)	(2,204)
Income taxes paid	(2,300)	(16,285)
Net cash flows provided by (used in) operating activities	46,853	94,849
Cash flows from investing activities		
Proceeds from sales of property, plant and equipment	189	395
Payments for acquisition of property, plant and equipment	(26,927)	(24,739)
Payments for acquisition of intangible assets	(7,837)	(7,680)
Proceeds from sales and redemption of investments	6,565	30,092
Payments for acquisition of investments	(20,610)	(38,908)
Proceeds from acquisition of subsidiaries	562	–
Decrease (increase) in time deposits	(2,411)	16,475
Other	(1,010)	(2,968)
Net cash flows provided by (used in) investing activities	(51,480)	(27,332)
Cash flows from financing activities		
Purchase of treasury shares	(0)	(0)
Increase (decrease) in current borrowings	13,407	1,049
Proceeds from non-current borrowings	3,170	3,079
Repayments of non-current borrowings	(19,360)	(20,936)
Proceeds from issuance of bonds	–	80,000
Repayments of lease liabilities	(1,045)	(8,244)
Dividends paid	(28,056)	(28,236)
Other	(245)	(261)
Net cash flows provided by (used in) financing activities	(32,131)	26,449
Increase (decrease) in cash and cash equivalents	(36,757)	93,966
Cash and cash equivalents at beginning of period	336,613	285,022
Effect of exchange rate changes on cash and cash equivalents	(4,149)	(3,786)
Cash and cash equivalents at end of period	295,705	375,202

(6) Notes to Condensed Interim Consolidated Financial Statements

Note to Going Concern Assumptions

Not applicable.

Changes in Accounting Policies

The same significant accounting policies used for the prior fiscal year's consolidated financial statements are applied to the condensed interim consolidated financial statements except for the accounting standards provided below.

Income tax expenses for the six months ended June 30, 2019 are calculated based on the estimated average annual effective tax rate.

The Group adopted the following standards starting from FY2019.

IFRS		Description of new standards, interpretations and amendments
IFRS 16	Leases	Amendment concerning accounting treatment for leases

Adoption of IFRS 16 "Leases"

Starting from FY2019, the Group adopted IFRS 16 "Leases" (issued in January 2016, hereinafter referred to as "IFRS 16").

On adoption of IFRS 16, leases previously classified as operating leases under the principles of IAS 17 "Leases" (hereinafter referred to as "IAS 17") were recognized as right-of-use assets and lease liabilities as of the date of the application of IFRS 16 (January 1, 2019). In addition, operating lease payments that were expensed in the condensed interim consolidated statement of income as incurred under the previous accounting standards are recorded as depreciation expense for right-of-use assets and interest cost for lease liabilities, and reclassified from a reduction in cash flows from operating activities to a reduction in cash flows from financing activities in the condensed interim consolidated statement of cash flows.

In accordance with IFRS 16, for the leases that the Group has contracted as a lessee, right-of-use assets are measured at acquisition cost, and lease liabilities are measured at the present value of total lease payables.

Right-of-use assets are depreciated by using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term.

Lease payments are apportioned between the financial costs and the reduction in the lease liabilities based on the interest method. The financial costs are recognized in the condensed interim consolidated statement of income.

The Group elects not to recognize right-of-use assets and lease liabilities for leases on intangible assets and short-term leases within 12 months. The Group recognizes the total lease payments associated with short-term leases on either a straight-line method or another systematic basis over the lease term.

In accordance with the transitional measures under IFRS 16, the Group retrospectively adopted IFRS 16 and recognized the cumulative effects of the application as an adjustment to the opening balance of retained earnings for 2019Q1. In transitioning to IFRS 16, the Group chooses the practical expedient detailed in IFRS 16 paragraph C3 and assesses whether contracts contain leases in accordance with IAS 17 and IFRIC 4 "Determining whether an Arrangement contains a Lease."

Lease liabilities are measured at present value of the remaining lease payments discounted using the lessee's incremental borrowing rate at the date of initial application. The weighted average lessee's incremental borrowing rate applied to lease liabilities recognized in the condensed interim consolidated statement of financial position at the date of initial application is 3.9%. Right-of-use assets are initially measured at the initial measurement amount of the lease liability adjusted by the amount of any prepaid or accrued lease payments.

As a result, compared with the application of the former accounting standard, as of the beginning of FY2019 Q1, right-of-use assets increased by ¥59,324 million as property, plant and equipment in the condensed interim consolidated statement of financial position, and retained earnings decreased by ¥23 million. The following is the reconciliation of operating lease contracts disclosed applying IAS 17 as of December 31, 2018 and lease liabilities recognized in the condensed consolidated statement of financial position at the date of initial application.

(Millions of yen)

	Amount
Operating lease contracts disclosed as of December 31, 2018	42,631
Operating lease contracts discounted using the incremental borrowing rate as of January 1, 2019	33,366
Finance lease contracts disclosed as of December 31, 2018	8,054
Lease contracts accounted for as short-term lease expenses	(213)
Cancellable operating lease contracts	28,339
Others	118
Lease liabilities as of January 1, 2019	69,665

The following practical expedients detailed in IFRS 16 paragraph C10 are used in the application of IFRS 16.

- A single discount rate is applied to portfolios of leases with reasonably similar characteristics.
- Leases for which the lease term ends within 12 months of the date of initial application are accounted for in the same way as short-term leases.
- Initial direct costs are excluded from the measurement of the right-of-use asset at the date of initial application.
- The Group uses hindsight to calculate the lease term for lease contracts including options to extend or terminate the lease.

Segment Information

(1) Overview of reportable segments

The Group's reportable segments are the constituent units of the Group for which separate financial information is available and which are subject to periodic reviews by the Board of Directors in order to make decisions on allocation of business resources and to evaluate the business performances of the respective segments.

As the Group's holding company, the Company directs the Group's strategic planning, monitors group operations and provides various services to its group companies. Business activities are conducted by the Group's subsidiaries and associates.

Centering on healthcare business, the Group operates activities inside and outside Japan relating to the following four reportable segments: "Pharmaceuticals," "Nutraceuticals," "Consumer products" and "Others" businesses.

The Group defines the reportable segments as follows: "Pharmaceuticals" comprises manufacturing and sales of prescription drugs, intravenous solutions, and others. "Nutraceuticals" comprises manufacturing and sales of functional beverages, etc., over-the-counter drugs and nutritional supplements. "Consumer products" comprises manufacturing and sales of mineral water, soft beverages and food products. "Others" encompasses logistics, warehousing, manufacturing and sales of chemical products, evaluation systems for LED displays and spectroanalysis devices.

(2) Revenue and performance by reportable segment

Revenue and performance by the Group's reportable segment are as follows.

Segment profit is based on operating profit.

Intersegment revenue and transfers reflect reasonable prices for intersegment transfers based on market value.

FY2018 (From January 1, 2018 to June 30, 2018)

(Millions of yen)

	Reportable segment					Adjustments (Note)	Condensed Interim Consolidated Statement of Income
	Pharma-ceuticals	Nutra-ceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	389,166	162,401	16,085	50,672	618,325	–	618,325
Intersegment revenue or transfers	–	310	158	18,407	18,876	(18,876)	–
Total	389,166	162,711	16,243	69,080	637,202	(18,876)	618,325
Segment profit	65,597	19,832	5,536	6,173	97,139	(18,596)	78,542

(Note) Adjustments to segment profit of ¥(18,596) million include intersegment eliminations of ¥(82) million, unallocated corporate expenses of ¥(18,999) million, and other income of ¥486 million. Corporate expenses include headquarter costs and other indirect expenses.

FY2019 (From January 1, 2019 to June 30, 2019)

(Millions of yen)

	Reportable segment					Adjustments (Note)	Condensed Interim Consolidated Statement of Income
	Pharma-ceuticals	Nutra-ceuticals	Consumer products	Others	Total		
Revenue							
Revenue from external customers	438,560	165,419	16,189	50,961	671,131	–	671,131
Intersegment revenue or transfers	–	13	–	19,161	19,175	(19,175)	–
Total	438,560	165,433	16,189	70,123	690,307	(19,175)	671,131
Segment profit	83,366	21,167	4,324	7,094	115,952	(19,428)	96,524

(Note) Adjustments to segment profit of ¥(19,428) million include intersegment eliminations of ¥(129) million, unallocated corporate expenses of ¥(19,683) million, and other income of ¥384 million. Corporate expenses include headquarter costs and other indirect expenses.