Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending December 31, 2016 [Japan GAAP]

November 11, 2016

Company name	: **Otsuka Holdings Company Limited**
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
URL	: http://www.otsuka.com/en/
Representative	: Tatsuo Higuchi President and Representative Director, CEO
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Scheduled date of quarterly securities report submission	: November 14, 2016
Scheduled date of dividend payment commencement	: -
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 Third Quarter of FY2016 (January 1, 2016 to September 30, 2016)

(1) Consolidated Operating Results (cumulative)

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

	Net sales		Operating income		Ordinary income		Net income attributable to owners of parent	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2016	902,797	(18.5)	113,579	(22.8)	116,128	(25.2)	90,598	(12.2)
FY2015	1,107,150	—	147,059	—	155,255	—	103,130	—

(Note) Comprehensive income: FY2016 ¥(35,173) million -%
FY2015 ¥88,759 million -%

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
FY2016	167.20	167.12
FY2015	190.33	190.31

(Note) The Company changed its fiscal year-end from March 31 to December 31 in FY2014. Consequently, consolidated financial statements were not prepared for the third quarter of the fiscal year ended December 31, 2014, and therefore % changes are not shown in FY2015 results.

(2) Consolidated Financial Position

	Total assets	Net assets	Shareholders' equity ratio	Book value per share
	Million yen	Million yen	%	Yen
As of September 30, 2016	2,302,210	1,600,492	68.3	2,903.94
As of December 31, 2015	2,528,510	1,683,436	65.4	3,053.82

(Reference) Shareholders' equity: As of September 30, 2016 ¥1,573,499 million
As of December 31, 2015 ¥1,654,746 million

2. Dividends

	Annual dividend per share				
	First Quarter	Second Quarter	Third Quarter	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
FY2015	-	50.00	-	50.00	100.00
FY2016	-	50.00	-		
FY2016 (forecast)				50.00	100.00

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

3. Forecasts of Consolidated Financial Results for FY2016 (January 1, 2016 to December 31, 2016)

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

	Net sales		Operating income		Ordinary income		Net income attributable to owners of parent		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2016	1,200,000	(17.0)	115,000	(24.3)	115,000	(28.1)	85,000	1.1	156.87

(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) Adoption of accounting methods specific to quarterly consolidated financial statements: None

(3) Changes in accounting policies, changes in accounting estimates and restatements of prior period financial statements due to error correction

1) Changes in accounting policies due to revisions of accounting standards: Yes
2) Changes in accounting policies due to other reasons: None
3) Changes in accounting estimates: None
4) Restatements of prior period financial statements due to error correction: None

(Note) Please see "2. Other Information (3) Changes in accounting policies, changes in accounting estimates and restatements of prior period financial statements due to error correction" on page 10 for detailed information.

(4) 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):
   September 30, 2016 557,835,617 shares
   December 31, 2015 557,835,617 shares
2) Number of shares of treasury shares as of the end of the reporting period:
   September 30, 2016 15,986,227 shares
   December 31, 2015 15,985,891 shares
3) Average number of shares outstanding during the reporting period:
   Quarter ended September 30, 2016 541,849,569 shares
   Quarter ended September 30, 2015 541,835,181 shares

*** Information Regarding Quarterly Review Procedures**

This quarterly financial report is exempt from quarterly review procedures as stipulated under the Financial Instruments and Exchange Act of Japan. At the time of disclosure of this quarterly financial report, the quarterly financial statement review procedures have been completed as stipulated under the Financial Instruments and Exchange Act of Japan, and the quarterly review report has been received on November 10, 2016.

*** Disclaimer Regarding Forward-Looking Statements and Other Items of Note**

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 see "1. Qualitative Information for the Third Quarter of FY2016 (3) Qualitative Information on Consolidated Operating Results Forecast" on page 10 for information regarding the forecast of consolidated financial results.

The Company plans to hold an earnings release conference call for institutional investors, analysts and the press on November 11, 2016. Presentation materials and the audio of the conference call will be available on the Company's website promptly after the conference call.

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(1) Qualitative Information on Consolidated Operating Results

<Summary of Operating Results for the Nine Months Ended September 30, 2016>

For the nine months of FY2016 (from January 1 to September 30, 2016), the Otsuka Group recorded consolidated net sales of ¥902,797 million (down 18.5% year on year), with operating income of ¥113,579 million (down 22.8%), ordinary income of ¥116,128 million (down 25.2%) and net income attributable to owners of parent of ¥90,598 million (down 12.2%).

The "Revised Accounting Standard for Business Combinations" (ASBJ Statement No. 21, September 13, 2013) and others have been applied starting from the first quarter of FY2016, and consequently, "net income" is now referred to as "net income attributable to owners of parent."

Results by business segment are as follows:

(Results for the Nine Months Ended September 30, 2016)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Net sales	555,607	245,862	30,827	104,869	(34,369)	902,797
Operating income (loss)	104,040	30,211	(486)	6,506	(26,691)	113,579

1) Pharmaceuticals

Under the Second Medium-Term Management Plan, which runs until the end of fiscal 2018, the Company is targeting sustainable growth over the medium and long term by positioning the antipsychotic agent *Abilify Maintena*, the antipsychotic agent *REXULTI*, and the vasopressin V_2 receptor antagonist *Samsca/JINARC* as its three global products and positioning the new anti-cancer agent *LONSURF* as one of three next-generation products[*1].

In the area of central nervous system ("CNS") disorders, global sales of the antipsychotic agent *ABILIFY* fell compared with the same period in the previous year due to the impact of the loss of exclusivity in the U.S. and Europe and NHI price revisions in Japan. However, global sales of *ABILIFY* intramuscular depot formulation *Abilify Maintena*[*2] (once-monthly injection) increased significantly compared with the same period in the previous year due to the growing number of markets. In the U.S., sales of *Abilify Maintena* increased compared with the same period in the previous year, supported by an increase in use for the treatment of acutely relapsed adults with schizophrenia, a ready-to-use prefilled syringe and an additional administration site at the deltoid muscle. The number of countries where it has been launched expanded in Europe, supporting a large increase in sales compared with the same period in the previous year. In Japan, sales of *ABILIFY for extended–release injectable suspension, for intramuscular use*, for which an additional administration site at the deltoid muscle was approved in March 2016, are rising steadily. The new antipsychotic agent *REXULTI*[*2] received approval from the U.S. Food and Drug Administration ("FDA") in July 2015 simultaneously for indications of schizophrenia and adjunctive therapy in major depressive disorder. Prescriptions have been growing since the drug was launched in the U.S. in August 2015 and the sales increased significantly compared with the same period in the previous year.

In Japan, antiepileptic drug *E Keppra*, which is co-promoted with UCB Japan, registered firm growth in market share as the top-selling brand[*3] in the domestic antiepileptic drug market, despite NHI price revisions. This reflected growth in prescriptions for epileptic pediatric patients and for the monotherapy treatment of partial-onset seizures, the launch of a drip formulation in December 2015, and approval for the indication of adjunctive therapy for generalized tonic-clonic seizures in February 2016. *Neupro Patch*, the world's only transdermal dopamine agonist on the market for the treatment of Parkinson's disease and restless legs syndrome, registered continued strong growth in sales compared with the same period in the previous year, particularly due to increased understanding of patch-based treatments for Parkinson's disease and growing recognition of its effect in improving wearing-off[*4] symptoms. Also, a new 18mg patch was launched in June 2016 for patients requiring higher doses.

Sales of *NUEDEXTA* climbed compared with the same period in the previous year. *NUEDEXTA* is developed by U.S. company Avanir Pharmaceuticals, Inc., which has strengths to develop drugs in the area of neurological disorders. The drug's growth in prescriptions and stronger sales reflected its increasingly recognized status as the world's first and only treatment for the neurologic disease pseudobulbar affect ("PBA") on the back of the strengthened sales network in the U.S. In addition, in January 2016, the U.S. FDA approved *ONZETRA Xsail* (sumatriptan nasal powder) for the acute treatment of migraine using a new intranasal medication delivery system. Sales of *ONZETRA Xsail* began in May 2016.

In the area of oncology, global sales of anti-cancer agent *TS-1* declined compared with the same period in the previous year, mainly due to the impacts of NHI price revisions and rival products in Japan. Sales of anti-cancer agent *UFT* and reduced folic acid formulation *Uzel* both declined compared with the same period in the previous year, due to the impact of rival products. Sales of long-acting 5-HT_3 receptor antagonist antiemetic agent *Aloxi* increased compared with the same period in the previous year, supported by growth of prescriptions for patients with gastric cancer, pancreatic cancer and lung cancer. Sales of anti-cancer agent *Abraxane* grew compared with the same period in the previous year, supported by an increase in prescriptions for pancreatic cancer, despite NHI price revisions in Japan. Global sales of *LONSURF*, a new anti-cancer agent, have been growing steadily. The drug was launched in Japan in May 2014 as a treatment of unresectable advanced or recurrent colorectal cancer, and Taiho Oncology Inc., a subsidiary of Taiho Pharmaceutical Co., Ltd., also started to sell the drug in the U.S. in October 2015, through in-house sales platform for the same indication. Also, Servier, which has concluded a license agreement for *LONSURF* in Europe with Taiho Pharmaceutical Co., Ltd., successively began selling the drug in European countries from August 2016, one country at a time.

Anti-cancer agent *SPRYCEL*, which is being promoted in Japan, the U.S. and Europe in collaboration with BMS[*5], has been widely recognized in the global market as a first-line treatment for chronic myeloid leukemia. However, distributions on a yen basis received by the Company based on sales declined compared with the same period in the previous year due to forex factors. *Busulfex*, an allogeneic hematopoietic stem cell pre-transplanting regimen now sold in more than 50 markets worldwide, has established a standard drug therapy approach as a conditioning agent administered prior to bone marrow transplants in place of total-body radiation. However, sales of *Busulfex* decreased compared with the same period in the previous year, due to the impact of generic products launched in the U.S.

In the area of cardiovascular system, despite NHI price revisions in Japan, *Samsca/JINARC*[*6], a vasopressin V_2 receptor antagonist developed by Otsuka Pharmaceutical, is gaining more acceptance among medical specialists due to its value as an oral aquaretic agent, supporting an increase in global sales compared with the same period in the previous year. Globally the drug has also started to be used as the world's first drug for the autosomal dominant polycystic kidney disease ("ADPKD"), an intractable kidney disease. In Japan, the prescriptions for the drug have increased, as understanding of the drug has grown gradually after the drug has been approved for this additional indication in March 2014. The drug is also sold in Canada and Europe for the treatment of ADPKD. As of September 30, 2016, *Samsca/JINARC* was available in 24 markets worldwide. Sales of antiplatelet agent *Pletaal/Pletal* declined compared with the same period in the previous year due to the impact of promotion of generic products and NHI price revisions in Japan.

In the area of digestive system, effective March 2016, it became possible to write long-term prescriptions of *TAKECAB*, co-promoted with Takeda Pharmaceutical Company Limited since its launch in February 2015, and prescriptions grew steadily. Also, sales of pack formulations for eradication of Helicobacter pylori started in June 2016. Sales of anti-gastritis and anti-gastric ulcer agent *Mucosta* declined compared with the same period in the previous year due to the impact of promotion of generic products and NHI price revisions in Japan.

In other areas, prescriptions for dry eye treatment *Mucosta ophthalmic suspension UD 2%* expanded steadily and sales grew compared with the same period in the previous year.

In the area of clinical nutrition, sales of the high-calorie TPN (total parenteral nutrition) solution *ELNEOPA* remained level compared with the same period in the previous year. This reflected recognition of the solution as a TPN kit product containing trace elements recommended in the 2013 guidelines of the Japanese Society for Parenteral and Enteral Nutrition ("JSPEN") and ongoing efforts to promote the solution to welfare facilities.

In the area of diagnostics, sales of Helicobacter pylori diagnostic agents and other products declined due to the impact of NHI price revisions, but sales rose overall compared with the same period in the previous year, mainly due to higher sales of *Otsuka Major BCR-ABL mRNA Measurement Kit*, which is used as a marker to monitor treatment effectiveness for chronic myeloid leukemia, and *QuickNavi*™*-Flu Influenza Diagnostic Kit*.

As a result, net sales in the pharmaceutical segment for the nine months ended September 30, 2016 totaled ¥555,607 million (down 26.3% from the same period in the previous year), with operating income of ¥104,040 million (down 29.9%).

*1: Three products of *LONSURF*, Lu AE58054 and SGI-110
*2: Alliance products, under the global alliance with H. Lundbeck A/S, developed by Otsuka Pharmaceutical
*3: Copyright © 2016 QuintilesIMS. Estimated based on "Japan Pharmaceutical Market, January-September 2016." All rights reserved, no reproduction without permission.
*4: Wearing-off is a complication of dopamine agonist treatments, where symptoms of Parkinson's disease can repeatedly improve and worsen over the course of a day. It is one of the most serious issues affecting the everyday lives of Parkinson's disease sufferers.
*5: Bristol-Myers Squibb Company
*6: Sold overseas as a treatment for ADPKD under the brand name *JINARC*.

2) Nutraceuticals

Sales volume for the *Pocari Sweat* electrolyte supplement drink increased in Japan compared with the same period in the previous year, despite a weak domestic market for sports drinks[*7]. Growth was supported by promotional efforts targeting young people and spreading awareness of the product's ability to prevent heat stroke during summer. Advertising was also reinforced with coordinated TV and online campaigns that encouraged participation from consumers, which was effectively linked with in-store promotional activities, spurring greater demand from consumers. To address hydration needs in different situations, *Pocari Sweat Jelly* for "edible hydration" was launched and *Pocari Sweat Ion Water*, the thirst-quenching beverage that supports optimum day-to-day condition, was relaunched in April 2016. Also, *Pocari Sweat Ion Water Powder (for 750ml)* is being rolled out in the market after being launched in June 2016. Overseas, where *Pocari Sweat* is sold in 19 markets worldwide, sales volume in Indonesia remained level compared with the same period in the previous year, although it was affected by the weakness in the economy and unseasonal weather. In China, sales of *Pocari Sweat 900ml*, which was launched in August 2016, are growing steadily, but sales volume in the China market over all declined compared with the same period in the previous year, affected by a slowdown in the economy.

Sales volume for carbonated nutritional drink *Oronamin C* declined compared with the same period in the previous year, but most recent sales volume results have been increasing compared with the previous year due to stepped up promotional activities implemented since April 2016.

In the *Calorie Mate* range of balanced nutrition food, *Calorie Mate Jelly* was launched in May 2016 with three flavors (*Apple, Lime & Grapefruit* and *Fruity Milk*) and is being rolled out steadily in the market. These new products and rising sales of block-type *Calorie Mate* supported an increase in sales volume across the *Calorie Mate* range compared with the same period in the previous year.

Also, in the soy-related business, sales volume rose strongly across the entire *SOYJOY* range in Japan, supported by the April 2016 launch of *SOYJOY Crispy*, which has a new texture and is available in three flavors (*Plain*, *Mixed Berry* and *Golden Berry*), helping to attract a different type of customer to the customers who purchase original *SOYJOY* products.

Sales of *EQUELLE*, a food product containing equol that supports women's health, progressed steadily, reflecting efforts by the Group to step up the provision of information to companies and consumers concerning women's health, focusing on the relationship between equol and physical and emotional changes in women.

Nature Made, supplied by subsidiary Pharmavite LLC of the U.S., has been the number one retail vitamin and supplement brand in the U.S. for nine consecutive years[*8]. Sales of *Nature Made* supplements continues to rise steadily on the back of an upswing in the U.S. market[*9]. In Japan, there was steady growth in sales of products such as multivitamin supplement series and five Foods with Nutrient Function Claims: *Lutein*, *Astaxanthin*, *Fish Oil Pearl*, *Super Fish Oil*, and *Ginkgo Biloba*. Sales were also firm for *MegaFood* and *INNATE*, natural food-based supplements of FoodState Inc. of the U.S.

Sales were steady at Nutrition & Santé SAS, an Otsuka Group subsidiary that operates in more than 40 countries, mainly in Europe, supported by growth in health food products sold under the *Gerblé* nutrition and health food brand and other brands, and gluten-free food products, particularly organic and soy products.

Kenja-no-shokutaku (wise man's dining) *Double Support*, a Food for Specified Health Use, has the functions of slowing down the body's absorption of both sugars and lipids, thereby reducing the rise in blood glucose levels and triglycerides after meals. Sales rose significantly due to stepped up promotional activities, mainly through drugstores, suggesting uses for the product in everyday situations. Sales of *Kenja-no-shokutaku Double Support* are also rising steadily in Hong Kong, where the product was launched in 2015.

In the cosmedics area, sales of the *UL•OS* men's skincare brand were firm overall, driven by growth in sales for cleansing-related products such as *Medicated Skin Wash* and *Medicated Scalp Shampoo*. *UL•OS Medicated Skin Whitening*, a pen-type skin treatment launched in 2015 that inhibits dark spots, has also proven to be popular with consumers thanks to its unique product features, supporting growth in the number of users. Also in South Korea, sales of the *UL•OS* brand increased significantly, supported by efforts to develop the brand. Sales of the women's skincare brand *InnerSignal* registered steady growth as a result of acquiring new customers and expanding the base of loyal users.

Sales volume of nutrient tonic *Tiovita* increased compared with the same period in the previous year, reflecting in-store sales promotions and advertising to attract new users.

Sales volume of oral rehydration solution *OS-1* increased compared with the same period in the previous year, reflecting greater awareness of the product and increased understanding about the product.

Sales of *Oronine H Ointment* increased steadily in Japan, supported by efforts to promote the benefits of a new laminated tube product launched in August 2015, which attracted new customers. Sales in Hong Kong increased compared with the same period in the previous year due to the rise in purchasing power of travelers from mainland China.

As a result, net sales in the nutraceutical segment for the nine months ended September 30, 2016 totaled ¥245,862 million (down 0.4% from the same period in the previous year), with operating income of ¥30,211 million (up 22.3%). In this business, the Group is making improvements to the value chain, such as rebuilding its product strategy to emphasize growth and profitability.

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3) Consumer products

Sales volume of *MATCH*, a carbonated electrolyte drink containing vitamins, increased compared with the same period in the previous year, reflecting the launch of a new product *Berry MATCH* in March 2016 and efforts to reenergize the brand by continuing to implement an aggressive marketing strategy, sales promotion activities and other initiatives. Sales volume for mineral water products, centered on *CRYSTAL GEYSER*, declined slightly compared with the same period in the previous year, despite active marketing efforts such as stepped up communication initiatives targeting growth in new customers. In the *Bon Curry* range of instant curry dishes, while there are impacts of competition, etc., ongoing steps were taken to increase brand value, such as implementing product strategies tailored to consumer needs and stepping up marketing and sales promotion activities.

As a result, net sales in the consumer products segment for the nine months ended September 30, 2016 totaled ¥30,827 million (down 7.8% from the same period in the previous year), with operating loss of ¥486 million (compared with an operating loss of ¥2,619 million for the same period in the previous year). In the consumer products segment, the Group is continuing its efforts to improve profitability by reviewing marketing strategies and sales promotion activities and improve the expense-to-sales ratio.

4) Others

In the specialty chemical business, sales remained level compared with the same period in the previous year with growth in the sales of deodorizers for construction materials, flame retardant agents used in mobile devices and conducting materials grew but decline in the sales volume of hydrazine. In the fine chemical business, sales decreased compared with the same period in the previous year, mainly due to making price reductions on pharmaceutical intermediates overseas and forex factors.

In the transportation and warehousing business, there was growth in new external customers and increased handling volume resulting from the promotion of a "common distribution platform (distribution of products to market for the Group as well as for other firms)" business. However, overall sales remained level compared with the same period in the previous year. Sales in the direct sales support business increased compared with the same period in the previous year mainly due to the growth in the volume of orders handled.

As a result, net sales in the other businesses for the nine months ended September 30, 2016 totaled ¥104,869 million (down 2.5% from the same period in the previous year), with operating income of ¥6,506 million (up 28.7%).

<Research and Development Activities>

Research and development expenses for the nine months ended September 30, 2016 totaled ¥105,151 million.
The primary areas of research and development as well as the status of new product development by business segment were as follows:

(Pharmaceuticals)
The Otsuka Group conducts research and development with a primary focus on the areas of the central nervous system and oncology. The Group also conducts research and development focusing on fields that are yet to be fully addressed such as cardiovascular system and ophthalmology.
Research and development expenses for the pharmaceutical business for the nine months ended September 30, 2016 were ¥98,631 million.

Research and development activities carried out during the nine months ended September 30, 2016 in the pharmaceutical business are summarized below.

Category	*Brand Name*, (Generic Name), Development Code	Status
Central nervous system / other neurological disorders	AVP-786	<U.S.> • Phase II trial for the disinhibition syndrome in neurodegenerative disorders was initiated in May 2016. • Development for the treatment of major depressive disorder was halted as Phase II trial did not provide sufficient evidence of efficacy to justify continued development.
	ONZETRA Xsail (sumatriptan) AVP-825	<U.S.> • Approval was granted in January 2016 for the indications of acute migraine. Also, sales started in May 2016.
	E Keppra (levetiracetam)	<Japan> • Approval was granted in February 2016 for the additional indication of adjunctive therapy for generalized tonic-clonic seizures.
	TAS-205	<Japan> • Phase II trial for the treatment of duchenne muscular dystrophy (“DMD”) was initiated in May 2016.
	ABILIFY (aripiprazole)	<Japan> • Approval was granted in September 2016 for the additional indication of irritability associated with pediatric autism spectrum disorder.
Oncology	*LONSURF* TAS-102	<Japan, U.S. and Europe> • Phase III trial for the treatment of gastric cancer was initiated in February 2016. < Europe> • Approval was granted in April 2016 for the indications of colorectal cancer.
	ASTX727	<U.S.> • Phase II trial for the treatment of myelodysplastic syndrome was initiated in January 2016.
	TAS3681	<U.S. and Europe> • Phase I trial for the treatment of prostate cancer was initiated in March 2016.
	TAS-116	<Japan> • Phase II trial for the treatment of gastrointestinal stromal tumor was initiated in May 2016.
	Yondelis ET-743	<Japan> • Phase I trial for the treatment of ovarian cancer was initiated in April 2016.
	TS-1/Teysuno (tegafur, gimeracil, oteracil) S-1	<Japan and Asia> • Development for the treatment of uterocervical cancer was halted as Phase III trial did not present sufficient evidence of efficacy.
	(fosnetupitant) Pro-NETU	<Japan> • Phase II trial for the treatment of nausea and vomiting related to the administration of anti-cancer agents was initiated in September 2016.

Category	*Brand Name*, (Generic Name), Development Code	Status
	TAS-114	<Japan, U.S. and Europe> • Phase II trial for the treatment of non-small cell lung cancer was initiated in August 2016.
	Iclusig (ponatinib)	<Japan> • Approval was granted for the indications of chronic myeloid leukemia and Philadelphia chromosome-positive acute lymphoblastic leukemia in September 2016.
Other categories	OPC-108459	<Japan and U.S.> • Development for the treatment of paroxysmal and persistent atrial fibrillation was halted as Phase I trial did not present sufficient scientific data to justify continued development.
	(emixustat) ACU-4429	<U.S.> • It was decided to discontinue trial for the treatment of dry age-related macular degeneration in May 2016 as Phase II/ III trial did not meet the primary endpoint. An agreement with Acucela Inc. for the co-development and commercialization of the drug was terminated in June 2016.
	(tetomilast) OPC-6535	<Japan, U.S. and Asia> • Development for the treatment of chronic obstructive pulmonary disease was halted as Phase II trial did not present sufficient scientific data to justify continued development.
	OPA-6566	<U.S.> • Development for the treatment of glaucoma was halted as Phase I/ II trial did not provide sufficient evidence of efficacy to justify continued development.
	Bilanoa (bilastine) TAC-202	<Japan> • Approval was granted in September 2016 for the indications of allergic rhinitis, and chronic urticaria and pruritus associated with skin disease.
	ZOSYN (tazobactam, piperacillin) YP-18	<Japan> • An application was filed for the indications of complicated skin and soft tissue infections (including diabetic foot infections) in July 2016.
	OPF-108	<Japan> • Approval was granted in July 2016 as a high-calorie TPN solution.
	Mikeluna combination ophthalmic solution OPC-1085EL	<Japan> • Approval was granted in September 2016 for the indications of glaucoma and ocular hypertension.
	OPA-15406	<Japan> • Phase II trial for the treatment of atopic dermatitis was initiated in September 2016.
Diagnostics	*WT1 mRNA Assay Kit II 'Otsuka'* ODK-1003	<Japan> • An application was filed as an in-vitro diagnostic agent for acute lymphoblastic leukemia in July 2016.
	WT1 mRNA RT-PCR Assay Kit ODK-1003-CN	<Asia> • An application was filed as an in-vitro diagnostic agent for myelodysplastic syndrome in August 2016.

(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.

SOYJOY Crispy, a new addition to the *SOYJOY* baked soy bar range, was launched in April 2016. Characterized by the light and crunchy texture of puffed soy, *SOYJOY Crispy* is available in three flavors (*Plain*, *Mixed Berry* and *Golden Berry*). In the *Pocari Sweat* range, *Pocari Sweat Jelly* for "edible hydration" was launched in April 2016, the first new form of *Pocari Sweat* since it was launched 36 years ago. *Pocari Sweat Ion Water Powder (for 750ml)* was launched in June 2016. In the *Calorie Mate* range of balanced nutrition food, *Calorie Mate Jelly* was launched in May 2016 with three flavors (*Apple*, *Lime & Grapefruit* and *Fruity Milk*) to suit different tastes and situations.

Research and development expenses for the nutraceutical business for the nine months ended September 30, 2016 were ¥3,565 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.

Research and development expenses for the consumer products business for the nine months ended September 30, 2016 were ¥312 million.

(Others)

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

Research and development expenses for the other businesses for the nine months ended September 30, 2016 were ¥2,642 million.

(2) Qualitative Information on Consolidated Financial Position

1) Assets

Total assets as of September 30, 2016 were ¥2,302,210 million compared to total assets of ¥2,528,510 million at the end of the previous fiscal year. This decrease of ¥226,299 million was due to reductions of ¥65,699 million in current assets, of ¥160,593 million in non-current assets and ¥7 million in deferred assets.

(Current Assets)

Total current assets as of September 30, 2016 were ¥1,111,182 million, a decrease of ¥65,699 million compared to ¥1,176,882 million of total current assets at the end of the previous fiscal year. This decrease was due to reductions in notes and accounts receivable-trade by ¥89,552 million, marketable securities by ¥52,154 million, inventory by ¥1,692 million, and other current assets by ¥2,536 million, while cash and deposits increased by ¥80,289 million.

(Non-current Assets)

Total non-current assets as of September 30, 2016 were ¥1,190,985 million, a decrease of ¥160,593 million compared to ¥1,351,578 million of total non-current assets at the end of the previous fiscal year. Reasons include decreases in the value of property, plant and equipment by ¥13,174 million, intangible assets by ¥112,500 million, and investment securities by ¥21,205 million.

2) Liabilities

(Current Liabilities)

Total current liabilities as of September 30, 2016 were ¥371,650 million, a decrease of ¥95,425 million compared to ¥467,075 million of total current liabilities at the end of the previous fiscal year. This decrease was mainly due to decreases in notes and accounts payable-trade by ¥7,419 million, short-term loans payable by ¥3,775 million, and other current liabilities by ¥91,990 million. Provisions for bonuses increased by ¥5,311 million.

(Non-current Liabilities)

Total non-current liabilities as of September 30, 2016 were ¥330,067 million, a decrease of ¥47,930 million compared to ¥377,998 million at the end of the previous fiscal year. This decrease was mainly due to reductions in long-term loans payable by ¥31,655 million and other non-current liabilities by ¥13,663 million.

3) Net Assets

Total net assets as of September 30, 2016 were ¥1,600,492 million, a decrease of ¥82,943 million compared to ¥1,683,436 million at the end of the previous fiscal year. This was mainly due to ¥38,086 million increase in total shareholders' equity as a result of ¥54,184 million payment of dividends and quarterly net income attributable to owners of parent of ¥90,598 million, and a ¥119,333 million decrease of accumulated other comprehensive income, which was due to an increase of ¥2,533 million in valuation differences on available-for-sale securities and a decrease of ¥119,463 million in foreign currency translation adjustments.

(3) Qualitative Information on Consolidated Operating Results Forecast

The consolidated financial results forecast for FY2016 as announced on August 9, 2016, has been amended based upon actual results for the nine months ended September 30, 2016, and taking into account projections of selling, general and administrative expenses for the remainder of the fiscal year.

Amendments to the consolidated financial results forecast for FY2016 (January 1, 2016 to December 31, 2016)

	Net Sales	Operating income	Ordinary income	Net income attributable to owners of parent	Basic earnings per share
	Million yen	Million yen	Million yen	Million yen	Yen
Previous forecast (A)	1,200,000	100,000	100,000	75,000	138.41
Revised forecast (B)	1,200,000	115,000	115,000	85,000	156.87
Amount of change (B-A)	—	15,000	15,000	10,000	
Change (%)	—	15.0	15.0	13.3	
(Reference) Consolidated results of FY2015	1,445,227	151,837	159,899	84,086	155.12

The forecast above is calculated using Japanese Generally Accepted Accounting Principles (J-GAAP). The Company plans to voluntarily adopt International Financial Reporting Standards (IFRS) starting with the fourth quarter financial results of FY2016.

Projected foreign exchange rates are as follows:

	USD	EUR
Previous forecast	108.00 yen	120.00 yen
Revised forecast	107.00 yen	119.00 yen
Foreign exchange rate for the nine months of FY2016	108.56 yen	121.05 yen

Reference

The following table shows the estimated consolidated financial forecasts for FY2016 calculated under IFRS announced today in "Notice Concerning Voluntary Adoption of International Financial Reporting Standards (IFRS)."

	Net sales	Operating income	Profit attributable to owners of parent	Basic earnings per share
	Million yen	Million yen	Million yen	Yen
FY2016	1,180,000	115,000	95,000	175.33

2. Other Information

(1) Changes in significant subsidiaries during the period

None

(2) Adoption of accounting methods specific to quarterly consolidated financial statements

None

(3) Changes in accounting policies, changes in accounting estimates and restatements of prior period financial statements due to error correction

(Application of Revised Accounting Standards for Business Combinations and related standards)

The "Revised Accounting Standard for Business Combinations" (ASBJ Statement No. 21, September 13, 2013, hereinafter referred to as the "Business Combinations Accounting Standards"), the "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, September 13, 2013, the "Consolidated Financial Statements Accounting Standard"), and the "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No. 7, September 13, 2013, the "Business Divestitures Accounting Standard") have been applied starting from the first quarter of FY2016. Consequently, changes in the equity of subsidiaries which continue to be controlled by the Company will be included in capital surplus, and costs associated with the acquisition of shares will be treated as expenses in the consolidated fiscal year in which they have been incurred. In addition, the final determination of provisional acquisition costs allocations for business combinations closed after the start of the first quarter of FY2016 will be reflected in the quarterly consolidated financial statements for the quarter in which the business combination closed. Additionally, the Company has changed the method of presenting consolidated quarterly net income. "Minority interests" are now referred to as "non-controlling interests." These changes are also reflected in the Company's previous first quarter consolidated financial statements and in its annual consolidated financial statements for the previous fiscal year.

The Company applies Business Combinations Accounting Standard 58-2 (4), Consolidated Financial Statements Accounting Standard 44-5 (4), and Business Divestitures Accounting Standard 57-4 (4) for the provisional accounting treatment of business combinations from the beginning of the first quarter of FY2016.

These changes will not have a material impact on the Company's profits and its capital surplus account during this fiscal year.

3. Quarterly Consolidated Financial Statements

(1) Consolidated Balance Sheets

(Millions of yen)

	As of December 31, 2015	As of September 30, 2016
ASSETS		
Current assets		
Cash and deposits	439,377	519,667
Notes and accounts receivable-trade	379,459	289,906
Marketable securities	127,601	75,447
Merchandise and finished goods	71,254	71,812
Work-in process	34,725	33,114
Raw materials and supplies	38,908	38,270
Other	86,288	83,752
Allowance for doubtful receivables	(733)	(786)
Total current assets	1,176,882	1,111,182
Non-current assets		
Property, plant and equipment	356,422	343,247
Intangible assets		
Goodwill	233,971	187,232
In-process research and development	238,301	170,931
Other	170,219	171,827
Total intangible assets	642,492	529,991
Investments and other assets		
Investment securities	258,928	237,722
Investments in capital	42,917	36,089
Net defined benefit asset	22,769	26,293
Other	28,831	17,980
Allowance for investment loss	(75)	(55)
Allowance for doubtful accounts	(707)	(284)
Total investments and other assets	352,663	317,745
Total non-current assets	1,351,578	1,190,985
Deferred assets	49	42
Total assets	2,528,510	2,302,210
LIABILITIES		
Current liabilities		
Notes and accounts payable-trade	82,690	75,271
Short-term loans payable	79,679	75,904
Income taxes payable	19,336	21,879
Provision for bonuses	14,149	19,461
Other provision	270	174
Other	270,950	178,959
Total current liabilities	467,075	371,650
Non-current liabilities		
Long-term loans payable	234,229	202,574
Other provision	2,495	2,372
Net defined benefit liability	9,753	9,112
Negative goodwill	17,227	15,379
Other	114,292	100,628
Total non-current liabilities	377,998	330,067
Total liabilities	845,073	701,717

Consolidated Balance Sheets—Continued

(Millions of yen)

	As of December 31, 2015	As of September 30, 2016
NET ASSETS		
Shareholders' equity		
Capital stock	81,690	81,690
Capital surplus	512,702	513,174
Retained earnings	1,025,663	1,063,278
Treasury shares	(47,262)	(47,263)
Total shareholders' equity	1,572,793	1,610,880
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	27,053	29,586
Deferred gains on hedges	130	(5)
Foreign currency translation adjustment	41,749	(77,713)
Remeasurements of defined benefit plans	13,019	10,751
Total accumulated other comprehensive income	81,952	(37,380)
Subscription rights to shares	―	84
Non-controlling interests	28,689	26,908
Total net assets	1,683,436	1,600,492
Total liabilities and net assets	2,528,510	2,302,210

(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Consolidated Statements of Income

(Millions of yen)

	FY2015 (From January 1, 2015 to September 30, 2015)	FY2016 (From January 1, 2016 to September 30, 2016)
Net sales	1,107,150	902,797
Cost of sales	334,416	294,641
Gross profit	772,734	608,155
Selling, general and administrative expenses		
Promotion expenses	160,506	82,727
Salaries and bonuses	95,903	92,267
Provision for bonuses	13,318	12,895
Retirement benefit expenses	2,392	3,360
Amortization of goodwill	10,525	8,923
Research and development expenses	141,852	105,151
Other	201,175	189,250
Total selling, general and administrative expenses	625,674	494,575
Operating income	147,059	113,579
Non-operating income		
Interest income	1,214	1,439
Dividend income	1,060	1,078
Amortization of negative goodwill	2,078	1,848
Share of profit of entities accounted for using equity method	8,073	11,185
Other	1,945	3,026
Total non-operating income	14,373	18,577
Non-operating expenses		
Interest expenses	2,928	2,620
Foreign exchange losses	2,490	12,675
Other	758	732
Total non-operating expenses	6,177	16,028
Ordinary income	155,255	116,128
Extraordinary income		
Gain on sales of non-current assets	705	358
Gain on sales of investment securities	112	16,868
Subsidy income	381	102
Other	289	98
Total extraordinary income	1,488	17,427
Extraordinary losses		
Impairment loss	171	7,017
Loss on valuation of investment securities	421	852
Loss on sales of shares of subsidiaries and associates	565	―
Other	463	544
Total extraordinary loss	1,621	8,415
Income before income taxes and minority interests	155,123	125,140
Income taxes		
Current	27,027	31,537
Deferred	24,099	1,941
Total income taxes	51,127	33,479
Net income	103,996	91,661
Net income attributable to non-controlling interests	865	1,063
Net income attributable to owners of parent	103,130	90,598

Consolidated Statements of Comprehensive Income

(Millions of yen)

	FY2015 (From January 1, 2015 to September 30, 2015)	FY2016 (From January 1, 2016 to September 30, 2016)
Net income	103,996	91,661
Other comprehensive income		
Valuation difference on available-for-sale securities	5,864	(2,175)
Deferred losses on hedges	(224)	(135)
Foreign currency translation adjustments	(13,479)	(103,689)
Remeasurements of defined benefit plans	(2,752)	(2,277)
Share of other comprehensive income of entities accounted for using equity method	(4,645)	(18,558)
Total other comprehensive income	(15,236)	(126,835)
Total comprehensive income	88,759	(35,173)
Total comprehensive income attributable to:		
Owners of parent	89,700	(33,245)
Non-controlling interests	(941)	(1,928)

(3) Notes regarding Quarterly Consolidated Financial Statements

(Note regarding Assumption of Going Concern)

Not applicable

(Note regarding Significant Changes in the Amount of Shareholders' Equity)

Not applicable

(Segment Information)

For the nine months of FY2015 (from January 1, 2015 to September 30, 2015)

1) Net sales and segment income (loss) by reporting segment

(Millions of yen)

	Pharma-ceuticals	Nutra-ceuticals	Consumer products	Others	Total	Adjustments	Consolidated
Net sales							
Sales to customers	753,854	240,393	33,198	79,704	1,107,150	―	1,107,150
Intersegment sales	―	6,345	250	27,804	34,400	(34,400)	―
Total	753,854	246,738	33,448	107,509	1,141,551	(34,400)	1,107,150
Segment income (loss)	148,351	24,696	(2,619)	5,056	175,485	(28,425)	147,059

Notes:

1) Adjustments to segment income (loss) of ¥(28,425) million include intersegment eliminations of ¥459 million and unallocated corporate expenses of ¥(28,884) million. Corporate expenses include headquarter costs and other indirect expenses.

2) Segment income (loss) is adjusted to operating income as stated in the quarterly consolidated statement of income.

2) Assets by reporting segment

A provisional purchase price allocation regarding the acquisition of Avanir Pharmaceuticals, Inc. (acquired in the first quarter of FY2015) was initially performed based on information available at the end of the second quarter of FY2015. Purchase price allocation has been completed during the third quarter of FY2015. As a result, "Pharmaceuticals" segment assets increased by ¥501,653 million.

3) Loss on impairment of non-current assets, goodwill and others by reporting segment

(Significant changes in goodwill)

A provisional purchase price allocation regarding the acquisition of Avanir Pharmaceuticals, Inc. (acquired in the first quarter of FY2015) was initially performed based on information available at the end of the second quarter of FY2015. Purchase price allocation has been completed during the third quarter of FY2015. As a result, goodwill attributed to the "Pharmaceuticals" segment decreased by ¥227,299 million.

For the nine months of FY2016 (from January 1, 2016 to September 30, 2016)

1) Net sales and segment income (loss) by reporting segment

(Millions of yen)

	Pharma-ceuticals	Nutra-ceuticals	Consumer products	Others	Total	Adjustments	Consolidated
Net sales							
Sales to customers	555,607	238,023	30,570	78,596	902,797	―	902,797
Intersegment sales	―	7,839	257	26,272	34,369	(34,369)	―
Total	555,607	245,862	30,827	104,869	937,167	(34,369)	902,797
Segment income (loss)	104,040	30,211	(486)	6,506	140,271	(26,691)	113,579

Notes:

1) Adjustments to segment income (loss) of ¥(26,691) million include intersegment eliminations of ¥735 million and unallocated corporate expenses of ¥(27,426) million. Corporate expenses include headquarter costs and other indirect expenses.

2) Segment income (loss) is adjusted to operating income as stated in the quarterly consolidated statement of income.

2) Loss on impairment of non-current assets, goodwill and others by reporting segment

(Significant impairment loss on non-current assets)

Due to changes in the business environment in each segment, the Company reviewed business plans for some of its consolidated subsidiaries. As a result, an impairment loss of ¥7,017 million was recorded under extraordinary losses due to less than initially expected earnings for property, plant and equipment, goodwill, and other intangible assets. Impairment losses were ¥2,320 million for the "Pharmaceuticals" segment, ¥4,690 million for "Nutraceuticals," ¥1 million for "Others," and ¥5 million for general group-related assets.