

Consolidated Financial Results for the Third Quarter of the Fiscal Year Ending December 31, 2015 [Japan GAAP]

November 13, 2015

Company name	: Otsuka Holdings Company Limited
Stock exchange listing	: Tokyo Stock Exchange
Code number	: 4578
URL	: http://www.otsuka.com/en/
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Scheduled date of quarterly securities report submission	: November 13, 2015
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 FY2015 (January 1, 2015 to September 30, 2015)

(1) Consolidated Financial Results (cumulative)

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

	Net sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
FY2015	1,107,150	—	147,059	—	155,255	—	103,130	—
FY2014	—	—	—	—	—	—	—	—

(Note) Comprehensive income:	FY2015	¥88,759 million	—%
	FY2014	— million	—%

	Basic earnings per share		Diluted earnings per share	
	Yen		Yen	
FY2015	190.33		190.31	
FY2014	—		—	

(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 business results for the nine months ended December 31, 2014 are not presented.

(2) Consolidated Financial Position

	Total assets		Net assets		Shareholders' equity ratio		Book value per share	
	Million yen		Million yen		%		Yen	
As of September 30, 2015	2,550,356		1,699,575		65.4		3,079.36	
As of December 31, 2014	2,178,184		1,658,600		74.7		3,004.38	

(Reference) Shareholders' equity:	As of September 30, 2015	¥1,668,551 million
	As of December 31, 2014	¥1,627,801 million

2. Dividends

	Annual dividend per share				
	First Quarter	Second Quarter	Third Quarter	Year-end	Total
	Yen				
FY2014	—	35.00	—	40.00	75.00
FY2015	—	50.00	—	—	—
FY2015 (forecast)	—	—	—	50.00	100.00

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

3. Forecasts of Consolidated Financial Results for FY2015 (January 1, 2015 to December 31, 2015)

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

	Net sales		Operating income		Ordinary income		Net income		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
FY2015	1,410,000	—	145,000	—	150,000	—	90,000	—	166.11

(Note) Revisions to financial forecast most recently announced: Yes

The Company changed its fiscal year-end from March 31 to December 31 in FY2014. Financial results for FY2014 and FY2015 are not directly comparable, since FY2014 only consisted of 9 months (FY2015: 12 months).

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: None
 - 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
- (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 stock):

September 30, 2015	557,835,617 shares
December 31, 2014	557,835,617 shares
 - 2) Number of shares of treasury stock as of the end of the reporting period:

September 30, 2015	15,985,871 shares
December 31, 2014	16,037,940 shares
 - 3) Average number of shares outstanding during the reporting period:

Quarter ended September 30, 2015	541,835,181 shares
Quarter ended December 31, 2014	— shares

(Note) Due to the change in the fiscal year end, consolidated financial statements were not prepared for the third quarter of the fiscal year ended December 31, 2014, and therefore the average number of shares outstanding for the nine months ended December 31, 2014 is not presented.

* Information Regarding the 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 statements 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 12, 2015.

* 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 FY2015 (3) Qualitative Information on Consolidated Financial Results Forecast" on page 11 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 13, 2015. 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 for the Third Quarter of FY2015

(1) Qualitative Information on Consolidated Financial Results

Following approval of the partial amendments of the Articles of Incorporation at the 6th Annual Shareholders Meeting held on June 27, 2014, the Company changed its consolidated fiscal year-end from March 31 to December 31. Consequently, consolidated financial statements were not prepared for the third quarter of the fiscal year ended December 31, 2014.

As a result, the consolidated statements of income and consolidated statements of comprehensive income stated in

“3. Quarterly Consolidated Financial Statements (2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income” are consolidated based on the period from January 1 to September 30 for FY2015 and not presented for FY2014.

Therefore, to provide a comparison with last year’s quarterly results, we have calculated results for the period from January 1 to September 30, 2014 for all consolidated companies, which are shown for reference purposes below.

<Summary of Financial Results for the Nine Months Ended September 30, 2015>

For the nine months of FY2015 (from January 1 to September 30, 2015), the Otsuka Group recorded consolidated net sales of ¥1,107,150 million (down 2.5% from ¥1,135,829 million for the same period in the previous year), with operating income of ¥147,059 million (down 4.5% from ¥153,953 million for the same period in the previous year), ordinary income of ¥155,255 million (down 6.8% from ¥166,602 million for the same period in the previous year) and net income of ¥103,130 million (down 7.5% from ¥111,488 million for the same period in the previous year).

Results by business segment are as follows:

(Results for the Nine Months Ended September 30, 2015)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Net sales	753,854	246,738	33,448	107,509	(34,400)	1,107,150
Operating income (loss)	148,351	24,696	(2,619)	5,056	(28,425)	147,059

(Reference: Results for the Nine Months Ended September 30, 2014)

(Millions of yen)

	Pharmaceuticals	Nutraceuticals	Consumer products	Others	Adjustments	Total
Net sales	819,743	215,914	33,728	99,734	(33,291)	1,135,829
Operating income (loss)	165,257	15,564	(441)	5,576	(32,004)	153,953

1) Pharmaceuticals

In the area of central nervous system (“CNS”) disorders, global sales of antipsychotic agent *ABILIFY* fell approximately 40% compared with the same period in the previous year due to loss of exclusivity in Europe and the U.S. In the U.S., sales of *ABILIFY* declined approximately 40% year on year, reflecting the impact of generic products approved in April 2015. Sales of *ABILIFY* in Europe also declined from the same period in the previous year as generic products were launched in more countries. In Asia, while sales of *ABILIFY* declined in South Korea due to loss of exclusivity, sales in Asia continued to grow overall on the back of higher sales in China and other Asian markets. In Japan, sales of *ABILIFY* continued to rise based on year-on-year comparison, supported by an increase in prescriptions for orally disintegrating tablets for the indications of schizophrenia, manic episodes of bipolar disorder and major depressive disorder.

Aripiprazole intramuscular depot formulation *Abilify Maintena* (once-monthly injection), one of the drugs launched under the global alliance with H. Lundbeck A/S (“Lundbeck”) to develop five compounds*¹, registered steady sales growth in the U.S., supported by efforts to promote the drug’s efficacy for the treatment of acutely relapsed adults with schizophrenia and the merits of a ready-to-use prefilled syringe launched in March 2015 and an additional administration route using the deltoid muscle approved in July 2015. In Europe, sales of *Abilify Maintena*, which has been launched in 23 countries as of September 30, 2015, continued to show steady growth. *Abilify Maintena* was also launched in Canada in May 2014, as well as in Japan in May 2015 as *ABILIFY for extended-release injectable suspension, for intramuscular use*, adding to the growing number of markets worldwide where the drug is now available. *REXULTI* (generic name: brexpiprazole), the second drug launched under the global alliance with Lundbeck, 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.

In Japan, antiepileptic drug *E Keppra*, which is co-promoted with UCB Japan, firmly maintained its position as the top-selling brand*² in the domestic antiepileptic drug market, achieving growth in market share. This reflected the drug’s high reputation for efficacy, growth in prescriptions for pediatric patients and approval in February 2015 for the monotherapy treatment of epileptic partial-onset seizures. *Neupro Patch*, the world’s only transdermal dopamine agonist, benefited from increased uptake as a patch-based treatment for Parkinson’s disease and restless legs syndrome. The drug is also gaining growing recognition for its important ability to improve wearing-off*³ symptoms in Parkinson’s disease, supporting continued strong growth in sales.

Sales of *NUDEXTA*, developed by U.S. company Avanir Pharmaceuticals, Inc. (“Avanir”) which became part of the Otsuka Group in January 2015, continued to rise. This has been supported by efforts to reinforce the sales network in the U.S., which

lifted growth in prescriptions as the drug gained recognition as the world's first and only treatment for the neurologic disease pseudobulbar affect (PBA).

In the area of oncology, sales of anti-cancer agent *TS-1* declined in Japan compared with the same period in the previous year, due to the impact of rival products for gastric cancer. Overseas, global sales of the drug fell slightly compared with the same period in the previous year, despite sales growth in China on the back of rising prescriptions. Sales of anti-cancer agent *UFT* declined due to the impact of rival products, and sales of reduced folic acid formulation *Uzel* were steady year on year on the back of renewed efforts to promote the drug using existing data. Sales of long-acting 5-HT₃ receptor antagonist antiemetic agent *Aloxi* increased compared to the same period in the previous year, supported by the use in new clinical departments. Sales of anti-cancer agent *Abraxane* grew strongly compared with the same period in the previous year, supported by an increase in prescriptions due to its approval for the additional indication of pancreatic cancer in December 2014. *Lonsurf*, a new anti-cancer agent, was launched in Japan in May 2014. Prescriptions for the indications of unresectable advanced or recurrent colorectal cancer are rising, leading to steady growth in sales of the drug.

In the area of hematological cancer treatment, anti-cancer agent *SPRYCEL*, which is being collaborated in Japan, the U.S. and Europe with BMS*⁴, has seen growth in prescriptions worldwide due to its position as a first-line treatment for chronic myeloid leukemia. Sales of the drug increased compared with the same period in the previous year, supported by forex factors. *Busulfex*, which is the only allogeneic hematopoietic stem cell pre-transplanting regimen approved by the U.S. FDA, is now sold by the Group and its partners in more than 50 markets worldwide, and its use as a conditioning agent administered prior to bone marrow transplants in place of total-body radiation has become established as a standard drug therapy approach. Growing recognition of the drug worldwide drove sales growth compared with the same period in the previous year.

In the area of cardiovascular system, the number of markets, where *Samsca/Jinarc* (generic name: tolvaptan), a vasopressin V₂-receptor antagonist developed by Otsuka Pharmaceutical was on sale, grew to 21 markets worldwide as of September 30, 2015. The drug is gaining more acceptance among medical specialists due to the new value it brings and its new, low-volume method of use as an oral aquaretic agent, supporting a large rise in global sales compared with the same period in the previous year. In Japan, *Samsca* was approved for the additional indication of autosomal dominant polycystic kidney disease (ADPKD) in March 2014, becoming the world's first drug therapy for this intractable kidney disease. Prescriptions for the drug are growing firmly. As a treatment for ADPKD, the drug was also launched in Canada in May 2015 and was approved in Europe in the same month under the brand name *Jinarc*. Sales of antiplatelet agent *Pletaal/Pletal* declined compared with the same period in the previous year due to the impact of promotion of generics in hospitals in Japan.

In the area of digestive system, *TAKECAB*[®], co-promoted with Takeda Pharmaceutical Company Limited, has seen steady growth in prescriptions due to an increase in the number of hospitals that have adopted the drug since its launch in February 2015. 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 generics in hospitals in Japan.

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

In the area of clinical nutrition, sales of the high-calorie TPN solution *ELNEOPA* increased, compared with the same period in the previous year due to firm sales reflecting active sales promotion efforts.

As a result, net sales in the pharmaceutical segment for the nine months ended September 30, 2015 totaled ¥753,854 million (down 8.0% from the same period in the previous year), with operating income of ¥148,351 million (down 10.2%).

*1: *Abilify Maintena*, *REXULTI*, Lu AE58054 and two new compounds currently being researched and developed by Lundbeck.

*2: ©2015 IMS Health. Estimated based on "Japan Pharmaceutical Market, September 2015." All rights reserved, no reproduction without permission.

*3: 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.

*4: Bristol-Myers Squibb Company

2) Nutraceuticals

In the *Pocari Sweat* electrolyte supplement drink range, sales volume in Japan increased compared with the same period in the previous year, despite a weak domestic market for sports drinks*⁵. Enhanced links between advertising and in-store sales promotions and efforts to promote the product's benefits among young consumers with a strong interest in exercise spurred greater demand from users. Overseas, where *Pocari Sweat* is sold in 19 markets worldwide, we continued efforts to cultivate consumers and promote the product's benefits. In China, sales volume rose compared with the same period in the previous year, reflecting successful promotion strategies and sales promotion activities using the characteristics of each retail channel. However, total overseas sales volume declined compared with the same period in the previous year, reflecting a decline in sales volume in Indonesia compared with the same period in the previous year due mainly to the impact of rival products.

Total brand sales volume for carbonated nutritional drink *Oronamin C* declined slightly compared with the same period in the previous year, despite steady growth in the number of stores that stock *Oronamin C Royalpolis*, which was relaunched in March 2015. *Oronamin C* was launched in Hong Kong in May 2015. *Oronamin C* is now sold in nine markets worldwide.

Sales volume for balanced nutrition food *Calorie Mate* increased compared with the same period in the previous year. This reflected ongoing efforts to increase consumer understanding about the product to further raise awareness of the *Calorie Mate* concept, and we have been securing new users since the launch of the plain flavor in September 2014. We also stepped up communication with students preparing for entrance exams and office workers.

The Otsuka Group operates its soy-related business in 11 markets worldwide, based on the concept of "Soylution," which sees soy as a solution to various health and environmental issues faced by consumers today. In Japan, the Group relaunched *SOYJOY*

Raisin, *SOYJOY Apple* and *SOYJOY Hawthorn Berry* with a more fruity texture in September 2015, which followed the relaunch of *SOYJOY Strawberry* and *SOYJOY Blueberry* in March 2015. This supported steady growth in the number of stores stocking the *SOYJOY* range.

The Group launched women's health food product *EQUELLE* in April 2014 as a readily available daily source of equol. Since then, the Group has been running sales promotions and providing information with a focus on the relationship between equol and the physical and emotional changes experienced by women during menopause. This has led to greater understanding about the product among consumers, supporting steady sales.

Subsidiary Pharmavite LLC of the U.S. supplies the *Nature Made* supplements, which is recommended by pharmacists and has been the number one retail national vitamin and supplement brand in the U.S. for eight consecutive years since 2007^{*6}. Sales of *Nature Made* supplements rose in the U.S. compared with the same period in the previous year in conjunction with an upswing in the U.S. market^{*7}. Also, Pharmavite acquired FoodState Inc. in the U.S. in December 2014. Sales of the company's natural food-based supplements, *MegaFood* and *INNATE* were also firm.

In September 2015, Otsuka Pharmaceutical relaunched three items under the *Nature Made* brand, *Lutein*, *Astaxanthin* and *Fish Oil Pearl*, and *Omugi Gohan* and *Omugi Gohan Japanese-style* under the *OMUGI SEIKATSU* brand as Foods with Nutrient Function Claims.

At Nutrition & Santé SAS, an Otsuka Group subsidiary that operates in more than 40 countries, mainly in Europe, gluten-free food products sold under the *Gerblé* nutrition and health food brand continued to drive growth, while sales of organic food products and soy products also grew steadily.

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 of the product continued to grow at a double-digit pace, supported by highly targeted advertising, providing information and sampling, driving growth in the user base. In April 2015, *Kenja-no-shokutaku Double Support* was launched in Hong Kong, the product's first overseas market.

In the cosmetics area, where the focus is on the concept of "healthy skin," new products in the *UL•OS* men's skincare brand, *UL•OS Adult Body Sheet* and *UL•OS Adult Facial Sheet*, registered steady growth in domestic sales after launching in March 2015. Also, *UL•OS Medicated Skin Whitening*, a new pen-type skin treatment that inhibits dark spots and freckles, was launched in August 2015. The number of stores that stock the product is growing steadily. In Korea, sales of the brand increased compared with the same period in the previous year, supported by steady efforts to develop the brand, leading to growth in the number of stores that stock the *UL•OS* range and increased brand exposure. Sales of the *InnerSignal* brand aimed at women who seek healthy and beautiful skin increased compared with the same period in the previous year as a result of steady progress in building a loyal base of customers to acquire new customers and boost repeat business.

Sales volume for nutrient tonic *Tiovita* declined compared with the same period in the previous year, due mainly to the shrinking market for nutrient tonics and the impact of rival products.

Sales volume for oral rehydration solution *OS-1* increased compared with the same period in the previous year due to greater awareness of the product. This reflected focused activities targeting medical personnel and healthcare professionals with the aim of getting them to recommend the drug to patients, the provision of various guidelines, support activities for the Hidden Dehydration Committee and active sales promotion efforts such as television commercials and sampling.

Sales of *Oronine H Ointment* increased year on year in Japan and in Hong Kong. In Japan, this was supported by efforts to promote the benefits of a new laminated tube product launched in August 2015 and in Hong Kong the increase was due to promotion activities on the back of a reinforced marketing structure.

As a result, net sales in the nutraceutical segment for the nine months ended September 30, 2015 totaled ¥246,738 million (up 14.3% from the same period in the previous year), with operating income of ¥24,696 million (up 58.7%).

*5: Inryo Soken data: Down 4% in sales in January–September 2015

*6: Pharmavite calculation based in part on data reported by Nielsen through its Scantrack[®] service for the Dietary Supplements category in dollar and unit sales, for the 52-week periods ending 12/29/2007 and 12/28/2008 in US Food Drug Mass channels; and for the 52-week periods ending 12/26/2009, 12/25/2010, 12/24/2011, 1/5/2013, 1/4/2014, and 1/3/2015 in US xAOC channels. ©2015 The Nielsen Company.

*7: Nielsen xAOC through 09/12/15 Up 4.3% for the last 4 periods

3) Consumer Products

Sales volume for *Match*, a carbonated electrolyte drink containing vitamins, declined compared with the same period in the previous year. Nevertheless, we are working to reenergize the brand in the market by continuing to implement an aggressive marketing strategy and sales promotion activities mainly targeting the high school student market. Although sales volume for mineral water products, centered on *Crystal Geyser*, declined compared with the same period in the previous year, we have reinforced our communication efforts targeting growth in new customers. In the *Bon Curry* range of instant curry dishes, sales volume increased compared with the same period in the previous year due to a stepped up marketing strategy and sales promotion activities that boosted brand value. This included the launch of new products, such as the upgraded *Bon Curry Gold* from 2013, which can be heated in a microwave oven without removing the curry pouch from the box, special winter and summer products for a limited period only, and *The Bon Curry* – the highest-quality product in the range so far.

In the consumer products segment, the Group is continuing its efforts to quickly improve profitability by reviewing marketing strategies and sales promotion activities and improve the expense-to-sales ratio.

As a result, net sales in the consumer products segment for the nine months ended September 30, 2015 totaled ¥33,448 million (down 0.8% from the same period in the previous year), with operating loss of ¥2,619 million (compared with an operating loss of ¥441 million for the same period in the previous year).

4) Others

In the specialty chemical business, sales of *TERPLUS*, pigment dispersing agents used in color filters and inkjets, increased compared with the same period in the previous year due to increases in the number of new users and sales to existing users. However, sales volume of hydrazine hydrate and sales volume of tire additives *BMH* and *PHZ* both declined. As a result, sales overall in the specialty chemical business were steady compared with the same period in the previous year.

In the fine chemical business, sales increased compared with the same period in the previous year due to higher unit sales prices for pharmaceutical intermediates overseas and forex factors.

In the transportation and warehousing business, the volume of products handled increased, driven by increase in external customers in line with the promotion of a “common distribution platform (distribution of products to market for the Group as well as for other firms)” business. As a result, sales increased compared with the same period in the previous year.

As a result, net sales in the other businesses for the nine months ended September 30, 2015 totaled ¥107,509 million (up 7.8% from the same period in the previous year), with operating income of ¥5,056 million (down 9.3%).

<Research and Development Activities>

Research and development expenses for the nine months ended September 30, 2015 totaled ¥141,852 million.

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

(Pharmaceuticals)

1) Therapeutic drugs

The Otsuka Group conducts research and development with a primary focus on addressing unmet medical needs in 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 activities carried out during the nine months ended September 30, 2015 in the area of therapeutic drugs are summarized below.

Category	Brand Name, (Generic Name), Development Code	Status
Central nervous system	<i>ABILIFY</i> for extended-release injectable suspension, for intramuscular use (aripiprazole)	<Japan> Approval was granted in March 2015 for the indication of schizophrenia.
	<i>E Keppra</i> (levetiracetam)	<Japan> A partial change approval was granted in February 2015 for effects and efficacy of monotherapy treatment of epileptic for partial-onset seizures. An application was filed in March 2015 for the treatment of epileptic for generalized onset seizures.
	(nalmefene) Lu AA36143	<Japan> Phase III trial was initiated in February 2015 for the reduction of alcohol consumption in patients with alcohol dependence.
	(dextromethorphan, quinidine) AVP-923	A development drug secured through the acquisition of Avanir in January 2015. The drug's development status is as follows: <U.S.> Currently in Phase II trial for the treatment of dyskinesia associated with Parkinson's disease.
	(deuterium-modified dextromethorphan, quinidine) AVP-786	A development drug secured through the acquisition of Avanir in January 2015. The drug's development status is as follows: <U.S.> Currently in Phase II trial for the treatment of major depressive disorder. Phase II trial for the treatment of residual symptoms of schizophrenia was initiated in September 2015. <U.S. and Europe> Phase III trial for the treatment of agitation associated with Alzheimer-type dementia was initiated in August 2015.
	(sumatriptan) AVP-825	A development drug secured through the acquisition of Avanir in January 2015. The drug's development status is as follows: <U.S.> New Drug Application (NDA) filing for approval of an indication of acute migraine currently being reviewed.
	Lu AF20513	<Europe> Phase I trial for the treatment of Alzheimer-type dementia was initiated in April 2015.

Category	Brand Name, (Generic Name), Development Code	Status
	<i>REXULTI</i> (brexpiprazole)	<U.S.> Approval was granted in July 2015 for the indications of schizophrenia and adjunctive therapy in major depressive disorder. Development for the treatment of attention deficit hyperactivity disorder (ADHD) in adults was halted following a review of the entire brexpiprazole development program.
Oncology	<i>Lonsurf</i> TAS-102	<U.S.> Approval was granted in September 2015 for the indications of colorectal cancer. <Europe> An application was filed in February 2015 for the indications of colorectal cancer. A license agreement was concluded with Servier in June 2015 for the development and commercialization of TAS-102 in Europe and other countries (excluding North America and Asia). <Japan> A partial change approval was granted in March 2015 for effects and efficacy of colorectal cancer.
	ASTX660	<U.S.> Phase I trials for the treatment of solid cancer and lymphoma were initiated.
	(guadecitabine) SGI-110	<U.S. and Europe> Phase III trial for the treatment of acute myeloid leukemia (AML) was initiated in March 2015. <Japan> Phase I trial for the treatment of AML was initiated in January 2015.
	TAS-117	<Japan> Phase I trial for the treatment of solid cancer was initiated in February 2015.
	TAS-118	<Japan and Asia> Phase III trial for the treatment of gastric cancer was initiated in January 2015.
	<i>Yondelis</i> (trabectedin) ET-743	<Japan> Approval was granted in September 2015 for the indications of malignant soft tissue sarcoma.
	<i>SPRYCEL</i> (dasatinib)	<U.S. and Europe> Development was halted as efficacy for the treatment of pancreatic cancer could not be confirmed in Phase II trial.
	OPB-31121	<Japan, U.S. and Asia> Development was halted as Phase I trial for the treatment of cancer could not provide sufficient data to justify progression to Phase II trial.

Category	Brand Name, (Generic Name), Development Code	Status
	OPB-51602	<Japan, U.S. and Asia> Development was halted as Phase I trial for the treatment of cancer could not provide sufficient data to justify progression to Phase II trial.
Cardiovascular system	<i>Samsca/Jinarc</i> (tolvaptan)	<Europe> A positive opinion for the maintenance treatment of autosomal dominant polycystic kidney disease (ADPKD) by the European Medicines Agency (EMA) was received in February 2015 and approval was granted by the European Commission (EC) in May 2015.
Other categories	<i>Zosyn</i> (tazobactam, piperacillin)	<Japan> Approval was granted in June 2015 for an additional indication of febrile neutropenia.
	<i>OLANEDINE</i> (olanexidin) OPB-2045G	<Japan> Approval was granted in July 2015 as antiseptics for external use.
	OPS-2071	<Japan and Asia> Phase II trials for the treatment of clostridium difficile infection and enteric infection were initiated in August 2015.
	(carteolol, latanoprost) OPC-1085EL	(Additional information) <Japan> An application was filed in October 2015 for the indications of glaucoma and ocular hypertension.

2) Diagnostic

The *Otsuka Major BCR-ABL mRNA Measurement Kit*, which is used as a marker to monitor treatment effectiveness for chronic myeloid leukemia, was launched in Japan in November 2014 and covered by Health Insurance in Japan in April 2015. C13-URA had been under development as a diagnostic agent to identify abnormal gastric emptying, but development was halted due to a lack of evidence showing its effectiveness as a diagnostic agent.

Research and development expenses for the pharmaceutical business for the nine months ended September 30, 2015 were ¥134,914 million.

(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 products and beverages that support the maintenance and improvement of day-to-day well-being.

In the cosmetics business, in March 2015, the Group relaunched *UL•OS Refresh Sheet* (medicated cosmetic) and launched two refreshing sheets designed specifically for the face and body, *UL•OS Adult Body Sheet* and *UL•OS Adult Facial Sheet*. Also, in August 2015, the Group launched *UL•OS Medicated Skin Whitening*, a new pen-type skin treatment that inhibits dark spots. As a result, the *UL•OS* range now has 17 products in nine different categories.

Research and development expenses for the nutraceutical business for the nine months ended September 30, 2015 were ¥3,778 million.

(Consumer products)

In the consumer products business, the Group is engaged in the research and development of original and unique products in the food and beverage field.

Research and development expenses for the consumer products business for the nine months ended September 30, 2015 were ¥331 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, 2015 were ¥2,827 million.

(2) Qualitative Information on Consolidated Financial Position

<Analysis of Financial Position>

1) Assets

Total assets as of September 30, 2015 were ¥2,550,356 million, an increase of ¥372,171 million compared to ¥2,178,184 million at the end of the previous fiscal year. This was due to a ¥62,280 million decrease in current assets, a ¥434,464 million increase in non-current assets and a ¥12 million decrease in deferred assets.

(Current Assets)

Total current assets as of September 30, 2015 were ¥1,183,321 million, a decrease of ¥62,280 million compared to ¥1,245,602 million at the end of the previous fiscal year. This decrease was mainly due to decreases in cash and deposits by ¥17,487 million, notes and accounts receivable-trade by ¥80,653 million, and other current assets by ¥37,684 million, while marketable securities increased by ¥68,722 million and inventory by ¥4,850 million.

(Non-current Assets)

Total non-current assets as of September 30, 2015 were ¥1,366,986 million, an increase of ¥434,464 million compared to ¥932,522 million at the end of the previous fiscal year. This increase was mainly due to increases in intangible assets due to the full consolidation of Avanir Pharmaceuticals, Inc. by ¥437,696 million and net defined benefit asset by ¥7,466 million, and a decrease in investment securities by ¥14,631 million.

2) Liabilities

(Current Liabilities)

Total current liabilities as of September 30, 2015 were ¥437,933 million, an increase of ¥906 million compared to ¥437,026 million at the end of the previous fiscal year. This was mainly due to increases in reserves for bonuses by ¥12,001 million and other current liabilities by ¥52,787 million, while notes and accounts payable-trade decreased by ¥48,024 million and short-term loans payable by ¥15,188 million.

(Non-current Liabilities)

Total non-current liabilities as of September 30, 2015 were ¥412,847 million, an increase of ¥330,289 million compared to ¥82,557 million at the end of the previous fiscal year. This increase mainly resulted from increases in long-term loans payable related to the acquisition of Avanir Pharmaceuticals, Inc. by ¥246,695 million and increases in other non-current liabilities by ¥85,973 million.

3) Net Assets

Total net assets as of September 30, 2015 were ¥1,699,575 million, an increase of ¥40,975 million compared to ¥1,658,600 million at the end of the previous fiscal year. This was mainly due to payment of ¥48,764 million in dividends, a ¥53,909 million increase in total shareholders' equity as a result of quarterly net income of ¥103,130 million, and a ¥13,160 million decrease of accumulated other comprehensive income, which was due to an increase of ¥5,858 million in valuation differences on available-for-sale securities and a decrease of ¥16,237 million in foreign currency translation adjustments.

(3) Qualitative Information on Consolidated Financial Results Forecast

The full-year consolidated financial results forecast for FY2015 announced on August 7, 2015 has been amended based upon the actual results for the nine months ended September 30, 2015 and taking into account projected sales of *ABILIFY* in the U.S. and selling, general and administrative expenses for the fourth quarter of FY2015.

Amendments to the consolidated financial results forecast for FY2015 (January 1, 2015 to December 31, 2015)

	Net Sales	Operating income	Ordinary income	Net income	Basic earnings per share
	Million yen	Million yen	Million yen	Million yen	Yen
Previous forecast (A)	1,380,000	120,000	125,000	80,000	147.65
Revised forecast (B)	1,410,000	145,000	150,000	90,000	166.11
Amount of change (B-A)	30,000	25,000	25,000	10,000	18.46
Change (%)	2.2	20.8	20.0	12.5	12.5
(Reference) Consolidated results of FY2014*	1,224,298	196,528	217,210	143,143	264.20

*FY2014 represents nine months.

Projected foreign exchange rate is as follows:

	USD	EUR
Previous forecast	120.00 yen	134.00 yen
Revised forecast	121.00 yen	135.00 yen
Foreign exchange rate for the nine months of FY2015	120.98 yen	134.74 yen

2. Other Information

(1) Changes in significant subsidiaries during the period

None

Note: While not directly relating to changes in significant subsidiary, Avanir Pharmaceuticals, Inc. was newly included in the scope of consolidation due to the acquisition of its shares in the first quarter of FY2015.

(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

None

3. Quarterly Consolidated Financial Statements
(1) Consolidated Balance Sheets

	(Millions of yen)	
	As of December 31, 2014	As of September 30, 2015
ASSETS		
Current assets		
Cash and deposits	523,135	505,647
Notes and accounts receivable-trade	406,431	325,777
Marketable securities	48,535	117,258
Merchandise and finished goods	80,011	82,031
Work-in process	31,783	35,883
Raw materials and supplies	41,915	40,647
Other current assets	114,330	76,645
Allowance for doubtful receivables	(541)	(569)
Total current assets	1,245,602	1,183,321
Non-current assets		
Property, plant and equipment	344,784	351,210
Intangible assets		
Goodwill	93,162	238,036
Other intangible assets	128,010	420,832
Total intangible assets	221,173	658,869
Investments and other assets		
Investment securities	270,804	256,173
Investments in capital	42,538	44,532
Net defined benefit asset	17,486	24,952
Other assets	36,574	32,035
Allowance for investment loss	(78)	(77)
Allowance for doubtful receivables	(759)	(709)
Total investments and other assets	366,565	356,906
Total non-current assets	932,522	1,366,986
Deferred assets	59	47
Total assets	2,178,184	2,550,356
LIABILITIES		
Current liabilities		
Notes and accounts payable-trade	130,784	82,759
Short-term loans payable	70,178	54,989
Income taxes payable	14,498	14,352
Reserve for bonuses	8,563	20,564
Provisions	613	89
Other current liabilities	212,389	265,177
Total current liabilities	437,026	437,933
Non-current liabilities		
Long-term loans payable	22,251	268,947
Other allowances	2,787	2,423
Net defined benefit liability	10,921	10,754
Negative goodwill	19,691	17,843
Other non-current liabilities	26,904	112,878
Total non-current liabilities	82,557	412,847
Total liabilities	519,584	850,780

Consolidated Balance Sheets—Continued

	(Millions of yen)	
	As of December 31, 2014	As of September 30, 2015
NET ASSETS		
Shareholders' equity		
Common stock	81,690	81,690
Capital surplus	512,747	512,702
Retained earnings	990,906	1,044,707
Treasury stock	(47,415)	(47,262)
Total shareholders' equity	1,537,928	1,591,837
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	13,152	19,010
Deferred gains on hedges	392	168
Foreign currency translation adjustments	57,161	40,923
Remeasurements of defined benefit plans	19,167	16,610
Total accumulated other comprehensive income	89,873	76,713
Minority interests	30,798	31,024
Total net assets	1,658,600	1,699,575
Total liabilities and net assets	2,178,184	2,550,356

(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)
Net sales	1,107,150
Cost of sales	334,416
Gross profit	<u>772,734</u>
Selling, general and administrative expenses	
Promotion expenses	160,506
Salaries and bonuses	95,903
Reserve for bonuses	13,318
Retirement benefit expenses	2,392
Amortization of goodwill	10,525
Research and development expenses	141,852
Other	201,175
Total selling, general and administrative expenses	<u>625,674</u>
Operating income	<u>147,059</u>
Non-operating income	
Interest income	1,214
Dividend income	1,060
Amortization of negative goodwill	2,078
Equity in earnings of unconsolidated subsidiaries and affiliated companies	8,073
Other	1,945
Total non-operating income	<u>14,373</u>
Non-operating expenses	
Interest expenses	2,928
Foreign exchange loss, net	2,490
Other	758
Total non-operating expenses	<u>6,177</u>
Ordinary income	<u>155,255</u>
Extraordinary income	
Gain on sales of non-current assets	705
Subsidy income	381
Gain on insurance adjustment	261
Other	141
Total extraordinary income	<u>1,488</u>
Extraordinary loss	
Loss on retirement of non-current assets	214
Impairment loss	171
Loss on valuation of investment securities	421
Loss on sales of shares of subsidiaries and associates	565
Other	249
Total extraordinary loss	<u>1,621</u>
Income before income taxes and minority interests	<u>155,123</u>
Income taxes	
Current	27,027
Deferred	24,099
Total income taxes	<u>51,127</u>
Income before minority interests	<u>103,996</u>
Minority interests in net income	865
Net income	<u>103,130</u>

Consolidated Statements of Comprehensive Income

	(Millions of yen)
	FY2015
	(From January 1, 2015 to September 30, 2015)
Income before minority interests	103,996
Other comprehensive income	
Valuation difference on available-for-sale securities	5,864
Deferred losses on hedges	(224)
Foreign currency translation adjustment	(13,479)
Remeasurements of defined benefit plans	(2,752)
Share of other comprehensive income of entities accounted for using equity method	(4,645)
Total other comprehensive income	(15,236)
Total comprehensive income	88,759
Total comprehensive income attributable to:	
Owners of parent	89,700
Minority interests	(941)

(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

	Pharmaceuticals	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

(Millions of yen)

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.