

Consolidated Financial Results

FY2016 Q3

(Nine Months Ended September 30, 2016)

November 11, 2016
Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results (FY2016 Q3)**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
- 4 Sales of Global Products & New Drugs in Japan**
- 5 Nutraceutical Segment Analysis**
- 6 FY2016 Forecast Amended**
- 7 Impact of IFRS Adoption**

1. Consolidated Financial Results (FY2016 Q3)

J-GAAP



(100 million yen)	FY2015 Jan – Sep	FY2016 Jan – Sep	Change
Net Sales	11,072	9,028	▲ 2,044
(Sales of ABILIFY)	2,911	763	▲ 2,148
(Sales of Global Products & New Drugs in Japan*)	1,240	1,918	+678
Operating Income	1,471	1,136	▲ 335
Ordinary Income	1,553	1,161	▲ 391
Net income attributable to owners of parent	1,031	906	▲ 125
R&D Expenses	1,419	1,052	▲ 367

【 Foreign Exchange Impact 】 (100 million yen)

		Average rate	FY2015	FY2016
Net Sales	approx. ▲485	1USD	¥120.98	¥108.56
Operating Income	approx. ▲40	1EUR	¥134.74	¥121.05

* Three global products (Abilify Maintena, Samsca /JINARC, REXULTI), LONSURF & New drugs in Japan (Products newly launched in Japan after 2009)

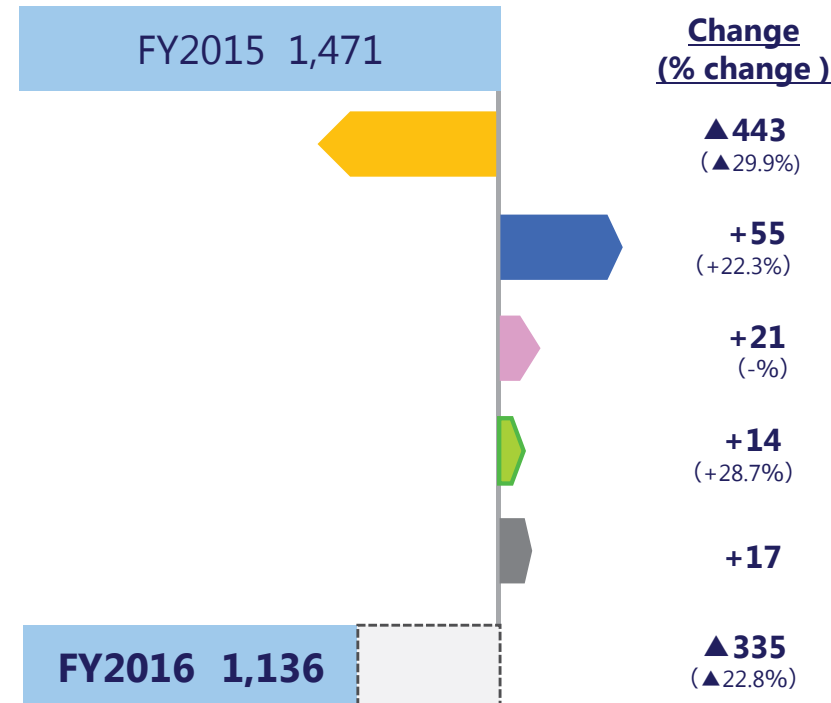
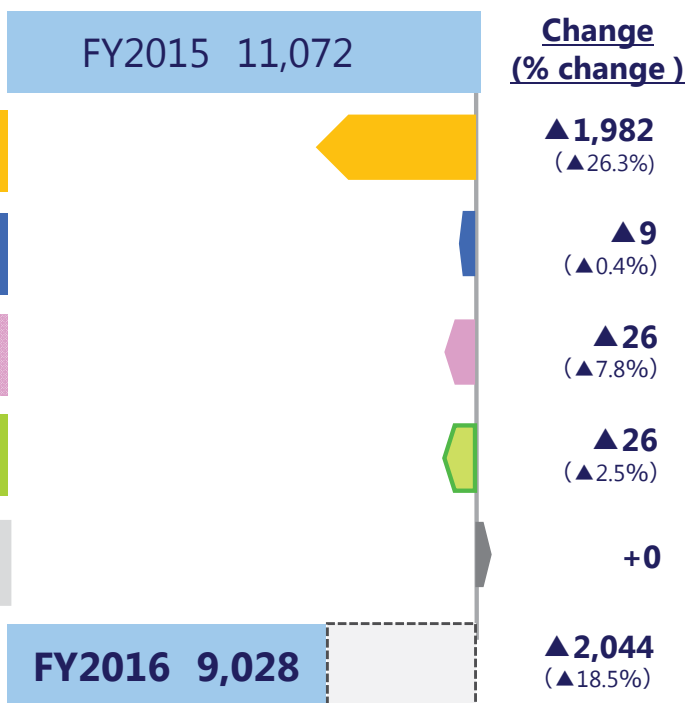
2. Business Segment Analysis



(100 million yen)

Net Sales

Segment (Operating) Income

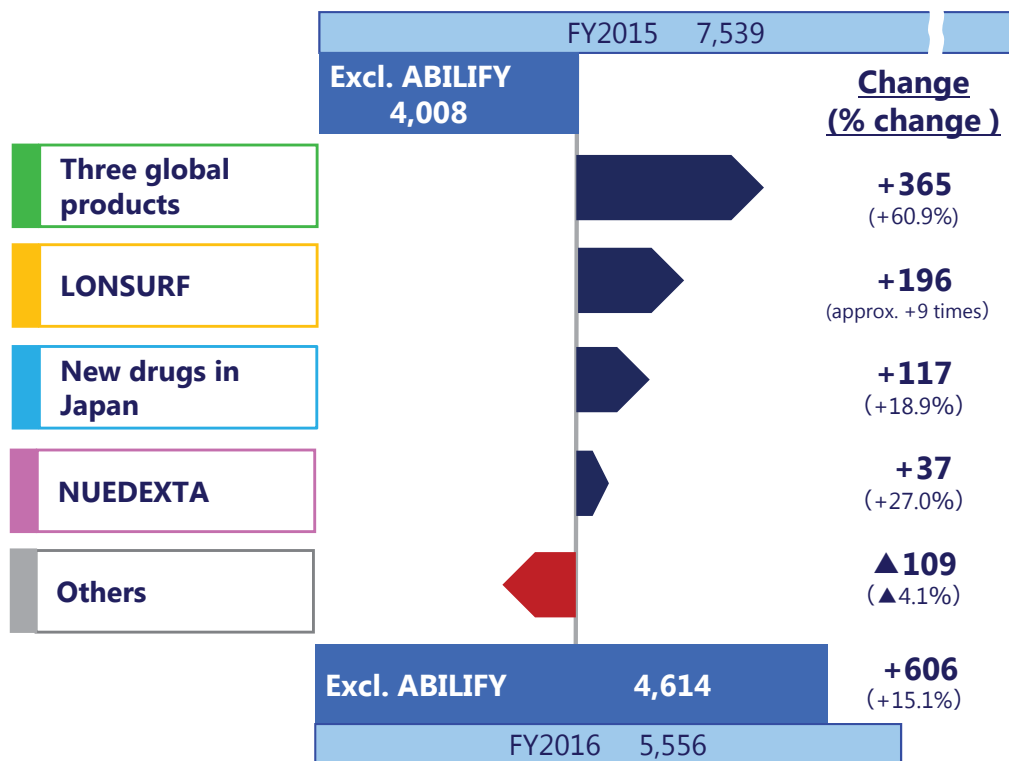


	Net Sales		Operating Income		Operating Margin (%)	
	FY2015	FY2016	FY2015	FY2016	FY2015	FY2016
Pharmaceuticals	7,539	5,556	1,484	1,040	19.7%	18.7%
Nutraceuticals	2,467	2,459	247	302	10.0%	12.3%
Consumer Products	334	308	▲ 26	▲ 5	▲ 7.8%	▲ 1.6%
Other	1,075	1,049	51	65	4.7%	6.2%
Corporate/Eliminations	▲ 344	▲ 344	▲ 284	▲ 267	-	-
Consolidated	11,072	9,028	1,471	1,136	13.3%	12.6%

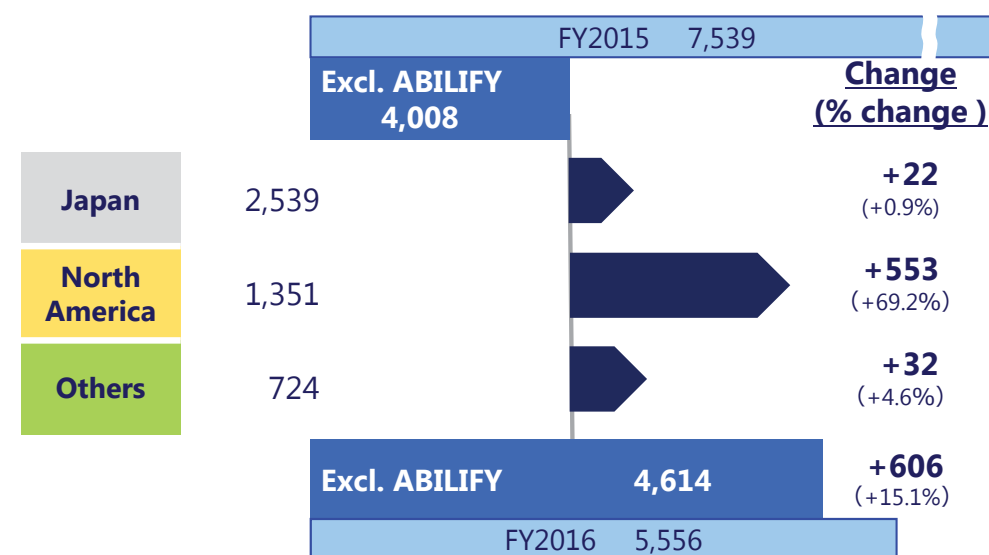
3. Pharmaceutical Segment Analysis

(100 million yen)

Net Sales

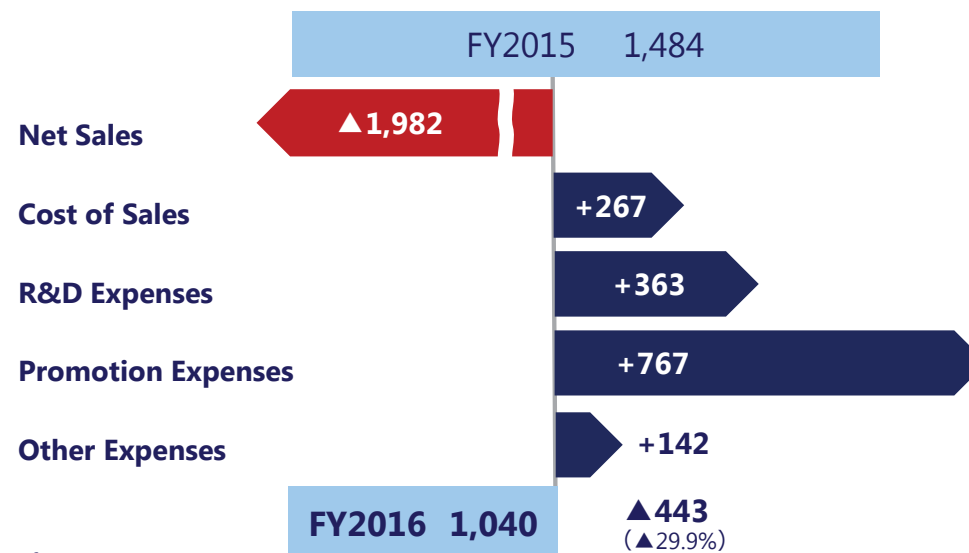


Net Sales by Market



Products	FY2015	FY2016	Change	% Change
ABILIFY	2,911	763	▲ 2,148	▲ 73.8%
Milestone/Upfront revenue	620	180	▲ 441	▲ 71.0%
Abilify Maintena	282	411	+129	+45.5%
Samsca/JINARC	294	353	+59	+20.0%
REXULTI	23	201	+178	+774.3%
LONSURF	24	220	+196	+826.6%
New drugs in Japan	616	733	+117	+18.9%
NUEDEXTA	137	174	+37	+27.0%
Others	2,631	2,522	▲ 109	▲ 4.1%
(Pletaal/Mucosta)	353	275	▲ 78	▲ 22.1%
Total excluding ABILIFY	4,008	4,614	+606	+15.1%
Pharma Total	7,539	5,556	▲ 1,982	▲ 26.3%

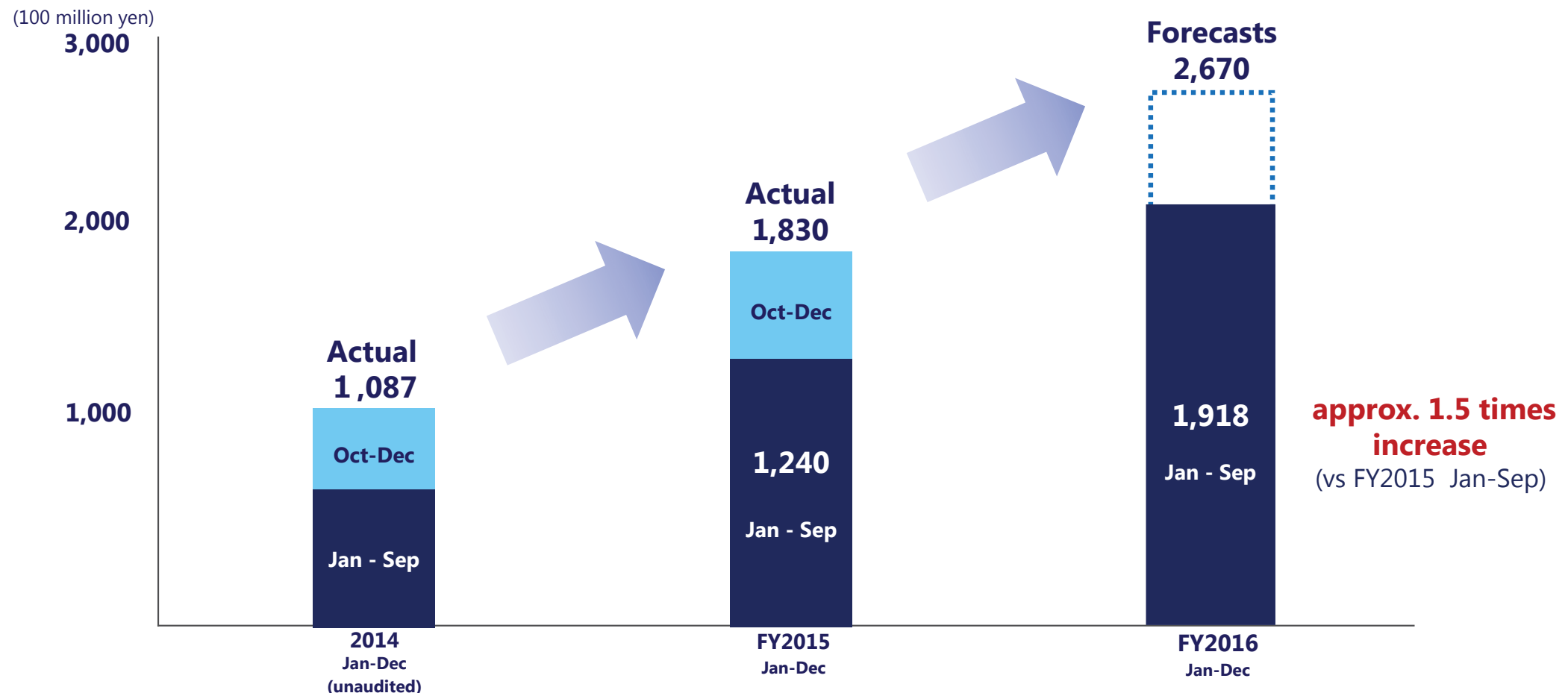
Segment (Operating) Income



"Excluding ABILIFY" in this material represents Net sales excluding ABILIFY & Milestone / Upfront revenue.

4. Sales of Global Products & New Drugs in Japan

Sales of growth drivers (" Three global products", "LONSURF" & "New drugs in Japan") steadily increased.

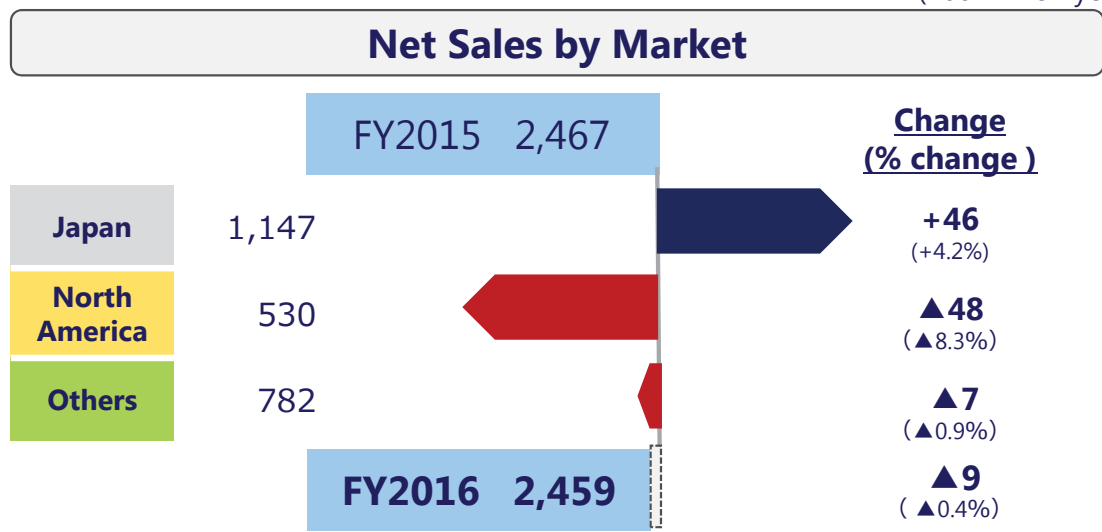
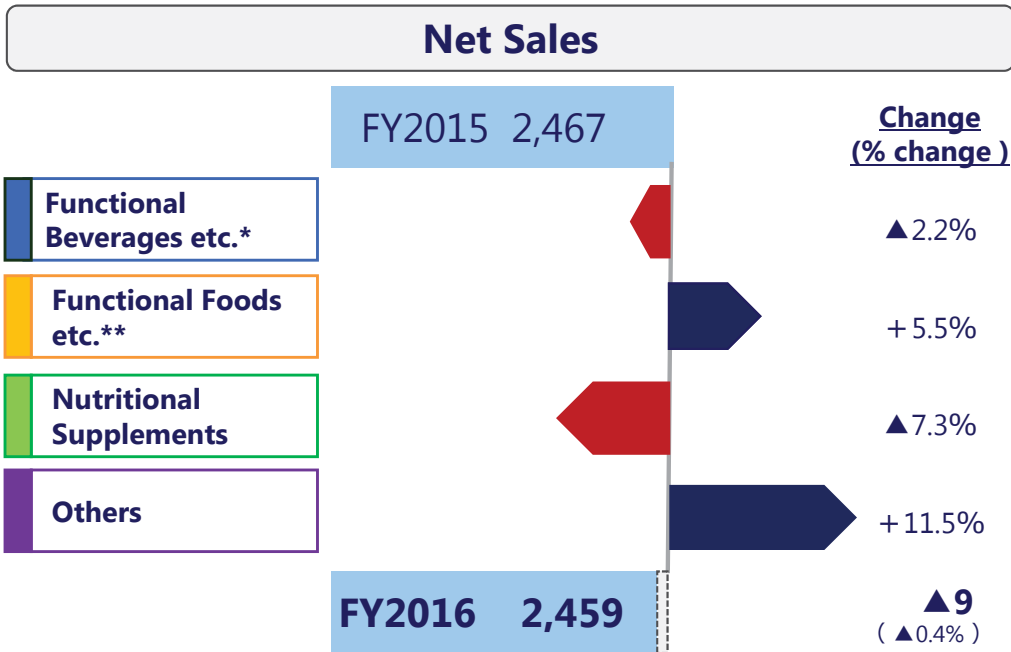


Product	FY2015 (Jan-Sep)	FY2016 (Jan-Sep)	FY2015 (Jan-Dec)	FY2016 (Jan-Dec) Forecast
New drugs in Japan	616	733	870	1,040
Next-generation products				
LONSURF	24	220	94	275
Abilify Maintena	282	411	404	575
Three global products				
Samsca/JINARC	294	353	416	490
REXULTI	23	201	46	290
Total (100 million yen)	1,240	1,918	1,830	2,670

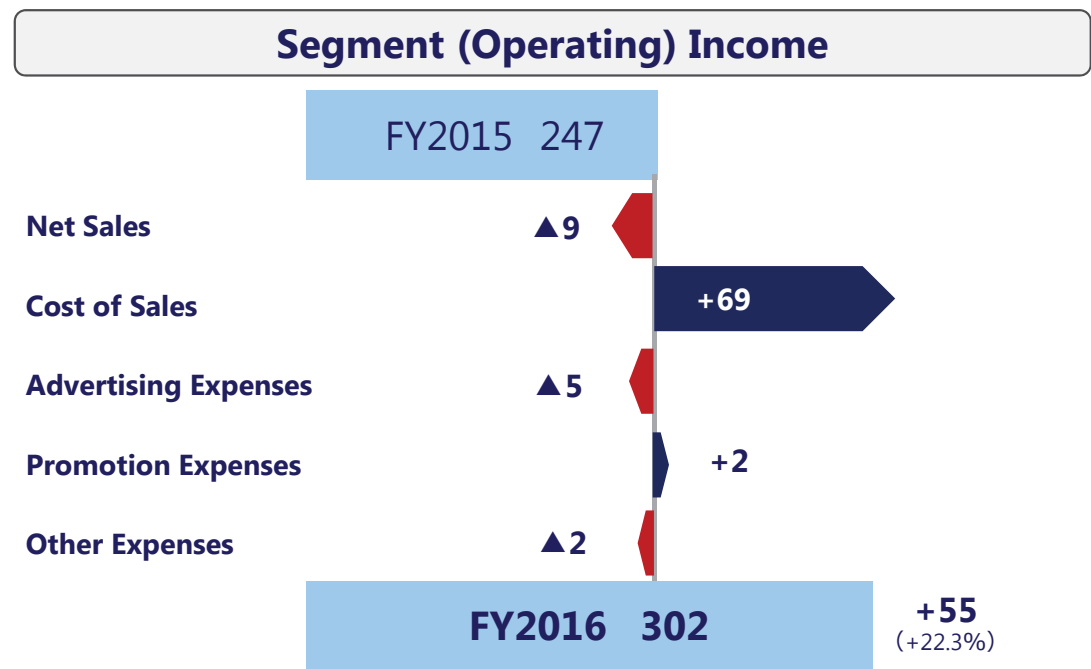
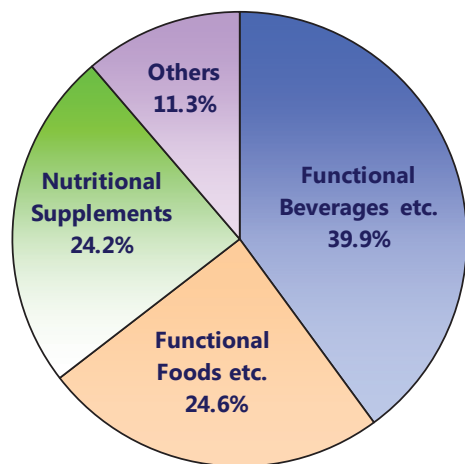
5. Nutraceutical Segment Analysis

Net Sales by Market increased on local currency basis without the impacts of foreign exchange rates.

(100 million yen)



* Pocari Sweat, Oronamin C, Tiovita, FIBE-MINI
 ** Nutrition & Sante products, Calorie Mate, SOYJOY



6. FY2016 Forecast Amended

J-GAAP

Forecasts for the full year have been revised upward based on the Nine months achievement and the progress of this year's overall plan.

(100 million yen)	Forecast as of August	Change	Forecast as of November	(Reference) IFRS Forecast
Net Sales	12,000	-	12,000	11,800
Operating Income	1,000	+150	1,150	1,150
Ordinary Income	1,000	+150	1,150	-
Net income attributable to owners of parent	750	+100	850	950
R&D Expenses	1,700	▲150	1,550	
Dividends per share	¥100.0	-	¥100.0	
Projected foreign currency exchange rate:				
1 USD	¥108.0	¥▲1.0	¥107.0	
1 EUR	¥120.0	¥▲1.0	¥119.0	

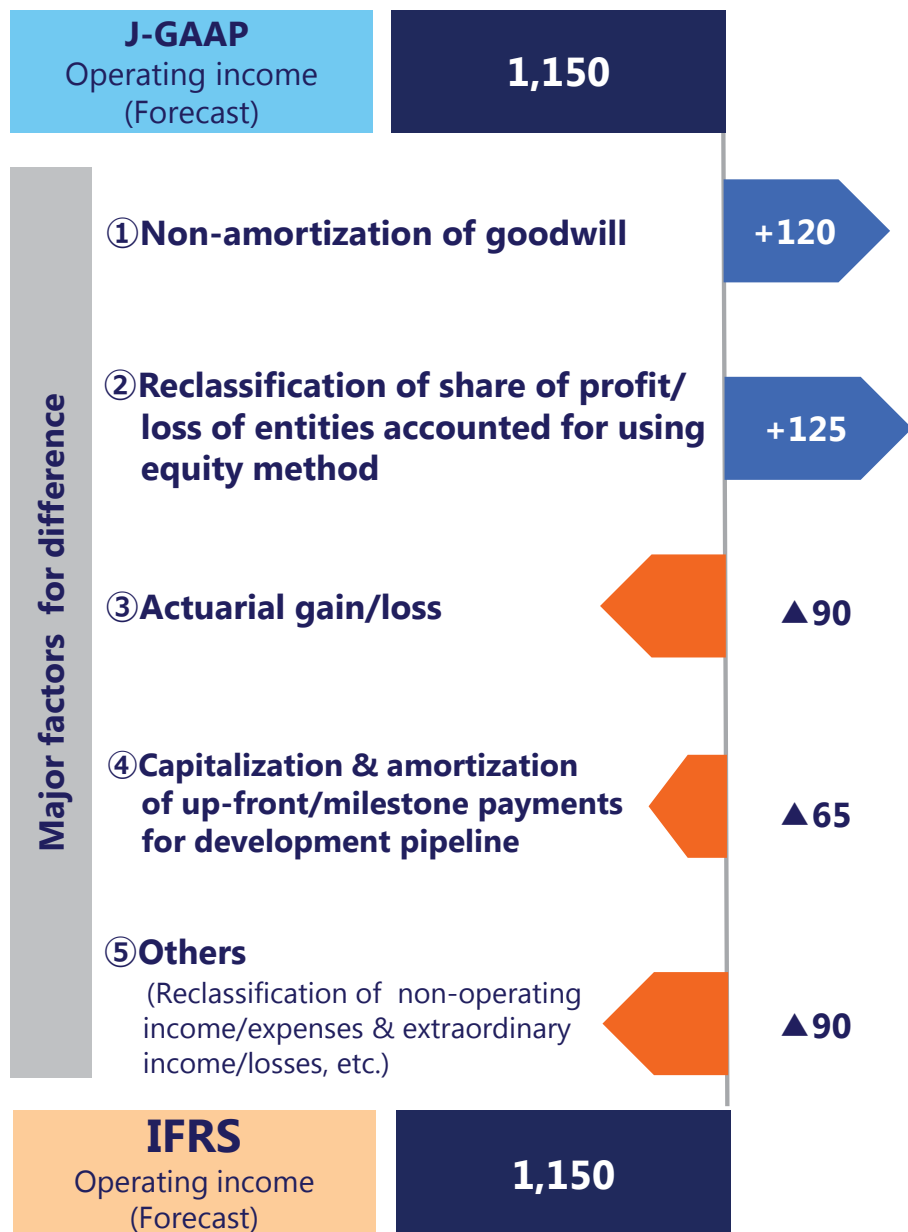
7. Impact of IFRS Adoption

FY2016 Forecast : Comparison between J-GAAP and IFRS

IFRS



(100 million yen)



Major differences between J-GAAP and IFRS that have impacts on consolidated operating income

No	J-GAAP	IFRS
①	Amortized within 20 years	Non-amortized, and impairment test required every fiscal year
②	Recognized within non-operating income	-Recognized as operating income since Otsuka considers all equity investments to be integral to Otsuka's operations. -Impact of non-amortization of goodwill is included.
③	Amortized over a fixed period (Amortized as gain in FY2016)	Recognize all amounts as other comprehensive income at once when occurred, not amortized.
④	Recognized as R&D expense when transitions occurred	-Capitalized when transactions occurred and amortized from the timing of approval by authorities. -Impairment test required in case of development discontinuation or when future cash flow to be worsen, etc.
⑤	Recognized income/loss from other than regular business as non-operating income/expenses, and for those recognized temporarily or unexpectedly as extraordinary income/losses.	-Most of non-operating income/expenses & extraordinary income/losses except finance income/expenses to be reclassified as operating income/loss. -Non-operating income/loss to be limited only to finance income/expenses.

Pharmaceutical Development Update

November 11, 2016

Otsuka Holdings Co., Ltd.

- 1 List of projects**
- 2 Key development progress in 3Q/FY2016**
 - ✓ Launch
 - ✓ Approval
 - ✓ Submission
 - ✓ Phase transition
- 3 FY2016 – Key projects scheduled for NDA submissions & P-3 (initial plan)**

1-1. Major projects under development : CNS and neurological disorders

(as of Sept. 30, 2016)



		P-1	P-2	P-3	NDA
Psychiatric disease	Schizophrenia		AVP-786 US	Brexpiprazole JP·EU	
	MDD			Brexpiprazole EU ASC-01 JP·Asia	
	Others			Aripiprazole extended release injectable Bipolar JP·US·EU Brexpiprazole PTSD US·EU Nalmefene Alcoholism JP	Aripiprazole Autism JP Approved
Neurological Disease	AD	AF20513 EU		Aripiprazole Agitation JP Brexpiprazole Agitation US·EU AE58054 US·EU AVP-786 Agitation US·EU	
	Others		AVP-923 PD US AVP-786 Disinhibition US TAS-205 DMD JP		

global project

Blue columns indicate changes since last update

1-2. Major projects under development : Oncology

(as of Sept. 30, 2016)



	P-1	P-2	P-3	NDA
Solid cancer	TAS-115 JP	SGI-110 HCC US·EU	TAS-118 Pancreatic cancer JP·Asia	
	TAS-117 JP	SGI-110 Ovarian cancer US·EU	TAS-118 Gastric cancer JP·Asia	
	TAS-119 US·EU	AT13387 NSCLC US·EU	TAS-102 Colorectal cancer Asia	
	TAS-120 JP·US·EU	TAS-116 GIST JP	TAS-102 Gastric Cancer JP·US·Asia	
	TAS-121 JP	TAS-114 NSCLC JP·US·EU		
	ET-743 JP			
	OPB-111001 EU			
	OPB-111077 US·Asia			
	OCV-C02 JP			
	ASTX660 US			
	TAS3681 US·EU			
Blood cancer		SGI-110 MDS, AML US	SGI-110 AML JP·Asia US·EU	
		ASTX727 MDS US		
		OCV-501 AML JP·Asia		
		AT7519 MM US		
Palliative & supportive care		Rebamipide (liquid) Oral mucositis JP	Nabiximols Cancer pain US	
		Pro-NETU Antiemetics JP		global project

Blue columns indicate changes since last update

1-3. Major projects under development : Others

(as of Sept. 30, 2016)



	P-1	P-2	P-3	NDA
Cardiovascular		Tolvaptan Cancerous edema JP		Tolvaptan Hepatic edema Asia
		Tolvaptan Volume overload in hemodialysis JP		Tolvaptan Cardiac edema Asia
		Tolvaptan Volume overload in peritoneal dialysis JP	Tolvaptan ADPKD US	Tolvaptan ADPKD Asia
Others		Delamaïnd Pediatric MDR-TB EU	Delamanid MDR-TB US	
		OPA-15406 Atopic dermatitis JP·US	Rebamipide ophthalmic suspension MD Dry eye JP	OPC-1085EL Glaucoma JP Approved
				TAC-202 Allergic rhinitis JP Approved
				TAC-202 Urticaria JP Approved
		OPC-2071 Infectious Disease JP·Asia	OPF-105 PPN infusions JP	OPF-108 TPN infusions JP Approved
Diagnostics		C13-CAC Diagnostic kit for gastric acid-related disease JP		

global project

Blue columns indicate changes since last update

2-1. Key Development Progress in Q3/2016 (as of Sept. 30, 2016)

<Launch>

Product name (Development code)	Country /Area	Indication	Characteristics
Lonsurf (TAS-102)	Europe	Colorectal cancer	<ul style="list-style-type: none"> Lonsurf is an oral antineoplastic drug, composed of trifluridine (FTD), a nucleoside analog and tipiracil which is an inhibitor of the FTD-degrading enzyme, thymidine (TPI)

<Approval>

Product name (Generic name)	Country /Area	Indication	Characteristics
REXULTI® (Brexipiprazole)	US	Maintenance treatment of schizophrenia	<ul style="list-style-type: none"> The efficacy of REXULTI may be mediated through a combination of dopamine D₂ receptors and serotonin 5-HT_{1A}(as a partial agonist) It binds to serotonin 5-HT_{2A} receptors(as an antagonist)
Abilify® (Aripiprazole)	Japan	Irritability associated with pediatric autism spectrum disorder	<ul style="list-style-type: none"> Dopamine partial agonist Stabilization of the dopamine system <p>Additional approval was granted for ABILFY 1mg tablet as starting dosage form.</p>

2-2. Key Development Progress in Q3/2016 (as of Sept. 30, 2016)

<Approval>

Product name (Generic name/ Development code)	Country/ Area	Indication	Characteristics
Iclusig® (Ponatinib)	Japan	Chronic myeloid leukemia Philadelphia chromosome- positive acute lymphoblastic leukemia	<ul style="list-style-type: none"> ➤ Tyrosine-kinase inhibitor developed by ARIAD Pharmaceuticals in the US ➤ Only BCR-ABL tyrosine-kinase inhibitor that is effective against the BCR-ABL T315I mutation
Mikeluna® (OPC-1085EL)	Japan	Glaucoma Ocular hypertension	<ul style="list-style-type: none"> ➤ Eye drop contains a combination of the non-selective β-blocker carteolol hydrochloride and the prostaglandin analogue latanoprost ➤ A combination of the two would ensure efficacy and improve adherence
Bilanoa® (TAC-202)	Japan	Allergic rhinitis Urticaria Itching resulting from skin diseases	<ul style="list-style-type: none"> ➤ An oral anti-allergy drug ➤ A second-generation histamine H₁ receptor antagonist
ELNEOPA-NF No. 1/No. 2 injection (OPF-108)	Japan	High calorie injection	<ul style="list-style-type: none"> ➤ The glucose, electrolyte, amino acid, multivitamin, and trace element injection for central vein infusion

2-3. Key Development Progress in Q3/2016 (as of Sept. 30, 2016)



<NDA Submission>

Product name	Country/Area	Indication	Characteristics
ZOSYN®	Japan	Complicated skin and soft tissue infections (including diabetic foot infections)	<ul style="list-style-type: none"> ➤ An injectable antibiotic combined with β-lactamase inhibitor <p>Combination of β-lactamase inhibitor tazobactam and semisynthetic antibiotic piperacillin, in a ratio of 1:8 in potency for intravenous administration</p>

<Diagnostic agent - Submission >

Product name	Country/Area	Indication
WT-1 mRNA assay kit II 'Otsuka'	Japan	Acute lymphoid leukemia
WT-1 mRNA assay kit (Real-time PCR)	Asia	Myelodysplastic syndromes

2-4. Key Development Progress in Q3/2016 (as of Sept. 30, 2016)

<P-2 transition>

Development code	Country/Area	Indication	Characteristics
TAS-114	Japan US Europe	Non-small-cell lung cancer	<ul style="list-style-type: none"> ➤ By inhibiting dUTPase, TAS-114 increases the intracellular concentration of dUTP(FdUTP) which enhances incorporation into DNA ➤ Increase in efficacy of 5-FU antineoplastic drug
Pro-NETU	Japan	Chemotherapy-induced nausea and vomiting	<ul style="list-style-type: none"> ➤ Phosphorylated prodrug which improves the water solubility of netupitant, an NK₁ receptor antagonist ➤ Pro-NETU shows the anti-emetic effect by competitively inhibiting NK₁ receptor and blocking binding of substance P
OPA-15406	Japan	Atopic dermatitis	<ul style="list-style-type: none"> ➤ A phosphodiesterase (PDE) 4 inhibitor

- The following projects were discontinued in this period.

AVP-786 (Major depressive disorder)

Reason : Lack of sufficient data to support the efficacy in P-2 trial

TS-1 (Cervical cancer)

Reason: Lack of sufficient data to support the efficacy in P-3 trial

OPA-6566 (Glaucoma)

Reason : Lack of sufficient scientific evidence in P-1/2 trial

3. FY2016 – Key projects scheduled for NDA submission & P-3 (initial plan)



Projects planned for NDA submission

Advanced to P-3 & NDA filing as scheduled

Area	Product name/ Generic name/ Development code	Country/Area	Indication
CNS/ Neurology	ASC-01	Japan	Major depressive disorder
	Abilify Maintena	US	Bipolar disorder
	Brexpiprazole	Japan	Schizophrenia
Oncology	TAS-102	Asia	Colorectal cancer

Projects scheduled to advance to P-3

Area	Development Code	Country/Area	Indication
CNS/ Neurology	AVP-786	Japan	Agitation associated with Alzheimer's dementia
Oncology	SGI-110	US	Relapsed or refractory myelodysplastic syndrome
	TAS-102	Japan/US/ Europe	Gastric Cancer