

Financial Highlights

(Billions of yen)

<J-GAAP>		FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Estimate FY2016 (Jan-Dec) (Forecast as of Nov 2016)	
									<J-GAAP>	<IFRS> (reference)*
Net sales	(Billions of yen)	1,154.6	1,218.1	1,452.8	1,224.3	1,445.2	1,107.2	902.8	1,200.0	1,180.0
	YoY	2.4%	5.5%	19.3%	7.9%	-8.1%		-18.5%		
Operating income	(Billions of yen)	148.7	169.7	198.7	196.5	151.8	147.1	113.6	115.0	115.0
	YoY	17.7%	14.1%	17.1%	7.4%	-29.0%		-22.8%		
Ordinary income	(Billions of yen)	152.1	184.5	215.2	217.2	159.9	155.3	116.1	115.0	
	YoY	18.5%	21.3%	16.7%	8.9%	-32.2%		-25.2%		
Net income	(Billions of yen)	92.2	122.4	151.0	143.1	84.1	103.1	90.6	85.0	95.0
	YoY	11.9%	32.8%	23.3%	2.7%	-45.8%		-12.2%		
R&D expenses	(Billions of yen)	159.2	192.4	249.0	172.9	201.0	141.9	105.2	155.0	
	YoY	-3.3%	20.8%	29.4%	4.6%	-19.5%		-25.9%		
Overseas net sales	(Billions of yen)	579.7	622.7	824.4	757.0	805.8	635.9	428.0	558.0	
	% of net sales	50.2%	51.1%	56.8%	61.8%	55.8%		47.4%	46.5%	

*Otsuka Holdings Co., Ltd. will voluntarily adopt the International Financial Reporting Standards (IFRS) for consolidated financial statements, in place of the Japanese Generally Accepted Accounting Principles (J-GAAP) previously adopted as of the fiscal year ending December 31, 2016 ("FY2016"). Non-operating income/expenses and extraordinary income/losses are included in operating income except for finance items which are recorded as finance income/expenses under IFRS.

(Yen)

Exchange rate (Yen)	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Estimate FY2016 (Jan-Dec) (Forecast as of Nov 2016)
US\$	79.79	79.80	97.72	106.72	121.10	120.98	108.56	107.00
Euro	111.12	102.55	129.77	140.20	134.30	134.74	121.05	119.00

(Billions of yen)

Selling, general and administrative expenses <J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Estimate FY2016 (Jan-Dec) (Forecast as of Nov 2016)
Selling, general and administrative expenses	616.6	654.6	812.4	681.5	844.1	625.7	494.6	685.0
(% of net sales)	53.4%	53.7%	55.9%	55.7%	58.4%	56.5%	54.8%	57.1%
Promotion expenses	174.4	156.2	192.0	188.0	195.6	160.5	82.7	
Personnel expenses	99.8	103.7	124.0	97.9	152.5	112.0	109.0	
Advertising expenses	25.1	29.5	34.2	26.0	33.3	25.1	31.0	
R&D expenses	159.2	192.4	249.0	172.9	201.0	141.9	105.2	155.0
(% of net sales)	13.8%	15.8%	17.1%	14.1%	13.9%	12.8%	11.6%	12.9%
R&D expenses of pharmaceutical business	149.3	183.5	240.8	166.1	191.4	134.9	98.6	145.0

(Billions of yen)

Capital expenditures <J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Estimate FY2016 (Jan-Dec) (Forecast as of Nov 2016)
Capital expenditures	43.3	63.3	179.0	88.2	523.9	502.0	39.8	55.0

(Billions of yen)

Depreciation <J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Estimate FY2016 (Jan-Dec) (Forecast as of Nov 2016)
Depreciation	48.1	45.5	49.8	45.5	71.4	53.2	52.1	70.0

Consolidated Statements of Income

<J-GAAP>	(Billions of yen)														
	FY2011	%	FY2012	%	FY2013	%	FY2014 (Apr-Dec)	%	FY2015	%	3Q FY2015 (Jan-Sep)	%	3Q FY2016 (Jan-Sep)	%	Change
Net sales	1,154.6	100.0%	1,218.1	100.0%	1,452.8	100.0%	1,224.3	100.0%	1,445.2	100.0%	1,107.2	100.0%	902.8	100.0%	-18.5%
Cost of sales	389.3	33.7%	393.8	32.3%	441.6	30.4%	346.3	28.3%	449.3	31.1%	334.4	30.2%	294.6	32.6%	-11.9%
Gross profit	765.3	66.3%	824.2	67.7%	1,011.1	69.6%	878.0	71.7%	996.0	68.9%	772.7	69.8%	608.2	67.4%	-21.3%
Selling, general and administrative expenses	616.6	53.4%	654.6	53.7%	812.4	55.9%	681.5	55.7%	844.1	58.4%	625.7	56.5%	494.6	54.8%	-21.0%
Promotion expenses	174.4		156.2		192.0		188.0		195.6		160.5		82.7		
Salaries and bonuses	81.3		85.4		107.1		89.9		138.2		95.9		92.3		
Reserve for bonuses	9.8		9.5		11.2		5.3		10.2		13.3		12.9		
Retirement benefit expenses	7.7		7.8		4.6		1.7		3.5		2.4		3.4		
Provision for directors' and audit & supervisory board members' retirement benefits	0.7		0.6		0.5		0.3		0.4		-		-		
Provision for directors' bonuses	0.4		0.3		0.6		0.6		0.3		-		-		
Depreciation	14.7		14.5		16.9		22.9		31.8		-		-		
Amortization of goodwill	4.7		4.8		3.7		3.8		14.0		10.5		8.9		
Research and development expenses	159.2	13.8%	192.4	15.8%	249.0	17.1%	172.9	14.1%	201.0	13.9%	141.9	12.8%	105.2	11.6%	-25.9%
Other	163.8		183.0		226.7		196.0		249.3		201.2		189.3		
Operating income	148.7	12.9%	169.7	13.9%	198.7	13.7%	196.5	16.1%	151.8	10.5%	147.1	13.3%	113.6	12.6%	-22.8%
Non-operating income	8.6		16.6		18.8		23.1		16.4		14.4		18.6		
Interest income	1.6		1.4		1.3		1.3		1.7		1.2		1.4		
Dividend income	1.3		1.5		1.3		1.0		1.6		1.1		1.1		
Amortization of negative goodwill	2.5		2.5		2.6		1.8		2.7		2.1		1.8		
Equity in earnings of unconsolidated subsidiaries and affiliates	1.2		3.1		3.2		3.9		8.0		8.1		11.2		
Foreign exchange gain, net	-		6.2		7.9		12.9		-		-		-		
Other	2.1		2.0		2.5		2.3		2.4		1.9		3.0		
Non-operating expenses	5.2		1.8		2.3		2.4		8.3		6.2		16.0		
Interest expenses	1.7		1.2		1.2		1.7		4.1		2.9		2.6		
Foreign exchange loss, net	2.7		-		-		-		3.0		2.5		12.7		
Other	0.7		0.6		1.1		0.8		1.2		0.8		0.7		
Ordinary income	152.1	13.2%	184.5	15.1%	215.2	14.8%	217.2	17.7%	159.9	11.1%	155.3	14.0%	116.1	12.9%	-25.2%
Extraordinary income	1.2		0.3		2.0		1.4		5.0		1.5		17.4		
Gain on sales of fixed assets	0.2		0.1		0.5		0.1		0.9		0.7		0.4		
Gain on change in equity interest	0.3		-		-		-		0.5		-		-		
Gain on sales of investment securities	-		-		0.3		0.0		2.8		-		16.9		
Gain on sales of shares of subsidiaries	-		-		0.3		-		-		-		-		
Subsidy income	-		-		0.9		0.9		0.4		0.4		0.1		
Gain on insurance adjustment	-		-		-		-		-		0.3		-		
Other	0.6		0.1		0.0		0.4		0.3		0.1		0.1		
Extraordinary loss	10.9		7.8		7.0		8.4		26.7		1.6		8.4		
Loss on retirement of fixed assets	0.6		0.7		0.9		0.6		1.2		0.2		-		
Impairment loss	2.7		2.6		3.4		5.4		18.8		0.2		7.0		
Loss on valuation of investment securities	3.7		4.4		0.2		1.5		0.9		0.4		0.9		
Loss on valuation of investments in capital	-		-		-		-		2.5		-		-		
Extra retirement payments	-		-		1.9		0.6		-		-		-		
Loss on transfer of business	0.7		-		-		-		-		-		-		
Provision for loss on business liquidation	2.2		-		-		-		-		-		-		
disaster related loss	0.3		-		-		-		-		-		-		
Loss on sales of subsidiaries' stocks	-		-		-		-		-		0.6		-		
Other	0.8		0.1		0.6		0.4		3.3		0.2		0.5		
Income before income taxes and minority interests	142.4		176.9		210.2		210.3		138.2		155.1		125.1		
Income taxes-current	55.0		62.0		81.3		46.2		37.8		27.0		31.5		
Income taxes-deferred	-5.4		-8.2		-23.6		19.8		18.7		24.1		1.9		
Total income taxes	49.6		53.8		57.7		66.1		56.4		51.1		33.5		-34.5%
Minority interests in net income	0.6		0.7		1.6		1.1		-2.4		0.9		1.1		
Net income	92.2	8.0%	122.4	10.1%	151.0	10.4%	143.1	11.7%	84.1	5.8%	103.1	9.3%	90.6	10.0%	-12.2%

Sales to Customers by Market

(Billions of yen)

Net sales by business segment <J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Consolidated sales	1,154.6	1,218.1	1,452.8	1,224.3	1,445.2	1,107.2	902.8	-18.5%
Pharmaceutical business	782.2	850.9	1,035.1	883.5	971.8	753.9	555.6	-26.3%
Japan	326.5	351.8	372.9	273.7	386.1	277.6	280.7	1.1%
North America	361.1	389.0	530.5	481.6	368.0	296.5	163.4	-44.9%
Others	94.7	110.0	131.7	128.3	217.7	179.7	111.5	-37.9%
Nutraceutical business	251.3	246.9	281.1	232.7	321.6	240.4	238.0	-1.0%
Japan	147.4	142.3	147.5	109.8	141.0	110.1	114.7	4.2%
North America	45.8	49.8	59.8	55.8	86.0	57.8	53.0	-8.3%
Others	58.1	54.8	73.9	67.1	94.6	72.5	70.3	-3.0%
Consumer products business	48.0	45.2	43.8	34.4	42.9	33.2	30.6	-7.9%
Japan	42.0	39.2	36.6	27.9	32.7	25.3	23.7	-6.3%
North America	5.4	5.4	6.9	6.1	9.7	7.5	6.5	-12.9%
Others	0.6	0.6	0.3	0.3	0.5	0.4	0.4	-15.4%
Other business	73.1	75.0	92.8	73.7	109.0	79.7	78.6	-1.4%
Japan	59.1	62.0	71.4	55.9	79.7	58.3	55.8	-4.3%
North America	1.3	1.4	2.3	1.8	1.9	1.4	2.2	56.8%
Others	12.7	11.6	19.0	16.0	27.4	20.0	20.6	3.0%
Japan -total	574.9	595.3	628.3	467.3	639.5	471.2	474.8	0.8%
North America - total	413.5	445.7	599.6	545.3	465.6	363.2	225.1	-38.0%
Others - total	166.2	177.1	224.9	211.7	340.2	272.7	202.8	-25.6%
Overseas net sales	579.7	622.7	824.4	757.0	805.8	635.9	428.0	-32.7%
Overseas net sales ratio	50.2%	51.1%	56.8%	61.8%	55.8%	57.4%	47.4%	

Net Sales and Operating Income by Geographical and Business Segment

(1) Geographical segment

(Billions of yen)

<J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Net sales	1,154.6	1,218.1	1,452.8	1,224.3	1,445.2	1,107.2	902.8	-18.5%
Japan*	779.1	842.5	982.1	738.2	835.5	629.4	587.8	-6.6%
North America*	437.5	474.1	652.1	601.9	542.1	419.7	260.7	-37.9%
Others*	142.4	138.2	204.4	189.6	259.1	196.8	175.7	-10.7%
Eliminations/corporate	-204.4	-236.7	-385.9	-305.4	-191.5	-138.7	-121.4	

*Intersegment sales are included.

(Billions of yen)

<J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Operating income	148.7	169.7	198.7	196.5	151.8	147.1	113.6	-22.8%
Japan	142.5	160.8	217.5	156.2	98.8	88.5	101.9	15.2%
North America	14.4	16.2	-5.0	12.8	-11.2	2.1	6.7	222.5%
Others	3.7	6.4	1.9	16.8	27.4	26.2	16.1	-38.6%
Eliminations/corporate	-12.0	-13.8	-15.7	10.7	36.8	30.3	-11.1	

(2) Business segment

(Billions of yen)

<J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Net sales	1,154.6	1,218.1	1,452.8	1,224.3	1,445.2	1,107.2	902.8	-18.5%
Pharmaceutical business*	782.2	850.9	1,035.1	883.5	971.8	753.9	555.6	-26.3%
Nutraceutical business*	254.8	251.8	287.1	238.2	330.2	246.7	245.9	-0.4%
Consumer products busines	49.2	46.9	43.9	34.5	43.2	33.4	30.8	-7.8%
Other business*	108.6	111.7	130.3	102.2	145.2	107.5	104.9	-2.5%
Eliminations/corporate	-40.3	-43.1	-43.7	-34.2	-45.2	-34.4	-34.4	

*Intersegment sales are included.

(Billions of yen)

<J-GAAP>	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Operating income	148.7	169.7	198.7	196.5	151.8	147.1	113.6	-22.8%
Pharmaceutical business	168.5	187.9	212.8	204.8	156.8	148.4	104.0	-29.9%
Nutraceutical business	22.1	21.4	25.4	21.9	31.3	24.7	30.2	22.3%
Consumer products busines	-2.3	-2.4	-2.2	-1.4	-3.3	-2.6	-0.5	-
Other business	1.9	3.9	7.2	5.5	5.9	5.1	6.5	28.7%
Eliminations/corporate	-41.6	-41.0	-44.5	-34.3	-38.8	-28.4	-26.7	

[Pharmaceutical business]

(Billions of yen)

Product name	Company	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change	Estimate FY2016 (Jan-Dec) <small>Forecast as of Nov 2016</small>
Antipsychotic agent ABILIFY	Otsuka Pharmaceutical	411.6	438.5	575.7	507.4	347.5	291.1	76.3	-73.8%	95.0
North America		316.1	336.1	455.5	416.5	242.1	210.5	23.3	-88.9%	27.0
<US\$ million>		<3,960>	<4,208>	<4,659>	<3,900>	<1,999>	<1,740>	<215>	-87.6%	<250>
Japan		24.8	28.6	34.4	23.7	35.6	25.9	23.4	-9.7%	32.5
Others		70.7	73.9	85.8	67.2	69.7	54.7	29.5	-46.0%	35.5
Antipsychotic agent/ Depot injection Abilify Maintena	Otsuka Pharmaceutical	-	-	4.3	14.4	40.4	28.2	41.1	45.5%	57.5
US		-	-	4.3	13.0	29.9	21.6	26.7	23.8%	37.0
Japan		-	-	-	1.3	0.7	0.7	2.9	338.3%	4.5
Others		-	-	-	1.4	9.2	6.0	11.5	90.8%	16.0
Antipsychotic agent REXULTI	Otsuka Pharmaceutical	-	-	-	-	4.6	2.3	20.1	774.3%	29.0
Agent for pseudobulbar affect (PBA) NUDEXTA	Otsuka Pharmaceutical	-	-	-	-	19.2	13.7	17.4	27.0%	23.0
Anti-platelet agent Pietaal/Pietal	Otsuka Pharmaceutical	50.3	45.8	44.2	26.2	31.4	23.4	18.0	-23.3%	24.5
Japan		44.1	40.1	36.8	20.7	23.3	17.3	12.4	-28.1%	17.0
Others		6.2	5.7	7.4	5.5	8.2	6.1	5.5	-9.6%	7.5
Anti-gastritis and anti-gastric ulcer agent Mucosta	Otsuka Pharmaceutical	28.7	23.0	22.0	12.9	15.8	11.9	9.6	-19.8%	12.0
Japan		26.0	20.5	18.8	10.1	11.4	8.5	6.3	-25.9%	8.0
Others		2.7	2.5	3.1	2.7	4.4	3.4	3.3	-4.8%	4.0
Anti-metabolite TS-1	Taiho Pharmaceutical	36.5	37.0	37.4	24.0	29.3	21.9	19.7	-10.0%	26.0
Anti-metabolite UFT	Taiho Pharmaceutical	12.9	11.2	9.5	6.3	7.5	5.5	4.9	-11.8%	6.5
Reduced folic acid formulation Uzel	Taiho Pharmaceutical	12.7	13.2	11.9	7.9	10.5	7.7	7.3	-5.8%	10.0
Antineoplastic LONSURF	Taiho Pharmaceutical	-	-	-	2.3	9.4	2.4	22.0	826.6%	27.5
5-HT ₃ receptor antagonist Aloxi	Taiho Pharmaceutical	7.9	10.0	11.0	8.8	12.9	9.3	10.2	9.9%	14.0
Antineoplastic Abraxane	Taiho Pharmaceutical	3.2	3.7	8.8	8.2	20.6	14.6	15.1	3.6%	20.0
Antiepileptic E Keppra	Otsuka Pharmaceutical	4.8	10.5	15.8	13.2	23.3	16.4	20.2	23.1%	28.0
V ₂ -vasopressin receptor antagonist Samsca/JINARC	Otsuka Pharmaceutical	6.7	12.8	21.0	20.8	41.6	29.4	35.3	20.0%	49.0
Japan		1.0	4.2	10.0	12.4	25.7	17.7	22.0	23.9%	29.5
US		4.9	7.5	9.3	6.0	11.8	8.8	8.9	1.7%	12.5
Others (including JINARC)		0.7	1.0	1.7	2.4	4.1	2.9	4.4	51.1%	7.0
Agent for dry eye Mucosta ophthalmic suspension	Otsuka Pharmaceutical	0.1	1.0	2.9	2.8	4.5	3.2	3.5	9.6%	5.0
Parkinsons' disease, RLS* treatment Neupro Patch	Otsuka Pharmaceutical	-	0.2	2.6	4.7	8.3	5.8	7.6	31.6%	11.0
Anticancer Sprycel (collaboration with BMS)	Otsuka Pharmaceutical	7.6	12.0	26.1	22.9	31.2	23.9	20.8	-12.7%	28.5
Antibiotic Zosyn/Tazocin (bulk supply)	Taiho Pharmaceutical	10.7	12.4	14.5	11.8	13.4	9.0	5.9	-34.9%	8.0
Diagnostics -total	Otsuka Pharmaceutical	7.9	8.8	12.6	8.5	12.2	8.6	9.6	11.5%	13.0
Parenteral nutrition (clinical nutrition) -total	Otsuka Pharmaceutical Factory	96.0	96.4	103.4	81.5	104.8	76.5	77.3	1.0%	105.0
Japan		88.6	88.8	91.6	68.2	88.2	64.1	62.9	-1.9%	86.0
Others		7.4	7.6	11.8	13.3	16.6	12.5	14.4	15.8%	19.0
Pharmaceutical business -total (excluding exports)	Japan	326.5	351.8	372.9	273.7	386.1	277.6	280.7	1.1%	385.0
Pharmaceutical business -total	Total	782.2	850.9	1,035.1	883.5	971.8	753.9	555.6	-26.3%	740.0
Milestone and upfront revenue		14.9	41.5	22.0	20.4	66.0	64.5	18.0	-72.1%	18.0

*RLS: Restless legs syndrome

【Nutraceutical business】

(10 thousand cases)

Product name	Company	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Pocari Sweat 1 case: 24 bottles, and other (10 thousand cases)	Otsuka Pharmaceutical								
Japan		2,912	2,709	2,860	2,006	2,625	2,182	2,333	6.9%
Overseas		1,963	2,151	2,684	2,256	2,608	2,028	1,932	-4.7%
SOYJOY 1 case: 48 bars (10 thousand cases)	Otsuka Pharmaceutical								
Japan		100	88	109	107	126	93	105	12.8%
Overseas		20	12	16	12	20	15	15	-0.2%
Oronamin C 1 case: 50 bottles (10 thousand cases)	Otsuka Pharmaceutical	1,081	1,067	1,105	830	1,025	788	762	-3.2%
Calorie Mate 1 case: 4 bars×30, and other (10 thousand cases)	Otsuka Pharmaceutical	351	335	340	280	381	281	304	8.4%
Tiovita Drink 1 case: 50 bottles (10 thousand cases)	Taiho Pharmaceutical	532	489	402	290	345	256	262	2.3%
Solmack (10 thousand of bottles)	Taiho Pharmaceutical	1,579	1,588	1,479	1,174	1,501	963	992	3.0%

* Overseas sales include sales of consolidated subsidiaries only.

【Consumer business】

(10 thousand cases)

Product name	Company	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Bottled Water 1 case: 24 bottles (10 thousand cases)	Otsuka Foods	679	567	580	396	504	387	382	-1.2%
Match 1 case: 24 bottles (10 thousand cases)	Otsuka Foods	451	521	514	447	527	428	447	4.7%
Other (tea drinks and other) 1 case: 24 bottles (10 thousand cases)	Otsuka Foods	317	300	265	177	232	162	167	3.0%

【Other business】

(Billions of yen)

Product name	Company	FY2011	FY2012	FY2013	FY2014 (Apr-Dec)	FY2015	3Q FY2015 (Jan-Sep)	3Q FY2016 (Jan-Sep)	Change
Functional chemicals	Otsuka Chemical	27.9	26.6	33.5	26.6	34.4	25.7	25.6	-0.4%
Fine chemicals	Otsuka Chemical	9.3	10.2	10.1	7.3	10.6	7.7	7.3	-5.6%

Otsuka Group Pipeline Information

(as of Sep 30, 2016)

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status
OPC-14597 <ABILIFY*> <Abilify Maintena*>: Depot injection	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Autism / Oral	JP	Approved
				Agitation associated with dementia of the Alzheimer's type / Oral	JP	Phase III
				Bipolar I / Depot injection	JP, US, EU	Phase III
OPC-34712 <REXULTI*>	brexpiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Major depressive disorder / Oral	EU	Phase III
				Schizophrenia / Oral	JP, EU	Phase III
				Agitation associated with dementia of the Alzheimer's type / Oral	US, EU	Phase III
				Posttraumatic stress disorder / Oral	US, EU	Phase III
Lu AE58054	idalopirdine	Lundbeck	Selective 5-HT ₆ receptor antagonist	Alzheimer's disease / Oral	US, EU	Phase III
ASC-01	aripiprazole, sertraline	Otsuka Pharmaceutical	Dopamine partial agonist / Selective serotonin reuptake inhibitor	Major depressive disorder / Oral	JP, Asia	Phase III
AVP-923	dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Sigma-1 receptor agonist	Dyskinesia associated with Parkinson's disease / Oral	US	Phase II
AVP-786	deuterium-modified dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Serotonin and norepinephrine reuptake inhibitor / Sigma-1 receptor agonist	Agitation associated with dementia of the Alzheimer's type / Oral	US, EU	Phase III
				Residual schizophrenia symptoms / Oral	US	Phase II
				Disinhibition syndrome in neurodegenerative disorders / Oral	US	Phase II
TAS-205		Taiho Pharmaceutical	PGD synthase inhibitor	Duchenne muscular dystrophy / Oral	JP	Phase II
Lu AA36143	nalmefene	Lundbeck	Opioid receptor antagonist	Lowering alcohol consumption of alcohol dependence / Oral	JP	Phase III
Lu AF20513		Lundbeck	β -amyloid vaccine	Preventing progression of Alzheimer's demetia / Injection	EU	Phase I

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.
*: Product names used outside Japan.

Otsuka Group Pipeline Information

(as of Sep 30, 2016)

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status
TAS-102 <LONSURF*>	trifluridine, tipiracil	Taiho Pharmaceutical	Anti-cancer	Colorectal cancer / Oral	Asia	Phase III
				Gastric cancer / Oral	JP, US, EU	Phase III
TAS-118	tegafur, gimeracil, oteracil, folinate	Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Pancreatic cancer / Oral	JP, Asia	Phase III
				Gastric cancer / Oral	JP, Asia	Phase III
Pro-NETU	fosnetupitant	Helsinn Healthcare	NK ₁ receptor antagonist	Chemotherapy-induced nausea and vomiting (CINV) / Injection	JP	Phase II
<clusig*>	ponatinib	Ariad Pharmaceuticals	Anti-cancer (Molecular-targeted drug)	Chronic myeloid leukemia / Oral	JP	Approved
<SATIVEX*>	nabiximols	GW Pharmaceuticals	Cannabinoid (THC, CBD)	Cancer pain / Oral spray	US	Phase III
SGI-110	guadecitabine	Astex	Anti-cancer	Ovarian cancer / Injection	US, EU	Phase II
				Hepatocellular carcinoma / Injection	US, EU	Phase II
				Acute myeloid leukemia, Myelodysplastic syndrome / Injection	US	Phase II
				Acute myeloid leukemia / Injection	US, EU JP, Asia	Phase III
AT13387		Astex	Anti-cancer (Molecular-targeted drug)	NSCLC / Injection	US, EU	Phase II
AT7519		Astex	Anti-cancer (Molecular-targeted drug)	Multiple myeloma / Injection	US	Phase II
ASTX727		Astex	Anti-cancer	Myelodysplastic syndrome / Oral	US	Phase II
ASTX660		Astex	Anti-cancer (Molecular-targeted drug)	Solid tumors, Lymphomas / Oral	US	Phase I
OPB-111077		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	US, Asia	Phase I
OPB-111001		Otsuka Pharmaceutical	Anti-cancer	Solid tumors / Oral	EU	Phase I
TAS-114		Taiho Pharmaceutical	Anti-cancer (Antitumor enhancer)	Non-small cell lung cancer / Oral	JP, US, EU	Phase II
TAS-115		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP	Phase I
TAS-116		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Gastrointestinal stromal tumor / Oral	JP	Phase II
TAS-117		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP	Phase I
TAS-119		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	US, EU	Phase I
TAS-120		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP, US, EU	Phase I
TAS-121		Taiho Pharmaceutical	Anti-cancer (Molecular-targeted drug)	Solid tumors / Oral	JP	Phase I
TAS3681		Taiho Pharmaceutical	Anti-androgenic agent	Prostate cancer / Oral	US, EU	Phase I
ET-743	trabectedin	PharmaMar	Anti-cancer	Ovarian cancer / Injection	JP	Phase I
OCV-501		Otsuka Pharmaceutical	WT1 targeted cancer vaccine	Secondary prevention of elderly acute myeloid leukemia / Injection	JP, Asia	Phase II
OCV-C02		OncoTherapy Science	Therapeutic cancer vaccine	Colorectal cancer / Injection	JP	Phase I
OPC-12759	rebamipide	Otsuka Pharmaceutical	Oral mucosal protectant / mucosal healing agent	Stomatitis associated with cancer chemoradiotherapy / Solution	JP	Phase II

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.
 *: Product names used outside Japan.

Otsuka Group Pipeline Information

(as of Sep 30, 2016)

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status
Cardiovascular						
OPC-41061 <Samsca / JINARC>	tolvaptan	Otsuka Pharmaceutical	V ₂ receptor antagonist	Hepatic edema / Oral	Asia	Filed
				Autosomal dominant polycystic kidney disease / Oral	US Asia	Phase III Filed
				Cardiac edema / Oral	Asia	Filed
				Carcinomatous edema / Oral	JP	Phase II
				Volume overload in hemodialysis / Oral	JP	Phase II
Volume overload in peritoneal dialysis / Oral	JP	Phase II				
Other areas						
TAC-202 <Bilanoa>	bilastine	Faes Farma	H ₁ receptor antagonist	Allergic rhinitis / Oral	JP	Approved
				Chronic urticaria, Pruritus associated with skin disease / Oral	JP	Approved
YP-18 <ZOSYN*>	tazobactam, piperacillin	Taiho Pharmaceutical	Antibiotic agent	Complicated skin, Soft tissue infections (including diabetic foot infections) / Injection	JP	Filed
OPC-67683 <Delyba*>	delamanid	Otsuka Pharmaceutical	Anti-tuberculosis agent	Multidrug-resistant tuberculosis / Oral	US	Phase III
				Multidrug-resistant tuberculosis for pediatrics / Oral	EU	Phase II
OPC-12759E <Mucosta Ophthalmic Suspension>	rebamipide	Otsuka Pharmaceutical	Mucin-production enhancing agent	Dry eyes / Eye drops MD (Multi Dose)	JP	Phase III
OPF-105	Glucose, electrolyte, amino acid, fat and multivitamin	Otsuka Pharmaceutical Factory	Protein and amino acid preparation	Peripheral parenteral nutrition solution / Injection	JP	Phase III
OPF-108	Glucose, electrolyte, amino acid, multivitamin, and trace element	Otsuka Pharmaceutical Factory	Protein and amino acid preparation	Total parenteral nutrition / Injection	JP	Approved
OPC-1085EL <Mikeluna combination ophthalmic solution>	carteolol, latanoprost	Otsuka Pharmaceutical	β receptor antagonist / PGF2α analogue	Glaucoma / Eye Drops	JP	Approved
OPA-15406		Otsuka Pharmaceutical	PDE4 inhibitor	Atopic dermatitis / Ointment	JP, US	Phase II
OPS-2071		Otsuka Pharmaceutical	New quinolone based antibacterial agent	Clostridium difficile infection, enteric infection / Oral	JP, Asia	Phase II
Diagnostics						
C13-CAC	calcium (13C)	Otsuka Pharmaceutical	13C-calcium carbonate breath test	Measurement of gastric acidity / In-vivo diagnostic agent	JP	Phase II
ODK-1003	WT1 mRNA RT-PCR Assay Kit	Otsuka Pharmaceutical	WT1 mRNA expression in RNA extracted from leukocytes	Diagnosis for ALL / In-vitro diagnostic agent	JP	Filed
ODK-1003-CN□	WT1 mRNA RT-PCR Assay Kit	Otsuka Pharmaceutical	WT1 mRNA expression in RNA extracted from leukocytes	Diagnosis for MDS / In-vitro diagnostic agent	Asia	Filed

Note: In general, Otsuka disclose compounds that are in Phase II or later stage of development, although some compounds in Phase I are disclosed in the above table.
* Product names used outside Japan.

Otsuka Group Pipeline Information

<Changes in Pipeline information Since June 2016>

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status	Change from 2Q FY2016
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Central nervous system, neurological disorders

OPC-14597 <ABILIFY*>	aripiprazole	Otsuka Pharmaceutical	Dopamine partial agonist	Autism / Oral	JP	Approved	Approved (Sep 2016)
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Oncology

Pro-NETU	fosnetupitant	Helsinn Healthcare	NK ₁ receptor antagonist	Chemotherapy-induced nausea and vomiting (CINV) / Injection	JP	Phase II	Added
TAS-114		Taiho Pharmaceutical	Anti-cancer (Antitumor enhancer)	Non-small cell lung cancer / Oral	JP, US, EU	Phase II	Phase I → Phase II
<Iclusig*>	ponatinib	Ariad Pharmaceuticals	Anti-cancer (Molecular-targeted drug)	Chronic myeloid leukemia / Oral	JP	Approved	Added

Other areas

TAC-202 <Bilanoa>	bilastine	Faes Farma	H ₁ receptor antagonist	Allergic rhinitis / Oral	JP	Approved	Approved (Sep 2016)
				Chronic urticaria, Pruritus associated with skin disease / Oral	JP	Approved	Approved (Sep 2016)
YP-18 <ZOSYN*>	tazobactam, piperacillin	Taiho Pharmaceutical	Antibiotic agent	Complicated skin, Soft tissue infections (including diabetic foot infections) / Injection	JP	Filed	Filed (Jul 2016)
OPF-108	Glucose, electrolyte, amino acid, multivitamin, and trace element	Otsuka Pharmaceutical Factory	Protein and amino acid preparation	Total parenteral nutrition / Injection	JP	Approved	Approved (Jul 2016)
OPC-1085EL <Mikeluna combination ophthalmic solution>	carteolol, latanoprost	Otsuka Pharmaceutical	β receptor antagonist / PGF _{2α} analogue	Glaucoma / Eye Drops	JP	Approved	Approved (Sep 2016)
OPA-15406		Otsuka Pharmaceutical	PDE4 inhibitor	Atopic dermatitis / Ointment	JP	Phase II	Added
ODK-1003	WT1 mRNA RT-PCR Assay Kit	Otsuka Pharmaceutical	WT1 mRNA expression in RNA extracted from leukocytes	Diagnosis for ALL / In-vitro diagnostic agent	JP	Filed	Filed (Jul 2016)
ODK-1003-CN	WT1 mRNA RT-PCR Assay Kit	Otsuka Pharmaceutical	WT1 mRNA expression in RNA extracted from leukocytes	Diagnosis for MDS / In-vitro diagnostic agent	Asia	Filed	Filed (Aug 2016)

<Discontinuation of project development>

Code / <Brand name>	Generic name	Origin	Category	Indication / Dosage form	Country / Region	Development status
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AVP-786	deuterium-modified dextromethorphan, quinidine	Avanir	NMDA receptor antagonist / Serotonin and norepinephrine reuptake inhibitor / Sigma-1 receptor agonist	Major depressive disorder / Oral	US	Phase II Development Discontinuation
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Reason for discontinuation of project development : Development discontinuation due to effectiveness not being able to confirmed in Phase II study.

S-1 <TS-1> <Teysono*>	tegafur, gimeracil, oteracil	Taiho Pharmaceutical	Anti-cancer (Anti-metabolite)	Uterocervical cancer / Oral	JP, Asia	Phase III Development Discontinuation
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Reason for discontinuation of project development : Phase III study did not meet its primary endpoint (Overall Survival).

OPA-6566		Otsuka Pharmaceutical	A _{2a} receptor agonist	Glaucoma / Eye Drops	US	Phase I / II Development Discontinuation
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Reason for discontinuation of project development : Development discontinuation due to effectiveness not being able to confirmed in Phase I / II study.

*: Product names used outside Japan.