

# **FY2017 Q1**

# **Consolidated Financial Results**

(Three Months Ended March 31, 2017)  
【IFRS】

**May 12, 2017**  
Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results (FY2017 Q1)**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
- 4 Sales of Key Growth Drivers**
- 5 Nutraceutical Segment Analysis**
- 6 FY2017 Forecast**

# 1. Consolidated Financial Results (FY2017 Q1)

Net sales achieved the same level as previous year driven by global products & new drugs in Japan.  
Operating profit was in line with FY2017 Forecast announced in Feb 2017.

(100 million yen)	FY2016 Jan – Mar	FY2017 Jan – Mar	Change	FY2017 Forecast Jan – Jun	% Achievement
<b>Net Sales</b>	<b>2,803</b>	<b>2,802</b>	<b>▲ 1</b> Forex impacts approx.▲40	<b>6,050</b>	46.3%
(Sales of Global Products & New Drugs in Japan *1 )	595	756	+161		
(Sales of ABILIFY)	340	178	▲162		
<b>Operating Profit</b>	<b>340</b>	<b>302</b>	<b>▲ 38</b>	<b>580</b>	52.0%
(Equity income)	38	44	+5		
<b>Profit attributable to owners of the Company</b>	<b>219</b>	<b>210</b>	<b>▲ 8</b>	<b>420</b>	50.0%
<b>R&amp;D Expenses</b>	<b>364</b>	<b>367</b>	<b>+2</b>	<b>850</b>	43.1%
<b>Operating Profit+ R&amp;D Expenses</b>	<b>704</b>	<b>668</b>	<b>▲ 36</b>	<b>1,430</b>	46.7%

## Foreign Exchange Impact \*2

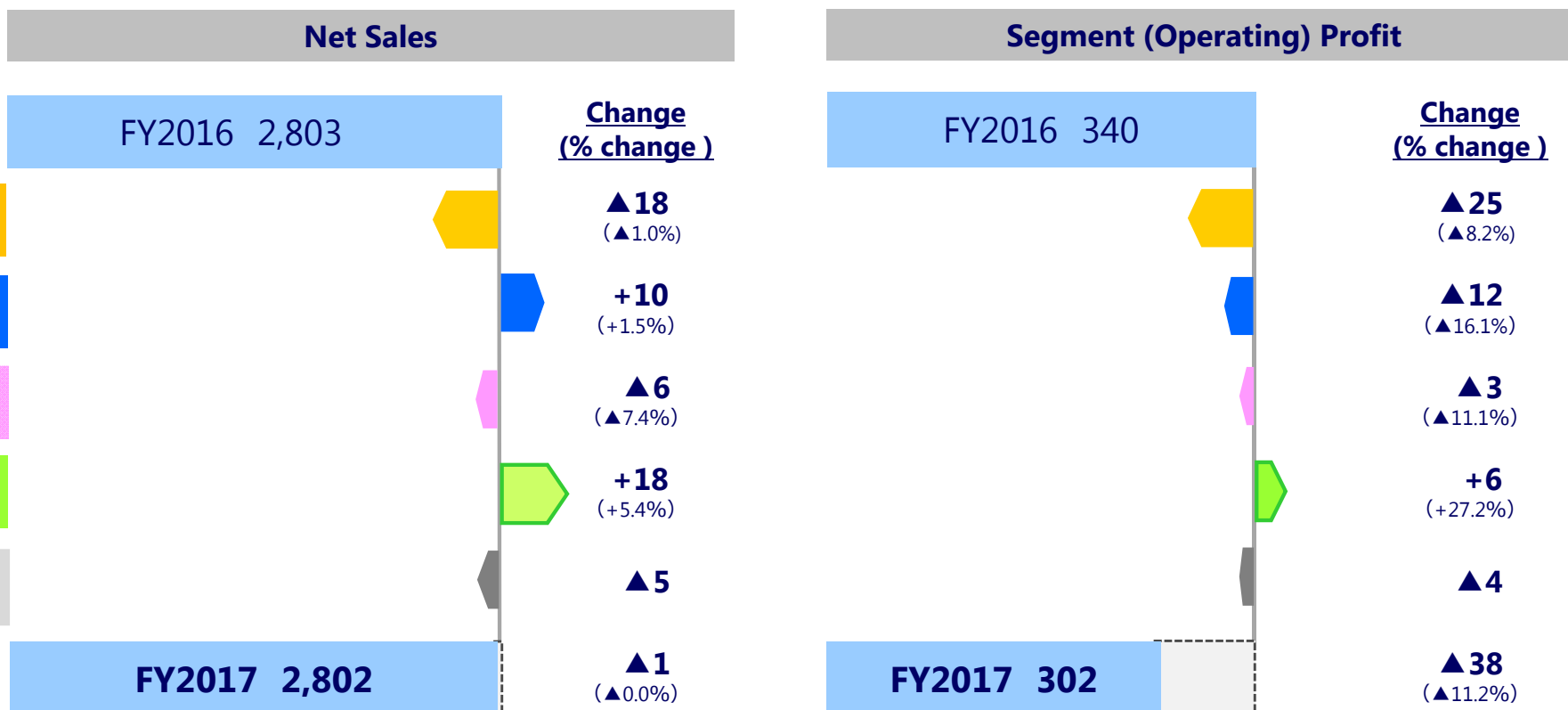
		Average Rate	FY2016	FY2017	Change
Net Sales	approx. ▲40	1USD	115.35 yen	113.60 yen	▲1.75 yen
Operating Profit	approx. ▲0	1EUR	127.14 yen	121.05 yen	▲6.09 yen

\* 1 Three global products (Abilify Maintena, Samsca/JINARC, REXULTI), LONSURF, and New Drugs in Japan (Products newly launched in Japan after 2009)

\* 2 Foreign Exchange Impact includes impact from emerging market currencies

# 2. Business Segment Analysis

(100 million yen)

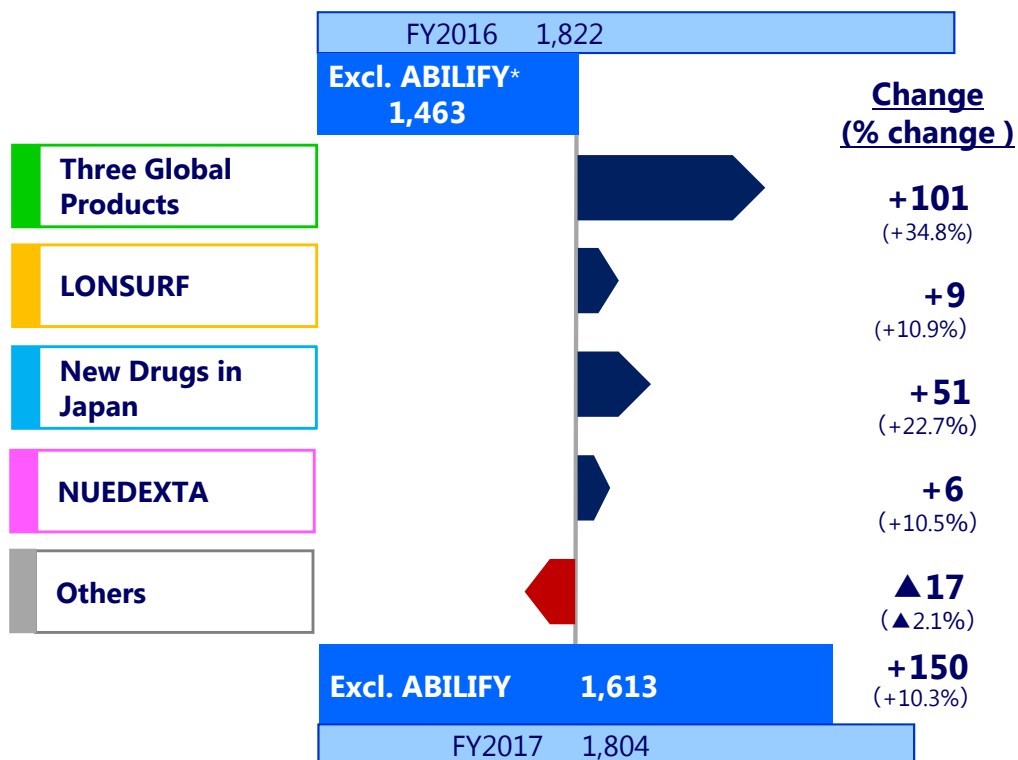


	Net Sales		Operating Profit		Operating Margin (%)		(Ref) Equity income	
	FY2016	FY2017	FY2016	FY2017	FY2016	FY2017	FY2016	FY2017
Pharmaceuticals	1,822	<b>1,804</b>	312	<b>287</b>	17.1%	<b>15.9%</b>	1	<b>8</b>
Nutraceuticals	671	<b>681</b>	74	<b>62</b>	11.0%	<b>9.1%</b>	▲0	<b>0</b>
Consumer Products	80	<b>74</b>	25	<b>22</b>	31.2%	<b>29.9%</b>	27	<b>25</b>
Other	336	<b>355</b>	21	<b>27</b>	6.2%	<b>7.5%</b>	10	<b>10</b>
Corporate/Eliminations	(106)	<b>(111)</b>	(92)	<b>(96)</b>	-	-	-	-
<b>Consolidated</b>	<b>2,803</b>	<b>2,802</b>	<b>340</b>	<b>302</b>	<b>12.1%</b>	<b>10.8%</b>	<b>38</b>	<b>44</b>

# 3. Pharmaceutical Segment Analysis

(100 million yen)

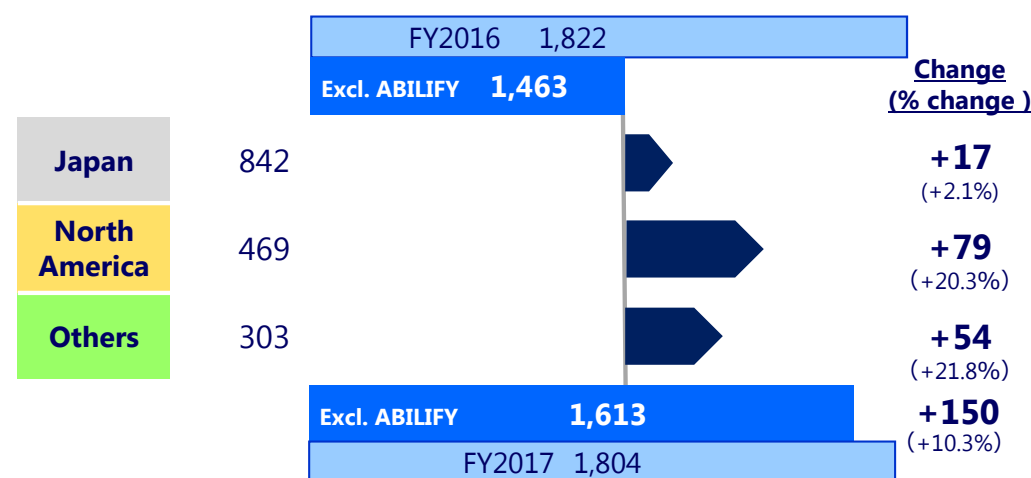
## Net Sales



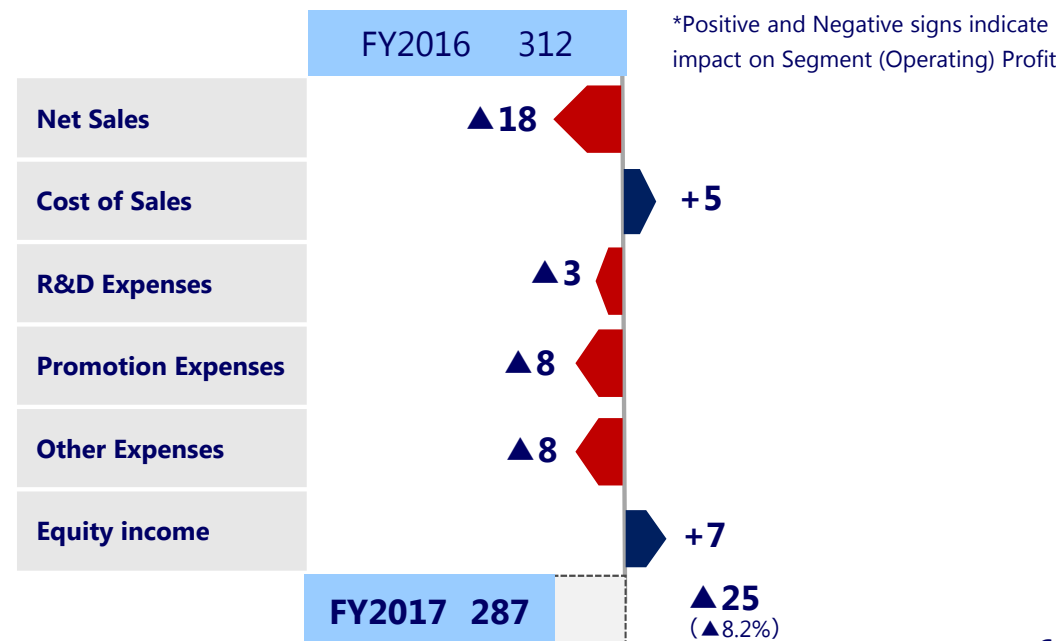
Products	FY2016	FY2017	Change	% Change
ABILIFY	340	178	▲162	▲47.6%
Milestone/Upfront revenue	19	12	▲6	▲33.6%
Abilify Maintena	134	156	+22	+16.3%
Samsca/JINARC	114	136	+22	+19.2%
REXULTI	44	101	+58	+132.0%
LONSURF	78	86	+9	+10.9%
New Drugs in Japan	226	277	+51	+22.7%
NUEDEXTA	56	62	+6	+10.5%
Others	812	795	▲17	▲2.1%
(Pletaal/Mucosta)	97	80	▲17	▲17.4%
<b>Total excluding ABILIFY</b>	<b>1,463</b>	<b>1,613</b>	<b>+150</b>	<b>+10.3%</b>
<b>Pharma Total</b>	<b>1,822</b>	<b>1,804</b>	<b>▲18</b>	<b>▲1.0%</b>

\*"Excluding ABILIFY" in this material represents Net sales excluding ABILIFY and Milestone/Upfront revenue.

## Net Sales by Market

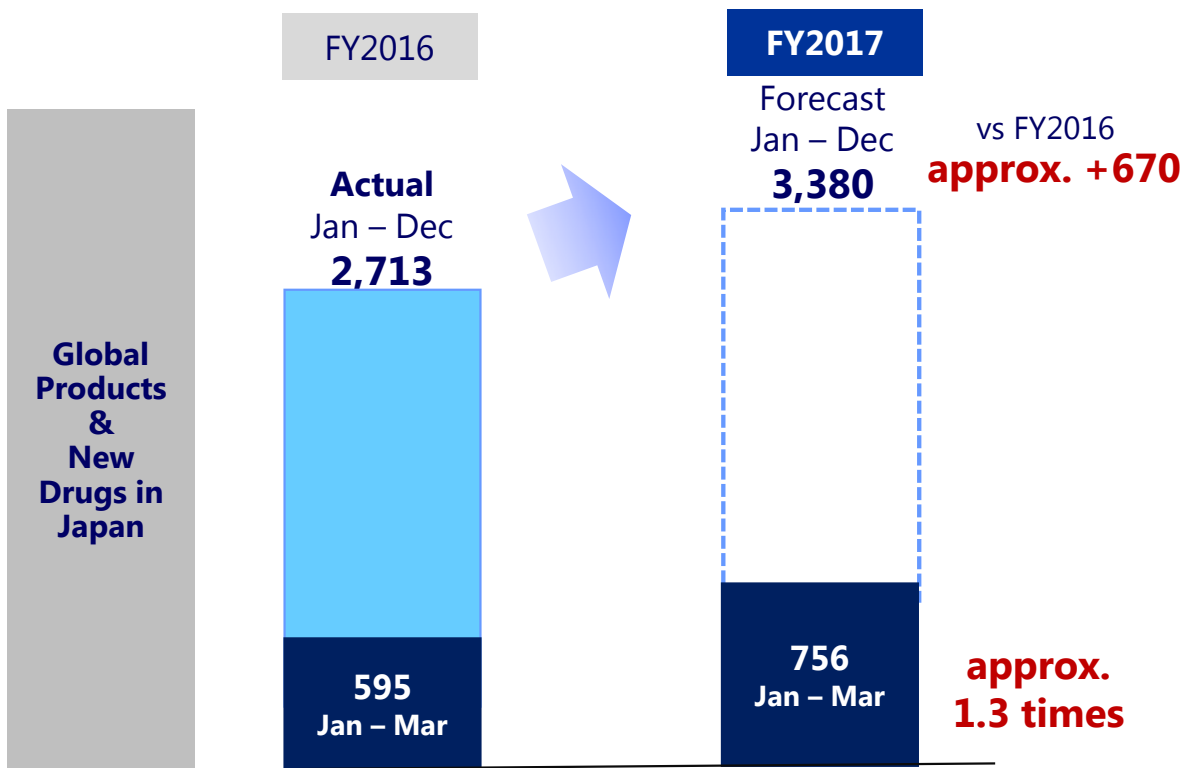


## Segment (Operating) Profit



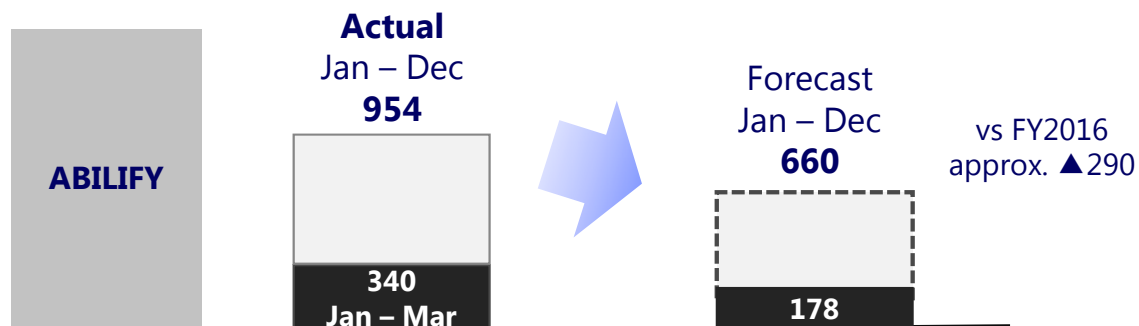
# 4. Sales of Key Growth Drivers

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



(100 million yen)

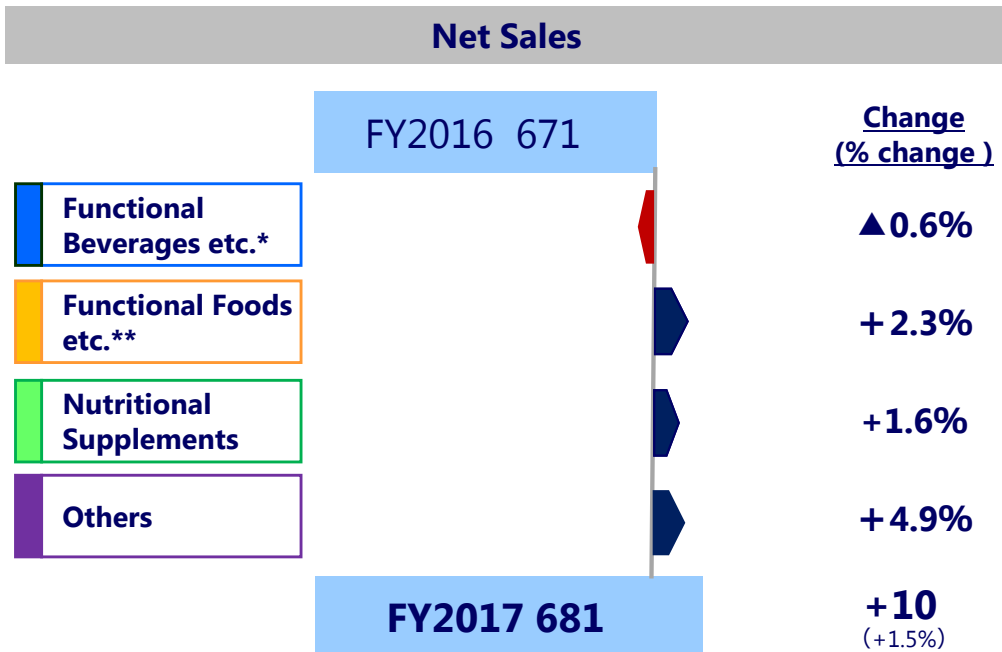
New Drugs	FY2016 Jan - Mar	FY2017 Jan - Mar	FY2016 Jan - Dec	FY2017 Jan - Dec
Abilify	134	156	572	725
Maintena	114	136	489	600
REXULTI	44	101	298	480
LONSURF	78	86	301	340
New Drugs in Japan	226	277	1,054	1,235
<b>Total</b>	<b>595</b>	<b>756</b>	<b>2,713</b>	<b>3,380</b>



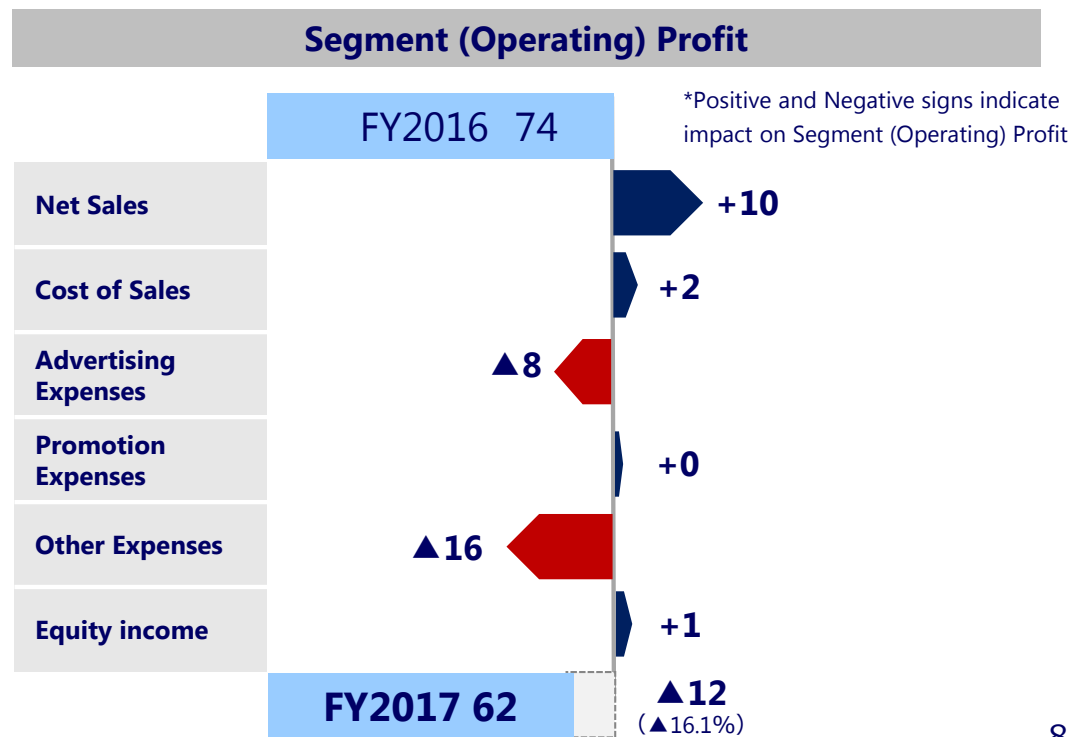
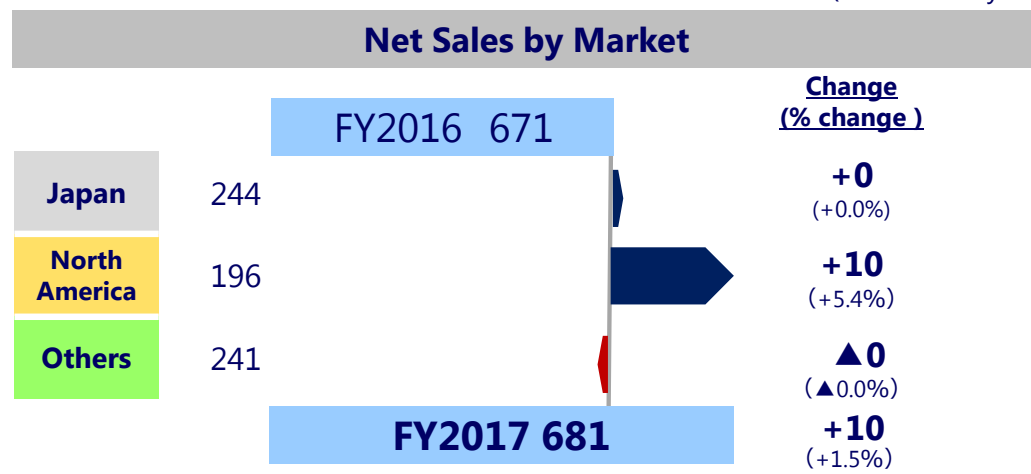
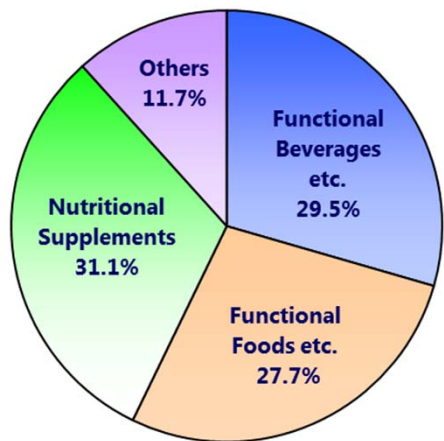
	FY2016 Jan - Mar	FY2017 Jan - Mar	FY2016 Jan - Dec	FY2017 Jan - Dec
<b>ABILIFY</b>	<b>340</b>	<b>178</b>	<b>954</b>	<b>660</b>

# 5. Nutraceutical Segment Analysis

Net Sales increased compared to the previous year regardless of the negative impact of foreign exchange rates.



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





## 6. FY2017 Forecast

(100 million yen)	Actual		Forecast as of February, 2017		
	FY2017 Jan – Mar		FY2017 Jan – Jun	FY2017 Jan – Dec	% Achievement
<b>Net Sales</b>	<b>2,802</b>		6,050	<b>12,600</b>	22.2%
<b>Operating Profit</b>	<b>302</b>		580	<b>1,200</b>	25.1%
<b>Profit attributable to owners of the Company</b>	<b>210</b>		420	<b>850</b>	24.7%
<b>R&amp;D Expenses</b>	<b>367</b>		850	<b>1,800</b>	20.4%
<b>Operating Profit + R&amp;D Expenses</b>	<b>668</b>		1,430	<b>3,000</b>	22.3%

Average Foreign Exchange rates

	Actual
1USD	113.60 yen
1EUR	121.05 yen

Assumption

1USD	115.0 yen
1EUR	120.0 yen

# Pharmaceutical Development Update

**May 12, 2017**

Otsuka Holdings Co., Ltd.

- 1 List of projects**
- 2 Key development progress in 1Q/FY2017**
- 3 Topics**
- 4 FY2017 - Key projects scheduled for NDA submissions & P-3 (initial plan)**

# 1-1. Major projects under development : Central nervous system and Neurology (as of Mar. 31, 2017)



Development status		P-1	P-2	P-3	NDA
Psychiatric disease	Schizophrenia	Brexiprazole long acting injection US	AVP-786 US		Brexiprazole JP·EU
	MDD			Brexiprazole EU ASC-01 JP·Asia	
	Others		Brexiprazole PTSD US·EU Centanafadine ADHD US	Nalmefene Alcoholism JP	Aripiprazole depot injection Bipolar US
Neurological disease	Alzheimer's disease	AF20513 EU		Brexiprazole Agitation 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

PTSD: Post traumatic stress disorder ADHD: Attention deficit hyperactivity disorder DMD: Duchenne muscular dystrophy

# 1-2. Major projects under development : Oncology

(as of Mar. 31, 2017)



Development status	P-1	P-2	P-3	NDA
Solid cancer	TAS-117 JP	SGI-110 Ovarian cancer US·EU AT13387 NSCLC US·EU TAS-114 NSCLC JP·US·EU <b>TAS-115 Prostate cancer JP</b> TAS-116 GIST JP	TAS-118 Pancreatic cancer JP·Asia	
	TAS-119 US·EU		TAS-118 Gastric cancer JP·Asia	
	TAS-120 JP·US·EU		TAS-102 Colorectal cancer Asia	
	TAS-121 JP		TAS-102 Gastric cancer JP·US·EU	
	ET-743 JP			
	OPB-111001 EU			
	OPB-111077 US·Asia			
	OCV-C02 JP			
	ASTX660 US			
	TAS3681 US·EU			
	<b>TAS4464 JP·US·EU</b>			
Blood cancer		ASTX727 MDS US OCV-501 AML JP·Asia AT7519 MM US	SGI-110 AML JP·US·EU·Asia <b>SGI-110 MDS JP·US·EU·Asia</b>	
		Rebamipide (liquid) Oral mucositis JP Pro-NETU Antiemetics JP		global project
	Palliative & supportive care			

Blue columns indicate changes since last update

# 1-3. Major projects under development : Others

(as of Mar. 31, 2017)

Development status	P-1	P-2	P-3	NDA
Cardiovascular/ Renal		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
			Vadadustat Renal anemia US	
Others		Delamanid Pediatric MDR-TB EU	Delamanid MDR-TB US	
		OPC-2071 Infectious disease JP·Asia		
		OPA-15406 Atopic dermatitis JP	Rebamipide ophthalmic suspension MD Dry eye JP	
		TAS-303 Stress urinary incontinence JP	OPF-105 PPN infusions JP	
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 Q1/2017

(as of Mar. 31, 2017)

## <Launch>

Product name	Country /Region	Indication	Characteristics
Mikeluna <sup>®</sup> Combination Ophthalmic Solution	Japan	Glaucoma Ocular hypertension	<ul style="list-style-type: none"> <li>➤ An Otsuka-developed eye drop containing a combination of the non-selective <math>\beta</math>-blocker cartelol hydrochloride and a prostaglandin analogue latanoprost</li> <li>➤ Free from benzalkonium chloride, the most frequently used preservative in eye drops</li> <li>➤ Stored at room temperature</li> </ul>

## <Filed>

Product name (Generic name)	Country /Region	Indication	Characteristics
REXULTI <sup>®</sup> (brexpiprazole)	Japan Europe	Schizophrenia	<ul style="list-style-type: none"> <li>➤ Binds to dopamine D<sub>2</sub> and serotonin 5-HT<sub>1A</sub> receptors (as a partial agonist)</li> <li>➤ Binds to serotonin 5-HT<sub>2A</sub> receptors (as an antagonist)</li> </ul>

# 2-2. Key Development Progress in Q1/2017

(as of Mar. 31, 2017)

## <P-3 transition>

Development code	Country/ Region	Indication	Characteristics
SGI-110	Japan US Europe Asia	Relapsed or refractory myelodysplastic syndrome (MDS)	<ul style="list-style-type: none"> <li>➤ DNA methyltransferase inhibitor</li> <li>➤ Dinucleotide of decitabine and deoxyguanosine</li> <li>Second-generation prodrug of decitabine</li> </ul>
	Japan US Europe Asia	Relapsed or refractory acute myeloid leukemia (AML)	

## <P-2 transition·Added to P-2 >

Generic name/ Development code	Country/ Region	Indication	Characteristics
Brexpiprazole	US Europe	Post Traumatic Stress Disorder (PTSD)	<ul style="list-style-type: none"> <li>➤ Binds to dopamine D<sub>2</sub> and serotonin 5-HT<sub>1A</sub> receptors (as a partial agonist)</li> <li>➤ Binds to serotonin 5-HT<sub>2A</sub> receptors (as an antagonist)</li> </ul>
Centanafadine	US	Attention deficit hyperactivity disorder (ADHD)	<ul style="list-style-type: none"> <li>➤ Triple (serotonin-norepinephrine-dopamine) reuptake inhibitor (SNDRI)</li> </ul>
TAS-115	Japan	Prostate cancer	<ul style="list-style-type: none"> <li>➤ Antiangiogenic effect by VEGFR inhibition and stronger antitumor effect by c-Met inhibition</li> </ul>



# 2-3. Key Development Progress in Q1/2017

(as of Mar. 31, 2017)

## <P-1 transition>

Generic name/ Development code	Country/ Region	Indication	Characteristics
Brexipiprazole long acting injection	US	Schizophrenia	<ul style="list-style-type: none"> <li>➤ Once-monthly long acting injection</li> <li>➤ 2 routes of administration: intramuscular &amp; subcutaneous injection</li> </ul>
TAS4464	Japan US Europe	Solid cancer Blood cancer	<ul style="list-style-type: none"> <li>➤ NAE inhibitor (NAE: NEDD 8 activating enzyme)</li> <li>➤ Expected antitumor effect by NAE inhibition and cell growth blockade by apoptosis induction</li> </ul>

- The following projects were discontinued in this period.

Aripiprazole (Agitation associated with dementia of the Alzheimer's type): R&D strategic reason

Aripiprazole depot injection (Bipolar): R&D strategic reason (Japan and Europe)

SGI-110 (Hepatocellular carcinoma) : Based on P-2 results

AE58054 (Alzheimer's disease): Based on P-3 results

Nabiximols (Cancer pain): Based on P-3 results

## Centanafadine

Stage: P-2

Indication: Attention deficit hyperactivity disorder (ADHD)

### Characteristics

- **Triple reuptake inhibitor**  
Inhibits serotonin-norepinephrine-dopamine reuptake

### Trial results

- Phase 2 b trial (US)
  - Subjects: 85 adult ADHD patients
  - Trial: Centanafadine (CTN) vs Placebo administered over a 3-week period, crossover method
  - Results: CTN group had 7 point improvement in ADHD rating scale compared to placebo group

### ADHD

ADHD: Attention deficit hyperactivity disorder

### Symptoms

- Development disorder characterized by inattention (distractibility and forgetfulness, etc.), hyperactivity and impulsivity (anxiety and restlessness, etc.)

### Drug treatment

- Stimulant drugs
- Non-stimulant drugs
- Issues
  - Problems associated with stimulant drugs: psychological dependency, drug resistance and potential abuse
  - Expectation of new drugs: comparable efficacy to stimulant drugs and comparable tolerability to non-stimulant drugs with a low risk of abuse

# 3-2. Topics (Oncology)

## TAS4464

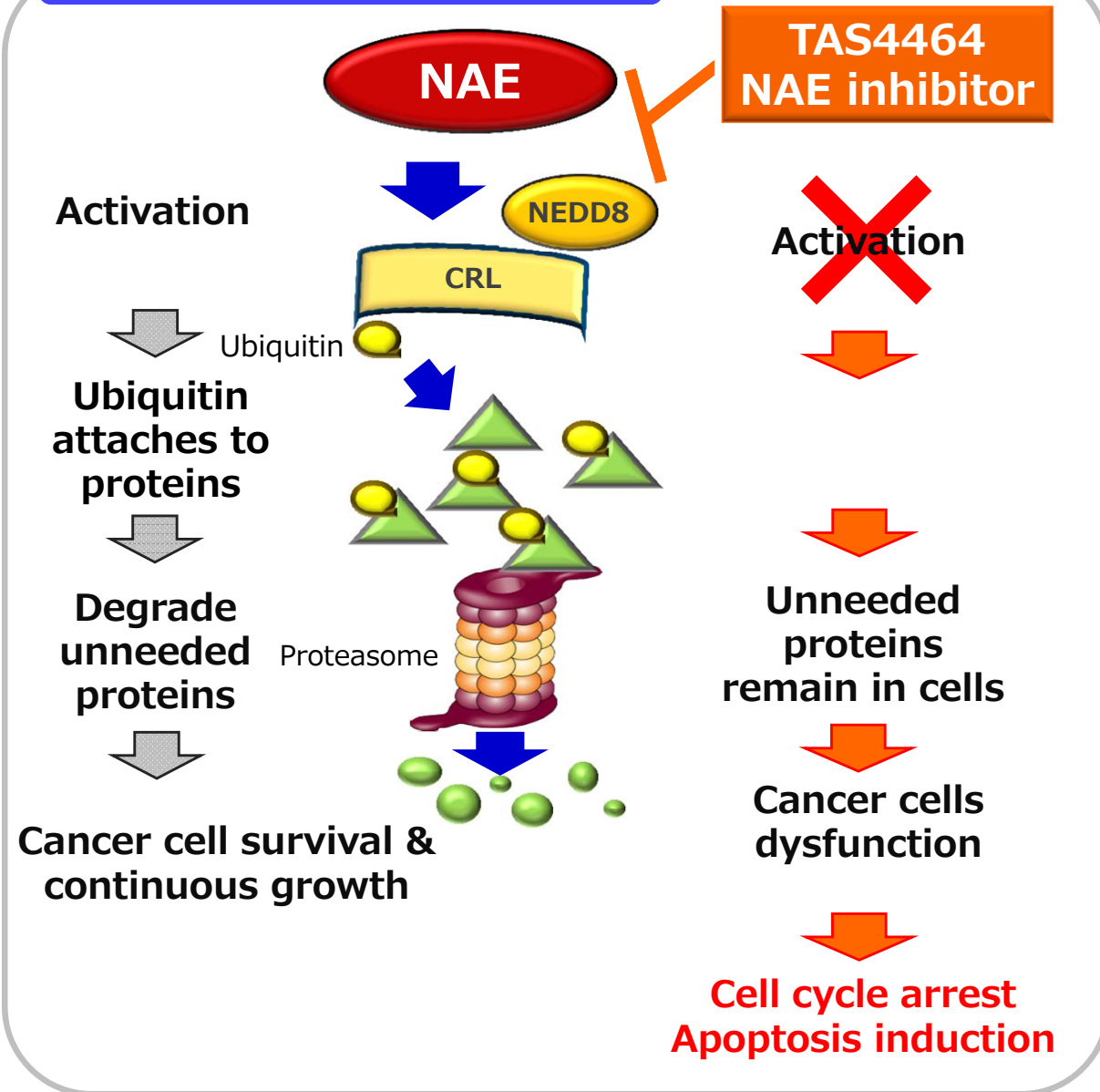
Stage: P-1

Indication: Solid cancer and blood cancer

### Characteristics

- NAE inhibitor (Injection)  
NAE: NEDD 8 Activating Enzyme
- NAE inhibitory action suppresses NEDD8 activation
  - Anti-tumor effect by stopping a cancer cell cycle and inducing apoptosis

### Mechanism of action



CRL: Enzymes that control a degradation of intracellular proteins.

Ubiquitin: It marks unneeded proteins to degrade.

Proteasome: Protein complexes that degrade unneeded proteins by enzymes.

# 4. FY2017 - Key projects scheduled for NDA submissions & P-3 (initial plan)

## Projects planned for NDA submission

NDA filing & Advanced to P-3 as scheduled

	Therapeutic Area	Generic name/ Development code	Country/Region	Indication
1	CNS/ Neurology	Brexpiprazole	Japan	Schizophrenia
2			Europe	Schizophrenia
3			US	Agitation associated with dementia of the Alzheimer's type
4		ASC-01	Japan	Major depressive disorder
5		Nalmefene	Japan	Alcoholism
6	Oncology	TAS-102	Asia	Colorectal cancer
7	Cardiovascular/ Renal	Tolvaptan	US	Autosomal dominant polycystic kidney disease (ADPKD)

## Projects scheduled to advance to P-3

	Therapeutic area	Generic name/ Development code	Country/Region	Indication
1	CNS/ Neurology	Brexpiprazole	US	Bipolar disorder mania
2	Oncology	SGI-110	Japan/ US/ Europe/Asia	Relapsed/refractory myelodysplastic syndrome (MDS)
3			Japan/US/ Europe/Asia	Relapsed/refractory acute myeloid leukemia (AML)
4		ASTX727	US	Untreated high-risk myelodysplastic syndrome (MDS)
5	Cardiovascular/ Renal	Tolvaptan	Japan	Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)