

Consolidated Financial Results

FY2015 Q1

(Three Months Ended March 31, 2015)

May 13, 2015
Otsuka Holdings Co., Ltd.

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- 1 Consolidated Financial Results (FY2015 Q1)**
- 2 Business Segment Analysis**
- 3 Pharmaceutical Segment Analysis**
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- 5 Nutraceutical Segment Analysis**
- 6 FY2015 Estimate**

1. Consolidated Financial Results (FY2015 Q1)

(100 million yen)

	FY2014 Jan - Mar	FY2015 Jan - Mar	Change	% Change
Net Sales	3,475	3,851	+375	+10.8%
Operating Income	173	516	+343	+198.1%
Ordinary Income	185	515	+330	+178.6%
Net Income	120	340	+220	+183.4%
R&D Expenses	770	447	▲323	▲41.9%

Foreign Exchange Impact : (100 million yen)

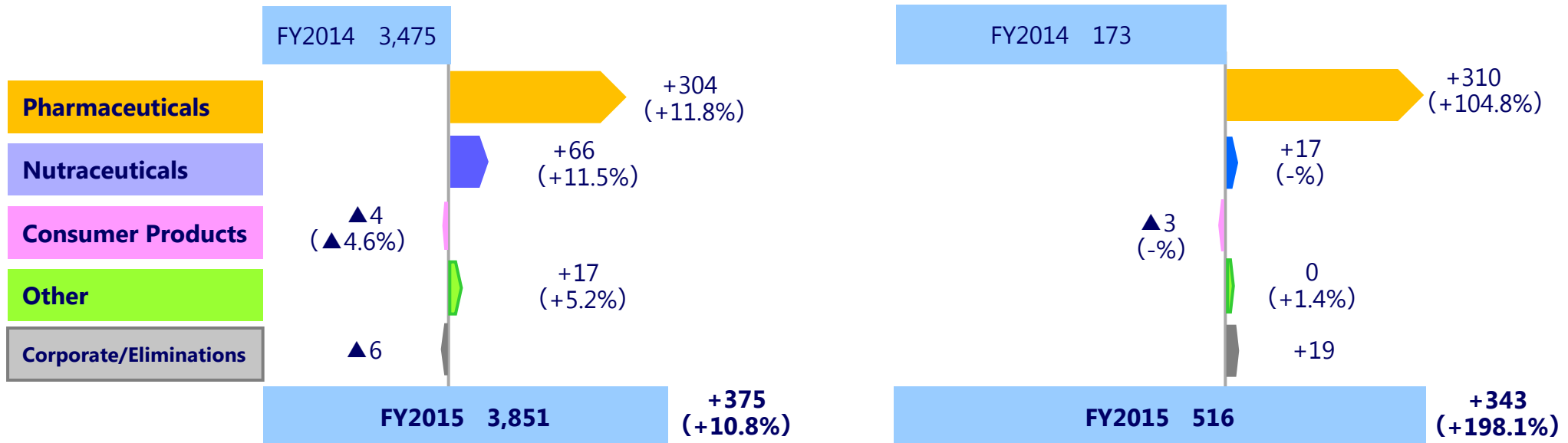
Net Sales	approx.	+250
Operating Income	approx.	▲0

2. Business Segment Analysis

*Parentheses represent % change (100 million yen)

Net Sales

Segment (Operating) Income



	Net sales		Operating income		Operating margin (%)	
	FY2014	FY2015	FY2014	FY2015	FY2014	FY2015
Pharmaceuticals	2,583	2,887	296	606	11.5%	21.0%
Nutraceuticals	570	636	▲12	4	▲2.1%	0.7%
Consumer Products	96	92	▲4	▲7	▲3.9%	▲7.1%
Other	324	341	13	13	3.9%	3.8%
Corporate/Eliminations	▲98	▲104	▲120	▲101	-	-
Consolidated	3,475	3,851	173	516	5.0%	13.4%

3. Pharmaceutical Segment Analysis

Net Sales

FY2014 2,583



FY2015 2,887

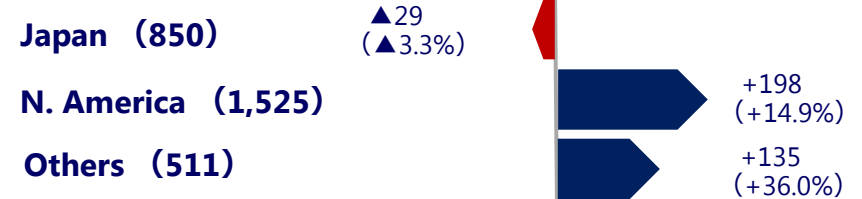
+304
(+11.8%)

Products	FY2014	FY2015
Abilify	1,468	1,555
Abilify Maintena	27	79
Sumsca	57	84
Oncology	269	311
Long-term products	141	118
Milestone	52	116
Others	568	624
Pharma Total	2,583	2,887

Net Sales by Market

(100 million yen)

FY2014 2,583

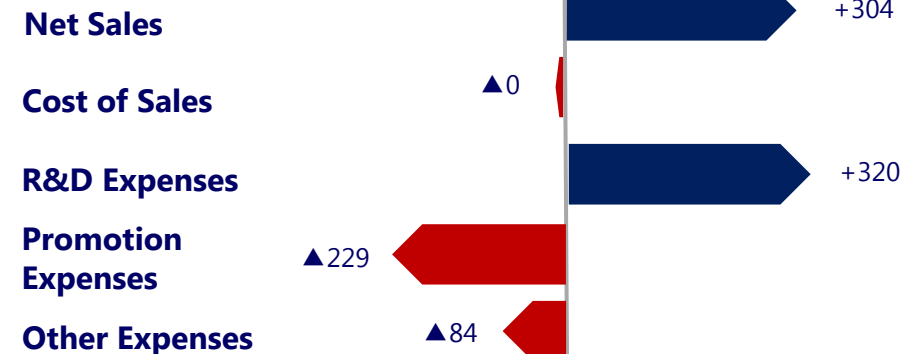


FY2015 2,887

+304
(+11.8%)

Segment (Operating) Income

FY2014 296



FY2015 606

+310
(+104.8%)

4. Abilify Sales

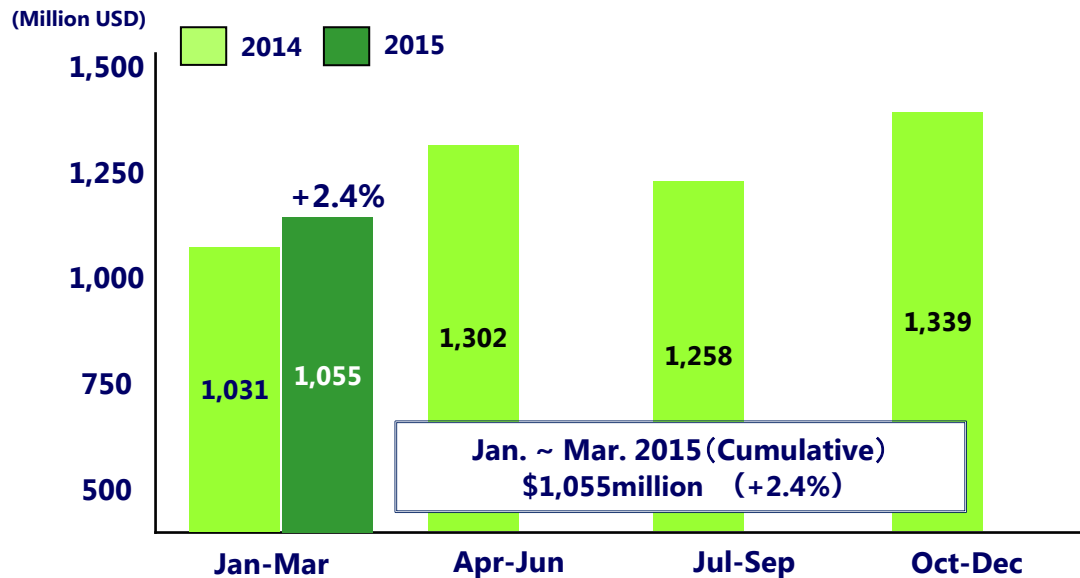
(100 million yen)

	FY2014 Jan – Mar	FY2015 Jan – Mar	Change	% Change
Abilify (Total)	1,468	1,555	+86	+5.9%

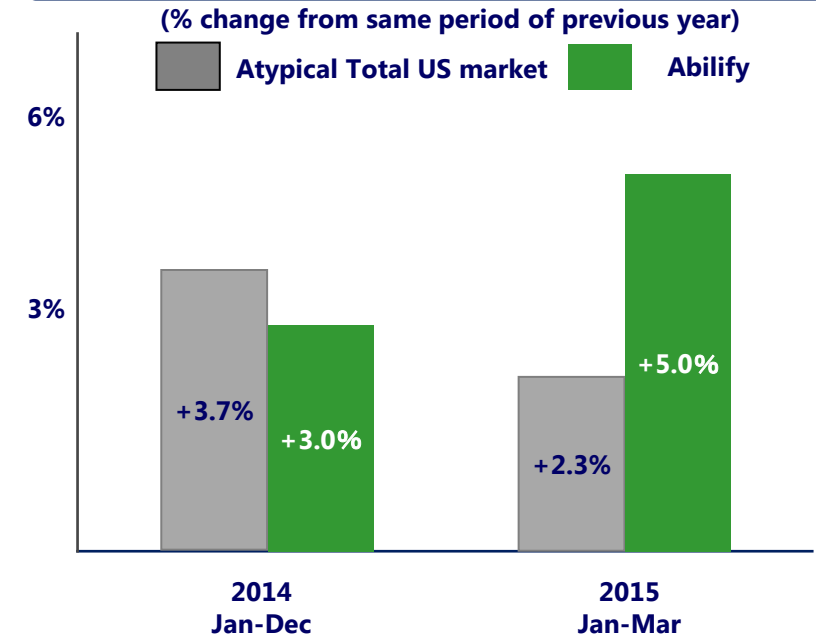
Abilify Sales by Market

US	1,060	1,257	+197	+18.6%
<Million USD>	1,031	1,055	+24	+2.4%
Japan	94	79	▲15	▲16.2%
Others	314	218	▲96	▲30.5%

Abilify Sales – Quarterly Evolution (US market)



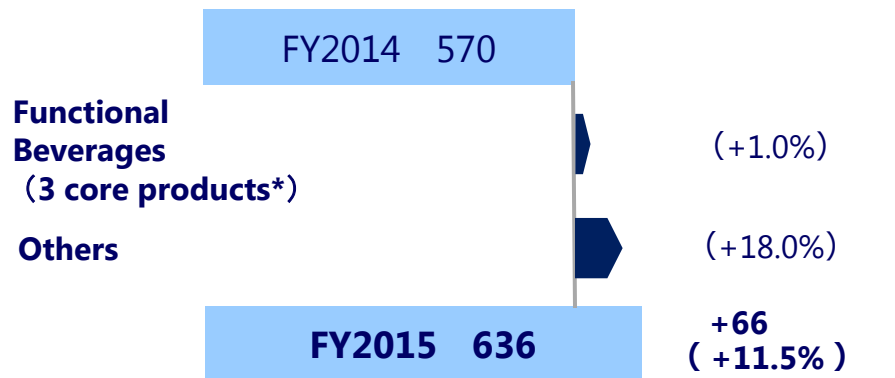
Atypical antipsychotic prescription market in US)



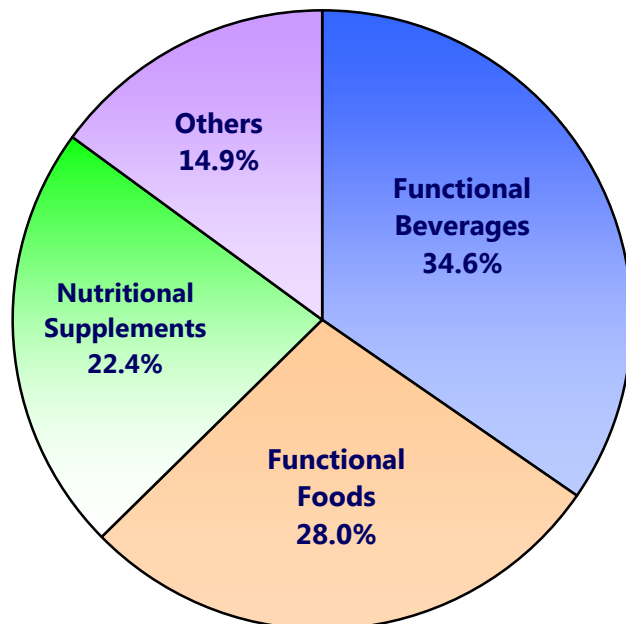
5. Nutraceutical Segment Analysis

(100 million yen)

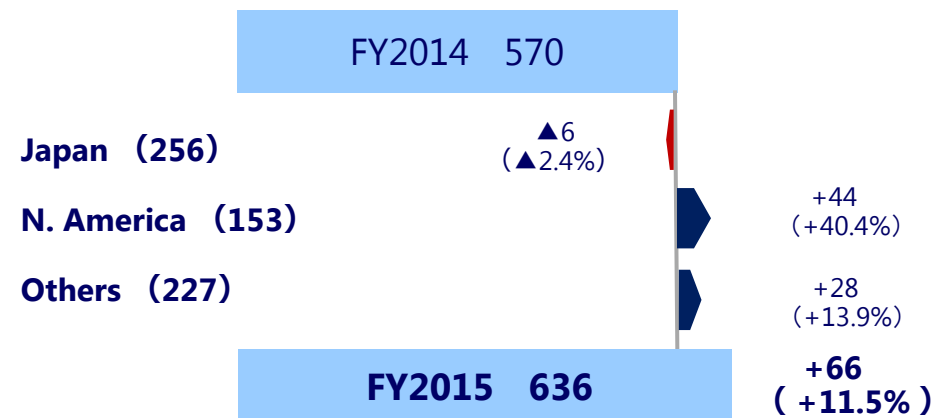
Net Sales



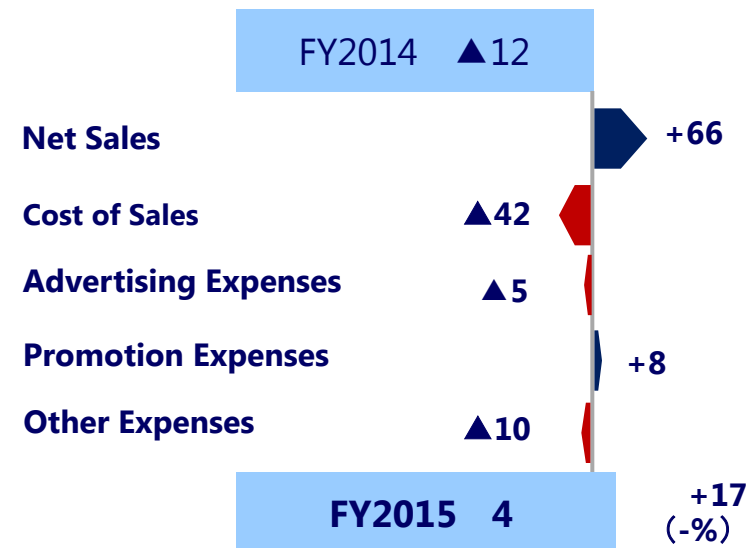
*Pocari Sweat, Oronamin C, Tiovita



Net Sales by Market



Segment (Operating) Income



6 . FY2015 Estimate

(100 million yen)

	Actual				Progress rate	
	FY2014 (Jan – Mar)	FY2015 (Jan – Mar)	Change	% Change	FY2015 (Jan – Dec) Estimate	% Progress
Net Sales	3,475	3,851	+375	+10.8%	13,700	28.1%
Operating Income	173	516	+343	+198.1%	1,100	46.9%
Ordinary Income	185	515	+330	+178.6%	1,200	42.9%
Net Income	120	340	+220	+183.4%	800	42.5%
R&D Expenses	770	447	▲323	▲41.9%	2,300	19.4%

Pharmaceutical Development Update

May 13, 2015

Otsuka Holdings Co., Ltd.

- 1 Major development projects**
- 2 Development update in 1Q/FY2015**
 - ✓ Launches
 - ✓ Approvals
 - ✓ NDA filings
 - ✓ Advanced to the next phase
- 3 Topics**
- 4 FY2015 – Progress of key projects advanced to P-III & scheduled NDA submissions (Initial plan)**

1-1. Major development projects: CNS and neurological disorders (as of Mar. 31, 2015)

		P-1	P-2	P-3	NDA
Mental Disease	Schizophrenia			Brexpiprazole JP·EU	Aripiprazole extended release injectable JP *Approved Brexpiprazole US
	MDD		AVP-786 US	Brexpiprazole EU ASC-01 JP·Asia	Brexpiprazole US
	Others		Brexpiprazole ADHD US	Aripiprazole Autism JP Aripiprazole extended release injectable Bipolar JP·US·EU Brexpiprazole PTSD US·EU Nalmefene Alcoholism JP	
Neurological Disease	Epilepsy				Levetiracetam Generalized seizures JP Levetiracetam Partial seizures (monotherapy) JP *Approved
	AD		AVP-923 Agitation in AD US	Aripiprazole Agitation in AD JP Brexpiprazole Agitation in AD US·EU AE58054 US·EU	
	Others	TAS-205 DMD JP	AVP-923 PD US		AVP-825 Migraine US

global project

Blue columns indicate changes since last update.

1-2. Major development projects: Oncology (as of Mar. 31, 2015)

	P-1	P-2	P-3	NDA	
Solid cancer	TAS-114 <small>JP·US ·EU</small>	Dasatinib Pancreatic cancer <small>US·EU</small>	TAS-118 Pancreatic cancer <small>JP· Asia</small>		
	TAS-115 <small>JP</small>	OCV-101 Pancreatic cancer <small>JP</small>	TAS-118 Gastric cancer <small>JP· Asia</small>		
	TAS-116 <small>JP</small>	SGI-110 HCC <small>US·EU</small>	TAS-102 Colorectal cancer <small>Asia</small>		TAS-102 Colorectal cancer <small>US·EU</small>
	TAS-117 <small>JP</small>	SGI-110 Ovarian cancer <small>US·EU</small>	S-1 Cervical cancer <small>JP· Asia</small>		
	TAS-119 <small>US·EU</small>	AT13387 Prostate cancer <small>US·EU</small>			
	TAS-120 <small>JP·US ·EU</small>	AT13387 NSCLC <small>US·EU</small>			
	TAS-121 <small>JP</small>				
	OPB-31121 <small>JP· Asia</small>				
	OPB-51602 <small>JP·US ·Asia</small>				
	OPB-111001 <small>EU</small>				
	OPB-111077 <small>US· Asia</small>				
OCV-C02 <small>JP</small>			ET-743 STS <small>JP</small>		
Blood cancer	ASTX727 <small>US</small>	OCV-501 AML <small>JP· Asia</small>	SGI-110 AML <small>US· EU</small>		
	SGI-110 <small>JP</small>	SGI-110 MDS, AML <small>US</small>			
		AT7519 MM <small>US</small>			
Palliative & supportive care		Rebamipide(liquid) Oral mucositis <small>JP</small>	nabiximols Cancer pain <small>US</small>		

global project

Blue columns indicate changes since last update.

1-3. Major development projects: Others (as of Mar. 31, 2015)

	P-1	P-2	P-3	NDA
Cardiovascular	<p>OPC-108459 AF JP·US</p>	<p>Tolvaptan Cancerpus edema JP</p> <p>Tolvaptan Volume overload in hemodialysis JP</p> <p>Tolvaptan Volume overload in peritoneal dialysis JP</p>	<p>Tolvaptan ADPKD US</p>	<p>Tolvaptan Hepatic edema Asia</p> <p>Tolvaptan Cardiac edema Asia</p> <p>Tolvaptan ADPKD EU</p>
Others		<p>Delamaïnd Pediatric MDR-TB EU</p> <p>OPC-6535 COPD JP·US ·Asia</p> <p>OPA-6566 Glaucoma US</p> <p>ACU-4429 AMD US</p> <p>OPA-15406 Atopic dermatitis US</p> <p>TAC-202 Urticaria JP</p>	<p>Delamanid MDR-TB US</p> <p>Rebamipide ophthalmic suspension MD Dry eye JP</p> <p>OPC-1085EL Glaucoma JP</p> <p>TAC-202 Allergic rhinitis JP</p> <p>OPF-105 PPN infusions JP</p> <p>OPF-108 TPN infusions JP</p>	<p>YP-18 Febrile neutropenia JP</p> <p>OPB-2045G Disinfectant JP</p>
Diagnostics		<p>C13-URA Gastric emptying determination US</p> <p>C13-CAC Diagnostic kit for gastric acid-related disease JP</p>		

global project

2-1. Key development progress in 1Q/FY2015 (as of Mar. 31, 2015)

- One product launched

Product name	Country·Area	
TAKECAB® tablets	Japan	Launched on Feb. 26 (Co-promotion with Takeda Pharmaceutical Co. Ltd.)

- Two projects approved

Product name	Country·Area	Indication
ABILIFY® extended-release injectable suspension, for intramuscular use	Japan	Schizophrenia
E Keppra®	Japan	Monotherapy for partial epilepsy

- Three applications submitted for approval

Generic name / Development code (Product name)	Country·Area	Indication
Levetiracetam (E Keppra®)	Japan	Generalized epilepsy
TAS-102	Europe	Colorectal cancer
ET-743	Japan	Malignant soft tissue sarcoma

2-2. Key development progress in 1Q/FY2015 (as of Mar. 31, 2015)

- Three projects advanced to P-III

Generic name / Development code	Country·Area	Indication
Nalmefene	Japan	Alcohol dependency
TAS-118	JP·Asia	Gastric cancer
SGI-110	US·EU	AML*

- Two projects advanced to P-I

Generic name / Development code	Country·Area	Indication
TAS-117	Japan	Solid cancer
SGI-110	Japan	AML

*AML: Acute myelocytic leukemia

3-1. Progress of key projects focused on the 2nd mid-term plan (3 global products)

Generic name / Development code	Country·Area	Development status
Aripiprazole extended-release injectable suspension	Japan	Schizophrenia: Approved in Mar. 2015 Bipolar disorder: Ongoing, Global P-III
	US	Schizophrenia: Launched the dual chamber pre-filled syringe in Mar. 2015 Submitted the deltoid muscle as a new injection site Bipolar disorder: Ongoing, Global P-III
	Europe	Schizophrenia: Launched , approved the deltoid muscle in Jan. 2015, and the dual chamber pre-filled syringe in Mar. 2015 Bipolar disorder: Ongoing, Global P-III
Brexipiprazole	Japan	Schizophrenia: Ongoing, P-III (to be filed by the year-end)
	US	Schizophrenia: Submitted, the PDUFA date set for Jul. 11, 2015 MDD*: Submitted, the PDUFA date set for Jul. 11, 2015 PTSD*: Ongoing, P-III AD* agitation: Ongoing, P-III ADHD*: Ongoing, P-II
	Europe	Schizophrenia: Ongoing, P-III MDD: Ongoing, P-III PTSD: Ongoing, P-III AD agitation: Ongoing, P-III
Tolvaptan	Japan	ADPKD*: Approved in Mar. 2014 for additional indication Fluid retention in patients on dialysis: Ongoing, P-II Cancerous edema: Ongoing, P-II
	US	ADPKD: Ongoing, P-III
	Europe	ADPKD: Received positive CHMP opinion (Approval recommended in EU)

* MDD: Major depressive disorder
 PTSD: Post-traumatic stress disorder
 AD: Alzheimer's disease
 ADHD: Attention-deficit hyperactivity disorder
 ADPKD: Autosomal dominant polycystic kidney disease

3-2. Progress of key projects focused on the 2nd mid-term plan

Next-generation 3 products

Generic name / Development code	Country·Area	Development status
Lonsurf	Japan	Colorectal cancer: Launched
	US	Colorectal cancer: Submitted, the PDUFA date set for Dec. 19, 2015
	Europe	Colorectal cancer: Submitted in Feb. 2015 for marketing approval
SGI-110	Japan	AML: P-I trial started from 1Q/FY2015
	US	AML: Global P-III trial started from 1Q/FY2015 Hepatocellular cancer: Ongoing, P-II Ovarian cancer: Ongoing, P-II
	Europe	AML: Global P-III trial started from 1Q/FY2015 Hepatocellular cancer: Ongoing, P-II Ovarian cancer: Ongoing, P-II
AE58054	US	AD: Ongoing, P-III
	Europe	AD: Ongoing, P-III

Key new drugs in Japan*

Product name / Development code	Development status
E Keppra®	Monotherapy for partial epilepsy: Approved in Feb. 2015 for additional indication Generalized epilepsy: Submitted in Mar. 2015 for additional indication
Abraxane®	Pancreatic cancer: Approved in Dec. 2014 for additional indications (breast cancer, gastric cancer and lung cancer)
ET-743	Malignant soft tissue sarcoma: Submitted in Jan. 2015 for marketing approval
TAC-202	Allergic rhinitis: Ongoing, P-III (to be filed by the year-end) Urticaria: Ongoing, P-II/III (to be filed by the year-end)

* Exclude combination drug and infusion

4. Major P-III projects and NDA submissions scheduled in FY2015

● Projects scheduled to proceed to P-III

Advanced to P-III as scheduled

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Nalmefene	Japan	Alcohol dependency
2	Oncology	SGI-110	US·EU	AML
3	Others	C13-CAC	Japan	Diagnostic kit for gastric acid-related diseases

Not included in the initial plan: TAS-118 Gastric cancer (JP·Asia, P-III)

● Projects scheduled to proceed to filing

NDA filing as scheduled

No.	Areas	Generic name / Development code	Country·Area	Indication
1	CNS	Aripiprazole	Japan	Autism
2		Brexpiprazole	Japan	Schizophrenia
3		Levetiracetam	Japan	Epilepsy (generalized seizures)
4	Oncology	TAS-102	Europe	Colorectal cancer
5		ET-743	Japan	Malignant soft tissue sarcoma
6		Ponatinib	Japan	CML*, ALL*
7	Others	Delamanid	US	MDR-TB*
8		OPC-1085EL	Japan	Glaucoma
9		TAC-202	Japan	Allergic rhinitis, Urticaria
10		OPF-108	Japan	Total parenteral nutrition

*CML: Chronic myeloid leukemia ALL: Acute lymphatic leukemia MDR-TB: Multidrug-resistant tuberculosis