

Outline of Consolidated Financial Results for the Year Ended March 31, 2015

May 13, 2015
NIPPON SHINYAKU CO., LTD.



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FY2014 Summary

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	76,517	100.0%	79,991	100.0%	3,473	4.5%
Operating income	8,038	10.5%	8,562	10.7%	523	6.5%
Ordinary income	8,598	11.2%	8,928	11.2%	330	3.8%
Net income	5,750	7.5%	5,882	7.4%	131	2.3%

Topics

- ◆5th Five-Year Medium-term Management Plan “Aiming for New Growth-Pursuit of Originality-” started.
- ◆Launch Zalutia for urinary disorder caused by benign prostatic hyperplasia (Apr.)
- ◆NS-304 (Selexipag) ...
 - Overseas : Meets Primary Endpoint in PⅢ (Jun.)
 - NDA (US/EU) by Actelion Pharmaceuticals Ltd.
 - Japan : Orphan drug designation by MHLW (Sep.)
- ◆NS-24 (Onetram tablet 100mg) ... Approval (Mar.)
- ◆ACT-064992 (Opumit tablet 10mg) ... Approval (Mar.)



Segmental Review

— Pharmaceuticals —

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	62,185	98.2%	62,898	94.8%	713	1.1%
Revenues from the licensing of industrial property rights	50	0.1%	2,510	3.8%	2,460	4,890.8%
Prulifloxacin	861	1.3%	842	1.3%	-18	-2.2%
Contract manufacturing business	248	0.4%	87	0.1%	-160	△64.7%
Net sales	63,345	100.0%	66,340	100.0%	2,994	4.7%

Increase in sales:

- **Tramal (+1,489 Million yen, +113.4%)**
(cancer pain and chronic pain)
- **Vidaza (+1,122 Million yen, +11.6%)**
(myelodysplastic syndrome)

New Product:

- **Zalutia (+1,613 Million yen)**
(urinary disorder caused by benign prostatic hyperplasia)

etc.

Decrease in sales:

- **GaslonN (-1,019 Million yen, -22.9%)**
(gastric ulcer, gastritis)
- **Hypen (-899 Million yen, -31.1%)**
(non-steroidal analgesic and anti-inflammatory agent)

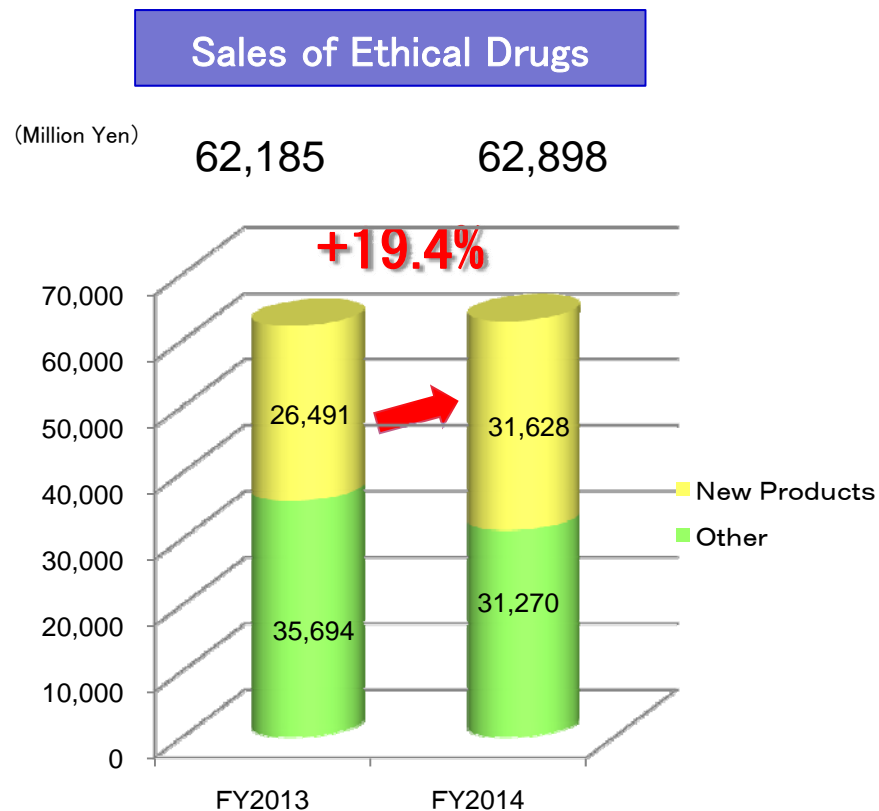
etc.



New Products Review — Pharmaceuticals —

◆ Sales Growth of New Products Group

New Products	FY2013	FY2014	Y on Y Change
Vidaza	9,692	10,814	+11.6%
Lunabell	6,216	6,553	+5.4%
Cialis	4,217	3,682	-12.7%
Adcirca	2,883	3,204	+11.2%
Tramal	1,314	2,803	+113.4%
Erizas	1,731	2,192	+26.6%
Zalutia	—	1,613	—
Regtect	436	764	+75.2%
Total	26,491	31,628	+19.4%





Segmental Review

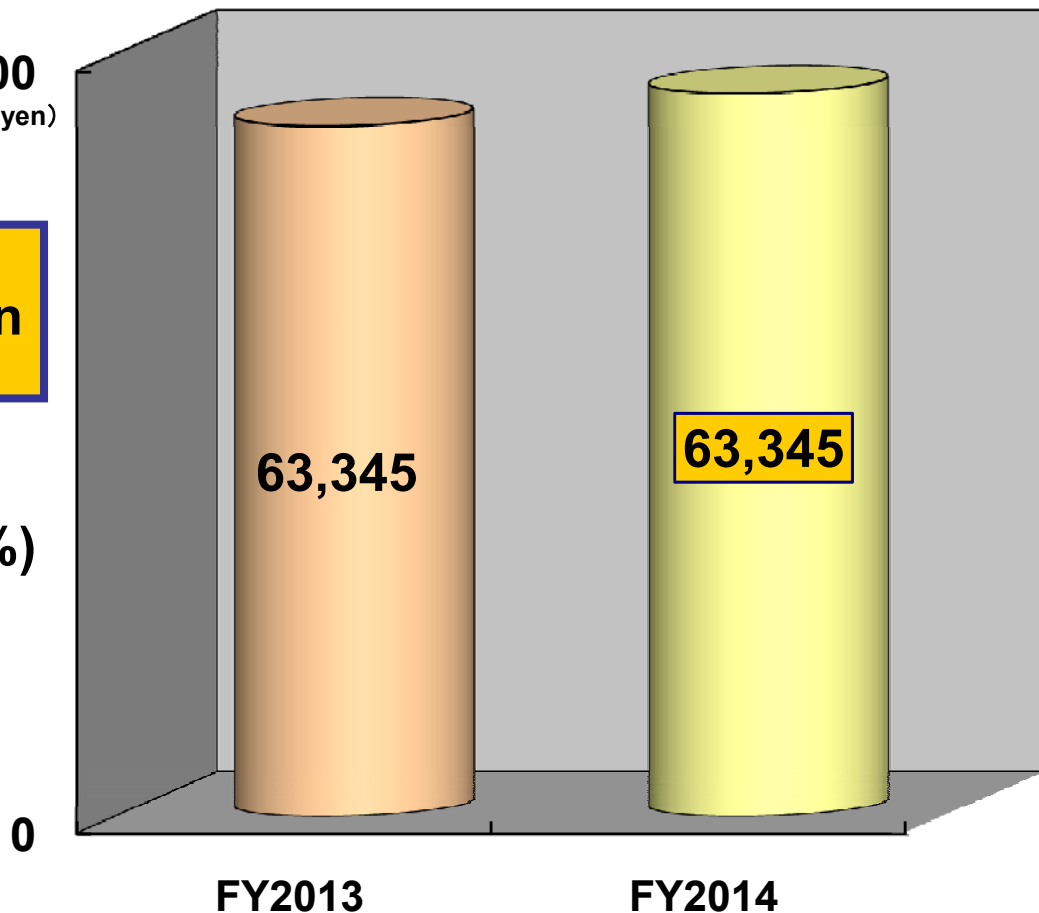
— Pharmaceuticals —

Net sales 66,340 million yen

Year-on-Year change

+ 2,994 million yen (+4.7%)

70,000
(Million yen)





Segmental Review

— Functional Food —

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	857	6.5%	747	5.5%	-109	-12.8%
Preservatives	1,764	13.4%	1,886	13.8%	121	6.9%
Protein preparations	7,119	54.0%	7,290	53.4%	171	2.4%
Nutritional ingredients	2,039	15.5%	2,295	16.8%	255	12.5%
Others	1,391	10.6%	1,431	10.5%	39	2.9%
Net sales	13,172	100.0%	13,651	100.0%	479	3.6%



Segmental Review

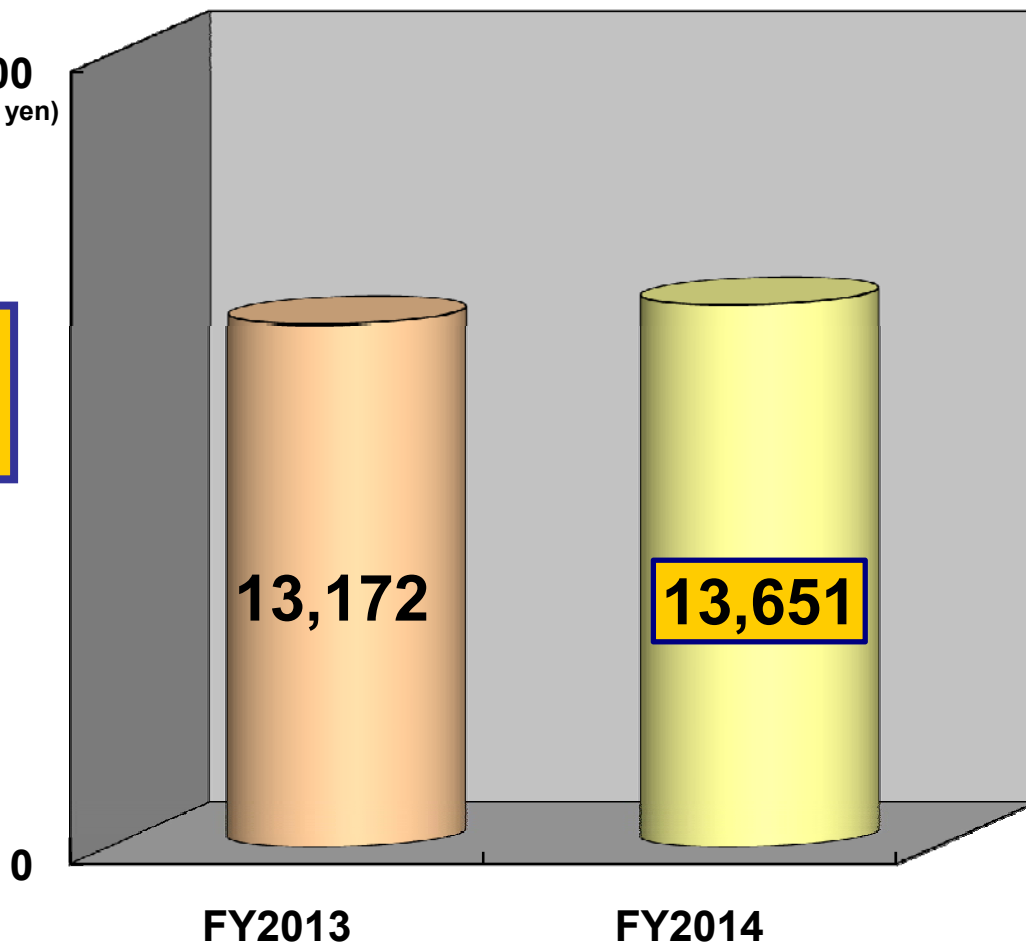
— Functional Food —

Net sales 13,651 million yen

Year-on-Year change

+479 million yen (+3.6%)

20,000
(Million yen)

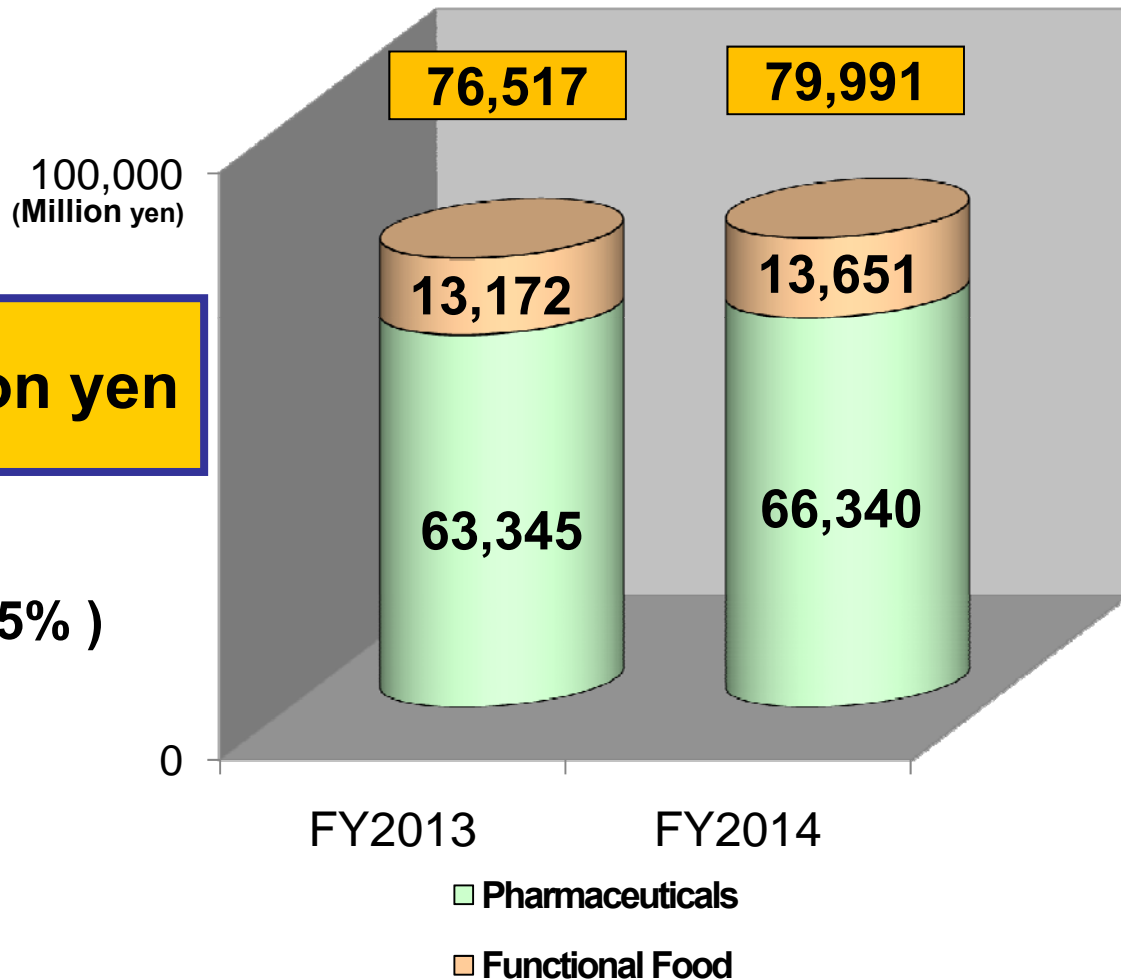




Net Sales

Net sales 79,991 million yen

**Year-on-Year change
+3,473 million yen (+4.5%)**





Consolidated Statements of Income

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	76,517	100.0%	79,991	100.0%	3,473	4.5%
Pharmaceuticals	63,345	82.8%	66,340	82.9%	2,994	4.7%
Functional Food	13,172	17.2%	13,651	17.1%	479	3.6%
Operating expenses	68,479	89.5%	71,429	89.3%	2,950	4.3%
Cost of sales	39,033	51.0%	41,226	51.5%	2,192	
SG&A expenses	19,914	26.0%	21,233	26.6%	1,319	
R&D expenses	9,530	12.5%	8,968	11.2%	-561	
Operating income	8,038	10.5%	8,562	10.7%	523	6.5%



Consolidated Statements of Income

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	8,038	10.5%	8,562	10.7%	523	6.5%
Non-operating income	1,019	1.3%	939	1.2%	-79	△7.8%
Non-operating expenses	460	0.6%	573	0.7%	113	24.7%
Ordinary income	8,598	11.2%	8,928	11.2%	330	3.8%
Income taxes	2,847	3.7%	3,046	3.8%	198	7.0%
Net income	5,750	7.5%	5,882	7.4%	131	2.3%



Dividends

		FY2013	FY2014
Dividends per share	Interim	¥11	¥12
	Year-end	¥12	¥13
	Annual	¥23	¥25
EPS		¥85.25	¥87.26
Dividends payout ratio		27.0 %	28.7 %
DOE		1.7 %	1.7 %



Consolidated Balance Sheet

(Million yen)

	FY2013	FY2014	YoY Change		FY2013	FY2014	YoY Change
	4Q	4Q	Amt		4Q	4Q	Amt
Assets	118,188	129,757	11,568	Liabilities	25,002	28,550	3,548
(Current assets)	74,683	80,422	5,738	(Current liabilities)	15,257	17,770	2,513
(Fixed assets)	43,504	49,334	5,829	(Long-term liabilities)	9,744	10,779	1,034
				Net assets	93,186	101,207	8,020
Total Assets	118,188	129,757	11,568	Total liabilities and net assets	118,188	129,757	11,568



Consolidated Statements of Cash Flows

(Million yen)

	FY2013	FY2014	YoY Change
	Results	Results	Amt
Operating activities	6,015	6,113	97
Investing activities	-3,357	-3,718	-361
Financing activities	-1,606	-1,773	-166
Cash and cash equivalents at end of year	21,229	21,914	684



Capital Investment

(Million yen)

	Results		
	FY2013	FY2014	Amt Chg
Capital investment	1,072	1,239	166
Depreciation	2,704	2,665	-38

Breakdown of Capital Investment

(Million yen)

	Results		
	FY2013	FY2014	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,017	1,160	142
Production	202	510	307
R&D	661	508	-152
Others	153	140	-12
<Sioe Pharmaceutical Co.,Ltd.>	22	14	-7
<Tajima Shokuhin Kogyo Co.,Ltd.>	32	64	32
Total capital investment	1,072	1,239	166



Business Forecast for FY2015

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	79,991	100.0%	90,000	100.0%	10,009	12.5%
Operating income	8,562	10.7%	9,300	10.3%	738	8.6%
Ordinary income	8,928	11.2%	9,500	10.6%	572	6.4%
Net income	5,882	7.4%	6,700	7.4%	818	13.9%

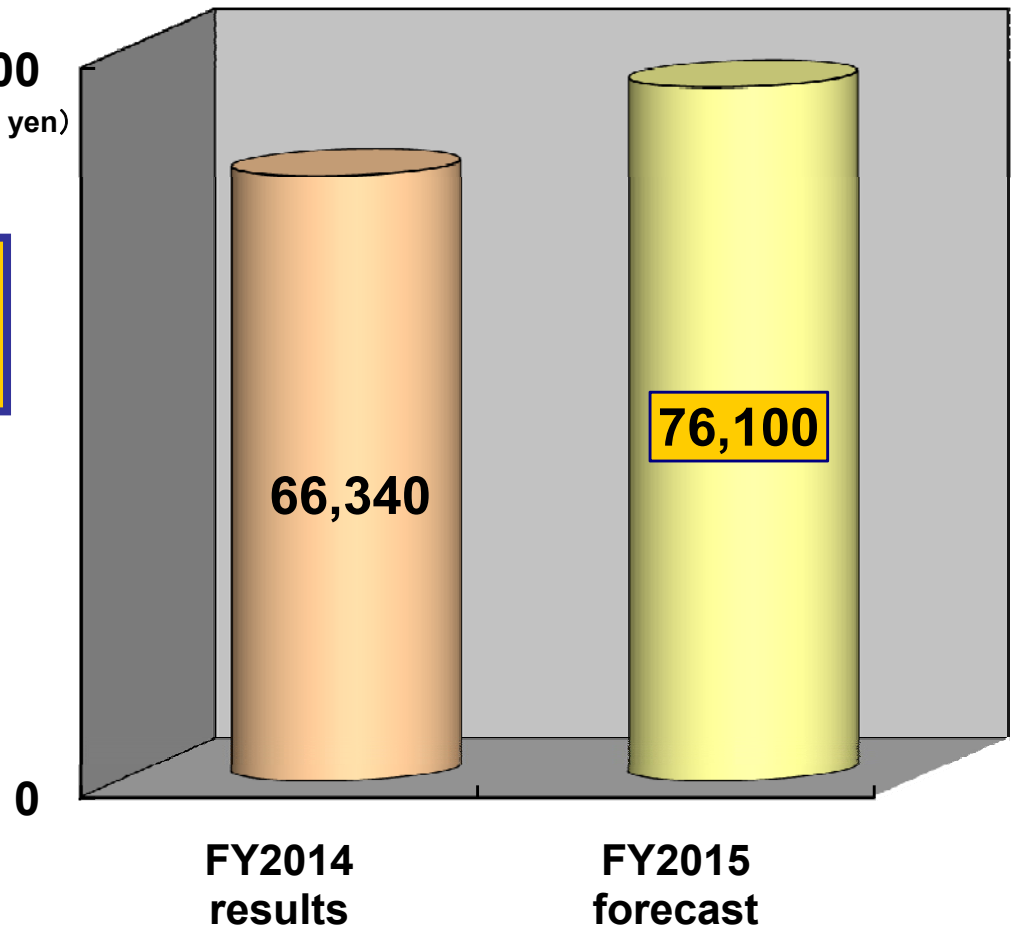


Segmental Forecast — Pharmaceuticals —

Net sales 76,100 million yen

**Year-on-Year change
+9,760 million yen (+14.7%)**

80,000
(Million yen)





Segmental Forecast

— Pharmaceuticals —

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	62,898	94.8%	70,050	92.0%	7,152	11.4%
Revenues from the licensing of industrial property rights	2,510	3.8%	5,000	6.6%	2,490	99.1%
Prulifloxacin	842	1.3%	750	1.0%	-92	- 11.0%
Contract manufacturing business	87	0.1%	300	0.4%	213	+242.3%
Net sales	66,340	100.0%	76,100	100.0%	9,760	14.7%

YoY change of new products (estimated)

- Zalutia (1,613 Million yen→10,000 Million yen, +519.9%)
- Tramal-Onetram (2,803 Million yen→5,200 Million yen, +85.5%)
- Vidaza (10,814 Million yen→11,500 Million yen, +6.3%)

Plan to launch

- Opumit (to be Launched in June 2015)
- Onetram (to be Launched in June 2015)

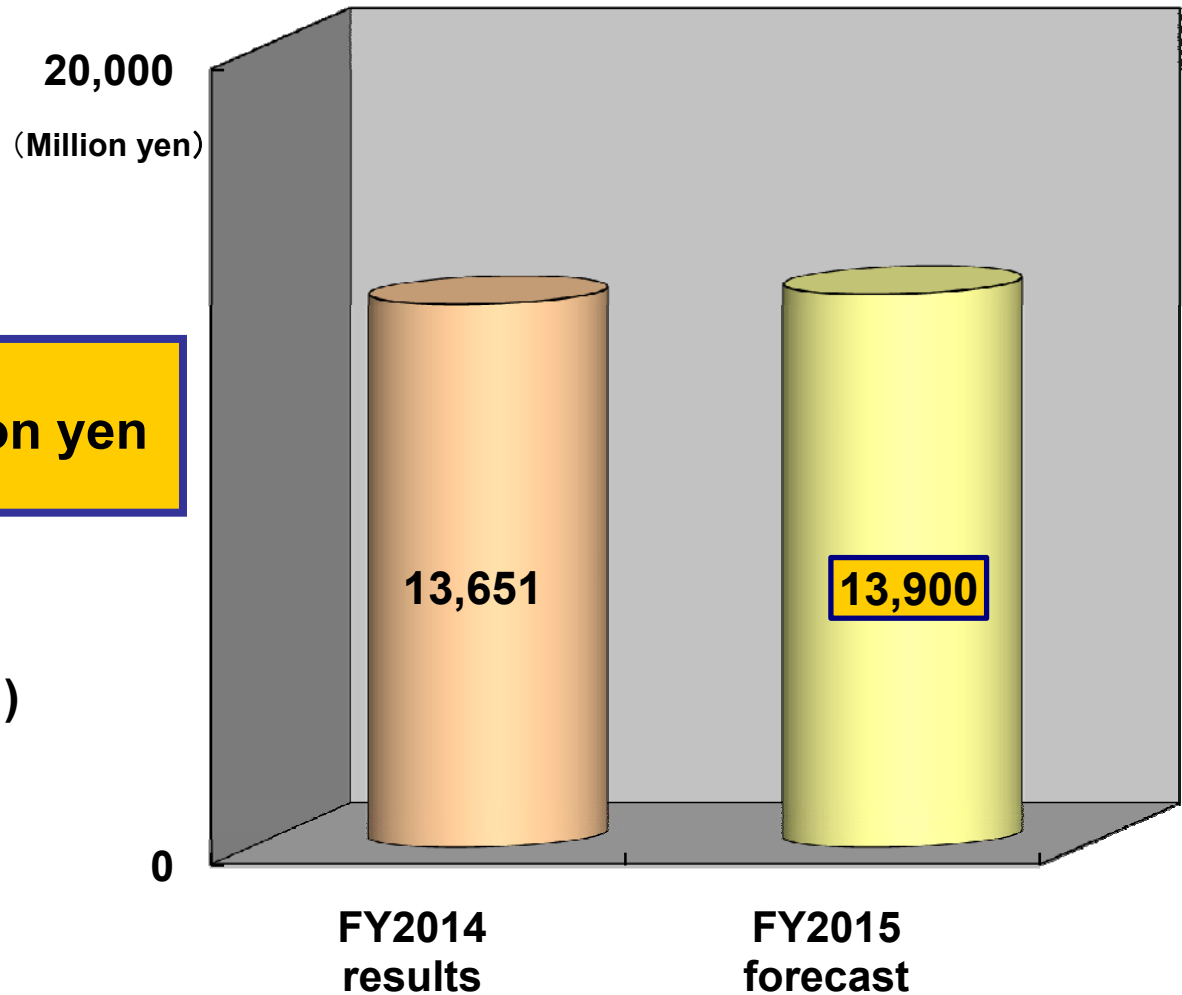


Segmental Forecast

— Functional Food —

Net sales 13,900 million yen

Year-on-Year change
+ 249 million yen (+1.8%)





Segmental Forecast

— Functional Food —

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	747	5.5%	830	6.0%	83	11.0%
Preservatives	1,886	13.8%	1,900	13.7%	14	0.7%
Protein preparations	7,290	53.4%	7,450	53.6%	160	2.2%
Nutritional ingredients	2,295	16.8%	2,320	16.7%	25	1.1%
Others	1,431	10.5%	1,400	10.0%	△ 31	△ 2.2%
Net sales	13,651	100.0%	13,900	100.0%	249	1.8%



Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue						
Net sales	79,991	100.0%	90,000	100.0%	10,009	12.5%
Pharmaceuticals	66,340	82.9%	76,100	84.6%	9,760	14.7%
Functional Food	13,651	17.1%	13,900	15.4%	249	1.8%
Operating expenses	71,429	89.3%	80,700	89.7%	9,271	13.0%
Cost of sales	41,226	51.5%	47,000	52.2%	5,774	
SG&A expenses	21,233	26.6%	23,000	25.6%	1,767	
R&D expenses	8,968	11.2%	10,700	11.9%	1,732	
Operating income	8,562	10.7%	9,300	10.3%	738	8.6%



Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	8,562	10.7%	9,300	10.3%	738	8.6%
Non-operating income	939	1.2%	900	1.0%	-39	- 4.2%
Non-operating expenses	573	0.7%	700	0.8%	127	22.0%
Ordinary income	8,928	11.2%	9,500	10.6%	572	6.4%
Income taxes	3,046	3.8%	2,800	3.1%	-246	- 8.1%
Net income	5,882	7.4%	6,700	7.4%	818	13.9%



Dividends Forecast

		FY2014	FY2015
Dividends per share	Interim	¥12	¥14
	Year-end	¥13	¥14
	Annual	¥25	¥28
EPS		¥87.26	¥99.43
Dividends payout ratio		28.7 %	28.2 %



Capital Investment Plan

(Million yen)

	FY2014 Results	FY2015 Forecast	Amt Chg
Capital investment	1,239	5,200	3960
Depreciation	2,665	2,500	-165

Breakdown of Capital investment

(Million yen)

	FY2014 Results	FY2015 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,160	5,050	3,889
Production	510	1,600	1,089
(Manufacturing facility for highly active medicines)	(-)	(1,000)	(1,000)
R&D	508	2,800	2,292
(Manufacturing facility for investigational drugs)	(19)	(1,850)	(1,830)
Others	140	650	509
<Sioe Pharmaceutical Co.,Ltd.>	14	50	35
<Tajima Shokuhin Kogyo Co.,Ltd.>	64	100	35
Total capital investment	1,239	5,200	3,960

Status of Development Pipeline



R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2013	FY2014	FY2015	FY2016
ACT-064992 (macitentan) <in-license>	NME	pulmonary arterial hypertension	Preparation for launching		NDA Filing	● approval	
NS-24 (tramadol hydrochloride) <in-license>	new formulation	cancer pain chronic pain	Preparation for launching		NDA Filing	● approval	
GA101 (obinutuzumab) <in-license>	NME	indolent non-Hodgkin's lymphoma aggressive non-Hodgkin's lymphoma	P III				
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	Preparation for NDA			NDA Filing	
		chronic thromboembolic pulmonary hypertension	P II				
		arteriosclerosis obliterans	P II				






R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2013	FY2014	FY2015	FY2016
NS-141 <in-house>	NME	pruritus associated with cutaneous disease	P II	P II →			
NS-986 <in-license>	NME	nocturia	P II	P II a →		P II b →	
NS-065/ NCNP-01 <in-house>	NME	duchenne muscular dystrophy	Preparation for P II			P II →	
NS-580 <in-house>	NME	endometriosis	P I			P I →	



R&D Compounds(Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2013	FY2014	FY2015	FY2016
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	US/EU Preparation for NDA	Actelion P III	 NDA Filing		
prulifloxacin <in-house>	NME	bacterial infections	China P III	Lee's Pharma P III	 NDA Filing		
NS-018 <in-house>	NME	myelofibrosis	US P I / II	 P I / II			



ACT-064992 (Macitentan)

- Treatment for PAH -

Development phase	<ul style="list-style-type: none">• Overseas: Approval [2013, Europe and USA]• Japan : Approval [Mar.2015 (Opsumit)]
Origin	[Feb.2010] Licensed-in from: Actelion Pharmaceuticals Ltd.(Switzerland)
Development	Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.
Indication	Pulmonary arterial hypertension
Mechanism of action	Tissue-specific dual endothelin receptor antagonist
Dosage form	Tablet
Feature	<ul style="list-style-type: none">• Less hepatic toxicity• Long-acting oral drug



NS-24 (Tramadol)

- Long-acting analgesic -

Development phase	Approval [Mar.2015 (Onetram)]
Origin	[Mar.2010] Licensed-in from: End Health Solution Inc. (Ireland) (available in 17 countries in the world)
Development	Nippon shinyaku
Indication	▪Cancer pain ▪Chronic pain
Dosage form	Sustained release tablet
Dosing regimen	Once a day
Feature	Long-acting analgesic with advantages of immediate release and sustained release



GA101 (Obinutuzumab)

- Treatment for non-Hodgkin's lymphoma -

Development Phase	<ul style="list-style-type: none">• Overseas: PIII (Multinational studies, Roche)• Japan: PIII (Multinational studies)
Origin	[Nov. 2012] Licensed-in from: Chugai Pharmaceutical Co., Ltd.
Development	Co-development in Japan: Chugai Pharmaceutical Co., Ltd.
Indication	<ul style="list-style-type: none">• Indolent non-Hodgkin's lymphoma• Aggressive non-Hodgkin's lymphoma
Mechanism of action	Anti-CD20 monoclonal antibody
Dosage form	Injection
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity



NS-304 (Selexipag)

- Treatment for pulmonary hypertension -

Development phase	<ul style="list-style-type: none">• Overseas: NDA filing• Japan : Preparation for NDA
Origin	<ul style="list-style-type: none">• Nippon Shinyaku
Development	<p>[Apr. 2008]</p> <ul style="list-style-type: none">• Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland)• Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.
Indication	<ul style="list-style-type: none">• Pulmonary arterial hypertension• Chronic thromboembolic pulmonary hypertension• Arteriosclerosis obliterans
Dosage form	Tablet
Mechanism of action	Selective PGI ₂ receptor agonist
Feature	Long-acting oral drug Orphan drug designation by EMA [Aug.2005], FDA [Apr.2010] and MHLW [Sep.2014]



NS-141

- Anti-pruritic drug -

Development phase	Additional PII (exploratory study)
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Pruritus associated with cutaneous disease
Dosage form	Ointment
Feature	<ul style="list-style-type: none">▪ New mechanism of action (not antihistaminic)▪ Effective against intractable pruritus which cannot be treated by existing treatments



NS-986

- Treatment for nocturia -

Development phase	PII (exploratory study) completed
Origin	[Mar.2013] Licensed-in from: Dainippon Sumitomo Pharma Co., Ltd.
Development	Nippon Shinyaku
Indication	Nocturia
Dosage form/ Dosing regimen	Tablet / Once a day
Mechanism of action	<ul style="list-style-type: none">▪ Muscarinic receptor antagonist▪ Na⁺ channel blocker
Feature	<ul style="list-style-type: none">▪ Rapid onset of effect▪ Improvement in nocturia refractory to existing antimuscarinic drugs



NS-065/NCNP-01

- Treatment for Duchenne Muscular Dystrophy -

Development Phase	An investigator-initiated clinical trial completed Preparation for PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Duchenne Muscular Dystrophy
Dosage form	Infusion
Mechanism of action	Exon Skipping
Feature	<ul style="list-style-type: none">• Improvement in symptoms and prevention of the disease progression by recovery of Dystrophin protein expression• morpholino based oligonucleotide with possible high safety profile and maximized activity



NS-580

- Treatment for endometriosis -

Development Phase	PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Endometriosis
Dosage form	Oral agent
Mechanism of action	Inhibition of membrane-associated prostaglandin E synthase-1
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency



Prulifloxacin

- Quinolone antibacterial -

Japan

Licensee	Development phase
• Meiji Seika Pharma Co., Ltd.	• Launch (Dec. 2002) / Sword® Tablets

Overseas

Licensee	Development phase
• Angelini (Italy)	<ul style="list-style-type: none"> • Approval (Sep. 2004) • Launch in Italy (Nov. 2004) • Approval in European countries (Apr. 2005)
• Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	• PIII (Jul. 2013)
• Algorithm (Lebanon)	<ul style="list-style-type: none"> • Launch in Lebanon (Jan. 2012) • NDA filing in 5 countries and preparation for NDA in 6 countries of the Middle East and North Africa



NS-018

- Treatment for myelofibrosis -

Development Phase	Overseas (USA): PI/II
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Myelofibrosis
Dosage form	Tablet
Mechanism of action	JAK2 tyrosine kinase inhibitor
Feature	<ul style="list-style-type: none">▪ Highly selective for active form of JAK2 tyrosine kinase▪ Possibly best-in-class treatment for myelofibrosis



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