

# Outline of Consolidated Financial Results for the Year Ended March 31, 2016

May 16, 2016  
NIPPON SHINYAKU CO., LTD.



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# FY2015 Summary

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	79,991	100.0%	84,209	100.0%	4,218	5.3%
Operating income	8,562	10.7%	8,549	10.2%	-13	-0.2%
Ordinary income	8,928	11.2%	8,952	10.6%	24	0.3%
Net income attributable to owners of the parent	5,882	7.4%	6,340	7.5%	458	7.8%

## Topics

### ◆NS-304 (Selexipag) ...

USA: Launched in January 2016

EU: In April 2016, a procedural re-adoption of recommendation for the Authorization by Committee for Medical Agency for Human Use (CHMP)

Japan: In January 2016, New Drug Application for PAH

### ◆NS-065 ... Japan: "SAKIGAKE" Designation in October 2015

Commencement of Phase I / II study in January 2016

USA: Commencement of exploratory Phase II in March 2016

### ◆Onetram tablet 100mg, Opsumit tablet 10mg ... launched in June 2015

### ◆Completion of API manufacturing building for clinical trials in March 2016



# Segmental Review

## -Pharmaceuticals-

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	63,172	95.2%	66,040	93.7%	2,868	4.5%
Profit in co-promotion	-	-	393	0.5%	393	-
Revenues from the licensing of industrial Active Pharmaceutical Ingredients	2,510	3.8%	3,208	4.6%	698	27.8%
Net sales	66,340	100.0%	70,489	100.0%	4,149	6.3%

### Increased in sales:

- **Zaltia (+4,025 million yen, +249.5%)**  
(urinary disorder caused by benign prostatic hyperplasia (BPH))
- **Vidaza (+1,546 million yen, +14.3%)**  
(myelodysplastic syndromes)
- **Profit of industrial property rights:**  
Out-licensed original product, approved in USA

### Decreased in sales

- **Eviprostat (-1,349 million yen, -24.2%) (BPH)**
- **GaslonN (-676 million yen, -18.4%)**  
(gastric ulcer, gastritis)



# Segmental Review

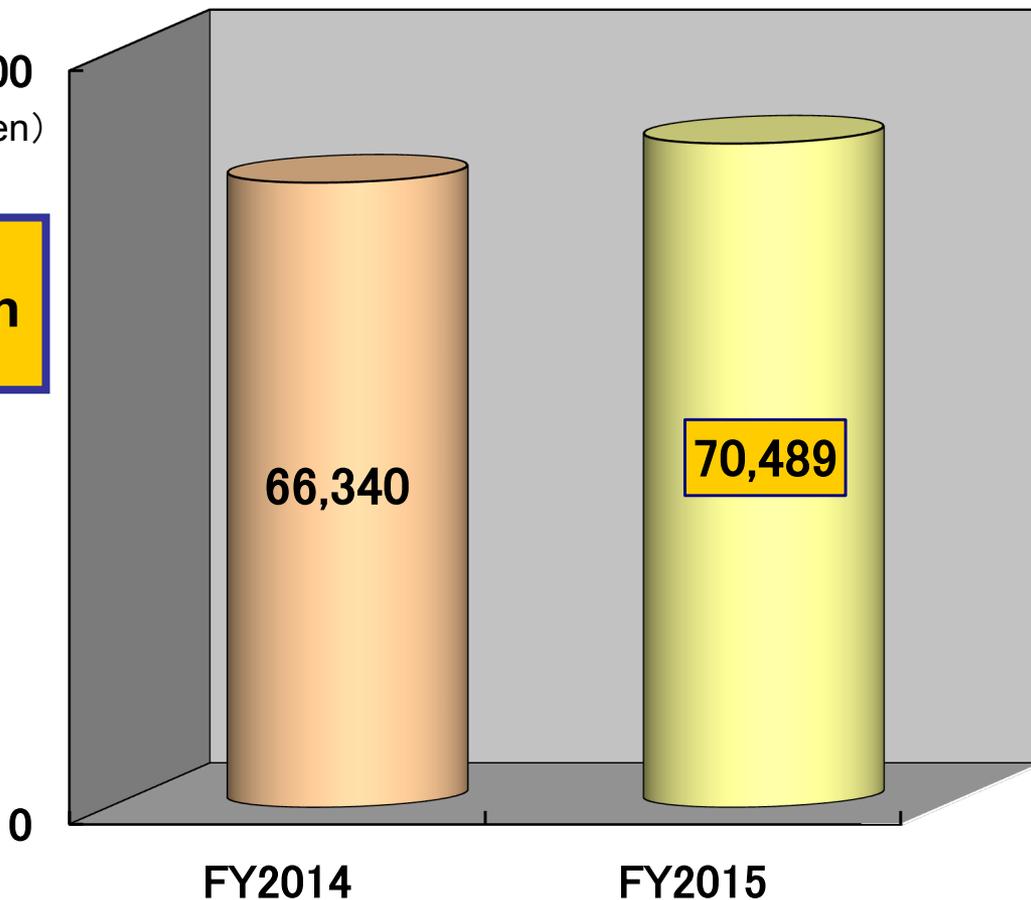
## -Pharmaceuticals-

80,000  
(million yen)

**Net sales 70,489 million yen**

**Year-on-Year change**

**+4,149 million yen (+6.3%)**





# Segmental Review

## -Functional Food-

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	747	5.5%	827	6.0%	79	10.6%
Preservatives	1,886	13.8%	1,906	13.9%	19	1.0%
Protein preparations	7,284	53.4%	7,403	54.0%	118	1.6%
Nutritional ingredients	2,301	16.9%	2,198	16.0%	-103	-4.5%
Others	1,430	10.4%	1,385	10.1%	-45	-3.2%
Net sales	13,651	100.0%	13,720	100.0%	68	0.5%



# Segmental Review

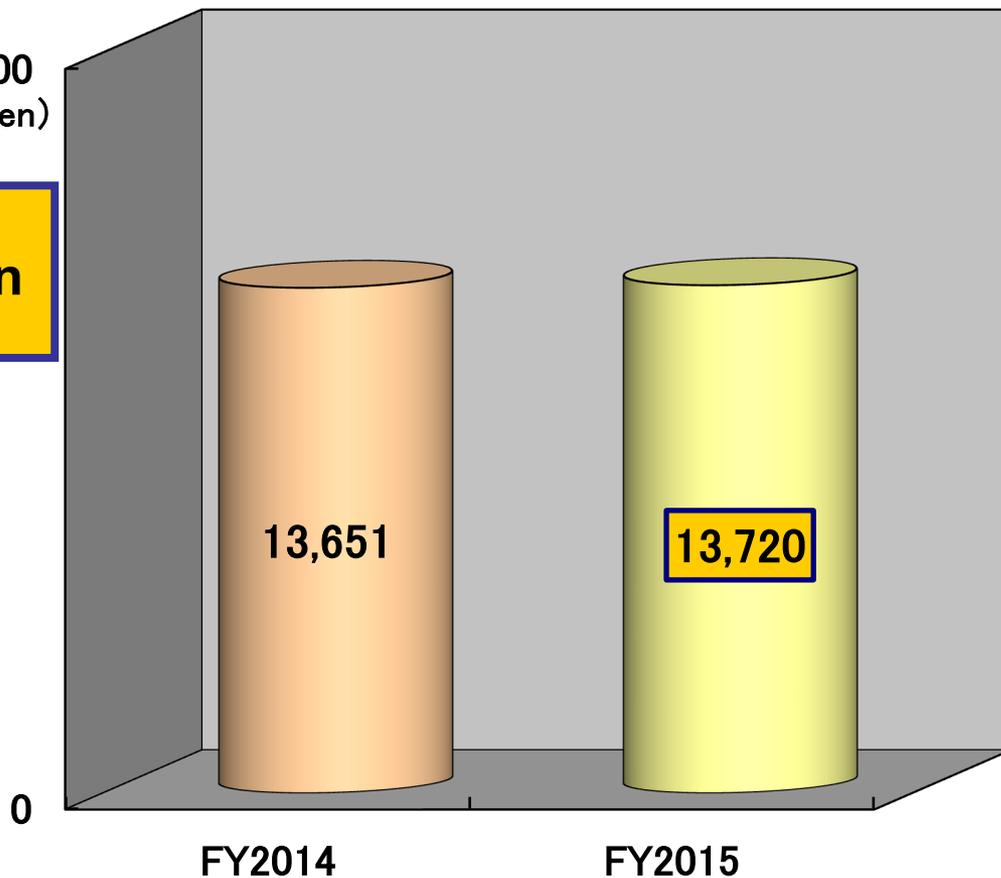
## -Functional Food-

20,000  
(million yen)

**Net sales 13,720 million yen**

**Year-on-Year change**

**+68 million yen (+0.5%)**





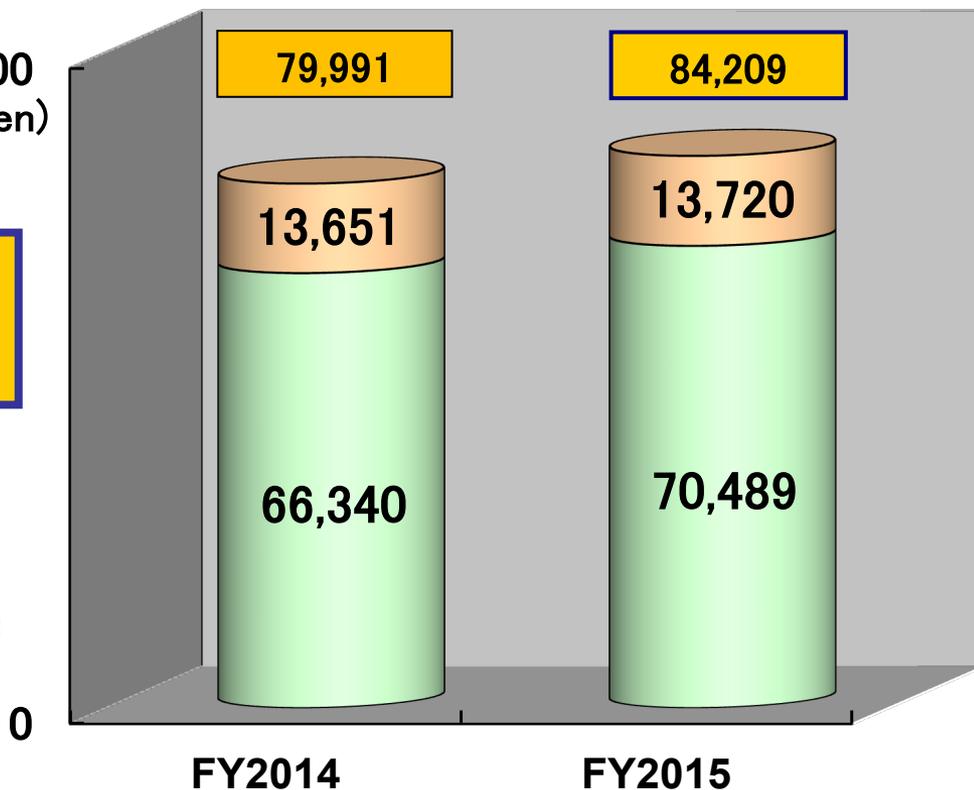
# Net Sales

100,000  
(million yen)

**Net sales 84,209 million yen**

**Year-on-Year change**

**+4,218 million yen (+5.3%)**



■ Pharmaceuticals  
■ Functional Food



# Consolidated Statements of Income

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	79,991	100.0%	84,209	100.0%	4,218	5.3%
Pharmaceuticals	66,340	82.9%	70,489	83.7%	4,149	6.3%
Functional Food	13,651	17.1%	13,720	16.3%	68	0.5%
<b>Operating expenses</b>	71,429	89.3%	75,660	89.8%	4,231	5.9%
Cost of sales	41,226	51.5%	44,016	52.3%	2,790	
SG&A expenses	21,233	26.6%	21,904	25.9%	670	
R&D expenses	8,968	11.2%	9,739	11.6%	770	
<b>Operating income</b>	8,562	10.7%	8,549	10.2%	-13	-0.2%



# Consolidated Statements of Income

(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	8,562	10.7%	8,549	10.2%	-13	-0.2%
Non-operating income	939	1.2%	1,246	1.5%	306	32.6%
Non-operating expenses	573	0.7%	842	1.1%	268	46.9%
Ordinary income	8,928	11.2%	8,952	10.6%	24	0.3%
Income taxes	3,046	3.8%	2,612	3.1%	-433	-14.2%
Net income attributable to owners of the parent	5,882	7.4%	6,340	7.5%	458	7.8%



# Dividends

		FY2014	FY2015
Dividends per share	Interim	¥12	¥14
	Year-end	¥13	¥14
	Annual	¥25	¥28
EPS		¥87.26	¥94.10
Dividends payout ratio		28.7 %	29.8 %
DOE		1.7 %	1.9 %



# Consolidated Balance Sheet

(Million yen)

	FY2014	FY2015	YoY Change		FY2014	FY2015	YoY Change
	4Q	4Q	Amt		4Q	4Q	Amt
<b>Assets</b>	129,757	135,370	5,612	<b>Liabilities</b>	28,550	32,607	4,057
(Current assets)	80,422	85,401	4,978	(Current liabilities)	17,770	20,569	2,798
(Fixed assets)	49,334	49,968	633	(Long-term liabilities)	10,779	12,037	1,258
				<b>Net assets</b>	101,207	102,762	1,554
<b>Total Assets</b>	129,757	135,370	5,612	<b>Total liabilities and net assets</b>	129,757	135,370	5,612



# Consolidated Statements of Cash Flows

(Million yen)

	FY2014	FY2015	YoY Change
	Results	Results	Amt
Operating activities	6,113	8,915	2,802
Investing activities	-3,718	-3,978	-260
Financing activities	-1,773	-1,907	-134
Cash and cash equivalents at end of year	21,914	24,748	2,833



# Capital Investment

(Million yen)

	FY2014	FY2015	
	Results	Results	Amt Chg
Capital investment	1,239	3,554	2,315
Depreciation	2,665	2,452	-213

## Breakdown of Capital Investment

(Million yen)

	FY2014	FY2015	
	Results	Results	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,160	3,445	2,285
Production	510	674	163
(Manufacturing facility for highly active medicines)	(-)	(108)	(108)
R&D	508	2,460	1,951
(Manufacturing facility for investigational drugs)	(19)	(1,793)	(1,774)
Others	140	311	170
<Consolidated subsidiary>	79	109	29
<b>Total capital investment</b>	<b>1,239</b>	<b>3,554</b>	<b>2,315</b>



# Business Forecast for FY2016

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	84,209	100.0%	93,000	100.0%	8,791	10.4%
Operating income	8,549	10.2%	11,500	12.4%	2,951	34.5%
Ordinary income	8,952	10.6%	11,900	12.8%	2,948	32.9%
Net income attributable to owners of the parent	6,340	7.5%	8,500	9.1%	2,160	34.1%



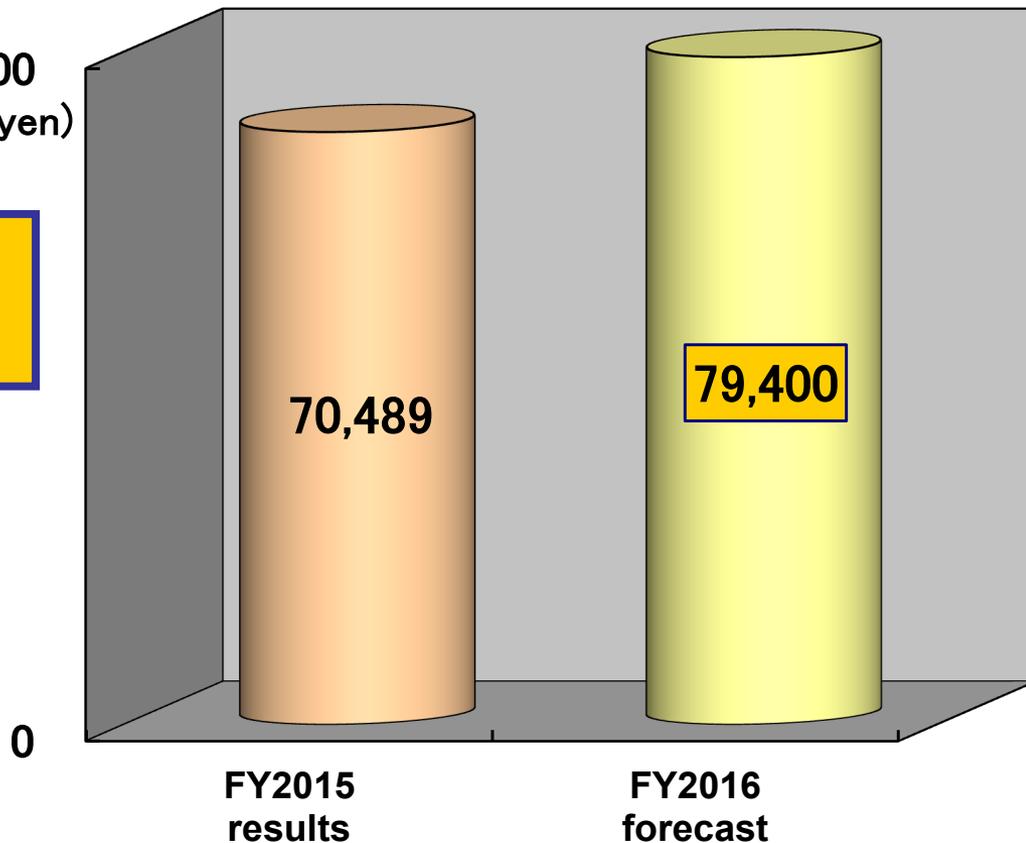
# Segmental Business Forecast -Pharmaceuticals-

80,000  
(million yen)

**Net sales 79,400 million yen**

**Year-on-Year change**

**+8,911 million yen (+12.6%)**





# Segmental Forecast -Pharmaceuticals-

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
<b>Ethical drugs</b>	<b>66,040</b>	<b>93.7%</b>	<b>65,600</b>	<b>82.6%</b>	<b>-440</b>	<b>-0.7%</b>
<b>Profit in co-promotion</b>	<b>393</b>	<b>0.5%</b>	<b>2,000</b>	<b>2.5%</b>	<b>1,607</b>	<b>407.9%</b>
<b>Revenues from the licensing of industrial Active Pharmaceutical Ingredients</b>	<b>3,208</b>	<b>4.6%</b>	<b>5,000</b>	<b>6.3%</b>	<b>1,792</b>	<b>55.8%</b>
	<b>846</b>	<b>1.2%</b>	<b>6,800</b>	<b>8.6%</b>	<b>5,954</b>	<b>702.9%</b>
<b>Net sales</b>	<b>70,489</b>	<b>100.0%</b>	<b>79,400</b>	<b>100.0%</b>	<b>8,911</b>	<b>12.6%</b>

## Growth of new products

- Zaltia (5,638 million yen → 10,000 million yen, +77.4%)
- Tramal·Onetram (4,306 million yen → 6,900 million yen, +60.2%)
- Vidaza (12,360 million yen → 13,000 million yen, +5.2%)



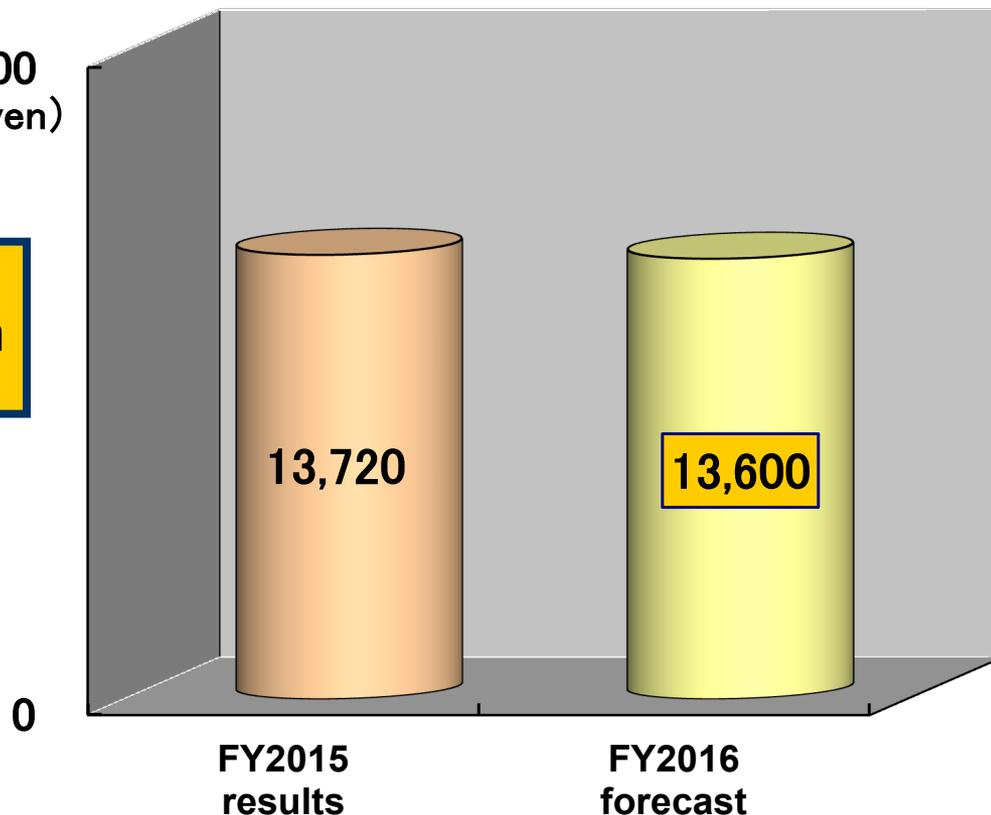
# Segmental Forecast -Functional Food-

**Net sales 13,600 million yen**

**Year-on-Year Change**

**-120 million yen (-0.9%)**

20,000  
(million yen)





# Segmental Forecast -Functional Food-

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	827	6.0%	980	7.2%	153	18.5%
Preservatives	1,906	13.9%	2,100	15.4%	194	10.2%
Protein preparations	7,403	54.0%	7,350	54.0%	-53	-0.7%
Nutritional ingredients	2,198	16.0%	1,790	13.2%	-408	-18.6%
Others	1,385	10.1%	1,380	10.2%	-5	-0.4%
Net sales	13,720	100.0%	13,600	100.0%	-120	-0.9%



# Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	84,209	100.0%	93,000	100.0%	8,791	10.4%
Pharmaceuticals	70,489	83.7%	79,400	85.4%	8,911	12.6%
Functional Food	13,720	16.3%	13,600	14.6%	-120	-0.9%
<b>Operating expenses</b>	75,660	89.8%	81,500	87.6%	5,840	7.7%
Cost of sales	44,016	52.3%	44,300	47.6%	284	
SG&A expenses	21,904	25.9%	23,300	25.1%	1,396	
R&D expenses	9,739	11.6%	13,900	14.9%	4,161	
<b>Operating income</b>	8,549	10.2%	11,500	12.4%	2,951	34.5%



# Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	8,549	10.2%	11,500	12.4%	2,951	34.5%
Non-operating income	1,246	1.5%	800	0.9%	-446	-35.8%
Non-operating expenses	842	1.1%	400	0.4%	-442	-52.5%
Ordinary income	8,952	10.6%	11,900	12.8%	2,948	32.9%
Income taxes	2,612	3.1%	3,400	3.7%	788	30.1%
Net income attributable to owners of the parent	6,340	7.5%	8,500	9.1%	2,160	34.1%



# Dividends Forecast

		FY2015	FY2016
Dividends per share	Interim	¥14	¥17
	Year-end	¥14	¥18
	Annual	¥28	¥35
EPS		¥94.10	¥126.18
Dividends payout ratio		29.8 %	27.7 %



# Capital Investment Plan

(Million yen)

	FY2015 Results	FY2016 Forecast	Amt Chg
Capital investment	3,554	3,600	46
Depreciation	2,452	2,800	348

## Breakdown of Capital investment

(Million yen)

	FY2015 Results	FY2016 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	3,445	3,500	55
Production	674	2,450	1,776
(Manufacturing facility for highly active medicines)	(108)	(1,969)	(1,861)
R&D	2,460	650	-1,810
Others	311	400	89
<Consolidated subsidiary>	109	100	-9
<b>Total capital investment</b>	<b>3,554</b>	<b>3,600</b>	<b>46</b>

# Status of Development Pipeline



# R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2014	FY2015	FY2016	FY2017
NS-304 (selexipag) <in-house>	NME	Pulmonary arterial hypertension	NDA Filing				
		Chronic thromboembolic pulmonary hypertension	P II				
		Arteriosclerosis obliterans	P II				
GA101 (obinutuzumab) <in-license>	NME	Indolent non-Hodgkin's lymphoma Aggressive non-Hodgkin's lymphoma	P III				NDA Filing
NS-141 <in-house>	NME	Pruritus associated with cutaneous disease	P II				
NS-065 <in-house>	NME	Duchenne muscular dystrophy	P I / II				
NS-580 <in-house>	NME	Endometriosis	P I				



# R&D Compounds(Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2014	FY2015	FY2016	FY2017
NS-304 (selexipag) <in-house>	NME	Pulmonary arterial hypertension	USA Approval EU NDA Filing	Actelion NDA Filing			
prulifloxacin <in-house>	NME	Bacterial infections	China Preparation for NDA	Lee's Pharma		NDA Filing	
NS-018 <in-house>	NME	Myelofibrosis	USA P I / II	P I / II			
NS-065 <in-house>	NME	Duchenne muscular dystrophy	USA P II			P II	



# NS-304 (Selexipag)

- Treatment for pulmonary hypertension -

Development phase	<ul style="list-style-type: none"><li>•USA: Launch</li><li>•EU: NDA filing</li><li>•Japan: NDA filing</li></ul>
Origin	<ul style="list-style-type: none"><li>•Nippon Shinyaku</li></ul>
Development	[Apr. 2008] <ul style="list-style-type: none"><li>•Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland)</li><li>•Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.</li></ul>
Mechanism of action	Selective PGI <sub>2</sub> receptor agonist
Indication	<ul style="list-style-type: none"><li>•Pulmonary arterial hypertension</li><li>•Chronic thromboembolic pulmonary hypertension</li><li>•Arteriosclerosis obliterans</li></ul>
Dosage form	Tablet
Feature	Long-acting oral drug



# GA101 (Obinutuzumab)

- Treatment for non-Hodgkin's lymphoma -

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



# 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"><li>▪ New mechanism of action (not antihistaminic)</li><li>▪ Effective against intractable pruritus which cannot be treated by existing treatments</li></ul>



# NS-065

## - Treatment for Duchenne Muscular Dystrophy -

Development Phase	▪USA: PII ▪Japan: PI/II
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Exon Skipping
Indication	Duchenne Muscular Dystrophy
Dosage form	Infusion
Feature	▪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
Mechanism of action	Inhibition of membrane-associated prostaglandin E synthase-1
Indication	Endometriosis
Dosage form	Oral agent
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"> <li>• Approval (Sep. 2004)</li> <li>• Launch in Italy (Nov. 2004)</li> <li>• Approval in European countries (Apr. 2005)</li> </ul>
• Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	• Preparation for NDA
• Algorithm (Lebanon)	<ul style="list-style-type: none"> <li>• Launch in Lebanon (Jan. 2012)</li> <li>• NDA filing in 6 countries and preparation for NDA in 1 countries</li> </ul>



# NS-018

## - Treatment for myelofibrosis -

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



# Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion or failure of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination, obtaining regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
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