

# Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2016

November 10, 2016  
NIPPON SHINYAKU CO., LTD.



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**NIPPON SHINYAKU CO., LTD.**



# 1H FY2016 Summary

( Million yen )

	1H FY2015		1H FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	39,413	100.0%	44,504	100.0%	5,090	12.9%
Operating income	2,110	5.4%	6,492	14.6%	4,382	207.7%
Ordinary income	2,335	5.9%	6,131	13.8%	3,795	162.5%
Net income attributable to owners of the parent	1,523	3.9%	4,483	10.1%	2,960	194.3%

## Topics

### ◆NS-304 (Selexipag) . . .

Europe: Approval in May 2016, first launch in June 2016

Japan : Orphan drug designation by MHLW for CTEPH in June 2016  
Approval for PAH in September 2016

### ◆NS-065/NCNP-01 . . . Fast track designation by FDA in October 2016



# Segmental Review

## -Pharmaceuticals-

( Million yen )

	1H FY2015		1H FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	31,635	98.0%	32,147	85.5%	512	1.6%
Profit in co-promotion	18	0.1%	988	2.6%	969	5,172.8%
Revenues from the licensing of industrial property rights	115	0.4%	4,196	11.2%	4,081	3,544.3%
Active Pharmaceutical Ingredients	474	1.5%	249	0.7%	-225	-47.5%
<b>Net sales</b>	<b>32,244</b>	<b>100.0%</b>	<b>37,582</b>	<b>100.0%</b>	<b>5,338</b>	<b>16.6%</b>

### Increase in sales:

- **Zalutia ( +1,514million yen , +65.2% )**  
(urinary disorder caused by benign prostatic hyperplasia)
- **Tramal, Onetram ( +707million yen, +33.7% )**  
(cancer pain, chronic pain)
- **Vidaza ( +653 million yen, +10.8% )**  
(myelodysplastic syndromes)
- **Contribution of milestone payment on European approval and royalty payments based on overseas sales of our original product selexipag**

### Decrease in sales:

- **Lunabell ( -753million yen, -21.6% )**  
(Remedy for dysmenorrhea)
- **Eviprostat ( -440 million yen, -20.2% )**  
(Remedy for benign prostatic hyperplasia)

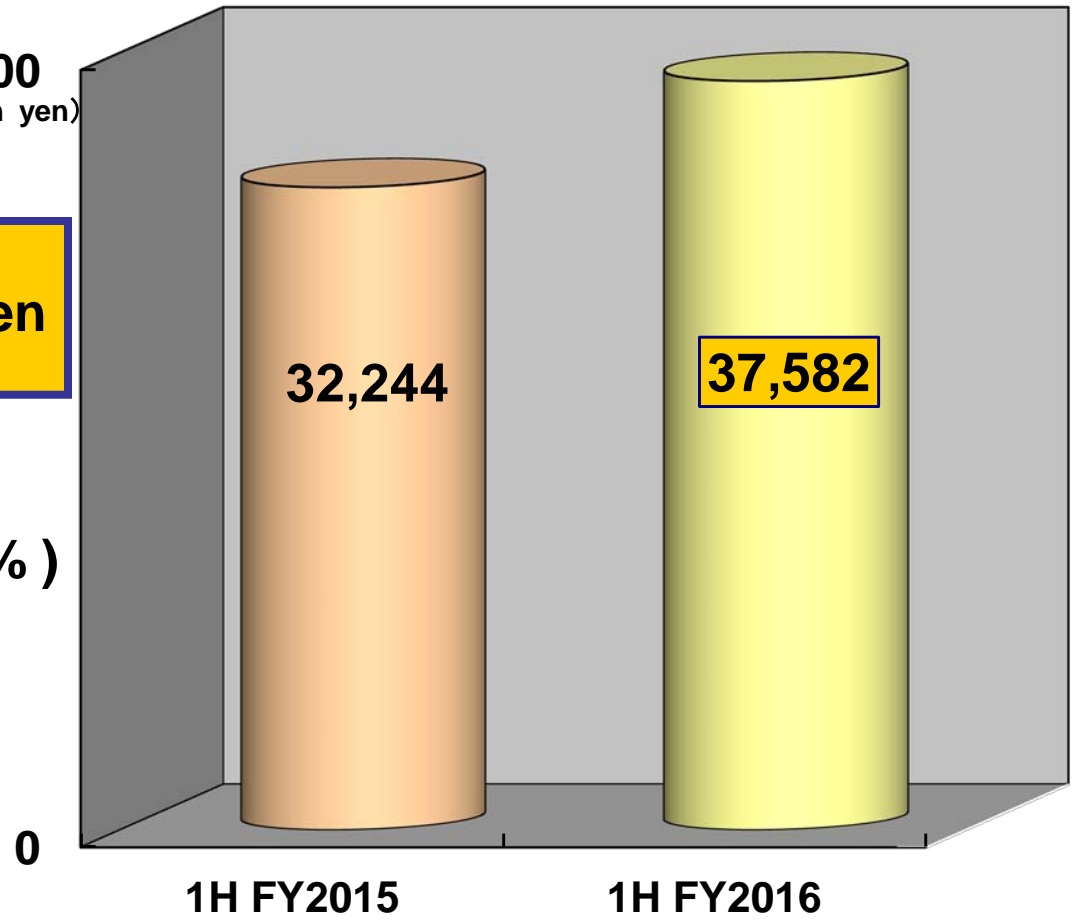


# Segmental Review -Pharmaceuticals-

**Net sales 37,582 million yen**

**Year-on-Year change  
+ 5,338 million yen ( +16.6% )**

**39,000**  
(Million yen)





# Segmental Review

## -Functional Food-

(Million yen)

	1H FY2015		1H FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	419	5.9%	395	5.7%	-24	-5.9%
Preservatives	923	12.9%	1,073	15.5%	150	16.3%
Protein preparations	3,873	54.0%	3,847	55.6%	-26	-0.7%
Nutritional ingredients	1,222	17.0%	891	12.9%	-330	-27.0%
Others	730	10.2%	714	10.3%	-16	-2.2%
Net sales	7,169	100.0%	6,922	100.0%	-247	-3.4%

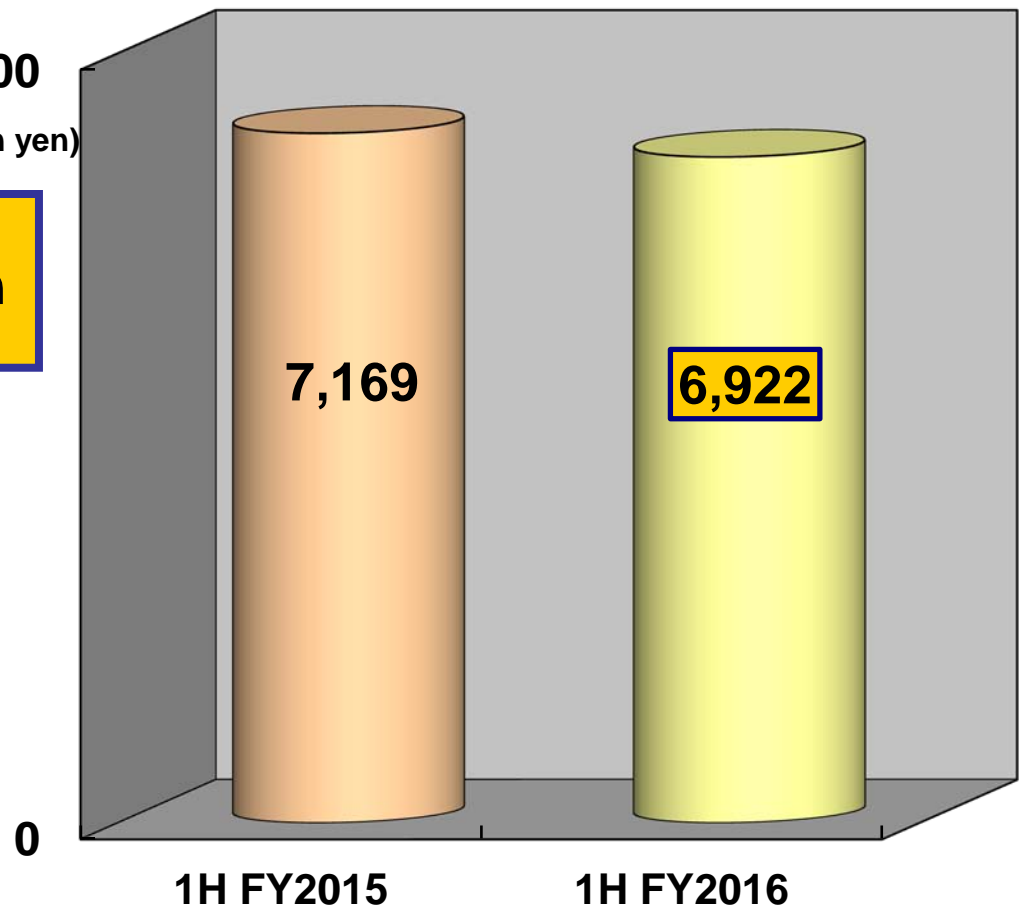


# Segmental Review

## -Functional Food-

**Net sales 6,922 million yen**

**Year-on-Year change**  
**-247 million yen ( -3.4% )**



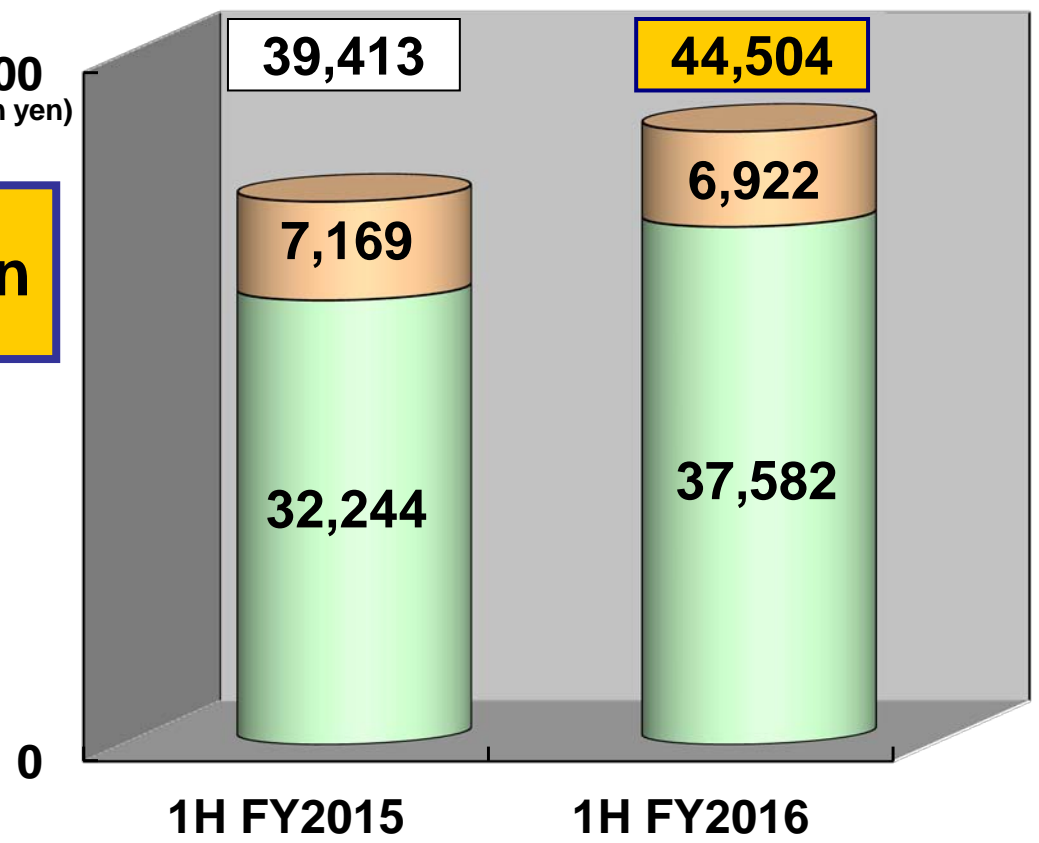


# Net Sales

**Net sales 44,504 million yen**

Year-on-Year change  
+ 5,090 million yen ( +12.9% )

50,000  
(Million yen)



- Functional Food
- Pharmaceuticals





# Consolidated Statements of Income (1)

(Million yen)

	1H FY2015		1H FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	<b>39,413</b>	<b>100.0%</b>	<b>44,504</b>	<b>100.0%</b>	<b>5,090</b>	<b>12.9%</b>
Pharmaceuticals	32,244	81.8%	37,582	84.4%	5,338	16.6%
Functional Food	7,169	18.2%	6,922	15.6%	-247	-3.4%
<b>Operating expenses</b>	<b>37,303</b>	<b>94.6%</b>	<b>38,011</b>	<b>85.4%</b>	<b>707</b>	<b>1.9%</b>
Cost of sales	21,569	54.7%	21,825	49.0%	256	
SG&A expenses	11,008	27.9%	11,133	25.0%	124	
R&D expenses	4,725	12.0%	5,052	11.4%	327	
<b>Operating income</b>	<b>2,110</b>	<b>5.4%</b>	<b>6,492</b>	<b>14.6%</b>	<b>4,382</b>	<b>207.7%</b>



# Consolidated Statements of Income (2)

(Million yen)

	1H FY2015		1H FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	2,110	5.4%	6,492	14.6%	4,382	207.7%
Non-operating income	483	1.2%	534	1.2%	51	10.6%
Non-operating expenses	258	0.7%	896	2.0%	638	247.3%
Ordinary income	2,335	5.9%	6,131	13.8%	3,795	162.5%
Income taxes, etc	812	2.0%	1,647	3.7%	835	102.8%
Net income attributable to owners of the parent	1,523	3.9%	4,483	10.1%	2,960	194.3%



# Consolidated Balance Sheet

(Million yen)

	FY2015	FY2016	Change		FY2015	FY2016	Change
	4Q Results	2Q Results	Amt		4Q Results	2Q Results	Amt
<b>Assets</b>	135,370	135,217	-152	<b>Liabilities</b>	32,607	29,255	-3,352
<b>(Current assets)</b>	85,401	86,072	671	<b>(Current liabilities)</b>	20,569	18,216	-2,353
<b>(Fixed assets)</b>	49,968	49,145	-823	<b>(Long-term liabilities)</b>	12,037	11,038	-999
				<b>Net assets</b>	102,762	105,962	3,200
<b>Total assets</b>	135,370	135,217	-152	<b>Total liabilities and net assets</b>	135,370	135,217	-152



# Consolidated Statements of Cash Flows

( Million yen )

	1H FY2015	1H FY2016	YoY Change
	Results	Results	Amt
Operating activities	-271	6,718	6,989
Investing activities	-1,554	-3,190	-1,635
Financing activities	-916	-947	-31
Cash and cash equivalents at end of quarter	19,192	26,964	7,772

Cash and cash equivalents at end of quarter : + 2,216 Million yen (YoY FY2015)



# Capital Investment

## Capital Investment and Depreciation

(Million yen)

	1H FY2015	1H FY2016	
	Results	Results	Amt Chg
Capital investment	1,157	1,512	355
Depreciation	1,184	1,353	169

## Breakdown of Capital Investment

(Million yen)

	1H FY2015	1H FY2016	
	Results	Results	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,102	1,496	393
Production	345	1,027	682
(Manufacturing facility for highly active medicines)	( - )	(944)	(944)
R&D	677	313	-364
Others	80	156	75
<Consolidated subsidiary>	54	16	-38
<b>Total capital investment</b>	<b>1,157</b>	<b>1,512</b>	<b>355</b>



# Business Forecast for FY2016

(Million yen)

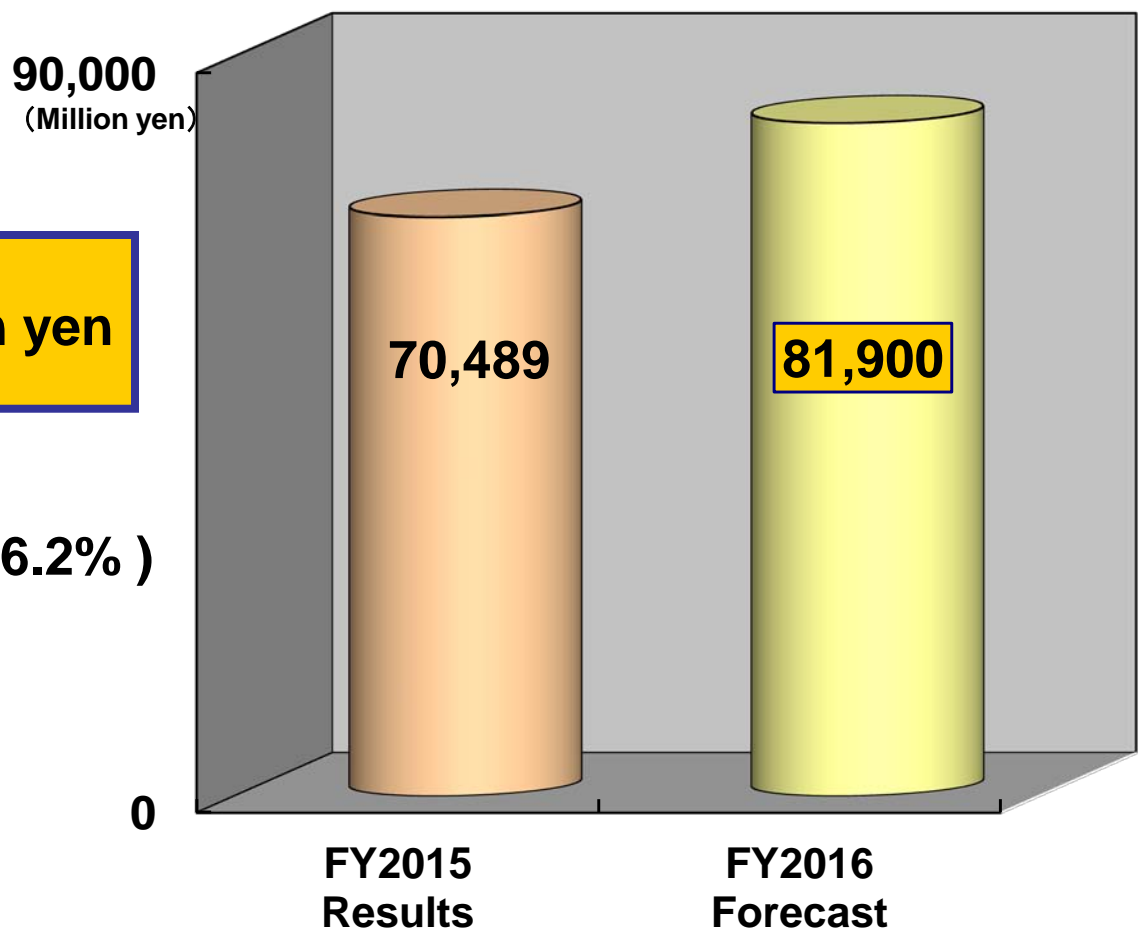
	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	84,209	100.0%	95,500	100.0%	11,291	13.4%
Operating income	8,549	10.2%	13,500	14.1%	4,951	57.9%
Ordinary income	8,952	10.6%	13,300	13.9%	4,348	48.6%
Net income attributable to owners of the parent	6,340	7.5%	9,000	9.4%	2,660	42.0%



# Segmental Forecast -Pharmaceuticals-

**Net sales 81,900 million yen**

**Year-on-Year change  
+11,411 million yen ( +16.2% )**





# Segmental Forecast

## -Pharmaceuticals-

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	66,040	93.7%	66,800	81.5%	760	1.2%
Profit in co-promotion	393	0.5%	2,300	2.8%	1,907	484.1%
Revenues from the licensing of industrial property rights	3,208	4.6%	6,600	8.1%	3,392	105.7%
Active Pharmaceutical Ingredients	846	1.2%	6,200	7.6%	5,354	632.0%
<b>Net sales</b>	<b>70,489</b>	<b>100.0%</b>	<b>81,900</b>	<b>100.0%</b>	<b>11,411</b>	<b>16.2%</b>

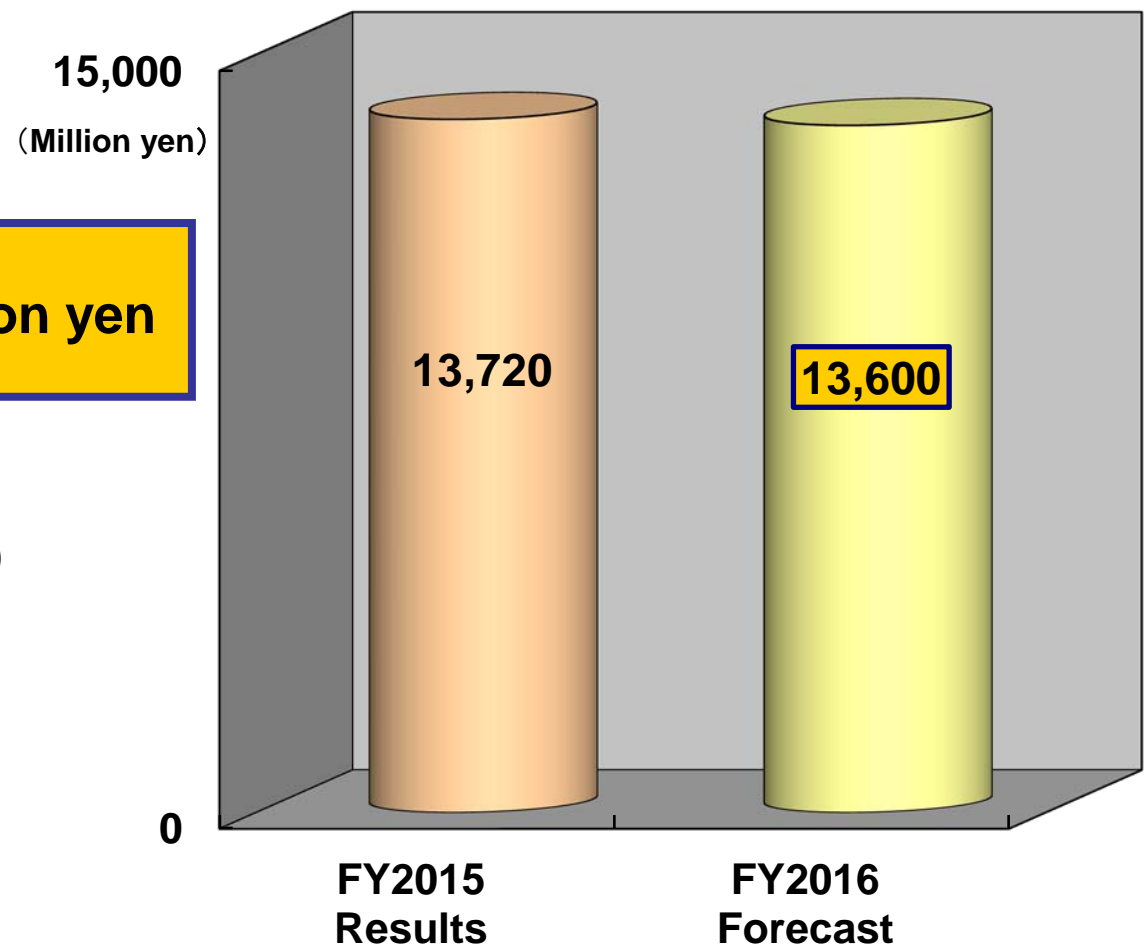




# Segmental Forecast -Functional Food-

**Net sales 13,600 million yen**

**Year-on-Year change  
- 120 million yen ( -0.9% )**





# 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%
<b>Net sales</b>	<b>13,720</b>	<b>100.0%</b>	<b>13,600</b>	<b>100.0%</b>	<b>-120</b>	<b>-0.9%</b>



# 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%	95,500	100.0%	11,291	13.4%
Pharmaceuticals	70,489	83.7%	81,900	85.8%	11,411	16.2%
Functional Food	13,720	16.3%	13,600	14.2%	-120	-0.9%
<b>Operating expenses</b>	75,660	89.8%	82,000	85.9%	6,340	8.4%
Cost of sales	44,016	52.3%	44,800	46.9%	784	
SG&A expenses	21,904	25.9%	23,300	24.4%	1,396	
R&D expenses	9,739	11.6%	13,900	14.6%	4,161	
<b>Operating income</b>	8,549	10.2%	13,500	14.1%	4,951	57.9%



# Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	8,549	10.2%	13,500	14.1%	4,951	57.9%
Non-operating income	1,246	1.5%	900	0.9%	-346	-27.8%
Non-operating expenses	842	1.1%	1,100	1.1%	258	30.5%
Ordinary income	8,952	10.6%	13,300	13.9%	4,348	48.6%
Extraordinary loss	-	-	750	0.8%	750	-
Income taxes, etc	2,612	3.1%	3,550	3.7%	938	35.9%
Net income attributable to owners of the parent	6,340	7.5%	9,000	9.4%	2,660	42.0%



# Dividends Forecast

		FY2015	FY2016
Dividends per share	Interim	¥14	¥18
	Year-end	¥14	¥19
	Annual	¥28	¥37
EPS		¥94.10	¥133.61
Dividends payout ratio		29.8%	27.7%



# Capital Investment Plan

## Capital Investment and Depreciation

(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)	(1,900)	(1,792)
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 Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2014	FY2015	FY2016	FY2017
NS-304 (selexipag) <in-house>	NME	Pulmonary arterial hypertension	Preparation for launching	NDA Filing		● approval	
		Chronic thromboembolic pulmonary hypertension	PIII	PII	PIII		
		Arteriosclerosis obliterans	PII	PII			
GA101 (obinutuzumab) <in-license>	NME	Indolent non-Hodgkin's lymphoma	PIII	PIII		NDA Filing	
NS-065/NCNP-01 <in-house>	NME	Duchenne muscular dystrophy	PI/II		PI/II		
NS-580 <in-house>	NME	Endometriosis	PI	PI			





# R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2014	FY2015	FY2016	FY2017
prulifloxacin <in-house>	NME	Bacterial infections	China Preparation for NDA	Lee's Pharma →		NDA Filing	
NS-018 <in-house>	NME	Myelofibrosis	USA PI/ II	PI/II →			
NS-065/NCNP-01 <in-house>	NME	Duchenne muscular dystrophy	USA PII		PII	→	



# NS-304 (Selexipag)

- Treatment for pulmonary hypertension and Arteriosclerosis obliterans-

Development phase	<p>&lt;PAH&gt;</p> <ul style="list-style-type: none"> <li>•USA ,EU : Launch</li> <li>•Japan: Preparation for launching</li> </ul> <p>&lt;CTEPH&gt; Japan: PIII</p> <p>&lt;ASO&gt; Japan: PIIb</p>
Origin	<ul style="list-style-type: none"> <li>•Nippon Shinyaku</li> </ul>
Development	<ul style="list-style-type: none"> <li>•[Apr. 2008] Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland)</li> <li>•Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.(PAH, CTEPH)</li> <li>•Nippon Shinyaku (ASO)</li> </ul>
Mechanism of action	Selective IP 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	Indolent non-Hodgkin's lymphoma
Dosage form	Injection
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity



# NS-065/NCNP-01

## - Treatment for Duchenne Muscular Dystrophy -

Development Phase	<ul style="list-style-type: none"><li>•USA : PII</li><li>•Japan : PI/II</li></ul>
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Exon 53 Skipping
Indication	Duchenne Muscular Dystrophy
Dosage form	Infusion
Feature	<ul style="list-style-type: none"><li>•Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression</li><li>•Morpholino based oligonucleotide with possible high safety profile and maximized activity</li></ul>



# 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 5 countries and preparation for NDA in 1 country</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>



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