

# Outline of Consolidated Financial Results for the Year Ended March 31, 2014

May 13, 2014  
NIPPON SHINYAKU CO., LTD.



# Operating Results

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	69,941	100.0%	76,517	100.0%	6,576	9.4%
Operating income	6,901	9.9%	8,038	10.5%	1,137	16.5%
Ordinary income	7,209	10.3%	8,598	11.2%	1,388	19.3%
Net income	4,647	6.6%	5,750	7.5%	1,102	23.7%



# Segmental Review

## — Pharmaceuticals —

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	57,344	98.3%	62,185	98.2%	4,840	8.4%
Revenues from the licensing of industrial property rights	104	0.2%	50	0.1%	-53	-51.6%
Prulifloxacin	664	1.1%	861	1.3%	196	29.5%
Contract manufacturing business	204	0.4%	248	0.4%	43	21.3%
<b>Net sales</b>	<b>58,318</b>	<b>100.0%</b>	<b>63,345</b>	<b>100.0%</b>	<b>5,026</b>	<b>8.6%</b>

### Increase in sales:

- **Vidaza ( +2,676 Million yen, +38.1% )**  
( Remedy for myelodysplastic syndrome )
- **Lunabell ( +1,589 Million yen, +34.3% )**  
( Remedy for dysmenorrhea )
- **Adcirca ( +969 Million yen, +50.6% )**  
( Remedy for pulmonary arterial hypertension )
- **Tramal ( +857 Million yen, +188.1% )**  
( Remedy for cancer pain and chronic pain )

etc.

### Decrease in sales:

- **Livostin ( -772 Million yen, -44.9% )**  
( Remedy for allergic rhinitis and allergic conjunctivitis )
- **Hypen ( -446 Million yen, -13.4% )**  
( Non-steroidal analgesic and anti-inflammatory agent )
- **Erizas ( -413 Million yen, -19.3% )**  
( Remedy for allergic rhinitis )

etc.



# Segmental Review

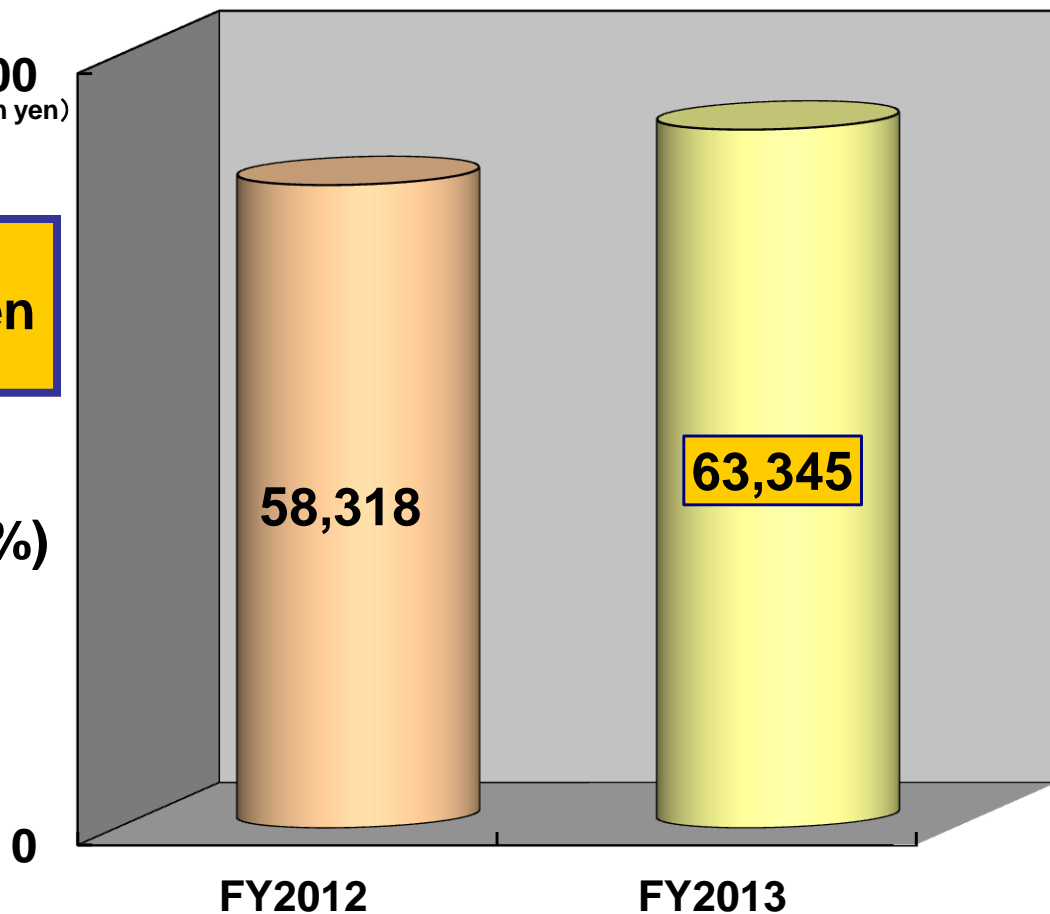
## — Pharmaceuticals —

**Net sales 63,345 million yen**

**Year-on-Year change**

**+ 5,026 million yen (+8.6%)**

70,000  
(Million yen)





# Segmental Review

## — Functional Food —

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	886	7.6%	855	6.5%	-30	-3.5%
Preservatives	1,682	14.5%	1,764	13.4%	81	4.9%
Protein preparations	5,818	50.1%	7,126	54.1%	1,307	22.5%
Nutritional ingredients	1,818	15.6%	2,032	15.4%	213	11.8%
Others	1,416	12.2%	1,393	10.6%	-23	-1.6%
Net sales	11,622	100.0%	13,172	100.0%	1,549	13.3%



# Segmental Review

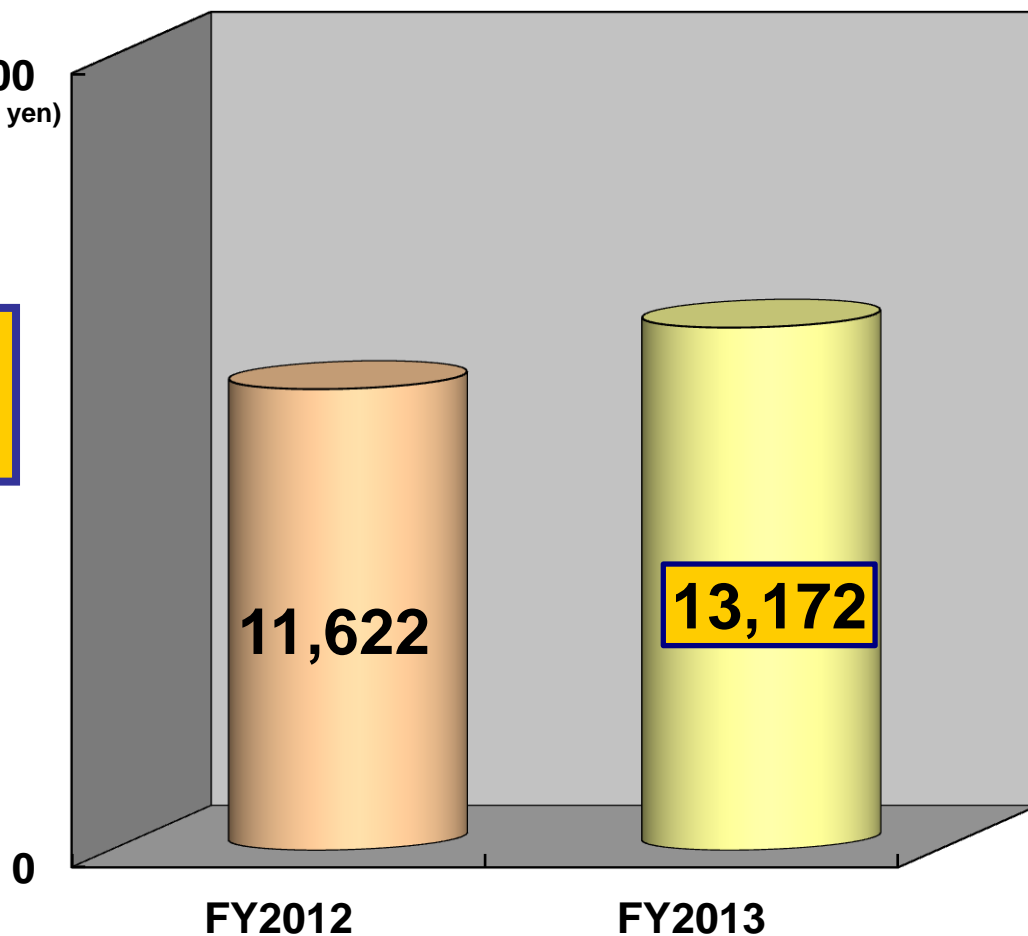
## — Functional Food —

**Net sales 13,172 million yen**

**Year-on-Year change**

**+1,549 million yen (+13.3%)**

20,000  
(Million yen)



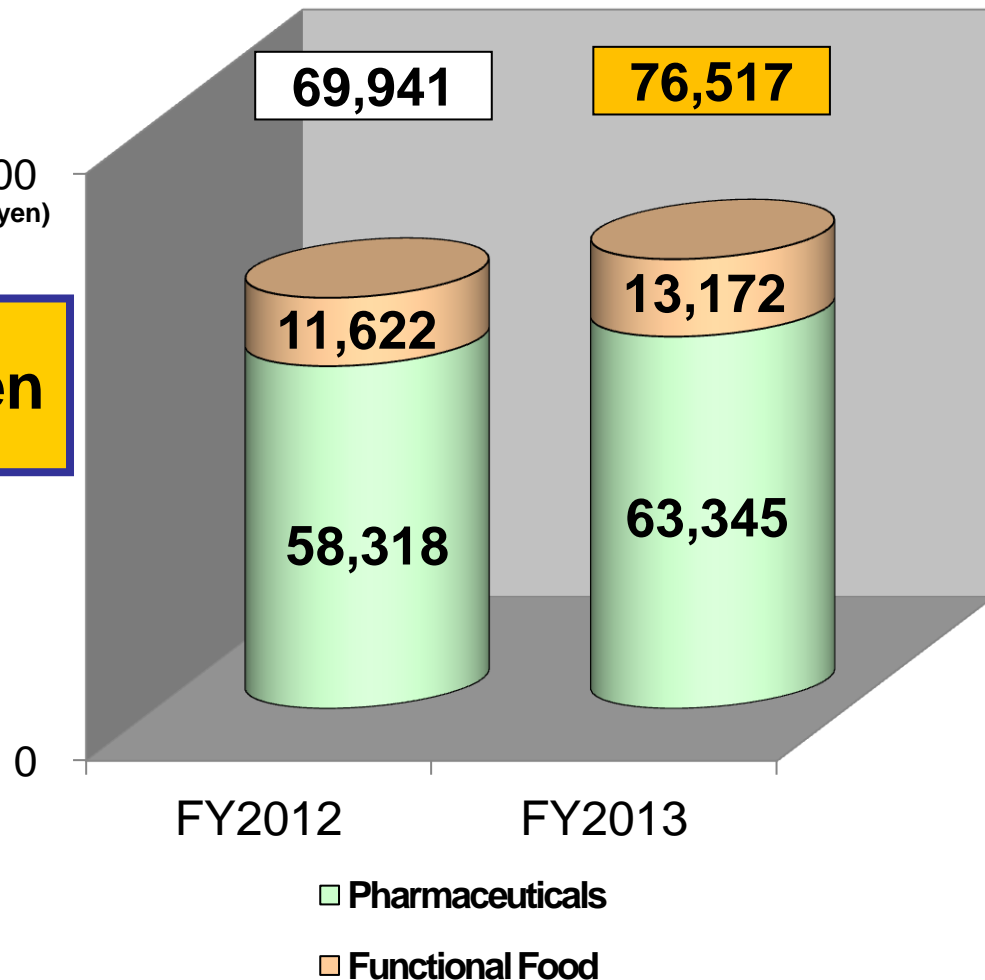


# Net Sales

**Net sales 76,517 million yen**

**Year-on-Year change  
+6,576 million yen ( +9.4% )**

100,000  
(Million yen)





# Consolidated Statements of Income

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	<b>69,941</b>	<b>100.0%</b>	<b>76,517</b>	<b>100.0%</b>	<b>6,576</b>	<b>9.4%</b>
<b>Pharmaceuticals</b>	<b>58,318</b>	<b>83.4%</b>	<b>63,345</b>	<b>82.8%</b>	<b>5,026</b>	<b>8.6%</b>
<b>Funcinal Food</b>	<b>11,622</b>	<b>16.6%</b>	<b>13,172</b>	<b>17.2%</b>	<b>1,549</b>	<b>13.3%</b>
<b>Operating expenses</b>	<b>63,040</b>	<b>90.1%</b>	<b>68,479</b>	<b>89.5%</b>	<b>5,438</b>	<b>8.6%</b>
<b>Cost of sales</b>	<b>34,776</b>	<b>49.7%</b>	<b>39,033</b>	<b>51.0%</b>	<b>4,257</b>	
<b>SG&amp;A expenses</b>	<b>19,214</b>	<b>27.5%</b>	<b>19,914</b>	<b>26.0%</b>	<b>700</b>	
<b>R&amp;D expenses</b>	<b>9,049</b>	<b>12.9%</b>	<b>9,530</b>	<b>12.5%</b>	<b>481</b>	
<b>Operating income</b>	<b>6,901</b>	<b>9.9%</b>	<b>8,038</b>	<b>10.5%</b>	<b>1,137</b>	<b>16.5%</b>





# Consolidated Statements of Income

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	6,901	9.9%	8,038	10.5%	1,137	16.5%
Non-operating income	846	1.2%	1,019	1.3%	173	20.5%
Non-operating expenses	538	0.8%	460	0.6%	-78	-14.5%
Ordinary income	7,209	10.3%	8,598	11.2%	1,388	19.3%
Extraordinary profit	77	0.1%	-	-	-77	-
Income taxes	2,639	3.7%	2,847	3.7%	208	7.9%
Net income	4,647	6.6%	5,750	7.5%	1,102	23.7%



# Dividends

		FY2012	FY2013
Dividends per share	Interim	¥10	¥11
	Year-end	¥11	¥12
	Annual	¥21	¥23
EPS		¥68.87	¥85.25
Dividends payout ratio		30.5 %	27.0 %
DOE		1.6 %	1.7 %



# Consolidated Balance Sheet

(Million yen)

	FY2012	FY2013	YoY Change		FY2012	FY2013	YoY Change
	4Q	4Q	Amt		4Q	4Q	Amt
<b>Assets</b>	113,730	118,188	4,458	<b>Liabilities</b>	24,201	25,002	801
(Current assets)	70,932	74,683	3,751	(Current liabilities)	15,677	15,257	-420
(Fixed assets)	42,798	43,504	706	(Long-term liabilities)	8,523	9,744	1,221
				<b>Net assets</b>	89,529	93,186	3,657
<b>Total Assets</b>	113,730	118,188	4,458	<b>Total liabilities and net assets</b>	113,730	118,188	4,458



# Consolidated Statements of Cash Flows

(Million yen)

	FY2012	FY2013	YoY Change
	Results	Results	Amt
Operating activities	3,767	6,015	2,247
Investing activities	-2,026	-3,357	-1,330
Financing activities	-1,413	-1,606	-193
Cash and cash equivalents at end of year	20,044	21,229	1,185



# Capital Investment

(Million yen)

	Results		
	FY2012	FY2013	Amt Chg
Capital investment	1,332	1,072	-259
Depreciation	2,759	2,704	-55

## Breakdown of Capital Investment

(Million yen)

	Results		
	FY2012	FY2013	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,182	1,017	-164
Production	193	202	10
R&D	532	661	129
Others	457	153	-304
<Sioe Pharmaceutical Co.,Ltd.>	49	22	-27
<Tajima Shokuhin Kogyo Co.,Ltd.>	101	32	-68
Total capital investment	1,332	1,072	-259



# Business Forecast for FY2014

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	76,517	100.0%	84,000	100.0%	7,483	9.8%
Operating income	8,038	10.5%	8,500	10.1%	462	5.7%
Ordinary income	8,598	11.2%	8,700	10.4%	102	1.2%
Net income	5,750	7.5%	6,000	7.1%	250	4.3%



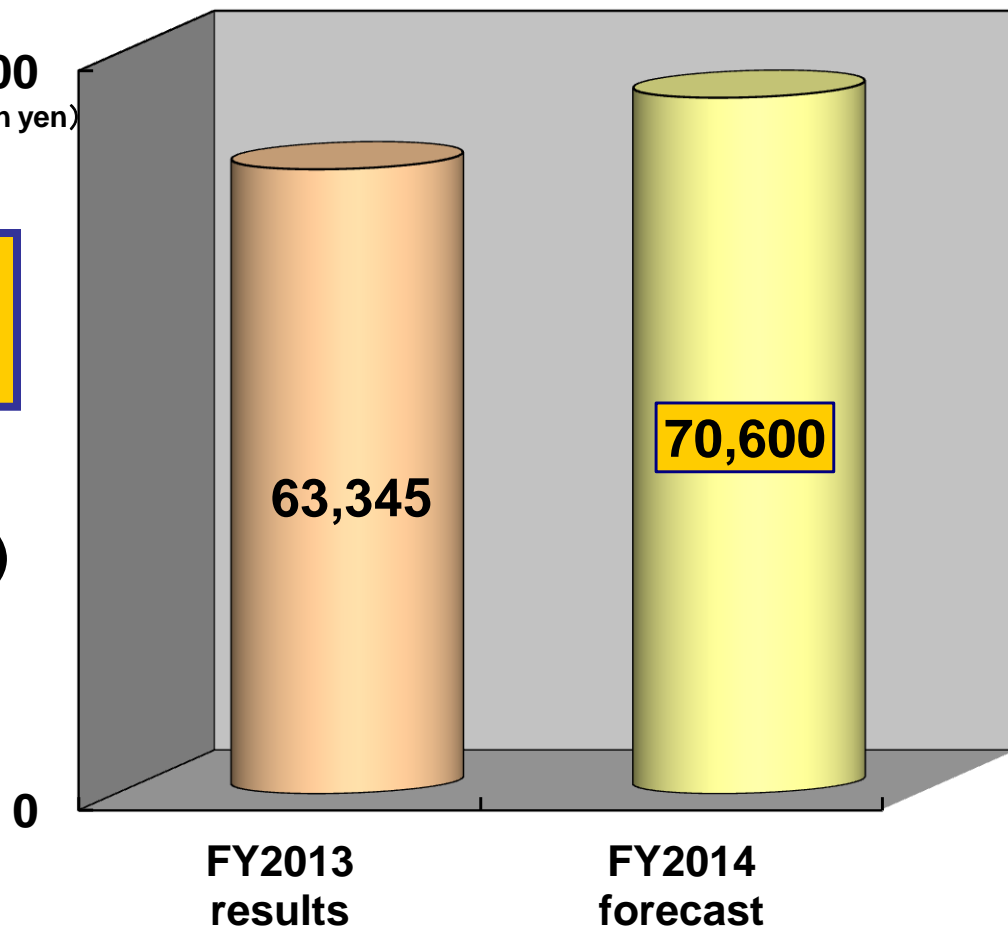
# Segmental Forecast

## — Pharmaceuticals —

**Net sales 70,600 million yen**

**Year-on-Year change  
+7,255 million yen ( +11.5% )**

75,000  
(Million yen)





# Segmental Forecast

## — Pharmaceuticals —

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	62,185	98.2%	67,420	95.5%	5,235	8.4%
Revenues from the licensing of industrial property rights	50	0.1%	2,200	3.1%	2,150	4272.7%
Prulifloxacin	861	1.3%	800	1.1%	-61	- 7.1%
Contract manufacturing business	248	0.4%	180	0.3%	-68	- 27.5%
<b>Net sales</b>	<b>63,345</b>	<b>100.0%</b>	<b>70,600</b>	<b>100.0%</b>	<b>7,255</b>	<b>11.5%</b>

### YoY change of new products (estimated)

- Vidaza (+11.4%)
- Lunabell (+7.8%)
- Zalutia (Launched in April 2014)



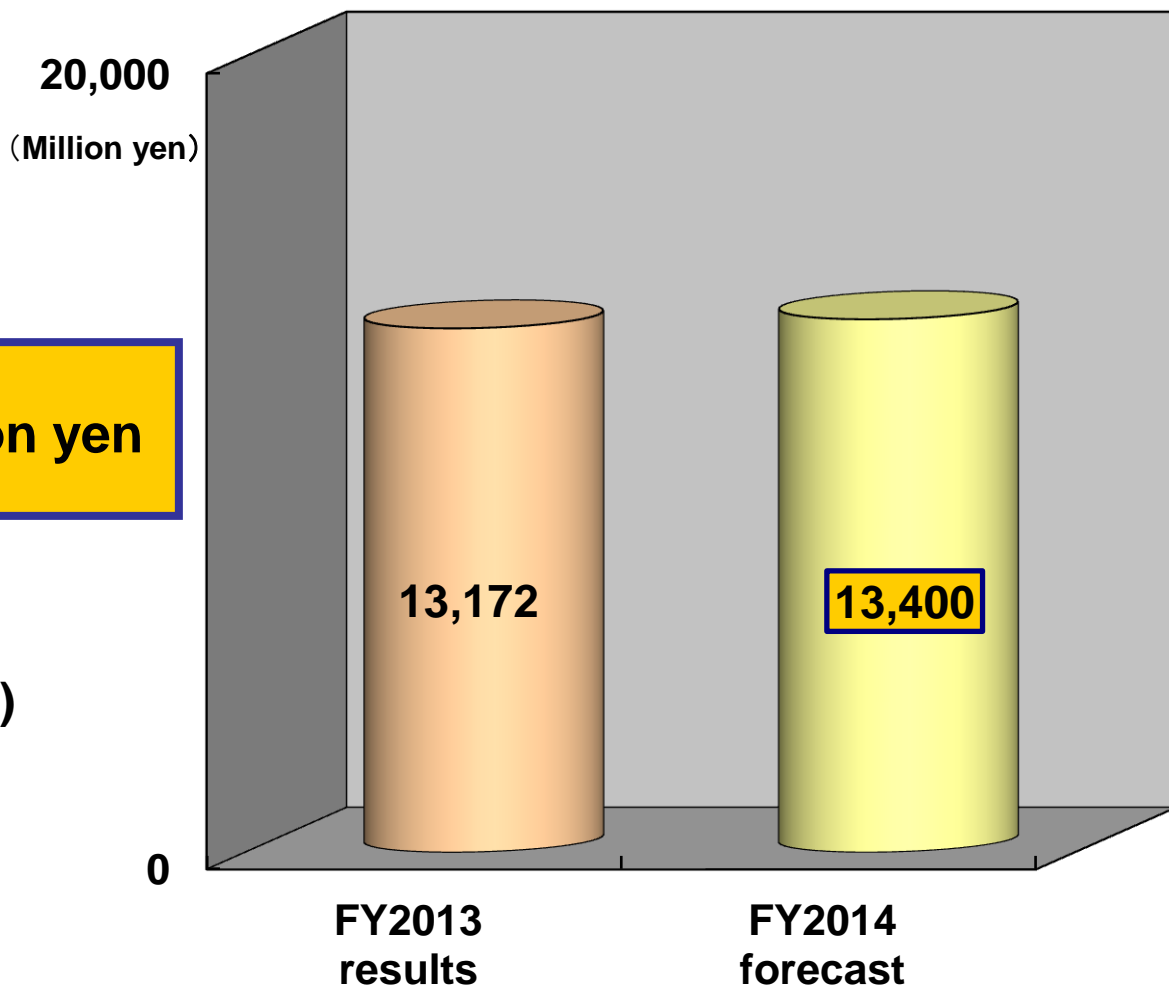


# Segmental Forecast

## — Functional Food —

**Net sales 13,400 million yen**

**Year-on-Year change**  
**+ 228 million yen ( +1.7% )**





# Segmental Forecast

## — Functional Food —

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	855	6.5%	920	6.9%	65	7.6%
Preservatives	1,764	13.4%	1,800	13.4%	36	2.0%
Protein preparations	7,126	54.1%	7,200	53.7%	74	1.0%
Nutritional ingredients	2,032	15.4%	2,050	15.3%	18	0.8%
Others	1,393	10.6%	1,430	10.7%	37	2.7%
<b>Net sales</b>	<b>13,172</b>	<b>100.0%</b>	<b>13,400</b>	<b>100.0%</b>	<b>228</b>	<b>1.7%</b>



# Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	76,517	100.0%	84,000	100.0%	7,483	9.8%
Pharmaceuticals	63,345	82.8%	70,600	84.0%	7,255	11.5%
Functinal Food	13,172	17.2%	13,400	16.0%	228	1.7%
<b>Operating expenses</b>	68,479	89.5%	75,500	89.9%	7,021	10.3%
Cost of sales	39,033	51.0%	43,100	51.3%	4,067	
SG&A expenses	19,914	26.0%	22,300	26.5%	2,386	
R&D expenses	9,530	12.5%	10,100	12.0%	570	
<b>Operating income</b>	8,038	10.5%	8,500	10.1%	462	5.7%



# Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	8,038	10.5%	8,500	10.1%	462	5.7%
Non-operating income	1,019	1.3%	700	0.8%	-319	- 31.3%
Non-operating expenses	460	0.6%	500	0.6%	40	8.7%
Ordinary income	8,598	11.2%	8,700	10.4%	102	1.2%
Income taxes	2,847	3.7%	2,700	3.2%	-147	- 5.2%
Net income	5,750	7.5%	6,000	7.1%	250	4.3%



# Dividends Forecast

		FY2013	FY2014
Dividends per share	Interim	¥11	¥12
	Year-end	¥12	¥13
	Annual	¥23	¥25
EPS		¥85.25	¥88.98
Dividends payout ratio		27.0 %	28.1 %



# Capital Investment Plan

(Million yen)

	FY2013 Results	FY2014 Forecast	Amt Chg
Capital investment	1,072	1,400	327
Depreciation	2,704	2,800	95

## Breakdown of Capital investment




(Million yen)

	FY2013 Results	FY2014 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,017	1,300	282
Production	202	480	277
R&D	661	620	-41
Others	153	200	46
<Sioe Pharmaceutical Co.,Ltd.>	22	40	17
<Tajima Shokuhin Kogyo Co.,Ltd.>	32	60	27
Total capital investment	1,072	1,400	327

# Status of Development Pipeline



# R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
ACT-064992 (macitentan) <in-license>	NME	pulmonary arterial hypertension	Preparation for NDA	P III		NDA Filing	
NS-24 (tramadol hydrochloride) <in-license>	new formulation	cancer pain chronic pain	Preparation for NDA	P III		NDA Filing	
GA101 (obinutuzumab) <in-license>	NME	indolent non-Hodgkin's lymphoma aggressive non-Hodgkin's lymphoma	P III	P III			





# R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	P II	P II			NDA Filing
		chronic thromboembolic pulmonary hypertension	P II	P II			
		arteriosclerosis obliterans	P II		P II		
NS-141 <in-house>	NME	pruritus associated with cutaneous disease	P II	P II			
NS-986 <in-license>	NME	nocturia	P II		P II		



# R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
prulifloxacin <in-house>	NME	bacterial infections	China P III	Lee's Pharma P III		NDA Filing	
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	US/EU P III	Actelion P III		NDA Filing	
NS-187 (bafetinib) <in-house>	NME	B-cell chronic lymphocytic leukemia	US P II	CytRx P II			
NS-018 <in-house>	NME	myelofibrosis	US P I / P II				



# ACT-064992 (Macitentan)

## - Treatment for PAH -

Development phase	<ul style="list-style-type: none"><li>• Overseas: Approval (2013, Europe and USA)</li><li>• Japan : Preparation for NDA</li></ul>
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"><li>• Less hepatic toxicity</li><li>• Long-acting oral drug</li></ul>



# NS-24 (Tramadol)

- Long-acting analgesic -

Development phase	Preparation for NDA
Origin	[Mar.2010] Licensed-in from: Paladin Labs Inc. (Canada) (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"><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.
Indication	<ul style="list-style-type: none"><li>▪ Indolent non-Hodgkin's lymphoma</li><li>▪ Aggressive non-Hodgkin's lymphoma</li></ul>
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	Orphan drug designation by EMEA (Aug.2005) ▪Overseas: PIII ▪Japan : PII
Origin	▪Nippon Shinyaku
Development	[Apr. 2008] ▪Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland) ▪Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.
Indication	▪Pulmonary hypertension ▪Arteriosclerosis obliterans
Dosage form	Tablet
Mechanism of action	Selective PGI <sub>2</sub> receptor agonist
Feature	Long-acting oral drug



# 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-986

## - Treatment for nocturia -

Development phase	PII (exploratory study)
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"><li>▪ Muscarinic receptor antagonist</li><li>▪ Na<sup>+</sup> channel blocker</li></ul>
Feature	<ul style="list-style-type: none"><li>▪ Rapid onset of effect</li><li>▪ Improvement in nocturia refractory to existing antimuscarinic drugs</li></ul>





# 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)	• PIII (Jul. 2013)
• Algorithm (Lebanon)	<ul style="list-style-type: none"> <li>• Launch in Lebanon (Jan. 2012)</li> <li>• Preparation for NDA in 11 countries of the Middle East and North Africa</li> </ul>



# NS-187 (Bafetinib)

- Tyrosine kinase inhibitor -

Development phase	Overseas: PII
Origin	Nippon Shinyaku
Development	[Dec. 2005] Licensed-out to (outside Japan): CytRx Corporation (USA)
Indication	B-cell chronic lymphocytic leukemia
Dosage form	Tablet
Mechanism of action	• Bcr-Abl tyrosine kinase inhibitor • Lyn tyrosine kinase inhibitor
Feature	Dual tyrosine kinase inhibitor



# 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"><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.
- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This English presentation was translated from the original Japanese version.  
In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.