

# Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2012

**NIPPON SHINYAKU CO., LTD.**



# Operating Results

(Million yen)

	2QFY2011		2QFY2012		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	32,173	100.0%	33,143	100.0%	970	3.0%
Operating income	3,011	9.4%	3,070	9.3%	59	2.0%
Ordinary income	3,133	9.7%	3,317	10.0%	183	5.9%
Net income	2,012	6.2%	2,093	6.3%	80	4.0%



# Segmental Review

## — Pharmaceuticals —

(Million yen)

	2QFY2011		2QFY2012		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	25,902	98.2%	26,773	98.1%	870	3.4%
Revenues from the licensing of industrial property rights	55	0.2%	76	0.3%	21	39.8%
Prulifloxacin	326	1.2%	345	1.3%	18	5.7%
Contract manufacturing business	94	0.4%	80	0.3%	Δ 13	Δ14.6%
<b>Net sales</b>	<b>26,379</b>	<b>100.0%</b>	<b>27,276</b>	<b>100.0%</b>	<b>897</b>	<b>3.4%</b>

**Increase in sales:**

- **Vidaza ( +78.0% )**  
( Remedy for myelodysplastic syndromes )
- **Adcirca ( +91.1% )**  
( Pulmonary arterial hypertension treatment agent )
- **Lunabell ( +22.9% )**  
( Remedy for dysmenorrhea )

etc.

**Decrease in sales:**

- **Hypen ( Δ22.2% )**  
( Non-steroidal analgesic and anti-inflammatory agent )
- **Eviprostat ( Δ11.8% )**  
( Remedy for benign prostatic hyperplasia )

etc.



# Segmental Review

## — Pharmaceuticals —

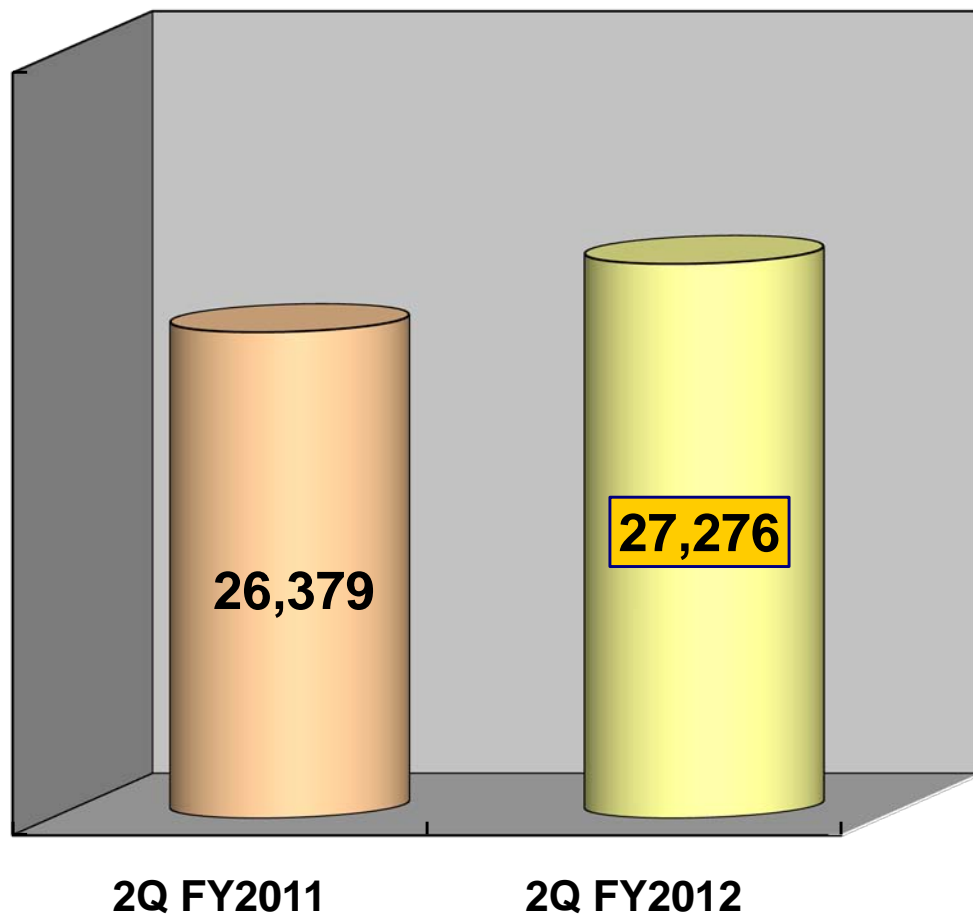
**Net sales 27,276 million yen**

**Year-on-Year change**

**Rose by 897 million yen ( +3.4% )**

30,000  
(Million yen)

20,000





# Segmental Review

## — Functional Food —

(Million yen)

	2QFY2011		2QFY2012		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	414	7.1%	417	7.1%	2	0.7%
Preservatives	756	13.1%	792	13.5%	35	4.7%
Protein preparations	3,005	51.9%	2,999	51.1%	△ 6	△0.2%
Nutritional ingredients	838	14.5%	934	15.9%	95	11.4%
Others	781	13.4%	725	12.4%	△ 56	△7.2%
Net sales	5,794	100.0%	5,867	100.0%	73	1.3%



# Segmental Review

## — Functional Food —

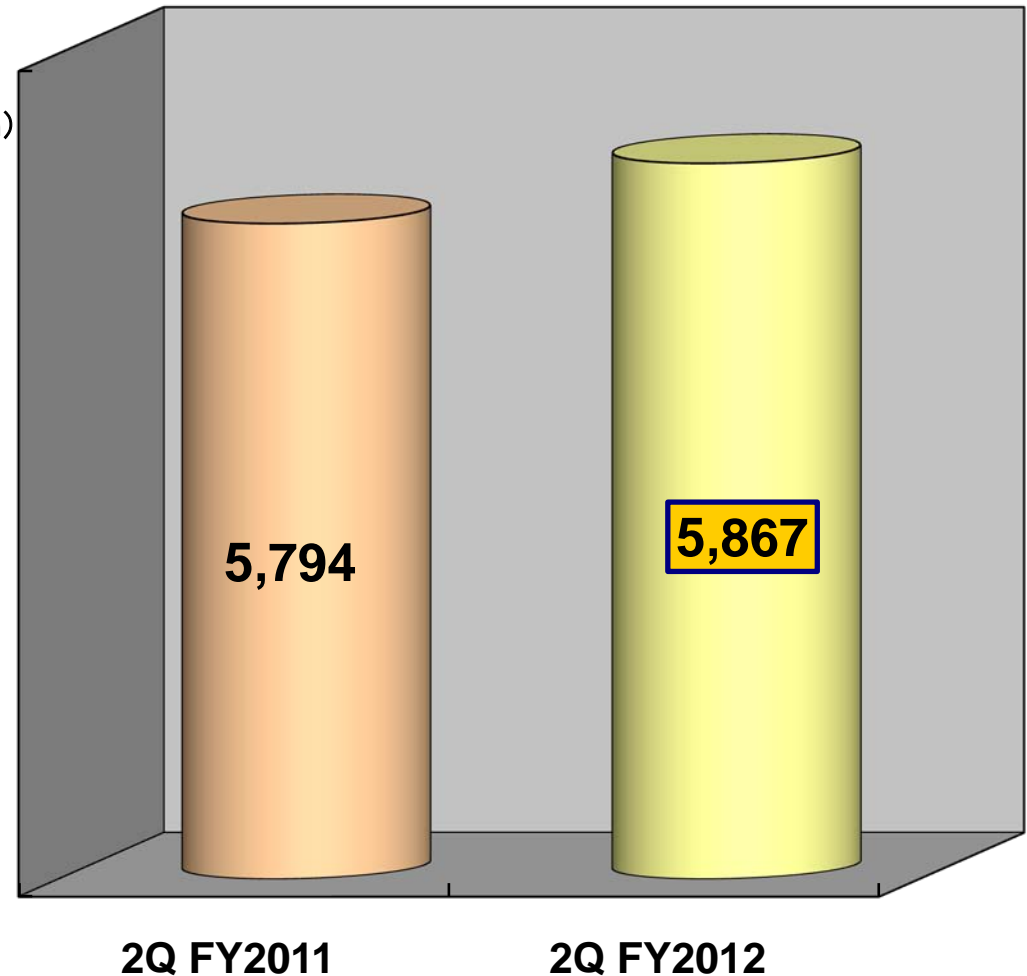
**Net sales 5,867 million yen**

**Year-on-Year change**

**Rose by 73 million yen ( +1.3% )**

6,000  
(Million yen)

5,000



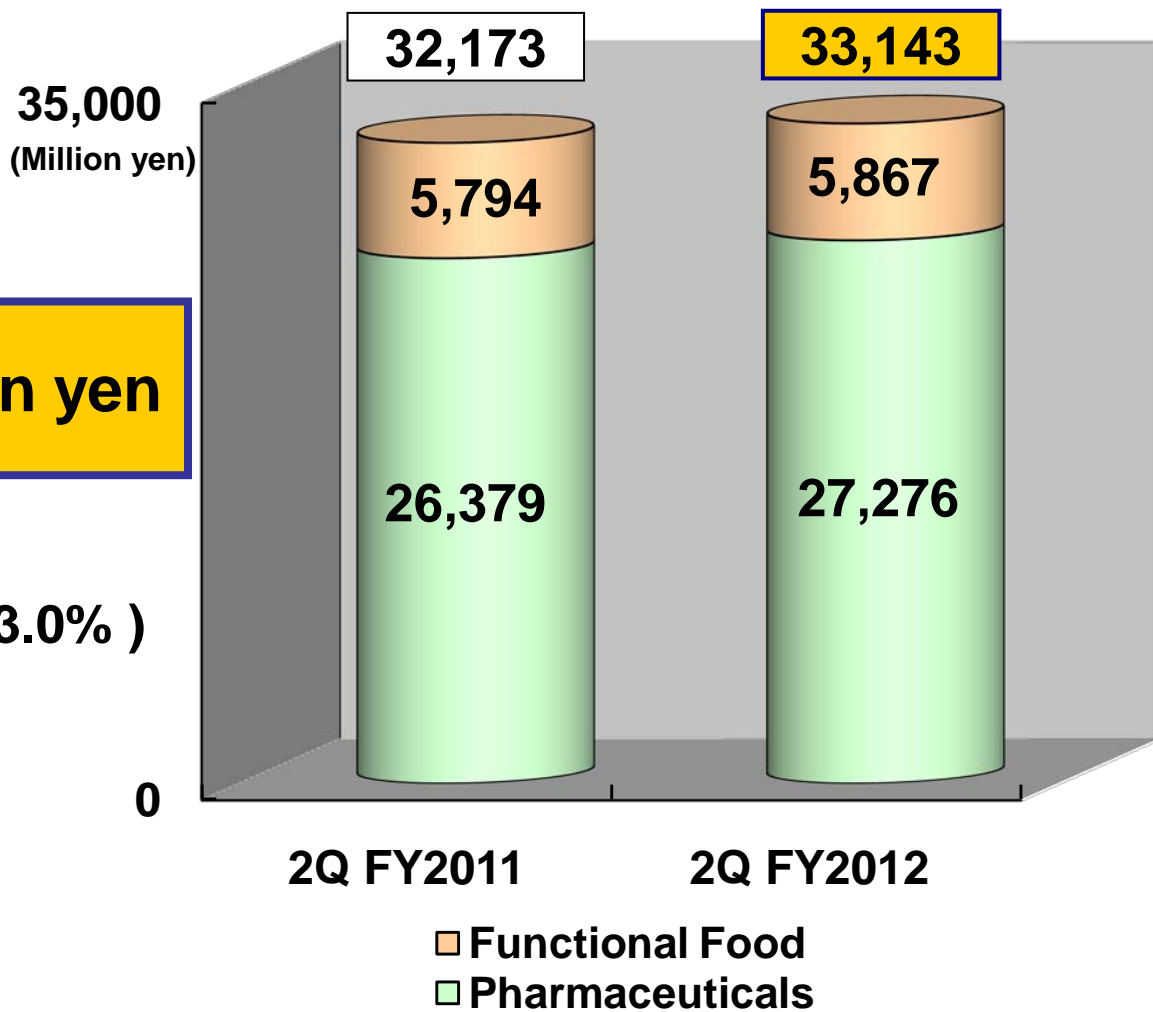


# Net Sales

**Net sales 33,143 million yen**

Year-on-Year change

Rose by 970 million yen ( +3.0% )





# Consolidated Statements of Income for the Quarter ①

(Million yen)

	2QFY2011		2QFY2012		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	32,173	100.0%	33,143	100.0%	970	3.0%
Pharmaceuticals	26,379	82.0%	27,276	82.3%	897	3.4%
Functinal Food	5,794	18.0%	5,867	17.7%	73	1.3%
<b>Operating expenses</b>	29,161	90.6%	30,073	90.7%	911	3.1%
Cost of sales	15,440	48.0%	16,548	49.9%	1,108	
SG&A expenses	9,362	29.1%	9,405	28.4%	43	
R&D expenses	4,359	13.5%	4,118	12.4%	△ 240	
<b>Operating income</b>	3,011	9.4%	3,070	9.3%	59	2.0%





# Consolidated Statements of Income for the Quarter ②

(Million yen)

	2QFY2011		2QFY2012		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	3,011	9.4%	3,070	9.3%	59	2.0%
Non-operating income	403	1.3%	436	1.3%	32	8.0%
Non-operating expenses	281	0.9%	189	0.6%	Δ 92	Δ32.7%
Ordinary income	3,133	9.7%	3,317	10.0%	183	5.9%
Income taxes, etc	1,120	3.5%	1,223	3.7%	103	9.2%
Net income	2,012	6.2%	2,093	6.3%	80	4.0%



# Consolidated Balance Sheet for the Quarter

(Million yen)

	FY2011	FY2012	YoY Change		FY2011	FY2012	YoY Change
	4Q	2Q	Amt		4Q	2Q	Amt
<b>Assets</b>	106,304	107,453	1,148	<b>Liabilities</b>	21,738	22,083	345
(Current assets)	66,333	68,623	2,290	(Current liabilities)	13,961	14,280	319
(Fixed assets)	39,971	38,829	Δ 1,141	(Long-term liabilities)	7,776	7,802	25
				<b>Net assets</b>	84,566	85,370	803
<b>Total Assets</b>	106,304	107,453	1,148	<b>Total liabilities and net assets</b>	106,304	107,453	1,148



# Consolidated Statements of Cash Flows for the Quarter

(Million yen)

	2QFY2011	2QFY2012	YoY Change
	Results	Results	Amt
Operating activities	4,768	4,380	Δ 387
Investing activities	Δ 241	Δ 770	Δ 529
Financing activities	Δ 708	Δ 708	0
Cash and cash equivalents at end of quarter	21,858	22,499	640



# Capital Investment

(Million yen)

	2QResults		
	FY2011	FY2012	Amt Chg
Capital investment	575	668	92
Depreciation	1,430	1,361	△ 69

## Breakdown of Capital Investment

(Million yen)

	2QResults		
	FY2011	FY2012	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	477	571	93
Production	201	72	△ 129
R&D	241	311	70
Others	35	188	152
<Sioe Pharmaceutical Co.,Ltd.>	64	9	△ 55
<Tajima Shokuhin Kogyo Co.,Ltd.>	34	88	54
<b>Total capital investment</b>	<b>575</b>	<b>668</b>	<b>92</b>



# Business Forecast for FY2012

(Million yen)

	FY2011		FY2012		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	67,304	100.0%	69,400	100.0%	2,096	3.1%
Operating income	6,012	8.9%	6,600	9.5%	588	9.8%
Ordinary income	6,193	9.2%	6,800	9.8%	607	9.8%
Net income	3,715	5.5%	4,300	6.2%	585	15.7%



# Segmental Forecast — Pharmaceuticals —

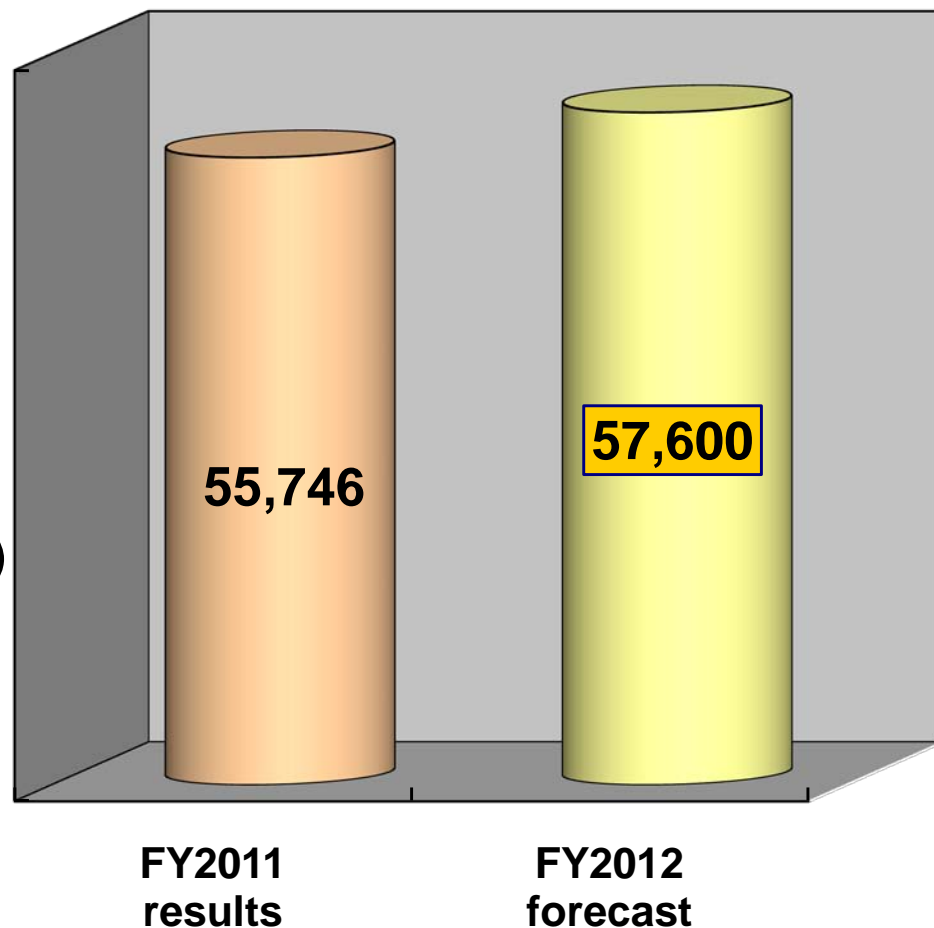
**Net sales 57,600 million yen**

**Year-on-Year change**

**Rose by 1,854 million yen ( +3.3% )**

60,000  
(Million yen)

30,000





# Segmental Forecast

## — Pharmaceuticals —

(Million yen)

	FY2011		FY2012		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
<b>Ethical drugs</b>	<b>54,235</b>	<b>97.3%</b>	<b>56,650</b>	<b>98.3%</b>	<b>2,415</b>	<b>4.5%</b>
<b>Revenues from the licensing of industrial property rights</b>	<b>116</b>	<b>0.2%</b>	<b>100</b>	<b>0.2%</b>	<b>△ 16</b>	<b>△ 14.2%</b>
<b>Prulifloxacin</b>	<b>1,209</b>	<b>2.2%</b>	<b>700</b>	<b>1.2%</b>	<b>△ 509</b>	<b>△ 42.1%</b>
<b>Contract manufacturing business</b>	<b>185</b>	<b>0.3%</b>	<b>150</b>	<b>0.3%</b>	<b>△ 35</b>	<b>△ 18.9%</b>
<b>Net sales</b>	<b>55,746</b>	<b>100.0%</b>	<b>57,600</b>	<b>100.0%</b>	<b>1,854</b>	<b>3.3%</b>



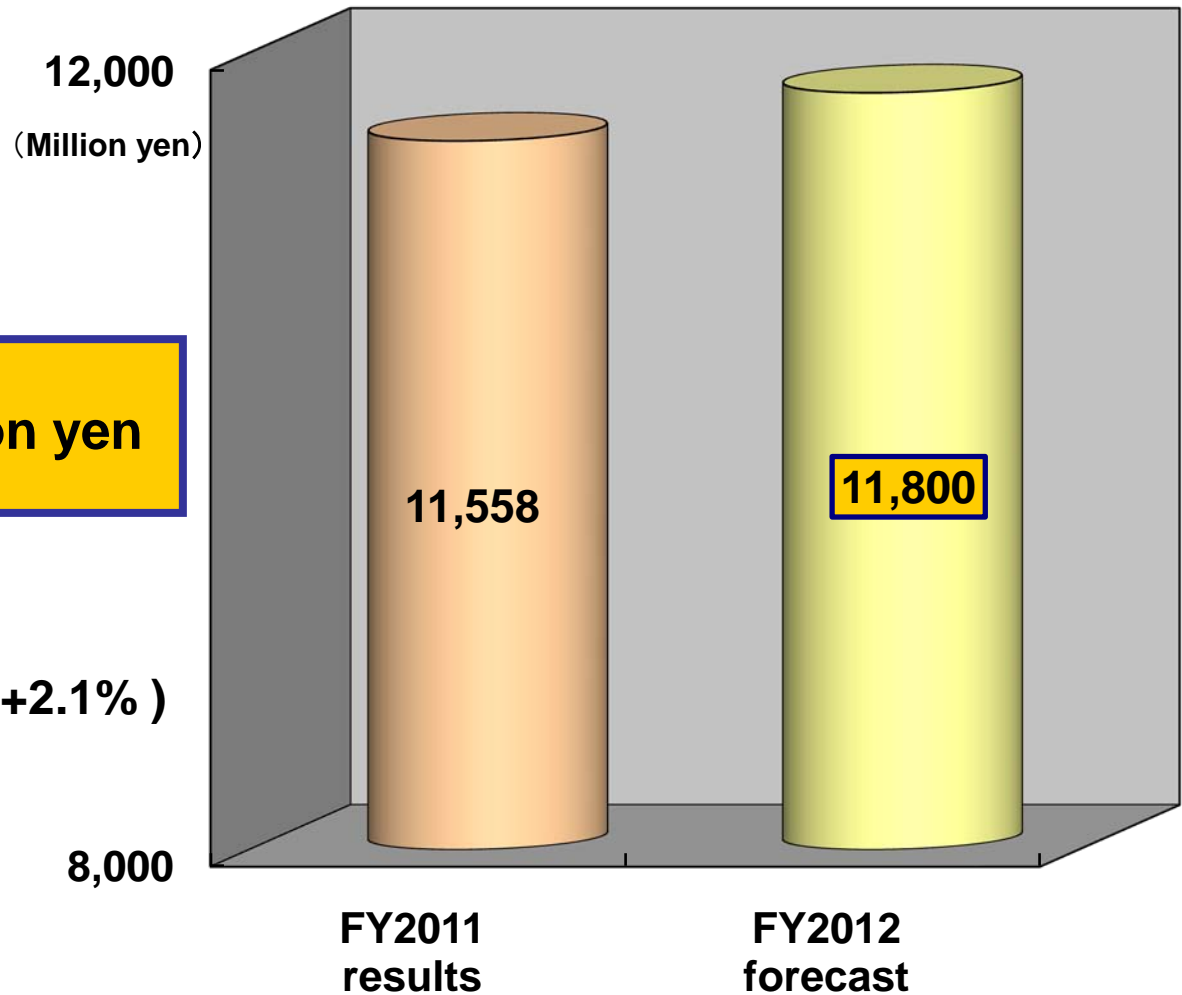
# Segmental Forecast

## — Functional Food —

**Net sales 11,800 million yen**

**Year-on-Year change**

**Rose by 242 million yen ( +2.1% )**







# Segmental Forecast

## — Functional Food —

(Million yen)

	FY2011		FY2012		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	905	7.8%	950	8.1%	45	5.0%
Preservatives	1,566	13.5%	1,620	13.7%	54	3.4%
Protein preparations	5,805	50.2%	6,020	51.0%	215	3.7%
Nutritional ingredients	1,749	15.1%	1,780	15.1%	31	1.8%
Others	1,533	13.4%	1,430	12.1%	Δ 103	Δ 6.7%
Net sales	11,558	100.0%	11,800	100.0%	242	2.1%



# Consolidated Statements of Income (Forecast) ①

(Million yen)

	FY2011		FY2012		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
<b>Revenue</b>						
<b>Net sales</b>	67,304	100.0%	69,400	100.0%	2,096	3.1%
Pharmaceuticals	55,746	82.8%	57,600	83.0%	1,854	3.3%
Functinal Food	11,558	17.2%	11,800	17.0%	242	2.1%
<b>Operating expenses</b>	61,291	91.1%	62,800	90.5%	1,509	2.5%
Cost of sales	32,702	48.6%	34,400	49.6%	1,698	
SG&A expenses	19,174	28.5%	19,200	27.7%	26	
R&D expenses	9,414	14.0%	9,200	13.3%	△ 214	
<b>Operating income</b>	6,012	8.9%	6,600	9.5%	588	9.8%



# Consolidated Statements of Income (Forecast) ②

(Million yen)

	FY2011		FY2012		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	6,012	8.9%	6,600	9.5%	588	9.8%
Non-operating income	858	1.3%	750	1.1%	△ 108	△ 12.6%
Non-operating expenses	677	1.0%	550	0.8%	△ 127	△ 18.8%
Ordinary income	6,193	9.2%	6,800	9.8%	607	9.8%
Income taxes, etc	2,477	3.7%	2,500	3.6%	23	0.9%
Net income	3,715	5.5%	4,300	6.2%	585	15.7%



# Dividends Forecast

		FY2011	FY2012
Dividends per share	Interim	¥9	¥10
	Year-end	¥10	¥11
	Annual	¥19	¥21
EPS		¥55.04	¥63.72
Dividends payout ratio		34.5 %	33.0 %



# Capital Investment Plan

(Million yen)

	FY2011 Results	FY2012 Forecast	Amt Chg
Capital investment	967	1,500	533
Depreciation	2,948	2,800	△ 148

## Breakdown of Capital investment

(Million yen)

	FY2011 Results	FY2012 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	841	1,330	489
Production	415	180	△ 235
R&D	342	580	238
Others	84	570	486
<Sioe Pharmaceutical Co.,Ltd.>	70	70	0
<Tajima Shokuhin Kogyo Co.,Ltd.>	56	100	44
<b>Total capital investment</b>	<b>967</b>	<b>1,500</b>	<b>533</b>

# Status of Development Pipeline



# R&D Compounds (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	2010	2011	2012	2013
NS-11 (acamprosatecalcium) <in-licence>	NME	support maintenance of abstinence from alcohol in patients with alcohol dependence	Pre-registration	P III		NDA Filing	Approval Planned ●
NS-315 (tramadol hydrochloride) <in-licence>	new indication	chronic non-cancer pain	Pre-registration	P III		NDA Filing	Approval Planned ●
LY450190 (tadalafil) <in-licence>	new indication	urinary disorder caused by benign prostatic hyperplasia	P III	Eli Lilly Japan k.k.			
NS-24 (tramadol hydrochloride) <in-licence>	new formulation	cancer pain chronic non-cancer pain	P III	P I	P III		
ACT-064992 (macitentan) <in-licence>	NME	pulmonary arterial hypertension	P III			P III	



# R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	2010	2011	2012	2013
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	P II	P II			
		chronic thromboembolic pulmonary hypertension	P II	P II			P III Planned
NS-141 <in-house>	NME	pruritus associated with atopic dermatitis	P II	P II			





# R&D Compounds(Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	2010	2011	2012	2013
prulifloxacin <in-house>	NME	bacterial infections	Korea Approval	Yuhan			
			China Preparation for P III	Lee's Pharma		P III Planned	NDA Filing
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	US/EU P III	Actelion社 P III	→		
NS-187 (bafetinib) <in-house>	NME	B-cell chronic lymphocytic leukemia	US P II	CytRx社 P II	→		
		chronic myelogenous leukemia	US/EU Preparation P II				
NS-018 <in-house>	NME	myelofibrosis	US P I / P II		→		



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