

**Outline of Consolidated Financial Results
for the 2nd Quarter Ended September 30, 2013**

NIPPON SHINYAKU CO., LTD.



Operating Results

(Million yen)

	2QFY2012		2QFY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	33,143	100.0%	35,593	100.0%	2,449	7.4%
Operating income	3,070	9.3%	3,106	8.7%	35	1.2%
Ordinary income	3,317	10.0%	3,220	9.0%	-96	-2.9%
Net income	2,093	6.3%	2,145	6.0%	52	2.5%



Segmental Review

— Pharmaceuticals —

(Million yen)

	2QFY2012		2QFY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	26,773	98.1%	28,560	98.3%	1,787	6.7%
Revenues from the licensing of industrial property rights	76	0.3%	23	0.1%	-53	-69.1%
Prulifloxacin	345	1.3%	370	1.3%	25	7.4%
Contract manufacturing business	80	0.3%	105	0.3%	25	31.0%
Net sales	27,276	100.0%	29,060	100.0%	1,784	6.5%

Increase in sales:

- **Vidaza (+1,222 million yen, +36.1%)**
(Remedy for myelodysplastic syndromes)
- **Lunabell (+519 million yen, +23.4%)**
(Remedy for dysmenorrhea)
- **Adcirca (+431 million yen, +49.0%)**
(Pulmonary arterial hypertension treatment agent)

etc.

Decrease in sales:

- **Hypen (-254 million yen, -14.1%)**
(Non-steroidal analgesic and anti-inflammatory agent)
- **Erizas (-243 million yen, -53.7%)**
(Dry Powder Inhaler for Allergic Rhinitis)
- **Eviprostat (-195 million yen, -7.4%)**
(Remedy for benign prostatic hyperplasia)

etc



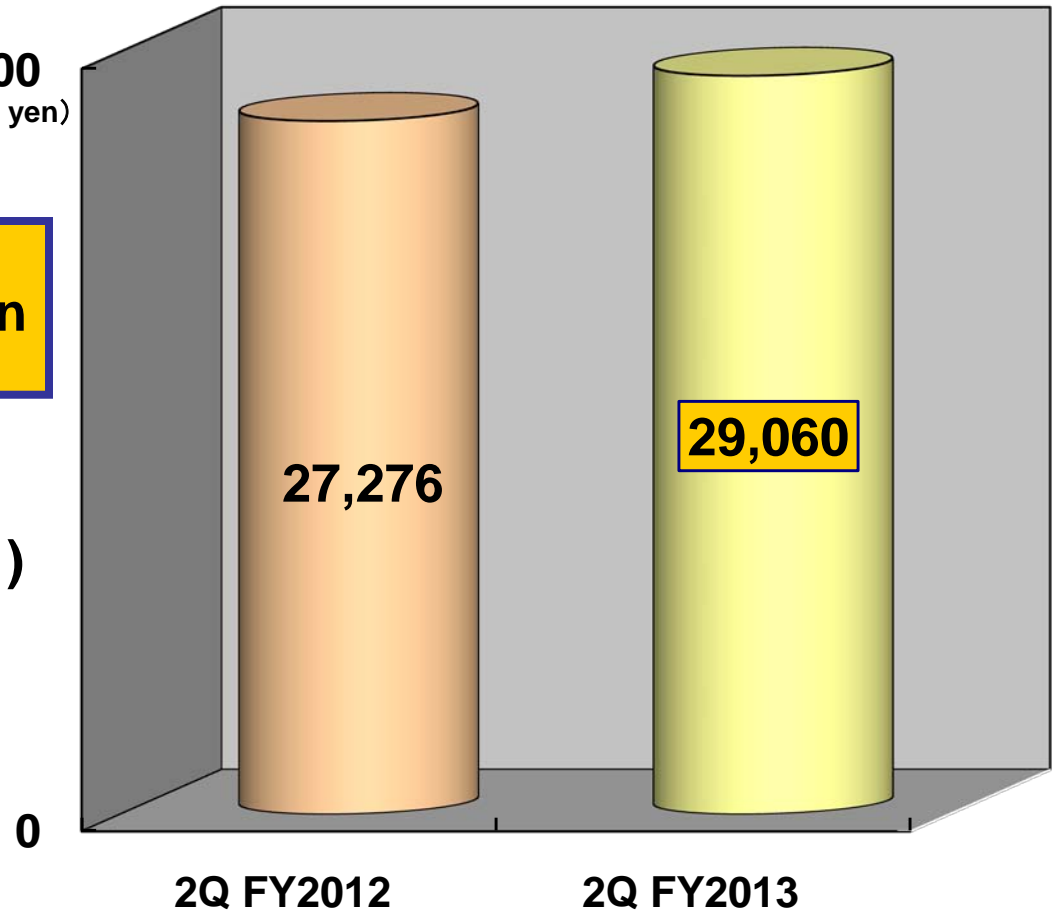
Segmental Review

— Pharmaceuticals —

Net sales 29,060 million yen

**Year-on-Year change
+ 1,784 million yen (+6.5%)**

30,000
(Million yen)





Segmental Review

— Functional Food —

(Million yen)

	2QFY2012		2QFY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	417	7.1%	444	6.7%	27	6.7%
Preservatives	792	13.5%	833	12.8%	41	5.3%
Protein preparations	2,999	51.1%	3,572	54.7%	573	19.1%
Nutritional ingredients	934	15.9%	964	14.8%	30	3.3%
Others	725	12.4%	716	11.0%	-9	-1.3%
Net sales	5,867	100.0%	6,532	100.0%	664	11.3%



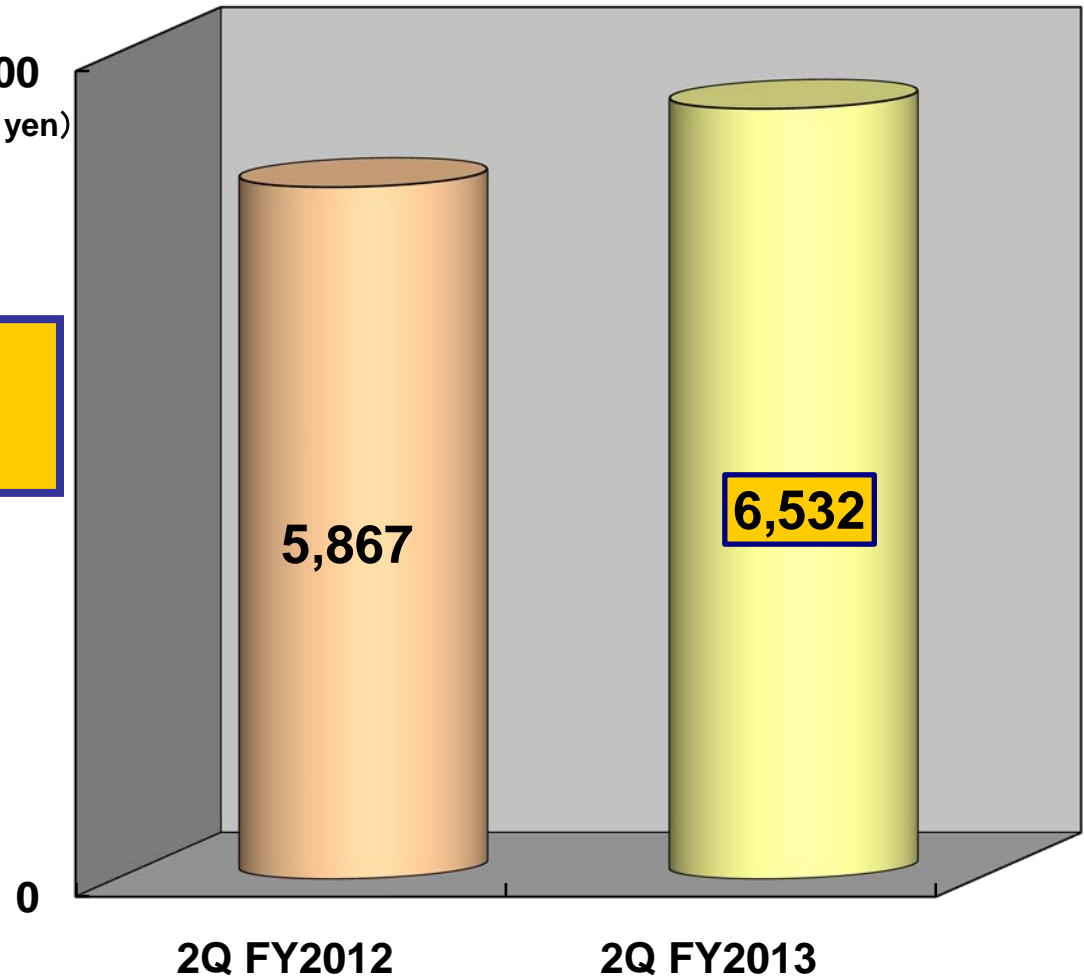
Segmental Review

— Functional Food —

Net sales 6,532 million yen

Year-on-Year change
+ 664 million yen (+11.3%)

7,000
(Million yen)

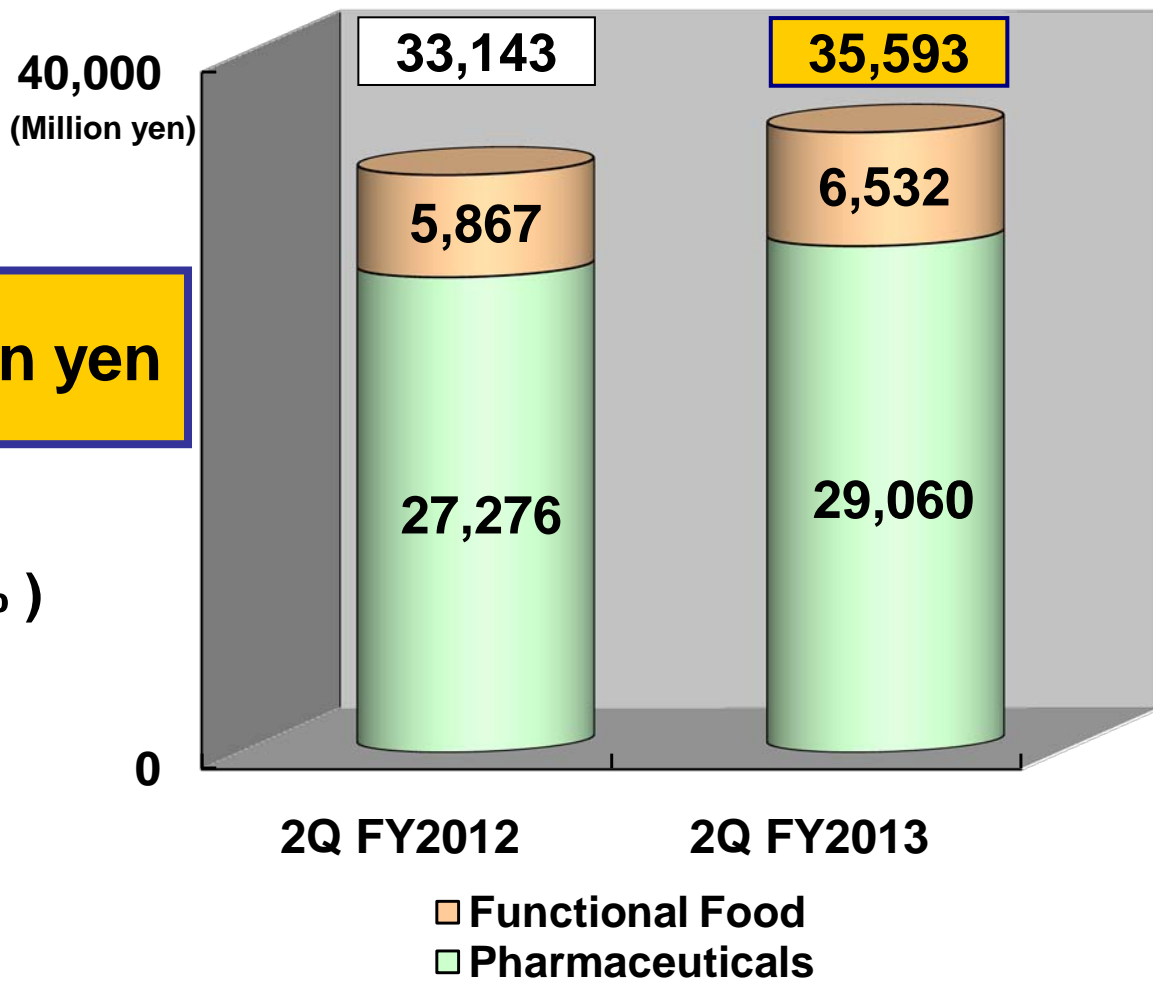




Net Sales

Net sales 35,593 million yen

**Year-on-Year change
+ 2,449 million yen (+7.4%)**





Consolidated Statements of Income ①

(Million yen)

	2QFY2012		2QFY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	33,143	100.0%	35,593	100.0%	2,449	7.4%
Pharmaceuticals	27,276	82.3%	29,060	81.6%	1,784	6.5%
Funcinal Food	5,867	17.7%	6,532	18.4%	664	11.3%
Operating expenses	30,073	90.7%	32,486	91.3%	2,413	8.0%
Cost of sales	16,548	49.9%	18,268	51.3%	1,719	
SG&A expenses	9,405	28.4%	9,686	27.3%	280	
R&D expenses	4,118	12.4%	4,532	12.7%	413	
Operating income	3,070	9.3%	3,106	8.7%	35	1.2%



Consolidated Statements of Income ②

(Million yen)

	2QFY2012		2QFY2013		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	3,070	9.3%	3,106	8.7%	35	1.2%
Non-operating income	436	1.3%	402	1.1%	-33	-7.7%
Non-operating expenses	189	0.6%	287	0.8%	98	51.9%
Ordinary income	3,317	10.0%	3,220	9.0%	-96	-2.9%
Income taxes, etc	1,223	3.7%	1,075	3.0%	-148	-12.2%
Net income	2,093	6.3%	2,145	6.0%	52	2.5%



Consolidated Balance Sheet

(Million yen)

	FY2012	FY2013	YoY Change		FY2012	FY2013	YoY Change
	4Q Results	2Q Results	Amt		4Q Results	2Q Results	Amt
Assets	113,730	113,576	-154	Liabilities	24,201	22,302	-1,898
(Current assets)	70,932	70,107	-824	(Current liabilities)	15,677	13,862	-1,815
(Fixed assets)	42,798	43,468	670	(Long-term liabilities)	8,523	8,440	-82
				Net assets	89,529	91,273	1,743
Total Assets	113,730	113,576	-154	Total liabilities and net assets	113,730	113,576	-154



Consolidated Statements of Cash Flows

(Million yen)

	2QFY2012	2QFY2013	YoY Change
	Results	Results	Amt
Operating activities	4,380	6,364	1,983
Investing activities	-770	-2,468	-1,697
Financing activities	-708	-801	-93
Cash and cash equivalents at end of quarter	22,499	23,206	707



Capital Investment

Capital investment and Depreciation (Million yen)

	2QResults		
	FY2012	FY2013	Amt Chg
Capital investment	668	660	-8
Depreciation	1,361	1,261	-100

Breakdown of Capital Investment (Million yen)

	2QResults		
	FY2012	FY2013	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	571	623	51
Production	72	38	-33
R&D	311	454	142
Others	188	130	-57
<Sioe Pharmaceutical Co.,Ltd.>	9	19	11
<Tajima Shokuhin Kogyo Co.,Ltd.>	88	17	-70
Total capital investment	668	660	-8



Business Forecast for FY2013

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	69,941	100.0%	75,300	100.0%	5,359	7.7%
Operating income	6,901	9.9%	7,600	10.1%	699	10.1%
Ordinary income	7,209	10.3%	7,900	10.5%	691	9.6%
Net income	4,647	6.6%	5,400	7.2%	753	16.2%



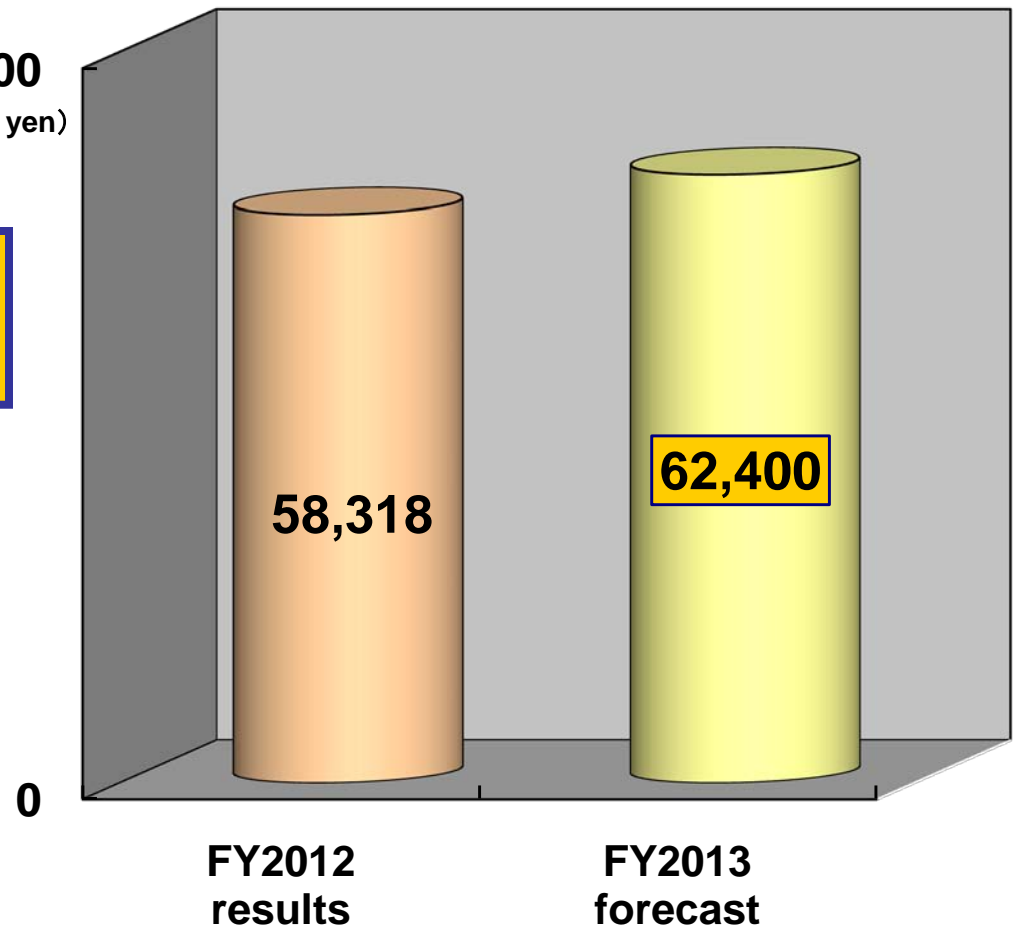
Segmental Forecast

— Pharmaceuticals —

Net sales 62,400 million yen

**Year-on-Year change
+4,082 million yen (+7.0%)**

75,000
(Million yen)





Segmental Forecast

— Pharmaceuticals —

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	57,344	98.3%	61,300	98.2%	3,956	6.9%
Revenues from the licensing of industrial property rights	104	0.2%	100	0.2%	-4	-3.9%
Prulifloxacin	664	1.1%	800	1.3%	136	20.3%
Contract manufacturing business	204	0.4%	200	0.3%	-4	-2.3%
Net sales	58,318	100.0%	62,400	100.0%	4,082	7.0%

YoY change(estimated)

- Vidaza (+42.5%)
- Lunabell (+12.4%)
- Cialis (+6.8%)
- Erizas (+39.8%)
- Adcirca (+41.1%)
- Tramal (+382.3%)

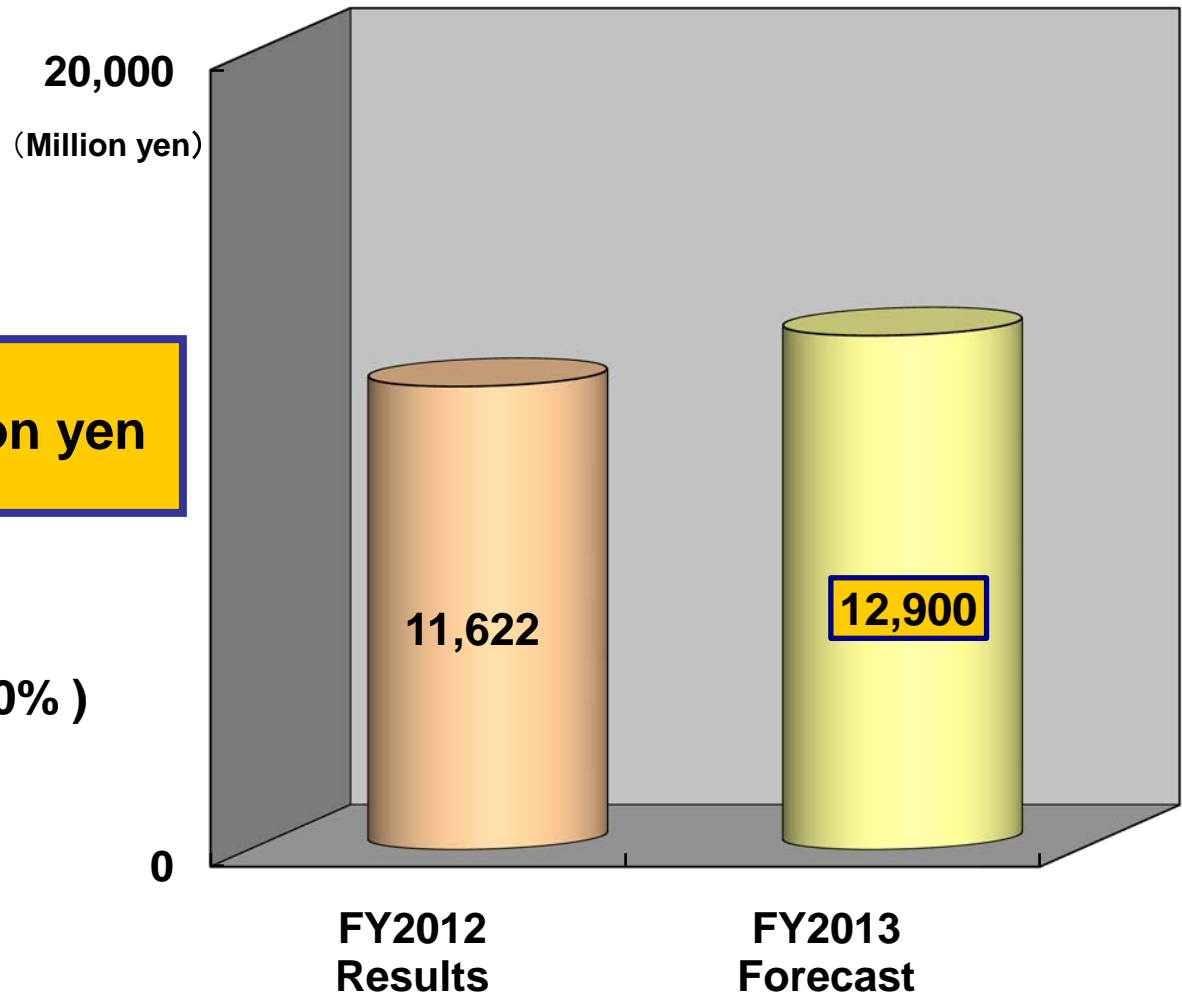


Segmental Forecast

— Functional Food —

Net sales 12,900 million yen

Year-on-Year change
+1, 278 million yen (+11.0%)





Segmental Forecast

— Functional Food —

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	886	7.6%	900	7.0%	14	1.6%
Preservatives	1,682	14.5%	1,750	13.6%	68	4.0%
Protein preparations	5,820	50.1%	7,050	54.7%	1,230	21.1%
Nutritional ingredients	1,817	15.6%	1,840	14.3%	23	1.3%
Others	1,417	12.2%	1,360	10.4%	-57	-4.0%
Net sales	11,622	100.0%	12,900	100.0%	1,278	11.0%



Consolidated Statements of Income (Forecast) ①

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue						
Net sales	69,941	100.0%	75,300	100.0%	5,359	7.7%
Pharmaceuticals	58,318	83.4%	62,400	82.9%	4,082	7.0%
Functinal Food	11,622	16.6%	12,900	17.1%	1,278	11.0%
Operating expenses	63,040	90.1%	67,700	89.9%	4,660	7.4%
Cost of sales	34,776	49.7%	38,100	50.6%	3,324	
SG&A expenses	19,214	27.5%	19,900	26.4%	686	
R&D expenses	9,049	12.9%	9,700	12.9%	651	
Operating income	6,901	9.9%	7,600	10.1%	699	10.1%



Consolidated Statements of Income (Forecast) ②

(Million yen)

	FY2012		FY2013		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	6,901	9.9%	7,600	10.1%	699	10.1%
Non-operating income	846	1.2%	800	1.1%	-46	-5.5%
Non-operating expenses	538	0.8%	500	0.7%	-38	-7.1%
Ordinary income	7,209	10.3%	7,900	10.5%	691	9.6%
Extraordinary profit	77	0.1%	-	-	-77	-
Extraordinary loss	-	-	-	-	-	-
Income taxes, etc	2,639	3.8%	2,500	3.3%	-139	-5.3%
Net income	4,647	6.6%	5,400	7.2%	753	16.2%



Dividends Forecast

		FY2012	FY2013
Dividends per share	Interim	¥10	¥11
	Year-end	¥11	¥12
	Annual	¥21	¥23
EPS		¥68.87	¥80.05
Dividends payout ratio		30.5 %	28.7 %



Capital Investment Plan

Capital investment and Depreciation

(Million yen)

	FY2012 Results	FY2013 Forecast	Amt Chg
Capital investment	1,332	1,200	-132
Depreciation	2,759	2,600	-159

Breakdown of Capital investment

(Million yen)

	FY2012 Results	FY2013 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,182	1,070	-112
Production	193	165	-27
R&D	532	693	160
Others	457	211	-245
<Sioe Pharmaceutical Co.,Ltd.>	49	40	-9
<Tajima Shokuhin Kogyo Co.,Ltd.>	101	90	-10
Total capital investment	1,332	1,200	-132

Status of Development Pipeline



R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2011	FY2012	FY2013	FY2014
LY450190 (tadalafil) <in-licence>	new indication	urinary disorder caused by benign prostatic hyperplasia	Application	Eli Lilly Japan k.k. P III	NDA Filed		
NS-24 (tramadol hydrochloride) <in-licence>	new formulation	cancer pain chronic pain	P III	P I	P III		NDA Filing
ACT-064992 (macitentan) <in-licence>	NME	pulmonary arterial hypertension	P III		P III		NDA Filing
GA101 (obinutuzumab) <in-licence>	NME	indolent non-Hodgkin's lymphoma aggressive non-Hodgkin's lymphoma	P III	P III			



R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2011	FY2012	FY2013	FY2014
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	P II	P II			
		chronic thromboembolic pulmonary hypertension	P II	P II			
		arteriosclerosis obliterans	P II			P II	
NS-141 <in-house>	NME	pruritus associated with atopic dermatitis	P II	P II			
NS-986 <in-licence>	NME	nocturia	Preparation for P II			P II Planned	



R&D Compounds(Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2011	FY2012	FY2013	FY2014
prulifloxacin <in-house>	NME	bacterial infections	Korea Approval	Yuhan			
			China P III	Lee's Pharma		P III →	NDA Filing
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	US/ES P III	Actelion P III	→		
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 / II		→		



LY450190 (Tadalafil)

- Treatment for urinary disorder caused by BPH -

Development phase	Application
Origin	[Apr.2009] Licensed-in from: Eli Lilly Japan K.K.
Development	Eli Lilly Japan K.K.
Indication	Urinary disorder caused by benign prostatic hyperplasia
Dosage form	Tablet
Mechanism of action	PDE5 inhibitor
Feature	New mechanism of action



NS-24 (Tramadol)

- Long-acting non-narcotic analgesic -

Development phase	P III
Origin	[Mar.2010] Licensed-in from: Paladin Labs Inc. (Canada) (available in 19 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



ACT-064992 (Macitentan)

- Treatment for PAH -

Development phase	<ul style="list-style-type: none">• Overseas: Application (at the end of 2012, Europe and USA) Approval (Oct.2013, USA)• Japan : PIII
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



GA101 (Obinutuzumab)

- Treatment for non-Hodgkin's lymphoma -

Development Phase	<ul style="list-style-type: none">▪ Overseas: PIII (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	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 ₂ 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">▪ 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) preparation
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



Prulifloxacin

- Quinolone antibacterial -

Japan

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

Overseas

Licensee	Development phase
▪ Angelini (Italy)	▪ Approval (Sep. 2004) ▪ Launch in Italy (Nov. 2004) ▪ Approval in European countries (Apr.2005)
▪ Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	▪ PIII (July 2013)
▪ Yuhan Corporation (Korea)	▪ Approval (Dec. 2007)



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">• Highly selective for active form of JAK2 tyrosine kinase• Possibly best-in-class treatment for myelofibrosis



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