

**Outline of Consolidated Financial Results
for the 2nd Quarter Ended September 30, 2014**

NIPPON SHINYAKU CO., LTD.



FY2014 2Q Summary

Net Sales

• **36,470** Million yen (YonY Change +2.5%)

Operating income

• **2,033** Million yen (YonY Change -34.5%)

Ordinary income

• **2,272** Million yen (YonY Change -29.4%)

Net income

• **1,440** Million yen (YonY Change -32.9%)

Topics

- ◆ Launch Zalutia for urinary disorder caused by benign prostatic hyperplasia (Apr.)
- ◆ ACT-064992(Macitentan)・・・Application by Actelion Pharmaceuticals Japan (May)
- ◆ NS-304・・・Overseas : Meets Primary Endpoint in PⅢ (Jun.)
Preparation for NDA by Actelion Pharmaceuticals Ltd.
Japan : Orphan drug designation by MHLW (Sep.)
- ◆ NS-24・・・Application (Jun.)
- ◆ Announcement of 5th Five-Year Medium-term-Management Plan “Aiming for New Growth-Pursuit of Originality-” (Aug.)



Segmental Review

— Pharmaceuticals —

(Million yen)

	2QFY2013		2QFY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	28,560	98.3%	29,011	98.5%	451	1.6%
Revenues from the licensing of industrial property rights	23	0.1%	64	0.2%	40	172.6%
Prulifloxacin	370	1.3%	364	1.2%	-5	-1.5%
Contract manufacturing business	105	0.3%	13	0.1%	-92	-87.4%
Net sales	29,060	100.0%	29,454	100.0%	393	1.4%

Increase in sales:

- **Tramal (+715 million yen, +162.1%)**
(cancer pain, chronic pain)
- **Vidaza (+438 million yen, +9.5%)**
(myelodysplastic syndromes)

New Product:

- **Zalutia (+753 million yen)**
(urinary disorder caused by benign prostatic hyperplasia)

etc.

Decrease in sales:

- **Hypen (-495million yen, -32.0%)**
(non-steroidal analgesic and anti-inflammatory agent)
- **GaslonN (-479 million yen, -19.8%)**
(gastric ulcer, gastritis)
- **Selectol (-260 million yen, -27.7%)**
(hypertension, angina pectoris)

etc



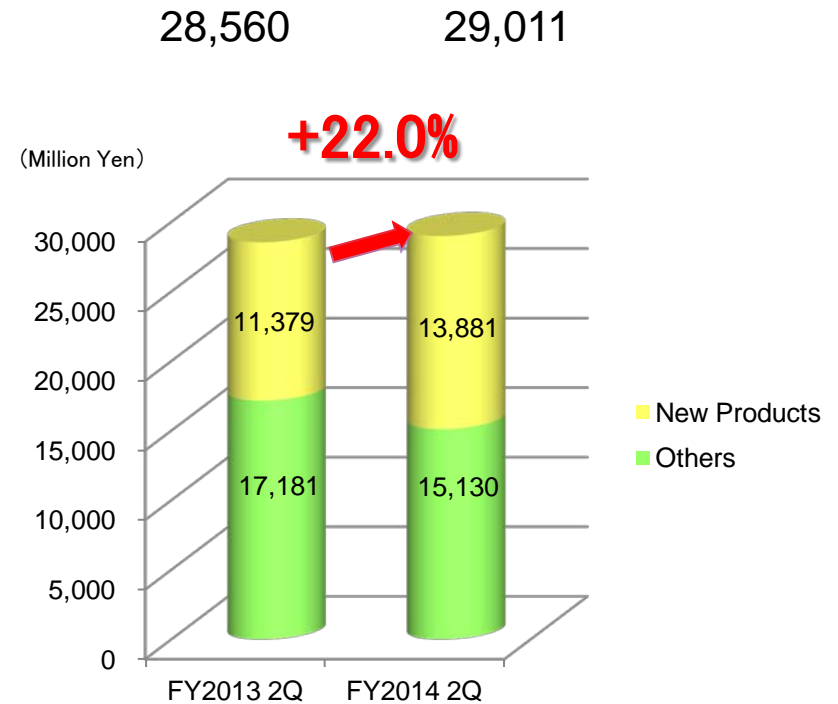
New Products Review

— Pharmaceuticals —

◆ Sales Growth of New Products Group

New Products	FY2013 2Q	FY2014 2Q	Y on Y Change
Vidaza	4,610	5,048	+9.5%
Lunabell	2,735	2,999	+9.7%
Cialis	1,917	1,737	-9.4%
Adcirca	1,311	1,440	+9.9%
Tramal	441	1,156	+162.1%
Zalutia	—	753	—
Erizas	209	399	+90.5%
Regtect	154	345	+123.7%
Total	11,379	13,881	+22.0%

Sales of Ethical Drugs





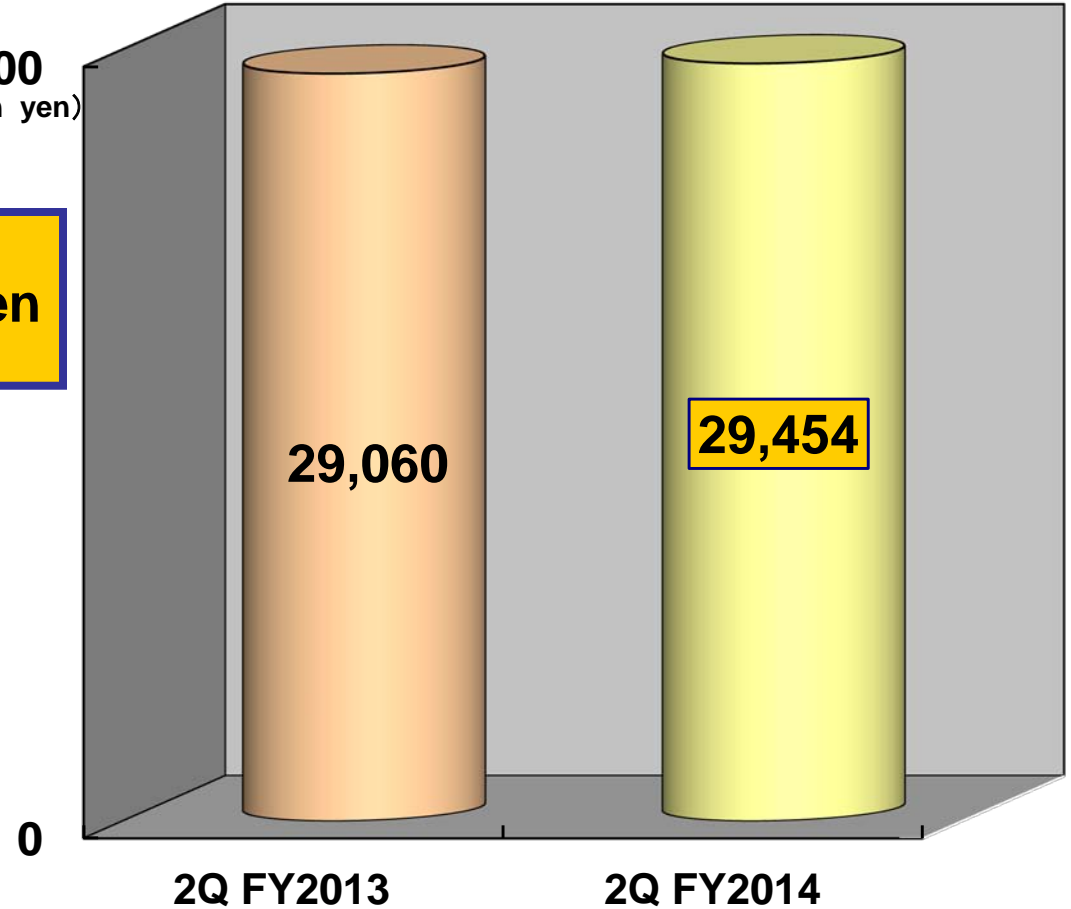
Segmental Review

— Pharmaceuticals —

Net sales 29,454 million yen

**Year-on-Year change
+ 393 million yen (+1.4%)**

30,000
(Million yen)





Segmental Review

— Functional Food —

(Million yen)

	2QFY2013		2QFY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	446	6.8%	352	5.0%	-93	-20.9%
Preservatives	833	12.8%	916	13.1%	82	9.9%
Nutritional ingredients	967	14.8%	1,155	16.5%	187	19.4%
Protein preparations	3,569	54.6%	3,836	54.7%	267	7.5%
Others	715	11.0%	754	10.7%	39	5.5%
Net sales	6,532	100.0%	7,015	100.0%	483	7.4%



Segmental Review

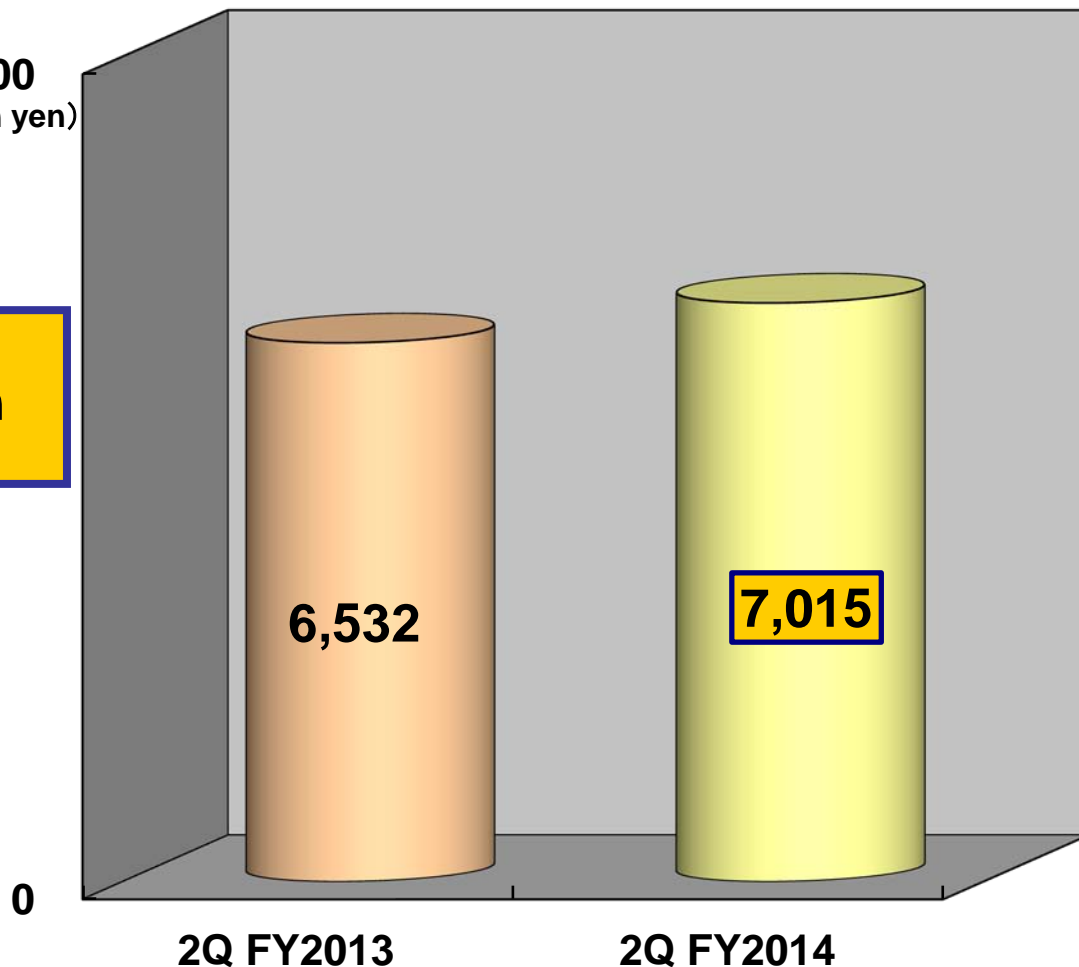
— Functional Food —

Net sales 7,015 million yen

Year-on-Year change

+ 483 million yen (+7.4%)

10,000
(Million yen)

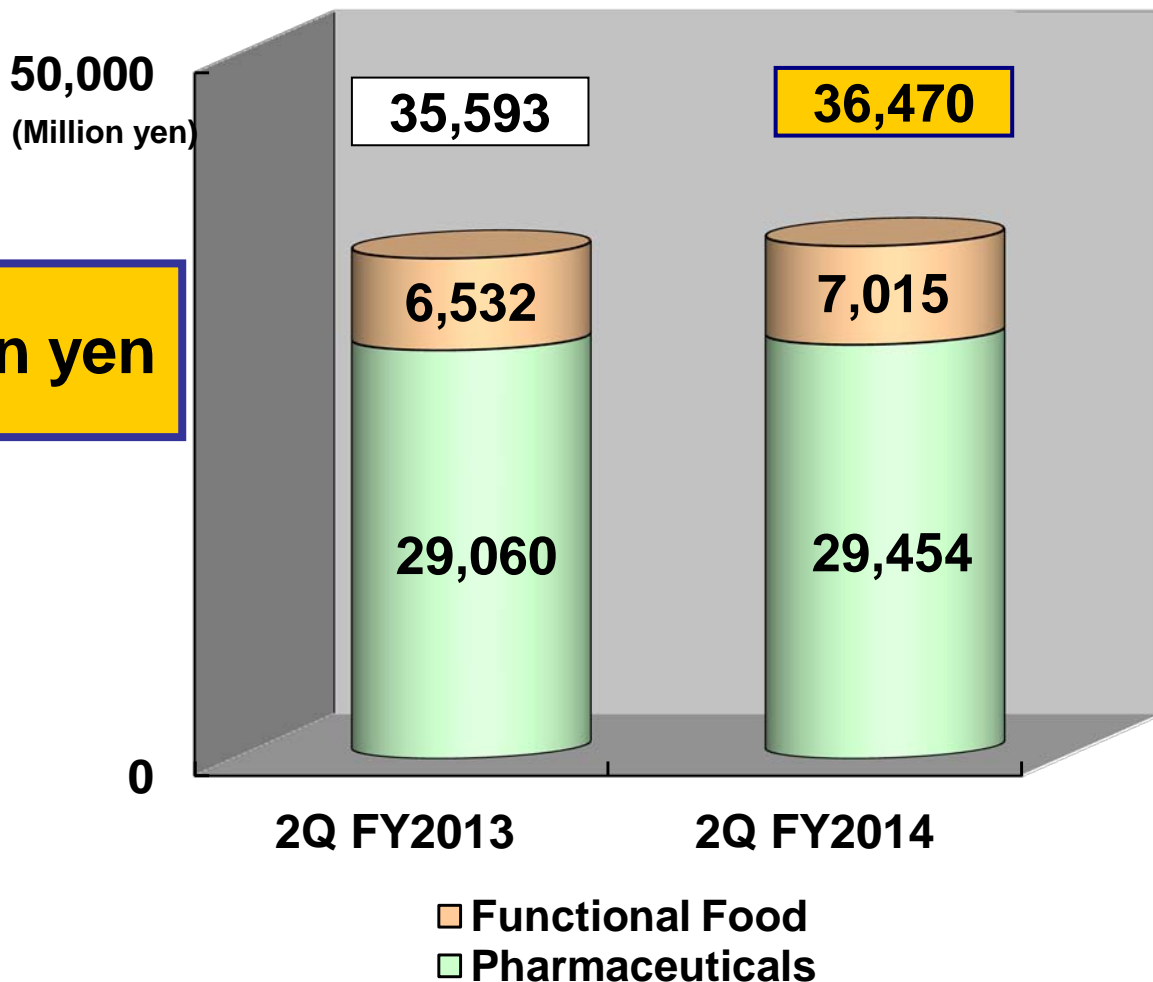




Net Sales

Net sales 36,470 million yen

**Year-on-Year change
+ 877 million yen (+2.5%)**





Consolidated Statements of Income ①

(Million yen)

	2QFY2013		2QFY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	35,593	100.0%	36,470	100.0%	877	2.5%
Pharmaceuticals	29,060	81.6%	29,454	80.8%	393	1.4%
Functional Food	6,532	18.4%	7,015	19.2%	483	7.4%
Operating expenses	32,486	91.3%	34,436	94.4%	1,949	6.0%
Cost of sales	18,268	51.3%	19,529	53.5%	1,261	
SG&A expenses	9,686	27.3%	10,663	29.3%	977	
R&D expenses	4,532	12.7%	4,243	11.6%	-288	
Operating income	3,106	8.7%	2,033	5.6%	-1,072	-34.5%



Consolidated Statements of Income ②

(Million yen)

	2QFY2013		2QFY2014		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	3,106	8.7%	2,033	5.6%	-1,072	-34.5%
Non-operating income	402	1.1%	442	1.2%	39	9.9%
Non-operating expenses	287	0.8%	203	0.6%	-84	-29.2%
Ordinary income	3,220	9.0%	2,272	6.2%	-948	-29.4%
Income taxes, etc	1,075	3.0%	831	2.3%	-243	-22.6%
Net income	2,145	6.0%	1,440	4.0%	-705	-32.9%



Consolidated Balance Sheet

(Million yen)

	FY2013	FY2014	YoY Change		FY2013	FY2014	YoY Change
	4Q Results	2Q Results	Amt		4Q Results	2Q Results	Amt
Assets	118,188	118,342	154	Liabilities	25,002	23,801	-1,200
(Current assets)	74,683	72,568	-2,115	(Current liabilities)	15,257	13,877	-1,380
(Fixed assets)	43,504	45,774	2,269	(Long-term liabilities)	9,744	9,924	179
				Net assets	93,186	94,541	1,354
Total Assets	118,188	118,342	154	Total liabilities and net assets	118,188	118,342	154



Consolidated Statements of Cash Flows

(Million yen)

	2QFY2013	2QFY2014	YoY Change
	Results	Results	Amt
Operating activities	6,364	1,690	-4,673
Investing activities	-2,468	-2,367	100
Financing activities	-801	-893	-91
Cash and cash equivalents at end of quarter	23,206	19,647	-3,559

Cash and cash equivalents at end of quarter : -1,582 Million yen (YoY FY2013)



Capital Investment

Capital Investment and Depreciation (Million yen)

	2QResults		
	FY2013	FY2014	Amt Chg
Capital investment	660	808	147
Depreciation	1,261	1,294	33

Breakdown of Capital Investment (Million yen)

	2QResults		
	FY2013	FY2014	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	623	762	139
Production	38	381	343
R&D	454	316	-137
Others	130	64	-66
<Sioe Pharmaceutical Co.,Ltd.>	19	8	-11
<Tajima Shokuhin Kogyo Co.,Ltd.>	17	37	20
Total capital investment	660	808	147



Business Forecast for FY2014

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	76,517	100.0%	81,000	100.0%	4,483	5.9%
Operating income	8,038	10.5%	8,500	10.5%	462	5.7%
Ordinary income	8,598	11.2%	8,700	10.7%	102	1.2%
Net income	5,750	7.5%	6,000	7.4%	250	4.3%

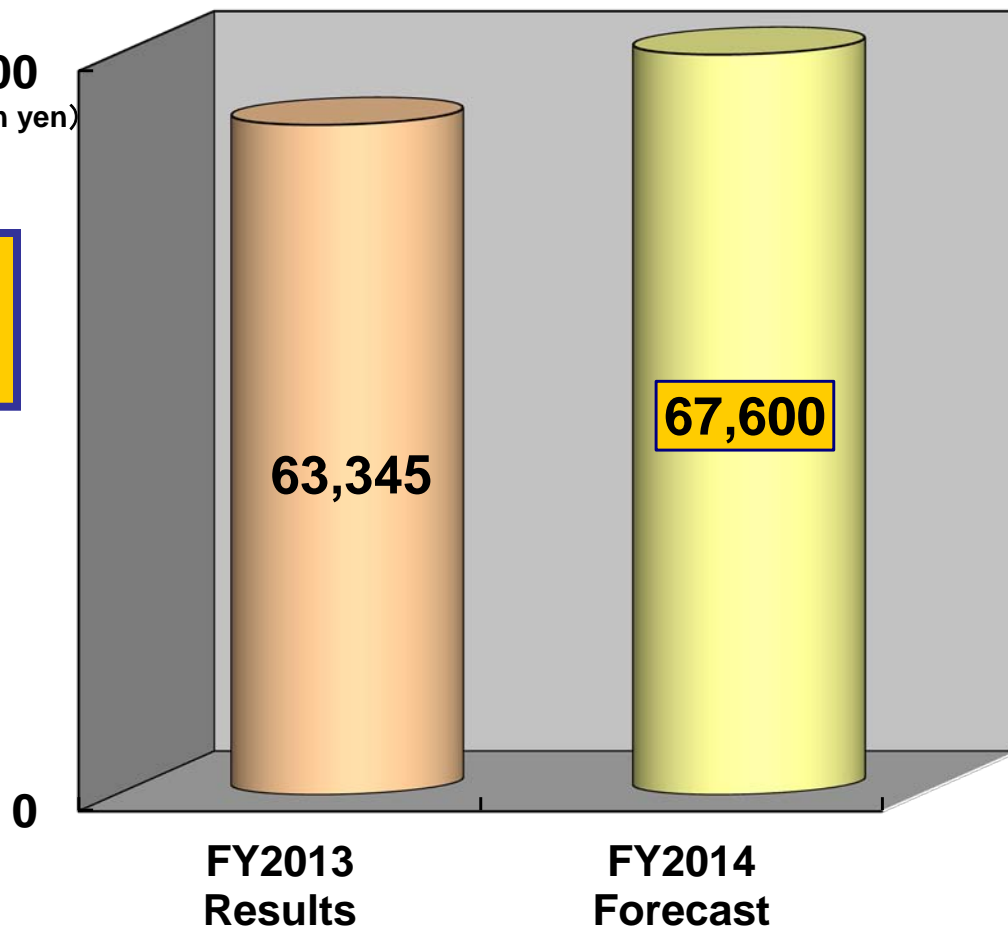


Segmental Forecast — Pharmaceuticals —

Net sales 67,600 million yen

**Year-on-Year change
+4,255 million yen (+6.7%)**

70,000
(Million yen)





Segmental Forecast

— Pharmaceuticals —

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	62,185	98.2%	64,420	95.3%	2,235	3.6%
Revenues from the licensing of industrial property rights	50	0.1%	2,200	3.2%	2,150	4272.7%
Prulifloxacin	861	1.3%	800	1.2%	-61	- 7.1%
Contract manufacturing business	248	0.4%	180	0.3%	-68	- 27.5%
Net sales	63,345	100.0%	67,600	100.0%	4,255	6.7%

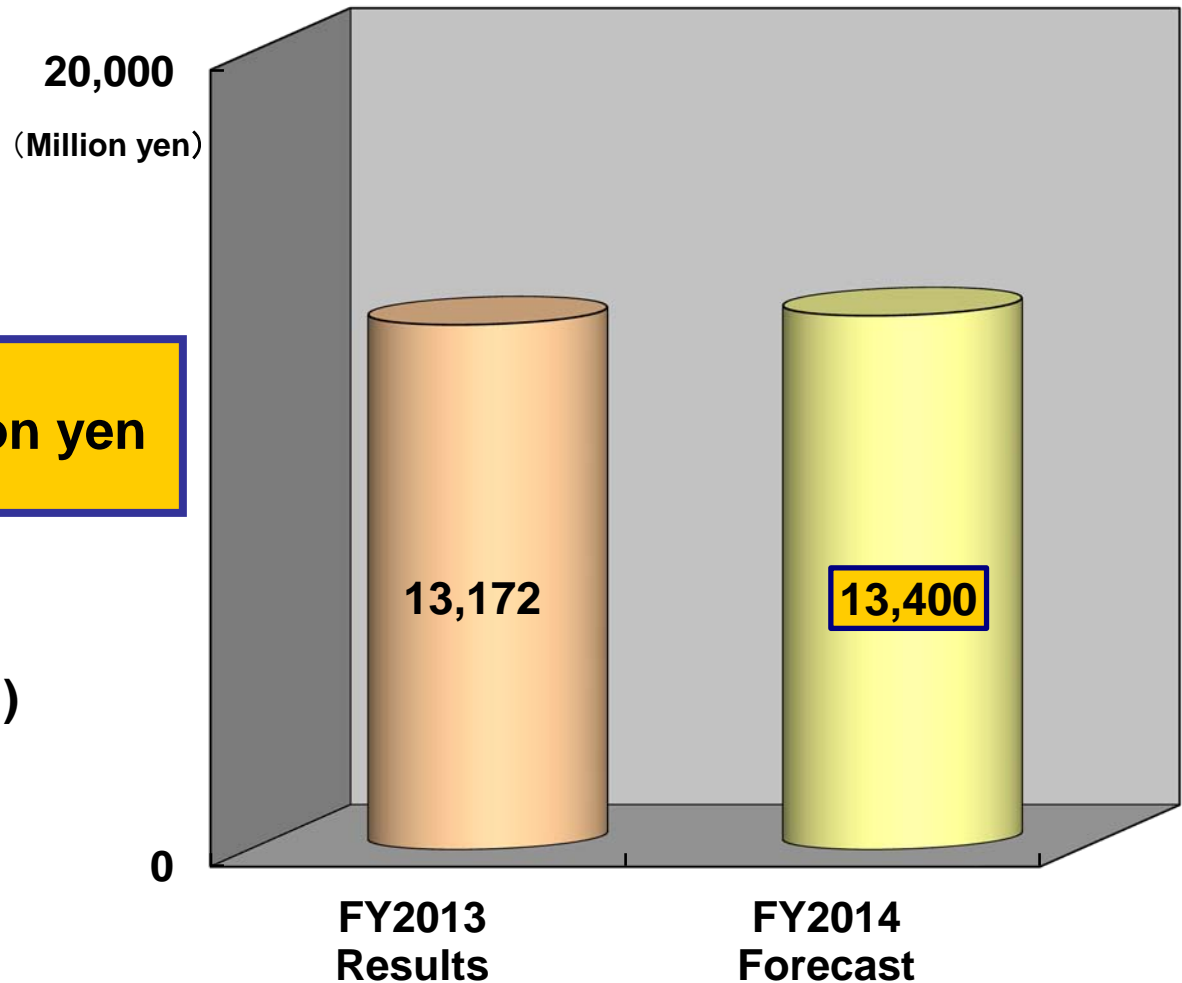


Segmental Forecast

— 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%
Nutritional ingredients	2,032	15.4%	2,050	15.3%	18	0.8%
Protein preparations	7,126	54.1%	7,200	53.7%	74	1.0%
Others	1,393	10.6%	1,430	10.7%	37	2.7%
Net sales	13,172	100.0%	13,400	100.0%	228	1.7%



Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2013		FY2014		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue						
Net sales	76,517	100.0%	81,000	100.0%	4,483	5.9%
Pharmaceuticals	63,345	82.8%	67,600	83.5%	4,255	6.7%
Functional Food	13,172	17.2%	13,400	16.5%	228	1.7%
Operating expenses	68,479	89.5%	72,500	89.5%	4,021	5.9%
Cost of sales	39,033	51.0%	41,700	51.5%	2,667	
SG&A expenses	19,914	26.0%	21,300	26.3%	1,386	
R&D expenses	9,530	12.5%	9,500	11.7%	△ 30	
Operating income	8,038	10.5%	8,500	10.5%	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	10.5%	462	5.7%
Non-operating income	1,019	1.3%	700	0.9%	-319	- 31.3%
Non-operating expenses	460	0.6%	500	0.6%	40	8.6%
Ordinary income	8,598	11.2%	8,700	10.7%	102	1.2%
Income taxes, etc	2,847	3.7%	2,700	3.3%	-147	- 5.2%
Net income	5,750	7.5%	6,000	7.4%	250	4.3%



Dividends Forecast

		FY2013	FY2014
Dividends per share	Interim	¥11	¥12
	Year-end	¥12	¥13
	Annual	¥23	¥25
EPS		¥85.25	¥89.02
Dividends payout ratio		27.0 %	28.1 %



Capital Investment Plan

Capital Investment and Depreciation

(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 Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
ACT-064992 (macitentan) <in-license>	NME	pulmonary arterial hypertension	Application	P III	→		NDA Filing
NS-24 (tramadol hydrochloride) <in-license>	new formulation	cancer pain chronic pain	Application	→		NDA Filing	
GA101 (obinutuzumab) <in-license>	NME	indolent non-Hodgkin's lymphoma aggressive non-Hodgkin's lymphoma	P III	→			
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	P II	→			NDA Filing
		chronic thromboembolic pulmonary hypertension	P II	→			
		arteriosclerosis obliterans	P II		P II	→	



R&D Compounds(Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
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 Compounds(Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2012	FY2013	FY2014	FY2015
NS-304 (selexipag) <in-house>	NME	pulmonary arterial hypertension	US/EU Preparation for NDA	Actelion P III		NDA Filing	
prulifloxacin <in-house>	NME	bacterial infections	China P III	Lee's Pharma 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 / II				



ACT-064992 (Macitentan)

- Treatment for PAH -

Development phase	<ul style="list-style-type: none">• Overseas: Approval [2013, Europe and USA]• Japan : Application [May.2014]
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



NS-24 (Tramadol)

- Long-acting analgesic -

Development phase	Application [Jun.2014]
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">▪ Overseas: PIII (Multinational studies, 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	<ul style="list-style-type: none">▪ Overseas: Preparation for NDA▪ Japan : PII
Origin	<ul style="list-style-type: none">▪ Nippon Shinyaku
Development	<p>[Apr. 2008]</p> <ul style="list-style-type: none">▪ Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland)▪ Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.
Indication	<ul style="list-style-type: none">▪ Pulmonary arterial hypertension▪ Chronic thromboembolic pulmonary hypertension▪ Arteriosclerosis obliterans
Dosage form	Tablet
Mechanism of action	Selective PGI ₂ receptor agonist
Feature	Long-acting oral drug Orphan drug designation by EMA [Aug.2005] Orphan drug designation by MHLW [Sep.2014]



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)
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 (Jul. 2013)
▪ Algorithm (Lebanon)	▪ Launch in Lebanon (Jan. 2012) ▪ Preparation for NDA in 11 countries of the Middle East and North Africa



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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