

Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2017

November 8, 2017

NIPPON SHINYAKU CO., LTD.



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1H FY2017 Summary

(Million yen)

	1H FY2016		1H FY2017		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	44,504	100.0%	49,666	100.0%	5,162	11.6%
Operating income	6,492	14.6%	9,266	18.7%	2,773	42.7%
Ordinary income	6,131	13.8%	9,678	19.5%	3,547	57.9%
Net income attributable to owners of the parent	4,483	10.1%	6,998	14.1%	2,515	56.1%

Topics

- ◆ Final completion of a manufacturing plant for highly active solid formulations in July
- ◆ GA101...submission in August
- ◆ NS-065/NCNP-01...Completion of patient enrollment



Segmental Review

-Pharmaceuticals-

(Million yen)

	1H FY2016		1H FY2017		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	32,396	86.2%	35,278	82.6%	2,881	8.9%
Profit in co-promotion	988	2.6%	1,891	4.4%	902	91.3%
Revenues from the licensing of industrial property rights	4,196	11.2%	5,536	13.0%	1,339	31.9%
Net sales	37,582	100.0%	42,706	100.0%	5,123	13.6%

Increase in sales:

- **Vidaza (+1,224 million yen, +18.2%)**
(myelodysplastic syndromes)
- **Zalutia (+1,139 million yen, +29.7%)**
(urinary disorder caused by benign prostatic hyperplasia)
- **Uptravi (+964 million yen, -)**
(pulmonary arterial hypertension)
- **Royalty payments based on overseas sales of our original product Uptravi**

Decrease in sales:

- **Eviprostat (-295 million yen, -16.9%)**
(benign prostatic hyperplasia)
- **Gaslon N (-190 million yen, -15.2%)**
(gastric ulcer, gastritis)

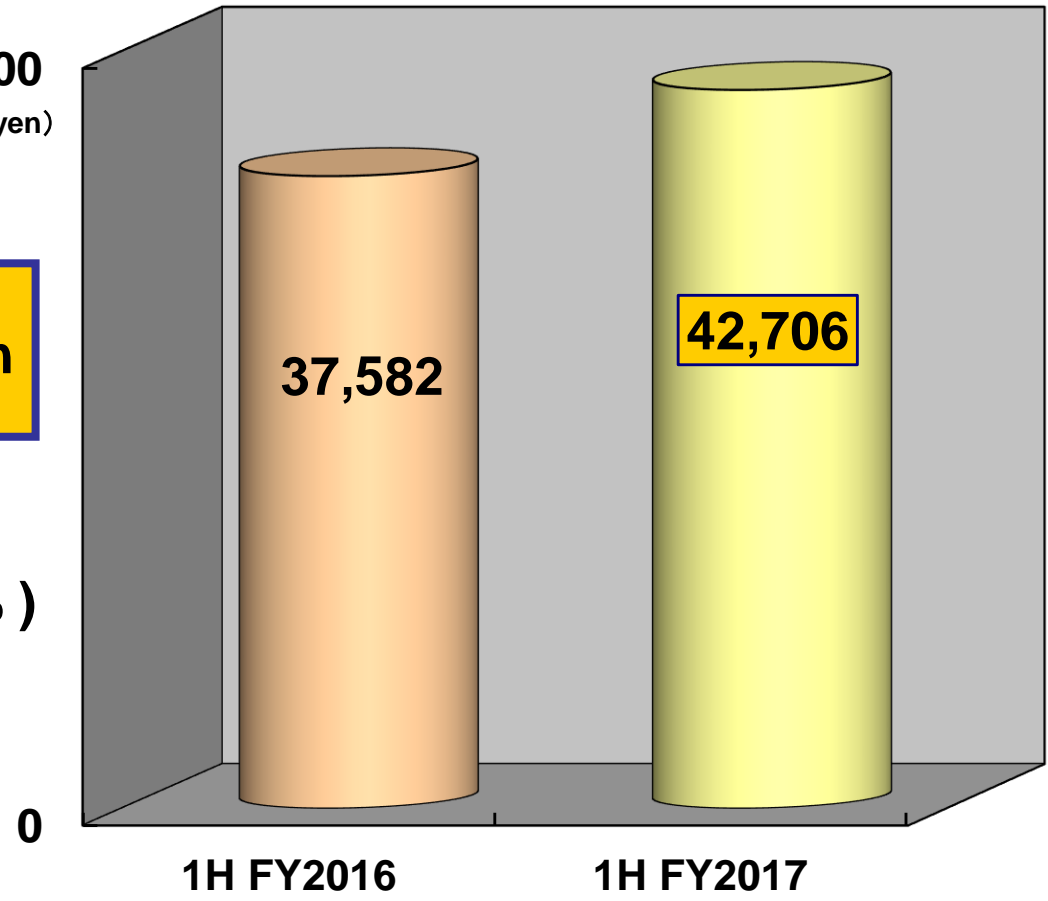


Segmental Review -Pharmaceuticals-

Net sales 42,706 million yen

**Year-on-Year change
+ 5,123 million yen (+ 13.6%)**

45,000
(Million yen)





Segmental Review

-Functional Food-

(Million yen)

	1H FY2016		1H FY2017		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	395	5.7%	432	6.2%	37	9.4%
Preservatives	1,073	15.5%	1,128	16.2%	55	5.2%
Protein preparations	4,739	68.5%	4,711	67.7%	-27	-0.6%
Others	714	10.3%	688	9.9%	-26	-3.7%
Net sales	6,922	100.0%	6,960	100.0%	38	0.6%



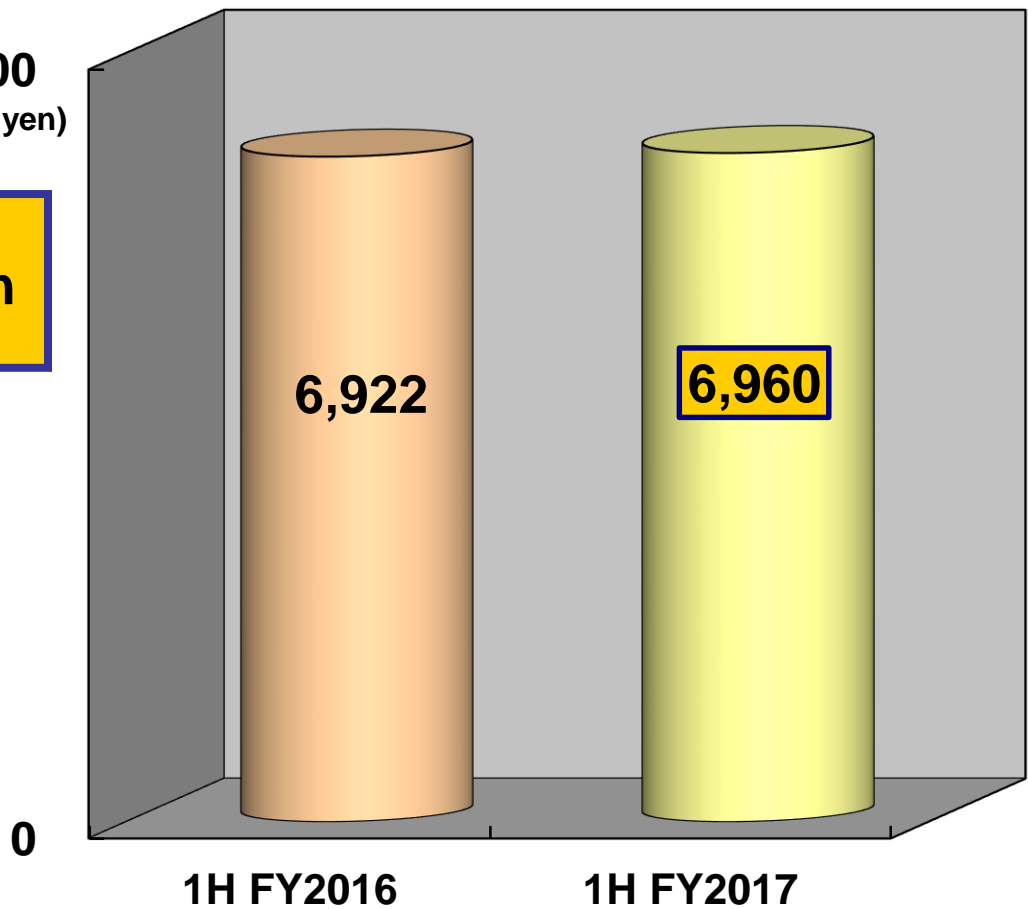
Segmental Review

-Functional Food-

8,000
(Million yen)

Net sales 6,960 million yen

**Year-on-Year change
+ 38 million yen (+ 0.6%)**



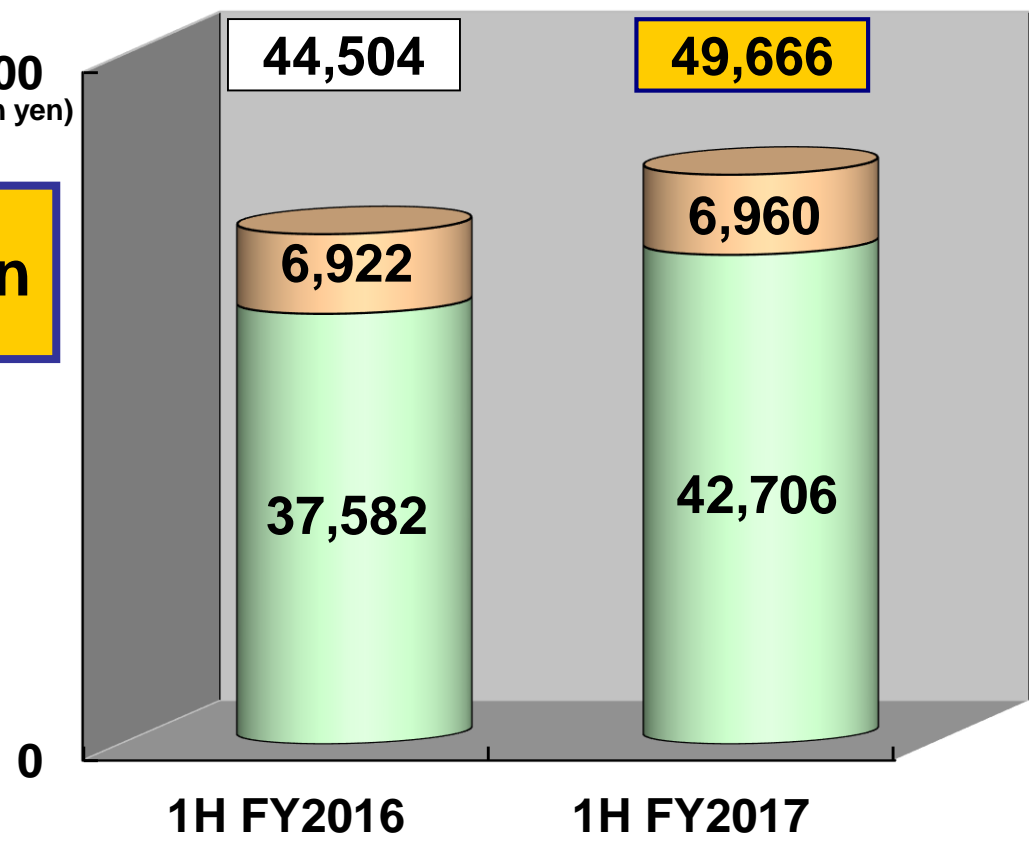


Net Sales

Net sales 49,666 million yen

**Year-on-Year change
+ 5,162 million yen (+ 11.6%)**

60,000
(Million yen)



■ Functional Food
■ Pharmaceuticals



Consolidated Statements of Income (1)

(Million yen)

	1H FY2016		1H FY2017		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	44,504	100.0%	49,666	100.0%	5,162	11.6%
Pharmaceuticals	37,582	84.4%	42,706	86.0%	5,123	13.6%
Functional Food	6,922	15.6%	6,960	14.0%	38	0.6%
Operating expenses	38,011	85.4%	40,400	81.3%	2,389	6.3%
Cost of sales	21,825	49.0%	22,479	45.3%	653	
SG&A expenses	11,133	25.0%	11,651	23.4%	517	
R&D expenses	5,052	11.4%	6,270	12.6%	1,218	
Operating income	6,492	14.6%	9,266	18.7%	2,773	42.7%



Consolidated Statements of Income (2)

(Million yen)

	1H FY2016		1H FY2017		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	6,492	14.6%	9,266	18.7%	2,773	42.7%
Non-operating income	534	1.2%	597	1.2%	62	11.7%
Non-operating expenses	896	2.0%	184	0.4%	-711	-79.4%
Ordinary income	6,131	13.8%	9,678	19.5%	3,547	57.9%
Income taxes, etc	1,647	3.7%	2,679	5.4%	1,031	62.6%
Net income attributable to owners of the parent	4,483	10.1%	6,998	14.1%	2,515	56.1%



Consolidated Balance Sheet

(Million yen)

	FY2016	FY2017	Change		FY2016	FY2017	Change
	4Q Results	2Q Results	Amt		4Q Results	2Q Results	Amt
Assets	150,905	152,378	1,472	Liabilities	36,589	31,682	-4,906
(Current assets)	98,787	97,401	-1,385	(Current liabilities)	27,001	21,974	-5,026
(Fixed assets)	52,118	54,976	2,858	(Long-term liabilities)	9,587	9,707	120
				Net assets	114,316	120,695	6,379
Total assets	150,905	152,378	1,472	Total liabilities and net assets	150,905	152,378	1,472



Consolidated Statements of Cash Flows

(Million yen)

	1H FY2016	1H FY2017	YoY Change
	Results	Results	Amt
Operating activities	6,718	-2,221	-8,939
Investing activities	-3,190	-3,844	-654
Financing activities	-947	-2,034	-1,086
Cash and cash equivalents at end of quarter	26,964	27,836	872

Cash and cash equivalents at end of quarter : - 8,077 Million yen (YonY FY2016)



Capital Investment

Capital Investment and Depreciation

(Million yen)

	1H FY2016	1H FY2017	
	Results	Results	Amt Chg
Capital investment	1,512	1,905	392
Depreciation	1,353	1,300	-52

Breakdown of Capital Investment

(Million yen)

	1H FY2016	1H FY2017	
	Results	Results	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	1,496	1,843	346
Production	1027	1,526	499
(Manufacturing facility for highly active medicines)	(944)	(1283)	(339)
R&D	313	173	-139
Others	156	143	-13
<Consolidated subsidiary>	16	62	45
Total capital investment	1,512	1,905	392



Business Forecast for FY2017

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	98,781	100.0%	102,000	100.0%	3,219	3.3%
Operating income	15,280	15.5%	17,500	17.2%	2,220	14.5%
Ordinary income	16,244	16.4%	18,000	17.6%	1,756	10.8%
Net income attributable to owners of the parent	11,749	11.9%	13,000	12.7%	1,251	10.6%

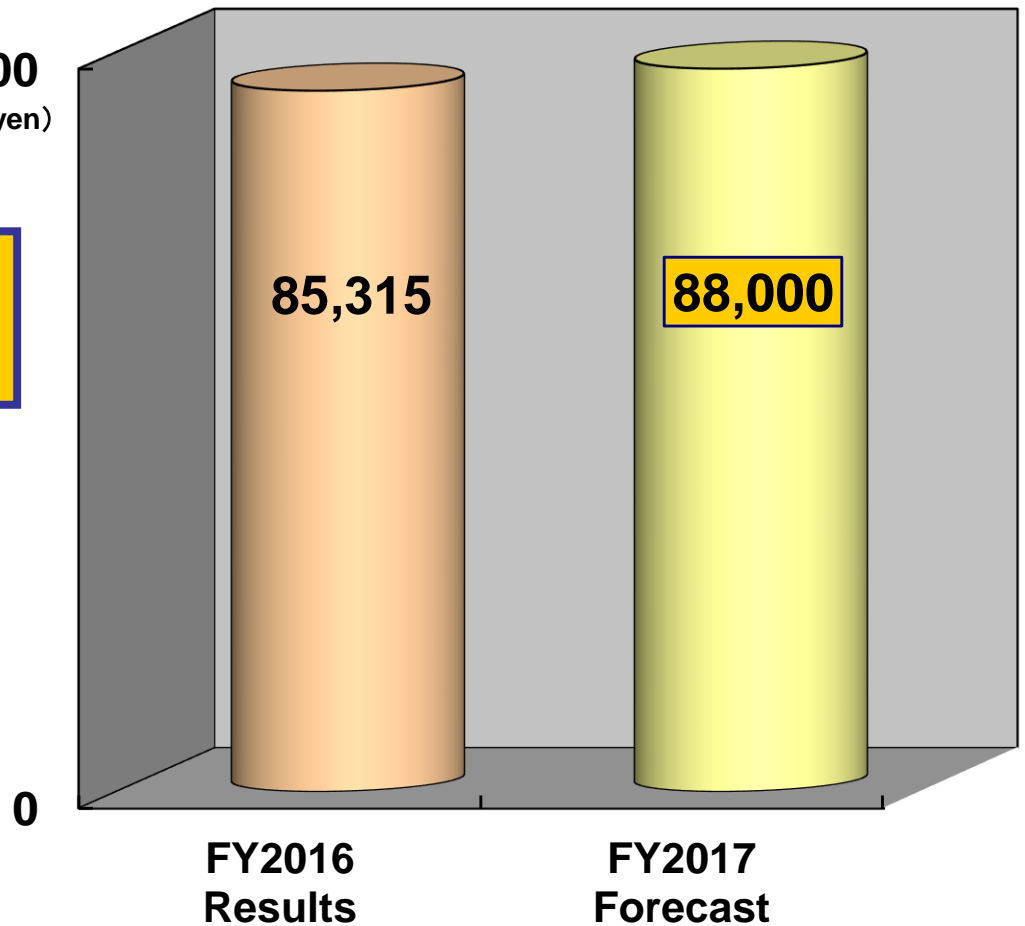


Segmental Forecast -Pharmaceuticals-

Net sales 88,000 million yen

**Year-on-Year change
+ 2,685 million yen (+ 3.1%)**

90,000
(Million yen)





Segmental Forecast

-Pharmaceuticals-

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	74,978	87.9%	72,700	82.6%	-2,278	-3.0%
Profit in co-promotion	2,928	3.4%	4,200	4.8%	1,272	43.4%
Revenues from the licensing of industrial property rights	7,408	8.7%	11,100	12.6%	3,692	49.8%
Net sales	85,315	100.0%	88,000	100.0%	2,685	3.1%

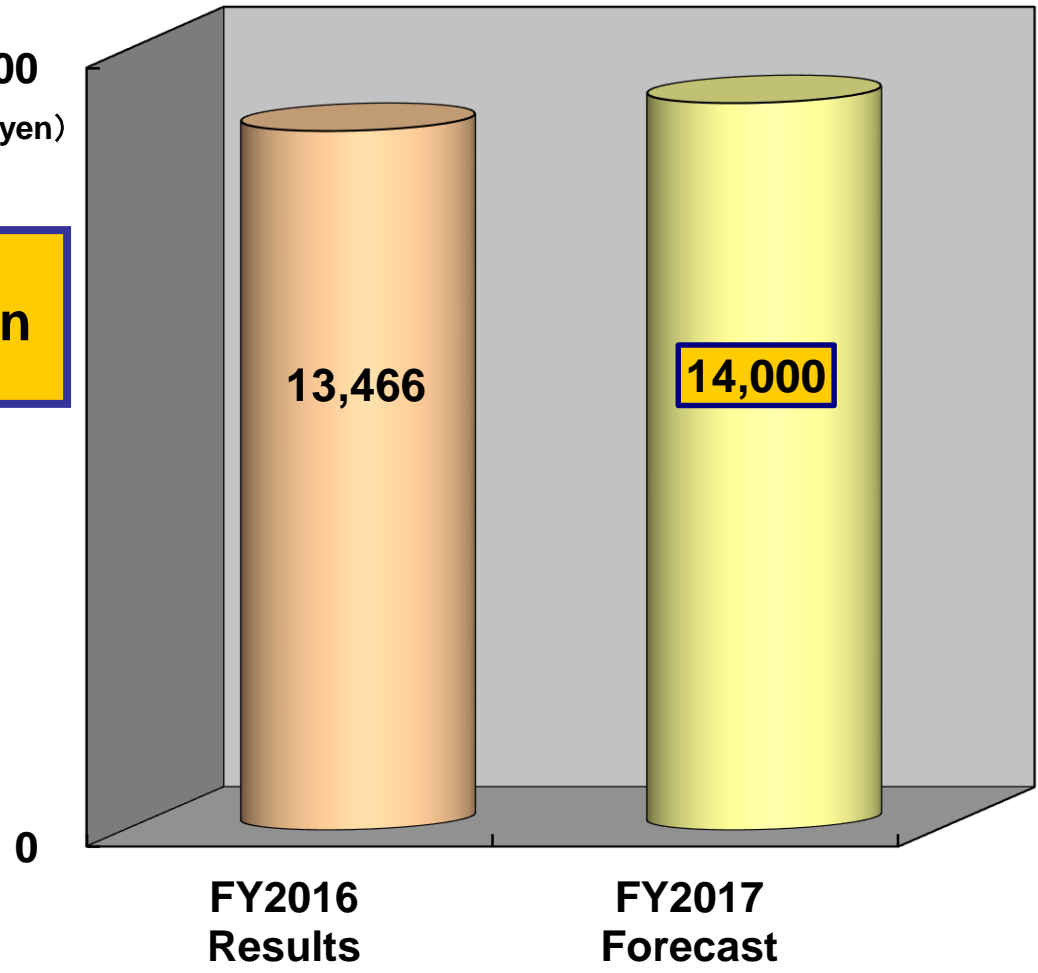


Segmental Forecast -Functional Food-

Net sales 14,000 million yen

**Year-on-Year change
+ 534 million yen (+4.0%)**

15,000
(Million yen)





Segmental Forecast -Functional Food-

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	847	6.3%	850	6.1%	3	0.3%
Preservatives	2,211	16.4%	2,400	17.1%	189	8.5%
Protein preparations	9,088	67.5%	9,400	67.1%	312	3.4%
Others	1,318	9.8%	1,350	9.7%	32	2.4%
Net sales	13,466	100.0%	14,000	100.0%	534	4.0%



Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue						
Net sales	98,781	100.0%	102,000	100.0%	3,219	3.3%
Pharmaceuticals	85,315	86.4%	88,000	86.3%	2,685	3.1%
Functional Food	13,466	13.6%	14,000	13.7%	534	4.0%
Operating expenses	83,501	84.5%	84,500	82.8%	999	1.2%
Cost of sales	44,835	45.4%	46,800	45.9%	1,965	
SG&A expenses	23,762	24.0%	24,000	23.5%	238	
R&D expenses	14,903	15.1%	13,700	13.4%	-1,203	
Operating income	15,280	15.5%	17,500	17.2%	2,220	14.5%



Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	15,280	15.5%	17,500	17.2%	2,220	14.5%
Non-operating income	1,587	1.6%	1,000	1.0%	-587	-37.0%
Non-operating expenses	623	0.7%	500	0.5%	-123	-19.8%
Ordinary income	16,244	16.4%	18,000	17.6%	1,756	10.8%
Extraordinary loss	766	0.8%	-	-	-766	-
Income taxes, etc	3,727	3.7%	5,000	4.9%	1,273	34.1%
Net income attributable to owners of the parent	11,749	11.9%	13,000	12.7%	1,251	10.6%



Dividends Forecast

		FY2016	FY2017
Dividends per share	Interim	¥18	¥26
	Year-end	¥30	¥26
	Annual	¥48	¥52
EPS		¥174.42	¥193.01
Dividends payout ratio		27.5%	26.9%



Capital Investment Plan

Capital Investment and Depreciation

(Million yen)

	FY2016 Results	FY2017 Forecast	Amt Chg
Capital investment	3,949	3,150	-799
Depreciation	2,648	2,900	252

Breakdown of Capital investment

(Million yen)

	FY2016 Results	FY2017 Forecast	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	3,906	3,000	-906
Production	2,324	1,950	-374
(Manufacturing facility for highly active medicines)	(1,874)	(1,300)	(-574)
R&D	726	650	-76
Others	855	400	-455
<Consolidated subsidiary>	42	150	108
Total capital investment	3,949	3,150	-799

Status of Development Pipeline



R&D Pipeline (Domestic)

Code No. (Generic name)	Application type	Indications	Stage	FY2015	FY2016	FY2017	FY2018
GA101 (obinutuzumab) <in-license>	NME	Follicular lymphoma	NDA filing	P III		NDA filing	
NS-304 (selexipag) <in-house>	new indication	Chronic thromboembolic pulmonary hypertension	P III	P II		P III	
		Arteriosclerosis obliterans	P II				
NS-580 <in-house>	NME	Endometriosis	P II	P I		P II	
NS-065/NCNP-01 <in-house>	NME	Duchenne muscular dystrophy	P I/II	P I/II			
NS-32 <in-license>	NME	Iron deficiency anemia	P I		P I		
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia	Preparation for development				
NS-73 <in-license>	NME	Veno-occlusive disease	Preparation for development				
NS-87 <in-license>	NME	Secondary acute myeloid leukemia	Preparation for development				



R&D Pipeline (Overseas)

Code No.	Application type	Indications	Stage	FY2015	FY2016	FY2017	FY2018
prulifloxacin <in-house>	NME	Bacterial infections	China NDA filing	Lee's Pharma P/III		NDA filing	
NS-065/NCNP-01 <in-house>	NME	Duchenne muscular dystrophy	USA P/II	P/II			
NS-018 <in-house>	NME	Myelofibrosis	USA P/II	P/II			



GA101 (Obinutuzumab)

- Treatment for CD20-positive B-cell follicular lymphoma -

Development Phase	<ul style="list-style-type: none">•EU : Approval (Roche)•USA : NDA filing (Roche)•Japan : NDA filing (Chugai Pharmaceutical Co., Ltd.)
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	CD20-positive B-cell follicular lymphoma (FL)
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 and arteriosclerosis obliterans -

Development Phase	<CTEPH> Japan: PIII <ASO> Japan: PIIb
Origin	Nippon Shinyaku
Development	<ul style="list-style-type: none">▪[Apr. 2008] Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd.(Switzerland)▪Co-development in Japan: Actelion Pharmaceuticals Japan Ltd.(CTEPH)▪Nippon Shinyaku (ASO)
Mechanism of action	Selective IP receptor agonist
Indication	<ul style="list-style-type: none">▪Chronic thromboembolic pulmonary hypertension (CTEPH)▪Arteriosclerosis obliterans (ASO)
Dosage form	Tablet
Feature	Long-acting oral drug



NS-580

- Treatment for endometriosis -

Development Phase	Japan: PIIa
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



NS-065/NCNP-01

- Treatment for Duchenne muscular dystrophy -

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



NS-32

- Treatment for iron deficiency anemia -

Development Phase	Japan: PI
Origin	[Dec. 2016] Licensed-in from: Pharmacosmos A/S
Development	Nippon Shinyaku
Mechanism of action	Strongly bound Iron Carbohydrate complex enabling iron correction in a single or low number of visits
Indication	Iron deficiency anemia
Dosage form	Injection
Feature	<ul style="list-style-type: none">▪ Allows high iron doses to be given with a good safety profile▪ Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron▪ Low immunogenic potential based on the short and linear oligosaccharide, isomaltoside▪ No profound hypophosphatemia



NS-917

- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2017] Licensed-in from: Delta-Fly Pharma
Development	Nippon Shinyaku
Mechanism of action	DNA strand-break by incorporating itself into DNA
Indication	Relapsed or refractory (r/r) acute myeloid leukemia (AML)
Dosage form	Injection
Feature	<ul style="list-style-type: none">▪ Significant anti-leukemic activity with unique mechanism of action from other nucleoside analogs at low dose continuous infusion▪ Tolerable safety profile available to elderly patients with r/r AML



NS-73

- Treatment of hepatic veno-occlusive disease -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Nippon Shinyaku in Japan
Mechanism of action	Protective action on vascular endothelium, normalization of the coagulation/fibrinolysis balance
Indication	Hepatic veno-occlusive disease (VOD)
Dosage form	Injection
Feature	<ul style="list-style-type: none">· VOD is a life-threatening complication which develops in patients following HSCT, and in severe cases, leading to death at high rates.· NS-73 is the first therapy which improves the survival rate of VOD patients. It has been launched in 31 countries.



NS-87

- Treatment of secondary acute myeloid leukemia -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Nippon Shinyaku in Japan
Mechanism of action	Liposomal combination of cytarabine and daunorubicin
Indication	Secondary acute myeloid leukemia (secondary AML)
Dosage form	Injection
Feature	<ul style="list-style-type: none">• NS-87 is the first therapy for the treatment of secondary AML in Japan.• The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow.



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)	▪ NDA filing in China
▪ Algorithm (Lebanon)	▪ Launch in Lebanon (Jan. 2012) ▪ Preparation for launch in 1 country and NDA filing in 5 countries



NS-018

- Treatment for myelofibrosis -

Development Phase	Overseas (USA): PI/II
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	<ul style="list-style-type: none">▪ Highly selective for active form of JAK2▪ Possibly best-in-class treatment for myelofibrosis



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