

Outline of Consolidated Financial Results for the Year Ended March 31, 2017

May 15, 2017
NIPPON SHINYAKU CO., LTD.



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FY2016 Summary

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	84,209	100.0%	98,781	100.0%	14,571	17.3%
Operating income	8,549	10.2%	15,280	15.5%	6,730	78.7%
Ordinary income	8,952	10.6%	16,244	16.4%	7,291	81.4%
Net income attributable to owners of the parent	6,340	7.5%	11,749	11.9%	5,409	85.3%

Topics

- ◆NS-304 (selexipag) ...
 - Europe : Approved in May 2016, Launched in June 2016
 - Japan : Orphan drug designation by MHLW for CTEPH in June 2016
Approved for PAH in September 2016, Launched in November 2016
- ◆NS-065/NCNP-01 ... Fast track designation by FDA in October 2016, Orphan drug designation and rare pediatric disease designation in January 2017
- ◆NS-32 ... licensed-in for iron deficiency anemia in December 2016
- ◆NS-917 ... licensed-in for relapsed/refractory acute myeloid leukemia, NS-73 ... licensed-in for hepatic veno-occlusive disease and NS-87 ... licensed-in for high risk acute myeloid leukemia, in March 2017



Segmental Review

-Pharmaceuticals-

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	66,040	93.7%	67,784	79.5%	1,744	2.6%
Profit in co-promotion	393	0.5%	2,928	3.4%	2,534	643.8%
Revenues from the licensing of industrial property rights	3,208	4.6%	7,408	8.7%	4,199	130.9%
Active Pharmaceutical Ingredients	846	1.2%	7,193	8.4%	6,347	749.4%
Net sales	70,489	100.0%	85,315	100.0%	14,826	21.0%

Increased in sales:

- **Zalutia (+2,668 million yen, +47.3%)**
(urinary disorder caused by benign prostatic hyperplasia (BPH))
- **Vidaza (+1,725 million yen, +14.0%)**
(myelodysplastic syndromes)
- **Milestone revenue for the approval of Uptravi in Europe, royalty revenue from overseas sales of Uptravi and sales of active pharmaceutical ingredients**

Decreased in sales:

- **Lunabell (-1,167million yen, -17.5%)**
(dysmenorrhea)
- **Eviprostat (-904 million yen, -21.4%)**
(BPH)

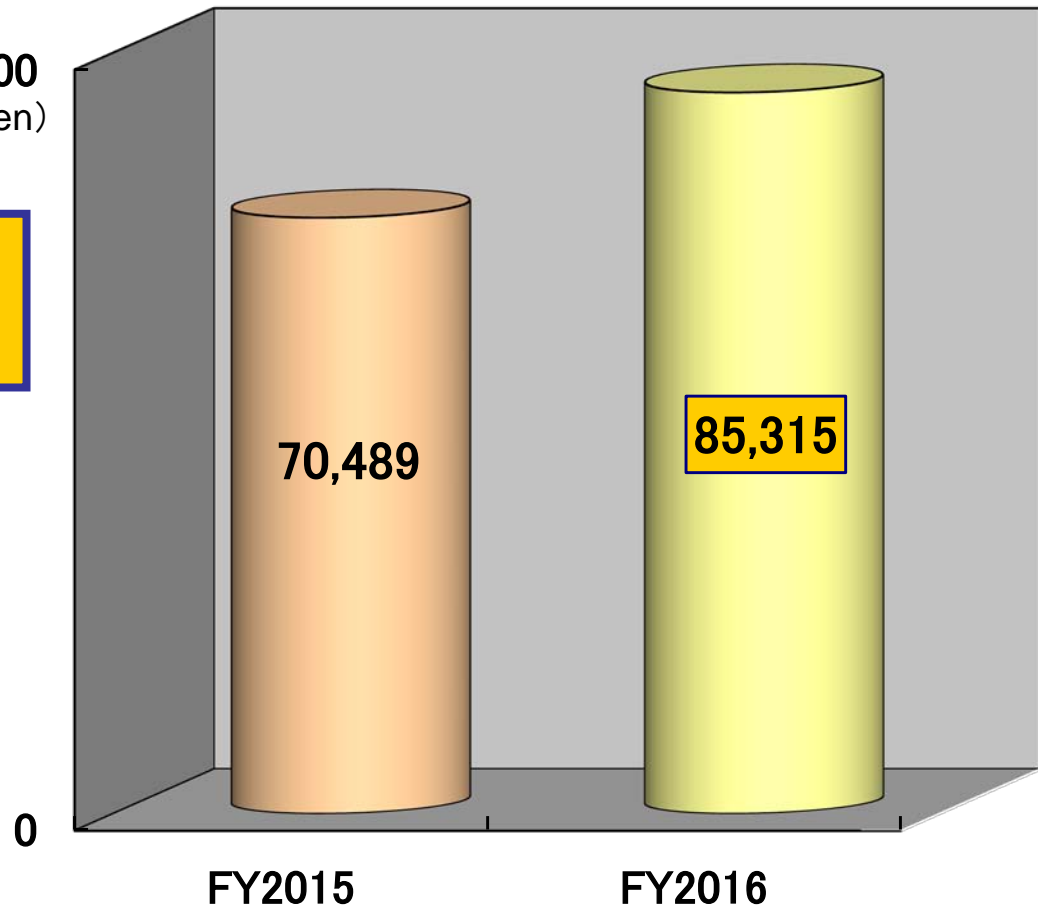


Segmental Review -Pharmaceuticals-

90,000
(Million yen)

Net sales 85,315 million yen

**Year-on-Year change
+14,826 million yen (+21.0%)**





Segmental Review

-Functional Food-

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	827	6.0%	847	6.3%	20	2.4%
Preservatives	1,906	13.9%	2,211	16.4%	305	16.0%
Protein preparations*	9,601	70.0%	9,088	67.5%	-513	-5.3%
Others	1,385	10.1%	1,318	9.8%	-66	-4.8%
Net sales	13,720	100.0%	13,466	100.0%	-254	-1.9%

* Protein preparations including nutritional ingredients



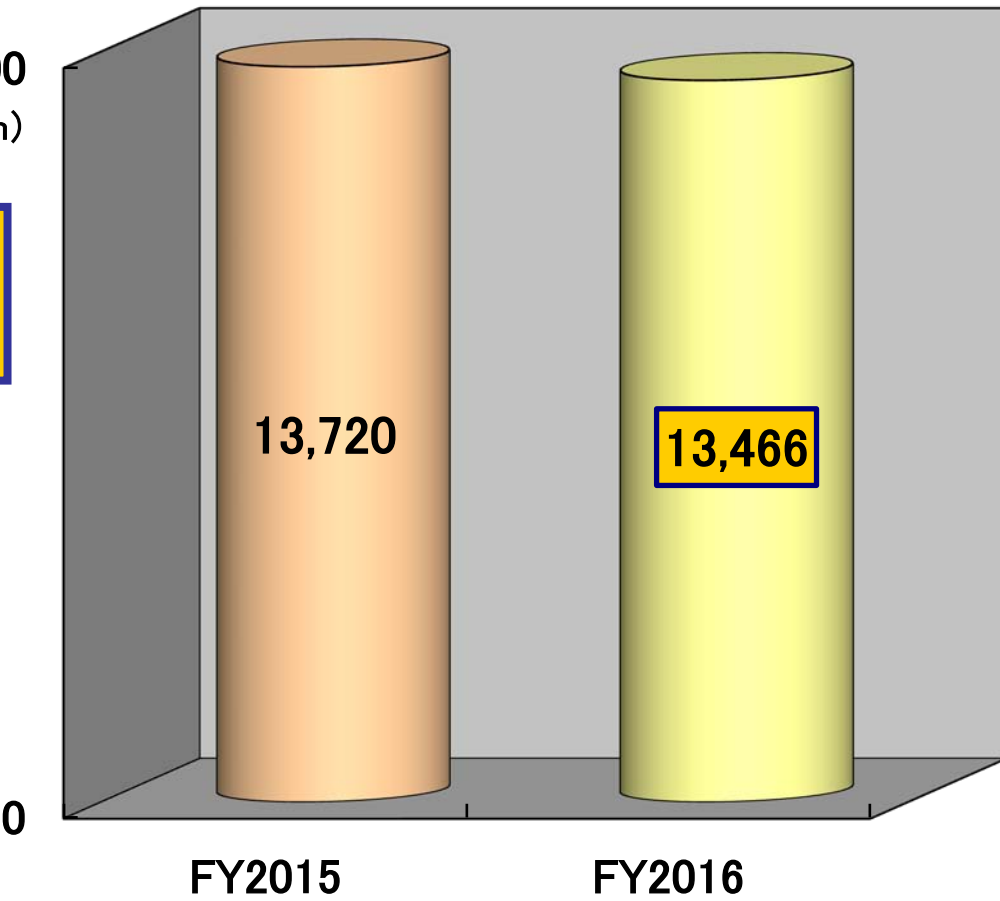
Segmental Review

-Functional Food-

Net sales 13,466 million yen

Year-on-Year change
-254 million yen (-1.9%)

14,000
(Million yen)



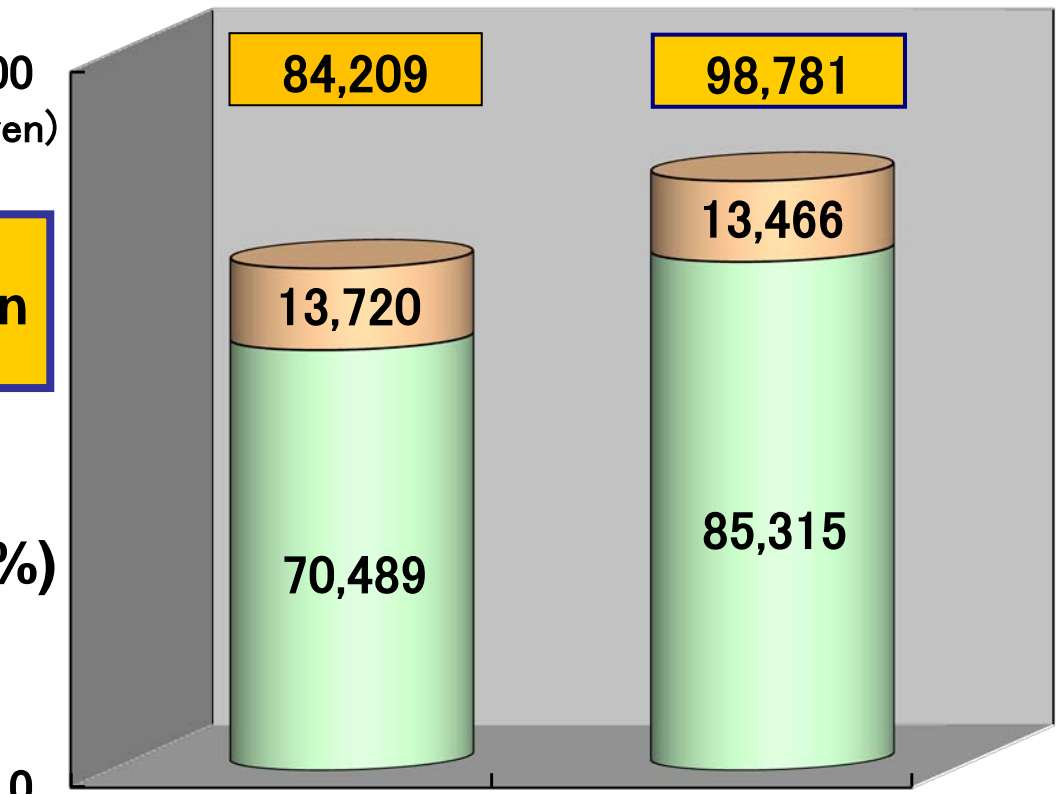


Net Sales

Net sales 98,781 million yen

**Year-on-Year change
+14,571 million yen (+17.3%)**

120,000
(Million yen)



FY2015

FY2016

- Pharmaceuticals
- Functional Food



Consolidated Statements of Income (1)

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	84,209	100.0%	98,781	100.0%	14,571	17.3%
Pharmaceuticals	70,489	83.7%	85,315	86.4%	14,826	21.0%
Functional Food	13,720	16.3%	13,466	13.6%	-254	-1.9%
Operating expenses	75,660	89.8%	83,501	84.5%	7,840	10.4%
Cost of sales	44,016	52.3%	44,835	45.4%	818	
SG&A expenses	21,904	25.9%	23,762	24.0%	1,857	
R&D expenses	9,739	11.6%	14,903	15.1%	5,164	
Operating income	8,549	10.2%	15,280	15.5%	6,730	78.7%



Consolidated Statements of Income (2)

(Million yen)

	FY2015		FY2016		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	8,549	10.2%	15,280	15.5%	6,730	78.7%
Non-operating income	1,246	1.5%	1,587	1.6%	341	27.4%
Non-operating expenses	842	1.1%	623	0.7%	-219	-26.1%
Ordinary income	8,952	10.6%	16,244	16.4%	7,291	81.4%
Extraordinary loss	-	-	766	0.8%	766	-
Income taxes, etc	2,612	3.1%	3,727	3.7%	1,115	42.7%
Net income attributable to owners of the parent	6,340	7.5%	11,749	11.9%	5,409	85.3%



Dividends

		FY2015	FY2016
Dividends per share	Interim	¥14	¥18
	Year-end	¥14	¥30
	Annual	¥28	¥48
EPS		¥94.10	¥174.42
Dividends payout ratio		29.8 %	27.5 %
DOE		1.9 %	3.0 %



Consolidated Balance Sheet

(Million yen)

	FY2015	FY2016	YoY Change		FY2015	FY2016	YoY Change
	4Q Results	4Q Results	Amt		4Q Results	4Q Results	Amt
Assets	135,370	150,905	15,535	Liabilities	32,607	36,589	3,981
(Current assets)	85,401	98,787	13,386	(Current liabilities)	20,569	27,001	6,431
(Fixed assets)	49,968	52,118	2,149	(Long-term liabilities)	12,037	9,587	-2,450
				Net assets	102,762	114,316	11,554
Total assets	135,370	150,905	15,535	Total liabilities and net assets	135,370	150,905	15,535



Consolidated Statements of Cash Flows

(Million yen)

	FY2015	FY2016	YoY Change
	Results	Results	Amt
Operating activities	8,915	19,082	10,167
Investing activities	-3,978	-5,916	-1,937
Financing activities	-1,907	-2,193	-285
Cash and cash equivalents at end of year	24,748	35,914	11,166



Capital Investment

Capital investment and Depreciation

(Million yen)

	FY2015	FY2016	
	Results	Results	Amt Chg
Capital investment	3,554	3,949	394
Depreciation	2,452	2,648	196

Breakdown of Capital Investment

(Million yen)

	FY2015	FY2016	
	Results	Results	Amt Chg
<NIPPON SHINYAKU CO.,LTD.>	3,445	3,906	461
Production	674	2,324	1,650
(Manufacturing facility for highly active medicines)	(108)	(1,874)	(1,766)
R&D	2,460	726	-1,733
Others	311	855	544
<Consolidated subsidiary>	109	42	-66
Total capital investment	3,554	3,949	394



Business Forecast for FY2017

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	98,781	100.0%	99,500	100.0%	719	0.7%
Operating income	15,280	15.5%	16,500	16.6%	1,220	8.0%
Ordinary income	16,244	16.4%	17,000	17.1%	756	4.7%
Net income attributable to owners of the parent	11,749	11.9%	12,500	12.6%	751	6.4%

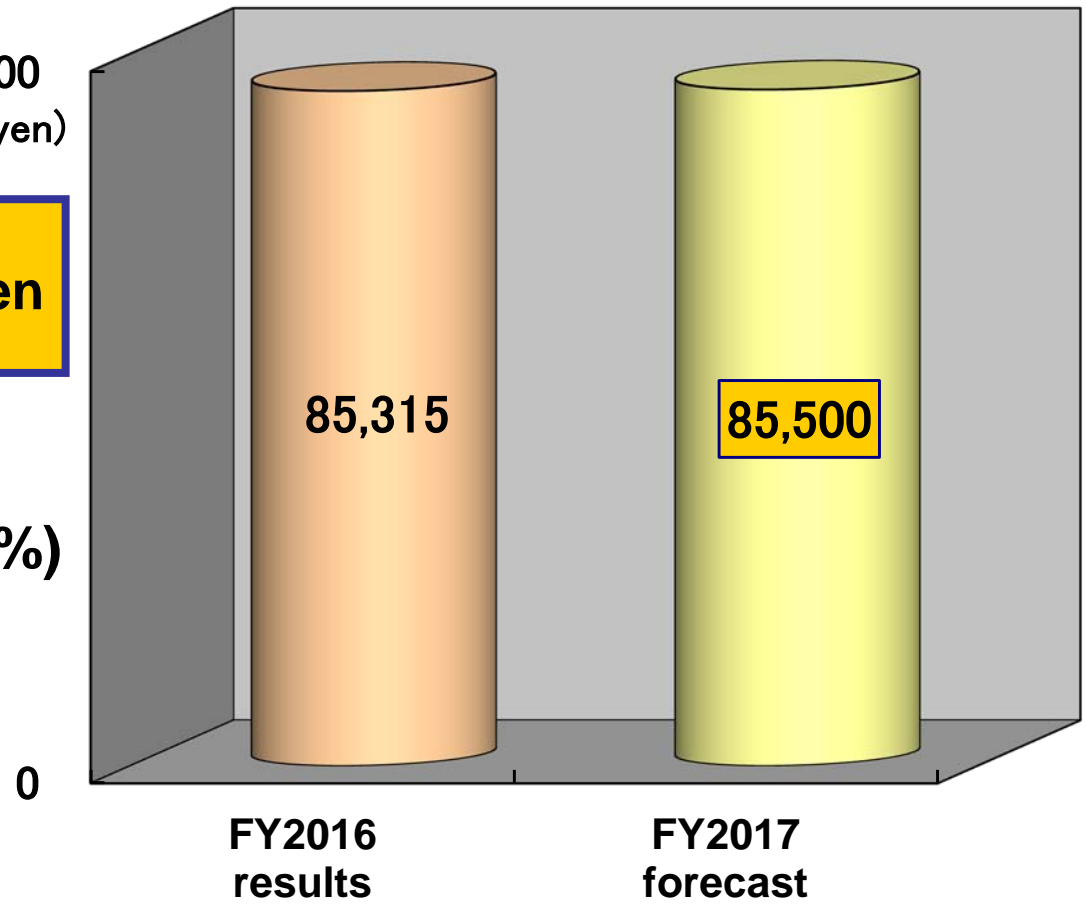


Segmental Forecast -Pharmaceuticals-

Net sales 85,500 million yen

**Year-on-Year change
+185 million yen (+0.2%)**

90,000
(Million yen)





Segmental Forecast -Pharmaceuticals-

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	74,978	87.9%	69,700	81.5%	-5,278	-7.0%
Profit in co-promotion	2,928	3.4%	4,700	5.5%	1,772	60.5%
Revenues from the licensing of industrial property rights	7,408	8.7%	11,100	13.0%	3,692	49.8%
Net sales	85,315	100.0%	85,500	100.0%	185	0.2%

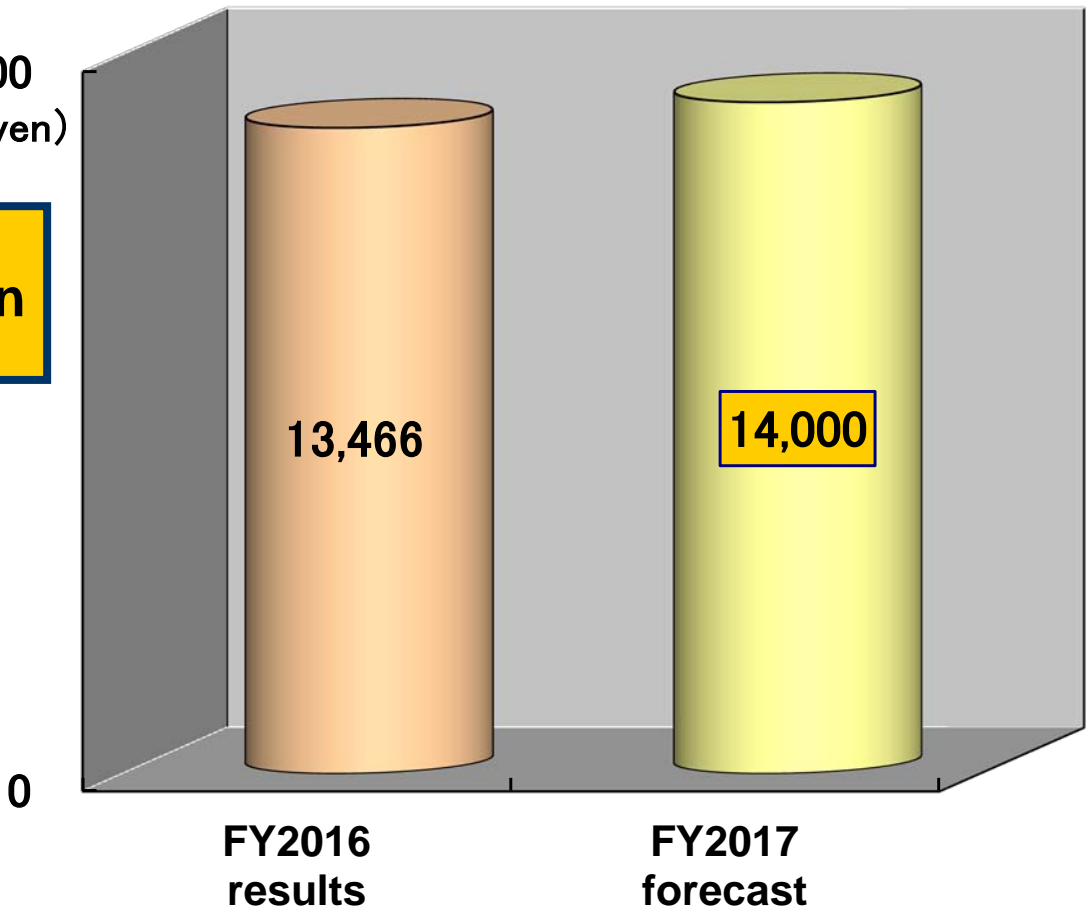


Segmental Forecast -Functional Food-

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%

* Protein preparations including nutritional ingredients



Consolidated Statements of Income (Forecast) (1)

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue						
Net sales	98,781	100.0%	99,500	100.0%	719	0.7%
Pharmaceuticals	(85,315)	(86.4%)	(85,500)	(85.9%)	(185)	(0.2%)
Functional Food	(13,466)	(13.6%)	(14,000)	(14.1%)	(534)	(4.0%)
Operating expenses	83,501	84.5%	83,000	83.4%	-501	-0.6%
Cost of sales	44,835	45.4%	46,200	46.4%	1,365	
SG&A expenses	23,762	24.0%	23,500	23.6%	-262	
R&D expenses	14,903	15.1%	13,300	13.4%	-1,603	
Operating income	15,280	15.5%	16,500	16.6%	1,220	8.0%



Consolidated Statements of Income (Forecast) (2)

(Million yen)

	FY2016		FY2017		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	15,280	15.5%	16,500	16.6%	1,220	8.0%
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%	17,000	17.1%	756	4.7%
Extraordinary loss	766	0.8%	-	-	-766	-
Income taxes, etc	3,727	3.7%	4,500	4.5%	773	20.7%
Net income attributable to owners of the parent	11,749	11.9%	12,500	12.6%	751	6.4%



Dividends Forecast

		FY2016	FY2017
Dividends per share	Interim	¥18	¥25
	Year-end	¥30	¥25
	Annual	¥48	¥50
EPS		¥174.42	¥185.58
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 Compounds (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Stage	FY2015	FY2016	FY2017	FY2018
NS-304 (selexipag) <in-house>	NME	Chronic thromboembolic pulmonary hypertension	PIII	PII →	→ PIII →		
		Arteriosclerosis obliterans	PII	→ PII →			
GA101 (obinutuzumab) <in-license>	NME	Indolent non-Hodgkin's lymphoma	PIII	→ PIII →		NDA Filing	
NS-065/NCNP-01 <in-house>	NME	Duchenne muscular dystrophy	PI/II	→ PI/II →			
NS-580 <in-house>	NME	Endometriosis	PI	→ PI →			
NS-32 <in-license>	NME	Iron deficiency anemia	PI		→ PI →		
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 Compounds (Overseas)

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



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



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.
Mechanism of action	Anti-CD20 monoclonal antibody
Indication	Indolent non-Hodgkin's lymphoma
Dosage form	Injection
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity



NS-065/NCNP-01

- Treatment for Duchenne muscular dystrophy -

Development Phase	<ul style="list-style-type: none">•USA : PII•Japan: PI/II
Origin	Nippon Shinyaku
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-580

- Treatment for endometriosis -

Development Phase	Japan: PI
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-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)	▪ Preparation for NDA
▪ 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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