NO BORDER

Going beyond it all, to the future of medicine.

Outline of Consolidated Financial Results for the Year Ended March 31, 2018

May 11, 2018 NIPPON SHINYAKU CO., LTD.

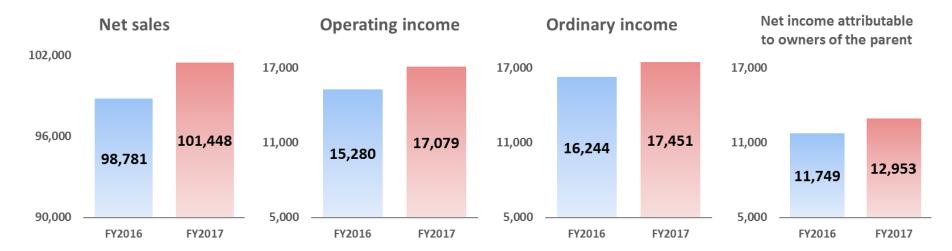


FY2017 Summary



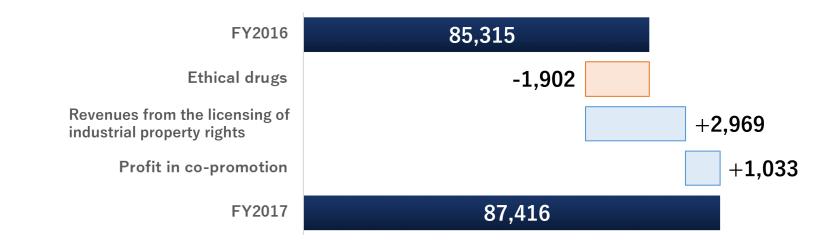


(Million yen)



🕟 NIPPON SHINYAKU CO., LTD.

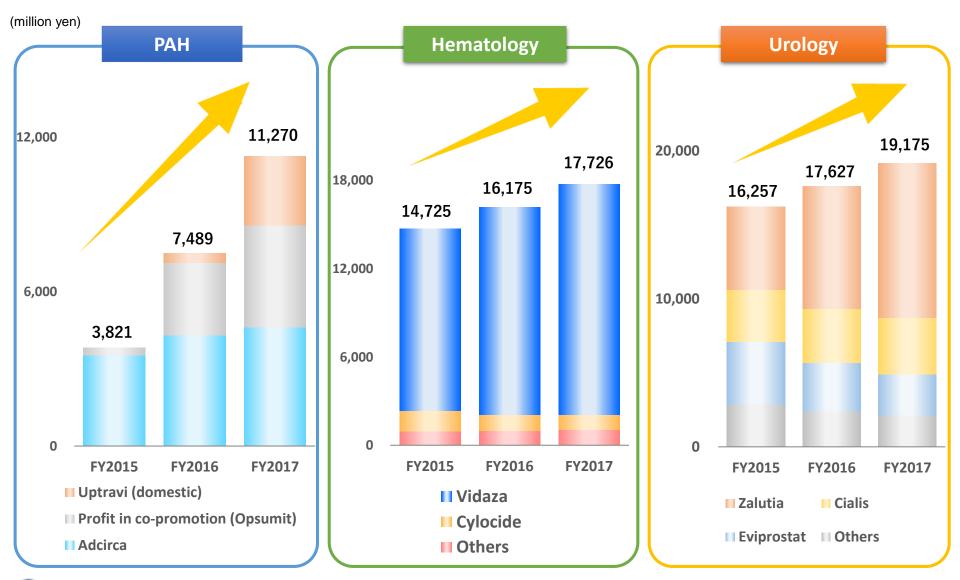
Segmental Review - Pharmaceuticals -



(Million yen)	FY2016		FY2	017	YoY Change		
(without year)	Results	Ratio	Results	Ratio	Amt	%	
Ethical drugs	74,978	87.9%	73,076	83.6%	-1,902	-2.5%	
Revenues from the licensing of industrial property rights	7,408	8.7%	10,378	11.9%	+2,969	+40.1%	
Profit in co-promotion	2,928	3.4%	3,962	4.5%	+1,033	+35.3%	
Net sales	85,315	100.0%	87,416	100.0%	+2,101	+2.5%	

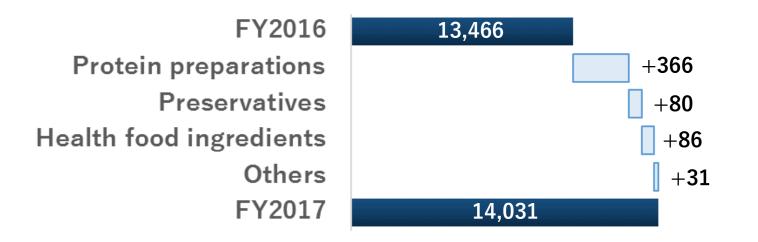


Three Main Fields of Focus



🔊 NIPPON SHINYAKU CO., LTD.

Segmental Review - Functional Food -

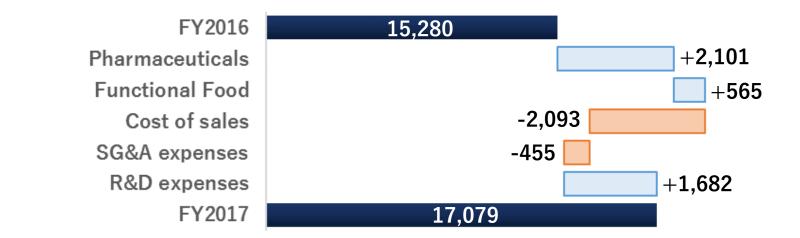


(Million yen)	FY2016		FY2	017	YoY Change	
(Willion yell)	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	9,088	67.5%	9,454	67.4%	+366	+4.0%
Preservatives	2,211	16.4%	2,298	16.4%	+86	+3.9%
Health food ingredients	847	6.3%	927	6.6%	+80	+9.5%
Others	1,318	9.8%	1,350	9.6%	+31	+2.4%
Net sales	13,466	100.0%	14,031	100.0%	+565	+4.2%



Operating income





(Million yen)	FY2	FY2016		017	YoY Change	
(withou yen)	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	98,781	100.0%	101,448	100.0%	+2,666	+2.7%
Pharmaceuticals	(85,315)	(86.4%)	(87,416)	(86.2%)	(+2,101)	(+2.5%)
Functional Food	(13,466)	(13.6%)	(14,031)	(13.8%)	(+565)	(+4.2%)
Operating expenses	83,501	84.5%	84,368	83.2%	+866	+1.0%
Cost of sales	44,835	45.4%	46,929	46.3%	+2,093	+4.7%
SG&A expenses	23,762	24.0%	24,217	23.9%	+455	+1.9%
R&D expenses	14,903	15.1%	13,221	13.0%	-1,682	-11.3%
Operating income	15,280	15.5%	17,079	16.8%	+1,799	+11.8%



Net income attributable to owners of the parent



(Million yen)	FY2016	FY2017	YoY Cl	nange
(WIIIIOII yell)	Results	Results	Amt	%
Operating income	15,280	17,079	+1,799	+11.8%
Non-operating income	1,587	1,122	-464	-29.3%
Non-operating expenses	623	751	+127	+20.5%
Ordinary income	16,244	17,451	+1,207	+7.4%
Extraordinary loss	766	-	-766	-
Income taxes, etc	3,727	4,497	+770	+20.7%
Net income attributable to owners of the parent	11,749	12,953	+1,203	+10.2%



Business Forecast for FY2018



(Million yen)	FY2017 Results	FY2018 Forecast	YoY Ch Amt	ange %	FY2018 (5 th MMP)
	Results	TUIECast	Amt	70	
Net sales	101,448	108,000	+6,552	+6.5%	110,000
Operating income	17,079	18,500	+1,421	+8.3%	18,000
Ordinary income	17,451	19,000	+1,549	+8.9%	-
Net income attributable to owners of the parent	12,953	14,000	+1,047	+8.1%	12,000



Segmental Forecast - Pharmaceuticals - 🕥

	FY20	FY2017)18	YoY Change	
(Million yen)	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	73,076	83.6%	72,800	77.7%	-276	-0.4%
Revenues from the licensing of industrial property rights	10,378	11.9%	15,500	16.6%	+5,122	+49.4%
Profit in co-promotion	3,962	4.5%	5,300	5.7%	+1,338	+33.8%
Net sales	87,416	100.0%	93,600	100.0%	+6,184	+7.1%



Segmental Forecast - Functional Food -

(Million yen)	FY20	FY2017		18	YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	9,454	67.4%	9,585	66.6%	+131	+1.4%
Preservatives	2,298	16.4%	2,450	17.0%	+152	+6.6%
Health food ingredients	927	6.6%	960	6.7%	+33	+3.5%
Others	1,350	9.6%	1,405	9.7%	+55	+4.1%
Net sales	14,031	100.0%	14,400	100.0%	+369	+2.6%



Consolidated Statements of Income (Forecast)

(Million yen)	FY20)17	FY20)18	YoY Change		
(Willion yell)	Results	Ratio	Forecast	Ratio	Amt	%	
Net sales	101,448	100.0%	108,000	100.0%	+6,552	+6.5%	
Pharmaceuticals	(87,416)	(86.2%)	(93,600)	(86.7%)	(+6,184)	(+7.1%)	
Functional Food	(14,031)	(13.8%)	(14,400)	(13.3%)	(+369)	(+2.6%)	
Cost of sales	46,929	46.3%	48,700	45.1%	+1,771	+3.8%	
SG&A expenses	24,217	23.9%	27,200	25.2%	+2,983	+12.3%	
R&D expenses	13,221	13.0%	13,600	12.6%	+379	+2.9%	
Operating income	17,079	16.8%	18,500	17.1%	+1,421	+8.3%	
Non-operating income	1,122	1.1%	1,000	0.9%	-122	-10.9%	
Non-operating expenses	751	0.7%	500	0.5%	-251	-33.4%	
Ordinary income	17,451	17.2%	19,000	17.6%	+1,549	+8.9%	
Income taxes, etc	4,497	4.4%	5,000	4.6%	+503	+11.2%	
Net income attributable to owners of the parent	12,953	12.8%	14,000	13.0%	+1,047	+8.1%	

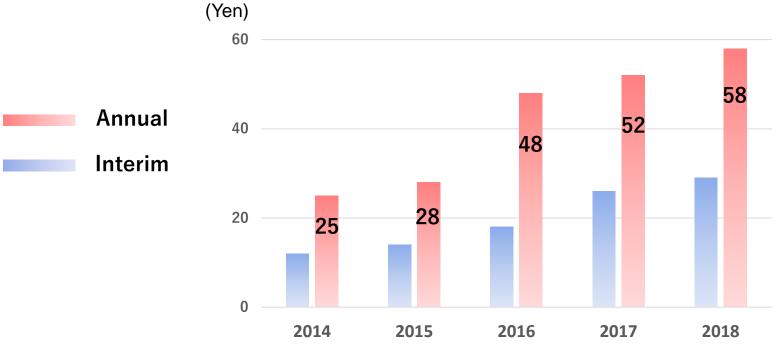


Dividends Forecast



		FY2017	FY2018
Dividends per share	Interim	¥26	¥29
Dividends per share	Annual	¥52	¥58
EPS		¥192.31	¥207.85
Dividends payout ratio		27.0 %	27.9 %

<u>Dividends Policy</u>
 Target payout ratio
 (performance-based)
 is around 30%.



Status of Development Pipeline



R&D Compounds (Domestic)

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Code No. (Generic name) <origin></origin>	Application type	Indications	Preparation for development	PI	PII	PIII	Preparation for NDA	NDA filing	
GA101 (obinutuzumab) <in-license></in-license>	NME	CD20-positive B-cell follicular lymphoma							
NS-73 (defibrotide) <in-license></in-license>	NME	Veno-occlusive disease							
NS-304		Chronic thromboembolic pulmonary hypertension							
(selexipag) <in-house></in-house>	New indication		Arteriosclerosis obliterans						
<in-nouse></in-nouse>		Lumbar spinal stenosis							
NS-580 <in-house></in-house>	NME	Endometriosis							
NS-17 (azacitidine) <in-license></in-license>	New indication	Acute myeloid leukemia							
NS-065/NCNP-01 <in-house></in-house>	NME	Duchenne muscular dystrophy							
NS-32 <in-license></in-license>	NME	Iron deficiency anemia							
NS-917 <in-license></in-license>	NME	Relapsed/refractory acute myeloid leukemia							
NS-87 <in-license></in-license>	NME	Secondary acute myeloid leukemia							



: changes from the third quarter

R&D Compounds (Overseas)

Code No.	Application	Indications	Preparation for	PI	PII	PIII	Preparation	NDA
<origin></origin>	type	mulcations	development				for NDA	filing
prulifloxacin <in-house></in-house>	NME	Bacterial infections						
NS-065/NCNP-01	NME	Duchenne muscular						
<in-house></in-house>		dystrophy						
NS-018	NME	Myelofibrosis						
<in-house></in-house>		wyelonbrosis						



Reference Materials



Consolidated Statements of Income



(Million yen)	FY2016		FY20	FY2017		YoY Change	
(winnon yen)	Results	Ratio	Results	Ratio	Amt	%	
Net sales	98,781	100.0%	101,448	100.0%	+2,666	+2.7%	
Pharmaceuticals	85,315	86.4%	87,416	86.2%	+2,101	+2.5%	
Functional Food	13,466	13.6%	14,031	13.8%	+565	+4.2%	
Cost of sales	44,835	45.4%	46,929	46.3%	+2,093	+4.7%	
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Operating income	15,280	15.5%	17,079	16.8%	+1,799	+11.8%	
Non-operating income	1,587	1.6%	1,122	1.1%	-464	-29.3%	
Non-operating expenses	623	0.7%	751	0.7%	+127	+20.5%	
Ordinary income	16,244	16.4%	17,451	17.2%	+1,207	+7.4%	
Extraordinary loss	766	0.8%	-	-	-766	-	
Income taxes, etc	3,727	3.8%	4,497	4.4%	+770	+20.7%	
Net income attributable to owners of the parent	11,749	11.9%	12,953	12.8%	+1,203	+10.2%	



Consolidated Balance Sheet



(Million yen)	FY2016	FY2017	YoY Change		FY2016	FY2017	YoY Change
(winnon yen)	4Q Results	4Q Results	Amt		4Q Results	4Q Results	Amt
Assets	150,905	158,192	+7,286	Liabilities	36,589	32,503	-4,085
(Current assets)	98,787	97,953	-833	(Current liabilities)	27,001	22,454	-4,547
(Fixed assets)	52,118	60,238	+8,120	(Long-term liabilities)	9,587	10,048	+461
				Net assets	114,316	125,689	+11,372
Total assets	150,905	158,192	+7,286	Total liabilities and net assets	150,905	158,192	+7,286

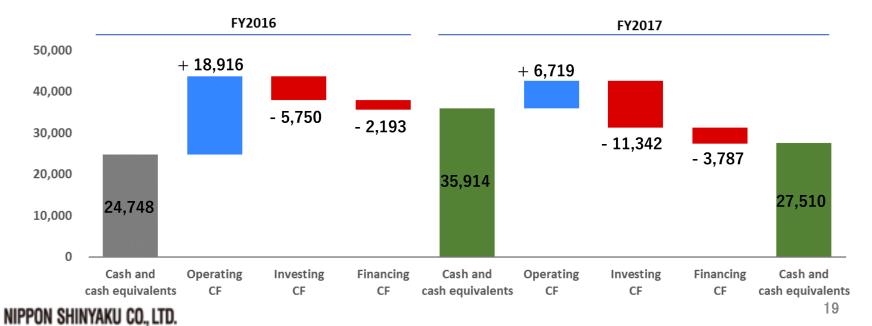
=Assets=		=Liabilities and Net assets =	
Cash and deposits	- 9,714	Notes and accounts payable	+ 2,407
Notes and accounts receivable	+ 3,149	Accounts payable	- 5,252
Securities	+ 3,162	Income taxes payable	- 1,777
Inventories	+ 1,768	Deferred tax liabilities	+ 1,184
Property, plant and equipment	+ 1,058	Retained earnings	+ 9,181
Investment securities	+ 4,627		
Long-term prepaid expenses	+ 2,535		

NIPPON SHINYAKU CO., LTD.

Consolidated Statements of Cash Flows



(Million yen)	FY2016 Results	FY2017 Results	YoY Change Amt
Operating activities	18,916	6,719	-12,197
Investing activities	-5,750	-11,342	-5,591
Financing activities	-2,193	-3,787	-1,594
Cash and cash equivalents at end of year	35,914	27,510	-8,404



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



Development Phase	 EU, USA : Approval (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-73 (Defibrotide)

- Treatment of hepatic veno-occlusive disease -



Development Phase	Japan: Preparation for NDA
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	 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 only drug for the treatment of VOD (EU/US guideline). It has been launched in 34 countries.

NS-304 (Selexipag)

- Treatment for pulmonary hypertension, arteriosclerosis obliterans, lumbar spinal stenosis -

Development Phase	<cteph> Japan: PIII <aso> Japan: PIIb <lss> Japan: PIIa</lss></aso></cteph>
Origin	Nippon Shinyaku
Development	 [Apr. 2008] Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd. (Switzerland) Co-development in Japan: Actelion Pharmaceuticals Japan Ltd. (CTEPH) Nippon Shinyaku (ASO) Nippon Shinyaku (LSS)
Mechanism of action	Selective IP receptor agonist
Indication	 Chronic thromboembolic pulmonary hypertension (CTEPH) Arteriosclerosis obliterans (ASO) Lumbar spinal stenosis (LSS)
Dosage form	Tablet
Feature	Long-acting oral drug



NS-580 - Treatment for endometriosis -



Development Phase	Japan: Plla
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Inhibition of membrane-associated prostaglandin E syntase-1
Indication	Endometriosis
Dosage form	Oral agent
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency



NS-17 - Treatment for acute myeloid leukemia -



Development Phase	Japan: PII
Origin	[Oct. 2006] Licensed-in from :Celgene Corporation
Development	Nippon Shinyaku
Mechanism of action	Inhibition of DNA methylation, Cytotoxic effects
Indication	acute myeloid leukemia
Dosage form	Injection
Feature	 Standard Treatment for acute myeloid leukemia that ineligible for intensive chemotherapy Improvement for life prognosis

NS-065/NCNP-01 - Treatment for Duchenne muscular dystrophy -



Development Phase	•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	 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	 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





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	 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-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
Mechanism of action	Liposomal combination of cytrabine and daunorubicin
Indication	Secondary acute myeloid leukemia (secondary AML)
Dosage form	Injection
Feature	 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





Development Phase	Overseas (USA): PI/II
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	 Highly selective for active form of JAK2 Possibly best-in-class treatment for myelofibrosis



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