

N O B O R D E R

Going beyond it all, to the future of medicine.

Outline of Consolidated Financial Results for the 2nd Quarter Ended Sep 30, 2018

**November 8, 2018
NIPPON SHINYAKU CO., LTD.**



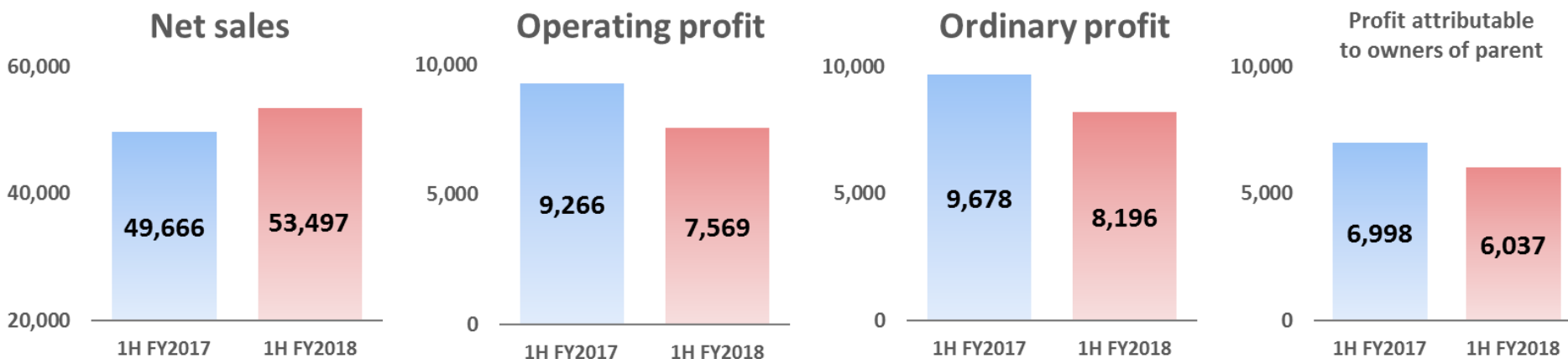
NIPPON SHINYAKU CO., LTD.

1H FY2018 Summary

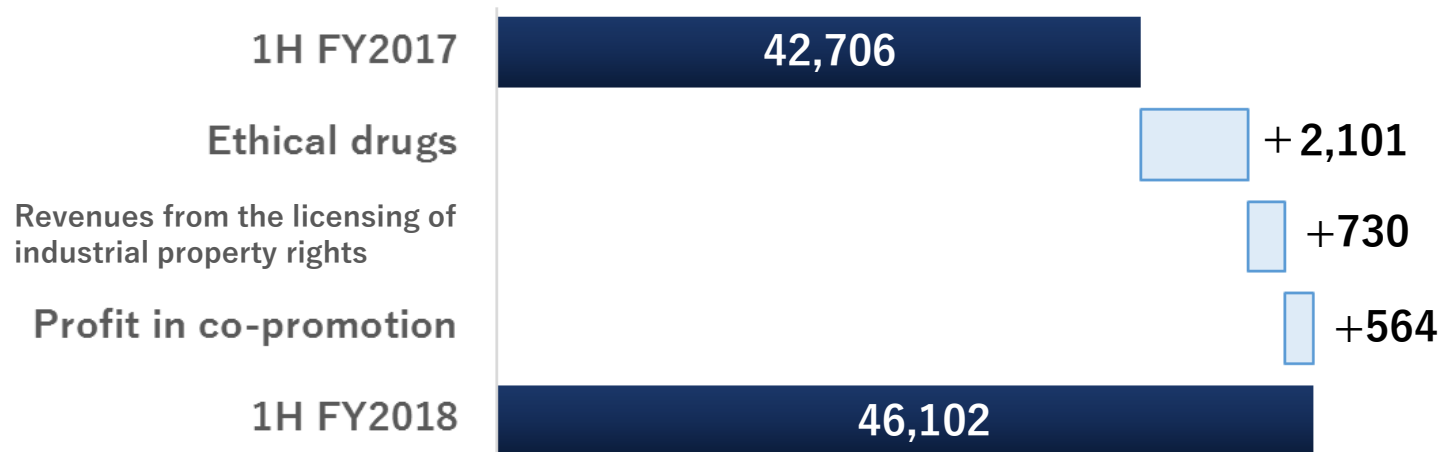


◆ Net sales	:	53,497 million yen	(+7.7%)
◆ Operating profit	:	7,569 million yen	(-18.3%)
◆ Ordinary profit	:	8,196 million yen	(-15.3%)
◆ Profit attributable to owners of parent	:	6,037 million yen	(-13.7%)

(Million yen)



Segmental Review - Pharmaceuticals -



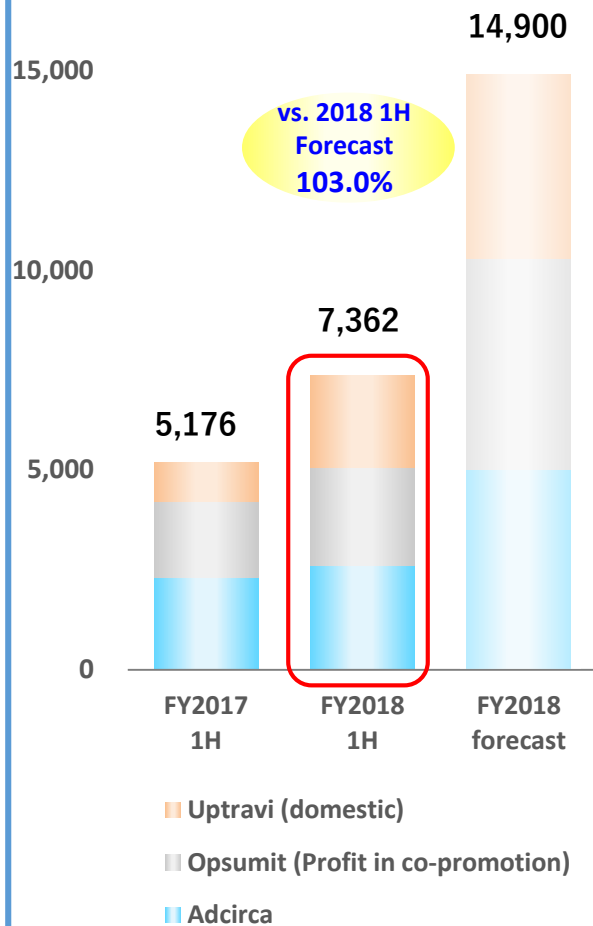
(Million yen)	1H FY2017		1H FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	35,278	82.6%	37,379	81.1%	+2,101	+6.0%
Revenues from the licensing of industrial property rights	5,536	13.0%	6,267	13.6%	+730	+13.2%
Profit in co-promotion	1,891	4.4%	2,455	5.3%	+564	+29.9%
Net sales	42,706	100.0%	46,102	100.0%	+3,396	+8.0%

Three Main Fields of Focus

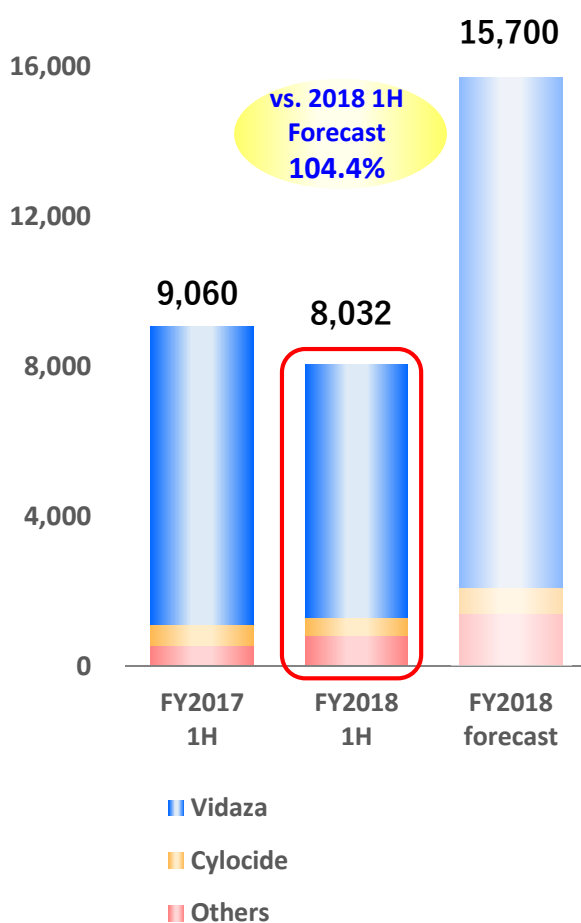


(million yen)

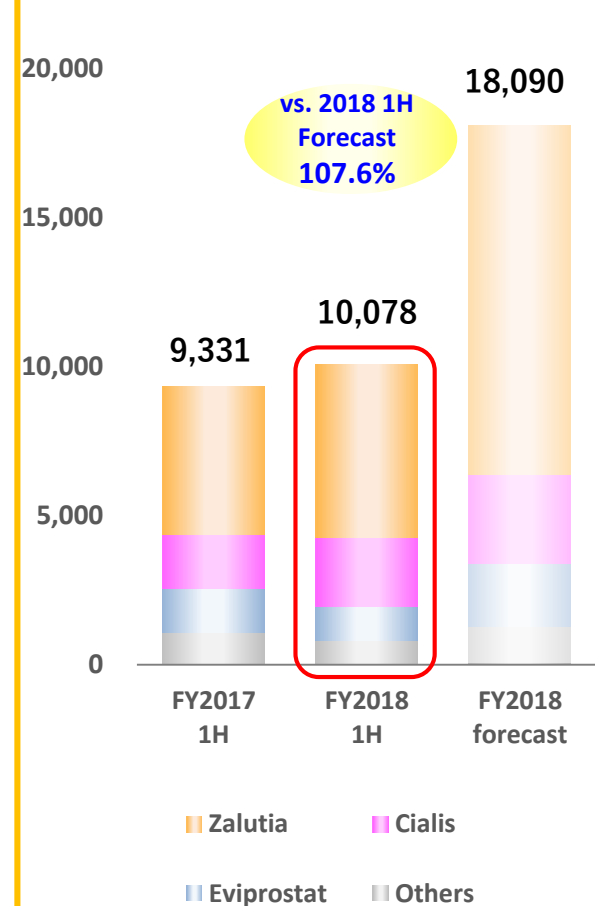
PAH



Hematology



Urology

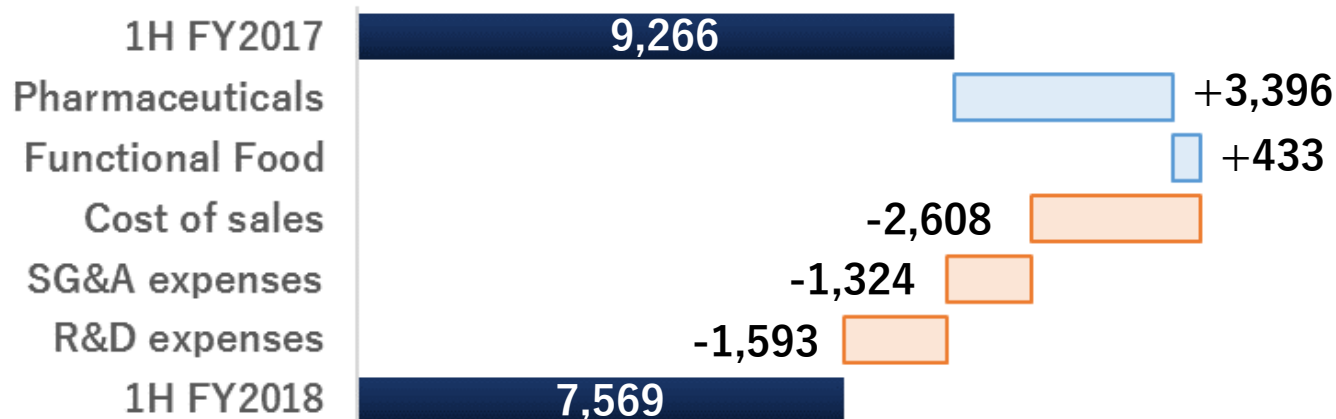


Segmental Review - Functional Food -



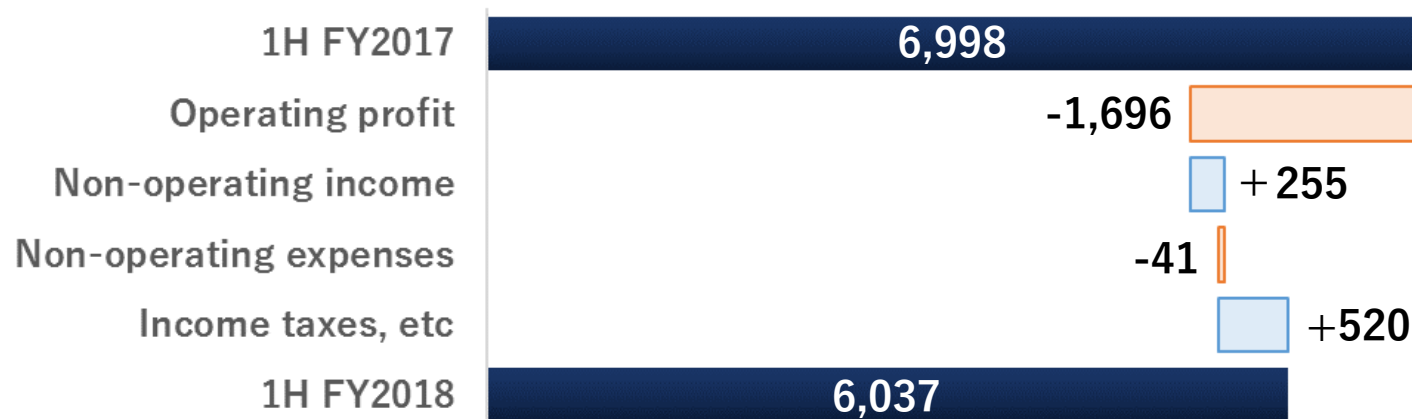
(Million yen)	1H FY2017		1H FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	4,711	67.7%	4,941	66.8%	+229	+4.9%
Preservatives	1,128	16.2%	1,140	15.4%	+12	+1.1%
Health food ingredients	432	6.2%	585	7.9%	+153	+35.6%
Others	688	9.9%	726	9.9%	+38	+5.5%
Net sales	6,960	100.0%	7,394	100.0%	+433	+6.2%

Operating profit



(Million yen)	1H FY2017		1H FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	49,666	100.0%	53,497	100.0%	+3,830	+7.7%
(Pharmaceuticals)	(42,706)	(86.0%)	(46,102)	(86.2%)	(+3,396)	(+8.0%)
(Functional Food)	(6,960)	(14.0%)	(7,394)	(13.8%)	(+433)	(+6.2%)
Operating expenses	40,400	81.3%	45,927	85.9%	+5,526	+13.7%
Cost of sales	22,479	45.3%	25,087	46.9%	+2,608	+11.6%
SG&A expenses	11,651	23.4%	12,975	24.3%	+1,324	+11.4%
R&D expenses	6,270	12.6%	7,864	14.7%	+1,593	+25.4%
Operating profit	9,266	18.7%	7,569	14.1%	-1,696	-18.3%

Profit attributable to owners of parent



(Million yen)	1H FY2017	1H FY2018	YoY Change	
	Results	Results	Amt	%
Operating profit	9,266	7,569	-1,696	-18.3%
Non-operating income	597	853	+255	+42.8%
Non-operating expenses	184	226	+41	+22.5%
Ordinary profit	9,678	8,196	-1,482	-15.3%
Income taxes, etc	2,679	2,158	-520	-19.4%
Profit attributable to owners of the parent	6,998	6,037	-961	-13.7%

Business Forecast for FY2018



(Million yen)	FY2017		FY2018		YoY Change		FY2018 (5th MMP)
	1H Results	FY Results	1H Results	FY Forecast	Amt	%	
Net sales	49,666	101,448	53,497	108,000	+6,552	+6.5%	110,000
Operating profit	9,266	17,079	7,569	18,500	+1,421	+8.3%	18,000
Ordinary profit	9,678	17,451	8,196	19,000	+1,549	+8.9%	-
Profit attributable to owners of the parent	6,998	12,953	6,037	14,000	+1,047	+8.1%	12,000

MMP: Medium-Term Management Plan

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2017		FY2018		YoY Change	
	1H Results	FY Results	1H Results	FY Forecast	Amt	%
Ethical drugs	35,278	73,076	37,379	72,800	-276	-0.4%
Revenues from the licensing of industrial property rights	5,536	10,378	6,267	15,500	+5,122	+49.4%
Profit in co-promotion	1,891	3,962	2,455	5,300	+1,338	+33.8%
Net sales	42,706	87,416	46,102	93,600	+6,184	+7.1%

Segmental Forecast - Functional Food -



(Million yen)	FY2017		FY2018		YoY Change	
	1H Results	FY Results	1H Results	FY Forecast	Amt	%
Protein preparations	4,711	9,454	4,941	9,585	+131	+1.4%
Preservatives	1,128	2,298	1,140	2,450	+152	+6.6%
Health food ingredients	432	927	585	960	+33	+3.5%
Others	688	1,350	726	1,405	+55	+4.1%
Net sales	6,960	14,031	7,394	14,400	+369	+2.6%

Consolidated Statements of Income (Forecast)



(Million yen)	FY2017		FY2018		YoY Change	
	1H Results	FY Results	1H Results	FY Forecast	Amt	%
Net sales	49,666	101,448	53,497	108,000	+6,552	+6.5%
(Pharmaceuticals)	(42,706)	(87,416)	(46,102)	(93,600)	(+6,184)	(+7.1%)
(Functional Food)	(6,960)	(14,031)	(7,394)	(14,400)	(+369)	(+2.6%)
Cost of sales	22,479	46,929	25,087	48,700	+1,771	+3.8%
(Cost of sales ratio)	(45.3%)	(46.3%)	(46.9%)	(45.1%)		
SG&A expenses	11,651	24,217	12,975	27,200	+2,983	+12.3%
R&D expenses	6,270	13,221	7,864	13,600	+379	+2.9%
Operating income	9,266	17,079	7,569	18,500	+1,421	+8.3%
Non-operating income	597	1,122	853	1,000	-122	-10.9%
Non-operating expenses	184	751	226	500	-251	-33.4%
Ordinary income	9,678	17,451	8,196	19,000	+1,549	+8.9%
Income taxes, etc	2,679	4,497	2,158	5,000	+503	+11.2%
Profit attributable to owners of the parent	6,998	12,953	6,037	14,000	+1,047	+8.1%



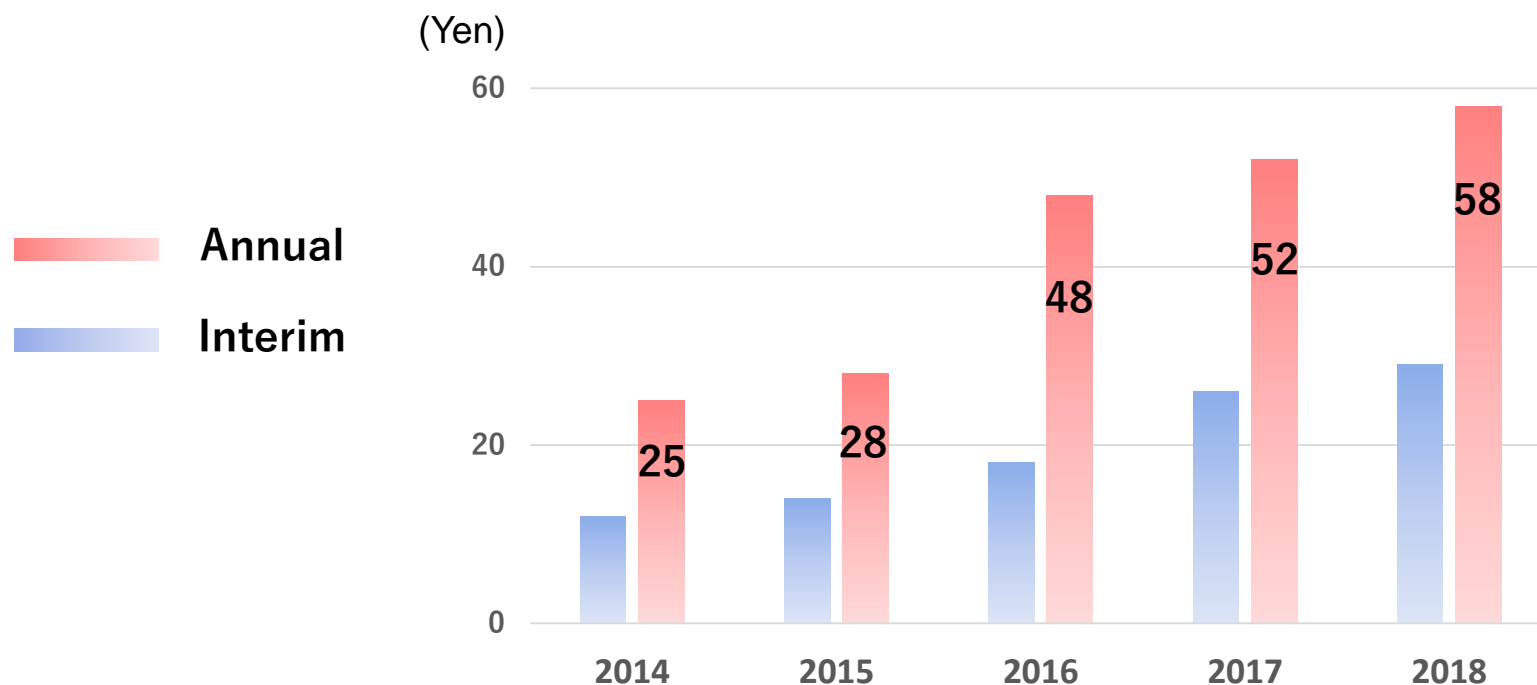
Dividends Forecast



		FY2017	FY2018
Dividends per share	Interim	¥26	¥29
	Annual	¥52	¥58
E P S		¥192.31	¥207.86
Dividends payout ratio		27.0 %	27.9 %

■ Dividends Policy

Target payout ratio
(performance-based)
is around 30%.



Status of Product Pipeline



NIPPON SHINYAKU CO., LTD.

R&D Compounds (Domestic)



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

 : change from the first quarter

R&D Compounds (Overseas)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	PII	PIII	NDA filing
prulifloxacin <in-house>	NME	Bacterial infections					
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					
NS-018 <in-house>	NME	Myelofibrosis					

Reference Materials



NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet



(Million yen)	End of FY2017	End of 2Q FY2018	YoY Change Amt		End of FY2017	End of 2Q FY2018	YoY Change Amt
Assets	155,887	160,377	+4,490	Liabilities	30,197	29,480	-717
Current assets	95,176	99,515	+4,339	Current liabilities	22,454	22,496	+42
Fixed assets	60,710	60,862	+151	Long-term liabilities	7,743	6,983	-759
				Net assets	125,689	130,897	+5,208
Total assets	155,887	160,377	+4,490	Total liabilities and net assets	155,887	160,377	+4,490

= Assets =

Cash and deposits	+2,610
Notes and accounts receivable	+2,063
Inventories	-428
Investment securities	+1,065

= Liabilities and Net assets =

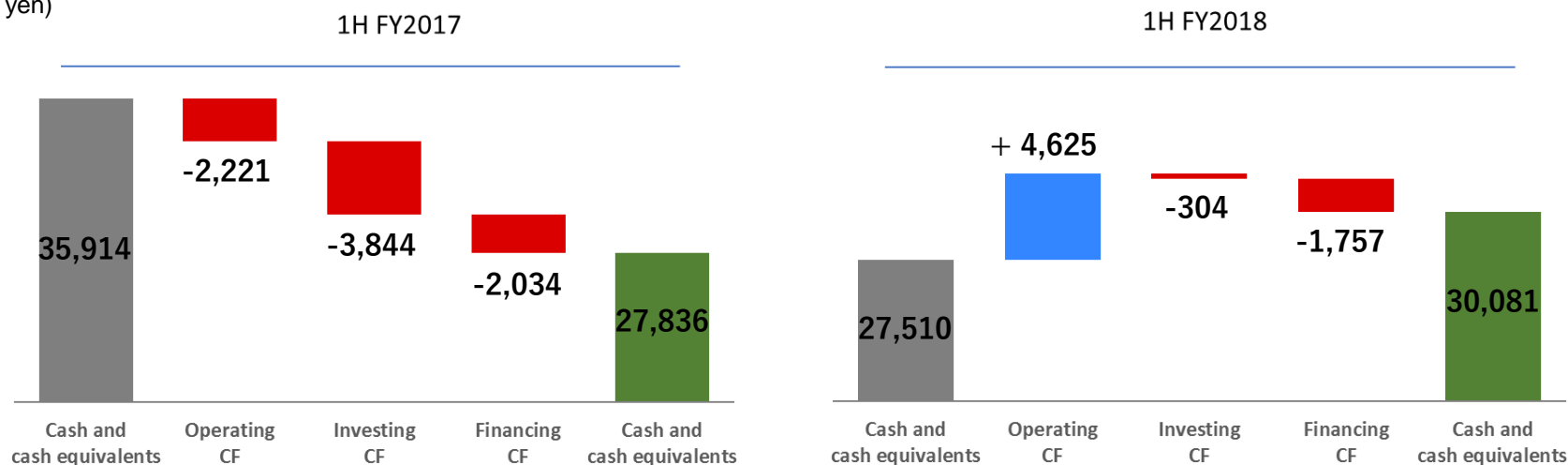
Notes and accounts payable	-1,150
Accounts payable	+425
Retained earnings	+4,286

Consolidated Statements of Cash Flows



(Million yen)	1H FY2017 Results	1H FY2018 Results	YoY Change Amt
Operating activities	-2,221	4,625	+6,846
Investing activities	-3,844	-304	+3,539
Financing activities	-2,034	-1,757	+277
Cash and cash equivalents at end of year	27,836	30,081	+2,244

(Million yen)



NS-73 (defibrotide)



- Treatment of hepatic veno-occlusive disease -

Development Phase	Japan : NDA filing (treatment) Japan : PIII (prevention)
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Nippon Shinyaku in Japan (treatment) Co-development in Japan : Jazz Pharmaceuticals (prevention)
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 only drug for the treatment of VOD (EU/US guideline). It has been launched in 35 countries.· NS-73 is the only drug for the prevention of VOD.



NS-304 (selexipag)

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



Development Phase	<CTEPH> Japan: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa
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)▪Nippon Shinyaku (LSS)
Mechanism of action	Selective IP receptor agonist
Indication	<ul style="list-style-type: none">▪Chronic thromboembolic pulmonary hypertension (CTEPH)▪Arteriosclerosis obliterans (ASO)▪Lumbar spinal stenosis (LSS)
Dosage form	Tablet
Feature	Long-acting oral drug



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



- 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	<ul style="list-style-type: none"> ▪ Standard Treatment for acute myeloid leukemia that ineligible for intensive chemotherapy ▪ Improvement for life prognosis

NS-065/NCNP-01 (viltolarsen)



- 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



- 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



- 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



- 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 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



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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