

Outline of Consolidated Financial Results for the 2nd Quarter Ended Sep. 30, 2019

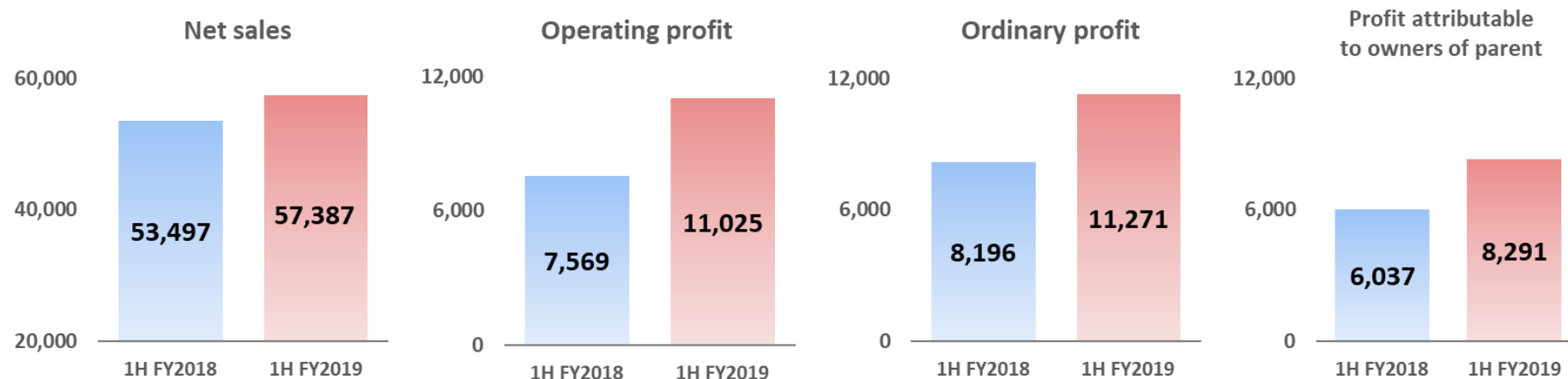
**November 8, 2019
NIPPON SHINYAKU CO., LTD.**

1H FY2019 Summary

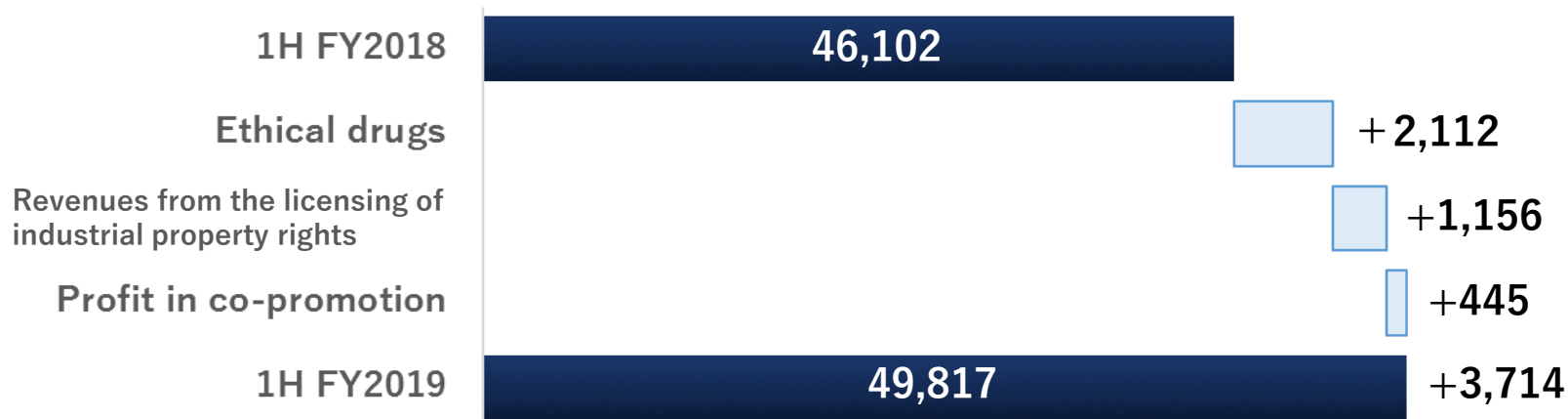


◆ Net sales	:	57,387 million yen	(+7.3%)
◆ Operating profit	:	11,025 million yen	(+45.7%)
◆ Ordinary profit	:	11,271 million yen	(+37.5%)
◆ Profit attributable to owners of parent	:	8,291 million yen	(+37.3%)

(Million yen)



Segmental Review - Pharmaceuticals -



(Million yen)	1H FY2018		1H FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	37,379	81.1%	39,491	79.3%	+2,112	+5.7%
Revenues from the licensing of industrial property rights	6,267	13.6%	7,424	14.9%	+1,156	+18.5%
Profit in co-promotion	2,455	5.3%	2,901	5.8%	+445	+18.1%
Net sales	46,102	100.0%	49,817	100.0%	+3,714	+8.1%

Net sales increased by 8.1% through growth of new products, revenues from the licensing of industrial property rights and profit in co-promotion.

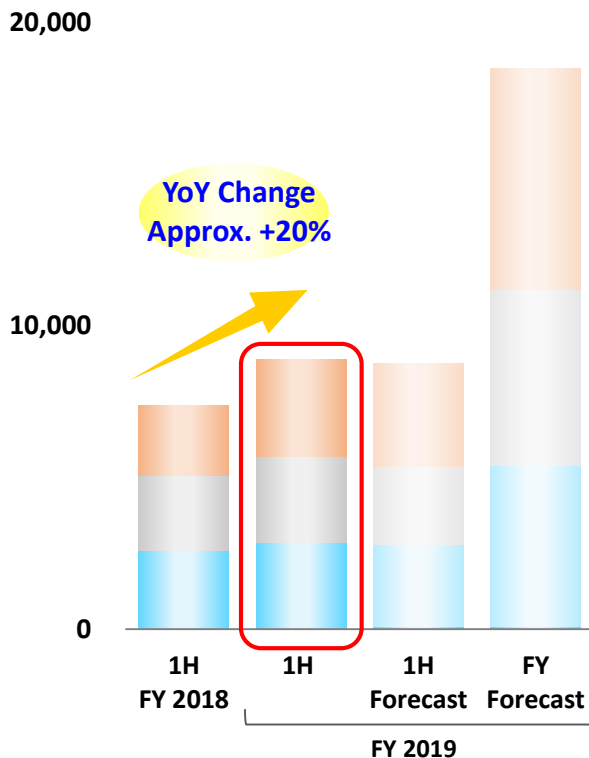


Three Main Fields of Focus

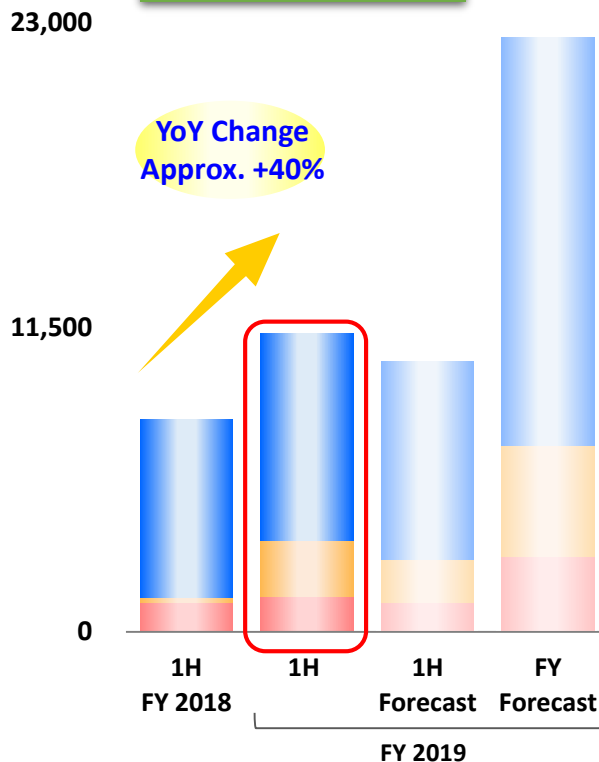


(million yen)

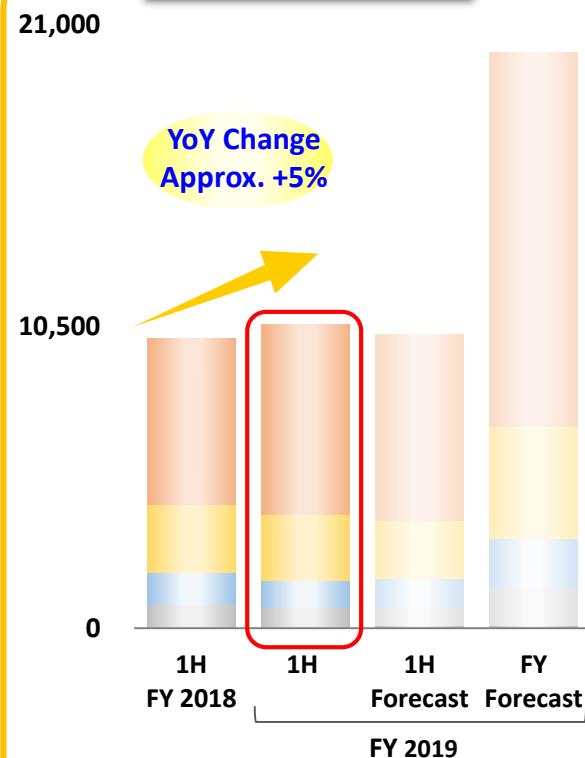
PAH



Hematology



Urology



Sales in the focus fields have smoothly progressed toward FY forecasts.

Segmental Review - Functional Food -



(Million yen)	1H FY2018		1H FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	4,941	66.8%	5,025	66.4%	+83	+1.7%
Preservatives	1,140	15.4%	1,176	15.5%	+35	+3.1%
Health food ingredients	585	7.9%	595	7.9%	+9	+1.7%
Others	726	9.9%	772	10.2%	+46	+6.4%
Net sales	7,394	100.0%	7,569	100.0%	+175	+2.4%

Net sales increased by 2.4% through growth of protein preparations.



Operating profit



(Million yen)	1H FY2018		1H FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	53,497	100.0%	57,387	100.0%	+3,889	+7.3%
(Pharmaceuticals)	(46,102)	(86.2%)	(49,817)	(86.8%)	(+3,714)	(+8.1%)
(Functional Food)	(7,394)	(13.8%)	(7,569)	(13.2%)	(+175)	(+2.4%)
Operating expenses	45,927	85.9%	46,361	80.8%	+433	+0.9%
Cost of sales	25,087	46.9%	26,307	45.8%	+1,220	+4.9%
SG&A expenses	12,975	24.3%	13,486	23.6%	+511	+3.9%
R&D expenses	7,864	14.7%	6,567	11.4%	-1,297	-16.5%
Operating profit	7,569	14.1%	11,025	19.2%	+3,455	+45.7%



Profit attributable to owners of parent



(Million yen)	1H FY2018	1H FY2019	YoY Change	
	Results	Results	Amt	%
Operating profit	7,569	11,025	+3,455	+45.7%
Non-operating income	853	767	-85	-10.0%
Non-operating expenses	226	521	+294	+130.3%
Ordinary profit	8,196	11,271	+3,075	+37.5%
Income taxes, etc	2,158	2,980	+821	+38.0%
Profit attributable to owners of parent	6,037	8,291	+2,254	+37.3%

Business Forecast for FY2019



(Million yen)	FY2018		FY2019		YoY Change	
	1H	FY	1H	FY	Amt	%
	Results	Results	Results	Forecasts		
Net sales	53,497	114,716	57,387	116,000	+1,284	+1.1%
Operating profit	7,569	20,644	11,025	21,000	+356	+1.7%
Ordinary profit	8,196	21,540	11,271	22,000	+460	+2.1%
Profit attributable to owners of parent	6,037	16,302	8,291	16,500	+198	+1.2%

We look for operating profit, ordinary profit and profit attributable to owners of parent to increase year on year.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2018		FY2019		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Ethical drugs	37,379	78,544	39,491	78,700	+156	+0.2%
Revenues from the licensing of industrial property rights	6,267	16,621	7,424	16,400	-221	-1.3%
Profit in co-promotion	2,455	5,057	2,901	6,000	+943	+18.6%
Net sales	46,102	100,223	49,817	101,100	+877	+0.9%

We expect an increase in net sales due to growth of new products, royalty income from Uptravi's overseas sales and profit in co-promotion.

Segmental Forecast - Functional Food -



(Million yen)	FY2018		FY2019		YoY Change	
	1H	FY	1H	FY	Amt	%
	Results	Results	Results	Forecasts		
Protein preparations	4,941	9,554	5,025	9,660	+106	+1.1%
Preservatives	1,140	2,310	1,176	2,470	+160	+6.9%
Health food ingredients	585	1,196	595	1,250	+54	+4.5%
Others	726	1,431	772	1,520	+89	+6.2%
Net sales	7,394	14,492	7,569	14,900	+408	+2.8%

We expect an increase in net sales by focusing further on developing new products and introducing high-value-added products that meet market needs.

Consolidated Statements of Income (Forecast)

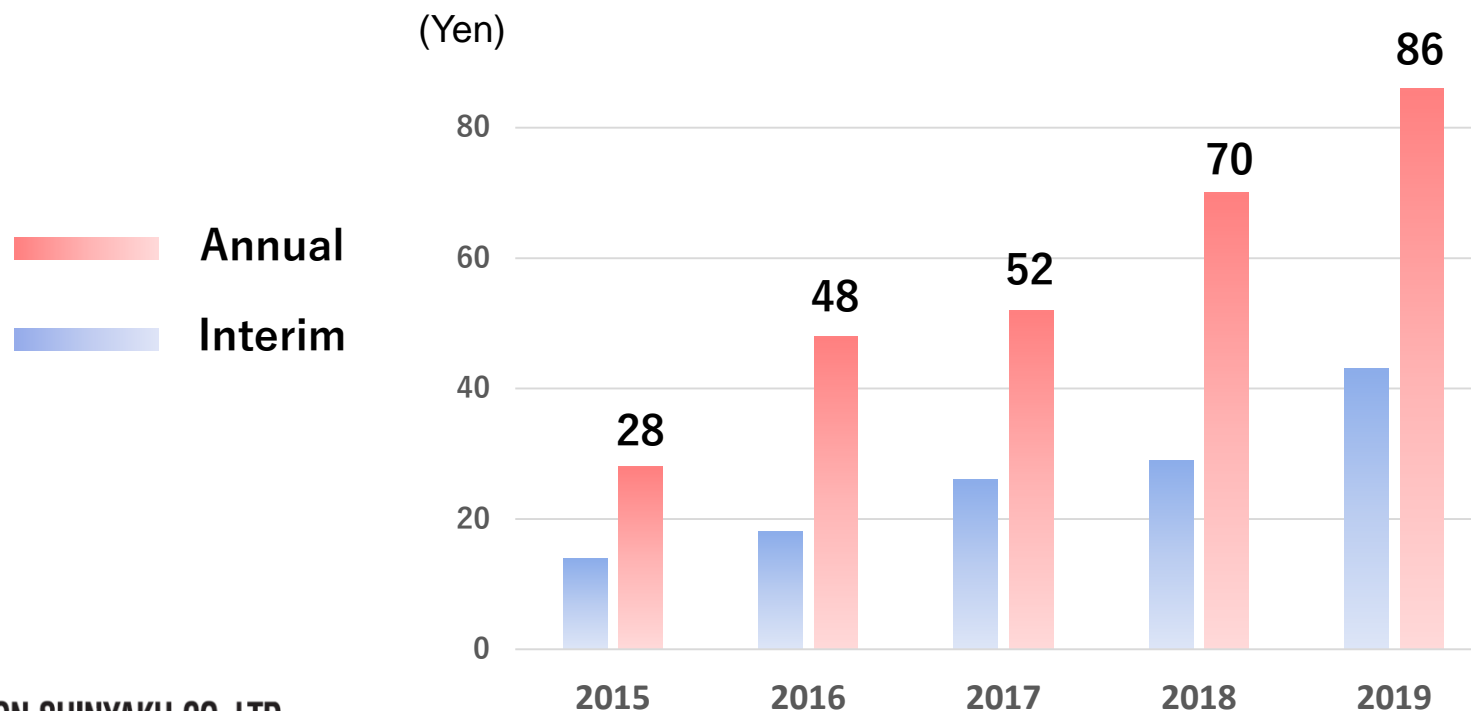


(Million yen)	FY2018		FY2019		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Net sales	53,497	114,716	57,387	116,000	+1,284	+1.1%
(Pharmaceuticals)	(46,102)	(100,223)	(49,817)	(101,100)	(+877)	(+0.9%)
(Functional Food)	(7,394)	(14,492)	(7,569)	(14,900)	(+408)	(+2.8%)
Cost of sales	25,087	50,952	26,307	51,600	+648	+1.3%
(Cost of sales ratio)	(46.9%)	(44.4%)	(45.8%)	(44.5%)		
SG&A expenses	12,975	26,418	13,486	28,300	+1,882	+7.1%
R&D expenses	7,864	16,701	6,567	15,100	-1,601	-9.6%
Operating income	7,569	20,644	11,025	21,000	+356	+1.7%
Non-operating income	853	1,435	767	1,500	+65	+4.5%
Non-operating expenses	226	539	521	500	-39	-7.4%
Ordinary income	8,196	21,540	11,271	22,000	+460	+2.1%
Income taxes, etc	2,158	5,237	2,980	5,500	+263	+5.0%
Profit attributable to owners of parent	6,037	16,302	8,291	16,500	+198	+1.2%

Dividends Forecast



		FY2018	FY2019
Dividends per share	Interim	¥29	¥43
	Annual	¥70	¥86
E P S		¥242.04	¥244.97
Dividends payout ratio		28.9 %	35.1 %



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-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	Preparation for PIII				
NS-73 (defibrotide) <in-license>	New indication	Sinusoidal obstruction syndrome (prevention)					
NS-32 <in-license>	NME	Iron deficiency anemia					
ZX008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome					
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-87 <in-license>	New combination	Secondary acute myeloid leukemia					
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia					

■ : changes from previous financial report 14



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				Preparation for PIII	
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
NS-018 <in-house>	NME	Myelofibrosis					

■ : change from previous financial report

Reference Materials



NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet



(Million yen)	End of FY2018	End of 2Q FY2019	YoY Change Amt		End of FY2018	End of 2Q FY2019	YoY Change Amt
Assets	168,763	171,042	+2,279	Liabilities	33,572	31,159	-2,413
Current assets	110,720	114,444	+3,724	Current liabilities	25,406	23,799	-1,607
Non-current assets	58,042	56,597	-1,444	Non-current liabilities	8,165	7,359	-806
				Net assets	135,190	139,883	+4,692
Total Asset	168,763	171,042	+2,279	Total liabilities and net assets	168,763	171,042	+2,279

= Assets =

Cash and deposits	+7,300
Notes and accounts receivable	-6,418
Inventories	+2,427
Investment securities	-2,097

= Liabilities and Net assets =

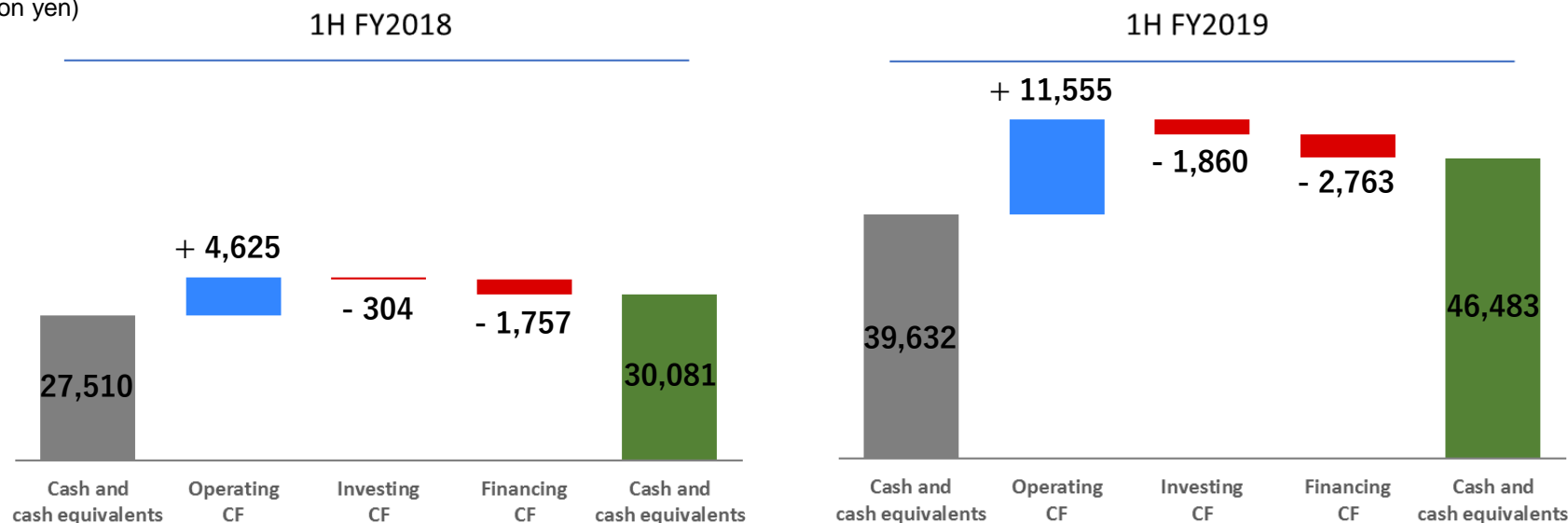
Notes and accounts payable	+2,177
Accounts payable	-2,051
Net defined benefit liability	-804
Retained earnings	+5,530

Consolidated Statements of Cash Flows



(Million yen)	1H FY2018 Results	1H FY2019 Results	YoY Change Amt
Operating activities	4,625	11,555	+6,930
Investing activities	-304	-1,860	-1,555
Financing activities	-1,757	-2,763	-1,006
Cash and cash equivalents at end of year	30,081	46,483	+16,401

(Million yen)



NS-065/NCNP-01 (viltolarsen)



- Treatment for Duchenne muscular dystrophy -

Development Phase	<ul style="list-style-type: none">▪ Japan: NDA filing▪ USA : NDA filing▪ Preparation for global PIII
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-73 (defibrotide)

- Prevention of hepatic sinusoidal obstruction syndrome -



Development Phase	Japan : PIII (prevention)
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Co-development in Japan : Jazz Pharmaceuticals
Mechanism of action	Protective action on vascular endothelium, normalization of the coagulation/fibrinolysis balance
Indication	Sinusoidal obstruction syndrome (SOS)
Dosage form	Injection
Feature	<ul style="list-style-type: none">· SOS 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 SOS (EU/US guideline). It has been launched in various countries.· NS-73 is the only drug for the prevention of SOS.



- Treatment for iron deficiency anemia -

Development Phase	Japan: PIII
Origin	[Dec. 2016] Licensed-in from: Pharmacosmos A/S
Development	Nippon Shinyaku
Mechanism of action	Iron
Indication	Iron deficiency anemia
Dosage form	IV bolus injection or IV drip infusion
Feature	<ul style="list-style-type: none"> • Can be administered in high doses allowing full iron correction in the majority of patients • Good safety profile with no dose dependent ADRs • Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron • No profound hypophosphatemia



- Treatment for rare intractable epilepsy -

Development Phase	Japan: PIII
Origin	[March. 2019] Commercial rights from: Zogenix, inc
Development	Zogenix, inc
Mechanism of action	Serotonin agonist
Indication	Dravet syndrome and Lennox-Gastaut syndrome
Dosage form	Oral liquid agent
Feature	<ul style="list-style-type: none">• Effective for Dravet syndrome and Lennox-Gastaut syndrome patients refractory to existing treatment options• ZX008 can be used in combination with other drugs, as standard of care for intractable epilepsy is based on combination therapy.

NS-304 (selexipag)

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



Development Phase	<CTEPH> Japan: PIII Overseas: 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)▪Overseas: Johnson & Johnson (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



- Treatment of secondary acute myeloid leukemia -

Development Phase	Japan: PI/II
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.



- 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

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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