

Outline of Consolidated Financial Results for the Year Ended March 31, 2021

May 18, 2021

NIPPON SHINYAKU CO., LTD.

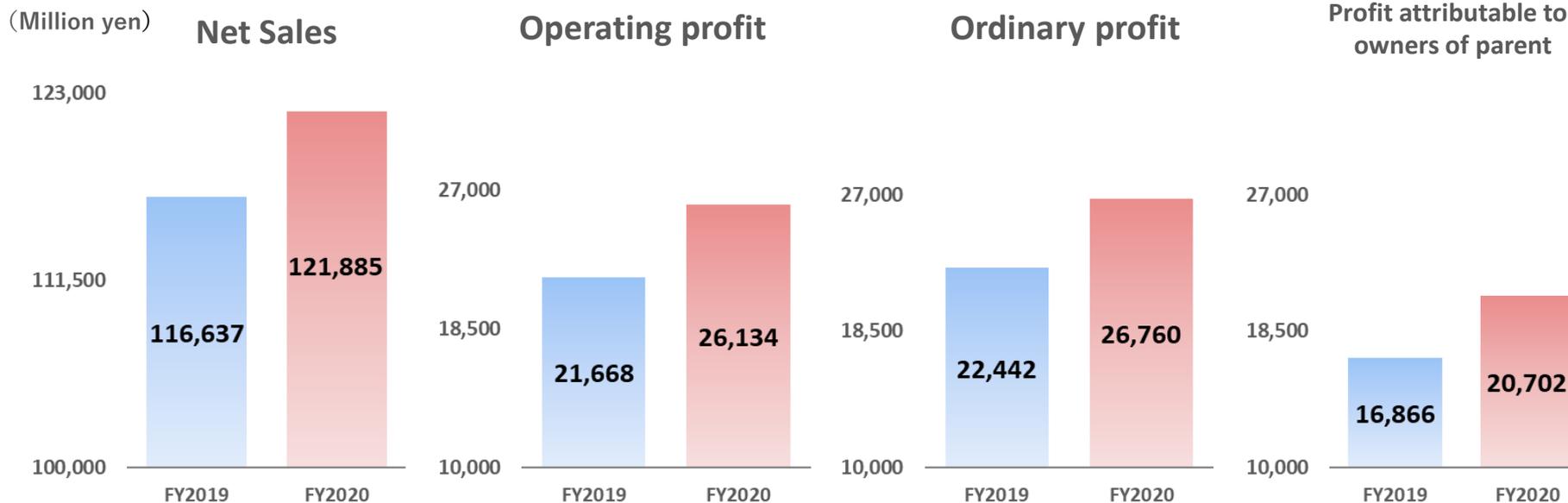


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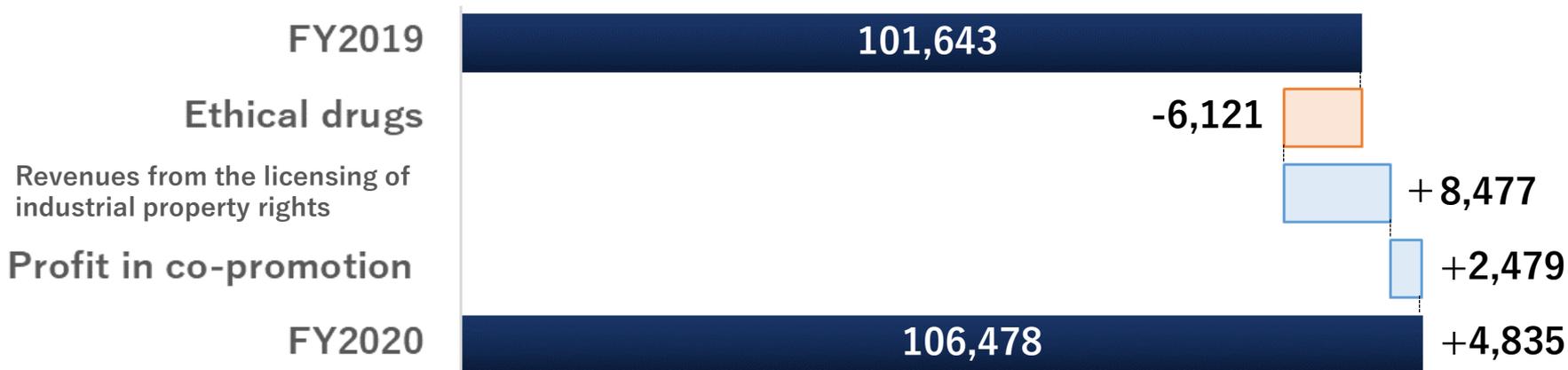
FY2020 Summary



◆ Net sales	:	121,885 million yen	(+4.5%)
◆ Operating profit	:	26,134 million yen	(+20.6%)
◆ Ordinary profit	:	26,760 million yen	(+19.2%)
◆ Profit attributable to owners of parent	:	20,702 million yen	(+22.7%)



Segmental Review - Pharmaceuticals -



(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	79,818	78.5%	73,697	69.2%	-6,121	-7.7%
Revenues from the licensing of industrial property rights	15,860	15.6%	24,338	22.9%	+8,477	+53.5%
Profit in co-promotion	5,963	5.9%	8,442	7.9%	+2,479	+41.6%
Net sales	101,643	100.0%	106,478	100.0%	+4,835	+4.8%

Net sales increased by 4.8% through revenues from the licensing of industrial property rights and profit in co-promotion.

Segmental Review - Functional Food -



(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	9,731	64.9%	10,121	65.7%	+390	+4.0%
Preservatives	2,475	16.5%	2,597	16.9%	+121	+4.9%
Health food ingredients	1,280	8.5%	1,257	8.2%	-23	-1.8%
Others	1,506	10.1%	1,431	9.2%	-75	-5.0%
Net sales	14,994	100.0%	15,406	100.0%	+412	+2.8%

Net sales increased by 2.8% due to growth of protein preparations and preservatives.

Operating profit



(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	116,637	100.0%	121,885	100.0%	+5,248	+4.5%
(Pharmaceuticals)	(101,643)	(87.1%)	(106,478)	(87.4%)	(+4,835)	(+4.8%)
(Functional Food)	(14,994)	(12.9%)	(15,406)	(12.6%)	(+412)	(+2.8%)
Operating expenses	94,969	81.4%	95,750	78.6%	+781	+0.8%
Cost of sales	53,155	45.6%	49,954	41.0%	-3,201	-6.0%
SG&A expenses	27,819	23.8%	29,691	24.4%	+1,872	+6.7%
R&D expenses	13,994	12.0%	16,104	13.2%	+2,110	+15.1%
Operating profit	21,668	18.6%	26,134	21.4%	+4,466	+20.6%

Profit attributable to owners of parent



(Million yen)	FY2019	FY2020	YoY Change	
	Results	Results	Amt	%
Operating profit	21,668	26,134	+4,466	+20.6%
Non-operating income	1,599	1,326	-272	-17.0%
Non-operating expenses	824	701	-123	-15.0%
Ordinary profit	22,442	26,760	+4,317	+19.2%
Extraordinary income	-	1,998	+1,998	-
Income taxes, etc	5,575	8,056	+2,481	+44.5%
Profit attributable to owners of parent	16,866	20,702	+3,835	+22.7%

Business Forecast for FY2021



(Million yen)	FY2020	FY2021	YoY Change	
	Results	Forecast	Amt	%
Net sales	121,885	135,000	+13,115	+10.8%
Operating profit	26,134	28,000	+1,866	+7.1%
Ordinary profit	26,760	28,500	+1,740	+6.5%
Profit attributable to owners of parent	20,702	21,000	+298	+1.4%

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

Segmental Forecast - Pharmaceuticals -



(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	73,697	69.2%	78,300	65.7%	+4,603	+6.2%
Revenues from the licensing of industrial property rights	24,338	22.9%	32,000	26.8%	+7,662	+31.5%
Profit in co-promotion	8,442	7.9%	9,000	7.5%	+558	+6.6%
Net sales	106,478	100.0%	119,300	100.0%	+12,822	+12.0%

Due to growth of new products, royalty revenue from Uptravi's overseas sales, profit in co-promotion, our net sales will increase.

Segmental Forecast - Functional Food -



(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	10,121	65.7%	9,850	62.7%	-271	-2.7%
Preservatives	2,597	16.9%	2,700	17.2%	+103	+4.0%
Health food ingredients	1,257	8.2%	1,100	7.0%	-157	-12.5%
Others	1,431	9.2%	2,050	13.1%	+619	+43.2%
Net sales	15,406	100.0%	15,700	100.0%	+294	+1.9%

We will enhance our research and development toward new products and continue to launch highly valued products with market needs to increase our net sales.

Consolidated Statements of Income (Forecast)

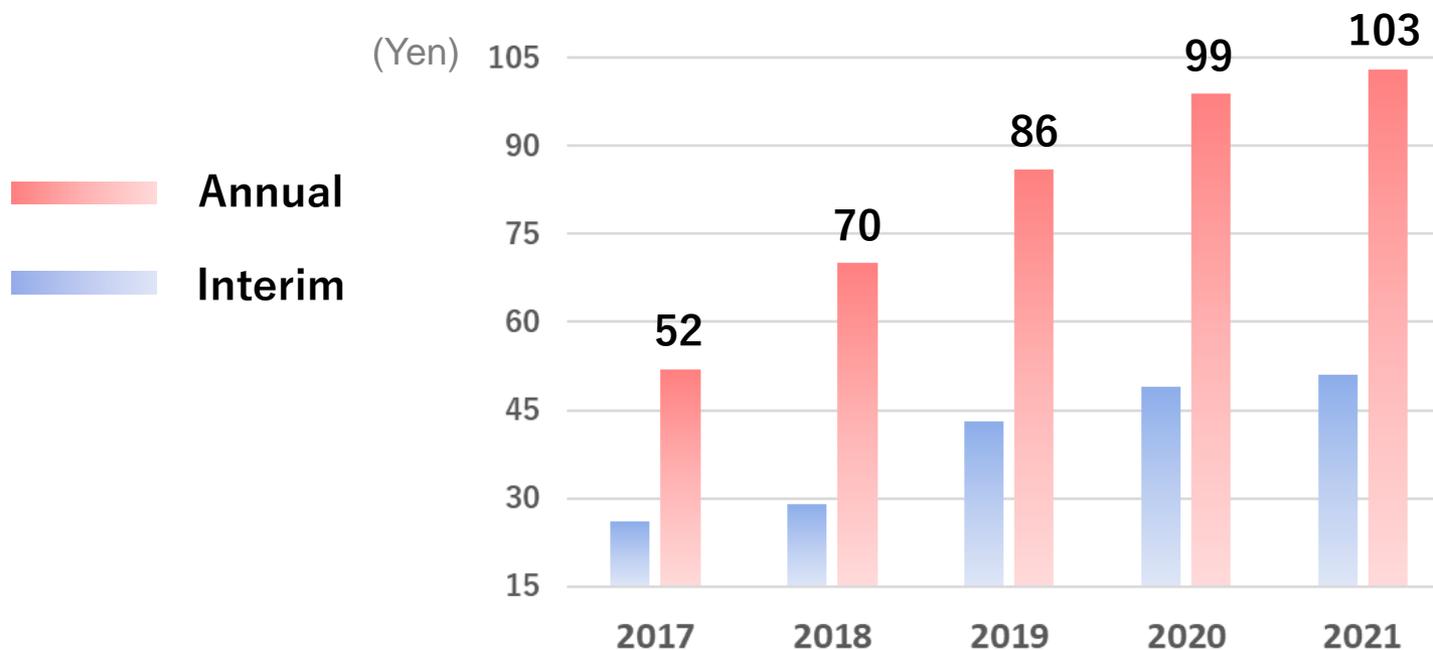


(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	121,885	100.0%	135,000	100.0%	+13,115	+10.8%
(Pharmaceuticals)	(106,478)	(87.4%)	(119,300)	(88.4%)	(+12,822)	(+12.0%)
(Functional Food)	(15,406)	(12.6%)	(15,700)	(11.6%)	(+294)	(+1.9%)
Cost of sales	49,954	41.0%	48,700	36.1%	-1,254	-2.5%
SG&A expenses	29,691	24.4%	31,800	23.6%	+2,109	+7.1%
R&D expenses	16,104	13.2%	26,500	19.6%	+10,396	+64.5%
Operating profit	26,134	21.4%	28,000	20.7%	+1,866	+7.1%
Non-operating income	1,326	1.1%	1,000	0.7%	-326	-24.6%
Non-operating expenses	701	0.5%	500	0.4%	-201	-28.7%
Ordinary profit	26,760	22.0%	28,500	21.1%	+1,740	+6.5%
Extraordinary income	1,998	1.6%	-	-	-	-
Income taxes, etc	8,056	6.6%	7,500	5.6%	-556	-6.9%
Profit attributable to owners of parent	20,702	17.0%	21,000	15.6%	+298	+1.4%

Dividends Forecast



		FY2020	FY2021
Dividends per share	Interim	¥49	¥51
	Annual	¥99	¥103
E P S		¥307.37	¥311.79
Dividends payout ratio		32.2 %	33.0 %



Status of Product Pipeline

R&D Compounds (Domestic)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	Preparation for PI	PI	PII	PIII	NDA	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					PIII in progress		
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension							
		Arteriosclerosis obliterans							
		Lumbar spinal stenosis							
	New dose	Pediatric pulmonary arterial hypertension							
NS-32 (ferric derisomaltose) <in-license>	NME	Iron deficiency anemia							
ZX008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome							
NS-580 <in-house>	NME	Endometriosis							
NS-87 <in-license>	New combination	Secondary acute myeloid leukemia							
NS-229 <in-house>	NME	Inflammatory diseases							
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia							
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm							

 : Changes from 3rd quarter 2020

R&D Compounds (Overseas)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	Preparation for P II	P II	P III	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	[Blue shaded area]				P III in progress	[Blue shaded area]
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension	[Blue shaded area]					
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis	[Blue shaded area]		[Dark blue shaded area]			

 : Changes from 3rd quarter 2020

Reference Materials

Consolidated Statements of Income



(Million yen)	FY2019		FY2020		YoY change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	116,637	100.0%	121,885	100.0%	+5,248	+4.5%
(Pharmaceuticals)	(101,643)	(87.1%)	(106,478)	(87.4%)	(+4,835)	(+4.8%)
(Functional Food)	(14,994)	(12.9%)	(15,406)	(12.6%)	(+412)	(+2.8%)
Cost of sales	53,155	45.6%	49,954	41.0%	-3,201	-6.0%
SG&A expenses	27,819	23.8%	29,691	24.4%	+1,872	+6.7%
R&D expenses	13,994	12.0%	16,104	13.2%	+2,110	+15.1%
Operating profit	21,668	18.6%	26,134	21.4%	+4,466	+20.6%
Non-operating income	1,599	1.4%	1,326	1.1%	-272	-17.0%
Non-operating expenses	824	0.8%	701	0.5%	-123	-15.0%
Ordinary profit	22,442	19.2%	26,760	22.0%	+4,317	+19.2%
Extraordinary income	-	-	1,998	1.6%	-	-
Income taxes, etc	5,575	4.8%	8,056	6.6%	+2,481	+44.5%
Profit attributable to owners of parent	16,866	14.5%	20,702	17.0%	+3,835	+22.7%

Consolidated Balance Sheet



(Million yen)	End of FY2019	End of FY2020	YoY Change Amt		End of FY2019	End of FY2020	YoY Change Amt
Assets	175,017	197,028	+22,011	Liabilities	29,256	34,485	+5,228
Current assets	121,925	139,090	+17,165	Current liabilities	24,965	31,514	+6,548
Fixed assets	53,091	57,937	+4,846	Long-term liabilities	4,290	2,970	-1,319
				Net assets	145,760	162,543	+16,782
Total assets	175,017	197,028	+22,011	Total liabilities and net assets	175,017	197,028	+22,011

= Assets =

Cash and deposits	+11,765
Notes and accounts receivable	-1,658
Inventories	+5,629
Investment securities	+3,204
Long-term prepaid expenses	+758

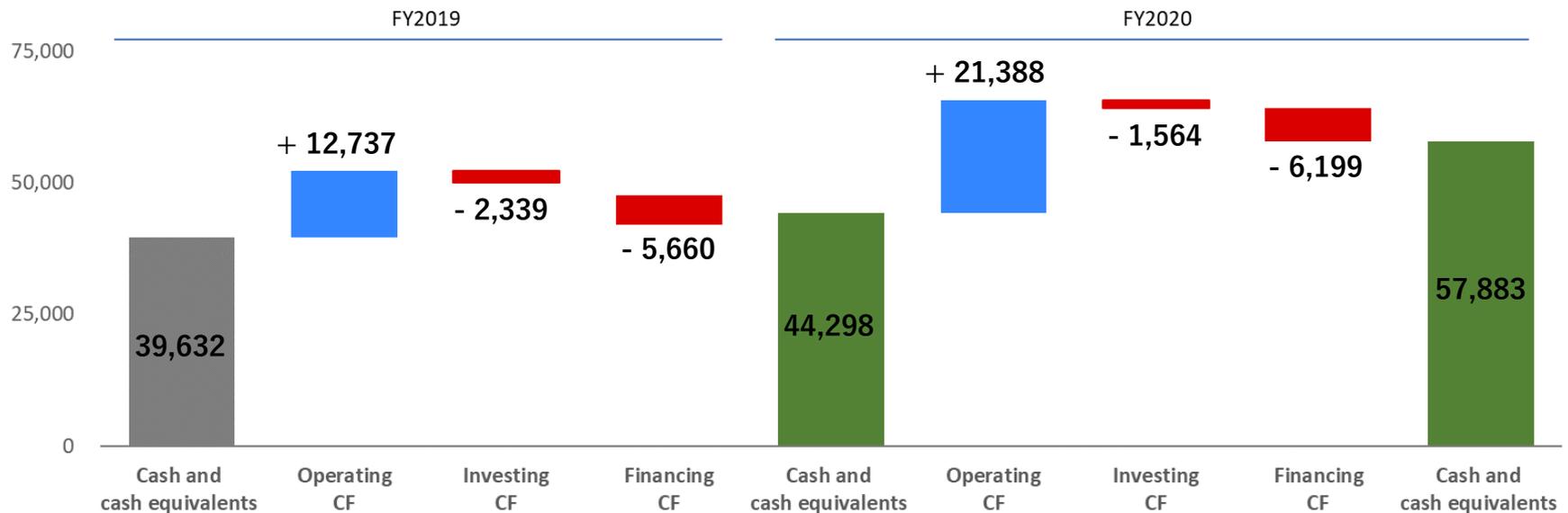
= Liabilities and Net assets =

Notes and accounts payable	-1,669
Accounts payable	+2,400
Income taxes payable	+4,597
Retirement benefit liability	-1,309

Consolidated Statements of Cash Flows



(Million yen)	FY2019 Results	FY2020 Results	YoY Change Amt
Operating activities	12,737	21,388	+8,650
Investing activities	-2,339	-1,564	+775
Financing activities	-5,660	-6,199	-538
Cash and cash equivalents at end of period	44,298	57,883	+13,584



NS-065/NCNP-01 (viltolarsen)



- Treatment for Duchenne muscular dystrophy -

Development Phase	<ul style="list-style-type: none">▪Japan: Launch▪USA : Launch▪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-304 (selexipag)



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

Development Phase	<CTEPH> Japan: NDA filing Overseas: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa <Pediatric PAH> Japan: PII
Origin	Nippon Shinyaku
Development	<ul style="list-style-type: none">• Co-development in Japan: Janssen Pharmaceutical K.K. (CTEPH / Pediatric PAH)• Overseas: Johnson & Johnson (CTEPH / Pediatric PAH)• 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)• Pediatric pulmonary arterial hypertension (Pediatric PAH)
Dosage form	Tablet
Feature	Long-acting oral drug



NS-32 (ferric derisomaltose)

- Treatment for iron deficiency anemia -



Development Phase	Japan: NDA filing
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 based on combination therapy



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 secondary acute myeloid leukemia -

Development Phase	Japan: PI/II
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals plc
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 inflammatory diseases -

Development Phase	Japan: PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK1 inhibitor
Indication	Inflammatory diseases (to be determined)
Dosage form	Oral agent
Feature	<ul style="list-style-type: none">• Potent and highly selective JAK1 inhibitor• High efficacy and good safety profiles are expected in the treatment for inflammatory diseases

NS-917

- Treatment for relapsed or refractory acute myeloid leukemia -



Development Phase	Japan: Preparation for PI
Origin	[Mar. 2017] Licensed-in from: Delta-Fly Pharma, Inc.
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-401 (tagraxofusp)



- Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2021] Licensed-in from: The Menarini Group
Development	Nippon Shinyaku
Mechanism of action	Induction apoptosis of cells by inhibiting protein synthesis by specifically targeting cancer cells expressing CD123
Indication	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Dosage form	Injection
Feature	<ul style="list-style-type: none">• Composed of diphtheria toxin (DT) fusion protein and recombinant human IL-3• Novel targeted therapy directed to CD123 on tumor cells• IL-3 binds to CD123-expressing tumor cells and delivers the cytotoxic diphtheria toxin to the cells, resulting in the blockage of protein synthesis in the cell and causing cell death in CD123-expressing cells.

NS-018 (ilginatinib)

- Treatment for myelofibrosis -



Development Phase	Overseas (USA): Preparation for PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	<ul style="list-style-type: none">• Potent and highly selective JAK2 inhibitor• High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count, for whom QOL improvement can't be obtained because no treatment is available.

Safe Harbor Statement

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