

Outline of Consolidated Financial Results for the Year Ended March 31, 2022

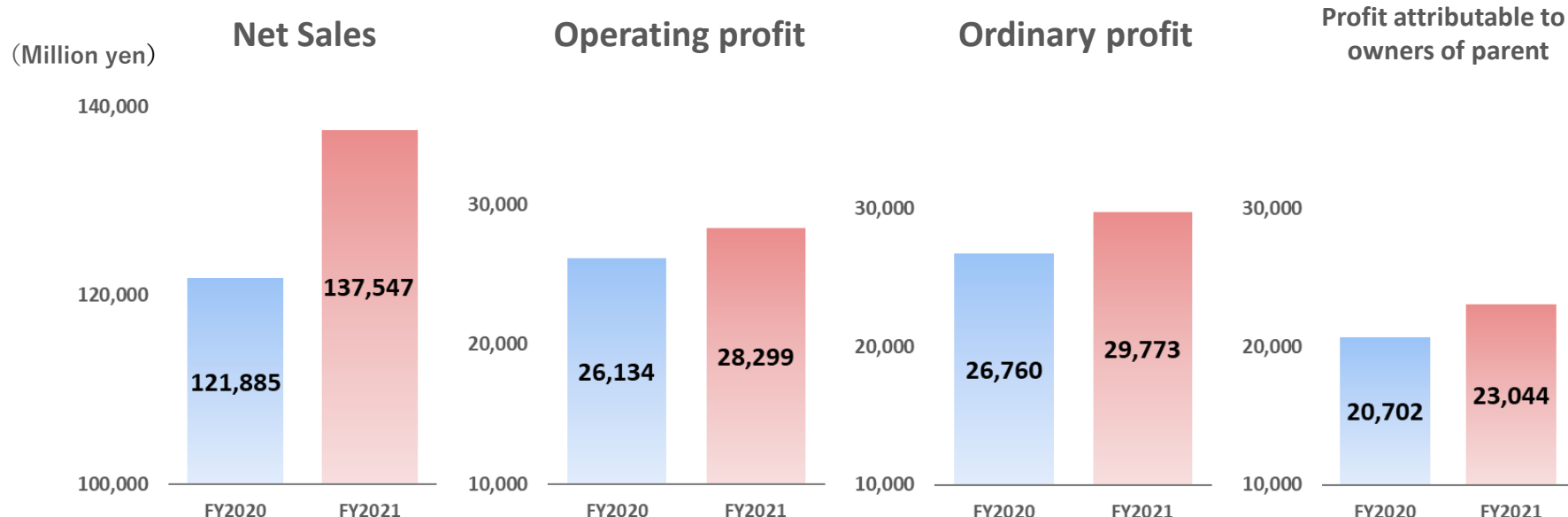
May 13, 2022

NIPPON SHINYAKU CO., LTD.

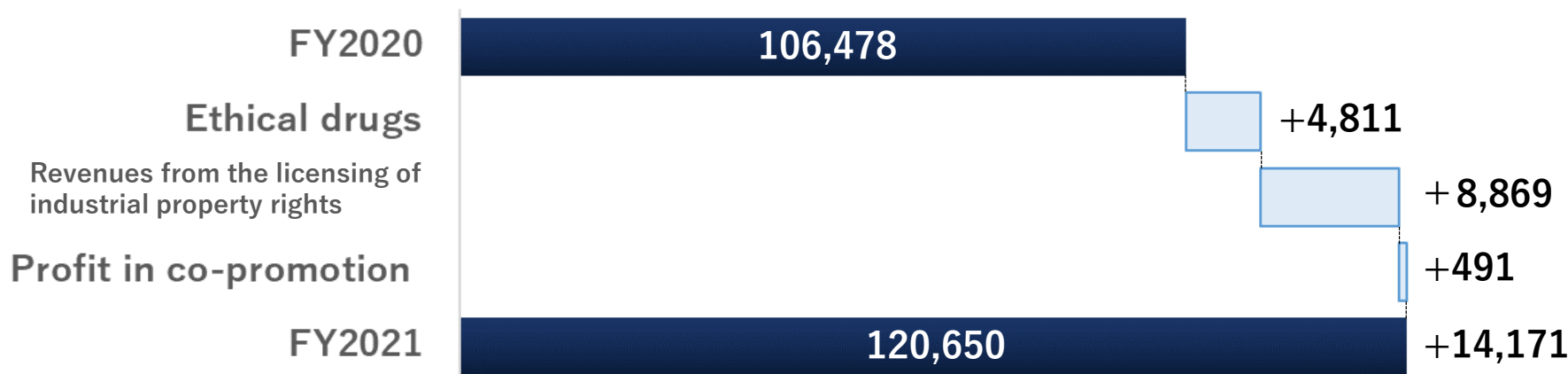
FY2021 Summary



◆ Net sales	:	137,547 million yen	(+12.8%)
◆ Operating profit	:	28,299 million yen	(+ 8.3%)
◆ Ordinary profit	:	29,773 million yen	(+11.3%)
◆ Profit attributable to owners of parent	:	23,044 million yen	(+11.3%)



Segmental Review - Pharmaceuticals -



(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	73,697	69.2%	78,508	65.1%	+4,811	+6.5%
Revenues from the licensing of industrial property rights	24,338	22.9%	33,207	27.5%	+8,869	+36.4%
Profit in co-promotion	8,442	7.9%	8,934	7.4%	+491	+5.8%
Net sales	106,478	100.0%	120,650	100.0%	+14,171	+13.3%

Net sales increased by 13.3% through growth of ethical drugs such as “Vidaza”, “Uptravi”, “Viltepso”, and revenues from the licensing of industrial property rights which contains of royalty revenue from Uptravi’s overseas sales and gain on sales from the priority review voucher.



Segmental Review - Functional Food -

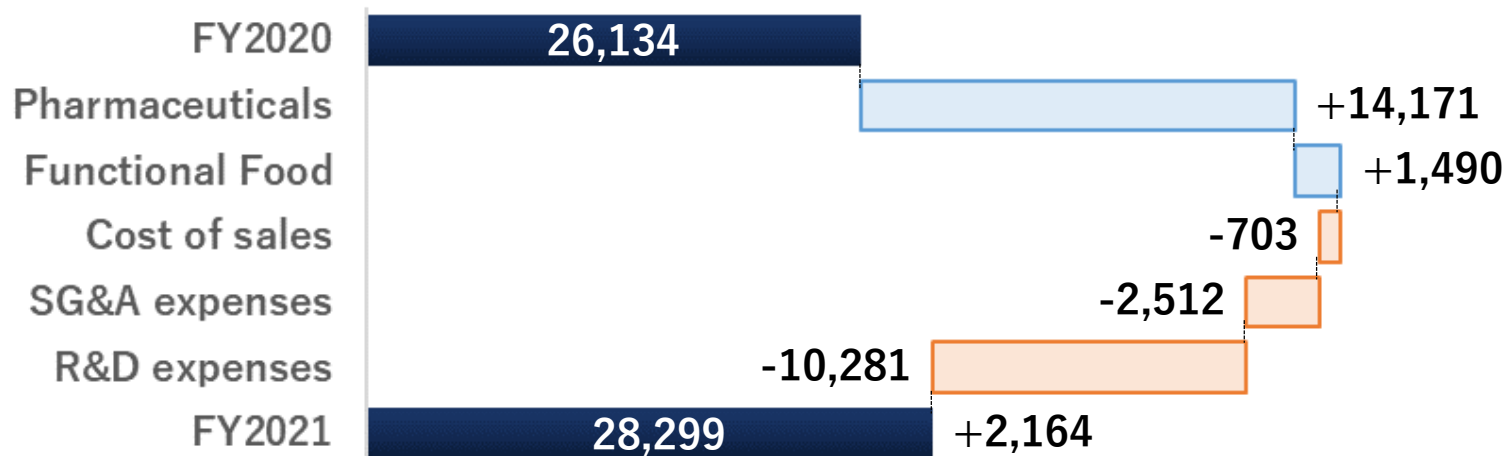


(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	10,121	65.7%	10,892	64.5%	+771	+7.6%
Preservatives	2,597	16.9%	2,787	16.5%	+190	+7.3%
Health food ingredients	1,257	8.2%	1,075	6.4%	-181	-14.4%
Others	1,431	9.2%	2,140	12.6%	+709	+49.6%
Net sales	15,406	100.0%	16,897	100.0%	+1,490	+9.7%

Net sales increased by 9.7% through sales from functional food products such as protein preparations, preservatives, etc.



Operating profit



(Million yen)	FY2020		FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	121,885	100.0%	137,547	100.0%	+15,662	+12.8%
(Pharmaceuticals)	(106,478)	(87.4%)	(120,650)	(87.7%)	(+14,171)	(+13.3%)
(Functional Food)	(15,406)	(12.6%)	(16,897)	(12.3%)	(+1,490)	(+9.7%)
Operating expenses	95,750	78.6%	109,248	79.4%	+13,497	+14.1%
Cost of sales	49,954	41.0%	50,657	36.8%	+703	+1.4%
SG&A expenses	29,691	24.4%	32,204	23.4%	+2,512	+8.5%
R&D expenses	16,104	13.2%	26,386	19.2%	+10,281	+63.8%
Operating profit	26,134	21.4%	28,299	20.6%	+2,164	+8.3%

Profit attributable to owners of parent



(Million yen)	FY2020 Results	FY2021 Results	YoY Change	
			Amt	%
Operating profit	26,134	28,299	+2,164	+8.3%
Non-operating income	1,326	2,359	+1,032	+77.8%
Non-operating expenses	701	884	+183	+26.2%
Ordinary profit	26,760	29,773	+3,013	+11.3%
Extraordinary income	1,998	-	-1,998	-
Income taxes, etc	8,056	6,729	-1,327	-16.5%
Profit attributable to owners of parent	20,702	23,044	+2,341	+11.3%

Business Forecast for FY2022 (IFRS)



(Million yen)	FY2021 Results*	FY2022 Forecast	YoY Change	
			Amt	%
Revenue	137,484	134,000	-3,484	-2.5%
Operating profit	32,936	27,000	-5,936	-18.0%
Profit before tax	33,266	27,500	-5,766	-17.3%
Profit attributable to owners of parent	25,011	21,500	-3,511	-14.0%

*Results for FY2021 are converted from JGAAP to IFRS
(Converted results for FY2021 are unaudited provisional values)

In order to improve international comparability, the company will voluntarily adopt International Financial Reporting Standards (IFRS) starting with the consolidated financial statements in the annual Securities Report for the year ended March 31, 2022.

Segmental Forecast - Pharmaceuticals (IFRS) -



(Million yen)	FY2021		FY2022		YoY Change	
	Results*	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	78,508	65.1%	75,700	65.8%	-2,808	-3.6%
Revenues from the licensing of industrial property rights	33,207	27.5%	29,800	25.9%	-3,407	-10.3%
Profit in co-promotion	8,934	7.4%	9,500	8.3%	+566	+6.3%
Revenue	120,650	100.0%	115,000	100.0%	-5,650	-4.7%

*Results for FY2021 are converted from JGAAP to IFRS
(Converted results for FY2021 are unaudited provisional values)

We look for sales of new products including “Viltepso” and “Upravi”, revenues from the licensing of industrial property rights containing royalty revenue from Uptravi’s overseas sales, and profit in co-promotion to grow. However, due to price revision by MHLW, launch of generic drugs for “Vidaza”, and a backlash from the loss of sales revenue from the priority review voucher booked in FY2021, we predict net sales to decline.

Segmental Forecast - Functional Food (IFRS) -



(Million yen)	FY2021		FY2022		YoY Change	
	Results*	Ratio	Forecast	Ratio	Amt	%
Protein preparations	10,870	64.6%	13,000	68.4%	+2,130	+19.6%
Preservatives	2,788	16.6%	2,900	15.3%	+112	+4.0%
Health food ingredients	1,078	6.4%	1,100	5.8%	+22	+2.0%
Others	2,096	12.4%	2,000	10.5%	-96	-4.6%
Revenue	16,834	100.0%	19,000	100.0%	+2,166	+12.9%

*Results for FY2021 are converted from JGAAP to IFRS
(Converted results for FY2021 are unaudited provisional values)

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

Forecast of Consolidated Statements of Income (IFRS)



(Million yen)	FY2021		FY2022		YoY Change	
	Results*	Ratio	Forecast	Ratio	Amt	%
Revenue	137,484	100.0%	134,000	100.0%	-3,484	-2.5%
(Pharmaceuticals)	(120,650)	(87.8%)	(115,000)	(85.8%)	(-5,650)	(-4.7%)
(Functional Food)	(16,834)	(12.2%)	(19,000)	(14.2%)	(+2,166)	(+12.9%)
Cost of sales	50,188	36.5%	51,000	38.1%	+812	+1.6%
SG&A expenses	32,195	23.4%	31,900	23.8%	-295	-0.9%
R&D expenses	22,870	16.6%	24,400	18.2%	+1,530	+6.7%
Other income	1,578	1.1%	800	0.6%	-778	-49.3%
Other expenses	872	0.6%	500	0.4%	-372	-42.7%
Operating profit	32,936	24.0%	27,000	20.1%	-5,936	-18.0%
Finance income	472	0.3%	500	0.4%	+28	+5.8%
Finance costs	142	0.1%	-	-	-142	-
Profit before tax	33,266	24.2%	27,500	20.5%	-5,766	-17.3%
Income tax expense, etc	8,254	6.0%	6,000	4.5%	-2,254	-27.3%
Profit attributable to owners of parent	25,011	18.2%	21,500	16.0%	-3,511	-14.0%

*Results for FY2021 are converted from JGAAP to IFRS
(Converted results for FY2021 are unaudited provisional values)



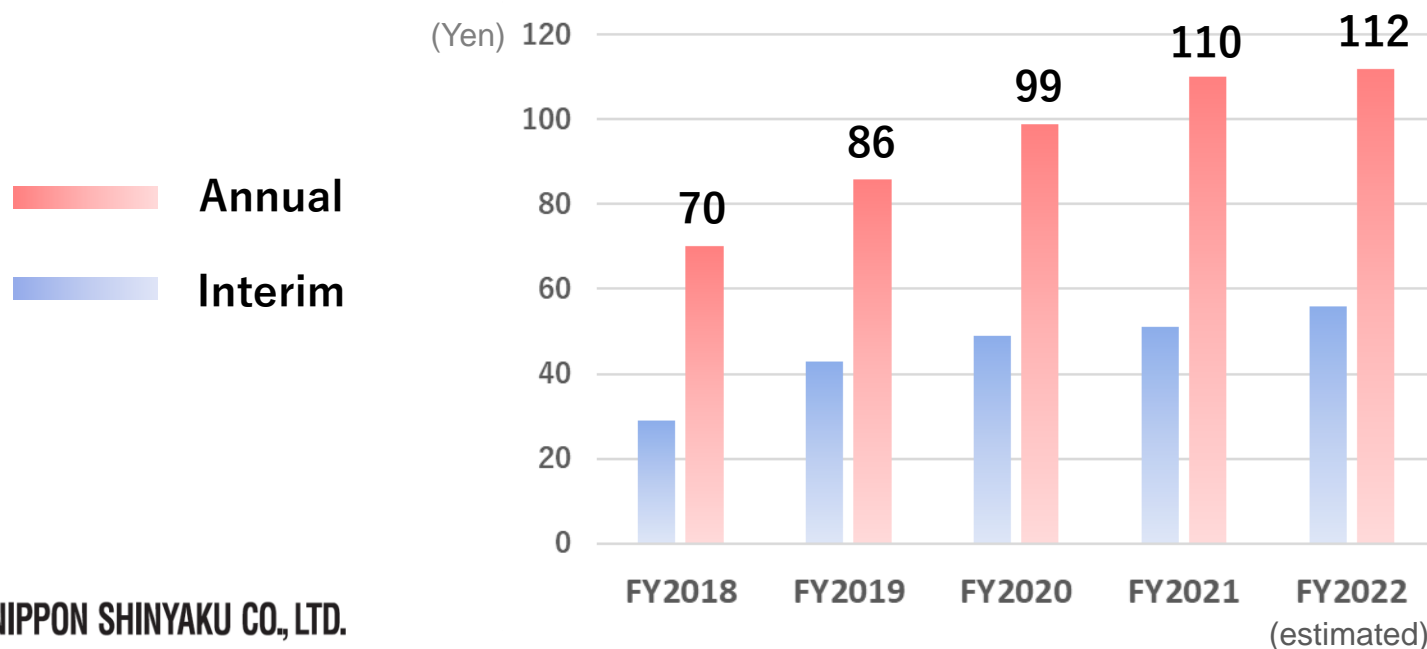
Dividends Forecast



		FY2021	FY2022
Dividends per share	Interim	¥51	¥56
	Annual	¥110	¥112
Net income per share / Basic earnings per share		¥342.14	¥319.21
Payout ratio (consolidated)		32.2 %	35.1 %

*Year-end dividend for FY 2021 is raised from 52 yen to 59 yen

*Basic earnings per share and payout ratio (consolidated) is calculated based on International Financial Reporting Standards (IFRS)



R&D Pipeline



NIPPON SHINYAKU CO., LTD.

R&D Pipeline (Domestic) ①



Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PII	Preparation for PIII	PIII	NDA	Preparation for launch	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					PIII in progress			
NS-32 (ferric derisomaltose) <in-license>	NME	Iron deficiency anemia								
ZX008 (fenfluramine hydrochloride) <in-license>	NME	Dravet syndrome								
ZX008 (fenfluramine hydrochloride) <in-license>	NME	Lennox-Gastaut syndrome								
GA101 (obinutuzumab) <in-license>	New indication	Lupus nephritis								

■ : Changes from 3rd Quarter FY2021

R&D Pipeline (Domestic) ②



Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PII	Preparation for PIII	PIII	NDA	Preparation for launch	Launch
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans								
	New dose	Pediatric pulmonary arterial hypertension								
NS-580 <in-house>	NME	Endometriosis								
NS-87 (daunorubicin / cytarabine) <in-license>	New combi- nation	Secondary acute myeloid leukemia								
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm								
NS-229 <in-house>	NME	Inflammatory diseases								
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia								

■ : Changes from 3rd Quarter FY2021

R&D Pipeline (Overseas)



Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for P II	PII	Preparation for PIII	PIII	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					PIII in progress	
CAP-1002 <partnership>	NME	Duchenne muscular dystrophy						
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis						

Reference Materials

Consolidated Statements of Income



(Million yen)	FY2020		FY2021		YoY change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	121,885	100.0%	137,547	100.0%	+15,662	+12.8%
(Pharmaceuticals)	(106,478)	(87.4%)	(120,650)	(87.7%)	(+14,171)	(+13.3%)
(Functional Food)	(15,406)	(12.6%)	(16,897)	(12.3%)	(+1,490)	(+9.7%)
Cost of sales	49,954	41.0%	50,657	36.8%	+703	+1.4%
SG&A expenses	29,691	24.4%	32,204	23.4%	+2,512	+8.5%
R&D expenses	16,104	13.2%	26,386	19.2%	+10,281	+63.8%
Operating profit	26,134	21.4%	28,299	20.6%	+2,164	+8.3%
Non-operating income	1,326	1.1%	2,359	1.7%	+1,032	+77.8%
Non-operating expenses	701	0.5%	884	0.7%	+183	+26.2%
Ordinary profit	26,760	22.0%	29,773	21.6%	+3,013	+11.3%
Extraordinary income	1,998	1.6%	-	-	-1,998	-
Income taxes, etc	8,056	6.6%	6,729	4.9%	-1,327	-16.5%
Profit attributable to owners of parent	20,702	17.0%	23,044	16.8%	+2,341	+11.3%



Consolidated Balance Sheet



(Million yen)	End of FY2020	End of FY2021	YoY Change Amt		End of FY2020	End of FY2021	YoY Change Amt
Assets	197,028	210,052	+13,024	Liabilities	34,485	33,285	-1,199
Current assets	139,090	149,632	+10,542	Current liabilities	31,514	29,288	-2,225
Fixed assets	57,937	60,419	+2,482	Long-term liabilities	2,970	3,997	+1,026
				Net assets	162,543	176,767	+14,223
Total assets	197,028	210,052	+13,024	Total liabilities and net assets	197,028	210,052	+13,024

= Assets =

Cash and deposits	+2,643
Notes and accounts receivable	+2,839
Inventories	+2,329
Property, plant and equipment	+2,574
Deferred tax asset	+1,305

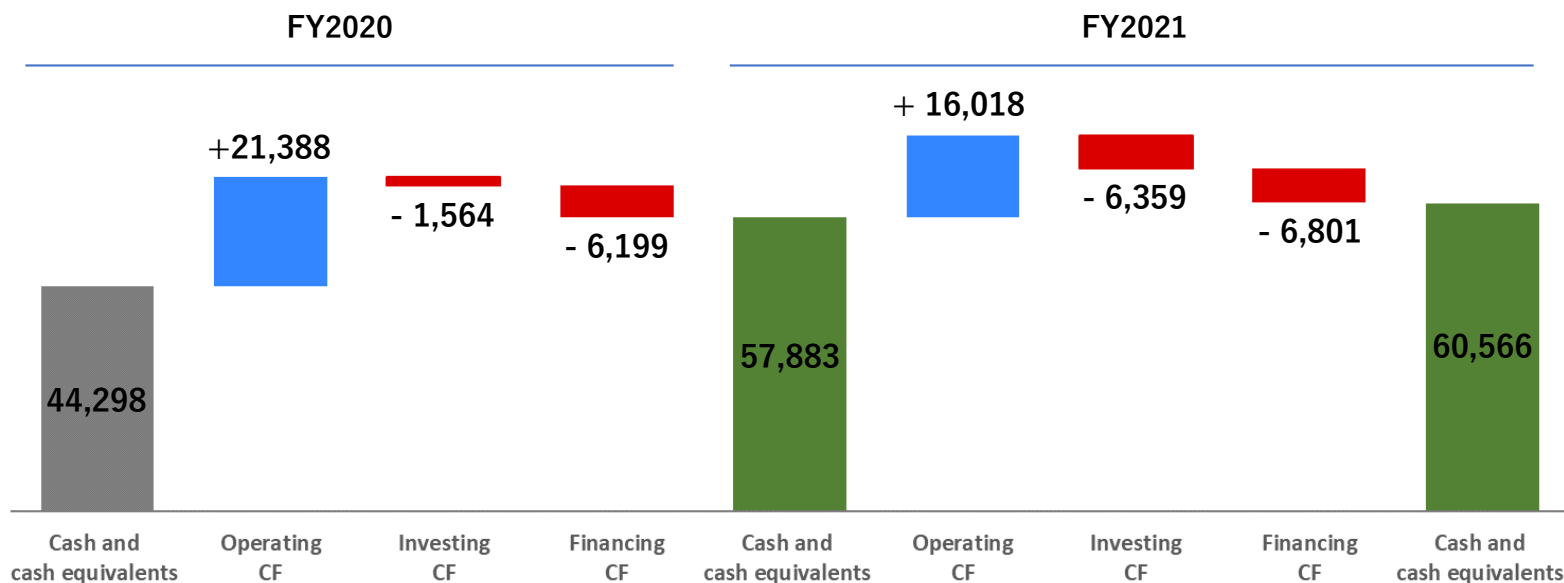
= Liabilities and Net assets =

Accounts payable	+2,956
Income taxes payable	-3,497
Accrued consumption taxes	-381
Net defined benefit liability	+1,033
Retained earnings	+16,241

Consolidated Statements of Cash Flows



(Million yen)	FY2020 Results	FY2021 Results	YoY Change Amt
Operating activities	21,388	16,018	-5,369
Investing activities	-1,564	-6,359	-4,795
Financing activities	-6,199	-6,801	-602
Cash and cash equivalents at end of period	57,883	60,566	+2,683



NS-065/NCNP-01 (viltolarsen)

- Treatment for Duchenne muscular dystrophy -



Development Phase	<ul style="list-style-type: none">• Japan : Launch• USA : Launch• Global : PIII in progress
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-32 (ferric derisomaltose)

- Treatment for iron deficiency anemia -



Development Phase	Japan : Preparation for launch
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



ZX008 (fenfluramine hydrochloride)

- Treatment for rare intractable epilepsy -



Development Phase	Japan : NDA filing (Dravet syndrome) Japan : PIII (Lennox-Gastaut syndrome)
Origin	[Mar. 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	USA : Preparation for PIII
Origin	[Jan. 2022] Partnership for commercialization : Capricor Therapeutics, Inc.
Development	Capricor Therapeutics, Inc.
Mechanism of action	Exosomes released from cardiosphere-derived cells
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	<ul style="list-style-type: none">• Exosomes released from this drug are expected to reduce oxidative stress, inflammation, fibrosis, and increase cell energy and myocyte generation, resulting in improvement of motor and cardiac functions• Its broad applicability makes it suitable for patients regardless of the type of genetic mutation

GA101 (Obinutuzumab)

- Treatment for lupus nephritis -



Development Phase	Japan : Preparation for PIII
Origin	[Nov. 2012] Licensed-in from : Chugai Pharmaceutical Co., Ltd.
Development	Co-development : Chugai Pharmaceutical Co., Ltd.
Mechanism of action	Anti-CD20 monoclonal antibody
Indication	Lupus nephritis
Dosage form	Injection
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity

NS-304 (selexipag)

- Treatment for pulmonary hypertension, arteriosclerosis obliterans -



Development Phase	Japan : PIIb (ASO) Japan : PII (Pediatric PAH)
Origin	Nippon Shinyaku
Development	<ul style="list-style-type: none">• Nippon Shinyaku (ASO)• Co-development : Janssen Pharmaceutical K.K. (Pediatric PAH)
Mechanism of action	Selective IP receptor agonist
Indication	<ul style="list-style-type: none">• Arteriosclerosis obliterans (ASO)• Pediatric pulmonary arterial hypertension (Pediatric PAH)
Dosage form	Tablet
Feature	Long-acting oral drug



- Treatment for endometriosis -

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

NS-018 (ilginatinib)

- Treatment for myelofibrosis -



Development Phase	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

NS-87 (daunorubicin / cytarabine)

- 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 daunorubicin and cytarabine
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

NS-401 (tagraxofusp)



- Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan : Preparation for PI/II
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





- 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 (radgocitabine)



- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan : 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

Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
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