Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2023

November 15, 2023
NIPPON SHINYAKU CO., LTD.

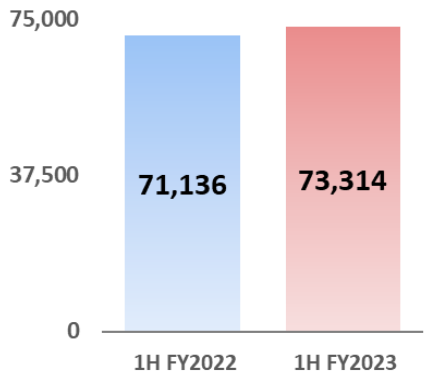
NIPPON SHINYAKU CO., LTD.

2Q FY2023 Summary

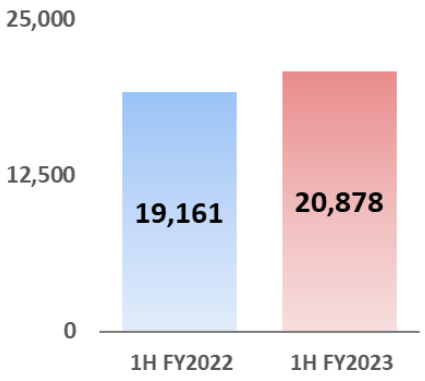
◆ Revenue	:	73,314 million yen	（+ 3.1%）
◆ Operating profit	:	20,878 million yen	（+ 9.0%）
◆ Profit before tax	:	21,146 million yen	（+ 9.0%）
◆ Profit attributable to owners of parent	:	16,176 million yen	（+ 6.3%）

Revenue

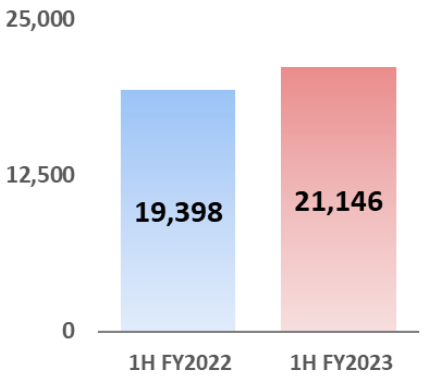
（Million yen）



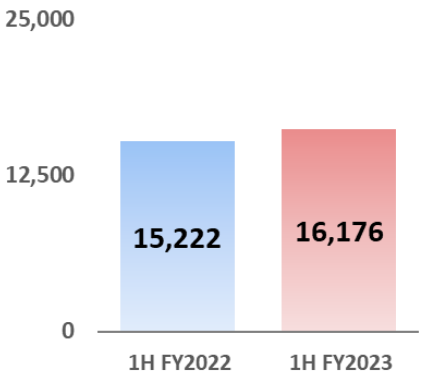
Operating profit



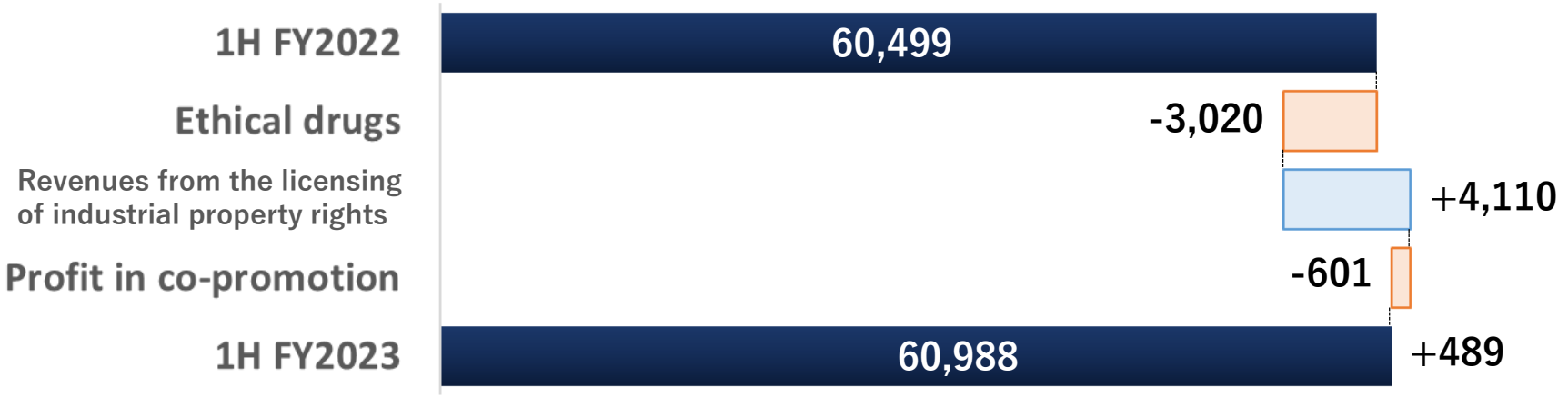
Profit before tax



Profit attributable to owners of parent



Segmental Review - Pharmaceuticals -

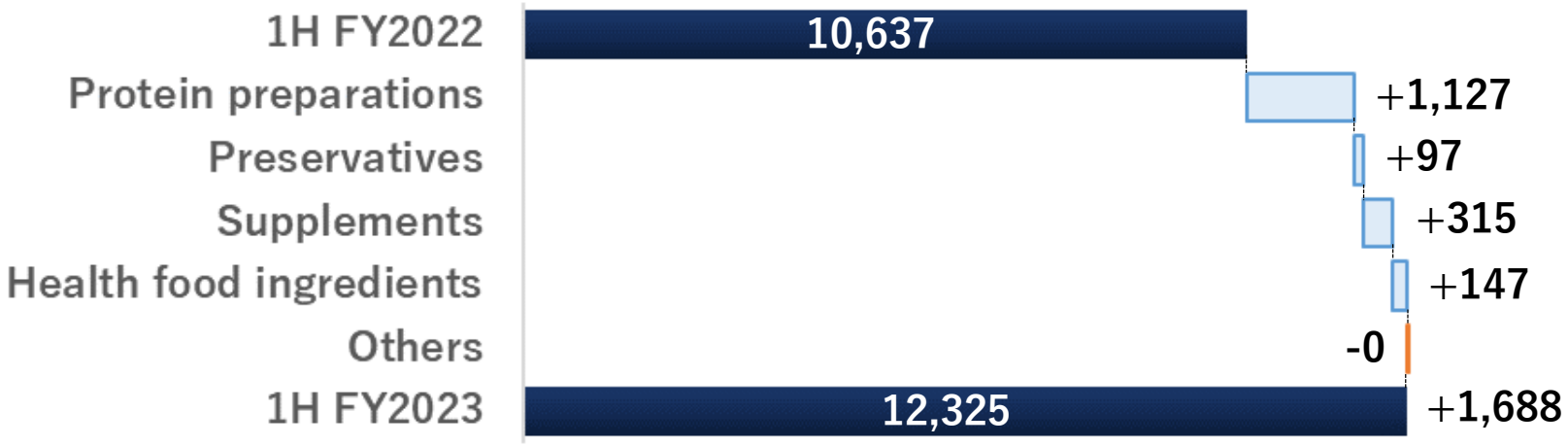


(Million yen)	1H FY2022		1H FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	41,023	67.8%	38,003	62.3%	-3,020	-7.4%
Revenues from the licensing of industrial property rights	14,469	23.9%	18,580	30.5%	+4,110	+28.4%
Profit in co-promotion	5,005	8.3%	4,404	7.2%	-601	-12.0%
Revenue	60,499	100.0%	60,988	100.0%	+489	+0.8%

Despite the effect of price revision by MHLW* and generic products, revenue of consolidated pharmaceuticals segment increased by 0.8% due to increase of sales of "Viltepso" and "Uptravi", and royalty revenue from Uptravi's overseas sales.

*MHLW : Ministry of Health, Labour and Welfare

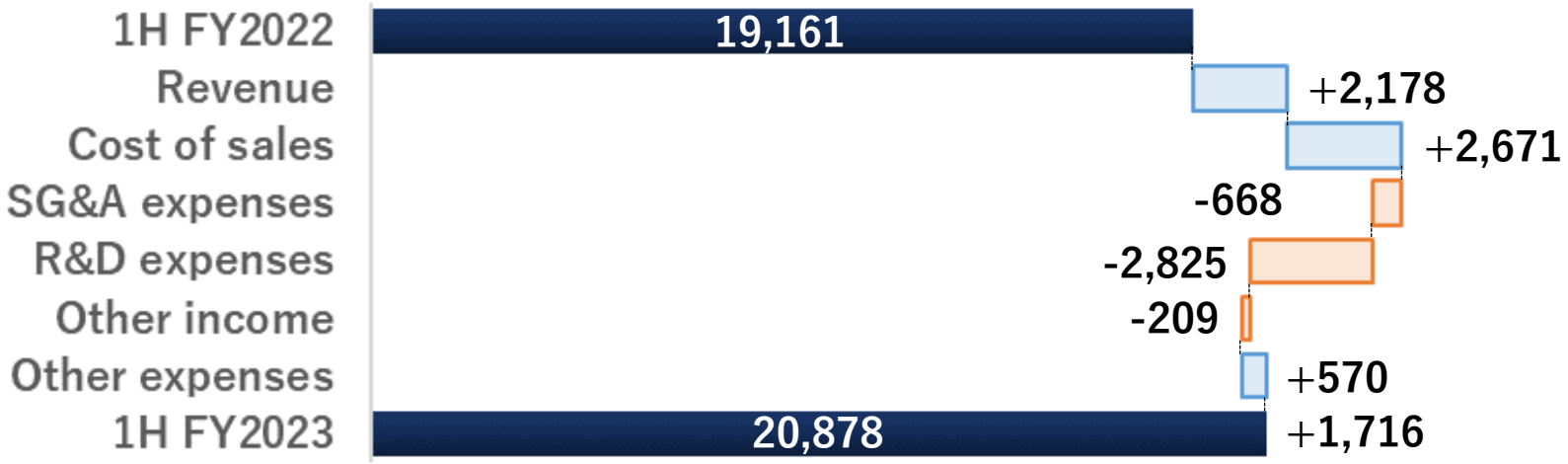
Segmental Review - Functional Food -



(Million yen)	1H FY2022		1H FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,360	69.2%	8,487	68.9%	+1,127	+15.3%
Preservatives	1,424	13.4%	1,522	12.3%	+97	+6.9%
Supplements	671	6.3%	987	8.0%	+315	+46.9%
Health food ingredients	511	4.8%	659	5.4%	+147	+28.9%
Others	668	6.3%	668	5.4%	-0	-0.1%
Revenue	10,637	100.0%	12,325	100.0%	+1,688	+15.9%

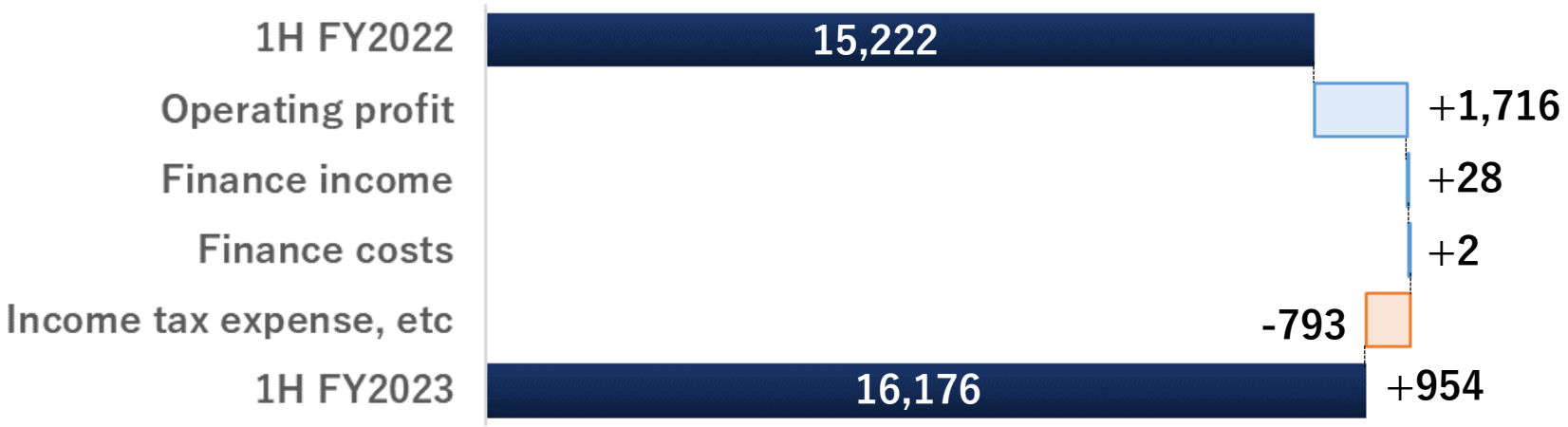
Revenue of consolidated functional food segment increased by 15.9% through sales increase of protein preparations and supplements.

Operating profit



(Million yen)	1H FY2022		1H FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**71,136**	**100.0%**	**73,314**	**100.0%**	**+2,178**	**+3.1%**
(Pharmaceuticals)	(60,499)	(85.0%)	(60,988)	(83.2%)	(+489)	(+0.8%)
(Functional Food)	(10,637)	(15.0%)	(12,325)	(16.8%)	(+1,688)	(+15.9%)
Cost of sales	**27,991**	**39.3%**	**25,320**	**34.5%**	**-2,671**	**-9.5%**
SG&A expenses	**16,284**	**22.9%**	**16,952**	**23.1%**	**+668**	**+4.1%**
R&D expenses	**9,691**	**13.6%**	**12,517**	**17.1%**	**+2,825**	**+29.2%**
Other income	**2,805**	**3.9%**	**2,596**	**3.5%**	**-209**	**-7.5%**
(Foreign exchange gain)	(2,521)	(3.5%)	(2,261)	(3.1%)	(-260)	(-10.3%)
Other expenses	**813**	**1.2%**	**242**	**0.3%**	**-570**	**-70.2%**
Operating profit	**19,161**	**26.9%**	**20,878**	**28.5%**	**+1,716**	**+9.0%**

Profit attributable to owners of parent



(Million yen)	1H FY2022 Results	1H FY2023 Results	YoY Change Amt	YoY Change %
Operating profit	19,161	20,878	+1,716	+9.0%
Finance income	297	326	+28	+9.5%
Finance costs	60	57	-2	-4.5%
Profit before tax	19,398	21,146	+1,747	+9.0%
Income tax expense, etc	4,176	4,970	+793	+19.0%
Profit attributable to owners of parent	15,222	16,176	+954	+6.3%

Business Forecast for FY2023

(Million yen)	FY2022		FY2023		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	**71,136**	**144,175**	**73,314**	**147,000**	**+2,825**	**+2.0%**
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	**+3,012**	**+2.5%**
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	**-187**	**-0.8%**
Operating profit	**19,161**	**30,049**	**20,878**	**33,500**	**+3,451**	**+11.5%**
Profit before tax	**19,398**	**30,489**	**21,146**	**34,000**	**+3,511**	**+11.5%**
Profit attributable to owners of parent	**15,222**	**22,812**	**16,176**	**26,000**	**+3,188**	**+14.0%**

Exchange rate (JPY)	FY2022		FY2023	
	1H Actual rate	FY Actual rate	1H Actual rate	2H Forecast rate
1USD	**134.0円**	**135.5円**	**141.0円**	**140.0円**

We expect royalty revenue from Uptravi's overseas sales and revenue of consolidated functional food segment to exceed the previous projection. Therefore, we have revised our annual forecasts of Revenue, Operating profit, Profit before tax, and Profit attributable to owners of parent.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2022		FY2023		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Ethical drugs	41,023	81,753	38,003	78,200	-3,553	-4.3%
Revenues from the licensing of industrial property rights	14,469	30,714	18,580	38,000	+7,286	+23.7%
Profit in co-promotion	5,005	9,520	4,404	8,800	-720	-7.6%
Revenue	60,499	121,988	60,988	125,000	+3,012	+2.5%

Despite the effect of price revision by MHLW* and launch of generic products, we predict revenue of consolidated pharmaceuticals segment to increase, due to increase of sales of "Viltepso" and "Uptravi", and royalty revenue from Uptravi's overseas sales.

Segmental Forecast - Functional Food -

(Million yen)	FY2022		FY2023		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Protein preparations	7,360	15,383	8,487	14,800	-583	-3.8%
Preservatives	1,424	2,905	1,522	3,000	+95	+3.3%
Supplements	671	1,428	987	1,900	+472	+33.0%
Health food ingredients	511	1,118	659	1,100	-18	-1.6%
Others	668	1,351	668	1,200	-151	-11.2%
Revenue	10,637	22,187	12,325	22,000	-187	-0.8%

We predict revenue of consolidated functional food segment to decrease due to the effect of sales price reduction of several products.

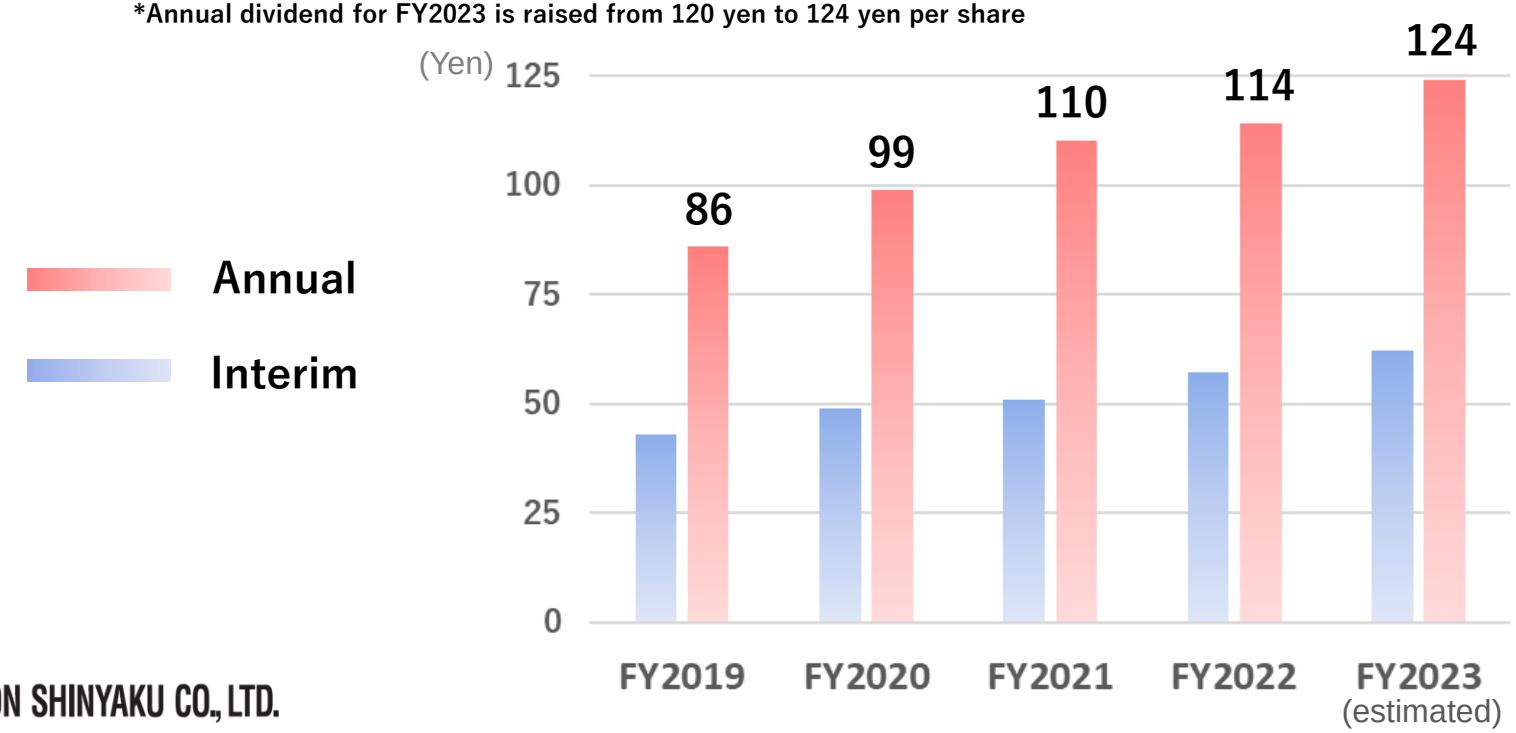
Forecast of Consolidated Statements of Income

(Million yen)	FY2022		FY2023		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	**71,136**	**144,175**	**73,314**	**147,000**	**+2,825**	**+2.0%**
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	(+3,012)	(+2.5%)
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	(-187)	(-0.8%)
Cost of sales	**27,991**	**55,980**	**25,320**	**49,000**	**-6,980**	**-12.5%**
SG&A expenses	**16,284**	**34,812**	**16,952**	**36,000**	**+1,188**	**+3.4%**
R&D expenses	**9,691**	**24,135**	**12,517**	**29,500**	**+5,365**	**+22.2%**
Other income	**2,805**	**1,908**	**2,596**	**1,400**	**-508**	**-26.7%**
Other expenses	**813**	**1,106**	**242**	**400**	**-706**	**-63.8%**
Operating profit	**19,161**	**30,049**	**20,878**	**33,500**	**+3,451**	**+11.5%**
Finance income	**297**	**575**	**326**	**600**	**+25**	**+4.3%**
Finance costs	**60**	**136**	**57**	**100**	**-36**	**-26.5%**
Profit before tax	**19,398**	**30,489**	**21,146**	**34,000**	**+3,511**	**+11.5%**
Income tax expense, etc	**4,176**	**7,676**	**4,970**	**8,000**	**+324**	**+4.2%**
Profit attributable to owners of parent	**15,222**	**22,812**	**16,176**	**26,000**	**+3,188**	**+14.0%**

Dividends Forecast

		FY2022	FY2023
Dividends per share	Interim	¥57	¥62
	Annual	¥114	¥124
Basic earnings per share		¥338.70	¥386.03
Payout ratio (consolidated)		33.7 %	32.1 %

*Interim dividend for FY2023 is raised from 60 yen to 62 yen per share
*Annual dividend for FY2023 is raised from 120 yen to 124 yen per share



R&D Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy						PIII in progress		
NS-87 (daunorubicin / cytarabine) <in-license>	New combi-nation	High-risk acute myeloid leukemia								
ZX008 (fenfluramine hydrochloride) <Distribution partnership>	New indication	Lennox-Gastaut syndrome								
		CDKL5 deficiency disorder								
GA101 (obinutuzumab) <in-license>	New indication	Lupus nephritis								
		Pediatric nephrotic syndrome								
		Extra renal lupus								
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans								
	New dose	Pediatric pulmonary arterial hypertension								

■ : Changes from 1st Quarter FY2023

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	Launch
NS-580 <in-house>	NME	Endometriosis								
		Chronic prostatitis / Chronic pelvic pain syndrome								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis								
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy								
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia								
NS-161 <in-house>	NME	Inflammatory diseases								
NS-025 <in-house>	NME	Urological diseases								
NS-863 <in-house>	NME	Cardiovascular diseases								

■ : Changes from 1st Quarter FY2023

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	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								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy								

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2022	End of 1H FY2023	YoY Change Amt		End of FY2022	End of 1H FY2023	YoY Change Amt
Assets	237,451	249,499	+12,047	Liabilities	41,518	37,725	-3,792
Current assets	157,873	163,459	+5,585	Current liabilities	35,183	32,109	-3,074
Non-current assets	79,578	86,040	+6,462	Non-current liabilities	6,334	5,616	-718
				Equity	195,933	211,774	+15,840
Total assets	237,451	249,499	+12,047	Total liabilities and equity	237,451	249,499	+12,047

＝Assets＝

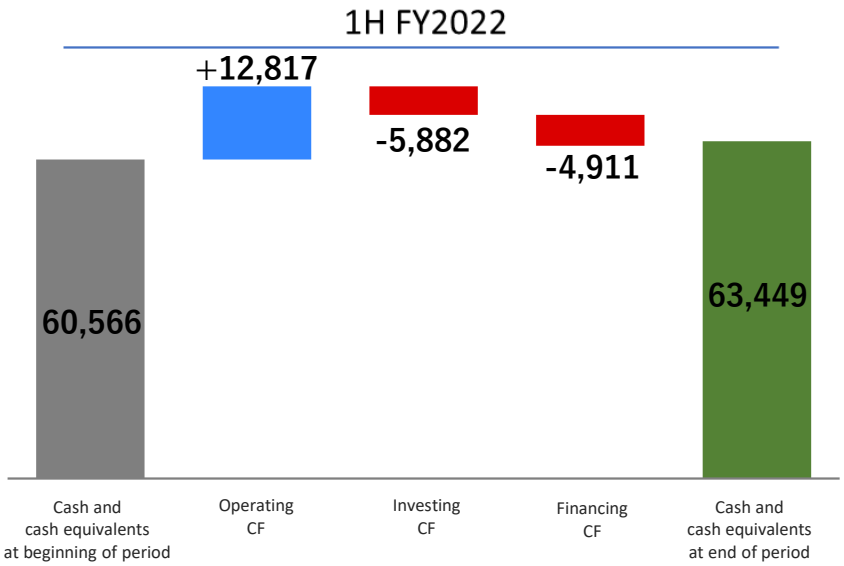
Cash and cash equivalents	+2,807
Trade and other receivables	+4,038
Other financial assets	+6,142

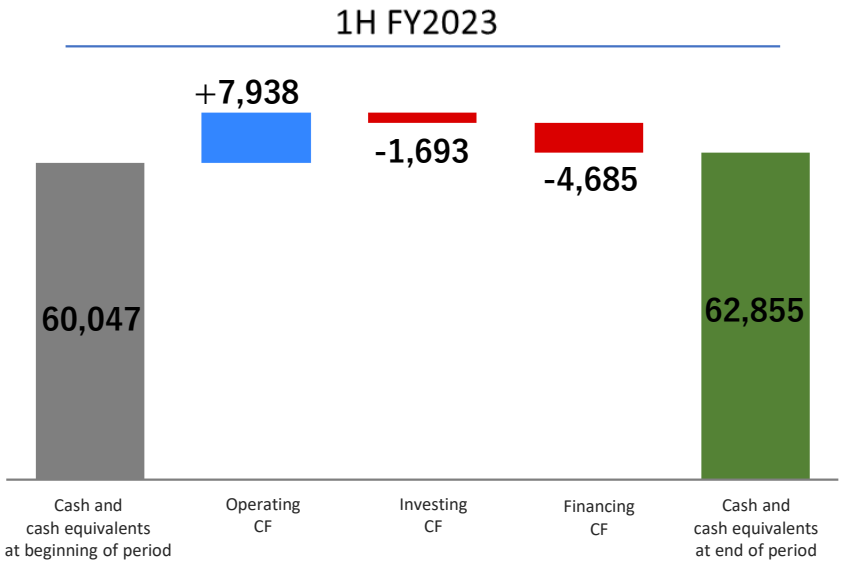
＝Liabilities and Equity＝

Income tax payable	-2,109
Retained earnings	+12,373

Consolidated Statements of Cash Flows

(Million yen)	1H FY2022 Results	1H FY2023 Results	YoY Change Amt
Operating activities	12,817	7,938	-4,879
Investing activities	-5,882	-1,693	+4,189
Financing activities	-4,911	-4,685	+226
Cash and cash equivalents at end of period	63,449	62,855	-593





NS-065/NCNP-01 (viltolarsen)
- Treatment for Duchenne muscular dystrophy -

Development Phase	・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	・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-87 (daunorubicin / cytarabine)
- Treatment for high-risk acute myeloid leukemia -

Development Phase	Japan : NDA filing
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals plc
Development	Nippon Shinyaku
Mechanism of action	Liposomal combination of daunorubicin and cytarabine
Indication	High-risk acute myeloid leukemia (High-risk AML)
Dosage form	Injection
Feature	・NS-87 is the first therapy for the treatment of high-risk AML in Japan ・Accumulation of NS-87 in the bone marrow enhance antitumor activity and reduces adverse events.

ZX008 (fenfluramine hydrochloride)
- Treatment for rare intractable epilepsy -

Development Phase	Japan : Launch (Dravet syndrome) Japan : NDA filing (Lennox-Gastaut syndrome) Japan : PIII (CDKL5 deficiency disorder)
Origin	[Mar. 2019] Distribution partnership in Japan : UCB S.A. (former Zogenix, Inc.)
Development	UCB S.A. (former Zogenix, Inc.)
Mechanism of action	5-HT (serotonin) releaser with agonist activity at several 5-HT receptors
Indication	Dravet syndrome Lennox-Gastaut syndrome CDKL5 deficiency disorder
Dosage form	Oral liquid agent
Feature	・Effective for Dravet syndrome, Lennox-Gastaut syndrome and CDKL5 deficiency disorder 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

CAP-1002
- Treatment for Duchenne muscular dystrophy -

Development Phase	USA : PIII
Origin	[Jan. 2022] Partnership for commercialization in the US [Feb. 2023] Partnership for commercialization in Japan : Capricor Therapeutics, Inc.
Development	Capricor Therapeutics, Inc.
Mechanism of action	Exosomes released from cardiosphere-derived cells
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・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, pediatric nephrotic syndrome, extra renal lupus -

Development Phase	Japan : PIII（LN） Global : PIII（PNS） Japan : PIII（ERL）
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 (LN) Pediatric nephrotic syndrome (PNS) Extra renal lupus (ERL)
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	・Nippon Shinyaku（ASO） ・Co-development : Janssen Pharmaceutical K.K.（Pediatric PAH）
Mechanism of action	Selective IP receptor agonist
Indication	・Arteriosclerosis obliterans (ASO) ・Pediatric pulmonary arterial hypertension (Pediatric PAH)
Dosage form	Tablet
Feature	Long-acting oral drug

NS-580

- Treatment for endometriosis, Chronic prostatitis/Chronic pelvic pain syndrome -

Development Phase	Japan : PIIb (Endometriosis) Japan : PIIa (CP/CPPS)
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Inhibition of membrane-associated prostaglandin E synthase-1
Indication	Endometriosis Chronic prostatitis/Chronic pelvic pain syndrome (CP/CPPS)
Dosage form	Oral agent
Feature	・Treatment for endometriosis without hormonal effect and with possible analgesic potency ・Treatment for CP/CPPS with high safety and long-term pain control

NS-018 (ilginatinib)
- Treatment for myelofibrosis -

Development Phase	Global : PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	・Potent and highly selective JAK2 inhibitor ・High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count

NS-089/NCNP-02（brogidirsen）
- Treatment for Duchenne muscular dystrophy -

Development Phase	Global：Preparation for PII
Origin	Co-development : National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 44 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-229

- Treatment for Eosinophilic granulomatosis with polyangiitis -

Development Phase	Global：Preparation for PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK1 inhibitor
Indication	Eosinophilic granulomatosis with polyangiitis （EGPA）
Dosage form	Oral agent
Feature	・Potent and highly selective JAK1 inhibitor ・High efficacy and good safety profiles are expected in the treatment for EGPA

NS-401 (tagraxofusp)

- Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan : 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	・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-050/NCNP-03
- Treatment for Duchenne muscular dystrophy -

Development Phase	Global：Preparation for PI/II
Origin	Co-development : National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 50 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-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	・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-161
- Treatment for inflammatory diseases -

Development Phase	Japan : PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	–
Indication	Inflammatory diseases (to be determined)
Dosage form	Oral agent
Feature	–

NS-025
- Treatment for urological diseases -

Development Phase	Japan : PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	–
Indication	Urological diseases (to be determined)
Dosage form	Oral agent
Feature	–

NS-863
- Treatment for cardiovascular diseases -

Development Phase	Japan : PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	–
Indication	Cardiovascular diseases (to be determined)
Dosage form	Oral agent
Feature	–

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.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion or failure of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination, obtaining regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
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