Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2022

November 14, 2022
NIPPON SHINYAKU CO., LTD.

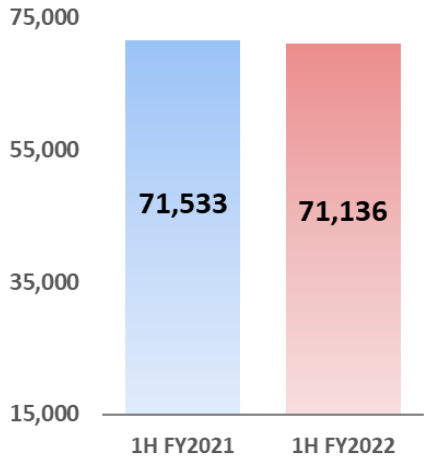
NIPPON SHINYAKU CO., LTD.

2Q FY2022 Summary

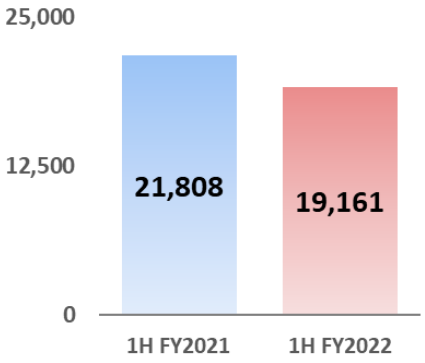
- **Revenue** : 71,136 million yen （- 0.6%）
- **Operating profit** : 19,161 million yen （- 12.1%）
- **Profit before tax** : 19,398 million yen （- 11.9%）
- **Profit attributable to owners of parent** : 15,222 million yen （- 7.9%）

Revenue

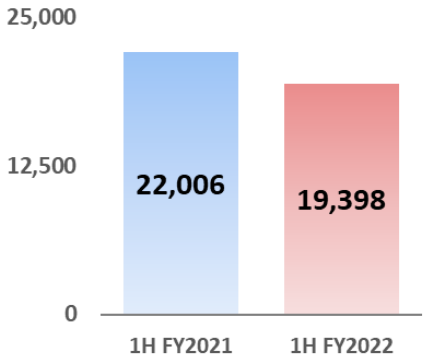
（Million yen）



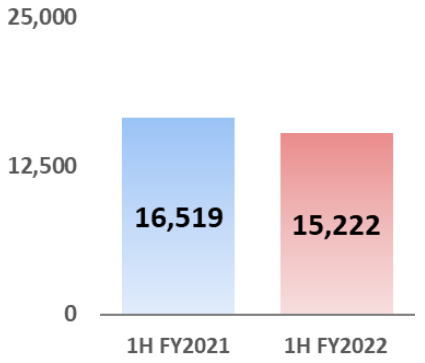
Operating profit



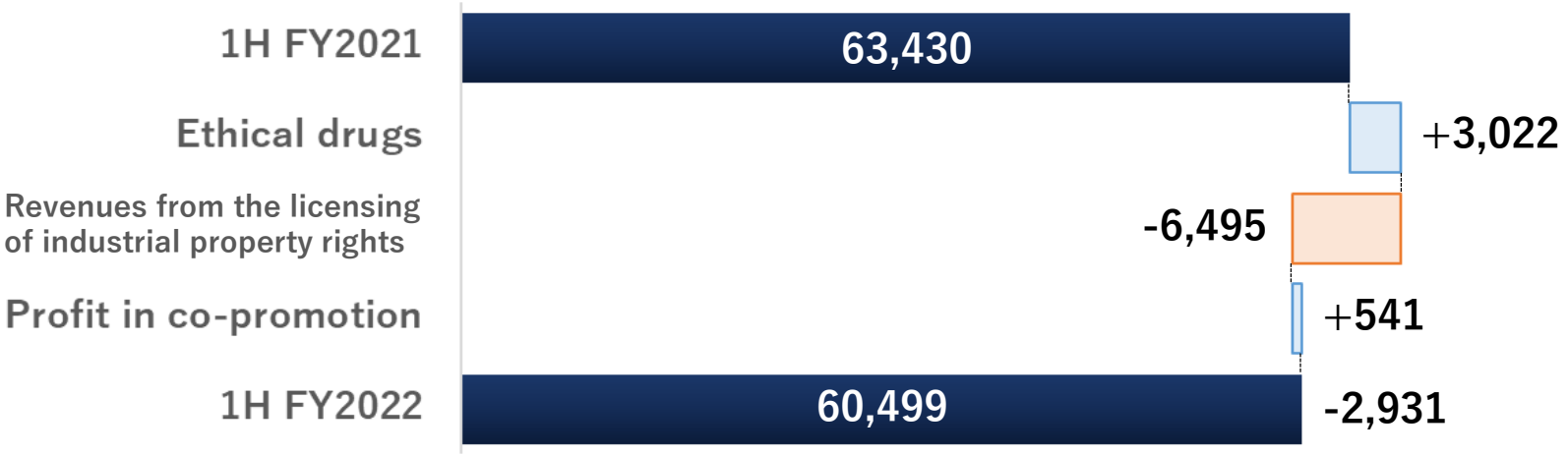
Profit before tax



Profit attributable to owners of parent



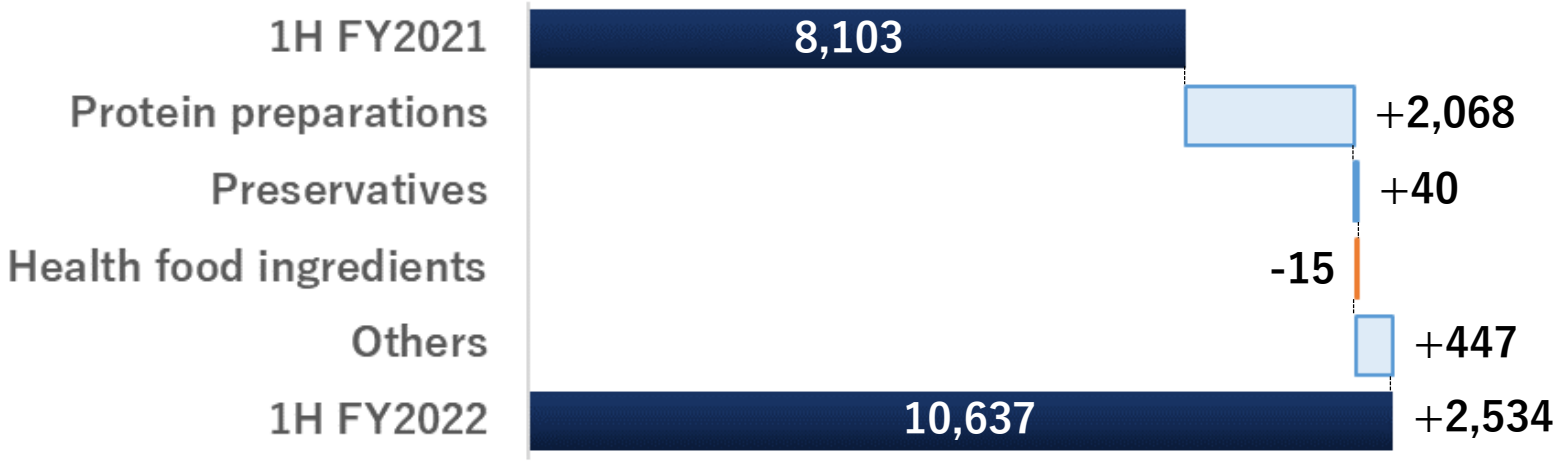
Segmental Review - Pharmaceuticals -



(Million yen)	1H FY2021		1H FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	38,001	59.9%	41,023	67.8%	+3,022	+8.0%
Revenues from the licensing of industrial property rights	20,964	33.1%	14,469	23.9%	-6,495	-31.0%
Profit in co-promotion	4,464	7.0%	5,005	8.3%	+541	+12.1%
Revenue	63,430	100.0%	60,499	100.0%	-2,931	-4.6%

Sales of Ethical drugs including “Viltepso” and “Uptravi”, Revenues from the licensing of industrial property rights containing royalty revenue from Uptravi’s overseas sales grew.
However, due to backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, Revenue of consolidated pharmaceuticals segment decreased by 4.6%.

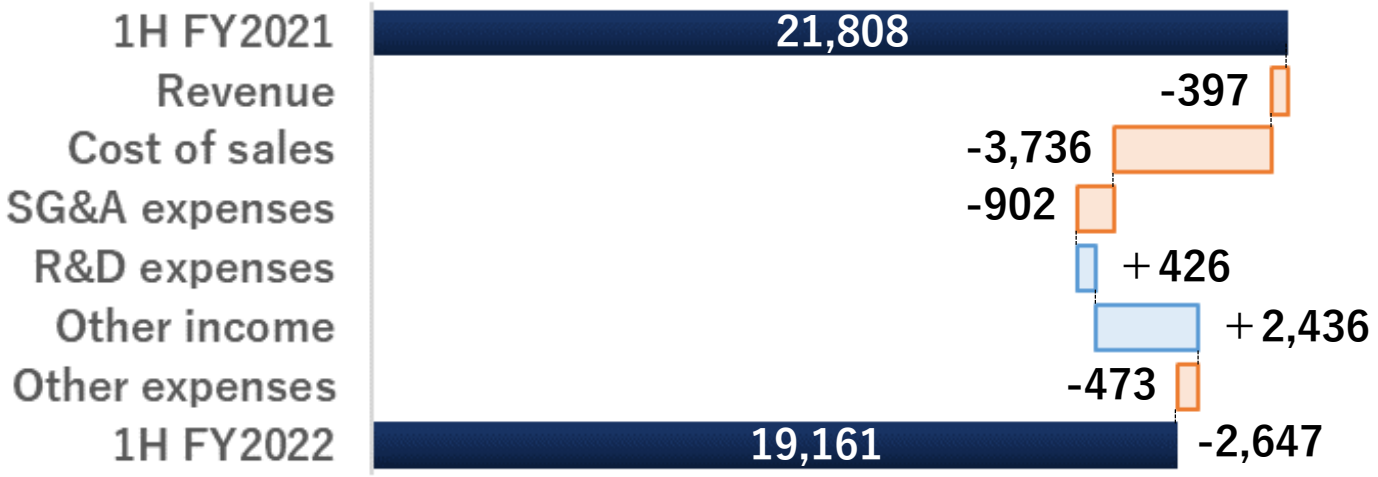
Segmental Review - Functional Food -



(Million yen)	1H FY2021		1H FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	5,292	65.3%	7,360	69.2%	+2,068	+39.1%
Preservatives	1,384	17.1%	1,424	13.4%	+40	+2.9%
Health food ingredients	527	6.5%	511	4.8%	-15	-3.0%
Others	893	11.1%	1,340	12.6%	+447	+50.1%
Revenue	8,103	100.0%	10,637	100.0%	+2,534	+31.3%

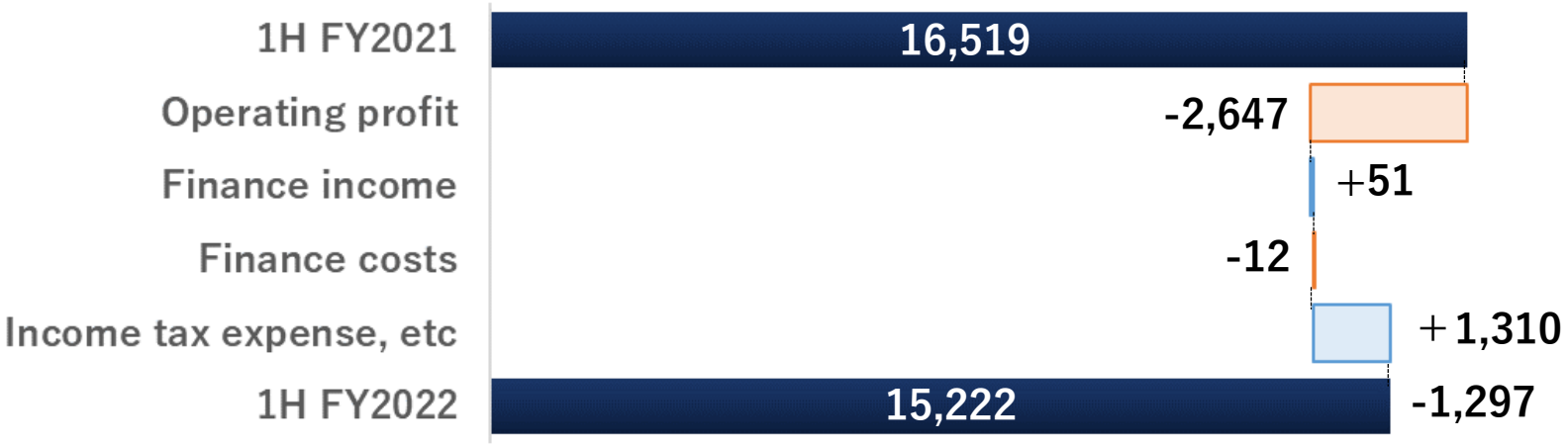
Revenue of consolidated functional food segment increased by 31.3% through sales from Protein preparations including milk proteins and supplements such as “WINZONE Protein”.

Operating profit



(Million yen)	1H FY2021		1H FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**71,533**	**100.0%**	**71,136**	**100.0%**	**-397**	**-0.6%**
(Pharmaceuticals)	(63,430)	(88.7%)	(60,499)	(85.0%)	(-2,931)	(-4.6%)
(Functional Food)	(8,103)	(11.3%)	(10,637)	(15.0%)	(+2,534)	(+31.3%)
Cost of sales	**24,254**	**33.9%**	**27,991**	**39.3%**	**+3,736**	**+15.4%**
SG&A expenses	**15,381**	**21.5%**	**16,284**	**22.9%**	**+902**	**+5.9%**
R&D expenses	**10,117**	**14.1%**	**9,691**	**13.6%**	**-426**	**-4.2%**
Other income	**369**	**0.5%**	**2,805**	**3.9%**	**+2,436**	**+660.1%**
Other expenses	**340**	**0.5%**	**813**	**1.2%**	**+473**	**+139.0%**
Operating profit	**21,808**	**30.5%**	**19,161**	**26.9%**	**-2,647**	**-12.1%**

Profit attributable to owners of parent



(Million yen)	1H FY2021 Results	1H FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	21,808	19,161	-2,647	-12.1%
Finance income	246	297	+51	+20.9%
Finance costs	48	60	+12	+26.0%
Profit before tax	22,006	19,398	-2,608	-11.9%
Income tax expense, etc	5,487	4,176	-1,310	-23.9%
Profit attributable to owners of parent	16,519	15,222	-1,297	-7.9%

Business Forecast for FY2022

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	**71,533**	**137,484**	**71,136**	**141,000**	**+3,516**	**+2.6%**
(Pharmaceuticals)	(63,430)	(120,650)	(60,499)	(119,500)	**-1,150**	**-1.0%**
(Functional Food)	(8,103)	(16,834)	(10,637)	(21,500)	**+4,666**	**+27.7%**
Operating profit	**21,808**	**32,948**	**19,161**	**30,000**	**-2,948**	**-8.9%**
Profit before tax	**22,006**	**33,301**	**19,398**	**30,400**	**-2,901**	**-8.7%**
Profit attributable to owners of parent	**16,519**	**24,986**	**15,222**	**24,000**	**-986**	**-3.9%**

We expect sales of functional food, Viltepso in the U.S., domestic pharmaceutical products, etc. 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)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Ethical drugs	38,001	78,508	41,023	79,800	+1,292	+1.6%
Revenues from the licensing of industrial property rights	20,964	33,207	14,469	30,200	-3,007	-9.1%
Profit in co-promotion	4,464	8,934	5,005	9,500	+566	+6.3%
Revenue	63,430	120,650	60,499	119,500	-1,150	-1.0%

We look for sales of new products such as “Viltepso” and “Upravi, royalty revenue from Uptravi’s overseas sales included in the Revenues from the licensing of industrial property rights, and Profit in co-promotion to grow. However, due to backlash from the loss of sales revenue from the priority review voucher booked in FY2021, we predict Revenue of consolidated pharmaceuticals segment to decrease.

Segmental Forecast - Functional Food -

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Protein preparations	5,292	10,870	7,360	15,000	+4,130	+38.0%
Preservatives	1,384	2,788	1,424	2,900	+112	+4.0%
Health food ingredients	527	1,078	511	1,100	+22	+2.0%
Others	899	2,096	1,340	2,500	+404	+19.2%
Revenue	8,103	16,834	10,637	21,500	+4,666	+27.7%

We predict Revenue of consolidated functional food segment to increase from the growth of sales of Protein preparations, supplements, etc.

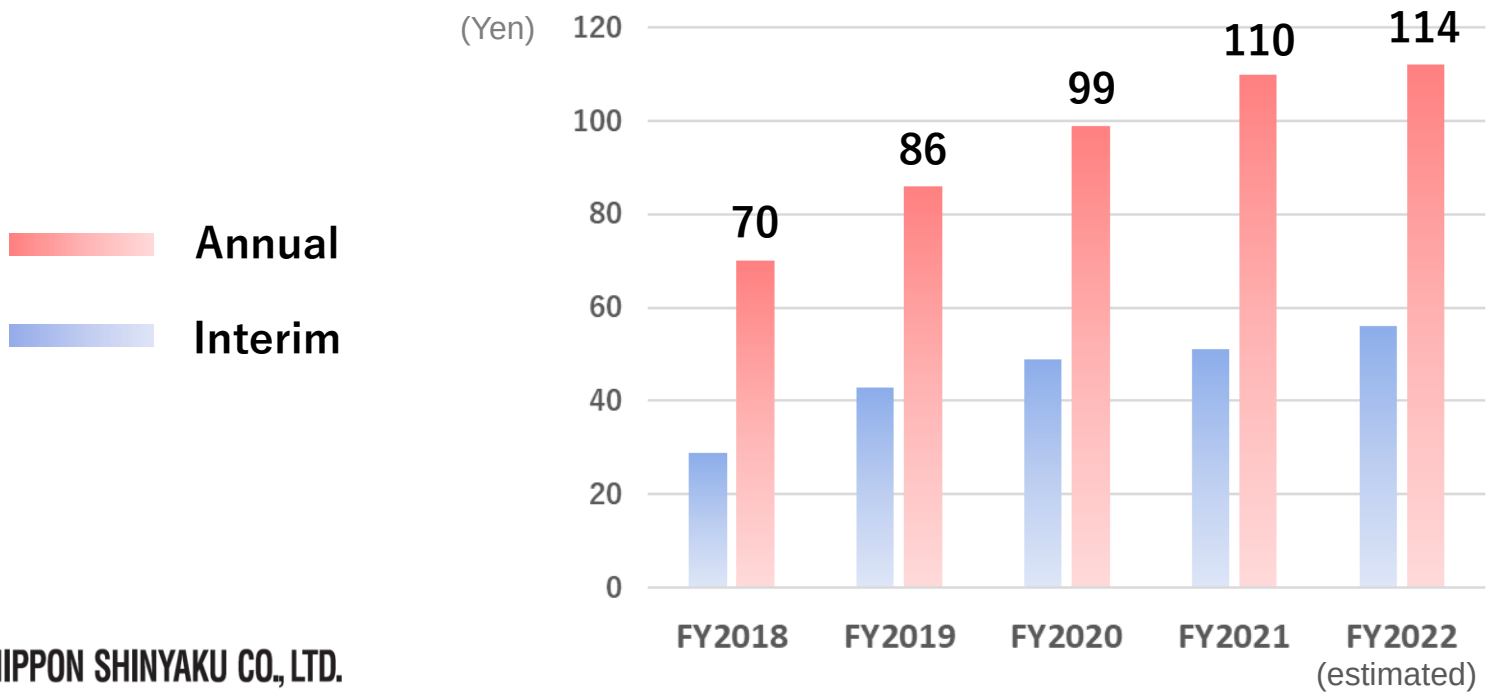
Forecast of Consolidated Statements of Income

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	71,533	137,484	71,136	141,000	+3,516	+2.6%
(Pharmaceuticals)	(63,430)	(120,650)	(60,499)	(119,500)	(-1,150)	(-1.0%)
(Functional Food)	(8,103)	(16,834)	(10,637)	(21,500)	(+4,666)	(+27.7%)
Cost of sales	24,254	50,191	27,991	54,900	+4,709	+9.4%
SG&A expenses	15,381	32,173	16,284	34,000	+1,827	+5.7%
R&D expenses	10,117	22,863	9,691	24,000	+1,137	+5.0%
Other income	369	1,573	2,805	3,000	+1,427	+90.6%
Other expenses	340	882	813	1,100	+218	+24.7%
Operating profit	21,808	32,948	19,161	30,000	-2,948	-8.9%
Finance income	246	472	297	500	+28	+5.8%
Finance costs	48	119	60	100	-19	-16.0%
Profit before tax	22,006	33,301	19,398	30,400	-2,901	-8.7%
Income tax expense, etc	5,487	8,315	4,176	6,400	-1,915	-23.0%
Profit attributable to owners of parent	16,519	24,986	15,222	24,000	-986	-3.9%

Dividends Forecast

		FY2021 (JGAAP)	FY2022 (IFRS)
Dividends per share	Interim	¥51	¥57
	Annual	¥110	¥114
Basic earnings per share		¥342.14	¥356.33
Payout ratio (consolidated)		32.2 %	32.0 %

*Interim dividend for FY2022 is raised from 56 yen to 57 yen per share
*Annual dividend for FY2022 is raised from 112 yen to 114 yen per share



R&D Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for PI	PI	PI/II	PII	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								
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans								
	New dose	Pediatric pulmonary arterial hypertension								

■ : Changes from 1st Quarter FY2022

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for PI	PI	PI/II	PII	PIII	NDA	Preparation for launch	Launch
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								
NS-161 <in-house>	NME	Inflammatory diseases								
NS-025 <in-house>	NME	Urological diseases								

■ : Changes from 1st Quarter FY2022

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for P II	PII	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

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2021	End of 1H FY2022	YoY Change Amt
Assets	219,943	225,374	+5,430
Current assets	149,724	155,339	+5,614
Non-current assets	70,219	70,035	-183
Total assets	219,943	225,374	+5,430

	End of FY2021	End of 1H FY2022	YoY Change Amt
Liabilities	39,057	33,870	-5,186
Current liabilities	32,029	27,365	-4,663
Non-current liabilities	7,027	6,504	-522
Equity	180,886	191,503	+10,617
Total liabilities and equity	219,943	225,374	+5,430

＝Assets＝

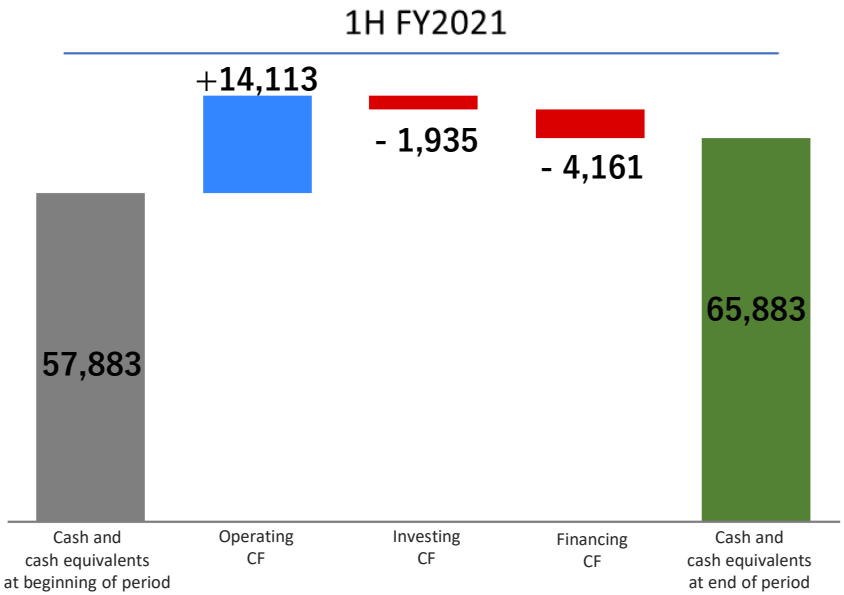
Cash and cash equivalents	+2,883
Other current assets	+1,752

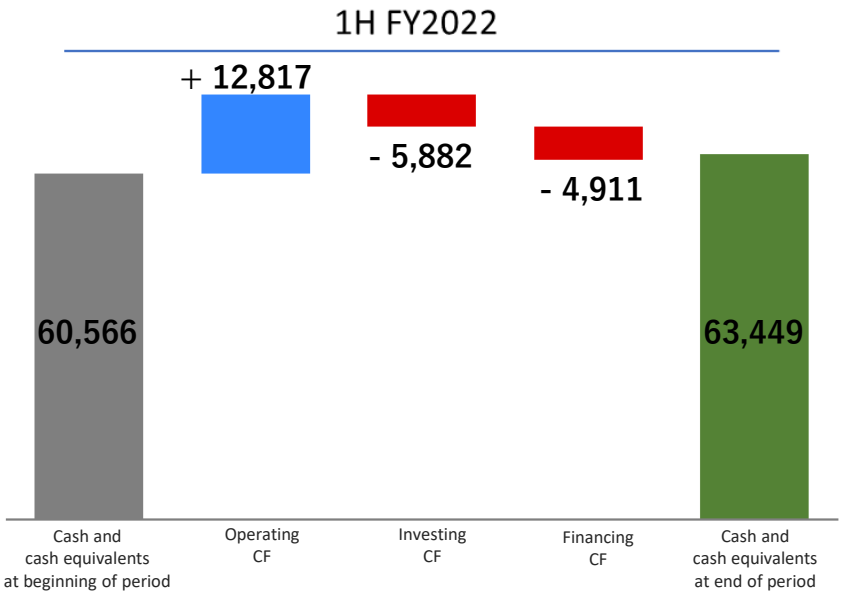
＝Liabilities and Equity＝

Trade and other payables	-5,892
Retained earnings	+11,264

Consolidated Statements of Cash Flows

(Million yen)	1H FY2021 Results	1H FY2022 Results	YoY Change Amt
Operating activities	14,113	12,817	-1,295
Investing activities	-1,935	-5,882	-3,947
Financing activities	-4,161	-4,911	-749
Cash and cash equivalents at end of period	65,883	63,449	-2,433





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-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	・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 : Preparation for launch (Dravet syndrome) Japan : PIII (Lennox-Gastaut syndrome)
Origin	[Mar. 2019] Commercial rights from : 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 and Lennox-Gastaut syndrome
Dosage form	Oral liquid agent
Feature	・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

CAP-1002
- Treatment for Duchenne muscular dystrophy -

Development Phase	USA : 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	・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 : 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	・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 -

Development Phase	Japan : PIIb
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	Overseas : Preparation for 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-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	・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 : 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-229
- 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	・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	・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 : Preparation for 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 : Preparation for PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	–
Indication	Urological diseases (to be determined)
Dosage form	Oral agent
Feature	–

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- 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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NIPPON SHINYAKU CO., LTD.

Nippon Shinyaku Co., Ltd.

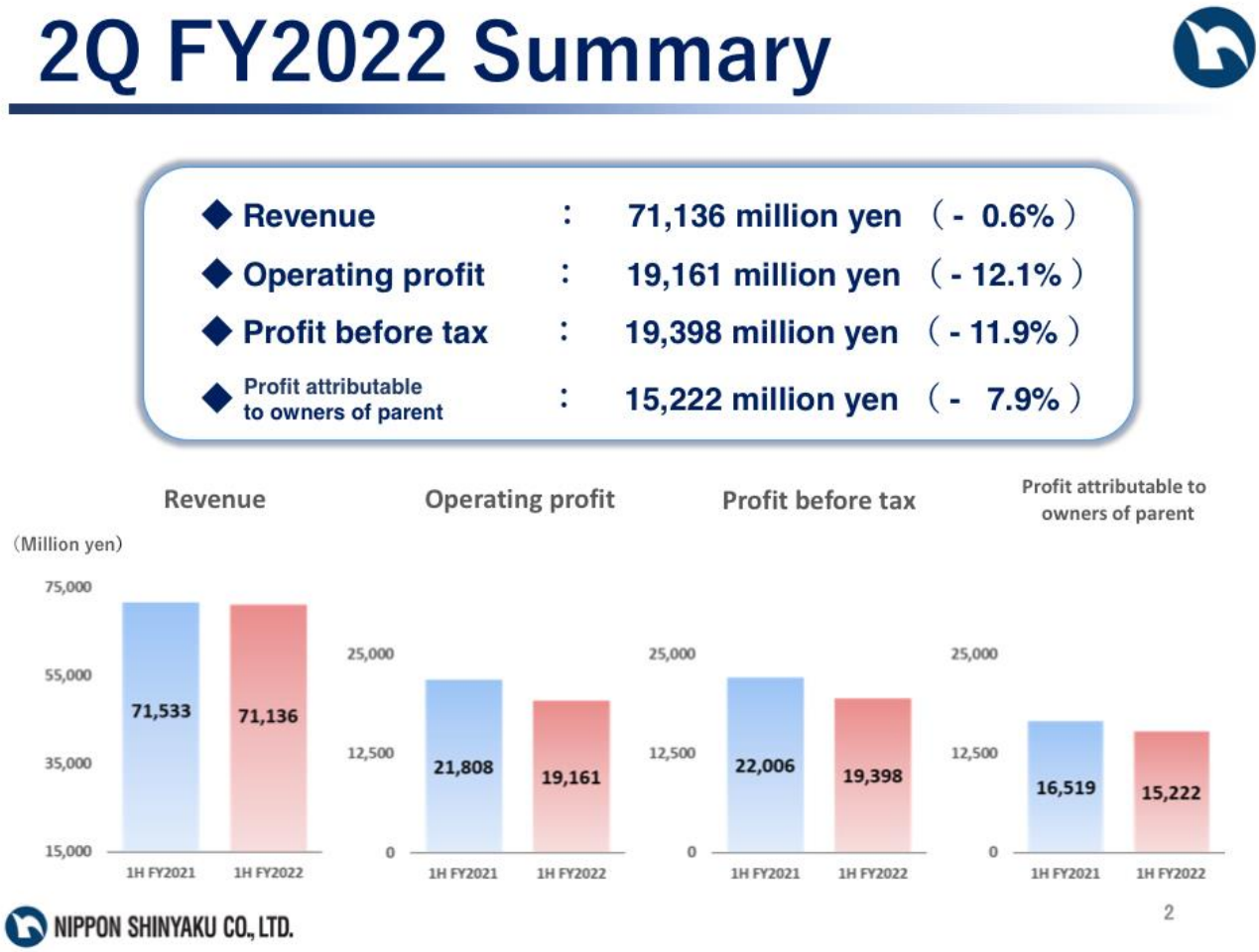
Financial Results for the Second Quarter Ended September 30, 2022

November 14, 2022

Nakai: I am Toru Nakai, President of Nippon Shinyaku Co., Ltd.

Thank you very much for participating in today's financial results briefing for FY2022Q2. I would like to express my greatest gratitude.

Today, I will explain our financial results for Q2 of FY2022 and the forecast for the full year of FY2022. After my presentation, Mr. Takagaki will discuss the progress of our R&D compounds.



I would like to begin with an overview of our performance in Q2 of FY2022. We reported consolidated revenue of JPY71,136 million, operating profit of JPY19,161 million, profit before tax of JPY19,398 million, and profit attributable to owners of parent of JPY15,222 million for the quarter.

Segmental Review - Pharmaceuticals -

(Million yen)	1H FY2021		1H FY2022		YoY Change	
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Ethical drugs	38,001	59.9%	41,023	67.8%	+3,022	+8.0%
Revenues from the licensing of industrial property rights	20,964	33.1%	14,469	23.9%	-6,495	-31.0%
Profit in co-promotion	4,464	7.0%	5,005	8.3%	+541	+12.1%
Revenue	63,430	100.0%	60,499	100.0%	-2,931	-4.6%

Sales of Ethical drugs including "Viltepso" and "Uptravi", Revenues from the licensing of industrial property rights containing royalty revenue from Uptravi's overseas sales grew.
However, due to backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, Revenue of consolidated pharmaceuticals segment decreased by 4.6%.

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In the pharmaceuticals business, although sales of Viltepso, a treatment for Duchenne muscular dystrophy, and sales of Uptravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, as well as royalty income from overseas sales of Uptravi grew, consolidated revenue of Pharmaceuticals business declined 4.6% YoY to JPY60,499 million, due to the loss of sales revenue of the priority review voucher booked in 1H FY2021.

Segmental Review - Functional Food -

(Million yen)	1H FY2021		1H FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	5,292	65.3%	7,360	69.2%	+2,068	+39.1%
Preservatives	1,384	17.1%	1,424	13.4%	+40	+2.9%
Health food ingredients	527	6.5%	511	4.8%	-15	-3.0%
Others	893	11.1%	1,340	12.6%	+447	+50.1%
Revenue	8,103	100.0%	10,637	100.0%	+2,534	+31.3%

Revenue of consolidated functional food segment increased by 31.3% through sales from Protein preparations including milk proteins and supplements such as "WINZONE Protein".

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In the functional food business, sales of protein products including milk protein and supplements such as WINZONE Protein for general consumers increased, resulting in consolidated revenue of JPY10,637 million, up 31.3% YoY.

Operating profit

(Million yen)	1H FY2021		1H FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	71,533	100.0%	71,136	100.0%	-397	-0.6%
(Pharmaceuticals)	(63,430)	(88.7%)	(60,499)	(85.0%)	(-2,931)	(-4.6%)
(Functional Food)	(8,103)	(11.3%)	(10,637)	(15.0%)	(+2,534)	(+31.3%)
Cost of sales	24,254	33.9%	27,991	39.3%	+3,736	+15.4%
SG&A expenses	15,381	21.5%	16,284	22.9%	+902	+5.9%
R&D expenses	10,117	14.1%	9,691	13.6%	-426	-4.2%
Other income	369	0.5%	2,805	3.9%	+2,436	+660.1%
Other expenses	340	0.5%	813	1.2%	+473	+139.0%
Operating profit	21,808	30.5%	19,161	26.9%	-2,647	-12.1%

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Next, in terms of operating expenses, the cost-of-sales ratio deteriorated 5.4 percentage point YoY to 39.3%, due to factors such as the sales mix, including a decrease in the licensing of industrial property rights.

SG&A expenses increased by 5.9% YoY to JPY16,284 million, mainly due to expenses related to the US subsidiary and an increase in sales promotion fees in line with increased domestic sales of Uptravi.

R&D expenses totaled JPY9,691 million, down 4.2%YoY, mainly due to a decrease in manufacturing costs for investigational nucleic acid drugs.

Other income totaled JPY28,05 million, mainly due to foreign exchange gains.

As a result, operating profit was JPY19,161 million, down 12.1%YoY.

Profit attributable to owners of parent

(Million yen)	1H FY2021 Results	1H FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	21,808	19,161	-2,647	-12.1%
Finance income	246	297	+51	+20.9%
Finance costs	48	60	+12	+26.0%
Profit before tax	22,006	19,398	-2,608	-11.9%
Income tax expense, etc	5,487	4,176	-1,310	-23.9%
Profit attributable to owners of parent	16,519	15,222	-1,297	-7.9%

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Profit before tax was JPY19,398 million, down 11.9% YoY, and profit attributable to owners of parent was JPY15,222 million, down 7.9% YoY.

Business Forecast for FY2022

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	71,533	137,484	71,136	141,000	+3,516	+2.6%
(Pharmaceuticals)	(63,430)	(120,650)	(60,499)	(119,500)	-1,150	-1.0%
(Functional Food)	(8,103)	(16,834)	(10,637)	(21,500)	+4,666	+27.7%
Operating profit	21,808	32,948	19,161	30,000	-2,948	-8.9%
Profit before tax	22,006	33,301	19,398	30,400	-2,901	-8.7%
Profit attributable to owners of parent	16,519	24,986	15,222	24,000	-986	-3.9%

We expect sales of functional food, Viltepso in the U.S., domestic pharmaceutical products, etc. 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.

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I will now explain our full-year business forecast for FY2022.

As announced on November 10, we have revised our previous forecast announced in May.

Consolidated revenue was revised from JPY134,000 million to JPY141,000 million, as the performance of the functional food business, Viltepso in the US, and domestic pharmaceuticals are expected to exceed the initial forecast.

As for consolidated profit, we revised operating profit from JPY27,000 million to JPY30,000 million, profit before tax from JPY27,500 million to JPY30,400 million, and profit attributable to owners of parent from JPY21,500 million to JPY24,000 million.

The exchange rate assumption was changed from JPY122 to USD1 at the beginning of the period to JPY140 to USD1.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Ethical drugs	38,001	78,508	41,023	79,800	+1,292	+1.6%
Revenues from the licensing of industrial property rights	20,964	33,207	14,469	30,200	-3,007	-9.1%
Profit in co-promotion	4,464	8,934	5,005	9,500	+566	+6.3%
Revenue	63,430	120,650	60,499	119,500	-1,150	-1.0%

We look for sales of new products such as “Viltepso” and “Upravi, royalty revenue from Uptravi’s overseas sales included in the Revenues from the licensing of industrial property rights, and Profit in co-promotion to grow. However, due to backlash from the loss of sales revenue from the priority review voucher booked in FY2021, we predict Revenue of consolidated pharmaceuticals segment to decrease.

In the pharmaceuticals business, although sales of new products such as Viltepso and Uptravi, royalty revenue from overseas sales of Uptravi and profit in co-promotion are expected to grow. However, due to the loss of sales revenue from the priority review voucher booked in the previous fiscal year, revenue is expected to decrease by 1% YoY to JPY119,500 million.

Segmental Forecast - Functional Food -

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Protein preparations	5,292	10,870	7,360	15,000	+4,130	+38.0%
Preservatives	1,384	2,788	1,424	2,900	+112	+4.0%
Health food ingredients	527	1,078	511	1,100	+22	+2.0%
Others	899	2,096	1,340	2,500	+404	+19.2%
Revenue	8,103	16,834	10,637	21,500	+4,666	+27.7%

We predict Revenue of consolidated functional food segment to increase from the growth of sales of Protein preparations, supplements, etc.

In the functional food business, revenue is expected to be JPY21,500 million, an increase of 27.7% YoY, due to growth in protein preparations and supplements.

Forecast of Consolidated Statements of Income

(Million yen)	FY2021		FY2022		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	71,533	137,484	71,136	141,000	+3,516	+2.6%
(Pharmaceuticals)	(63,430)	(120,650)	(60,499)	(119,500)	(-1,150)	(-1.0%)
(Functional Food)	(8,103)	(16,834)	(10,637)	(21,500)	(+4,666)	(+27.7%)
Cost of sales	24,254	50,191	27,991	54,900	+4,709	+9.4%
SG&A expenses	15,381	32,173	16,284	34,000	+1,827	+5.7%
R&D expenses	10,117	22,863	9,691	24,000	+1,137	+5.0%
Other income	369	1,573	2,805	3,000	+1,427	+90.6%
Other expenses	340	882	813	1,100	+218	+24.7%
Operating profit	21,808	32,948	19,161	30,000	-2,948	-8.9%
Finance income	246	472	297	500	+28	+5.8%
Finance costs	48	119	60	100	-19	-16.0%
Profit before tax	22,006	33,301	19,398	30,400	-2,901	-8.7%
Income tax expense, etc	5,487	8,315	4,176	6,400	-1,915	-23.0%
Profit attributable to owners of parent	16,519	24,986	15,222	24,000	-986	-3.9%

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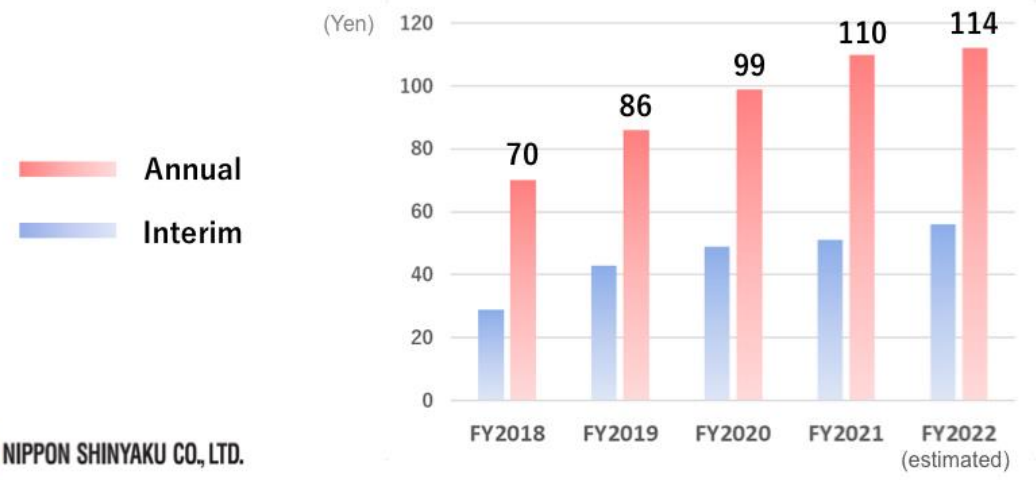
Next, regarding operating expenses, the cost-of-sales ratio is expected to be 38.9%, a deterioration of 2.4 percentage points YoY. SG&A expenses are expected to be JPY34,000 million, and R&D expenses are expected to be JPY24,000 million.

As a result, operating profit is expected to be JPY30,000 million, profit before tax JPY30,400 million, and profit attributable to owners of parent JPY24,000 million.

Dividends Forecast

		FY2021 (JGAAP)	FY2022 (IFRS)
Dividends per share	Interim	¥51	¥57
	Annual	¥110	¥114
Basic earnings per share		¥342.14	¥356.33
Payout ratio (consolidated)		32.2 %	32.0 %

*Interim dividend for FY2022 is raised from 56 yen to 57 yen per share
*Annual dividend for FY2022 is raised from 112 yen to 114 yen per share

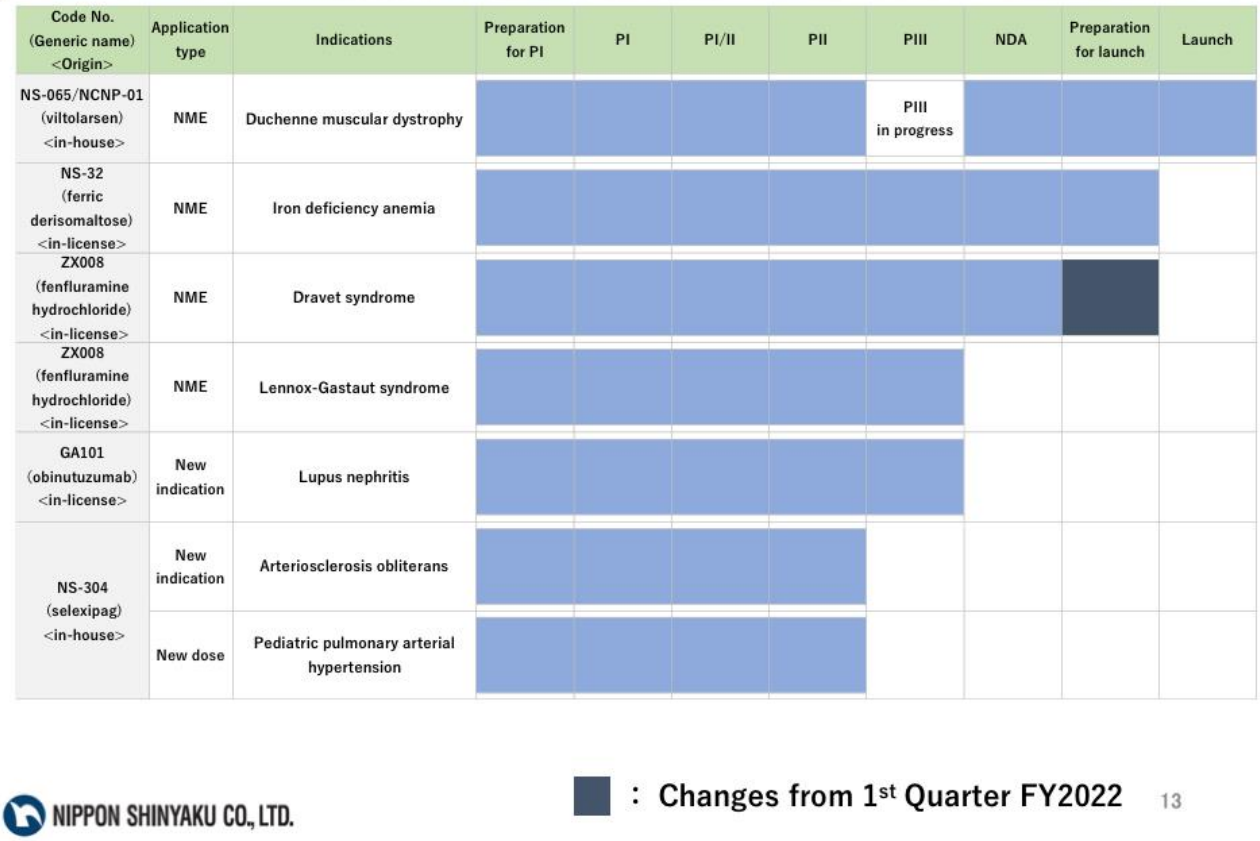


As for dividends, we plan to link dividends to business performance during the Sixth Mid-term Management Plan, with a consolidated payout ratio of around 35%.

In accordance with this dividend policy, we plan to increase the interim dividend by JPY1 per share to JPY57 per share, and the annual dividend forecast by JPY2 per share to JPY114 per share for FY2022, as profit attributable to owners of parent is expected to exceed the initial forecast.

This concludes my presentation of the financial results for Q2 of FY2022 and the forecast for FY2022.

R&D Pipeline (Domestic)



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■ : Changes from 1st Quarter FY2022 13

Takagaki: I will continue with an explanation of the progress of R&D compounds.

First, I will explain the development situation in Japan.

A treatment for Duchenne muscular dystrophy, NS-065/NCNP-01, Viltepso, was launched in May 2020. A global Phase III study is currently underway.

In March this year, we obtained manufacturing and marketing approval for NS-32, MonoVer, a treatment for iron deficiency anemia, and are currently preparing for its launch.

As for ZX008, a treatment for intractable epilepsy, UCB Japan Co., Ltd. obtained manufacturing and marketing approval for Dravet syndrome under the name of Fintepla in September 2022. We are currently preparing for its launch. In addition, UCB S.A. is conducting a Phase III study for Lennox-Gastaut syndrome.

In June of this year, we initiated a Phase III study of GA101 for lupus nephritis in collaboration with Chugai Pharmaceutical Co.

Nippon Shinyaku has been independently conducting Phase IIb study of NS-304 for arteriosclerosis obliterans since February of this year. In addition, Phase II study for pediatric pulmonary arterial hypertension is ongoing in collaboration with Janssen Pharmaceutical K.K.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for PI	PI	PI/II	PII	PIII	NDA	Preparation for launch	Launch
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								
NS-161 <in-house>	NME	Inflammatory diseases								
NS-025 <in-house>	NME	Urological diseases								

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■ : Changes from 1st Quarter FY2022

As for NS-580, a treatment for endometriosis, we completed Phase IIa study and started Phase IIb study in June this year.

As for NS-87, a treatment for secondary acute myeloid leukemia, Phase I/II study is ongoing.

In July of this year, we initiated a Phase I/II study for NS-401, a treatment for blastic plasmacytoid dendritic cell neoplasm.

A Phase I study is ongoing for JAK1 inhibitor, NS-229, for inflammatory diseases.

As for NS-917, a treatment for relapsed/refractory acute myeloid leukemia, we have been conducting Phase I study since February this year.

We have newly added two in-house discovered compounds to our pipeline.

We are currently preparing Phase I study of NS-161 for inflammatory diseases and Phase I study of NS-025 for urological diseases.

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for P II	PII	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					

I will continue with an explanation of the overseas R&D situation.

A treatment for Duchenne muscular dystrophy, NS-065/NCNP-01, Viltepso, was launched in the U.S. in August 2020 and global Phase III study is currently underway. It received Orphan Drug Designation in Europe in June 2020.

With regard to CAP-1002, a treatment for Duchenne muscular dystrophy, we concluded a sales and distribution partnership agreement with Capricor Therapeutics Inc. for the territory of U.S. in January 2022. Currently, Capricor Therapeutics Inc. is conducting Phase III study in the U.S.

We are currently preparing for Phase 2 study in the U.S. for NS-018, a treatment for myelofibrosis. Procedures with investigational sites and screening of eligible patients are underway.

That is all for an overview of our research and development activities.