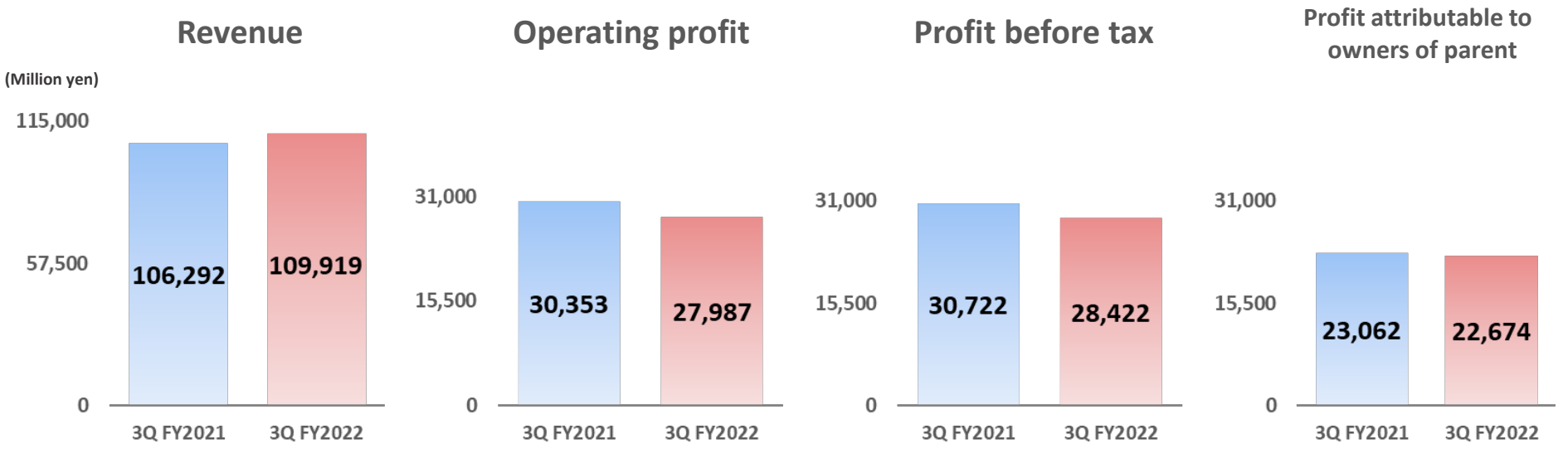
Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2022

February 10, 2023
NIPPON SHINYAKU CO., LTD.

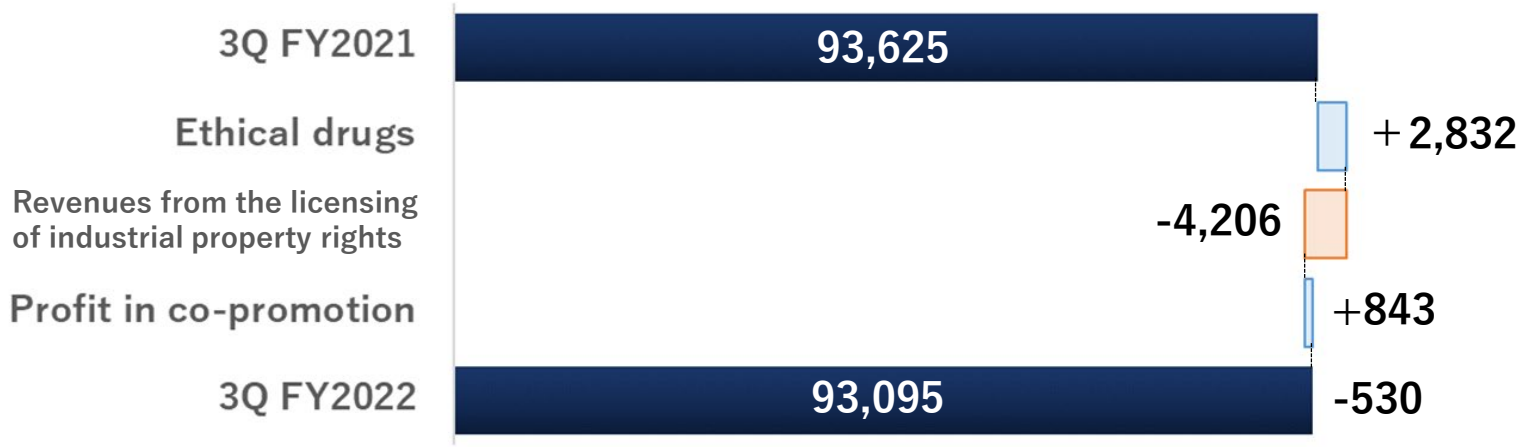
NIPPON SHINYAKU CO., LTD.

3Q FY2022 Summary

- **Revenue** : 109,919 million yen （+3.4%）
- **Operating profit** : 27,987 million yen （- 7.8%）
- **Profit before tax** : 28,422 million yen （- 7.5%）
- **Profit attributable to owners of parent** : 22,674 million yen （- 1.7%）



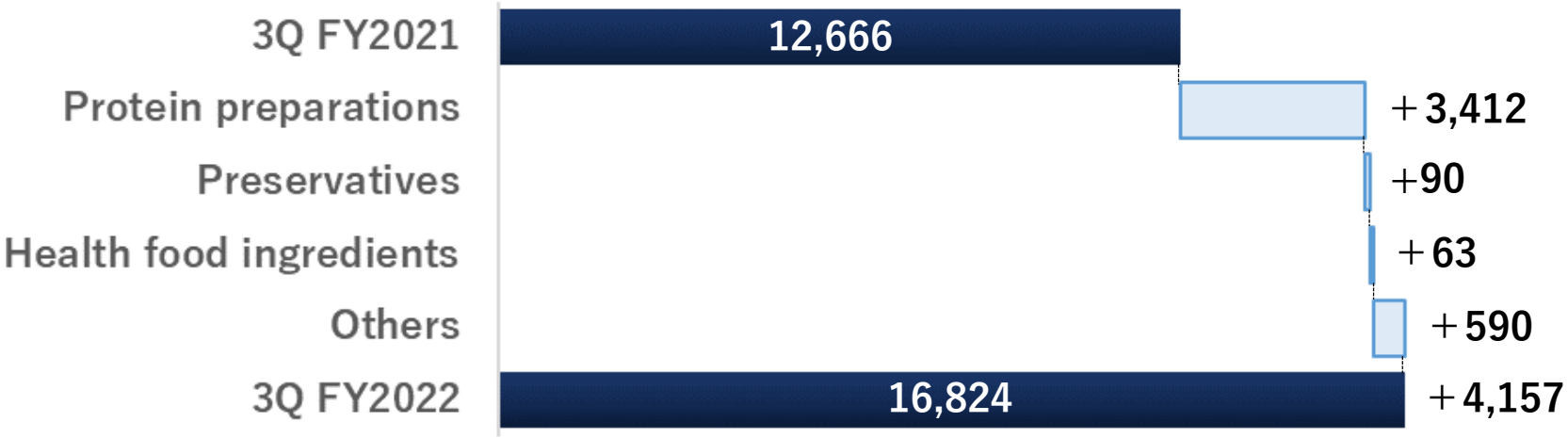
Segmental Review - Pharmaceuticals -



(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	60,020	64.1%	62,853	67.5%	+2,832	+4.7%
Revenues from the licensing of industrial property rights	26,814	28.6%	22,607	24.3%	-4,206	-15.7%
Profit in co-promotion	6,791	7.3%	7,634	8.2%	+843	+12.4%
Revenue	93,625	100.0%	93,095	100.0%	-530	-0.6%

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 price revision by MHLW and backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, Revenue of consolidated pharmaceuticals segment decreased by 0.6%.

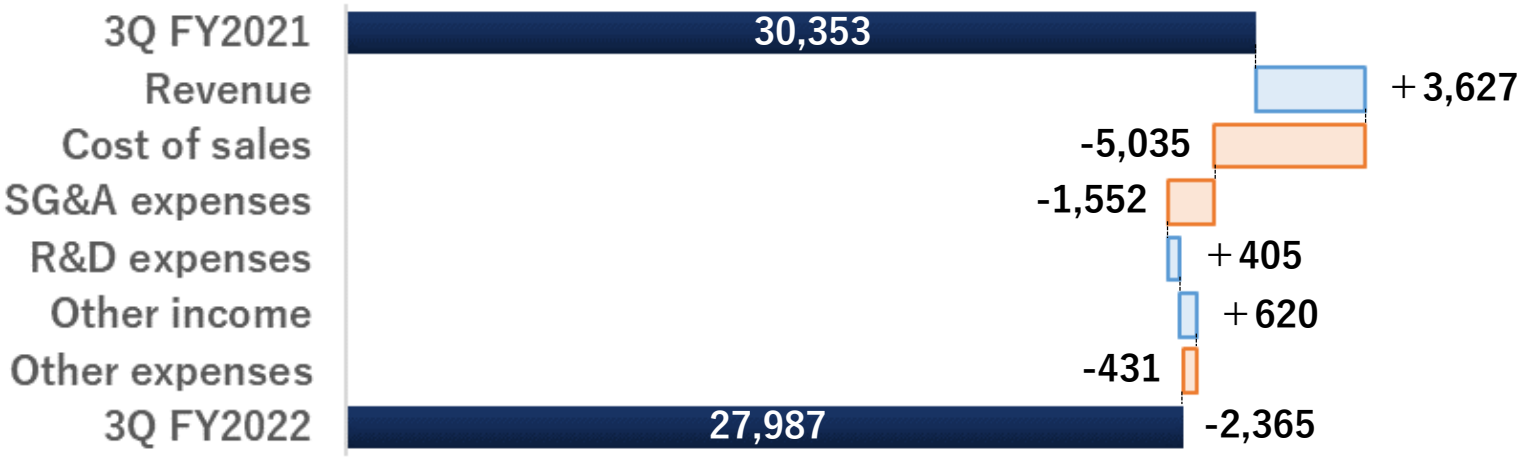
Segmental Review - Functional Food -



(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	8,170	64.5%	11,583	68.8%	+3,412	+41.8%
Preservatives	2,163	17.1%	2,253	13.4%	+90	+4.2%
Health food ingredients	787	6.2%	851	5.1%	+63	+8.1%
Others	1,545	12.2%	2,136	12.7%	+590	+38.2%
Revenue	12,666	100.0%	16,824	100.0%	+4,157	+32.8%

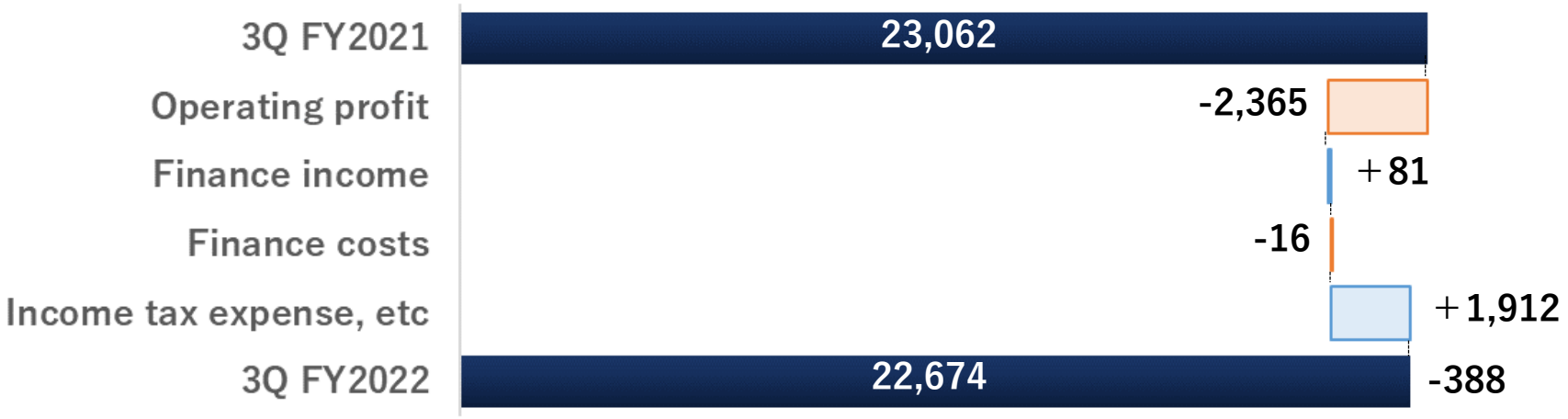
Revenue of consolidated functional food segment increased by 32.8% through sales from Protein preparations including milk proteins and Supplements such as “WINZONE Protein”.

Operating profit



(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**106,292**	**100.0%**	**109,919**	**100.0%**	**+3,627**	**+3.4%**
(Pharmaceuticals)	(93,625)	(88.1%)	(93,095)	(84.7%)	(-530)	(-0.6%)
(Functional Food)	(12,666)	(11.9%)	(16,824)	(15.3%)	(+4,157)	(+32.8%)
Cost of sales	**37,520**	**35.3%**	**42,556**	**38.7%**	**+5,035**	**+13.4%**
SG&A expenses	**23,239**	**21.9%**	**24,791**	**22.6%**	**+1,552**	**+6.7%**
R&D expenses	**15,541**	**14.6%**	**15,135**	**13.8%**	**-405**	**-2.6%**
Other income	**871**	**0.8%**	**1,492**	**1.4%**	**+620**	**+71.2%**
Other expenses	**509**	**0.4%**	**941**	**0.8%**	**+431**	**+84.7%**
Operating profit	**30,353**	**28.6%**	**27,987**	**25.5%**	**-2,365**	**-7.8%**

Profit attributable to owners of parent



(Million yen)	3Q FY2021 Results	3Q FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	30,353	27,987	-2,365	-7.8%
Finance income	452	533	+81	+18.0%
Finance costs	82	98	+16	+19.5%
Profit before tax	30,722	28,422	-2,300	-7.5%
Income tax expense, etc	7,660	5,748	-1,912	-25.0%
Profit attributable to owners of parent	23,062	22,674	-388	-1.7%

Business Forecast for FY2022

(Million yen)	FY2021		FY2022		
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecasts
Revenue	**106,292**	**137,484**	**109,919**	**78.0%**	**141,000**
(Pharmaceuticals)	(93,625)	(120,650)	(93,095)	(77.9%)	(119,500)
(Functional Food)	(12,666)	(16,834)	(16,824)	(78.3%)	(21,500)
Operating profit	**30,353**	**32,948**	**27,987**	**93.3%**	**30,000**
Profit before tax	**30,722**	**33,301**	**28,422**	**93.5%**	**30,400**
Profit attributable to owners of parent	**23,062**	**24,986**	**22,674**	**94.5%**	**24,000**

Revenue and each profit have progressed toward achievement of FY forecasts.

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>	New indication	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								

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 2nd Quarter, 2022

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					

■ : Changes from 2nd Quarter, 2022

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2021	End of 3Q FY2022	Change Amt
Assets	219,943	231,876	+11,933
Current assets	149,724	158,427	+8,703
Non-current assets	70,219	73,448	+3,229
Total assets	219,943	231,876	+11,933

	End of FY2021	End of 3Q FY2022	Change Amt
Liabilities	39,057	35,908	-3,148
Current liabilities	32,029	29,740	-2,288
Non-current liabilities	7,027	6,167	-860
Equity	180,886	195,968	+15,081
Total liabilities and equity	219,943	231,876	+11,933

＝Assets＝

Trade and other receivables	＋8,428
Other financial assets	＋4,342
Property, plant and equipment	＋2,856
Intangible assets	＋1,542

＝Liabilities and equity＝

Income taxes payable	-1,906
Retained earnings	+15,102

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 : 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 : 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 : 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	–

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.
- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This English presentation was translated from the original Japanese version.
  In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

NIPPON SHINYAKU CO., LTD.

Nippon Shinyaku Co., Ltd.

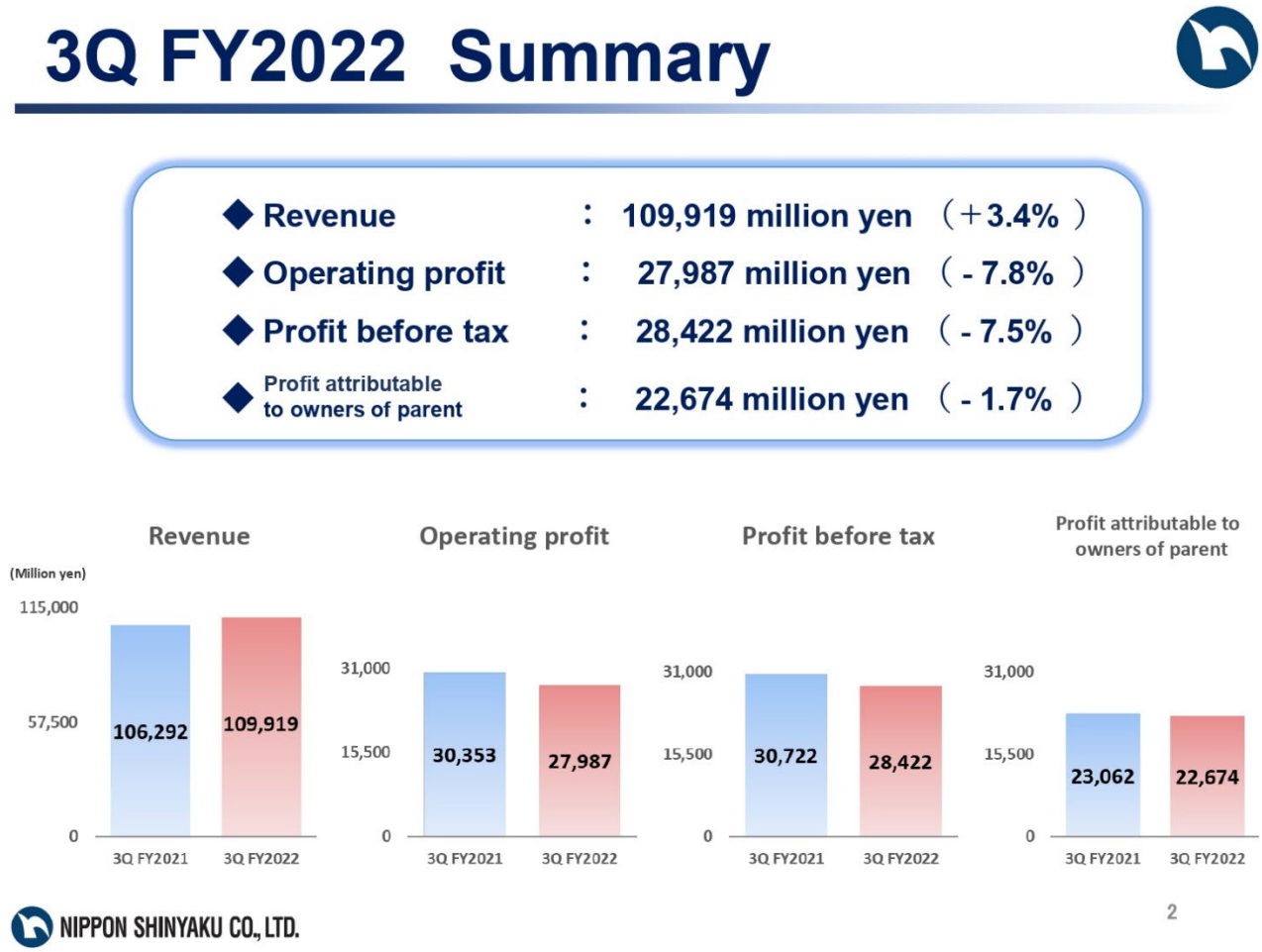
Financial Results for the Third Quarter Ended December 31, 2022

February 10, 2023

Presentation

Edamitsu: I am Edamitsu in charge of the Business Management & Sustainability Division. Thank you very much for joining our financial results briefing today. I would like to express my greatest gratitude.

I would now like to explain our business results and R&D progress for Q3 of FY2022 in accordance with the presentation materials posted on our website.



Please refer to slide two.

The summary of results for Q3 of FY2022 is as follows: consolidated revenue of JPY109,919 million, operating profit of JPY27,987 million, profit before taxes of JPY28,422 million, and quarterly profit attributable to owners of the parent of JPY22,674 million.

Segmental Review - Pharmaceuticals -

(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	60,020	64.1%	62,853	67.5%	+2,832	+4.7%
Revenues from the licensing of industrial property rights	26,814	28.6%	22,607	24.3%	-4,206	-15.7%
Profit in co-promotion	6,791	7.3%	7,634	8.2%	+843	+12.4%
Revenue	93,625	100.0%	93,095	100.0%	-530	-0.6%

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 price revision by MHLW and backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, Revenue of consolidated pharmaceuticals segment decreased by 0.6%.

NIPPON SHINYAKU CO., LTD.

3

Please refer to slide three.

In the pharmaceuticals business, although sales of VILTEPSO, treatment for Duchenne muscular dystrophy, and UPTRAVI, treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and royalty income from overseas sales of UPTRAVI grew, consolidated revenue of the pharmaceuticals business decreased 0.6% YoY to JPY93,095 million due to the loss of sales revenue from the priority review voucher that existed in the same period of the previous year.

Segmental Review - Functional Food -

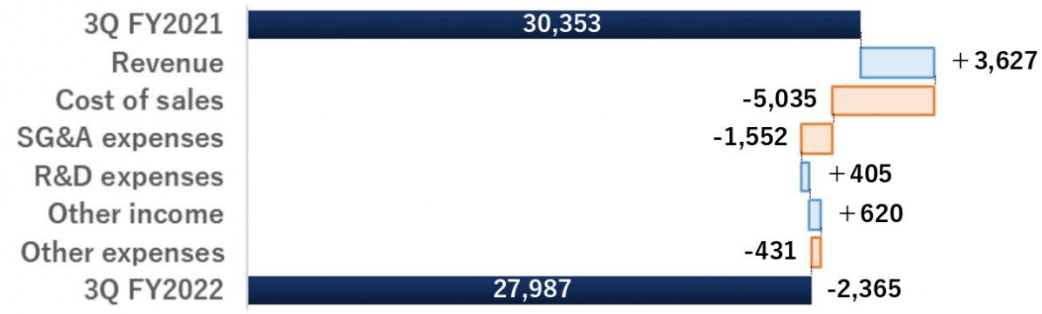
(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	8,170	64.5%	11,583	68.8%	+3,412	+41.8%
Preservatives	2,163	17.1%	2,253	13.4%	+90	+4.2%
Health food ingredients	787	6.2%	851	5.1%	+63	+8.1%
Others	1,545	12.2%	2,136	12.7%	+590	+38.2%
Revenue	12,666	100.0%	16,824	100.0%	+4,157	+32.8%

Revenue of consolidated functional food segment increased by 32.8% through sales from Protein preparations including milk proteins and Supplements such as "WINZONE Protein".

Please refer to slide four.

In the functional foods business, sales of protein products such as milk protein and sports supplements centering on WINZONE Protein increased, resulting in a 32.8% YoY increase in consolidated sales revenue to JPY16,824 million.

Operating profit



(Million yen)	3Q FY2021		3Q FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	106,292	100.0%	109,919	100.0%	+3,627	+3.4%
(Pharmaceuticals)	(93,625)	(88.1%)	(93,095)	(84.7%)	(-530)	(-0.6%)
(Functional Food)	(12,666)	(11.9%)	(16,824)	(15.3%)	(+4,157)	(+32.8%)
Cost of sales	37,520	35.3%	42,556	38.7%	+5,035	+13.4%
SG&A expenses	23,239	21.9%	24,791	22.6%	+1,552	+6.7%
R&D expenses	15,541	14.6%	15,135	13.8%	-405	-2.6%
Other income	871	0.8%	1,492	1.4%	+620	+71.2%
Other expenses	509	0.4%	941	0.8%	+431	+84.7%
Operating profit	30,353	28.6%	27,987	25.5%	-2,365	-7.8%

Please refer to slide five.

The cost of sales ratio worsened by 3.4 percentage points from the same period last year to 38.7%, mainly due to the loss of revenue from the sale of priority review voucher.

Selling, general and administrative (SG&A) expenses increased 6.7% YoY to JPY24,791 million, mainly due to an increase in U.S. marketing expenses and an increase in sales promotion fees in line with increased domestic sales of UPTRAVI.

R&D expenses decreased to JPY15,135 million, down 2.6% from the same period last year, mainly due to a decrease in investigational new drug manufacturing costs.

As a result, operating profit was JPY27,987 million, down 7.8% YoY.

Profit attributable to owners of parent

(Million yen)	3Q FY2021 Results	3Q FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	30,353	27,987	-2,365	-7.8%
Finance income	452	533	+81	+18.0%
Finance costs	82	98	+16	+19.5%
Profit before tax	30,722	28,422	-2,300	-7.5%
Income tax expense, etc	7,660	5,748	-1,912	-25.0%
Profit attributable to owners of parent	23,062	22,674	-388	-1.7%

Please refer to slide six.

Profit before tax was JPY28,422 million, down 7.5% from the same period last year, and profit attributable to owners of the parent was JPY22,674 million, down 1.7% from the same period last year.

Business Forecast for FY2022

(Million yen)	FY2021		FY2022		
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecasts
Revenue	**106,292**	**137,484**	**109,919**	**78.0%**	**141,000**
(Pharmaceuticals)	(93,625)	(120,650)	(93,095)	(77.9%)	(119,500)
(Functional Food)	(12,666)	(16,834)	(16,824)	(78.3%)	(21,500)
Operating profit	**30,353**	**32,948**	**27,987**	**93.3%**	**30,000**
Profit before tax	**30,722**	**33,301**	**28,422**	**93.5%**	**30,400**
Profit attributable to owners of parent	**23,062**	**24,986**	**22,674**	**94.5%**	**24,000**

Revenue and each profit have progressed toward achievement of FY forecasts.

Please refer to slide seven.

The consolidated earnings forecast for FY2022 remains unchanged from the revised plan announced on November 10 last year, with consolidated revenue of JPY141,000 million, operating profit of JPY30,000 million, profit before tax of JPY30,400 million, and profit attributable to owners of the parent of JPY24,000 million.

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>	New indication	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								

I will continue with an explanation of the progress of R&D items.

First, I would like to explain the development situation in Japan.

NS-065/NCNP-01 (Viltepso), for the treatment of Duchenne muscular dystrophy, was launched in May 2020 and are currently in global Phase III trials.

In March 2022, we obtained manufacturing and marketing approval for NS-32 (MonoVer), an iron deficiency anemia treatment, and are currently preparing for its launch.

A Phase III study of ZX008 for the treatment of intractable epilepsy, Lennox-Gastaut syndrome, is currently being conducted by UCB.

A Phase III study of GA101 for the treatment of lupus nephritis, is being conducted from June 2022, in collaboration with Chugai Pharmaceutical Co.

In February 2022, Nippon Shinyaku independently initiated a Phase IIb study of NS-304 for the indication of arteriosclerosis obliterans. In addition, a 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								

: Changes from 2nd Quarter, 2022

For NS-580, a treatment for endometriosis, Phase IIa study has been completed and Phase IIb study is underway from June 2022.

A Phase I/II study of NS-87, a treatment for secondary acute myeloid leukemia, is underway.

A Phase I/II study of NS-401, a treatment for blastic plasmacytoid dendritic cell neoplasm, is underway from July 2022.

A Phase I study of the JAK1 inhibitor NS-229 is underway for the treatment of inflammatory diseases.

A Phase I trial for NS-917 for the treatment of relapsed/refractory acute myeloid leukemia is underway from February 2022.

Phase I trials have been initiated for NS-161, which is being developed for the treatment of inflammatory diseases, and for NS-025, which is being developed for the treatment of 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					

: Changes from 2nd Quarter, 2022

Next, I will explain the status of overseas development.

NS-065/NCNP-01 (Viltepso), for the treatment of Duchenne muscular dystrophy, was launched in the US in August 2020 and are currently in a global Phase III study. 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 US in January 2022. Currently, Capricor Therapeutics Inc. is conducting Phase III study in the US.

Phase II study for NS-018, a drug for myelofibrosis, is underway globally.

This concludes the overview of our R&D activities.