Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2023

February 9, 2024
NIPPON SHINYAKU CO., LTD.

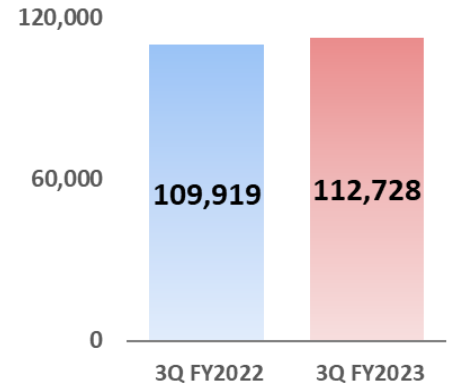
NIPPON SHINYAKU CO., LTD.

3Q FY2023 Summary

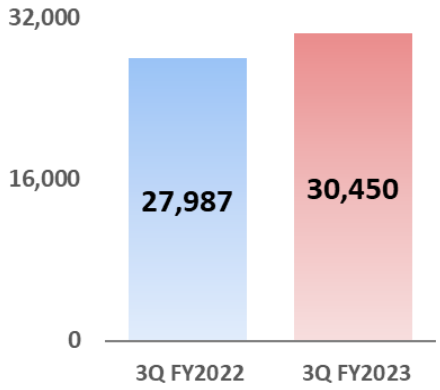
- **Revenue** : 112,728 million yen (+2.6%)
- **Operating profit** : 30,450 million yen (+8.8%)
- **Profit before tax** : 30,973 million yen (+9.0%)
- **Profit attributable to owners of parent** : 24,002 million yen (+5.9%)

Revenue

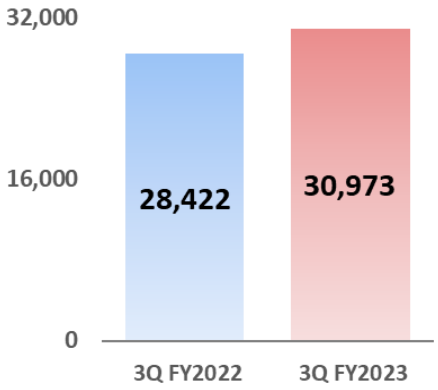
(Million yen)



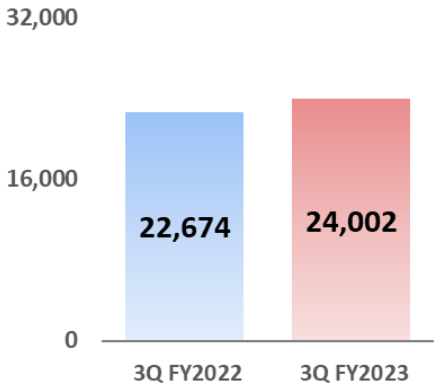
Operating profit



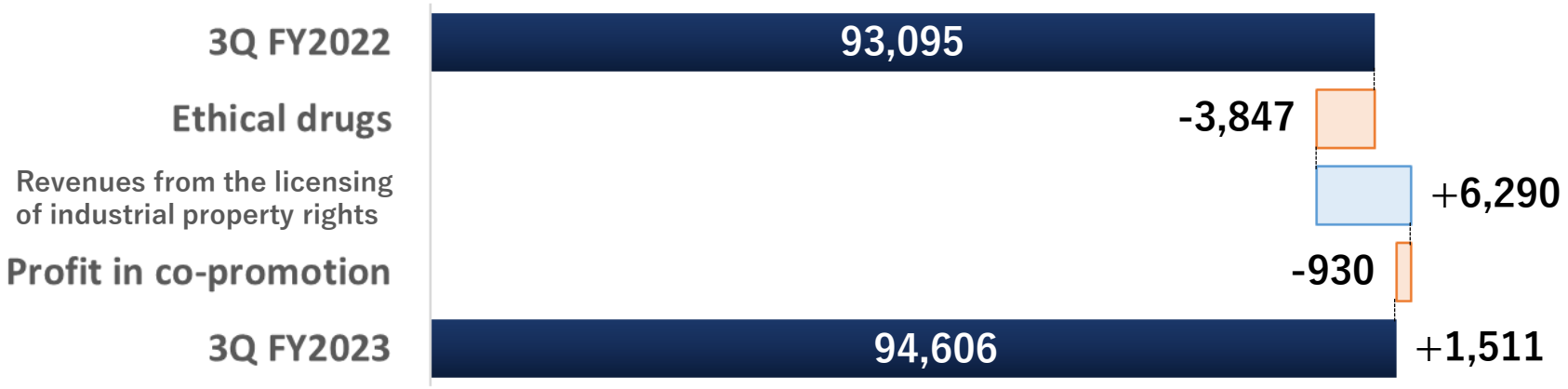
Profit before tax



Profit attributable to owners of parent



Segmental Review - Pharmaceuticals -

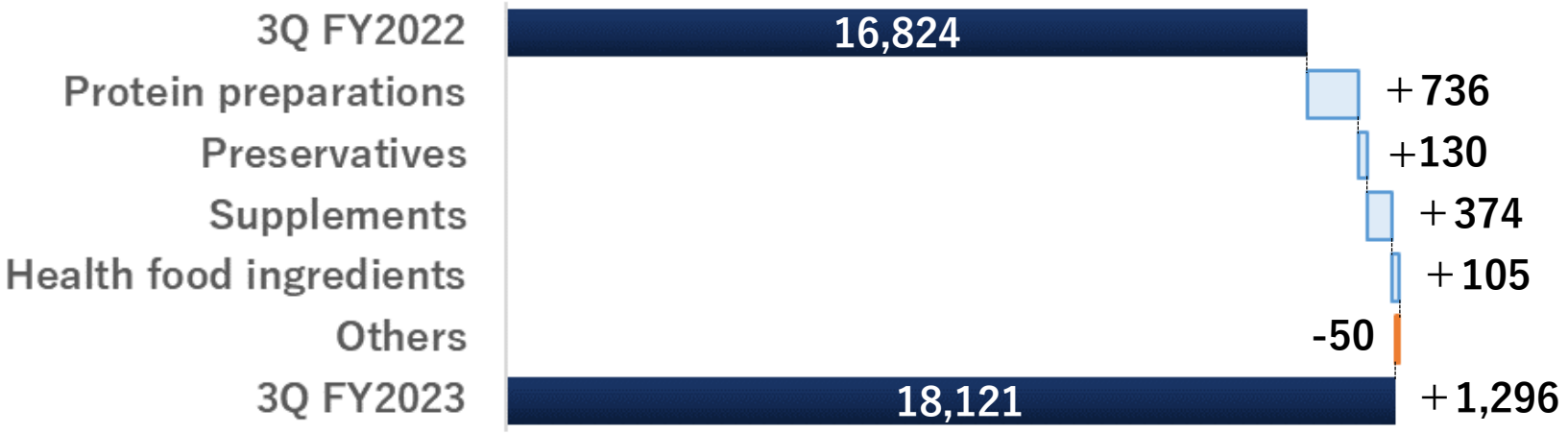


(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	62,853	67.5%	59,005	62.4%	-3,847	-6.1%
Revenues from the licensing of industrial property rights	22,607	24.3%	28,897	30.5%	+6,290	+27.8%
Profit in co-promotion	7,634	8.2%	6,703	7.1%	-930	-12.2%
Revenue	93,095	100.0%	94,606	100.0%	+1,511	+1.6%

Despite the effect of price revision by MHLW* and generic products, revenue of consolidated pharmaceuticals segment increased by 1.6% due to increase of sales of “Viltepso” and “Uptravi”, and royalty revenue from Uptravi’s overseas sales.

*MHLW : Ministry of Health, Labour and Welfare

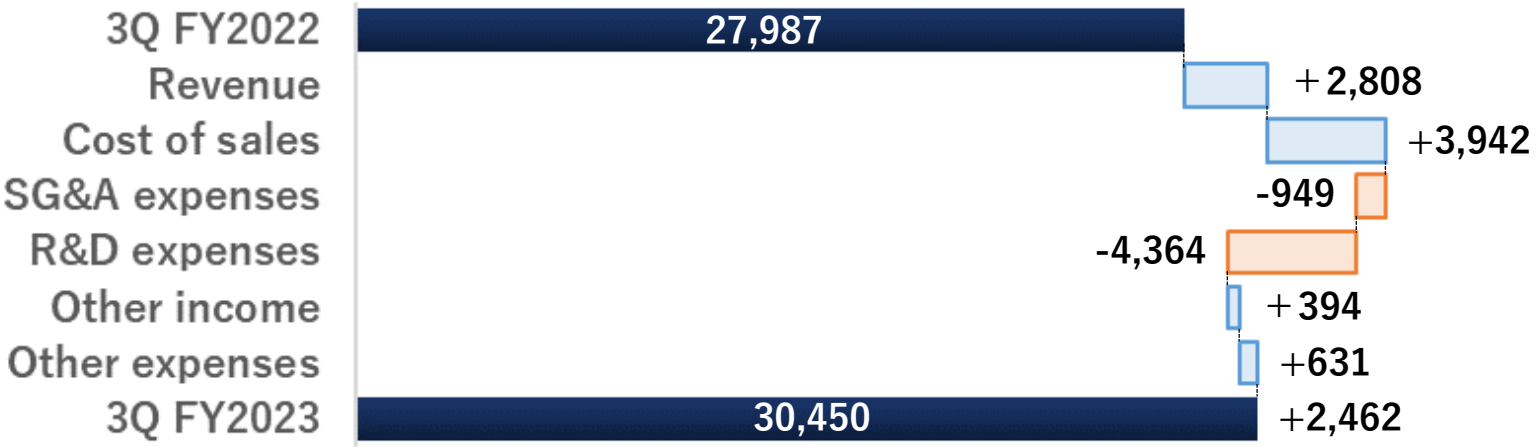
Segmental Review - Functional Food -



(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	11,583	68.8%	12,319	68.0%	+736	+6.4%
Preservatives	2,253	13.4%	2,383	13.1%	+130	+5.8%
Supplements	1,091	6.5%	1,466	8.1%	+374	+34.3%
Health food ingredients	851	5.1%	957	5.3%	+105	+12.4%
Others	1,044	6.2%	994	5.5%	-50	-4.8%
Revenue	16,824	100.0%	18,121	100.0%	+1,296	+7.7%

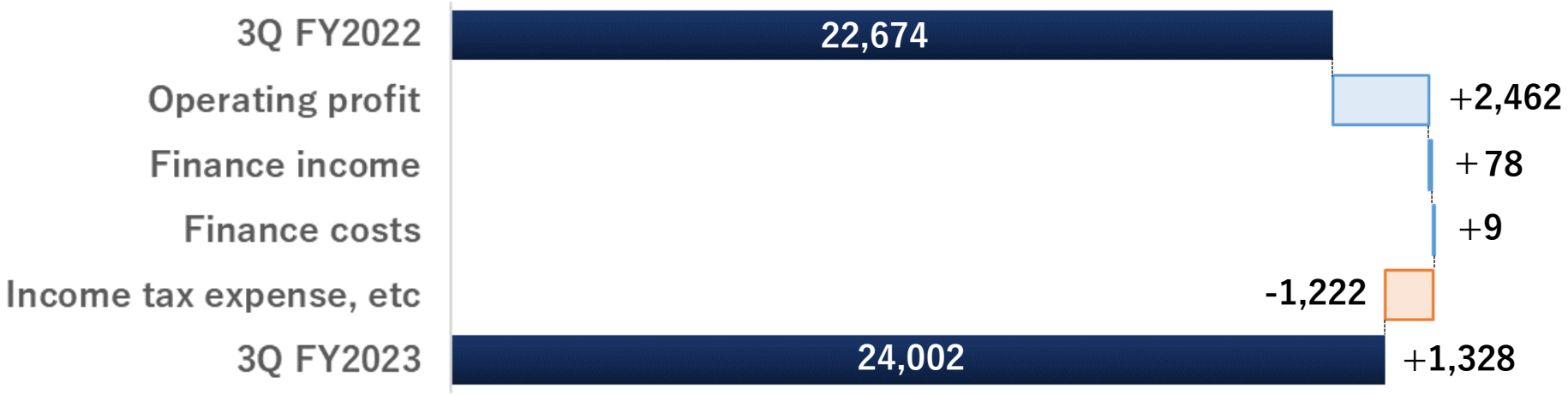
Revenue of consolidated functional food segment increased by 7.7% through sales increase of protein preparations and supplements.

Operating profit



(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**109,919**	**100.0%**	**112,728**	**100.0%**	**+2,808**	**+2.6%**
(Pharmaceuticals)	(93,095)	(84.7%)	(94,606)	(83.9%)	(+1,511)	(+1.6%)
(Functional Food)	(16,824)	(15.3%)	(18,121)	(16.1%)	(+1,296)	(+7.7%)
Cost of sales	**42,556**	**38.7%**	**38,613**	**34.3%**	**-3,942**	**-9.3%**
SG&A expenses	**24,791**	**22.6%**	**25,741**	**22.8%**	**+949**	**+3.8%**
R&D expenses	**15,135**	**13.8%**	**19,500**	**17.3%**	**+4,364**	**+28.8%**
Other income	**1,492**	**1.4%**	**1,887**	**1.7%**	**+394**	**+26.4%**
(Foreign exchange gain)	(998)	(0.9%)	(1,361)	(1.2%)	(+362)	(+36.3%)
Other expenses	**941**	**0.8%**	**309**	**0.3%**	**-631**	**-67.1%**
Operating profit	**27,987**	**25.5%**	**30,450**	**27.0%**	**+2,462**	**+8.8%**

Profit attributable to owners of parent



(Million yen)	3Q FY2022 Results	3Q FY2023 Results	YoY Change Amt	YoY Change %
Operating profit	27,987	30,450	+2,462	+8.8%
Finance income	533	611	+78	+14.8%
Finance costs	98	89	-9	-9.7%
Profit before tax	28,422	30,973	+2,550	+9.0%
Income tax expense, etc	5,748	6,970	+1,222	+21.3%
Profit attributable to owners of parent	22,674	24,002	+1,328	+5.9%

Business Forecast for FY2023

(Million yen)	FY2022		FY2023		YoY Change	
	3Q Results	FY Results	3Q Results	FY Forecasts	Amt	%
Revenue	**109,919**	**144,175**	**112,728**	**147,000**	**+2,825**	**+2.0%**
(Pharmaceuticals)	(93,095)	(121,988)	(94,606)	(125,000)	**+3,012**	**+2.5%**
(Functional Food)	(16,824)	(22,187)	(18,121)	(22,000)	**-187**	**-0.8%**
Operating profit	**27,987**	**30,049**	**30,450**	**33,500**	**+3,451**	**+11.5%**
Profit before tax	**28,422**	**30,489**	**30,973**	**34,000**	**+3,511**	**+11.5%**
Profit attributable to owners of parent	**22,674**	**22,812**	**24,002**	**26,000**	**+3,188**	**+14.0%**

Exchange rate (JPY)	FY2022		FY2023	
	3Q Actual rate	FY Actual rate	3Q Actual rate	2H Forecast rate
1USD	**136.5 yen**	**135.5 yen**	**143.3 yen**	**140.0 yen**

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	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	Around the spring of FY2024 P3 data presentation						PIII analyzing		
NS-87 (daunorubicin / cytarabine) <in-license>	New combi-nation	High-risk acute myeloid leukemia	Application：FY2023 Approval (expected)：FY2023								
ZX008 (fenfluramine hydrochloride) <Distribution partnership>	New indication	Lennox-Gastaut syndrome	Application：FY2023 Approval (expected)：FY2023								
		CDKL5 deficiency disorder	Study Completion：FY2026								
GA101 (obinutuzumab) <in-license>	New indication	Lupus nephritis	Expansion of indications：from 2026 onward								
		Pediatric nephrotic syndrome	Expansion of indications：from 2026 onward								
		Extra renal lupus	Expansion of indications：from 2026 onward								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans	Study Completion：FY2024								
	New dose	Pediatric pulmonary arterial hypertension	Study Completion：FY2025								
NS-580 <in-house>	NME	Endometriosis	Study Completion：FY2023								
		Chronic prostatitis / Chronic pelvic pain syndrome	Study Completion：FY2024								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy	Study Completion：FY2025								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis	Study Completion：FY2025								
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm	Study Completion：FY2026								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy	Study Completion：FY2026								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia	Study Completion：FY2024								
NS-161 <in-house>	NME	Inflammatory diseases	Study Completion：FY2024								
NS-025 <in-house>	NME	Urological diseases	Study Completion：FY2024								
NS-863 <in-house>	NME	Cardiovascular diseases	Study Completion：FY2024								

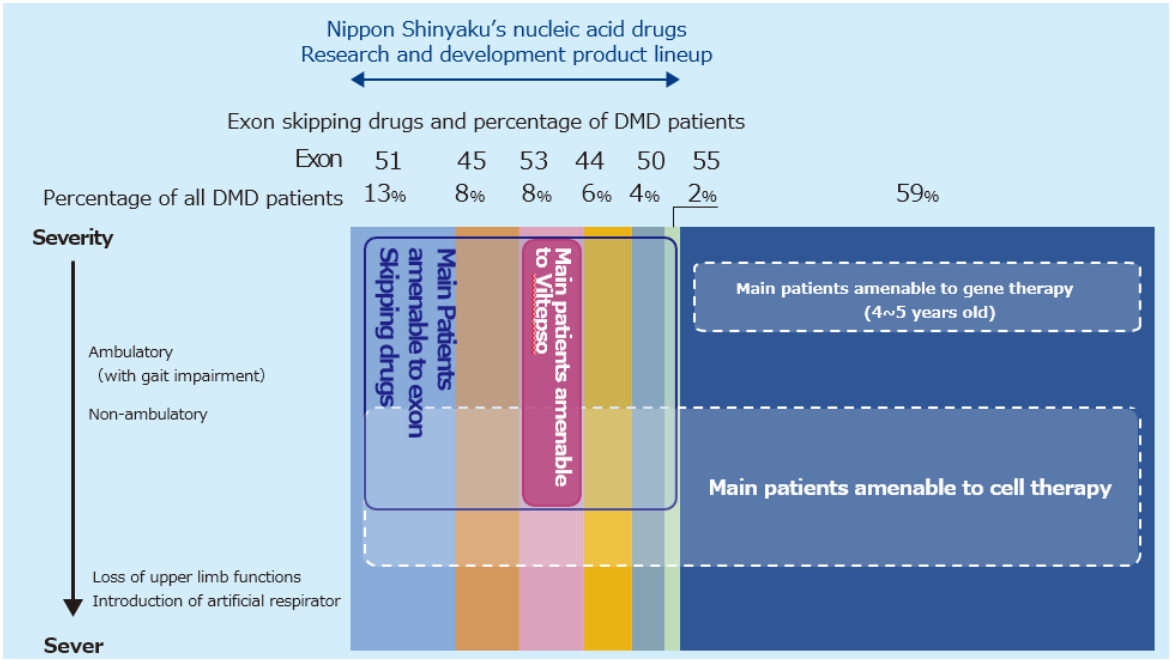
Schedule : study completion date described in jRCT or ClinicalTrials.gov

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	Around the spring of FY2024 P3 data presentation						PIII analyzing		
CAP-1002 <partnership>	NME	Duchenne muscular dystrophy	Topline data：End of 2024								
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis	Study Completion：FY2024（TBD）								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy	Study Completion：FY2025								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis	Study Completion：FY2025								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy	Study Completion：FY2026								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

Positioning in the three DMD treatments



(¥million)	Apr-Dec				Annual	
	2022	2023	YoY Change	Progress for FY	2022	2023 (estimated)
Viltepso	10,717	13,225	23.4%	72.3%	14,341	18,300
(Japan)	(3,188)	(3,332)	(4.5%)	(69.4%)	(4,139)	(4,800)
(U.S.)	(7,528)	(9,892)	(31.4%)	(73.3%)	(10,201)	(13,500)

- We believe that an optimal combination is selected from the three treatments (Nucleic acid drug, cell therapy, and gene therapy) depending on the patient's genetic background and stage of the disease.
- Despite the launch of gene therapy in the U.S. in 2023, sales of U.S. Viltepso increased.

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2022	End of 3Q FY2023	YoY Change Amt
Assets	237,451	247,830	+10,378
Current assets	157,873	160,901	+3,028
Non-current assets	79,578	86,928	+7,350
Total assets	237,451	247,830	+10,378

	End of FY2022	End of 3Q FY2023	YoY Change Amt
Liabilities	41,518	32,513	-9,004
Current liabilities	35,183	27,193	-7,989
Non-current liabilities	6,334	5,319	-1,014
Equity	195,933	215,316	+19,383
Total liabilities and equity	237,451	247,830	+10,378

＝Assets＝

Other financial assets (NCA)	+6,037
Other current assets	+3,504
Trade and other receivables	+2,821

＝Liabilities and equity＝

Income taxes payable	-5,435
Retirement benefit liability	-617
Retained earnings	+16,023

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	–

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NIPPON SHINYAKU CO., LTD.

Nippon Shinyaku Co., Ltd.

Financial Results Briefing for the Third Quarter Ended December 31, 2023

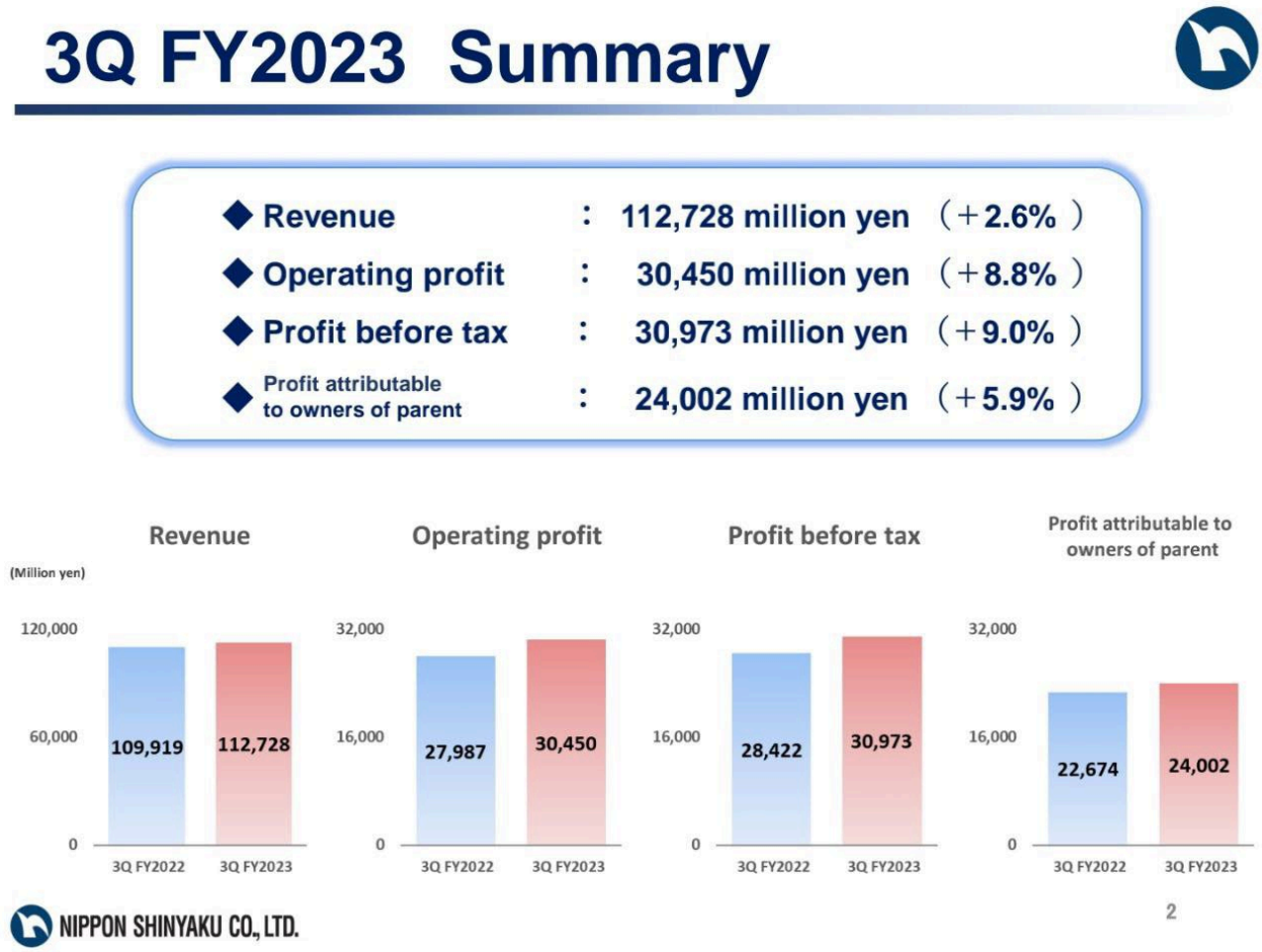
February 9, 2024

Presentation

Edamitsu: I am Takanori Edamitsu, Director and General Manager of the Business Management & Sustainability Division at Nippon Shinyaku Co., Ltd.

Thank you very much for taking time out of your busy schedule to attend our financial results presentation today. I really appreciate it.

I would first like to explain our business results for Q3 of FY2023 and the progress of our R&D activities, in accordance with the presentation materials posted on our website.



A summary of results for Q3 of FY2023 is as follows: consolidated revenue of JPY112,728 million, operating profit of JPY30,450 million, profit before tax of JPY30,973 million, and profit attributable to owners of parent of JPY24,002 million.

Segmental Review - Pharmaceuticals -

(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
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Ethical drugs	62,853	67.5%	59,005	62.4%	-3,847	-6.1%
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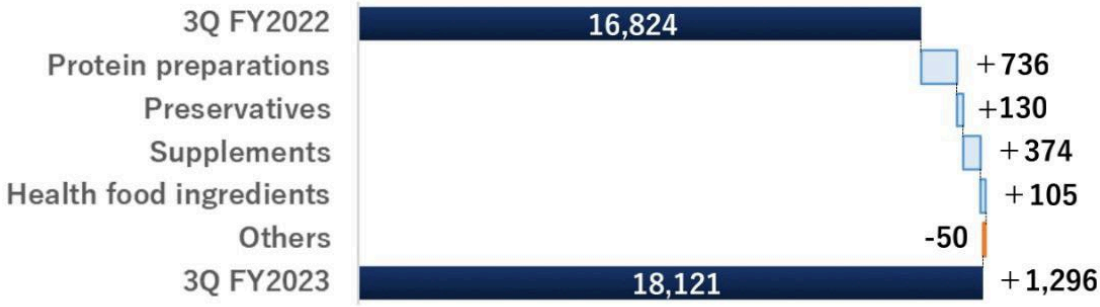
Despite the effect of price revision by MHLW* and generic products, revenue of consolidated pharmaceuticals segment increased by 1.6% due to increase of sales of "Viltepso" and "Uptravi", and royalty revenue from Uptravi's overseas sales.

*MHLW : Ministry of Health, Labour and Welfare

In the pharmaceuticals business, despite the effects of NHI price revisions and generics, growth in the sales of Viltepso, a treatment for Duchenne muscular dystrophy, and Uptravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, as well as growth in royalty income from the overseas sales of Uptravi, our consolidated net sales of the pharmaceutical business increased by 1.6% YoY to JPY94,606 million.

Segmental Review - Functional Food -



(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	11,583	68.8%	12,319	68.0%	+736	+6.4%
Preservatives	2,253	13.4%	2,383	13.1%	+130	+5.8%
Supplements	1,091	6.5%	1,466	8.1%	+374	+34.3%
Health food ingredients	851	5.1%	957	5.3%	+105	+12.4%
Others	1,044	6.2%	994	5.5%	-50	-4.8%
Revenue	16,824	100.0%	18,121	100.0%	+1,296	+7.7%

Revenue of consolidated functional food segment increased by 7.7% through sales increase of protein preparations and supplements.

In the functional food business, sales of protein preparations and sports supplements increased, and consolidated net sales in the functional food business increased by 7.7% YoY to JPY18,121 million.

Operating profit

(Million yen)	3Q FY2022		3Q FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	109,919	100.0%	112,728	100.0%	+2,808	+2.6%
(Pharmaceuticals)	(93,095)	(84.7%)	(94,606)	(83.9%)	(+1,511)	(+1.6%)
(Functional Food)	(16,824)	(15.3%)	(18,121)	(16.1%)	(+1,296)	(+7.7%)
Cost of sales	42,556	38.7%	38,613	34.3%	-3,942	-9.3%
SG&A expenses	24,791	22.6%	25,741	22.8%	+949	+3.8%
R&D expenses	15,135	13.8%	19,500	17.3%	+4,364	+28.8%
Other income	1,492	1.4%	1,887	1.7%	+394	+26.4%
(Foreign exchange gain)	(998)	(0.9%)	(1,361)	(1.2%)	(+362)	(+36.3%)
Other expenses	941	0.8%	309	0.3%	-631	-67.1%
Operating profit	27,987	25.5%	30,450	27.0%	+2,462	+8.8%

The cost of sales ratio improved by 4.4 percentage points YoY to 34.3%, due to factors such as the sales mix, including an increase in revenues from the licensing of industrial property rights.

SG&A expenses increased by 3.8% YoY to JPY25,741 million, mainly due to US marketing expenses and an increase in sales promotion fees associated with increased domestic sales of Uptravi.

R&D expenses totaled JPY19,500 million, up 28.8% YoY, mainly due to an increase in contract research expenses.

As a result, operating profit was JPY30,450 million, up 8.8% YoY.

Profit attributable to owners of parent

(Million yen)	3Q FY2022 Results	3Q FY2023 Results	YoY Change Amt	YoY Change %
Operating profit	27,987	30,450	+2,462	+8.8%
Finance income	533	611	+78	+14.8%
Finance costs	98	89	-9	-9.7%
Profit before tax	28,422	30,973	+2,550	+9.0%
Income tax expense, etc	5,748	6,970	+1,222	+21.3%
Profit attributable to owners of parent	22,674	24,002	+1,328	+5.9%

Profit before tax was JPY30,973 million, up 9% YoY, and profit attributable to owners of parent company was JPY24,002 million, up 5.9% YoY.

Business Forecast for FY2023

(Million yen)	FY2022		FY2023		YoY Change	
	3Q Results	FY Results	3Q Results	FY Forecasts	Amt	%
Revenue	**109,919**	**144,175**	**112,728**	**147,000**	**+2,825**	**+2.0%**
(Pharmaceuticals)	(93,095)	(121,988)	(94,606)	(125,000)	**+3,012**	**+2.5%**
(Functional Food)	(16,824)	(22,187)	(18,121)	(22,000)	**-187**	**-0.8%**
Operating profit	**27,987**	**30,049**	**30,450**	**33,500**	**+3,451**	**+11.5%**
Profit before tax	**28,422**	**30,489**	**30,973**	**34,000**	**+3,511**	**+11.5%**
Profit attributable to owners of parent	**22,674**	**22,812**	**24,002**	**26,000**	**+3,188**	**+14.0%**

Exchange rate (JPY)	FY2022		FY2023	
	3Q Actual rate	FY Actual rate	3Q Actual rate	2H Forecast rate
1USD	136.5 yen	135.5 yen	143.3 yen	140.0 yen

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

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The consolidated earnings forecast for FY2023 remains unchanged from the revised plan announced on November 13, 2023, with consolidated revenue of JPY147 billion, operating profit of JPY33.5 billion, profit before tax of JPY34 billion, and profit attributable to owners of parent of JPY26 billion.

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

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	Around the spring of FY2024 P3 data presentation						PIII analyzing		
NS-87 (daunorubicin / cytarabine) <in-license>	New combi-nation	High-risk acute myeloid leukemia	Application : FY2023 Approval (expected) : FY2023								
ZX008 (fenfluramine hydrochloride) <Distribution partnership>	New indication	Lennox-Gastaut syndrome	Application : FY2023 Approval (expected) : FY2023								
		CDKL5 deficiency disorder	Study Completion : FY2026								
GA101 (obinutuzumab) <in-license>	New indication	Lupus nephritis	Expansion of indications : from 2026 onward								
		Pediatric nephrotic syndrome	Expansion of indications : from 2026 onward								
		Extra renal lupus	Expansion of indications : from 2026 onward								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

First, let me explain the development situation in Japan.

The Duchenne muscular dystrophy treatment drug NS-065/NCNP-01, Viltepso that skips exon 53, was launched in May 2020. The global Phase III study has now been completed and analysis is underway.

The Phase I/II study for NS-87, a treatment for high-risk acute myeloid leukemia, was completed and an application for approval was submitted in June 2023, which was approved by the Second Committee on Drugs on February 5, 2024.

In June 2023, UCB submitted a partial change application for ZX008, a drug for the treatment of intractable epilepsy, for an additional indication for Lennox-Gastaut syndrome. In addition, UCB is conducting a Phase III study for CDKL5 deficiency starting in July 2023.

For GA101, a Phase III study for lupus nephritis and a Phase III study for pediatric idiopathic nephrotic syndrome are being conducted in collaboration with Chugai Pharmaceutical Co., Ltd.

In addition, a Phase III study for extra renal lupus is ongoing from October 2023.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans	Study Completion : FY2024								
	New dose	Pediatric pulmonary arterial hypertension	Study Completion : FY2025								
NS-580 <in-house>	NME	Endometriosis	Study Completion : FY2023								
		Chronic prostatitis / Chronic pelvic pain syndrome	Study Completion : FY2024								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy	Study Completion : FY2025								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis	Study Completion : FY2025								
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm	Study Completion : FY2026								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy	Study Completion : FY2026								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

A Phase IIb study of NS-304 for the indication of arteriosclerosis obliterans is being conducted by Nippon Shinyaku on its own. In addition, a Phase II study for pediatric pulmonary arterial hypertension is underway in collaboration with Janssen Pharmaceutical K.K.

A Phase IIb study of NS-580 for the treatment of endometriosis is underway. In addition, a Phase IIa study for chronic prostatitis and chronic pelvic pain syndrome is ongoing from June 2023.

A global Phase II study for Duchenne muscular dystrophy drug NS-089/NCNP-02 that skips exon 44 is being prepared.

A global Phase II study for NS-229, a treatment for eosinophilic granulomatosis with polyangiitis, is being prepared.

A Phase I/II study of NS-401 for the treatment for blastic plasmacytoid dendritic cell neoplasm is ongoing.

A global Phase I/II study for Duchenne muscular dystrophy treatment drug NS-050/NCNP-03 that skips exon 50 is being prepared.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia	Study Completion : FY2024								
NS-161 <in-house>	NME	Inflammatory diseases	Study Completion : FY2024								
NS-025 <in-house>	NME	Urological diseases	Study Completion : FY2024								
NS-863 <in-house>	NME	Cardiovascular diseases	Study Completion : FY2024								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

Phase I study are underway for NS-917, a treatment for relapsed/refractory acute myeloid leukemia.

Phase I studies are underway for NS-161, which is being developed for inflammatory diseases, NS-025, which is being developed for urological diseases, and NS-863, which is being developed as a treatment for cardiovascular diseases.

R&D Pipeline (Overseas)

Code No. (Generic name) <Origin>	Application type	Indications	Schedule	PI	Preparing for PI/II	PI/II	Preparing for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	Around the spring of FY2024 P3 data presentation						PIII analyzing		
CAP-1002 <partnership>	NME	Duchenne muscular dystrophy	Topline data : End of 2024								
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis	Study Completion : FY2024 (TBD)								
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy	Study Completion : FY2025								
NS-229 <in-house>	NME	Eosinophilic granulomatosis with polyangiitis	Study Completion : FY2025								
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy	Study Completion : FY2026								

Schedule : study completion date described in jRCT or ClinicalTrials.gov

I will continue with an explanation of the status of overseas development.

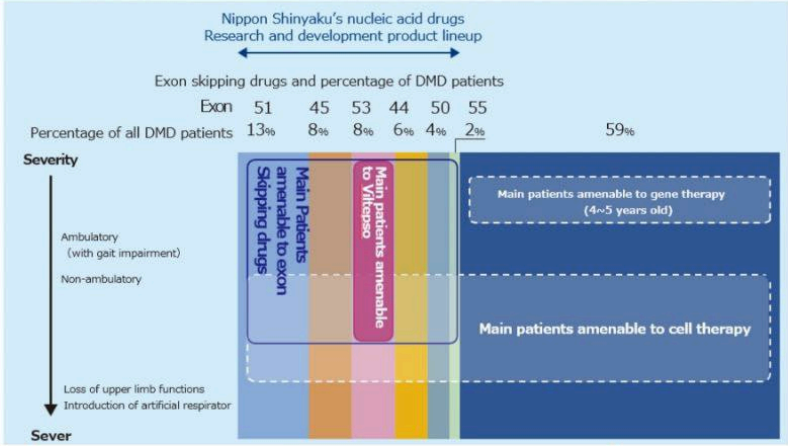
The Duchenne muscular dystrophy treatment drug NS-065/NCNP-01, Viltepso, was launched in the US in August 2020. The global Phase III study has now been completed and analysis is underway.

For CAP-1002, a treatment for Duchenne muscular dystrophy, we entered into a marketing collaboration agreement with Capricor Therapeutics in the US in January 2022 and in Japan in February 2023. Capricor Therapeutics is currently conducting a Phase III study in the US.

A global Phase II study is underway for NS-018, a treatment for myelofibrosis.

Global studies of the NS-089/NCNP-02, NS-229, and NS-050/NCNP-03 is being prepared.

Positioning in the three DMD treatments



(¥ million)	Apr-Dec				Annual	
	2022	2023	YoY Change	Progress for FY	2022	2023 (estimated)
Viltepso	10,717	13,225	23.4%	72.3%	14,341	18,300
(Japan)	(3,188)	(3,332)	(4.5%)	(69.4%)	(4,139)	(4,800)
(U.S.)	(7,528)	(9,892)	(31.4%)	(73.3%)	(10,201)	(13,500)

- We believe that an optimal combination is selected from the three treatments (Nucleic acid drug, cell therapy, and gene therapy) depending on the patient's genetic background and stage of the disease.
- Despite the launch of gene therapy in the U.S. in 2023, sales of U.S. Viltepso increased.

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Finally, I will explain about our approach to treatment in the DMD area.

In regard to each of the three therapies, namely, nucleic acid medicine, cell therapy, and gene therapy, we believe that the optimal treatment will be selected according to the patient's genetic background and disease progression and that these three therapies will coexist in the future.

In the US, where gene treatment was launched in 2023, sales of Viltepso continued to grow, with cumulative US Viltepso sales in Q3 up 31.4% YoY.

By offering a lineup of therapeutic agents in multiple modalities for DMD, Nippon Shinyaku will work to ensure that as many patients as possible receive optimal treatment.

This concludes my explanation.

Q3 FY023 Results Briefing (Q&A Summary)

Held on February 9, 2024

NO	Questions	Response
1	P3 study for Viltepso is under analysis now, so when will topline data be published?	It will be published in this spring.
2	Have you decided on the conference presentation of the study for Viltepso targeting ambulant and non-ambulant patients completed in June 2023?	It has been determined. The data is expected to be released by the end of FY2023.
3	Sales of U.S. Viltepso are up more than 19% QoQ. It was pointed out on the IR meeting for 2Q that the shipments were delayed. Is it correct to understand that Viltepso originally scheduled to be shipped in 2Q was actually shipped in 3Q?	That is correct.
4	Regarding Sales of U.S. Viltepso, I think its sales in 3Q increased QoQ. Is there any special factor in 3Q, such as delayed shipment in 2Q?	There is not any major special factor.
5	It can be thought that sales of U.S. Viltepso in 4Q will increase QoQ due to the fact that sales in 3Q increased QoQ. Based on the current situation, do you think that you are able to achieve its forecast, which was lowered in November last year.	We think that it is possible from the situation in January.
6	The dollar based sales forecast of U.S. Viltepso was lowered by 2Q. The reason was that doctors and patients were concerned about whether to choose gene therapy or nucleic acid, and the acquisition of new patients was delayed compared to the initial expectation. I think that its sales in 3Q are inline to the revised forecast. Please tell us whether the situation explained in the IR meeting for 2Q has changed by focusing on the new patient acquisition.	In the IR meeting for 2Q, we explained the situation between AdCom in May last year and release of P3 data released. During this period, doctors and patients had high expectations for gene therapy and they struggled with a decision of their treatment. Therefore, the number of patients enrolled and administered in 1H was lower compared to the initial plan.
7	After the data of the gene therapy was published, patients who are positive towards treatment with nucleic acid drugs have appeared again. That kind of patients are new patients for you, so the contribution to sales has not been seen at present. However, does this situation suggest the possibility of sales of U.S. Viltepso returning to the original track in the future?	That is right.
8	It was around the end of October that P3 results for ELEVIDYS were published. Have there been significant shifts in Viltepso sales between October and November to December?	There is no change.

9	One of the payers has a policy of reimbursement for exon skipping drugs after using gene therapy. Is there any patient who has been given exon skipping after gene therapy?	Such patients have not been reported yet.
10	Is there any patient switched from Viltepso to gene therapy?	There is not such patients.
11	I am interested in why patients who have been administered Viltepso do not switch to gene therapy. I would like to know the background, such as whether there is no need for gene therapy because the patient's condition is stable with Viltepso, or whether target age group of Viltepso and gene therapy is non-competitive.	We do not have personal information of patients administered Viltepso in the U.S. such as their ages. It has been a while since Viltepso was launched in the U.S. and we can assume that the number of patients aged 4 to 5 is small now, but it is unclear.
12	Is there any reason why the new patients choose nucleic acid drug rather than gene therapy?	There has been no significant impact on the acquisition of new patients of Viltepso after the accelerated approval of gene therapy, so we are not sure of the reason.
13	Are new patients of Viltepso both switching from Sarepta's drug and drug-naive?	That is correct.
14	It seems that the market penetration rate of Viltepso in the U.S. is increasing considerably. Do you think there is still room for its growth?	We believe there is still room for growth in 53 exon skipping drugs.
15	As stated in the document of Central Social Insurance Medical Council, the number of patients of Viltepso in Japan at the peak would be 128. How many progress have you made toward 128 patients, including the number of patients who have discontinued the treatment?	Viltepso has been administered to about 100 patients, including those who discontinued the treatment.
16	Is the number of patients of Viletepso increasing? Will the number of patients be fixed to some extent in the future?	We assume that the number of patients will increase because patients develop DMD every year.
17	Sales of Viltepso in Japan appears to be low progress. I remember that there was a comment in the IR meeting for 2Q that you had an outlook on the patients administered Viltepso in 2H. Is it possible to achieve the forecast?	Although the administration of Viltepso has been delayed a little than expected, candidate patients for administration have been confirmed.
18	I would like to know if there is any information on how DMD specialists in Japan asess gene therapy.	Regarding to the way of thinking towards gene therapy of domestic DMD specialists, we are not aware of doctors fully supporting gene therapy. Gene therapy has not yet approved in Japan, and there is no doctor actively making a comment on gene therapy as far as we are aware.
19	In the situation where no doctor strongly supports gene therapy, which is expected to be launched in Japan in the future, do you think it will be difficult for CAP-1002 to penetrate the market in Japan when it is newly launched?	In the U.S. gene therapy targets ambulatory patients aged 4 to 5 with accelerated approval, while CAP-1002 is expected to target non-ambulatory patients. Therefore, we consider that CAP-1002 can be differentiate from gene therapy. If P3 topline data is published by Capricor Therapeutics in the future, it is expected that CAP-1002 will be smoothly introduced in Japan as the new treatment option.
20	You invested in Capricor Therapeutics. Is this recorded in the balance sheet?	Yes. It is recorded as other financial assets.

21	The interim analysis of CAP-1002 led to the decision to continue P3 study and you need to pay milestone to Capricor Therapeutics. Are you going to pay it after January?	Since the interim analysis was released in December last year, we did not pay milestone in cash in 3Q. However, we have recorded it in the balance sheet.
22	Is the recruiting of NS-089/NCNP-02 going well? When is the FPI of NS-050/NCNP-03?	We originally planned for FPI of NS-089/NCNP-02 in 1H FY2023, but patients expected to be enrolled were not eligible for criteria in screening. Currently nine sites are opened and there are several patients awaiting screening there, so it is possible to expect FPI immediately. We assumes FPI of NS-050/NCNP-03 in 1H FY2024, partly because it took longer than originally planned to open the sites.
23	You mentioned that FPI of NS-050/NCNP-03 is in 1H FY2024, but the range in 1H is as wide as 6 months. Could you tell us more detailed schedule?	There are several candidates for NS-050/NCNP-03, but the timing of FPI can be changed depending on the results of the screening. Therefore, we will set FPI in 1H FY2024.
24	Is any study for a new pipeline going to be started next fiscal year? Is NS-050/NCNP-03 followed by NS-051/NCNP-04 scheduled to start next fiscal year?	NS-051/NCNP-04 is also expected to start next fiscal year.
25	What is the target of the amount of dystrophin protein expression for NS-051/NCNP-04?	Regarding NS-051/NCNP-04, we expect the amount of dystrophin protein expression as much as of NS-089/NCNP-02, which showed an increase in dystrophin protein expression to more than 10% in the investigator-initiated clinical trial.
26	At the R&D meeting in December, it was explained that the entry for P2b study of NS-580 had been completed. Will the study be completed in the end of February this year?	I think it will be completed as scheduled.
27	If the data from P2b study of NS-580 is as expected, will you look for a global partner?	We would like to consider this possibility.
28	Regarding the progress of the performance in 3Q, I think that the progress of R&D expenses is well toward the forecast, but is there any expense that can unachieve forecast? Dose everything progress as planned?	Almost all of expenses are generally going according to plan.
29	What is the actual exchange rate between 1Q and 3Q?	The actual rate is ¥143.3 to USD.
30	Regarding to sales and profit in the functional food business, sales in 3Q tend to be higher than the other quarters in recent years. However, in this year sales in 3Q is less than in 1H. On the other hand, profit is higher than in 1H. What are these factors?	We were expected that sales would decline because of drop in the raw material prices and a stronger yen. Raw material prices were not lower than expected due to the depreciation of the yen against assumed exchange rate, but sales fall slightly due to the fact that raw material prices were passed on to sales prices. Nevertheless, when raw material prices fall, profit tends to increase due to a slight time lag in passing through to sales prices.
31	Is the period of the next medium-term management plan five years? Will you explain the next medium-term management plan, including how to overcome the patent cliff?	I think it will probably be five years, though we are considering it now. In addition, we also plan to explain how to overcome the patent cliff.