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

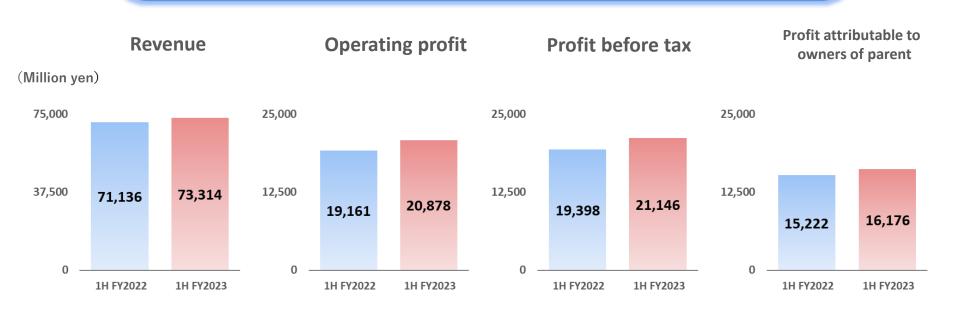
November 15, 2023 NIPPON SHINYAKU CO., LTD.



2Q FY2023 Summary

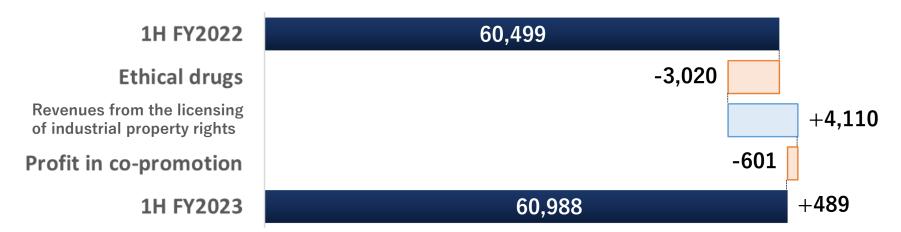


- ♠ Revenue : 73,314 million yen (+ 3.1%)
- ◆ Operating profit : 20,878 million yen (+ 9.0%)
- ◆ Profit before tax : 21,146 million yen (+ 9.0%)
- ◆ Profit attributable to owners of parent
 : 16,176 million yen
 (+ 6.3%)



Segmental Review - Pharmaceuticals -





(Million yen)	1H FY	′2022	1H FY	′2023	YoY Change		
(willion yen)	Results	Ratio	Results	Ratio	Amt	%	
Ethical drugs	41,023	67.8%	38,003	62.3%	-3,020	-7.4%	
Revenues from the licensing of industrial property rights	14,469	23.9%	18,580	30.5%	+4,110	+28.4%	
Profit in co-promotion	5,005	8.3%	4,404	7.2%	-601	-12.0%	
Revenue	60,499	100.0%	60,988	100.0%	+489	+0.8%	

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

*MHLW: Ministry of Health, Labour and Welfare



Segmental Review - Functional Food -



 1H FY2022
 10,637

 Protein preparations
 +1,127

 Preservatives
 +97

 Supplements
 +315

 Health food ingredients
 +147

 Others
 -0

 1H FY2023
 12,325

(Million yen)	1H FY	′2022	1H FY	′2023	YoY Change		
(Willion yen)	Results	Ratio	Results	Ratio	Amt	%	
Protein preparations	7,360	69.2%	8,487	68.9%	+1,127	+15.3%	
Preservatives	1,424	13.4%	1,522	12.3%	+97	+6.9%	
Supplements	671	6.3%	987	8.0%	+315	+46.9%	
Health food ingredients	511	4.8%	659	5.4%	+147	+28.9%	
Others	668	6.3%	668	5.4%	-0	-0.1%	
Revenue	10,637	100.0%	12,325	100.0%	+1,688	+15.9%	

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

Operating profit



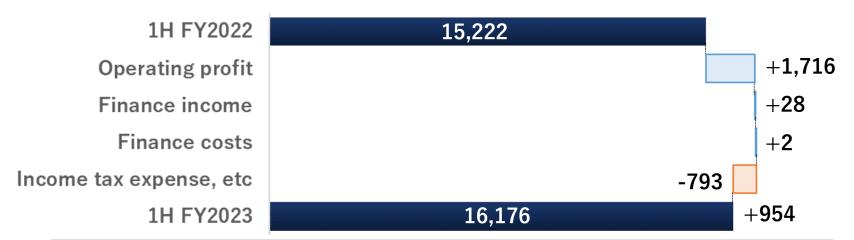
1H FY2022
Revenue
Cost of sales
SG&A expenses
R&D expenses
Other income
Other expenses
1H FY2023



(Million yen)	1H FY	2022	1H FY2	2023	YoY CI	nange
(Willion yen)	Results	Ratio	Results	Ratio	Amt	%
Revenue	71,136	100.0%	73,314	100.0%	+2,178	+3.1%
(Pharmaceuticals)	(60,499)	(85.0%)	(60,988)	(83.2%)	(+489)	(+0.8%)
(Functional Food)	(10,637)	(15.0%)	(12,325)	(16.8%)	(+1,688)	(+15.9%)
Cost of sales	27,991	39.3%	25,320	34.5%	-2,671	-9.5%
SG&A expenses	16,284	22.9%	16,952	23.1%	+668	+4.1%
R&D expenses	9,691	13.6%	12,517	17.1%	+2,825	+29.2%
Other income	2,805	3.9%	2,596	3.5%	-209	-7.5%
(Foreign exchange gain)	(2,521)	(3.5%)	(2,261)	(3.1%)	(-260)	(-10.3%)
Other expenses	813	1.2%	242	0.3%	-570	-70.2%
Operating profit	19,161	26.9%	20,878	28.5%	+1,716	+9.0%

Profit attributable to owners of parent





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

Business Forecast for FY2023



	FY2	022	FY2	2023	YoY Change		
(Million yen)	1H	FY	1H	FY	A mat	%	
	Results	Results Results		Forecasts	Amt	70	
Revenue	71,136	144,175	73,314	147,000	+2,825	+2.0%	
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	+3,012	+2.5%	
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	-187	-0.8%	
Operating profit	19,161	30,049	20,878	33,500	+3,451	+11.5%	
Profit before tax	19,398	30,489	21,146	34,000	+3,511	+11.5%	
Profit attributable to owners of parent	15,222	22,812	16,176	26,000	+3,188	+14.0%	
Evolundo voto	FY2	022	FY2	2023	I		
Exchange rate	1H	FY	1H	2H			
(JPY)	Actual rate	Actual rate	Actual rate	Forecast rate			
1USD	134.0円	135.5円	141.0円	140.0円			

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

Segmental Forecast - Pharmaceuticals -



	FY2	022	FY2	2023	YoY Change		
(Million yen)	1H	FY	1H FY		Amt	%	
	Results Results		Results Forecasts		Amt	/0	
Ethical drugs	41,023	81,753	38,003	78,200	-3,553	-4.3%	
Revenues from the licensing of industrial property rights	14,469	30,714	18,580	38,000	+7,286	+23.7%	
Profit in co-promotion	5,005	9,520	4,404	8,800	-720	-7.6%	
Revenue	60,499	121,988	60,988	125,000	+3,012	+2.5%	

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

Segmental Forecast - Functional Food -



	FY20	022	FY2	2023	YoY Change		
(Million yen)	1H FY Results Results		1H	FY	Amt	%	
			Results	Forecasts	Allit	/0	
Protein preparations	7,360	15,383	8,487	14,800	-583	-3.8%	
Preservatives	1,424	2,905	1,522	3,000	+95	+3.3%	
Supplements	671	1,428	987	1,900	+472	+33.0%	
Health food ingredients	511	1,118	659	1,100	-18	-1.6%	
Others	668	1,351	668	1,200	-151	-11.2%	
Revenue	10,637	22,187	12,325	22,000	-187	-0.8%	

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

Forecast of Consolidated Statements of Income



	FY20	022	FY2	.023	YoY Ch	iange
(Million yen)	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Revenue	71,136	144,175	73,314	147,000	+2,825	+2.0%
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	(+3,012)	(+2.5%)
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	(-187)	(-0.8%)
Cost of sales	27,991	55,980	25,320	49,000	-6,980	-12.5%
SG&A expenses	16,284	34,812	16,952	36,000	+1,188	+3.4%
R&D expenses	9,691	24,135	12,517	29,500	+5,365	+22.2%
Other income	2,805	1,908	2,596	1,400	-508	-26.7%
Other expenses	813	1,106	242	400	-706	-63.8%
Operating profit	19,161	30,049	20,878	33,500	+3,451	+11.5%
Finance income	297	575	326	600	+25	+4.3%
Finance costs	60	136	57	100	-36	-26.5%
Profit before tax	19,398	30,489	21,146	34,000	+3,511	+11.5%
Income tax expense, etc	4,176	7,676	4,970	8,000	+324	+4.2%
Profit attributable to owners of parent	15,222	22,812	16,176	26,000	+3,188	+14.0%

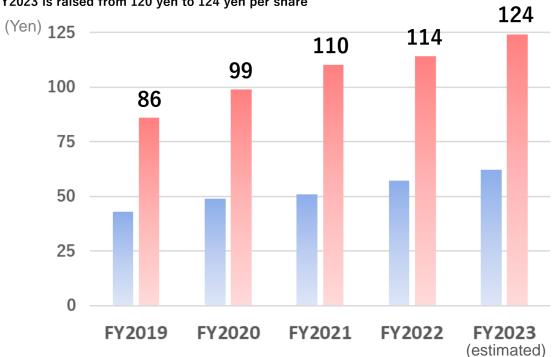
Dividends Forecast

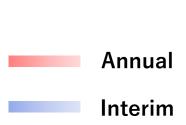


		FY2022	FY2023
Dividends per share	Interim	¥57	¥62
Dividends per share	Annual	¥114	¥124
Basic earnings per share		¥338.70	¥386.03
Payout ratio (consolidated)		33.7 %	32.1 %

^{*}Interim dividend for FY2023 is raised from 60 yen to 62 yen per share

^{*}Annual dividend for FY2023 is raised from 120 yen to 124 yen per share





R&D Pipeline



R&D Pipeline (Domestic)



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



R&D Pipeline (Domestic)



Code No. (Generic name) <origin></origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	Launch
NS-580	NINGE	Endometriosis								
<in-house></in-house>	NME	Chronic prostatitis / Chronic pelvic pain syndrome								
NS-089/NCNP-02 (brogidirsen) <in-house></in-house>	NME	Duchenne muscular dystrophy								
NS-229 <in-house></in-house>	NME	Eosinophilic granulomatosis with polyangiitis								
NS-401 (tagraxofusp) <in-license></in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm								
NS-050/NCNP-03 <in-house></in-house>	NME	Duchenne muscular dystrophy								
NS-917 (radgocitabine) <in-license></in-license>	NME	Relapsed/refractory acute myeloid leukemia								
NS-161 <in-house></in-house>	NME	Inflammatory diseases								
NS-025 <in-house></in-house>	NME	Urological diseases								
NS-863 <in-house></in-house>	NME	Cardiovascular diseases								4

R&D Pipeline (Overseas)



Code No. (Generic name) <origin></origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house></in-house>	NME	Duchenne muscular dystrophy						PIII in progress		
CAP-1002 <partnership></partnership>	NME	Duchenne muscular dystrophy								
NS-018 (ilginatinib) <in-house></in-house>	NME	Myelofibrosis								
NS-089/NCNP-02 (brogidirsen) <in-house></in-house>	NME	Duchenne muscular dystrophy								
NS-229 <in-house></in-house>	NME	Eosinophilic granulomatosis with polyangiitis								
NS-050/NCNP-03 <in-house></in-house>	NME	Duchenne muscular dystrophy								

Reference Materials



Consolidated Balance Sheet



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

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

=Liabilities and Equity=	
Income tax payable	-2,109
Retained earnings	+12,373

Consolidated Statements of Cash Flows



		(Million yen)		1H FY2022 Results	1H FY2023 Results	3 Ү	oY Change Amt		
	Opera	ating activitie	es	12,817	7,93	8	-4,879		
	Inves	ting activitie	S	-5,882	-1,69	3	+4,189		
	Finan	Financing activities		-4,911	-4,68	5	+226		
	Cash and cash equivalents at end of period		63,449	62,85	5	-593			
		1H FY2022					1H FY2023		
60,566	+12,817	-5,882	-4,911	63,449	60,047	+7,938	-1,693	-4,685	62,85
Cash and cash equivalents beginning of period	Operating CF	Investing CF	Financing CF	Cash and cash equivalents at end of period	Cash and cash equivalents at beginning of period	Operating CF	Investing CF	Financing CF	Cash an cash equiva at end of p



NS-065/NCNP-01 (viltolarsen)

- Treatment for Duchenne muscular dystrophy





NS-87 (daunorubicin / cytarabine)

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- 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)

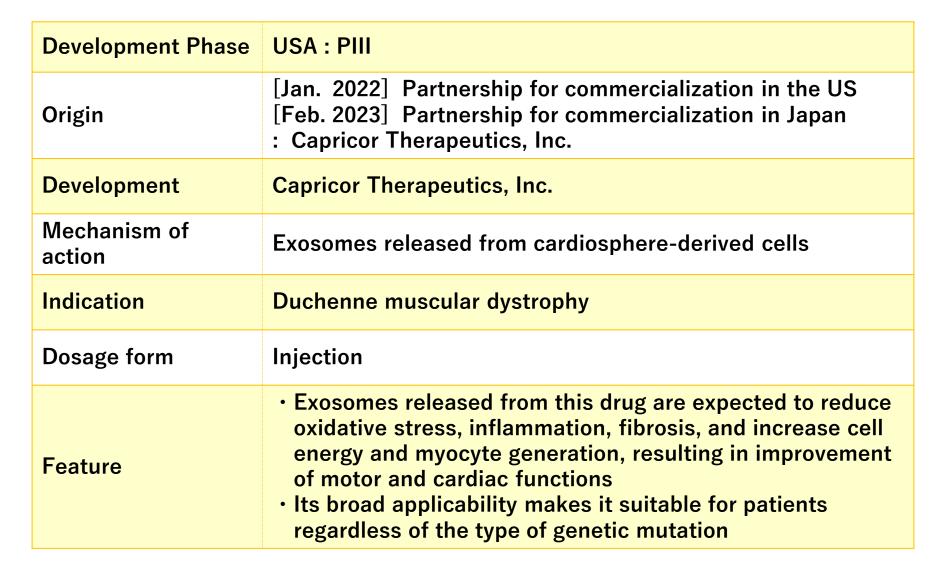
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- Treatment for rare intractable epilepsy -

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





GA101 (Obinutuzumab)

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- 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

- 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





- 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

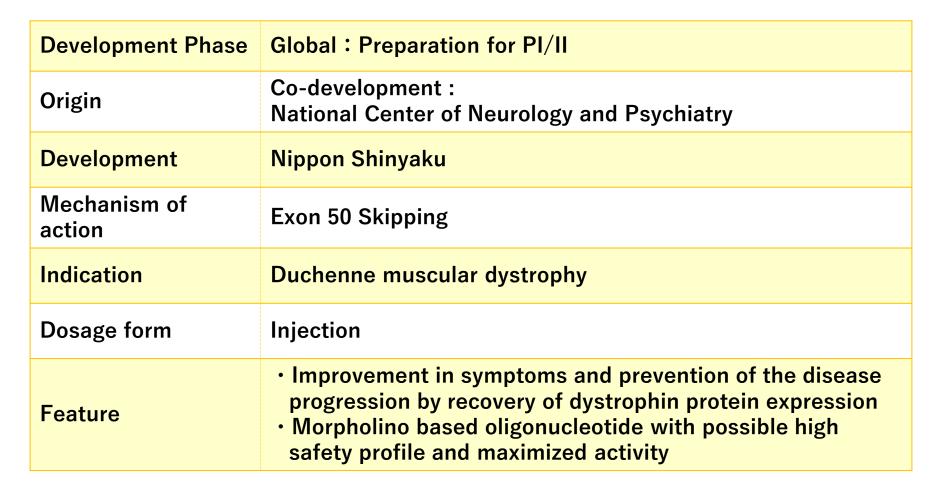
NS-401 (tagraxofusp)

- 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





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



- 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	





- 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	



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- 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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- 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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 include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw
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- 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.

IR Meeting (2Q FY2023)

November 15, 2023

Presentation

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

Thank you very much for participating in our presentation for the Q2 financial results for FY2023. I appreciate it very much.

Today, I would like to report on our business performance for Q2 for FY2023 and our full-year business forecast for FY2023, and Mr. Takagaki will explain to you the progress of our R&D items.

2Q FY2023 Summary



 ♠ Revenue
 : 73,314 million yen
 (+ 3.1%)

 ♠ Operating profit
 : 20,878 million yen
 (+ 9.0%)

 ♠ Profit before tax
 : 21,146 million yen
 (+ 9.0%)

 ♠ Profit attributable to owners of parent
 : 16,176 million yen
 (+ 6.3%)



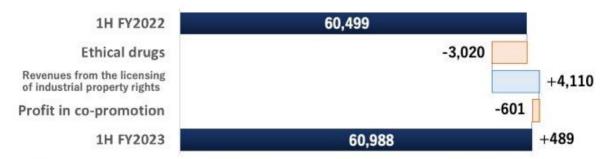


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As an overview of our performance in Q2 of FY2023, we reported consolidated revenue of JPY73,314 million, operating profit of JPY20,878 million, profit before income tax of JPY21,146 million, and profit attributable to owners of parent of JPY16,176 million.

Segmental Review - Pharmaceuticals -





(88:111:)	1H FY	/2022	1H FY	/2023	YoY Change		
(Million yen)	Results	Ratio	Results	Ratio	Amt	%	
Ethical drugs	41,023	67.8%	38,003	62.3%	-3,020	-7.4%	
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Revenue	60,499	100.0%	60,988	100.0%	+489	+0.8%	

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

*MHLW: Ministry of Health, Labour and Welfare



In the pharmaceuticals business, consolidated net sales increased 0.8% YoY to JPY60,988 million despite the effect of price revision by MHLW and generic products, due to growth in sales of Viltepso, a treatment for Duchenne muscular dystrophy, and Uptravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and royalty income from overseas sales of Uptravi.

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Segmental Review - Functional Food -



1H FY2022	10,637	
Protein preparations	- W	+1,127
Preservatives		+97
Supplements		+315
Health food ingredients		+147
Others		-0
1H FY2023	12,325	+1,688

(88:H:)	1H FY	/2022	1H FY	/2023	YoY C	hange
(Million yen)	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,360	69.2%	8,487	68.9%	+1,127	+15.3%
Preservatives	1,424	13.4%	1,522	12.3%	+97	+6.9%
Supplements	671	6.3%	987	8.0%	+315	+46.9%
Health food ingredients	511	4.8%	659	5.4%	+147	+28.9%
Others	668	6.3%	668	5.4%	-0	-0.1%
Revenue	10,637	100.0%	12,325	100.0%	+1,688	+15.9%

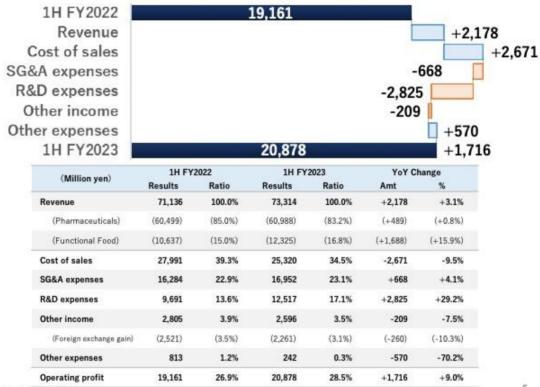
Revenue of consolidated functional food segment increased by 15.9% through sales increase of protein preparations and supplements.



In the functional food business, sales of protein preparations and supplements increased, and consolidated net sales in the functional food business increased 15.9% YoY to JPY12,325 million.

Operating profit





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Next, as for operating expenses, the cost to sales ratio improved by 4.8 percentage points YoY to 34.5%, due to factors such as the sales mix, including an increase in industrial property and other revenues.

SG&A expenses increased 4.1% YoY to JPY16,952 million, mainly due to increased sales expenses in the US and promotional commission fees due to increased domestic sales of Uptravi.

R&D expenses totaled JPY12,517 million, up 29.2% YoY, mainly due to an increase in contract research expenses and investigational drug manufacturing costs.

Other income totaled JPY2,596 million, mainly due to foreign exchange gains.

As a result, operating profit was JPY20,878 million, up 9.0% YoY.

Profit attributable to owners of parent



1H FY2022		15,222		
Operating profit				+1,71
Finance income				+28
Finance costs				+2
Income tax expense, etc			-79	3
1H FY2023	NAMES OF TAXABLE	16,176		+954
(Million yen)	1H FY2022	1H FY2023	YoY C	STATE OF THE STATE
	Results	Results	Amt	%
Operating profit	19,161	20,878	+1,716	+9.0%
Finance income	297	326	+28	+9.5%
Finance costs	60	57	-2	-4.5%
Profit before tax	19,398	21,146	+1,747	+9.0%
Income tax expense, etc	4,176	4,970	+793	+19.0%



Profit attributable to

owners of parent

6

+6.3%

Profit before tax was JPY21,146 million, up 9% YoY, and profit attributable to owners of parent was JPY16,176 million, up 6.3% YoY.

16,176

+954

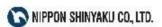
15,222

Business Forecast for FY2023



	FY2	022	FY2	2023	YoY Ch	ange	
(Million yen)	1H Results	FY Results	1H Results	FY Forecasts	Amt	%	
Revenue	71,136	144,175	73,314	147,000	+2,825	+2.0%	
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	+3,012	+2.5%	
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	-187	-0.8%	
Operating profit	19,161	30,049	20,878	33,500	+3,451	+11.5%	
Profit before tax	19,398	30,489	21,146	34,000	+3,511	+11.5%	
Profit attributable to owners of parent	15,222	22,812	16,176	26,000	+3,188	+14.0%	
Exchange rate	FY2	022	FY2	2023			
(JPY)	1H Actual rate	FY Actual rate	1H Actual rate	2H Forecast rate			
1USD	134.0円	135.5円	141.0円	140.0円			

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



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As announced on November 13, we have revised our consolidated forecast for FY2023, which was announced in May.

Consolidated revenue was revised from JPY145,000 million to JPY147,000 million because royalty income from overseas sales of Uptravi and the functional food business are expected to exceed the initial forecast.

As for consolidated profit, we revised operating profit from JPY32,000 million to JPY33,500 million, profit before tax from JPY32,500 million to JPY34,000 million and profit attributable to owners of parent from JPY25,000 million to JPY26,000 million.

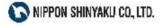
The exchange rate assumption was changed from JPY130 to USD1 at the beginning of the period to JPY140 to USD1.

Segmental Forecast - Pharmaceuticals -



	FY2	022	FY2	2023	YoY Ch	ange	
(Million yen)	1H	FY	1H	FY	Amt	%	
	Results Resu		Results	Forecasts	Amt	70	
Ethical drugs	41,023	81,753	38,003	78,200	-3,553	-4.3%	
Revenues from the licensing of industrial property rights	14,469	30,714	18,580	38,000	+7,286	+23.7%	
Profit in co-promotion	5,005	9,520	4,404	8,800	-720	-7.6%	
Revenue	60,499	121,988	60,988	125,000	+3,012	+2.5%	

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



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In the pharmaceutical business, we forecast revenue of JPY12,500 million, an increase of 2.5% YoY.

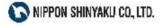
Despite the effect of price revision by MHLW and launch of generic products, we expect an increase in revenue due to growth in sales of Viltepso and Uptravi, as well as growth in royalty revenue from overseas sales of Uptravi.

Segmental Forecast - Functional Food -



	FY2	022	FY2	2023	YoY Ch	ange	
(Million yen)	1H Results	FY Results	1H Results	FY Forecasts	Amt	% -3.8%	
Protein preparations	7,360	15,383	8,487	14,800	-583		
Preservatives	1,424	2,905	1,522	3,000	+95	+3.3%	
Supplements	671	1,428	987	1,900	+472	+33.0%	
Health food ingredients	511	1,118	659	1,100	-18	-1.6%	
Others	668	1,351	668	1,200	-151	-11.2%	
Revenue	10,637	22,187	12,325	22,000	-187	-0.8%	

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



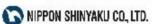
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In the functional food business, revenue is expected to be JPY22,000 million, down 0.8% YoY due to the impact of lower sales prices of some products.

Forecast of Consolidated Statements of Income



	FY2	022	FY2	2023	YoY Ch	ange	
(Million yen)	1H Results	FY Results	1H Results	FY Forecasts	Amt	%	
Revenue	71,136	144,175	73,314	147,000	+2,825	+2.0%	
(Pharmaceuticals)	(60,499)	(121,988)	(60,988)	(125,000)	(+3,012)	(+2.5%)	
(Functional Food)	(10,637)	(22,187)	(12,325)	(22,000)	(-187)	(-0.8%	
Cost of sales	27,991	55,980	25,320	49,000	-6,980	-12.5%	
SG&A expenses	16,284	34,812	16,952	36,000	+1,188	+3.4%	
R&D expenses	9,691	24,135	12,517	29,500	+5,365	+22.2%	
Other income	2,805	1,908	2,596	1,400	-508	-26.7%	
Other expenses	813	1,106	242	400	-706	-63.8%	
Operating profit	19,161	30,049	20,878	33,500	+3,451	+11.5%	
Finance income	297	575	326	600	+25	+4.3%	
Finance costs	60	136	57	100	-36	-26.5%	
Profit before tax	19,398	30,489	21,146	34,000	+3,511	+11.5%	
Income tax expense, etc	4,176	7,676	4,970	8,000	+324	+4.2%	
Profit attributable to owners of parent	15,222	22,812	16,176	26,000	+3,188	+14.0%	



Next, regarding operating expenses, the cost to sales ratio is expected to be 33.3%, an improvement of 5.5 percentage points YoY.

SG&A expenses are expected to be JPY36,000 million, and R&D expenses are expected to be JPY29,500 million.

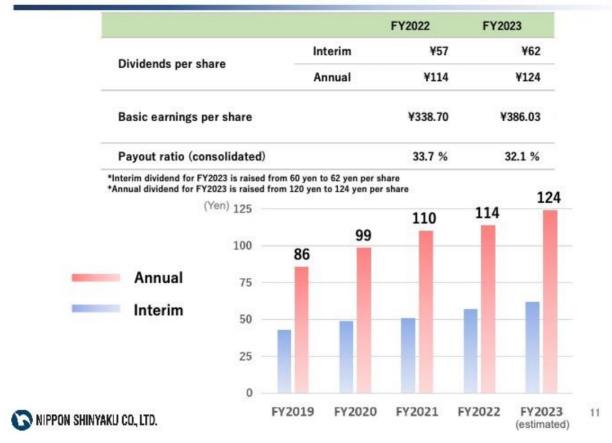
As a result, operating profit is expected to be JPY33,500 million and profit before tax is expected to be JPY34,000 million.

 $Profit \, attributable \, to \, owners \, of \, parent \, is \, expected \, to \, be \, JPY26,000 \, million, \, an \, increase \, from \, the \, previous \, year.$

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Dividends Forecast





As for dividends, we plan to pay dividends with a consolidated payout ratio of around 35% as a performance-linked dividend for the period of the Sixth Mid-Term Management Plan.

In accordance with this dividend policy, we plan to increase the interim dividend by JPY2 per share to JPY62 per share, and the annual dividend forecast by JPY4 per share to JPY124 per share for FY2023, as profit attributable to owners of parent is expected to exceed the initial forecast.

This concludes my presentation for the financial results for Q2 for FY2023 and the forecast for FY2023.

R&D Pipeline (Domestic)



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



: Changes from 1st Quarter FY2023

Takagaki: I will continue with the progress of R&D items.

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

Duchenne muscular dystrophy treatment drug NS-065/NCNP-01, Viltepso that skips exon 53, was launched in May 2020 and is currently in global Phase III trials.

The Phase I/II study for NS-87, a treatment for high-risk acute myeloid leukemia, was completed and an application for approval was filed in June 2023.

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 nephrotic syndrome are being conducted in collaboration with Chugai Pharmaceutical Co. In addition, a Phase III study for extra renal lupus was initiated in October 2023.

A Phase IIb study of NS-304 for 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.

R&D Pipeline (Domestic)



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

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: Changes from 1st Quarter FY2023

Phase IIb study is underway for NS-580, an endometriosis treatment. In addition, a Phase IIa study for chronic prostatitis and chronic pelvic pain syndrome was initiated in June 2023.

A global Phase II study for NS-089/NCNP-02, a treatment for Duchenne muscular dystrophy that skips exon 44, is in preparation.

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

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

A global Phase I/II study for NS-050/NCNP-03, a treatment for Duchenne muscular dystrophy that skips exon 50, is in preparation.

Phase I trials for NS-917 for the treatment of relapsed/refractory acute myeloid leukemia is underway.

Phase I trials are underway 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.

For NS-863, which is under development for the treatment of cardiovascular diseases, Phase I trials were initiated in August 2023.

R&D Pipeline (Overseas)



Code No. (Generic name) <origin></origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	NDA filing	Launch
NS-065/NCNP-01 (viltolarsen) <in-house></in-house>	NME	Duchenne muscular dystrophy						PII in progress		
CAP-1002 <partnership></partnership>	NME	Duchenne muscular dystrophy								
NS-018 (ilginatinib) <in-house></in-house>	NME	Myelofibrosis								
NS-089/NCNP-02 (brogidirson) <in-house></in-house>	NME	Duchenne muscular dystrophy								
NS-229 <in-house></in-house>	NME	Eosinophilic granulomatosis with polyanglitis								
NS-050/NCNP-03 <in-house></in-house>	NME	Duchenne muscular dystrophy								



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.

We have signed a partnership agreement for commercialization for CAP-1002 for the treatment of Duchenne muscular dystrophy with Capricor Therapeutics, Inc. in the US in January 2022 and in Japan in February 2023. Capricor Therapeutics, Inc. is currently conducting Phase III trials in the US.

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

We are currently preparing global trials for NS-089/NCNP-02, NS-229 and NS-050/NCNP-03.

This concludes the overview of our R&D activities.

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FY2023 Q2 Financial Results Briefing Q&A (Summary)

Held on November 15, 2023

NO	Questions	Answers
1	In the U.S., sales of Viltepso in the second quarter are lower than in the first quarter in US dollars. Did the timing	The number of cases for Viltepso is steadily increasing, but the shipments at the end of September were delayed. The
	of the shipment, the quick start program, and ELEVIDYS have an impact on the sales of Viltepso in the second	shipments were confirmed in October. However, we lowered its full-year forecast for dollar-based sales of Viltepso
	quarter?	slightly. The number of patients has been increasing steadily, but it has not kept up with the initial assumption slightly.
		The accelerated approval for Sarepta's gene therapy, ELEVIDYS, at the end of June and they released topline results
		from P3 study of ELEVIDYS at the end of October. There are few patients who can be treated with ELEVIDYS by the
		approval in June, and the doctors cannot decide the treatment plan with its topline results. That is the reason for the
		slow pace of patient acquisition of Viltepso. In addition, the quick start program was launched in late June. We initially
		explained that this would accelerate the increase of patients switching from the competitor's drug, but we have actually
		acquired the patients switching from it without using the quick start program. The U.S. team carefully introduces the
		quick start program because if we emphasize quick start program and acquire patients, this can be prescribing guidance.
		We would like the patients to switch to Viltepso due to its efficacy. After they making the decision to use our drug, we
		explain the quick start program as a support to fill the insurance gap. If they do not need it, they normally switch without
		it. Previously I may have explained the quick start program will be a catalyst for future sales, but I would like to correct
		what I said before. Also, to the question of whether gene therapy has an impact on Viltepso, our answer is that it could
		have an impact in terms of acquiring the patients which has been slightly slower than expected at the beginning of this
		fiscal year but there is no patient switching from Viltepso to competitor's drug.
2	Estimates from Sarepta's sales suggest that more than 20 people had undergone the gene therapy. Does the	Your understanding is correct. It is not clear whether the gene therapy will be fully or partially approved. The medical
	confusion of medical sites continue until how FDA judges topline results for ELEVIDYS become clear?	sites are currently reviewing treatment policies.

3	Now the medical sites in the U.S. are waiting for how the FDA approves ELEVIDYS, but I think they are waiting	As you pointed out, some of the patients amenable to exon 53 skipping drugs are probably waiting for the FDA's
	for it because they are interested in using it to a certain extent. Does that mean that there may be some patients to	decision. Still, with regard to whether patients who opt for gene therapy will return to exon skipping therapy, we have
	choose gene therapy if the indications are extended?	started to discuss how to use both gene therapy and exon skipping drugs with payers. One of the payers has a policy of
		reimbursement for exon skipping drugs after using gene therapy, although this is only one example. The environment
		for combining gene therapy and exon skipping has started to be prepared. We are trying to tell the doctors and the payers
		that the administration of exon skipping drugs after gene therapy is meaningful.
4	Does the top-line results from ELEVIDYS P3 study show no change in the clinical field?	It's been a few weeks since the topline results were released at the end of October, and we haven't seen any dramatic
	222 the top the testing from 222 the first standy show no change in the change in the	changes.
5	It can be imagined that ELEVIDYS makes the medical sites confused, but how long will it take for this situation	Regardless of the trend in gene therapy, we would like to continue to convey straightforwardly with 4-Year of clinical
	to settle down?	trial data of Viltepso that starting therapy as early as possible will lead to the maintenance and improvement of the long-
	to settle down:	
		term prognosis of patients. The U.S. team is working on this policy.
6	Please tell us about the age groups of new and existing patients of Viltepso in the U.S. Do the patients and doctors	Regarding the age groups, we are unfortunately unable to obtain the information because it is personal information, so
	take a positive view of the combination of exon skipping drugs and gene therapy, as the payer reimburses the	we cannot answer the question. However, we can explain the ratio of drug-naïve and switching from competitor's drug
	combination?	to all of our patients. 30% of the patient administering Viltepso has switched from competing products, and 90% of
		them had been treated by 53 skipping drugs and the other 10% had been treated by 51 skipping. The total number of
		patients administered Viltepso is still less than the number of patients of competing products, but the number of patients
		using competing products is decreasing. We obtained the information that one of the payers has a policy of
		reimbursement for exon skipping drugs after using gene therapy recently, and we don't know what decision the patient
		or doctors will make based on the policy.
7	You said that one of the payers has a policy of reimbursement for exon-skipping drugs after using gene therapy.	It is unclear whether there are patients who have been reimbursed for the combination according to the payer's policy.
	I think that about two years have passed since the first dose of gene therapy, ELEVIDYS. Is there anyone already	
	combining it with nucleic acid drugs? If so, did the combination trigger the reimbursement?	
8	Is there any information that the exon skipping drugs have been used after using gene therapy?	I have not heard of it.
9	I think the RACER53, P3 study of Viltepso, will be completed soon and then the data will be analyzed. When	The study was completed on October 19 after the examination of the last patient, and the data will be compiled and
	will you be able to obtain the results and how will you unveil them?	analyzed. We expect to be able to unveil the results of the analysis of the data around next spring. We will inform you
		of how to unveil it.
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10	Please tell us your evaluation of the topline results in P3 study of ELEVIDYS.	I would like to avoid making comments on other companies. In general, full approval cannot be obtained unless the
		primary endpoints are achieved. However, we cannot predict how FDA will judge ELEVIDYS.
11	It is difficult to compare Viltepso and ELEVIDYS because primary endpoints of their P3 trial are different.	The primary endpoint of Viltepso is TTSTAND. We cannot compare their primary endpoints directly, but we think that
	Therefore, depending on the situation, patients aged 4 to 5 years may be treated with gene therapy, and afterward	it is possible to compare them including secondary endpoints of P3 study of ELEVIDYS. With regard to which drug to
	if their condition progresses, they may switch to exon skipping drugs. If the results of the P3 study of Viltepso	use first, some doctors have suggested that it might be better to use exon skipping drugs first when stem cells are
	are good, I think there is an option of administering exon skipping drugs from the beginning. Is there anything	sufficient and then use gene therapy when they are decreased. This is a problem that can be solved after the actual
	you can suggest, although each data is not apples to apples comparison?	clinical experience has been accumulated.
12	I think the sales of Viltepso in US dollars in the second quarter were lower than in the first quarter. Was there any	If so, it would be a little higher than in the first quarter because the shipments in late June and early July were delayed.
	possibility that the sales in the second quarter exceed those in the first quarter lower if the shipment had not been	The number of patients administered Viltepso has been steadily increasing.
	delayed ?	
13	I think it is a risk for you that one wholesaler is taking charge of a distribution of big sales in the U.S. Do you	As a major wholesaler, we do business with two wholesalers, which are taking responsibility for delivering Viltepso for
	have the idea of diversifying this risk?	home infusion. The other wholesalers also deliver it directly to hospitals. Specialty pharmacy, a wholesaler undertaking
		the delivery for home infusion, is the cause of the delayed shipment. However, because of their ability to prepare for
		home infusion, we think that doing with them is the best way in terms of access to drugs. We will make a judgment
		about whether this can be a risk or not with seeing both the advantages and disadvantages.
14	I hope that the sales scale of Viltepso will be a level that is less affected by timing of shipments as soon as possible.	If the current situation continues, this could happen. We aim to grow the gross sales which is less affected by the timing
	Will this kind of shipping delays in the future as well?	of shipments.
15	In the quarterly report, sales in other regions are stated as 1.2 billion yen. Why did sales there increase YoY in	Sales in other regions include the sales related to supplying Viltepso as an unapproved drug delivery program. Viltepso
	spite of few sales last year? As the cost of sales ratio is declining, please tell us if the sales in other regions affect	is unapproved outside Japan and the U.S., but with aiming to expand to supply Viltepso to other countries more, it is
	the cost of sales ratio.	recorded in sales in other regions. Cost of sales for it is incurred.
16	If you record the amount of Viltepso about the same as the its cost in the sales in other regions, will this cause the	As unapproved drug delivery program, Viltepso is provided by another company, so administrative fees and other
	cost of sales ratio to deteriorate? How would an increase in the supply of Viltepso as an unapproved drug delivery	overhead costs. Therefore, we provide Viltepso to the company for the amount of the cost plus extra fees. The increase
	program affect cost of sales?	in sales of this will have a slight negative impact on the current average cost rate.

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17	The forecast for SG&A expenses and R&D expenses for FY2023 is increased. Are there any factors that increase	Milestone becomes an asset. Exchange rate is the biggest factor behind the increase of their forecast. For SG&A
	them other than foreign exchange? If the interim analysis of CAP-1002 works well, it will probably trigger the	expenses, it was as planned in the first half, and in the second half costs for NS Pharma will increase due to foreign
	milestone, but even if you pay it, I think it will only be recorded in the balance sheet and it will not affect R&D	exchange factors. As you can see, R&D expenses were not achieved the target for the first half because the costs of
	expenses. What other factors contributed to the increase in the forecast for FY2023 despite the failure to achieve	nucleic acid production were partially delayed to the second half. In addition, the costs for clinical development in the
	the initial target for R&D expenses in the first half?	U.S., will increase due to foreign exchange factors.
18	Isn't the foreign exchange gain considered much in the full-year forecast?	If the current level of ¥151 per dollar (in mid-November) continues until March next year, the exchange rate gain will
		increase because our forecast rate is ¥140 per dollar in the second half.
19	Although the development of NS-089 and NS-050 was initially planned for FPI in the first half of FY2023, the	As you can see, neither of them achieved FPI in the first half. The FPI of NS-089 is delayed due to a variety of factors,
	status has not changed from preparing for next study. Please tell us about the situation.	including lack of manpower at medical institutions. NS-050 is also delayed due to the hospitals' circumstances, we
		believe both will be able to achieve FPI by the end of this fiscal year.
20	P2 study of NS-580 for endometriosis is about to be completed. Will the future development plan be decided on	The clinical trial data for endometriosis has not unveiled. Based on the results of the P2 study for endometriosis, we
	the basis of the results of the recently launched P2a study for chronic prostatitis/chronic pelvic pain syndrome, or	intend to proceed its development without waiting for the results of the P2a trial for chronic prostatitis/chronic pelvic
	will the development for endometriosis proceed without waiting for the results of the P2a study? If you adopt the	pain syndrome. The market of this disease is a major, so we basically consider pursuing its development on a global
	latter case, are you going to include overseas as well as domestic? Are you looking for partners to sell?	scale while looking for partners overseas. We will continue to make preparations for the clinical trial consultations
		overseas without delay, while seeking partners.
21	I heard that interim analysis of P3 study of CAP-1002 was by the end of the year. Is it unchanged?	The interim analysis will be conducted as scheduled.
22	As for CAP-1002, the results of the interim analysis of Cohort A in the P3 study will be unveiled by the end of	Cohort A is a cohort that uses CAP-1002 manufactured at an investigational drug site. That's enough to get the approval.
	this year, and the final results will probably come out next year. Please tell us the purpose of Cohort B.	Cohort B will be tested with it manufactured at another site that has been set up for commercial use from the outset.
		This is a test to confirm whether the same result can be obtained even using it from different manufacturing sites. The
		specific schedule is not disclosed. We would like you to think cohort B will be completed a few years after the
		completion of cohort A.
23	Did you consider the buyback based on the current stock price situation?	We have received questions and requests about whether or not the Board of Directors is discussing the buyback at
		various meetings or other occasions. Our executives always sincerely discuss the buyback, effective use of cash on hand
		and stock prices. The Board of Directors has also begun the discussion.
24	What is a theme of the R&D Meeting this December?	It will mainly be our pipeline updates. We will let you know the details later.
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