Outline of Consolidated Financial Results for the Year Ended March 31, 2024

May 14, 2024
NIPPON SHINYAKU CO., LTD.

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FY2023 RESULTS AND FY2024 FULL-YEAR FORECASTS

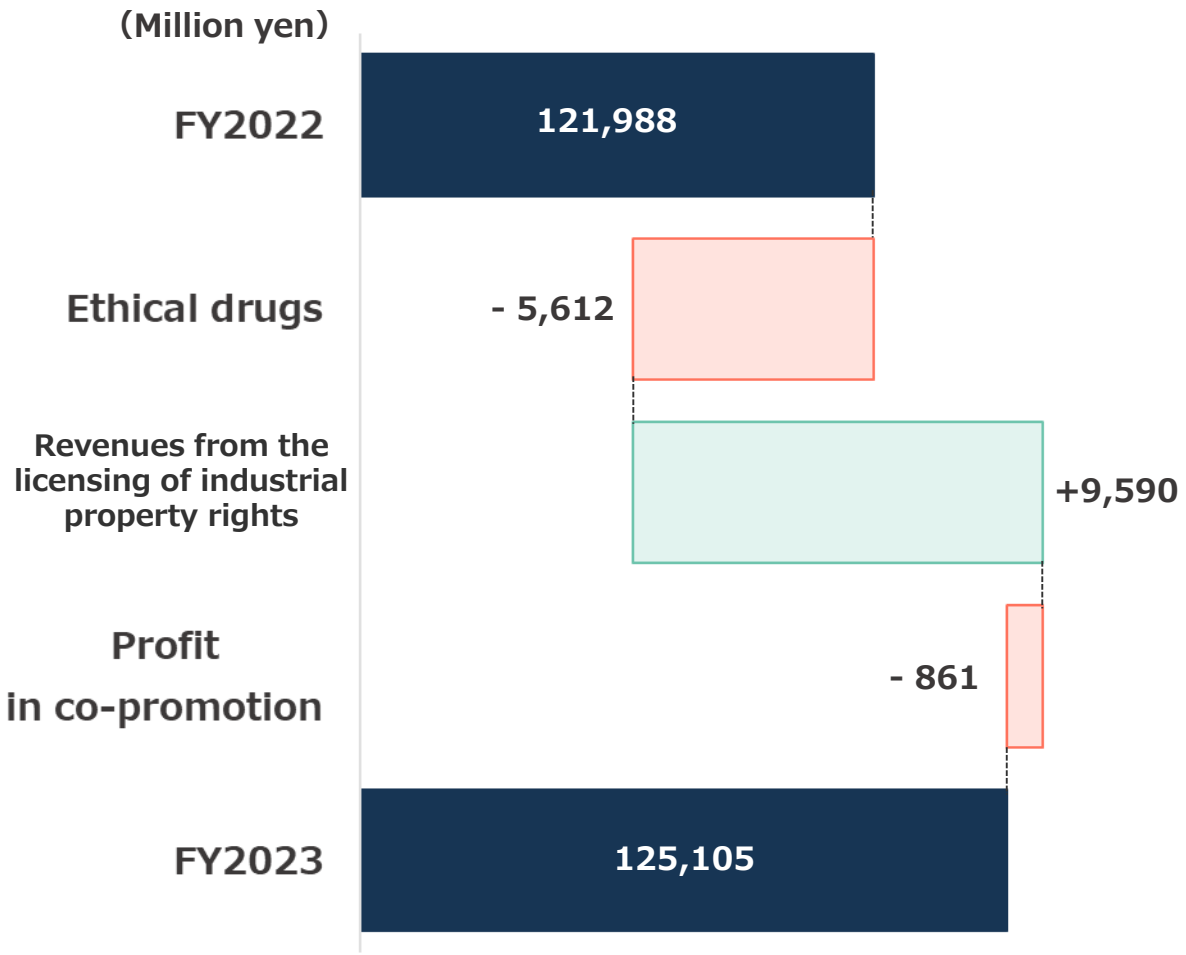
Toru Nakai

Representative Director, President

FY2023 Summary

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**144,175**	**100.0%**	**148,255**	**100.0%**	**+4,080**	**+2.8%**
(Pharmaceuticals)	(121,988)	(84.6%)	(125,105)	(84.4%)	(+3,116)	(+2.6%)
(Functional Food)	(22,187)	(15.4%)	(23,150)	(15.6%)	(+963)	(+4.3%)
Cost of sales	**55,980**	**38.8%**	**50,234**	**33.9%**	**-5,746**	**-10.3%**
SG&A expenses	**34,812**	**24.1%**	**34,959**	**23.6%**	**+146**	**+0.4%**
R&D expenses	**24,135**	**16.7%**	**31,676**	**21.4%**	**+7,541**	**+31.2%**
Other income	**1,908**	**1.3%**	**3,163**	**2.1%**	**+1,254**	**+65.7%**
(Foreign exchange gain)	(1,193)	(0.8%)	(2,486)	(1.7%)	(+1,292)	(+108.4%)
Other expenses	**1,106**	**0.8%**	**1,252**	**0.8%**	**+146**	**+13.2%**
Operating profit	**30,049**	**20.8%**	**33,295**	**22.5%**	**+3,245**	**+10.8%**
Finance income	**575**	**0.4%**	**650**	**0.4%**	**+75**	**+13.1%**
Finance costs	**136**	**0.1%**	**329**	**0.2%**	**+193**	**+142.4%**
Profit before tax	**30,489**	**21.1%**	**33,616**	**22.7%**	**+3,127**	**+10.3%**
Income tax expense, etc	**7,676**	**5.3%**	**7,765**	**5.2%**	**+88**	**+1.2%**
Profit attributable to owners of parent	**22,812**	**15.8%**	**25,851**	**17.4%**	**+3,038**	**+13.3%**

Segmental Review - Pharmaceuticals -



Ethical Drugs 76,141 million yen
(- 5,612 million yen, - 6.9%, YoY)

- ✓ Sales growth of Uptravi, Viltepso, etc.
- ✓ Decrease in sales of Vidaza, Tramal/Onetram, etc.
- ✓ Impact of NHI price revision

Revenues from the industrial property rights
40,304 million yen
(+9,590 million yen, +31.2%, YoY)

- ✓ Royalty revenue growth due to overseas sales of Uptravi

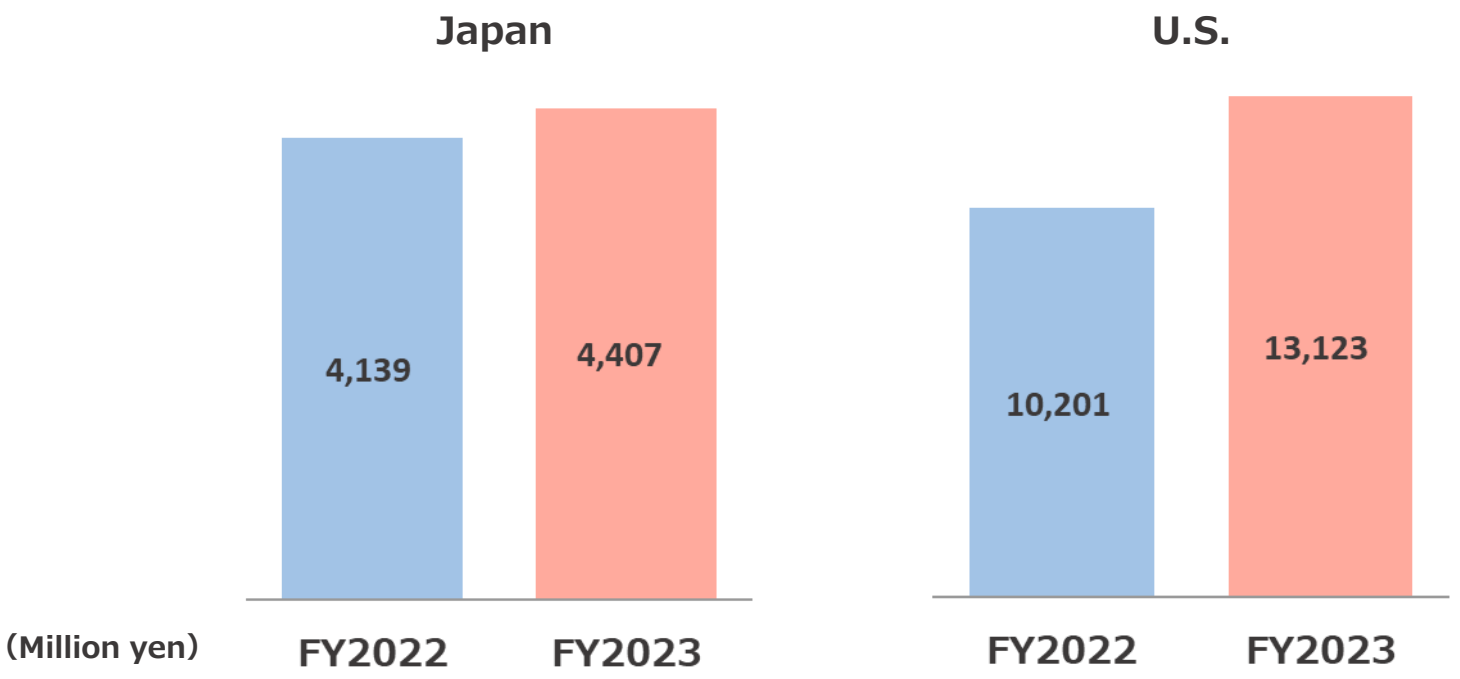
Profit in co-promotion 8,658 million yen
(- 861 million yen, - 9.0%, YoY)

- ✓ Sales growth of Opsumit and Erleada
- ✓ End of co-promotion of Zytiga

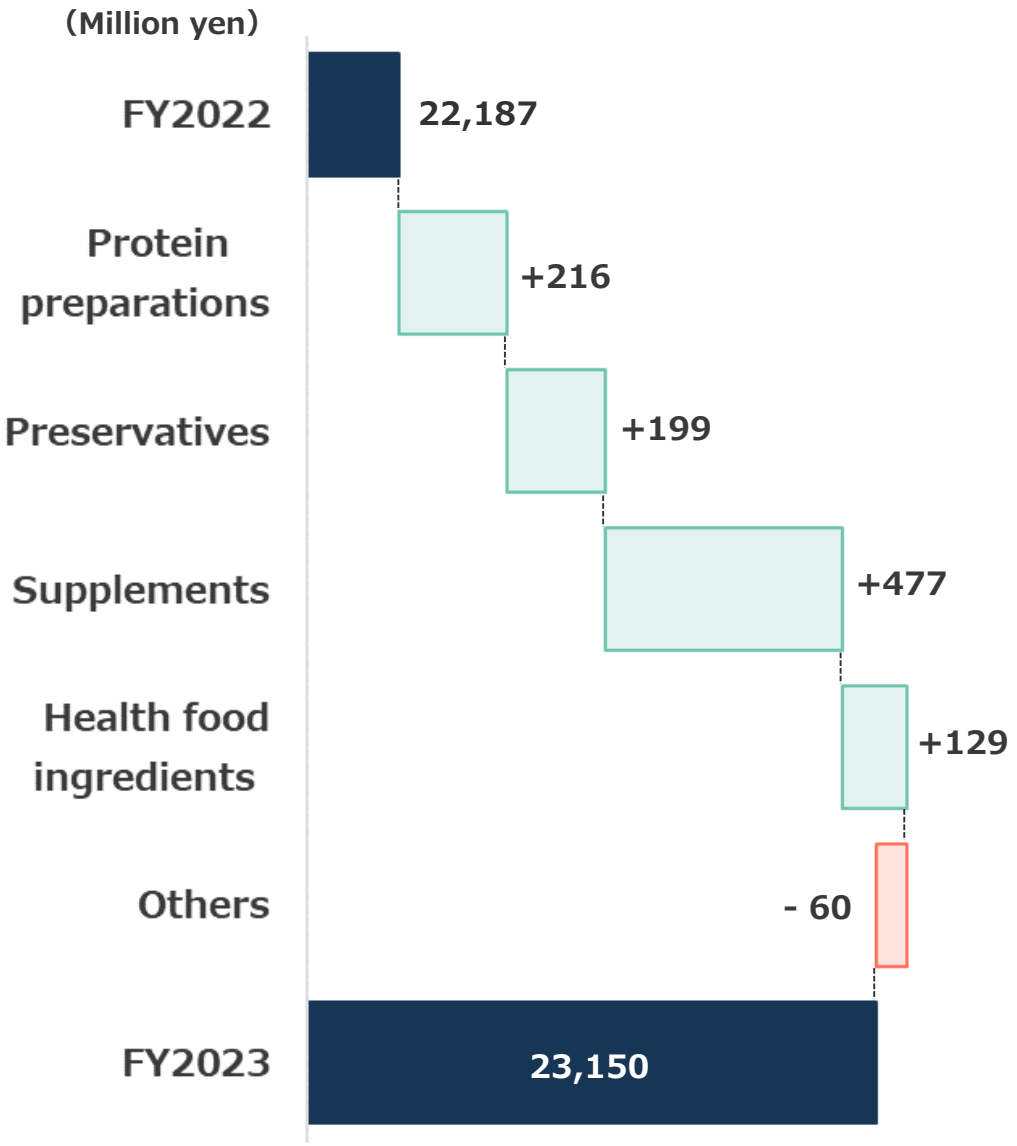
Sales Trends of Viltepso® (viltolarsen)

(Million yen)		FY2022 Results	FY2023 Results	YoY Change Amt	YoY Change %	
Viltepso	Japan	4,139	4,407	+268	+6.5%	✓The number of patients currently being administered is more than two-thirds of the peak number of 128 patients in the data from Chuikyo (Central Social Insurance Medical Council) .
	U.S.	10,201	13,123	+2,922	+28.6%	✓The number of patients receiving and wishing to receive Viltepso is increasing☐ ✓The results of P2 trial (Galactic53 trial) were presented as a poster presentation at 2024 MDA conference.
	total	14,341	17,530	+3,189	+22.2%	

Exchange rate	FY2022 Actual rate	FY2023 Actual rate
1USD	135.5yen	144.6yen



Segmental Review - Functional Food -



Protein preparations 15,600 million yen
(+216 million yen, +1.4%, YoY)

- ✓ Steady sales growth in protein preparations due to end of pandemic impact
- ✓ Increase in selling prices due to higher raw material prices

Preservatives 3,105 million yen
(+199 million yen, +6.9%, YoY)

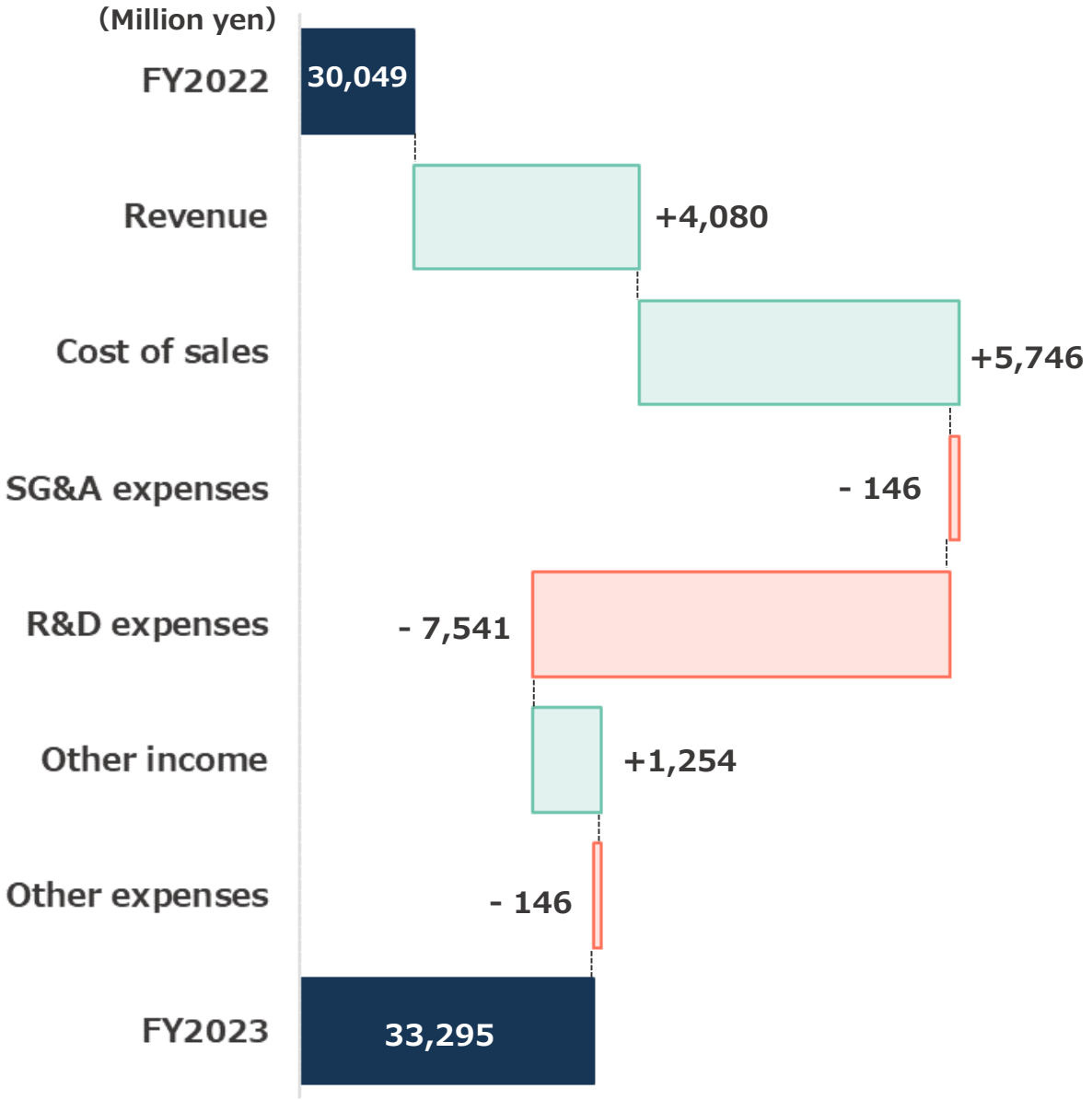
- ✓ Focus on new customer acquisition and extended use

Supplements 1,905 million yen
(+477 million yen, +33.4%, YoY)

- ✓ Sales growth of WINZONE Protein and other products due to increased sporting events nationwide

Health food ingredients 1,248 million yen
(+129 million yen, +11.6%, YoY)

Operating Profit



Cost of sales 50,234 million yen
(- 5,746 million yen, -10.3%, YoY)
The ratio was improved by 4.9 points YoY.

- ✓ Negative impact of NHI price revision
- ✓ Cost of sales ratio improvement due to factors such as revenues from industrial property rights and the change in sales segment mix (pharma vs. food)

SG&A expenses 34,959 million yen
(+146 million yen, +0.4%, YoY)

- ✓ Increase in labor costs
- ✓ Decrease in commission for promotional activities of Tramal/Onetram

R&D expenses 31,676 million yen
(+7,541 million yen, +31.2%, YoY)

- ✓ Increase in contract research expenses (nucleic acid drugs, etc.)

Other income 3,163 million yen
(+1,254 million yen, +65.8%, YoY)

- ✓ Foreign exchange gains (+1,292 million yen)

Business Forecast for FY2024 (consolidated)

(Million Yen)	FY2023 Results	FY2023 Ratio	FY2024 Forecast	FY2024 Ratio	YoY Change Amt	YoY Change %
Revenue	148,255	100.0%	150,000	100.0%	+1,745	+1.2%
(Pharmaceuticals)	(125,105)	(84.4%)	(128,500)	(85.7%)	(+3,395)	(+2.7%)
(Functional Food)	(23,150)	(15.6%)	(21,500)	(14.3%)	(-1,650)	(-7.1%)
Cost of sales	50,234	33.9%	48,900	32.6%	-1,334	-2.7%
SG&A expenses	34,959	23.6%	38,700	25.8%	+3,741	+10.7%
R&D expenses	31,676	21.4%	31,500	21.0%	-176	-0.6%
Other income	3,163	2.1%	500	0.3%	-2,663	-84.2%
Other expenses	1,252	0.8%	400	0.3%	-852	-68.1%
Operating profit	33,295	22.5%	31,000	20.7%	-2,295	-6.9%
Finance income	650	0.4%	600	0.4%	-50	-7.8%
Finance costs	329	0.2%	100	0.1%	-229	-69.7%
Profit before tax	33,616	22.7%	31,500	21.0%	-2,116	-6.3%
Income tax expense, etc	7,765	5.2%	7,000	4.7%	-765	-9.9%
Profit attributable to owners of parent	25,851	17.4%	24,500	16.3%	-1,351	-5.2%

Exchange rate	FY2023 Actual rate	FY2024 Forecast rate
1USD	144.6yen	140.0yen

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2023		FY2024		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	76,141	60.9%	77,700	60.5%	+1,559	+2.0%
Revenue from the licensing of industrial property rights	40,304	32.2%	41,700	32.4%	+1,396	+3.5%
Profit in co-promotion	8,658	6.9%	9,100	7.1%	+442	+5.1%
Revenue	125,105	100.0%	128,500	100.0%	+3,395	+2.7%

Despite the impacts from NHI price revision and the competitions with generics, we expect an increase in revenues mainly due to the growth of Viltepso and Uptravi as well as growth in royalty income associated with overseas sales of Uptravi.

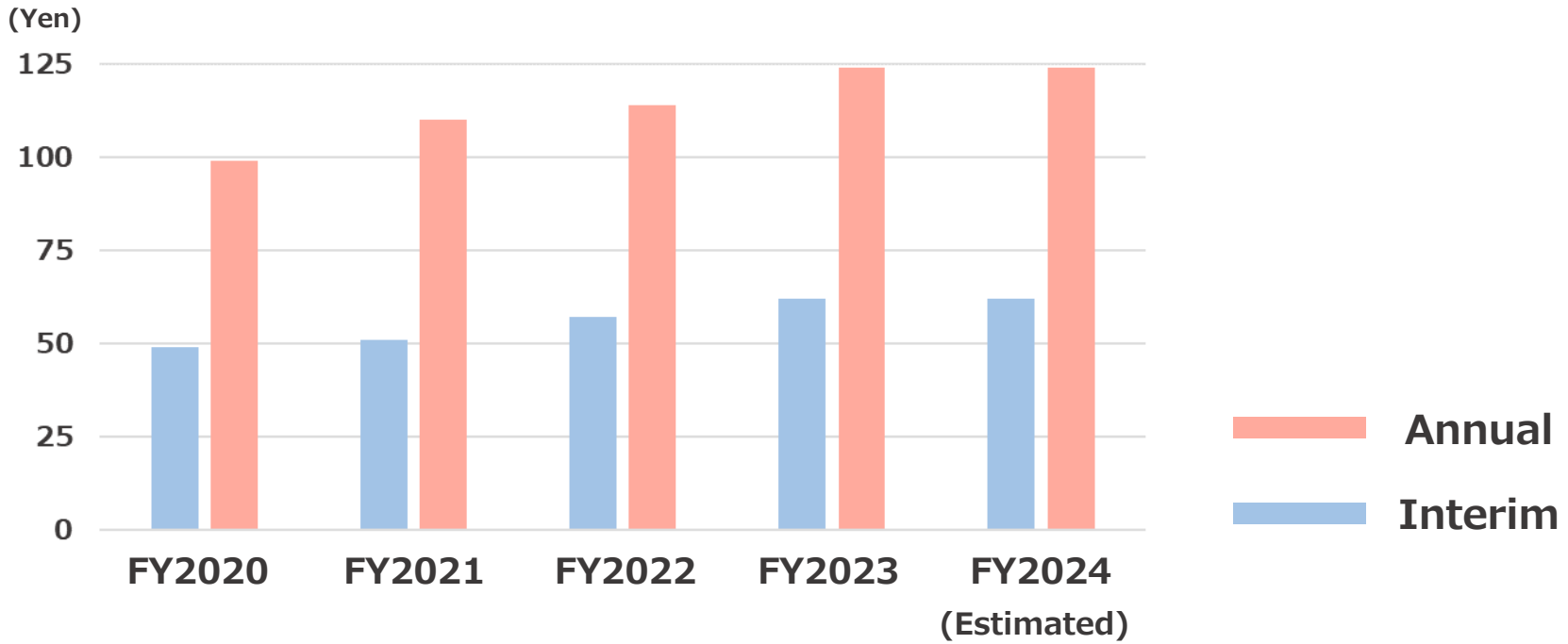
Segmental Forecast - Functional Food -

(Million yen)	FY2023		FY2024		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	15,600	67.4%	13,000	60.5%	-2,600	-16.7%
Preservatives	3,105	13.4%	3,200	14.9%	+95	+3.0%
Supplements	1,905	8.2%	3,100	14.4%	+1,195	+62.7%
Health food ingredients	1,248	5.4%	1,100	5.1%	-148	-11.9%
Others	1,291	5.6%	1,100	5.1%	-191	-14.8%
Revenue	23,150	100.0%	21,500	100.0%	-1,650	-7.1%

Although we will further focus on development and introduction of new products and strengthen sales efforts in marketed products, a decrease in sales is expected due to the impact from declining prices of some products.

Dividends Forecast

		FY2023	FY2024
Dividends per share	Interim	¥62	¥62
	Annual	¥124	¥124
Basic earnings per share		¥383.82	¥363.76
Payout ratio (consolidated)		32.3 %	34.1 %



R&D PIPELINE

Kazuchika Takagaki
Director, Research & Development

R&D Updates (1/2)

For updates since February 9, 2024, see highlighted text in red.

Recent status/event	Code No. (Generic name)	Product name	Indications and topics	Schedule
Launch	ZX008 (fenfluramine)	Fintepla	Lennox-Gastaut syndrome (additional indication)	Approved in March 2024
Approval	NS-87 (daunorubicin / cytarabine)	Vyxeos	high-risk acute myeloid leukemia	Approved in March 2024 To be launched after NHI drug price listing
In application	NS-304 (selexipag)	Uptravi	pediatric pulmonary arterial hypertension	April 2024
Start of P3	ZX008 (fenfluramine)	Fintepla	CDKL5 deficiency	July 2023
	GA101 (obinutuzumab)	Gazyva	systemic lupus erythematosus without nephropathy	October 2023
Start of P2	NS-089/NCNP-02 (brogidirsen)	–	Duchenne muscular dystrophy	February 2024
Start of P1	NS-863	–	cardiovascular diseases	August 2023
In-license (Vicore Pharma, Sweden)	C21	–	idiopathic pulmonary fibrosis	Contract signed in February 2024
Alliance Agreement (Eli Lilly Japan)	LY3527727 (piltobrutinib)	–	mantle cell lymphoma (MCL) / chronic lymphocytic leukemia (CLL)	Contract signed in March 2024
Temporarily suspended	NS-580	–	endometriosis chronic prostatitis / chronic pelvic pain syndrome	–
Terminated	NS-018 (ilginatinib)	–	myelofibrosis	–
	NS-161	–	inflammatory disease	–

R&D Updates (2/2)

For updates since February 9, 2024, see highlighted text in red.

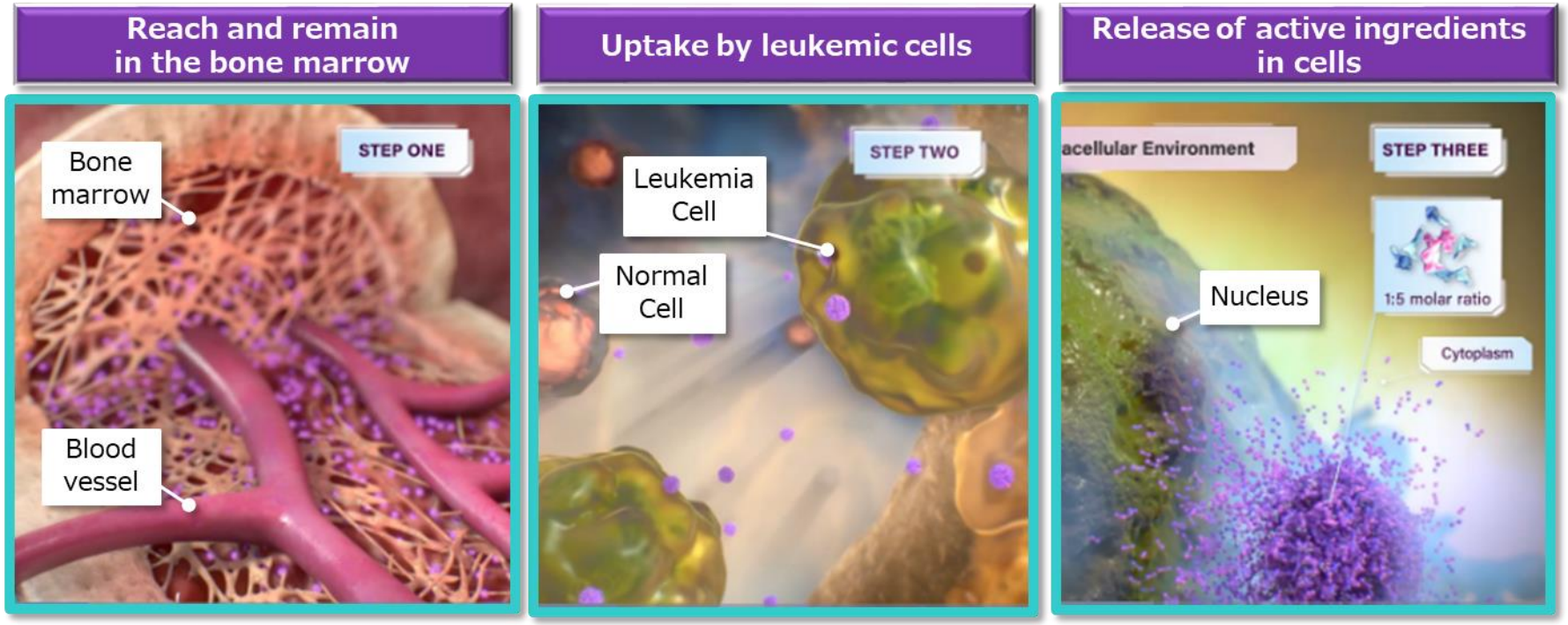
Recent status/event	Code No. (Generic name)	Product name	Indications and topics	Schedule
Conference Presentations	NS-065/NCNP-01 (viltolarsen)	Viltepso	Phase 2 trial (Galactic53): 2024 Muscular Dystrophy Association Clinical & Scientific Conference	March 2024
Manuscript	NS-065/NCNP-01 (viltolarsen)	Viltepso	Long-term study analysis data (after 4 years of treatment):Journal of Neuromuscular Diseases	May 2023
	NS-089/NCNP-02 (brogidirsen)	–	Non-clinical data: (Molecular Therapy Nucleic Acids)	October 2023
Rare Pediatric Disease Designation	NS-089/NCNP-02 (brogidirsen)	–	Duchenne muscular dystrophy	June 2023 (U.S.)
Breakthrough Therapy Designation				July 2023 (U.S.)
Orphan Drug Designation				July 2023 (U.S.)
				December 2023 (EU)
Orphan Drug Designation	NS-401 (tagraxofusp)	–	blastic plasmacytoid dendritic cell neoplasm	August 2023 (Japan)
Orphan Drug Designation	NS-229	–	eosinophilic granulomatosis with polyangiitis	January 2024 (EU)
Alliance (MiNA Therapeutics)	–	–	a joint research agreement with the aim of creating nucleic acid medicines that are expected to be applied to an intractable and rare disease in the CNS field	April 2024

Vyxeos® (NS-87)

Combination for I.V. Injection for the Treatment of High-risk AML

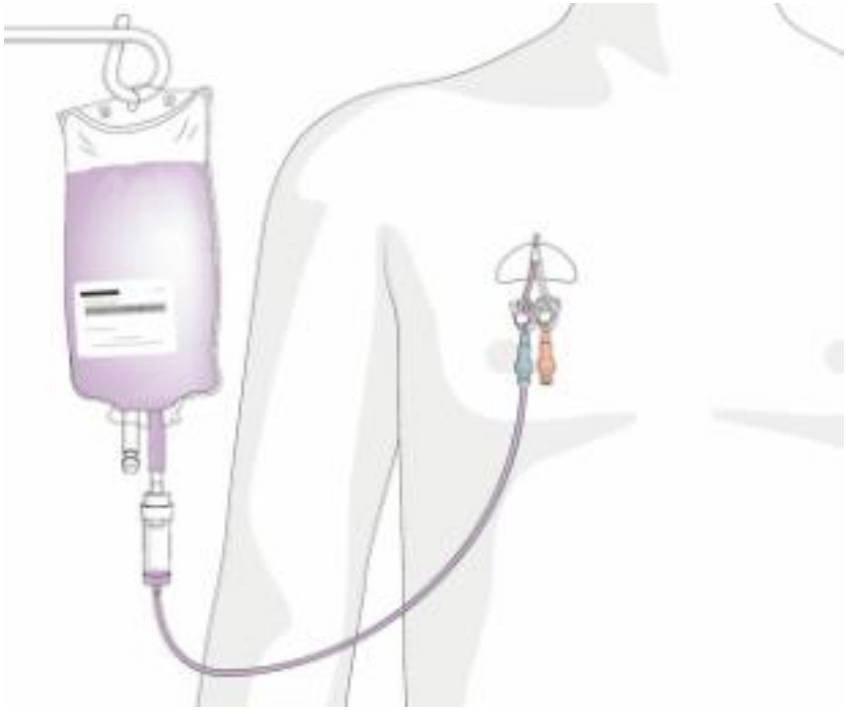
Characteristics of Vyxeos® (NS-87)

- Liposomal formulation of cytarabine and daunorubicin in a 5:1 molar ratio
- It reaches the bone marrow as liposomes and remains for a long time.
- After the drug is taken up into leukemic cells in the bone-marrow, cytarabine and daunorubicin are released to exert their antitumor effects.



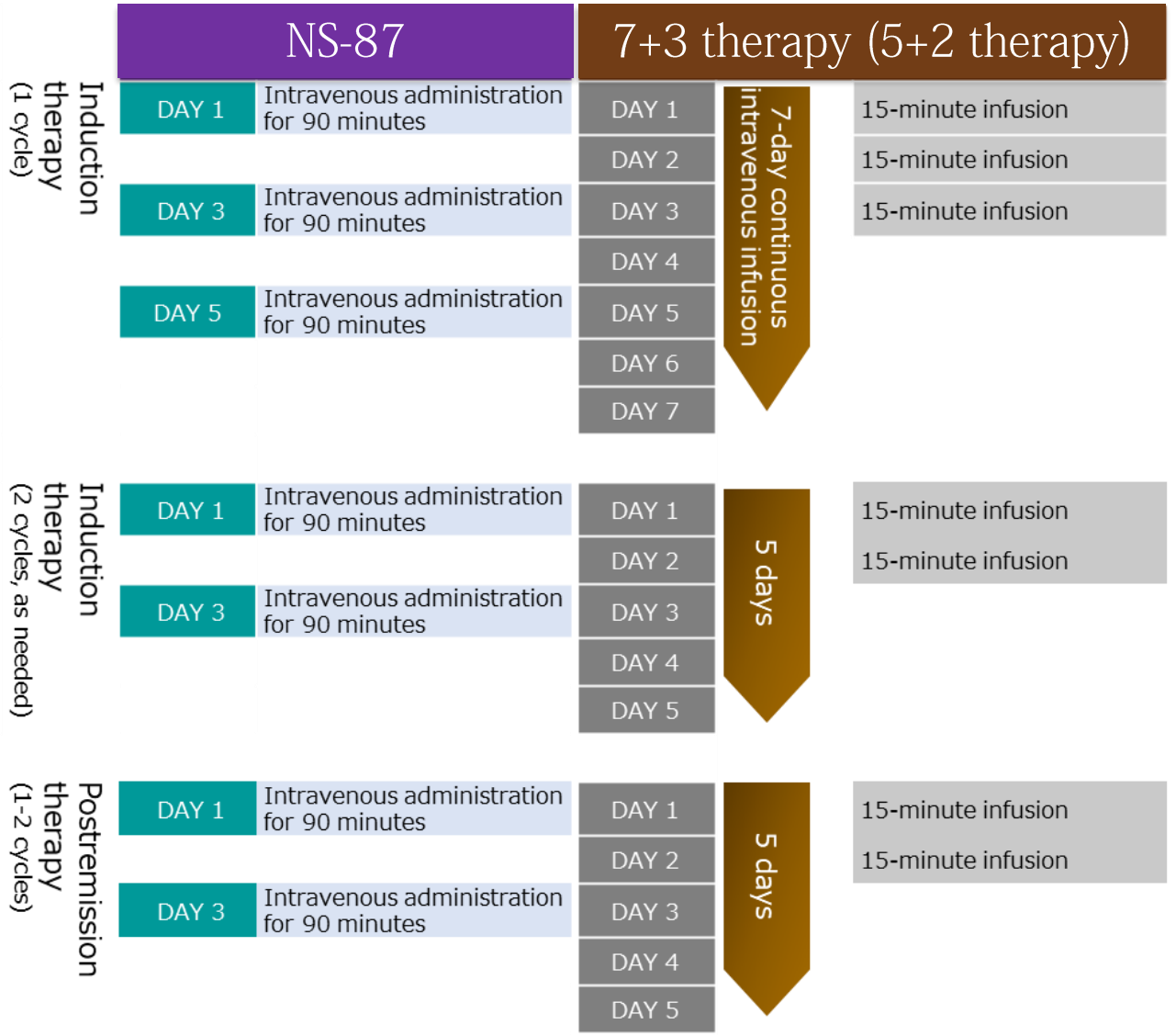
Reference: JAZZ Pharmaceuticals website
"Mechanism of Delivery"
https://vyxeospro.com/mechanism-of-delivery

Time and Duration of Vyxeos® (NS-87)



JAZZ-HP VYXEOS preparation and administration
https://vyxeospro.com/dosing-ordering/preparation

NS-87 vs 7+3 therapy (overseas P3 study)



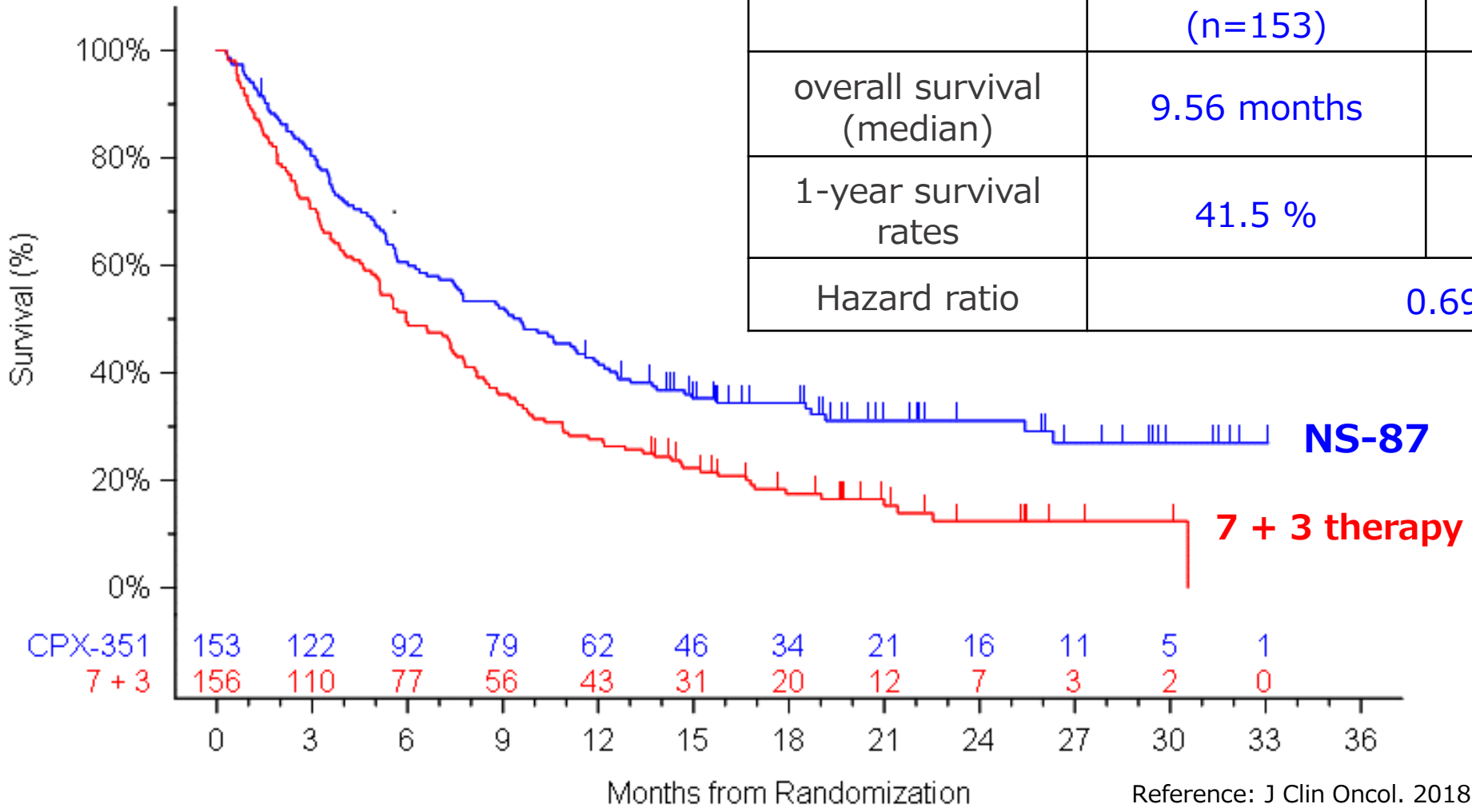
Vyxeos® (NS-87) Overseas P3 study

Subjects: Untreated high-risk AML 309 aged 60-75 years
Control group: 7 + 3 therapy (AraC 100 mg/m^2 + DNR 60 mg/m^2)

[Primary: overall survival(OS)]

	NS-87 (n=153)	7+3 therapy (n=156)
overall survival (median)	9.56 months	5.95 months
1-year survival rates	41.5 %	27.6 %
Hazard ratio	0.69	

Log rank p=0.003



Reference: J Clin Oncol. 2018 Sep 10;36(26):2684-2692

REFERENCE MATERIALS

Sales By Product in Pharmaceutical Segment

(Million yen)

Brand name	Indications	FY2022 Results	FY2023 Results	YoY Change	FY2024 Forecast
Viltepso	Duchenne muscular dystrophy	14,341	17,530	+22.2%	20,100
(Japan)		(4,139)	(4,407)	(+6.5%)	(4,600)
(U.S.)		(10,201)	(13,123)	(+28.6%)	(15,500)
Uptravi	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	10,543	12,918	+22.5%	15,400
Vidaza	myelodysplastic syndrome/ acute myeloid leukemia	15,951	10,383	- 34.9%	4,800
Gazyva	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	4,904	4,695	- 4.3%	5,100
Tramal/Onetram	cancer pain, chronic pain	5,358	3,927	- 26.7%	2,700
Cialis	erectile dysfunction	2,938	2,499	- 15.0%	2,700
Erizas	allergic rhinitis	2,640	2,284	- 13.5%	2,100
Zalutia	urinary disorder caused by benign prostatic hyperplasia	2,826	2,256	- 20.2%	1,600
Adcirca	pulmonary arterial hypertension	2,649	2,255	- 14.9%	1,700
Defitelio	sinusoidal obstruction syndrome	2,524	2,221	- 12.0%	2,300
Profit in co-promotion		9,520	8,658	- 9.0%	9,100
Revenues from the licensing of industrial property rights		30,714	40,304	+31.2%	41,700
Revenue		121,988	125,105	+2.6%	128,500

Sales by Product Group in Functional Food Segment

(Million yen)	FY2022		FY2023		YoY Change		FY2024
	Results	Ratio	Results	Ratio	Amt	%	Forecast
Protein preparations	15,383	69.3%	15,600	67.4%	+216	+1.4%	13,000
Preservatives	2,905	13.1%	3,105	13.4%	+199	+6.9%	3,200
Supplements	1,428	6.4%	1,905	8.2%	+477	+33.4%	3,100
Health food ingredients	1,118	5.0%	1,248	5.4%	+129	+11.6%	1,100
Others	1,351	6.1%	1,291	5.6%	-60	-4.5%	1,100
Revenue	22,187	100.0%	23,150	100.0%	+963	+4.3%	21,500

Consolidated Balance Sheet

(Million yen)	End of FY2022	End of FY2023	Change Amt		End of FY2022	End of FY2023	Change Amt
Assets	237,451	263,404	+25,952	Liabilities	41,518	42,870	+1,352
Current assets	157,873	164,285	+6,411	Current liabilities	35,183	37,336	+2,153
Non-current assets	79,578	99,119	+19,541	Non-current liabilities	6,334	5,533	-801
				Equity	195,933	220,534	+24,600
Total aseets	237,451	263,404	+25,952	Total liabilities and equity	237,451	263,404	+25,952

Assets

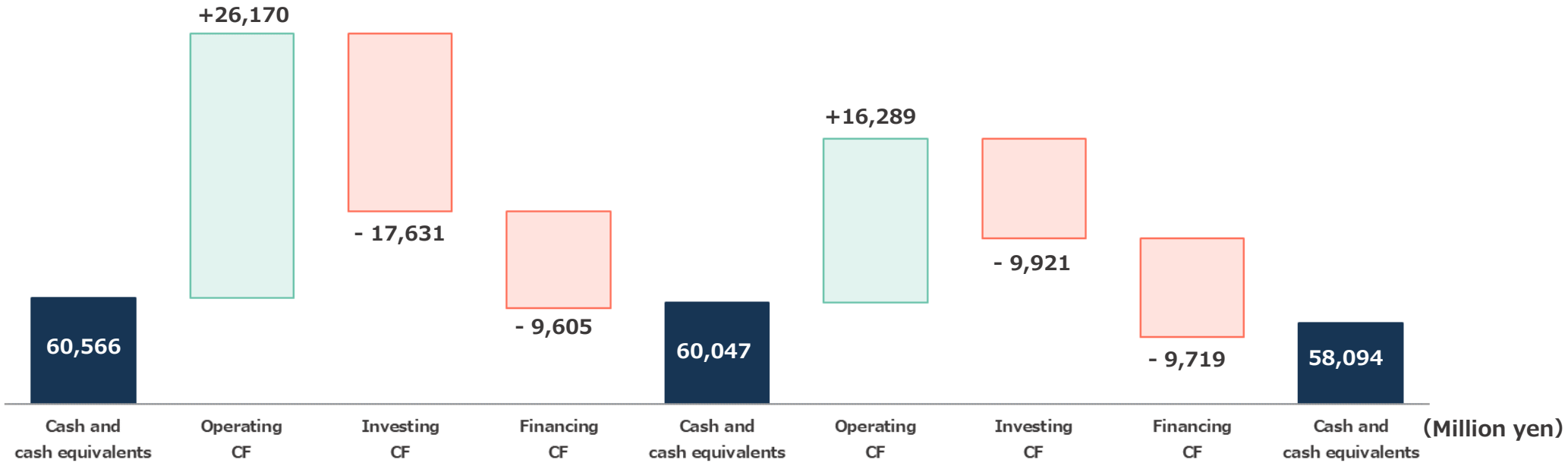
Inventories	+ 2,752
Trade and other receivables	+ 2,551
Other financial assets (non-current)	+ 10,553

Liabilities and Shareholders' Equity

Trade and other payables	+4,627
Liabilities for retirement benefits	- 805

Consolidated Statements of Cash Flows

(Million yen)	FY2022 Results	FY2023 Results	YoY Change Amt
Operating activities	26,170	16,289	-9,880
Investing activities	-17,631	-9,921	7,710
Financing activities	-9,605	-9,719	-113
Cash and cash equivalents at end of period	60,047	58,094	-1,953



Pipeline（1/2）

Stage	Code No. (Generic name)	Origin	Application type	Indications	Schedule	Country
Launch P3	NS-065/NCNP-01	In-house	NME	Duchenne muscular dystrophy	Around the spring of FY2024 P3 data presentation	Japan/U.S.
Preparing for launch	NS-87 (daunorubicin / cytarabine)	In-house	New combination	high-risk acute myeloid leukemia	Approval : March in 2024	Japan
NDA filing	NS-304 (selexipag)	In-house	New dose	pediatric pulmonary arterial hypertension	Study Completion : FY 2024 Application : April in 2024	Japan
NDA filing P3	LY3527727 (pirtobrutinib)	Alliance agreement	NME	mantle cell lymphoma	—	Japan
P3	ZX008 (fenfluramine hydrochloride)	Distribution partnership	New indication	CDKL5 deficiency disorder	Study Completion : FY2026	Japan
	GA101 (obinutuzumab)	In-license	New indication	lupus nephritis	Projected submission : 2026	Japan
				pediatric nephrotic syndrome	Projected submission : 2026	Japan
				extra renal lupus	Projected submission : 2027 and beyond	Japan
	CAP-1002	Partnership	NME	Duchenne muscular dystrophy	Topline data : end of 2024	U.S.
	LY3527727 (pirtobrutinib)	Alliance agreement	NME	chronic lymphocytic leukemia	—	Japan

Pipeline（2/2）

Stage	Code No. (Generic name)	Origin	Application type	Indications	Schedule	Country
P2	NS-304 (selexipag)	In-house	New indication	arteriosclerosis obliterans	Study Completion : FY2024	Japan
	NS-580	In-house	NME	endometriosis	Temporarily suspended	Japan
				chronic prostatitis/ chronic pelvic pain syndrome	Temporarily suspended	Japan
	NS-089/NCNP-02 (brogidirsen)	In-house	NME	Duchenne muscular dystrophy	Study Completion : FY2025 FPI : February in 2024	Japan/U.S.
Preparing for P2	NS-229	In-house	NME	eosinophilic granulomatosis with polyangiitis	Study Completion : FY2025	Japan/U.S.
P1/2	NS-401 (tagraxofusp)	In-license	NME	blastic plasmacytoid dendritic cell neoplasm	Study Completion : FY2026	Japan
Preparing for P1/2	NS-050/NCNP-03	In-house	NME	Duchenne muscular dystrophy	Study Completion : FY2027 FPI : 1H of FY2024（estimated）	Japan/U.S.
P1	NS-917 (radgocitabine)	In-license	NME	relapsed/refractory acute myeloid leukemia	Study Completion : FY2024	Japan
	NS-025	In-house	NME	urological diseases	Study Completion : FY2024	Japan
	NS-863	In-house	NME	cardiovascular diseases	Study Completion : FY2024	Japan

NS-065/NCNP-01 (viltolarsen)

- Treatment for Duchenne muscular dystrophy -

Development Phase	・Japan : Launch ・U.S. : Launch ・Global : P3 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 : Approval
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 : Launch（Lennox-Gastaut syndrome) Japan : P3 (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.

LY3527727(pirtobrutinib)

- Treatment for Mantle cell lymphoma, Chronic lymphocytic leukemia -

Development Phase	NDA filing, P3
Origin	[Mar. 2024] Alliance agreement in Japan : Eli Lilly Japan
Development	Eli Lilly Japan
Mechanism of action	A reversible non-covalent BTK inhibitor
Indication	mantle cell lymphoma (MCL) chronic lymphocytic leukemia (CLL)
Dosage form	Oral agent
Feature	・A highly selective, non-covalent (reversible) inhibitor of the enzyme Bruton's tyrosine kinase (BTK), with having a novel binding mechanism.

CAP-1002

- Treatment for Duchenne muscular dystrophy -

Development Phase	U.S. : P3
Origin	[Jan. 2022] Partnership for commercialization in U.S. [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 : P3 (LN) Global : P3 (PNS) Japan : P3 (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 : P2b (ASO) Japan : P2, NDA filing (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 : P2b (endometriosis) Japan : P2a (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-089/NCNP-02（brogidirsen）

- Treatment for Duchenne muscular dystrophy -

Development Phase	Global : P2
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 P2
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 : P1/2
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 P1/2
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 : P1
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-025

- Treatment for urological diseases -

Development Phase	Japan : P1
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 : P1
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	–
Indication	Cardiovascular diseases (to be determined)
Dosage form	Oral agent
Feature	–

Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.

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

- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.

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- This English presentation was translated from the original Japanese version. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

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Nippon Shinyaku Co., Ltd.

IR Meeting (Q4/FY2023)

May 14, 2024

Presentation

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

Thank you very much for taking time out of your busy schedule to participate in our FY2023 financial results briefing today. I appreciate it very much.

Today, I would like to report on our business performance for FY2023 and our full-year business forecast for FY2024, and Mr. Takagaki will explain the progress of our R&D pipeline.

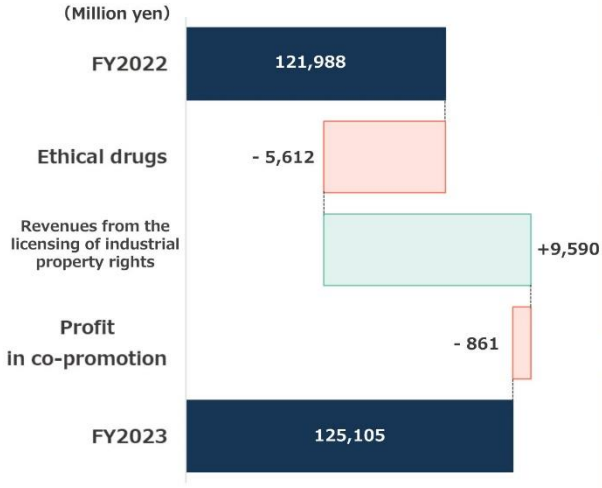
FY2023 Summary

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	144,175	100.0%	148,255	100.0%	+4,080	+2.8%
(Pharmaceuticals)	(121,988)	(84.6%)	(125,105)	(84.4%)	(+3,116)	(+2.6%)
(Functional Food)	(22,187)	(15.4%)	(23,150)	(15.6%)	(+963)	(+4.3%)
Cost of sales	55,980	38.8%	50,234	33.9%	-5,746	-10.3%
SG&A expenses	34,812	24.1%	34,959	23.6%	+146	+0.4%
R&D expenses	24,135	16.7%	31,676	21.4%	+7,541	+31.2%
Other income	1,908	1.3%	3,163	2.1%	+1,254	+65.7%
(Foreign exchange gain)	(1,193)	(0.8%)	(2,486)	(1.7%)	(+1,292)	(+108.4%)
Other expenses	1,106	0.8%	1,252	0.8%	+146	+13.2%
Operating profit	30,049	20.8%	33,295	22.5%	+3,245	+10.8%
Finance income	575	0.4%	650	0.4%	+75	+13.1%
Finance costs	136	0.1%	329	0.2%	+193	+142.4%
Profit before tax	30,489	21.1%	33,616	22.7%	+3,127	+10.3%
Income tax expense, etc	7,676	5.3%	7,765	5.2%	+88	+1.2%
Profit attributable to owners of parent	22,812	15.8%	25,851	17.4%	+3,038	+13.3%

Please see page three of the slides.

As an overview of our performance in FY2023, we reported consolidated revenue of JPY148,255 million, operating profit of JPY33,295 million, profit before income taxes of JPY33,616 million, and net profit attributable to owners of the parent of JPY25,851 million.

Segmental Review - Pharmaceuticals -



Ethical Drugs 76,141 million yen
(- 5,612 million yen, - 6.9%, YoY)

- ✓ Sales growth of Uptravi, Viltepso, etc.
- ✓ Decrease in sales of Vidaza, Tramal/Onetram, etc.
- ✓ Impact of NHI price revision

Revenues from the industrial property rights
40,304 million yen
(+9,590 million yen, +31.2%, YoY)

- ✓ Royalty revenue growth due to overseas sales of Uptravi

Profit in co-promotion 8,658 million yen
(- 861 million yen, - 9.0%, YoY)

- ✓ Sales growth of Opsumit and Erleada
- ✓ End of co-promotion of Zytiga

Please see page four of the slides.

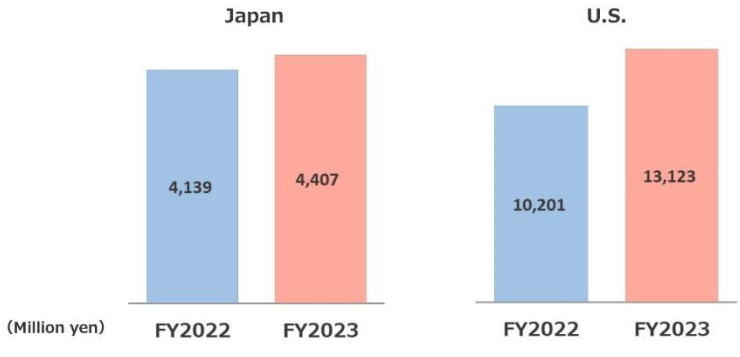
In the pharmaceuticals business, although sales of products such as Vidaza decreased due to the impact of drug price revisions and generic products, sales of Uptravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and Viltepso, a treatment for Duchenne muscular dystrophy, increased, as well as royalty income from overseas sales of Uptravi.

As a result, consolidated revenue was JPY125,105 million, an increase of 2.6% YoY.

Sales Trends of Viltepso® (viltolarsen)

(Million yen)		FY2022 Results	FY2023 Results	YoY Change Amt	YoY Change %	
Viltepso	Japan	4,139	4,407	+268	+6.5%	✓The number of patients currently being administered is more than two-thirds of the peak number of 128 patients in the data from Chuikyo (Central Social Insurance Medical Council) .
	U.S.	10,201	13,123	+2,922	+28.6%	✓The number of patients receiving and wishing to receive Viltepso is increasing☐ ✓The results of P2 trial (Galactic53 trial) were presented as a poster presentation at 2024 MDA conference.
	total	14,341	17,530	+3,189	+22.2%	

Exchange rate	FY2022 Actual rate	FY2023 Actual rate
1USD	135.5yen	144.6yen



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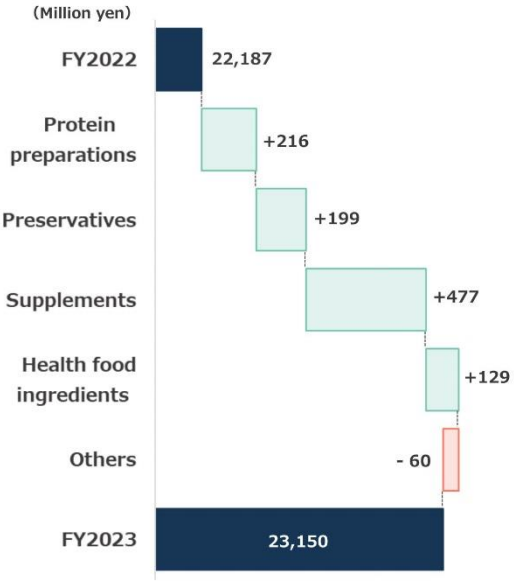
Please see page five of the slides.

Here we show sales of Viltepso, a treatment for Duchenne muscular dystrophy, which is marketed in Japan and the United States.

As for sales results for FY2023, sales in both Japan and the US increased YoY, totaling JPY4,407 million in Japan and JPY13,123 million in the US.

Segmental Review - Functional Food -



Protein preparations 15,600 million yen
(+216 million yen, +1.4%, YoY)

- ✓ Steady sales growth in protein preparations due to end of pandemic impact
- ✓ Increase in selling prices due to higher raw material prices

Preservatives 3,105 million yen
(+199 million yen, +6.9%, YoY)

- ✓ Focus on new customer acquisition and extended use

Supplements 1,905 million yen
(+477 million yen, +33.4%, YoY)

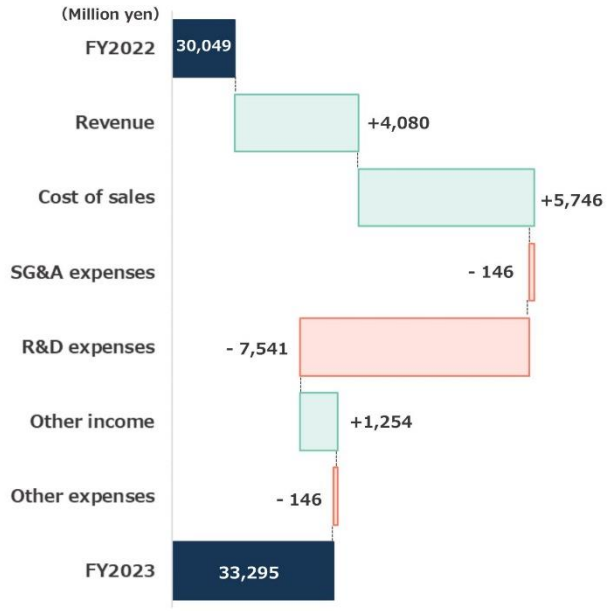
- ✓ Sales growth of WINZONE Protein and other products due to increased sporting events nationwide

Health food ingredients 1,248 million yen
(+129 million yen, +11.6%, YoY)

Please see page six of the slides.

In the functional food business, sales of supplements and other products, centering on WINZONE Protein, increased due to changes in the market, including an increase in the number of sporting events held in various regions as the impact of the new coronavirus infection eased, resulting in consolidated net sales of JPY23,150 million, up 4.3% YoY.

Operating Profit



Cost of sales 50,234 million yen
(- 5,746 million yen, -10.3%, YoY)
The ratio was improved by 4.9 points YoY.
- ✓ Negative impact of NHI price revision
- ✓ Cost of sales ratio improvement due to factors such as revenues from industrial property rights and the change in sales segment mix (pharma vs. food)

SG&A expenses 34,959 million yen
(+146 million yen, +0.4%, YoY)
- ✓ Increase in labor costs
- ✓ Decrease in commission for promotional activities of Tramal/Onetram

R&D expenses 31,676 million yen
(+7,541 million yen, +31.2%, YoY)
- ✓ Increase in contract research expenses (nucleic acid drugs, etc.)

Other income 3,163 million yen
(+1,254 million yen, +65.8%, YoY)
- ✓ Foreign exchange gains (+1,292 million yen)

Please see page seven of the slides.

As for operating expenses, the cost of sales ratio improved by 4.9 percentage points YoY to 33.9%, due to factors such as industrial property revenues and sales mix, despite the impact of the NHI price revision.

SG&A expenses increased 0.4% YoY to JPY34,959 million, mainly due to an increase in personnel expenses, despite a decrease in commission fees for Tramal's promotional activities.

R&D expenses totaled JPY31,676 million, up 31.2% YoY, mainly due to an increase in contract research expenses. As a result, operating profit was JPY33,295 million, up 10.8% YoY.

Business Forecast for FY2024 (consolidated)

(Million Yen)	FY2023 Results	FY2023 Ratio	FY2024 Forecast	FY2024 Ratio	YoY Change Amt	YoY Change %
Revenue	148,255	100.0%	150,000	100.0%	+1,745	+1.2%
(Pharmaceuticals)	(125,105)	(84.4%)	(128,500)	(85.7%)	(+3,395)	(+2.7%)
(Functional Food)	(23,150)	(15.6%)	(21,500)	(14.3%)	(-1,650)	(-7.1%)
Cost of sales	50,234	33.9%	48,900	32.6%	-1,334	-2.7%
SG&A expenses	34,959	23.6%	38,700	25.8%	+3,741	+10.7%
R&D expenses	31,676	21.4%	31,500	21.0%	-176	-0.6%
Other income	3,163	2.1%	500	0.3%	-2,663	-84.2%
Other expenses	1,252	0.8%	400	0.3%	-852	-68.1%
Operating profit	33,295	22.5%	31,000	20.7%	-2,295	-6.9%
Finance income	650	0.4%	600	0.4%	-50	-7.8%
Finance costs	329	0.2%	100	0.1%	-229	-69.7%
Profit before tax	33,616	22.7%	31,500	21.0%	-2,116	-6.3%
Income tax expense, etc	7,765	5.2%	7,000	4.7%	-765	-9.9%
Profit attributable to owners of parent	25,851	17.4%	24,500	16.3%	-1,351	-5.2%

Exchange rate	FY2023 Actual rate	FY2024 Forecast rate
1USD	144.6yen	140.0yen

Please see page eight of the slides. Next, I will explain our earnings forecast for FY2024.

Consolidated sales revenue is expected to be JPY150,000 million. Regarding operating expenses, the cost of sales ratio is expected to be 32.6%, an improvement of 1.3 percentage points YoY. SG&A expenses are expected to be JPY38,700 million, and R&D expenses are expected to be JPY31,500 million.

As a result, we expect operating profit of JPY31,000 million, profit before income taxes of JPY31,500 million, and net profit attributable to owners of the parent of JPY24,500 million, a decrease from the previous year.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2023		FY2024		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	76,141	60.9%	77,700	60.5%	+1,559	+2.0%
Revenue from the licensing of industrial property rights	40,304	32.2%	41,700	32.4%	+1,396	+3.5%
Profit in co-promotion	8,658	6.9%	9,100	7.1%	+442	+5.1%
Revenue	125,105	100.0%	128,500	100.0%	+3,395	+2.7%

Despite the impacts from NHI price revision and the competitions with generics, we expect an increase in revenues mainly due to the growth of Viltepso and Uptravi as well as growth in royalty income associated with overseas sales of Uptravi.

Please see page nine of the slides.

In the pharmaceuticals business, we forecast revenue of JPY128,500 million, an increase of 2.7% YoY. Despite the effect of NHI price revision and generic products, the Company expects an increase in revenues due to growth in sales of Viltepso, Uptravi, and other products, as well as growth in royalty income from overseas sales of Uptravi.

Segmental Forecast - Functional Food -

(Million yen)	FY2023		FY2024		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	15,600	67.4%	13,000	60.5%	-2,600	-16.7%
Preservatives	3,105	13.4%	3,200	14.9%	+95	+3.0%
Supplements	1,905	8.2%	3,100	14.4%	+1,195	+62.7%
Health food ingredients	1,248	5.4%	1,100	5.1%	-148	-11.9%
Others	1,291	5.6%	1,100	5.1%	-191	-14.8%
Revenue	23,150	100.0%	21,500	100.0%	-1,650	-7.1%

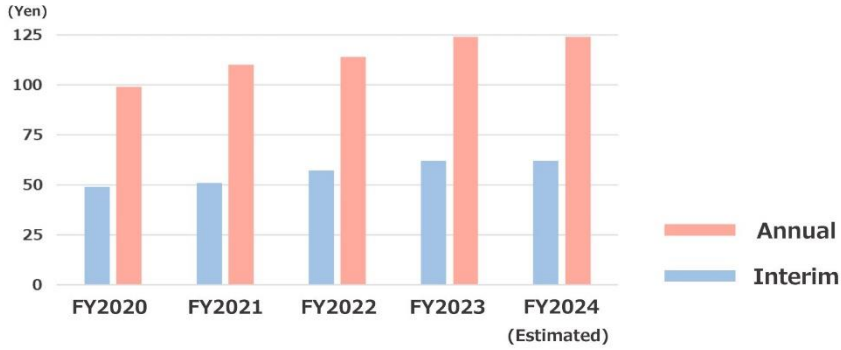
Although we will further focus on development and introduction of new products and strengthen sales efforts in marketed products, a decrease in sales is expected due to the impact from declining prices of some products.

Please see page 10 of the slides.

In the functional food business, we expect sales revenue to decrease 7.1% YoY to JPY21,500 million, due in part to the impact from declining prices of some products, although we will strengthen our efforts in marketed products.

Dividends Forecast

		FY2023	FY2024
Dividends per share	Interim	¥62	¥62
	Annual	¥124	¥124
Basic earnings per share		¥383.82	¥363.76
Payout ratio (consolidated)		32.3 %	34.1 %



Please see page 11 of the slides.

We plan to pay an annual dividend of JPY124 for the current fiscal year, with an interim dividend of JPY62 per share and a year-end dividend of JPY62 per share.

This concludes my presentation for the financial results for FY2023 and the forecast for FY2024.

R&D Updates (1/2)

For updates since February 9, 2024, see highlighted text in red.

Recent status/event	Code No. (Generic name)	Product name	Indications and topics	Schedule
Launch	ZX008 (fenfluramine)	Fintepla	Lennox-Gastaut syndrome (additional indication)	Approved in March 2024
Approval	NS-87 (daunorubicin / cytarabine)	Vyxeos	high-risk acute myeloid leukemia	Approved in March 2024 To be launched after NHI drug price listing
In application	NS-304 (selexipag)	Uptravi	pediatric pulmonary arterial hypertension	April 2024
Start of P3	ZX008 (fenfluramine)	Fintepla	CDKL5 deficiency	July 2023
	GA101 (obinutuzumab)	Gazyva	systemic lupus erythematosus without nephropathy	October 2023
Start of P2	NS-089/NCNP-02 (brogidirsen)	–	Duchenne muscular dystrophy	February 2024
Start of P1	NS-863	–	cardiovascular diseases	August 2023
In-license (Vicore Pharma, Sweden)	C21	–	idiopathic pulmonary fibrosis	Contract signed in February 2024
Alliance Agreement (Eli Lilly Japan)	LY3527727 (piltobrutinib)	–	mantle cell lymphoma (MCL) / chronic lymphocytic leukemia (CLL)	Contract signed in March 2024
Temporarily suspended	NS-580	–	endometriosis chronic prostatitis / chronic pelvic pain syndrome	–
Terminated	NS-018 (ilginatinib)	–	myelofibrosis	–
	NS-161	–	inflammatory disease	–

Takagaki: I am Kazuchika Takagaki, in charge of research and development. I would like to continue with an explanation of the progress of R&D pipeline updated since the financial results for Q3 FY2023.

Please see page 13 of the slides.

In March 2024, we added the indication of Lennox-Gastaut syndrome to Fintepla, and the drug is already being utilized in clinical settings.

NS-87 Vyxeos, a treatment for high-risk acute myeloid leukemia, received manufacturing and marketing approval in March 2024, and preparations are underway for its launch.

In April 2024, we filed an application for NS-304, Uptravi, for an additional indication in Japan for pediatric pulmonary arterial hypertension.

A global Phase II study has been initiated for NS-089/NCNP-02, a treatment for Duchenne muscular dystrophy that skips exon 44.

In February 2024, we entered into an exclusive license agreement with Vicore Pharma for the development and marketing of C21 for the treatment of idiopathic pulmonary fibrosis in Japan.

The approval of LY3527727, a reversible, non-covalent BTK inhibitor, for the treatment of mantle cell lymphoma, for which an alliance agreement was concluded with Eli Lilly Japan in March 2024, recently passed the Drug Subcommittee II on May 9, 2024.

In addition to mantle cell lymphoma, we also have an alliance agreement for the indication of chronic lymphocytic leukemia, and global Phase II studies are ongoing for both indications.

Under the terms of the agreement, Eli Lilly Japan will be responsible for the supply of the product in Japan after obtaining the manufacturing and marketing approval for the product, and we will be responsible for distribution and sales, as well as field activities to provide product information.

The development of NS-580 for both endometriosis and chronic prostatitis/chronic pelvic pain syndrome has been temporarily suspended.

The development of NS-018 and NS-161 has been discontinued.

R&D Updates (2/2)

For updates since February 9, 2024, see highlighted text in red.

Recent status/event	Code No. (Generic name)	Product name	Indications and topics	Schedule
Conference Presentations	NS-065/NCNP-01 (viltolarsen)	Viltepso	Phase 2 trial (Galactic53): 2024 Muscular Dystrophy Association Clinical & Scientific Conference	March 2024
Manuscript	NS-065/NCNP-01 (viltolarsen)	Viltepso	Long-term study analysis data (after 4 years of treatment):Journal of Neuromuscular Diseases	May 2023
	NS-089/NCNP-02 (brogidirsen)	–	Non-clinical data: (Molecular Therapy Nucleic Acids)	October 2023
Rare Pediatric Disease Designation	NS-089/NCNP-02 (brogidirsen)	–	Duchenne muscular dystrophy	June 2023 (U.S.)
Breakthrough Therapy Designation				July 2023 (U.S.)
Orphan Drug Designation				July 2023 (U.S.)
				December 2023 (EU)
Orphan Drug Designation	NS-401 (tagraxofusp)	–	blastic plasmacytoid dendritic cell neoplasm	August 2023 (Japan)
Orphan Drug Designation	NS-229	–	eosinophilic granulomatosis with polyangiitis	January 2024 (EU)
Alliance (MiNA Therapeutics)	–	–	a joint research agreement with the aim of creating nucleic acid medicines that are expected to be applied to an intractable and rare disease in the CNS field	April 2024

Please see page 14 of the slides.

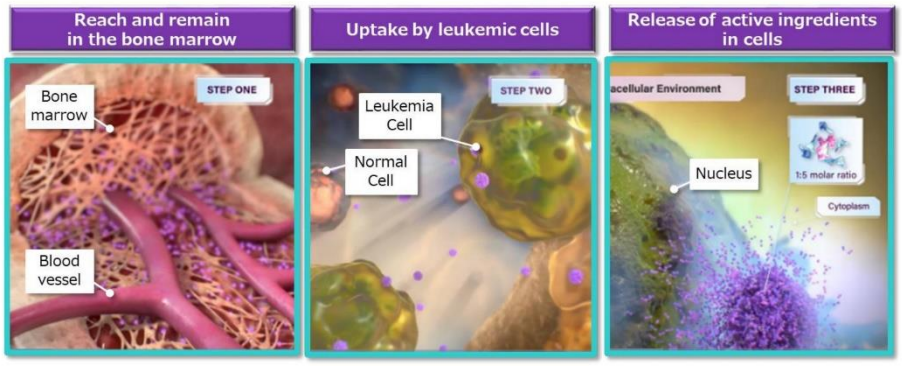
The results of the Galactic53 trial, a Phase II study of viltolarsen, were presented in a poster at the MDA conference in Florida in March 2024.

In April 2024, we entered into a research collaboration agreement with MiNA Therapeutics for the discovery of nucleic acid medicines with potential indications for intractable and rare diseases in the field of central nervous system disorders.

We believe that this will enable us to apply nucleic acid medicine technology to the central nervous system and deliver new medicines to patients suffering from intractable or rare diseases.

Characteristics of Vyxeos® (NS-87)

- **Liposomal formulation of cytarabine and daunorubicin in a 5:1 molar ratio**
- **It reaches the bone marrow as liposomes and remains for a long time.**
- **After the drug is taken up into leukemic cells in the bone-marrow, cytarabine and daunorubicin are released to exert their antitumor effects.**



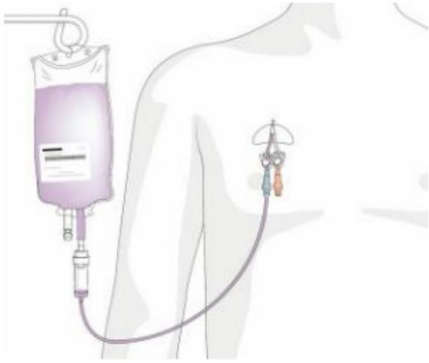
Reference: JAZZ Pharmaceuticals website
"Mechanism of Delivery"
https://vyxeospro.com/mechanism-of-delivery

I would now like to explain the features of NS-87, Vyxeos, which received manufacturing and marketing approval in March 2024.

Please see page 16 of the slides.

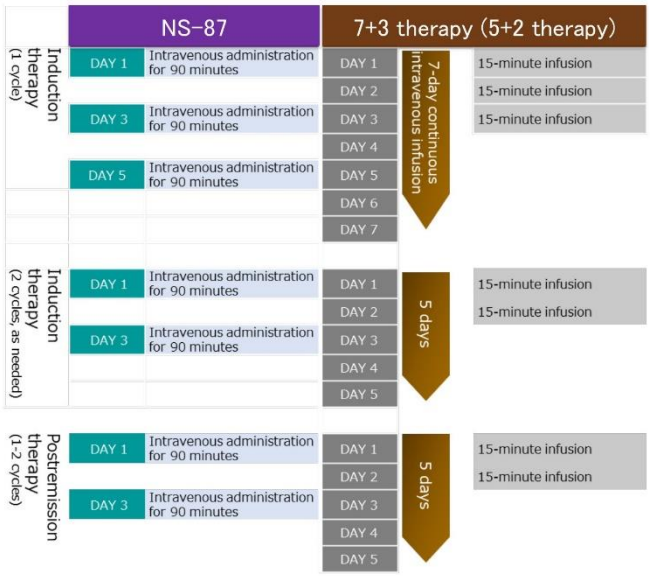
Vyxeos is a liposomal formulation containing cytarabine and daunorubicin, which are conventionally used in the treatment of leukemia, in a 5:1 ratio for the best antitumor effect. It is known to reach the bone marrow in liposome form and remain there for a long time. When taken up by leukemic cells and the liposomes are degraded within the cells, the active ingredient is released, and the drug takes effect.

Time and Duration of Vyxeos® (NS-87)



JAZZ-HP VYXEOS preparation and administration
https://vyxeospro.com/dosing-ordering/preparation

NS-87 vs 7+3 therapy (overseas P3 study)



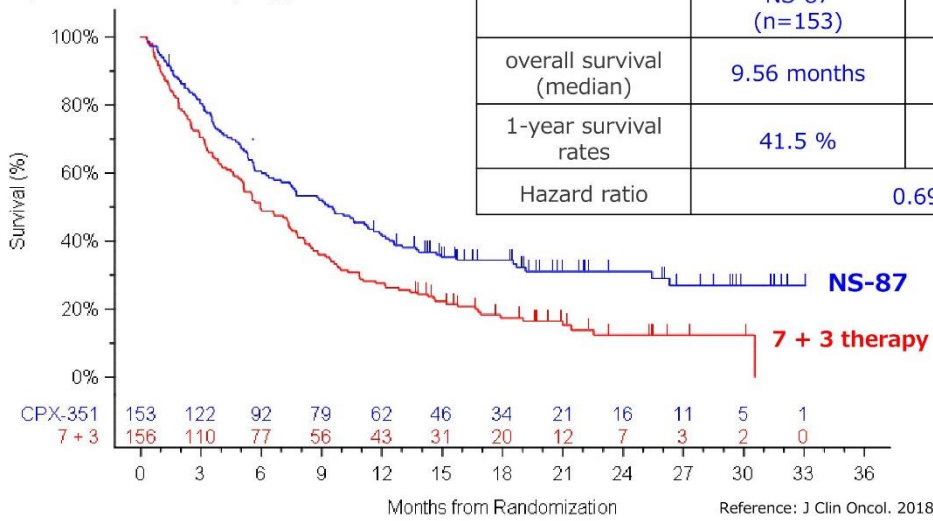
Please see page 17 of the slides.

Conventional 7+3 therapy requires continuous intravenous infusion for five to seven days in one cycle, but Vyxeos requires administration for three days on days one, three, and five in the first cycle, and from the second cycle onwards, if necessary, it will be administered intravenously for 90 minutes on days one and three. This may reduce the burden of treatment for both patients and healthcare professionals.

Vyxeos® (NS-87) Overseas P3 study

Subjects: Untreated high-risk AML 309 aged 60-75 years
Control group: 7 + 3 therapy (AraC 100 mg/m² + DNR 60 mg/m²)

[Primary: overall survival(OS)]



	NS-87 (n=153)	7+3 therapy (n=156)
overall survival (median)	9.56 months	5.95 months
1-year survival rates	41.5 %	27.6 %
Hazard ratio	0.69	

Reference: J Clin Oncol. 2018 Sep 10;36(26):2684-2692

Please see page 18 of the slides.

Here are the results of the overseas Phase III study.

The subjects were 309 untreated high-risk AML patients aged 60-75 years. Overall survival with conventional 7+3 therapy was 5.95 months, compared to 9.56 months with Vyxeos, significantly prolonging overall survival.

Overseas, it is approved for the treatment of therapy-related AML and AML with myelodysplastic changes in more than 30 countries or regions, including the United States and Europe. In May 2022, an orphan drug designation was granted to this drug by the Ministry of Health, Labour and Welfare in Japan.

We believe that we can contribute to the treatment of high-risk AML by appropriately delivering this drug to patients and healthcare professionals who need it.

This concludes the overview of our R&D activities.

FY2023 Financial Results Presentation Q&A (Summary)

May 14, 2024

NO	Questions	Answer.
1	Is the discontinuation of development of NS-018 due to the competitive environment of other JAK2 inhibitors and other drugs?	NS-018 began development targeting patients with myelofibrosis with platelet counts of less than 50,000, anticipating less competition. In contrast with our expectations, a competing product was approved for use in patients with platelet counts of less than 50,000, resulting in lower than expected patient enrollment in our trials. After considering the marketability of the product based on the speed of development, we decided to discontinue further development of NS-018.
2	We understand that NS-018 was discontinued based on a strategic decision due to delays in patient recruitment. Depending on the results of the clinical trial, could it have been licensed out?	We thought that the asset could be out-licensed or developed in-house depending on the results of the overseas P2b clinical trial, but after looking at the data, without waiting for the study to be completed, we decided to discontinue it.
3	Why was NS-580 temporarily suspended? Also, what is required to resume the trial?	We reviewed the long-term non-clinical data for NS-580 and compared the risk-benefit in the two target diseases, which led to our decision to temporarily suspend the trial. We will continue to review the results of the P2b clinical trial for endometriosis and other studies, but we believe that it will take about six months to determine whether the data from animal studies can be extrapolated to humans.

4	Why are there more announcements of discontinuation and temporary suspension of development at this year's earnings announcements?	We have been in an expansionary phase so far and the number of our development pipeline has been increasing rapidly. Looking ahead, we will prioritize investments with a high probability of success from a risk-benefit perspective, with a view to medium-to-long-term growth. Every discontinuation or temporary suspension has different reasons. It is the result of strategic thinking and removing inferior items from the prioritization process.
5	The share price is falling. Is there anything you are trying to change in the future, such as being more proactive in partnering?	As there are limits to what we can do on our own, we are thinking of finding a partner and out-licensing from an early stage. We have been thinking of collaborating with partners who have global development and sales capabilities after completing POC in-house. Our policy on a product-by-product basis will be announced later.
6	In the supplemental material, the FPI of NS-050 has not changed in 1H 2024. Why has the end date the trial been moved back one year from the previous date?	For NS-050, there was a gradual dose escalation in the P1 study, which lengthened the duration of the study and pushed back the completion date of it.
7	When do you expect to start clinical trial of NS-051?	As announced previously, the trial of NS-051 will begin during this fiscal year.
8	Sales of Viltepso of the last fiscal year were lower than expected, perhaps due to. Is gene therapy the reason for the weak sales of Viltepso in the last fiscal year?	There was no real impact from gene therapy. The pace of patient acquisition is steady; we explained at the Q2 FY23 results meeting that there was a bit of market turmoil in the first half of the year, but since then it has recovered. The number of new patients on a monthly basis has returned to normal.

9	Is the U.S. bridge program specific to Viltepso? Or is it also specific to CAP-1002 and other exon skipping drugs? Is such a program essential to penetrate in the U.S. market for Duchenne Muscular Dystrophy (DMD) drugs?	Bridge programs provide drugs free of charge to patients during gaps in their insurance coverage. In the U.S. patients must renew or switch their insurance plans each year, which can result in a gap in coverage at the beginning of the year. The reason why sales of Viltepso declined on a YoY and dollar basis in the 4Q of the last fiscal year was because more cases than expected were provided free of charge in the bridge program in February to fill the gap and there were no sales for those cases. We believe that a similar program will be necessary for CAP-1002.
10	What is the duration of the insurance gap for U.S. patients in the event of insurance renewal？	It is about one month.
11	When will you release the P3 clinical trial data for Viltepso?	We are preparing to release the data soon.
12	The P3 clinical trial of Viltepso completed more than 6 months ago. Have you already discussed the data with the authorities?	This will be explained in the P3 clinical trial data release.
13	If the results of the P3 clinical trial for Viltepso are positive, will it be possible to submit an NDA in Europe, China and other Asian countries/regions?	There is no change from the previous announcement. In China, based on the results of the P3 clinical trial, we will prepare for an NDA again. In Europe, based on discussions with the authorities on the Pediatric Investigation Plan, we expect the drug to be approved for a limited age group of patients who are eligible for exon 53 skipping. The number of patients eligible for the drug is expected to expand as our other clinical trials of Viltepso proceed.
14	What are your plans for Europe and China, including partnering?	We will commercialize Viltepso in China by utilizing our own local subsidiary. In Europe, we will consider strategic options: building our own sales presence, partnering, and collaborating with other companies.
15	What if the P3 clinical trial results for Viltepso are unfavorable?	I would like to answer after the P3 clinical trial data is released.

16	How will sales of Viltepso's unapproved drug contribute significantly to the company's revenues? Will it be sold at higher unit prices if the drug is officially approved in the future?	The situation varies from country to country. If the drug is approved, it will be marketed in that country. If the drug is not approved in the country where a P3 clinical trial participant resides, it will be provided free of charge under our EAP (Expanded Access Program). Other examples are that some patients pay for the drug themselves, and some countries have charitable funds.
17	In an interview with an industry newspaper, President Nakai said that the DMD pipeline, including CAP-1002 and other exon skipping drugs, would allow for future growth. Do you still think the same?	Capricor Therapeutics is conducting a P3 clinical trial called HOPE-3 in two groups, Cohort A and Cohort B. We had previously informed you that the timeline for CAP-1002 was to proceed with an application after reviewing the results of these studies. Capricor Therapeutics has announced that there will be a pre-BLA Type B meeting in May of this year, and they believe that a rolling submission will be made based on the results of that meeting. We have heard that the timing of the readout of the ongoing P3 clinical trial is scheduled for the end of this year, and that the previous Type B meeting with the FDA confirmed that the FDA will approve the drug based on the Cohort A results alone. In light of these factors, the timing of approval and launch may be earlier than we had previously indicated. In light of this, the costs associated with CAP-1002's launch preparation are included as NS Pharma's SG&A expenses in our forecast of SG&A expenses for this fiscal year.
18	You mentioned that SG&A expenses for CAP-1002 were a factor in the increase in SG&A this quarter. How much is the actual amount?	We would like to refrain from disclosing specific amounts.

19	Does Capricor Therapeutics have the capacity to manufacture the volume to meet the market's demand after the successful completion of the trial of CAP-1002?	Capricor Therapeutics's current manufacturing capacity is to make investigational drugs for 61 patients in Cohort A and 44 patients in Cohort B, for a total of around 100 patients. The investigational drug manufacturing site for Cohort B in San Diego will make the commercial formulation, but to meet GMP standards, Capricor Therapeutics is currently investing intensively. They have the capacity to meet the needs of the patients identified at this time, but recognize that they need to scale up for the entire DMD patient population and are moving forward with plans to increase manufacturing volumes to supply CAP-1002 to patients.
20	According to Clinicaltrials.gov, Top-line data of CAP-1002 is scheduled for disclosure in December, will it be for Cohort A only?	We understand that Capricor Therapeutics was able to successfully demonstrate to the authorities the non-clinical comparative equivalence of both sites A and B, which allowed the company to market the product manufactured in Cohort B with the data from the Cohort A study.
21	Will there be any further development in the partnership with Capricor Therapeutics?	We have a very friendly and close working relationship with Capricor Therapeutics, and we will continue to monitor the development progress of CAP-1002 and consider every option within our overall strategy.
22	What is the sales forecast for Vyxeos (NS-87) this fiscal year?	Although we do not disclose sales forecasts, we are eager to deliver the product to as many patients as possible. Pirtobrutinib, for which we have entered into an alliance agreement with Eli Lilly Japan, is also scheduled for launch this fiscal year, and as a company that is highly recognized in the blood cancer field in Japan, we hope to make up for the decline in Vidaza sales with these two products.
23	Will pirtobrutinib in the alliance agreement with Eli Lilly Japan be recorded as sales or co-promotion?	The sales will be recorded on our own.

24	Is the new Medium-term Management Plan for a period of five years? Will the pipeline decline due to the discontinuation or temporary suspension of some candidate products affect future dividend payout ratios?	I will discuss the details during the briefing on the Medium-term Management Plan, but we are considering a five-year period in principle, through FY2028. I hope to be able to introduce what the company will be like in FY2028 after the patent cliff of Uptravi, and what it aims to be like beyond that.
25	I think the fact that the dividend forecast is the same as the previous year is having a negative impact on the stock price. Are plans for major investments, including M&A, keeping the dividend level low?	The dividend forecast is based on the company's decision to use cash for long-term growth investments rather than returning it to shareholders in the short term. We will focus more on growth investments such as the acquisition of sales/distribution networks and in-licensing to complement the Uptravi's patent cliff. All growth opportunities will be considered.