Outline of Consolidated Financial Results for the Year Ended March 31, 2023

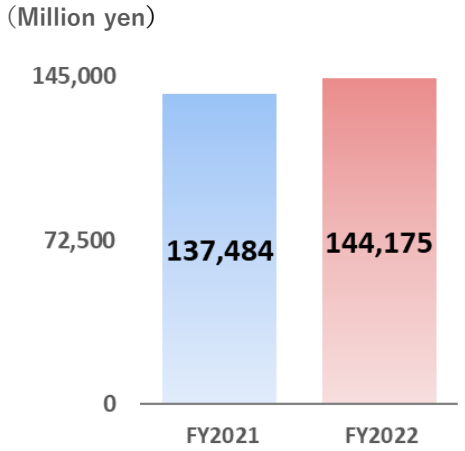
May 15, 2023
NIPPON SHINYAKU CO., LTD.

NIPPON SHINYAKU CO., LTD.

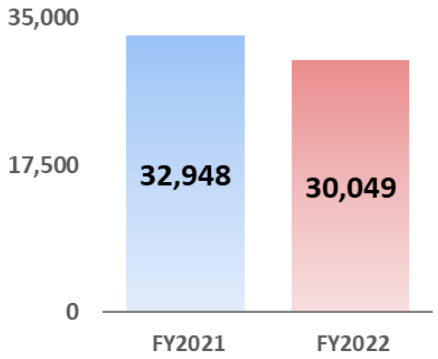
FY2022 Summary

- **Revenue** : 144,175 million yen （+ 4.9%）
- **Operating profit** : 30,049 million yen （- 8.8%）
- **Profit before tax** : 30,489 million yen （- 8.4%）
- **Profit attributable to owners of parent** : 22,812 million yen （- 8.7%）

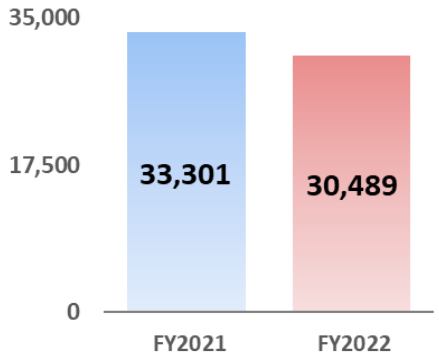
Revenue



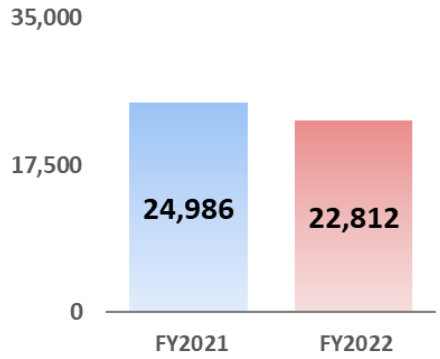
Operating profit



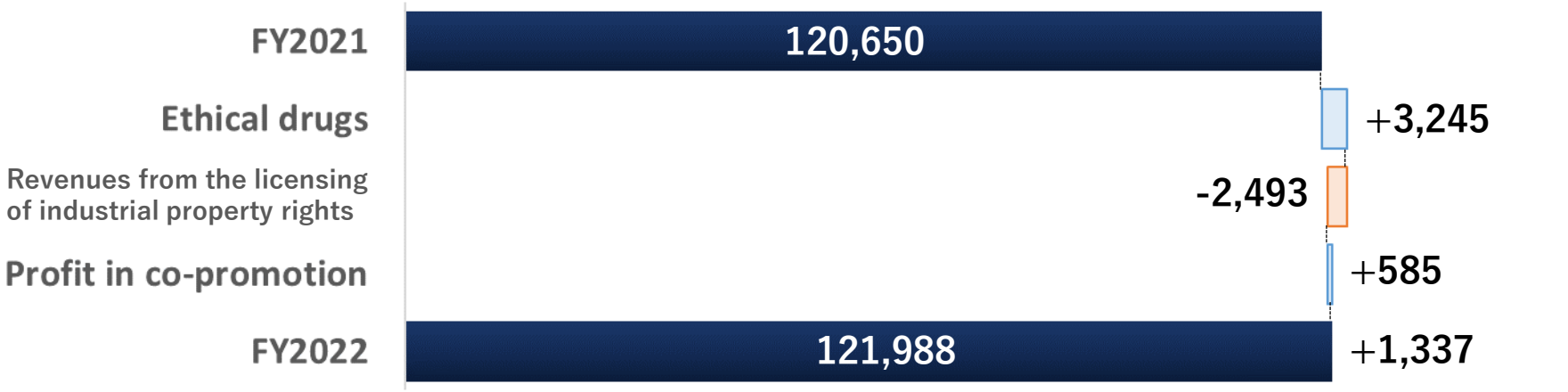
Profit before tax



Profit attributable to owners of parent



Segmental Review - Pharmaceuticals -



(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	78,508	65.1%	81,753	67.0%	+3,245	+4.1%
Revenues from the licensing of industrial property rights	33,207	27.5%	30,714	25.2%	-2,493	-7.5%
Profit in co-promotion	8,934	7.4%	9,520	7.8%	+585	+6.6%
Revenue	120,650	100.0%	121,988	100.0%	+1,337	+1.1%

Despite the effect of price revision by MHLW* and backlash from the loss of sales revenue from the priority review voucher, Revenue of consolidated pharmaceuticals segment increased by 1.1% due to increase of sales of Ethical drugs such as "Uptravi" and "Viltepso", and royalty revenue from Uptravi's overseas sales.

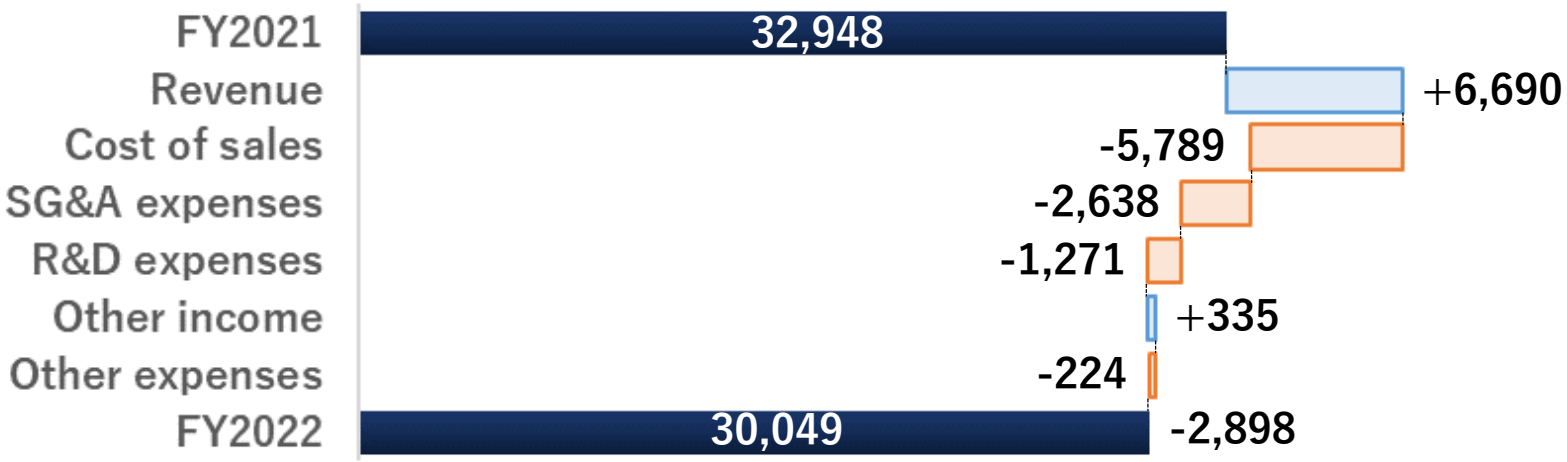
*MHLW : Ministry of Health, Labour and Welfare

Segmental Review - Functional Food -

(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	10,841	64.4%	15,383	69.3%	+4,542	+41.9%
Preservatives	2,790	16.6%	2,905	13.1%	+114	+4.1%
Health food ingredients	1,085	6.4%	1,118	5.0%	+32	+3.0%
Others	2,116	12.6%	2,779	12.6%	+663	+31.3%
Revenue	16,834	100.0%	22,187	100.0%	+5,352	+31.8%

Revenue of consolidated functional food segment increased by 31.8% mostly due to increase of demand from lowering COVID-19 cases and price revisions to offset price hikes of raw materials.

Operating profit



(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**137,484**	**100.0%**	**144,175**	**100.0%**	**+6,690**	**+4.9%**
(Pharmaceuticals)	(120,650)	(87.8%)	(121,988)	(84.6%)	(+1,337)	(+1.1%)
(Functional Food)	(16,834)	(12.2%)	(22,187)	(15.4%)	(+5,352)	(+31.8%)
Cost of sales	**50,191**	**36.5%**	**55,980**	**38.8%**	**+5,789**	**+11.5%**
SG&A expenses	**32,173**	**23.4%**	**34,812**	**24.1%**	**+2,638**	**+8.2%**
R&D expenses	**22,863**	**16.6%**	**24,135**	**16.7%**	**+1,271**	**+5.6%**
Other income	**1,573**	**1.1%**	**1,908**	**1.3%**	**+335**	**+21.3%**
Other expenses	**882**	**0.6%**	**1,106**	**0.9%**	**+224**	**+25.4%**
Operating profit	**32,948**	**24.0%**	**30,049**	**20.8%**	**-2,898**	**-8.8%**

Profit attributable to owners of parent

(Million yen)	FY2021 Results	FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	32,948	30,049	-2,898	-8.8%
Finance income	472	575	+102	+21.7%
Finance costs	119	136	+17	+14.3%
Profit before tax	33,301	30,489	-2,812	-8.4%
Income tax expense, etc	8,315	7,676	-639	-7.7%
Profit attributable to owners of parent	24,986	22,812	-2,173	-8.7%

Business Forecast for FY2023

(Million yen)	FY2022 Results	FY2023 Forecast	YoY Change Amt	YoY Change %
Revenue	144,175	145,000	+825	+0.6%
Operating profit	30,049	32,000	+1,951	+6.5%
Profit before tax	30,489	32,500	+2,011	+6.6%
Profit attributable to owners of parent	22,812	25,000	+2,187	+9.6%

We look for Revenue, Operating profit, Profit before tax, Profit attributable to owners of parent to increase year on year.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	81,753	67.0%	79,200	64.2%	-2,553	-3.1%
Revenues from the licensing of industrial property rights	30,714	25.2%	35,000	28.3%	+4,286	+14.0%
Profit in co-promotion	9,520	7.8%	9,300	7.5%	-220	-2.3%
Revenue	121,988	100.0%	123,500	100.0%	+1,512	+1.2%

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 "Upravi", and royalty revenue from Uptravi's overseas sales.

*MHLW : Ministry of Health, Labour and Welfare

Segmental Forecast - Functional Food -

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	15,383	69.3%	14,200	66.0%	-1,183	-7.7%
Preservatives	2,905	13.1%	3,000	14.0%	+95	+3.3%
Supplement	1,428	6.4%	1,800	8.4%	+372	+26.0%
Health food ingredients	1,118	5.0%	1,200	5.6%	+82	+7.3%
Others	1,351	6.1%	1,300	6.0%	-51	-3.8%
Revenue	22,187	100.0%	21,500	100.0%	-687	-3.1%

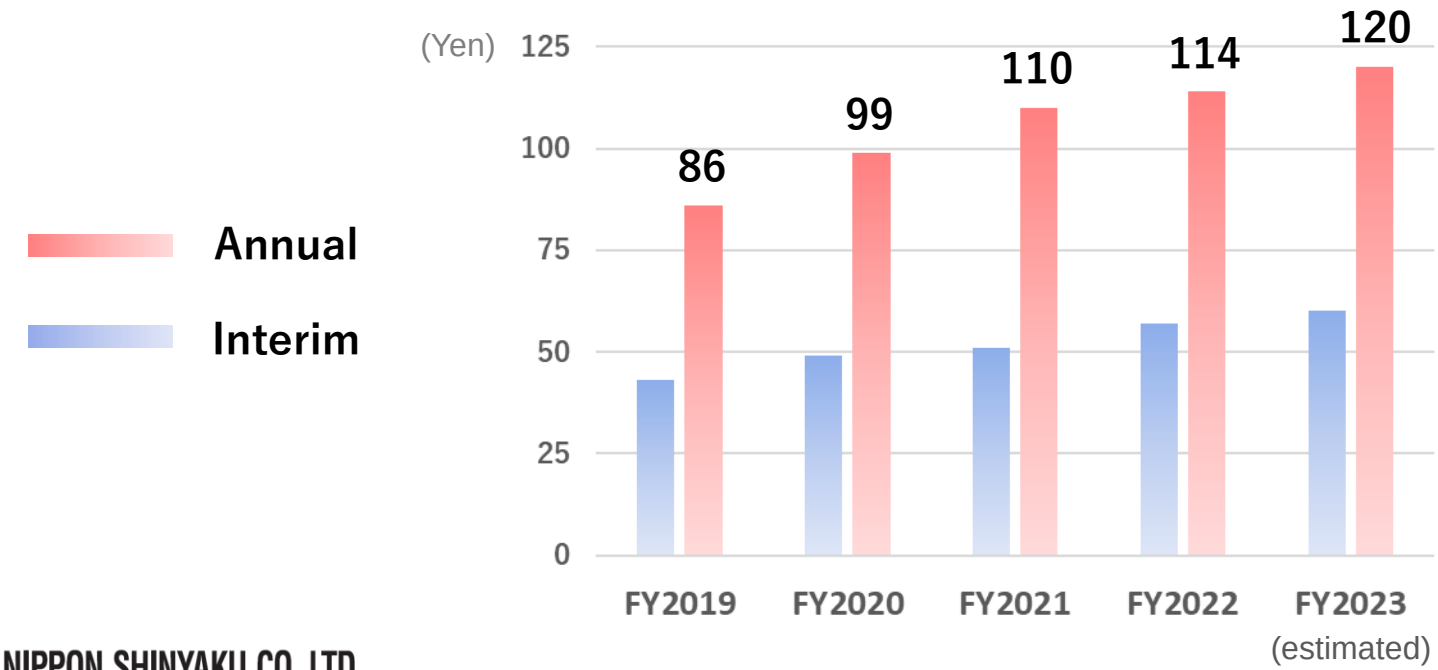
Despite enhancement of research and development toward new products, due to the effect of sales price reduction of several products, we predict Revenue of consolidated functional food segment to decrease.

Forecast of Consolidated Statements of Income

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue	144,175	100.0%	145,000	100.0%	+825	+0.6%
(Pharmaceuticals)	(121,988)	(84.6%)	(123,500)	(85.2%)	(+1,512)	(+1.2%)
(Functional Food)	(22,187)	(15.4%)	(21,500)	(14.8%)	(-687)	(-3.1%)
Cost of sales	55,980	38.8%	50,000	34.5%	-5,980	-10.7%
SG&A expenses	34,812	24.1%	35,000	24.1%	+188	+0.5%
R&D expenses	24,135	16.7%	28,000	19.3%	+3,865	+16.0%
Other income	1,908	1.3%	400	0.3%	-1,508	-79.0%
Other expenses	1,106	0.9%	400	0.3%	-706	-63.8%
Operating profit	30,049	20.8%	32,000	22.1%	+1,951	+6.5%
Finance income	575	0.4%	500	0.3%	-75	-13.1%
Finance costs	136	0.1%	-	-	-136	-
Profit before tax	30,489	21.1%	32,500	22.4%	+2,011	+6.6%
Income tax expense, etc	7,676	5.3%	7,500	5.2%	-176	-2.3%
Profit attributable to owners of parent	22,812	15.8%	25,000	17.2%	+2,188	+9.6%

Dividends Forecast

		FY2022	FY2023
Dividends per share	Interim	¥57	¥60
	Annual	¥114	¥120
Basic earnings per share		¥338.70	¥371.18
Payout ratio (consolidated)		33.7 %	32.3 %



6th Five-year Mid-term Management Plan Target

(million yen)	FY2023 Mid-term Target	FY2023 Forecast	Difference Amt	Difference %
Revenue	150,000	145,000	-5,000	-3.3%
Operating profit	40,000	32,000	-8,000	-20.0%
Profit attributable to owners of parent	30,000	25,000	-5,000	-16.7%

Assumptions for unachieved target :

impact from COVID-19
- Uptake of VILTEPSO in the US was delayed

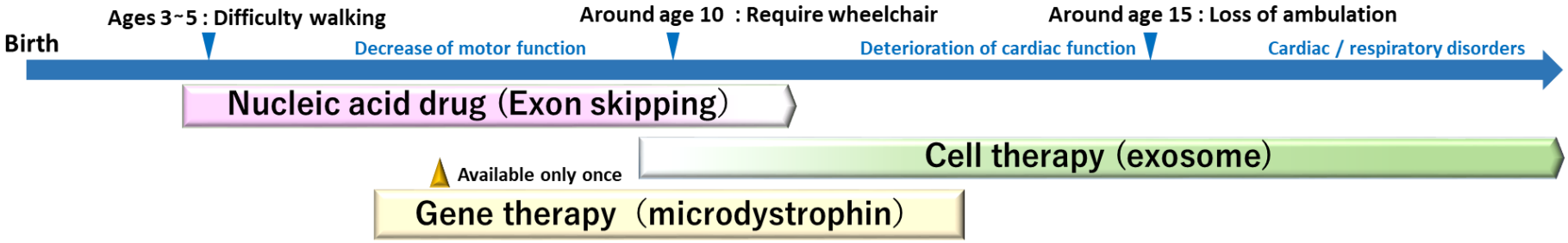
Negative impact from implementation of annual price revision by MHLW*
- Sales of domestic products declined more than expected

We seek further growth from our developing DMD pipeline, cell therapy, new modalities such as gene therapy and other pipeline products.

*MHLW : Ministry of Health, Labour and Welfare

Position within the three DMD treatments

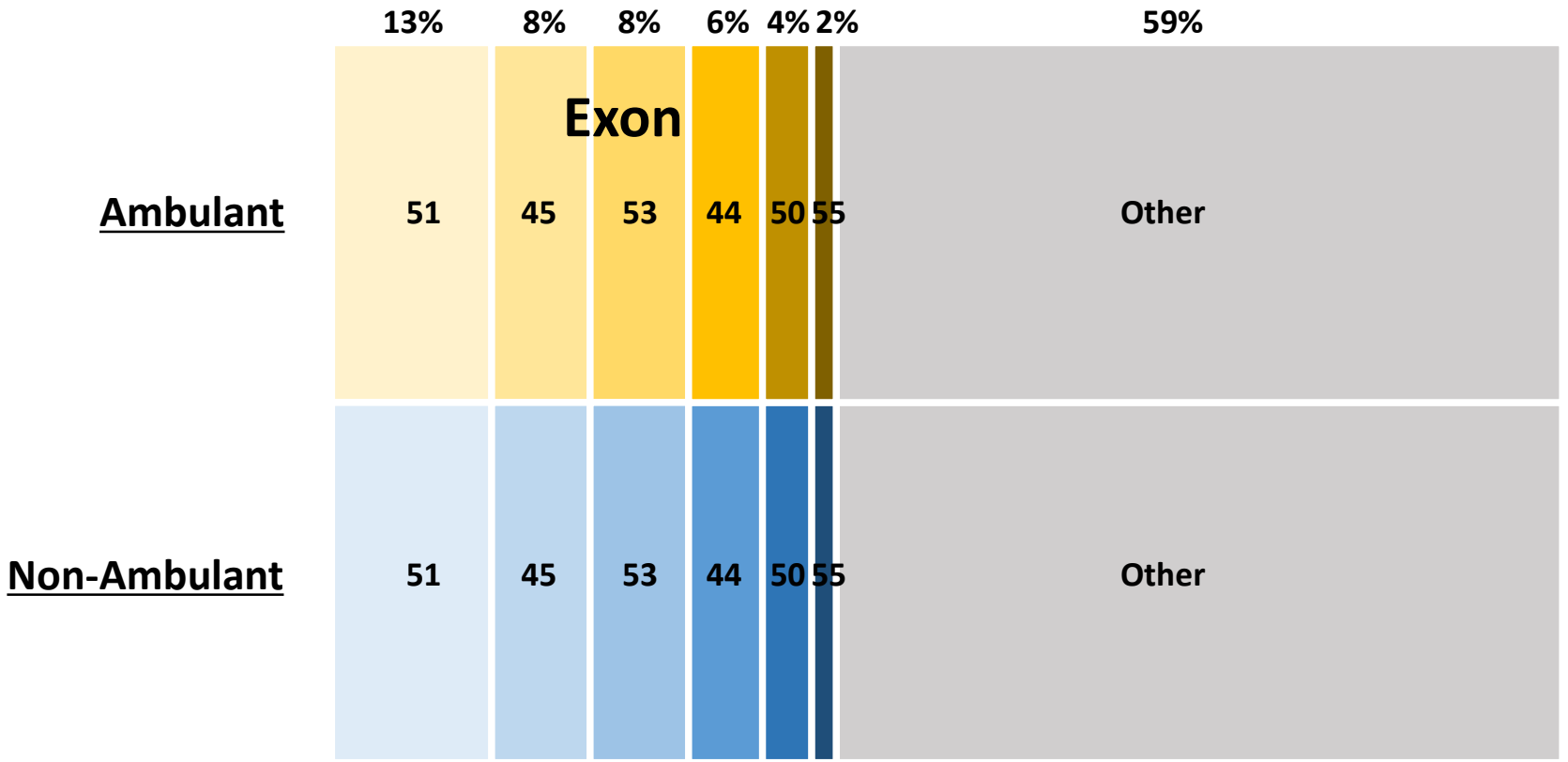
	Advantage	Disadvantage
Nucleic acid drug (Exon skipping)	・Multiple doses are possible ・Long-term safety and efficacy data are available	・Target patients are limited ・Therapeutic effects only towards skeletal muscle
Cell therapy (exosome)	・Potentially effective not only for skeletal muscle, but also for the heart ・Can improve upper limb function in patients who are non-ambulant	・Effect towards ambulant patients have not been examined. ・Difficulty in cell specification and distribution
Gene therapy (microdystrophin)	・Potentially effective not only for skeletal muscle but also for the heart ・May be available to DMD patient who is not amenable to exon skipping.	・High and systemic dose resulting to immunotoxicity ・Currently difficult to administer multiple doses. ・Not clear whether short-chain dystrophin adequately improves motor function



・Young patients：Prevent muscle cells from being destroyed by treating with exon skipping therapy
・Older patients with less muscle cells：Switch to gene therapy
・After effect of gene therapy diminished：Go back to exon skipping or switch to cell therapy

We believe that there are optimal combination of treatments depending on the patient's genetic background, medical (health) condition and timing.

Percentage of patients amenable to exon skipping therapy out of all DMD patients



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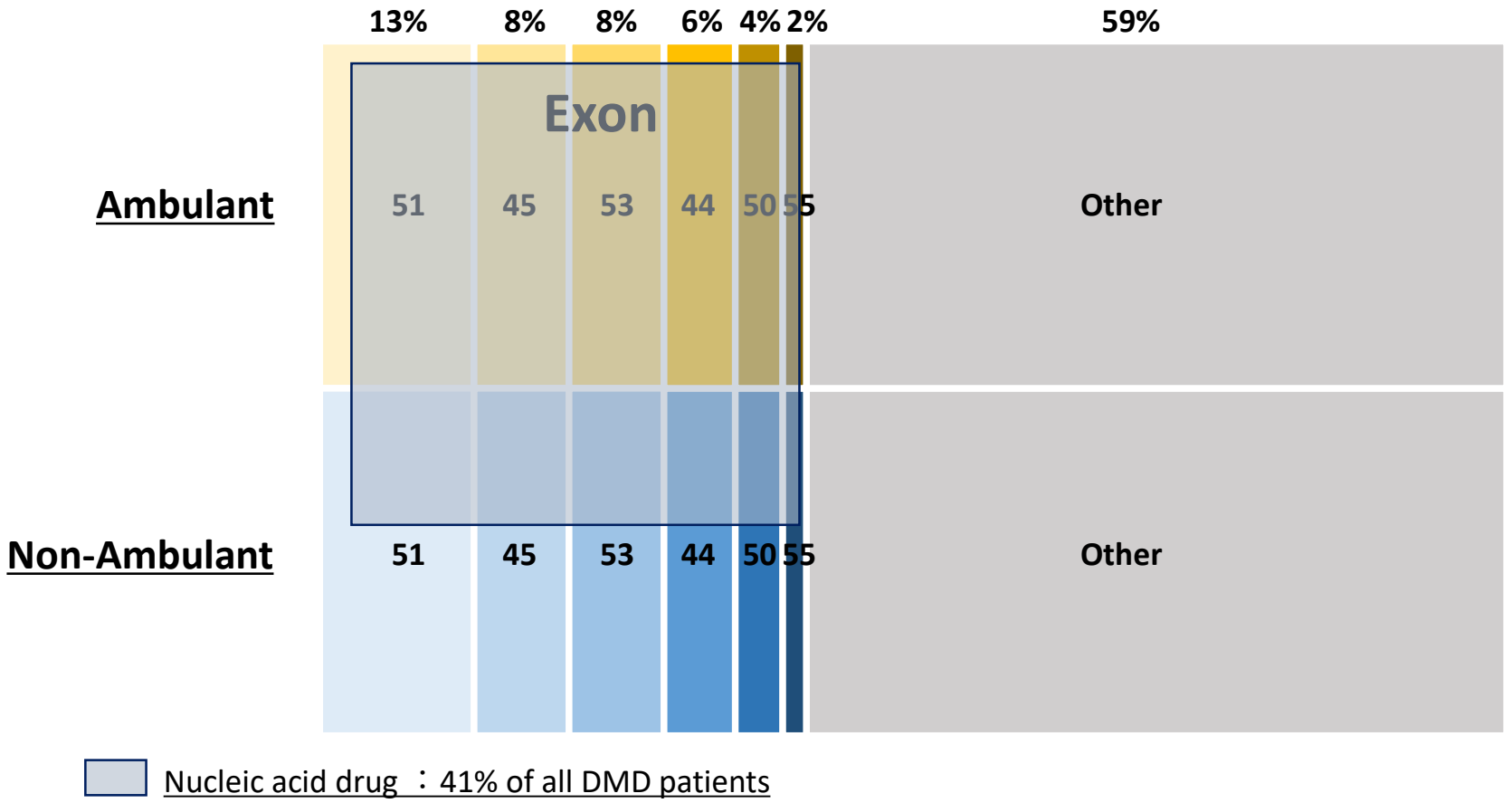
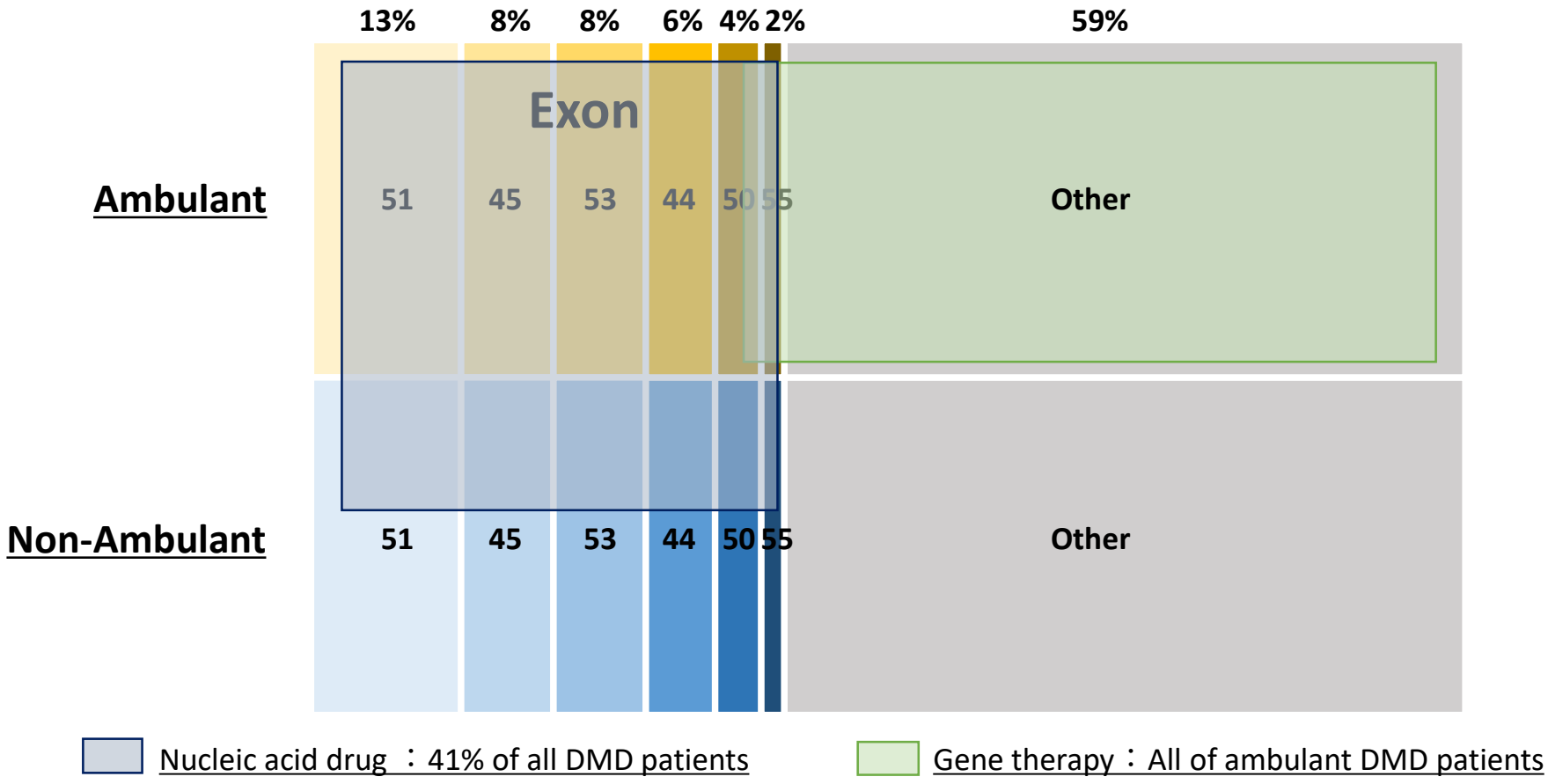
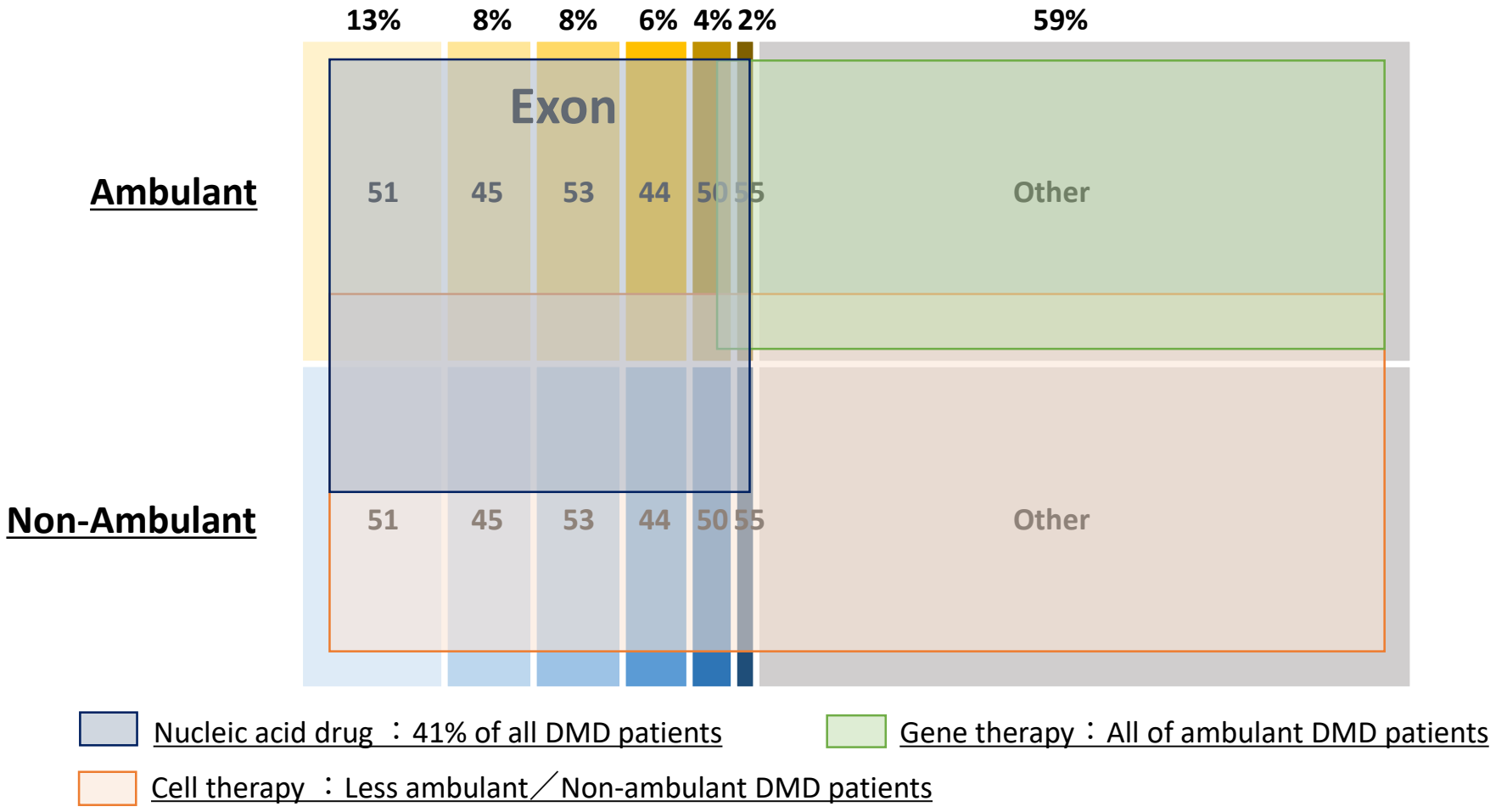


Nucleic acid drug ：41% of all DMD patients

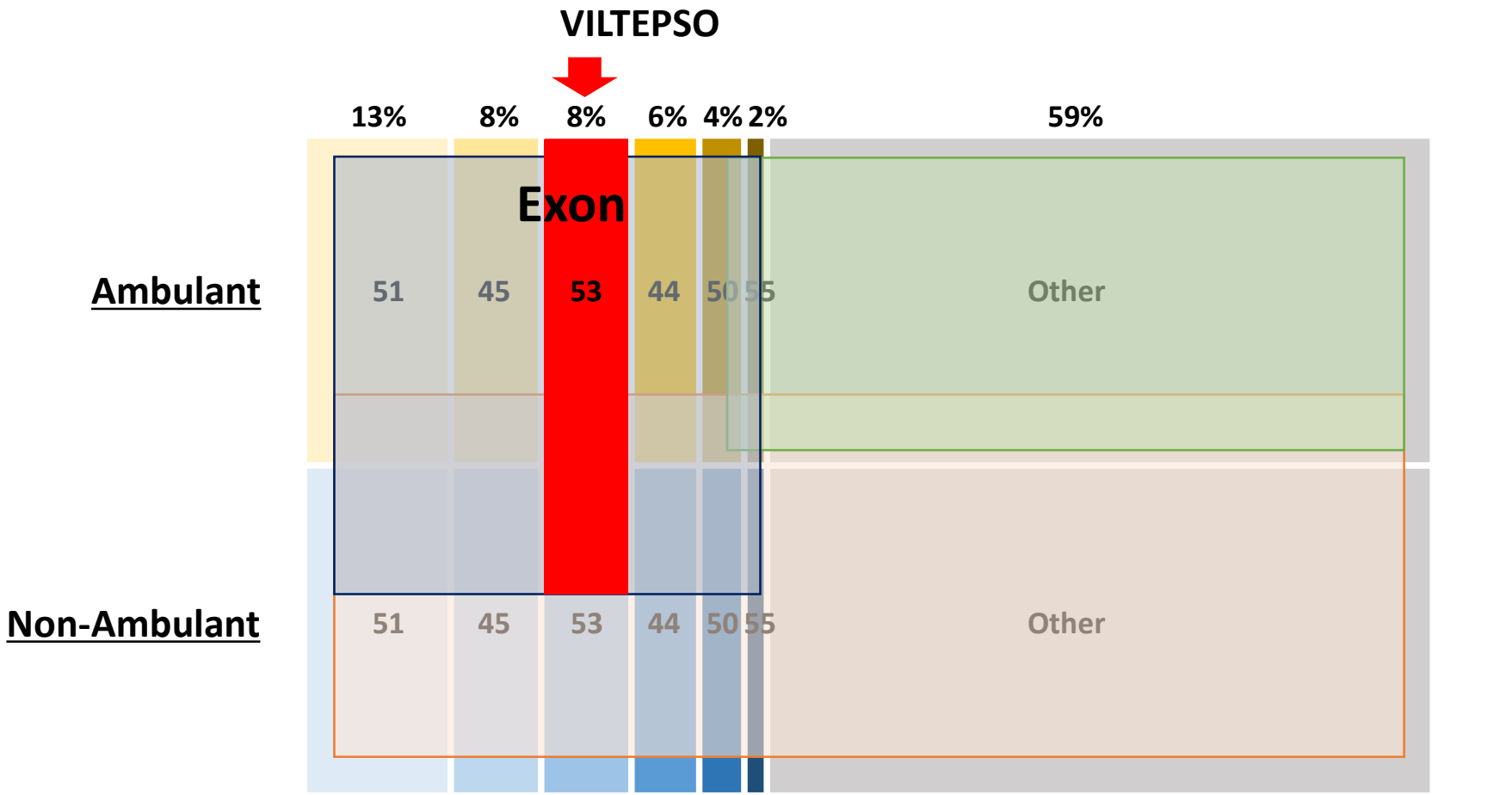
Percentage of patients amenable to exon skipping therapy out of all DMD patients



Percentage of patients amenable to exon skipping therapy out of all DMD patients



Percentage of patients amenable to exon skipping therapy out of all DMD patients



Nucleic acid drug ：41% of all DMD patients

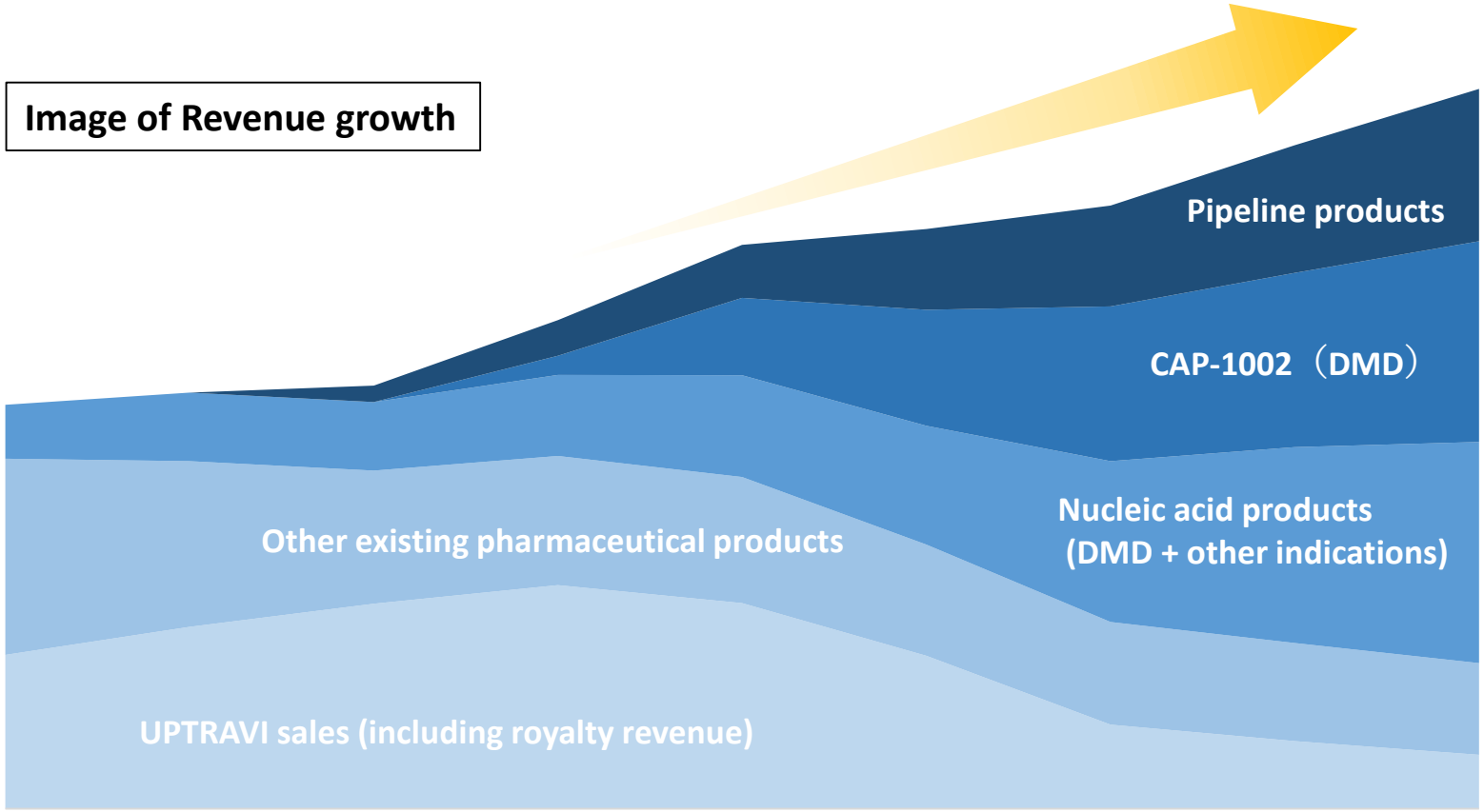
Gene therapy：All of ambulant DMD patients

Cell therapy ：Less ambulant／Non-ambulant DMD patients

We aim to provide therapy for all DMD patients.

Striving for sustainable growth

Image of Revenue growth



Pipeline products (in-house)

- NS-018
- NS-580
- NS-229
- NS-025
- NS-161

etc.

Our Nucleic acid products, CAP-1002, and other developing in-house pipeline products will more than offset LOE* of UPTRAVI and drive our growth to become a company with Revenue of 300 billion yen.

*LOE : Loss of exclusivity

R&D Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy						PIII in progress	
ZX008 (fenfluramine hydrochloride) <in-license>	New indication	Lennox-Gastaut syndrome							
GA101 (obinutuzumab) <in-license>	New indication	Lupus nephritis							
	New indication	Pediatric nephrotic syndrome							
NS-304 (selexipag) <in-house>	New indication	Arteriosclerosis obliterans							
	New dose	Pediatric pulmonary arterial hypertension							
NS-580 <in-house>	NME	Endometriosis							

■ : Changes from 3rd Quarter FY2022

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	Launch
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy							
NS-87 (daunorubicin / cytarabine) <in-license>	New combi-nation	Secondary acute myeloid leukemia							
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm							
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy							
NS-229 <in-house>	NME	Inflammatory diseases							
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia							
NS-161 <in-house>	NME	Inflammatory diseases							
NS-025 <in-house>	NME	Urological diseases							

■ : Changes from 3rd Quarter FY2022

R&D Pipeline (Overseas)

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

■ : Changes from 3rd Quarter FY2022

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Statements of Income

(Million yen)	FY2021		FY2022		YoY change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	**137,484**	**100.0%**	**144,175**	**100.0%**	**+6,690**	**+4.9%**
(Pharmaceuticals)	(120,650)	(87.8%)	(121,988)	(84.6%)	(+1,337)	(+1.1%)
(Functional Food)	(16,834)	(12.2%)	(22,187)	(15.4%)	(+5,352)	(+31.8%)
Cost of sales	**50,191**	**36.5%**	**55,980**	**38.8%**	**+5,789**	**+11.5%**
SG&A expenses	**32,173**	**23.4%**	**34,812**	**24.1%**	**+2,638**	**+8.2%**
R&D expenses	**22,863**	**16.6%**	**24,135**	**16.7%**	**+1,271**	**+5.6%**
Other income	**1,573**	**1.1%**	**1,908**	**1.3%**	**+335**	**+21.3%**
Other expenses	**882**	**0.6%**	**1,106**	**0.9%**	**+224**	**+25.4%**
Operating profit	**32,948**	**24.0%**	**30,049**	**20.8%**	**-2,898**	**-8.8%**
Finance income	**472**	**0.3%**	**575**	**0.4%**	**+102**	**+21.7%**
Finance costs	**119**	**0.1%**	**136**	**0.1%**	**+17**	**+14.3%**
Profit before tax	**33,301**	**24.2%**	**30,489**	**21.1%**	**-2,812**	**-8.4%**
Income taxes, etc	**8,315**	**6.0%**	**7,676**	**5.3%**	**-639**	**-7.7%**
Profit attributable to owners of parent	**24,986**	**18.2%**	**22,812**	**15.8%**	**-2,173**	**-8.7%**

Consolidated Balance Sheet

(Million yen)	End of FY2021	End of FY2022	Change Amt		End of FY2021	End of FY2022	Change Amt
Assets	219,943	237,451	+17,508	Liabilities	39,057	41,518	+2,461
Current assets	149,724	157,873	+8,149	Current liabilities	32,029	35,183	+3,154
Non-current assets	70,219	79,578	+9,359	Non-current liabilities	7,027	6,334	-693
				Equity	180,886	195,933	+15,047
Total assets	219,943	237,451	+17,508	Total liabilities and equity	219,943	237,451	+17,508

＝Assets＝

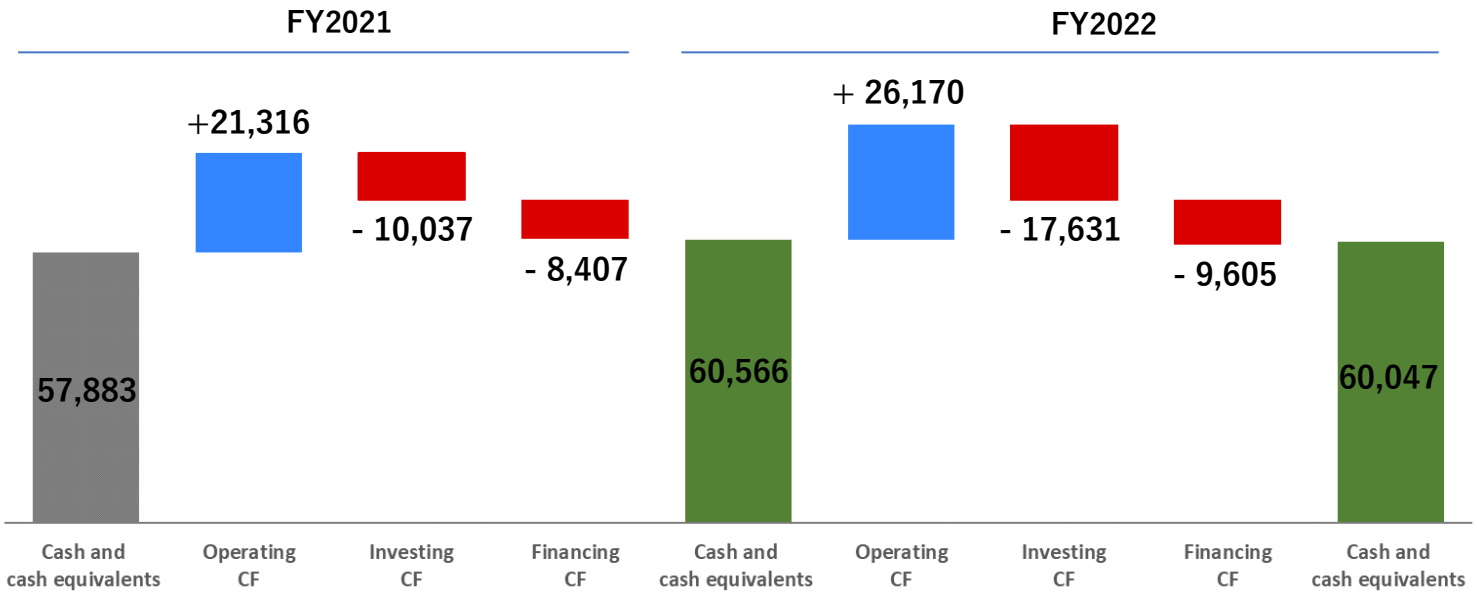
Trade and other receivables	+1,507
Other financial assets	+6,380
Property, plant and equipment	+3,910
Intangible assets	+3,105

＝Liabilities and Equity＝

Income taxes payable	+3,008
Retirement benefit liability	-611
Retained earnings	+15,129

Consolidated Statements of Cash Flows

(Million yen)	FY2021 Results	FY2022 Results	YoY Change Amt
Operating activities	21,316	26,170	+4,854
Investing activities	-10,037	-17,631	-7,594
Financing activities	-8,407	-9,605	-1,197
Cash and cash equivalents at end of period	60,566	60,047	-518



NS-065/NCNP-01 (viltolarsen)
- Treatment for Duchenne muscular dystrophy -

Development Phase	・Japan : Launch ・USA : Launch ・Global : PIII in progress
Origin	Co-development : National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 53 Skipping
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression ・Morpholino based oligonucleotide with possible high safety profile and maximized activity

ZX008 (fenfluramine hydrochloride)
- Treatment for rare intractable epilepsy -

Development Phase	Japan : Launch (Dravet syndrome) Japan : PIII (Lennox-Gastaut syndrome)
Origin	[Mar. 2019] Commercial rights from : UCB S.A. (former Zogenix, Inc.)
Development	UCB S.A. (former Zogenix, Inc.)
Mechanism of action	5-HT (serotonin) releaser with agonist activity at several 5-HT receptors
Indication	Dravet syndrome and Lennox-Gastaut syndrome
Dosage form	Oral liquid agent
Feature	・Effective for Dravet syndrome and Lennox-Gastaut syndrome patients refractory to existing treatment options ・ZX008 can be used in combination with other drugs, as standard of care for intractable epilepsy based on combination therapy

CAP-1002
- Treatment for Duchenne muscular dystrophy -

Development Phase	USA : PIII
Origin	[Jan. 2022] Partnership for commercialization in the US [Feb. 2023] Partnership for commercialization in Japan : Capricor Therapeutics, Inc.
Development	Capricor Therapeutics, Inc.
Mechanism of action	Exosomes released from cardiosphere-derived cells
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Exosomes released from this drug are expected to reduce oxidative stress, inflammation, fibrosis, and increase cell energy and myocyte generation, resulting in improvement of motor and cardiac functions ・Its broad applicability makes it suitable for patients regardless of the type of genetic mutation

GA101 (Obinutuzumab)

- Treatment for lupus nephritis, pediatric nephrotic syndrome -

Development Phase	Japan : PIII（LN） Global : PIII（PNS）
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)
Dosage form	Injection
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity

NS-304 (selexipag)

- Treatment for pulmonary hypertension, arteriosclerosis obliterans -

Development Phase	Japan : PIIb （ASO） Japan : PII （Pediatric PAH）
Origin	Nippon Shinyaku
Development	・Nippon Shinyaku （ASO） ・Co-development : Janssen Pharmaceutical K.K. （Pediatric PAH）
Mechanism of action	Selective IP receptor agonist
Indication	・Arteriosclerosis obliterans (ASO) ・Pediatric pulmonary arterial hypertension (Pediatric PAH)
Dosage form	Tablet
Feature	Long-acting oral drug

NS-580
- Treatment for endometriosis -

Development Phase	Japan : PIIb
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	Inhibition of membrane-associated prostaglandin E synthase-1
Indication	Endometriosis
Dosage form	Oral agent
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency

NS-018 (ilginatinib)
- Treatment for myelofibrosis -

Development Phase	Global : PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	・Potent and highly selective JAK2 inhibitor ・High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count

NS-089/NCNP-02（brogidirsen）
- Treatment for Duchenne muscular dystrophy -

Development Phase	Global：Preparation for PII
Origin	Co-development : National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 44 Skipping
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression ・Morpholino based oligonucleotide with possible high safety profile and maximized activity

NS-87 (daunorubicin / cytarabine)
- Treatment for secondary acute myeloid leukemia -

Development Phase	Japan : PI/II
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals plc
Development	Nippon Shinyaku
Mechanism of action	Liposomal combination of daunorubicin and cytarabine
Indication	Secondary acute myeloid leukemia (secondary AML)
Dosage form	Injection
Feature	・NS-87 is the first therapy for the treatment of secondary AML in Japan ・The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow

NS-401 (tagraxofusp)

- Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan : PI/II
Origin	[Mar. 2021] Licensed-in from: The Menarini Group
Development	Nippon Shinyaku
Mechanism of action	Induction apoptosis of cells by inhibiting protein synthesis by specifically targeting cancer cells expressing CD123
Indication	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)
Dosage form	Injection
Feature	・Composed of diphtheria toxin (DT) fusion protein and recombinant human IL-3 ・Novel targeted therapy directed to CD123 on tumor cells ・IL-3 binds to CD123-expressing tumor cells and delivers the cytotoxic diphtheria toxin to the cells, resulting in the blockage of protein synthesis in the cell and causing cell death in CD123-expressing cells

NS-050/NCNP-03
- Treatment for Duchenne muscular dystrophy -

Development Phase	Global：Preparation for PI/II
Origin	Co-development : National Center of Neurology and Psychiatry
Development	Nippon Shinyaku
Mechanism of action	Exon 50 Skipping
Indication	Duchenne muscular dystrophy
Dosage form	Injection
Feature	・Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression ・Morpholino based oligonucleotide with possible high safety profile and maximized activity

NS-229
- Treatment for inflammatory diseases -

Development Phase	Japan : PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK1 inhibitor
Indication	Inflammatory diseases (to be determined)
Dosage form	Oral agent
Feature	・Potent and highly selective JAK1 inhibitor ・High efficacy and good safety profiles are expected in the treatment for inflammatory diseases

NS-917 (radgocitabine)

- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan : PI
Origin	[Mar. 2017] Licensed-in from : Delta-Fly Pharma, Inc.
Development	Nippon Shinyaku
Mechanism of action	DNA strand-break by incorporating itself into DNA
Indication	Relapsed or refractory (r/r) acute myeloid leukemia (AML)
Dosage form	Injection
Feature	・Significant anti-leukemic activity with unique mechanism of action from other nucleoside analogs at low dose continuous infusion ・Tolerable safety profile available to elderly patients with r/r AML

NS-161
- Treatment for inflammatory diseases -

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

NS-025
- Treatment for urological diseases -

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

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Nippon Shinyaku Co., Ltd.

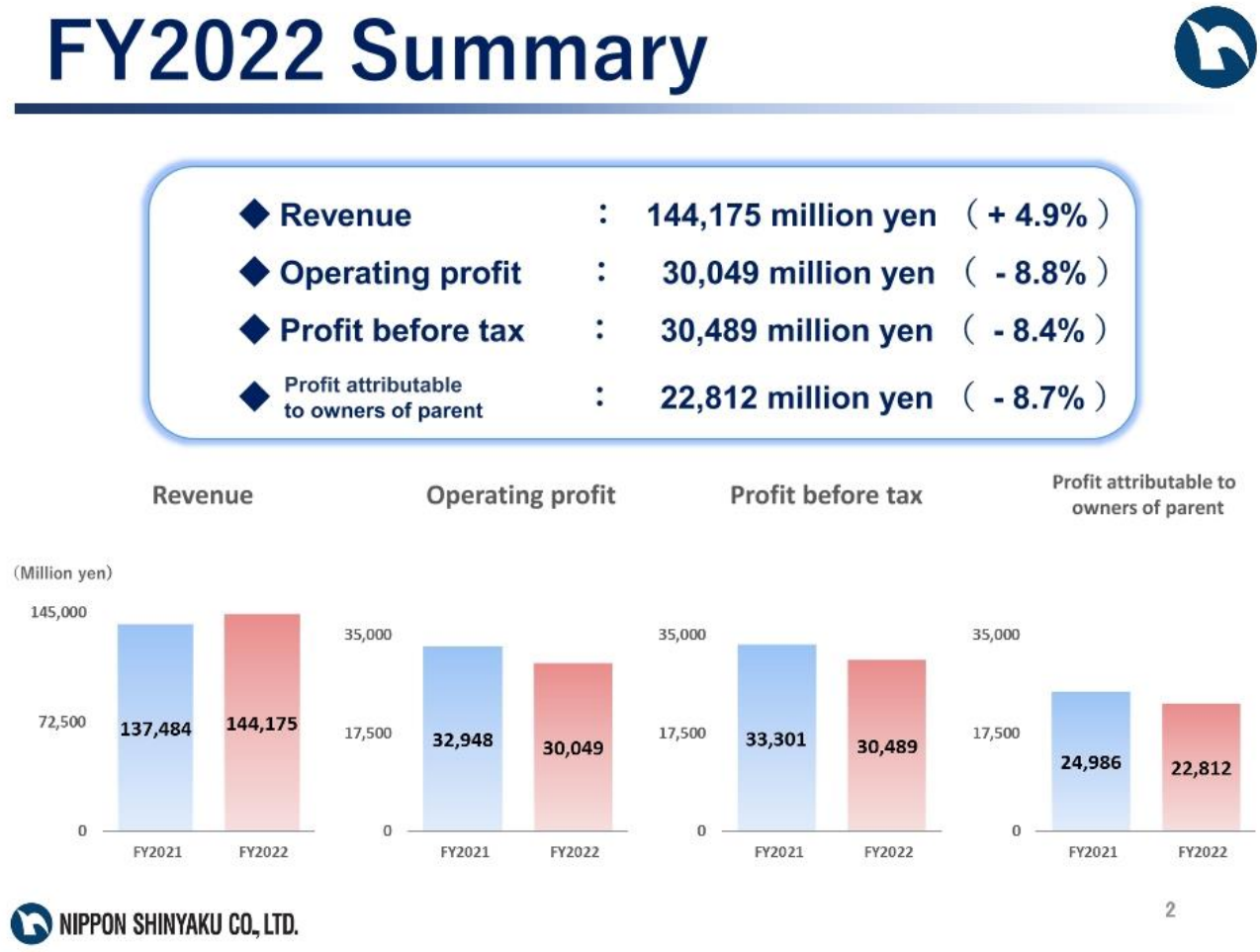
Financial Results Briefing for the Fiscal Year Ended March 2023

May 15, 2023

Presentation

Nakai: I am Toru Nakai, President of Nippon Shinyaku, Co., Ltd. Thank you very much for participating in our financial results briefing for FY2022 today. I appreciate it very much.

Today, I would like to report on our business performance for FY2022 and our full-year business forecast for FY2023, and Mr. Takagaki will explain the progress of our R&D items.



As an overview of our performance in FY2022, we reported consolidated revenue of JPY144,175 million, operating profit of JPY30,049 million, profit before tax of JPY30,489 million, and profit attributable to owners of parent of JPY22,812 million.

Segmental Review - Pharmaceuticals -

(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	78,508	65.1%	81,753	67.0%	+3,245	+4.1%
Revenues from the licensing of industrial property rights	33,207	27.5%	30,714	25.2%	-2,493	-7.5%
Profit in co-promotion	8,934	7.4%	9,520	7.8%	+585	+6.6%
Revenue	120,650	100.0%	121,988	100.0%	+1,337	+1.1%

Despite the effect of price revision by MHLW* and backlash from the loss of sales revenue from the priority review voucher, Revenue of consolidated pharmaceuticals segment increased by 1.1% due to increase of sales of Ethical drugs such as "Uptravi" and "Viltepso", and royalty revenue from Uptravi's overseas sales.

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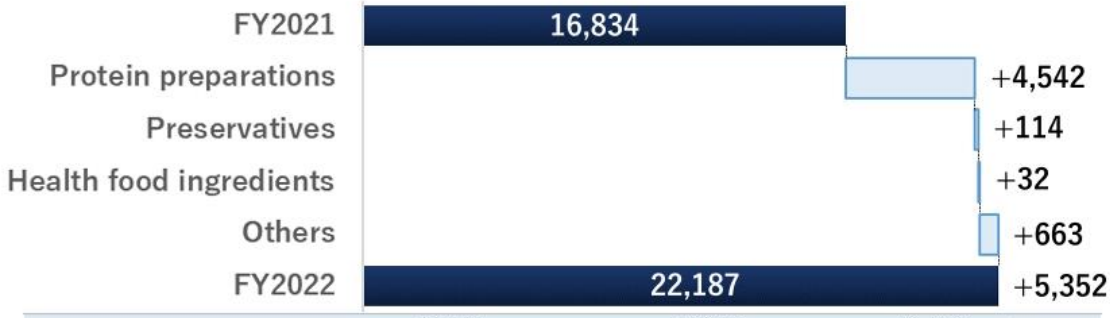
*MHLW : Ministry of Health, Labour and Welfare 3

In the pharmaceuticals business, despite the effect of price revision by MHLW and backlash from the loss of sales revenue from the priority review voucher, the sales of Uptravi, a treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and Viltepso, a treatment for Duchenne muscular dystrophy, and royalty income from overseas sales of Uptravi grew. As a result, consolidated net sales increased 1.1% YoY to JPY121,988 million.

Segmental Review - Functional Food -



(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	10,841	64.4%	15,383	69.3%	+4,542	+41.9%
Preservatives	2,790	16.6%	2,905	13.1%	+114	+4.1%
Health food ingredients	1,085	6.4%	1,118	5.0%	+32	+3.0%
Others	2,116	12.6%	2,779	12.6%	+663	+31.3%
Revenue	16,834	100.0%	22,187	100.0%	+5,352	+31.8%

Revenue of consolidated functional food segment increased by 31.8% mostly due to increase of demand from lowering COVID-19 cases and price revisions to offset price hikes of raw materials.

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In the functional food business, sales of protein products and other products increased due to a recovery in demand resulting from the easing of the impact of COVID-19 and the transfer of higher raw material prices to selling prices, resulting in consolidated net sales of JPY22,187 million, up 31.8% YoY.

Operating profit

(Million yen)	FY2021		FY2022		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Revenue	137,484	100.0%	144,175	100.0%	+6,690	+4.9%
(Pharmaceuticals)	(120,650)	(87.8%)	(121,988)	(84.6%)	(+1,337)	(+1.1%)
(Functional Food)	(16,834)	(12.2%)	(22,187)	(15.4%)	(+5,352)	(+31.8%)
Cost of sales	50,191	36.5%	55,980	38.8%	+5,789	+11.5%
SG&A expenses	32,173	23.4%	34,812	24.1%	+2,638	+8.2%
R&D expenses	22,863	16.6%	24,135	16.7%	+1,271	+5.6%
Other income	1,573	1.1%	1,908	1.3%	+335	+21.3%
Other expenses	882	0.6%	1,106	0.9%	+224	+25.4%
Operating profit	32,948	24.0%	30,049	20.8%	-2,898	-8.8%

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In terms of operating expenses, the cost of sales ratio worsened by 2.3 percentage points from the same period last year to 38.8%, mainly due to the backlash from the loss of sales revenue from the priority review voucher.

Selling, general and administrative (SG&A) expenses increased 8.2% YoY to JPY34,812 million, mainly due to an increase in sales promotion fees in line with increased domestic sales of Uptravi and an increase in US marketing expenses.

R&D expenses totaled JPY24,135 million, up 5.6% YoY, mainly due to an increase in manufacturing costs for investigational nucleic acid drugs in line with progress in clinical trials.

As a result, operating profit was JPY30,049 million, down 8.8% YoY.

Profit attributable to owners of parent

(Million yen)	FY2021 Results	FY2022 Results	YoY Change Amt	YoY Change %
Operating profit	32,948	30,049	-2,898	-8.8%
Finance income	472	575	+102	+21.7%
Finance costs	119	136	+17	+14.3%
Profit before tax	33,301	30,489	-2,812	-8.4%
Income tax expense, etc	8,315	7,676	-639	-7.7%
Profit attributable to owners of parent	24,986	22,812	-2,173	-8.7%

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Profit before tax was JPY30,489 million, down 8.4% YoY, and profit attributable to owners of parent was JPY22,812 million, down 8.7% YoY.

Business Forecast for FY2023

(Million yen)	FY2022 Results	FY2023 Forecast	YoY Change Amt	YoY Change %
Revenue	144,175	145,000	+825	+0.6%
Operating profit	30,049	32,000	+1,951	+6.5%
Profit before tax	30,489	32,500	+2,011	+6.6%
Profit attributable to owners of parent	22,812	25,000	+2,187	+9.6%

We look for Revenue, Operating profit, Profit before tax, Profit attributable to owners of parent to increase year on year.

I will now explain our full-year business forecast for FY2023.

Consolidated revenue is expected to be JPY145 billion, and consolidated income is expected to increase to JPY32 billion for operating profit, JPY32.5 billion for profit before tax, and JPY25 billion for profit attributable to owners of parent.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	81,753	67.0%	79,200	64.2%	-2,553	-3.1%
Revenues from the licensing of industrial property rights	30,714	25.2%	35,000	28.3%	+4,286	+14.0%
Profit in co-promotion	9,520	7.8%	9,300	7.5%	-220	-2.3%
Revenue	121,988	100.0%	123,500	100.0%	+1,512	+1.2%

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 "Upravi", and royalty revenue from Uptravi's overseas sales.

*MHLW : Ministry of Health, Labour and Welfare

In the pharmaceutical business, we forecast net sales of JPY123.5 billion, an increase of 1.2% YoY.

Despite the effect of price revision by MHLW and launch of generic products, the Company expects an increase in sales of Viltepso, Uptravi, and other products, as well as growth in royalty revenue from overseas sales of Uptravi.

Segmental Forecast - Functional Food -

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	15,383	69.3%	14,200	66.0%	-1,183	-7.7%
Preservatives	2,905	13.1%	3,000	14.0%	+95	+3.3%
Supplement	1,428	6.4%	1,800	8.4%	+372	+26.0%
Health food ingredients	1,118	5.0%	1,200	5.6%	+82	+7.3%
Others	1,351	6.1%	1,300	6.0%	-51	-3.8%
Revenue	22,187	100.0%	21,500	100.0%	-687	-3.1%

Despite enhancement of research and development toward new products, due to the effect of sales price reduction of several products, we predict Revenue of consolidated functional food segment to decrease.

In the functional food business, sales revenue is expected to be JPY21.5 billion, down 3.1% YoY due to the impact of lower sales prices of some products.

Forecast of Consolidated Statements of Income

(Million yen)	FY2022		FY2023		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Revenue	144,175	100.0%	145,000	100.0%	+825	+0.6%
(Pharmaceuticals)	(121,988)	(84.6%)	(123,500)	(85.2%)	(+1,512)	(+1.2%)
(Functional Food)	(22,187)	(15.4%)	(21,500)	(14.8%)	(-687)	(-3.1%)
Cost of sales	55,980	38.8%	50,000	34.5%	-5,980	-10.7%
SG&A expenses	34,812	24.1%	35,000	24.1%	+188	+0.5%
R&D expenses	24,135	16.7%	28,000	19.3%	+3,865	+16.0%
Other income	1,908	1.3%	400	0.3%	-1,508	-79.0%
Other expenses	1,106	0.9%	400	0.3%	-706	-63.8%
Operating profit	30,049	20.8%	32,000	22.1%	+1,951	+6.5%
Finance income	575	0.4%	500	0.3%	-75	-13.1%
Finance costs	136	0.1%	-	-	-136	-
Profit before tax	30,489	21.1%	32,500	22.4%	+2,011	+6.6%
Income tax expense, etc	7,676	5.3%	7,500	5.2%	-176	-2.3%
Profit attributable to owners of parent	22,812	15.8%	25,000	17.2%	+2,188	+9.6%

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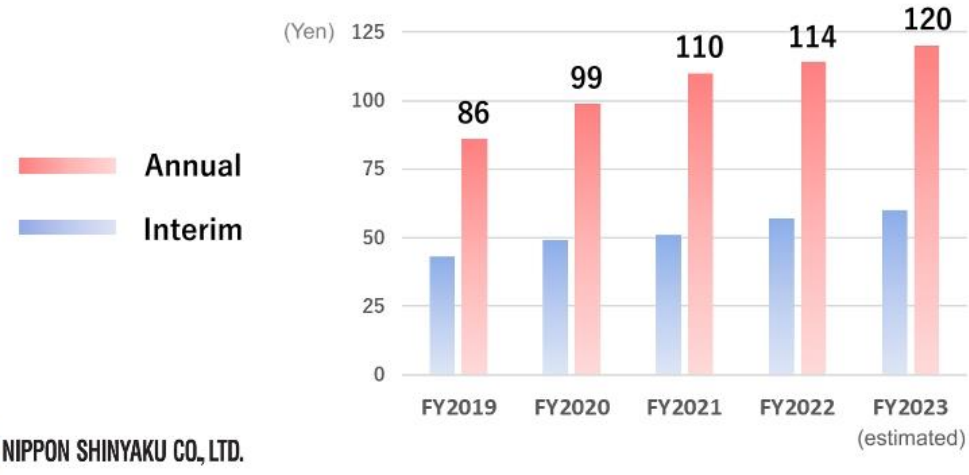
Next, regarding operating expenses, the cost to sales ratio is expected to be 34.5%, an improvement of 4.3 percentage points YoY.

SG&A expenses are expected to be JPY35 billion, and R&D expenses are expected to be JPY28 billion.

As a result, we expect operating profit of JPY32 billion, profit before tax of JPY32.5 billion, and profit attributable to owners of parent of JPY25 billion, an increase from the previous year.

Dividends Forecast

		FY2022	FY2023
Dividends per share	Interim	¥57	¥60
	Annual	¥114	¥120
Basic earnings per share		¥338.70	¥371.18
Payout ratio (consolidated)		33.7 %	32.3 %



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In accordance with this dividend policy, we plan to pay an interim dividend of JPY60 per share and a year-end dividend of JPY60 per share, for an annual dividend of JPY120 per share.

6th Five-year Mid-term Management Plan Target

(million yen)	FY2023 Mid-term Target	FY2023 Forecast	Difference Amt	Difference %
Revenue	150,000	145,000	-5,000	-3.3%
Operating profit	40,000	32,000	-8,000	-20.0%
Profit attributable to owners of parent	30,000	25,000	-5,000	-16.7%

Assumptions for unachieved target :

impact from COVID-19
- Uptake of VILTEPSO in the US was delayed

Negative impact from implementation of annual price revision by MHLW*
- Sales of domestic products declined more than expected

We seek further growth from our developing DMD pipeline, cell therapy, new modalities such as gene therapy and other pipeline products.

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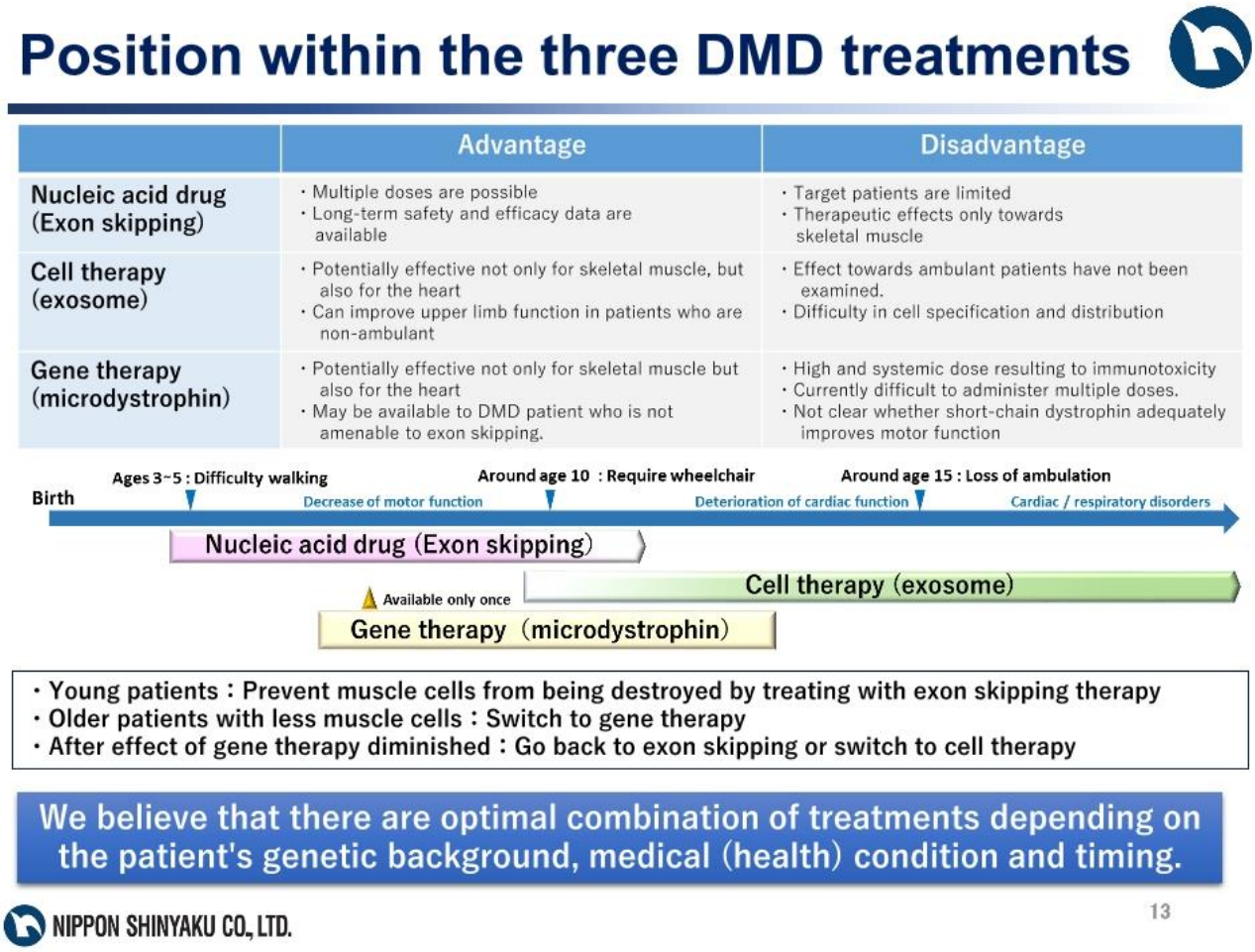
*MHLW : Ministry of Health, Labour and Welfare 12

FY2023 will be the final year of our sixth five-year mid-term management plan.

We expect to fall short of our mid-term target due to the delayed launch of Viltepso in the US from the impact of COVID-19 and the decrease in domestic product sales due to the negative impact from implementation of annual price revision by MHLW in the mid-year period.

On the other hand, we believe that long-term growth is possible through the development of new modalities such as gene therapy and pipeline items outside the DMD field, in addition to the nucleic acid drugs and cell therapy drug currently under development.

Let me once again explain our approach to growth.



First, let me explain the DMD area and the position of the three modalities we are currently working on in DMD therapy. Nucleic acid drug, cell therapy, and gene therapy each have their own advantages and disadvantages.

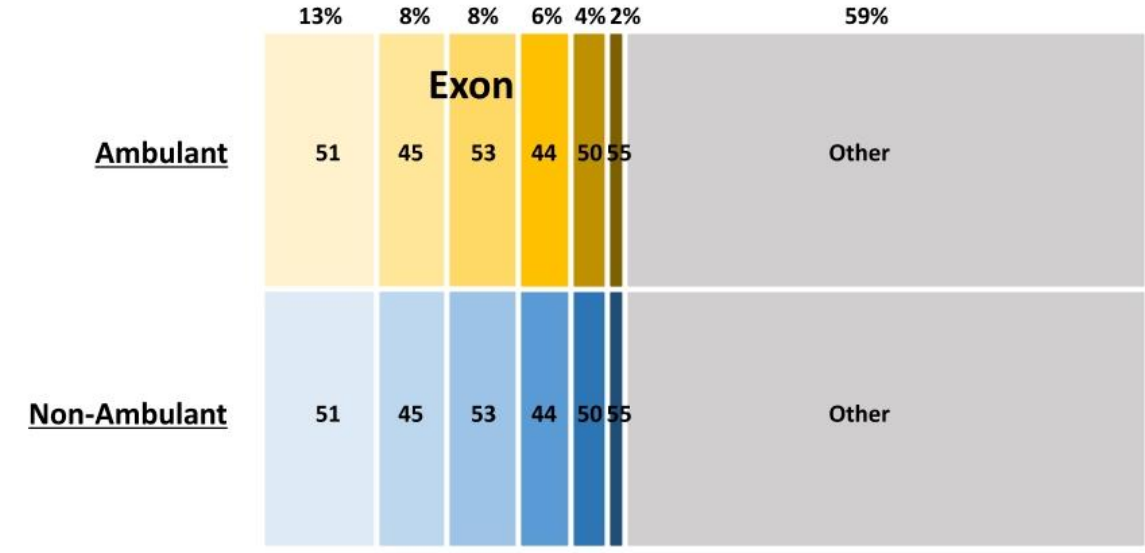
We believe that there are optimal combination of treatments depending on the patient's genetic background, medical condition and timing.

Since muscle stem cells are abundant and muscle regeneration is active and DMD gene expression is high at younger ages, it is desirable for patients eligible for exon skipping therapy to express near full-length dystrophin protein by exon skipping therapy to prevent muscle breakdown and maintain muscle mass.

After that, as you age, when the number of stem cells decreases, muscle regeneration decreases, and DMD gene expression decreases, gene therapy that introduces microdystrophin from the outside is considered effective.

On the other hand, since the effect of gene therapy is theoretically difficult to sustain for a long period of time, we believe that patients will return to exon skipping therapy when the effect diminishes, or if symptoms have progressed to the point of inability to walk, cell therapy will be the treatment of choice.

Percentage of patients amenable to exon skipping therapy out of all DMD patients



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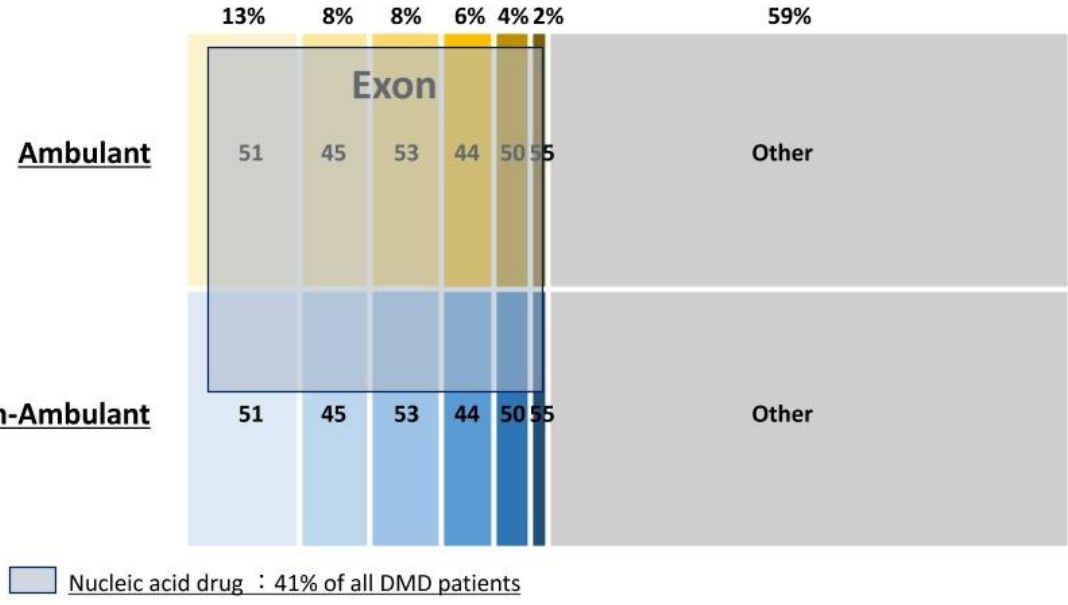
This is the percentage of DMD patients eligible for each exon skipping treatment.

Using the diagram here, I will explain the three DMD treatment target patients that we are working on.

Percentage of patients amenable to exon skipping therapy out of all DMD patients



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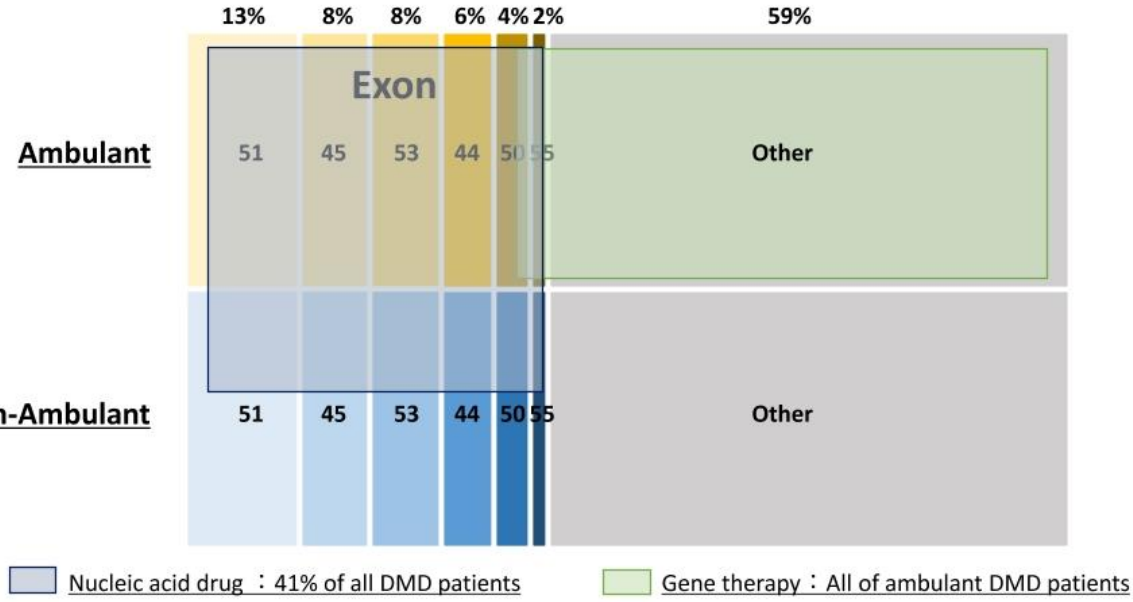
Including items under development, nucleic acid drugs treat approximately 41% of all DMD patients.

Currently, nucleic acid drugs primarily treat patients who are ambulatory.

Percentage of patients amenable to exon skipping therapy out of all DMD patients



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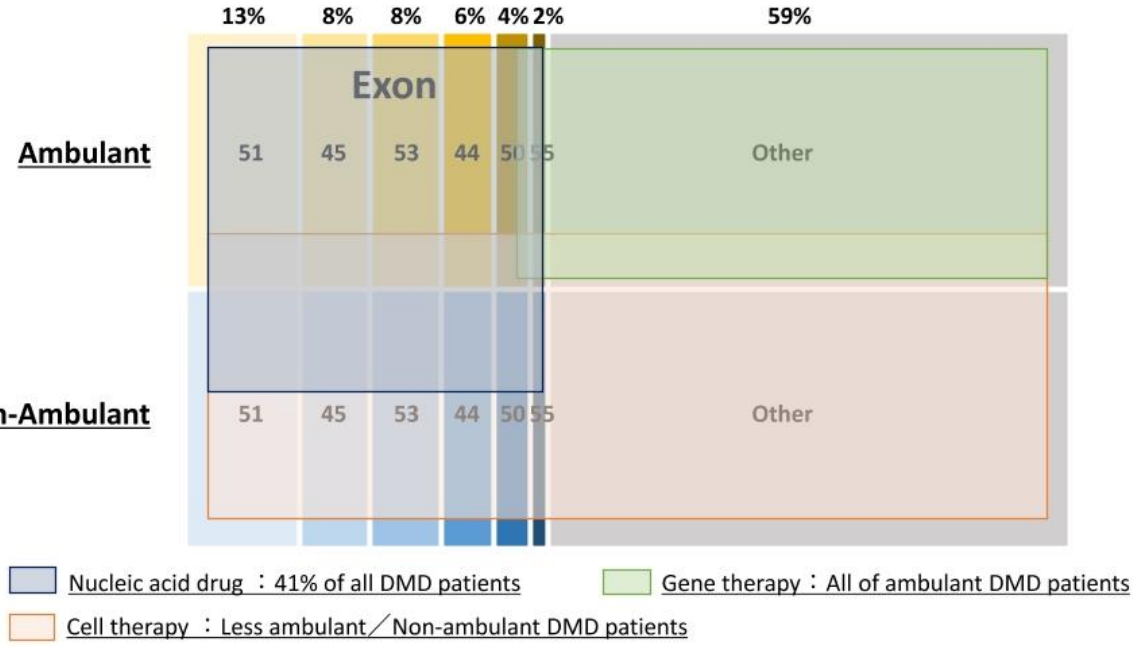
Assuming from current available data, we believe that gene therapy will treat approximately 59% of all DMD patients who are not eligible for exon skipping therapy.

Currently, clinical trials toward ambulatory patients are leading for gene therapy.

Percentage of patients amenable to exon skipping therapy out of all DMD patients



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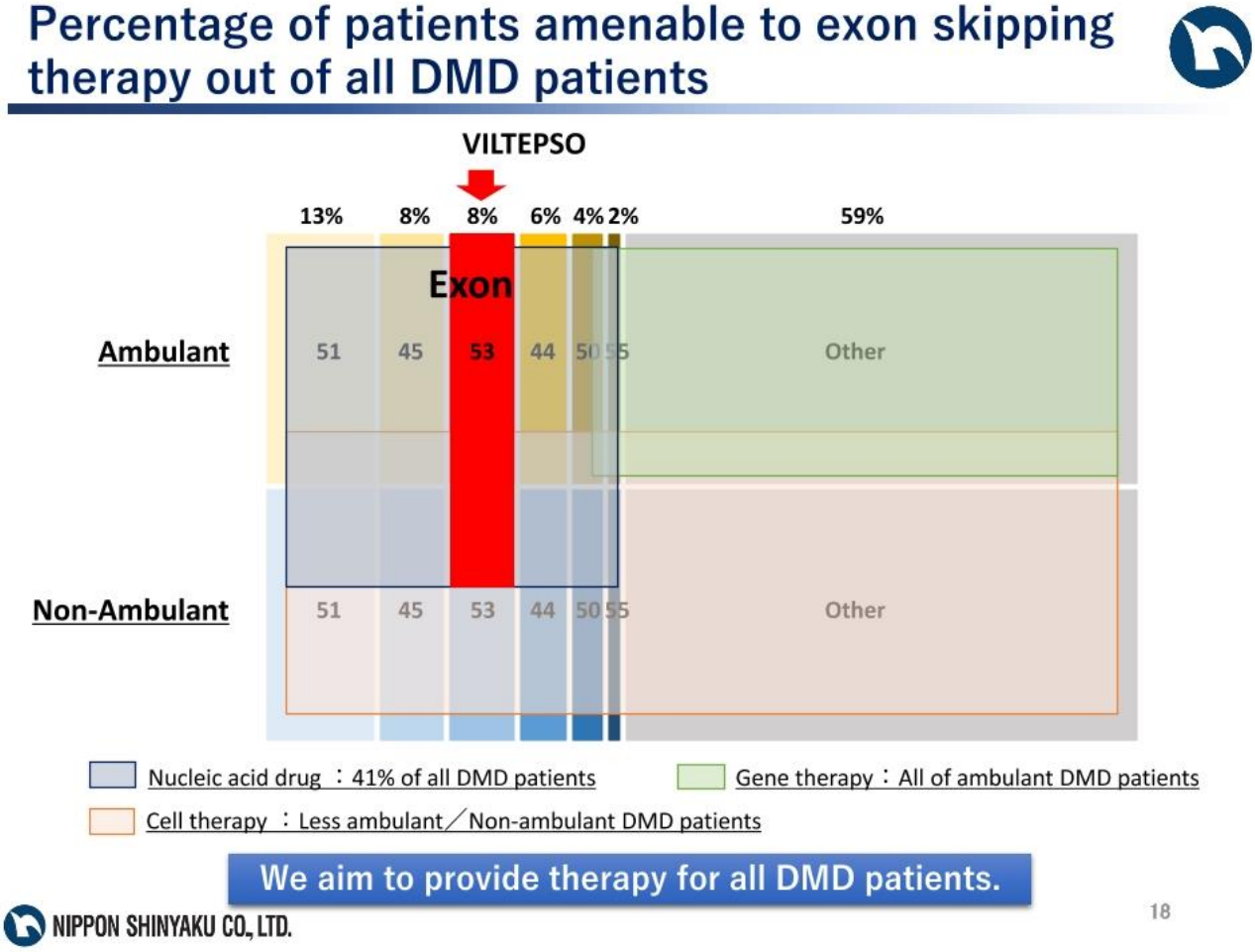
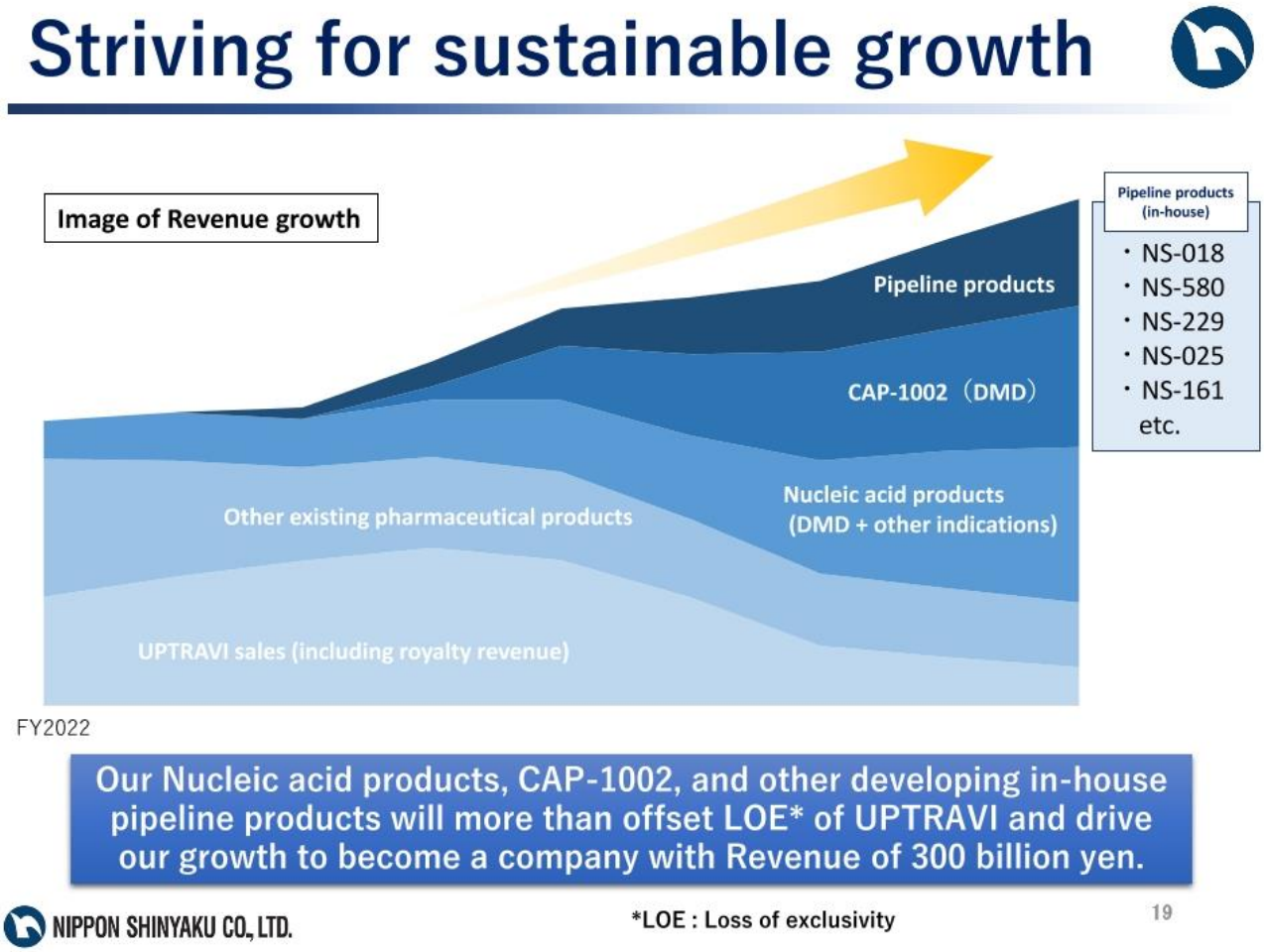
Cell therapy is available to all DMD patients with reduced ability to walk or who are unable to walk.



Viltepso, an exon 53-skipping drug currently marketed by the Company, targets approximately 8% of all DMD patients.

In addition to Viltepso, we intend to develop subsequent nucleic acid drugs, cell therapy, and gene therapy, and in the future, we hope to provide therapeutic agents for all DMD patients.



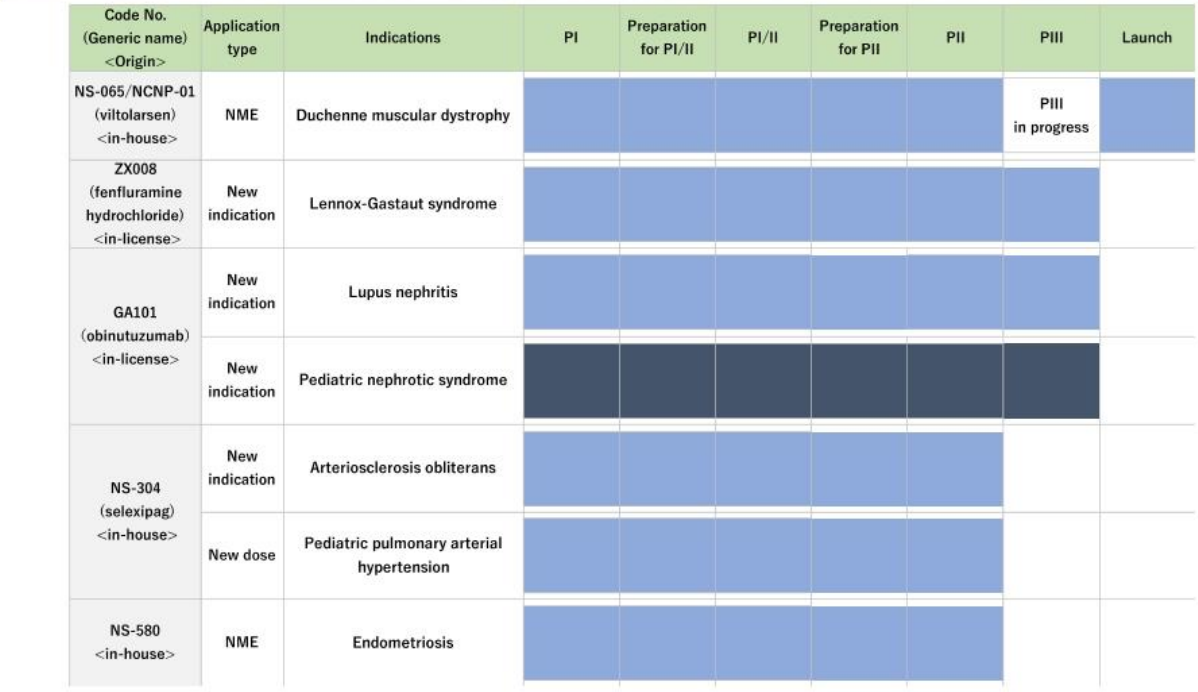
The patent for Uptravi, which has driven our growth, is scheduled to expire in October 2026 in the US and in April 2027 in the rest of the world.

In order to overcome the patent cliff, we would like to draw a growth scenario in our seventh mid-term management plan to be disclosed in the next fiscal year through the launch of CAP-1002, nucleic acid drugs following Viltepso, as well as NS-018 and NS-580, which are in-house developed drugs.

In the long term, we aim to achieve sustainable growth through the launch of in-house developed drugs such as NS-229, NS-161, and NS-025, which are planned to be rolled out globally.

This concludes my presentation for the financial results for FY2022 and the forecast for FY2023.

R&D Pipeline (Domestic)



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■ : Changes from 3rd Quarter FY2022 21

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

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

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

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

A Phase III study of “GA101” for lupus nephritis is in Phase III trials in collaboration with Chugai Pharmaceutical Co. In addition, a Phase III study for pediatric nephrotic syndrome was initiated in March 2023.

Nippon Shinyaku independently initiated a Phase IIb study of NS-304 for the indication of arteriosclerosis obliterans.

In addition, a Phase II study for pediatric pulmonary arterial hypertension is underway in collaboration with Janssen Pharmaceutical K.K.

Phase IIb study is underway for NS-580, an endometriosis treatment.

R&D Pipeline (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	PI	Preparation for PI/II	PI/II	Preparation for PII	PII	PIII	Launch
NS-089/NCNP-02 (brogidirsen) <in-house>	NME	Duchenne muscular dystrophy							
NS-87 (daunorubicin / cytarabine) <in-license>	New combi-nation	Secondary acute myeloid leukemia							
NS-401 (tagraxofusp) <in-license>	NME	Blastic plasmacytoid dendritic cell neoplasm							
NS-050/NCNP-03 <in-house>	NME	Duchenne muscular dystrophy							
NS-229 <in-house>	NME	Inflammatory diseases							
NS-917 (radgocitabine) <in-license>	NME	Relapsed/refractory acute myeloid leukemia							
NS-161 <in-house>	NME	Inflammatory diseases							
NS-025 <in-house>	NME	Urological diseases							

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■ : Changes from 3rd Quarter FY2022

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

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

A Phase I/II study of NS-401 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.

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

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

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

R&D Pipeline (Overseas)

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

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Next, I will explain the status of overseas development. NS-065/NCNP-01 (Viltepso), for the treatment of Duchenne muscular dystrophy, was launched in the US in August 2020 and are currently in a global Phase III study. It was also designated as an orphan drug in Europe in June 2020.

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

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

To reiterate, we are currently preparing global studies for NS-089/NCNP-02 and NS-050/NCNP-03.

This concludes the overview of our R&D activities.

FY2022 Financial Results Briefing Q&A (Summary)

Held on May 15, 2023

NO	Questions	Answers
1	VILTEPSO's U.S. sales fluctuated up and down in the previous fiscal year in terms of Q3 and Q4. The company appears to be expecting moderate growth in the current fiscal year, but including the current status of patient entry, I would like to know about the current situation. Also, please tell us about the dollar-yen exchange rate assumptions.	Exchange rate assumptions for the current fiscal year is 130 yen per U.S. dollar. Sales in 4Q rose slightly, but 1-time factors such as the timing of orders and rebate payments to Medicaid made it difficult to understand sales moving up and down. The sales volume base, which is the volume base delivered from wholesalers and pharmacies to medical institutions, is growing steadily in QonQ, and the number of patients administered is increasing. In terms of the current situation, the number of patients administered as of April was greater than expected. We believe that this is a good start for FY2023 U.S. VILTEPSO sales, given that such patients are administered over the course of the year.
2	Are the doctors focusing on gene and cell therapy also convinced with VILTEPSO's 4 year data?	In the United States, we are already using the 4 year data for promotion, and we have been reported from the promotion team in the U.S. that reputations of the data is very good. In the United States, there are more than 100 patients administering VILTEPSO, which includes patients switching from the competitor’s drug. Therefore, we assume that by presenting data of dystrophin expression and 4 year data, we are able to increase persuasiveness of VILTEPSO further leading to penetration into the medical field.
3	In the United States, despite the planned launch of the Quick Start Program during FY2022, why is the launch delayed to June 2023?	It took time to negotiate a contract with a service provider. Currently, contract negotiations have been terminated and preparations are under way.
4	Due to LOE of UPTRAVI between 2026 and 2027, sales will reduce. However, could we assume that other products will cover the patent cliff of UPTRAVI?	We will cover the patent cliff and continue to grow by launching and growing sales of new products such as nucleic acid drugs following VILTEPSO and CAP-1002, and by in-licensing new products.
5	In the image of sales, why does the growth in sales of nucleic acid drugs	Please consider this as an image. For the current fiscal year, forecasts for sales of VILTEPSO in

	seem low? I had thought that there was still room for growth in respect of VILTEPSO, but how do you see the growth in the next few years?	Japan is 4.8 billion yen and 13.5 billion yen in the U.S. Considering the U.S. market, sales of Sarepta's exon 51 skipping drug is about 500M dollars, and amenable to 13% of all DMD patients. Exon 53 skipping is amenable to 8% of all DMD patients, so if you think it is 8/13, we can assume that the potential market of exon 53 skipping will be about 300M dollars. When we add up sales of VILTEPSO and Sarepta's product, it is about 180M dollars, which is only about 60% of 300M dollars. As a result, we think there is still room for growth.
6	In explaining the long-term outlook, you have mentioned that pipeline products such as NS-229, NS-025, NS-161 are aimed to be expanded globally, but what is the policy for development at this point in time?	In terms of our basic approach to global expansion, we think that we can develop in-house products for intractable or rare diseases that are not so large as in market size, or, in other terms, diseases for which the number of specialized facilities where patients are concentrated and information is provided is not so many. As there are some products for which indications are not disclosed, we cannot say which products will be developed in-house. However, we will expand products for intractable diseases and rare diseases globally. For items that require major investments in clinical trials and sales, we will consider cooperating with other companies.
7	Is the positioning of the 3 therapies in DMD company's opinion? Even if Sarepta presents data on improvement of motor function through gene therapy earlier than the result of phase 3 study data of VILTEPSO, can it still be assumed that the positioning of the 3 therapies is as explained?	If the results of Sarepta's P3 trial of gene therapy were to be presented earlier than the result of VILTEPSO's P3 trial, we believe that the data for gene therapy would be a new piece of evidence of efficacy and safety. On the other hand, there is a limit to the duration of the effect of gene therapy, and it is considered that the effect will diminish in the future. Therefore, we believe that patients who have received gene therapy once and have lost the effect will be looking for therapies to replace, bringing patients back to administering nucleic acid drugs or switching to cell therapy. In addition, the positioning of the 3 therapies is just one of many clinical perceptions. After both gene therapy and nucleic acid drugs are fully approved and further used in clinical practice, we will genuinely know which therapy is best. For now, we

		have indicated that such positioning is appropriate.
8	Based on FDA's Advisory Committee presentation, Sarepta's gene therapy has a considerably shortened set of dystrophins. I thought the function of dystrophins is just a spring, but it seems that nNOS and α-syntrophin are linked in R16, R17 of spectrin-like repeats and have a function to alter local blood flow, but Sarepta's gene therapy does not include this part. Could we assume that these functions are preserved in VILTEPSO? Furthermore, can we assume that appealing this point to doctors will have a certain amount of persuasiveness for further use?	It depends on the type of gene mutation, but protein created by exon skipping has fewer missing parts therefore we believe that the function is maintained. Although it is known that the C-terminal membrane-bonding region is omitted in microdystrophin and that dystrophin is a large protein which interacts with various proteins etc., it is presumed that only a part of the interaction can be recovered on gene therapy. It has long been acknowledged and is widely known that protein made by exon skipping that is close to its full length is better. We will explain this to the HCPs by making understandable materials.
9	I thought that clinical trials for NS-051 was planned to start at the first half of this fiscal year. Is there any delay?	It took a little while to reach an agreement with FDA on NS-089, NS-050. We have decided to reflect the results of the discussion for clinical trials of NS-051, resulting for clinical trials to begin somewhere during this fiscal year.
10	In ClinicalTrials.gov, NS-018 P2b study is scheduled to complete in the spring of next year, but are there any prospects for completion of the trial?	The company is striving to proceed clinical trials of NS-018 as planned. Negotiations are held with the authorities in each country, mainly in Europe. We will further increase the number of countries to negotiate approval of proceeding clinical trials and increase the number of sites in countries where trials have been approved. To accelerate the pace of development, the company's international development operations have been under the direct control of the president since April. Regarding the slow clinical development that many are concerned about, the president will also be actively involved in accelerating the development speed. An Investigator Meeting will be held next month, and the president will also attend the meeting, to accelerate the speed of the trial by communicating with the clinical trial site staff.
11	What are your medium-to long-term ideas for the functional food business? The sales targets in the medium-term management plan have	We do not intend to separate the functional food business at the moment. Aside from capital efficiency, we think there are business synergies between the functional food and

	been achieved, but when considering capital efficiency, is the functional food business meeting your company's standards? Given LOE of UPTRAVI, what do you think about the functional food business under the circumstances where capital should be shifted to the pharmaceutical business? In relation to this, there are targets for ROE but do you plan to disclose other targets such as ROIC in the next medium-term management plan?	pharmaceutical businesses. In the United States, many companies communicate well with consumers. However, we feel that we need to appeal toward consumers, and we think that there are points we can learn about consumer marketing from the functional food business. We would also like to consider such synergies. We are currently discussing whether or not to disclose various target indicators, including ROIC other than ROE, in the next medium-term management plan, and we would like to ask you to wait for a while.