Nippon Shinyaku Co., Ltd.

FY2025 Earnings Call and Presentation

May 15, 2026

Event Summary

[Company Name]	Nippon Shinyaku Co., Ltd.
[Event Type]	Earnings Announcement
[Event Name]	FY2025 Earnings Call and Presentation
[Fiscal Period]	FY2026 Annual
[Date]	May 15, 2026
[Number of Speakers]	6

Toru Nakai	Representative Director, President
Takanori Edamitsu	Director, Business Management & Sustainability
Kazuyuki Iwata	Director, Sales and Marketing
Keiichi Kuwano	Director, Research & Development
Manabu Beppu	Corporate Officer, Head of R&D Planning and Administration Div.
Naoki Inoue	Department Manager, Public Relations & Investor Relations Dept.

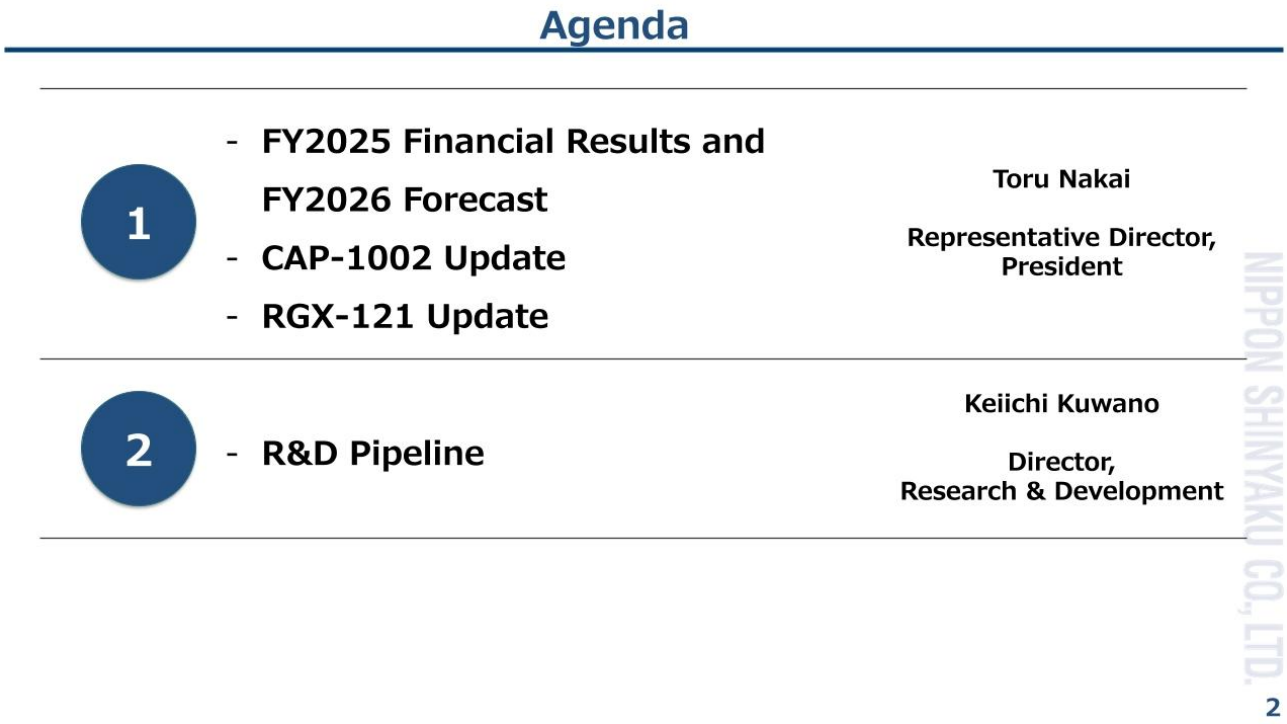
Presentation

Inoue: Now it is time to begin the financial results briefing of Nippon Shinyaku Co., Ltd. for FY2025.

To begin with, I would like to introduce attendees from our company. This is Nakai, Representative Director, President. This is Edamitsu, Director, Business Management & Sustainability. This is Iwata, Director, Sales and Marketing. This is Kuwano, Director, Research & Development. I am Inoue from Public Relations & Investor Relations Department, and I will serve as the moderator.

The content of this presentation will be available on our website as an on-demand video streaming and transcript, so please be aware of this when asking questions after the presentation.

Then, Mr. Nakai, please start.



Nakai: I am Toru Nakai, President of Nippon Shinyaku. Thank you very much for taking time out of your busy schedules to participate in our financial results briefing for FY2025. I deeply appreciate it.

Today, I will discuss our financial results of FY2025 and our forecast for FY2026, as well as updates on CAP-1002 and RGX-121. After that, Mr. Kuwano, who is in charge of research and development, will explain the R&D pipeline.

Highlight

FY2025 Financial Results

- ✓ **Increased revenue in both the pharmaceuticals and functional food businesses, marking the fourth consecutive period of revenue growth**
- ✓ **Increased operating profit, marking the third consecutive period of growth**

FY2026 Full-Year Forecast

- ✓ **Revenue: 200 billion yen (Up 17.1% YoY)**
- ✓ **Operating profit: 38 billion yen (Up 7.1% YoY)**

Then, I will explain the financial results of FY2025 and the forecast for FY2026.

First of all, this slide shows the highlights of the financial results disclosed at noon today.

In FY2025, both the pharmaceuticals and functional food businesses reported an increase in revenue, marking the fourth consecutive year of revenue growth. Operating profit also increased for the third consecutive year.

For FY2026, we expect revenue to increase by 17.1% YoY to JPY200 billion, and operating profit to increase by 7.1% YoY to JPY38 billion.

FY2025 Summary

- **Increased revenue in both the pharmaceuticals and functional food businesses, marking the fourth consecutive period of revenue growth**
- **Increased cost of sales and SG&A expenses led to a slight increase in operating profit. Profit attributable to owners of parent decreased due to changes in the tax rate.**

(million yen)	FY2024		FY2025		YoY	
	actual	ratio	actual	ratio	change	%
Revenue	**160,232**	**100.0%**	**170,771**	**100.0%**	**+10,539**	**+6.6%**
(Pharmaceuticals)	(138,654)	(86.5%)	(148,484)	(86.9%)	(+9,829)	(+7.1%)
(Functional Food)	(21,577)	(13.5%)	(22,287)	(13.1%)	(+710)	(+3.3%)
Cost of sales	51,116	31.9%	57,460	33.6%	+6,343	+12.4%
SG&A expenses	38,011	23.7%	43,565	25.5%	+5,554	+14.6%
R&D expenses	34,341	21.4%	36,713	21.5%	+2,372	+6.9%
Other income	874	0.5%	3,025	1.8%	+2,151	+246.0%
(Foreign exchange gain)	-	-	(2,265)	(1.3%)	(+2,265)	-
Other expenses	2,186	1.4%	560	0.4%	-1,625	-74.3%
Operating profit	**35,450**	**22.1%**	**35,496**	**20.8%**	**+46**	**+0.1%**
Finance income	830	0.5%	1,132	0.7%	+301	+36.3%
Finance costs	145	0.1%	166	0.1%	+20	+14.1%
Profit before tax	**36,135**	**22.6%**	**36,462**	**21.4%**	**+327**	**+0.9%**
Income tax expense, etc.	3,577	2.2%	6,741	3.9%	+3,164	+88.5%
Profit attributable to owners of parent	**32,558**	**20.3%**	**29,721**	**17.4%**	**-2,837**	**-8.7%**

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Let me explain in detail from here. Please take a look at slide five.

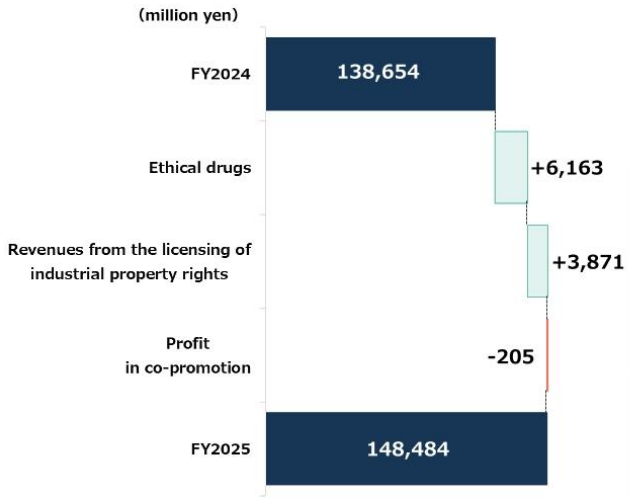
As a summary of the results of FY2025, on a YoY basis, consolidated revenue increased by JPY10,539 million to JPY170,771 million, operating profit increased by JPY46 million to JPY35,496 million, and profit before tax increased by JPY327 million to JPY36,462 million.

With respect to income tax expense, the income tax rate decreased in FY2024 due to the recognition of the recoverability of deferred tax assets in NS Pharma, but this has no impact on FY2025, resulting in an increase in income tax expense, etc.

As a result, profit attributable to owners of parent decreased by JPY2,837 million to JPY29,721 million.

Segmental Review - Pharmaceuticals -

- **Growth in domestic sales of Uptravi, Fintepla, etc., including the contribution of Erleada, and royalty income from overseas sales of Uptravi**



Ethical drugs 90,062 million yen (+6,163 million yen, +7.3%, YoY)

- ✓ Growth of Uptravi and Fintepla
- ✓ Erleada's revenue has been recognized by the company through a reverse co-promotion arrangement.

Revenues from the licensing of industrial property rights 49,457 million yen (+3,871 million yen, +8.5%, YoY)

- ✓ Royalty revenue growth due to overseas sales increase of Uptravi

Profit in co-promotion 8,964 million yen (-205 million yen, -2.2%, YoY)

- ✓ Yuvanci's sales increased, but revenue recognition for Erleada has changed.

1. previously recorded as profit in co-promotion, but now recorded as product sales and cost of goods sold, based on contract revisions

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Please move on to slide six.

In the pharmaceuticals business, despite the effects of the National Health Insurance drug price revisions and generic competition, consolidated revenue increased by 7.1% YoY to JPY148,484 million, thanks to growth in domestic sales of Uptravi, royalty income from overseas sales of the same product, and growth of new product lines such as Fintepla, as well as the contribution of Erleada, which has been recorded as sales of the Company since October last year based on contract revisions.

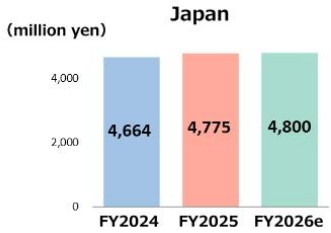
Sales Trends of Viltepso® (viltolarsen)

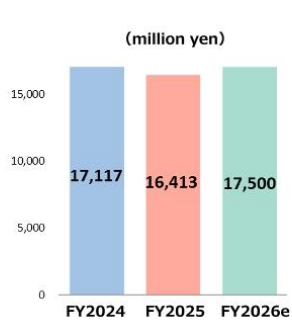
- **The average dose per patient has decreased due to younger patient population, resulting sales decline of Viltepso in the U.S. However, sales growth is expected due to an increase in the number of new patients and longer-term administration**

(million yen)	FY2024 actual	FY2025 actual	YoY change	YoY %	FY2026 forecast	Notes on FY2025 results
Japan	4,664	4,775	+110	+2.4%	4,800	✓ The number of patients currently on therapy with Viltepso is more than three-quarters of the peak number of 128 patients in the data from Chuikyo[1]. ✓ Promoting early diagnosis and intervention for younger patients
US	17,117	16,413	-704	-4.1%	17,500	✓ Insurance reauthorizations became stricter after launch of multiple DMD treatment options.
(million US$)	(112.18)	(108.86)	(-3.32)	(-3.0%)	(116.67)	✓ The average dose per patient has decreased due to younger patient population, but revenue growth is expected as a result of longer-term administration
Total	21,782	21,188	-593	-2.7%	22,300	.

1. Central Social Insurance Medical Council

Exchange rates	FY2024 actual	FY2025 actual	FY2026 assumption
USDJPY	152.6	150.8	150.0





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Here we show the sales of Viltepso, which is sold in Japan and the United States.

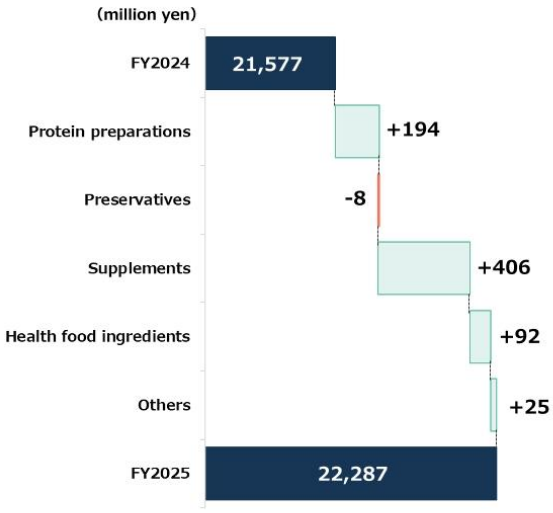
Sales results of FY2025 were JPY4,775 million in Japan and JPY16,413 million in the United States. In the US, the sales in dollar terms also decreased YoY. The number of patients dropping out of the medication has increased due to stricter insurance reauthorizations, after the launch of several high-cost DMD therapies on the market. However, we have been continuously acquiring new patients.

Although the average dose per patient has decreased as the number of patients administered the drug is getting younger, we expect revenue to increase as the drug is expected to be administered over a longer period of time.

In light of this, for the full year of FY2026, we expect revenue of JPY4,800 million in Japan and JPY17,500 million in the US.

Segmental Review - Functional Food -

- **Increased segment revenue due to the launch of new products and strengthened sales activities**
- **Sales decline in preservatives due to competitive market**



Protein preparations 13,680 million yen
(+194 million yen, +1.4%, YoY)
✓ Growth in the egg protein share and strong sales of protein powder

Preservatives 3,269 million yen
(-8 million yen, - 0.3%, YoY)
✓ Rising prices have led to consumers holding back on purchases, resulting in a decrease in user output.

Supplements 2,821 million yen
(+406 million yen, +16.8%, YoY)
✓ Sales increase in both athletes and anti-aging care category
✓ New products for children and plant-based protein products launched in February 2026

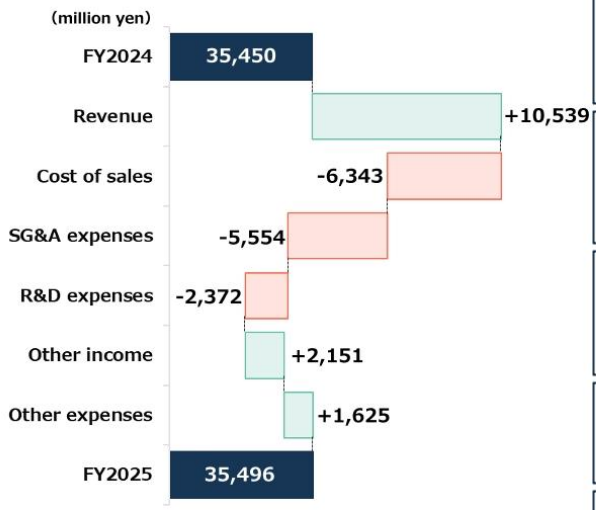
Health food ingredients 1,214 million yen
(+92 million yen, +8.2%, YoY)
✓ Expanded demand for beauty-related products

Please turn to slide eight.

In the functional food business, sales of preservatives declined as rising prices have led to consumers holding back on purchases, but sales of protein preparations, supplements, and health food ingredients increased, resulting in consolidated segment revenue of JPY22,287 million, up 3.3% YoY.

Operating Profit

- **Slight increases in profits due to increase in cost of sales and SG&A expenses, etc.**



Revenue 170,771 million yen
(+10,539 million yen, +6.6%, YoY)
- ✓ Growth of new product lines including Uptravi and Fintepla
- ✓ Through reverse co-promotion, Erleada is now included in revenue for the company
- ✓ Royalty revenue growth due to overseas sales of Uptravi

Cost of sales 57,460 million yen
(+6,343 million yen, +12.4%, YoY)
The ratio was 33.6%, worsened by 1.7 points YoY.
- ✓ Negative impact from changes in pharmaceutical product sales mix and NHI drug price revisions

SG&A expenses 43,565 million yen
(+5,554 million yen, + 14.6%, YoY)
- ✓ Increase in the U.S. sales expenses of NS Pharma
- ✓ Increase in commission for promotional activities of Uptravi due to domestic sales increase

R&D expenses 36,713 million yen
(+2,372 million yen, +6.9%, YoY)
- ✓ Increase in contract research expense and raw material costs related to investigational products

Other income 3,025 million yen
(+2,151 million yen, + 246.0%, YoY)
- ✓ Increase in foreign exchange gains

Please move on to slide nine.

Next, in terms of cost of sales, the cost of sales ratio worsened by 1.7 percentage point YoY to 33.6%, mainly due to the sales mix and the impact of NHI drug price revisions.

SG&A expenses increased by 14.6% YoY to JPY43,565 million, mainly due to an increase in sales expenses at NS Pharma in preparation for the new product launches.

R&D expenses amounted to JPY36,713 million, up 6.9% YoY, mainly due to an increase in contract research expenses and raw material costs related to investigational products.

With regard to other income, foreign exchange gains increased.

As a result, operating profit slightly increased by 0.1% YoY to JPY35,496 million.

Business Forecast for FY2026 (consolidated)

(million yen)	FY2025 actual	FY2025 ratio	FY2026 forecast	FY2026 ratio	YoY change	YoY %
Revenue	**170,771**	**100.0%**	**200,000**	**100.0%**	**+29,228**	**+17.1%**
(Pharmaceuticals)	(148,484)	(86.9%)	(176,500)	(88.3%)	(+28,015)	(+18.9%)
(Functional Food)	(22,287)	(13.1%)	(23,500)	(11.8%)	(+1,212)	(+5.4%)
Cost of sales	57,460	33.6%	73,000	36.5%	+15,539	+27.0%
SG&A expenses	43,565	25.5%	47,500	23.8%	+3,934	+9.0%
R&D expenses	36,713	21.5%	40,500	20.3%	+3,786	+10.3%
Other income	3,025	1.8%	1,000	0.5%	-2,025	-67.0%
Other expenses	560	0.4%	2,000	1.0%	+1,439	+256.5%
Operating profit	**35,496**	**20.8%**	**38,000**	**19.0%**	**+2,503**	**+7.1%**
Finance income	1,132	0.7%	800	0.4%	-332	-29.3%
Finance costs	166	0.1%	200	0.1%	+33	+20.5%
Profit before tax	**36,462**	**21.4%**	**38,600**	**19.3%**	**+2,137**	**+5.9%**
Income tax expense, etc.	6,741	3.9%	8,300	4.2%	+1,558	+23.1%
Profit attributable to owners of parent	**29,721**	**17.4%**	**30,300**	**15.2%**	**+578**	**+1.9%**

Reasons for the differences

Revenue
- ✓ The U.S. launch of CAP-1002 (deramiocel)
- ✓ Growth in the domestic products
- ✓ Royalty revenue growth due to overseas sales increase of Uptravi

Cost of Sales
- ✓ Erleada and CAP-1002 (deramiocel)

SG&A expenses
- ✓ Increase in the U.S. sales expenses of NS Pharma
- ✓ Increase in commission for promotional activities of Uptravi due to domestic sales increase

R&D expenses
- ✓ Increase in contract research expense

The foreign exchange rates (USDJPY) are 152.6 for FY2024a, 150.8 for FY2025a and 150.0 for FY2026e. FY2026e's sensitivity indicates that for every ¥1 depreciation of the yen against the USD, revenue is expected to increase by approximately ¥550 million and operating profit is expected to increase by approximately ¥410 million.

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Please move on to slide 10.

Next, I will explain the business forecast for FY2026.

Consolidated revenue is expected to be JPY200 billion, an increase of 17.1% YoY.

Regarding cost of sales, the cost of sales ratio is expected to deteriorate by 2.9 percentage points to 36.5%.

SG&A expenses are expected to amount to JPY47,500 million, mainly due to an increase in sales expenses at NS Pharma in preparation for the new product launches. R&D expenses are expected to be JPY40,500 million, mainly due to an increase in contract research expenses.

As a result, operating profit is expected to increase to JPY38,000 million, profit before tax to JPY38,600 million, and profit attributable to owners of parent to JPY30,300 million.

Revenue Forecast – Pharmaceuticals Segment -

(million yen)	FY2025 actual	FY2025 ratio	FY2026 forecast	FY2026 ratio	YoY change	YoY %
Ethical Drugs	90,062	60.7%	114,900	65.1%	+24,837	+27.6%
Revenues from the licensing of industrial property rights	49,457	33.3%	53,000	30.0%	+3,542	+7.2%
Profit in co-promotion	8,964	6.0%	8,600	4.9%	-364	-4.1%
Revenue	148,484	100.0%	176,500	100.0%	+28,015	+18.9%

Sales increase is expected due to the following factors;

1. New product launch in the U.S. : CAP-1002 (deramiocel)
2. Contribution of new products in Japan: Erleada, Fintepla, Uptravi, etc.
3. Growth in royalty income: overseas sales of Uptravi

Please move on to slide 11.

In the pharmaceuticals segment, revenue is expected to be JPY176,500 million, an increase of 18.9% YoY.

In addition to CAP-1002, which is scheduled to be launched in the US by the end of this year, as well as to new domestic products such as Erleada, Fintepla, and Uptravi, we expect growth in royalty income associated with overseas sales of Uptravi.

Revenue Forecast - Functional Food Segment-

(million yen)	FY2025 actual	FY2025 ratio	FY2026 forecast	FY2026 ratio	YoY change	YoY %
Protein preparations	13,680	61.4%	14,200	60.4%	+519	+3.8%
Preservatives	3,269	14.7%	3,400	14.5%	+130	+4.0%
Supplements	2,821	12.7%	3,400	14.5%	+578	+20.5%
Health food ingredients	1,214	5.4%	1,250	5.3%	+35	+2.9%
Others	1,302	5.8%	1,250	5.3%	-52	-4.0%
Revenue	22,287	100.0%	23,500	100.0%	+1,212	+5.4%

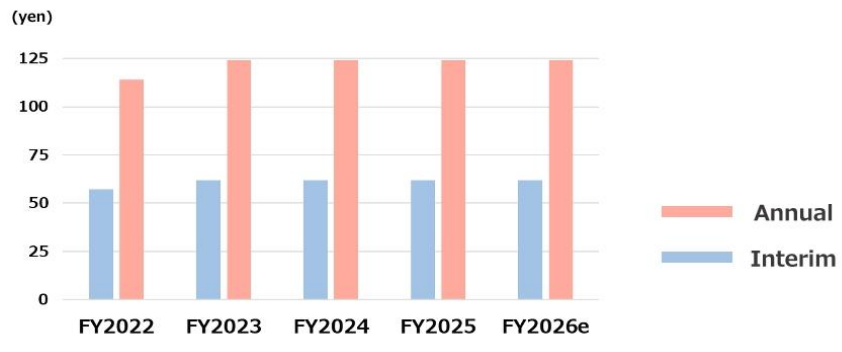
Sales increase is expected through development and launch of new products and strengthen sales efforts in key products.

Please move on to slide 12.

In the functional food segment, we expect revenue of JPY23,500 million, an increase of 5.4% YoY, by further focusing on the development and launch of new products and strengthening our efforts in key products.

Dividends Forecast

		FY2025	FY2026e
Dividends per share	Interim	¥62	¥62
	Annual	¥124	¥124
Basic earnings per share		¥441.00	¥449.55
Payout ratio (consolidated)		28.1 %	27.6 %
Dividend on equity ratio		3.1 %	-



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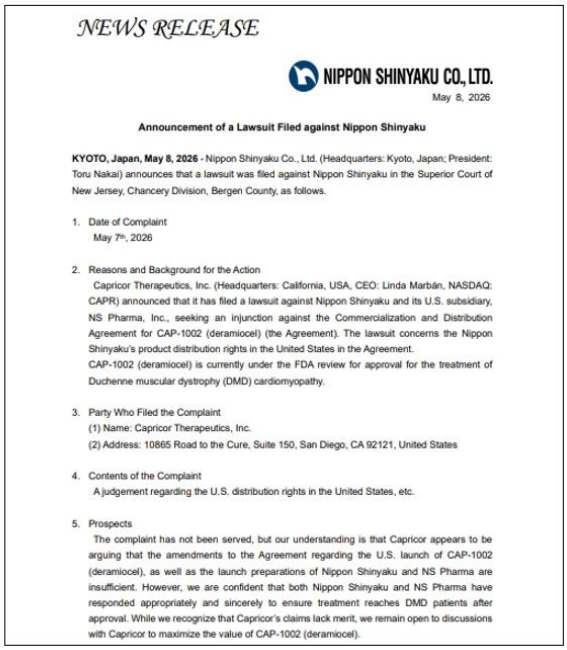
For FY2025, the Company will pay a year-end dividend of JPY62 per share, which, together with the earlier interim dividend of JPY62 per share, will result in an annual dividend of JPY124 per share.

For FY2026, the Company plans to pay an interim dividend of JPY62 per share and a year-end dividend of JPY62 per share, which will result in an annual dividend of JPY124 per share.

That is all for my explanation of the financial results of FY2025 and the forecast for FY2026.

CAP-1002 (deramiocel) : Regulatory Update



NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

May 8, 2026

Announcement of a Lawsuit Filed against Nippon Shinyaku

KYOTO, Japan, May 8, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan; President: Toru Nakai) announces that a lawsuit was filed against Nippon Shinyaku in the Superior Court of New Jersey, Chancery Division, Bergen County, as follows.

1. Date of Complaint
   May 7th, 2026

2. Reasons and Background for the Action
   Capricor Therapeutics, Inc. (Headquarters: California, USA, CEO: Linda Marbán, NASDAQ: CAPR) announced that it has filed a lawsuit against Nippon Shinyaku and its U.S. subsidiary, NS Pharma, Inc., seeking an injunction against the Commercialization and Distribution Agreement for CAP-1002 (deramiocel) (the Agreement). The lawsuit concerns the Nippon Shinyaku's product distribution rights in the United States in the Agreement.
   CAP-1002 (deramiocel) is currently under the FDA review for approval for the treatment of Duchenne muscular dystrophy (DMD) cardiomyopathy.

3. Party Who Filed the Complaint
   (1) Name: Capricor Therapeutics, Inc.
   (2) Address: 10865 Road to the Cure, Suite 150, San Diego, CA 92121, United States

4. Contents of the Complaint
   A judgement regarding the U.S. distribution rights in the United States, etc.

5. Prospects
   The complaint has not been served, but our understanding is that Capricor appears to be arguing that the amendments to the Agreement regarding the U.S. launch of CAP-1002 (deramiocel), as well as the launch preparations of Nippon Shinyaku and NS Pharma are insufficient. However, we are confident that both Nippon Shinyaku and NS Pharma have responded appropriately and sincerely to ensure treatment reaches DMD patients after approval. While we recognize that Capricor's claims lack merit, we remain open to discussions with Capricor to maximize the value of CAP-1002 (deramiocel).

- **On May 7th, 2026, a lawsuit was filed against Nippon Shinyaku in the Superior Court of New Jersey, Chancery Division, Bergen County.**
- **In order to ensure treatment reaches DMD patients after approval, both Nippon Shinyaku and NS Pharma have engaged in discussions with Capricor in a proper and sincere manner. In accordance with the Agreement regarding the U.S. launch of CAP-1002 (deramiocel), we have made thorough preparations for the product launch.**
- **While we recognize that Capricor's claims lack merit, we remain open to constructive discussions with Capricor in the best interests of DMD patients and their families in the U.S.**

NIPPON SHINYAKU CO., LTD.

Source : May 8, 2026, Company press release 15

Next, I will explain the update of CAP-1002.

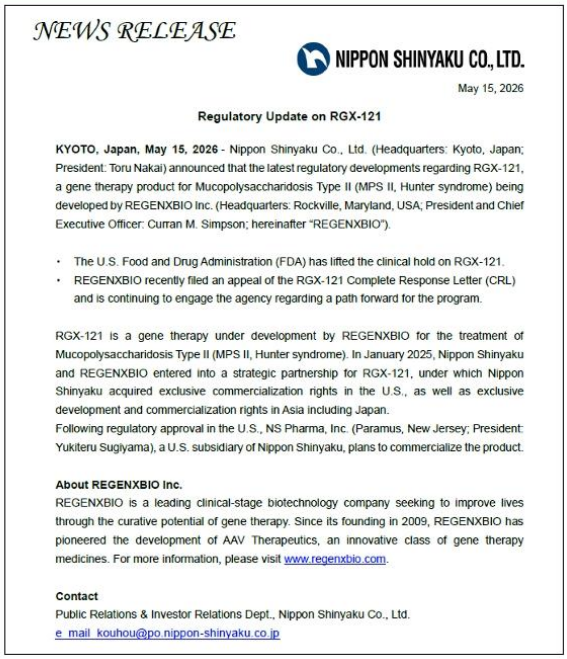
Please move on to slide 15.

On May 7, Capricor filed a lawsuit against the Company and its US subsidiary, NS Pharma, seeking termination of the US marketing agreement for CAP-1002, which has been filed for approval with the expected indication of DMD cardiomyopathy. As we currently understand it, Capricor is claiming that the Company is insufficiently prepared to handle the revision of the current contract and to launch CAP-1002 in the US.

We have been taking appropriate and sincere measures to ensure that the treatment of DMD patients will not be delayed and have been preparing for the launch of the product. While we recognize that Capricor's claims lack merit, we are committed to continuing our dialogue with Capricor in the best interests of DMD patients and their families in the US.

The forecast for FY2026 that I have just explained incorporates sales and marketing expenses for CAP-1002. However, we will revise this forecast as necessary in light of the status of the lawsuit by Capricor.

RGX-121 (clemidsogene lanparvovec) : Regulatory Update



NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

May 15, 2026

Regulatory Update on RGX-121

KYOTO, Japan, May 15, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto, Japan; President: Toru Nakai) announced that the latest regulatory developments regarding RGX-121, a gene therapy product for Mucopolysaccharidosis Type II (MPS II, Hunter syndrome) being developed by REGENXBIO Inc. (Headquarters: Rockville, Maryland, USA; President and Chief Executive Officer: Curran M. Simpson; hereinafter "REGENXBIO").

- The U.S. Food and Drug Administration (FDA) has lifted the clinical hold on RGX-121.
- REGENXBIO recently filed an appeal of the RGX-121 Complete Response Letter (CRL) and is continuing to engage the agency regarding a path forward for the program.

RGX-121 is a gene therapy under development by REGENXBIO for the treatment of Mucopolysaccharidosis Type II (MPS II, Hunter syndrome). In January 2025, Nippon Shinyaku and REGENXBIO entered into a strategic partnership for RGX-121, under which Nippon Shinyaku acquired exclusive commercialization rights in the U.S., as well as exclusive development and commercialization rights in Asia including Japan.
Following regulatory approval in the U.S., NS Pharma, Inc. (Paramus, New Jersey; President: Yukiteru Sugiyama), a U.S. subsidiary of Nippon Shinyaku, plans to commercialize the product.

About REGENXBIO Inc.
REGENXBIO is a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. Since its founding in 2009, REGENXBIO has pioneered the development of AAV Therapeutics, an innovative class of gene therapy medicines. For more information, please visit www.regenxbio.com.

Contact
Public Relations & Investor Relations Dept., Nippon Shinyaku Co., Ltd.
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- **The clinical hold placed by the U.S. Food and Drug Administration (FDA) on RGX-121 in January 2026 has been lifted.**
- **The FDA issued a Complete Response Letter[1] in February 2026. REGENXBIO recently filed an appeal of it and is continuing to engage the agency regarding a path forward for the program.**
- **Nippon Shinyaku will continue to work closely with REGENXBIO to establish a timeline for the product launch.**

1. Complete Response Letters (CRLs) are issued directly to product sponsors when the FDA completes its review cycle and determines that it cannot grant an approval of an application in its current form.

Source : May 15, 2026, Company press release

Next, I will explain the update of RGX-121.

Please move on to slide 17.

RGX-121 was placed on clinical hold by the FDA in January 2026, which has since been lifted. The FDA issued a Complete Response Letter in February 2026, for which REGENXBIO subsequently filed an appeal. The Company will continue to work closely with REGENXBIO to determine a schedule for the future.

That is all from me.

Next, Mr. Kuwano, in charge of research and development, will explain the R&D pipeline.

R&D Updates (1/2)

For updates from Q3 FY2025 financial results announcement on February 9, 2026, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
Launch	NS-401 (tagraxofusp)	Elzonris	blastic plasmacytoid dendritic cell neoplasm (BPDCN)	March 2026
P3	NS-065/NCNP-01 (viltolarsen)	Viltepso	CSR for Study 301 under the FDA's review	January 2026
			Inquiring with FDA regarding the protocol for Study 303	
Additional indication	ACT-064992 (macitentan)	Opsumit	Johnson & Johnson obtained approval for the treatment of pediatric patients with pulmonary arterial hypertension (PAH) in Japan	December 2025
Additional indication	LY3527727 (pirtobrutinib)	Jaypirca	for patients with relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma) who are resistant or intolerant to other BTK inhibitors	September 2025
Filed	RGX-121 (clemidsogene lanparvovec)	–	The clinical hold placed by the FDA on RGX-121 in January 2026 has been lifted.	Disclosed in May 2026 (U.S.)
			The FDA issued a Complete Response Letter in February 2026. REGENXBIO recently filed an appeal against it and is continuing to engage the agency regarding a path forward for the program.	
Filed	CAP-1002 (deramiocel)	–	The FDA has set a new PDUFA target action date of August 22, 2026	March 2026 (U.S.)
Filed	GA101 (obinutuzumab)	Gazyva	Idiopathic nephrotic syndrome	May 2026
Revision of electronic package insert			Combination therapy with venetoclax has become available for previously untreated chronic lymphocytic leukemia	November 2025
P3			Roche announced Global Phase Ⅲ INShore Study topline results for Idiopathic nephrotic syndrome in children and young adults	October 2025
P3	ZX008 (fenfluramine hydrochloride)	–	UCB announced that P3 for CDKL5 deficiency disorder (CDD) indication met primary and most key secondary clinical endpoints	June 2025
Start of P3	NS-304 (selexipag)	–	Arteriosclerosis obliterans	April 2026
Preparation for P2	NS-035	–	Fukuyama congenital muscular dystrophy	January 2026
	NS-863	–	Pulmonary arterial hypertension	March 2026
			Pulmonary hypertension associated with interstitial lung disease	March 2026
Start of P1	NS-245	–	Treatment for inflammatory diseases	December 2025

Kuwano: I am Kuwano in charge of research & development. I will continue with the R&D pipeline that has been updated since the financial results briefing for Q3 of FY2025.

Please move on to slide 19.

NS-401, Elzonris, was listed on the NHI drug price list and launched on March 18. As for RGX-121, the clinical hold has been lifted. Also, REGENXBIO recently filed an appeal against the CRL. As for the status of CAP-1002, the situation is as explained earlier by Nakai, and the PDUFA date is set for August 22.

As for Gazyva, yesterday on May 14, Chugai Pharmaceutical submitted an application to the Ministry of Health, Labor and Welfare for an expanded indication for idiopathic nephrotic syndrome. As for NS-304, selexipag, a domestic Phase III study for the indication of arteriosclerosis obliterans, was initiated in April.

Both NS-035, for the treatment of Fukuyama congenital muscular dystrophy, and NS-863, for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease, are in preparation for Phase II studies.

R&D Updates (2/2)

For updates from Q3 FY2025 financial results announcement on February 9, 2026, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
Collaboration	–	–	Collaboration agreement with xFOREST Therapeutics on Drug Discovery Research Targeting RNA Structures	March 2026
Collaboration	–	–	Launch of co-creation project to evaluate drug discovery seeds with FRONTEO, Inc.	December 2025
Research Alliance (Boston Children's Hospital)	–	–	a strategic alliance with the aim of developing and delivering innovative therapies for rare diseases	July 2025 (U.S.)
Fast Track Designation	NS-229	–	eosinophilic granulomatosis with polyangiitis (EGPA)	September 2025 (U.S.)
Orphan Drug Designation	NS-051/NCNP-04	–	Duchenne muscular dystrophy	September 2025 (U.S.)
Academic conference presentation	NS-089/NCNP-02 (brogidirsen)		3.5-Year clinical trial data presentation at the World Muscle Society 2025 Congress	October 2025

Please move on to slide 20.

The Company concluded a collaboration agreement with xFOREST Therapeutics on drug discovery research targeting RNA structures in March 2026. Under the agreement, the Company will systematically advance the discovery and evaluation of small molecule compounds that target RNA structures.

That is all for the R&D pipeline.

Question & Answer

Inoue [M]: Then, we will now go to the question-and-answer session.

We will take questions first from analysts and institutional investors and then move on to questions from the press.

If you have any questions, please click the raise hand button. If connected from a phone, you can raise your hand by pressing the star key and nine. When asking questions, please state the name of the company and your name before speaking.

Now, we will take your questions.

Mr. Yamaguchi from Citigroup Global Markets, please ask your questions.

Yamaguchi [Q]: I am Yamaguchi from Citigroup Global Markets. Thank you for your explanation.

This may be a sensitive question, and I know it is difficult to say many things because this is related to a lawsuit. My understanding of what you just said is that the original license agreement currently exists, and Nippon Shinyaku is preparing for it, but Capricor Therapeutics is saying that they have already hired staff to prepare for it. I think the next step might be a preliminary injunction or various other moves, but in your statement, you said that you would review the forecast according to the circumstances. When I heard it, you sounded as if the launch might be suspended.

As it stands, the original license agreement is still there, so have you talked about the preparatory steps with Capricor? Or since Nippon Shinyaku and Capricor are now in litigation, has the negotiation come to a standstill? Could you tell us a little more since everyone is very interested in what is going on?

Nakai [A]: Thank you for your question.

We are currently continuing to prepare for the launch. Although the complaint was served on NS Pharma on May 13, US time, we will make proper preparations for the launch of the product, and we will communicate appropriately with Capricor regarding the collaboration between the two companies. For the time being, we will internally work to avoid receiving a preliminary injunction order, and if the injunction order is not issued, there will be no way to stop our activities of launch preparation for CAP-1002. In that case, both NS Pharma and Capricor will proceed with preparations for the launch, based on the original license agreement.

Yamaguchi [Q]: Thank you.

Second, you did not update on Phase III of Viltepso, but isn’t there any update on the current US situation, including negotiations with the FDA?

Kuwano [A]: I will answer that question.

As you just mentioned, we did not have any specific updates, so I didn't mention that, but we would like to continue to communicate with the FDA, so we move forward. There is no update at the moment.

Yamaguchi [M]: I understand. Thank you.

Nakai [A]: I would like to add one more thing. As I mentioned earlier, the complaint has been served on our subsidiary, NS Pharma. However, since our headquarters is located in Japan, it is expected to take several months to serve the complaint on Nippon Shinyaku under the Hague Convention.

Yamaguchi [M]: Thank you.

Inoue [M]: Now, Mr. Tanaka from Mizuho Securities, please ask your question.

Tanaka [Q]: I am Tanaka from Mizuho Securities. This is hard to ask, but looking at the complaint, it seems that the meeting between Mr. Nakai and Ms. Marbán took place on March 27 this year. Then your side proposed the PLD, but Capricor could no longer tolerate the situation. NS Pharma distributes Viltepso in the U.S. and presumably has expertise in U.S. insurance reimbursement, so why did the issues that Capricor raised occur?

Nakai [A]: Thank you for your question. Capricor and Nippon Shinyaku have been aware of the pricing issue since March 2025, one year ago, and as a means of resolving the situation, both sides have proposed to each other to amend the original license agreement. As to why such a situation occurred, given the experience with Viltepso, as for Viltepso, this kind of problem does not occur because it is a product transfer between a parent company and a subsidiary. Both Nippon Shinyaku and Capricor were not aware in advance that the pricing issues in this case could arise from something between two independent companies.

Tanaka [Q]: In fact, Capricor is writing in the complaint that NS Pharma proposed an amendment on April 10, asking Capricor a surrender of the product. Does that mean it's difficult to sell because it won't be reimbursed through any other method?

Nakai [A]: Please understand that we cannot disclose the specifics of what both sides were thinking during that discussion. We do not believe that the scheme change based on the PLD model we proposed would be particularly disadvantageous to Capricor. The PLD model is a model for price reporting to the US authorities, and is mainly used for biosimilars. We have proposed it to Capricor after confirming that several such PLD models have been used for new drugs. Therefore, we thought it was reasonable to proceed with this scheme because it involves the minimum necessary modification in accordance with the content of the original license agreement that we concluded.

Tanaka [Q]: I understand. I don't know how long a preliminary injunction is supposed to take, but how long do you think it will take? Is there anything you can say here?

Nakai [A]: This has already been published by the court in New Jersey. In US time, NS Pharma must file a written opposition by May 26. In response, Capricor must file an answer by June 2. The hearing date has been set for June 3.

Tanaka [Q]: So, will there be a hearing on June 3?

Nakai [A]: You are correct.

Tanaka [Q]: I understand. And secondly, I would like to ask Mr. Kuwano - and this is related to the earlier question - do you have any idea why the update of Viltepso is not going forward with the additional Phase III? I think Sarepta submitted supplemental new drug applications in April.

Kuwano [A]: I will answer that question. We do not know all the details of Sarepta's situation. It seems that they are communicating with the FDA, but it is difficult to tell whether or not they have actually had a meeting with the FDA. I have a feeling that they might just be communicating through written documents, just like we are.

However, aside from other companies, as I answered last time, the FDA is in the process of carefully considering how to handle these DMD drugs or exon-skipping drugs in general, and their response to us has been delayed. My personal guess is that there will be some kind of cohesive answer to both Sarepta and us once the FDA's policy is clearly defined. That is all.

Tanaka [M]: I understand. Thank you.

Inoue [M]: Now, Mr. Hashiguchi from Daiwa Securities, please ask your question.

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Thank you for taking my question.

I understand that NS Pharma proposed the PLD model to Capricor. I would like to know whether your side expressed an intention to purchase the other rights for deramiocel, and if so, do you continue to do so under this situation, which has developed into a lawsuit?

Nakai [A]: Thank you for your question. We do not think that there is any disadvantage to Capricor with what we are proposing, and it is not as if we are proposing taking something out from them, but simply in terms of which side reports the price to the authorities, we were discussing on the necessary modifications on the original Agreement. In the PLD model, NS Pharma is the entity that reports prices. Capricor cannot accept that. It seems that they still feel that CAP-1002 is theirs.

We had no intention of making CAP-1002 our own just because we adopted the PLD model, but rather to promote collaboration under a framework of equal partnership between the two companies, with Capricor in charge of development and manufacturing and NS Pharma in charge of sales and marketing. We have been explaining to them that we would like to collaborate with them based on such a framework. However, they insisted that they would like to be the main entity to report prices to the US authorities, and no agreement was reached on amending the original license Agreement.

Hashiguchi [Q]: Thank you. In that case, I think that the current right of your company is limited in terms of indications and regions compared to the future potential, as the indication is limited to DMD and sales are limited to Japan and the US. Is it correct to say that this is not a proposal to expand the scope of the right?

Nakai [A]: You are correct.

Hashiguchi [Q]: Thank you. Second, I would like to ask you about the assumption for the sales forecast of JPY11.4 billion for deramiocel. Could you comment on the timing of the launch, and how have the number of patients, frequency of administration, and price been assumed to expect this figure?

Nakai [A]: Well, I think we have already informed you that we are planning to release the product by the end of this year. With regard to the breakdown…

Edamitsu [A]: Excuse me, I am Edamitsu. As we mentioned, the PDUFA date is August 22, and we would like to launch the product as soon as possible before the end of the year. Is there anything that the secretariat can add about the details?

The Secretariat [A]: I will answer. We do not disclose the number of patients in detail, but since the drug is to be administered once every three months and we plan to launch the product within this year, we are assuming that a certain number of patients will start the second administration. That is all.

Hashiguchi [Q]: When you disclosed the FY2026 sales forecast for deramiocel a year ago, I think it was JPY7.3 billion. Regarding why it is larger than the previous forecast, you just said that some patients will have a second administration, but may there be an exchange rate factor, or a price revision?

Nakai [A]: I will answer that question. It's due to a gap in the timing of the launch. This time we are assuming the launch before the end of this year. PDUFA date is August 22 and the launch is a few months from there. Last time, PDUFA date was scheduled for July, I think.

Edamitsu [A]: August 31, 2025.

Nakai [A]: It was, but the timing of the launch is a little different, so that is why we have a difference.

Hashiguchi [M]: Thank you. That is all.

Inoue [M]: Now, Mr. Wakao from JPMorgan Securities, please ask your question.

Wakao [Q]: I am Wakao from JPMorgan. Thank you. First, to confirm Mr. Tanaka's question regarding the preliminary injunction, you said that there will be a hearing on June 3. Do you think that a conclusion will be reached on the same day?

Edamitsu [A]: I will answer that question. A hearing date has been set for June 3, but we do not know whether a decision will be reached immediately on that date. However, we believe that it will be out promptly anyway. That is all.

Wakao [Q]: I understand. Second, if the preliminary injunction is dismissed, you said that you are selling the product. However, I think under the current agreement, there are economic issues to begin with, so even if the launch is possible, there would be disadvantages for both companies in actually doing so. What is your company's understanding of this?

If you actually sell the product, the ASP will probably be formed based on Capricor's wholesale price to your company, so I think that ultimately neither your company nor Capricor will be able to generate a profit. I would appreciate it if you could let me know about that.

Nakai [A]: Thank you for your question. The issue with price reporting and pricing under the current agreement is that the price of the transaction from Capricor to NS Pharma will be the price covered by insurance. If NS Pharma becomes the price reporting entity, the price sold by NS Pharma to the market will be the price reported, and we proposed that if the agreement is changed so that NS Pharma is the price reporting entity, this price reporting issue will be eliminated. Under the current agreement, such pricing issue inevitably arises. So, we insisted that with the change of the reporting entity, the project would be able to proceed without any change in economic conditions or pricing. I think this is a rational proposal we have been putting forward. I hope this answers your current question.

Wakao [Q]: What I wanted to ask is, even if the preliminary injunction is dismissed, in the end, if the terms of the current agreement are not modified, there is no way to sell the product, is there?

Nakai [A]: You are right. I think that part needs to be corrected.

Wakao [Q]: Well, okay. If so, even if the preliminary injunction is dismissed, I think that at some stage you will have to come to terms with each other, but on the other hand, I think that the lawsuit itself will continue. So, whether the injunction is granted or denied, I believe there is a risk that the current situation will persist. How are you going to deal with that risk?

Nakai [A]: We are aware that patients being unable to access CAP-1002 is highly detrimental to the patients themselves, as well as to both of our companies. Therefore, we will consider what we need to do to make CAP-1002 truly available to patients and take action in the future. I think that's what we are going to do.

As to what exactly is being contemplated, I would like to refrain from giving you an answer.

Wakao [Q]: I understand. Thank you. Also, one more thing I would like to know is, in light of the various questions we have had about the situation with Viltepso, as well as the fact that there was a structural problem with the original agreement for CAP-1002, I think that there are some issues that need to be addressed in the area of commercialization and the regulatory compliance of your US business. Do you think that NS Pharma has a challenge now? In addition, I think that the US business will become even more important in the future as you launch new products, including gene therapy drugs. I would like to know again how your company will strengthen the US business. That is all.

Nakai [A]: Regarding the pricing and contractual issues with Capricor, we recognized the pricing issue and sought to revise the agreement to address it. Unfortunately, negotiations with Capricor have reached this situation. On the other hand, regarding RGX-121 with REGENXBIO, we have already agreed to proceed under the PLD model, so the PLD model is not a strange scheme at all. I feel that this is a management issue in terms of the relationship with Capricor. We will continue to proceed as we have in the past, and we will take measures as necessary for the so-called risks in the US business. We are not in a situation where our US business is going down the drain, and we believe that we are capable of handling the Capricor matter properly.

We are not in a position to update on Viltepso including the discussion with the FDA at this time, but we would like to use the results of the continuation study of Viltepso from Study 301 as materials for communication with the FDA, so we will be working on that as well. We have already established a structure for regulatory affairs and reinforced our MDs, and we will continue to build the necessary organization as needed.

Wakao [M]: Thank you very much. That is all.

Inoue [M]: Now, Mr. Yamakita from Jefferies, please ask your question.

Yamakita [Q]: I am Yamakita from Jefferies. Thank you for your explanation. I am very sorry to be persistent, but I would like to ask about the lawsuit by Capricor.

It is written in the complaint that your company's proposal was a PLD model and Capricor rejected it, but is it correct to understand that Capricor has also made a proposal to your company and that the details of that proposal are not currently stated anywhere? This is the first question.

Nakai [A]: Capricor has made a proposal, as announced in the conference call, for a co-commercialization approach. We would like to avoid mentioning specific details.

Yamakita [Q]: Thank you. You said that the specifics are undisclosed, but you mentioned before that neither of the proposals were for the benefit of either party. In other words, is it correct that a proposal from Capricor is not to increase Capricor's share or to take profit from your company?

Nakai [A]: Well, I can't go into detail, but we are generally working in such a way that we want to minimize any necessary modifications.

Yamakita [Q]: Thank you. Lastly, I would like to ask about Viltepso. In H1, you revised the guidance in February, and I think you expected a recovery in H2, but in the end, you failed to meet the guidance for the fiscal year that just ended. I think you expect growth again this fiscal year, in the US. Is there any difference in the way this is forecasted from the way you forecasted for the H1 results? Please answer.

Nakai [A]: Well, regarding Viltepso, the number of patients receiving the medication has been progressing according to plan. What I mean is the total number of patients on medication, though, as new patients come to complement those who are dropping out.

The average dose per patient has decreased because the patients newly receiving the medication are very young, so although progress has been made in terms of the number of patients, the reduction in average dose per patient negatively impacted its contribution to the total sales amount. This is the result of the situation.

On the other hand, if they start the medication at a young age, they will be administered for a long time. Since this means that the duration of the medication will be longer, that will contribute to the future growth, so we are making this plan with high expectation.

Yamakita [Q]: I understand. The average age of the entire patient population is getting younger, so in the previous fiscal year, you faced a negative result due to drops, but are you assuming that you can bring it to a positive result in this fiscal year? Is it correct to say that the average age is getting that young?

Nakai[A]: Well, young patients have a longer period of time before dropping out, so they can use Viltepso for a longer period of time, and this has the cumulative effect.

Yamakita [M]: Thank you. That is all from me.

Inoue [M]: Now, Mr. Wada from SMBC Nikko Securities, please ask your question.

Wada [Q]: I am Wada from SMBC Nikko Securities. Thank you. I would like to ask about the sales and profits of deramiocel. Are you assuming that this scale of sales will be profitable if the current economic conditions continue?

Nakai [M]: Are you asking only for this fiscal year?

Wada [M]: Yes. You are right. You expect JPY11.4 billion.

Nakai [A]: The JPY11.4 billion is only from the last quarter after the end of the year, but since sales expenses are incurred throughout the year, there is no particularly large contribution to earnings in FY2026. But the structure is designed to make a solid contribution to profits if it becomes to contribute throughout the year.

Wada [Q]: Thank you. And I would also like to ask about RGX-121. You have shown the slide. I would like to ask whether it is likely to be approved or not. I think the commissioner of the FDA has changed recently, and do you feel that the status of the FDA's response has changed?

Nakai [A]: It was only recently that the commissioner resigned, so we are not sure what the impact will be. As the background to the appeal, we have heard that the FDA has a sense that there is some inconsistency between the FDA's decision on RGX-121, for which a CRL was received that denied approval, and the fact that other products have been approved. We have heard from REGENXBIO that they are fully aware of the need to make decisions in a consistent manner within the FDA.

Wada [M]: I understand. Thank you. That is all.

Inoue [M]: Now, Mr. Kawamura from SBI SECURITIES, please ask your question.

Kawamura [Q]: Thank you for your explanation. I am Kawamura from SBI SECURITIES. Thank you. I'm really sorry to be so persistent, but could you follow up and tell me about CAP-1002?

Based on the Q&A so far, and also on Capricor's Q1 result, your company wanted a PLD model and the other party wanted joint commercialization. I believe Capricor commented that they couldn't stand the idea of your company being involved in the various regulatory relationships and initiatives.

What part of Capricor's proposal was most unacceptable to your company, while both proposals are compromised in terms of profits?

Nakai [A]: That would mean that I would have to talk about the details of Capricor's proposal here, so I would like to refrain from answering about the details of the joint commercialization scheme, as we cannot disclose that.

Kawamura [Q]: I understand. Also, with all the uncertainties that have emerged, when will you be able to give us a plan B for the future, or explain to us in concrete terms what will happen in the future?

I know there are a lot of things that could happen, such as an immediate or delayed ruling, but could you tell me when you will be able to give us a more concrete explanation of your company's future?

Nakai [A]: Thank you for your question. Well, first of all, we will work to avoid receiving an injunction by addressing this issue. Depending on that situation, we will know more about the future status of this CAP-1002.

We will also be discussing how to collaborate with Capricor on this CAP-1002, although that will depend on the court's decision.

As Capricor and we have repeatedly said, we share the same desire to bring CAP-1002 or deramiocel to patients as soon as possible. The other party is saying that NS Pharma is not ready for sales, but NS Pharma has more than five years of experience in the sales of Viltepso.

They have a solid track record in the DMD field in the US, so I do not think that the future trend will be that Capricor can only do what it can do on its own. We believe that their claim is not true. NS Pharma is making preparations without delay, and progress is being made on the sales structure.

As for your question about when there will be an update in the future, as soon as we know the situation with Capricor, we will have an opportunity to explain appropriately.

Kawamura [M]: I understand. Thank you. That is all.

Inoue [M]: Some of you have raised your hands for the second time, but due to time constraints, I would like to make the next question the last one from the analysts and institutional investors.

Mr. Lee from Morgan Stanley MUFG Securities, please ask your question.

Lee [Q]: Yes. I am Lee from Morgan Stanley MUFG Securities. Since our time is limited, I will ask only one question. What are the cost assumptions for the new fiscal year?

First, R&D has increased this time. I think this is due to an additional Phase III trial of Viltepso, or Study 303, and I would like to know whether the cost of starting this is factored in. SG&A has also increased this time, due to the cost of sales for CAP-1002. How much is this factored in? I think the amount has been increased quite a bit YoY, so please tell me about these two points.

Edamitsu [A]: I am Edamitsu. As for the first question about Viltepso, the situation has been as explained earlier, and it depends on how the situation unfolds, but we are assuming that the timing will be as we have explained. We have calculated R&D expenses based on that assumption.

As for your second question, as I explained earlier, taking into account the sales and expenses, the impact on performance and profit is not so large this fiscal year. I would like to refrain from giving specific figures about the cost. That is all.

Lee [Q]: Thank you. Let me ask an additional question. Sarepta did not do the additional Phase III, and filed for the regular application, so I think your company should do better to handle that in the same way. If Phase III is no longer needed, you would expect a reduction in R&D.

In addition, even if CAP-1002 is not released this year, which I think should not happen, that will not have much impact on the operating profit plan for this fiscal year. I think that could be a rather positive thing, so please let me know if that is the correct understanding. That is all.

Nakai [A]: Yes. Well, if the additional Phase III study of Viltepso is not needed or required, we believe that we can remove that amount from the cost.

As for CAP-1002, as you have pointed out, it will not contribute to sales and will be removed from expenses, so if CAP-1002 is removed from sales and then from expenses, the situation would probably be neutral in terms of operating profit.

Lee [Q]: Thank you. By the way, regarding the Phase III, do you have any thoughts that your company could address this in the same way as Sarepta?

Kuwano [A]: Yes. We would like to be flexible to include such possibilities.

Lee [M]: Thank you. That is all.

Inoue [M]: We will now take questions from the press. If you have any questions, please click the raise hand button. When asking questions, please state the name of the company and your name before speaking.

Mr. Kuriyama from Yakuji Nippo, please.

Kuriyama [Q] I am Kuriyama from Yakuji Nippo. I'm sorry to be persistent, but I would like to ask about deramiocel. President Nakai mentioned that the pricing issue under the current agreement is that price of the transaction from Capricor to NS Pharma will be the price covered by insurance.

Do you mean that the wholesale price from Capricor to NS Pharma would be the so-called insurance reimbursement price, or the selling price, so it would not sell at the selling price as expected? Is it correct to understand that this pricing would make it impossible to provide the drug in an economically viable manner?

Nakai [A]: Yes. You are correct.

Kuriyama [Q]: I understand. Was there any recognition of this issue when the license agreement was signed?

Nakai [A]: No. We were not aware of that.

Kuriyama [Q]: I understand. I would like to ask about one more point. I understand that you have been preparing for the launch of deramiocel so far, but what specific preparations have you made and how much money have you invested in them? In light of this lawsuit, could you tell me a little more about the status of such preparations, whether they are still ongoing or have been suspended for a little while, and the impact of the lawsuit?

Nakai [A]: The status of preparation and various launch preparation tasks are detailed, so I won't explain them in particular this time. Taking personnel recruitment as an example, as I mentioned earlier, the recruitment of personnel for the sales department, or for "commercial" as we call it, has been proceeding smoothly, and the establishment of the system is almost complete.

In the fiscal year that ended, FY2025, NS Pharma increased the number of employees by 40, so that is the situation. Therefore, we already have sufficient personnel to launch CAP-1002 or deramiocel.

I would like to refrain from explaining for a moment as to how much this is.

Kuriyama [Q]: I understand. If so, as for whether the preparation would temporarily suspend or not depending on the lawsuit, would it be correct to say that the preparations are already complete?

Nakai [A]: Well, we have almost completed the establishment of the system.

Only the truly essential tasks remain, and we will allocate the necessary budget to complete them. Therefore, we feel that it is not reasonable for them to claim that the sales structure and preparation for the launch is insufficient or inadequate.

Kuriyama [M]: I understand. Thank you very much. That is all.

Inoue [M]: Now, Ms. Ishii from Nikkei, please ask your question.

Ishii [Q]: Thank you. I am Ishii from Nikkei. I would like to ask you about your performance in the previous fiscal year, FY2025. Regarding the background to the decrease in net profit despite the increase in revenue, there are SG&A expenses, R&D expenses, and NHI price revisions, and other factors. What is your view on expenses?

Edamitsu [A]: I am Edamitsu. I'm a little unsure about the intent of your question just now, but the Company has used it as planned. Does this answer your question?

Ishii [Q]: Thank you. Net profit decreased by 9% YoY. Which specific expenses had the most significant impact on this?

Edamitsu [A]: I'm sorry. You are talking about profit attributable to owners of parent. Profit attributable to owners of parent was affected by special factors in the previous fiscal year. In other words, this is a reversal of the temporary reduction in the tax burden due to the recoverability of deferred tax assets in NS Pharma, a subsidiary, in the previous fiscal year. This level will continue for the foreseeable future. That is all.

Ishii [Q]: Thank you. Also, I would like to ask one more question. Regarding CAP-1002, I know there is the litigation, but do you anticipate that there will be no profit reported if the trial results are good, but the approval is not granted?

Nakai [A]: Thank you for your question. The results of the Phase III trial were very positive, so the review clock is now running again, and a decision on whether to approve or not is scheduled for August 22.

We expect that the approval will be granted, and we are not thinking that it will not be approved.

Ishii [M]: Thank you. That is all.

Inoue [M]: Now, Mr. Takayama from Kyoto Shimbun, please ask your question.

Takayama [Q]: I am Takayama from Kyoto Shimbun. Have you factored in the impact of the situation in the Middle East in your forecast for the current fiscal year?

Nakai [A]: Thank you for your question. In particular, we have not factored in any significant impact on both the pharmaceuticals and functional food businesses. That is all.

Takayama [Q]: I understand. Just one more point. With the exception of deramiocel, could you give me a few words, President Nakai, regarding your company's overall business this fiscal year?

Nakai [A]: Yes. For the current fiscal year, the sales forecast for deramiocel is expected to be JPY11.4 billion. If we exclude that, 11.4 billion would be reduced from the 200 billion in revenue plan. If we also remove SG&A expenses as well as the costs associated with deramiocel, there will be no significant impact on this fiscal year's performance, and I would like you to understand that the operating profit itself will not be significantly changed from the 38 billion that we have announced today.

Takayama [M]: I understand. Thank you.

Inoue [M]: Now, Mr. Shimomura from Nikkan Yakugyo, please ask your question.

Shimomura [Q]: I am Shimomura from Nikkan Yakugyo. I would like to ask you about the medium-term management plan up to FY2025. You mentioned a variety of things this time, and based on these situations, do you think that you are able to achieve the targets for the medium-term management plan?

Nakai [A]: Thank you for your question. Yes, we expect to achieve the medium-term management plan.

Since there was a lawsuit filed by Capricor this time, we have refrained from giving a long-term outlook on how CAP-1002 will turn out, but we are actually planning to market the product. Assuming that this progress is made, I believe that the achievement of the medium-term management plan is fully possible.

Shimomura [Q]: Am I correct in understanding that you can get through the patent cliff of Uptravi?

Nakai [A]: Yes. We believe so.

Shimomura [M]: Thank you very much.

Inoue [M]: Ms. Kawachi from Nikkei Biotechnology & Business, please.

Kawachi [Q]: I am Kawachi from Nikkei Biotechnology & Business. Regarding RGX-121, could you tell me whether you intend to continue the clinical trial to obtain additional data in preparation for resubmission, or whether there is a possibility that you will conduct a completely new trial, including a review of the protocol?

Nakai [A]: Well, RGX-121 is a gene therapy, so we are thinking that Phase III would be feasible if we continue to observe patients who are currently receiving the drug. Also, after we start negotiations or discussions with the FDA, it will become clear what kind of trials are necessary and what kind of data will be required. That is all I can tell you at the moment.

Kawachi [Q]: Thank you. You are at the stage of starting discussions with the FDA, so I assume that the approval schedule will be delayed. If you have any target for when you would like to clarify the updated schedule, I would appreciate it if you could let me know.

Nakai [A]: Thank you for your question. As soon as the content of our discussions with the FDA indicates that this is something that should be made public, we will be able to inform you in a timely and appropriate manner. If the progress is in line with a normal situation, it will be included in the update of R&D products at the time of the next Q1 financial results briefing.

Kawachi [Q]: Thank you. As the last question, I believe that the clinical hold has not yet been lifted on RGX-111. If you have any plans for its future development, please let me know.

Nakai [A]: Thank you for your question. The clinical hold has not yet been lifted for RGX-111, as you pointed out. The FDA has sent us a letter of clinical hold, indicating what they want us to show, and REGENXBIO is now addressing that accordingly.

As for what can be done by when, REGENXBIO has not disclosed that, and I would like to refrain from disclosing that.

Kawachi [Q]: Am I correct in understanding that it is your company's policy to continue to promote development positively?

Nakai [A]: Yes. You are correct.

Kawachi [M]: Thank you. That is all.

Inoue [M]: Some of you have raised your hands for the second time, but due to time constraints, I would like to make the next question the last one.

Mr. Sakaguchi from RISFAX, please.

Sakaguchi [Q]: I am Sakaguchi from RISFAX. I would like to ask only one question. Regarding deramiocel, depending on the decision on June 3, will there be any impact on the medium-term management plan?

Nakai [A]: Well, as I mentioned earlier, it is still unclear whether or not we will be able to find out anything definite on June 3, but depending on the actual outcome of the hearing, we may have to take a variety of different approaches.

Sakaguchi [M]: I understand. That is all. Thank you.

Inoue [M]: Some of you have raised your hands, but if you have any additional questions, please contact our public relations or investor relations staff.

With that, we conclude the financial results briefing of Nippon Shinyaku for FY2025. Thank you very much for joining us today.

[END]