Nippon Shinyaku Co., Ltd.

FY2025/Q2 Earnings Call and Presentation

November 14, 2025

Event Summary

[Company Name]	Nippon Shinyaku Co., Ltd.
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[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 Dept.
Hideyasu Takechi	Corporate Officer, Department Manager, Corporate Planning Dept.

Presentation

Takechi: It is time to begin the financial results briefing of Nippon Shinyaku Co., Ltd. for Q2 of FY2025. Prior to the meeting, I would like to introduce today's attendees.

From the left side facing you, we have Mr. Nakai, Representative Director, President; Mr. Kuwano, Director, Research & Development; Mr. Iwata, Director, Sales and Marketing; and Mr. Edamitsu, Director, Business Management & Sustainability. Also, in attendance from the secretariat is Mr. Beppu, Corporate Officer, Head of R&D Planning and Administration Dept. I am Takechi, Corporate Officer, Department Manager, Corporate Planning Dept., and I will serve as the moderator. Thank you very much for your cooperation today.

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

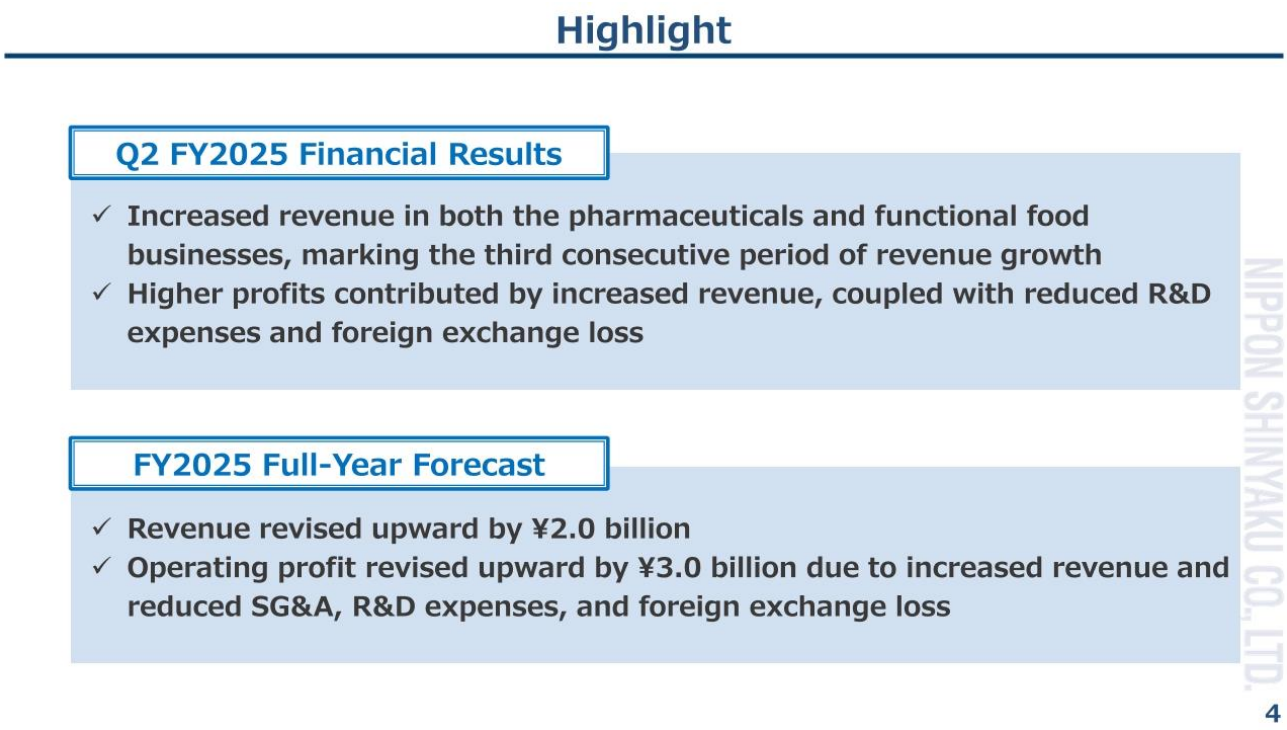
Now, Mr. Nakai, please start.

Nakai: I am Toru Nakai, President of Nippon Shinyaku. Thank you very much for taking time out of your busy schedules today to participate in our financial results briefing for Q2 of FY2025. Thank you very much.

Today, I would like to share with you our financial results for Q2 of FY2025 and our forecast for FY2025, as well as an update on CAP-1002 or deramiocel and our sales preparations in the United States.

Mr. Kuwano, who is in charge of R&D, will then explain the progress of R&D items.

I will now explain our results of Q2 of FY2025 and our forecast for FY2025.



To begin with, I would like to share with you some key points from today's financial results presentation.

In Q2 of FY2025, both the pharmaceuticals and functional food businesses reported increases in revenue, marking the third consecutive period of revenue growth. Operating profit increased due to higher revenue and lower R&D expenses and foreign exchange losses.

For FY2025, we have revised our revenue forecast upward by JPY2 billion and our operating profit forecast upward by JPY3 billion due to lower expenses and foreign exchange losses.

Q2 (Interim Period) FY2025 Summary

- **Increased revenue in both the pharmaceuticals and functional food businesses, marking the third consecutive period of revenue growth**
- **Increased operating profit and decreased profit attributable to owners of parent**

(million yen)	Q2 FY2024 actual	Q2 FY2024 ratio	Q2 FY2025 actual	Q2 FY2025 ratio	YoY change	YoY %
Revenue	**79,332**	**100.0%**	**79,647**	**100.0%**	**+315**	**+0.4%**
(Pharmaceuticals)	(68,496)	(86.3%)	(68,561)	(86.1%)	(+64)	(+0.1%)
(Functional Food)	(10,836)	(13.7%)	(11,086)	(13.9%)	(+250)	(+2.3%)
Cost of sales	**24,935**	**31.4%**	**25,336**	**31.8%**	**+400**	**+1.6%**
SG&A expenses	**18,031**	**22.7%**	**20,357**	**25.6%**	**+2,325**	**+12.9%**
R&D expenses	**16,732**	**21.1%**	**14,637**	**18.4%**	**-2,095**	**-12.5%**
Other income	**455**	**0.6%**	**521**	**0.7%**	**+66**	**+14.7%**
(Foreign exchange gain)	-	-	(153)	(0.2%)	(+153)	-
Other expenses	**2,219**	**2.9%**	**258**	**0.3%**	**-1,960**	**-88.3%**
(Foreign exchange loss)	1,935	(2.4%)	-	-	(-1,935)	-
Operating profit	**17,867**	**22.5%**	**19,580**	**24.6%**	**+1,712**	**+9.6%**
Finance income	**396**	**0.5%**	**550**	**0.7%**	**+153**	**+38.8%**
Finance costs	**65**	**0.1%**	**101**	**0.2%**	**+35**	**+54.4%**
Profit before tax	**18,198**	**22.9%**	**20,029**	**25.1%**	**+1,830**	**+10.1%**
Income tax expense, etc.	**1,825**	**2.3%**	**4,268**	**5.3%**	**+2,442**	**+133.8%**
Profit attributable to owners of parent	**16,373**	**20.6%**	**15,760**	**19.8%**	**-612**	**-3.7%**

Let me explain in detail from here. Please turn to page five.

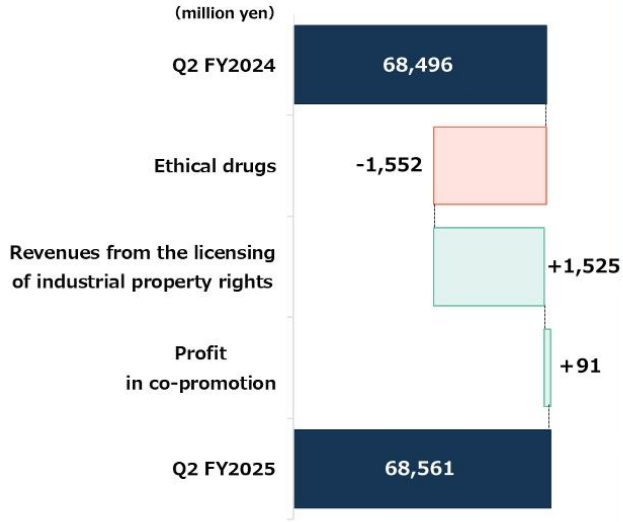
As an overview of our performance in Q2 of FY2025, on a YoY basis, consolidated revenue increased by JPY315 million to JPY79,647 million, operating profit increased by JPY1,712 million to JPY19,580 million, and profit before tax increased by JPY1,830 million to JPY20,029 million.

With respect to income tax expenses, the profit 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 the current year's income tax expenses. Therefore, income tax expense, etc., has increased.

As a result, profit attributable to owners of parent decreased by JPY612 million to JPY15,760 million.

Segmental Review - Pharmaceuticals -

- **Negative impacts of the National Health Insurance drug price revisions and generic competition**
- **Growth in domestic sales of Uptravi, Fintepla, etc., and royalty income from overseas sales of Uptravi**



Ethical drugs 39,587 million yen
(-1,552 million yen, -3.8%, YoY)

- ✓ Shipments of Viltepso outside Japan and the U.S. under Managed Access Program delayed to 2H FY2025
- ✓ Decline in sales of off-patent brand-name drugs such as Vidaza due to drug price revisions and generic competition
- ✓ Growth of new product lines including Fintepla, Uptravi, and Vyxeos

Revenues from the industrial property rights 24,181 million yen
(+1,525 million yen, +6.7%, YoY)

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

Profit in co-promotion 4,792 million yen
(+91 million yen, +2.0%, YoY)

- ✓ Sales growth of Yuvanci

Please turn to page six.

In the pharmaceuticals business, although sales of Vidaza and other products declined due to drug price revisions and generic competition, domestic sales of Uptravi, royalty income from overseas sales of the same product, and growth in new product lines such as Fintepla resulted in consolidated revenue of JPY68,561 million, up 0.1% YoY.

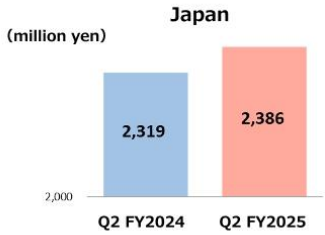
Sales Trends of Viltepso® (viltolarsen)

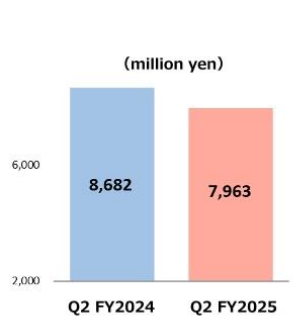
Sales of Viltepso in the U.S. declined YoY in Q2 FY2025, but the full-year forecast (dollar-based) shows a slight increase due to the acquisition of new patients.

(million yen)	Q2 FY2024 actual	Q2 FY2025 actual	YoY change	YoY %	FY2025 forecast	Notes on Q2 FY2025 results
Japan	2,319	2,386	+66	+2.9%	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]. ✓ Currently identifying patients under the age of 20 who are eligible for treatment.
US	8,682	7,963	-718	-8.3%	16,300	✓ Insurance reauthorizations became stricter after launch of multiple DMD treatment options. ✓ U.S. sales for FY2025 are projected to slightly increase on a dollar basis due to the acquisition of new patients. (FY2024 sales actual: US$112.19 million)
(million US$)	(56.88)	(54.54)	(-2.34)	(-4.1%)	(114.06)	
Total	11,002	10,349	-652	-5.9%	21,100	

1. Central Social Insurance Medical Council

Exchange rates	Q2 FY2024 actual	Q2 FY2025 actual	2H FY2025 forecast
USDJPY	152.8	146.0	140.0





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

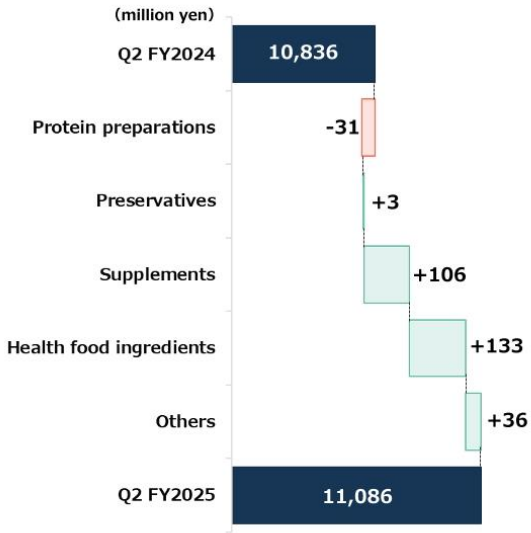
The sales results in Q2 of FY2025 were JPY2,386 million in Japan and JPY7,963 million in the United States.

For the full year of FY2025, we expect sales of JPY4.8 billion in Japan and JPY16.3 billion in the US.

In the US, sales are expected to increase slightly for the full year on a dollar basis due to an increase in the number of newly registered patients, despite a YoY decrease in Q2.

Segmental Review - Functional Food -

- **Slight decline in protein preparations sales due to competitive market**
- **Growing Health food ingredients amid rising demand for beauty-related products, and robust supplements helped by the market expansion**



Protein preparations 6,861 million yen
(-31 million yen, -0.5%, YoY)
- ✓ Sales prices decline of protein preparations for the processed food industry
- ✓ Decrease in demand due to customers switching to cheaper raw materials

Preservatives 1,624 million yen
(+3 million yen, +0.2%, YoY)
- ✓ Promoting consultative sales to key users

Supplements 1,309 million yen
(+106 million yen, +8.9%, YoY)
- ✓ Sales increase in both athletes and anti-aging care category

Health food ingredients 621 million yen
(+133 million yen, +27.5%, YoY)
- ✓ Expanded demand for beauty-related products

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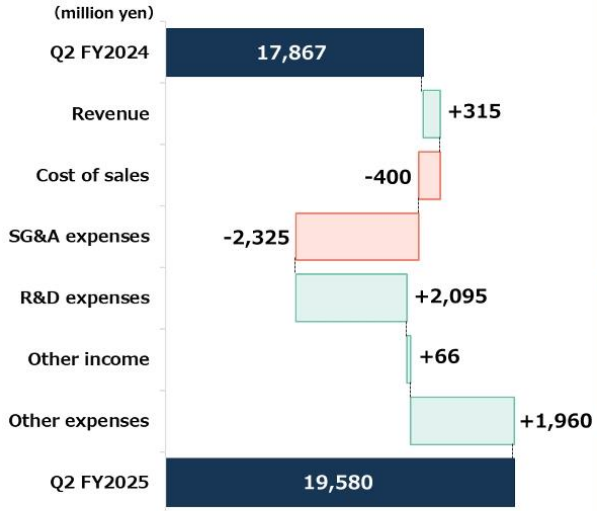
In the functional food business, sales of protein preparations declined due to the severe market environment, but sales of health food ingredients and supplements increased, resulting in consolidated revenue of JPY11,086 million, up 2.3% YoY.

Operating Profit

- **Higher profits contributed by increased revenue, coupled with reduced R&D expenses and foreign exchange loss**



Revenue 79,647 million yen
(+ 315 million yen, + 0.4%, YoY)
- ✓ Growth of new product lines including Fintepla, Uptravi, and Vyxeos
- ✓ Royalty revenue growth due to overseas sales of Uptravi

Cost of sales 25,336 million yen
(+400 million yen, +1.6%, YoY)
The ratio was 31.8%, worsened by 0.4 points YoY.
- ✓ Negative impact from changes in pharmaceutical product sales mix and NHI drug price revisions

SG&A expenses 20,357 million yen
(+2,325 million yen, +12.9%, 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 14,637 million yen
(-2,095 million yen, -12.5%, YoY)
- ✓ Decrease in contract research expense and raw material costs related to investigational products

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Next, in terms of operating expenses, the cost of sales ratio worsened by 0.4 percentage points YoY to 31.8%, mainly due to the sales mix and the impact of the NHI price revisions.

Selling, general and administrative expenses increased by 12.9% YoY to JPY20,357 million, mainly due to an increase in marketing expenses at NS Pharma in preparation for the launch of new products.

R&D expenses totaled JPY14,637 million, down 12.5% YoY, mainly due to a decrease in contract research expenses and material costs related to investigational products.

As for other expenses, foreign exchange losses decreased. As a result, operating profit increased by 9.6% YoY to JPY19,580 million.

Business Forecast : Upward Full-Year Revision from August

- **Operating profit revised upward by ¥3.0 billion due to increased revenue and reductions in SG&A, R&D expenses, and foreign exchange loss**

(Million yen)	FY2025 Forecasts		YoY	
	Previous*	Revised	change	%
Revenue	166,000	168,000	+2,000	+1.2%
(Pharmaceuticals)	(143,000)	(145,000)	(+2,000)	(+1.4%)
(Functional Food)	(23,000)	(23,000)	-	-
Cost of sales	51,200	57,000	+5,800	+11.3%
SG&A expenses	44,000	43,000	-1,000	-2.3%
R&D expenses	39,500	35,000	-4,500	-11.4%
Other income	600	1,000	+400	+66.7%
Other expenses	1,900	1,000	-900	-47.4%
Operating profit	30,000	33,000	+3,000	+10.0%
Finance income	700	900	+200	+28.6%
Finance costs	100	200	+100	+100.0%
Profit before tax	30,600	33,700	+3,100	+10.1%
Income tax expense, etc.	6,600	7,400	+800	+12.1%
Profit attributable to owners of parent	24,000	26,300	+2,300	+9.6%

Revenue 168,000 million yen (+2,000 million yen, +1.2% from previous forecast)

✓ Erleada's reverse co-promotion (previously recorded as profit in co-promotion, but now recorded as product sales and cost of goods sold, based on contract revisions)

Cost of sales 57,000 million yen (+5,800 million yen, +11.3% from previous forecast)

✓ Start of Erleada's reverse co-promotion

SG&A expenses 43,000 million yen (-1,000 million yen, -2.3% from previous forecast)

✓ Decrease in U.S. sales expenses due to the PDUFA delay for RGX-121

R&D expenses 35,000 million yen (-4,500 million yen, -11.4% from previous forecast)

✓ Shifting the cost recognition for Viltepso and other items to subsequent fiscal years, etc.

* August 7, 2025 (Q1 FY2025 financial results announcement)

The foreign exchange rate assumed for 2H FY2025 business forecast is ¥140 per USD and its sensitivity indicates that for every ¥1 depreciation of the yen against the USD, revenue is expected to increase by approximately ¥240 million and operating profit is expected to increase by approximately ¥240 million.

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I will now continue with a discussion of our forecast for FY2025.

Here we show the difference between the revised forecast and the previous forecast.

Consolidated revenue is expected to be JPY168 billion, an increase of JPY2 billion from the previous forecast.

Selling, general and administrative expenses are expected to decrease by JPY1 billion to JPY43 billion due to an expected decrease in marketing expenses at NS Pharma, which will be mainly caused by a delay of the expected approval date for RGX-121 as a result of an extension of the review period by the FDA.

R&D expenses are expected to decrease by JPY4.5 billion to JPY35 billion, mainly due to the shift in the fiscal year in which expenses for Viltepso and other items are incurred.

Other expenses are expected to be JPY1 billion due to a decrease in foreign exchange losses.

As a result, operating profit is expected to increase by JPY3 billion to JPY33 billion, profit before tax is expected to increase by JPY3.1 billion to JPY33.7 billion, and profit attributable to owners of parent is expected to increase by JPY2.3 billion to JPY26.3 billion.

Revised Business Forecast for FY2025 (consolidated)

(million yen)	FY2024 actual	FY2024 ratio	FY2025 forecast	FY2025 ratio	YoY change	YoY %
Revenue	**160,232**	**100.0%**	**168,000**	**100.0%**	**+7,767**	**+4.8%**
(Pharmaceuticals)	(138,654)	(86.5%)	(145,000)	(86.3%)	(+6,345)	(+4.6%)
(Functional Food)	(21,577)	(13.5%)	(23,000)	(13.7%)	(+1,422)	(+6.6%)
Cost of sales	**51,116**	**31.9%**	**57,000**	**33.9%**	**+5,883**	**+11.5%**
SG&A expenses	**38,011**	**23.7%**	**43,000**	**25.6%**	**+4,988**	**+13.1%**
R&D expenses	**34,341**	**21.4%**	**35,000**	**20.8%**	**+658**	**+1.9%**
Other income	**874**	**0.5%**	**1,000**	**0.6%**	**+125**	**+14.3%**
Other expenses	**2,186**	**1.4%**	**1,000**	**0.6%**	**-1,186**	**-54.3%**
Operating profit	**35,450**	**22.1%**	**33,000**	**19.6%**	**-2,450**	**-6.9%**
Finance income	**830**	**0.5%**	**900**	**0.5%**	**+69**	**+8.4%**
Finance costs	**145**	**0.0%**	**200**	**0.1%**	**+54**	**+37.5%**
Profit before tax	**36,135**	**22.6%**	**33,700**	**20.1%**	**-2,435**	**-6.7%**
Income tax expense, etc.	**3,577**	**2.3%**	**7,400**	**4.4%**	**+3,822**	**+106.9%**
Profit attributable to owners of parent	**32,558**	**20.3%**	**26,300**	**15.7%**	**-6,258**	**-19.2%**

Foreign exchange rates (USDJPY)

Q2 FY2024 actual	Q2 FY2025 actual	2H FY2025 forecast
152.8	146.0	140.0

The foreign exchange rate assumed for 2H FY2025 business forecast is ¥140 per USD and its sensitivity indicates that for every ¥1 depreciation of the yen against the USD, revenue is expected to increase by approximately ¥240 million and operating profit is expected to increase by approximately ¥240 million.

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Please move on to page 11.

I will explain our revised forecast for FY2025 compared to actual results of FY2024.

Revenue is expected to be JPY168 billion, up 4.8% YoY.

As for operating expenses, the cost of sales ratio is expected to deteriorate by 2 percentage points to 33.9%.

Selling, general and administrative expenses are expected to increase by 13.1% to JPY43 billion, and R&D expenses are expected to increase by 1.9% to JPY35 billion.

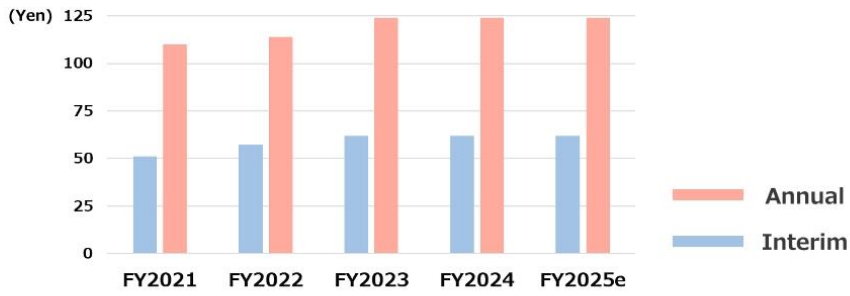
As a result, operating profit is expected to decrease by 6.9% to JPY33 billion, profit before tax will decrease by 6.7% to JPY33.7 billion, and profit attributable to owners of parent will decrease by 19.2% to JPY26.3 billion.

The exchange rate for the second half of FY2025 is assumed to be JPY140 to the US dollar.

Dividends Forecast

- **The Company's policy is to maintain stable dividends while taking into consideration the dividend on equity ratio (DOE).**

		FY2024	FY2025
Dividends per share	Interim	¥62	¥62
	Annual	¥124	¥124(e)
Basic earnings per share		¥483.40	¥390.20(e)



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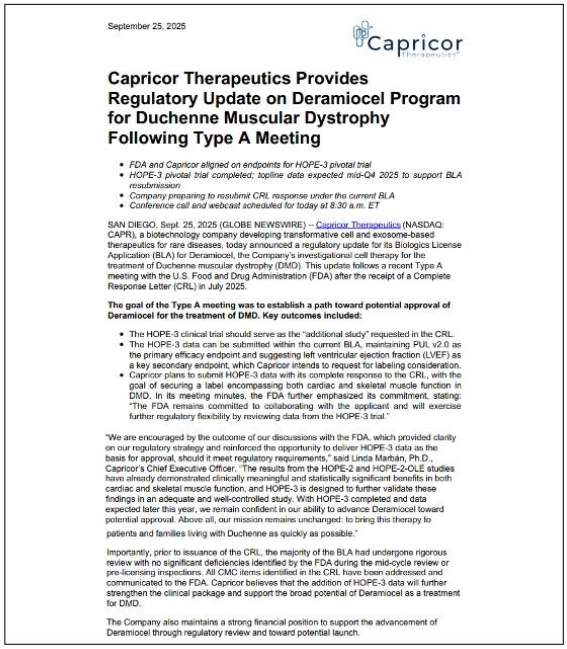
For the current fiscal year, the Company plans to pay a year-end dividend of JPY62 per share, which, together with the interim dividend, will result in an annual dividend of JPY124 per share. We will continue to pay stable dividends while taking DOE into consideration. This concludes my explanation of the results of Q2 of FY2025 and our forecast for FY2025.

CAP-1002 (deramiocel) update



September 25, 2025

Capricor Therapeutics

Capricor Therapeutics Provides Regulatory Update on Deramiocel Program for Duchenne Muscular Dystrophy Following Type A Meeting

- *FDA and Capricor aligned on endpoints for HOPE-3 pivotal trial*
- *HOPE-3 pivotal trial completed; topline data expected mid-Q4 2025 to support BLA resubmission*
- *Company preparing to resubmit CRL response under the current BLA*
- *Conference call and webcast scheduled for today at 8:30 a.m. ET*

SAN DIEGO, Sept. 25, 2025 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced a regulatory update for its Biologics License Application (BLA) for Deramiocel, the Company's investigational cell therapy for the treatment of Duchenne muscular dystrophy (DMD). This update follows a recent Type A meeting with the U.S. Food and Drug Administration (FDA) after the receipt of a Complete Response Letter (CRL) in July 2025.

The goal of the Type A meeting was to establish a path toward potential approval of Deramiocel for the treatment of DMD. Key outcomes included:

- The HOPE-3 clinical trial should serve as the "additional study" requested in the CRL.
- The HOPE-3 data can be submitted within the current BLA, maintaining PUL v2.0 as the primary efficacy endpoint and suggesting left ventricular ejection fraction (LVEF) as a key secondary endpoint, which Capricor intends to request for labeling consideration.
- Capricor plans to submit HOPE-3 data with its complete response to the CRL, with the goal of securing a label encompassing both cardiac and skeletal muscle function in DMD. In its meeting minutes, the FDA further emphasized its commitment, stating: "The FDA remains committed to collaborating with the applicant and will exercise further regulatory flexibility by reviewing data from the HOPE-3 trial."

"We are encouraged by the outcome of our discussions with the FDA, which provided clarity on our regulatory strategy and reinforced the opportunity to deliver HOPE-3 data as the basis for approval, should it meet regulatory requirements," said Linda Marbán, Ph.D., Capricor's Chief Executive Officer. "The results from the HOPE-2 and HOPE-2-OLE studies have already demonstrated clinically meaningful and statistically significant benefits in both cardiac and skeletal muscle function, and HOPE-3 is designed to further validate these findings in an adequate and well-controlled study. With HOPE-3 completed and data expected later this year, we remain confident in our ability to advance Deramiocel toward potential approval. Above all, our mission remains unchanged: to bring this therapy to patients and families living with Duchenne as quickly as possible."

Importantly, prior to issuance of the CRL, the majority of the BLA had undergone rigorous review with no significant deficiencies identified by the FDA during the mid-cycle review or pre-licensing inspections. All CMC items identified in the CRL have been addressed and communicated to the FDA. Capricor believes that the addition of HOPE-3 data will further strengthen the clinical package and support the broad potential of Deramiocel as a treatment for DMD.

The Company also maintains a strong financial position to support the advancement of Deramiocel through regulatory review and toward potential launch.

- **Capricor Therapeutics provided update following a Type-A meeting in August 2025 after the receipt of a Complete Response Letter (CRL) the previous month.**
- **It is expected that the FDA will restart the review clock upon Capricor's submission of the HOPE-3 results with a formal complete response to the CRL.**
- **According to Capricor, key outcomes from the meeting include that the HOPE-3 data can be submitted within the current BLA, maintaining PUL v2.0 as the primary efficacy endpoint and suggesting left ventricular ejection fraction (LVEF) as a key secondary endpoint, while maintaining the existing indication for DMD-associated cardiomyopathy with potential opportunity for label expansion.**

Source : press release by Capricor Therapeutics on September 25,2025
Capricor Therapeutics Provides Regulatory Update on Deramiocel Program for Duchenne Muscular Dystrophy Following Type A Meeting :: Capricor Therapeutics, Inc. (CAPR)

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

Please take a look at page 14.

I would like to explain CAP-1002, for which Capricor Therapeutics has submitted a BLA, in accordance with the press releases issued by Capricor.

The HOPE-3 study, which has already been completed, is positioned as an additional study required by the CRL, and the FDA is expected to restart its review upon the acceptance of the data.

As for the primary endpoint of the HOPE-3 study, change from PUL v2.0, which evaluates upper limb function, to LVEF, which evaluates cardiac function, was not permitted, and Capricor intends to maintain LVEF as a key secondary endpoint for approval in DMD-associated cardiomyopathy.

CAP-1002 (deramiocel) : U.S. development timeline update

- **Following outcome of discussions with the FDA at the Type-A meeting, Capricor plans to submit HOPE-3 data under the current BLA.**
- **HOPE-3 topline data is expected to be available in the coming weeks (Q4 2025).**

Source : Capricor Therapeutics

	Before CRL (July 15, 2025 announcement)	Latest (as of Nov 10, 2025 announcement)
BLA submission	BLA submission was completed by the end of 2024, and the FDA accepted it in March 2025.	The HOPE-3 data (Cohort A and B) can be submitted within the current BLA
PDUFA (FDA approval) date	August 31, 2025	TBD[1] (Once the FDA accepts the resubmitted BLA, a new PDUFA date will be provided.)
Review period	n/a	Anticipated to be up to six months following resubmission under a Type 2 classification[1]
Expected launch date	As soon as possible post PDUFA	TBD following resubmission and establishment of new PDUFA date[1]
Designations	1. Regenerative Medicine Advanced Therapy 2. Orphan Drug 3. Rare Pediatric Disease	All designations remain valid (regardless of a CRL).
Expected approval type	Full approval with existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 Open Label Extension (OLE) trials compared to natural history data	Full approval with HOPE-3 data added to current BLA. PUL v2.0 remains the primary efficacy endpoint with left ventricular ejection fraction (LVEF) included as secondary endpoint.
Target indication	Cardiomyopathy Associated with Duchenne Muscular Dystrophy (DMD)	Aim to maintain indication of Cardiomyopathy Associated with Duchenne Muscular Dystrophy (DMD) with possible label expansion
Key event(s)	Late-cycle meeting and Advisory Committee were planned.	The HOPE-3 data (Cohort A and B) expected to be available in the coming weeks (Q4 2025).

1. Classification 1 or 2 applies to NDA, BLA, and efficacy supplement resubmissions under PDUFA after a Complete Response Letter. Under Type 2 classification, a resubmission includes items not specified as Class 1, such as major amendments to the original application, and is subject to an FDA review period of up to six months.

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Regarding the future development schedule, the new target date for completion of the FDA review, the PDUFA date, has not yet been determined, but top-line data, including Cohort A and cohort B from the HOPE-3 study, is expected to be disclosed by the end of 2025.

The timing of the market launch is to be determined as soon as the PDUFA date is determined, and preparations are underway with a view to launching the product in 2026.

Preparations for New Product Launches in the U.S. (1/2)

- **Focus on recruitment activities and reallocating human resources toward the launches of CAP-1002 and RGX-121 in the U.S.**

Focus on recruitment activities

NS Pharma (NSP), the U.S. subsidiary has hired 30 employees since January 2025, planning to add approximately 10 more employees to Commercial Division.

Newly hired Payer Communications, Marketing, and Sales teams are currently preparing for new product launches.

(As of October 2025, NSP has approximately 160 employees. Of these, about 80 are assigned to either the Commercial or Medical Divisions, including 24 Sales Representatives.)

Field team reorganization

Sales Representatives divided between
KAMs (Key Account Managers) and
ABMs (Area Business Managers) to enhance specialization.

Enhancing collaboration among field team
- Sales Representatives (KAM/ABM)
- Insurance Reimbursement Specialists
  (DPA: Director of Patient Access)
- Patient Support Specialists
  (PEL: Patient Engagement Lead)

The reorganization largely completed as of the end of Q2 FY2025 (Until the new product is launched, they focus on Viltepso promotional activities)

This new organization will also handle ATSN-101 and RGX-111 in the future.

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I will now explain the status of sales preparation in the US.

Please turn to page 17.

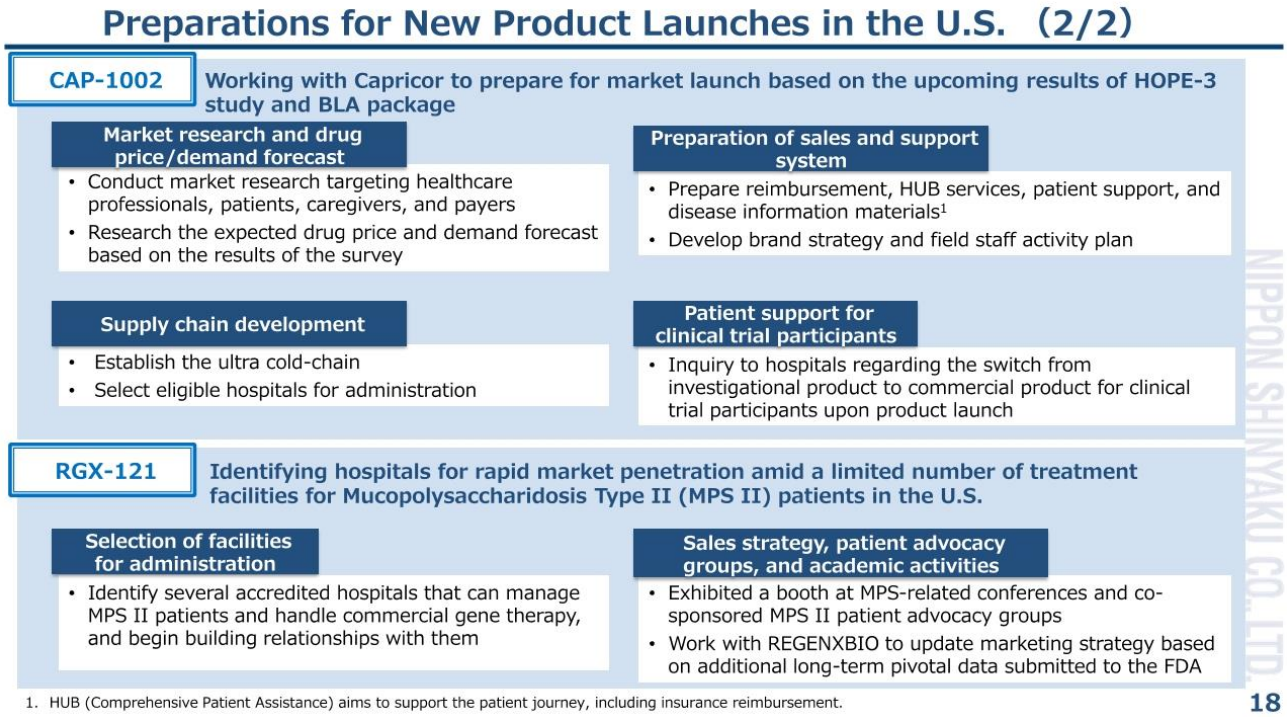
In preparation for the US launch of CAP-1002 and RGX-121, NS Pharma has stepped up its recruiting efforts and has hired approximately 30 people since January 2025. As a result, as of October 2025, NS Pharma has approximately 160 employees, of which approximately 80 are in the Commercial or Medical Divisions.

In the future, the Commercial Division plans to add about 10 more employees.

For the 24 sales representatives, we have divided them into Key Account Managers or KAMs and Area Business Managers or ABMs in order to enhance their expertise.

In addition, field staff in charge of sales, insurance reimbursement, and patient support work together in the same area to enhance a sense of unity as a team. As of the end of Q2 of FY2025, this structure is almost complete, and the Company is currently focusing on sales promotion activities for Viltepso.

They intend to adopt the same system for subsequent licensed-in products such as ATSN-101 and RGX-111.



Please move on to page 18.

Next, I will talk about the specific preparations for the launch of the products in the United States.

For CAP-1002, we will work with Capricor to conduct market research based on the results of the HOPE-3 study and information from the BLA, and use the results to make drug price assumptions and demand forecasts.

As for the sales and support system, we are developing an insurance reimbursement system and building a HUB service, a comprehensive patient support service.

As for the supply chain, we are developing a supply network for ultra-cold chain and are selecting hospitals capable of administering the product.

Since patients participating in clinical trials are on a waiting list for commercial products, we are also working with medical institutions to confirm the switching procedure.

Regarding RGX-121, since mucopolysaccharidosis type II is a rare disease and the number of treatment facilities is limited, we have selected the facilities that can handle the therapy and have begun building relationships with them.

In addition, we are working with REGENXBIO to increase awareness by exhibiting at booths at related conferences and sponsoring patient advocacy groups, as well as updating our marketing strategy based on long-term data.

Thus, the Company is steadily preparing for sales in the US market while further deepening relationships of trust with its partners.

We will continue to do our utmost to bring our products to as many patients as possible as soon as possible.

This concludes my explanation.

Mr. Kuwano, in charge of research and development, will continue with an explanation of the progress of research and development.

R&D Updates (1/2)

For updates from Q1 FY2025 financial results announcement on August 7, 2024, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
P3	NS-065/NCNP-01 (viltolarsen)	Viltepso	・FDA review of the Study 301 report is scheduled to be completed by December, 2025. ・The protocol of Study 303 is currently under review by the FDA.	October 2025
Launch	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
Launch	NS-304 (selexipag)	Uptravi	Uptravi Tablets for Pediatric 0.05 mg	March 2025
Additional indication			pediatric pulmonary arterial hypertension	December 2024
Launch	ACT-064992D (macitentan / tadalafil)	Yuvanci	pulmonary arterial hypertension	November 2024
Filed	RGX-121 (clemidsogene lanparvovec)	–	Mucopolysaccharidosis Type II (FDA review period extended with new PDUFA date[1] of Feb. 8, 2026)	August 2025 (U.S.)
Filed	CAP-1002 (deramiocel)	–	Duchenne muscular dystrophy cardiomyopathy (Capricor received CRL[2] from FDA)	July 2025 (U.S.)
Filed	NS-401 (tagraxofusp)	–	blastic plasmacytoid dendritic cell neoplasm (BPDCN)	March 2025
P3	GA101 (obinutuzumab)	Gazyva	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

1. PDUFA date : the target action date for completion of the review by the FDA
2. 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.

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Kuwano: I am Kuwano in charge of research and development.

I will explain the progress of R&D items that have been updated since Q1 of FY2025.

Please take a look at page 20.

With regard to Viltepso, we have confirmed that the FDA's review of the study 301 report is expected to be completed by the end of December.

We are also referring the final protocol of study 303 to the FDA. NS Pharma, our US subsidiary, is working with the R&D department at the headquarters to select the countries and facilities for the 303 study so that the study can begin as soon as the protocol is finalized.

As for Jaypirca, in September, we received approval for an additional indication for patients with relapsed or refractory chronic lymphocytic leukemia who are resistant or intolerant to other BTK inhibitors.

As for RGX-121, the FDA has extended the review period, and the PDUFA date, the target date for completion of the FDA review, has been changed from November 9, 2025 to February 8, 2026.

For Gazyva, Roche announced top-line results from the Phase III study for idiopathic nephrotic syndrome in children and young adults.

The study showed statistically and clinically significant improvement in the primary endpoint of sustained complete remission at one year post-treatment in the Gazyva group compared to the mycophenolate mofetil group.

R&D Updates (2/2)

For updates from Q1 FY2025 financial results announcement on August 7, 2024, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
In-license agreement signed (REGENXBIO Inc.)	RGX-121 (clemidsogene lanparvovec)	–	Mucopolysaccharidosis Type II	January 2025 (U.S. and Asia including Japan)
	RGX-111	–	Mucopolysaccharidosis Type I	
In-license agreement signed (Atsena Therapeutics)	ATSN-101	–	GUCY2D-associated Leber congenital amaurosis	November 2024 (U.S. and Japan)
Option Agreement signed for Commercialization (AB2 BIO Ltd.)	Tadekinig alfa	–	NLRC4 mutation and XIAP deficiency	January 2025 (U.S.)
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				April 2025 (U.S.)
Orphan Drug Designation	NS-051/NCNP-04	–	Duchenne muscular dystrophy	September 2025 (U.S.)
Rare Pediatric Disease Designation				January 2025 (U.S.)
Senkuteki Iyakuhin (Pioneering Drug) Designation and Orphan Drug Designation	NS-089/NCNP-02 (brogidirsen)	–	Duchenne muscular dystrophy	December 2024 (Japan)
Academic conference presentation			3.5-Year clinical trial data presentation at the World Muscle Society 2025 Congress	October 2025 (U.S.)
Publication			the results of an investigator-initiated clinical trial (First in human trial) in Cell Reports Medicine	January 2025

NIPPON SHINYAKU CO., LTD.

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As for NS-229, a treatment for eosinophilic granulomatosis with polyangiitis, in September, we received fast track designation in the US.

As for NS-051/NCNP-04, in September, we received orphan drug designation in the US.

The efficacy and safety of NS-089/NCNP-02 for up to 3.5 years of administration were presented at the 30th annual international congress of the World Muscle Society held in Australia in October.

This presentation is based on an investigator-initiated clinical trial conducted by NCNP and an open-Label, extension study conducted by our company, which evaluated the efficacy and safety of the drug in six patients with Duchenne muscular dystrophy for up to 3.5 years from the start of treatment, suggesting that the drug may help prevent disease progression.

This concludes my explanation of the progress of research and development.

Question & Answer

Takechi [M]: We will now begin the question-and-answer session. We will take questions first from analysts and institutional investors, and then move on to questions from members of the press.

If anyone in the audience has any questions, please raise your hand so that we may nominate you. A staff member will hold the microphone for you. If you have any questions online, please press the raise your hand button.

Before asking questions, please state your name and the name of the company.

Now, we will take your questions. Mr. Tanaka, please ask your question.

Tanaka [Q]: I am Tanaka from Mizuho Securities. Thank you for your presentation today.

First of all, I would like to ask about financial results. As for Erleada's reverse co-promotion, this time you have recorded as product sales and cost of goods, and how will the share of profits change?

Also, the annual securities report says that the co-promotion contract remains in effect until April 2027, but since a five-year patent extension has already been granted, is it correct to assume that this will also be extended for five years?

Nakai [A]: Thank you for your question. I will now give a brief explanation.

As for the share of profits and how the change in contract will change them, in principle, there will be no significant change. Therefore, sales will be recorded, and the cost of sales will be recorded accordingly. After subtracting these costs, and also subtracting expenses related to SG&A, the final profit remaining will be roughly the same level.

As for what will happen to the term of the contract, the original contract is as announced in the annual securities report, and the term of the contract will actually be extended as well. This is one of the reasons why we have changed the contract. We have been very active in sales activities in the urology field in Japan, and we recognize that this is the company that has a sufficient presence in the urology field.

We will continue to deliver Erleada in the field of urology for a longer period of time, and by doing so, we would like to contribute to patients and the Company's business performance.

As to the specific number of years we have extended the contract, I am sorry, but due to our relationship with our partner, I am unable to answer that question at this time.

Tanaka [Q]: I understand. You have added JPY6.3 billion of Erleada sales to the full-year forecast of FY2025, but is this from the second half of this fiscal year? When will this start?

Nakai [A]: From the second half of FY2025.

Tanaka [Q]: The second question is also about the financial results. Sales of Viltepso outside Japan and US decreased dramatically in Q2 of FY2025, and I think this is one of the reasons why there is not much increase in pharmaceutical sales forecast even if JPY6.3 billion of Erleada sales has been added to the total. What happened?

Nakai [A]: Thank you very much. In fact, as for sales of Viltepso outside Japan and US, sales are generated on an export basis. Therefore, sales can be recorded at the timing of shipments, and there were no shipments in Q2. Shipments are planned for second half, so that is the situation.

Tanaka [Q]: Does this mean that if we look at the full year, it will remain the same? Or is it decreased due to the portion of Q2 that has not been exported?

Nakai [A]: The total for the full year is almost the same. The trend is similar to the previous fiscal year. You can understand that only the timing of the shipments has been shifted to the second half of FY2025.

Tanaka [Q]: I understand. Also, regarding CAP-1002, the results are coming out soon, and of course I hope they are all positive, but your company originally said that LVEF has a higher chance of success because it is assessed with cMRI (Cardiac Magnetic Resonance Imaging). What is going on in the statistical analysis plan or something because this did not become the primary endpoint?

In case that there is no difference in PUL v2.0, would the FDA be Okay if LVEF is also analyzed and there is a difference?

Also, in the Earnings Call by Capricor this week, I think they said they were going to judge the effectiveness by cohort B in San Diego. Please explain this in detail.

Nakai [A]: Thank you very much. In the event that the primary endpoint is not met, how the secondary endpoint is handled would be a matter of negotiation or discussion with the FDA. I believe the same explanation has been provided from Capricor.

That being said, Capricor describes the cardiac function as a key secondary endpoint, even though it is not a primary. So, if the primary endpoint is not met and a favorable p-value is obtained for LVEF, Capricor will actively negotiate with the FDA, and I believe that the FDA will be open to such negotiations with Capricor.

As for cohort B, we believe that our explanation is almost the same as the explanation given by Capricor, but cohort B is actually a manufacturing facility for commercial products, and the results of cohort B will be more important and analyzed carefully for approval.

Tanaka [Q]: If comparing between the overall analysis of combined A and B and the analysis of cohort B, would you say that the analysis of cohort B is more important?

Nakai [A]: cohort B is for commercial, and cohort B is examining the differences in the MRI of the heart. I would like you to follow up continuously, but I think that Capricor is trying to negotiate by focusing more on the differences there.

Capricor has announced that the powering for both Cohorts A and B is 90%, while the powering for cohort B alone is 80%, so it is our understanding that they are placing more importance on cohort B, while the power is slightly different.

Tanaka [M]: I understand. Thank you very much.

Takechi [M]: Next, Mr. Hashiguchi.

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Can you tell me a few things about the situation of Viltepso in the US?

The number of newly registered patients is increasing, and I think a slight increase for the full year means an increase in the second half of FY2025. Is it safe to assume that this is a slight change in trend?

Or is it better to understand that the trend is unchanged from the past trend of generally flat or slightly increasing, as you mentioned before, and it is within the range that fluctuates from period to period?

First, how should we see this?

Nakai [A]: Thank you very much. I will answer. In the United States, Q2 started off on a flat note, as we indicated at the time of the briefing in May.

Gradually, the number of new patients increased, but there were also a few cases of patients who dropped out of the protocol. In Q2, these dropouts impacted slightly on revenue.

The pace of patient acquisition has been increasing further, in later Q2. This is related to the competition, and some patients who were administered gene therapy came back to Viltepso.

Therefore, I feel the environment will change in the future, where patients who switched from Viltepso to gene therapy, or patients who used gene therapy from the beginning, are returning to Viltepso.

In addition, as for the NS Pharma team, we have been enhancing their human resources in order to establish the NS Pharma system, and the team is now focusing more on Viltepso. We are confident that we will be able to make it grow in the medium to long term.

Hashiguchi [Q]: Thank you. I would also like to confirm the future course of communication with the authorities. At the time of the review completion of the study 301 report that is scheduled for December, can you obtain their review on the study 303 protocol as well, or will the timing be delayed?

Also, can you give me an idea of when and in what form you expect to be able to explain these results to us?

Nakai [M]: Thank you very much. Regarding the status of the review of Viltepso by the FDA, I will ask Kuwano in charge of research and development to explain.

Kuwano [A]: My name is Kuwano. I think we have already made some announcements, but as I mentioned earlier, the response from the FDA will come back in December. Prior to that, we have already submitted our interpretation of the results of study 301. Therefore, we expect to hear back from them, and we have also submitted the final version of the protocol for study 303 based on the FDA's request.

Therefore, we expect to have some kind of response on these two studies by the end of December. Depending on the content of the response, if it meets our expectations, we will immediately move on to the next action. Otherwise, we will need to continue negotiations.

We would like to report to you when things become clear.

Hashiguchi [Q]: When do you think will that become clear? It may depend on what the response is.

Kuwano [A]: Yes. I believe so.

Nakai [A]: I would like to add some. As Mr. Hashiguchi said, that depends on the content of the response. If the content of the response has a major impact on our business, we will disclose it to everyone as soon as possible.

Hashiguchi [Q]: Thank you very much. Lastly, could you please explain why Vyxeos is not growing?

Nakai [A]: Thank you very much. As for Vyxeos, at the time of our main closing of accounts in May, we had planned for a very high growth. Based on the situation in Q2, Mr. Iwata, who is in charge of sales, will answer your question.

Iwata [A]: I will explain. Vyxeos is for high-risk AML where the conventional treatment is ICT, intensive chemotherapy and a combination therapy of azacitidine and venetoclax. The agent coming in between there is Vyxeos.

Vyxeos contains the same ingredient as conventional products, but it is liposomized, so the efficacy and side effects of Vyxeos is different from those of conventional products. However, the reason for the delay is that we could not fully communicate the difference.

In fact, we are now in the process of presenting the clinical significance of liposomalization to doctors, and external surveys have shown that the mechanism of action is now well understood. We are now in the process of conveying the clinical experience of the product by doctors who have used it since it was launched.

So, the liposomalization was not communicated well, which is the main reason for this delay.

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

Takechi [M]: Well then, Mr. Sakai, please ask your question.

Sakai [Q]: I am Sakai from UBS Securities. This may be similar to the previous question. Even during the FDA's review of study 301, the president mentioned that patients are coming from gene therapy and that new patients are being enrolled. Am I correct in understanding that the FDA did not impose any particular regulations on that?

Also, can I assume that once the review of the results of study 301 is completed, this will enter a new round of the process, and that this will have an impact on the sales side of the business?

Nakai [A]: Thank you for your question. In fact, we have not been restricted in any way by the FDA from marketing Viltepso in the United States. So, we are in the situation of promoting Viltepso in the US with the current accelerated approval status. With its accelerated approval status, insurance companies are reimbursing us, and we are promoting the product by differentiating it from competitors, such as gene therapy and other exon skipping drugs.

Sakai [Q]: Thank you very much. I would also like to ask about that for domestic sales. I think this is discussed with the PMDA, but it is so-called conditional approval, isn't it? There are many problems with the conditional approval drugs at other companies. For the time being, I think that the discussions between PMDA and your company are proceeding without any particular problems, but what should we expect in the domestic market in the future?

Nakai [M]: Thank you for your question. Regarding the status of discussions with the PMDA in Japan, Mr. Kuwano from R&D will explain.

Kuwano [A]: Thank you for your question. In fact, we have received offers from the PMDA and the MHLW to discuss this Viltepso, and we are actually discussing it. We plan to continue the conversation over a little more time in the future.

Things are going well in terms of content, and I think we are having a positive conversation.

Sakai [Q]: Regarding the number of patients in Japan, I think you are getting close to the numbers submitted by Central Social Insurance Medical Council. Of course, there are some dropouts, so I think you should think about how many the net is. How should we think about this in the future?

Are you entering a phase where, to some extent, some dropouts are inevitable? I think you mentioned that the actual number of patients was much higher, so could you give me some more perspective on that?

Nakai [A]: Thank you very much. I will give you a brief explanation first, and then Iwata will give you more details.

The actual number of peak patients provided by Central Social Insurance Medical Council is 128, and the number of patients already on medication is more than three-fourths of that number. Some of them have dropped out of the protocol.

We have already identified almost all of the patients in Japan who are eligible for exon 53 skipping, and we have also identified those under the age of 20 who have the potential for treatment. Some patients are being prepared to receive medication. Supplemental information will also be provided by Iwata.

Iwata [A]: As for the future outlook, the actual incidence rate is about 1 in 7,500 of the 700,000 people who have the disease. Considering that about 8% of them are boys, there is a few per year. I think it would be four people or so.

In fact, we are still finding new patients on a regular basis for the past few years. I think this trend will continue. We expect to continue to be able to deliver this drug to a few new cases each year. That is all.

Sakai [M]: Thank you very much.

Takechi [M]: Mr. Wada, please.

Wada [Q]: I am Wada from SMBC Nikko Securities. Thank you very much. I have two questions. First, I would like to ask about the upward revision, especially the cost part.

Based on the cost assumptions, I think the rate of progress against the revised SG&A and R&D expenses is still slightly heavier in the second half of FY2025. In particular, since only a little more than 40% of R&D expenses have progressed, they are much heavier in the second half. What do you plan?

Since you mentioned earlier about study 303 for Viltepso, I am wondering if that is already included or not?

Nakai [M]: Thank you very much. Mr. Edamitsu, in charge of business management, will answer your questions.

Edamitsu [A]: I am Edamitsu. Let me explain. Based on the results of Q2, costs have also been reviewed this time. Regarding your question about Viltepso, we have naturally factored in the situation and have revised our plans.

To be more precise, the review completion date for RGX-121 has been extended by about three months since the previous announcement, so we have revised our SG&A expenses accordingly. The Q2 results for research and development expenses were slightly shifted to the second half of FY2025 due to the delay in clinical development, and there was also a further shift due to the impact of that delay. That is all.

Wada [Q]: Thank you very much. Second, I would like to ask you about NS-089 in your development pipeline.

Novartis has acquired Avidity, which has a lead pipeline, Del-zota, an exon-skipping drug in Phase II, and a nucleic acid version of an ADC, which they call AOC, an antibody oligonucleotide conjugate. I think this is in a similar phase.

I think the acquisition will accelerate the development and sales of nucleic acids, and I would like to ask if there will be any change in your next-generation, second- and third-line nucleic acid development, or partnerships and strategies. I would like to ask you to include your assessment of their pipeline.

Nakai [M]: Thank you for your question. First of all, Mr. Kuwano from R&D will talk about how ours are different from Avidity's Del-zota and how we will compete with them.

Kuwano [A]: We naturally consider the recently acquired product by Novartis to be a very serious threat.

We have compared our efficacy with their efficacy on the published data and found that the efficacy of exon skipping, dystrophin expression, motor function, and other factors are about the same, although there are some differences.

The biggest difference, however, is the frequency of administration. Their product is administered once in six weeks and our product needs to be administered weekly, so the convenience is higher for their product.

On the other hand, as far as safety is concerned, I believe there were two dropouts out of nine cases for the 5 mg dose of Avidity's product. I understand that one case of anaphylaxis was reported, but as is the case with Viltepso, which is already on the market, our product is morpholino nucleic acid, which is extremely safe. I think this is a very significant feature.

So, in total, there are many differences. Although convenience is of course a disadvantage, we would like to deliver this product to patients by taking advantage of its high safety profile. That is all.

Nakai [A]: You also asked whether we are going to do it alone with respect to next-generation nucleic acid medicine, for example, and what our strategic plans are like in this area. I will answer that question.

We are still researching the next-generation nucleic acid drugs that will follow the morpholino nucleic acid PMO, such as NS-089 and NS-050, in our own laboratory. We are currently studying various technologies for higher activity and for longer efficacy, such as exosomes, for example, aiming for collaboration with partners or other companies that have good technologies.

Therefore, we do not intend to do these new next-generation areas on our own, but to work with the best partners. If it becomes necessary to proceed with development by force to some extent, we would like to be flexible in working with companies that are more powerful than our company.

Wada [M]: I understand very well. Thank you very much.

Takechi [M]: Now among participants from online, Mr. Lee from Morgan Stanley MUFG Securities, please ask your question.

Lee [Q]: I am Lee from Morgan Stanley. Thank you for taking my question. I have two questions.

First, both R&D and SG&A have been reduced in this upward revision. I understand that both of them were due to a periodic shift, but am I correct in understanding that all of the items due to this periodic shift were shifted to the next fiscal year?

Nakai [M]: Thank you for your question. Edamitsu will answer this question as well.

Edamitsu [A]: Yes, that understanding is correct.

Lee [Q]: Thank you very much. Is it correct to assume that the entire amount that has been delayed this time will be accrued in the next fiscal year?

Edamitsu [A]: That is correct.

Lee [Q]: Okay, thank you very much. The second question is about the new drug. The competitor, Sarepta's exon skipping drug, has also failed to meet its primary endpoint in Phase III.

I am wondering if whether the FDA is being cautious in this regard, as there has been a string of failures of these exon-skipping drugs, as I recall. What do you think about this as a risk?

Nakai [A]: Thank you for your question. In fact, in the validation study for our Viltepso and for Sarepta's item, the primary endpoints were not achieved, but in the course of various multifaceted analyses, there are some groups where the exon-skipping drugs are actually showing efficacy.

We have explained to the FDA that the reason study 301 did not meet its primary endpoint was not so much a drug issue as it was a study design issue. Discussions with the FDA are ongoing, and the FDA nor the market is skeptical about exon-skipping drugs of ours and Sarept's, and they have not determined that this is not something that is worthy of approval.

We do not believe that the FDA is being skeptical on this point.

Lee [Q]: Okay, thank you very much. Lastly, as for the profit forecast in the medium-term management plan, during the main closing in May, another analyst asked if you would be able to enter another V-shaped recovery, or re-growth, in FY2028 after one profit drop due to the LOE of Uptravi in FY2027.

At that time, President Nakai said he did not think there were any mountain. He told us that FY2025 was the bottom and that the Company would grow steadily rightward starting in FY2026. Is there still no change in this concept? CAP-1002 and other items such as RGX-121 are a bit delayed, so please let me check to see if there is any change in thinking in this regard. That is all.

Nakai [A]: Thank you for your question. I remember that we announced in May that the bottom of the market would be in FY2025, but the timing of the launch of CAP-1002 and RGX-121 seems to have been delayed.

The other factor is that, taking into account the fact that R&D expenses are likely to be shifted slightly, as mentioned in the previous question, we believe that such shifts may have some impact, although we have not yet provided a forecast for FY2026. We will be able to guide you through a proper scrutiny of this area later.

Lee [Q]: Thank you very much. In any case, I understand that there is no change in the idea that FY2026 is the bottom and that you will continue to grow steadily after that. Is that correct?

Nakai [A]: Yes. Considering the way the business is currently proceeding, I think that understanding is correct.

Lee [M]: I understand. Thank you for your kind explanation. That's all from me.

Takechi [M]: Mr. Yamakita from Jefferies Securities, please.

Yamakita [Q]: I am Yamakita from Jefferies Securities. Thank you very much. Let me just confirm one point.

As for Viltepso in the US, I think the stricter screening process for insurance coverage renewal will have a considerable impact as a whole. I believe that DMD drugs will become more expensive in the market as a whole as more DMD drugs are being brought into the market.

I understand that your company's Viltepso is no longer reimbursed to patients whose symptoms have progressed, but the number of patients whose symptoms have progressed is increasing.

Therefore, I think there is a risk that the impact of this will be quite large. Taking this into account, do you still think that the second half of FY2025 will see a slight increase in sales?

Also, if possible, after next year, I think you will reach the break-even point, so how much risk should we consider for a gradual decline past the break-even point? Please let me know about this.

Nakai [A]: Thank you very much. I took your question as a question about where the Viltepso peaks out.

As we have already indicated, it has actually been five years since the launch of Viltepso, and after five years, we have actually seen some cases where some patients have deteriorated in their conditions, and have dropped out of the protocol because they are not eligible for insurance reimbursement. As we have informed you, the growth has slowed down a bit due to such cases.

As for the upside information, as mentioned in the previous question, patients who were on gene therapy are now coming to us, and we are also seeing a certain percentage of new patients switched to Viltepso from patients on competing exon skipping drugs.

We are confident that the percentage of such patients will increase in the future, and we would like to promote the superiority of our drugs in order to achieve further growth. We would like to continuously grow our business so that we will not be in a situation so early where we are no longer able to grow.

Yamakita [Q]: Thank you very much. The growth part is understandable, as you mentioned, and we have high expectations for it, but is it correct to say that the forecast for the second half of FY2025 incorporates the decrease as well? Let me just confirm this.

Nakai [A]: Thank you very much. Well, based on the fact that it takes a little time for insurance reimbursement, which is offset by the increased pace of new acquisitions, the figures for the second half of FY2025 are based on the assumption that the drug will continue to grow.

Yamakita [M]: I understand very well. Thank you very much. That's all from me.

Takechi [M]: Are there any other questions from analysts and institutional investors? Mr. Tanaka, please ask your question.

Tanaka [Q]: Sorry, one more time, please. You did not explain this, but there are about 1,000 to 2,000 patients for NS-035, Fukuyama muscular dystrophy, maybe in Japan alone.

The results of the physician-led clinical trial have already been announced, and although I have not seen very accurate data, I have heard that the results were favorable.

How do you plan to conduct company-led clinical trials for the future and when do you want to bring the product to market? This time, there was no update on the market plan at all. Please let me know.

Nakai [M]: Thank you very much. Mr. Kuwano in charge of R&D will answer your question regarding the development plan of NS-035.

Kuwano [A]: Thank you for your question. As you pointed out, we also think that they have achieved very good results in their investigator-initiated clinical trials.

In fact, we are sponsoring a continuous administration study, and we would like to conduct the next phase of the trial. We will announce the details at an appropriate time. We would like to actively move forward with this project.

Tanaka [Q]: The number of patients is much larger than that of Viltepso in Japan, so you should proceed faster.

Kuwano [A]: Thank you very much. We are working to proceed expeditiously. In fact, the name of our company, Nippon Shinyaku, is based on the philosophy that we want to produce medicines for Japanese people by Japanese people, and I believe that it is our mission to produce medicines for such diseases. Thank you very much.

Takechi [M]: Then, we will now take questions from the press. Before asking a question, please state your name and the name of the company. Any questions?

Shimomura [Q]: I am Shimomura from JIHO Nikkan Yakugyo. I would like to ask about overseas sales. Please tell me the overseas sales and the ratio of overseas sales to sales of the last fiscal year and those for the current fiscal year.

Nakai [A]: Thank you for your question. Ratio of overseas sales in the previous fiscal year and Q2 of the current year.

Shimomura [Q]: And the actual amount.

Nakai [A]: The actual amount. Can the secretariat answer this?

Takechi [M]: I will answer later.

Shimomura [Q]: Based on that, I think you mentioned in the medium-term management plan that you wanted to raise the ratio to about 45% in the final year of FY2028. What is the current progress? I don't know the ratio, so I don't know about this, but I would like to know the degree of accomplishment and the likelihood of accomplishment.

Nakai [A]: Thank you very much. The secretariat will provide specific figures later, but we are currently experiencing steady growth in overseas sales, and the ratio of overseas sales to total sales is increasing. I think I can answer that we are on track to achieve the target of 45%.

Shimomura [Q]: I think there may be some change in the figures based on your earlier talk about the situation overseas and the situation in the US, but is it your understanding that you will be able to achieve the goal even considering the situation there?

Nakai [A]: Thank you very much. In fact, we believe that the RGX-121 and CAP-1002, both of which are scheduled to go on sale in the US, will make a significant contribution to the total amount of sales.

We believe that overseas sales will grow significantly as these products are launched in the next fiscal year and beyond.

Shimomura [Q]: Let me ask one more question, please. In relation to the long-term listed products, I believe that the premiums for selective treatments have been introduced. I would like to know more about that.

You described the breakdown of revenue or the increase or decrease factors, and I would like to know exactly how much it was.

Nakai [A]: Thank you for your question. Long-listed products account for a very small percentage of our total sales.

Therefore, although such long-term listed products, such as Zalutia for benign prostatic hyperplasia, are actually affected by the selective treatment system, the impact on the Company's overall figures is not so great. The premiums for selective treatments have not significantly affected the Company's performance, in particular.

Shimomura [M]: I understand.

Takechi [M]: How about other questions?

Tsubokura [Q]: I am Tsubokura from the Chemical Daily (Kagaku Kogyo Nippo). I would like to make a few confirmations about the breakdown of pharmaceuticals on page 23 of the document.

Regarding the downward revision of Viltepso and Vyxeos due to the market environment, would the dropout of Viltepso, which you just explained, and the slight delay in the penetration of the benefits of Vyxeos as a drug, be the effects of the market environment described here?

Nakai [A]: Thank you for your question. The Viltepso in US, which is written on the top of the table on page 23, and Vyxeos are as I answered in my previous question.

For Viltepso, as I explained earlier, we have revised downward due to some dropouts and the fact that insurance reimbursement took a little longer than expected. The downward revision is for the portion that was not achieved in Q2, and as I mentioned earlier, we expect to be able to achieve the figures in the second half of FY2025 as originally planned.

As mentioned in the previous question about Vyxeos, we compete with strong chemotherapy, and I regret that the usefulness of Vyxeos was not sufficiently communicated to doctors.

We would like to lower the downward revision as much as possible by having our sales force focus on these areas and turn around the situation.

Tsubokura [Q]: Okay, thank you. And I have one more question. In relation to the discussions with the FDA, we have heard from some companies that the US administration's reduction of FDA personnel and the government shutdown have had an impact on some aspects of the discussions. How do you feel such impact on your company?

Nakai [A]: Thank you very much. We have not seen such a situation where the speed of FDA review is actually slowing down, for items that our partners are applying for.

Such things as the approval date being pushed back are all part of the original review process, and we are responding to requests from the authorities by providing more detailed information and data. I don't perceive that such FDA staffing cut or anything like that has an impact.

Tsubokura [M]: I understand. Thank you very much.

Takechi [M]: Okay, we will end with the next question. Mr. Okada from Yakuji Nippo, please.

Okada [Q]: Thank you for your help. I am Okada from Yakuji Nippo. Regarding the NS Pharma system, you said that the system was almost completed with 160 employees, and you said that 10 additional employees for commercials would be added. Am I correct in understanding that the system is almost completed with 170 employees?

Nakai [A]: Thank you for your question. We believe that it will be fine for the launch of CAP-1002 and RGX-121 with these plus 10 members, for a total of 170 members.

We actually have 80 people for a commercial and medical team currently, and those plus 10 people are involved in the sales activities of Viltepso, CAP-1002, and RGX-121. We have 160 plus 10, or 170 in total, and then subtracting 80 or 90 from that are the members for business development and introduction activities in the US. The rest are for administrative work.

Therefore, in terms of the status of sales preparation, I would like you to understand that the system construction is complete with an additional 10 employees.

Okada [Q]: Thank you very much. Also, I'm sorry if this has already come up or if I'm missing something, but could you tell me about peak sales estimates for CAP-1002 and RGX-121?

Nakai [A]: Thank you for your question. We hope you understand that we are not yet in a position to disclose specific figures to you regarding peak sales.

As for CAP-1002, expected indication is DMD cardiomyopathy and we are currently progressing with it. In terms of DMD cardiomyopathy, we believe that a very large number of patients will be targeted.

Specifically speaking, there are 15,000 DMD patients in the United States. It is said that about half of the 15,000 patients have some kind of heart disorder or reduced function.

As to whether or not half of the 15,000 is actually indicated for this drug and whether or not it can be used for all patients with DMD cardiomyopathy, this will depend on the outcome of the negotiations with the FDA. We are now in the process of conducting a close examination of the 7,500 patients, half of the maximum 15,000, to see which ones are eligible for this drug, and we are also in discussions with the FDA.

On the other hand, as for RGX-121, it is said that there are approximately 500 patients with mucopolysaccharidosis type II in the United States. Since there are currently some drugs in use here as well, peak sales will depend on how much market share can be obtained from among the 500 people.

The unique feature of this drug is that it can be used from the age of four months, while the competition is a drug used from slightly older patients. Therefore, we expect this drug to be used as soon as it becomes eligible for treatment in newborn babies diagnosed with mucopolysaccharidosis type II. Thank you very much.

Okada [Q]: Okay, thank you. Let me just make one last confirmation. You mentioned that CAP-1002 is targeted to be on the market in 2026, and is it correct that RGX-121 is also scheduled for 2026?

Nakai [A]: Thank you very much. The actual target date for completion of the review is February 8, 2026. From there, we will make a few preparations for sales, and from there we aim to launch the product as soon as possible, which would be in FY2026. We are currently expecting it to be in early April.

Okada [M]: I understand. Thank you very much.

Takechi [M]: With that, we will now conclude the financial results briefing of Nippon Shinyaku for Q2 of FY2025.

Thank you very much for your participation today.

[END]