Nippon Shinyaku Co., Ltd.

FY2026/Q1 Earnings Call

August 6, 2026

Event Summary

[Company Name]	Nippon Shinyaku Co., Ltd.	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	FY2026/Q1 Earnings Call	
[Date]	August 6, 2026	
[Number of Speakers]	5	
	Toru Nakai	Representative Director, President
	Takanori Edamitsu	Managing Director, Business Management
	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 Q1 of FY2026.

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

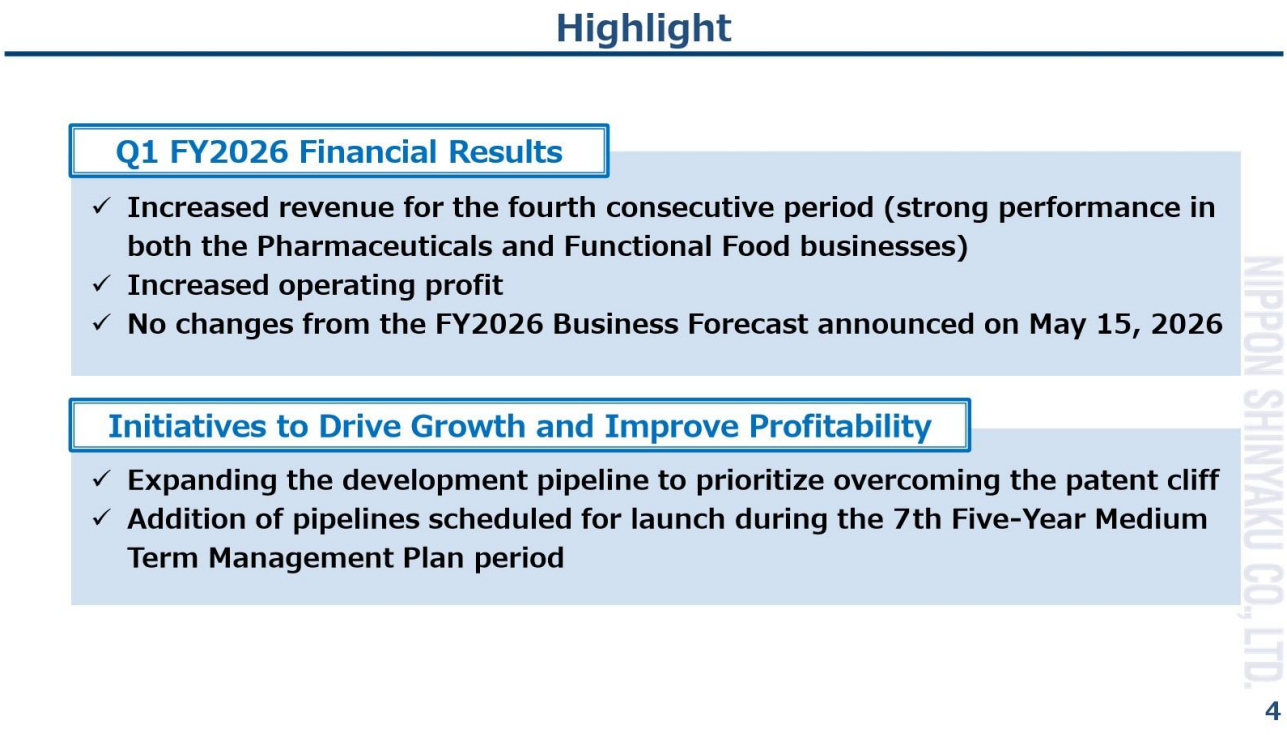
The content of this presentation will be available on our website as an on-demand video streaming and transcript, so please be aware of this when asking questions after the presentation.

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 schedule to participate in our financial results briefing for Q1 of FY2026. I deeply appreciate it.

Today, I will discuss our financial results of Q1 of FY2026, as well as updates on deramiocel.

After that, Mr. Kuwano, who is in charge of research and development, will explain the R&D pipeline and updates on Viltepso.



Then, I will explain the financial results of Q1 of FY2026.

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

In Q1 of FY2026, both the pharmaceuticals and functional food businesses grew their performance, marking the fourth consecutive period of revenue growth. Operating profit also increased. At this time, there are no changes to our business forecast for this fiscal year.

In addition, at today's briefing, we will also explain the measures we are taking to overcome Uptravi's patent cliff.

Q1 FY2026 Summary (consolidated)

- **As a result of strong performance in both the Pharmaceuticals and Functional Food businesses, revenue increased for the fourth consecutive period.**
- **Although various expenses increased, profits rose due to factors such as foreign exchange gains.**

(million yen)	Q1 FY2025		Q1 FY2026		YoY	
	actual	ratio	actual	ratio	change	%
Revenue	**39,546**	**100.0%**	**49,066**	**100.0%**	**+9,520**	**+24.1%**
(Pharmaceuticals)	(34,163)	(86.4%)	(43,256)	(88.2%)	(+9,092)	(+26.6%)
(Functional Food)	(5,382)	(13.6%)	(5,810)	(11.8%)	(+428)	(+8.0%)
Cost of sales	12,655	32.0%	17,726	36.1%	+5,070	+40.1%
SG&A expenses	9,995	25.3%	11,075	22.6%	+1,080	+10.8%
R&D expenses	6,189	15.7%	9,197	18.7%	+3,008	+48.6%
Other income	169	0.4%	1,364	2.8%	+1,194	+703.6%
(Foreign exchange gain)	-	-	(727)	(1.5%)	(+727)	-
Other expenses	794	1.9%	119	0.3%	-674	-85.0%
(Foreign exchange loss)	(645)	(1.6%)	-	-	(-645)	-
Operating profit	**10,081**	**25.5%**	**12,311**	**25.1%**	**+2,230**	**+22.1%**
Finance income	468	1.2%	689	1.4%	+220	+47.1%
Finance costs	46	0.1%	41	0.1%	-4	-10.1%
Profit before tax	**10,504**	**26.6%**	**12,959**	**26.4%**	**+2,455**	**+23.4%**
Income tax expense, etc.	2,248	5.7%	2,850	5.8%	+601	+26.8%
Profit attributable to owners of parent	**8,255**	**20.9%**	**10,109**	**20.6%**	**+1,853**	**+22.5%**

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5

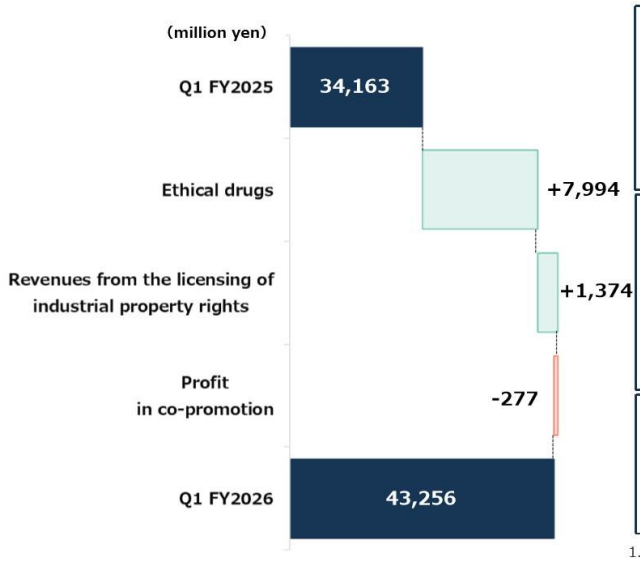
Let me explain in detail from here. Please move on to slide five.

As a summary of the results of this quarter, on a YoY basis, consolidated revenue increased by JPY9,520 million to JPY49,066 million, operating profit increased by JPY2,230 million to JPY12,311 million, and profit before tax increased by JPY2,455 million to JPY12,959 million.

Profit attributable to owners of parent increased by JPY1,853 million to JPY10,109 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 28,129 million yen (+7,994 million yen, +39.7%, YoY)

- ✓ Growth of Uptravi, Fintepla and other products
- ✓ Erleada[1], which is recognized in our product sales through a reverse co-promotion arrangement, also contributed to the segment revenue.

Revenues from the licensing of industrial property rights 12,885 million yen (+1,374 million yen, +11.9%, YoY)

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

Profit in co-promotion 2,240 million yen (-277 million yen, -11.0%, 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

Please move on to slide six.

In the pharmaceuticals business, despite the effects of the National Health Insurance drug price revisions and generic competition, domestic sales of Uptravi and royalty income from overseas sales of the same product expanded. Also, growth of new product lines such as Fintepla and Jaypirca was reported.

In addition, due to the contribution from Erleada, which has been recognized as revenue from our products since last October following a contract revision, consolidated revenue for the pharmaceuticals business increased by 26.6% YoY to JPY43,256 million.

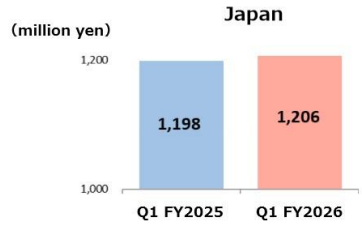
Sales Trends of Viltepso® (viltolarsen)

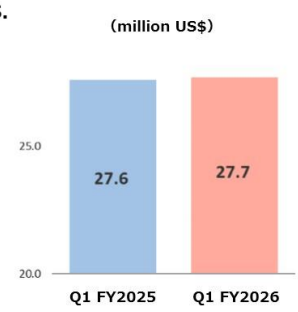
- **Expected U.S. sales growth due to new patient starts, increased dosing as treated patients gain weight, among other factors.**

(million yen)	Q1 FY2025 actual	Q1 FY2026 actual	YoY change	YoY %	FY2026 forecast	Notes on Q1 FY2026 results
Japan	1,198	1,206	+7	+0.6%	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	3,995	4,431	+435	+10.9%	17,500	✓ Insurance reauthorizations became stricter after launch of multiple DMD treatment options. ✓ Expected sales growth due to new patient starts, increased dosing as treated patients gain weight, among other factors.
(million US$)	(27.6)	(27.7)	(+0.1)	(+0.5%)	(116.6)	
Total	5,194	5,637	+443	+8.5%	22,300	

1. Central Social Insurance Medical Council

Exchange rates	Q1 FY2025 actual	Q1 FY2026 actual	FY2026 assumption
USDJPY	144.6	159.5	150.0





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7

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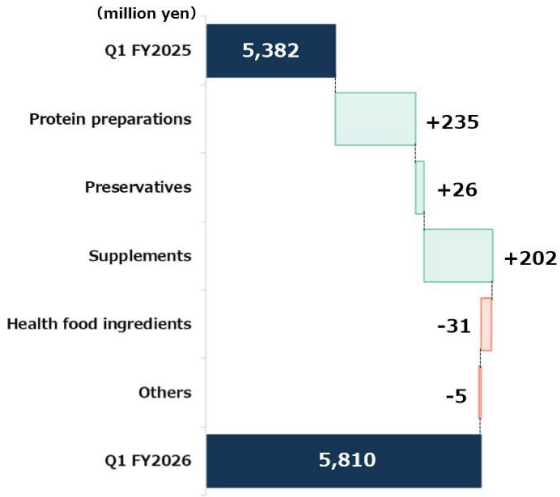
Here we show the sales of Viltepso, which is sold in Japan and the United States.

Sales results of this quarter increased slightly, with JPY1,206 million in Japan and JPY4,431 million in the United States.

Some patients has dropped out of the medication due to stricter insurance reauthorizations, after the launch of several high-cost DMD therapies on the market. However, we expect sales of this drug to continue growing by acquiring new cases and ensuring treatment continuity.

Segmental Review - Functional Food -

- **Increased segment revenue due to the launch of new products and strengthened sales activities**
- **Strong performance in core categories such as milk protein and sports supplements**



Protein preparations 3,554 million yen
(+235 million yen, +7.1%, YoY)
✓ Strong sales of protein powder

Preservatives 823 million yen
(+26 million yen, +3.3%, YoY)
✓ Sales of shelf-life extenders and glycine increased due to promotional efforts aimed at expanding usage among major customers.

Supplements 815 million yen
(+202 million yen, +33.1%, YoY)
✓ Sales of athletes category are growing due to the expansion of the protein market.
✓ The anti-aging care category is also performing well.

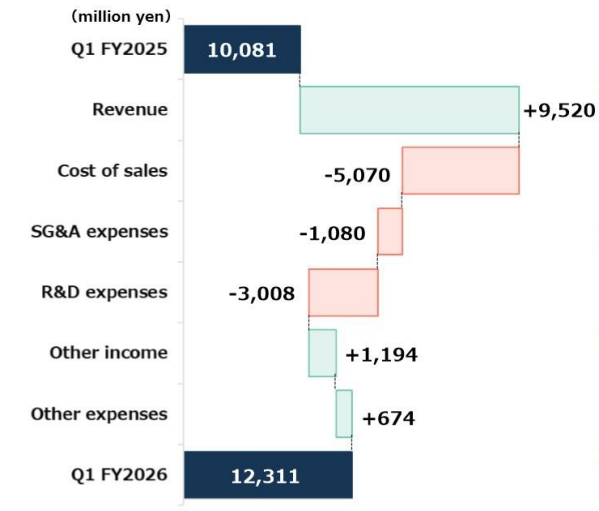
Health food ingredients 278 million yen
(-31 million yen, -10.1%, YoY)
✓ Sales to major customers have declined.

8

Please move on to slide eight. In the functional food business, sales of protein preparations and sports supplements increased, resulting in consolidated segment revenue of JPY5,810 million, up 8% YoY.

Operating Profit

- **Profit increased due to higher revenue and foreign exchange gains.**



Revenue 49,066 million yen
(+9,520 million yen, +24.1%, YoY)
✓ Growth of new product lines including Uptravi, Fintepla and Jaypirca
✓ Through reverse co-promotion, Erleada is included in revenue.
✓ Royalty revenue growth due to overseas sales of Uptravi

Cost of sales 17,726 million yen
(+5,070 million yen, +40.1%, YoY)
The ratio was 36.1%, worsened by 4.1 points YoY.
✓ Negative impact from changes in pharmaceutical product sales mix, NHI drug price revisions and other factors

SG&A expenses 11,075 million yen
(+1,080 million yen, +10.8%, YoY)
✓ Increase in the U.S. sales expenses of NS Pharma

R&D expenses 9,197 million yen
(+3,008 million yen, +48.6%, YoY)
✓ Increase in contract research expense, etc.
✓ Upfront Payment for the Option Agreement for EXG-7001

Other income 1,364 million yen
(+1,194 million yen, +703.6%, YoY)
✓ Increase in foreign exchange gains, etc.

9

Please move on to slide nine. Next, in terms of operating expenses, the cost of sales ratio worsened by 4.1 percentage points YoY to 36.1%, mainly due to the sales mix and the impact of NHI drug price revisions.

SG&A expenses increased by 10.8% YoY to JPY11,075 million, mainly due to an increase in sales expenses at the US subsidiary.

R&D expenses amounted to JPY9,197 million, up 48.6% YoY, mainly due to an increase in contract research expense and upfront payment.

As for other income, foreign exchange gains increased.

As a result, operating profit increased by 22.1% YoY to JPY12,311 million.

Business Forecast for FY2026 (consolidated)

(million yen)	FY2025 Q1 actual	FY2025 FY actual	FY2026 Q1 actual	FY2026 progress in 1H	FY2026 1H forecast	FY2026 FY forecast
Revenue	**39,546**	**170,771**	**49,066**	**51.6%**	**95,000**	**200,000**
(Pharmaceuticals)	(34,163)	(148,484)	(43,256)	(51.8%)	(83,500)	(176,500)
(Functional Food)	(5,382)	(22,287)	(5,810)	(50.5%)	(11,500)	(23,500)
Cost of sales	**12,655**	**57,460**	**17,726**		**33,800**	**73,000**
SG&A expenses	**9,995**	**43,565**	**11,075**		**23,500**	**47,500**
R&D expenses	**6,189**	**36,713**	**9,197**		**19,500**	**40,500**
Other income	**169**	**3,025**	**1,364**		**300**	**1,000**
Other expenses	**794**	**560**	**119**		**1,000**	**2,000**
Operating profit	**10,081**	**35,496**	**12,311**	**70.4%**	**17,500**	**38,000**
Finance income	**468**	**1,132**	**689**		**400**	**800**
Finance costs	**46**	**166**	**41**		**100**	**200**
Profit before tax	**10,504**	**36,462**	**12,959**	**72.8%**	**17,800**	**38,600**
Income tax expense, etc.	**2,248**	**6,741**	**2,850**		**3,800**	**8,300**
Profit attributable to owners of parent	**8,255**	**29,721**	**10,109**	**72.2%**	**14,000**	**30,300**

The sensitivity of the exchange rate after Q1 FY2026 is assumed to be an increase of approx. 420 million yen in revenue and approx. 360 million yen in operating profit for every 1 yen depreciation of the yen.

Foreign exchange rates (USDJPY)

Q1 FY2025 actual	Q1 FY2026 actual	FY2026 assumption
144.6	159.5	150.0

Please move on to slide 10.

Next, I will explain the business forecast for FY2026.

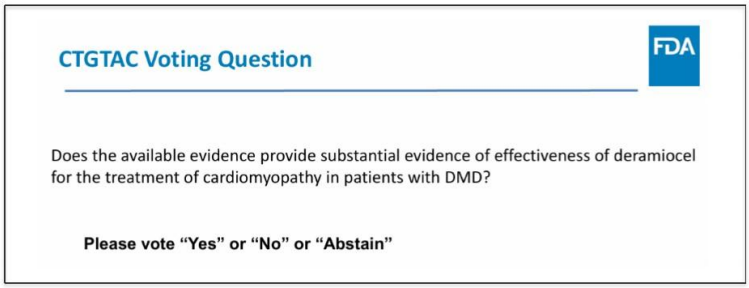
At this time, there are no changes to the full-year forecast announced in May, and we expect consolidated revenue to reach JPY200 billion.

As for operating expenses, cost of sales is expected to be JPY73,000 million, SG&A expenses to be JPY47,500 million, and R&D expenses to be JPY40,500 million.

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

CAP-1002 (deramiocel) : Regulatory Update

- **On July 29, 2026, the U.S. Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee met to discuss CAP-1002 (deramiocel).**
- **In response to the CTGTAC voting question, "Does the available evidence provide substantial evidence of effectiveness of deramiocel for the treatment of cardiomyopathy in patients with DMD?", the final vote by the 12 advisory committee members was 3 votes for "Yes," 9 votes for "No," and 0 abstentions.**



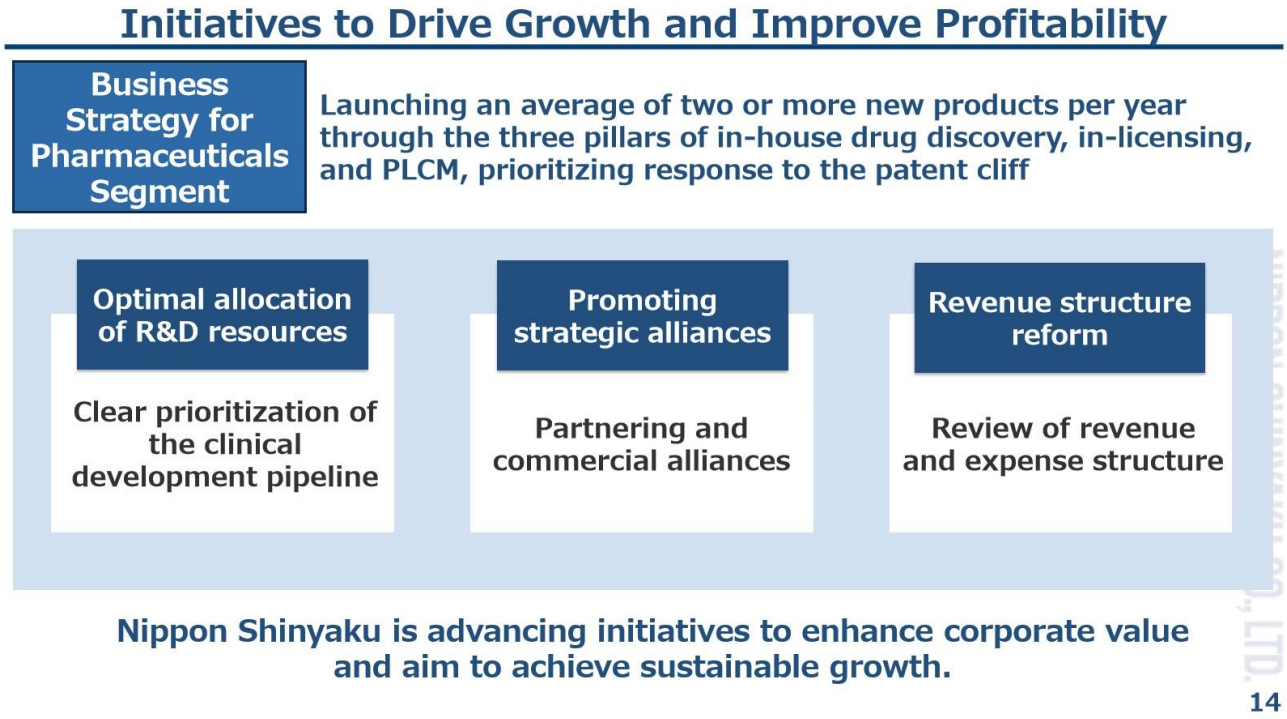
Source : The U.S. Food and Drug Administration
CTGTAC July 29, 2026 Meeting Announcement

12

Next, I will explain the update of deramiocel. Please move on to slide 12.

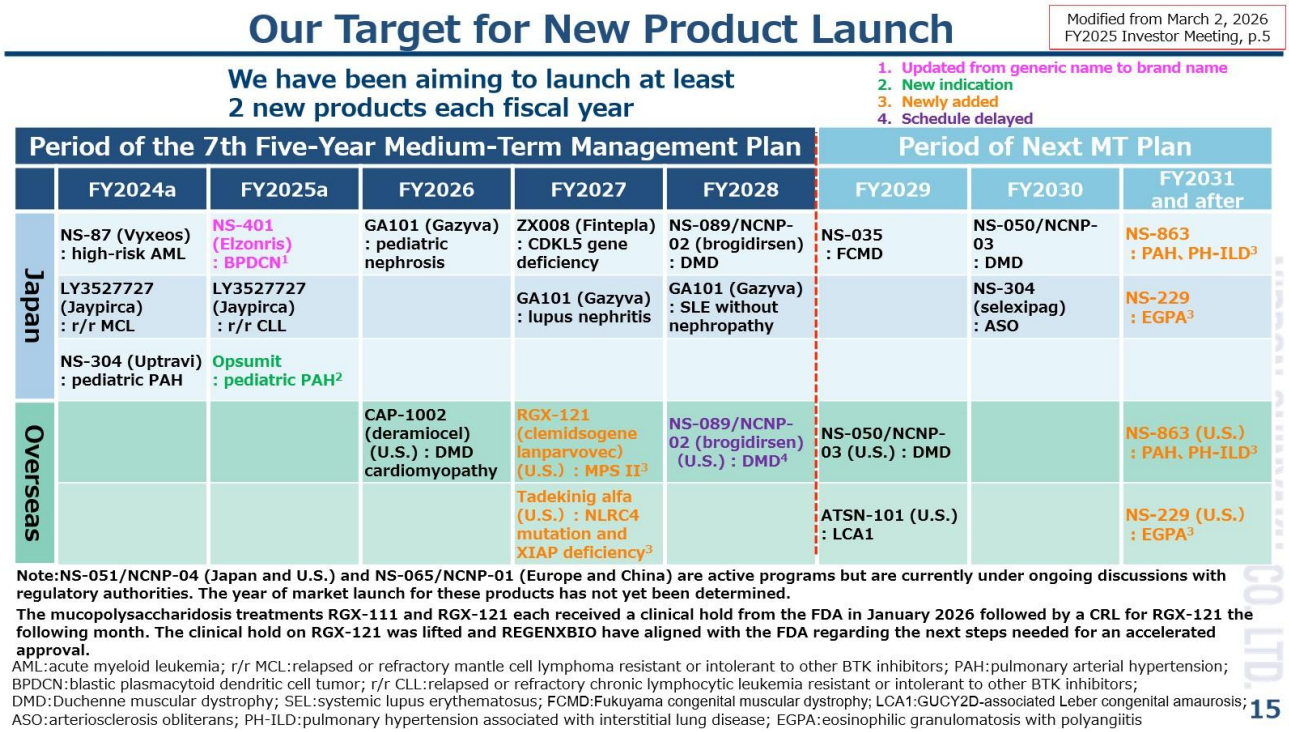
On July 29, an FDA Advisory Committee meeting was held regarding deramiocel, for which Capricor Therapeutics has filed an application. At that Advisory Committee meeting, in response to the voting question, "Does the available evidence provide substantial evidence of effectiveness of deramiocel for the treatment of cardiomyopathy in patients with DMD?", the final vote by the 12 Advisory Committee members was three votes for "Yes," nine votes for "No," and zero abstentions. The majority of the committee concluded that deramiocel's efficacy as a treatment for DMD cardiomyopathy had not been sufficiently demonstrated.

While there is some uncertainty surrounding deramiocel, our growth strategy is not limited to that alone. Regardless of the business environment, we will steadily advance our initiatives to enhance corporate value and strive to achieve sustainable growth.



In the following section, I will explain our initiatives to drive growth and improve profitability. Please move on to slide 14.

Our company will make addressing Uptravi's patent cliff our top priority and will further advance our efforts to drive growth and improve profitability through strategies such as optimizing the allocation of R&D resources by clarifying development priorities within our pipeline, promoting strategic alliances—including in-licensing and out-licensing and sales partnerships—and reforming our revenue structure by reviewing revenue and expenses.



Our Target for New Product Launch

Modified from March 2, 2026
FY2025 Investor Meeting, p.5

We have been aiming to launch at least 2 new products each fiscal year

1. Updated from generic name to brand name
2. New indication
3. Newly added
4. Schedule delayed

	Period of the 7th Five-Year Medium-Term Management Plan					Period of Next MT Plan		
	FY2024a	FY2025a	FY2026	FY2027	FY2028	FY2029	FY2030	FY2031 and after
Japan	NS-87 (Vyxeos) : high-risk AML	NS-401 (Elzonris) : BPDCN[1]	GA101 (Gazyva) : pediatric nephrosis	ZX008 (Fintepla) : CDKL5 gene deficiency	NS-089/NCNP-02 (brogidirsen) : DMD	NS-035 : FCMD	NS-050/NCNP-03 : DMD	NS-863 : PAH、PH-ILD[3]
	LY3527727 (Jaypirca) : r/r MCL	LY3527727 (Jaypirca) : r/r CLL		GA101 (Gazyva) : lupus nephritis	GA101 (Gazyva) : SLE without nephropathy		NS-304 (selexipag) : ASO	NS-229 : EGPA[3]
	NS-304 (Uptravi) : pediatric PAH	Opsumit : pediatric PAH[2]						
Overseas			CAP-1002 (deramiocel) (U.S.) : DMD cardiomyopathy	RGX-121 (clemidsogene lanparvovec) (U.S.) : MPS II[3]	NS-089/NCNP-02 (brogidirsen) (U.S.) : DMD[4]	NS-050/NCNP-03 (U.S.) : DMD		NS-863 (U.S.) : PAH、PH-ILD[3]
				Tadekinig alfa (U.S.) : NLRC4 mutation and XIAP deficiency[3]		ATSN-101 (U.S.) : LCA1		NS-229 (U.S.) : EGPA[3]

Note:NS-051/NCNP-04 (Japan and U.S.) and NS-065/NCNP-01 (Europe and China) are active programs but are currently under ongoing discussions with regulatory authorities. The year of market launch for these products has not yet been determined.

The mucopolysaccharidosis treatments RGX-111 and RGX-121 each received a clinical hold from the FDA in January 2026 followed by a CRL for RGX-121 the following month. The clinical hold on RGX-121 was lifted and REGENXBIO have aligned with the FDA regarding the next steps needed for an accelerated approval.

AML:acute myeloid leukemia; r/r MCL:relapsed or refractory mantle cell lymphoma resistant or intolerant to other BTK inhibitors; PAH:pulmonary arterial hypertension; BPDCN:blastic plasmacytoid dendritic cell tumor; r/r CLL:relapsed or refractory chronic lymphocytic leukemia resistant or intolerant to other BTK inhibitors; DMD:Duchenne muscular dystrophy; SEL:systemic lupus erythematosus; FCMD:Fukuyama congenital muscular dystrophy; LCA1:GUCY2D-associated Leber congenital amaurosis; ASO:arteriosclerosis obliterans; PH-ILD:pulmonary hypertension associated with interstitial lung disease; EGPA:eosinophilic granulomatosis with polyangiitis

15

Please move on to slide 15.

This slide shows the plan for new product launch by fiscal year.

We have added RGX-121 and Tadekinig alfa to the list of products scheduled for launch by FY2028, during the period covered by the 7th Five-Year Medium-Term Management Plan.

We will also continue to advance the development of products such as NS-863 and NS-229, which we expect to be key drivers of our growth over the medium to long term, so that we can bring them to market as soon as possible.

Going forward, through in-house drug discovery, in-licensing, and product lifecycle management, we will strive to achieve sustainable growth by aiming to launch an average of at least two new products and secure at least one in-licensed product annually. That is all from me.

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

R&D Updates (1/2)

For updates from FY2025 financial results announcement on May 15, 2026, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
Launch	NS-304 (selexipag)	Uptravi	Uptravi Tablets 0.8 mg	May 2026
Launch	NS-401 (tagraxofusp)	Elzonris	blastic plasmacytoid dendritic cell neoplasm (BPDCN)	March 2026
P3	NS-065/NCNP-01 (viltolarsen)	Viltepso	CSR for Study 302 (P3 extension study) has been submitted to the FDA.	July 2026 (U.S.)
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)	–	REGENXBIO have aligned with the FDA regarding the next steps needed for an accelerated approval.	June 2026 (U.S.)
			The clinical hold placed by the FDA on RGX-121 in January 2026 has been lifted.	Disclosed in May 2026 (U.S.)
Filed	CAP-1002 (deramiocel)	–	The FDA Cellular, Tissue, and Gene Therapies Advisory Committee was held.	July 2026 (U.S.)
			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
E-labaling revision			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
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
	NS-025	–	urological disease	July 2026
			xerostomia (dry mouth) associated with Sjögren's disease	July 2026
Start of P1	NS-245	–	treatment for inflammatory diseases	December 2025

17

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 for FY2025. Please move on to slide 17.

We have recently launched a new 0.8 mg tablet of Uptravi. This is expected to improve patients' medication adherence.

With regard to Viltepso, we have submitted the CSR for the global Phase III extension study to the FDA. I will explain the developments regarding Viltepso in more detail later.

Regarding RGX-121, we held a Type-A meeting and reached an agreement with the FDA on the process for resubmitting the BLA.

As for deramiocel, as Mr. Nakai explained earlier, an FDA Advisory Committee meeting was held on July 29. The PDUFA date has been set for August 22.

With regard to NS-025, which we are developing for the treatment of urological diseases, we have entered into a license agreement with Aquelys Therapeutics, a US biotechnology company, granting it exclusive worldwide rights to develop, manufacture, and market the product, with the exception of rights in Japan for certain indications. Going forward, the company will proceed with clinical trials targeting xerostomia associated with Sjögren's disease.

R&D Updates (2/2)

For updates from FY2025 financial results announcement on May 15, 2026, see highlighted text in red.

Update	Code No. (Generic name)	Brand name	Indications and topics	Schedule
Exercise of option rights (AB2 BIO Ltd.)	Tadekinig alfa	–	U.S. commercialization for the treatment for monogenic IL-18 driven hyperinflammatory syndrome in patients with NLRC4 and XIAP mutations	July 2026 (U.S.)
Agreement of option rights (Elixirgen Therapeutics, Inc.)	EXG-7001	–	Duchenne muscular dystrophy (DMD) exclusive worldwide rights to development and commercialization	June 2026
Sponsored research agreement (Boston Children's Hospital)	–	–	for developing innovative therapeutic drugs in the field of neurology	June 2026 (U.S.)
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
Orphan Drug Designation	NS-035	–	Fukuyama congenital muscular dystrophy (FCMD)	June 2026
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

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18

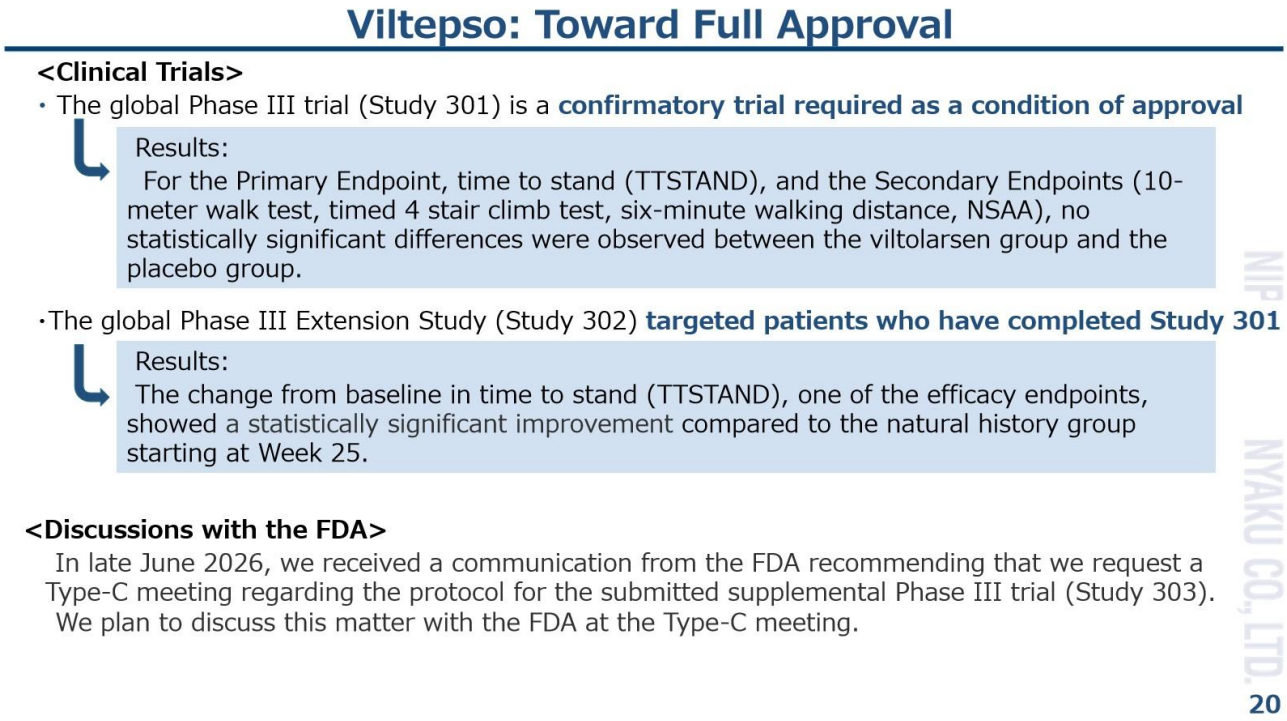
Please move on to slide 18.

Regarding Tadekinig alfa, which we are developing in Europe and the United States for the prospective indications of NLRC4 mutation and XIAP deficiency under an option agreement signed with AB2 BIO in January 2025, we have exercised our option rights to acquire the exclusive rights to commercialize the product in the United States.

Next, regarding EXG-7001, which Elixirgen Therapeutics is developing with DMD as a potential indication, we have entered into an option agreement that allows us to acquire exclusive worldwide rights to its development and commercialization.

In addition, in June, we entered into a joint research agreement with Boston Children’s Hospital with the aim of conducting research and development on innovative treatments for neurological conditions such as epilepsy.

Also, NS-035, a treatment for Fukuyama congenital muscular dystrophy, has been designated as an orphan drug by the Ministry of Health, Labour and Welfare.



Next, I will explain the update of Viltepso.

In May 2024, we announced the results of Study 301, a trial required as a condition for approval, which showed no statistically significant difference in the primary endpoint compared to the placebo group.

We conducted Study 302, a 96-week extension study, in patients who had completed Study 301. The results of this study showed a statistically significant improvement in one of the endpoints assessing motor function compared to the natural history group.

We believe this result is clinically significant, as patients treated with Viltepso maintained their motor function for three years, including the duration of Study 301.

In addition, regarding Study 303—the supplemental Phase III trial for which we had submitted an inquiry to the FDA—we received notification from the FDA in late June recommending that a Type-C meeting be held. In light of this, we intend to hold discussions with the FDA at the Type-C meeting.

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.

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

Yamaguchi [Q]: Hello, I am Yamaguchi from Citigroup Global Markets. My first question is a bit of a sensitive one, but given the various issues surrounding deramiocel, including the fact that the Advisory Committee raised some doubts about the product's approval prospects and that there is still an ongoing dispute between your company and Capricor, I would like to ask, if possible, whether there have been any developments regarding the new business model that is the subject of this dispute.

Assuming that approval isn't granted in the first place, I imagine Capricor will continue with various things afterward; but from your company's perspective, while it's included in this fiscal year's earnings forecast, is there a possibility that you might decide to cut your losses at some point and start over from scratch? This might sound like a bit of a hypothetical scenario, but could you please comment on that point first?

Nakai [A]: Thank you for your question. First, regarding the status of the lawsuit with Capricor, a hearing date has been set for August 10, and we are awaiting to see if the court will issue a ruling or make any comments at the hearing. To answer your question, we are just waiting to see how it plays out.

Regarding the future approval of deramiocel, in our current financial results, we have included deramiocel sales in our projections for FY2026 as of now.

Since the FDA has not yet issued its final decision, we would prefer to refrain from commenting on how we plan to proceed with deramiocel at this time.

Yamaguchi [Q]: Thank you. In addition, I understand you've reached the Type-C meeting for Study 303 for Viltepso. In terms of the schedule, could you please provide a timeline indicating when you plan to have the Type-C meeting and how soon after that we can expect to see the next development?

Kuwano [A]: As I mentioned earlier, the results of Study 302 have just come in. Taking these results into account, even though we've already submitted the protocol, we're having internal discussions about whether we should revise it slightly. We plan to hold the Type-C meeting once those discussions have progressed further.

Given that, the timing is still undecided at this point.

Yamaguchi [Q]: Sorry, that was a misunderstanding on my part. In other words, have the data from Study 302 just recently become available?

Kuwano [A]: Yes.

Yamaguchi [Q]: You mentioned that it's more effective than the natural course of the disease.

Kuwano [A]: That's exactly right, so I believe this result will be extremely helpful as we conduct Study 303, and I also believe it supports the approach we plan to take in Study 303 going forward. So, we would like to give this matter careful consideration, and we intend to conduct the supplemental trial using the optimal protocol.

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

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

Tanaka [Q]: I am Tanaka from Mizuho Securities. Following up on the previous question, since the recent Study 302 showed a statistically significant improvement compared to the natural history group in terms of time to stand, just hearing that makes me wonder if the other endpoints weren't quite as good. So, is it correct to say that you are considering switching the endpoint to time to stand since it's quite difficult to demonstrate a difference in the primary endpoint, or NSAA, in Study 303 in such a short time frame?

Kuwano [A]: Thank you for pointing that out. We are currently reevaluating the situation, including whether or not we should make changes in that regard.

Tanaka [Q]: Thank you. Second, we received an update on the launch schedule for the new drugs. Among those, RGX-121 and Tadekinig alfa are scheduled for FY2027. Regarding RGX-121, if the BLA had been resubmitted by the end of September, I think there was a possibility that approval could have been granted earlier within two months. Does the fact that it's listed for FY2027 mean this is a conservative estimate?

Nakai [A]: Well, I've heard that the review period can be either two months or six months after we resubmit a BLA. So, if it takes six months, I think it will definitely be released in FY2027. In the best-case scenario, if we resubmit the BLA in September and the review takes two months, approval would be granted in H2 of this fiscal year, or at the end of the year, and the product could then be launched. Therefore, in the very best-case scenario, a launch within this fiscal year is possible. However, as Mr. Tanaka pointed out, this is a conservative estimate.

Tanaka [Q]: Also, regarding Tadekinig alfa, which is listed below that, I heard that you're aiming to get it done sometime in early 2028, or around January through March 2028. Is that about right?

Nakai [A]: Well, we're planning to aim for approval and launch toward the end of FY2027, specifically in January through March 2028.

Tanaka [Q]: I understand. Last, regarding these Q1 financial results, sales performance, particularly product sales excluding items such as royalty revenue in the pharmaceuticals have been strong. Mr. Edamitsu, could you please explain whether there were any factors other than the products already disclosed that contributed to this?

Edamitsu [A]: Regarding your question about whether there were any developments in the products other than items not specifically disclosed, there is nothing in particular to report. As for our results for April through June, we have been making strong progress in line with our plans and even exceeding them.

Tanaka [Q]: For example, looking at Q1 of the last fiscal year, exports of Viltepso to countries where it isn't approved were quite low, although of course we can't know for sure since the quarterly report wasn't released. I am wondering if that has returned to normal, or if there might be some other reason for it. Is that an odd assumption?

Edamitsu [A]: You are correct on that point. Exports to unapproved countries are also increasing significantly YoY.

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

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

Wakao [Q]: I am Wakao from JPMorgan. I have a few questions. First, let me ask about CAP-1002.

Upon reviewing the contents of this AdCom meeting, I see that the FDA documents also point out that the analytical methods underwent various changes along the way, eventually evolving to SAP 3.0, although the methods were not originally agreed upon with the FDA. Were you already aware of this issue? Also, if approval is not granted, what scenarios do you anticipate? This overlaps a bit with Mr. Yamaguchi's question, but I think it's very important, so could you please explain?

Nakai [A]: I took that to mean you were asking how much information we had obtained. Since we are not the primary developer, of course, we did not have all the clinical trial data. The situation was such that we requested only the information necessary for sales preparation from Capricor and received that information from them.

As for what information we had and what information we did not have, since this matter is currently related to the lawsuit, I must refrain from providing a specific answer at this time.

Another question concerns the impact on the performance of this fiscal year and beyond, in the event that the application is not approved. However, even if it is not approved and we exclude deramiocel's sales and expenses from our forecast, we do not believe this will have a significant impact on this fiscal year's operating profit. Furthermore, regarding our forecast in the event that such a situation—that is, non-approval—were to occur, we plan to review it carefully and provide an explanation at our interim results briefing in November.

Also, regarding the medium- to long-term impact, in the event of such a rejection, we will work to improve profitability through these three initiatives, including optimizing the allocation of R&D resources by clarifying development priorities for our pipeline, as outlined in the slide I presented earlier.

Therefore, regarding our medium- to long-term plans, we intend to present a new growth strategy that reflects these initiatives.

Wakao [Q]: As a follow-up, if the other party receives a Complete Response Letter and requests additional trials—that is, if they request further studies in the future—should we assume that your company will participate in those studies, or should we expect that if approval is not granted, the partnership will be dissolved? Or is there a possibility that, depending on the circumstances, your company might participate in the additional trials? How about that point?

Nakai [A]: Regarding that point as well, I'm afraid we are not yet in a position to provide an answer at this time. I would appreciate your understanding.

Wakao [Q]: I understand. Also, regarding CAP-1002, I believe there are intangible assets involved. If your company were to terminate the partnership, I think there might be a possibility of an impairment loss. Could you please elaborate on this point?

Edamitsu [A]: This is just a hypothetical scenario, but since we do recognize intangible assets on our balance sheet, there is a possibility of impairment should development be discontinued or a partnership be dissolved.

Wakao [Q]: Could you tell me the amount of the intangible assets?

Edamitsu [A]: That information is confidential.

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

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

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. I understood from your remarks that, should it become clear that deramiocel is unlikely to generate revenue, you intend to pursue the initiatives outlined on page 14.

Setting aside the specific figures, as far as the general direction is concerned, I understand that you intend to curb R&D and SG&A expenses, and that this represents a shift toward greater restraint compared to the medium-term plan originally announced about two years ago.

On the other hand, regarding growth investments, which you referred to at the time as dynamic allocation, is it correct to understand that your approach will remain the same, or that you are actually planning to increase them?

Also, given that operating cash flow may decline to some extent compared to projections, could you please share your thoughts on shareholder returns?

Nakai [A]: With regard to growth investments, we will focus more on in-licensing of late-stage development products, as well as alliances and sales partnerships, that can contribute to profits in the short term. That is where we plan to invest funds as part of our growth strategy, and it is the content we have outlined under the strategic alliances in the center of the slide.

Regarding shareholder returns, our basic approach is to make decisions not only based on performance in a single fiscal year, but also by taking into account our medium- to long-term profitability, financial foundation, and the balance with growth investments. We currently have no plans to change the shareholder return policy we have presented to you, and our current policy is based on our desire to pay stable dividends while taking DOE into consideration.

Hashiguchi [Q]: Thank you. It's not that there will be no changes simply because the FDA hasn't made a decision yet; rather, it means that even if approval is not granted, there are currently no plans to immediately change the shareholder return policy.

Nakai [A]: Yes. We intend to move forward with the intention of maintaining our shareholder return policy unchanged, based on the initiatives outlined on page 14 of these slides.

Hashiguchi [Q]: Thank you. Last, I have a question about Viltepso. When the FDA recommended a Type-C meeting, did you receive any additional comments or opinions? Also, if that were not the case, how did your company interpret this?

Since it was recommended that a Type-C meeting be held before submitting the Study 302 report, it seems this recommendation was not based on a review of Study 302. Given these recent developments from the FDA, should we interpret this as meaning you are beginning to gain the FDA's understanding of the overall approach—namely, proceeding with Study 303 while maintaining the accelerated approval status your company originally intended—or is it still too early to say based on this information alone? What are your thoughts on this?

Kuwano [A]: As for whether they explicitly stated anything additional, since they are the regulatory authorities, they did not say so explicitly. However, we had originally proposed conducting a new Phase III trial while keeping this product on the market.

They said it was still too early, and we waited for over a year, but this time, they indicated that we had finally reached the stage where concrete discussions can take place, and that is why they proposed this Type-C meeting. When looking at the situation as a whole, we believe that the upcoming discussions will likely be conducted with keeping our products on the market in mind. That is all.

Hashiguchi [M]: Thank you. 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. My first question is regarding the initiatives to drive growth and improve profitability—specifically, the optimal allocation of R&D resources and review of revenue and expense structure. I believe this refers to reviewing costs, and I'd like to ask about the level of commitment, or rather, how quickly these measures will be implemented.

Of course, the question is how soon you'll proceed once you know that deramiocel won't be approved. Looking at the P&L, I think you're heading into a rather challenging period starting next fiscal year, partly due to the LOE for Uptravi. However, from a balance sheet perspective, since your company has built up a cash reserve and has no debt, I don't think there's any real issue with the Company's continued operations, even if you don't rush to cut costs to that extent.

Given the current situation, will you implement cost cuts thoroughly and promptly and generate profits? Or will you focus on in-licensing and invest in future growth? Could you give me an idea of how quickly cost-cutting measures are typically implemented in this area?

Nakai [A]: The patent cliff will actually begin in FY2027. Therefore, as it stands, our profits are likely to decline significantly, and we intend to implement cost controls in FY2027 and FY2028 to ensure a solid profit position.

So, to answer your question, we intend to move forward with a sense of urgency, aiming to pursue profits effectively from a relatively early stage.

Yamakita [Q]: I understand. Thank you very much. I have one more question about the other category in product sales. I believe this was also mentioned in Mr. Tanaka's question earlier. Based on my calculations, it looks like this has increased by just under JPY3 billion YoY. Of that total, Jaypirca accounts for JPY600 million to JPY700 million, and I believe the rest comes from product sales in unapproved regions. Is there a specific factor that accelerated these sales [inaudible], or was it simply a slight boost due to exchange rates? Could you give me a few hints about this?

Edamitsu [A]: Rather than the impact of exchange rates, as I mentioned earlier, the recovery in sales of unapproved drugs is a very significant factor. That is all.

Yamakita [M]: So, you're saying that sales of unapproved drugs are being increased not just in foreign currency terms, but also in local currency terms.

Thank you very much. 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. I would like to ask about NS Pharma. I would like to know the current status of the sales structure in the US and what plans NS Pharma has for its staff in the event that deramiocel is not approved.

Nakai [A]: We are almost ready to begin sales. In the event of a rejection, given that the schedules for products such as Tadekinig alfa, which we discussed today, and RGX-121 are becoming clearer, I believe we will establish a sales structure tailored to those products in the US market and the resources required for them.

Therefore, if there is an excess for these two products, I believe we will have to cut back. Also, as I mentioned earlier, we are focusing on the initiatives I introduced**:** pipeline development and strategic alliances. If we can secure a licensed-in product that is likely to sell quickly in the US market, we will handle it with the optimal number of staff within NS Pharma's sales organization.

Therefore, we will certainly consider the option of reducing to move forward with the business in the US.

Wada [Q]: Thank you. Looking at the slide you just showed us, with regard to in-licensing, I fully understand and agree that it makes sense to replenish your pipeline with products in later stages of development. However, as products like NS-025 are now being licensed out, might the stance for out-licensing change?

Nakai [A]: To reiterate, based on the amount of R&D resources we can realistically allocate and our overall management resources, we intend to clearly define which projects to prioritize, which products to develop in-house, and which products require partnerships with other companies. Please understand that for products we decide not to develop in-house, we will proactively outsource them to other companies.

Wada [Q]: Finally, regarding the R&D section, EXG-7001, for which you have signed an option agreement with Elixirgen, is a full-length messenger RNA therapeutic, I believe, for dystrophin. Could you please tell me how I should identify the events that would trigger the exercise of this option, and what you see as the technical challenges or hurdles that need to be overcome before it receives approval?

Kuwano [A]: As for the trigger, we're currently continuing to conduct some basic research on that, and we'd like to make a decision as appropriate based on the results of that research.

In terms of the technical aspects, while I think there are still some technical challenges to achieving systemic expression of full-length dystrophin as expected, or rather, in an ideal manner, even at this stage, I believe it is feasible, provided that the experimental results are favorable. However, we would like to continue exploring ways to further expand this research.

Wada [M]: 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. I have two questions. The first question is about the additional trial for Viltepso, discussions with the FDA, and so on.

I think for your competitor, [inaudible] has already been decided, and they were able to file their application even though they didn't meet the primary endpoint in the exon-skipping 45 and 53 clinical trials. I think this is also part of the broader context, but going forward, at the Type-C meeting, is it possible that your company might combine the real-world data from 301 and 302 and, rather than proceeding to Phase III, use this to seek NDA or full approval? Is that a plausible scenario? Since your competitor has successfully filed, I am wondering why you are going through an extra Phase III trial. If possible, could you please explain this? This is my first question.

Kuwano [A]: We've certainly been considering exactly what you're saying. In fact, as we're currently seeking final approval, we don't fully know what the exact requirements for full approval will be yet, so we would like to thoroughly discuss those points at the Type-C meeting. Taking all of that into account, we would like to explore whether the ideas you mentioned can be realized.

Kawamura [Q]: I understand. Thank you very much. Following the Type-C meeting, is it safe to assume that we'll receive an update around the time of the next financial results briefing?

Kuwano [A]: As I mentioned earlier, the schedule for the Type-C meeting hasn't been finalized yet, so I suspect we might not make it in time for the next briefing. However, we intend to move forward with discussions as quickly as possible and work toward resolving this matter.

Kawamura [Q]: This is going to be held soon, right? I think there were some cases in the past where events didn't take place as planned or you didn't receive a response. Since you've already received a recommendation from them, it's safe to assume the meeting will be held soon, right?

Kuwano [A]: We have absolutely no intention of dragging this out. As I mentioned earlier, we are currently reviewing the protocol, and once we have a clearer idea of that protocol, we intend to take concrete steps toward actual consultations.

Kawamura [Q]: I understand. Thank you very much.

Second, I would like to confirm regarding Uptravi's patent, including whether generics will be available and [inaudible].

Basically, I think the LOE is in April 2027, but could we have some hope that it might be extended a bit due to plasma-related patents or something like that? Also, is it correct to understand that, even after the patent expires, you will still receive royalties as long as the other party continues to sell the product?

Nakai [A]: Since generics are actually scheduled to enter the market in April 2027 or later, I would like you to understand that the existence of plasma-derived product patents does not mean that generics will not be introduced.

In the agreement with Johnson & Johnson, the royalty rate does not change simply because generic versions enter the market. Rather, the agreement stipulates that we will continue to receive royalties at a fixed rate, or a certain percentage of sales, even if sales themselves decline.

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

Inoue [M]: Now, Mr. Lee from Morgan Stanley MUFG Securities, please ask your question.

Lee [Q]: I am Lee from Morgan Stanley MUFG Securities. I know this is a bit of a what-if scenario, and I'm really sorry to bring this up, but regarding deramiocel, could I just follow up one more time?

Regarding what Mr. Yamakita mentioned earlier about how seriously you plan to pursue cost management, assuming the result turns out to be somewhat disappointing, would it be correct to assume that revenue will drop sharply next fiscal year? I understand that deramiocel accounts for a significant portion of your company's revenue in the coming fiscal year and beyond.

Or which side do you lean toward: "I won't let that happen, and I'll manage costs properly," or "It'll drop next fiscal year, but not by that much"? Let me confirm this point.

Nakai [A]: I'm not quite sure if Mr. Lee and we are on the same page about how much the figure will drop. We aim to enter FY2027 and FY2028 in a position to secure a certain level of profitability even in the face of the patent cliff, by enforcing rigorous cost controls with no sacred cows.

We may have another opportunity to provide more details about this in the future, so we hope you'll wait for that announcement.

Lee [Q]: Thank you. Regarding what was just discussed, I was wondering if this might be hinting at a revision to the medium-term plan. Should I assume that the current medium-term plan will indeed require some revision?

Nakai [A]: Taking that into account, based on the initiatives I outlined earlier on page 14, I would like to present once again our growth strategy outlining how Nippon Shinyaku will evolve as a company.

Lee [Q]: Thank you. Last, I would like to ask about new drugs. Regarding Viltepso, your competitor has filed an application without additional trials, and I believe Mr. Kawamura also asked about that possibility. On the

other hand, considering approvals in Europe and China, I think you should conduct another new trial. Is that the right approach? What do you think?

Kuwano [A]: As you pointed out, obtaining approvals in Europe and China requires a successful Phase III trial, so I believe that conducting the Phase III trial we are currently planning is a natural extension of that direction.

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

Inoue [M]: Mr. Tanaka from Mizuho Securities, would you like to ask a second-round question?

Tanaka [Q]: Thank you for accepting my second-round question. I think NS-089 has been postponed only for one year. I was told that they're expected to be released within this fiscal year, although the Phase II top-line results has been running a bit behind schedule. Could you first tell me how much of a delay you are expecting?

Kuwano [A]: This trial consists of part one and part two, and actually part one has faced continuous delays for more than a year. I had been thinking that we would need to adjust the schedule at some point, so I decided to make the announcement at this time. Roughly speaking, it is running a few months behind schedule. At first glance, this table is organized by year, so you might think we are facing a delay of one year, but please consider it to be a period of several months.

We are currently conducting part two, and since things are going very smoothly so far, we intend to proceed in a way that prevents any further delays in the schedule. That is all.

Tanaka [Q]: Basically, you haven't changed your view that, as other companies have done, you can obtain accelerated approval based on dystrophin expression, right?

Kuwano [A]: That is right. We are currently proceeding on that basis.

Tanaka [Q]: Last, I was told that the contract with Boston Children's Hospital covers epilepsy as the target disease, so I just wanted to confirm if that's correct. Even though you're conducting research on Fintepla, I'm wondering if your company has actually conducted any research that addresses epilepsy. Could you please explain the background behind your decision to select this particular study?

Kuwano [A]: Our company focuses on intractable and rare diseases, and while we are concentrating our efforts on several specific areas within that field, one of them is the neuromuscular field. This applies to Viltepso, as well as to Fintepla, which you mentioned.

We consider epilepsy to be a very important and promising field for the future. For that reason, we believe this disease would be an ideal subject for collaborative research with one of the world's leading institutions. That is why we are moving forward with this project. That is all.

Tanaka [Q]: Is there any development? It's been about three years now, hasn't it?

Kuwano [A]: Well, a few years, I guess.

Tanaka [Q]: Does it last for several years? In the meantime, do you already have a specific idea of potential targets or compounds, or are you starting completely from scratch? Please let me know.

Kuwano [A]: I can't go into too much detail, but we select our partners with an eye toward whether the collaboration will actually lead to drug discovery, so I would like you to understand that we're conducting research with organizations where we have a reasonable expectation that this might happen.

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

Inoue [M]: I think you may have many questions, but due to time constraints, I would like to make the next question the last one from the analysts and institutional investors. Mr. Mizuno from Tokio Marine Asset Management, please ask your question.

Mizuno [Q]: Regarding AB2 BIO's drug for which the option was exercised, I've been reviewing various documents and looking at AB2 BIO's website, but I'm still not quite sure how frequently patients with this condition are actually seen. I assume it's a rare disease, and I'd like to know just how rare it is.

Also, it seems that AB2 BIO is currently conducting clinical trials for this drug for another indication as well. Will your company be involved in those trials going forward, or does the option that was exercised this time apply strictly to this indication?

Nakai [A]: Since this is a very rare disease, as a rough estimate of the number of patients with NLRC4 mutation, the prevalence is approximately 1.7 cases per 1 million people. Based on that, the estimated number of patients in the United States is about 600.

On the other hand, XIAP deficiency has a prevalence of 0.5 per million people. The estimated number of patients in the United States is roughly 200, bringing the total estimated number of patients to about 800. The key activity required for Tadekinig alfa is to ensure that these patients receive an accurate diagnosis of the disease and are subsequently able to begin treatment.

As for other indications, I have heard that AB2 BIO conducted a Phase II clinical trial overseas for adult-onset Still's disease. However, since we do not currently hold the right to that disease, I believe there is a possibility of forming a partnership in that area as our collaboration progresses.

Mizuno [Q]: Thank you. Just to add, the AB2 BIO materials state that the survival period after diagnosis for this disease is extremely short—on the order of a few months. So, I'm wondering how much this trial might extend that survival period, and if it does extend it, whether the number of patients might increase beyond 600 as survival rates improve. What do you think?

Nakai [M]: Do you know about that, secretariat?

Beppu [A]: I am Beppu from the R&D Planning and Administration Division in the secretariat. Regarding your question about whether this drug might extend survival and lead to an increase in the number of patients, this is a disease with few patients, and the number of cases in which the drug has been administered is still not very high. Therefore, we have not yet obtained evidence to determine whether this leads to an extension of survival.

However, since its effectiveness as a biomarker has already been demonstrated, I believe there is a possibility that this could happen once the drug is approved and put into use.

The time to relapse during the treatment period has been measured in clinical trials, and since there is a trend toward a longer time to relapse, we believe there is a possibility that this could lead to prolonged survival. That is all.

Mizuno [M]: Since the copyright likely belongs to AB2 BIO, I understand that your company cannot disclose the data without authorization. However, I would appreciate it if you could share as much of the clinical trial data, including the data that led to this approval application, as possible, once it reaches a stage where disclosure is permitted. Thank you.

Inoue [M]: We will now take questions from the press. When asking questions, please state the name of the company and your name before speaking.

Ms. Abe from the Nikkan Kogyo Shimbun, please ask your question.

Abe [Q]: I am Abe from the Nikkan Kogyo Shimbun. I have two questions. One of them concerns costs, and the other concerns the section on initiatives aimed at growth, which was on page 14 of today's presentation.

Regarding the first point about costs, I believe that in recent years, rising global prices for raw materials, energy, logistics, and labor have had a significant impact on corporate operations. From your company's perspective, which cost drivers do you believe have become particularly more severe compared to the beginning of the fiscal year? I would also appreciate it if you could share the background, the extent of the impact, and, if you're willing, any countermeasures.

Nakai [A]: We have indeed observed the impact of the situation in the Middle East and other factors, including rising prices for raw materials—particularly packaging materials in our case—as well as persistently high logistics costs and increased overseas expenses due to the weak yen. However, at this point, there is no significant impact on our business operations or supply.

As for what we are actually doing, we are managing the situation by reviewing our procurement processes and implementing cost-reduction measures to minimize the impact.

Abe [Q]: Thank you. Second, on slide 14, under the section on revenue structure reform, it mentions "review of revenue and expense structure." Could you please explain specifically what this entails?

For example, could you tell me, if there is anything specific you can share at this time, about measures such as reducing reliance on specific sectors or reviewing the allocation of R&D investments?

Nakai [A]: Specifically, regarding the optimal allocation of R&D resources on the left side of page 14, since we will be limiting our R&D resources, I would like you to understand that we will evaluate the development risks, business viability, and competitive environment for each product within those limited resources to determine which products to prioritize and invest in.

Regarding strategic alliances in the middle section, in terms of out-licensing, we will license out products, as mentioned earlier in the left section, that we cannot develop on our own, thereby recouping our investments. Additionally, with regard to in-licensing and sales partnerships, we will in-license products in the later stages of development or those nearing market launch as one of our growth drivers.

Furthermore, regarding the revenue structure reform shown on the right, our strategy involves increasing sales through the alliances and in-licensing I mentioned earlier. As for our cost structure, we will thoroughly review all aspects of it, without exception, across the entire group and pursue growth through rigorous revenue management.

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

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

Ishii [Q]: I am Ishii from Nikkei. I have two questions. The first question concerns the slide 14. You just mentioned that for the optimal allocation of R&D resources, you will evaluate each product category given your limited resources. If there are any differences from previous practices, I would appreciate it if you could explain them again.

Nakai [A]: This is what we are presenting as a course of action in the event that deramiocel is not approved. Therefore, up until now, we had been planning to allocate our R&D resources on the assumption that, if deramiocel is approved, it will make a significant contribution to our company's growth.

If the application is not approved, given our limited R&D resources, we will need to set priorities more clearly. For projects with lower priority, we will not proceed with development on our own.

Furthermore, there may even be some product lines that we have to discontinue, and this is where our approach differs from what we've done in the past.

Ishii [Q]: Thank you. By the way, are there any differences from the past when it comes to promoting strategic alliances and sales partnerships?

Nakai [A]: Regarding strategic alliances, up until now we have been operating under the assumption that top-line growth, or revenue growth, would continue for the foreseeable future. Therefore, we had planned to focus on earlier-stage strategic alliances, such as licensed-in products, as well as technology partnerships and joint research aimed at enhancing our drug discovery capabilities.

However, if approval is not granted, we will seek alliance opportunities in the later stages of development. I would like you to understand that this is the key difference.

Ishii [Q]: Thank you for your detailed explanation. Second, even though operating profit and net income for Q1 were strong, with progress exceeding 70% over the H1 target figures, I would like to know if there is a reason why the business forecast was left unchanged.

Edamitsu [A]: Regarding our progress, while there are some positive aspects, when viewed as a whole, things are proceeding largely as planned—and even slightly better than expected—so we have determined that there is no need to revise our forecast at this time. That is all.

Ishii [M]: Thank you.

Inoue [M]: Mr. Sakaguchi from RISFAX, please.

Sakaguchi [Q]: I am Sakaguchi from RISFAX. I would like to ask President Nakai, regarding the FDA Advisory Committee meeting on deramiocel, what are your thoughts on this? I'd like to hear your honest thoughts.

Nakai [A]: As I mentioned earlier, the Advisory Committee's conclusion was, unfortunately, a negative one. However, since the Advisory Committee's conclusion do not constitute the FDA's final decision, our only option is to wait for the results of the FDA's review.

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

Inoue [M]: Since there seems to be no one else with questions, I will conclude the question-and-answer session.

With that, we conclude the financial results briefing of Nippon Shinyaku for Q1 of FY2026.

Thank you very much for joining us today.