



**JCR Pharmaceuticals Co., Ltd.**

Financial Results Briefing for the Fiscal Year Ended March 2025

May 13, 2025

## Event Summary

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[Company Name]	JCR Pharmaceuticals Co., Ltd.	
[Company ID]	4552-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	Financial Results Briefing for the Fiscal Year Ended March 2025	
[Fiscal Period]	FY2024 Q4	
[Date]	May 13, 2025	
[Number of Pages]	30	
[Time]	18:00 – 19:26 (Total: 86 minutes, Presentation: 42 minutes, Q&A: 44 minutes)	
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	6	
	Shin Ashida	Representative Director, Chairman, President and CEO
	Toru Ashida	Director, Senior Managing Executive Officer, Sales, Executive Director, Sales Division
	Hiroyuki Sonoda, PhD	Director, Senior Managing Executive Officer, Research, Executive Director, Research Division
	Yoh Ito	Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division
	Anne Bechet	Senior Executive Officer, Executive Director, Development Division JCR Europe B.V. General Manager, JCR Luxembourg S.A. Director, JCR USA Inc. General Manager

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\*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A or whose questions were read by moderator/company representatives.

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# Presentation

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**Moderator:** We will now begin the JCR Pharmaceuticals Co., Ltd. financial results briefing for the fiscal year that ended March 31, 2025.

In addition to the announcement of financial results, we also announced today a change of representative directors, including a change of chairman and president, effective on April 1, 2026. We will also explain this.

First, let us explain today's language settings. At the bottom of your Zoom window, use the translation icon to select Off, Japanese, or English.

This briefing is being recorded for posting on our website at a later date.

Let me begin by introducing today's speakers. The six members are Shin Ashida, Representative Director, Chairman, President and CEO; Toru Ashida, Director, Senior Managing Executive Director, Sales, Executive Director, Sales Division; Hiroyuki Sonoda, Director, Senior Managing Executive Officer, Research, Executive Director, Research Division; Anne Bechet, JCR Europe B.V. General Manager, JCR USA Inc. General Manager, Senior Executive Officer, Executive Director, Development Division; Yoh Ito, Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division; and lastly Yoshihiro Ohta, Director, Accounting Department, Corporate Strategy Division.

I will continue with an explanation of the materials to be used today. The materials to be used today were posted on our website on May 13 at 16:00. If you want to have the documents on hand, please obtain them from there.

Next, I will explain the flow of today's briefing. Today's session will last approximately one hour and will include a presentation and a Q&A session. Questions will be taken after all presentations have been completed. In addition to questions related to business performance, we expect that there will be questions regarding the change of representative directors effective April 1 next year, so we have extended the finishing time by 30 minutes to 19:30.

We will begin today with a greeting from Chairman Ashida. After that, Ito will explain the consolidated financial results for the fiscal year that ended March 31, 2025 and the forecast for the fiscal year ending March 31, 2026. Anne Bechet will explain the progress of development items, and Sonoda will explain the progress of research activities. Let's get started.

**Shin Ashida:** I am Ashida. Thank you all for attending at such a late hour. The fiscal year ended March 31, 2025, we posted a loss of approximately JPY4,700 million due to delays in license agreement, the disposal of raw materials stockpiled during the COVID-19 pandemic, and the disposal of clinical trial samples that were no longer usable.

This deficit is the third since I started the company 50 years ago. We believe that we will be able to newly make a firm profit from this fiscal year by letting go of what we lost and making a loss this time.

Today, I am also pleased to announce my successors as chairman and president. JCR started 50 years ago as a company that sold so-called raw materials, but we have been in the biotech business for 50 years. It is research that we have put the most effort into. For the past 50 years, we have been constantly thinking about how to create something new by devoting our resources to this area of research.

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First, net sales were JPY33,072 million, operating income was minus JPY6,650 million, and net income was minus JPY4,759 million. All of these results show YoY declines in both sales and income.

This was mainly due to the fact that the planned license agreement was not concluded during the period, and also due to the fact that the Company examined the inventory of manufacturing-related materials and investigational drugs, etc. and recorded a loss on those items that are not expected to be used in the future. Net sales were JPY33,072 million, as I mentioned, and I will explain the breakdown of this figure on the next slide.

The cost of sales was JPY11,333 million, which includes JPY1,950 million as loss on the disposal of manufacturing-related materials, as I just mentioned. After subtraction, gross profit was JPY21,738 million.

Selling, general, and administrative expenses totaled JPY28,300 million, of which selling, general and administrative expenses, excluding R&D expenses, were JPY12,900 million. This represents an increase of JPY470 million compared with the previous year. R&D expenses totaled JPY15,400 million. This is an increase of JPY4,200 million compared with the previous year, of which JPY1,060 million includes the disposal of investigational drugs, etc., so in real terms, R&D expenses are approximately JPY14,400 million after subtracting this amount.

After subtracting these items, operating income is minus JPY6,600 million, as I mentioned, non-operating income is plus JPY260 million, and non-operating expenses amount to JPY1,088 million. The difference from last year is slim, but this is due to the posting of a foreign exchange loss this fiscal year.

Another topic was a decrease in losses of affiliates held via the equity method. This is Mycenax, which holds shares in a Taiwanese CDMO. We have sold a portion of this and it has been excluded from the equity method of accounting.

Ordinary income was minus JPY7,400 million. Subsequently, after deducting taxes, and extraordinary gains and losses, net income for the period was JPY4,700 million.

One topic of special note is that, as written at the bottom of the supplementary explanation on the right-hand side of the page, the finalization of the subsidy for the construction of the active pharmaceutical ingredients plant at the Kobe Science Park Center was delayed from this period to the next period, and the expected extraordinary income was not recorded this period.

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## Breakdown of Net Sales (Consolidated)

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Consolidated	(Unit: million yen)			
	FY2023	FY2024		
	Results	Results	Year-on-year	
			Difference	Ratio
GROWJECT®	17,913	18,098	+184	+1.0%
IZCARGO®*	5,171	5,718	+547	+10.6%
TEMCELL®HS Inj.	3,236	2,904	(331)	(10.2)%
Treatments for renal anemia	4,652	3,784	(868)	(18.7)%
Epoetin Alfa BS Inj. [JCR]	1,994	1,690	(303)	(15.2)%
Darbepoetin Alfa BS Inj. [JCR]	2,658	2,093	(564)	(21.2)%
Agalsidase Beta BS I.V. Infusion [JCR]	1,661	1,149	(512)	(30.8)%
<b>Total Core Products</b>	<b>32,636</b>	<b>31,655</b>	<b>(981)</b>	<b>(3.0)%</b>
Income from contractual payment	7,413	517	(6,896)	(93.0)%
Other*	2,820	898	(1,922)	(68.1)%
<b>Total Net Sales</b>	<b>42,871</b>	<b>33,072</b>	<b>(9,799)</b>	<b>(22.9)%</b>

\* Sales of IZCARGO® related to NPS is included in Other.

### Additional Remarks

- GROWJECT® revenue increased despite the NHI price revision in April 2024, supported by higher sales volume.
- IZCARGO® continued its strong momentum, posting a 10.6% increase in year on year revenue.
- TEMCELL®HS Inj. revenue declined 10.2% year on year due to intensifying market competition, but remained in line with forecasts.
- Sales of the treatments for renal anemia remained aligned with the supply plans of Kissei Pharmaceutical Co., Ltd.
- Sales of AgalsidaseBeta BS I.V. Infusion [JCR] remained aligned with the supply plans of Sumitomo Pharma Co., Ltd..
- Revenue from licensing-related payments fell short of initial projections because the licensing agreements were not concluded within FY2024.
- Other revenue decreased following the termination of contract manufacturing agreements.

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Here is a breakdown of sales by product.

First, GROWJECT, with sales of approximately JPY18,100 million, an increase of 1%, or JPY184 million, compared with the previous year. This drug was subject to NHI price revision, but since the sales volume increased, the sales figure also rose. In addition, as you will see later in the appendix, our market share has remained stable at around 41%.

Next is IZCARGO, which achieved sales of JPY5,700 million, for a YoY increase of JPY547 million, which is an increase of more than 10%. The net increase in the number of patients receiving this treatment was six cases. We have also provided an Appendix for this as well, which we hope you will refer to later.

Sales of TEMCELL were JPY2,900 million, which was down 10.2% compared with a year earlier. This was due to changes in the competitive environment, but the initial plan was achieved.

The two renal anemia drugs and Agalsidase Beta are sold by Kissei Pharmaceutical Co., Ltd., and Sumitomo Pharma Co., Ltd., respectively. Sales are in line with the supply plans, which is based on the shipment plans and sales plans of the sellers.

Total sales of core products were JPY31,655 million, down JPY981 million from the previous year.

Contract revenue totaled JPY517 million, a JPY6,800 million decrease from the previous year. As mentioned at the beginning of this presentation, we were not able to conclude a planned license agreement during the current fiscal year, resulting in a much lower result than we had expected at the beginning of the fiscal year.

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The decrease in other sales is due to a decrease in contract manufacturing in the previous fiscal year. Total sales were JPY33,072 million.

Before going to the forecast, I would like to ask you to go back one slide. As I forgot to mention earlier in the summary of financial results, we announced a revision of the earnings forecast on March 27. I would like to explain some of the differences compared to that time.

Net sales are in line with the forecast, which at that time was an increase of JPY72 million, but operating income was a large loss of JPY650 million. This is largely due to the fact that many expenses, especially development expenses, were recorded earlier than originally expected. This factor was very large.

Ordinary income was an unexpected large loss of JPY777 million due to foreign exchange losses caused by a strong yen. That is all regarding variance.

Financial Status (Consolidated)				Reach Beyond, Together 			
(Unit: million yen)							
	End-Mar. 2024	End-Mar. 2025	Change • Main Increase/decrease		End-Mar. 2024	End-Mar. 2025	Change • Main Increase/decrease
Current assets	57,581	51,056	Total (6,524)	Current liabilities	30,135	43,988	Total +13,852
			• Cash and deposits (5,559)				• Short-term borrowings +17,105
			• Accounts receivable - trade, and contract assets (2,698)				• Income taxes payable (1,620)
			• Inventories +822				
				Non-current liabilities	15,615	13,431	Total (2,183)
							• Long-term borrowings (2,300)
Non-current assets	44,644	53,798	Total +9,154	Total liabilities	45,750	57,420	Total +11,669
			• Property, plant and equipment +7,369				Total (9,040)
			• Deferred tax assets +1,697	Total net assets	56,475	47,435	• Net loss (4,759)
							• Treasury shares (2,103)
Total	102,226	104,855	2,629	Total	102,226	104,855	2,629
Additional Remarks							
<ul style="list-style-type: none"><li>Property, plant, and equipment increased due to the start of construction of the New Drug Product Plant in the Kobe Science Park Center.</li><li>Short-term borrowings increased to fund the construction of the new facility and working capital, reflecting reclassification from Long-term borrowings.</li></ul>				End-Mar. 2024		End-Mar. 2025	
				Equity ratio		54.2%	44.8%

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Now, let's look at the financial situation.

In the period that just ended, total assets amounted to JPY104,800 million, of which net assets amounted to JPY47,400 million. The equity ratio, as you can see on the lower right, is 44.8%. In terms of net assets, there was a repurchase of treasury stock during the period. That is one thing of special note.

The increase in fixed assets, shown on the left-hand side of the page, especially in property, plant, and equipment, is due to the start of construction of a new drug product plant at the Kobe Science Park Center, which we have also announced.

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Short-term loans payable increased due to the construction of the new drug product plant, as well as to procure funds for working capital and due to the reclassification from long-term loans payable.

## FY2025 Consolidated Financial Forecasts

Reach Beyond, Together 

(Unit : million yen)

Consolidated	FY2024 Results	FY2025(Forecast)		
		Forecast	Year-on-year	
			Difference	Ratio
Net Sales	33,072	37,800	+4,727	+14.3%
Cost of Sales	11,333	8,200	(3,133)	(27.6)%
Gross Profit	21,738	29,600	+7,861	+36.2%
Selling, General and Administrative Expenses	28,389	27,000	(1,389)	(4.9)%
SG&A Expenses	12,958	12,000	(958)	(7.4)%
R&D Expenses	15,431	15,000	(431)	(2.8)%
Operating Profit (Loss)	(6,650)	2,600	+9,250	-
Ordinary Profit (Loss)	(7,477)	2,400	+9,877	-
Profit(Loss)Attributable to Owners of Parent	(4,759)	3,000	+7,759	-
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	16,994	17,100	+105	+0.6%

### Additional Remarks

- Net sales is expected to increase year on year, as growth in IZCARGO® sales and higher licensing income are likely to outweigh.
- Cost of sales is expected to decline year on year, as the previous year included one-time losses related to the disposal of raw materials.
- SG&A expenses are expected to decline, reflecting greater operational efficiency, while R&D expenses are also projected to decrease, as last year's figures included one-time write-offs of investigational products—costs that are not anticipated this year despite ongoing progress in global clinical trials.
- Operating income is forecast to increase primarily reflecting higher licensing revenue.
- A one-time gain is expected to be recorded as Extraordinary income, stemming from the reversal of depreciation charges previously booked for the API Plant at Kobe Science Park Center, following the final confirmation of the government subsidy amount.

Net Sales	FY2024	FY2025 (Forecast)	Difference
Cost of Sales Ratio	34.3%	21.7%	(12.6)%
Cost of Sales Ratio *Excluding income from contractual payment	34.8%	25.4%	(9.4)%
R&D Expenses Ratio	46.7%	39.7%	(7.0)%
Operating Profit Ratio	(20.1)%	6.9%	+27.0%

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Next, I will explain our forecast for the current fiscal year ending March 31, 2026.

First, we forecast net sales of JPY37,800 million, operating income of JPY2,600 million, and net income of JPY3,000 million.

As for sales, as I will explain in detail later, we expect an increase in sales of IZCARGO and an increase in contract revenues. We are also projecting an increase of JPY4,700 million compared with the previous year. The cost of sales is expected to decrease significantly from the previous year due to the absence of loss on disposal of manufacturing-related materials, which was recorded in the previous year. As for the cost of sales ratio, which is shown in the table at the bottom right, particularly the cost of sales ratio excluding contracts, which is 25.4%, assumes a significant decrease. Gross profit is at JPY29,600 million .

Selling, general, and administrative expenses, excluding R&D expenses, total JPY12,000 million . This is expected to decrease from the previous year due to efficient business execution, etc. As for R&D expenses, as I mentioned earlier, there is no loss from the disposal of investigational drugs this fiscal year, but there is progress in global clinical trials. Overall, compared with the previous year it will decrease, but on a real basis it will increase. Again, this is due to the progress of clinical trials. As a result, operating income is JPY2,600 million .

The net income forecast is JPY3,000 million, but we expect to be able to determine the amount of the subsidy for the active pharmaceutical ingredients plant at the Kobe Science Park Center, which is shown at the bottom of the supplementary explanation, in the current fiscal year. The Company expects to record an extraordinary

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gain equivalent to the depreciation expense recorded in the previous fiscal year due to the corresponding reduced-value entry.

## Breakdown of Net Sales – FY2025 Consolidated Financial Forecasts

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(Unit : million yen)

Consolidated	FY2024 Results	FY2025(Forecast)		
		Forecast	Year-on-year	
			Difference	Ratio
GROWJECT®	18,098	17,800	(298)	(1.6)%
IZCARGO®*	5,718	6,400	+681	+11.9%
TEMCELL®HS Inj.	2,904	2,700	(204)	(7.0)%
Treatments for renal anemia	3,784	3,100	(684)	(18.1)%
Epoetin Alfa BS Inj. [JCR]	1,690	800	(890)	(52.7)%
Darbepoetin Alfa BS Inj. [JCR]	2,093	2,300	+206	+9.9%
AgalsidaseBeta BS I.V. Infusion [JCR]	1,149	1,100	(49)	(4.3)%
Total Core products	31,655	31,100	(555)	(1.8)%
Income from contractual payment	517	5,500	+4,982	+963.2%
Other*	898	1,200	+301	+33.5%
Total net sales	33,072	37,800	+4,727	+14.3%

\* Sales of IZCARGO®related to NPS is included in Other

### Additional Remarks

- GROWJECT® is expected to see lower revenue due to the NHI price revision, despite ongoing efforts to grow market share by promoting the value of its auto-injector device and expanding outreach to new and potential patients.
- IZCARGO® is projected to maintain sales growth through continued efforts under the dedicated MR model launched in April 2023 and joint promotional activities with Sumitomo Pharma Co., Ltd.
- TEMCELL®HS Inj. revenue is expected to decline, reflecting a more competitive market landscape.
- Revenue from the treatments for renal anemia and AgalsidaseBeta BS I.V. Infusion [JCR] is forecast to remain in line with the supply schedules of our marketing partners.
- Licensing revenue is expected to exceed that of the prior year, based on the planned completion.

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This is my last slide.

By product, sales of GROWJECT are forecast to total JPY17,800 million. The amount is a 1.6% decrease, but since the NHI price revision is 3.6% for the mainstay 12-milligram product, the increase in volume terms is approximately 2%. As for IZCARGO, we expect sales to increase by more than 10% this fiscal year, to JPY6,400 million. As for TEMCELL, we expect a decrease in sales of approximately JPY200 million due to the change in the competitive environment that I mentioned earlier. The following products, Epoetin Alfa, Darbepoetin Alfa, and Agalsidase Beta, are products whose sales are outsourced to other companies. The sales assumptions are based on the supply plan with each company.

Contract revenue is expected to be JPY5,500 million, including up-front payment from the conclusion of the license agreement and achievement of milestones in the collaborative research for which a contract has already been concluded.

Total sales are expected to be JPY37,800 million, an increase of JPY4,700 million from the previous year.

That is all.

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## JR-141 (pabinafusp alfa: BBB-penetrating ERT for MPS II)

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### Global Phase III study (JR-141-GS31): STARLIGHT study Overview

### Current Status

(Summary)

#### ◆ Cohort A : (Neuronopathic patients)

N=60



#### ◆ Cohort B : (Attenuated patients)

N=20



- Number of clinical trial sites  
28 sites  
12 countries
- Achieved **over 95%** of patient recruitment

- Close collaboration with agencies to target to file as soon as possible
- Consultation with FDA to be conducted by June 2025

### Overview

Objectives	<ol style="list-style-type: none"> <li>1. To assess the efficacy of JR-141 on CNS signs and symptoms in MPS-II subjects relative to standard ERT</li> <li>2. To assess control of somatic signs and symptoms by JR-141 relative to standard ERT</li> </ol>
Endpoints	<ul style="list-style-type: none"> <li>• Changes in HS in CSF, CNS symptoms (cognitive, behavior, attention)</li> <li>• Control of systemic sign and symptoms</li> </ul>
ClinicalTrials.gov	Identifier : <a href="https://clinicaltrials.gov/ct2/show/study/NCT04573023">NCT04573023</a>

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**Bechet\***: Good evening, and thank you very much for joining us tonight. My name is Anne Bechet, and I will present all the latest progress on our clinical development portfolio.

We will start with JR-141, which is our lead asset, and a blood-brain-penetrating ERT for MPSII. We have discussed previously about the conduct of our phase III study called STARLIGHT. It consists of two cohorts, one cohort A, with neuronopathic patients for a total of 60 patients, randomized one-to-one between JR-141 and the standard of care.

And the cohort B, constituted of attenuated patients for which we target the recruitment of 20 patients, also randomized one-to-one between JR-141 and the standard of care. We have progressed in the study very well with having opened to date 28 sites in over 12 countries. The cohort B recruitment was achieved fully last year, and we have booked major progress in the past months in advancing the recruitment of our cohort A.

I am pleased to share that we have achieved that present over 95% of patient recruitment, and that we are hence in an excellent position to complete this recruitment as per our previously announced timelines.

We continue collaborating very closely with the relevant agencies to target our filing as soon as possible, whether it be in the USA or in Europe, and we will be having a meeting with FDA in the course of June 2025.

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### Achieved steady progress in clinical development for rare diseases with no available treatment

#### JR-441

BBB-penetrating heparan N-sulfatase (rDNA origin)  
Indication: MPS type IIIA

- Oct 2023 Initiation of Phase I/II study (Germany)
  - Completed patient enrollment
- Oct 2024 Initiation of Phase I study (Japan)
  - Completed patient enrollment

#### JR-446

BBB-penetrating  $\alpha$ -N-acetylglucosaminidase (rDNA origin)  
Indication: MPS type IIIB

- Dec 2024 Initiation of Phase I/II study (Japan)
- Completed the first safety review by the independent data monitoring committee
  - No safety concerns at this point, decided to continue the study

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We have progressed very well on the rest of our pipeline with very steady progress in our assets for disease where there is no available treatment. This is the case for JR-441, which is an enzyme replacement therapy, also passing through the blood-brain barrier to treat MPS IIIA.

As a reminder, we have initiated this study in October 2003 with our clinical phase I/II in Germany, and have successfully recruited all the patients that were on our radar for the protocol. In October 2024, we have initiated as well our first clinical study in Japan for which the patient enrollment has also been completed.

We are on schedule and able to communicate results as purpose communication in the second half of 2025. Concerning JR-446, which is an enzyme replacement therapy for MPS IIIB, we're very pleased to communicate that we have initiated our phase I/II study in Japan in December of 2024.

The first patients have been successfully treated. The first safety data have been reviewed by an independent data monitoring committee and the study has gotten the green light to continue since there were no safety concerns at this point.

I would also like to share that for this study we have been very successful in identifying already the patients that we will recruit and we have already patients lined up until the completion of our recruitment.

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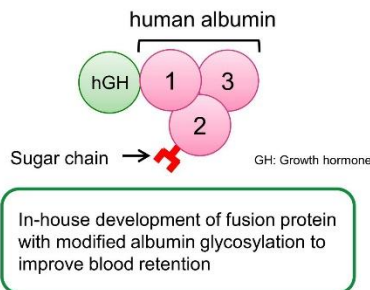
## Growth Hormone Product

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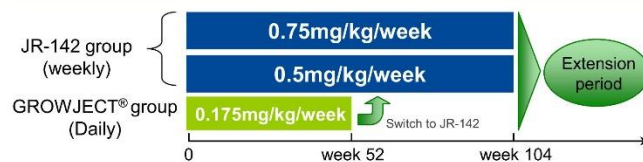
**JR-142**

Long-acting growth hormone (rDNA origin)  
Indication: Pediatric growth hormone deficiency

### Modified albumin-fused GH



### Phase III study design



#### Overview

<b>Objective</b>	• Verify the non-inferiority, and evaluate the efficacy and safety of JR-142 to GROWJECT®
<b>Endpoint</b>	• Change in height SDS for chronological age from the first administration (Week 52)
<b>Target number of patients</b>	• 54

Dec 2024 First dosing in first subject in Phase III

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Now to follow up on our growth hormone product, JR-142. JR-142 is a long-acting growth hormone product for growth hormone deficiency. It is administered to the patients once per week instead of daily infusion.

It originates from the modified albumin fused growth hormone. Our phase III design consists of two arms. The JR-142 group weekly at two different doses 0.75 mg/kg/week or 0.5 mg/kg/week with a comparator arm being GROWJECT which is the daily administration at 0.175 mg/kg/week.

The overall objective is to verify the non-inferiority of JR-142 as well as evaluate and confirm the efficacy and safety of JR-142 respected to GROWJECT. We will measure height for those patients as an endpoint and we target to recruit in total 54 patients.

We have successfully initiated this study with the first patient dosed achieved in December of 2024. The recruitment is of course ongoing as we speak.

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## Overview of Clinical or late Preclinical Pipeline

Code	Indication	Status				Milestones/Comments
		Preclinical	Phase 1	Phase 2	Phase 3	
JR-141	MPS II (Hunter syndrome)	Global Ph3				<ul style="list-style-type: none"> <li>Q3 FY2025: Enrollment completion</li> <li>~FY2027: Approval in US, EU, Brazil</li> </ul>
JR-142	Pediatric GHD	Ph3 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph3</li> </ul>
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed				<ul style="list-style-type: none"> <li>Extension study ongoing</li> <li>Partnering intensified</li> </ul>
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany)				<Ph1/2> <ul style="list-style-type: none"> <li>Patient enrollment completed</li> <li>2H FY2025: 1-year clinical data</li> </ul>
		Ph1 (Japan)				<Ph1> <ul style="list-style-type: none"> <li>Patient enrollment completed</li> </ul>
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph1/2</li> <li>Partnering with MEDIPAL HOLDINGS</li> </ul>
JR-471	Fucosidosis					<ul style="list-style-type: none"> <li>Partnering with MEDIPAL HOLDINGS</li> </ul>

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In short, we have booked a lot of progress on our clinical development pipeline.

With a very significant advancement of our recruitment on our JR-141 clinical study, we are at present in a very good position to complete the enrollment as per past communications by Q3 2025. We have also initiated our JR-142 study as communicated with our first patient dose at the end of December 2024.

We also have of course in our portfolio JR-171 which is an MPS I, enzyme replacement therapy also passing the blood-brain barrier. The extension study is still ongoing, and the partnering discussions also are intensified.

We've continued our MPS IIIA assets without issue in terms of enrollment. We don't have safety issues to date either that would preclude the continuation of the trial and we have achieved the enrollment of our patients in the Japanese trial.

JR-446 for MPS IIIB is partnered with MEDIPAL and has seen the major milestone of achieving the first dosing of the patients at the end of 2024. The efforts on Fucosidosis and the activities to bring a therapy to this very neglected population are also ongoing in partnership with MEDIPAL.

Thank you.

**Sonoda:** My name is Sonoda. From here, I would like to talk about the progress of our research activities.

I will introduce two topics today. One is enzyme replacement therapy for lysosomal disease, and the other is gene therapy, adeno-associated viruses (AAV). I would like to discuss these two topics.

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## Overview of Clinical or late Preclinical Pipeline

Code	Indication	Status				Milestones/Comments
		Preclinical	Phase 1	Phase 2	Phase 3	
JR-141	MPS II (Hunter syndrome)	Global Ph3				<ul style="list-style-type: none"> <li>Q3 FY2025: Enrollment completion</li> <li>~FY2027: Approval in US, EU, Brazil</li> </ul>
JR-142	Pediatric GHD	Ph3 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph3</li> </ul>
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed				<ul style="list-style-type: none"> <li>Extension study ongoing</li> <li>Partnering intensified</li> </ul>
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany)				<ul style="list-style-type: none"> <li>&lt;Ph1/2&gt;</li> <li>Patient enrollment completed</li> <li>2H FY2025: 1-year clinical data</li> </ul>
		Ph1 (Japan)				<ul style="list-style-type: none"> <li>&lt;Ph1&gt;</li> <li>Patient enrollment completed</li> </ul>
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph1/2</li> <li>Partnering with MEDIPAL HOLDINGS</li> </ul>
JR-471	Fucosidosis					<ul style="list-style-type: none"> <li>Partnering with MEDIPAL HOLDINGS</li> </ul>
JR-479	GM2 gangliosidosis					—

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This is the first. This shows the development pipeline.

As Anne Bechet explained, at the bottom of the list, there is an item called JR-479, which is still in the non-clinical phase. This is for a disease called GM2 gangliosidosis, which is one of the lysosomal diseases. It is known as one of the most severe pathologies of lysosomal diseases, especially with the wide range of central nervous system (CNS) symptoms. Since it is a very serious disease for which there is no effective treatment, we are now actively working on it.

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## Evaluation in a Mouse Model of GM2 gangliosidosis

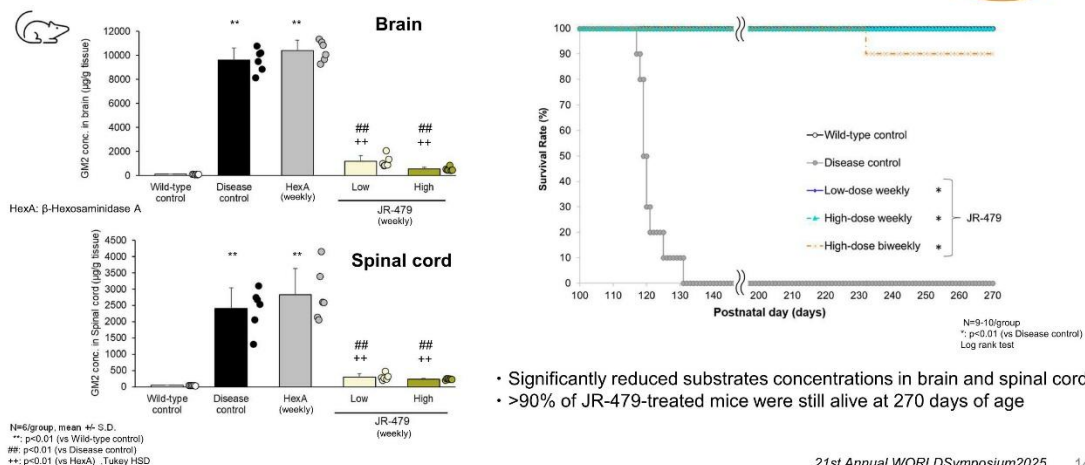
Reach Beyond, Together 

### JR-479

BBB-penetrating  $\beta$ -Hexosaminidase A (rDNA origin)

Indication: GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease)

Enzyme replacement therapy



Today, I would like to talk about the results of a non-clinical mice study of JR-479, a therapeutic candidate for GM2 gangliosidosis.

I will use just this one slide.

JR-479, as I mentioned, is an enzyme product applied with the BBB-penetrating technology, J-Brain Cargo. The bar graphs on the left show how much of the toxic substance, in this case GM2, which accumulated in the brain or spinal cord of model mice, reduced after the administration of JR-479. The far left of the bar graph shows the normal mice, so the bar is low.

This means that there is no accumulation of toxic substances in the brain or spinal cord. Next to that is the disease model, and shown in a black bar there. If GM2 accumulates just as shown here, if you give an enzyme there that does not pass through the BBB and does not reach brain, shown in a gray bar, but the accumulated substance in the brain or spinal cord will not decrease.

Meanwhile, JR-479 is shown in the bars to the right. Those two bars show the results of two kinds of dose, low dose and high dose. In both cases, you can see very large reductions in the brain and spinal cord. The right side of the page shows the survival rate of a model mouse with a large decrease in the amount of accumulated substances in the brain or spinal cord.

As I mentioned, Model mice also show very severe pathology, just like patients. With the gray bar, if there is no treatment, as shown here, about 130 or 140 days after birth, most of the mice will die. In contrast, the treatment group, shown in blue or orange, maintains a very high survival rate, as you can see from the lines. Of course, normal mice survive 100% of the time, so they are hidden behind this blue line, but the same high survival rate can be maintained with enzyme replacement therapy.

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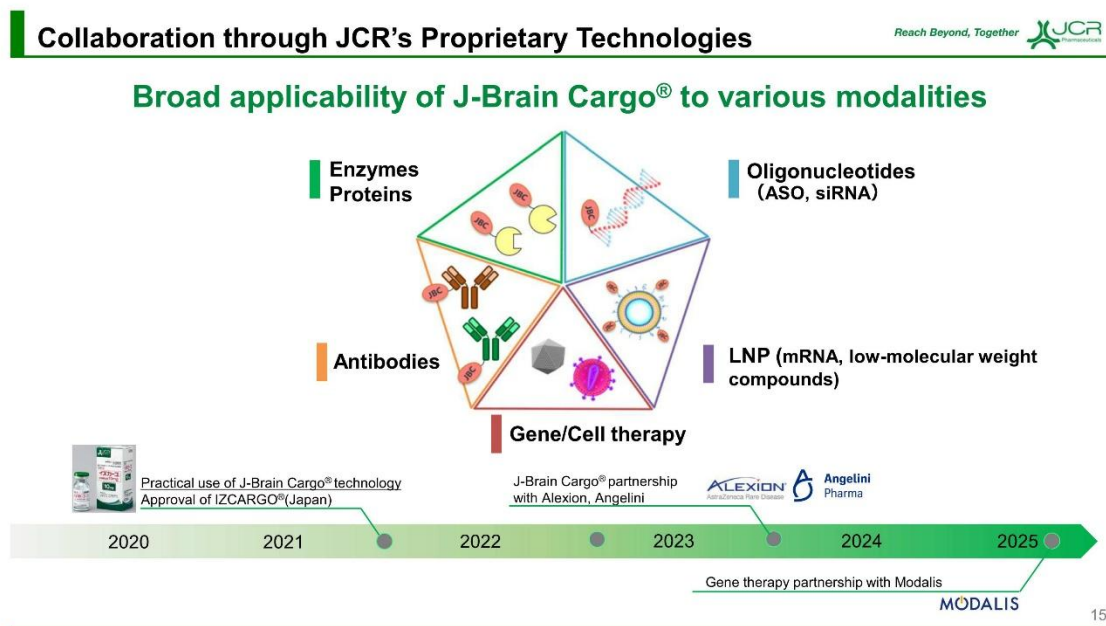
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While there is currently no effective treatment for this disease, we believe that we have achieved good results, even though current data came from model mice. We hope to move this up to the clinical phase soon, following behind others, such as JR-141, JR-441, and JR-446.



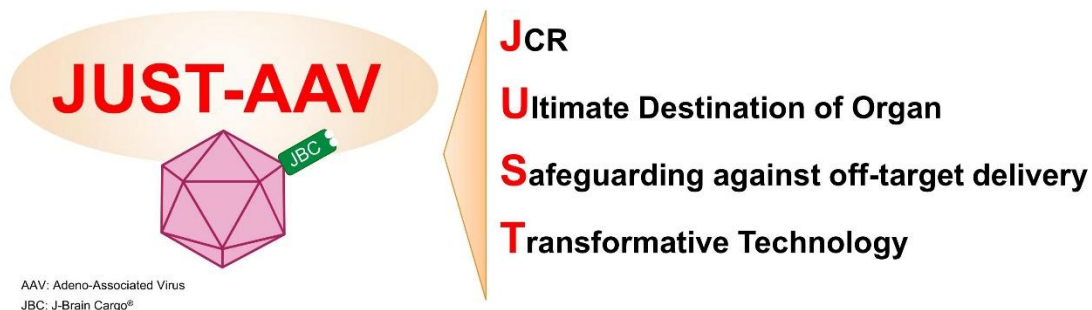
I talked enzyme product, but since J-Brain Cargo is a platform technology, it can be applied not only to enzymes but also to a variety of other modalities. Of these, the area we have been paying the most attention to, or rather, putting most effort into, is gene therapy.

In addition, we have demonstrated the applicability to antibody drugs, oligonucleotides, and nanoparticles. Based on these, collaborations with other companies are progressing, and we would like to continue to actively promote them in the future.

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**AAV with directionality to target tissues/organs and reduced migration to specific tissues/organs**

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Today I would like to talk about gene therapy, and adeno-associated viruses (AAV).

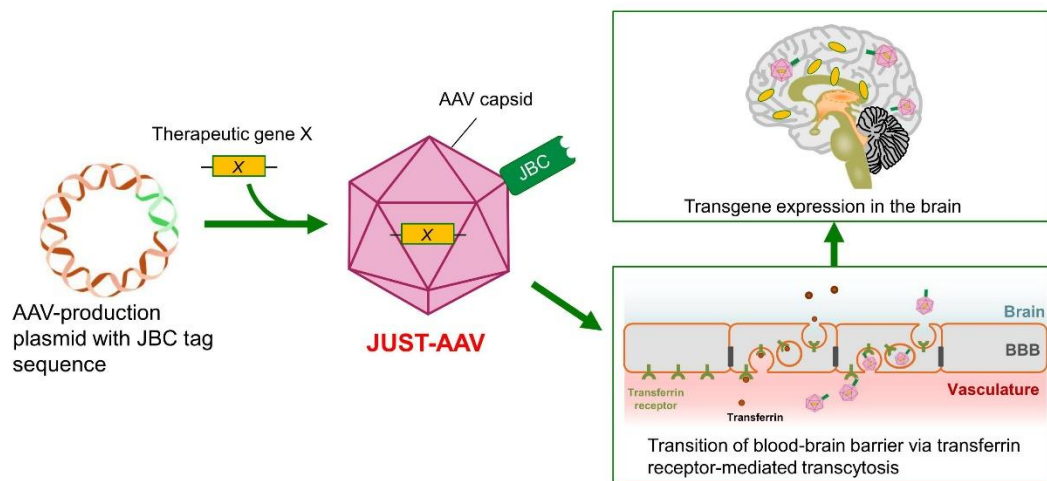
I have already talked about adeno-associated viruses with J-Brain Cargo applied as a new platform technology. This time, we have given a new name to this technology. I would like to talk about the naming of it.

The English is written on the right-hand side here, and it describes the features of the new platform technology. We have used this acronym, JUST-AAV, as the name. This is an AAV that has tropism to target tissues, such as the brain and muscles, and also reduces tropism to organs where we do not want the maximum accumulation from the viewpoint of safety, such as the liver. This AAV contains the technology to enter areas where it should go and to not go where it is not wanted to go, so we have named it JUST-AAV.

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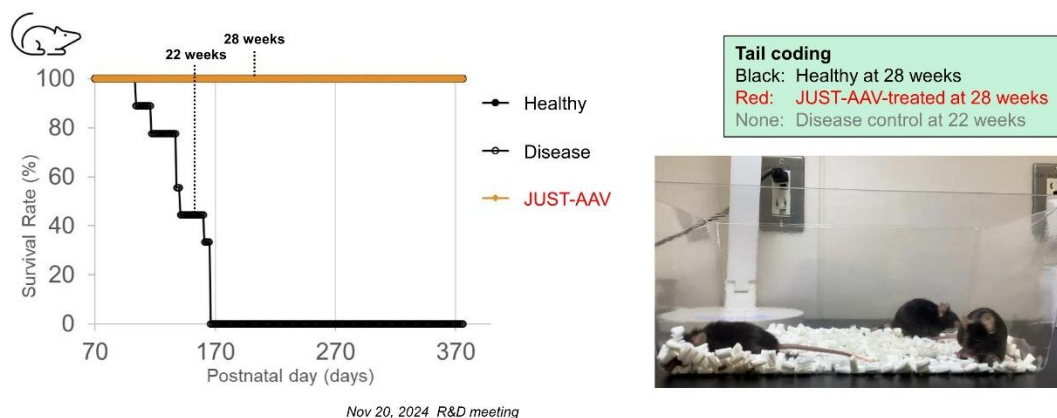
In that context, for example, if we target the brain, here, we show what the mechanism of action of JUST-AAV.

The pink drawing in the middle shows the capsid of the AAV. Then, there's the structure with a tag that allows targeting, in this case, a green tag. This is, of course, a schematic diagram, but by creating an AAV like this and administering it, this tag will guide it toward the target tissue. At the same time, the concept is that the capsid itself is modified to reduce its distribution to the liver and other tissues where it is not wanted to go. Reducing that distribution also allows more of it to go to targeted tissue.

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JUST-AAV resulted in survival of more than 370 days, similar to healthy mice

CLN2: Neuronal ceroid lipofuscinosis type 2

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Gene therapy using the new JUST-AAV.

Again, the results are from mice, but I would like to share one piece of the data with you. Again, this is a type of lysosomal disease called neuronal ceroid lipofuscinosis type 2, and we are looking at survival rates using a mouse model of this disease.

On the left is a graph showing their survival rates. Black is the disease model. It is indicated by a black line. In 170 days, all the mice had died. In this study, we are giving these mice a single intravenous dose of JUST-AAV and seeing how much it changes their survival rate. As indicated by the orange line, mice treated with a single dose of JUST-AAV showed survival similar to that of normal mice.

I would like to show in the video on the right the kind of behavior the mouse is actually undertaking. Tail coading is applied to each mouse, and the normal model mouse is the one painted black. The mouse without any coading is the disease model. The one that is shivering is the disease model. It's not normal, so much so that just a quick glance at the behavior reveals that the actions are completely abnormal. The mouse that are administered JUST-AAV and whose tails are marked red will have improved behavior to a level where they are indistinguishable from normal mouse. Reflecting this, survival rates have returned to levels comparable to those of normal mice.

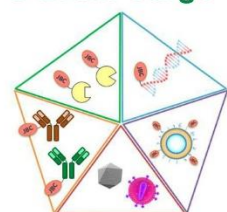
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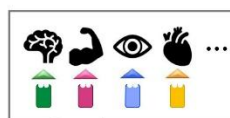
Partnering our groundbreaking technologies and creating breakthrough therapies in various disease areas beyond rare

### J-Brain Cargo®



Blood-Brain Barrier transport applicable to various modalities

### JUST-AAV



AAV with enhanced delivery to target tissues and reduced liver tropism

Lysosomal Storage Disorders

Neurodegeneration

Muscular Diseases

Neuroinflammation

Neuro-oncology

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What I have shown you is an example of the application of J-Brain Cargo's technology to enzyme product and gene therapy.

In this way, we are developing the basic technology, creating new products, and creating and developing assets in the area of rare diseases. We are also continuing to license the technology itself and are actively promoting collaboration with other companies. We also hope to do so in the future.

I have been talking about using J-Brain Cargo for various modalities, but with the addition of this new technology for AAV, which we have named JUST-AAV, we will be able to contribute to our own drug discovery as well as to collaborations with other companies. We are conducting R&D targeting lysosomal diseases and rare diseases. However, through licensing or collaboration, we would also like to use this basic technology in other larger disease areas to contribute to treating such diseases, patients, and their families.

That's all from me.

**Moderator:** Thank you for your attention.

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## Question & Answer

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**Moderator [M]:** We will now move on to the question-and-answer session. Please note that questions will be asked and answered one at a time with each person limited to two questions at a time. However, you may raise your hand as many times as you like.

We will now begin the Q&A session with analysts and the media. First is Mr. Yamaguchi. Please go ahead.

**Yamaguchi [Q]:** Thank you. I am Yamaguchi from Citigroup Global Markets Japan. Thank you for taking my questions. My first question is about page eight and the global development of JR-141. You mentioned that you plan to hold a consultation with the FDA by June 2025, but what is the purpose of this meeting, and will it enable the accelerated application and accelerated approval that have been the focus of attention since last year? Can you please tell us about this, including whether that is what you are talking about here? This is my first question.

**Bechet [A]\*:** Of course, the actual content of such meetings is confidential overall and confidential for strategic reasons. However, JCR's goal is to identify the best and fastest way to get approval in the US.

**Yamaguchi [Q]:** My second question is your assumption of income from contracts for this fiscal year. In the case of the previous fiscal year, agreements with two partners including JR-171 did not work out. In the end, you had to make two downward revisions because you did not get either. This time around, I am not sure if the part for products such as JR-171 is included. The delay by the partners will probably happen from the previous period, but is that all that is in there? I think this has resulted in quite a bit of volatility in performance, so please tell us about your assumptions and how accurate they are.

**Ito [A]:** I will answer this. First of all, as for the premise of contract income this time, we are not assuming the out-licensing of JR-171 or any other products you just mentioned. However, the contract that was scheduled to be signed in the previous fiscal year has been postponed to the current fiscal year, so the contract fee and upfront payment income have been factored in. In addition, as already mentioned, milestone income from joint research already in progress has also been factored in. The figures presented here take into account these factors.

As for the degree of certainty, as you pointed out, we made two downward revisions in the previous fiscal year, and we apologize for any inconvenience caused. We did refer to the figures for the previous term as solid, but we do regard the figures for this fiscal year as fully achievable. We have set these figures in the hope that we will not continue to revise them downward.

**Yamaguchi [Q]:** Thank you. I would like to ask one more little question. You mentioned that the out-licensing of JR-171 and JR-141, whether one by one or collectively, has not been included in the performance this time. Is there any way that you can update us on the current status of your out-licensing activities?

**Ito [A]:** We are continuing our out-licensing activities and are in discussions with companies that are interested in both assets. As I have mentioned previously, some companies are interested in both JR-171 and JR-141. We will make further announcements on this when we have made progress and are ready to make an announcement. Thank you very much.pa

**Yamaguchi [M]:** Thank you very much.

**Moderator [M]:** Thank you very much. The next question will be from Mr. Sakai. Please go ahead.

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**Sakai [Q]:** My name is Sakai from UBS Securities Japan. Just to confirm about JR-141, is this data on Americans? I think it is obviously essential for consulting with the FDA. Could you please tell us what the situation is around that?

**Bechet [A]\*:** Regarding JR-141, of course, the data is not only on Americans. It is a global joint trial, so we would like to make a global registration in the US, and we would also like to apply in European countries as well. We had several consultations with the FDA last year, and this June's FDA consultation is a continuation of those, again to confirm the development plan and to ensure that the best and fastest path to application can be followed.

**Sakai [Q]:** As a challenge, I think it is quite difficult to convince them regarding this number of patients and cases. However, do you still believe that the FDA will give the OK at this time?

**Bechet [A]\*:** You are right. We have a large data pool at JCR, so of course, we also have data from ongoing Phase III trials, but we also have additional trials completed in Japan and a trial in Brazil. So, we are going to integrate that. This means that it has been in the market for several years now. Therefore, we have an extensive data pool that will further strengthen our position.

**Sakai [Q]:** I understand. Thank you very much.

Chairman Ashida said it is time for Mr. Ashida and Mr. Sonoda to take over, so basically I don't know which one to ask, but I think that the current route, the environment in which JCR is now placed, is not an easy phase. At this stage, is there anything in particular you want to change? Mr. Sonoda, I am sure that you know every nook and cranny of the Company's assets since you have been involved in R&D for a long time, but is there any message you would like to share with us at this point?

**Toru Ashida [A]:** Thank you very much. I am Toru Ashida. What I can tell you at this point today is that, as the current chairman, Shin Ashida, mentioned at the beginning of the meeting, there have been various discussions at the Nominating and Compensation Committee and other committees over the past several years. In addition, in response to the resolution at today's Board of Directors meeting, I personally take the decision very seriously at this time. I will prepare for April 2026 by consulting with the current chairman as well as with the new president. The three of us, as a management team, will consider what form the new management structure should take. We will discuss and prepare for it thoroughly.

**Sonoda [A]:** I am Sonoda. Thank you for your question. Basically, I don't think that just because the top management has been replaced, the Company's policy or what it is doing will suddenly change. Based on rare diseases, we would like to maintain our commitment to develop new drugs for patients and their families who are currently suffering from a lack of drug development.

At the same time, however, as you have just mentioned, we are aware that this is a very big issue, how to make it sustainable when considering the environment in which we are placed or the environment of the pharmaceutical industry as a whole. If it comes to the conclusion that we can reach out to non-rare diseases because that is what we have to do to maintain sustainability in order to continue development for rare diseases, then we may have the possibility of working on non-rare diseases. If we just keep doing what we are doing now, I don't think it will work out just by itself.

For example, even if we look at a single technology, 10 years ago, we were the leader in this technology, but soon, other companies were catching up. I believe that the AAV will be in a similar environment in a few more years as well. In R&D, we will always invest and develop new technologies. This is the same as before, and it will continue. However, we would like to consider a wider range of options for how to use them in the future. Thank you for your question.

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**Moderator [M]:** Thank you very much. Now, the next question is from Mr. Nagao. Please go ahead.

**Nagao [Q]:** My name is Nagao from Kobe Shimbun newspaper. Thank you for your assistance.

First of all, Chairman and President Shin Ashida said that it has been half a century this year since the Company was founded, and it is amazing that the Company has come so far in a single generation. Looking back over the past, if you had to name two or three crossroads that have been essential to your leap to the present, I would like to ask what they are. This is my first question.

**Shin Ashida [A]:** We started with our employees really as a venture to produce raw materials, so we started with all of our employees working together and focusing on creating things. This is number one.

Second, when thinking later about what to do and how to maintain the company, we needed to create products. Starting with urokinase, we decided to create other raw materials, so we put an emphasis on research. In order to earn money for our research, we spent more than 30% of our sales on research.

As a result, in addition to urokinase, the Company created the epidermal growth factor, kallidinogenase, and then interferon alpha, and things like that.

Third, the Company went public over the counter. When the Company went public over the counter, its sales were less than JPY3 billion. What was beneficial about going public over the counter was that we were able to issue CBs in Switzerland at that time. I think the key was that the CBs were used to fund the construction of new laboratories and factories, which have developed into the current laboratories and manufacturing plants.

**Nagao [Q]:** The second question I would like to ask is the reason for the change at this time. As mentioned, I would like to ask Mr. Ashida, the chairman and president, to explain again what kind of phase the Company is currently in, what path he would like the company to follow, and why you have chosen two new representatives.

**Shin Ashida [A]:** At this point, as I'm sure you all know, I am now past 80, and I feel that I will not live that much longer. My abilities will probably be declining more and more, too. For several years now, we have been thinking about how to create a structure around the Nominating and Compensation Committee. When I think about our company, we sell products, but as I mentioned earlier, we are a venture-like company, and we allow people to do research freely.

I don't think I have ever once told Sonoda, who is being asked to be president, to do this or that. We have done our work freely. We have also invested money in our manufacturing division, but we put as much money as possible into research and also into making good products. I think this was good, and I hope that they will continue to develop a great JCR with this spirit, which is why I chose them.

**Nagao [M]:** Thank you very much.

**Moderator [M]:** Thank you very much. The next question is from Yamakita-san. Please go ahead.

**Yamakita [Q]:** My name is Yamakita, from Jefferies Japan. Thank you for taking my questions. I have two.

The first question is. The situation in the US has been changing at a dizzying pace recently with tariffs, drug price reductions, the FDA situation, etc. Is there anything that your company is paying particular attention to or that could be a risk to your company? I think direct risks are limited, but if you can think of anything, even indirectly, please let us know.

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**Bechet [A]\*:** We continue to work with the FDA, as we have been saying. So far, we have not noticed any difference in terms of timeline or engagement. It is difficult to comment on what will happen in the future, but at this stage, we see no reason why such changes should have a significant impact on our operations. However, we will keep a close eye on future events. If there are any major differences, we will have to react and respond to them.

**Yamakita [Q]:** Thank you very much. This is my second question. Regarding the change in management structure, from what you have just said, I think the theme is more about rejuvenation, and I feel that the management structure will become more like a venture with a sense of speed. In that sense, to what extent do you intend to make the management structure more like a venture, perhaps issuing new shares to invest in new areas, or perhaps rejuvenating the company at such a level or even making it a venture?

**Shin Ashida [A]:** I think there are various options, such as issuing new shares, but my wish for the young managers is to create an environment that allows them to invest as much money as possible in research.

**Sonoda [A]:** I would like to comment on this to prevent any misunderstanding. I don't really think that we are aiming for the kind of venture spirit where venture companies issue shares and make money, though I won't deny the possibility of that happening in the future. The venture spirit we feel is the spirit of drug discovery. We call it our venture spirit when we take such risks and try new things. We are not trying to protect our profits by making a living on generics, biosimilars, and the like but by boldly taking on the challenge of developing technologies and drugs that patients want and need, investing in such technologies and drugs, and conducting research. I would be happy if you could understand this as our venture spirit.

**Yamakita [M]:** I understood very well. Thank you for taking my questions. That's all from me.

**Moderator [M]:** Thank you very much. The next question is from Okada-san. Please go ahead.

**Okada [Q]:** Thank you. My name is Okada, from Yakuji Nippo (Pharmaceutical Daily News).

For my first question, did you have any conditions, age or otherwise, for selecting a new chairman or president?

**Shin Ashida [A]:** In terms of the conditions, as I mentioned, the Company developed around research, and because we want this to continue, we chose Sonoda. The main reason we considered the two of them was that we chose Toru Ashida to support that role, both financially and in terms of personnel. In addition, we would like to create a good structure over the next year for the people who will support the two of them.

**Toru Ashida [A]:** I myself was in the clinical trial industry for more than 10 years before joining JCR, but I am not from the pharmaceutical industry. The Company was founded when I was an elementary school student. When I was still a child, about 10 years after its founding, employees, researchers, and factory workers often came to our house. When I was a high school student, I worked part-time at the urokinase factory, and the spirit of that period of the town factory has been ingrained in my body.

In that sense, as Mr. Sonoda said about the venture spirit, it involves some risk. I would like to research what I can do for that, and I would like to support Mr. Sonoda in his efforts to create an organization and culture that will enable JCR to produce innovations that only JCR can produce for the next 50 years.

**Okada [Q]:** I understand. Thank you. I have one more question. Just to confirm, in the area of contract revenue for this fiscal year, you said earlier that you understood that this is mainly JR-141 and that JR-171 was not included. Is that correct?

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**Ito [A]:** Regarding your current question, neither JR-141 nor JR-171 are included in the contract revenue for this fiscal year. As mentioned earlier, we cannot make a contract that assumes the contract from a previous period. We expect to receive those that have been delayed until this period, and milestone income from the progress of research with our joint research partners. In that sense, we have not included in this fiscal year's budget the contract revenues from the out-licensing of assets, such as JR-141 and JR-171.

**Okada [Q]:** Are you saying that last year also did not include JR-141 and JR-171?

**Ito [A]:** JR-141 was not included in the previous fiscal year. For JR-171, it was included in the original budget. The reason for the downward revision, which I think happened in January, was that we thought that we would be able to obtain the JR-171 license in the previous fiscal year and had included it in the budget, but the contract was no longer expected to be awarded.

**Okada [Q]:** I understand. Can you tell us about the products you are anticipating for this fiscal year?

**Ito [A]:** I will refrain from answering what is expected for this fiscal year.

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

**Moderator [M]:** Thank you very much. The next question is from Mr. Hashiguchi. Please go ahead.

**Hashiguchi [Q]:** I am Hashiguchi from Daiwa Securities. Thank you.

The first question is about the relationship between how you plan for contract revenue and your company's stance on out-licensing negotiations. Since JR-141 is a stand-alone product and Phase III trials are continuing, it may not matter much for the progress of development whether a partner is found or not. On the other hand, regarding JR-171, I think what you have said before is that it is necessary to find a partner in order to further develop it in the future. In that sense, is it correct to understand that although JR-171 is not factored into the upfront contract payments and earnings forecast, your company is negotiating with such a stance that you would like to find a partner as soon as possible? Is it a situation where you are taking a little time?

**Ito [A]:** Thank you for your question, Mr. Hashiguchi. You are correct, and JR-171 is now an asset that is subject to partnership. We are still in discussions with several companies regarding this matter, and we would like to out-license JR-171 as soon as possible.

**Hashiguchi [Q]:** Thank you very much. What should we understand about why it is not included in the plan?

**Ito [A]:** As I mentioned earlier, we made two downward revisions last year, so as much as possible, we do not want to revise downward. With that in mind, we have not included JR-171 in this forecast of contract revenue.

**Hashiguchi [Q]:** Thank you. Secondly, regarding JR-141, I have not seen any announcement from the FDA that it has received breakthrough therapy designation. Why is that? Denali has received breakthrough therapy designation for a compound similar to JR-141 and for a compound in a similar clinical trial development situation in the United States. I see that you have FDA support, but has your company applied for this? If your company does not have this designation, what do you think the difference is between your company and Denali?

**Bechet [A]\*:** What you say is correct. At this point, we still have to do that.

**Hashiguchi [Q]:** In other words, you have not applied yet?

**Bechet [A]\*:** We applied a few years ago, but the data was not advanced enough, so we have not yet received the designation.

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**Hashiguchi [Q]:** I think their thinking may have changed in some areas, so is it correct to say that there is a possibility that you will try again in the near future?

**Bechet [A]\*:** I believe this will be part of a broader discussion with the FDA. We will let you know when that time comes.

**Hashiguchi [M]:** Thank you.

**Moderator [M]:** The next question is from Narita-san. Please go ahead.

**Narita [Q]:** My name is Narita from the Nikkan Yakugyo. I would like to ask one question. Chairman and President Ashida, you will assume the position of director and founder on April 1 next year, and you will be entrusting the management to the chosen two. I would like to ask how you yourself will be involved in the future and what stance will you take? Thank you.

**Shin Ashida [A]:** I will leave the management to the two of them and the people surrounding them. I will also leave to them the talking to the companies and people I have been involved with, but I think it will be my job to support them from the side so that they can make good contacts with such companies.

**Narita [M]:** Thank you.

**Moderator [M]:** Thank you very much. The next question is from Mr. Muraoka. Please go ahead.

**Muraoka [Q]:** Thank you very much. I am Muraoka from Morgan Stanley MUFG Securities. I would like to confirm something about the contract money. When the Company revised downward for the previous fiscal year in March, I remember speaking with the IR person who said, as was said today, that the contract payment had been delayed beyond that period, but the nuance was that hopefully it would enter the April-June period. Is it safe to say that there is a high probability that a significant portion of the JPY5.5 billion for the current fiscal year can be deposited during the April to June period?

**Ito [A]:** Regarding when can we complete the contract that has been delayed, we are now assuming that the contract will be signed in H1.

**Muraoka [Q]:** In other words, is it better to think of it as the July to September period rather than April to June?

**Ito [A]:** Yes, we regard that as being more likely.

**Muraoka [Q]:** I understand. Assuming about JPY5 billion was delayed beyond the period that just ended, the JPY5.5 billion guidance for this period would be roughly about JPY500 million if the amount that finished by March occurred this year. It's just about addition and subtraction. For this fiscal year, perhaps if the delay had not happened in the previous year's period, would a normal run have resulted in guidance for a loss of JPY3 billion? I guess it's lucky that the delay happened and you were able to start this fiscal year with a profitable guidance. Should I assume that no, actually, you should still be able to make a substantial increase this period, including JR-171?

**Ito [A]:** Regarding this fiscal year, I don't think we are in a position to say how much more we can add. For the current fiscal year, the amount that has been delayed from the previous fiscal year will first be recorded in the current fiscal year, and we will be in the black for the current fiscal year. However, regarding your question about what if that didn't happen, I think we could have assumed revenue from a different contract payment. Unfortunately, we incurred a loss last fiscal year, but we would like to create a system that will allow us to continue to make a profit from this point on.

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**Muraoka [Q]:** I understand. Thank you. One more thing, about the FDA meeting, is my understanding correct that it is a so-called Type B meeting?

**Bechet [A]\*:** In this case, it is a Type C meeting.

**Muraoka [Q]:** As far as I know, Type B was a pre-application consultation, and Type C was a different type of consultation. Am I understanding this wrong?

**Bechet [A]\*:** There are different types of FDA meetings with different targets, but all will fit into the respective stages of development. That is on what kind of answers they are looking for. On our part, for this meeting, we are putting together Type C answers in the sense that they are evaluating, for example, accelerated approval and progress in the future.

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

**Moderator [M]:** Thank you very much. The next question is from Mr. Nagao. Please go ahead.

**Nagao [Q]:** Please excuse me for my repeated appearance. This is Nagao from Kobe Shimbun newspaper. I have two questions. This is the first time since what year and month since the Company last recorded a loss? I would like to ask the reason for the loss posted at that time.

**Shin Ashida [A]:** I've lost track of the year and the month, but we were taking urokinase from urine, obtaining a trypsin inhibitor, and obtaining interferon from white blood cells when Creutzfeldt-Jakob disease broke out. There was a time when the MHLW decided not to recognize human blood and urine because Creutzfeldt-Jakob disease could be transmitted via human blood and also from urine. I remember that we had a lot of raw materials at that time, and we lost money when we lost urine in the first year and blood in the second year.

**Nagao [Q]:** It seems like a very long time ago, during the founding period.

**Shin Ashida [A]:** I don't think it was a founding period, but rather a period when the recombinant stuff eventually changed from the kind of extraction we were doing to the recombinant stuff.

**Nagao [Q]:** I see. Is it possible to ask public relations about it later?

**Ito [A]:** Sorry, I would like to add something. I am Ito. As to your question about when the Company was in the red, it was in the fiscal year that ended March 31, 2006, and the fiscal year that ended March 31, 2007.

**Nagao [Q]:** Does the current explanation explain why it happened then?

**Ito [A]:** The reality at that time was as just explained by Chairman Ashida.

**Nagao [Q]:** I see. For my second question, I am sorry, but I understand that the production of urokinase, a protease derived from urine, was the founding business, but for what purpose was this enzyme used? What is it the raw material of?

**Shin Ashida [A]:** Urokinase is an enzyme that dissolves blood clots. The enzyme is produced from urine, and the substance is injected intravenously. The first company to produce it as a pharmaceutical product was former GREEN CROSS CORPORATION. The second was MOCHIDA PHARMACEUTICAL CO., LTD. . I forget how long ago, but after that, about 10 major Japanese companies bought the raw materials from us in order to sell urokinase, and that was the start of our company.

**Nagao [Q]:** What is the correct way to spell urokinase? What was the first one that was made?

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**Shin Ashida [A]:** Maybe Green Cross used urokinase and Mochida was uronase. I think the name was something like that.

**Nagao [Q]:** I see, each company had their own product name. What was made by JCR?

**Shin Ashida [A]:** We supplied the raw materials.

**Nagao [Q]:** I see. The raw material derived from urine. I understand. Thank you.

**Moderator [M]:** Thank you very much. Are there any further questions? If there are no further questions, we will conclude the question-and-answer session.

This concludes the financial results briefing for the fiscal year that ended March 31, 2025 of JCR Pharmaceuticals. Thank you all very much for your participation today.

[END]

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