JCR Pharmaceuticals Co., Ltd.

FY2025 Third Quarter Results Briefing Session

January 28, 2026

Event Summary

[Company Name]	JCR Pharmaceuticals Co., Ltd.
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[Participants]	
[Number of Speakers]	2

Yoh Ito	Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division
Kazunori Tanizawa	Expert Fellow

[Analyst Names]*	
Kazuaki Hashiguchi	Daiwa Securities
Shinichiro Muraoka	Morgan Stanley MUFG Securities
Kota Maeda	Nomura Securities
Miyabi Yamakita	Jefferies Japan
Hidemaru Yamaguchi	Citigroup Global Markets Japan

*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.

Presentation

Moderator: We would like to start the FY2025 Q3 results briefing session of JCR Pharmaceuticals Co., Ltd.

Disclaimer Regarding Forward-Looking Statement

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- This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Company's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.
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- The figures in this document are rounded down to the nearest million yen, and percentages are rounded to the nearest whole number. As a result, there may be discrepancies in the total figures.

We would like to mention some points before the start of the briefing. In this presentation, we may state forward-looking statements based on our current expectations, all of which are subject to risks and uncertainties.

Today's presentation and the materials used are intended to provide information about our business to shareholders, investors, and the press. The information on the developed products and pharmaceuticals is not intended as advertising, medical advice, or the like. A script of today's presentation and Q&A session will be available on our official website at a later date.

Let me now introduce today's speakers. Yoh Ito, Senior Executive Officer, Executive Director, Corporate Strategy Division. Kazunori Tanizawa, Expert Fellow. These two members.

The materials to be used today were posted on our website at 5:00 PM today. If you need the documents at hand, please refer to them.

This presentation will last approximately one hour and will include a presentation and Q&A session. Questions will be taken in batches after all presentations have been completed. The Q&A session will last approximately 40 minutes.

Ito will now explain the consolidated financial results for Q3 of the fiscal year ending March 31, 2026. Thank you very much.

Overview: Consolidated Financial Results

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(Unit : million yen)

Consolidated	FY2024	FY2025			
	Q3 YTD	Q3 YTD	Year-on-year Difference	Year-on-year Ratio	Progress Rate
Net Sales	25,880	**30,353**	+4,472	+17.3%	76.8%
Cost of Sales	7,007	**6,767**	(239)	(3.4)%	72.0%
Gross Profit	18,873	**23,585**	+4,712	+25.0%	78.4%
Selling, General and Administrative Expenses	19,627	**23,158**	+3,530	+18.0%	78.0%
SG&A Expenses	9,702	**9,786**	+83	+0.9%	74.1%
R&D Expenses	9,925	**13,372**	+3,447	+34.7%	81.0%
Operating profit	(754)	**427**	+1,181	-	-
Non-operating Income	200	**895**	+694	+345.6%	-
Non-operating Expenses	827	**611**	(216)	(26.1)%	-
Ordinary profit	(1,380)	**711**	+2,091	-	-
Extraordinary Income	1,065	**2,091**	+1,026	+96.4%	-
Extraordinary Losses	2	**31**	+29	-	-
Profit before Income Taxes	(317)	**2,772**	+3,089	-	-
Income Taxes	258	**1,028**	+769	+297.1%	-
Profit Attributable to Owners of Parent	(576)	**1,744**	+2,320	-	-
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	11,121	**14,117**	+2,996	+26.9%	79.8%

Additional Remarks

- Net Sales increased, driven by higher upfront and milestone payments from licensing agreements.
- Cost of sales ratio (excluding income from contractual payment) rose slightly due to lower capacity utilization.
- SG&A increased mainly due to higher co-promotion fees in line with sales growth.
- R&D expenses increased following an upfront payment for license rights.
- Non-operating income rose on foreign exchange gains.
- Extraordinary income reflected subsidy Income for the Kobe Science Park Center (API Plant).

Net Sales	FY2024 Q3 YTD	FY2025 Q3 YTD	Difference
Cost of Sales Ratio	27.1%	**22.3%**	(4.8)%
Cost of Sales Ratio *excluding income from contractual payment	25.9%	**26.4%**	+0.5%
R&D Expenses Ratio	38.3%	**44.1%**	+5.7%
Operating Profit Ratio	(2.9)%	**1.4%**	+4.3%

YTD: year to date 3

Ito: My name is Ito. Thank you very much for your participation in our meeting today. I will now explain the consolidated results for Q3, which we announced today at 5:00 PM.

First of all, the financial results this time show that net sales for Q3 totaled JPY30,353 million, operating profit was JPY427 million, and profit attributable to owners of parent was JPY1,744 million, representing an increase in both sales and profit compared to the same period last year.

There are two points: One is that we have recorded an upfront payment for the contract with Italfarmaco, which was released on December 24. The other one, which also took quite a long time, is our Kobe Science Park Center API plant. This was constructed with the support of a subsidy, and the subsidy has finally been confirmed, and as a result, the subsidy income has been recorded as extraordinary income. A stand-alone release on this has also been issued today.

Breakdown of Net Sales (Consolidated)

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(Unit: million yen)

Consolidated	FY2024	FY2025			
	Q3 YTD	Q3 YTD	Year-on-year		Progress Rate
			Difference	Ratio	
GROWJECT™	14,177	**13,539**	(638)	(4.5)%	76.1%
IZCARGO™ *	4,456	**5,179**	+723	+16.2%	80.9%
TEMCELL™HS Inj.	2,296	**2,212**	(84)	(3.7)%	81.9%
Treatments for renal anemia	2,595	**2,346**	(249)	(9.6)%	65.2%
Epoetin Alfa BS Inj. [JCR]	1,250	**595**	(654)	(52.4)%	54.1%
Darbepoetin Alfa BS Inj. [JCR]	1,345	**1,750**	+405	+30.1%	70.0%
Agalsidase Beta BS I.V. Infusion [JCR]	1,149	**863**	(285)	(24.8)%	54.0%
Total Core Products	24,675	**24,141**	(533)	(2.2)%	75.2%
Income from contractual payment	517	**5,249**	+4,732	+914.9%	90.5%
Other*	688	**961**	+273	+39.7%	-
Total Net Sales	25,880	**30,353**	+4,472	+17.3%	76.8%

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

Additional Remarks

- GROWJECT™, IZCARGO™, and TEMCELL™ HS Inj. continued steady performance.
- GROWJECT™ revenue declined due to drug price revisions.
- Sales of the treatments for renal anemia treatments were in line with supply plans to Kissei Pharmaceutical Co., Ltd.
- Sales of Agalsidase Beta BS I.V. Infusion [JCR] were in line with supply plans to Sumitomo Pharma Co., Ltd.
- Licensing revenue primarily consisted of upfront and milestone payments.
- Other income increased due to higher sales from the NPS program.

YTD: year to date 4

Before going into the details of the financial results, I would like to first explain the sales by product on the next page.

First, sales of GROWJECT, IZCARGO, and TEMCELL all remained steady. Sales of GROWJECT totaled JPY13,500 million, a decrease of JPY600 million from the previous year, but the number of units sold was slightly higher than the previous year, so the decrease was mainly due to the NHI price revision.

Sales of IZCARGO totaled JPY5,100 million, an increase of JPY700 million from the previous year. TEMCELL sales were JPY2,200 million, a decrease of JPY80 million from the previous year, but as you can see here, the annual progress rate for both drugs are steady.

The sales of Epoetin Alfa and Darbepoetin Alfa are based on the supply plan with Kissei Pharmaceutical, which is our sales partner. The sales of Agalsidase Beta are based on the supply plan with Sumitomo Pharma.

As for Epoetin Alfa, sales were approximately JPY600 million, a decrease of JPY650 million compared to the previous year, and sales of Darbepoetin Alfa were JPY1,750 million, an increase of JPY400 million compared to the previous year. Sales of Agalsidase Beta were JPY860 million, a decrease of JPY285 million from the previous year.

However, we have revised the sales figures for all three products in the revised earnings forecast, which I will explain later.

Under this, income from contractual payment totaled JPY5,249 million, an increase of JPY4,732 million over the previous year. In Other, sales were JPY961 million, an increase of JPY273 million over the previous year, which was due to increased sales from the NPS program.

Total sales were JPY30,300 million, or JPY4,470 million more than the same period last year.

Overview: Consolidated Financial Results

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(Unit : million yen)

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Net Sales	25,880	**30,353**	+4,472	+17.3%	76.8%
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Operating profit	(754)	**427**	+1,181	-	-
Non-operating Income	200	**895**	+694	+345.6%	-
Non-operating Expenses	827	**611**	(216)	(26.1)%	-
Ordinary profit	(1,380)	**711**	+2,091	-	-
Extraordinary Income	1,065	**2,091**	+1,026	+96.4%	-
Extraordinary Losses	2	**31**	+29	-	-
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Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	11,121	**14,117**	+2,996	+26.9%	79.8%

Additional Remarks

- Net Sales increased, driven by higher upfront and milestone payments from licensing agreements.
- Cost of sales ratio (excluding income from contractual payment) rose slightly due to lower capacity utilization.
- SG&A increased mainly due to higher co-promotion fees in line with sales growth.
- R&D expenses increased following an upfront payment for license rights.
- Non-operating income rose on foreign exchange gains.
- Extraordinary income reflected subsidy Income for the Kobe Science Park Center (API Plant).

Net Sales	FY2024 Q3 YTD	FY2025 Q3 YTD	Difference
Cost of Sales Ratio	27.1%	**22.3%**	(4.8)%
Cost of Sales Ratio *excluding income from contractual payment	25.9%	**26.4%**	+0.5%
R&D Expenses Ratio	38.3%	**44.1%**	+5.7%
Operating Profit Ratio	(2.9)%	**1.4%**	+4.3%

YTD: year to date 3

Let me go back to page one and explain the contents of the financial statements.

As I mentioned, net sales were JPY30,300 million and cost of sales was JPY6,767 million, a decrease of JPY239 million compared to the previous year. However, please see the cost of sales ratio, top of the table at the bottom right. The cost of sales ratio, excluding income from contractual payment, is shown in the second row, and it is 26.4%, which is a positive increase of 0.5% compared to the same period last year.

As we have said in our two previous quarterly results presentations, this is a slight increase due to lower factory utilization rates. Gross profit after deductions was JPY23,585 million, an increase of JPY4,700 million compared to the same period last year.

SG&A expenses are JPY23,158 million, of which selling, general, and administrative expenses are JPY9,786 million. This is an increase of JPY83 million, mainly due to an increase in commissions paid to co-promotion partners.

R&D expenses totaled JPY13,372 million, an increase of JPY3,447 million. As I mentioned at the beginning of this presentation, we have included in R&D expenses an upfront payment for the licensing rights we obtained as a result of the agreement with Italfarmaco. On the other hand, normal development is progressing smoothly.As a result, operating profit was JPY427 million. Non-operating income of JPY895 million is about JPY700 million more than in the previous year, mainly due to foreign exchange gains. Non-operating expenses totaled JPY611 million. Ordinary profit was JPY711 million.

Extraordinary income of JPY2,091 million was recorded. In this extraordinary income, the subsidy for the API plant at the Kobe Science Park Center, which I mentioned earlier, has been finalized, and the associated subsidy income has been recorded here. The amount is approximately JPY1,880 million.

Extraordinary losses amounted to JPY31 million, resulting in profit before income taxes of JPY2,700 million, and after deducting income taxes, profit for Q3 amounted to JPY1,744 million.

Revision of FY2025 Consolidated Financial Forecast

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	Net Sales (Unit: million yen)	Operating Profit (Unit: million yen)	Ordinary Profit (Unit: million yen)	Profit Attributable to Owners of Parent (Unit: million yen)	Earnings Per Share (Unit: yen)
Previously announced forecasts	37,800	2,600	2,400	3,000	24.22
Revised forecasts	**39,500**	**400**	**400**	**1,600**	**13.12**
Change	1,700	(2,200)	(2,000)	(1,400)	-
Change (%)	4.5%	(84.6)%	(83.3)%	(46.7)%	-
Actual Results of the previous fiscal year	33,072	(6,650)	(7,477)	(4,759)	(38.43)

Additional Remarks

Net Sales: revised upward by 1,700 million yen, reflecting stronger-than-expected sales of renal anemia and treatment for fabry disease
Operating profit: revised downward by 2,200 million yen due to higher COGS and SG&A

- ✓ COGS: +1,200 million yen, from the previous forecast, driven by higher sales and changes in the product mix
- ✓ SG&A: +1,200 million yen, as depreciation prior to subsidy confirmation for the Kobe Science Park Center (API Plant) was recognized and higher Q3 spending was factored in
- ✓ R&D: +1,500 million yen, following an upfront payment for the exclusive license for givinostat in Q3

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Now, I will explain the revision to the consolidated financial forecast announced simultaneously this time.

As you can see, we have revised profits downward.

Net sales figures are shown on the next page.

Revision of FY2025 Consolidated Financial Forecast

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(Unit: million yen)

	Previously announced forecasts	**Revised forecasts**	Change	Change(%)	Reference: FY2024 Results
GROWJECT™	17,800	17,800	—	—	18,098
IZCARGO™*	6,400	6,400	—	—	5,718
TEMCELL™HS Inj.	2,700	2,700	—	—	2,904
Treatments for renal anemia	3,100	3,600	500	16.1%	3,784
Epoetin Alfa BS Inj. [JCR]	800	1,100	300	37.5%	1,690
Darbepoetin Alfa BS Inj. [JCR]	2,300	2,500	200	8.7%	2,093
Agalsidase Beta BS I.V. Infusion [JCR]	1,100	1,600	500	45.5%	1,149
Total Core Products	31,100	32,100	1,000	3.2%	31,655
Income from contractual payment	5,500	5,800	300	5.5%	517
Other*	1,200	1,600	400	33.3%	898
Total Net Sales	37,800	39,500	1,700	4.5%	33,072

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

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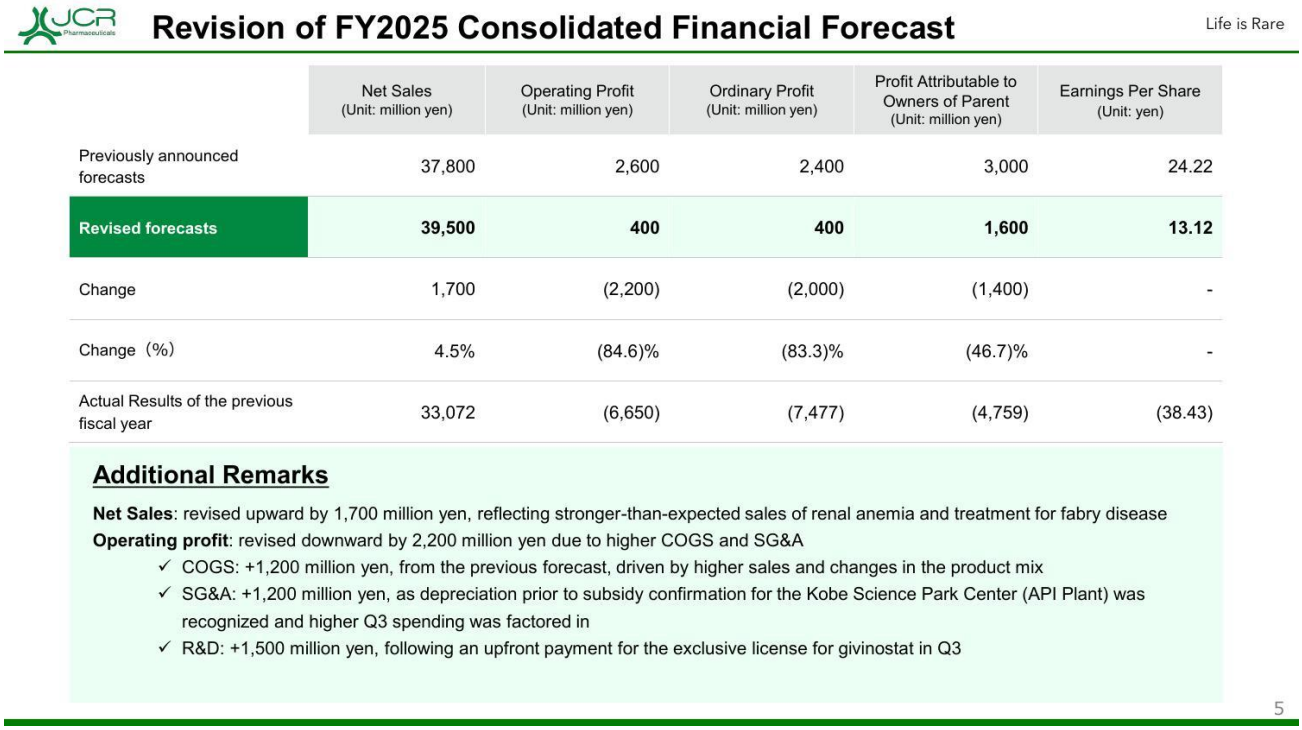
As you can see here, GROWJECT, IZCARGO, and TEMCELL are all assumed to be as initially announced and forecast.

On the other hand, for Epoetin Alfa, Darbepoetin Alfa, and Agalsidase Beta, we expect to add JPY300 million, JPY200 million, and JPY500 million, respectively. These are all increases in collaboration with Kissei Pharmaceutical and Sumitomo Pharma, and I hope you will understand that these figures are based on discussions with them.

Income from contractual payment was JPY5,800 million, an increase of JPY300 million from the original budget of JPY5,500 million. This means that there is an expected one-time contract payment by the end of this March, and we are increasing the figure by that amount.

Other shows an increase of JPY400 million in sales, totaling JPY1,600 million, primarily due to anticipated growth in NPS program sales. Total net sales are expected to be JPY39,500 million, an increase of JPY1,700 million.

Please go back to the previous page.



Revision of FY2025 Consolidated Financial Forecast

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	Net Sales (Unit: million yen)	Operating Profit (Unit: million yen)	Ordinary Profit (Unit: million yen)	Profit Attributable to Owners of Parent (Unit: million yen)	Earnings Per Share (Unit: yen)
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Change (%)	4.5%	(84.6)%	(83.3)%	(46.7)%	-
Actual Results of the previous fiscal year	33,072	(6,650)	(7,477)	(4,759)	(38.43)

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- ✓ COGS: +1,200 million yen, from the previous forecast, driven by higher sales and changes in the product mix
- ✓ SG&A: +1,200 million yen, as depreciation prior to subsidy confirmation for the Kobe Science Park Center (API Plant) was recognized and higher Q3 spending was factored in
- ✓ R&D: +1,500 million yen, following an upfront payment for the exclusive license for givinostat in Q3

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As I mentioned earlier, we are projecting an increase in net sales of JPY1,700 million from JPY37,800 million to JPY39,500 million, but operating profit has been revised downward by JPY2,200 million.

The first factor is cost of sales. The cost of sales increases partly due to higher sales volume, but the increase is often amplified by changes in the product mix. We expect an increase of JPY1,200 million over our initial forecast.

Regarding SG&A expenses, as I have mentioned several times, the subsidy for the Kobe Science Park Center API plant has been finalized. Depreciation incurred up to this finalization is recorded. The reason why we are deliberately stating that the depreciation is being recorded here is that we originally assumed that the finalization of the subsidy would occur earlier in the fiscal year, but since it was delayed until this December, we are recording depreciation for that portion of the subsidy.

In addition, we have increased the amount by JPY1,200 million, taking into account the past performance and the increase in royalties on sales, as I mentioned earlier.

Next, R&D expenses have been revised upward by JPY1,500 million from the previously announced forecast, as an upfront payment for Givinostat, which was in-licensed from Italfarmaco, has been included in R&D expenses in Q3 of this fiscal year.

The above are the revisions to the consolidated financial forecast.

Agreement with Italfarmaco (Press Release in Dec, 2025)[1]

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- **Development and Commercialization of Givinostat for DMD**
  - Exclusive licensing agreement (Japan)
- **Strategic collaboration for the treatment of rare diseases**
  - Enhancing both companies' portfolios
  - Exploring joint opportunities across JCR's R&D pipeline and platform technologies

1. January 23, 2026: Briefing session held regarding the agreement with Italfarmaco (link)

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We recently had a briefing on January 23; we released a press release regarding the contract with Italfarmaco on December 24 of last year. We have obtained the rights for the development and commercialization of Givinostat for the treatment of Duchenne muscular dystrophy, and this is a conclusion of an exclusive license agreement in Japan.

We have also entered into a strategic alliance for the treatment of rare diseases to expand our portfolios and explore joint opportunities using our R&D pipeline and platform technologies.

Givinostat: Oral Non-Steroidal Treatment for DMD

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1 Distinct mechanism of action from other DMD therapies

- HDAC inhibitor with mutation-agnostic mechanism of action

2 Regulatory approvals outside Japan

- Approved in major markets, including the US and the EU[1]
- Clinical evidence demonstrated in placebo-controlled study

3 Synergy with our core strengths

- Extensive expertise in rare disease drug development
- Robust network with clinicians treating patients with DMD
  - >60% coverage of DMD-treating institutions with existing products (internal data)

4 Strong commercial potential in Japan

- ~3,500 individuals in Japan diagnosed with DMD[2]
  - Over 1,000 individuals: Ambulatory, ≥6 years of age[3]
  - Over 3,000 individuals: ≥6 years of age[3]

DMD, duchenne muscular dystrophy

1. US: Approved for patients with DMD aged 6 years and older, EU: Conditionally approved for ambulatory DMD patients aged 6 years and older and already being treated with corticosteroids
2. Kawai M. *No To Hattatsu.* (Japanese) 2013;45(Supple.):S324 3. Company estimates based on Remudy (Registry of Muscular Dystrophy) and Nakamura H et al. *Orphanet J Rare Dis.* 2013;8:60

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I would like to mention Givinostat, although this is a duplicate of the explanation I gave the other day. This is an oral, non-steroidal DMD treatment.

It has a different mechanism of action from existing drugs and is an HDAC inhibitor that can be used independently of genetic mutations, making it suitable for a wider range of patients.

This drug has been approved in the US, Europe, and other major countries, and from the Japanese point of view, there is a drug lag, and we are aware that this is a long-awaited drug. We believe that the drug has solid evidence shown in placebo-controlled clinical trials.

We have introduced this drug, which we believe is a product that synergizes with our strengths. As you know, we have extensive development experience in the pediatric and rare disease areas. We also have a strong network of doctors who follow up with these DMD patients. We believe that we have already covered more than 60% of the facilities that follow DMD patients in the sales of our existing products.

We also believe that this drug has great commercial potential. We believe that there are approximately 3,500 DMD patients in Japan. This is indicated in the US for patients 6 years of age and older, which means that there are more than 3,000 patients, considering that they are 6 years of age and older. In Europe, it is indicated for patients aged 6 years and older who are ambulatory; even considering this, there would be over 1,000 patients.

When we speak of commercial potential, we mean that it is a drug with broad applicability in situations where steroids are the only option; we believe this is a drug that can be widely adopted. We believe that if you estimate the annual treatment cost of non-steroidal drugs currently approved in Japan, you can get an idea of the scale of the applicability.

As for when the product will be put on the market, as I mentioned the other day, we are aiming to obtain approval by 2028.

Overview of Clinical or Late Preclinical Pipeline

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Code	Indication	Status	Milestones/Comments
		Preclinical / Phase 1 / Phase 2 / Phase 3	
JR-141	MPS II (Hunter syndrome)	Global Ph3	• On track for ~FY2027: Approval in US, EU, Brazil
JR-142	Pediatric GHD	Ph3 (Japan)	• Patient recruitment on track
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed	• Partnering activities ongoing
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany) Ph1 (Japan)	• Ph1/2: Achieved 1-year clinical data for the initially planned dose groups • Ph1: Patient enrollment completed • Actively pursuing early approval in Japan
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)	• Recruitment of first cohort completed • Actively pursuing early approval in Japan • Partnered with MEDIPAL HOLDINGS
JR-471	Fucosidosis		• Commencement of natural history study • Partnered with MEDIPAL HOLDINGS
JR-479	GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease)		• Partnered with MEDIPAL HOLDINGS
Givinostat	Duchenne muscular dystrophy	Approved in major markets, including the US and the EU	• Under discussions with PMDA toward domestic approval by 2028

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My explanation, the last slide, is about the clinical or late preclinical pipeline.

JR-141, from the top, is in Phase 3 of the global trial and is progressing well. As we have said in the past, approvals in the US, Europe, and Brazil are planned in FY2027.

JR-142, this is a weekly formulation of growth hormone, and patient enrollment is progressing well. It is in Phase 3. JR-171, we are negotiating for its out-licensing.

JR-441, a drug for mucopolysaccharidosis type IIIA, has collected one year of clinical data in the initially planned treatment groups during the Phase1/2 trials in Germany. The target number of patients has also been enrolled in the Phase 1 trial in Japan. We are taking steps to obtain approval in Japan as soon as possible.

We have completed the enrollment of the first cohort of patients for JR-446, a drug for mucopolysaccharidosis type IIIB, and we are working to obtain approval for this drug as soon as possible in Japan. This drug has been licensed to MEDIPAL HOLDINGS.

JR-471, fucosidosis treatment. We have started natural history research on this drug, which is also licensed out to MEDIPAL HOLDINGS.

JR-479 is another drug licensed to MEDIPAL HOLDINGS this year. It is in the preclinical stage.

The bottom is Givinostat, which I mentioned earlier, and I would like to reiterate that we are currently discussing the development plan with the authorities with the aim of obtaining approval in Japan as early as possible, by 2028.

That is all I have to say.

Question & Answer

Moderator [M]: We will now move to the question-and-answer session. We will take questions first from analysts and then from the media.

When it is your turn to ask a question, I will make a nomination. Please mention your company name and your name before asking questions. Questions will be asked in a question-and-answer format, with a limit of two questions per person, but you may raise your hand as many times as you like.

I will now begin the question-and-answer session. First of all, Mr. Yamaguchi, please go ahead.

Yamaguchi [Q]: I'm Yamaguchi from Citi. Thank you very much. The first question is related to Givinostat. I can see it as a one-time payment of roughly JPY1.5 billion. We may not know because the contract has not started, but looking at the full-year forecast alone, it has been revised downward significantly, so I wonder if there will be any additional, temporary payment as for Givinostat in the future, other than this one-time payment.

Or, you may not be sure whether you'll pursue R&D next fiscal year or beyond, but if you do, I'd like to know more about the total costs involved, such as how much it would cost.

Ito [A]: Thank you for your question, Mr. Yamaguchi. We can't disclose the details of the contract, but it is generally set at the time of approval, for example, or at the time of certain criteria, such as when a certain quantity of sales has been made. However, we recognize that this in itself is not particularly something that can be gained significantly from a normal contract.

As for development, it is still not clear what kind of development will take place, so it is difficult to say how much it will cost, but we would like to do it as quickly as possible with as little cost as possible. That is the kind of plan we would like to follow.

Tanizawa [A]: We are currently examining about the trial, but we do not envision a large-scale trial at this time. That is all.

Yamaguchi [Q]: Thank you very much. The second is about an interim analysis of JR-141. I vaguely remember that it was supposed to come out in H1 of 2026, but is there any progress on that now? Can you give us a hint on whether it is likely to come out on schedule or not?

Ito [M]: What you just mentioned is an interim analysis of 60% of patients.

Yamaguchi [M]: Yes, you are right.

Ito [A]: We are in the process of making progress on that after two years, and I think we are making good progress.

Yamaguchi [Q]: You mean, it is H1 of 2026, so it will be disclosed as soon as it is put together. You are not sure when it will be of H1 of the year, is this what you mean as your schedule?

Ito [A]: Regarding this matter, we are discussing various future steps with the authorities, so I have nothing further to say.

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

Moderator [M]: Thank you very much, Mr. Yamaguchi. Now, Mr. Muraoka, please go ahead.

Muraoka [Q]: Thank you. I'm Muraoka from Morgan Stanley. I too would like to ask you about Givinostat first. I was not able to attend the last briefing, "Briefing Session on the Agreement with Italfarmaco Announced on December 24, 2025," so I only read the notes of the briefing, but I think I understood a little comment from your company in the section on R&D costs for the next fiscal year onward, that JCR would not have any R&D burden in the last briefing. Is that our misunderstanding? First, I would like to ask about that point.

Tanizawa [A]: Thank you for your question. I'm Tanizawa. As for the development costs, as you are aware, they are borne not by JCR but by the partner.

Muraoka [Q]: So, I understand that R&D expenses will not increase from the next fiscal year starting in April, but when milestone payments are made, they will be included in R&D expenses at that time, since your company is under J-GAAP?

Ito [A]: In Mr. Yamaguchi's earlier question, I talked about development plans, etc., but as you said, we are not responsible for development costs. I apologize for any confusion that may have arisen earlier, but I would like to correct it.

When future milestones are achieved, they will be recognized as R&D expenses; however, there are questions regarding when these expenses will be incurred and what they will be charged against. This time, they are being recognized as development expenses. For example, if a one-time payment is made after approval, this can be capitalized as an asset and then amortized over time. That will also depend on when we make the payment.

Muraoka [Q]: Thank you. Let me ask you to elaborate it a bit more. It is likely to affect my projections for the next and the following fiscal year.

In other words, there will be no increase in R&D expenses in Givinostat in the next fiscal year, since I believe the launch was scheduled for 2028. There may be some in 2027 if you can apply just in time, but the possibility is slim. I think it would be very natural, in my opinion, to assume that there will be a one-time payment at the application milestone in 2028, and that R&D will increase a bit then. Any comments on my own arbitrary assumption would be appreciated.

Ito [A]: It is difficult for me to comment on this, but I think one point, from an accounting point of view is whether it would be recorded as a one-time expense or amortized as an asset.

If I were to speak on the assumption of 2028, I think it is conceivable that what you just mentioned is something like that. I may not have answered your question, but this is what I can say at this moment.

Muraoka [Q]: Thank you. Just one more, about Givinostat. I understand that you also mentioned at the last briefing that this is a 20% share in the US. Is this a share of the number of patients, or a share of sales? What share?

Is it a share among those who can walk or is it a share among those over 6 years old? It's hard to imagine the product having that many sales. Or, the month when ELEVIDYS rapidly lost momentum, I'm not quite sure which stage you're referring to, so could you please explain it again?

Ito [A]: This is what we heard from Italfarmaco, and I think it was approved in the US in March of 2024. So, about one year and nine months until the end of last year, the share of patients at that stage. To put it more simply, I meant to say that the drug has spread to the point where one in five patients is using the drug in the past one year and a half, or one year and nine months.

Muraoka [Q]: I think the number of DMD patients in the US was 15,000, so that means 3,000 patients are using this drug, is that correct?

Ito [A]: There may be a way to assume that denominator, but that's basically what it is.

Muraoka [Q]: Then another question, is the use period of this short? This is the duration of use in the real world.

Tanizawa [A]: Yes, you are right. As I mentioned earlier, the period of use after approval is still about one year and nine months, but the drug itself will continue to be used throughout the lifetime.

Muraoka [M]: I see. I'll try the calculation again. At any rate, I have asked two questions, so I will end here once and for all.

Moderator [M]: Thank you for your questions, Mr. Muraoka. Then, Mr. Hashiguchi, please go ahead.

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Thank you very much. The first is about the development pipeline and the meaning of the phrase "Actively pursuing early approval in Japan for JR-441 and JR-446," which you explained this time on the slide on page nine.

I don't think this has been explained before, but I was wondering if it is correct to understand that you are aiming for an early conditional approval based on the results of the Phase 1 or Phase 1/2 trials that have been conducted this time. And at this point, have you obtained sufficient data for such an application, or do you expect to do so in the future?

The situation may be different for each drug, but could you give us more details?

Ito [A]: Thank you for your question, Mr. Hashiguchi. Regarding the point you just made, JR-441 and JR-446 are both aiming for conditional early approval in Japan, and we are considering the possibility of doing so with the data obtained from this Phase 1/2 trials.

Hashiguchi [Q]: Have you already obtained such data? Or is it a situation where the data has not yet been compiled and you are hoping to get such data?

Ito [A]: I can't give you the details at this time, but we would like to file an application for approval with the data that comes out as the trial progresses.

Hashiguchi [Q]: Can you comment on the specific timing of when you are aiming to apply at this point?

Ito [A]: Sorry, I can't comment on that right now.

Hashiguchi [Q]: Thank you very much. Another point is that in your revision of the sales forecast, you commented that it was the result of discussions with the sales companies, Kissei Pharmaceutical, and others. Please explain the meaning of that.

Is this a matter of temporarily settling the issue in a manner of bringing forward the next period, or has the content of the drug price revision become sufficiently clear, leading to a change in the price compared to previous assumptions? I would appreciate it if you could tell me as much as possible, including how the story might affect the outlook for the next fiscal year and beyond.

Ito [A]: Yes, I see. First of all, as you know, Chugai Pharmaceutical will discontinue sales of their drugs in the field of Epoetin Alfa and Darbepoetin Alfa. Chugai's Epogin, right? I believe it is assumed that demand for our Epoetin or Darbepoetin will increase because Chugai announced the sales discontinuation.

We have been exchanging information with Kissei Pharmaceutical on a regular basis;, so we expect to have additional orders or sales.

The sales projection of Agalsidase Beta has also been revised upward due to strong sales by Sumitomo Pharma to medical institutions.

Hashiguchi [M]: I see, thank you. That is all.

Moderator [M]: Thank you very much, Mr. Hashiguchi. Mr. Maeda, your question, please go ahead.

Maeda [Q]: Thank you. I am Maeda from Nomura Securities. First, I would like to ask about the revision of the income from contractual payment. There has been a revised increase of JPY300 million this time. Could you please clarify whether this is related an existing contract that was originally in place, or it if is entirely new contract terms?

Or if there are any positives or negatives, such as the loss of something that was originally thought to be there, I would like to know about that as well.

Ito [A]: Yes, I see. The additional JPY300 million this time is for a new contract. This represents an increase based on the assumption that the likelihood of concluding a contract within the current fiscal period has risen significantly, despite it being something we have traditionally negotiated.

Maeda [Q]: Am I correct in understanding that this is not an extension line of the joint research with Acumen or something like that?

Ito [A]: Please understand that this is not an extension line of the conventional one.

Maeda [Q]: I see. One more thing, regarding R&D expenses, since you conducted in-licensing this time, I was wondering if R&D expenses are likely to be bumpy due to such one-time expenses such as upfront fees for the asset in-licensed or future in-licensing.

I would like to know if your company's accounting approach is to offset upfront contract income with one-time in-licensing expenses, or to keep R&D expenses at a certain level, or to bring the final profit to a positive level somehow, if there is any such approach.

Ito [A]: First of all, as far as the accounting approach is concerned, we are under Japanese GAAP, so upfront payments for the in-licensing unapproved drug must be recorded as expenses.

How we handle this is that it is a positive addition to R&D expenses, but it is naturally an investment in the future, and we decide whether or not to invest based on the anticipated benefits of that investment. If we believe that it will have a very significant effect, and we decide that we should conduct in-licensing even if it means increasing R&D expenses or increasing costs, or even reducing profits, then we will conduct it, even if it means increasing costs and reducing profits.

Does this answer your question?

Maeda [Q]: Thank you very much. In that sense, with the final deficit in the fiscal year ended March 31, 2025, is it correct to say that we must consider this risk for the fiscal year ending March 31, 2026 or for the fiscal year ending March 31, 2027 and beyond?

Ito [A]: Naturally, we always strive to avoid deficits and ensure profitability, and we hope to be able to do so.

Last year, we incurred a large deficit, which caused a great deal of inconvenience, and we are always thinking about how to avoid such a situation. In other words, how far can we go within that range? We may have to make adjustments in various areas, but we will be basically considering whether it is possible to do so.

Maeda [M]: I see, thank you. That's all from me.

Moderator [M]: Thank you very much, Mr. Maeda. Next question, Mr. Yamakita, please go ahead.

Yamakita [Q] : My name is Yamakita from Jefferies. Thank you very much. The first question from me is about Givinostat.

I thought the amount of up-front payment was a bit low after hearing the positive figure of 20% share in the US, but since Italfarmaco is not a biotech company, it does not need that much cash, so it is not so strange to think that the payment is concentrated on royalties, sales milestones, and the latter half. If there is anything you can comment on, please do.

Ito [A]: Thank you for your question. I can't give you any details on that point, however, especially if it's tail-heavy, or heavier in the latter half. I don't think it's particularly heavier compared to a standard case.

However, this time, we are looking to form a long-term partnership with Italfarmaco, not just a contract for this one drug. As you mentioned, they are a company mainly focusing on small molecules and we are a biopharmaceutical company. Therefore, we believe this agreement is based on the expectation that by focusing on the distinct strengths of both companies, we can explore various forms of collaboration moving forward.

Yamakita [Q]: In that case, there is the matter of which party pays which during the joint research. If they were to pay your company, would it be appropriate to consider this figure as an offset?

Ito [A]: Of course, this is an independent contract, but I think it can be said that the contract is based on the expectation of various cooperative relationships in the future.

Yamakita [Q]: I understand. Thank you very much. Second point, regarding IZCARGO. Is the unit price of this drug increasing? I think sales are quite strong, but Q4 looks somewhat conservative, but the plan has not been revised, and if unit prices are growing and are strong, is there any reason why they have not been revised?

Ito [A]: In the case of the current fiscal year, we had a significant increase in Q1 for IZCARGO, and after that, as you can see from this, the number of patients has been almost flat in terms of figures, so I think it reflects that.

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

Ito [M]: Thank you very much.

Moderator [M]: Thank you, Mr. Yamakita. Next, Mr. Muraoka, please go ahead.

Muraoka [Q]: Thank you very much for the second round. As a confirmation, or rather, a way of thinking about the next fiscal year, I have a question about the flip side of the story of whether JR-141 is likely to get a contract, although the competitors Re-Genex and Denali are facing PDUFA next month and in April, respectively.

If Re-Genex and Denali lose two in a row, does your company have any prospects for a partner who would sign on rather quickly? If so, can we hear, for example, that we can expect a one-time payment well into May?

I am very sorry that this question is too hypothetical, but it is very critical for the next term and I would appreciate any hints you can give me.

Ito [A]: Thank you for your question. I am not qualified to say what will happen to other companies, but I can honestly say that it is difficult to say what will happen in the situation you mentioned.

Naturally, there are a number of potential partners we are talking with, but it is difficult to say how this will affect the situation. That said, I have to admit that it is difficult to answer whether we are talking about something like April or May in itself. Sorry.

Muraoka [Q]: If both companies failed, is it correct to understand that there's no one for you at this point who can sign off on it?

Ito [A]: I think the answer to your question is that I can't say whether or not there is such a thing.

Muraoka [Q]: I see. Thank you very much. Another question, also about one-time payment related to JR-446, MPS IIIB. You mentioned that you were pursuing approval in Japan. Since this is a MEDIPAL-partnered product, is this a situation where you can expect a large milestone income if you can apply for it in the next fiscal year?

I don't know what has happened in the past with MEDIPAL products that have progressed this far, but what expectations should I have in terms of performance?

Ito [A]: Thank you. We are not able to discuss the details of the contract with MEDIPAL, but if it is approved, sales in Japan will naturally increase, but in terms of money, the number of patients in Japan alone is not that large, so it is necessary to take that into consideration.

However, we are sure that we would be very grateful for such a thing. I think it can be said that it is definitely something that is appreciated in terms of sales.

Muraoka [Q]: I see, thank you. This may also be a question of what basis to ask, but I think that recently there has been an increase in talk in Japan about buyouts in the healthcare area, management buyouts, fund buyouts, etc.

The situation that your company is in right now, where your business performance goes up and down drastically due to slight changes in R&D expenses, and where you are unable to have a good conversation with the capital market, I would appreciate it if you could give us your thoughts on this recent increase in buyouts. What do you think?

Ito [A]: I think you are right; as you just said, the increase in R&D expenses will cause significant fluctuations in performance. We have received many such comments, and we know that the problem is basically that our revenue base is unstable.

This has led to a structure in which the main profit and loss is dependent on income from contractual payment, and we believe that the most important issue for us is how to break away from this structure.

In that sense, we are determined to develop Givinostat quickly and bring it to market in Japan. We believe that this drug has the potential to significantly transform our sales and profit figures, so we aim to realize that potential. Or, as we are talking about a little further down the road, we will work with SanBio to stabilize our profit and loss base by realizing the Akugo project, in which we expect to be contracted to manufacture products for SanBio.

As you asked earlier on what would happen if the one-time payment increased, we would like to quickly bring our financial situation and profit/loss to a point where we can withstand such a situation, and we consider this to be a major issue. We are taking various measures to achieve this goal.

Muraoka [Q]: Thank you. It is safe to say that you are not thinking about something like distancing yourself from the capital market for a time, is that correct?

Ito [A]: We do not see it that way at this time.

Muraoka [M]: I see, thank you very much. That is all.

Moderator [M]: Thank you for your questions, Mr. Muraoka. Next question, Mr. Maeda, please go ahead.

Maeda [Q]: Thank you very much for the second round. I would like to ask you about the joint research with Acumen, and I would like to know if it is progressing as quickly as you had hoped at the beginning of the contract.

In particular, are they making good progress in acquiring the non-clinical data they plan to acquire by early 2026? What bottlenecks, if any, are occurring? I would appreciate any hints you can give me in this area. Thank you very much.

Ito [A]: I have heard that the progress of the contract with Acumen is proceeding without any particular change from what was initially expected.

Maeda [Q]: Is it difficult to comment further?

Ito [A]: Yes, you are right. It is difficult to say more than that.

Maeda [M]: I see. Thank you very much.

Moderator [M]: Thank you very much, Mr. Maeda. Next, Mr. Yamakita, please go ahead.

Yamakita [Q]: Thank you very much for the second round. This might be a bit of a vague question, but recently there seems to be a lot of discussion about new clinical trial approaches. For instance, the FDA is considering introducing Bayesian statistical analysis methods for rare disease clinical trials and making the criteria for determining their efficacy a bit more flexible. Additionally, they're exploring reducing the number of clinical trials if there is sufficient detection capability.

How much of your company is ready to adopt such new methods? Is there a clear indication that you have had quite a few discussions with the FDA about such areas in the US? Or are you going to be cautious after the precedent has been set? Please make a comment if there is any policy.

I thought Bayesian-related matters might significantly impact your company's assets, so I asked because I was curious about the possibility of implementation and practical application.

Ito [A]: Thank you for your question, Mr. Yamakita. I am not an expert in such matters, but we have a regulatory expert in the US, so I am gathering information in this area.

We have heard that various new approaches are emerging in the field of rare diseases, and if such approaches are useful in accelerating our development, we would like to consider coordinating with them as much as possible.

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

Moderator [M]: Thank you, Mr. Yamakita. Next, Mr. Yamaguchi, please start your question.

Yamaguchi [Q]: I'm Yamaguchi. I would like to confirm one thing, do you have any progress in the last three months toward out-licensing negotiations about JR-171?

Ito [A]: Thank you for your question. I have nothing special to say about JR-171, especially in the last three months.

However, there are various potential partners that are interested in this, and we hope to be able to make good announcements as soon as possible, but we have no particular progress to offer in response to your questions over the past three months. I think that is the answer to your question.

Yamaguchi [Q]: Thank you very much. As Mr. Muraoka also mentioned earlier, isn't there any particular progress on JR-141 as well? There are many things to consider, such as competition, etc.

Ito [A]: There is nothing in particular that I can tell you as of today about JR-141 either. We are working hard on this, and we hope to be able to announce it as soon as possible.

Yamaguchi [Q]: I see. So you are saying that you are not in a position to identify the next fiscal year or the following year in terms of timing, from your company, is that correct?

Ito [A]: I mean that I am not able to comment on such matters right now.

Yamaguchi [M]: I understand. Thank you very much, that's all from me.

Moderator [M]: Thank you very much, Mr. Yamaguchi. Do you have any other questions? Now, I would like to take questions from the media as well, if anyone has any questions.

Mr. Okada, please go ahead.

Okada [Q]: Thank you. This is Okada of Yakuji Nippo. Agalsidase Beta had sales of JPY860 million so far, and with the upward revision, you are expecting sales to double to JPY1.6 billion in Q4.

I think you mentioned earlier that sales to medical institutions are increasing, but I was wondering if you could tell us a little bit more about the factors.

Ito [A]: As I mentioned earlier, this is an upward revision due to increased demand at Sumitomo Pharma. Since Sumitomo Pharma is the actual seller of these products, we have nothing more to say about it.

Okada [M]: I see, thank you.

Moderator [M]: Thank you very much, Mr. Okada. The next question, Ms. Narita, please go ahead.

Narita [Q]: I am Narita from the Nikkan Yakugyo. I would like to ask you about Akugo. I believe that you have concluded a manufacturing contract with SanBio for the trial production, but if there is anything that has been decided on the future manufacturing schedule, please let us know.

Ito [A]: Regarding that, the current situation has not changed from the point where we have a contract for the trial production. We believe that at some point in the not-too-distant future, although we cannot specify when, we will probably enter into a contract for commercial production.

So I think we will be able to talk about specifics when that happens, but at this point, we are still in the process of signing a contract for the trial production, so there is no specific schedule that I can talk about.

Narita [Q]: I see. Would it be difficult for you to disclose, like, the contract in the next year or something like that as well?

Ito [A]: I hope we can do it soon, but I hope you understand that I cannot comment at this time as to when.

Narita [M]: I see. Thank you very much.

Moderator [M]: Ms. Narita, thank you very much. Is there any other question? If there are no more questions, I would like to conclude, although I have a little extra time. Thank you very much. We would like to end the question-and-answer session.

This concludes the FY2025 Q3 results briefing session of JCR Pharmaceuticals. Thank you very much for your participation today.

Ito [M]: Thank you very much.

[END]

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