JCR Pharmaceuticals Co., Ltd.

FY2026 First Quarter Results Briefing Session

July 30, 2026

Event Summary

[Company Name]	JCR Pharmaceuticals Co., Ltd.	
[Company ID]	4552-QCODE	
[Event Language]	JPN	
[Event Type]	Earnings Announcement	
[Event Name]	FY2026 First Quarter Results Briefing Session	
[Fiscal Period]	FY2026 Q1	
[Date]	July 30, 2026	
[Number of Pages]	21	
[Time]	17:30 – 18:17 (Total: 47 minutes, Presentation: 15 minutes, Q&A: 32 minutes)	
[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	3	
	Yoh Ito	Managing Executive Officer, Executive Director, Corporate Strategy Division
	Naoki Kawata	Director, Corporate Strategy Department, Corporate Strategy Division
	Kazunori Tanizawa	Expert Fellow, Director, New Product Planning Office, Corporate Strategy Division
[Analyst Names]*	Hidemaru Yamaguchi	Citigroup Global Markets
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Miyabi Yamakita	Jefferies
	Ryuta Kawamura	SBI SECURITIES
	Kazuaki Hashiguchi	Daiwa Securities
	Yo Mizuno	Tokio Marine Asset Management
[Reporter Names]*	Koichi Okada	Yakuji Nippo

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

Presentation

Moderator: We will now begin the financial results briefing for Q1 of the fiscal year ending March 2027 for JCR Pharmaceuticals Co., Ltd.

Before the briefing begins, we would like to make a note to all viewers. We will post the script for today's presentation and Q&A session on our website at a later date. Please note that in today's presentation, we may make forward-looking statements based on current expectations. However, please be aware that all such statements involve risks and uncertainties.

Today's presentation is intended to provide information about our business to shareholders, investors, and members of the media. It is not intended for promotional or advertising purposes, nor is it intended to provide medical advice or similar guidance.

Now, let me introduce today's speakers.

Yoh Ito, Managing Executive Officer, Executive Director, Corporate Strategy Division.

Ito: Thank you for coming today.

Moderator: Naoki Kawata, Director, Corporate Strategy Department, Corporate Strategy Division.

Kawata: Thank you for coming today.

Moderator: Kazunori Tanizawa, Expert Fellow, Director, New Product Planning Office, Corporate Strategy Division.

Tanizawa: Thank you for coming today.

Moderator: Today's speakers are these three individuals. Today's material was posted on our website at 15:30 today. If you need the material, please refer to it.

This information session is expected to last about one hour, including the presentation and a question-and-answer session. We have scheduled approximately 40 minutes for the Q&A session, and we will take questions from the audience after all presentations have concluded.

Managing Executive Officer, Ito will now provide an explanation.

Ito: Thank you very much for joining us at this earnings briefing. I will now explain our Q1 financial results.

Overview: Consolidated Financial Results (Q1 FY2026)

Life is Rare

(million yen)	FY2025 Q1 YTD	FY2026 Q1 YTD	Year-on-year Difference	Year-on-year Ratio	FY2026 Progress Rate
Net Sales	8,569	**9,700**	+1,130	+13.2%	21.2%
Cost of Sales	2,357	**2,249**	(107)	(4.6)%	21.2%
Gross Profit	6,212	**7,450**	+1,238	+19.9%	21.2%
Selling, General and Administrative Expenses	6,818	**9,554**	+2,736	+40.1%	28.1%
SG&A Expenses	3,469	**3,665**	+195	+5.6%	25.2%
R&D Expenses	3,348	**5,888**	+2,540	+75.9%	30.4%
Operating profit	(606)	**(2,103)**	(1,497)	-	-
Non-operating Income	74	**261**	+186	+249.4%	-
Non-operating Expenses	218	**242**	+23	+11.0%	-
Ordinary profit	(749)	**(2,084)**	(1,334)	-	-
Extraordinary Income	0	**0**	0	0.0%	-
Extraordinary Losses	1	**0**	(1)	(100.0)%	-
Profit before Income Taxes	(751)	**(2,084)**	(1,333)	-	-
Income Taxes	(205)	**(176)**	+28	-	-
Profit Attributable to Owners of Parent	(546)	**(1,907)**	(1,361)	-	-
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	3,518	**6,523**	+3,004	+85.4%	26.8%

Additional Remarks

- Net sales increased mainly due to higher contract revenue.
- Cost of sales ratio (excluding contract revenue) improved due to a favorable product mix.
- R&D expenses increased year on year and exceeded the plan, primarily due to the concentration of certain global clinical trial costs in the current period, and higher CRO-related expenses.
- Non-operating income increased mainly due to the recording of compensation income and foreign exchange gains.
- Non-operating expenses increased mainly due to higher interest expenses.

Net Sales	Q1 FY2025 YTD	Q1 FY2026 YTD	Difference
Cost of Sales Ratio	27.5%	**23.2%**	(4.3)%
Cost of Sales Ratio *Excluding contract revenue	27.7%	**26.1%**	(1.6)%
R&D Expenses Ratio	39.1%	**60.7%**	+21.6%
Operating Profit Ratio	(7.1)%	**(21.7)%**	(14.6)%

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Here is an overview of the financial results.

Net sales were JPY9,700 million, operating loss was JPY2,100 million, and loss attributable to owners of the parent was JPY 1,900 million.

Although net sales increased by JPY1,100 million, operating profit decreased by approximately JPY1,500 million.

Before we move on to the details of P&L, I'd like to explain the breakdown of sales by product on the next page.

Consolidated Net Sales Breakdown (Q1 FY2026)

Life is Rare

(million yen)	FY2025 Q1 YTD	FY2026 Q1 YTD	FY2026 Year-on-year Difference	FY2026 Year-on-year Ratio	FY2026 Progress Rate
GROWJECT™	4,495	**3,744**	(750)	(16.7)%	21.4%
IZCARGO™	1,562	**1,669**	+106	+6.8%	24.1%
TEMCELL™ HS Inj.	845	**721**	(123)	(14.6)%	26.7%
Treatments for renal anemia	897	**748**	(148)	(16.6)%	19.9%
Epoetin Alfa BS Inj. [JCR]	122	**183**	+61	+50.1%	12.5%
Darbepoetin Alfa BS Inj. [JCR]	775	**565**	(209)	(27.1)%	24.6%
Agalsidase Beta BS I.V. Infusion [JCR]	426	**256**	(169)	(39.9)%	12.3%
Total Core Products	8,226	**7,139**	(1,086)	(13.2)%	21.6%
Contract revenue	106	**1,474**	+1,367	+1278.8%	18.1%
Other	236	**1,086**	+850	+359.9%	-
Total Net Sales	8,569	**9,700**	+1,130	+13.2%	21.2%

Additional Remarks

- GROWJECT™ sales decreased year on year, partly due to the impact of the April 2026 NHI drug price revisions. Although sales fell short of the quarterly plan, JCR continues to aim to achieve the full-year plan.
- The number of patients treated with IZCARGO™ increased ahead of plan.
- TEMCELL™ HS Inj. remained solid against plan.
- Treatments for renal anemia posted sales in line with the supply plan for Kissei Pharmaceutical Co., Ltd.
- Agalsidase Beta BS I.V. Infusion [JCR] sales were in line with the supply plan for Sumitomo Pharma Co., Ltd.
- Contract revenue increased mainly due to receiving an option payment under the existing agreement.

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First, as I mentioned earlier, total sales, at the bottom of the table, were JPY9,700 million, representing an increase of JPY1,100 million compared to the same period last year.

Let's take a look at each product.

First, sales for GROWJECT totaled JPY3,744 million, a decrease of JPY750 million compared to the same period last year. Sales declined YoY, partly due to the impact of the drug price revision. This fell short of the quarterly target. This was because the interval between the shipments at the end of March and those in April was quite long due to the calendar schedule, which resulted in March shipments being stronger than expected.

Partly because of that, sales didn't grow much in April and May, and although June was strong, overall sales fell short of our target. Sales have been holding up well so far this month, and we believe we will be able to meet our full-year target. We intend to work toward achieving that goal.

IZCARGO's sales totaled JPY1,669 million, an increase of JPY106 million compared to the same period last year. The number of cases increased faster than planned. We have included a graph regarding this in the appendix. Since we acquired more cases than expected in Q1, we anticipate that we will exceed our budget for the full year.

TEMCELL's sales totaled JPY721 million, a decrease of JPY123 million YoY, but they remained solid compared to our projections.

Sales of Epoetin alfa and Darbepoetin alfa, both drugs used for the treatments of renal anemia, are in accordance with the supply agreement with Kissei Pharmaceutical Co., Ltd. Although the progress rate against the annual sales target for Epoetin alfa was quite low, this was due to a discrepancy between the planning stage and the actual supply stage. We believe we will be able to meet the target for the full year. Shipments of Darbepoetin alfa proceeded largely as scheduled.

Sales of Agalsidase beta totaled JPY256 million, a decrease of JPY169 million compared to the same period last year. As with epoetin alfa, progress of this was also significantly behind schedule. However, this was also

due to a timing difference. Some shipments originally scheduled for Q1 have been postponed to Q2. We expect the full-year results to be in line with our projections.

Total pharmaceutical sales amounted to JPY7,139 million, a decrease of JPY1,086 million. This was significantly below the target. Since we planned for sales to be roughly the same as the previous year, the YoY decline of approximately JPY1.1 billion also applies to the results against the plan.

Next, contract revenue totaled JPY1,474 million, an increase of JPY1,367 million compared to the same period last year. This was primarily due to the receipt of consideration resulting from the exercise of options under existing contracts, as announced in our press release. However, although this figure was higher than the previous year's, we did not meet our budget because some of the revenue we had anticipated for Q1 was carried over to Q2 and beyond.

Other revenue totaled JPY1,086 million, an increase of JPY850 million. The majority of this JPY850 million was attributable to the increase in sales resulting from NPS (Named Patient Supply).

Please go back to the previous page. I just explained net sales.

Cost of sales was JPY2,249 million.

Please refer to the table in the lower right corner. The cost of sales ratio, excluding contract revenue, in the second row from the top, was 26.1%, a decrease of 1.6 percentage points from the previous year. This was due to the impact of the product mix, with the most significant factor being the increase in sales of IZCARGO, including NPS.

As a result, gross profit totaled JPY7,450 million, an increase of JPY1,238 million compared to the previous year.

Selling, general, and administrative expenses totaled JPY9,554 million, an increase of JPY2,700 million. Of this total, selling and general administrative expenses amounted to JPY3,665 million, an increase of JPY195 million, while research and development expenses totaled JPY5,888 million, an increase of JPY2,500 million.

Although R&D expenses increased significantly, we had originally anticipated a considerable increase from the previous year in our plan. This increase of JPY2,540 million exceeded that figure by several hundred million yen. The main factors were the concentration of a portion of global clinical trial expenses in the current period and an increase in CRO-related expenses. R&D expenses also increased compared to the same period last year.

As a result, we posted an operating loss of JPY2,100 million.

Non-operating income totaled JPY261 million. This is a compensation income. This concerns a procedural error related to supplier tariff. In addition, we recognized foreign exchange gains.

Non-operating expenses totaled JPY242 million, with the majority of this increase attributable to higher interest expenses.

We posted an ordinary loss of JPY2,084 million, and a loss attributable to owners of the parent of JPY1,900 million.

See page four. This page contains the information presented during the update briefing on givinostat held on July 15.

Based on the results of the consultation meeting with the PMDA, we plan to submit the MAA (marketing authorization application) by the end of 2026.

As for the timeline, we plan to submit the MAA based on overseas data within 2026, obtain approval within 2027, and begin sales.

Meanwhile, separate from the MAA, we will conduct additional clinical trial targeting Japanese participants. The purpose is to evaluate pharmacokinetics and safety. We have already submitted the initial clinical trial notification (CTN).

Unmet Medical Needs in DMD Treatment

Life is Rare

Only two therapies approved in Japan (excluding steroid therapy)

	Approval status			Target DMD Patients[1]
	Japan	US	EU	
Gene therapy	✓2	✓	—	Japan; Negative for anti-AAVrh74 antibodies Ambulatory patients 3 years to less than 8 years
Exon skipping	✓2	✓	—	Japan; Patients with specific genetic mutations[3]

Eligible patients remain limited by age and genetic mutation criteria, leaving substantial unmet medical needs in DMD

Givinostat	—	✓	✓2	**US;** **≥6 years** **EU;** **Ambulatory patients ≥6 years on concomitant steroid therapy**

AAV, adeno associated virus; DMD, duchenne muscular dystrophy
1. Based on labels for each product 2.Conditional approval 3. Patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping

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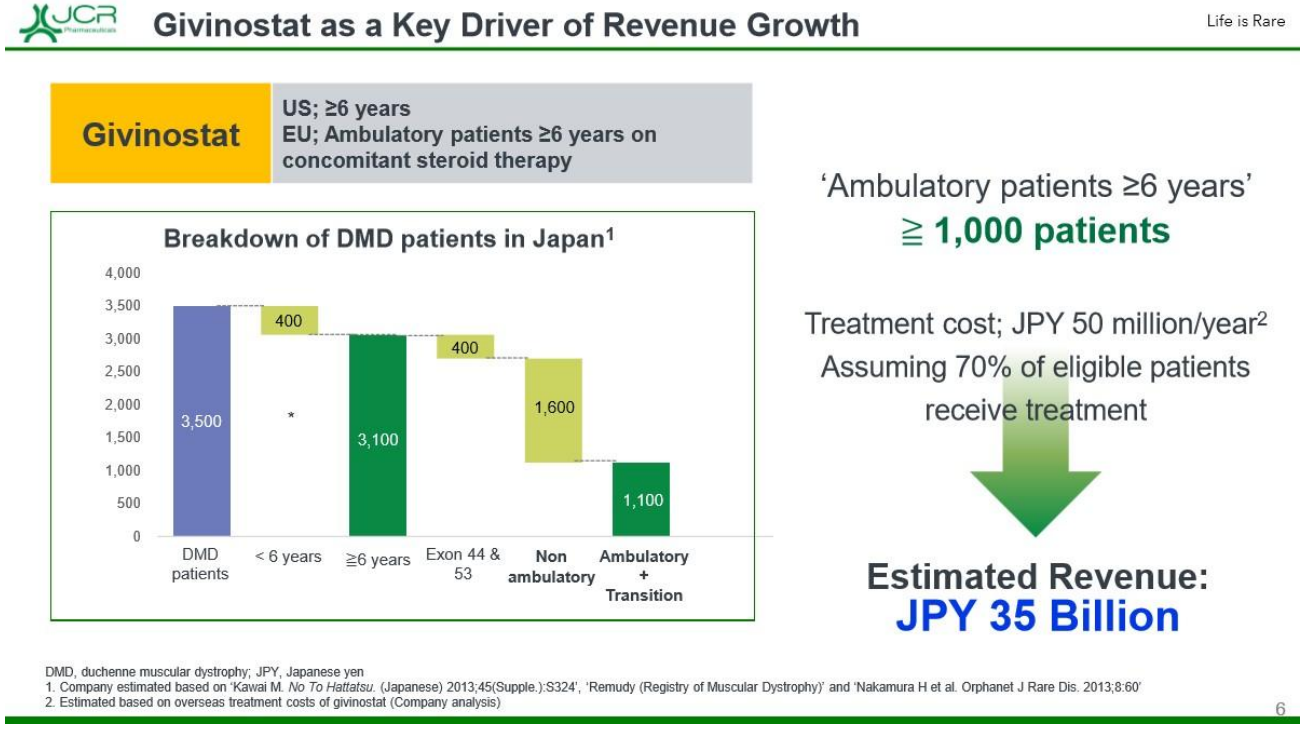
With regard to DMD (Duchenne muscular dystrophy) treatment, two drugs, excluding steroids, have been approved in Japan. These are gene therapy and exon skipping therapy.

Because the patient population eligible for treatments is limited by age or genetic mutations, there is, in other words, a significant unmet medical need.

In contrast, givinostat is indicated for all patients aged six years and older in the United States and for ambulatory patients aged six years and older while taking steroids in Europe. In any case, this is a medication that can be used for a very wide range of patients.



With that in mind, even when limited to ambulatory patients, there are more than 1,000 such patients in Japan.

Assuming annual treatment costs of JPY50 million and that 70% of eligible patients use givinostat, sales would total approximately JPY35 billion.

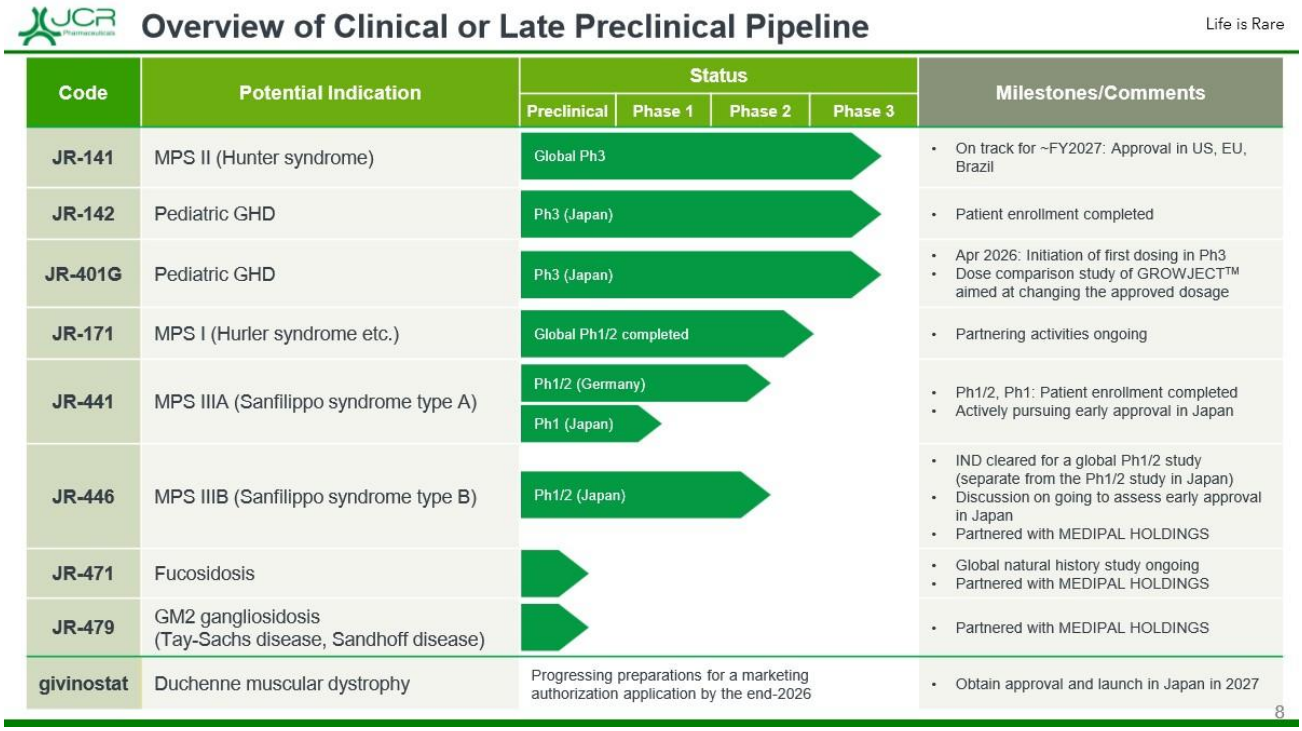
If the product's application expands to include non-ambulatory patients, we can expect correspondingly higher sales.

This was released on July 21. IZCARGO has obtained its first marketing authorization outside of Japan.

It is often said that our revenue structure is unstable, and we ourselves recognize this to be true. This is one of the measures we are taking to stabilize that current structure, even if only slightly.

As part of our business expansion strategy leveraging Japanese marketing authorization, we have entered into a marketing and distribution agreement with Taiba.

This month, in July 2026, we were able to obtain marketing authorization in the United Arab Emirates. Under the agreement, JCR will seek marketing authorization for IZCARGO in countries across the Middle East and North Africa (MENA) region, while Taiba will be responsible for sales and distribution there.



The final slide covers the development pipeline.

There haven't been any particularly significant changes this time.

First, regarding JR-141, at the top of the list, as previously planned, we expect to receive approval in the US, EU, and Brazil in FY2027, and we are continuing to communicate with the regulatory authorities toward that goal.

As for the third drug, JR-401G, which was added to this list relatively recently, we began administering it to the first patient in April 2026, as explained previously.

As for JR-446, as we mentioned earlier, we have completed the IND (Investigational New Drug) application for the global Phase 1/2 trial.

As I mentioned earlier, regarding givinostat, which is listed at the bottom, we plan to submit a regulatory application by the end of 2026, obtain approval by the end of 2027, and begin sales.

That is all.

Question & Answer

Moderator [M]: Thank you for listening. We will now move on to the question-and-answer session.

We will first take questions from analysts, followed by questions from the media. We will answer each of your questions individually. You may ask up to two questions at a time, but you may raise your hand as many times as you like.

Now, Mr. Yamaguchi, please proceed.

Yamaguchi [Q]: Thank you. This is Yamaguchi from Citigroup Global Markets.

My first question concerns the results for Q1, which Mr. Ito has just explained in detail.

In terms of sales, there were some variations depending on the product. For example, GROWJECT was a bit weak, while IZCARGO slightly exceeded its target. In addition, contract revenue was slightly below the forecast. However, you have not revised your full-year forecast. Looking at Q1 alone, R&D expenses seem to have increased slightly, and there appeared to be variations depending on items, but are you expecting all of them to even out over the full fiscal year?

R&D seems like it might increase somewhat, and I have a feeling IZCARGO might see a bit of growth. I think milestones will probably end up on track for the full year after all. Could you please explain this again in terms of the progress rate against the full-year plan?

Ito [A]: Thank you very much, Mr. Yamaguchi.

As you said, we have not revised our full-year plan, and we believe we can achieve our full-year forecast.

First, regarding contract revenue, as I mentioned earlier, some of the revenue originally scheduled for Q1 has been only delayed, so we expect to meet our full-year target.

Since development costs increased significantly this time compared to the same period last year, you may have been wondering what would happen. However, we will also tighten our control over expenses, and we're hoping to somehow wrap things up as planned. I do think that, depending on the circumstances, the results might end up slightly exceeding expectations.

As for product sales, as you mentioned, GROWJECT's sales were slightly down in Q1, but I believe we will be able to meet our full-year target.

As I mentioned earlier, since we acquired IZCARGO cases in Q1 much sooner than expected, I believe that, given this, we may exceed our annual plan. IZCARGO's NPS is not involved promotions, but I mentioned earlier, this area is also performing steadily.

Taking these factors into account, and as we continue our various activities, we intend to pursue new revenue opportunities and firmly achieve our full-year targets. If any corrections are necessary, we will, of course, disclose them promptly.

Yamaguchi [Q]: Thank you.

Next, regarding givinostat—I apologize for my lack of knowledge—but what is the current status of a clinical trial for non-ambulatory patients? Also, you mentioned “within the year,” but since it’s currently July, could you let me know, if you have an estimate, when exactly between August and the end of December you’re expecting this to happen?

Tanizawa [A]: Thank you. This is Tanizawa.

I believe the first question is about the progress of the global clinical trial for non-ambulatory patients. Italfarmaco has conducted a relatively large-scale placebo-controlled trial in this population. We have not yet obtained these results. As soon as we receive it, we would like to refer to it.

We have not yet disclosed which month the applications will be made this year. To reiterate, we would appreciate your understanding that, at this time, we are making preparations to submit the application by the end of the year.

Yamaguchi [Q]: Thank you. I'm sorry to keep bringing this up, but do you think you'll be able to submit the MAA by the end of the year, or is the timeline pretty tight? I'm not asking when, though.

Tanizawa [A]: The fact that we’re making this announcement means we believe we can achieve it. We are currently working as a company to achieve this goal.

Yamaguchi [M]: Thank you. That's all from me.

Moderator [M]: Thank you very much.

Next, Mr. Muraoka, please proceed.

Muraoka [Q]: Thank you. I am Muraoka from Morgan Stanley.

The first point concerns the contract revenue. Is this JPY1.4 billion for a single case? Or could it be that quite a few projects just happened to be concentrated in these past three months?

Ito [A]: Thank you for your question, Mr. Muraoka.

I would prefer not to comment on how many cases there were. As I mentioned, the exercise of option rights by Acumen Pharmaceuticals is included in that. That accounts for a fairly large portion of this total.

Muraoka [Q]: Understood. Has there been any news regarding SanBio? Is there a possibility that this could be included here? I have a feeling it’s unlikely, though.

Ito [A]: As we have mentioned before, the agreement regarding the manufacture of SanBio’s AKUUGO is a pilot production contract. As I believe we have answered this question before, we do not anticipate any revenue for this fiscal year.

If there are any updates, we’d like to let you all know.

Muraoka [Q]: I understand, thank you.

The other question concerns NPS. You’ve just received approval in the UAE, and I expect it will go on sale shortly. I think that once it goes on sale in the Middle East, it will have a negative impact on NPS sales. Is that included in this fiscal year’s budget?

Ito [A]: You mentioned the negative impact on NPS, but so far, NPS has primarily been sold in Europe. Now that we've obtained approval from the UAE and will be rolling this out in other Middle East countries as well, the fact that this product is selling well will not have any negative impact on that. If we make sales from this, it will add to our profit.

We prepared the budget with the expectation that this product would be approved and launched in the Middle East.

Muraoka [Q]: Understood. Once sales begin in the Middle East, including the UAE, where will those sales be categorized in your company's financial statements?

Ito [A]: I think that's something we'll have to consider going forward. Under the current classification system, it would be included in the other category. However, we are currently considering whether we should classify and disclose this as overseas sales once we obtain official approval to release it.

Muraoka [M]: I understand. I hope sales pick up soon. Thank you. That's all.

Ito [M]: Thank you.

Moderator [M]: Thank you very much.

The next question is from Mr. Yamakita.

Yamakita [Q]: This is Yamakita from Jefferies. Thank you for your explanation.

First, there was mentioned that the contract revenue was pushed back to Q2. I'm not sure if you'll be able to comment on this, but I'd like to know if this means that a licensing deal scheduled for H1 has been postponed, or if you could provide any other clues. You also mentioned that there would be one out-licensing deal in each of H1 and H2. If there are any updates on the progress of those deals, please let us know.

Ito [A]: I would prefer to refrain from commenting on what has been postponed. When you just mentioned "one each in H1 and H2," I believe you were referring to what we said at the May briefing—that we expected the timing of the out-licensing of JR-141 and JR-171 to be split between H1 and H2.

Negotiations regarding the out-licensing are progressing. We are currently in discussions. I cannot say exactly when that will be at this time, but once it is achieved, we will, of course, disclose it immediately. We'll do our best to get the news out as quickly as possible.

Yamakita [Q]: Thank you.

The second point concerns Other revenue. I understand that this includes NPS as well as CRO revenue from MEDIPAL. How is NPS progressing?

Also, I'm sorry to ask this so late, but what is the estimated size of NPS? If there's anything you can tell us, please let us know.

Ito [A]: Compared to the same period last year, other revenue increased by JPY850 million. I mentioned earlier that it was the majority, but about 80% of that increase is attributable to NPS.

As for the potential sales volume, since we are not conducting any promotional activities for this, we do not have a sales target. However, the fact that sales are increasing means that the number of patients being prescribed the medication is rising.

When I see that, I think it means doctors are coming to understand the drug's benefits, and as a result, prescriptions for it are likely increasing significantly. I think this means that people understand the IZCARGO.

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

Moderator [M]: Thank you very much. Does anyone else have any questions?

Mr. Kawamura, please proceed.

Kawamura [Q]: Thank you for your explanation. This is Kawamura from SBI SECURITIES.

Please tell us about GROWJECT. You said that the numbers will balance out for the full fiscal year.

Looking at the market share based on drug prices on page 11, it appears that the competitor is catching up significantly from the decline due to shipment restrictions.

This depends, in part, on the fact that their drug price is higher. Could you please explain, to the extent possible, whether market share is actually growing at hospitals, pharmacies, and private practices?

Kawata [A]: I'll answer that question.

As you pointed out, on a quarterly basis, Novo Nordisk's market share, represented by the purple line, is catching up to ours. One reason for this, as we have explained previously, is that the price of Novo's long-acting formulations is relatively high.

Furthermore, looking at the hospital market and medical care, i.e. GP (General Practitioner) and HP (Hospital), our strong position in the GP sector remains unchanged, while long-acting formulations continue to gain traction in the HP sector.

We intend to maintain the sales of GROWJECT, which underpins our business, by further strengthening our competitive edge in the GP segment while also leveraging our strengths in the HP segment, such as our short-acting formulations and delivery devices.

Ito [A]: Let me add one point. The Q1 sales were down JPY750 million from the previous quarter. Since this market share is based on drug prices, I believe that was also a factor that made our share appear lower. I've added an additional detail.

Kawamura [Q]: Understood, thank you.

My second point—and I know I'm harping on this a bit—is about the contract revenue. This is a crucial factor in achieving your full-year targets. Given the status of competing products and other factors, are the negotiations for JR-141 and JR-171 proceeding smoothly? If there are any updates regarding degree of certainty or other related matters, could you please share them with us again?

This is the last question.

Ito [A]: Thank you for your question. I will answer your question.

You all always ask us what kinds of items we include when we're putting together a budget. As we always say, we include only what we believe we can achieve.

In that sense, the budgets for these two items are included, negotiations are actually ongoing, and progress is being made. Therefore, I believe we will be able to complete the negotiation for out-licensing of these two items as scheduled.

Kawamura [M]: Understood, thank you. That's all from me.

Moderator [M]: Thank you very much.

Next, Mr. Hashiguchi, please proceed.

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

The first point is about AKUUGO. Please tell us about the potential for this to contribute to your business performance in the near future.

In the past, you used to explain that you didn't know because many details hadn't been decided yet. I understand that, in principle, all the necessary materials have been come out—regarding drug pricing, the guidelines for promotion of optimal use, the details of the approval, and post-marketing surveys.

Given this situation, could you please tell us how you currently assess the likelihood that this will contribute to your company's performance in the near future?

Ito [A]: I mentioned the situation regarding the manufacturing contract for AKUUGO earlier. I believe that we will actually sign a commercial production contract.

In that case, the addition of a manufacturing site will be needed, which would require regulatory approval for a partial change—a process that would take about one year. Since the product will be shipped after that process is complete, I think it will still take a little while before we can recognize the revenue.

I think we'll be able to discuss this matter in more detail once we've signed a commercial production contract.

Hashiguchi [Q]: I had absolutely no idea what you meant by "a little." Whether you were referring to a few months or a few years, I couldn't make out the nuance at all.

Kawata [A]: I'll answer that.

As Ito mentioned earlier, a change to the terms of the manufacturing and marketing approval—application for partial amendment—will be required. This is not something we at JCR are doing. It is something that SanBio is doing. Generally, this takes about a year, so it will take years rather than just a few months.

However, we currently expect that it will not last as long as 3 years to 5 years. However, we are not yet able to provide a specific timeline.

Hashiguchi [Q]: Got it, thank you.

The second point is: What are your thoughts on how communication with us should proceed regarding the process for obtaining approval for JR-141 in the United States and Europe?

Generally speaking, there is first a press release announcing that Phase III trial yielded the expected results, followed by a press release announcing that an application has been submitted, and then a press release announcing that approval has been granted. We usually see at least three releases.

Based on your company's current stance, do you think you would be able to make any of these announcements? Or is it possible that you might skip the announcement at first?

Kawata [A]: As for when and what we will be able to disclose, I would prefer to refrain from commenting at this time. However, since there is no doubt that this is material information, I believe we will disclose the appropriate details at the appropriate time.

Given that we are investing such a significant amount in research and development, we naturally understand that this is a situation that causes concern among our investors. Therefore, we intend to proceed strategically so that we can communicate effectively at the appropriate stages.

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

Moderator [M]: Thank you very much.

Next, Mr. Yamaguchi, please proceed.

Yamaguchi [Q]: This is Yamaguchi from Citi. This is my second question. Thank you very much.

Following up on what we were discussing earlier, Is there a high likelihood of submitting an application for givinostat in Japan for non-ambulatory patients—as you've done this case—without conducting trials, using data from the US?

Tanizawa [A]: I believe your question is regarding the details of the indication granted upon approval. In the United States, givinostat has already been approved for use in patients who are non-ambulatory—that is, unable to walk. Therefore, our plan is to aim to file an application in Japan using the same procedure.

We won't know sure until it is finally approved. However, as you will see from the clinical trial design, we will be conducting clinical trials in Japan for both patients who are ambulatory and those who are non-ambulatory, so I believe these negotiations will be extremely important in that regard as well.

The need among patients who are non-ambulatory is indeed very high, and we are determined to secure approval for this indication.

Yamaguchi [Q]: I'm sorry, I misunderstood. Although it says "Ambulatory" on the slide 6 "Key Driver of Revenue Growth," what this means is that, regardless of whether an area is ambulatory or not, opportunities are being pursued—just as they are in the United States.

Tanizawa [A]: Yes, you're absolutely right.

Yamaguchi [Q]: In that case, does that mean the number of patients could be not just 1,000, but 1,600 more than that, as mentioned on the slide?

Tanizawa [A]: That's right. Although we will need to continue to carefully assess the number of patients, I believe we should include non-ambulatory patients in our assumption. You're absolutely right.

Yamaguchi [M]: Got it. Thank you very much.

Moderator [M]: Thank you very much.

Next, Mr. Mizuno, please proceed.

Mizuno [Q]: This is Mizuno from Tokio Marine Asset Management. Thank you very much. I was just about to ask the exact same question as Mr. Yamaguchi. I'm sorry to keep asking you this.

Even if the drug is initially approved only for ambulatory patients, if favorable data emerge from a domestic Phase 2 trial, an expansion of the indication could make it available to non-ambulatory patients as well. So, you're saying it doesn't end with the very first approval?

Tanizawa [A]: Our goal this time is to ensure that the initial approval covers both patients, ambulatory and non-ambulatory.

As I mentioned earlier, we expect various points of debate to arise during the review process, but we would like to strongly emphasize that there is a high unmet need for non-ambulant patients, and that unless it is included, we will not be able to meet the expectations of Japanese patients. We intend to discuss that matter thoroughly.

If, as in EU, the treatment is initially limited to ambulatory patients, we will naturally aim to expand its indications. However, as I mentioned earlier, that is not something we are really anticipating.

Mizuno [Q]: Thank you.

Regarding the partnership with Taiba for IZCARGO, I imagine that in Taiba's territory, things like insurance reimbursements in the UAE, for example, are probably quite advanced.

In general, how well is access to medical care established in this region? I'm not very familiar with the area, but if you know anything, could you please let me know?

Kawata [A]: I'll answer that.

Although it is quite difficult to give a precise answer, Taiba is a major pharmaceutical company in this region and is well-versed in local business practices and regulatory requirements.

After consulting with Taiba regarding the healthcare environment, regulatory framework, and pricing, we decided to expand our operations in this region through this company.

On the other hand, it is known from epidemiological data that the number of patients in this region is relatively high, and it is often referred to as a hotspot. Therefore, we believe there are ample opportunities for revenue.

Mizuno [Q]: Is there racial differences? I've heard before that the data suggests about 1 in every 50,000 people.

Kawata [A]: Epidemiological data indicate that Hunter syndrome occurs in 1 in every 100,000 to 170,000 birth, primarily affecting boys. Of course, I think there are differences depending on the region. I think it's difficult to obtain country-specific epidemiological data for the Middle East, but I believe the figure is likely between 100,000 and 170,000.

Mizuno [Q]: You mentioned before that Brazil is also a hotspot, didn't you? At the givinostat update session the other day, I asked a question about the in-licensing of drugs for rare diseases. I believe there are quite a few items in the strategies for the pharmaceutical and biotech sectors outlined in the basic policy on Economic and Fiscal Management and Reform that are likely to provide a tailwind for your company. Are there any policies that you feel are particularly beneficial to your company?

Kawata [A]: I think we'll need to consider various options once specific policies are announced.

However, based on what we've been following up on the discussions over the past few years, I think the key issue is how to resolve the problems of drug loss and lag, particularly in the areas of pediatrics and intractable diseases.

When I think about it that way, I believe, as Mr. Mizuno said, that this environment will likely work in our favor. We intend to closely monitor the situation to see exactly how things will unfold from here.

Mizuno [Q]: Thank you. To date, your company has had the opportunity to make various capital investments thanks to grants. The policy document also contains quite a bit of similar content. In light of that, does your company think its current manufacturing capacity is sufficient?

Kawata [A]: If your question is regarding capital investment, I believe we should be able to handle it to a large extent at the active pharmaceutical ingredient that has already been completed and finished dosage form plants that we are moving forward.

Mizuno [M]: Thank you. That's all from me.

Moderator [M]: Thank you very much. Are there any questions, including from members of the media?

Mr. Okada, please.

Okada [Q]: Thank you for your continued support. This is Okada from Yakuji Nippo.

Could you please tell us about IZCARGO's target timeline and projected timeline for sales in the Arab region, as well as the estimated post-launch revenue and the scale of the expected growth?

Kawata [A]: While I cannot provide details on the timing or the scale of sales at this stage, I believe this will be around the time when the business foundation begins to take shape.

Okada [Q]: I understand you're expanding into markets outside the Arab world as well. Could you tell us roughly how many countries you're planning to enter?

Ito [A]: It says Middle East and North Africa, and we anticipate taking steps to obtain approval in several countries within this region. We do not disclose the number of countries.

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

Moderator [M]: Thank you very much. Do you have any other questions?

Since there appear to be no further questions, we will now close the question-and-answer session.

With that, we will now conclude JCR Pharmaceuticals' financial results briefing for Q1 of the fiscal year ending March 2027. Thank you very much for your participation today.

[END]

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