JCR Pharmaceuticals Co., Ltd.

FY2025 First Quarter Results Conference Call

July 30, 2025

Event Summary

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[Participants]		
[Number of Speakers]	4	
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	Anne Bechet	Senior Executive Officer, Executive Director, Development Division JCR Europe B.V. General Manager, JCR USA Inc. General Manager
	Naoki Kawata	Director, Corporate Strategy Department, Corporate Strategy Division
	Yoshihiro Oota	Director, Accounting Department, Corporate Strategy Division
[Analyst Names]*	Hidemaru Yamaguchi	Citigroup Global Markets Japan
	Kazuaki Hashiguchi	Daiwa Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities

Fumiyoshi Sakai	UBS Securities Japan
Miyabi Yamakita	Jefferies Japan
Kota Maeda	Nomura Securities
Ryuta Kawamura	SBI SECURITIES

*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 will now begin the JCR Pharmaceuticals Co., Ltd., FY2025 first quarter results conference call.

Today's presentation and Q&A session will be scripted and distributed on our official website at a later date.

Before the start of the briefing, we would like to remind all viewers a few points. Please be reminded that today's presentation may contain forward-looking statements based on current expectations, all of which are subject to risks and uncertainties.

In addition, today's presentation and the materials used are intended to provide information about our business to shareholders, investors, and the press. Information on developments and pharmaceutical products is not intended for the purpose of advertising or medical advice.

I would like to introduce today's attendees. Yoh Ito, Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division.

Ito: Hello.

Moderator: Anne Bechet, Senior Executive Officer, Executive Director, Development Division.

Bechet: Hello.

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

Kawata: Hello.

Moderator: Lastly, Yoshihiro Oota, Director, Accounting Department, Corporate Strategy Division.

Oota: Hello.

Moderator: These are the four attendees. I will continue with an explanation of the materials to be used today. This document was posted on our website at 16:00 today. If you need the documents at hand, please refer to them.

Next, I will explain the flow of today's briefing. Today's session will last approximately one hour and will include a presentation and Q&A session. Questions will be taken after all presentations have been completed. The Q&A session is scheduled to last approximately 40 minutes.

Next, Ito will explain the consolidated results for FY2025 first quarter, followed by Anne Bechet, who will discuss the progress of development items. Thank you.

Overview: Consolidated Financial Results

Reach Beyond, Together

(Unit : million yen)

Consolidated	FY2024	FY2025			
	Q1 YTD	Q1 YTD	Year-on-year Difference	Year-on-year Ratio	Progress Rate
Net Sales	8,145	**8,569**	+424	+5.2%	22.7%
Cost of Sales	2,073	**2,357**	+284	+13.7%	28.8%
Gross Profit	6,072	**6,212**	+139	+2.3%	21.0%
Selling, General and Administrative Expenses	6,368	**6,818**	+449	+7.1%	25.3%
SG&A Expenses	3,192	**3,469**	+277	+8.7%	28.9%
R&D Expenses	3,175	**3,348**	+172	+5.4%	22.3%
Operating Loss	(296)	**(606)**	(309)	-	-
Non-operating Income	505	**74**	(430)	(85.2)%	-
Non-operating Expenses	466	**218**	(247)	(53.2)%	-
Ordinary Loss	(257)	**(749)**	(492)	-	-
Extraordinary Income	627	**-**	(627)	(100.0)%	-
Extraordinary Losses	0	**1**	+1	+946.1%	-
Profit (Loss) before Income Taxes	369	**(751)**	(1,120)	-	-
Income Taxes	168	**(205)**	(373)	-	-
Profit (Loss) Attributable to Owners of Parent	201	**(546)**	(747)	-	-
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	3,462	**3,518**	+56	+1.6%	20.6%

Additional Remarks

- Net Sales increased 5.2% year over year.
- Cost of sales ratio (Excluding income from contractual payment) rose due to lower plant utilization compared to the same period last year.
- SG&A expenses were higher, mainly reflecting increased commission payments to co-promotion partners.
- R&D expenses increased, primarily due to the progress of clinical development activities overseas.
- Non-operating income declined due to lower foreign exchange gains, while non-operating expenses decreased, mainly due to a reduction in equity-method investment losses.

Net Sales	FY2024 Q1 YTD	FY2025 Q1 YTD	Difference
Cost of Sales Ratio	25.5%	**27.5%**	+2.0%
Cost of Sales Ratio *Excluding income from contractual payment	25.5%	**27.9%**	+2.4%
R&D Expenses Ratio	39.0%	**39.1%**	+0.1%
Operating Profit Ratio	(3.6)%	**(7.1)%**	(3.5)%

YTD: year to date 3

Ito: I, Ito, will now explain the consolidated financial results for Q1.

Please refer to the first page.

First, Net sales totaled JPY8,569 million, up JPY424 million from the same period previous year. Middle row, operating loss, JPY606 million, negative JPY309 million from the same period previous year. The bottom line, profit (loss) attributable to owners of parent, was negative JPY546 million, negative JPY747 million from the same period previous year, an increase in revenue but a decrease in profit.

Before going into this breakdown, I would like to first explain the contents of net sales.

Breakdown of Net Sales (Consolidated)

Reach Beyond, Together JCR Pharmaceuticals

(Unit: million yen)

Consolidated	FY2024	FY2025			
	Q1 YTD	Q1 YTD	Year-on-year		Progress Rate
			Difference	Ratio	
GROWJECT®	4,649	**4,495**	(154)	(3.3)%	25.3%
IZCARGO®*	1,372	**1,562**	+190	+13.9%	24.4%
TEMCELL®HS Inj.	730	**845**	+115	+15.8%	31.3%
Treatments for renal anemia	907	**897**	(10)	(1.2)%	28.9%
Epoetin Alfa BS Inj. [JCR]	515	**122**	(393)	(76.3)%	15.3%
Darbepoetin Alfa BS Inj. [JCR]	392	**775**	+382	+97.6%	33.7%
Agalsidase Beta BS I.V. Infusion [JCR]	277	**426**	+149	+53.8%	38.7%
Total Core Products	7,936	**8,226**	+289	+3.6%	26.5%
Income from contractual payment	15	**106**	+91	+582.2%	1.9%
Other*	193	**236**	+43	+22.4%	-
Total Net Sales	8,145	**8,569**	+424	+5.2%	22.7%

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

Additional Remarks

- GROWJECT®, IZCARGO®, and TEMCELL® HS Inj. all outperformed internal budgets and maintained strong momentum.
- GROWJECT® saw a 3.3% year-over-year decline in revenue due to NHI price revision, although unit volumes exceeded those of the prior-year period.
- Sales of the treatments for renal anemia remained aligned with the supply plans of Kissei Pharmaceutical Co., Ltd.
- Sales of Agalsidase Beta BS I.V. Infusion [JCR] remained aligned with the supply plans of Sumitomo Pharma Co., Ltd.
- Milestone revenue was recorded under existing licensing agreements.
- Other income increased, primarily due to higher sales from the NPS program.

YTD: year to date 4

Please move on to the next page.

The first three from the top: GROWJECT, IZCARGO, and TEMCELL, all exceeded our budget and are performing steadily.

The top item, GROWJECT, reported net sales of JPY4,495 million, negative JPY154 million, or 3.3% in ratio, from the same period previous year. However, the NHI price revision of 3.6% had a negative impact, and the sales volume exceeded that of the same period previous year. As I mentioned earlier, the trend in the budget is also strong.

Please check page 13 of the Appendix later, which shows that the market share is declining.

This is due to the difference in NHI prices between the weekly formulation of which sales share has been growing gradually. This share is in monetary terms, so we are showing a decrease in share in that sense.

On the other hand, on a volume basis, as I mentioned earlier, there has been an increase compared to the same period previous year.

Next is IZCARGO, with sales of JPY1,562 million, a 13.9% increase over the same period previous year. As shown in the Appendix, there was an increase of five cases on the net.

Next is TEMCELL, with sales of JPY845 million, an increase of 15.8%. This also exceeded the budget, a solid trend.

The sales of Epoetin Alfa and Darbepoetin Alfa, both of which are sold on consignment to Kissei Pharmaceutical, are in accordance with the supply plan with Kissei. Overall sales of renal anemia drugs decreased slightly from the same period of the previous year, down JPY10 million.

Next is Agalsidase Beta, with sales of JPY426 million, YoY increase of JPY149 million. We have asked Sumitomo Pharma. to sell this product, and the sales are in accordance with the supply plan with Sumitomo.

The total pharmaceutical sales were JPY8,226 million, YoY increase of JPY289 million.

Next, income from contractual payment for Q1 was JPY106 million, which was received for the achievement of milestones in existing joint research.

In terms of contract revenue, we have publicly released the news of JUST-AAV contract with Alexion and the contract with Acumen in July, and one-time payments related to those contracts will be recorded in Q2.

Also, there are projects that have been carried over from the previous fiscal year to the current fiscal year in terms of contract fee income. We have talked about this before, but we expect to sign a contract for that project in Q2, and once the contract is signed, we expect to be able to book it as sales in Q2.

Other sales totaled JPY236 million, an increase of JPY43 million from the same period of the previous year, is due to an increase in sales from the NPS program for IZCARGO.

As a result, total sales amounted to JPY8,569 million, an increase of JPY424 million over the same period previous year.

Please go back to the first page, the net sales amount is JPY8,569 million as I mentioned. Cost of sales was JPY2,357 million, a positive JPY284 million.

The table on the lower right shows that the cost of sales ratio, excluding contracts, was 27.9%, an increase of positive 2.4% over the same period previous year. This increase was due to a decrease in the factory utilization rate compared to the same period of the previous year.

As a result, gross profit was JPY6,212 million, an increase of JPY139 million from the same period previous year.

Meanwhile, Selling, General and Administrative Expenses increased by JPY449 million YoY to JPY6,818 million. SG&A expenses totaled JPY3,469 million, up JPY277 million from the same period of the previous year.

This increase is due to higher commissions paid to co-promotion partners. This will naturally increase if sales increase, but in addition, there was a milestone payment in Q1, which is a payment that occurs when a milestone is achieved.

This was anticipated in the current year's budget. We had expected to achieve the target a little later, but since the target was achieved ahead of schedule in Q1, the one-shot amount had an impact, resulting in a large positive impact.

R&D expenses totaled JPY3,348 million, an increase of JPY172 million. This was mainly due to progress in clinical development overseas.

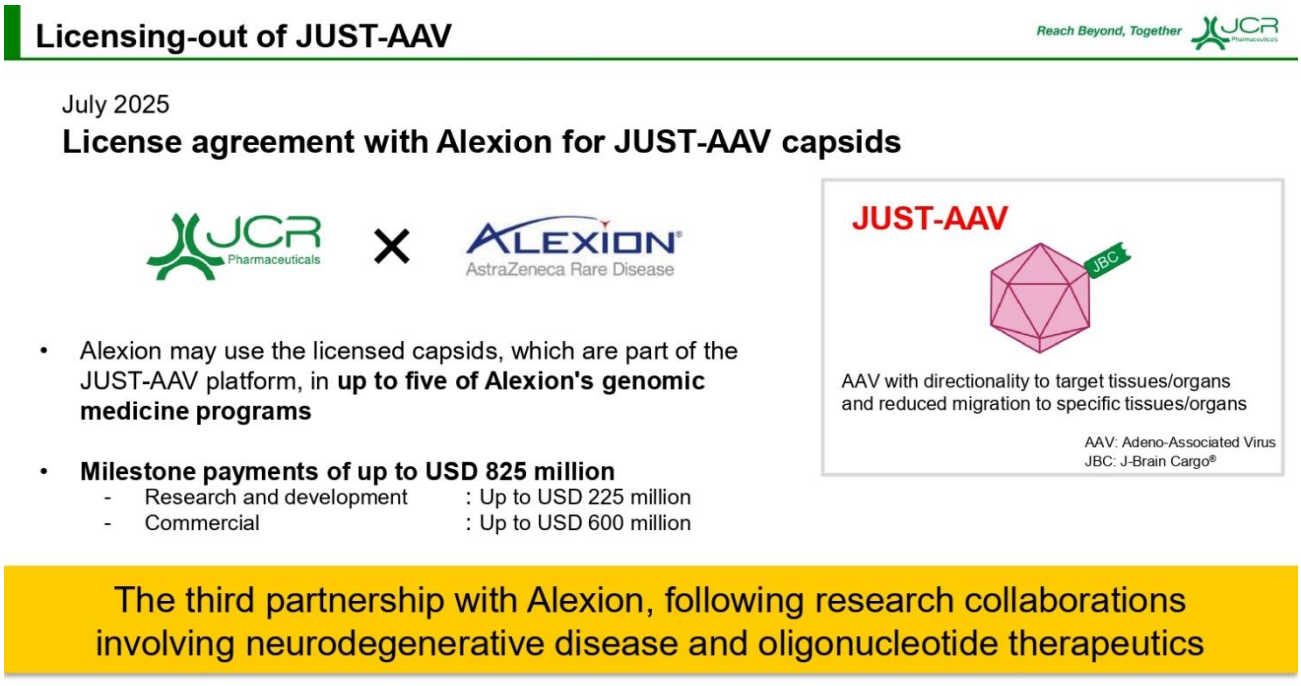
As a result, operating loss was JPY606 million.

Non-operating income was JPY74 million, down JPY430 million from the previous year. This means that foreign exchange gains that were recorded in the previous fiscal year were not recorded this fiscal year.

Next, non-operating expenses below that were JPY218 million, a decrease of JPY247 million from the same period of the previous year. This decrease is largely due to a reduction in equity-method investment losses.

As a result, ordinary loss was JPY749 million.

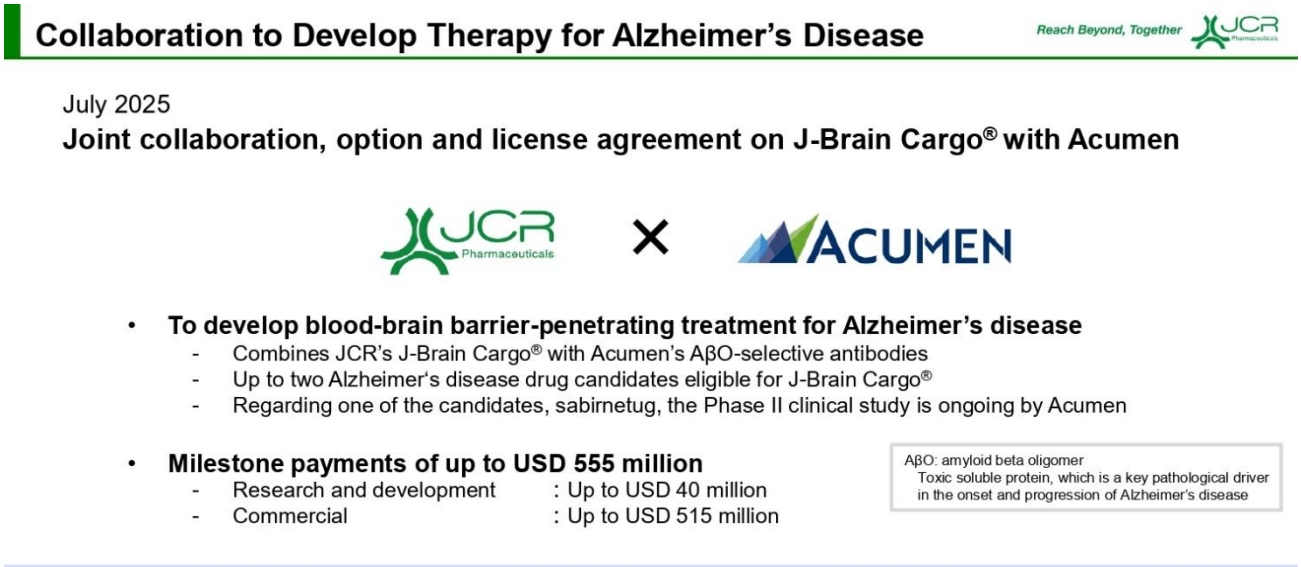
While there was an extraordinary income in the previous year, there was no extraordinary income this year, and profit (loss) before income taxes was a negative JPY546 million, a decrease of JPY747 million from the same period previous year.



The next page is the breakdown of sales, as I explained earlier, so please turn to the following page.

This is the content released on July 8. We have signed a license agreement with Alexion for JUST-AAV, an AAV technology applying on our J-Brain Cargo.

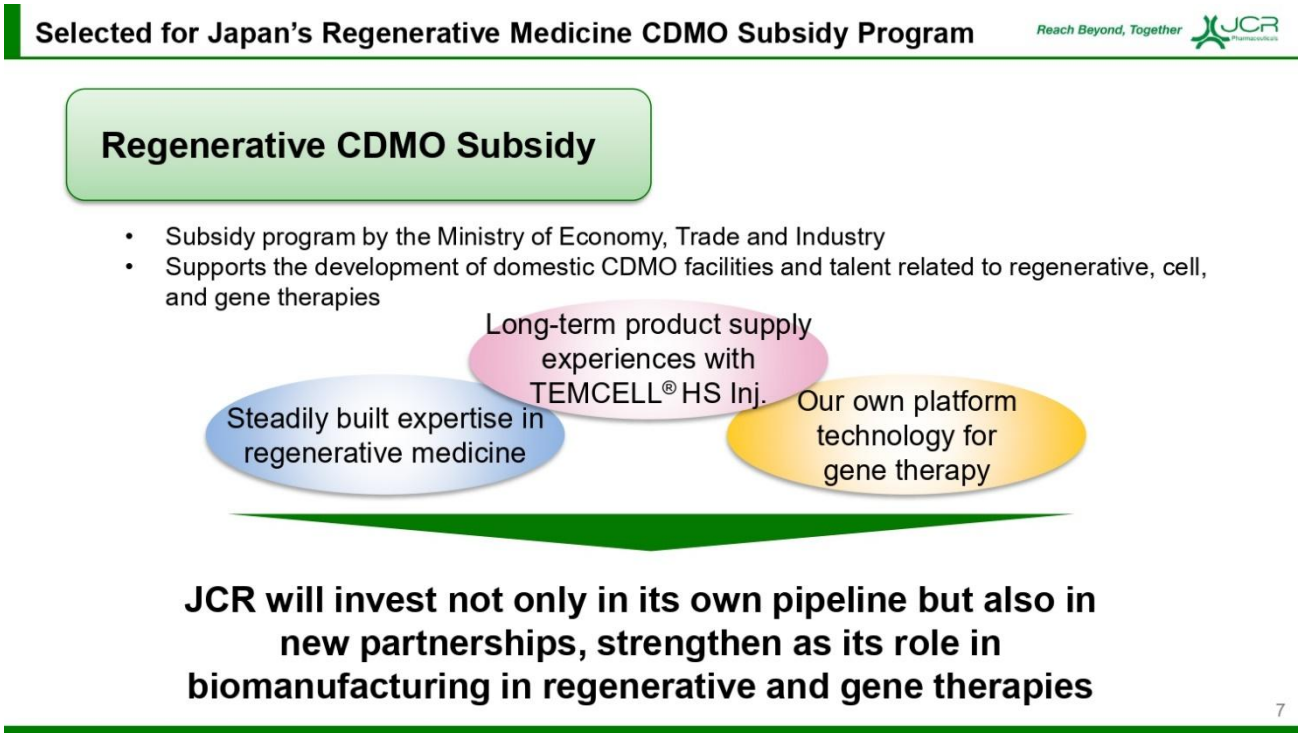
As we mentioned in the press release, this is our third partnership with Alexion, following the joint research on neurodegenerative disease drugs and nucleic acid drugs.



Let's move on to the next page.

This is an option agreement with Acumen for the licensing of J-Brain Cargo technology, which was released on July 15, and is a partnership for the development of therapeutic drugs for Alzheimer's disease.

This is a partnership to tackle Alzheimer's disease using our proprietary J-Brain Cargo technology, and our technology will be applied to Alzheimer's disease, which is a very large market.



Next, this is the last slide of my explanation.

This is about the information that we have been selected for the Regenerative CDMO grant project, which was released on July 16.

This is one of the projects of the Ministry of Economy, Trade and Industry, which provides support for the development of CDMO manufacturing bases and human resource development related to regenerative, cell, and gene therapies.

As you can see, we have experience in manufacturing and supplying TEMCELL stably for a long period of time. This has allowed us to accumulate know-how and technical capabilities in regenerative medicine products.

Although we are still in the contract stage for trial production, we have signed a contract with SanBio Co., Ltd. for the trial production of AKUUGO, and are currently in the trial production stage. Once the contract is finalized, we plan to utilize this subsidy to proceed with the development of manufacturing facilities for this product.

Also, as we mentioned earlier about the gene therapy partnership, we are also looking into the development of facilities for the manufacture of products using our proprietary gene therapy platform technology.

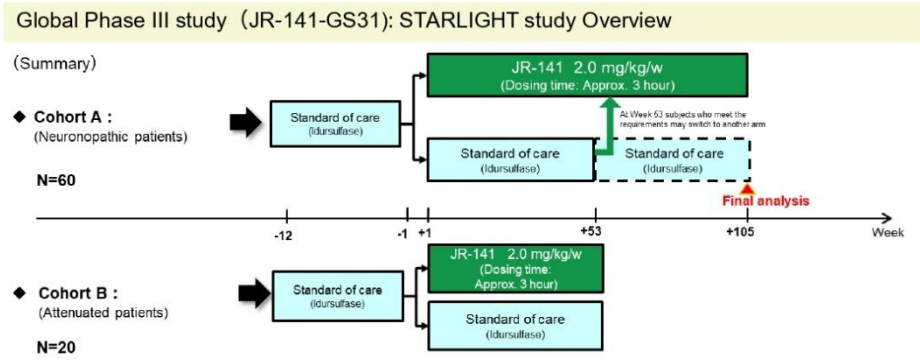
In any case, we will continue to invest in manufacturing facilities that will realize new value that only we can provide.

This is a subsidy for CDMO projects, but we are not developing CDMOs as a company as part of our sales menu. However, in the past, we have contracted out the production of vaccine solutions, and we believe that such production, which can only be realized by us, would be a very high value-added business, and we would like to be proactive in this area.

This concludes my explanation of the financial results.

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

Reach Beyond, Together



- **Enrollment of the target number of 80 participants achieved**
- **Constructive meeting took place with FDA in June 2025**
  - Ongoing discussion on path forward to BLA

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Bechet*: Good afternoon. Thank you for joining us. This is Anne Bechet speaking. I will give an update on the progress of our developmental pipeline.

To start of course with an update on our JR-141 asset, the blood-brain barrier-penetrating ERT for MPS II. With a reminder about the design of our global phase III study, the Starlight study.

This is a study with two cohorts that are open label (assessor blind), one cohort A that is made of 60 neuronopathic patients equally distributed between Idursulfase, the standard of care, and JR-141.

Cohort B is made of 20 patients, also equally distributed between standard of care and JR-141.

We are delighted to report that we have achieved a major milestone in the history of the study as we have completed the enrollment of our target number of 80 patients. We also had a very constructive meeting with the FDA that took place in June 2025.

We will continue to have discussions with the FDA concerning the path forward to our BLA. Based on the discussions that we had, we continue with our plans to file based on biomarker as well as the totality of evidence connected through our Japanese and Brazilian trials.

Overview of Clinical or late Preclinical Pipeline

Reach Beyond, Together JCR Pharmaceuticals

Code	Indication	Status				Milestones/Comments
		Preclinical	Phase 1	Phase 2	Phase 3	
JR-141	MPS II (Hunter syndrome)	Global Ph3				• Achievement of the patient enrollment • ~FY2027: Approval in US, EU, Brazil
JR-142	Pediatric GHD	Ph3 (Japan)				• Dec 2024: Initiation of first dosing in Ph3
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed				• Extension study ongoing • Partnering intensified
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany) Ph1 (Japan)				<Ph1/2> • Patient enrollment completed • 2H FY2025: 1-year clinical data <Ph1> • Patient enrollment completed
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)				• Dec 2024: Initiation of first dosing in Ph1/2 • Partnering with MEDIPAL HOLDINGS
JR-471	Fucosidosis					• Partnering with MEDIPAL HOLDINGS

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Here is an overview of our clinical or late clinical pipeline.

We have just debriefed about the status of our MPS II asset, JR-141, with the achievement of our recruitment for the study. At present, we continue with our plans and the timing as previously communicated.

JR-142, a pediatric growth hormone, long-acting growth hormone, has been initiated with the first dosing in December 2024. The recruitment is progressing as we speak.

JR-171 asset, an MPS I medicine, has completed now the global phase I/II study with the phase of intensified partnering.

JR-441 which is an asset for MPS IIIA has progressed significantly as well with the initial target patient enrollment completed. We are on schedule for generating the first one year clinical data. in the second-half of 2025. The patient enrolment for our Japanese trial has been completed as well.

JR-446, our MPS IIIB asset, has also been initiated in December 2024 in continuous partnership with Medical Holdings.

The activities of fucosidosis are undergoing with a partnership with Medical Holdings. This was my last slide. Thank you for your attention.

Moderator: Thank you for your attention.

Question & Answer

Moderator [M]: We will now begin the question-and-answer session. Mr. Yamaguchi, please ask questions.

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

First, I would like to ask a few more questions about the FDA's June meeting that Ms. Anne Bechet just commented on at the end.

I heard that you could apply with biomarkers, with total evidence, and with data from Brazil and Japan. Is my understanding correct? I would like to ask you, including this STARLIGHT data, including whether you need data on patients in the US.

Also, I know you have a partner, but if you can foresee a filing date, please let me know.

Bechet [A]*: We cannot disclose the full contents of the discussion with the FDA for confidential and strategic reasons. However, our meeting with the FDA was very productive and very constructive.

In general terms, as indicated, we discussed our path forward for registration based on data from the currently ongoing phase III study as well as the totality of the data available from the studies we have conducted in Japan as well as in Brazil. We have additionally discussed aspects related to non-clinical matters.

The FDA has invited us to continue to the dialogue and is continuously supporting us towards the goal of possible earlier registration. At present, we continue with our plans to file according to the timelines that have always been communicated to date.

Yamaguchi [Q]: One more thing that you mentioned at the beginning, and I think I missed something, is the concept of milestones.

The portion of a wholesale carried over from previous year was expected to be included in Q2, but Q1 will be based on past progress. You mentioned that Alexion and the other ones, Acumen you have mentioned were included there but let me check that again.

Ito [A]: First of all, JPY100 million recorded in Q1 is the income from the joint research with other companies that we have concluded in the past and from the achievement of milestones set in the ongoing research.

The contract with Alexion that you mentioned, the contract for JUST-AAV, or Acumen, which was subsequently released, both of these contracts were signed in July, so the one-time costs for these contracts will be recorded in Q2, so it is not included in Q1.

Yamaguchi [Q]: Wholesale is also Q2, right?

Ito [A]: We expect to be able to sign a contract in Q2 for the project you mentioned that has been postponed from the previous year and record the amount.

Moderator [M]: Mr. Hashiguchi, please go ahead.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities.

The first is about what still needs to be done for the JR-141 application.

You mentioned that Phase III data will also be used in the application. Am I correct in understanding that this is an application after taking 53 weeks of data? Therefore, I would like to confirm once again whether it is correct to understand that the process will proceed as previously indicated, with applications to be submitted by FY2027.

Bechet [A]*: Yes, this is correct. We need the phase III data to proceed with the filing in the USA, and our BLA. The plans that were communicated earlier are still the ones we are following at present.

Hashiguchi [Q]: The second point is about cost of sales.

Earlier, you mentioned that SG&A expenses were higher than expected for Q1, but you said that this had been factored into the full-year plan, so I understand that progress is ahead of schedule but that you expect to ultimately reach the planned level.

On the other hand, cost of sales progress is high. Should we expect the impact of this decline in operating rates to remain to some extent in Q2 and beyond, becoming a factor that will cause results to exceed plans?

Ito [A]: Regarding the cost, we have only seen results for Q1, so it is difficult to say whether these results will continue, but we think there is a possibility that the cost will remain slightly higher than originally planned. This is all I can say at this time.

Moderator [M]: Next, Mr. Muraoka, please ask your question.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley. It's about JR- 141.

The application will be submitted after the results of the 53-week trial are released, which means that the results will be available around this time next year. From there, the application and release will proceed as outlined in the materials; however, if you say FY2027, and Denali obtains approval in January as planned, you may fall behind Denali by about a year to a year and a half.

That being said, I'm afraid that this matter will work negatively for the JR-141 partnering negotiations, but is that possible? Once again, will it be like a discussion from scratch with your partner? How should we think about that, the status of the discussion, and the tone of the discussion, based on this meeting?

Ito [A]: Regarding the partnering negotiations, of course, we had already had them before we had the discussions with the FDA, and we already knew that we were going to have discussions with the FDA, so we decided to wait and see how things went, as I have already told you.

Negotiations are underway again in response to these results, and my sense is that these results have not had any negative impact on the negotiations. Rather, I believe that the stage has shifted to a discussion of what terms and conditions we should sign the contract based on these results.

Muraoka [Q]: In other words, the conditions may affect a bit, and the amount of money may be a bit less, but the probability of a decision is increasing. Is that what you mean?

Ito [A]: We don't know if the amount will be less or not, but in any case, we had a meeting, and we shared the results of that meeting, and we are negotiating the contract on that basis. I think the process is as you mentioned.

Muraoka [Q]: One more question. A few days ago, Kissei had issued an earnings revision and said that they would be selling shares, although your company name was not mentioned.

I have a feeling that, hypothetically, your company's stock, this may be the final selling, but if it comes up, do you plan to take any action? Or, will you just continue to see stocks being sold on the market as before? How should we think about it?"

Ito [A]: I don't know if our shares will be sold or not, and I have not heard anything about that at this time, but hypothetically speaking, if they were to talk about selling our shares, I think it is possible that they would sell them on the market.

However, as you are well aware, the sale of shares has had an impact on the stock price in the past. Taking this into consideration, we would like to propose measures that would have less impact on market prices during our discussions.

Moderator [M]: Mr. Sakai, please go ahead.

Sakai [Q]: This is Sakai from UBS Securities.

Back to the beginning, about the contract fee.

Alexion and Acumen, when you disclosed this information, you gave figures for milestones, but you did not mention any contract money. Therefore, I think this contract money will be included separately, but is my understanding correct that this is already included in the forecast of JPY5.5 billion for this fiscal year's contract money, and that the forecast will not be changed, or that there is no need to change it?

Or is there something else that will affect this part, the full-year forecast of JPY5.5 billion? Can you tell us about that, including the wholesaler's portion, and then the progress of the out-licensing, although you may not have mentioned JR-171?

Ito [A]: First of all, the one-time payment for the contracts with Alexion and Acumen has already been factored into the earnings forecast, as we have already released, so this will not affect the originally disclosed amount.

Next, regarding the contract that was expected to be concluded previous fiscal year but has been postponed to the current fiscal year, as mentioned in the previous question, we expect to conclude the contract in Q2. Therefore, we assume that if the contract can be signed in Q2, it will be recorded.

Regarding the out-licensing of other assets, as I mentioned at the time of the announcement of the full-year financial results, this is not included in the budget for the one-time contract payment for the current fiscal year. If such contracts can be concluded, we believe that it will be a factor contributing to upward revision.

We are still negotiating contracts for both assets, and there are companies that show interests, so we are still in discussions with them. So as soon as we have something to announce in that form, we would like to do so.

Sakai [Q]: I would like to confirm something. Then, Alexion and Acumen are included in the JPY5.5 billion. And the other assets were not counted in the budget at this time, is my understanding correct?

Ito [A]: I would like to repeat it for confirmation. For Alexion and Acumen, we had budgeted and assumed the one-time contract payment announced in July. The projects that have been postponed from the previous fiscal year to the current fiscal year are included in the budgeted amount of the contractual payment announced at the beginning of the fiscal year.

On the other hand, you mentioned the out-licensing of other assets, JR-171 and JR-141, and those are not included in the budget for the contractual payment announced at the beginning of the fiscal year.

Sakai [Q]: So, it would appear that most of the contractual payments for the full year will be booked in Q2, right?

Ito [A]: That's what I meant about the three contracts I just mentioned.

In addition to that, there are other things that we expect to receive from existing joint research projects when milestones are achieved, depending on the progress of the research, so there may be other things that will be accounted for when the period progresses again.

Sakai [Q]: Another one is the contract with SanBio, AKUUGO. Am I correct in understanding that one condition of this agreement is that the price of shipment of AKUUGO, or the NHI price, will be determined?

Naturally, since your company manufactures the products, I am sure you have a good grasp of the manufacturing costs, but how much you can ship the products for is related to the NHI price. I understand that the price of the product is not yet determined, but that this is one of the variable conditions. Is that correct?

Ito [A]: I don't think we are at the stage yet where we can talk about the terms and conditions of this agreement.

We know that we are still in the trial manufacturing stage, so the most important point is whether or not we can make this product properly. Once that has been confirmed, we will begin discussing the details and conditions of the contract.

I think the first thing we need to do now is to conduct a thorough trial production.

Sakai [Q]: Now, it is being produced on a pilot basis, like a test production, isn't it?

Ito [A]: That's right. That is the content of the trial production, so that is the type of production we are currently doing.

Moderator [M]: Mr. Yamakita, please go ahead.

Yamakita [Q]: This is Yamakita from Jefferies.

The first question, about the discussion with the FDA on JR-141.

I know that JR-141 was on the agenda, but was there any discussion of how this could be applied to JR-171? In response to that, you said that the status of JR-141 negotiations was likely to proceed based on discussions with the FDA, but has there been any change in the status of JR-171 negotiations?

Bechet [A]*: The meeting we held with the FDA was specifically dedicated to JR-141 and JR-141 data. So, of course there are generalities in terms of use of biomarkers that we could generally apply across our portfolio, but in no way can we apply all the information we have received for JR-141 towards JR-171.

There are a lot of useful information in terms of how to consider biomarkers and how to apply it in the file, however, that we could leverage across our platform.

Yamakita [Q]: Is there any impact on the status of negotiations?

Ito [A]: You mentioned the status of the JR-171 negotiations, and I have nothing to add to what I have already said about the status of the JR-171 negotiations.

Yamakita [Q]: Second, regarding the deal with Alexion and Acumen, was it already known at the time the earnings forecast was made, and did it come out quickly after the meeting with the FDA because you were waiting for it?

Also, are there any more of these early-stage partnership pipelines, or if there are some still in progress, or did it come out completely? I would appreciate any comments you may have about these points.

Ito [A]: First of all, in July, we made two releases in succession, and as far as I am aware, there is no particular relationship between these two releases and the meeting with the FDA.

As you say, it was included in the budget, so discussions were already underway at the time the budget was drawn up, and we believed that it was highly likely to be approved.

As for the out-licensing of early-stage, this does not mean that everything has already come out, and we are still in discussions with several companies. Although we have not announced it publicly, some feasibility studies on our technology are being conducted, and we hope to continuously issue releases about collaborations during this term.

Moderator [M]: Mr. Maeda, please go ahead.

Maeda [Q]: I am Maeda from Nomura Securities. I would like to ask just one question.

I think you mentioned that you are going to apply this J-Brain Cargo to the pipeline that has already progressed to the P2 trial in collaboration with Acumen, what is the possible timing for them to exercise the option agreement?

Also, what kind of data, for example, in this P2 study, might we exercise this option agreement? Can you please comment on this point if possible?

Ito [A]: I think that your question is about the conditions under which the option will be exercised in relation to the contract with Acumen, but I am not able to discuss the details of the contract at this time, so I will refrain from answering your question.

Moderator [M]: Mr. Yamaguchi, please go ahead.

Yamaguchi [Q]: This is Yamaguchi from Citigroup Global Markets. Let me ask just one question.

This is a repeat question, but regarding the effect of the FDA meeting that Ms. Anne Bechet mentioned earlier, I may have misunderstood.

If this FDA meeting had not been held, when would your company have submitted its JR-141 application in the US, and how much of a potential acceleration, or early application, would this meeting have brought about? Is there any influence or is there not?

From what you said earlier, I also heard that the timing of the application would not change, but could you tell me about that one more time? Sorry to ask the same thing.

Bechet [A]*: Yes, this is correct. We continue with our plans to file based on biomarker targeting an accelerated approval pathway.

Yamaguchi [Q]: Since you said that you are going to apply, that means that the original plan, which you answered someone's question earlier that you will apply after the Phase III data from the US is available, will change, won't it?

Bechet [A]*: No, there is no change of plans, actually. We have discussed with the FDA of our current plans to follow based on biomarker, the totality of evidence. And that is the discussion that we have had with them. There is at present no change in the plans that we have anticipated to follow and our timelines are hence according to original communications.

Yamaguchi [Q]: So the timing of the application will not change whether you have a meeting with the FDA or not?

Bechet [A]*: This is correct.

Moderator [M]: Mr. Hashiguchi, please go ahead.

Hashiguchi [Q]: My name is Hashiguchi from Daiwa Securities.

Since this is the third contract with Alexion, I think it can be said that the other party is satisfied to some extent in the joint research based on the first and second contracts.

Is it going to continue to be difficult for a while for your company to disclose the progress and results of this existing contract? Is there an agreement on disclosure where the other party has the right to disclose and your company is not allowed to release much? If it is possible to disclose it, at what stage of development will it become possible to disclose it?

This time, we have been informed that approximately JPY100 million in milestones have been included in existing contracts. We would appreciate it if you could let us know when we can expect to receive this specific information.

Ito [A]: I don't have an answer for you as to what the timing is right now, but I would like to go back and examine this point carefully.

Therefore, we have previously disclosed information on milestones that we have achieved in the past, and we will review the information again and would like to disclose any information that can be disclosed. We will disclose the progress of such information at the earliest possible opportunity.

I am very sorry that I am not able to say anything definite at this time, but I would like to respond in that manner in the future, and I would appreciate your understanding.

Hashiguchi [Q]: I would like to ask one more point regarding the capital investment you mentioned on page seven.

I understand that you can use subsidies, but, of course, your company may have to take some out of your own pocket. Based on the capital investment you are currently considering, how much do you think your fixed costs are likely to increase annually? If you have any ideas as to the timing, please let us know.

Ito [A]: Now, I cannot say what the scale of this capital investment is, but the total amount of this subsidy is JPY38.3 billion, and 13 companies have been selected. Therefore, the simple average per company is less than JPY3 billion, which is not that far off from the ballpark amount.

I hope you will understand that we are not in a position to give specifics as to when we will be able to do so in the future.

Moderator [M]: Mr. Muraoka, please go ahead.

Muraoka [Q]: Hello, this is Muraoka from Morgan Stanley.

Let me repeat Mr. Yamaguchi's earlier question but let me confirm it so that there will be no confusion.

So JR-141 means that based on this meeting, there is no change to the US approval in FY2027, as it says in the upper right corner of page 10, is that correct? In other words, am I correct in saying that the concept of obtaining the Phase III results in 2026, then applying, and then US approval in 2027 has not changed?

Bechet [A]*: Yes. Of course, we're always targeting filing as early as possible. But at present, this is our current target.

Muraoka [Q]: I also have a question regarding contractual payments, or performance after Q2.

I think Q2 will be full of profit if it is accomplished as planned, but I'm talking about beyond that; Q3, Q4, if there is no additional contract money as planned, you will continue to have another quarterly loss and deficit, if that is the calculation.

Based on what you've said, I think that if I were a potential partner of JR-141, I would wait to see the phase III results of JR-141. Should we expect a loss for the Q3 and Q4?

Ito [A]: In the budget originally presented at the beginning of the term, operating income is JPY2.6 billion and the contract revenue is JPY5.5 billion, so there is a gap of JPY3 billion there. I believe that there is a gap of JPY3 billion between gross profit from products and expenses, but the budget has not changed, so if you consider that base is continuing, I think it is possible to see that on a quarterly basis.

Muraoka [Q]: Of course, I think it is a matter of course to make maximum efforts to add something.

Ito [A]: Of course. It is natural to want to increase sales and profits as much as possible. Obviously, we are making daily efforts to further increase sales in various negotiations and in domestic sales, and we will commit to showing you the best results possible.

Moderator [M]: Mr. Yamakita, please go ahead.

Yamakita [Q]: I am Yamakita from Jefferies. Let me ask only one question.

As for JR-141 discussions with the FDA, is it correct to say that this was the best case conclusion that your company had previously envisioned? Or did your company anticipate in advance that there would be cases that could be applied for more quickly?

Bechet [A]*: So the actual contents of the discussion we had with the FDA are confidential for strategic reasons. We had a very constructive discussion targeting a filing as early as possible based on the status of our program. We need definitely the data of our Phase III in order to proceed with our filing. And hence we are at present continuing with the plans that we have originally set up and previously communicated. We're on target with delivering according to the timelines that we have always communicated.

Moderator [M]: Mr. Kawamura, please go ahead.

Kawamura [Q]: My name is Kawamura from SBI Securities.

Let me check again about JR-141.

The timing of application approval has remained unchanged from the original plan, but by holding this meeting, you have gained a clearer understanding of what data package is required for the application, what kind of preclinical data is necessary, what kind of biomarkers are required, and what kind of bridging data from actual clinical trials should be presented. Is that correct?

Bechet [A]*: During this meeting with the FDA, we received a very robust guidance and comments from the FDA to ensure that we have a solid package for registration. So as far as the FDA's expectations concerning clinical data are clear.

Moderator [M]: Since there are no other questions, we will conclude the question-and-answer session.

This concludes the JCR Pharmaceuticals Co., Ltd., FY2025 first quarter results conference call.

Thank you very much for your participation today.

Ito [M]: Thank you.

[END]

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