JCR Pharmaceuticals Co., Ltd.

Q1 Financial Results Briefing for the Fiscal Year Ending March 2025

July 30, 2024

Event Summary

[Company Name]	JCR Pharmaceuticals Co., Ltd.	
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[Venue]	Webcast	
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[Participants]		
[Number of Speakers]	3	
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	Naoki Kawata	Director, Corporate Strategy Department, Corporate Strategy Division
	Yoshihiro Ohta	Director, Accounting Department, Corporate Strategy Division
[Analyst Names]*	Hidemaru Yamaguchi	Citigroup Global Markets
	Kazuaki Hashiguchi	Daiwa Securities
	Fumiyoshi Sakai	UBS Securities
	Shinichiro Muraoka	Morgan Stanley MUFG Securities
	Shinya Tsuzuki	Mizuho Securities
	Hiroyuki Matsubara	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: Thank you very much for joining us today for the conference call to announce the financial results of JCR Pharmaceuticals Co., Ltd. for Q1 of the fiscal year ending March 31, 2025.

Before we begin the conference, I would like to say a few words to our investors. In the following discussion, we may state forward-looking statements based on our current expectations, all of which are subject to risks and uncertainties. Investors are advised in advance that actual results may differ materially from the forecasts.

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

Today's participants from JCR Pharmaceuticals are the following three people. Yoh Ito, Senior Corporate Officer, Director, Corporate Strategy Division.

Ito: Thank you very much.

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

Kawata: Thank you very much.

Moderator: Yoshihiro Ohta, Director, Accounting Department, Corporate Strategy Division.

Ohta: Thank you very much.

Moderator: Next, I will explain the flow of today's conference call. Today, Mr. Ito will provide an overview of the financial results for Q1 of the fiscal year ending March 31, 2025 and the progress of R&D, followed by a Q&A session. The Q&A session will last approximately 45 minutes.

Now, Mr. Ito, could you please?

Overview: Consolidated Financial Results

Reach Beyond, Together JCR Pharmaceuticals

(Unit : million yen)

Consolidated	FY2023 Q1 YTD	FY2024 Q1 YTD	Year-on-year Difference	Year-on-year Rate of change	Progress Rate
Net Sales	10,808	**8,145**	(2,663)	(24.6%)	19.7%
Cost of Sales	3,363	**2,073**	(1,289)	(38.4%)	19.9%
Gross Profit	7,445	**6,072**	(1,373)	(18.4%)	19.7%
Selling, General and Administrative Expenses	5,379	**6,368**	+989	+18.4%	25.0%
SG&A Expenses	3,084	**3,192**	+108	+3.5%	25.5%
R&D Expenses	2,294	**3,175**	+881	+38.4%	24.4%
Operating Profit	2,066	**(296)**	(2,362)	(114.3%)	(5.5%)
Non-operating Income	520	**505**	(15)	(3.0%)	-
Non-operating Expenses	326	**466**	+139	+42.9%	-
Ordinary Profit	2,260	**(257)**	(2,518)	(111.4%)	(5.6%)
Extraordinary Income	-	**627**	+627	-	-
Extraordinary Losses	0	**0**	0	-	-
Profit before Income Taxes	2,260	**369**	(1,891)	(83.7%)	-
Income Taxes	650	**168**	(482)	(74.2%)	-
Profit Attributable to Owners of Parent	1,610	**201**	(1,408)	(87.5%)	5.4%
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	2,469	**3,462**	+992	+40.2%	23.0%

Additional Remarks

- The decrease in Cost of Sales due to the decrease in Sales of Core Products.
- Non-operating Expenses include depreciation of Kobe Science Park Centre(KSPC). Non-current assets eligible for grants for KSPC are expected to be offset by special suspense account for tax purpose reduction entry by the end of the current financial year.
- Gain on cancellation of contract is accounted for Extraordinary Income.

(Unit: number of people)

	As of June 30,2023	As of June 30,2024	Difference
Number of Employees (Consolidated)	911	**991**	+80

Net Sales	FY2023 Q1	FY2024 Q1	Rate of change
Cost of Sales Ratio	31.1%	**25.5%**	(5.7%)
Cost of Sales Ratio *Excluding income from contractual payment	36.6%	**25.5%**	(11.1%)
R&D Expenses Ratio	21.2%	**39.0%**	+17.8%

YTD: year to date 1

Ito: I would like to explain our consolidated financial results for Q1.

First, please see the consolidated financial results summary. Net sales for FY2024 Q1 totaled JPY8,145 million, a decrease of JPY2,663 million from the same period last year.

Operating profit in the middle part of the table was a negative JPY296 million, down JPY2,362 million from the same period last year.

Before proceeding to the details of the financial results, I would like to first explain the breakdown of net sales.

Breakdown of Net Sales (Consolidated)

Reach Beyond, Together JCR Pharmaceuticals

(Unit: million yen)

Consolidated	FY2023	FY2024			
	Q1 YTD	Q1 YTD	Year-on-year		Progress Rate
			Difference	Rate of change	
GROWJECT®	4,222	**4,649**	+426	+10.1%	25.4%
IZCARGO®	1,214	**1,372**	+158	+13.0%	24.1%
TEMCELL®HS Inj.	1,063	**730**	(333)	(31.4%)	26.1%
Treatments for renal anemia	1,615	**907**	(707)	(43.8%)	21.6%
Epoetin Alfa BS Inj. [JCR]	602	**515**	(87)	(14.5%)	23.4%
Darbepoetin Alfa BS Inj. [JCR]	1,012	**392**	(620)	(61.3%)	19.6%
Agalsidase Beta BS I.V. Infusion [JCR]	471	**277**	(194)	(41.2%)	25.2%
Total Core Products	8,587	**7,936**	(650)	(7.6%)	24.7%
Income from contractual payment	1,612	**15**	(1,596)	(99.0%)	0.2%
Other	609	**193**	(416)	(68.3%)	17.5%
Total Net Sales	10,808	**8,145**	(2,663)	(24.6%)	19.7%

Additional Remarks

- Sales of GROWJECT® and IZCARGO® increased by more than 10% year-on-year, progressing well.
- Sales of TEMCELL® were down 31.4% year-on-year, but sales progressed as planned against the full-year forecast. The full-year forecast is expected to be 13.5% lower than FY2023's results due to changes in the competitive environment.
- Sales of treatments for renal anemia were in line with the supply plan to our sales partner, Kissei Pharmaceutical Co., Ltd.
- Sales of Agalsidase Beta BS I.V. Infusion [JCR] were in line with the supply plan to our sales partner, Sumitomo Pharma Co., Ltd.
- Income from contractual payment is expected to be biased toward the second half of the year.

Total sales for Q1 of FY2024, shown in the bottom row, were JPY8,145 million, a decrease of JPY2,663 million from the same period last year, as I mentioned earlier.

Of this decrease, approximately JPY1,600 million was due to a decrease in income from contractual payment in the third row from the bottom due to the absence of major contracts, etc. during the quarter.

Below that, other, which represents contract manufacturing and other sales, decreased by approximately JPY410 million. Together, these two factors result in a decrease of approximately JPY2 billion.

The total sales of core products, with green background, totaled JPY7,936 million, down JPY650 million from the previous year.

As you can see from the breakdown, the sales decline of Epoetin Alfa and Darbepoetin Alfa, which are renal anemia drugs, and Agalsidase Beta, listed in the middle rows, was quite significant. All of these sales are outsourced to Kissei Pharmaceutical Co., Ltd. or Sumitomo Pharma Co., Ltd.

However, all of these sales are in accordance with the supply plans of our sales partners, and for the full year, we expect sales to be in line with the plan we originally presented.

As for the three products we sell in-house, first, sales of GROWJECT totaled JPY4,649 million in Q1, up JPY426 million from the same period last year.

Below that, IZCARGO sales were JPY1,372 million, up JPY158 million from the same period last year. Both products have achieved sales growth more than 10%.

These results exceeded the plan, both in terms of the annual progress rate and the internal budget.

TEMCELL sales were JPY730 million, down JPY333 million from the same period last year. As noted in the middle of the second item in the additional remarks of sales breakdown on the right, we are forecasting a 13.5% decrease from the previous year's results this fiscal year due to changes in the competitive environment, as we have previously mentioned.

Looking at this quarter alone, sales are down very significantly from the same period last year, but as you can see from the progress rate, we are achieving our sales as planned.

Returning to the previous page, I would like to explain the breakdown of the financial results.

As I mentioned earlier, net sales were JPY8,145 million, and cost of sales was JPY2,073 million, a significant decrease of JPY1,289 million.

This decrease in cost of sales is of course due to the decrease in sales, but as shown in the table below right, the cost of sales ratio in Q1 was 25.5% compared to 31.1% in the same period last year.

As I mentioned earlier, there was no contract revenue in Q1. Nevertheless, the cost of sales ratio decreased.

In addition, the cost of sales ratio excluding income from contractual payment decreased by 11.1%.

This large decrease in the cost of sales ratio is due to the fact that a large portion of the approximately JPY1 billion decrease in sales that I mentioned earlier was due to the decrease in sales of products with high cost of sales ratios.

The significant decrease in rejected lots during Q1 also contributed significantly to the decrease in the cost of sales ratio.

Returning to the table on the left, gross profit after deducting cost of sales was JPY6,072 million, a decrease of JPY1,373 million.

Selling, general, and administrative expenses totaled JPY6,368 million, an increase of JPY989 million from the same period last year.

This was mainly due to an increase in R&D expenses of JPY880 million from the same period last year to JPY3,175 million.

As we mentioned when we announced our full-year results, the increase in R&D expenses, especially development expenses, is due to the increase in expenses resulting from the increase in personnel, which is due to the establishment of a system that enables us to bring our products to the filing stage in-house, mainly in Europe, the increase in development sites for JR-141, and the fact that other products are entering the clinical stage.

Selling, general, and administrative expenses increased by approximately JPY100 million.

After adding these items together, operating profit was a negative JPY296 million, as I mentioned earlier.

Non-operating income totaled JPY505 million, of which JPY435 million was foreign exchange gains.

Non-operating expenses totaled JPY466 million. Of this amount, equity in losses of affiliates was JPY200 million. As a special factor, as shown in the second row of the additional remarks on the right, non-operating expenses include JPY214 million for depreciation of the Kobe Science Park Center (KSPC). The non-current asset eligible for grants for KSPC is expected to be offset by special suspense account for tax purpose reduction entry by the end of the current fiscal year.

As a result, ordinary profit was negative JPY257 million.

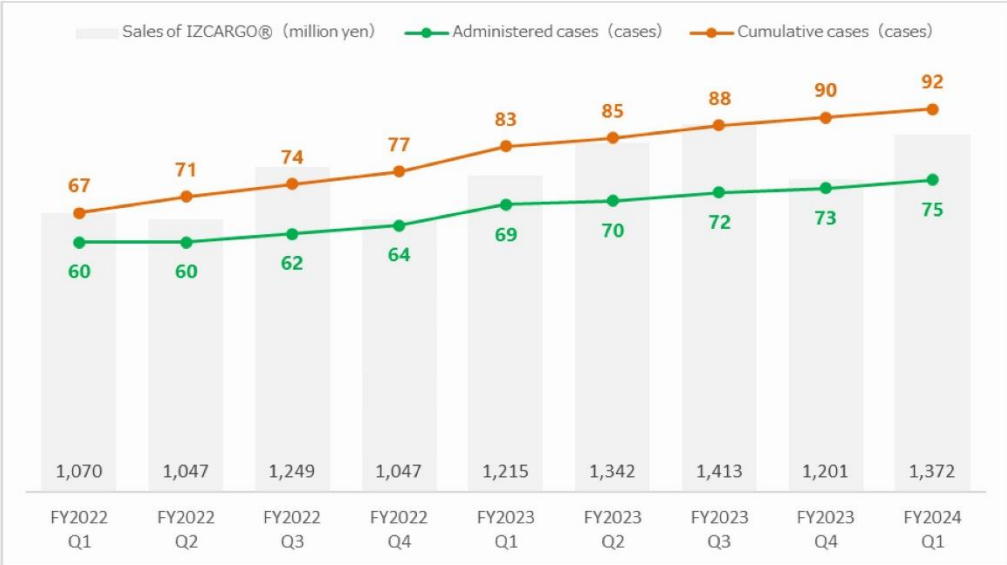
Extraordinary income of JPY627 million was recorded, which is a gain on contract cancellation.

As a result of these factors, the bottom line, profit attributable to owners of parent, was JPY201 million.

Since the breakdown of sales was explained earlier, I will now explain the domestic sales of IZCARGO on the next page.

IZCARGO® Prescription Status in Japan

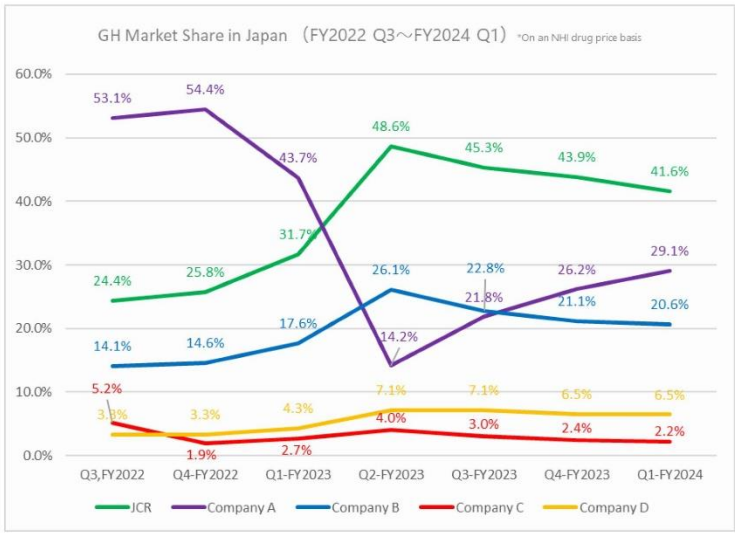
Reach Beyond, Together



On the far right, the number of cases under administration at the end of Q1 is 75. The number of cases increased by two during Q1.

If you look at the orange graph above it, you will see that the number of cases increased from 90 to 92, also an increase of two cases, and that there were no withdrawals in Q1.

GROWJECT® Market Share Trends in Japan (Quarterly)



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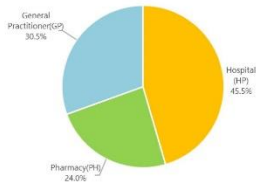
■ Human Growth Hormone Market in Japan



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■ GROWJECT® Market Share by buyer

	Jun 2024	Sales Change FY2024 Q1 (vs. FY2023 Q1) *On an NHI drug price basis
HP Market	33.6%	+520 million yen
PH Market	31.3%	+273 million yen
GP Market	62.1%	+279 million yen

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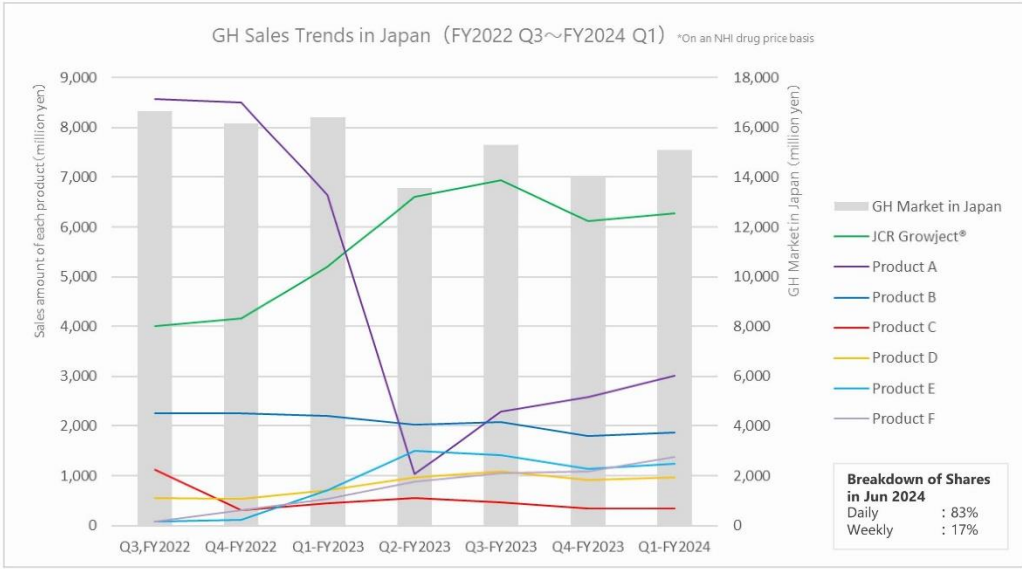
HP: Hospital
GP: General Practitioner
PH: Pharmacy

Next, we move on to the domestic market trends for GROWJECT. Let’s look at the share first.

The green line at the top is our share. At the end of Q1, our market share was 41.6%, with the purple Company N below it at 29.1%. Our market share decreased slightly from the previous quarter.

Sales are shown on the next slide.

GROWJECT® Sales Trends in Japan (Quarterly)



As you can see, sales increased through Q1 on the far right. As I mentioned earlier, sales for Q1 have exceeded the original forecast. Sales have also been strong since the beginning of July, and we are optimistic that we will be able to achieve our sales plan for the current fiscal year.

To give you some background, last year, when Novo Nordisk had the supply problem, we acquired over 200 new accounts. We are making good progress in attracting new patients, including these new accounts.

In addition, the acquisition of new patients for SGA hypotonia is progressing well.

As for the future, the summer vacation months of July and August are expected to be a time when more people undergo GH stimulation test, etc., and new patients can be acquired, leading to an increase in sales. As I mentioned earlier, sales for the month of July exceeded the plan. We call it the summer campaign in the field of sales, and we hope to somehow get through this summer with a strong performance and overachieve our plans for the current fiscal year.

FY2024 Progress of Developmental Pipelines

Reach Beyond, Together JCR Pharmaceuticals

JR-141

BBB-penetrating iduronate-2-sulfatase (rDNA origin)
Indication: MPS type II
Brand name: IZCARGO® (Launched only in Japan, INN：pabinafusp alfa)

- Global Phase III study (JR-141-GS31: STARLIGHT study)
  - Completed enrollment of more than 60% of the eligible patients in Cohort A
- Revised package insert of IZCARGO® in Japan

JR-441

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

- Phase I/II study (JR-441-101)
  - Completed enrollment of the target number of 12 patients

JR-446

BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)
Indication: MPS type IIIB

- Phase I/II study (JR-446-101)
  - Completed the clinical trial notification process in Japan

I would now like to explain the progress of developmental pipelines in Q1.

The global Phase III clinical study of JR-141 is progressing smoothly as planned. For Cohort A, 60% of patient enrollment has been completed.

For IZCARGO, as an IZCARGO product sold in Japan, the package insert has been revised. One of the changes is the elimination of the maximum administration rate, which may lead to a reduction in administration time. Since there have been cases where the difference in administration time from competing products has been a bottleneck, we will continue to closely monitor future trends.

The Phase I/II clinical study of JR-441 is progressing well, with the target number of 12 patients enrolled.

For JR-446, the notification of the clinical trial plan for Phase I/II clinical study has been accepted, and as announced in the release, the clinical trial is scheduled to start in September, and administration is scheduled to begin.

FY2024 Progress of Developmental Pipelines

Reach Beyond, Together JCR Pharmaceuticals

JR-142

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

- Phase III study (JR-142-301)
  - Completed the clinical trial notification process in Japan

JR-031HIE

human (allogeneic) bone marrow-derived mesenchymal stem cells
Indication: Neonatal Hypoxic Ischemic Encephalopathy
Brand name: TEMCELL®HS Inj.

- Decided to discontinue development based on the results of Phase I/II study

The clinical trial plan for JR-142, a weekly formulation of growth hormone, has been accepted for Phase III clinical study and will soon enter clinical trials.

The decision has been made to discontinue the development of JR-031HIE, TEMCELL, for an expanded indication.

R&D Pipeline

Reach Beyond, Together JCR Pharmaceuticals

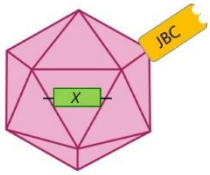
Code	Indication	Status	Upcoming Milestones
JR-141	MPS II (Hunter syndrome)	Global Ph3	• ~FY2027: Approval in US, EU, Brazil
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed	• Extension study is ongoing • Licensing out under negotiation
JR-142	Pediatric GHD	Ph2 (Analysis completed)	• FY2024: Phase 3
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Global Ph1/2	• 2nd Half FY2025: 1-year clinical data is expected
JR-446	MPS IIIB (Sanfilippo syndrome type B)	CTN process completion	• 1st Half FY2024: FPI in Phase 1/2
JR-471	Fucosidosis	Pre-clinical	—

The next page shows the development pipelines, which includes the topics I have mentioned.

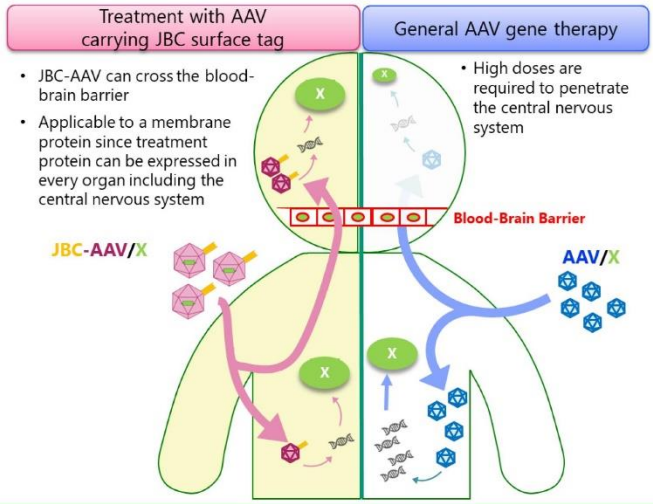
Other Topics

Reach Beyond, Together JCR Pharmaceuticals

- **Announced platform technology of gene therapy applied J-Brain Cargo®**
  - July The 7th International Forum of Lysosomal Disorders
  - October The 31st Annual Congress of the European Society of Gene & Cell Therapy (planned)



J-Brain Cargo®(JBC)-modified adeno-associated virus (JBC-AAV)



This is the last slide of my explanation.

In July, Mr. Sonoda made a presentation at the 7th International Forum of Lysosomal Disorders on the platform technology of gene therapy applied J-Brain Cargo, which was introduced by Mr. Sonoda at the announcement of financial results in May. A release has been issued on this.

In October, we plan to present additional data at the European Society for Gene and Cell Therapy.

As mentioned in the release, non-clinical studies in mice and monkeys have confirmed that the vector is efficiently delivered to the brain. It has also been confirmed that it is delivered to the brain with significantly reduced accumulation in the liver, suggesting the possibility of lowering the risk of liver toxicity caused by AAV.

That is all I have to say. Thank you very much.

Question & Answer

Moderator [M]: I will explain to investors how to ask questions. If you have any questions, please press the raise-hand button. When I call your name, please unmute and mention your company name and your name before asking your question.

Please note that questions should be asked in a question-and-answer format, with each person limited to two questions at a time, but you may raise your hand as many times as you like. We will now begin the Q&A session.

First of all, Mr. Yamaguchi, please ask your question.

Yamaguchi [Q]: My name is Yamaguchi from Citigroup Global Markets. I would like to ask two questions.

We have heard that you have exceeded your company's expectations regarding GROWJECT. On the other hand, Novo Nordisk is recovering early, and your company's market share is down a bit. I am sorry, which part of the situation are you referring to when you say that the results have exceeded expectations even under such circumstances? You mentioned many things, such as securing patients, but looking at the market share, the situation seems a bit grim.

Ito [A]: Yes, there are many ways to look at the market share.

One factor is that many patients stop treatment in March each year, which reduces growth in Q1 beginning in April. We have experienced this, while at Novo Nordisk, while this is only an estimate, we believe that many of the patients may have taken a break from their medication and stopped treatment early when Novo Nordisk was unable to supply products last year.

We therefore believe that Novo Nordisk may not have been affected by such seasonal factors and may have increased sales. As for market share, I think that effect may have been seen.

On the other hand, our sales or sales volume, as I mentioned earlier, have been steady. One reason for this is the acquisition of new patients due, in part, to new accounts. In addition, when Novo Nordisk had supply problems last year, we took various measures and were able to increase the supply, which I believe helped us gain a certain level of trust. We hope to continue to grow that in the future.

Yamaguchi [Q]: Thank you. Is the competition for new patients still quite active in the industry as a whole, or is your share of new patients increasing, even relative to the competition? I believe your company is very active in marketing right now.

Ito [A]: In terms of new patients, we are probably getting more than half of the market.

Yamaguchi [Q]: Understood, thank you. My second question. I imagine that the contract cancellation payment is probably related to Takeda Pharmaceuticals Company Limited (hereinafter "Takeda Pharmaceuticals") and the reversion of the global commercialization rights of IZCARGO.

It would take two years until the data, including the interim analysis, becomes available, so there is still a little time, but have you started looking for other partners? Can you find a partner? There are not so many players. Please tell us about IZCARGO's global partners.

Ito [A]: We regained the global commercialization rights from Takeda Pharmaceuticals. Regarding this, as you mentioned, we have begun activities to find a new partner.

You mentioned that there is still time, but I believe there are many factors that we need to consider as to when is the best time for licensing out. In fact, several companies have now expressed interest, and we have received inquiries. We would like to discuss these various matters as we look for a licensee.

Yamaguchi [Q]: Could you comment on the timing or not yet?

Ito [A]: I think it is too early to answer your question about timing.

Yamaguchi [M]: I understand. Thank you very much. That's all for now from me.

Ito [M]: Thank you very much.

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

Hashiguchi [Q]: I am Hashiguchi from Daiwa Securities. Thank you. First, I would like to ask you about the impact of the revision of the package insert of IZCARGO.

You mentioned that the maximum administration rate limit has been eliminated. How many people were originally administered at the maximum administration rate? For how many patients will the administration rate be able to be increased to the same administration time as the competing products due to the revision of the package insert?

I know it is difficult to generalize, as I believe there are very large differences among individuals, but could you give us some more indication as to the magnitude of the impact of this revision?

Ito [A]: As you mentioned, we believe that we can actually reduce the administration time to the same level as competing products. We have heard that there have been cases where our products have been used once, but the administration time became a bottleneck. For example, for working people who need to drive to hospitals, the length of administration time is a bottleneck. We have heard of such cases, especially in rural areas.

Our sales team is aware of such bottleneck cases based on past experience and conversations with doctors. We believe that by tackling these areas, we will be able to increase the number of patients who use IZCARGO.

Hashiguchi [Q]: So, you can increase the administration rate to the same level as competing products?

Kawata [A]: I, Kawata of the Corporate Strategy Department, will answer. Specific administration time will vary for individual patients. Therefore, I do not think it is appropriate to give a direct answer as to whether it will be the same as the existing drug ELAPRASE in general.

However, I think there is a possibility that it could be shortened depending on each patient's condition. As Mr. Ito mentioned earlier, I believe that there will be more opportunities for patients who have been unable to use it in the past.

Hashiguchi [Q]: I think the protein content per vial is originally four times, so the speed must be four times to get the same administration time. Is this difficult?

Kawata [A]: From what we have heard internally so far, it seems that it will be possible to administer the drug in about the same period of time as the existing drug, ELAPRASE.

Hashiguchi [Q]: I understand. Thank you very much. The second question is whether the termination of the agreement with Takeda for JR-141 will in any way affect the out-licensing negotiations for JR-171.

Since JR-171 has traditionally been negotiated separately from JR-141, is there no particular impact? Or has the reversion of the JR-141 commercialization rights changed some of your company's strategy for the JR-171, which has affected the negotiations to some extent? I would appreciate your comments, including those regarding the most recent progress.

Ito [A]: Thank you. Regarding JR-171, I have nothing more to say than that we are continuing to negotiate. Since we have regained the rights to JR-141, some of the companies that have made inquiries have asked us about handling JR-141 and JR-171 as a set.

It is difficult to say what impact this will have, but I would like to say that some companies have expressed such interest as a matter of fact.

Hashiguchi [Q]: For your company, which is preferable, having each handled by a separate company or having a company that takes care of them as a set?

Ito [A]: I can only say that it depends on individual conditions.

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

Moderator [M]: Thank you very much. Mr. Sakai, please ask your question.

Sakai [Q]: My name is Sakai from UBS. First of all, this is not a question, but there was a part of Mr. Ito's explanation that I did not understand well. Regarding other, did you use any terminology such as decrease in rejected lots?

Ito [A]: Yes.

Sakai [Q]: What does that mean?

Ito [A]: I mentioned that in my explanation of cost of sales. Especially in the case of biopharmaceuticals, I think it is fair to say, we sometimes budget for a certain amount of rejected lots.

This naturally leads to an increase in the cost of sales, but in Q1, this was extremely low, and this was a factor that improved the cost of sales ratio.

Sakai [Q]: If so, does that mean that this will be a factor that increases the cost of sales from Q2 onward?

Ito [A]: Rejected lots are not the only factor in lowering the cost of sales. The product mix has a very large impact. Add to that the factor of rejected lots, and we do not know what the breakdown will be.

If rejected lots occur as normally assumed, it would theoretically work in the direction of worsening the cost of sales ratio.

Sakai [Q]: Understood, thank you. I would like to ask you about the domestic sales of IZCARGO indicated in the table on page three. I recall that you once said that your target for the total number of patients treated in Japan was about 140 cases, and that your sales target was around JPY10 billion.

I think the actual results are still a little short of those. Are there any changes to the planned figures at this time?

If not, it would be helpful to know what the peak figure would be.

Ito [A]: I don't think we have ever talked about what the peak figure will be. We obtained 13 cases in the last fiscal year, and we hope to obtain a similar level of new patients in the current fiscal year.

Sakai [Q]: In other words, the goal of 140 eligible patients in Japan has not changed?

Ito [A]: I think the number of eligible patients in Japan is a bit higher. Mr. Kawata, do you have the figure?

Kawata [A]: Yes, our internal estimate is that the number of patients in Japan is about 150 to 170.

Sakai [Q]: So, you are saying that the IZCARGO is administered to between 150 and 170 patients.

Kawata [A]: Well, we expect that the total number of patients using ELAPRASE our drug, or Hunterase will be about that.

Sakai [Q]: Okay. So, we can use your company's IZCARGO share in calculation.

Kawata [A]: That's what I mean.

Sakai [Q]: Okay. Thank you very much. Sorry, I have one more question.

In the end, you ended up with an operating loss this time, but I think you said that this was within your expectations. I believe you explained that this is due to the concentration of one-time contract payments in H2.

I believe that it is a mandatory target that a one-time contract payment will be recorded somewhere in Q3 and Q4, is this understanding correct?

Earlier, you mentioned the reversion of rights to JR-141. Is the situation unchanged?

Ito [A]: As you mentioned, we are projecting that contract revenue will be skewed toward the second half (H2). We will make every effort to achieve the amounts indicated in this plan.

As I mentioned at the time of our last financial results announcement, we are presenting this as an achievable goal.

Sakai [Q]: Okay. That has already been factored into the budget, so I don't think it will result in a revision of the forecasts, but do you intend to make an announcement once the contract has been signed?

Ito [A]: If we are able to sign a contract, we will make an announcement to the public about the contract. However, whether to disclose upfront fees or other economic terms of individual contracts depends on the circumstances of the other party and the situation at the time.

However, if the contract has been signed or other circumstances meet the requirements for a revised announcement to be made, we will of course make a revised announcement.

Sakai [Q]: Okay, so it depends on the timing, the amount, and the content.

Ito [A]: Yes. You are right.

Sakai [M]: You say it will be in H2. I understand. Thank you very much. That is all.

Ito [M]: Yes, thank you for your understanding.

Moderator [M]: Thank you very much. Mr. Muraoka, please ask your question.

Muraoka [Q]: My name is Muraoka from Morgan Stanley. Thank you.

I am afraid I am repeating the same content, but this question is related to Mr. Sakai's last question. I understand the concentration in H2. Does it seem unlikely that we can expect any lump sum income in the three months of Q2, which has already begun, with respect to JR-171, or anything else?

To put it a little differently, if the gross profit margin in Q1 was too good, should we be prepared for an operating loss in Q2 as well? We need to be prepared, so any comments would be appreciated.

Ito [A]: We are not disclosing our interim forecast, but looking at the current progress, we believe that the contract payments will be as Mr. Muraoka mentioned.

Although it depends on the cost and cost of sales ratio, we do not see any problem even if we assume what Mr. Muraoka just mentioned.

Muraoka [Q]: Thank you very much. Now, I had a little trouble hearing your words, so let me just confirm. You mentioned that you do not expect contractual payments in Q2?

Ito [A]: That's what I mean, yes.

Muraoka [Q]: Okay. Then, I look forward to H2. Another question is about the administration rate of IZCARGO or the effect of improved conditions of use. According to page three, I believe 17 patients have stopped receiving the drug so far. How many of these 17 had problems with the administration rate?

Kawata [A]: We do not know the exact number. However, as in the case Mr. Ito mentioned earlier, there were indeed adults driving cars who were unable to continue to be administered our medications because of the administration time.

As far as we know, there are several such people, although we cannot say exactly whether there are 10 or fewer.

Muraoka [Q]: Thank you very much. If the number is around 10, do you understand that the administration rate was quite a problem for about half of the people who stopped?

Kawata [A]: I only said 10 as an example. We understand that the administration time is a bottleneck not only for these 17 patients, but also for some patients who are not yet using our drugs.

Muraoka [M]: Understood. Thank you very much. That is all.

Moderator [M]: Thank you very much. Mr. Tsuzuki, please ask your question.

Tsuzuki [Q]: My name is Tsuzuki from Mizuho Securities. Thank you very much. Let me ask you two questions as well. The first is about finding a partner for JR-141. You said that several companies have expressed interest. Were you in contact with these several companies before the deal with Takeda Pharmaceuticals take or were they new after the Takeda Pharmaceuticals deal?

Ito [A]: There are both. While we were under contract with Takeda Pharmaceuticals, some companies were interested in other assets, for example, and also asked us about JR-141. Some companies also contacted us about JR-141 after we published our release about the matter with Takeda Pharmaceuticals.

Tsuzuki [Q]: Understood. Thank you very much.

I would like to ask one more question about the share of GROWJECT. It certainly appears that Novo Nordisk's market share has recovered, but I would like to confirm that my understanding is correct.

I am now looking at the market trends in sales on page five. For example, there is a sudden increase in the size of the market from Q4 to Q1, and it appears that Novo Nordisk took most of this increase.

After all, it seems to me that some hospitals prefer Novo Nordisk products more than others, andtheir inventory has suddenly increased, not that they are switching to your products.

I recognize that this happened from Q2 to Q3, too, and I think the same is true from Q4 to Q1. Is my understanding correct?

Kawata [A]: I think such an inference would also be possible. However, as Mr. Ito mentioned earlier, hospitals that have newly set up accounts continue to use our products, and our existing customers also continue to use them. Therefore, we recognize that we are not in a situation where we are losing market share.

One more point, although we do not present this as data, we understand that there has been no significant change in the volume of goods distributed in the market as a whole, compared to the same period of the previous year.

In this context, our figures have exceeded our plan due to new patients or switching. From this perspective, we do not have the impression that Novo Nordisk's market share is growing rapidly.

I would like to add one more point, which was not mentioned earlier in Mr. Ito's explanation. Novo Nordisk's market share expansion is in terms of value. The price of the long-acting drug has increased by 7% in the April NHI price revision due to the premium for pediatric indication. The expansion of market share includes this. Overall, we understand that the competition in the field is not working against us as much as the increase in Novo Nordisk's market share.

Tsuzuki [Q]: Understood. In that sense, you made the statement that you have acquired 50% of the new patient market.

Kawata [A]: Yes, that is correct.

Tsuzuki [M]: Yes, I understand. Thank you very much. That is all.

Moderator [M]: Thank you very much. Mr. Matsubara, please ask your question.

Matsubara [Q]: My name is Matsubara from Nomura Securities. Let me ask you two questions as well.

My first question is about GROWJECT. Is there currently no switch to another company's formulation in new accounts? Also, since you just mentioned that you are getting 50% of new patients, I can guess that your market share will expand from the current 41.6%, but can you tell us what the current situation is?

Kawata [A]: Regarding your question about whether switching has occurred at hospitals that have opened new accounts, switching itself has occurred. However, I think the accurate answer is that it is within the range of our expectations.

We are unable to give specific percentages because we do not have figures, but it is the sales division's view that the percentage is less than 10%.

One more point about new patients, sorry, can you repeat the question again?

Matsubara [Q]: You mentioned earlier that you are getting about 50% of new patients, so I can guess that your market share will expand from the current 41.6%. Can you tell us the current situation?

Kawata [A]: The sales division is aiming for a 50% market share. Currently, our competition with Novo Nordisk is still a seesaw struggle. As I mentioned earlier, we are fighting well in the field, and whether we can achieve a 50% prescription share, we understand that we are in a situation where we can aim for that.

Matsubara [Q]: I understand very well. Thank you very much. The second is about JR-446. I'm looking at the details of the Phase I/II study right now. It states that the estimated end date is August 2029. With 10 participating patients, I believe it does not take this long. Can you give us some background on this?

Kawata [A]: I will answer this as well. The information disclosed regarding JR-446 is based on a general, standard time frame.

However, we are making various efforts to launch the product as soon as possible under the current major changes in the regulatory environment, but we do not provide any information about specific study designs.

Matsubara [Q]: Thank you very much. Is there any difficulty in finding Sanfilippo type B patients?

Kawata [A]: Regarding Sanfilippo type B, or perhaps Sanfilippo syndrome as a whole, we already know that there are many patients in Japan, for example, in specific areas. Therefore, we believe that we are in a position to conduct clinical trials efficiently.

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

Moderator [M]: Thank you very much. Mr. Kawamura, please ask your question.

Kawamura [Q]: I am Kawamura from SBI. Thank you for your explanation. I have two quick questions.

First, IZCARGO was launched in May 2021, which I believe is about three years ago. Compared to the original assumptions, I believe the average patient weight and average number of doses have increased quite a bit. Can you give us any hints as to how much the number of vials has increased from the six assumed from the document submitted to the Central Social Insurance Medical Council?

Kawata [A]: Thank you very much. We believe that this is an indicator that should be watched with interest in the future. For the average weight, it would be roughly six vials, and our sales division told us that the level is slightly higher than that at the moment.

Kawamura [Q]: Thank you very much. The second point concerns contract revenue. Just to confirm, the out-licensing of JR-141 is not included in your company's plan for this fiscal year, is it? Given the timing of the contract cancellation and the timing of the financial results announcement, it is natural to assume that this is not incorporated. Please allow me to confirm this, as it is missing from Takeda Pharmaceuticals' announcement. I thought it might be possible that you knew about it unofficially and included it.

Ito [A]: Yes, as you mentioned, the release of the Takeda Pharmaceuticals' matter came after the announcement of the financial results, so it is not included in our assumptions for this fiscal year.

Kawamura [M]: It's not included. I understand. Thank you very much. That is all.

Ito [M]: Thank you very much.

Moderator [M]: Thank you very much. Do you have any other questions? If there are no further questions, this concludes the Q&A session. That concludes today's conference call. Thank you very much for your participation today.

Ito [M]: Thank you very much.

[END]

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