# JCR Pharmaceuticals Co., Ltd.

Q2 Financial Results Briefing for the Fiscal Year 2024

October 30, 2024

# Event Summary

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|---|---|
| **[Company Name]** | JCR Pharmaceuticals Co., Ltd. |
| **[Company ID]** | 4552-QCODE |
| **[Event Language]** | JPN |
| **[Event Type]** | Earnings Announcement |
| **[Event Name]** | Q2 Financial Results Briefing for the Fiscal Year 2024 |
| **[Fiscal Period]** | FY2024 Q2 |
| **[Date]** | October 30, 2024 |
| **[Number of Pages]** | 24 |
| **[Time]** | 19:15 – 20:18<br>(Total: 63 minutes, Presentation: 35 minutes, Q&A: 28 minutes) |
| **[Venue]** | Webcast |
| **[Venue Size]** | |
| **[Participants]** | |
| **[Number of Speakers]** | 6 |

| | |
|---|---|
| Shin Ashida | Representative Director, Chairman, President, and CEO |
| Toru Ashida | Director, Senior Managing Executive Officer, Sales, Executive Director, Sales Division |
| Hiroyuki Sonoda, Ph.D. | Director, Senior Managing Executive Officer, Research, Executive Director, Research Division |
| Yoh Ito | Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division |
| Anne Bechet | JCR Europe B.V. General Manager, JCR Luxemburg S.A. Director, JCR USA Inc. General Manager Senior Executive Officer, Executive Director, Development Division |

| | | |
|---|---|---|
| | Yoshihiro Ohta | Director, Accounting Department, Corporate Strategy Division |
| **[Analyst Names]*** | Hidemaru Yamaguchi | Citigroup Securities |
| | Fumiyoshi Sakai | UBS |
| | Shinichiro Muraoka | Morgan Stanley |
| | Shinya Tsuzuki | Mizuho Securities |
| | Miyabi Yamakita | Jefferies Japan Ltd. |

*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**: Welcome to the financial results briefing of JCR Pharmaceuticals Co., Ltd. for Q2 of the fiscal year 2024.

Now, let me introduce today's attendee. Shin Ashida, Representative Director, Chairman, President, and CEO.

**Shin Ashida:** Hello.

Toru Ashida, Director, Senior Managing Executive Officer, Sales, Executive Director, Sales Division.

**Toru Ashida**: Hello.

**Moderator**: Hiroyuki Sonoda, Director, Senior Managing Executive Officer, Research, Executive Director, Research Division.

**Sonoda**: Hello.

**Moderator**: Anne Bechet, JCR Europe B.V. General Manager, JCR USA Inc. General Manager, Senior Executive Officer, Executive Director, Development Division.

**Bechet**: Hello.

**Moderator**: Yoh Ito, Senior Executive Officer, Corporate Strategy, Executive Director, Corporate Strategy Division.

**Ito**: Hello.

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

**Ohta**: Hello.

**Moderator**: I will now continue with an explanation of the materials we will use today. The materials to be used today were posted on our website at 4:00 PM on October 30. If you need the documents at hand, please visit that website.

Next, I will explain the proceedings of this financial result briefing. Today's session will last approximately one hour and will include a presentation and Q&A session. Questions will be received collectively after all the presentations have been completed. The entire briefing is scheduled to last approximately 30 minutes.

Today, after Mr. Ashida, the Chairman, gives his opening remarks, Mr. Ito will discuss the consolidated financial results for Q2 of the fiscal year 2024, Ms. Anne Bechet will explain the progress of development items, and Dr. Sonoda will explain the application of J-Brain Cargo to a variety of modalities.

Now, Mr. Ashida, please.

**Shin Ashida**: This is Ashida. Hello.

For the period ended in September, the current fiscal year, , we posted an operating loss of JPY730 million and a loss of JPY690 million. This is due to the fact that license fees are charged in H2, but there are no license fees at all for H1 on this fiscal year.

This H1 sales of the products we sell are growing very steadily. Growth Hormones, GROWJECT, IZCARGO, and TEMCELL are all selling better than we expected.

We have been building our clinical trial team ever since last year in order to create an organization structure that can successfully conduct global clinical trials. Our clinical trial team is finally in place, and we expect to accelerate our global clinical trials.

We, until last year, had separate teams for Japanese clinical trials and for global clinical trials. We are accelerating our clinical trials by doing them globally as one team this year. Anne Bechet will report on clinical trial later.

We are now seeing a very large increase in clinical development and R&D expenses, which will increase from JPY11 billion in the previous fiscal year to JPY13 billion this fiscal year.

However, we believe that product sales and license fees can be reliably anticipated, and that profits for the full year will be within our forecasted range. We look forward to your continued support.

First, please allow Anne Bechet to explain the clinical trial.

## Overview: Consolidated Financial Results

Reach Beyond, Together

(Unit : million yen)

| Consolidated | FY2023 | FY2024 | | | |
|---|---|---|---|---|---|
| | Q2 YTD | Q2 YTD | Year-on-year | | Progress Rate |
| | | | Difference | Ratio | |
| Net Sales | 24,272 | **16,657** | (7,615) | (31.4)% | 40.3% |
| Cost of Sales | 5,881 | **4,330** | (1,550) | (26.4)% | 41.6% |
| Gross Profit | 18,391 | **12,326** | (6,064) | (33.0)% | 39.9% |
| Selling, General and Administrative Expenses | 11,493 | **13,066** | +1,573 | +13.7% | 51.2% |
| SG&A Expenses | 5,957 | **6,489** | +532 | +8.9% | 51.9% |
| R&D Expenses | 5,535 | **6,576** | +1,040 | +18.8% | 50.6% |
| Operating Profit | 6,898 | **(739)** | (7,637) | - | - |
| Non-operating Income | 796 | **134** | (662) | (83.1)% | - |
| Non-operating Expenses | 568 | **1,016** | +447 | +78.7% | - |
| Ordinary Profit | 7,126 | **(1,621)** | (8,747) | - | - |
| Extraordinary Income | - | **1,065** | +1,065 | - | - |
| Extraordinary Losses | 5 | **0** | (5) | (96.5)% | - |
| Profit before Income Taxes | 7,120 | **(556)** | (7,676) | - | - |
| Income Taxes | 1,867 | **134** | (1,732) | (92.8)% | 9.0% |
| Profit Attributable to Owners of Parent | 5,253 | **(691)** | (5,944) | - | - |
| | | | | | |
| Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations | 6,273 | **7,314** | +1,040 | +16.6% | 48.6% |

### Additional Remarks

- Revenue and profit decreased year-on-year, primarily due to a reduction in contract revenue, which is expected to be recorded in the second half of the fiscal year.
- The cost of sales ratio (excluding contract revenue) has continued to decline year-on-year since the first quarter.
- The increase in R&D expenses was mainly due to the establishment of overseas development structures and the advancement of clinical trials.
- Non-operating expenses included losses from equity method investments, depreciation, and foreign exchange losses.
- Special gains included income from the cancellation of stock options and Gain on reversal of share acquisition rights.

(Unit: number of people)

| | As of September 30, 2023 | As ofSeptember 30, 2024 | Difference |
|---|---|---|---|
| Number of Employees (Consolidated) | 932 | **997** | +65 |

| Net Sales | FY2023 Q2 YTD | FY2024 Q2 YTD | Ratio |
|---|---|---|---|
| Cost of Sales Ratio | 24.2% | **26.0%** | +1.8% |
| Cost of Sales Ratio *Excluding income from contractual payment | 34.3% | **26.0%** | (8.3)% |
| R&D Expenses Ratio | 22.8% | **39.5%** | +16.7% |
| Operating Profit Ratio | 28.4% | **(4.4%)** | (32.9)% |

YTD: year to date



2

**Ito**: This is Ito. Hello. Before Anne discusses the development, I will discuss the consolidated results for Q2.

First, the consolidated financial summary shows net sales of JPY16.6 billion. Operating income was negative JPY739 million, and net income was negative JPY691 million for the quarter. Compared to the same period of the previous year, both sales and profits decreased.

## Breakdown of Net Sales (Consolidated)

Reach Beyond, Together JCR Pharmaceuticals

(Unit: million yen)

| Consolidated | FY2023 | FY2024 | | | |
|---|---|---|---|---|---|
| | Q2 YTD | Q2 YTD | Year-on-year | | Progress Rate |
| | | | Difference | Ratio | |
| GROWJECT® | 8,746 | **9,401** | +654 | +7.5% | 51.4% |
| IZCARGO® | 2,556 | **2,845** | +288 | +11.3% | 49.9% |
| TEMCELL®HS Inj. | 1,901 | **1,521** | (380) | (20.0)% | 54.3% |
| Treatments for renal anemia | 2,674 | **1,764** | (910) | (34.0)% | 42.0% |
| Epoetin Alfa BS Inj. [JCR] | 1,046 | **962** | (83) | (8.0)% | 43.8% |
| Darbepoetin Alfa BS Inj. [JCR] | 1,628 | **801** | (826) | (50.8)% | 40.1% |
| Agalsidase Beta BS I.V. Infusion [JCR] | 590 | **714** | +123 | +21.0% | 64.9% |
| Total Core Products | 16,470 | **16,246** | (224) | (1.4)% | 50.6% |
| Income from contractual payment | 7,112 | **15** | (7,096) | (99.8)% | 0.2% |
| Other | 689 | **395** | (294) | (42.7)% | 35.9% |
| Total Net Sales | 24,272 | **16,657** | (7,615) | (31.4)% | 40.3% |

*The figures for Q2 of FY2023 were revised from the figures announced at the time of publication previous year since the sales generated by the NPS program in IZCARGO® have been reclassified as Other.

### Additional Remarks

- GROWJECT® underwent a (4.9%) reduction in reimbursement prices in April, but increased sales volume led to a 7.5% revenue growth year-on-year.
- IZCARGO® performed well, with an 11.3% revenue increase compared to the previous year.
- TEMCELL®HS Inj. revenue fell by 20.0% year-on-year due to competitive market conditions but achieved 54.3% of the full-year revenue target.
- Sales for the renal anemia treatment are in line with the supply plan for Kissei Pharmaceutical Co., Ltd.
- Agalsidase Beta BS I.V. Infusion [JCR] sales are consistent with the supply plan for Sumitomo Pharma Co., Ltd.
- Contract revenue is projected to be higher in the second half of the fiscal year.
- Other revenue declines are attributed to lower outsourced manufacturing sales.



YTD: year to date 3

First, let me explain the contents of the sales. As Ashida mentioned earlier, GROWJECT, IZCARGO, and TEMCELL are all performing well.

GROWJECT has sales of JPY9.4 billion. Compared to the previous year, this is an increase of JPY654 million, an increase of 7.5%, and 51.4% progress of the plan.

The market share has remained stable at around 41% to 42%. In addition, the acquisition of new patients has been strong, and these results are reflected in the figures.

Next is IZCARGO, with sales of JPY2.845 billion. Compared to the same period of the previous year, this represents an increase of JPY288 million, an increase of more than 11%.

This is also progressing as planned and slightly ahead of the plan. The number of new cases acquired this fiscal year is two, but we expect to acquire several more in H2. The fact that all patients who were on the drug at the beginning of the period have continued to use it is also a reason for the good performance and strong sales.

The maximum dosing time limit has been eliminated, and we believe that this will contribute to the acquisition of some new cases in the future.

Next, TEMCELL posted sales of JPY1.521 billion, down JPY380 million from the previous year, but the annual progress rate was 54.3%, showing a favorable trend. Due to the relationship with competing drugs, we have set the plan lower than the previous year, but the sales have been strong.

Sales of renal anemia drugs and Agalsidase Beta are in accordance with the supply plans of Kissei Pharmaceutical Co., Ltd. and Sumitomo Pharma Co., Ltd., which are in charge of sales, respectively. This figure will rise and fall throughout the fiscal year, but in the end, we expect it to be in line with the planned figure.

Total sales of pharmaceuticals were JPY16.2 billion, a decrease of around JPY200 million from the previous year. Contract revenue, as mentioned earlier, is JPY15 million. Sales in the other part of the segment totaled JPY395 million, a decrease of around JPY290 million due to a decrease in sales from contract manufacturing, which was the case in the previous year.

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Reach Beyond, Together

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YTD: year to date 2

Cost of sales was JPY4.3 billion on sales of JPY16.6 billion. This is a JPY1.5 billion decrease from the previous fiscal year.

Please see the table on the right. There is a section that says, "cost of sales ratio*excluding income from contractual payment." This figure was 26%, down more than 8% from the previous year. This means that the cost ratio is turning around.

One reason for this is that, due to the product mix, sales of items with low-cost ratios rose and sales of items with high-cost ratios fell. Another factor is that the cost ratio itself has been reduced due to various efforts at the production site. These factors have resulted in a favorable cost of sales ratio, a trend that has continued since Q1.

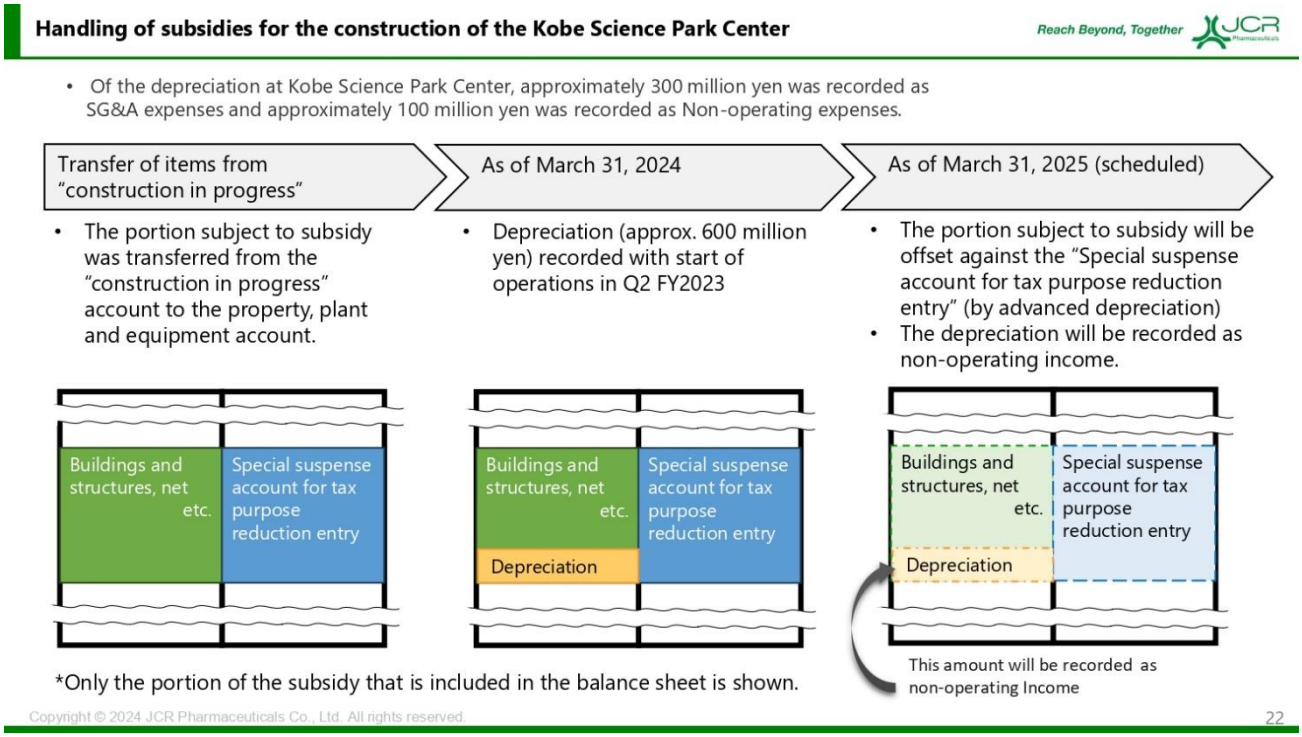
Next is selling, general and administrative expenses, which totaled JPY13 billion.

Selling, general and administrative expenses were JPY6.4 billion, an increase of JPY500 million from the same period last year. This is progressing as planned against the plan.

Next, research and development expenses were JPY6.576 billion, up JPY1 billion from the previous year. As mentioned earlier, we expect an increase of approximately JPY2 billion in a full year. The progress of this half year has been in line with the plan. As we have said before, the increase is mainly due to the establishment of overseas development organizations and progress in clinical development.

As a result, operating income is negative JPY739 million, as I mentioned earlier. Below that, we recorded JPY134 million in non-operating income and JPY1.016 billion in non-operating expenses.

As noted in the brief, non-operating expenses include equity in losses of affiliates, depreciation and amortization, or foreign exchange losses due to yen appreciation. I would like to add a few explanations regarding this depreciation portion.




This is the section at the end of the appendix. We have received a subsidy from the Ministry of Health, labor and welfare for the bulk pharmaceuticals plant at the Kobe Science Park Center.

In the diagram on the far left, what was a construction in progress account to the property has been transferred to plant and equipment account now that the factory has started operating.

This occurred during the last fiscal year.

As of the end of March of last fiscal year, as I mentioned earlier, the plant became operational, and we have written off a portion of this property, plant, and equipment. This was JPY600 million. We are continuing to amortize this quarter as further manufacturing continues.

At the end of this period, the subsidy eligible portion is offset against the special account for unsettled advanced depreciation, and a reduction entry is made. At this point, the subsidy is finalized. With that, the reduction entry is made. This write-off will be recorded as non-operating income.

In contrast, depreciation was originally recorded as a non-operating expense in this non-operating income as a quid pro quo for a future profit to be recorded at the end of the current period. Q1 was handled in that manner.

As a result of discussions with the auditing firm, we have recorded depreciation expenses of JPY400 million for the Kobe Science Park Center during the past six months, of which JPY300 million was recorded as SG&A expenses and JPY100 million as non-operating expenses.

I am sorry to be so technical, but since this is the case, where it is posted to has changed between Q1 and Q2, so please keep that in mind.

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Reach Beyond, Together

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YTD: year to date 2

Ordinary income was consequently negative at JPY1.621 billion, with extraordinary income of JPY1,065 billion. This is a gain on reversal of subscription rights to shares. This is a gain resulting from the change of the restricted stock compensation plan from stock options. Basically, we hope you understand that this corresponds to the difference between the stock price when stock options were recorded in the past and the stock price when restricted stock is introduced this time. In addition, a gain on contract cancellation was recorded, which had already been recorded in Q1.

As a result, net income for the period was a negative JPY691 million.

## Financial Status (Consolidated)

Reach Beyond, Together JCR Pharmaceuticals

(Unit: million yen)

| | End-Mar. 2024 | End-Sep. 2024 | Change • Main Increase/decrease | | End-Mar. 2024 | End-Sep. 2024 | Change • Main Increase/decrease |
|---|---|---|---|---|---|---|---|
| **Current assets** | 57,581 | **56,307** | **Total (1,274)**<br>• Cash and deposits (484)<br>• Accounts receivable - trade, and contract assets (2,579)<br>• Inventories +1,830 | **Current liabilities** | 30,135 | **34,133** | **Total +3,998**<br>• Short-term borrowings +7,312<br>• Income taxes payable (1,534)<br>• Accrued consumption taxes (1,818) |
| | | | | **Non-current liabilities** | 15,615 | **13,438** | **Total (2,176)**<br>• Long-term borrowings (2,200) |
| **Non-current assets** | 44,644 | **48,314** | **Total +3,670**<br>• Property, plant and equipment +1,713<br>• Investment securities +2,963 | **Total liabilities** | 45,750 | **47,572** | **Total +1,822** |
| | | | | **Total net assets** | 56,475 | **57,049** | **Total +573**<br>• Valuation difference on available-for-sale securities +1,863<br>• Share acquisition rights (737) |
| **Total** | 102,226 | **104,622** | **2,396** | **Total** | 102,226 | **104,622** | **2,396** |

| | End-Mar. 2024 | End-Sep. 2024 |
|---|---|---|
| **Equity ratio** | 54.2% | **54.1%** |

**Additional Remarks**

- The increase in Non-current assets is largely attributed to ongoing construction for the new formulation plant at Kobe Science Park Center and increased investments in securities.
- Current liabilities grew mainly due to an increase in short-term borrowing related to construction and other initiatives at Kobe Science Park Center.




Next, I would like to explain the balance sheet.

Total assets at the end of this September totaled JPY104.6 billion. Of this, net assets total JPY57 billion, and the equity ratio is 54.1%. The sales have remained almost unchanged since the end of March.

The first point I would like to explain this time is the increase in property, plant, and equipment in fixed assets. This is due to the construction of a new formulation building at the Kobe Science Park Center, resulting in an increase in construction in progress.

In addition, investment securities increased. This is a partial sale of shares in Mycenax Biotech Inc., a Taiwanese CDMO manufacturing contractor that we acquired two years ago. This company was removed from the equity method of accounting. As a result, investment securities are now valued at market value, and investment securities are increasing. The commensurate increase is the unrealized gains, losses, on available-for-sale securities, which is included in total net assets.

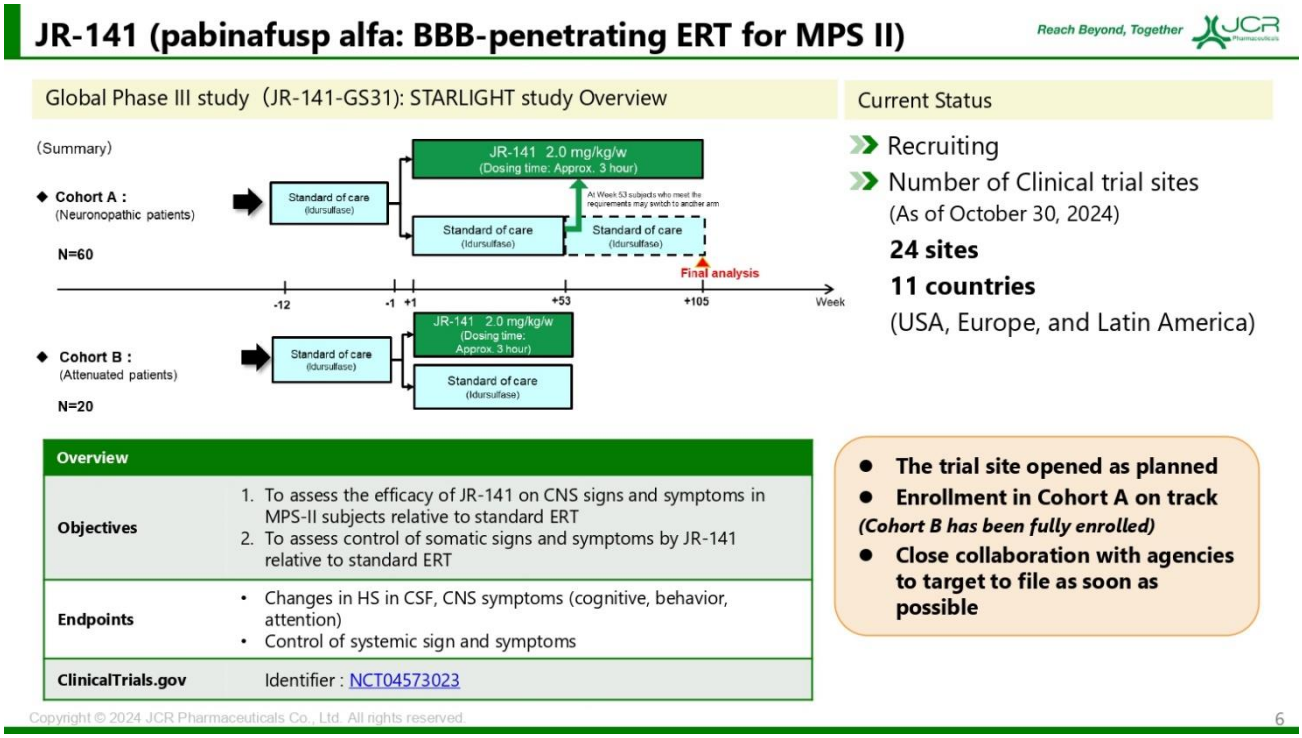
On the right side, current liabilities increased. The JPY7.3 billion increase in short-term borrowings is due to an increase in short-term borrowings for the construction of the new formulation building at the Kobe Science Park Center, as well as other working capital.

In addition, the negative JPY2.2 billion in long-term debt means that this portion has been transferred to the short-term, as it is the portion that will be redeemed in less than one year and will be repaid in less than one year.

That is all for the explanation of the balance sheet.

Lastly, we have released a press release today regarding the repurchase of our own shares. This decision was made in consideration of various circumstances, including the recent stock price level and the response to policy shareholdings.

That's all from me.




**Bechet***:Good evening. My name is Anne Bechet, and it's an honor to be here to present an update about the clinical development ongoing at JCR.

So, we will start with an update on our lead asset, JR-141. This is an enzyme replacement therapy that penetrates the blood -brain barrier (BBB) for MPS II.

We have a global phase III study ongoing at the moment under the name JR-141-GS31, otherwise known as our STARLIGHT study, for which we also have a website that can be consulted.

Our study consists in two cohorts, one cohort A of 60 patients who are neuronopathic patients, one cohort B with 20 patients, constituted of attenuated patients. Those patients in both cohorts are randomized one -to - one between JR-141 and the standard of care. The study at present is recruiting as planned. Our sites are opening also with the appropriate speed that we had set up at initiation of the study. As previously communicated, we recruited 60% of our cohort A patients back in June. We have fully completed the enrollment of our cohort B, and we are working in very close collaboration with the agencies to target to file as soon as possible.

## Progress of Developmental Pipelines

Reach Beyond, Together JCR Pharmaceuticals

**JR-441** BBB-penetrating heparan N-sulfatase (rDNA origin)
Indication: MPS type IIIA

- **Japan**: Phase I study (JR-441-JP11)
  - Completed the clinical trial notification process in Japan
- **Germany**: Phase I/II study (JR-441-101)
  - Progressing as planned
  - Enrollment of the target number of 12 patients completed

**JR-446** BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)
Indication: MPS type IIIB

- **Japan**: Phase I/II study (JR-446-101)
  - Completed the clinical trial notification process in Japan
  - First patient in is expected in 2nd half of FY2024




We can move to our next assets. So, first an update on JR -441, which is an enzyme replacement therapy for MPS IIIA.

We have two studies currently ongoing, one in Germany that has started already last year. This is a phase I/II study, which is progressing also as planned. We have recruited without difficulty our target number of patients. All patients are still being treated and we do not have any safety concerns to date.

For Japan, we have initiated the clinical trial notification (CTN), which is now completed. This year we'll give an update about this study very soon.

For JR -446, this is an asset directed to treat MPS IIIB. We have submitted the clinical trial notification process, which is now completed, and we expect to treat the first patient in the second half of 2024 and in any case before December.

And if we have a look at our overall portfolio, next slide.

## 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 | • ~FY2027: Approval in US, EU, Brazil |
| JR-171 | MPS I (Hurler syndrome etc.) | Global Ph1/2 completed | • Extension study ongoing<br>• Partnering intensified |
| JR-142 | Pediatric GHD | Ph3 (Japan) → CTN process completion | • Initiation of Phase 3 in FY2024 |
| JR-441 | MPS IIIA (Sanfilippo syndrome type A ) | Ph1/2 (Germany)<br>Ph1 (Japan) → CTN process completion | <Ph1/2><br>• Patient enrollment completed<br>• 2nd Half FY2025: 1-year clinical data |
| JR-446 | MPS IIIB (Sanfilippo syndrome type B ) | → CTN process completion | • 2nd Half FY2024: FPI in Phase 1/2 |
| JR-471 | Fucosidosis | | — |




So, this is the overview of our clinical or late preclinical pipeline.

We have JR-141 that we have just discussed were exactly on track as per our previous communications in terms of next milestones, targeting 2027 for approval in one of several of the main territories.

MPS I, our extension study is ongoing. Our patients are being treated with no safety concerns and the partnering activities are being intensified.

Our JR-142 asset, which is a pediatric growth hormone product, has gone through the CTN process and is now completed. We will initiate and treat the first patients before the end of this fiscal year.

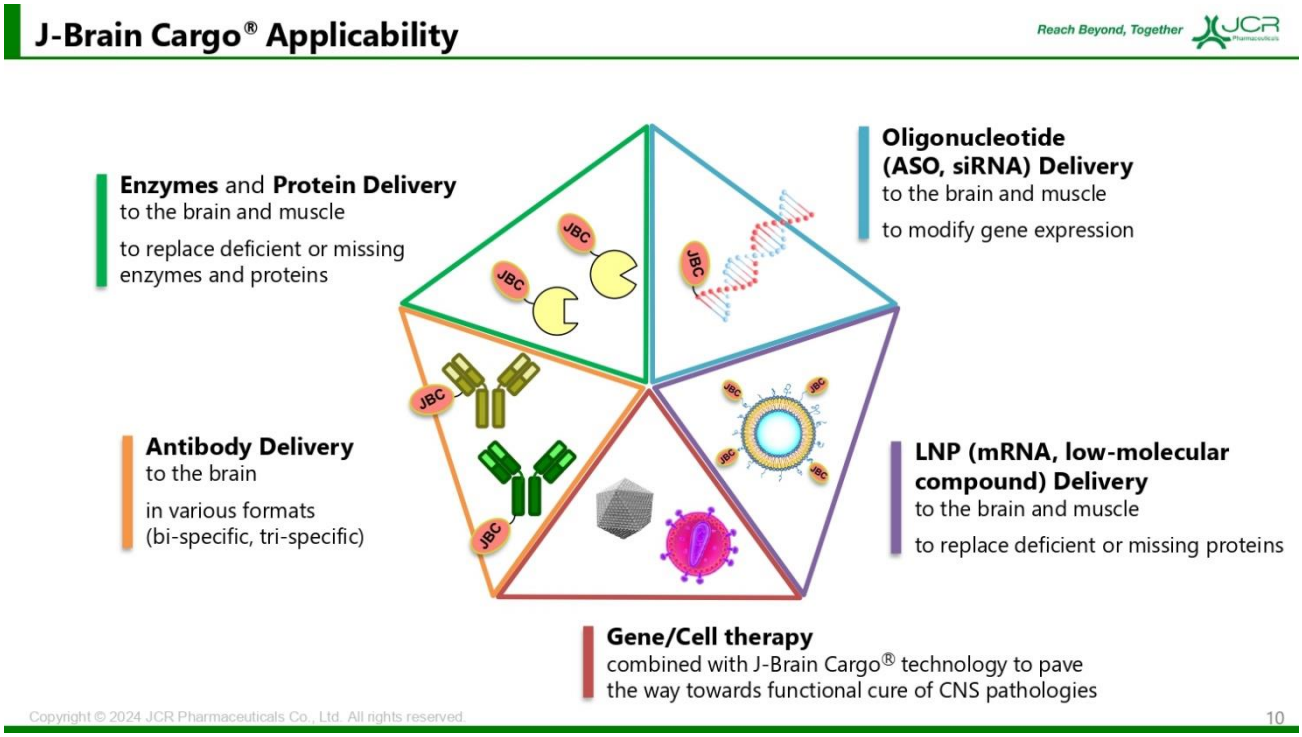
MPS IIIA, we have just discussed about it. Our phase I/II is progressing very well and on schedule for delivering the first 1-year clinical data in the second half of 2025.

And the phase I/II in Japan will be subjected to an update by JCR very soon.

Our MPS IIIB program also on track with a CTN process completed and a first patient treated very soon.

And we have Fucosidosis on which we work at present in collaboration with MEDIPAL.

Thank you for your attention.




**Sonoda**: This is Sonoda. Today, I would like to introduce the application of J-Brain Cargo to diverse modalities, especially to gene therapy.

As you all know, we are now focusing on enzyme treatments for lysosomal diseases. This pentagon shows the five different modalities, and the upper left part, this is the part that we are focusing on the most right now, applying the technology to develop products as our pipeline. The technology itself can be used for other modalities.

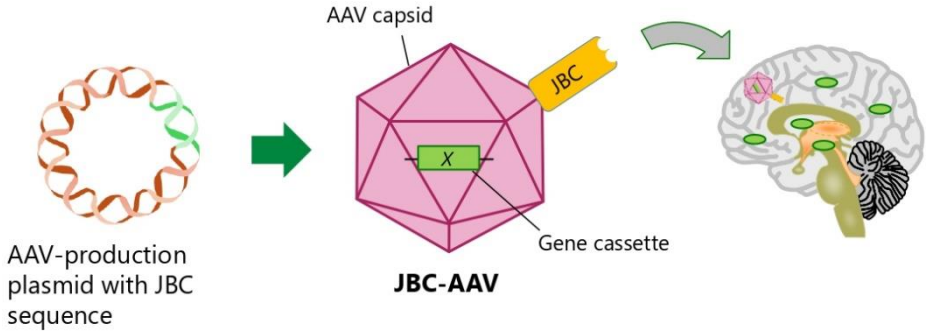
It could be antibody drugs, oligonucleotide therapeutics, lipid nanoparticles, or gene therapy. There are of course other possibilities besides this, but we are obtaining various data on our own mice and monkeys in the institute regarding these five modalities.

Regarding gene therapy in this context, various technologies are emerging. The greatest need is for technology that specifically delivers genes to specific sites, such as the brain or muscles.

We have a technology called J-Brain Cargo that can deliver drugs to the brain. Attempts to combine this with gene therapy technology to create new gene therapy vectors have been successful. I would like to introduce these progresses.

## Applying J-Brain Cargo® to Gene Therapy

Reach Beyond, Together JCR




- JCR-proprietary gene therapy technology
- J-Brain Cargo® domain embedded in AAV production plasmid for viral delivery into the CNS




Here is a schematic of what vectors we have been creating.

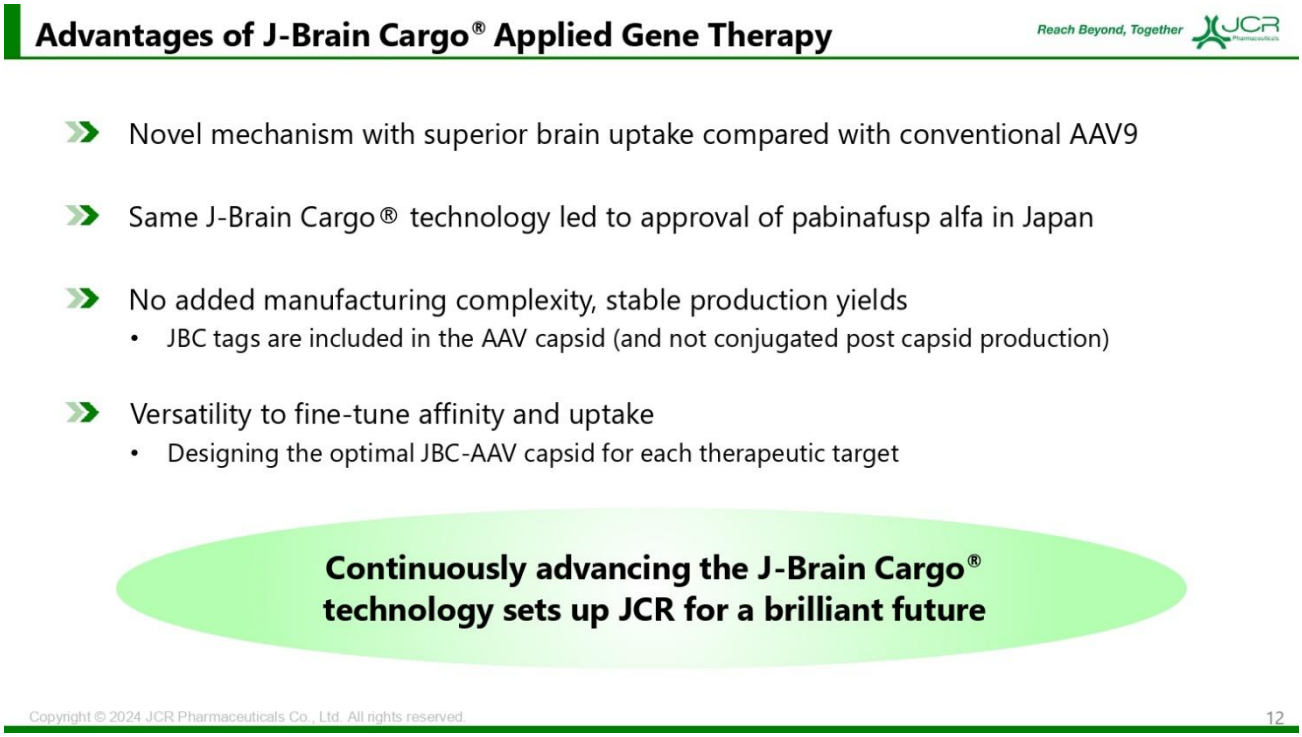
The leftmost side is a picture of a plasmid. Plasmids, which are made to place genes and get them into cells, are designed in many ways here.

In this, the gene that makes the AAV is placed, and here we would put our J-Brain Cargo molecules in it together. Where to place them, how much to put in them, and so on, is where the know-how comes in. Using these plasmids, we transfect the cells and introduce them into the cells.

Then those cells make viruses. The virus that emerged is shown in this middle picture. The pink color forming the shape is AAV, adeno-associated virus. Out in orange, this is the J-Brain Cargo sequence, which is like a tag to deliver to the brain.

This is drawn as an image, so the actual shape may be a little different. This is just an image. On the surface of the AAV, a tag to go to the brain is attached. When this is administered intravenously, this tag becomes a landmark and carries this AAV, the gene-carrying virus, into the brain.

This is our own technology since this new AAV was applied J-Brain Cargo. The insertion of this tag on the surface of the capsid is the key to this technology.




This slide describes the advantages of using this technology and how good it is.

First of all, there are many different types of AAVs, but AAV9 among conventional AAVs is said to be the best in terms of reaching the brain. This technology is something completely different from that, something that can be delivered to the brain by a new mechanism.

This technology is already approved in Japan for use in IZCARGO. We are currently conducting global clinical trials for other items, and the technology we are using there is fundamentally the same thing, the same principle. So, this AAV gene therapy is applied  a technology that has been validated and proven in humans.

Another thing is that one of the major problems with gene therapy for AAV is productivity. Mass production of AAVs has not been established. For AAVs, manufacturing is the biggest bottleneck. Even if you create a very good AAV in your research, if it is not something that can actually be used to make investigational drugs or be produced commercially, it will be difficult to turn it into a business.

So, while it is important to create an AAV with very high performance, it is also very important to create an AAV that can be manufactured at the same time. From the early stage of the development, we have secured that part of the process, that is, we have created molecules that do not lose productivity.

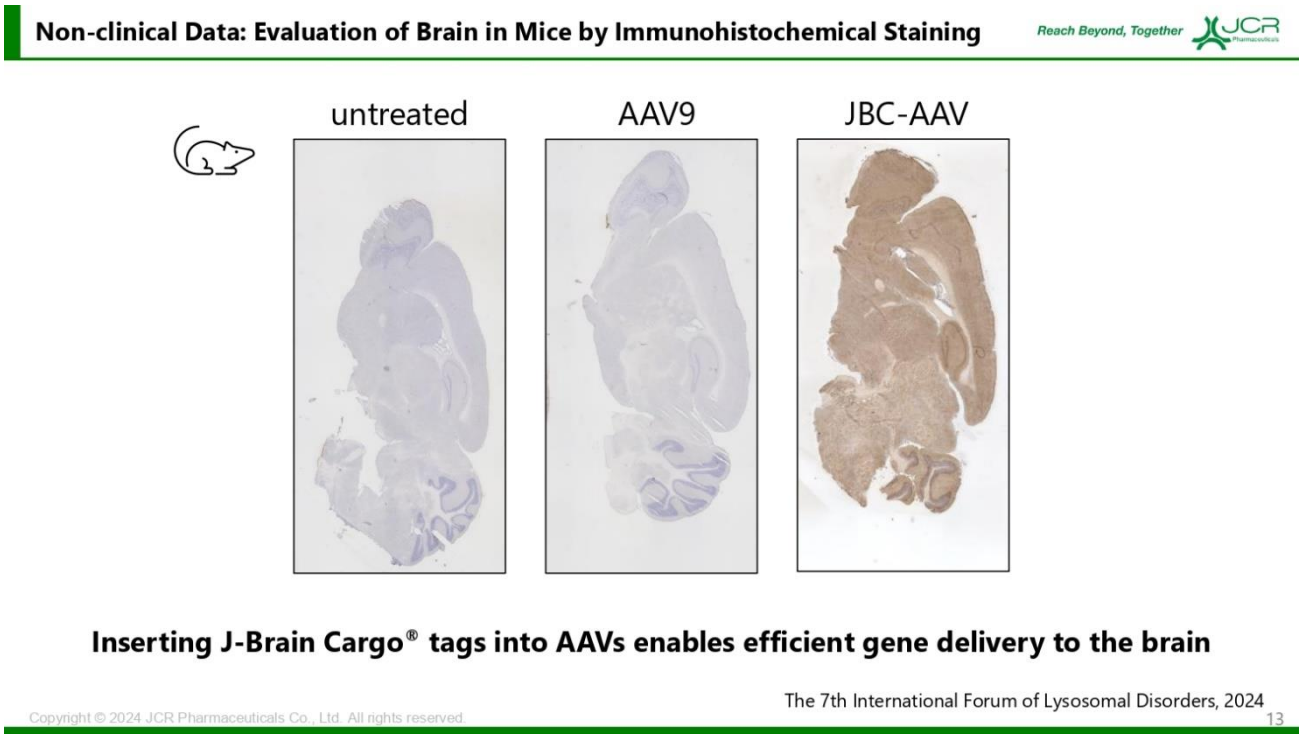
Also, if you look at the figure of tagged AAV in the previous slide, you might think that it is tagged afterwards. What we are doing now is that it is generated having the tag with it.

Therefore, there is no need to add the tag later. The AAV is generated from the cells, but it comes out as a finished product. It will be refined and used. Its manufacturing process is similar to the manufacturing process for AAVs.

Finally, we are now creating various types of J-Brain Cargo. That is because there are many different types of enzymes in enzyme replacement therapy. Also, we use various types of J-Brain Cargo when applying it to

antibody drugs and nucleic acid drugs, as I mentioned earlier. So, we already have various types of J-Brain Cargo which are different in affinities or molecule sizes, and so on.

So, by combining such things, the new AAV can be adjusted and optimized in various ways. We believe this is a major advantage of our technology.



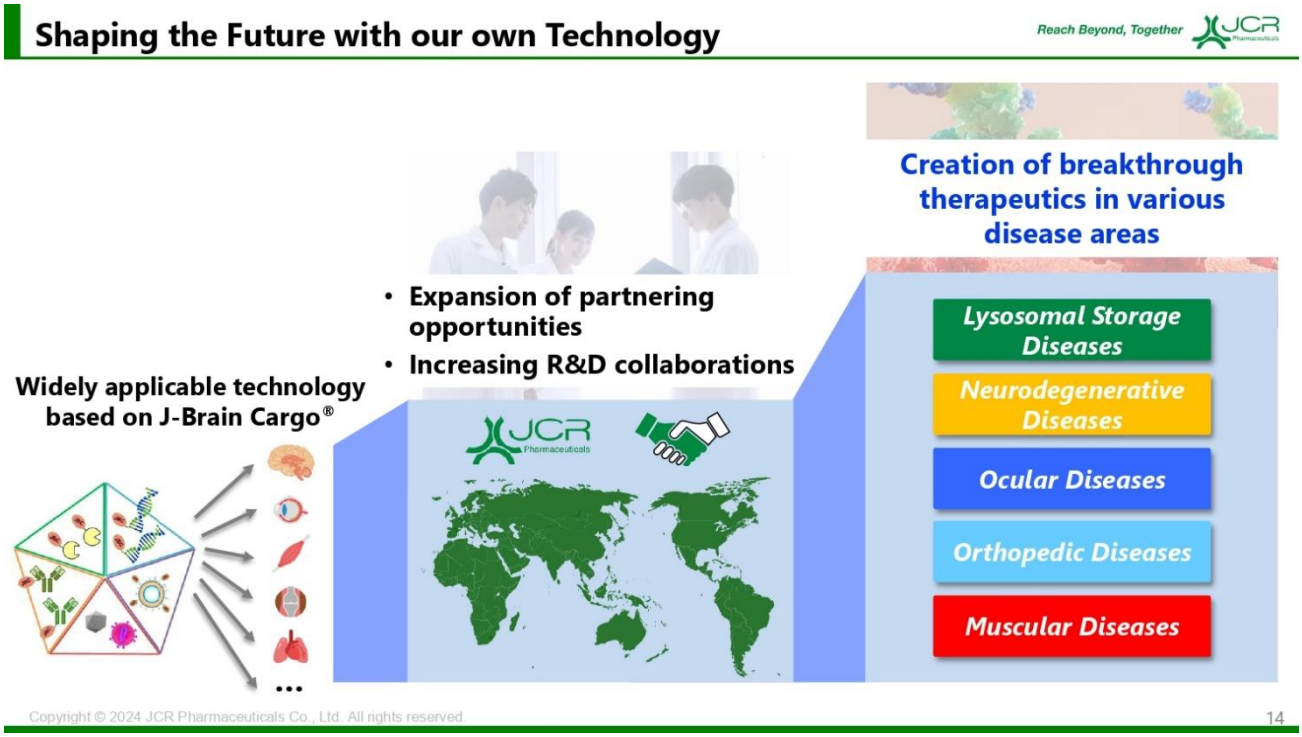

Here, I would like to present one piece of data.

This is the data of mice. We make sections of whole mouse brains and use a method called immunostaining to show where and how much AAV reaches and expresses the target genes. The brown tint is positive, and that is the picture of what we want to express.

The leftmost mouse is untreated and not administered anything. The middle one is AAV9, which, as I mentioned earlier, is an AAV that has been used frequently. On the right is our newly developed AAV, called JBC-AAV.

This is obvious at a glance. You can see that there is almost no staining in the untreated and the middle with AAV9, whereas the new vector on the right shows very intense staining of the entire brain.

Thus, by using the new vector, we have been able to show very high expression in mice in the brain, and although I will not show the data today, we have already obtained similar results in monkeys.




As I showed at the beginning, the pentagon is shown at the bottom left, and we are conducting research and development so that J-Brain Cargo can be used for various modalities.

Today, I showed you about gene therapy. Our technology is about delivering various modalities to the brain. And that it can also be delivered to organs that are not the brain by using the same base technology as J-Brain Cargo. I believe that by combining these, we will be able to deliver various modalities to various organs.

The range of applicability is very wide, but the range of diseases we can cover and the range of diseases that can be covered by technology are not exactly the same. We would like to expand our business opportunities by licensing and partnering with other companies for this technology that can cover other areas, and we are currently running several such collaborations in parallel.

This new gene therapy technology is very close to completion, and we are seeing good results, so of course we will use this as our own pipeline in the future, but we would also like to use this technology for further partnering opportunities.

That's all from me.

Thank you for your kind attention today.

## Question & Answer

**Moderator [M]**: We will now move on to the question-and-answer session.

**Yamaguchi [Q]**: My name is Yamaguchi from Citigroup Securities.

The first question is about the impact of the change in the US FDA's review stance on lysosomal disease on your pipeline.

Today we received an update on the current status of both JR-141 and JR-171. With this change in the FDA's stance, I believe that if there is a biomarker study, they will accept the application even if there is no pivotal, although I think they probably need data from Americans.

What is the impact on your company's current situation, including JR-141 and JR-171, and how much time will be saved in the development process?

**Bechet [A]*:** For JCR, we very much welcome these changes in the regulatory authorities. It increases flexibility. And it is good to know that the threshold for application and acceptance has been lowered. This is especially important in rare diseases. This is not only in JCR. For patients in all cases, with such conditions, this is a welcomed progress.

JCR is, of course, working closely with the regulators to determine how best to adapt the plan. By doing so, we hope to apply as soon as possible. This dialogue is ongoing, and we expect that the specific schedule will change in the future as a result of regulatory changes.

Therefore, we would like to apply as soon as possible. Of course, we would like to do this in cooperation with the regulatory authorities and in cooperation with the FDA.

**Yamaguchi [Q]**: Does “apply as soon as possible” include the year 2025? Will it be 2024 in some cases? Are you still unsure of the specifics there?

**Bechet [A]*:** Currently, we are still analyzing the data. As for dialogue with the FDA, we will start next year. I am sure this dialogue will further clarify the schedule.

**Yamaguchi [Q]**: As mentioned at the beginning by the chairman and president, I think you are talking about JR-171 or other alliances. As for JR-141, I think there was some talk about putting it all together, since it is coming back from Takeda Pharmaceuticals.

I don't know about the timing, but have there been any changes on the partnership side as a result of this change in the FDA? If so, what would be the changes?

**Ito [A]**: We are now moving forward with the tie-up. We are in specific discussions regarding JR-171, and we are also in discussions with several companies interested in JR-141.

Regarding the recent changes in the FDA, we have naturally talked about various issues during such negotiations. One of the points of interest, as you asked earlier, is how this change will affect the timeline.

I cannot discuss the details, but I can tell you that we are in negotiations with several companies for the out-licensing of the respective assets.

**Sakai [Q]**: My name is Sakai with UBS.

First of all, I think it is positive that the FDA's attitude has changed this time and that its policy is gradually changing, but on the other hand, what do you think about the speed of your company's development?

At the beginning of the meeting, Chairman Ashida mentioned that a global system for development, application, and various other global activities had been established. Is this a story for the future, and does it suggest that things will accelerate and move forward in the future? For example, there is a table on page eight of the various development stages that you introduced today. Is there any change that will occur? I don't think development will progress overnight. On the other hand, you mentioned that R&D expenses will also increase, so how do you plan to balance the two?

**Shin Ashida [A]**: The fact that we have a system in place means that we can accelerate the global development of clinical development. We gathered about 40 people with previous experience abroad for global development. Now that we have a complete system in place, we will be able to accelerate clinical development at a very rapid pace.

**Sakai [Q]**: I think Mr. Schmidt has resigned. Do you mean that the system and structures were established this June and later included that?

**Shin Ashida [A]:** Yes. This structure has been in place since April of this year or so. Schmidt remains as an advisor to science.

**Sakai [Q]**: I may have missed it in your explanation, but by Q1 and Q2, two cases of IZCARGO were acquired, or rather, entered into treatment. It was mentioned that several more patients are expected to be enrolled in H2, and that patients to date have continued to use the product, and that there have been no dropouts.

Then, the number of eligible patients at the peak in Japan, as I recall from the data of the Central Social Insurance Medical Council, was about 110. I think it was mentioned at the end of the last semester that it had already reached 100 people. If so, are you seeing a high possibility that the number of patients in Japan will exceed the initial 110?

**Toru Ashida [A]**: I, Ashida, will answer your question.

What you said was correct. For H1, September, there are 75 cases for IZCARGO, as shown in the table that has just appeared. In Q4, there will be no dropout cases this fiscal year, especially in H2, and we are planning to have several cases, including patients already scheduled for treatment, so we believe that we will be able to reach our target number of patients in H2.

**Sakai [Q]**: In H2, so how many cases was your company's target as of Q4 of this term?

**Ito [A]**: Last year we gained 13 new cases. We are proceeding with sales activities based on the assumption that the number of cases will be similar to that in the current fiscal year.

I think you mentioned earlier how many patients there are, and we think that there are about 200 patients. I am sure that new patients may be identified through various screenings, etc., but that is the way we see it at present.

**Sakai [Q]**: The figures from the Central Social Insurance Medical Council indicate that there has been a considerable increase.

**Ito [A]**: From the figures you just mentioned, I think that is correct.

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

Regarding JR-141, the US FDA application, Denali is planning to file in early 2025, and I think you announced recently that it is accelerated and that it will be a biomarker. Should we assume that the Company can apply at the same time as Denali Therapeutics Inc.? Should we assume that the timing of the application will be later than in Denali? Which is more likely?

**Bechet [A]*:** As I mentioned earlier, what we are doing now is reviewing all the data we have gathered to date. And we are working with the FDA to explore all possibilities on a biomarker basis with respect to the application. Whether it will be at the same time as Denali or delayed will depend on the FDA.

Another point I would like to emphasize is that there is a big difference between filing an application and getting approval. I believe this is the same for Denali and for any company with accelerated approval.

**Muraoka [Q]**: For IZCARGO, my question is about the commercial aspect in the US. If the approval is delayed by six months compared to the competition, how much would you consider it a commercial disadvantage?

**Ito [A]**: I'm sure there are many ways of viewing this point, but we are thinking now that if it is only six months, as you mentioned, it may not be too much of a disadvantage, considering the superiority of the drug and other factors.

**Muraoka [Q]**: Do you feel that one year would be too much? I would like to know to what extent you consider this to be permissible.

**Ito [A]**: I cannot answer that specifically. We believe that the rest will actually come down to the superiority of the drugs, the differences, and such.

**Muraoka [Q]**: Just one more thing, regarding the JBC-AAV gene therapy vector, is the main scenario for future business development to license out this technology and wait for future royalties? Do you envision collaborating together, for example in lysosomal disease, and do you envision mainly partners to develop gene therapy together? Which is it?

**Sonoda [A]**: Both. We are not leaning one way or the other but would like to work on diseases where we can create our own pipeline and complete the whole process by ourselves. Of course, it is our own technology.

We just don't think we can use up all the technologies we developed on our own. We really think that we have made very good vectors, so if you just look at the data, we really think that our vectors are at the top level in the world. So, in order to make this good vector available to as many patients as possible, we would like to be very flexible if we can find partners to work with. As for diseases that we can handle on our own, of course we would like to handle them ourselves.

**Yamakita[Q]**: My name is Yamakita from Jefferies Securities. I would like to ask two questions.

The first question is about J-Brain Cargo's AAV technology. I think that AAV may become too potent when administered in too large a dose, and for this reason, I think that the permeability of the blood-brain barrier

may be quite important. Regarding this permeability technology, is it something that has gone up compared to what it was in IZCARGO? Specifically, I would like to know if there are any areas where this type of technology is being raised within J-Brain Cargo.

**Sonoda [A]**: I can't give you a figure right at this moment to compare with IZCARGO. Since they use the same mechanism and the same platform technology, so I think it is acceptable to assume that they are roughly at the same level.

However, for the AAVs that penetrate through the BBB to get to the brain, I don't think it is conducted. Mice studies give good results to a certain extent, but it is not so easy to do so in humans. So, I think it is difficult to use it in a wide range of areas because of the need for high dosage and the toxicity it causes.

Compared to that, I think it will be a completely different world, so it is difficult to give a figure for how many times this is the case, but we believe that by using our new vectors, many diseases that could not be treated before will become candidates for treatment.

**Yamakita [Q]**: My second point, briefly, is about TEMCELL. Since competition emerged, I was expecting a more vigorous drop, but do you have any specific reasons why the drop was less than expected?

**Toru Ashida [A]**: Regarding TEMCELL, as you have just asked, the plan itself was initially set at about 80% of the plan due to the launch of a competing product this fiscal year. However, for diseases such as gastrointestinal tract where TEMCELL is originally strong, TEMCELL is still being used strictly from the secondary treatment for those where competing products do not work. We are making very good progress against our projections and plans, and rather than a gradual decline, we are evaluating that TEMCELL's positioning is now very stable.

**Tsuzuki [Q]**: I am Tsuzuki from Mizuho Securities.

I think there is this contract revenue of JPY8.1 billion, but I would like to ask how certain you are about this. If JR-141 and JR-171 are delayed, would it be made up in the form of technology licensing, for example? Is there other option rights included? Can you first tell us the certainty of this contract revenue of JPY8.1 billion?

**Ito [A]**: Regarding the 8.1 billion figure, as we have said since the beginning of the fiscal year, we have set a firm figure that we believe we can achieve. We are working hard to achieve this figure in H2, and since this figure is set as such, we believe that we will manage to achieve it during H2.

**Tsuzuki [Q]**: Another point is about the J-Brain Cargo tag for AAV capsids. It was quite interesting to read in specialized journals and such about the core capsid location and ratio, and how hepatotoxicity could be avoided and the dosage lowered by an order of magnitude.

Is this likely to be targeted by a major system as a technology licensing? Or is it likely to take the form of a biotech company? I would be happy to receive more information on these points, including timelines.

**Sonoda [A]**: Now, it is difficult to answer your questions. However, there are some companies interested in AAV, both large and biotech.

As you know, I wonder if the AAV fever is really over for a time, as it once was. Still, they are waiting for a new type of AAV. I see the fever as being over because it is very difficult to find the right AAV today. As new ones come out, as I mentioned earlier, diseases that were not previously covered will be covered. In that sense, I believe there are many potential partners for companies, large and small.

In terms of timeline, it is still difficult to say when we will be able to do so. However, we have actually already done such things as actually talking with people who are interested in the project and having them confirm the sensitivity of the project and what it is like before collaboration.

In the not-too-distant future, we will be able to do many things together with our partners, and we are also planning to create a new pipeline ourselves using this technology. It is difficult to say when this will happen because of the nature of research and drug development. As a JCR stand-alone, we would like to target rare diseases.

**Tsuzuki [M]**: I think it would be very interesting if hepatotoxicity is avoided and the dosage can be lowered by an order of magnitude, so I have high hopes. Thank you very much.

**Moderator [M]**: Okay, last question, Mr. Mizuno, please.

**Mizuno [Q]**: I have two vague questions, and I'd appreciate it if you can give us even qualitative answers.

I know you presented about AAV at conferences in August and October, but is there anything you can tell us about the reactions?

Also, I understand that you will tell us more about that conference presentation at the upcoming R&D briefing, is that understanding correct?

**Sonoda [A]**: In July and October, I made presentations at conferences. We had many inquiries after the oral and poster presentations, and there were also many questions at the conference.

As I said before, everyone, those of you who are doing gene therapy are always looking for these new vectors. We have an advantage in tagging, and since we have a variety of tags to begin with, we are able to make various adjustments.

We at J-Brain Cargo are currently developing various technologies for the brain, and these tags are interchangeable. It allows us to target different organizations. For those who can quickly understand this concept, it probably seems very appealing, and there were many questions in this area.

**Mizuno [Q]**: One more thing, I think there will be an additional announcement later this week, but Roche's Alzheimer's drug, Brainshuttle, this technology is also similar to your technology. It is not a question of which is better or worse, but since this Roche technology has produced quite good data on Alzheimer's disease, is this a tailwind or a headwind for your company? Could you please provide some comments in that area, even qualitative ones?

**Sonoda [A]**: I see it as a tailwind. The reason is that there are not many people or companies that properly understand the science of this BBB.

It's easy to understand it in a flash, but not many people can quickly answer the question, "What is the difference between going through the BBB and entering the CSF?" I thought I had no choice but to show with data how important it is to really go beyond the BBB in making a CNS drug.

We have been showing this in lysosomal disease, but for Roche to show it in such a way in Alzheimer's disease, which is not a rare disease like lysosomal disease, I think it had a considerable impact.

When you look at that data, when you see how well that dosage works compared to others, I think there is a growing awareness that the BBB-penetrating technology is essential for the development of drugs for the brain.

Then, will those companies that would like to launch such products with Roche's technology be able to do so? No, that will hardly be the case. We are one of the leading companies in this BBB technology, and we are also a company that strongly promotes licensing and partnering in this field. There have actually been inquiries for our BBB technology after Roche's news, so I think this is a tail wind.

**Moderator [M]**: I am sorry, but due to time constraints, we will now conclude the question-and-answer session.

Finally, I would like to inform you all. On November 20, we will be holding an R&D meeting on the gene therapy research we are working on. We look forward to your participation.

With that, we now close the financial results briefing of JCR Pharmaceuticals Co., Ltd. for Q2 of the fiscal year 2024. Thank you very much for joining us today.

[END]

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***Document Notes***

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