



JCR Pharmaceuticals Co., Ltd.

Financial Results Briefing for the Fiscal Year Ended March 2022 Presentation

May 12, 2022

Event Summary

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[Participants]	
[Number of Speakers]	3
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Presentation

Ashida: My name is Ashida. Thank you all for your support. Today, we will present the financial results for the fiscal year ending March 31, 2022.

These marked the 10th consecutive fiscal year of revenue growth. We achieved record revenue and profits for the second consecutive fiscal year. The production of AstraZeneca's vaccine stock solution was successfully completed as contracted. Even excluding the consideration for AstraZeneca's vaccine solution, sales and profits increased and reached a record high.

In May 2021, IZCARGO began sales in Japan, where sales exceeded initial expectations. We look forward to further market penetration in the future. In September 2021, we entered into a licensing agreement with Takeda Pharmaceutical for JR-141. In March 2022, we entered into a joint research and development agreement for J-Brain Cargo gene therapy with Takeda. In this fiscal year, we have achieved the sales and operating profit forecasts set for the fiscal year ending March 31, 2023, the final year of the REVOLUTION mid-term plan. Of course, we will continue to take on our key management issues.

We are also actively working to further accelerate and enhance our efforts to date under the principles of the SDGs. Regarding CO₂ reduction, we introduced hybrid or electric vehicles over 10 years ago. Each plant is also implementing measures to save energy. In addition, we have created a comfortable work environment for our employees, with the aim of ensuring that they can work for a long time regardless of gender or age. The turnover rate for the previous year was 1.1%.

I believe that research will be a very important issue for our company in the future. Research and development expenses for the fiscal year ending March 31, 2022, totaled JPY7.1 billion. Research and development expenses for the fiscal year ending March 31, 2023, are expected to be JPY9 billion. We would like to accelerate our research for the evolution and development of J-Brain Cargo technology and for the development of new fundamental technology to follow J-Brain Cargo. To this end, we would like to invest R&D funds without hesitation.

We appreciate your continued understanding and support.

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FY2021
results
(Apr. 1, 2021-
Mar. 31, 2022)

Net sales, operating income, ordinary income and profit have all reached record highs

Net sales : 51,082 million yen, Year-on-year +69.8%

Operating income : 19,933 million yen, YoY +141.1%

Ordinary income : 20,512 million yen, YoY +141.6%

Profit : 14,507 million yen, YoY +110.5%

- Core products: IZCARGO® ended up largely exceeding initial forecasts (3,003 million yen). GROWJECT® grew on a volume basis (+4.7%) but saw sales decrease YoY due to the impact of NHI price revisions.
- SG&A expenses and R&D expenses increased YoY, but the effect of the increase in sales led to a significant increase in each profit item.

Ohta: I am Ohta from accounting. I would like to provide an overview of the financial results for the fiscal year ending March 31, 2022.

During the period under review, we achieved record figures and business results. Net sales totaled JPY51.082 billion, up 69.8% from the previous year. Operating profit also increased 141.1% YoY to JPY19.933 billion. Ordinary income was JPY20.512 billion, up 141.6% YoY. Net income was JPY14.507 billion, up 110.5% YoY, a significant increase in both sales and income.

Our main product, IZCARGO, was launched in the current fiscal year, and so far, results have greatly exceeded our initial forecast. Sales of GROWJECT increased by 4.7% on a volume basis but were affected by the NHI drug price revision.

Although both selling, general and administrative expenses and research and development expenses increased from the same period of the previous year, each stage of profit increased significantly due to the effect of increased sales.

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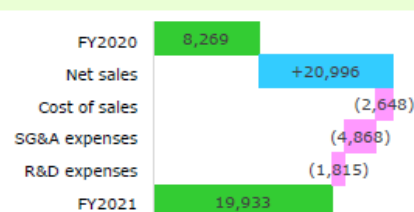


Consolidated Results

(Unit: million yen)

Consolidated	FY2020 (Apr. 1, 2020- Mar. 31, 2021) A	FY2021 (Apr. 1, 2021-Mar. 31, 2022)		Reference Forecast (after revision)
		B	Year-on- year (B-A)/A	
Net sales	30,085	51,082	+69.8%	52,000
Cost of sales	7,812	10,461	+33.9%	8,300
Gross profit	22,272	40,620	+82.4%	43,700
SG&A expenses	8,643	13,511	+56.3%	11,700
R&D expenses	5,360	7,175	+33.9%	10,300
Operating income	8,269	19,933	+141.1%	21,700
Ordinary income	8,488	20,512	+141.6%	21,700
Profit attributable to owners of parent/Profit	6,892	14,507	+110.5%	15,400
Ratio of cost of sales	26.0%	20.5%	(5.5)%	
Ratio of cost of R&D	17.8%	14.0%	(3.8)%	
Operating profit ratio	27.5%	39.0%	+11.5%	
(Reference)				
R&D expenses**	5,856	7,671	+31.0%	11,080

◆ Operating income 19,933 million yen
Year-on-year: +11,664 million yen



Main change factors (YoY)

- Significant increase in net sales mainly through license revenue and AZD1222 bulk solution
+20,996 million yen
- Increase in the cost of sales due to an increase in net sales
(2,648) million yen
- Increase in SG&A expenses due to personnel increases, royalties for sales, and commission expenses limited to the current period, etc.
(4,868) million yen

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Financial 2

I would like to continue with an overview of the financial results.

Net sales increased significantly to JPY51.082 billion, up 69.8% from the same period last year. Gross profit was JPY40.62 billion, a significant increase over the previous year.

Meanwhile, selling, general, and administrative expenses totaled JPY13.511 billion, up 56.3% YoY. Research and development expenses, also here, totaled JPY7.175 billion, up 33.9% YoY.

As a result, operating profit increased significantly to JPY19.933 billion, up 141.1% YoY. Ordinary income was JPY20.512 billion, and final income was JPY14.507 billion, an increase of 110.5% over the same period last year.

The ratio of net sales to total sales is shown below. The cost of sales ratio was 20.5%, a negative of 5.5% compared to the same period last year. The ratio of R&D expenses was 14.0%, down from 17.8% in the previous year. The operating profit ratio for the current fiscal year was 39.0%, compared to 27.5% in the previous fiscal year, a significant increase of 11.5%.

The main reasons for the change are listed on the right side. First, operating profit increased due to a JPY20.996 billion increase in net sales compared with the same period last year. As a result, cost of sales increased by JPY2.648 billion. In addition, selling, general, and administrative expenses and R&D expenses increased. As a result, operating profit was JPY19.933 billion.

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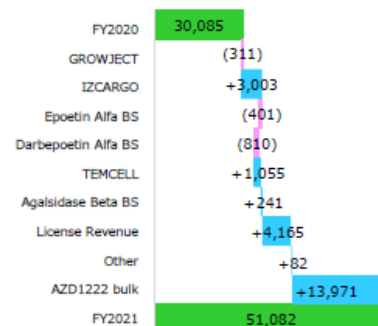


Breakdown of net sales (Consolidated)

(Unit: million yen)

	FY2020 (Apr. 1, 2020- Mar. 31, 2021)		FY2021 (Apr. 1, 2021-Mar. 31, 2022)			Reference
		Composition ratio		Composition ratio	Year-on-year (B-A)/A	Forecast (after revision)
GROWJECT®	13,256	44.1%	12,945	25.3%	(2.3)%	13,900
IZCARGO®	-	-	3,003	5.9%	-	2,800
Treatments for renal anemia	7,087	23.6%	5,875	11.5%	(17.1)%	6,400
Epoetin Alfa BS Inj. [JCR]	3,278	10.9%	2,876	5.6%	(12.2)%	2,700
Darbepoetin Alfa BS Inj. [JCR]	3,809	12.7%	2,998	5.9%	(21.3)%	3,700
TEMCELL® HS Inj.	2,441	8.1%	3,497	6.9%	+43.2%	3,200
Agalsidase Beta BS I.V. Infusion [JCR]	470	1.6%	711	1.4%	+51.3%	800
Total pharmaceutical products	23,255	77.3%	26,032	51.0%	+11.9%	27,100
License Revenue	6,406	21.3%	10,571	20.7%	+65.0%	10,200
Other	18	0.1%	102	0.2%	(5.2 times)	0
AZD1222 bulk	404	1.3%	14,375	28.1%	(35.6 times)	14,700
Total Net Sales	30,085	100.0%	51,082	100.0%	+69.8%	52,000

◆ Net sales 51,082 million yen
Year-on-year: +20,996 million yen



Main change factors (YoY)

- More market penetration of IZCARGO® than expected
+3,003 million yen
- Increase in license revenue (global licensing-out of JR-141, collaborative research on gene therapy, etc.)
+4,165 million yen
- Shipment of AZD1222 bulk solution according to the contract
+13,971 million yen

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I would like to continue with the breakdown of net sales.

First, sales of GROWJECT totaled JPY12.945 billion, down 2.3% YoY. Total sales of IZCARGO were JPY3.003 billion, a greater rate of increase than we had initially forecast.

On the other hand, sales of renal anemia drugs totaled JPY5.875 billion, down 17.1% YoY.

Sales of TEMCELL showed a significant increase of 43.2% over the same period last year, increasing to JPY3.497 billion. Agalsidase Beta sales totaled JPY711 million, up 51.3% YoY.

The total sales of pharmaceuticals, including these sales, amounted to JPY26.032 billion, an increase of 11.9% over the same period last year. This is obviously quite a significant increase.

Contract revenue also increased by 65% from the same period last year to JPY10.571 billion, again a significant increase. In addition, JPY14.375 billion was recorded for the current fiscal year for AZD1222 coronavirus vaccine solution. This was also a large increase from the previous year.

As a result, total net sales were JPY51.082 billion, an increase of 69.8% YoY.

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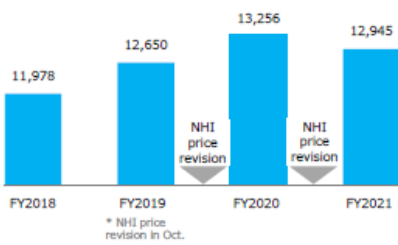
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Net Sales Trends by Product

Recombinant human growth hormone product
GROWJECT®



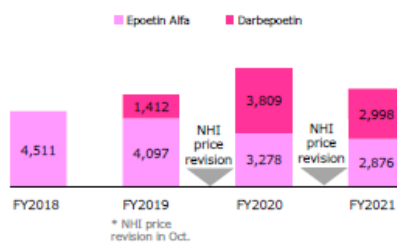
(Unit: million yen)

Recent topics

- Oct. 2020: Change in sales structure
- Oct. 2020: Launch of Melon Nikki™

Recombinant erythropoietin product
Epoetin Alfa BS Inj. [JCR]

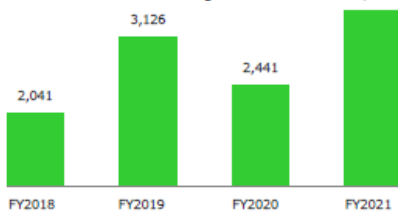
Long-acting erythropoiesis-stimulating agent
Darbepoetin Alfa BS Inj. [JCR]



Recent topics

- Apr.-May 2021: Restricted shipment of Epoetin Alfa BS Inj. [JCR] syringe products
- Aug. 2021: Eliminated restrictions on shipments of Darbepoetin Alfa BS Inj. [JCR] syringe products

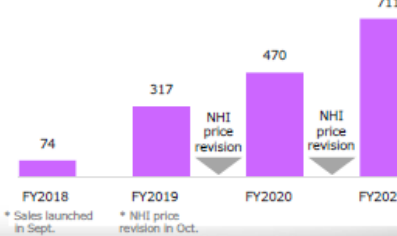
Human somatic stem cell-processed products
Human (allogenic) bone marrow-derived mesenchymal stem cells
TEMCELL® HS Inj.



Recent topics

- Apr.-Aug. 2020: Shipment restrictions due to inventory shortage

Recombinant treatment for Fabry disease
Agalsidase Beta BS I.V. Infusion [JCR]



The graph below shows sales by product. This summarizes what I've just explained.

Sales of GROWJECT decreased slightly in the current fiscal year. However, the situation is favorable on a volume basis.

The right-hand side of the chart shows sales of Epoetin Alfa and Darbepoetin Alfa. As I mentioned earlier, there was a decrease in revenue here. As shown on the right, the shipment restriction of Epoetin Alfa was lifted in April, and that of Darbepoetin was lifted in August 2021. These factors have also contributed to the decrease in revenues.

TEMCELL appears at the bottom left. Last fiscal year, sales of this product declined slightly due to inventory constraints that led to shipping restrictions. This fiscal year, sales were favorable due to the absence of these factors.

Agalsidase Beta, at the bottom right, has also seen a steady increase in sales since its launch.

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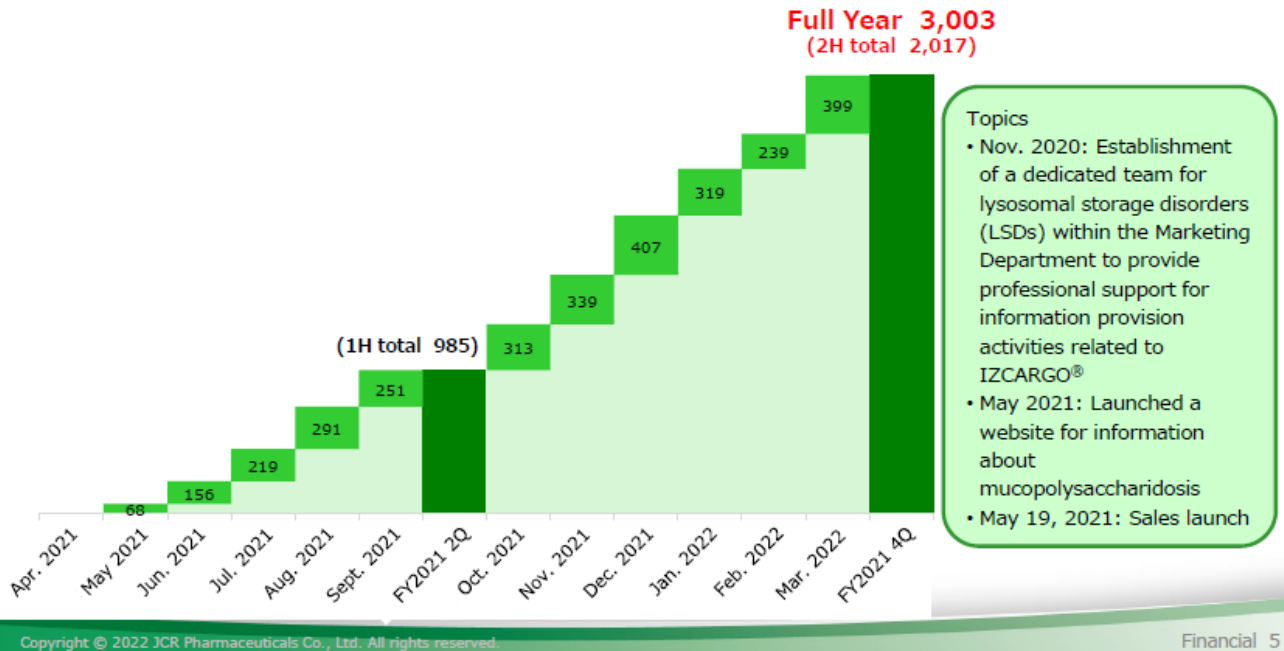
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IZCARGO® Monthly Sales Trends

(Unit: million yen)



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The following table shows the monthly sales of IZCARGO.

Sales have been increasing steadily every month, with sales of JPY399 million for the month of March 2022, and cumulative sales of JPY3.003 billion.

In November, a dedicated unit for lysosomal disease was established within the Marketing Department to provide active information provision support related to IZCARGO.

In addition, we are in the process of launching an information website on mucopolysaccharidosis in May and are actively working to increase sales.

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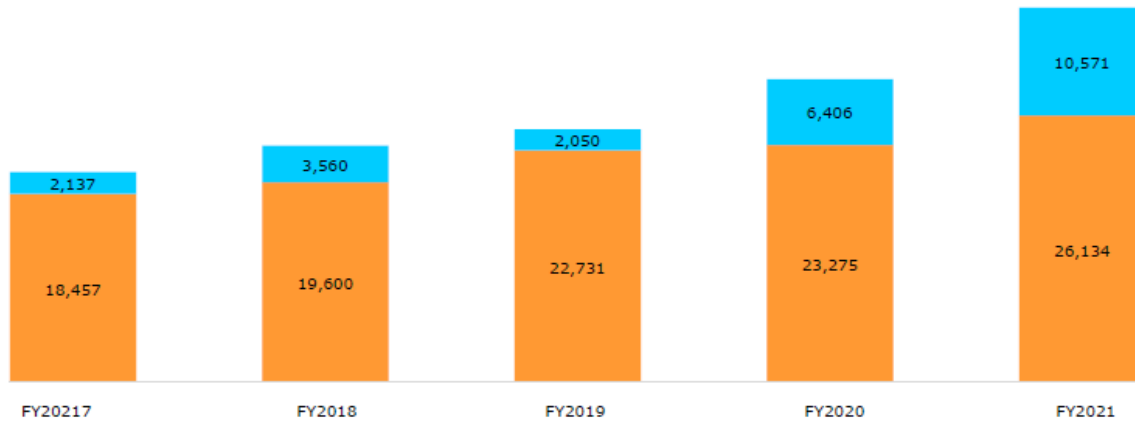


Net Sales Trends (Excluding AZD1222 Bulk Solution)

Products* sales License revenue

(Unit: million yen)

* Products: GROWJECT, IZCARGO, treatment for renal anemia, TEMCELL, Agalsidase Beta BS I.V. Infusion [JCR], others



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Next, I'll talk about sales trends. This shows trends, excluding production of the coronavirus vaccine solution.

The orange portion of the chart shows sales of manufactured goods. As for this side, the situation has been favorable for the past five years, with a steady increase. For the current fiscal year, we have recorded JPY26.134 billion.

The blue area above shows contract revenue. This amount was JPY10.571 billion in the current fiscal year and is increasing steadily.

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Financial Status (Consolidated)

(Unit: million yen)

	Mar. 2021	Mar. 2022	Change · Main Increase/decrease		Mar. 2021	Mar. 2022	Change · Main Increase/decrease
Current assets	48,545	62,188	Total +13,642 · Cash and deposits +4,472 · Accounts receivable-trade +7,402 · Inventories +1,082	Current liabilities	29,028	42,054	Total +13,025 · Special suspense account for tax purpose reduction entry +8,167 · Short-term loans payable +2,300
				Non-current liabilities	6,199	3,990	Total (2,208) · Long-term loans payable (2,300)
				Total liabilities	35,227	46,045	+10,817
Non-current assets	25,238	34,946	Total +9,707 · Property, plant and equipment +9,610	Total net assets	38,557	51,089	Total +12,531 · Dividends (2,170) · Recorded profit +14,446
Total	73,784	97,134	+23,349	Total	73,784	97,134	+23,349
				Equity ratio	51.3%	51.8%	

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I would like to continue with an explanation of our financial status.

On the left is the total assets, JPY97.134 billion. Compared to the beginning of the fiscal year, it has increased by JPY23.349 billion. The main breakdown of the increase is as follows: current assets increased by JPY13.642 billion and fixed assets increased by JPY9.707 billion. Regarding current assets, cash and deposits amounted to JPY4.472 billion. Accounts receivable increased by JPY7.402 billion.

On the other hand, liabilities totaled JPY46.045 billion, up JPY10.817 billion from JPY35.227 billion at the end of the previous fiscal year. Current liabilities increased by JPY13.025 billion.

Total net assets amounted to JPY51.089 billion, up JPY12.531 billion from the previous year. There was net income of JPY14.446 billion and dividends of JPY2.170 billion paid out of the net income.

The equity ratio was 51.8%, up 0.5% from the end of the previous fiscal year.

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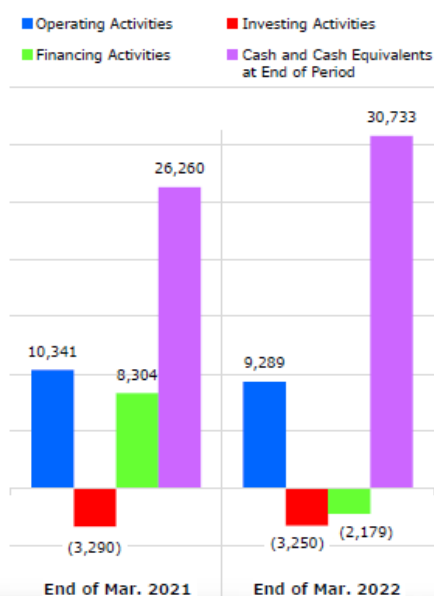
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Cash Flows (Consolidated)

(Unit: million yen)



	End of Mar. 2021 A	End of Mar. 2022 B	Year-on-year B - A
Income before income taxes	8,653	19,404	10,751
Depreciation and amortization	1,892	1,945	52
Accounts receivable-trade	(205)	(7,402)	(7,197)
Inventories	(4,699)	(1,082)	3,617
Accounts payable-trade	2,253	(1,608)	(3,861)
Other	2,446	(1,966)	(4,413)
Operating Activities	10,341	9,289	(1,052)
Securities	0	0	0
Capital investment	(4,780)	(11,333)	(6,552)
Other	1,490	8,083	6,593
Investing Activities	(3,290)	(3,250)	40
Loans payable	9,420	0	(9,420)
Cash dividends paid/ treasury stock	(1,069)	(2,158)	(1,089)
Other	(46)	(20)	25
Financing Activities	8,304	(2,179)	(10,483)
Net increase (decrease) in cash and cash equivalents	15,332	4,472	(10,859)
Cash and Cash Equivalents at End of Period	26,260	30,733	4,472
[Reference]			
Depreciation and amortization	1,892	1,945	
Capital investment	3,319	4,472	

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Next, I would like to explain the status of cash flows.

First, as I mentioned earlier, the balance of cash and deposits at the end of the period was JPY30.733 billion, an increase of JPY4.472 billion from the beginning of the period.

First, cash flow from operating activities amounted to JPY9.289 billion. The main breakdown is as follows: income before income taxes was JPY19.404 billion. Another major factor is trade receivables, which increased by JPY7.402 billion at the end of the fiscal year. Inventories increased by JPY1.082 billion. The main factor was a decrease of JPY1.608 billion in notes and accounts payable trade.

Net cash used in investing activities was JPY3.250 billion. The main factor was capital expenditures of JPY11.333 billion, while grants of about JPY8 billion were received. This resulted in a net cash outflow from investing activities of JPY3.250 billion.

Net cash used in financing activities was JPY2.179 billion. The main item was JPY2.158 billion in cash dividends paid.

As a result, cash and cash equivalents increased by JPY4.472 billion.

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 Asia's Meetings, Globally

Earnings Forecast (Apr. 1, 2022- Mar. 31, 2023)

Net sales : 45,000 million yen, Year-on-year (11.9)%
Operating income : 14,500 million yen, YoY (27.3)%
Ordinary income : 14,500 million yen, YoY (29.3)%
Profit : 10,300 million yen, YoY (29.0)%

- Sales and profit will decrease compared to FY2021 due to termination of the AZD1222 bulk solution manufacturing business. However, we will aim for increased sales and profit in businesses excluding the AZD1222 bulk solution manufacturing business.

	FY2021	FY2022	Year-on-year
Net sales excluding AZD1222 bulk solution	36,706 million yen	43,070 million yen	+17.3%

- Aim to expand domestic share of IZCARGO®.
 - Offset the impact of NHI price revisions through increased sales volume of GROWJECT® and aim for steady increases.
 - Transfer sales duties of Agalsidase Beta BS I.V. Infusion [JCR] to Sumitomo Pharma Co., Ltd. starting from this fiscal year.
 - Work actively on licensing business including licensing-out of lysosomal storage disorders (LSDs) pipeline products and technological collaboration, and forecast license revenue of 15,400 million yen.
- While SG&A expenses are forecast to decrease YoY based on changes in the sales composition ratio, R&D expenses are forecast to increase as a result of progress on global clinical trials.
 - SG&A expenses: (7.5)%
 - R&D expenses: +25.4%

I would like to continue by explaining our forecast for the fiscal year ending March 31, 2023.

First, we forecast net sales of JPY45 billion, operating profit of JPY14.5 billion, ordinary income of JPY14.5 billion, and net income of JPY10.3 billion. We forecast a fall in both sales and profits compared to the fiscal year ending March 31, 2022.

The main reason for this is the termination of the AZD1222 new coronavirus vaccine stock solution manufacturing business, which is expected to result in lower sales and profits. However, we aim to increase sales and profits in all businesses except the AZD1222 bulk liquid production business.

Here are the sales figures excluding AZD1222 solution. The result for the fiscal year ending March 31, 2022, was JPY36.706 billion, and we expect JPY43.07 billion for the fiscal year ending March 31, 2023, a 17.3% increase.

The increase in sales can be attributed to our efforts to further expand the domestic market share of IZCARGO.

In addition, we are aiming for a steady increase in sales volume of GROWJECT, which should offset the impact of the NHI price revision.

In addition, sales operations for Agalsidase Beta BS JCR for intravenous infusion will be transferred to Sumitomo Pharma. We aim to expanding our market share and sales.

In addition, we will continue to be active in the licensing business and here as well, through out-licensing of lysosomal disease development items and technical tie-ups. As a result, contract revenue is expected to be JPY15.4 billion.

While selling, general and administrative expenses are expected to decrease from the previous year due to the change in the sales composition ratio, R&D expenses are expected to increase from the previous year due to the progress of global clinical trials.

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FY2022 Forecast (Consolidated)

(Unit: million yen)

Consolidated	FY2021 (Apr. 1, 2021- Mar. 31, 2022) A	FY2022 forecast (Apr. 1, 2022- Mar. 31, 2023) B	Increase/ decrease B - A	Year-on-year (B-A)/A
Net Sales	51,082	45,000	(6,082)	(11.9)%
Cost of sales	10,461	9,000	(1,461)	(14.0)%
Gross profit	40,620	36,000	(4,620)	(11.4)%
SG&A expenses	13,511	12,500	(1,011)	(7.5)%
R&D expenses	7,175	9,000	+1,824	+25.4%
Operating Income	19,933	14,500	(5,433)	(27.3)%
Ordinary Income	20,512	14,500	(6,012)	(29.3)%
Profit	14,507	10,300	(4,207)	(29.0)%
Ratio of Cost of Sales	20.5%	20.0%	(0.5)%	
Ratio of Cost of R&D	14.0%	20.0%	+6.0%	
Operating Profit Ratio	39.0%	32.2%	(6.8)%	
(Reference)				
R&D expenses	7,671	9,500	+1,829	+23.8%

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Financial 10

I would like to continue with an explanation of the contents of the income statement.

To reiterate, forecast net sales are JPY45 billion, down JPY6.082 billion from the same period last year.

Gross profit is forecast to be JPY36 billion. Selling, general, and administrative expenses are forecast to be JPY12.5 billion, a decrease of JPY1.011 billion from the previous year.

On the other hand, as I mentioned earlier, we will aggressively invest in R&D for overseas global expansion, and expansion as a whole. We expect to spend JPY9 billion for R&D during the current fiscal year. Compared to the fiscal year ending March 31, 2022, the increase is JPY1.824 billion. However, we will continue to invest aggressively in research and development, which is essential for further development in the future.

As a result, operating profit is expected to be JPY14.5 billion. The figure for ordinary profit is JPY14.5 billion. Final net income is forecast to be JPY10.3 billion. Compared to the fiscal year ending March 31, 2022, income will decrease by 29.0%.

The following table shows the ratio of sales to total sales.

First, we forecast a cost of sales ratio of 20%. This is a 0.5% decrease from the previous year. This is due to a change in the sales mix.

R&D expenses are 20% of net sales. The previous year's figure for the fiscal year ended March 31, 2022, was 14%, which represents a 6% increase. As I mentioned earlier, we are actively engaged in R&D this fiscal year. While R&D costs are rising, we are maintaining the 20% ratio to net sales that we set out in our mid-term management plan.

As a result, the operating profit margin was 32.2%, a decrease of 6.8% from the previous year.

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FY2022 Forecast (Consolidated)

(Unit: million yen)

	FY2021 (Apr. 1, 2021-Mar. 31, 2022)		FY2022 forecast (Apr. 1, 2022-Mar. 31, 2023)		Increase/ decrease (B-A)
	A	Composition ratio	B	Composition ratio	
GROWJECT®	12,945	25.3%	13,100	29.1%	154
IZCARGO®	3,003	5.9%	5,210	11.6%	2,206
Treatments for renal anemia	5,875	11.5%	4,930	11.0%	(945)
Epoetin Alfa BS Inj. [JCR]	2,876	5.6%	2,630	5.8%	(246)
Darbepoetin Alfa BS Inj. [JCR]	2,998	5.9%	2,300	5.1%	(698)
TEMCELL® HS Inj.	3,497	6.9%	3,530	7.8%	32
Agalsidase Beta BS I.V. Infusion [JCR]	711	1.4%	760	1.7%	48
Total Core Products	26,032	51.0%	27,530	61.2%	1,497
License Revenue	10,571	20.7%	15,400	34.2%	4,828
Other	102	0.2%	140	0.3%	37
AZD1222 bulk	14,375	28.1%	1,930	4.3%	(12,445)
Total Net Sales	51,082	100.0%	45,000	100.0%	(6,082)

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Financial 11

Next, I would like to present the sales forecast.

First, for GROWJECT, we expect an increase of JPY154 million from the fiscal year ending March 31, 2022, to JPY13.1 billion, as the NHI price revision will be compensated for by an increase on a volume basis.

In addition, we expect sales of IZCARGO to reach JPY5.21 billion, an increase of JPY2.2 billion compared to the fiscal year ending March 31, 2022. This is due to further expansion of market share.

On the other hand, sales of renal anemia treatments are expected to be JPY4.93 billion, down JPY945 million from the fiscal year ending March 31, 2022.

Sales of TEMCELL are forecasted at JPY3.53 billion, about the same level as the fiscal year ending March 31, 2022.

We also forecast sales of JPY760 million for Agalsidase Beta BS intravenous infusion JCR. This is increasing on a volume basis.

As a result, total sales of main products are expected to be JPY27.53 billion, an increase of JPY1.497 billion from the same period last year.

Contract revenue is expected to be JPY15.4 billion, an increase of JPY4.828 billion over the fiscal year ending March 31, 2022.

Also, regarding AZD1222 bulk solution, the figure for the fiscal year ending March 31, 2022, is JPY14.375 billion. In the fiscal year ending March 31, 2023, we will only record JPY1.93 billion. This was planned for the fiscal year ending March 31, 2022 but has been slightly delayed.

As a result, we forecast total sales of JPY45 billion. This concludes the summary of our financial results for the fiscal year ended March 31, 2022, and our forecast for the fiscal year ending March 31, 2023. Thank you for your attention.

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Agenda

- R&D Highlights
- R&D Updates
- Vaccine Stock Production Business

- Interim Summary of Midterm Business Plan “REVOLUTION”

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Business 1

Sonoda: Hello, everyone. I am Sonoda, Research and Corporate Strategy. I am pleased to present our business report for the fiscal year ending March 31, 2022.

First, the table of contents. I will cover R&D highlights and a progress report. After that, I will talk about the vaccine solution production business. Finally, I would like to talk about the interim summary of the mid-term management plan, "REVOLUTION."



Research and Development Highlights (Sep 2021 – Apr 2022)

2021

- ◆ Sep. Entered into an exclusive collaboration and commercialization agreement for **JR-141** (pabinafusp alfa) **with Takeda** in certain regions



- ◆ Oct. EMA grants **PRIME DESIGNATION** to **JR-141** (pabinafusp alfa).



2022

- ◆ Jan. EMA grants Orphan Designation to **JR-441** for Sanfilippo type A syndrome



- ◆ Feb. **IZCARGO®** granted **New Treatment Award** by **WORLDSymposium™ 2022**.



- ◆ Feb. **First patient dosed in JR-141** (pabinafusp alfa) Global Phase 3 Clinical Trial



- ◆ Mar. **JR-479** for GM2 gangliosidosis enters **Development**

- ◆ Mar. **Exclusive license and collaboration agreement** concluded with Takeda to develop **gene therapies using J-Brain Cargo® technology** for lysosomal storage disorders



- ◆ Mar. R&D Meeting held for institutional investors and analysts

- ◆ Apr. Teijin and JCR research on JTR-161 dental pulp stem cells terminated

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Business 2

First, R&D topics. Topics in the second half of the FY2021 are presented here.

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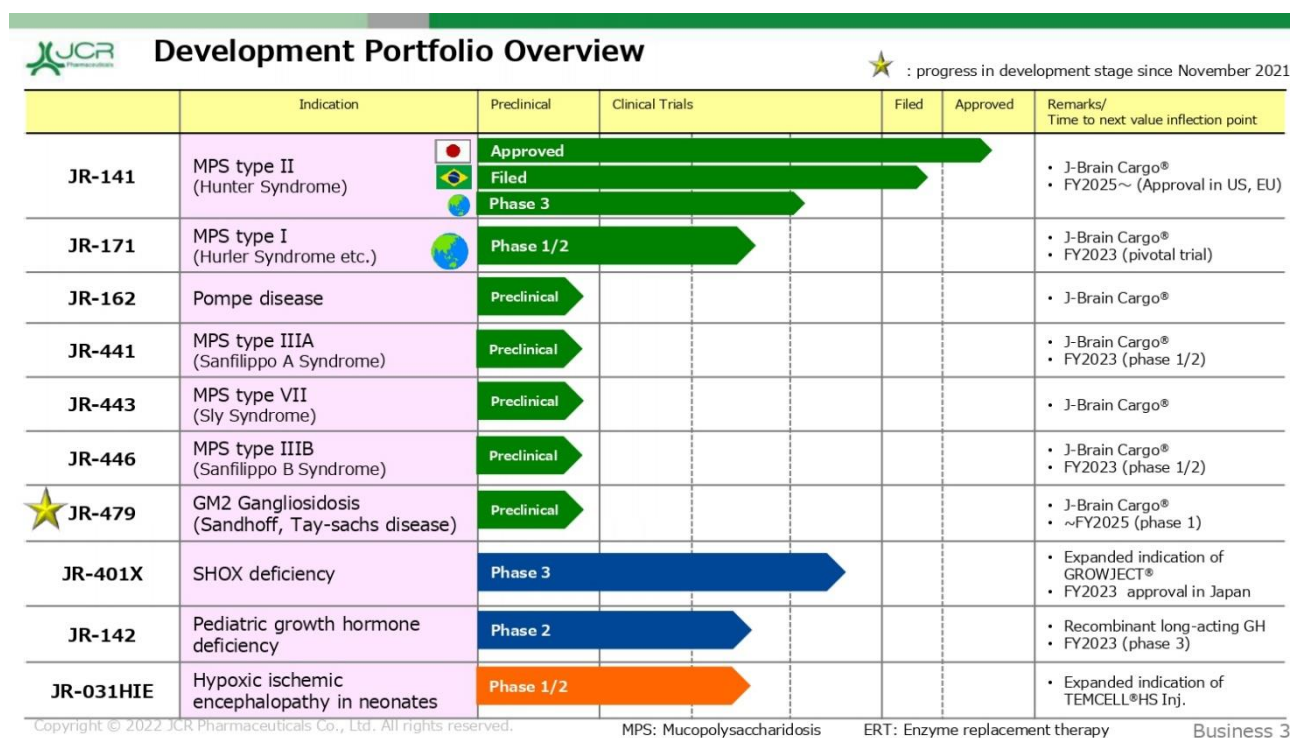
Regarding JR-141, IZCARGO, we signed a commercialization agreement with Takeda Pharmaceutical in September last year. We have since received the PRIME DESIGNATION in Europe. In February of this year, IZCARGO received the New Treatment Award at the WORLDSymposium, the world's largest conference on lysosomal diseases. We recognize this as a great honor.

Subsequently, patients began receiving the treatment in the global Phase III trial.

Next is JR-441, for the treatment of Sanfilippo A. This compound received orphan drug designation in Europe this year.

We have also begun development of a new product, JR-479, a treatment for GM2 gangliosidosis.

In March of this year, we also entered into a joint research, development, and licensing agreement with Takeda for gene therapy using J-Brain Cargo.



This is our current R&D pipeline.

The green arrows on the upper side are related to lysosomal disease. The blue arrows on the lower side are related to growth hormone. The orange arrows are related to regenerative medicine products.

I'd like to draw your attention to JR-479, near the bottom, which is marked with a star. This item is new on the list.

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Progress on JR-141 (JR-141-GS31)

JR-141

IZCARGO® (Brand name in Japan)
pabinafusp alfa: BBB-penetrating iduronate-2-sulfatase (rDNA origin)

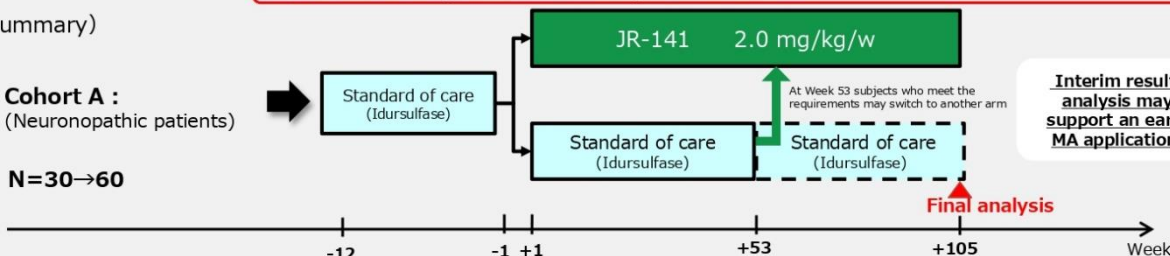


- ◆ Sep. 2021: Entered into an exclusive collaboration and commercialization agreement for JR-141 with Takeda in certain regions
- ◆ Oct. 2021: PRIME Designation from EMA
- ◆ Feb. 2022: First Patient Dosed in global phase 3 study
- ◆ Number of subjects in cohort A changed from 30 to 60

(Summary)

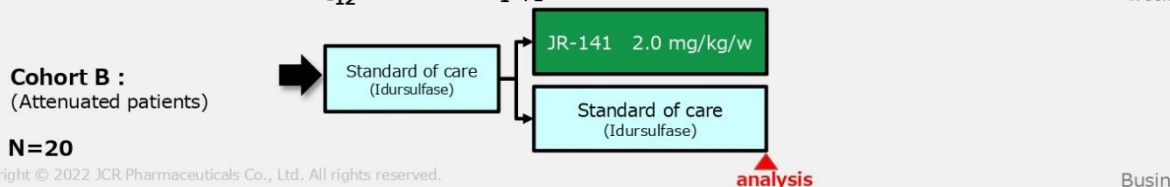
◆ Cohort A :
(Neuronopathic patients)

N=30→60



◆ Cohort B :
(Attenuated patients)

N=20



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Business 4

From here I would like to talk a little about the global Phase III trial for JR-141.

The figure here, which we have shown in previous briefings, summarizes the clinical trial.

Patients began receiving the treatment in February, 2022. The number of subjects in the trial has been changed. The total number of subjects was changed from 50 to 80 based on discussions between Takeda and JCR. The objective was to increase the probability of success of the trial. There has been no change in any other areas.



Progress on JR-171

JR-171

lepunafusp alfa: BBB-penetrating α-L-iduronidase (rDNA origin)



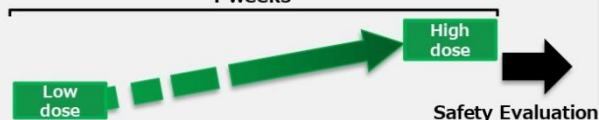
Summary of Global Phase 1/2 Clinical Trial (JR-171-101)

- ◆ May 2022: Completed patient recruitment of Part 2

Part 1 N=4
 ✓ 18 years or older
 ✓ No or mild intellectual disability



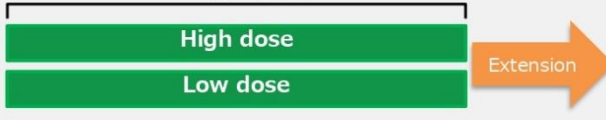
4 weeks



Part 2 N=14 or more
 ✓ 0 years or older
 (2 years or older in the United States)
 ✓ Irrespective of disease severity



Randomized allocation 12 weeks



	Part 1	Part 2
Primary endpoint	Safety	
Secondary and exploratory endpoints	<ul style="list-style-type: none"> • Plasma drug concentration, pharmacokinetic parameters • Exploratory efficacy for central nervous system and systemic symptoms 	
Geography	Japan·Brazil	Japan·Brazil·USA
Clinical trials identifier	clinicaltrials.gov NCT04227600	

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Business 5

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Next, the development status of JR-171.

This is also in the global clinical trial phase. This treatment is undergoing Phase I and II global trials. Patient recruitment was completed as scheduled in March of this year. We expect the test to proceed smoothly in the future.



Progress on JR-171

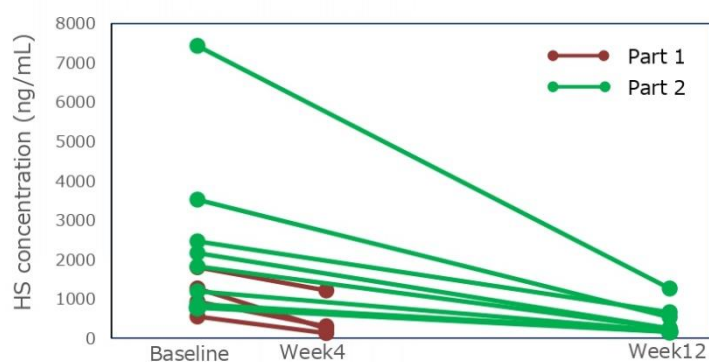
JR-171

lepunafusp alfa: BBB-penetrating α -L-iduronidase (rDNA origin)



Phase 1/2 Global Clinical Trial (JR-171-101) :

Change in CSF Heparan sulfate (HS) Concentrations as surrogate for substrate reduction in the CNS



CSF HS concentrations decreased in all subjects

CSF: Cerebrospinal fluid

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Business 6

I would like to present some actual clinical data for this study.

The data will show the concentration of heparan sulfate in the patient's cerebrospinal fluid. The area marked baseline is before treatment. The graph shows heparan sulfate concentration in the cerebrospinal fluid at baseline, and at treatment weeks 4 or 12. As you can see here, the heparan sulfate concentration in cerebrospinal fluid decreases in all subjects. This is the same trend seen in the JR-141 (IZCARGO) trial, so we see this as very promising for JR-171 as well.

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SCRIPTS
Asia's Meetings, Globally

JR-479 (BBB)-penetrating β -Hexosaminidase A

Indication :	GM2 gangliosidosis <ul style="list-style-type: none"> └ Tay-Sachs disease : Deficiency in α-subunit of β-Hexosaminidase └ Sandhoff disease : Deficiency in β-subunit of β-Hexosaminidase 	
Frequency* ¹ :	Tay-Sachs : 1/100,000~300,000 life births Sandhoff : Less than Tay-Sachs disease * ¹ Internal analysis	
Disease overview :	GM2 gangliosidosis is an autosomal recessive LSD caused by a deficiency in the GM2 ganglioside-metabolizing enzyme β -Hexosaminidase A. GM2 ganglioside is abundant in the brain, and GM2 gangliosidosis gives rise to progressive central nervous system (CNS) symptoms. It is difficult to distinguish between Tay-Sachs and Sandhoff disease by clinical symptoms. LSD: Lysosomal Storage Disease	
	Type	Age at onset
	Classical type (infantile)	3 to 5 months
	Subacute type (juvenile)	2 to 10 years of age
	Late onset	20 to early 30 years of age
	Clinical symptoms	
	<ul style="list-style-type: none"> • Psychomotor developmental delay, regression, visual impairment, hearing impairment, seizures, etc. • Usually leads to death by 3 years of age 	
	<ul style="list-style-type: none"> • Similar to infantile type, but slightly milder. Progressive ataxia, regression, convulsions, etc. • Leads to death between 5 and 15 years of age 	
	<ul style="list-style-type: none"> • Mild intellectual disability, but characterized by ataxia and progressive neurological symptoms 	

Animal studies demonstrated the brain delivery of JR-479 and subsequent reduction in causative substrates. Phase 1/2 study is planned to initiate by 2025.

Next is JR-479, a new development compound, for the treatment of GM2 gangliosidosis.

GM2 gangliosidosis is another type of lysosomal disease. However, what makes this disease different from other lysosomal diseases is that it has more severe CNS symptoms. Therefore, we believe that J-Brain Cargo, a technology that allows treatments to pass through the blood-brain barrier, will be very effective in this disease.

In this disease, we have already confirmed in tests using mice and monkeys that this compound crosses the blood-brain barrier and is distributed in CNS tissue. We have also confirmed that it can reduce the amount of substrate that accumulates in the brain and other parts of the central nervous system using mouse models. We are moving forward to start clinical trials for this compound within the next three years.

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JCR's LSD Pipeline comprises 18 Programs

: progress in development stage since November 2021

Approved	JR-141 Japan MPS II (Hunter)	Fabry disease		
Filed	JR-141 Brazil MPS II (Hunter)			
Clinical	JR-141 Global MPS II (Hunter)	JR-171 Global MPS I (Hurler)		
Non-clinical	JR-162 Pompe		JR-441 MPS IIIA (Sanfilippo A)	JR-446 MPS IIIB (Sanfilippo B)
Process development	JR-443 MPS VII (Sly)		JR-479 GM2 Gangliosidosis	Fucosidosis
PoC in model mouse	Niemann-Pick	Batten, Late-infantile	Krabbe disease	Batten, Infantile (CLN1)
	Gaucher	α-Mannnosidosis	GM1 Gangliosidosis	MLD
Basic research			Galactosialidosis	
	Indications with existing somatic		Indications with no established standard of care	

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Here is a list of all the lysosomal diseases that JCR is currently working on.

Those on the left, above the orange bar, already have existing treatments available. By existing treatments, we mean treatments that don't use technology allowing them to cross the blood-brain barrier. Basically, these existing treatments are just enzyme replacement therapy.

Those on the right, above the blue bar, have no other effective or approved treatments, including enzyme replacement therapy. The new JR-479 is highlighted here in red, and we can see it in the middle on the right. We can see that it has progressed through some stages of development already.

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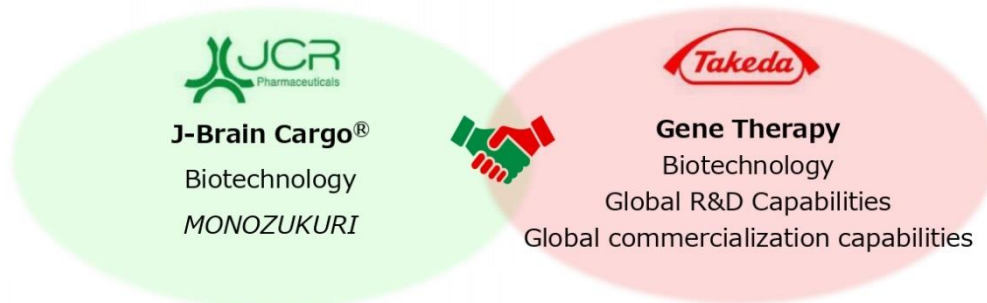
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Gene Therapy Update

- » **Mar. 28, 2022: JCR enters into an exclusive license and collaboration agreement with Takeda to develop gene therapies using J-Brain Cargo® platform.**
 - Initial focus: Lysosomal Storage Diseases
 - Option: Expansion into additional rare diseases and other indications



While keeping our core strengths, focus on developing the next J-Brain Cargo® assets and game-changing medicines

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Next, I would like to give an update on gene therapy.

As I mentioned earlier, in March of this year, we signed an agreement with Takeda covering gene therapy using J-Brain Cargo. We will first target lysosomal disease, but the agreement also covers rare diseases other than lysosomal disease. This includes more common diseases.

This is a partnership of our blood-brain barrier technology and Takeda's gene therapy technology. By combining these two cutting-edge technologies, we hope to work toward the development of new drugs that could revolutionize medical treatment.

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- **All orders under the Dec. 30, 2020 contract have been fulfilled.**
 - Sales recorded based on shipments. (Partial sales will be recorded in FY2022).
 - No lot failures demonstrates strength in the manufacturing field.
- **A new plant is under construction in the Kobe Science Park under the Ministry of Health, Labour and Welfare's Sponsorship.**
 - Estimated completion of construction : October 2022



Image of "Kobe Science Park Plant"

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Business 10

Next, an update on the vaccine solution production business.

All of our planned production for the last fiscal year was completed by the end of the year. We have achieved excellent results in the production of these products, with no lot-outs.

We were also able to produce a good yield of very high-quality product. As a company, we have been building our skill in manufacturing and production since our inception. With this project, we have been able to fully demonstrate our strength in this area.

As part of the Ministry of Health, Labor and Welfare's project to improve the vaccine production system, a new factory is currently under construction in the Kobe Science Park, and is scheduled to be completed in fall of this year.

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“REVOLUTION” : Important Business Challenges

➤ JCR will address 6 important business challenges in anticipation of our full-fledged globalization.



Top priority business challenge

in anticipation of growing presence of JCR in the rare disease area

[1] **Qualitative and quantitative reorganization of the quality assurance system**

Furthermore, JCR will accelerate agendas listed below as important business challenges in anticipation of a rapid expansion of business in the late 2020s.

- [2] **Action for sustainable growth of the sales of our products**
For strengthening of our foundation for profits:
Exploring new therapeutic targets in addition to lysosomal storage diseases:
- [3] **Expansion of basic research activities**
- [4] **Evaluation and implementation of further capital investment for manufacturing and research**
For full-fledged globalization in the near future:
- [5] **Product strategy planning including evidence generation**
For maximizing business values in the lysosomal storage disease area:
- [6] **Transformation of operations and organizations along with human resource development**
For our full-fledged globalization:

I would now like to move on to an interim summary of the "REVOLUTION" mid-term management plan.

First of all, listed here are the six important tasks we designated in the "REVOLUTION" mid-term management plan.

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Qualitative and quantitative reorganization of the quality assurance system	Quality assurance system updated – Newly established the Analytical R&D Center – Started construction of a quality testing building (scheduled for completion in FY2022)
Action for sustainable growth of the sales of our products	Strengthening of GROWJECT®’s sales base – Launch smartphone apps for electric devices and development of new devices Market penetration of IZCARGO® beyond expectations
Expansion of basic research activities	Steady progress in development of LSD products Expansion into various modalities via application of J-Brain Cargo® technology
Evaluation and implementation of further capital investment for manufacturing and research	Expansion of API and formulation manufacturing capacity to enable parallel development of multiple products – Acquired land for construction of a new plant. (47,000m ²)
Product strategy planning including evidence generation	Obtaining long-term clinical data for IZCARGO® Established of an organization dedicated to LSD
Transformation of operations and organization along with human resource development	Reorganized into a functional and efficient organization Development of next-generation of global leaders Expansion of IT infrastructure to improve productivity and reform work styles

Interim summaries for each are presented here. I would like to start from the top.

First, in terms of qualitative and quantitative expansion of our quality assurance system, we have been working to renew our quality assurance system from research to commercial production by establishing a new organization and starting construction of a new testing building.

Second is initiatives for sustainable growth of existing products. We have been actively developing electric devices to strengthen the foundation of growth projects. We are also developing smartphone applications that can be used with these devices. As our president, Ashida mentioned earlier, we have achieved greater market penetration than we had expected.

Third, regarding the expansion of basic and applied research, as I explained earlier, all pipelines for lysosomal diseases are progressing well. In addition to lysosomal disease, as I mentioned at the R&D briefing the other day, we are now beginning to see the possibility of using J-Brain Cargo in a variety of other modalities.

Regarding the fourth point, considering and initiating aggressive capital investment in production and research, we expect to develop lysosomal disease items as well as other items in the future. We are aggressively expanding our manufacturing capacity, considering the APIs and materials necessary for this purpose.

Fifth is product strategy development, and this includes scientific studies to provide more information about our products. Long-term clinical data for IZCARGO in Japan is already available. I believe this is very important data. Again, in order to obtain and interpret the data, we have set up an organization dedicated to lysosomal disease within our sales dept. We would like to obtain a wealth of data, including clinical data in Japan, so that we can better demonstrate the value of these treatments.

Lastly, I would like to talk about business and organizational restructuring and human resource development. Our goal is an organization that can act efficiently at a high level of function. JCR has been aiming for such an organization in the past, but now that we are moving toward our second founding phase of globalization, we are trying to create an organization that is even more agile than it is now. We are nurturing next-generation

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leaders who can work globally, as well as expanding our IT infrastructure. We are already working on these things so that the foundation is in place to support further growth.



Midterm Business Plan “REVOLUTION” : GUIDANCE



- Although the quantitative guidance set forth in the “REVOLUTION” was achieved in FY2021, we will continue to work on the Six Important Business Challenges and accelerate REVOLUTION with the aim of maximizing value in our global business.

Currency: JPY

	FY2019 Results	First Year FY2020 Results	Second year FY2021 Results	Final year Forecast for FY2022	Guidance (Final year Goals)
Sales	24billion	30 billion	51 billion	45.0 billion	32~36 billion
Operating income	3.2billion	8.2 billion	19.9 billion	14.5 billion	7~10 billion
R&D expenditures	24.2%	17.82%	14.0%	20.0%	Around 20 %
Dividend Ratio	36.8%	21.5%	18.8%	23.6%	Around 30 %*

*Under a stable dividend policy, weighing an anticipation of our stockholders and the balance of financial soundness

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Next, a few words about the figures.

In the guidance, on the far-right side, we had set these figures as our final-year goals. This table presents the first two years of actual results in the "REVOLUTION" plan, as well as the projected figures for the final year of the plan, that is, the current fiscal year.

As I mentioned earlier, the second year of the "REVOLUTION" plan has just ended, and we have already achieved the final-year target figures. We also plan to exceed our target figures for this fiscal year.

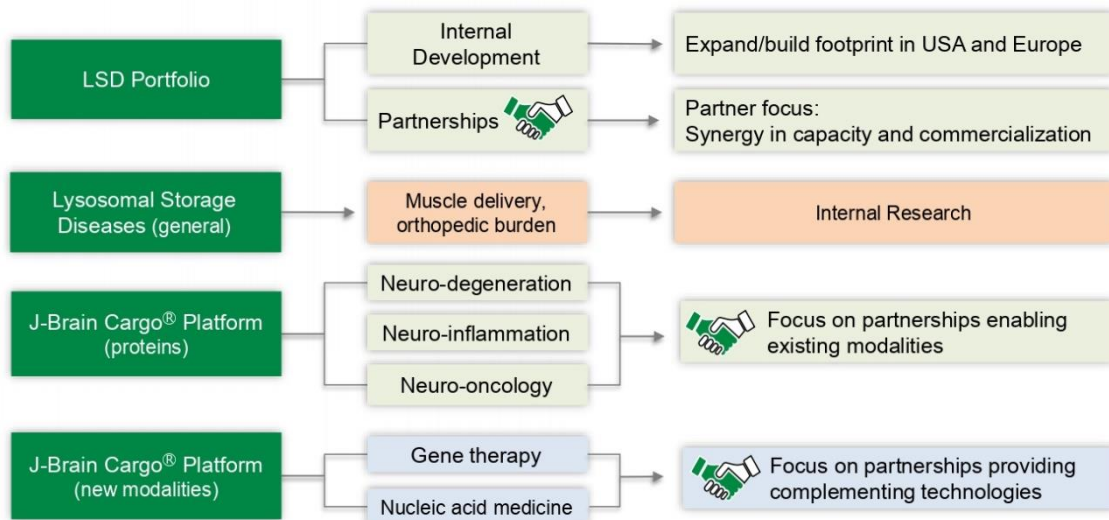
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Partnerships are at the core of JCR's growth and acceleration strategy



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Business 15

I would like to introduce a little about our vision and growth scheme to achieve this.

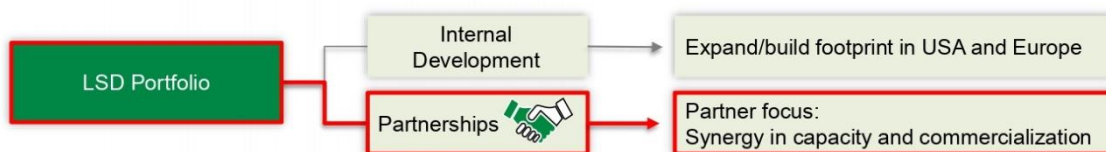
This was also presented at our recent R&D meeting. There are four main parts of our vision, shown in the green boxes on the left, and the first is to continue development for lysosomal disease. Within the lysosomal disease pipeline, we will also be moving forward with lysosomal diseases that target areas outside of the central nervous system. We are also aiming to use J-Brain Cargo technology in other disease areas beside lysosomal disease. This is our vision for the future.

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Partnerships are at the core of JCR's growth and acceleration strategy



Indication	Status	Number of patients*1		Est. Market size*2	
		Japan	Worldwide	Japan(2019)	Worldwide(2019)
MPS II (Hunter syndrome)	Ph III	Approx. 250	Approx. 7,800	Approx. 7.6 billion JPY	Approx. 87.0 billion JPY
MPS I (Hurler syndrome etc.)	Ph I/II	Approx. 60	Approx. 3,600	TBD	Approx. 70.0 billion JPY
MPS IIIA (Sanfilippo type A)	FY2023~ Ph I	Approx. 30 (AB total)	Approx. 4,000	TBD	>70.0 billion JPY
MPS IIIB (Sanfilippo type B)	FY2023~ Ph I		Approx. 1,800		
MPS VII (Sly syndrome)	TBD	Several	Approx. 200	TBD	Approx. 9.8 billion JPY
GM2 gangliosidosis	~FY2025 Ph I	Approx. 30	TBD	TBD	TBD
Pompe disease	TBD	Approx. 80	Approx. 10,000	Approx. 3.0 billion JPY	Approx. 111.0 billion JPY

Source: JCR analysis *1 Number of patients: Calculated by JCR based on information published in the Ministry of Health, Labour and Welfare's research and others
*2 Market size: Internal analysis

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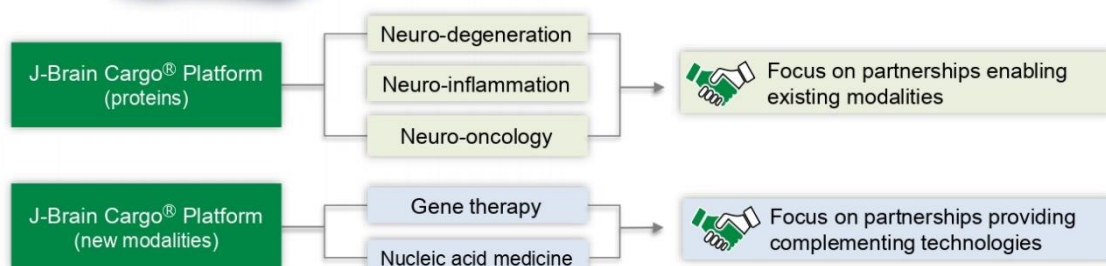
Business 16

The first item is development relating to lysosomal disease. This is obviously part of our pipeline at present. Our basic strategy is to collaborate mainly with partners to treat diseases where there are thousands of sufferers worldwide. However, within that strategy, we also target diseases where there are only hundreds of sufferers worldwide. Treatments for diseases with only a few hundred people are called ultra-orphans, and there may be a possibility of in-house development of such items. However, our fundamental policy is to collaborate with partners for global clinical development and sales.



Partnerships through deployment of J-Brain Cargo® are expected to become a major business pillar

Multi-Modality Innovator
contributing to a wide range of disease areas



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Also, the horizontal development of the technology and its application to other areas.

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We have already obtained very promising data here, as we discussed a little at the recent R&D briefing. By utilizing these new technologies in multiple modalities, we can enter into multiple disease areas. Even with these new directions, JCR's specialty is in rare diseases, including lysosomal disease. We can use our technology, applying it to new modalities, and with new techniques. As we enter these new areas, we will do so in collaboration with partners, as I mentioned earlier.



JCR's Sustainability : Efforts during "REVOLUTION"



Target	Realization of sustainability through activities based on RD·E·S·G		
 <p>Rare Disease</p> <ul style="list-style-type: none"> Meeting the Challenge of Unmet Medical Needs Accelerating R&D Efforts to Raise Awareness 	 <p>Environment</p> <ul style="list-style-type: none"> Information Disclosure in Accordance with TCFD Environmental protection initiatives in factories under construction 	 <p>Society</p> <ul style="list-style-type: none"> Work environment that fosters compatibility of family with work Enhanced training programs for human resource development 	 <p>Corporate Governance</p> <ul style="list-style-type: none"> Establish a governance structure as a prime market company Improving the effectiveness of the Board of Directors
Contribution through our business	Unite the capabilities of "Team JCR" for the "REVOLUTION" of our business in quality and quantity Acceleration of "Realizing medical care for those living with rare diseases"		



JCR selected as a constituent of FTSE Blossom Japan Sector Relative Index

The FTSE Blossom Japan Sector Relative Index is created by global index provider FTSE Russell. It reflects the performance of Japanese companies that demonstrate strong environmental, social and governance (ESG) practices relative to their respective sectors and is designed to be sector neutral. To promote the transition to a low-carbon economy, companies with particularly high greenhouse gas emissions are included only if their improvement efforts are positively evaluated using the TPI Management Quality Score.

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Last but not least, I would like to introduce a few of our sustainability initiatives.

As you all know, we specialize in the field of rare diseases. We consider it one of our major ESG activities to contribute to the lives of patients living with rare diseases.

In addition, we aim to strengthen our sustainability efforts by focusing more on ESG issues, including energy, and a comfortable working environment for employees, as described here.

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New challenges in the final year and beyond

- Maximize product value by maximizing global development potential.
- Establish alliances with partners capable of maximizing the value of J-Brain Cargo® technology as a new business pillar.
- Achieve sustainable growth through forward-looking investments.
- Develop a corporate culture of "Team JCR," shift to an appropriate personnel size and organizational structure that meets the medium- to long-term corporate image, and work to develop and secure human resources.

This is the last slide. As the final year of the mid-term plan, we have listed here our new goals and challenges.

Regarding global development, JR-141 is our first experience. However, we are hoping to make the most of the experience gained there for future development items, including 171 and beyond. By doing so, we will maximize the product value of items such as 171, 441, 446, 476, as well as for others to follow.

We will also actively pursue alliances with partners in lysosomal disease and other areas to maximize the value of J-Brain Cargo technology.

In addition, we would like to build a foundation for the future by investing in R&D and manufacturing areas that will contribute to future earnings, such as the vaccine business obtained in FY2021.

In building these foundations, it is important to have a corporate culture of "Team JCR," an organizational structure that matches this culture, and, most importantly, human resource development. We intend to actively invest in these areas.

That is all from me. Thank you very much.

[END]

Document Notes

1. Portions of the document where the audio is unclear are marked with [Inaudible].
2. Portions of the document where the audio is obscured by technical difficulty are marked with [TD].
3. Speaker speech is classified based on whether it [Q] asks a question to the Company, [A] provides an answer from the Company, or [M] neither asks nor answers a question.
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