



JCR Pharmaceuticals Co., Ltd.

Financial Results Briefing for the Fiscal Year Ended March 2023

May 12, 2023

Event Summary

[Company Name]	JCR Pharmaceuticals Co., Ltd.	
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[Venue]	Webcast	
[Venue Size]		
[Participants]		
[Number of Speakers]	7	
	Shin Ashida	Representative Director, Chairman, President, and CEO
	Toru Ashida	Senior Vice President Sales Executive Director, Sales Division
	Mathias Schmidt	Vice President Clinical Development
	Hiroyuki Sonoda	Vice President Research Executive Director, Research Division
	Yoh Ito	Senior Corporate Officer Corporate Strategy Executive Director, Corporate Strategy Division
	Yutaka Honda	Senior Corporate Officer Administration Executive Director, Administration Division and Director, General Affairs Department
	Yoshihiro Ohta	Director, Accounting Department, Corporate Strategy Division

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	Ryuta Kawamura	SBI SECURITIES
	Hiroyuki Matsubara	Nomura Securities
	Shinya Tsuzuki	Mizuho Securities

*Analysts that SCRIPTS Asia was able to identify from the audio who spoke during Q&A.

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Presentation

Moderator: Thank you very much for your patience. We will now begin the meeting on FY2022 results and new midterm business plan of JCR Pharmaceuticals Co., Ltd.

First, we'd like to explain the language settings for those who are attending through the web. Please select off or Japanese or English, from the interpreting icon at the bottom of your Zoom window.

Before we begin, we'd like to remind you of a few important points. In this presentation, we may make forward-looking statements based on our current expectations, all of which are subject to risks and uncertainties. However, investors should be aware that actual results may differ materially from those discussed in the forward-looking statements.

The presentation and the materials here today are intended to provide shareholders, investors, and the press with information about our business. The information of our products on the market and in the pipeline is not intended for the purpose of advertising or medical advice. This meeting is being recorded for the purpose of posting on our website. Please note that some of the presenters may speak while wearing a mask during presentation.

First of all, I would like to introduce today's speakers.

From the right, Shin Ashida, Representative Director, Chairman, President, and CEO; Toru Ashida, Senior Vice President, Executive Director, Sales Division; Mathias Schmidt, Vice President, Clinical Development, he is joining remotely from the US; Hiroyuki Sonoda, Vice President, Executive Director, Research Division.

In the back row from the left, Yoh Ito, Senior Corporate Officer, Executive Director, Corporate Strategy Division; Yutaka Honda, Senior Corporate Officer, Executive Director Administration Division; and Yoshihiro Ohta, Director, Accounting Development, Management Division.

Next, I'd like to explain the materials we will use today. The materials have been posted on our website at 16:00 on May 11. If you need the materials at hand, please refer to them. The materials will also be distributed at the venue. Please raise your hand if you don't have one.

Let me explain the flow of today's briefing. Today's meeting will last two hours, including the Q&A session. Questions will be taken after all the presentations have been completed. The Q&A session is expected to last approximately one hour.

Now, Mr. Shin Ashida, President and the CEO, would like to make a few remarks.

Shin Ashida: Good afternoon, ladies and gentlemen. Thank you for your attendance. My name is Ashida of JCR Pharma. I would like to take this opportunity to thank you for your continued understanding and support for our company.

In today's financial results briefing session, each of our officers in charge will report on the financial results for the fiscal year ending March 31, 2023, as well as our research and development activities, and also explain our new midterm business plan, Reach Beyond Together, which we have newly formulated.

During the past midterm plan period, we have achieved stable growth and produced many positive results. In particular, the world's first successful commercialization of J-Brain Cargo was a major achievement for us. This achievement was made possible entirely because of our strength in R&D and manufacturing. We are one of

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the few companies in Japan that can handle the entire process of pharmaceuticals, from research to manufacturing, in an integrated fashion. We are using this modality of J-Brain Cargo to further promote research and development for rare diseases centered on lysosomal storage diseases. We will also use this modality to further promote research and development for rare diseases with respect to innovative protein products and gene therapies.

We are committed to providing as many patients and families as possible with medicines with features that only JCR can offer, which we believe is our mission. In a new five-year midterm business plan, we will strengthen various initiatives to secure a stable management foundation and maximize our corporate value.

In the previous fiscal year, the production of AstraZeneca's vaccine bulk drug substance was completed as planned, which combined with the decrease in revenue from the contract, led to a decline in both revenue and earnings. On the other hand, we initiated negotiations for a global alliance for lysosomal disease drug and sought to expand our modality licensing, amongst others. We have been engaging in a number of negotiations for a variety of agreements.

As a result, in October, we signed an agreement with MEDIPAL for the global commercialization of ultra-rare disease. In March, we signed a global research collaboration agreement with Alexion, the rare disease division of AstraZeneca for the treatment of neurodegenerative diseases. In addition, as we put out a press release yesterday, we signed an agreement with Angelini for the development of an epilepsy drug utilizing our J-Brain Cargo technology. We will continue to invest actively in research and development, which replace the core of our company in the current fiscal year and beyond.

We are also working on a new drug for the treatment of Sanfilippo Syndrome type A, a JR-41, which is expected to enter the clinical stage as soon. Preparations for the clinical stage of JR-446 next year are also steadily progressing. In addition, as with Alexion and Angelini, we will continue to proactively pursue opportunities to license out the J-Brain Cargo technology to other companies.

In what we call our company's second founding phase that we're in right now, as an attempt to nurture the next generation of global leaders, we have started a training program called the JCR Academy. We will continue to be more proactive than ever in our efforts to develop talents for the Company, so we will continue to constantly challenge ourselves to create new value. We look forward to your continued understanding and support. Thank you very much for your attention.

Moderator: Now, Mr. Ohta will now give an overview of the financial results.

Ohta: My name is Ohta from the accounting department. I would like to give you the overview of the financial results of FY2022.

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**通期実績
(2023年3月期)**
**契約金収入およびAZD1222原液製造の減収により
減収減益**

売上高	: 34,343百万円 (前期比 △32.8%)
営業利益	: 4,975百万円 (前期比 △75.0%)
経常利益	: 5,418百万円 (前期比 △73.6%)
親会社株主に帰属する 当期純利益	: 3,772百万円 (前期比 △74.0%)

- 主力製品：イズカーゴ®は前期比で増加したものの、グロウジェクト®ならびに腎性貧血治療薬は薬価改定の影響を受け前期比から減収となった。
- 販売・一般管理費は社員数の増加により人件費は増加しているものの、各コスト削減の積み上げの結果、前期比で減少。一方、研究開発費は順調に進捗していることにより前期比で増加となった。

As Ashida mentioned earlier, there was the completion of the contract revenue. Because of the bulk solution manufacturers, there was the YoY decrease in sales profit. Net sales was JPY34,343 billion. That was 32.8% minus from the previous year. Operating income was JPY4,975 billion, minus 75%. The operating income was JPY5,418 billion. That was minus 73.6% YoY. Net profit was JPY3,772 billion. That was minus 74% from the previous year. We made some revisions of the forecast in March, and these numbers are consistent with those mostly.

As for the major products, regarding IZCARGO, there was an increase YoY, but GROWJECT, as well as the renal anemia drug sales showed a decrease YoY because of the NHI price reduction. C&A showed a decrease YoY thanks to the various cost reduction measures, although there was the decline in the personnel cost due to the decline of the increase of the number of employees. The R&D expenses increased from previous year due to steady progress.

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連結決算概要

(単位：百万円)

連結	2022年3月期 A	2023年3月期		参考 予想 (修正後)
		B	前期比 (B-A)/A	
売上高	51,082	34,343	△32.8%	34,200
売上原価	10,461	8,886	△15.1%	-
売上総利益	40,620	25,456	△37.3%	-
販売・一般管理費	13,511	11,678	△13.6%	11,500
研究開発費	7,175	8,802	+22.7%	8,900
営業利益	19,933	4,975	△75.0%	5,000
経常利益	20,512	5,418	△73.6%	5,200
親会社株主に帰属する 四半期/当期純利益	14,507	3,772	△74.0%	3,800

対売上高	売上原価率	20.5%	25.9%	+5.4%
	研究開発費率	14.0%	25.6%	+11.6%
	営業利益率	39.0%	14.5%	△24.5%

(ご参考)

共同開発先による負担控除前の 研究開発費	7,671	9,480	+23.6%	-
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◆営業利益 4,975百万円 対前期△14,958百万円

2022年3月期	19,933
売上高	△16,738
売上原価	+1,574
販売・一般管理費	+1,832
研究開発費	△1,626
2023年3月期	4,975

(単位：百万円)

主な増減要因（前年同期比）

- ・ 契約金収入減少・AZD1222原液製造の終了による売上高の減少
△16,738百万円
- ・ 売上高減少に伴う売上原価の減少
+1,574百万円
- ・ コスト削減の積み上げによる販売・一般管理費の改善
+1,832百万円
- ・ 研究開発への積極的な投資
△1,626百万円

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Financial 2

Next page shows details about those numbers. On the right hand, there are the reasons of changes. Mostly, I have already given the explanation, but regarding the R&D, around the middle, there was the JPY8.8 billion. That was the 27% increase from the previous year. At the bottom and regarding the R&D, it was before the deduction of the share of the joint development partner. This year, it was JPY9.4 billion, that was increased by 23% this year. We have been making active investments on R&D.



売上高内訳（連結）

(単位：百万円)

品目	2022年3月期		2023年3月期			参考 予想 (修正後)
	構成比		構成比	前期比		
グロウジェクト®	12,945	25.3%	12,261	35.7%	△5.3%	12,000
イズカーゴ®	3,003	5.9%	4,428	12.9%	+47.4%	4,500
腎性貧血治療薬	5,875	11.5%	4,696	13.7%	△20.1%	4,750
エポエチンアルファ BS注「JCR」	2,876	5.6%	2,710	7.9%	△5.8%	2,650
ダルベポエチンアルファ BS注「JCR」	2,998	5.9%	1,986	5.8%	△33.7%	2,100
テムセル®HS注	3,497	6.9%	3,404	9.9%	△2.7%	3,400
アガルシダーゼ ベータ BS点滴静注「JCR」	711	1.4%	964	2.8%	+35.6%	1,000
医薬品等合計	26,032	51.0%	25,755	75.0%	△1.1%	25,650
契約金収入	10,571	20.7%	6,546	19.1%	△38.1%	6,500
その他	102	0.2%	109	0.3%	+7.3%	120
AZD1222原液製造	14,375	28.1%	1,931	5.6%	△86.6%	1,930
売上高合計	51,082	100.0%	34,343	100.0%	△32.8%	34,200

◆売上高 34,343百万円 対前期△16,738百万円

2022年3月期	51,082
グロウジェクト	△683
イズカーゴ	+1,424
テムセル	△92
エポエチンアルファBS	△166
ダルベポエチンアルファBS	△1,011
アガルシダーゼ ベータBS	+253
契約金	△4,025
その他	+7
AZD1222原液	△12,443
2023年3月期	34,343

(単位：百万円)

主な増減要因（前年同期比）

- ・ グロウジェクト薬価改定（△8.1%）
△683百万円
- ・ イズカーゴ 17例への処方開始
+1,424百万円
- ・ ダルベポエチン薬価改定（△12.3%）に対するキッセイ薬品工業との販売価格調整など
△1,011百万円
- ・ 契約金収入 契約交渉の期ずれなど
△4,025百万円
- ・ AZD1222原液製造の予定通りの終了
△12,443百万円

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Now, regarding the sales breakdown for each product. GROWJECT, minus 5.3% from the previous year and the reasons of changes are shown on the right. There was the NHI price revision of minus 8.1%. That resulted

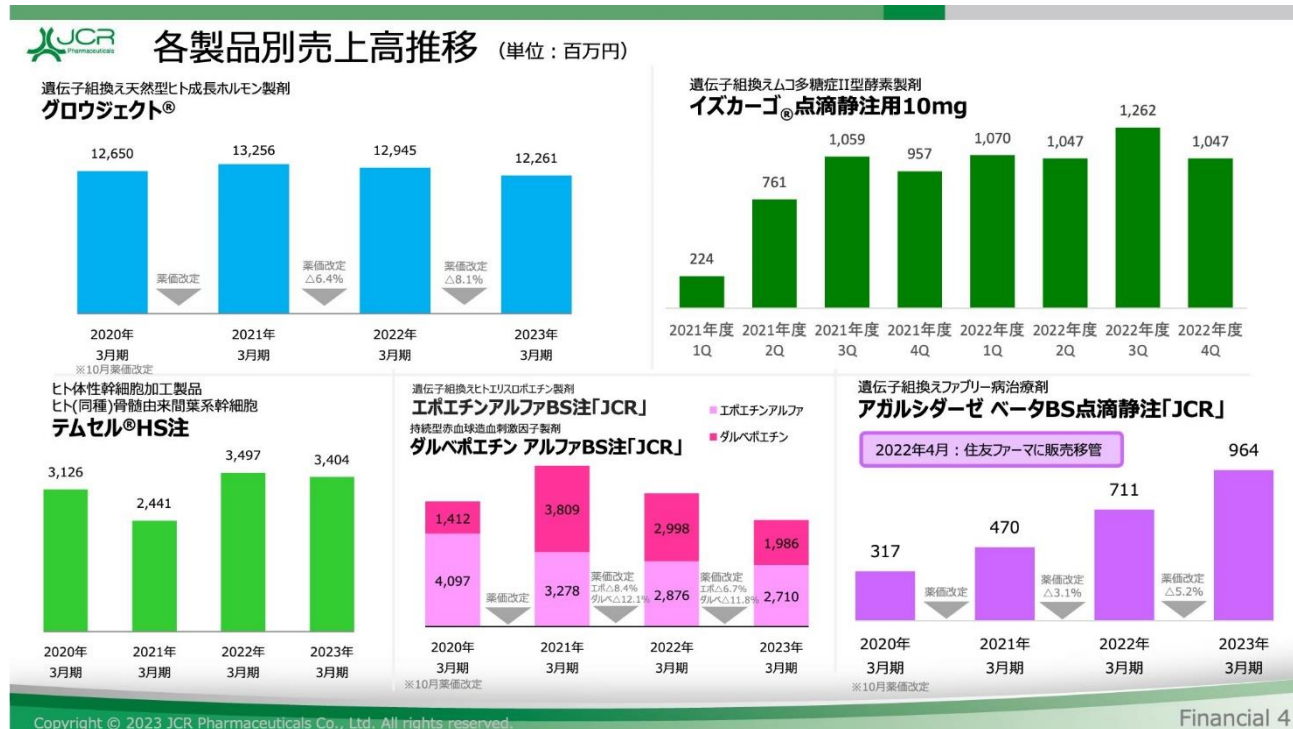
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in the negative 5.3% growth of the project. Then, for the IZCARGO, 70 cases started the prescription. Because of that, there was an increase of JPY1.424 billion. That was the 47% increase over previous year.



Regarding the renal anemia drugs, for the Darbeoetin, there was the reduction of the NHI price by 12.3%, and that resulted in the negative growth. Also, regarding the contract revenue, and there was a negotiation delay and that resulted in the negative JPY4 billion. Also, there was a termination of batch solution production of AZD1222 as planned, and there was a major impact from that.

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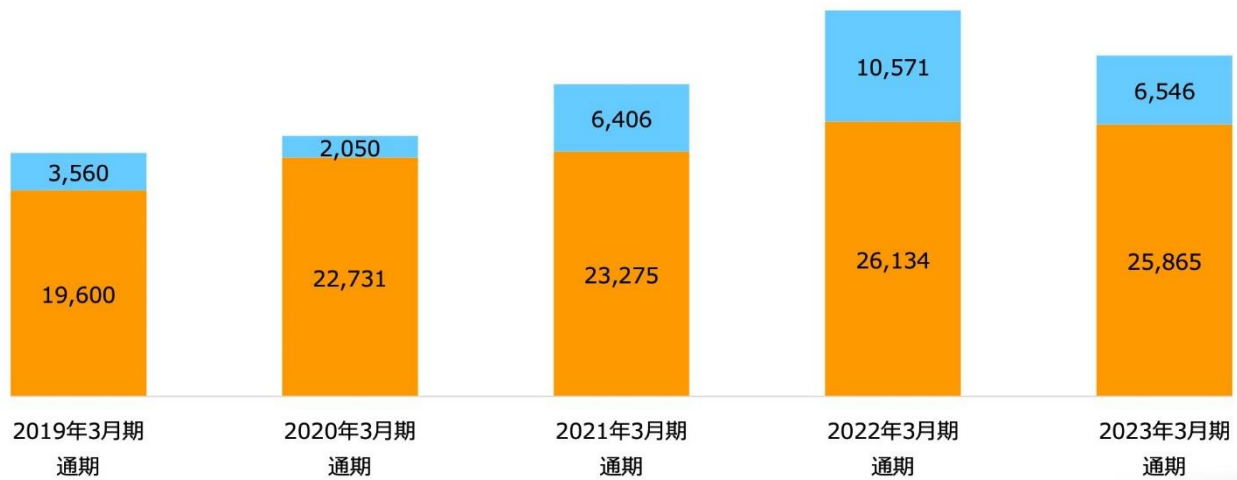




売上高推移（AZD1222原液を除く）

（単位：百万円）

■ 製商品*売上高 ■ 契約金
*製商品：グロウジェット、イズカーゴ、腎性貧血治療薬、テムセル、アガルシダーゼベータBS注「JCR」、その他



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Now, let me show you the sales of different products for your reference. The orange shows the total of sales of products, and the blue shows the contract money. The orange part, the sales of products are increasing steadily as you see.

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	2022年 3月末	2023年 3月末	増減 ・主な増減項目		2022年 3月末	2023年 3月末	増減 ・主な増減項目
流動資産	62,188	47,802	計 △ 14,385 ・現預金 △17,454 ・売掛金 △ 4,448 ・たな卸資産 + 3,854	流動負債	42,054	35,762	計 △ 6,292 ・未払法人税等 △ 5,881 ・短期借入金 + 1,650
				固定負債	3,990	6,761	計 + 2,770 ・長期借入金 + 3,050
固定資産	34,946	47,135	計 + 12,188 ・有形固定資産 + 5,898 ・関係会社株式 + 6,710	負債合計	46,045	42,523	△ 3,521
				純資産合計	51,089	52,413	計 + 1,324 ・配当金 △ 2,740 ・利益計上 + 3,772
合計	97,134	94,937	△ 2,196	合計	97,134	94,937	△ 2,196

自己資本率	51.8%	54.2%
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Next page, please. Next, I would like to explain the fiscal status.

Assets totaled JPY94,937 billion, down JPY2.196 billion YoY. For current assets, reduction by JPY14.385 billion. Cash and cash equivalents were down by JPY17.454 billion. We will take a look at cash flow statements, and I will provide the details further on this. Regarding fixed assets, it was up by JPY12.188 billion YoY. The main reasons are as follows: first tangible fixed assets were up by JPY5.8 billion YoY. Kobe Science Park, a new plant was inaugurated, and that was the main reason. Equities of affiliates were up by JPY6.71 billion. Last year, a Taiwanese company, Mycenax, we made an equity investment in that company last year. That's the main reason behind this. Because of this, assets total were down by JPY2.196 billion YoY.

Regarding liabilities, JPY42.054 billion YoY, reduction by JPY35.762 billion. The main reasons for decrease are unpaid corporate taxes, down by JPY5.8 billion. That is the main reason. Now, for this last fiscal year, profit was posted. At the end of last fiscal year, unpaid corporate taxes were posted, and they were paid this year. Thus, it was shut down. On the other hand, borrowings, we took out borrowings. As a result, borrowings increased by JPY4.7 billion YoY. Equity capital, JPY51.089 billion, up by JPY1.324 billion YoY. Profit was posted at JPY3.772 billion and dividend payment of JPY2.74 billion, as a result, increase of JPY1.324 billion. Now as to the equity ratio, 54.2%. It's up by 2.4% YoY.

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キャッシュ・フロー（連結）



(単位：百万円)	2022年3月期 A	2023年3月期 B	増減 B-A
税金等調整前純利益	19,404	5,412	△13,991
減価償却費	1,945	1,997	+52
売上債権・未収入金（△増加）	△ 7,501	3,269	+10,771
棚卸資産（△増加）	△ 1,082	△ 3,877	△ 2,795
仕入債務・未払金（+増加）	1,424	△ 2,162	△ 3,587
法人税等支払	△ 2,517	△ 8,279	△ 5,761
その他	△ 2,362	△ 1,859	+523
営業活動によるCF	9,289	△ 5,500	△ 14,789
関係会社株式取得	—	△ 6,717	△ 6,717
設備投資	△ 11,333	△ 8,560	+2,773
その他	8,083	275	△ 7,808
投資活動によるCF	△ 3,250	△ 15,002	△ 11,752
借入金	—	4,700	+4,700
配当金・自己株式	△ 2,158	△ 2,729	△ 570
その他	△ 20	△ 22	△ 2
財務活動によるCF	△ 2,179	1,948	+4,127
現金及び現金同等物の増減額	4,472	△ 17,454	△ 21,927
期末現金及び現金同等物	30,733	13,278	△17,454

【ご参考】

減価償却費	1,945	1,997
設備投資（助成金控除後）	4,472	4,330

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Next, let us take a look at consolidated cash flow.

As I said earlier, cash and cash equivalents, it was down by JPY17 billion, and that's because operating cash flow was down by JPY5.5 billion YoY. The main factors behind that include corporate tax payment JPY8.27 billion, that is the biggest factor behind the reduction in operating cash flow. Cash flow from investment activities, expenditure of JPY15 billion. For that, as I said, affiliates equities, acquisition of share of Mycenax in Taiwan, a cash out of JPY6.7 billion, and CapEx, JPY8.56 billion cash expenditure. Because of that, a total expenditure of JPY15 billion from investment cash flow.

Now, as for cash flow finances, borrowings of JPY4.7 billion were taken, a total of positive JPY1.98 billion. As a result, the total came to JPY13.2 billion, and depreciation and CapEx numbers are also given as a reference. For depreciation, it was JPY1.95 billion, on par with last fiscal year and CapEx, after subtracting subsidies, it is flat YoY, JPY4.33 billion. Depreciation correction was 1.997, almost the same as last fiscal year.

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業績予想 (2024年3月期)

売上高	: 36,900百万円 (前期比 + 7.4%)
営業利益	: 5,600百万円 (前期比 +12.5%)
経常利益	: 5,200百万円 (前期比 △ 4.0%)
親会社株主に帰属する 当期純利益	: 3,800百万円 (前期比 + 0.7%)

- 主力製品売上高の堅調な維持および、確実な契約交渉見込みにおいて、堅実な増収を目指す。
 - ・ イズカーゴ®は今期より住友ファーマ株式会社と共同プロモーションを開始。
 - ・ グロウジェクト®は少子化による市場縮小傾向および薬価改定 (△5.1%) の影響を織り込む。今期からSHOX異常症に対する適応拡大が期待されるが、患者数から売上高への影響は大きくないと予想。
 - ・ 腎性貧血治療薬は出荷量は増加し、増収を見込む。
 - ・ ライセンス事業への積極的な取り組みを継続し、契約金収入8,100百万円を見込む。
- 販売・一般管理費は引き続き前期比減を見込む一方で、グローバル臨床試験の進捗を受けて研究開発費のさらなる前期比増加を見込む。
 - ・ 販売・一般管理費 △ 3.2%
 - ・ 研究開発費 + 10.2%

Next, let me give you the forecast highlight for the year ending March 2024.

As for sales revenue, we are expecting a 7.4% increase YoY at JPY36.9 billion. For operating income, we are expecting 12.5 percentage points increase YoY to be JPY5.6 billion, and recurring income or ordinary income, down 4% YoY at JPY5.2 billion. Net income of JPY3.8 billion, which is up 0.7% YoY. Now, sales of the main products are expected to be robust and in negotiating contracts, we would like to say that the chances of having successful closure of these contracts are quite high.

Through that, we would like to seek to increase sales. Regarding IZCARGO, this fiscal year, we are starting a co-promotion with Sumitomo Pharma. Regarding GROWJECT, because of the declining birth rate, the market is shrinking and price revision of 5.1%, these factors are reflected. Renal anemia therapies, shipments are expected to increase, so we are forecasting an increase in revenue from that.

We would like to proactively engage with our licensing businesses. Revenue from licensing contracts are expected to be JPY8.1 billion. Regarding SG&A, we are expecting it to decrease YoY. On the other hand, due to progress made in global clinical studies for R&D expenses, we are looking to invest more in R&D expenses. R&D expenses are expected to rise. These are the highlights in terms of numbers.

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連結	2023年3月期 A	2024年3月期(予) B	増減 B - A	増減率 (B-A)/A
売上高	34,343	36,900	+ 2,556	+ 7.4%
売上原価	8,886	10,300	+ 1,413	+15.9%
売上総利益	25,456	26,600	+ 1,143	+ 4.5%
販売・一般管理費	11,678	11,300	△ 378	△ 3.2%
研究開発費	8,802	9,700	+ 897	+10.2%
営業利益	4,975	5,600	+ 624	+12.5%
経常利益	5,418	5,200	△ 218	△ 4.0%
親会社株主に帰属する 当期純利益	3,772	3,800	+ 27	+ 0.7%

対売上高	売上原価率	25.9%	27.9%	+ 2.0%
	研究開発費率	25.6%	26.3%	+ 0.7%
	営業利益率	14.5%	15.2%	+ 0.7%

(ご参考)

共同開発先による負担控除前の 研究開発費	9,480	11,700	+ 2,219	+ 23.4%
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補足説明（前年同期比）

営業利益への影響

- 売上高の増加 +2,556百万円
- 主に腎性貧血治療薬の販売数量増加などに伴う売上原価の増加 △1,413百万円
- 研究開発費の増加 △897百万円
- 人件費増加の一方で、各コスト削減積み上げによる販売一般管理費の減少 +378百万円
⇒ 営業利益 +624百万円

経常利益への影響

- 昨年、第三者割当増資の引受を実施した台湾Mycenax社に関する持分法投資損失の計上
⇒ 経常利益 △218百万円

当期純利益への影響

- 税額控除等による税負担率の減少
⇒ 当期純利益 +27百万円

On the right-hand side, the impacts, the factors are noted. As I may be repeating, for revenue, up JPY2.5 billion. With the increase in revenue, the cost of sales will increase. For operating income, down JPY1.4 billion and R&D expenses will increase by JPY897 million YoY. Operating income altogether will increase by JPY624 million to be JPY5.6 billion. As to the impact on ordinary income, we acquired a share of Mycenax in Taiwan through third-party allotment. There is going to be a loss under equity law.

Ordinary income is expected to go down by JPY218 million YoY. With that, net income of JPY3.8 billion. R&D, after subtracting the partner's share, JPY11.7 billion is the number that we are forecasting. YoY, that's an increase by JPY2.219 billion, up 23.4%. This is a reflection of our very proactive engagement in R&D and how we are being quite active in investing in R&D.

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品目	2023年3月期		2024年3月期 (予)		増減 (B-A)
	A	構成比	B	構成比	
グロウジェクト®	12,261	35.7%	10,900	29.5%	△1,361
イズカーゴ®	4,428	12.9%	5,200	14.1%	+771
腎性貧血治療薬	4,696	13.7%	5,400	14.6%	+703
エポエチンアルファ BS注「JCR」	2,710	7.9%	2,600	7.0%	△110
ダルベポエチンアルファ BS注「JCR」	1,986	5.8%	2,800	7.6%	+813
テムセル® HS注	3,404	9.9%	3,100	8.4%	△304
アガルスダーゼ ベータ BS点滴静注「JCR」	964	2.8%	1,600	4.3%	+635
医薬品等合計	25,755	75.0%	26,200	71.0%	+444
契約金収入	6,546	19.1%	8,100	22.0%	+1,553
その他	109	0.3%	2,600*	7.0%	+2,490
AZD1222原液製造	1,931	5.6%	—	—	△1,931
売上高合計	34,343	100.0%	36,900	100.0%	+2,556

※製造受託など

Let me give you the forecast for each of the products.

GROWJECT. JPY10.9 billion of sales is expected. As I said earlier, we're impacted by 5.1% reduction through price revision. That is the main factor. On the other hand, for IZCARGO, the revenue expected is JPY1.2 billion, an increase by JPY771 million YoY. For renal anemia therapies in total, revenue of JPY5.4 billion increased by JPY703 million YoY. TEMCELL, JPY3.1 billion sales, down by JPY304 million YoY. That is our forecast now. Agalsidase Beta, JPY1.6 billion, up by JPY635 million YoY. With these combined pharmaceutical products, JPY26.2 billion, increased by JPY444 million YoY.

As for revenue from agreements, JPY8.1 billion, other revenue, JPY2.6 billion. Other revenue of JPY2.6 billion includes contract manufacturing. With all of others, total revenue expected is JPY36.9 billion. That's to be up by JPY2.556 billion YoY. These are our plans.

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患者さん一人ひとりの背景に向き合い、治療を支える医療従事者に寄り添った営業体制を構築

- ① 製品化別MRへの体制変更。イズカーゴ専任MRは全国で8名。
- ② 住友ファーマ株式会社とのコ・プロモーションの開始（2023年4月24日～）。

⇒ライソゾーム病領域に対するアプローチ・情報収集力を強化

⇒住友ファーマ社が長年培ってきたライソゾーム病領域における経験・知識と、イズカーゴの製品力による相乗効果

Next, I would like to explain IZCARGO prescription. Toru Ashida will explain that.

Toru Ashida: Toru Ashida, Senior Vice President, Executive Director. I will explain IZCARGO and its status of prescriptions.

Since its launch, market penetration has progressed faster than we had expected, mainly among patients with apparent needs for IZCARGO administration as simplified by severe cases, young cases, and new cases. By the end of March 2023, the cumulative number of cases reached 77, and the number of administered cases 64, reaching a patient share of nearly 50% of the estimated domestic market in less than two years after the launch. In order to further expand subscriptions and deliver this product to a broader patient population, we need to approach patients who have not yet received administration. We have come to that stage.

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JR-141

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

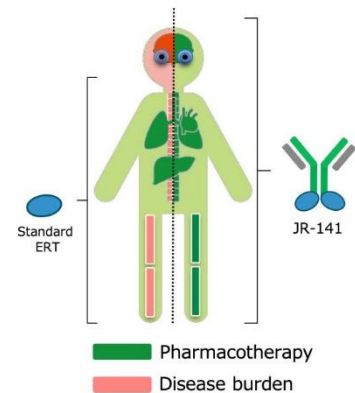
Objective : JR-141-GS31

1. To demonstrate the significant efficacy of JR-141 on CNS signs and symptoms in MPS-II subjects relative to standard ERT.

JR-141 is expected to have superior activity on neurologic signs and symptoms of MPS-II by reducing substrate in the brain.

2. To demonstrate control of somatic signs and symptoms by JR-141 that is comparable to standard ERT.

JR-141 is expected to control somatic symptoms and biomarkers comparable to standard ERT (even though some improved symptom control may be seen due to dual uptake mechanism by JR-141)



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As will be explained in the following R&D report, there are patients with mild disease who are exhibiting cognitive development, functional decline, and JR-141 has been shown to provide benefits to these patients. Due to the characteristics of IZCARGO, it's for the patients with severe type or CNS symptoms of parent would benefit from the product. The current challenge is to get the message across to the patients who are categorized as mild cases with solid data to support this message.

In MPS-II, there's no one-size-fit-all approach in providing the necessary information. That is because patient backgrounds are quite diverse. We have to look at them one by one. We're required to approach these patients' background and health care professionals who support the treatment with care. In order to do so, well, for TEMCELL, we have 1,000 MRs, for IZCARGO, GROWJECT, for each product, we have introduced a specific promotional structure. For MPS-II, IZCARGO 1,000 MRs will be assigned throughout Japan. By so doing, we will be able to better provide information in line with the needs of doctors and patients.

From April 24 onwards, we are we have initiated co-promotion with Sumitomo Pharma. Since Sumitomo Pharma is well recognized in lysosomal diseases, they have made a great contribution as a partner. In addition, we have established a special relationship with Sumitomo Pharma for more than 20 years, including the co-promotion of growth hormone therapies in the past and the recent transfer of sales of Agalsidase Beta BS.

The synergy between our lysosomal products and Sumitomo Pharma sales force is supported by the previous year's sales of Agalsidase, so collaboration with Sumitomo Pharma works with our approach to clinicians and patients and provide more information on IZCARGO. We expect more prescriptions to be delivered as a result.

That concludes my presentation. Thank you.

Moderator: Now, Mr. Sonoda will report on R&D highlights.

Sonoda: Hello, everybody. My name is Sonoda, I'm in charge of R&D. I'd like to talk about the highlights of research and development.

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First, since last year, in October last year, these are the topics that we've seen. Because of the time limitation, I'd like to just explain the major ones later on. I will talk about the two things that is the progress of research and development and upcoming development schedule. The first, R&D products. There are three topics, the lysosome or the LSD therapeutics, other diseases, and also the application of various modalities.

First, LSD and JR-141, IZCARGO. As you know, this is the first product that we applied the J-Brain Cargo. In Japan, we received the approval in 2021. Globally, this is in Phase III right now. In Japan and Brazil, there are many cases that received this product. The capacity or the features of the IZCARGO and the J-Brain Cargo is now getting apparent. I would like to talk about that.



JR-141 Long-term results^① (Presented at WORLDSymposium™ 2023)

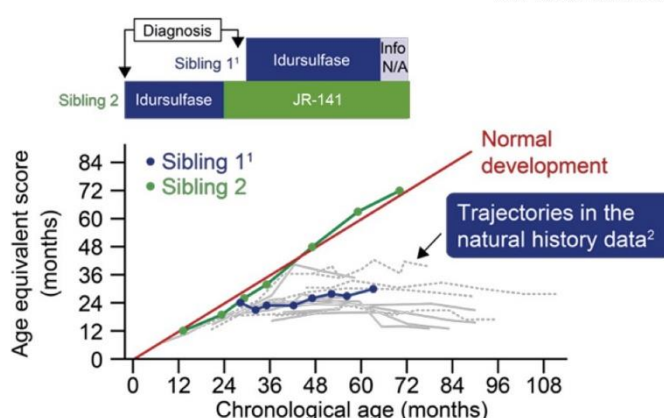
JR-141

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

Please follow the link provided below for the content of the WORLDSymposium™2023 presentation [giugliani-16-9-poster-05b.pdf](#)

BBB: Blood-brain barrier

- Sibling 1 received idursulfase and had a neurodevelopment course similar to the natural history of severe mucopolysaccharidosis type II.
- Sibling 2 received pabinafusp alfa and continued on a normal neurodevelopment trajectory.
- In patients with neuronopathic mucopolysaccharidosis type II, age-equivalent score typically declines by age 5.



¹Tomita K et al. JIMD Rep 2021;62:9-14. ²Seo JH et al. Mol Genet Metab Rep 2020;24:100630.

» Sibling case report supports importance of early treatment with BBB-penetrant enzyme replacement therapy for patients with mucopolysaccharidosis type II

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The graph shown here from the presentation that was made at the world symposium - that is the largest conference of LSD. This is the case of siblings. Both of them had LSD. The graph shows the development of these two siblings, the sibling one is the elder one. Green is the younger brother. Unfortunately, the older brother was not able to enjoy the benefit of IZCARGO because of the age and Sibling two received IZCARGO from some point. The red line shows the normal development. That means that when the child is two years old, and if the development age is two, that is on the red line. That means that the development below this red line shows the delay of the development. The blue one is the older one. Sibling one shows a similar development as the natural history data of this MPS II. Sibling two, that is the younger browser, the development shows normal development.

In the past, usually for MPS II, there is a decline of development by age five. In this case, the older brother didn't have any delays shown. This means that IZCARGO and J-Brain Cargo is making a lot of benefit for the patients to receive the benefit of the drug. This shows that when the drug is administered at this early point, the patients can enjoy the benefit of the drug from the earlier point of view.

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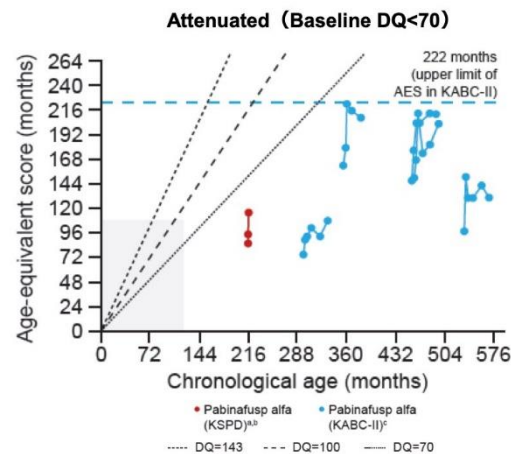


JR-141

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

Please follow the link provided below for the content of the WORLDSymposium™2023 presentation
[giugliani-16-9-poster-05b.pdf](#)

- Some cases classified as attenuated type also have cognitive decline
- These patients with JR-141 showed an increase in age-equivalent scores for cognition over time



➤ **Data suggests drug efficacy of JR-141 for CNS symptoms in attenuated patients with cognitive impairment.**

CNS: central nervous system

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The second one are the milder cases. The horizontal axis is the chronological age, and the development is in the vertical axis. One line shows one patient. In this case, the mild cases also show some delay of development. If IZCARGO is used for such patients, there is a possibility that there will be the recovery of development for the patients. In the past, for the severe cases, they suffered from brain damage, and there is a delay of development. It was also said that for the milder cases, there is no such that damage or the delay of development. That was not the case. There are some cases, mild cases, that show the delay.

Recently, there is a change in the way of thinking that mild cases will develop some severe symptoms at some point in the future. There will be some damage of the brain or there is a damage of the development at some point. It's important to administer the drug before such patients show such the delay of development. The drug that crosses BBB would be very important to be administered at an earlier point.

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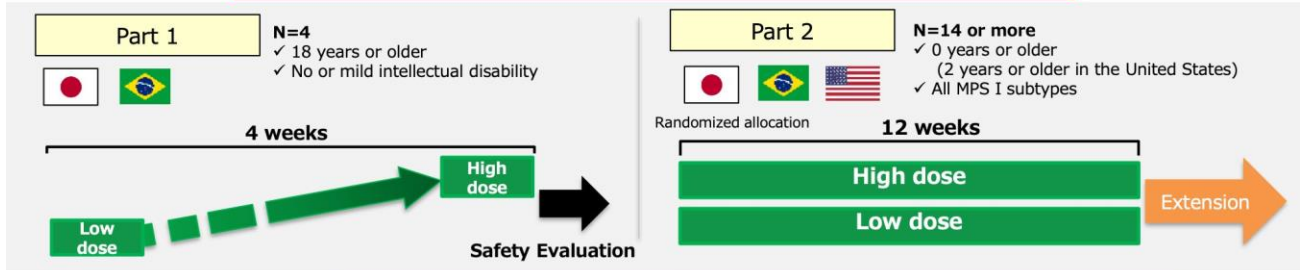


Progress on JR-171

JR-171 lepunafusp alfa: BBB-penetrating α -L-iduronidase (rDNA origin)

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

◆ **Apr. 2023: Dosing has been completed and data analysis is ongoing**



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

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Business 7

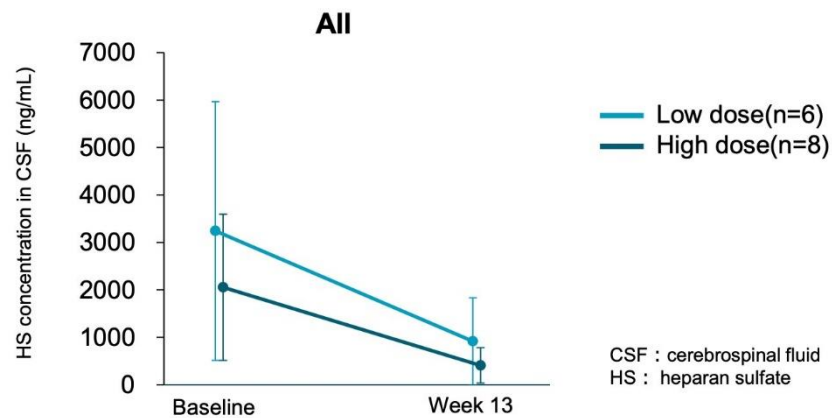
The next topic is about the JR-171. This is MPS-I or the Halo syndrome.



JR-171 Ph1/2 Clinical trial results① (Presented at WORLDSymposium™ 2023)

JR-171 lepunafusp alfa: BBB-penetrating α -L-iduronidase (rDNA origin)

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



➤ **Reduction of CSF biomarker was observed in all patients**

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The Phase I/II study is under the data analysis space. The administration has been completed. In this case, there is a Part One and Part Two. Part One is a 4-week dosing and Part Two is a 12-week dosing with the high and low doses. The results are shown here. This is the CSF; the concentration shows the heparan sulfate in the CSF. All patients showed the decline of the heparan sulfate consultation in CSF. For the JR-171, again, this is not a brain that the peripheral tissues, there is an effect on peripheral tissues.

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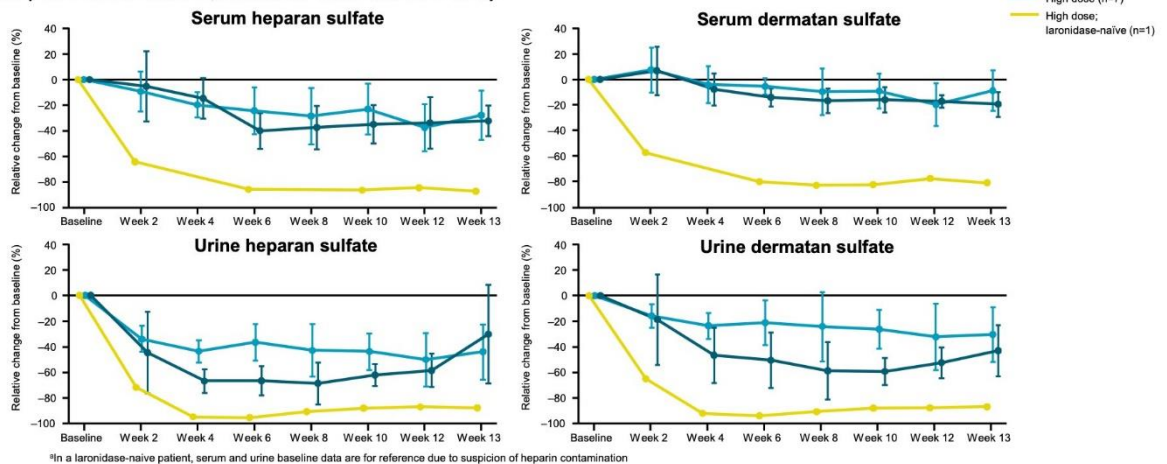
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Summary of Global Phase 1/2 Clinical Trial (JR-171-101)



➤ In both laronidase-naïve and treated patients, HS and DS concentrations in urine and serum decreased from baseline to week 13

DS : dermatan sulfate

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On the top one, the serum, the bottom two graphs show the urine consideration. On the left side is the heparan sulfate and on the right side, the dermatan sulfate. Those are the major, the serum and urine.

Please take a look at the cases where the patients are switched from the traditional cases or the treatment naïve cases. In both cases, there is a very good decline of the concentration of these compounds in terms of the biomarker level.



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

➤ Improvements observed in Phase 1/2

<p>Language</p> <ul style="list-style-type: none"> - Expression and communication - Comprehension - livelier, longer, and more focused conversations 	<p>Motor</p> <ul style="list-style-type: none"> - Gait - Ability to climb stairs - Shoulder and knee joints - Limb and finger strength 	<p>Other domains</p> <ul style="list-style-type: none"> - Obstructive sleep apnea - Concentration - Attention to environment - Mood - Social interactions
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In addition to the biomarkers, there are improvements reported, such as the language, the motor skills, the concentration, and the focus, the conversation, as well as the communication capacity, and attention.

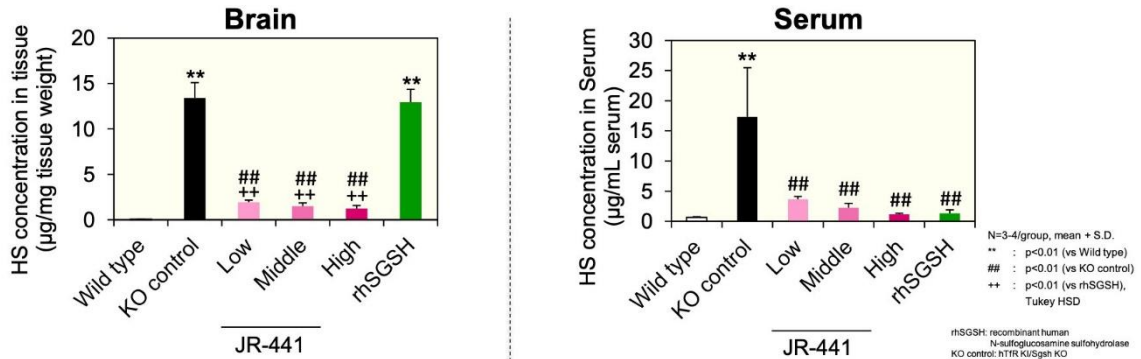
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JR-441 BBB-penetrating heparan N-sulfatase (rDNA origin)

- JR-441 dose-dependently decreased HS concentrations in CSF and brain
- Both JR-441 and rhSGSH decreased HS concentrations in serum and peripheral tissues



➤ **BBB-penetrant enzyme replacement therapy is also important for mucopolysaccharidosis type IIIA (Sanfilippo A Syndrome)**

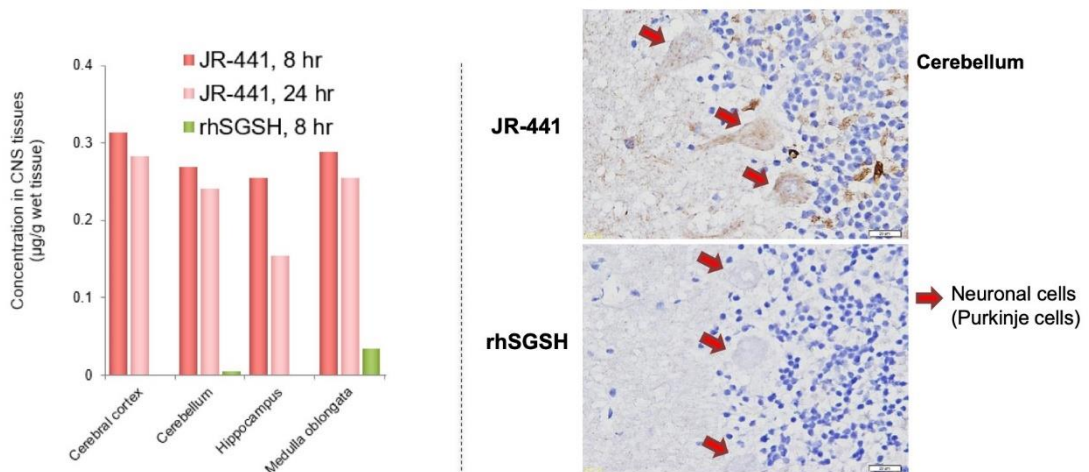
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Now, let me talk about the JR-441. This is in the nonclinical stage product, this is the Sanfilippo A or the MPS IIIA treatment. For this product, we have the results of the PK in mouth, as well as the monkey data for the brain penetration. In the first month, the results. On the left side is the brain on the right side is the serum. In the graph from the left, wild type, so the normal mouse. There is no accumulation of the heparan sulfate. The graph shows the level of the heparan sulfate.

JR-441 BBB-penetrating heparan N-sulfatase (rDNA origin)

Biodistribution of JR-441 in the CNS of Cynomolgus Monkeys



➤ **JR-441 was distributed across various regions of the brain**

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The second one from the left knockout control. That is the disease model. Against such disease models, the pink bar shows the JR-441, and also far right is the normal enzyme which do not penetrate into the brain. In the case of serum on the right side, with any type, there is a decline of the substrate, the heparan sulfate. On

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the left side on the brain only, JR-441 penetrated BBB shows the decline of the results. This is the data from the Cynomolgus Monkey.

On the left side, after the administration, the brain was taken out, and the drug concentration was measured. On the far right, the red side is the section was made of the brain and the immunostaining was done to see the location of the drug. The pink shows the JR-441, and the green is the normal enzyme. On the left graph, the higher bar, longer bar shows the higher concentration or that's better. For 8 hours and 24 hours later after the dosing, good concentration of the JR-441 is observed. The efficacy can be expected. As for the normal enzyme, a very little level.

On the right side, immunostaining data, on the top is the JR-441, the monkey, and the bottom is the monkey received a normal enzyme. The red arrow shows the Purkinje cells in the cerebellum. On the top, you see the outline of the cells in brown, and the brown part means that JR-441 is present. In the case of the normal enzyme, there is no such staining. That means that there is no such enzyme. We were able to confirm the data in mouse, as well as Cynomolgus monkey, that JR-441 penetrates the brain and is located it in the brain. The clinical trial will start shortly for the JR-441, and we have high hopes for this drug.



Our responsibility for Ultra-Rare Diseases

✓ A particularly small group of patients with LSDs

Generally no established standard of care

Difficult for large companies to enter the market due to profitability

“Creation of new therapeutics” and “System for providing global patients”
Contribution to Ultra-rare arena made possible by JCR,
a leading company of creating innovative LSD therapeutics.

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Now, so far, I have talked about the three products. Those are the rare disease therapies. The number of patients is only about several thousand. Among the LSD, there are some ultra-rare diseases. The number of patients is much lower than that. The number of patients is so low, such as the several hundred in the world, in such cases, well, there are some researchers in that academia. However, for the pharmaceutical companies, it may be difficult to work on those. We want to develop drugs for such diseases, and we have been working on that. We have been thinking of doing something for that.

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Global Approach to Ultra-Rare Diseases

Oct. 2022 : Signed an agreement with MEDIPAL HOLDINGS for the global commercialization of biotherapeutics ultra-rare diseases

- Granting of exclusive negotiation rights for the global commercialization of four ultra rare diseases.
- Conclusion of licensing agreement for global commercialization of JR-471 (Therapeutics for Fucosidosis)



- On the distribution of pharmaceuticals
Long-standing know-how and knowledge



- Expertise in biopharmaceuticals
- R&D in the rare disease arena

The two companies have built and maintained a good relationship for many years

- 2016: The two companies developed an Ultra-Low Cold Chain System for the TEMCELL®
- 2017: Strengthen Business and Capital Alliance with MEDIPAL HOLDINGS

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In October last year, we made an announcement with MEDIPAL HOLDINGS. We decided to work on the global development of other rare diseases. This is a very good contractor for us. More than that, this is quite good news for patients of such diseases. MEDIPAL HOLDINGS has the distribution know-how, and we have the elite expertise. Using those, we would like to deliver the drug for the other rare disease patients.



Application for CNS Diseases other than LSDs①

- Mar. 2023 : Concluded research collaboration, option and license agreement with Alexion to develop the treatment using J-Brain Cargo® for neurodegenerative disease



The first international partnership to apply the J-Brain Cargo® technology for the treatment of a neurodegenerative disease.

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Second is the other diseases other than LSD. In March, we made the announcement. First is the contract with Alexion. Our J-Brain Cargo technology is to be used for the treatment of the neurodegenerative diseases, and we made some license agreements. We do not disclose the actual content, but we have the technology to

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penetrate the BBB. Alexion has the know-how about the neurodegenerative diseases. We would like to take advantage of those.



Application for CNS Diseases other than LSDs②

» **May 2023 : Concluded an agreement of global collaboration for the development and commercialization of novel biologic therapies in epilepsy**



Angelini
Pharma



- ✓ Epilepsy is thought to affect more than 50 million people worldwide*
- ✓ JCR will also be eligible to receive additional payments of **up to US\$505.5 million** upon reaching development and commercial milestones, as well as tiered royalties on post-approval net sales.

*WHO, <https://bit.ly/3VvsC5E>

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Another one, yesterday, we made an announcement that this is an agreement with Angelini Line, which we announced yesterday. This is the development of the anti-epilepsy drug. As you know, epilepsy is a very serious disease. If we can have the development of the treatment of epilepsy, which is refractory, that will be quite the epoch-making things. We would like to deliver the meaningful significant therapy for that.

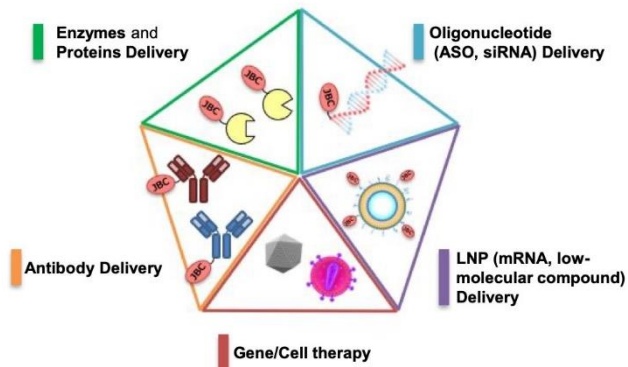
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» **Mar. 2023 : Achievement of preclinical proof-of-concept milestone using J-Brain Cargo® technology for LSD in gene therapy collaboration with Takeda**



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Lastly, that you talk about the modalities other than enzymes. In March 2022, we had the R&D explanation meeting, and the left diagram is the same one as that. We have Pentagon, and there are five things. For this year, we have the POC in animal, all of those five modalities. On the bottom, it says the gene cell therapy. For the gene therapy, we started the collaboration with Takeda in March 2022, and we have achieved the nonclinical POC in March this year. In LSD, we do the development ourselves and take the clinical POC and prove that. For other modalities and other disease areas, we don't have enough resource to cover both. Going forward, also, we would like to work on the different modalities in collaboration with other partners.

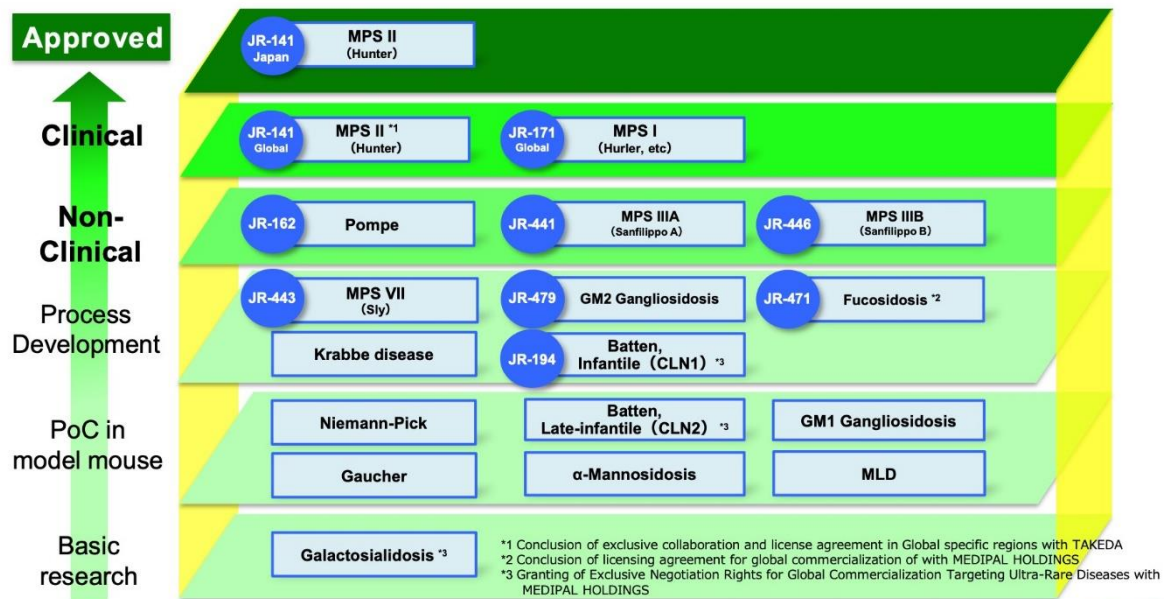
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JCR's LSD Pipeline comprises 17 Programs applied J-Brain Cargo®



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Business 21

Now, let me talk about the development schedule. This shows the LSD pipeline using the J-Brain Cargo, and there are 17 programs. On the bottom is the basic research and going up later in the R&D stages. As you see, there are so many pipeline products. For those within our company, we are working on research and development. For some of these products, we also do joint work with others. For the LSD, we will continue to focus on that going forward. Therefore, the global development, we will collaborate with companies which have the capability to do that, so that a clinical study can start as soon as possible.



Development Portfolio

★Updated

Code	Indication	Status	Next Milestones	Remarks
JR-141	MPS type II (Hunter Syndrome)	Approved	-	• SAKIGAKE/ Orphan Drug
		Phase 3	~FY2027 Approval in US, EU, Brazil	• Conclusion of exclusive collaboration and license agreement in Global specific regions with TAKEDA • US: Orphan Drug/ Fast Track/ RPDD • EU: Orphan Drug/ PRIME/
JR-171	MPS type I (Hurler Syndrome etc.)	Phase 1/2 (Under Analysis)	FY2024 Phase 3 ★	• US: Orphan Drug/ Fast Track • EU: Orphan Drug
JR-441	MPS type IIIA (Sanfilippo A Syndrome)	Preclinical	FY2023 Phase1/2	• EU: Orphan Drug
JR-446	MPS type IIIB (Sanfilippo B Syndrome)	Preclinical	FY2024 Phase1/2 ★	-
JR-479	GM2 Gangliosidosis (Sandhoff, Tay-Sachs disease)	Preclinical	~FY2025 Phase1	-
JR-471	Fucosidosis	Process Development	-	• Conclusion of a contract on the Granting of Exclusive Negotiation Rights for Global Commercialization with MEDIPAL HOLDINGS
JR-162	Pompe disease	Preclinical	-	-
JR-443	MPS type VII (Sly Syndrome)	Preclinical	-	-
JR-401X	SHOX deficiency	Filed	-	• Expanded indication of GROWJECT®
JR-142	Pediatric growth hormone deficiency	Phase 2 (Analysis Completed)	FY2023 Phase 3	• Recombinant long-acting Growth Hormone
JR-031HIE	Hypoxic ischemic encephalopathy in neonates	Phase 1/2 (Under Analysis)	-	• Expanded indication of TEMCELL®

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This is the last slide. This shows the whole pipeline of the R&D. The next milestone column is the next important actions in the schedule. This shows when the clinical stage will start. As I mentioned, the JR-441,

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we'll start the Phase I/II study shortly. That is the third product for us. Just like 141 and 171, we would like to show the usefulness of the J-Brain Cargo, as well as the efficacy of 441.

That is all from me. Thank you very much.

Moderator: Let's discuss the new mid-term business plan. Over to you to, Ito-san.

Ito: My name is Ito. I'm responsible for corporate strategy. Let me discuss Reach Beyond Together, our new midterm business plan. There may be some overlaps with the presentations already made, but I look forward to your attention.

Top message



We have provided society with pharmaceuticals featuring new mechanisms available for the first time anywhere in the world such as TEMCELL® and IZCARGO®. Our J-Brain Cargo® technology, which we have established and focused on developing further, will enable us to provide patients around the world with drugs that can be expected to have significant benefits for diseases that were previously untreatable.

JCR is now one of the few companies in Japan that can operate the entire process of biopharmaceuticals, from research through to manufacturing, and is focusing on further accelerating R&D for rare diseases, particularly Lysosomal Storage Diseases. We will also greatly expand the scope of R&D while cooperating with partners. Through developments such as innovative protein drugs and gene therapy, we will deliver "medicines that can only be made by JCR" for as many patients as possible and their families.

During the upcoming second foundation, we will make aggressive investments in R&D in order to continue generating new value with pharmaceuticals that have been developed in Japan for the first time in the world.

Shin Ashida
Representative Director, Chairman,
President, CEO and COO

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1

The first slide is the message from our President or Chairman. I would like to read it.

We have provided society with pharmaceuticals featuring new mechanisms available for the first time anywhere in the world, such as TEMCELL and IZCARGO, our J-Brain Cargo technology, which we have established and focused on developing further. It will enable us to provide patients around the world with drugs that can be expected to have significant benefits for diseases that were previously untreatable. JCR is now one of the few companies in Japan that can operate the entire process of biopharmaceuticals from research through manufacturing and is focusing on further accelerating R&D for rare diseases, particularly LSDs.

We will also greatly expand to the scope of R&D while cooperating with partners through development of products, such as innovative protein drugs and gene therapies. We will deliver medicines that can only be made by JCR for as many patients as possible on their families. During the upcoming second foundation, SAGE, we will make aggressive investments in R&D in order to continue generating new value with pharmaceuticals that have been developed in Japan for the first time in the world. This is the content that I would like to cover.

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Having built foundational “R&D” and “Manufacturing” capabilities, we can deliver value only JCR can provide to patients with rare diseases and their families.



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3

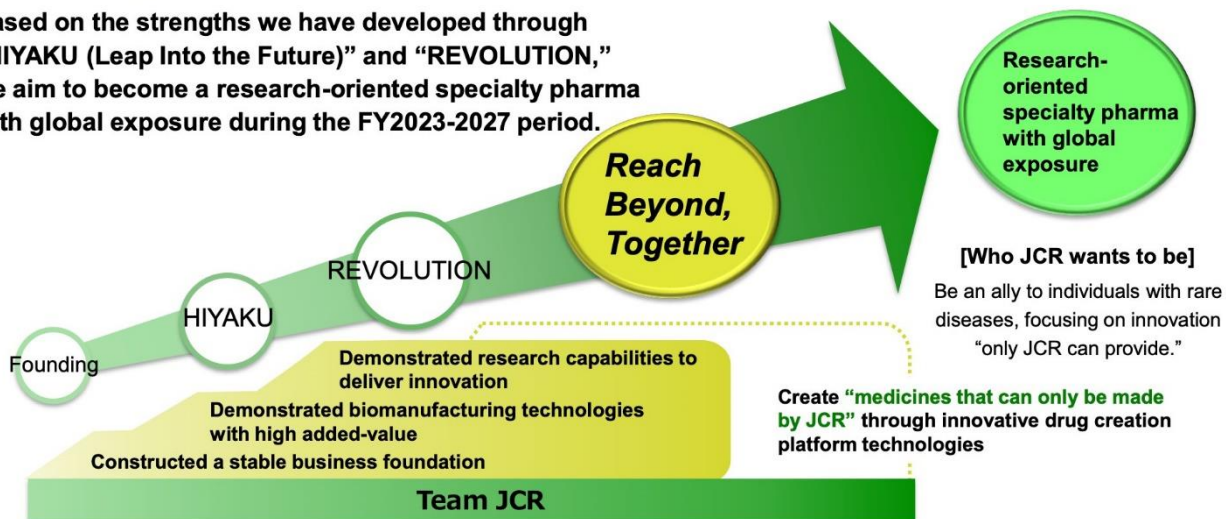
Next slide, please. Our credo or our vision, let me convey this to you. The picture on the left-hand side is the LSD patient and their family. We have our own unique R&D capability and manufacturing capabilities; we would like to combine them. Even if the disease is very rare or ultra-rare for the patient and their family, we would like to provide what only JCR can make and provide. That's what we're going to continue to pursue.

Positioning of Midterm Business Plan for FY2023-2027

Corporate Philosophy

Contributing towards people’s healthcare through pharmaceutical products.

Based on the strengths we have developed through “HIYAKU (Leap Into the Future)” and “REVOLUTION,” we aim to become a research-oriented specialty pharma with global exposure during the FY2023-2027 period.



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Next, I would like to explain the position of our new midterm business plan, contributing to people's health care through pharmaceutical products. That's our corporate philosophy and Reach Beyond Together, with this plan, well, before we had HIYAKU and REVOLUTION, the strength that we have developed through past midterm business plans, we will strengthen them and try to achieve the vision.

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Summary of “REVOLUTION”: Our Growth



JCR has achieved continuous growth through strategic investment to realize new added value for society, based on a robust management base.

	HIYAKU		REVOLUTION			
	FY2015	FY2019	1st year FY2020	2nd year FY2021	Last year FY2022	Guidance (Target for FY2022)
Net sales (¥ billion)	17.4	24.7	30.0	51.0	34.3	32.0 to 36.0
Operating income (¥ billion)	2.1	3.2	8.2	19.9	4.9	7.0 to 10.0
R&D expenditures (¥ billion) (to sales)	3.3 (19.2%)	5.9 (24.2%)	5.3 (17.8%)	7.1 (14.0%)	8.8 (25.6%)	Approx. 20%
Capital investment (¥ billion)	1.2	5.2	3.9	10.6	8.0	-
Employees (Consolidated)	526	667	732	817	879	-
Dividend payout ratio	39.2%	36.8%	21.5%	18.8%	65.9%	Approx. 30%

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Now, before I get into the new midterm business plan, I would like to provide a recap or summary of the midterm business plan for FY2020 to FY2022 revolution. To look at the numbers first. The final year of this plan, FY2022, second from the right, revenue, JPY34.3 billion; operating income, JPY4.9 billion; R&D expenditure, JPY 8.8 billion.

Now, prior to that, there was HIYAKU. If you could look at the final year of HIYAKU FY2019, net sales JPY24.7 billion; operating income, JPY3.2 billion, R&D expenditure, JPY5.9 billion. You can see how we have grown from HIYAKU revolution. On the far right, the guidance as of FY2022 is given. As for net sales, we have achieved our guidance. Unfortunately, for the operating income, we have fallen short.

However, have a look at R&D expenditure, it's 25.6% of the sales. It has far exceeded the guidance of 20%. R&D expenditure, if it's added on to the income, JPY13.7 billion in FY2022. Our final year of HIYAKU prior to REVOLUTION, it was JPY9.1 billion. The first year of [Hinkaku], JPY13 billion, so we overachieved the numbers. For the past three years, what have been the topics in year two, FY2021, AstraZeneca vaccine was commissioned, and there was sales of JPY14.4 billion, JPY51 billion of sales, and operating income of JPY19.1 billion, which were record highs.

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Review of “REVOLUTION”: Six Important Accomplishments



Key imperatives	Accomplishments
Qualitative and quantitative reorganization of the quality assurance system	Remodeled QA system from research to manufacturing—Analytical R&D center Improved data integrity—Introduction of LIMS
Action for sustainable growth of the sales of our products	GROWJECT®—Developed Melon Nikki™ app for improving treatment adherence Developed fully-automated electric injector and novel device development
Expansion of basic research activities	Generated 17 drug candidates for Lysosomal Storage Diseases Applied J-Brain Cargo® to various modalities—partnered with multiple companies AlliedCel, a joint venture to realize the social implementation of regenerative medicine and cell therapy
Evaluation and implementation of further capital investment for manufacturing and research	Expanded DS/DP capacity, enabling multiple developments in parallel – Expanded research center, Kobe Science Park Center – Established collaboration with Mycenax Biotech Inc. through equity participation
Product strategy planning including evidence generation	Communicated the value of J-Brain Cargo® technology via conferences and publications Sales forces specialized in pediatric field Transferred marketing rights for Agalsidase Beta BS to Sumitomo Pharma
Transformation of operations and organizations along with human resource development	Optimized organizational efficiency, started global development, and created international footprints. Established JCR Academy to nurture next-generation leaders with global perspective Implemented state-of-the-art IT infrastructure to improve productivity Reformed workplace policies

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Under REVOLUTION, there were six management imperatives. One, qualitative, quantitative reorganization of quality assurance system for this within the R&D group. Analytical R&D center was newly established. From research to commercialization, we have remodeled our Q&A system. Regarding sustainable growth, GROWJECT was firmly established. In growth hormone therapy, we became number two, we solidified our position. Melon Nikki application software and new devices were also developed. In terms of the exciting basic research activities, J-Brain Cargo was applied to broader applications, and we have had a number of agreements, which I will touch upon later.

Capital investment, manufacturing research, and capacity increase was our challenge. Kobe Science Park Center, the DS Center, was newly built, and we also have collaboration with CDO in Taiwan, Mycenax Biotech, it's now an equity law affiliate. Regarding product strategy planning, including evidence generation, we have accumulated evidence with respect to J-Brain Cargo, and we have transferred marketing rights for Agalsidase Beta BS to Sumitomo Pharma to derive greater efficiencies in our sales activities. Transformation of operations and organizations for human resource development, we have established JCR Academy to foster a new generation of leaders with global perspectives.

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Achievements of “REVOLUTION” and Its Significance



Achievements		Significance for the future
Realization of J-Brain Cargo® technology	<ul style="list-style-type: none"> Entering development stage of JR-443, JR-446, JR-479, JR-471 Launch of IZCARGO®, the world's first-ever BBB penetrating type ERT, in Japan Agreement with Takeda for joint development and business development of JR-141 Agreement with Takeda for joint R&D and license of gene therapy, milestone achievement for gene therapy Agreement with Medipal Holdings on Ultra Four project (four ultra-rare lysosomal storage diseases) Out-licensing of J-Brain Cargo® to Alexion, AstraZeneca Rare Disease (Alexion), Angelini, and Sumitomo Pharma 	<ul style="list-style-type: none"> ● Applicability of J-Brain Cargo® to various disease areas ● Foundation of licensing revenue from partnering strategy ● Supply chain construction towards global standard manufacturing ● Realization of our globalization based on subsidiaries
Strategic CAPEX and demonstration of prominent biomanufacturing capability	<ul style="list-style-type: none"> Investment in Mycenax, CDMO in Taiwan Completion of Kobe Science Park Center Completion of the AstraZeneca COVID-19 vaccine drug substance production 	
Foundation for global expansion		

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Next slide, please. What are the achievements under REVOLUTION?

A commercialization of brain cargo technology, we launched this cargo. For JR141, we have an agreement with Takeda for joint development and business development. With Takeda as well, we now have agreement for joint R&D and licensing of gene therapy, milestone achievement for gene therapy. In March, the nonclinical milestone was met. With MEDIPAL HOLDINGS, we have an agreement for Ultra Four project for ultra-rare LSDs.

For licensing out of J-Brain Cargo, we have agreements with Alexion, AstraZeneca, rare disease, Angelini, and Sumitomo Pharma. Strategic CapEx and demonstration of permanent bio manufacturing capabilities, we have been commissioned by AstraZeneca for vaccine production, and we have completed that highly evaluated by AstraZeneca. In terms of founding global expansion, JCR USA, JCR Brazil, and JCR Europe were established. As a distribution hub in Luxembourg, we have set up a center. As to the future significance of these activities, they are noted on the right-hand side of the slide.

Next, please. To continue, our new midterm business plan between FY2027, Reach Beyond Together. Under this new plan, we're going to address five initiatives, mainly.

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Five Initiatives

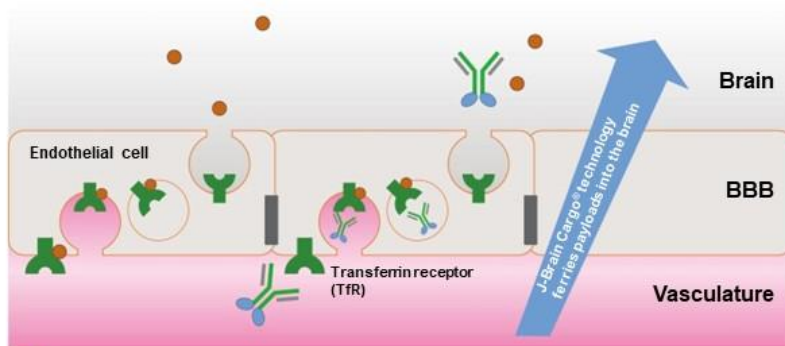
- 1 **Creation of innovative core technologies**
- 2 Demonstrating global standard production capacity
- 3 Expansion of global quality assurance system in terms of quality and quantity
- 4 Early launch of products for rare diseases
- 5 Human resource development to support growth

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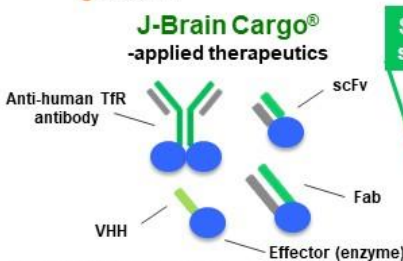
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First one, creation of innovative core technologies. Next, please.

BBB Penetrating Technology J-Brain Cargo®



IZCARGO®, world's first drug proven to penetrate the BBB to deliver ERT to CNS. Launched in Japan in 2021.



Selecting J-Brain Cargo® molecules best suited for unique effector properties

Protein engineering know-how accumulated since the company's founding

- Plentiful J-Brain Cargo® variations
- Creation of biopharmaceuticals that are difficult to produce

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Our own unique technology, J-Brain Cargo, it penetrates BBB to deliver a drug to the brain. This J-Brain Cargo, not just one time, there are a number of variations. Lower left, please have a look at the chart. The blue part is the drug. The top part of that could be varied. There are variations to the top part of this. Depending on the type of drug, we can choose the J-Brain Cargo variation so that we can best deliver the drug to the brain.

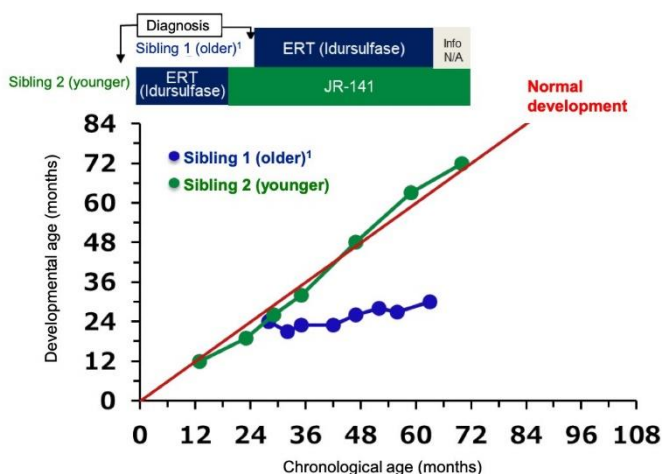
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Case report in a sibling case of MPS II with identical genetic mutation



For Sibling 2, normal development was confirmed over 72 months old (as of November 2022), following treatment for pabinafusp alfa(JR-141) (planning to obtain long-term data in the future as well)

J-Brain Cargo® technology is a platform technology that delivers drugs necessary for the central nervous system across the blood-brain barrier, and is expected to be applied to various diseases

1. Based on Tomita K et al., JIMD Reports, 2021, 1-6

What is the potential of J-Brain Cargo? Let me show you a case report. This is about a case of siblings with MPS type two with identical genetic mutation. On the horizon axis, chronological age, on the vertical axis development age. On the left-hand side, blue is the older sibling if alfa [inaudible] was given. Green is the younger sibling. JR-141 was administered as part of therapy. Normal development up to month 72 was observed, and J-Brain Cargo, therefore, is a technology that can be applied to a broader range of diseases.

Applicability of Platform Technology to Various Diseases

Cutting-edge drug development following J-Brain Cargo® technology

The J-Brain Cargo® Platform reaches beyond the CNS



J-Brain Cargo®

J-XXX Cargo

J-YYY Cargo

Target organ



Brain



Eye



Skeletal muscle



Cartilage



Other

Typical examples of target diseases

Lysosomal Storage Disease

Neurodegenerative Disease

Ocular Disease

Bone Disease

Muscular Disease



Approval of IZCARGO®(Japan)

Gene therapy Partnership with Takeda



JBC partnership with Alexion, Angelini



2020

2021

2022

2023

JBC partnership with Sumitomo Pharma (2015) Sumitomo Pharma



Ultra-rare diseases partnership with MEDIPAL MEDIPAL



Based on the basic concept of J-Brain Cargo, we would like to come out with innovative drugs. Enzymes, antibodies, gene therapies for different modalities, this technology can be applied. Other than J-Brain Cargo next-generation cargoes, it says that JXX, JYY is on the right-hand side, targeting a variety of organs. For

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example, brain, eye, skeletal muscle, cartilage, and others. With these targets in mind, we are continuing with developments of new platform technologies.

For diseases other than LSDs, we will be able to target different diseases in the future. With respect to gene therapy, we have an agreement with Takeda and for neurodegenerative diseases, we have a collaboration with AstraZeneca. We have agreement with Angelini in that regard.

Five Initiatives

- 1 Creation of innovative core technologies
- 2 Demonstrating global standard production capacity**
- 3 Expansion of global quality assurance system in terms of quality and quantity**
- 4 Early launch of products for rare diseases
- 5 Human resource development to support growth

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Next, please. The second and the third of the five initiatives, the demonstration of global stranded production capacity, and expansion of global QA system in terms of quality and quantity, let me go on to explain that.

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 **SCRIPTS**
Asia's Meetings, Globally

Strength in “MONOZUKURI” (Manufacturing)



Seishin Plant



Kobe Plant



Research Institute



Murotani Plant



Kobe API Plant



Bioresearch Center



Clinical Trial Material Manufacturing Center and Cell Processing Center (CPC)



New formulation building (To be completed in 2027)

Kobe Science Park Center (Completed in 2022)

- Our sites are operating at full capacity.
- More than 15 years of manufacturing experience with single-use technologies
- Integrated quality control system from research to product
- Quality assurance system dedicated to biopharmaceuticals
- Approximately 400 highly skilled employees
- Close cross-sectoral collaboration between physically adjacent research and production in Kobe area

Site	Production Capacity
Murotani Plant 1	2x 400L; 2x 80L
Murotani Plant 2	2x 2,000L; 2x 200L (Single-use)
Clinical Trial Material Center	1x500L, 1x200L (Single-use)
Kobe API Plant	2x 2,000L; 2x 200L (Single-use)
Kobe Plant	Filling and packaging
Seishin Plant and CPC	Regenerative medical products
Kobe Science Park Center	4x 2,000L, 4x 200L (Single-use)

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Next slide, please. One of our strengths is our manufacturing MONOZUKURI capability. As is on the left-hand side, as you can see from the pictures, we have five plants, and all sites are operating at full capacity. More than 15 years manufacturing experience we have for QA and QC, we have integrated process from research to manufacturing and quality assurance system that we have is dedicated to pharmaceuticals. In terms of human resource development, we have 400 highly skilled employees who share the same mission and philosophy. We have closed cross-sectoral collaboration between physically adjacent research and production facilities in the Kobe area. That is our strength.

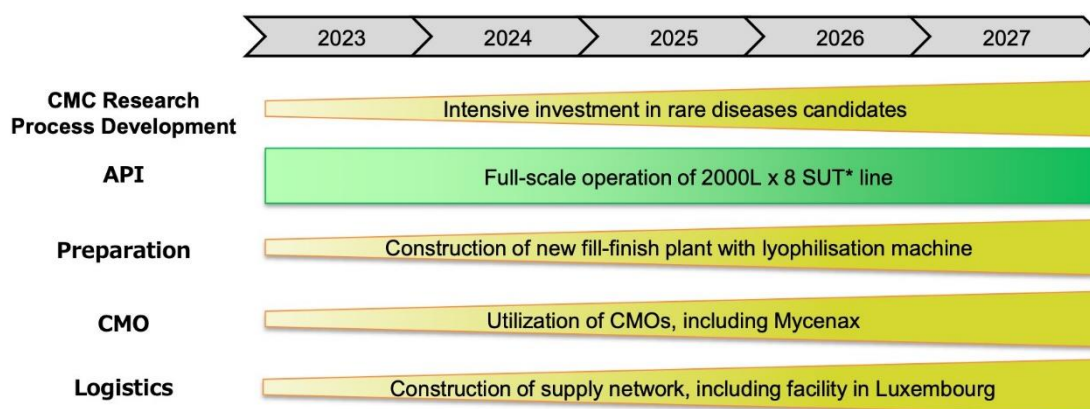
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- Over \$300m CAPEX and investment in CDMOs, leading to supply expansion.
- Constructing a resilient global supply chain for emergencies.



Next, in view of the global supply, what initiatives are we representing? Let me explain that.

In the last few years, well during the current midterm business plan, we are going to invest JPY40 billion, and we're trying to increase our supply capacity. There are going to be pandemic and natural disasters, even under those circumstances, we would like to provide a global supply chain that can provide stable supply. For DS, we have Kobe Science Park Center, single-use line was newly added. It will be fully operational. 2000L x 8 SUT line will be available for preparation. A new fill/finish plant with lyophilisation machine is going to be completed during this period.

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Existing drugs

Domestic market

- Growth hormone
- Biosimilars
- TEMCELL® HS Inj.

Initiatives for stable supply

- Sophisticated procedures and robust quality control
- Securing raw materials
- Securing appropriate benefits

Drugs for Rare Diseases Vaccines

Global strategic items

- J-Brain Cargo® development products: 10+
- Gene therapy products
- Vaccines (upon government request)

Initiatives for frontiers

- Manufacturing with new technologies
- GMP audit by regulatory authorities from outside Japan
- On-track development
- Small lot size

Next, our initiatives regarding MONOZUKURI. Existing drugs, mainly targeted for the domestic market. We're going to continue to work on stable supply. There's going to be price revisions every year. The question is, how can we secure a sufficient profit or income? That's the challenge. For rare disease therapies, we have both domestic and global markets on our minds. GMP audit by regulatory authorities overseas. Because these are rare diseases, the production is going to be very small. Those are some of the challenges we have to address.

Five Initiatives

- 1 Creation of innovative core technologies
- 2 Demonstrating global standard production capacity
- 3 Expansion of global quality assurance system in terms of quality and quantity
- 4 Early launch of products for rare diseases**
- 5 Human resource development to support growth

Number four, early launch of products for rare diseases. Next slide, please.

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Basic research	Non-clinical	Clinical (Phase I/II)	Clinical (Phase III)	Review period	Approved
JR-194 (Batten's disease type I)	JR-441 MPS type III A (Sanfilippo A syndrome)	JR-171 MPS type I (Hurler syndrome, etc.)	JR-141 MPS type II (Hunter syndrome)		JR-141 MPS type II (Hunter Syndrome)
Krabbe disease	JR-446 MPS type III B (Sanfilippo B syndrome)				
GM1 gangliosidosis					
CLN2 (Batten's disease type II)	JR-162 Pompe disease				
Gaucher disease	JR-443 MPS type VII (Sly syndrome)				
α-Mannosidosis					
Niemann-Pick	JR-479 GM2 gangliosidosis (Tay-Sachs, Sandhoff disease)				
Metachromatic leukodystrophy					
Galactosialidosis	JR-471 Fucosidosis				

Aiming to begin clinical trials for five items
(Candidates)
JR-441, JR-446, JR-479, JR-471, JR-194, Krabbe disease

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Here's the slide regarding brain cargo applied candidates for LSDs. As you can see, prior to nonclinical, we have 15 compounds in the pipeline. Five are to enter the clinical stage in this period.

Five Initiatives

- 1 Creation of innovative core technologies
- 2 Demonstrating global standard production capacity
- 3 Expansion of global quality assurance system in terms of quality and quantity
- 4 Early launch of products for rare diseases
- 5 Human resource development to support growth**



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Number five, human resource development to support growth. Next slide, please.

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Human Capital Management: Human Resource Strategy [1]



Human Resource Strategy

Continue investment in human capital, and establish a human resource strategy that helps to improve corporate value

Construction of a dynamic human resource portfolio that will help to accomplish the strategy

- Assessing the current status of our human resource portfolio
- Ensuring diversity through mid-career recruitment, producing synergetic effects with pool of existing human resources
- Creating the optimal human resource portfolio

Development and organizational permeation of diversity & inclusion

- Deepening "R&D" and "Monozukuri" (manufacturing) through inclusion of knowledge and experiential value possessed by professional human resource with diverse attributes
- Management and monitoring of inclusion

Activation of individuals and organizations Promotion of improvements to engagement

- Improving engagement by proactively transmitting JCR's vision both in and outside the company
- Support for employee growth, ambition throughout the entire organization through establishing an environment, enhancing energy

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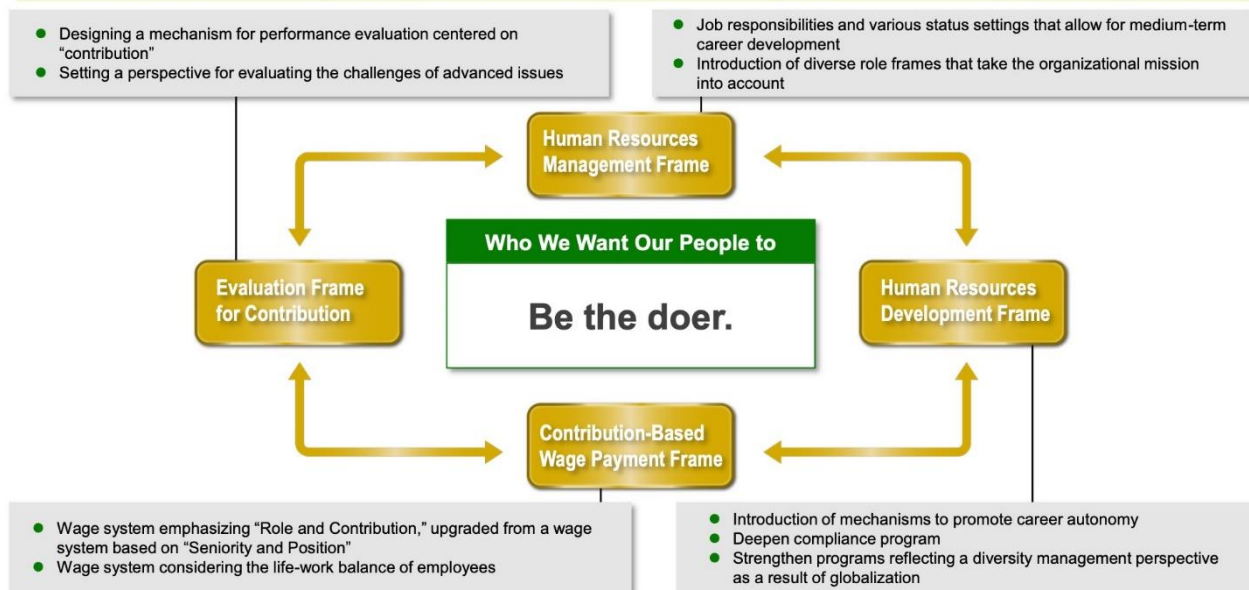
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Human capital management is often touted these days. We will continue with our investment in human capital so that our talents can contribute to enhancing our corporate value. There are three pillars. Number one. Building of a dynamic human resource portfolio. Secondly, to promote diversity inclusion. Number three, activation of individuals and organizations and to improve engagement.

Human Capital Management: Human Resource Strategy [2]



Build a human resource management frame as a framework to realize the image of who we want our people to become



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Next, please. This is the second slide for our human resources strategy. Who do we want our people to be? We want our people to meet the vision, and we will create a framework of human resource development. To meet that mission, there are four parts. Valuation framework for contribution, human resources management

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framework, human resources development framework, and contribution-based wage payment scheme. From this part onward, I would like to talk about our initiatives regarding sustainability.

Sustainability Initiatives



Ideal state of mind		Achieve sustainability through business activities based on RD-E-S-G	
 <h3>Rare Diseases</h3> <ul style="list-style-type: none"> Development of drugs for ultra-rare diseases and construction of new business models Efforts to improve access to medicines (Named Patient Supply) to deliver innovative medicines to people around the world 			
 <h3>Environment</h3> <ul style="list-style-type: none"> Investigation and implementation of measures to reduce environmental impact through business activities Promote environmentally friendly procurement on the premise of ensuring the quality and stable supply of pharmaceuticals 	 <h3>Society</h3> <ul style="list-style-type: none"> Address the challenge of unmet medical needs by creating platform technologies Develop human resources so that each member of "Team JCR" can shine in their own station 	 <h3>Corporate Governance</h3> <ul style="list-style-type: none"> Pursue governance in line with the company's growth Ensure thorough compliance and strengthen risk management 	

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Next, since before, the RDESG has been the key phrase we've been using.

RD stands for rare diseases. In terms of addressing sustainability issues, we are going to continue our focus on rare diseases. That's what we're looking to do, developing therapies for rare and auto rare diseases, delivering them to the patient community. To provide access to medicines for patients, we have been working our name to patient supply as well.

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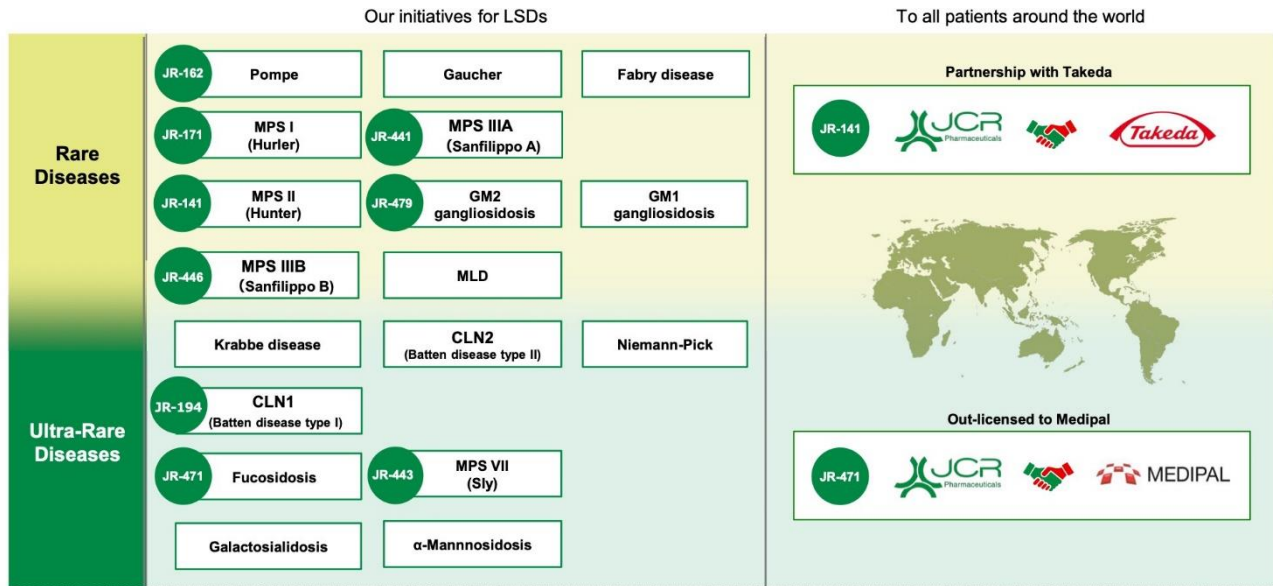




Initiatives for Rare Diseases



JCR aims to realize medical care that leaves no one behind through our business activities.



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Next, initiatives for rare diseases. On the left-hand side, the pipeline for LSD therapies we are addressing. We are delivering this to the patient communities around the world through our business activities. We will leave no one behind. That is what we are looking to achieve, no one left behind. Tackling the challenge of realizing a sustainable society, let me share with you some of our achievements. On the far left, realizing sustainable medical care, health care as initiatives, as is the top left, we have donated a share to Kyoto University's fund for sustained support. Second from the bottom, this continued support for Momiji no Ie, a medical short-term admission facility. We're providing support for medical care for patients and their facilities.

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Tackling the Challenge of Realizing a Sustainable Society



Realization of sustainable medical care	Growth of people and organizations	Tackling the challenge of solving social issues																				
<p>We will continue to maximize the value created through our business activities and return it to all people, especially patients.</p> <p>We will continue our efforts to respond to the unmet medical needs of patients and their families with innovative drug discovery centered on research and development and manufacturing.</p>	<p>We will build an organization in which each employee can grow with a career outlook and return new value to society.</p> <p>We value our unique corporate culture and core values, which are not constrained by fixed ideas, and strive to enhance the working environment that fosters the abundant creativity of employees and realizes gender equality.</p>	<p>We will realize business activities that take the natural environment into consideration.</p> <p>We will strive to raise awareness of the effective use of limited resources so that each and every employee can take the initiative to act.</p>																				
Initiatives																						
<p>Continued support of researchers Contributions to the Kyoto University Honjo Tasaku Fund and the Cancer Immunotherapy Research Fund (allotment of treasury shares)</p>	<p>Training of global workers</p> <ul style="list-style-type: none"> Enhancement of training systems to support employee growth Develop next-generation global leaders (JCR Academy) 	<p>Initiatives for Carbon Neutrality</p> <ul style="list-style-type: none"> Installation of solar power generation systems (Research Laboratories, Kobe Science Park Center and building at HQ) Reduction of waste (reuse of wastepaper and waste plastics, which are difficult to recycle as biomass boiler fuel) Adoption of rental uniforms made from recycled materials Switch to LED lighting Shift business and other company vehicles to hybrid cars and electric/hydrogen vehicles 																				
<p>Development of medical researchers capable of playing an active role on a global scale Support for the International Foundation for Medical Research</p>	<p>Diversity and inclusion</p> <ul style="list-style-type: none"> Creating an environment where employees can thrive regardless of gender Promotion of employment of persons with disabilities Promotion of diverse work styles including telecommuting Turnover rate (permanent employees): 2.5% in FY2019 / 2.8% in FY2022 "2018 (3rd) Hyogo Women's Active Participation Company" Promote initiatives to develop in-house childcare centers Encouragement of male participation in childcare Obtained "Eruboshi (second stage)" certification Received the "Corporate Award for Balancing Work and Life" 																					
<p>Support for pediatric medical care and insurance medical care Support for the Mother and Child Health Incentive Award</p>																						
<p>Medical, welfare and nursing care support Support for the Medical Service Award</p>																						
<p>Realization of medical care for patients and their families Continuous support for the "Momiji no Ie" medical short-term admission facility</p>																						
<p>Initiatives to contribute to global health Support for the activities of the non-profit foundation Global Foundation for Life Sciences</p>	<table border="1"> <thead> <tr> <th></th> <th>FY2015</th> <th>FY2019</th> <th>FY2022</th> </tr> </thead> <tbody> <tr> <td>Percentage of female employees</td> <td>33.2%</td> <td>37.2%</td> <td>40.6%</td> </tr> <tr> <td>Percentage of female managers</td> <td>6.2%</td> <td>10.7%</td> <td>12.5%</td> </tr> <tr> <td>Percentage of female new graduates</td> <td>27.3%</td> <td>31.8%</td> <td>59.1%</td> </tr> <tr> <td>Percentage of acquisition of childcare leave (male)</td> <td>0.0%</td> <td>14.2%</td> <td>66.7%</td> </tr> </tbody> </table>			FY2015	FY2019	FY2022	Percentage of female employees	33.2%	37.2%	40.6%	Percentage of female managers	6.2%	10.7%	12.5%	Percentage of female new graduates	27.3%	31.8%	59.1%	Percentage of acquisition of childcare leave (male)	0.0%	14.2%	66.7%
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Growth of people and organizations in the middle of diversity and inclusion is a key point, as is in the table below, FY2015 to FY2022, the ratio of female managers and female new graduates, you can see that they are rising. FY2022, percentage of female new graduates, 59.1%, percentage of childcare leave by male employees back in FY2015 was 0, FY2022, 66.7%. Two out of three male employees take up childcare leave.

Toward 2027 and Beyond



Since its founding in 1975, JCR has continued to grow by developing its unique "R&D" and "Monozukuri (manufacturing)". The creation of J-Brain Cargo® technology, which is one of its monumental achievements, can potentially be applied to not only the field of rare diseases but the treatment of various diseases as well.

Additionally, we believe that it is JCR's mission to create innovative platform technologies following J-Brain Cargo® technology, deliver the drugs generated through those technologies to patients and their families around the world, and contribute to treatments.

In order to carry out this mission, rather than establish quantitative guidance in this Midterm Business Plan, we will determinedly invest in the opportunities for growth through advancements in R&D. Then, we will aim to maximize value for patients and their families, JCR employees and shareholders through the creation of new innovation.

The second foundation marks the beginning of a new challenge toward growth.

– For patients and their families –

Reach Beyond, Together

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2027, the final year, beyond that, what's going to be our resolve? Since our foundation in 1975, JCR has continued to grow by developing its unique R&D and MONOZUKURI, the creation of J-Brain Cargo technology, which is one of its monumental achievements, can have the potential to be applied to not just rare diseases, but other diseases as well.

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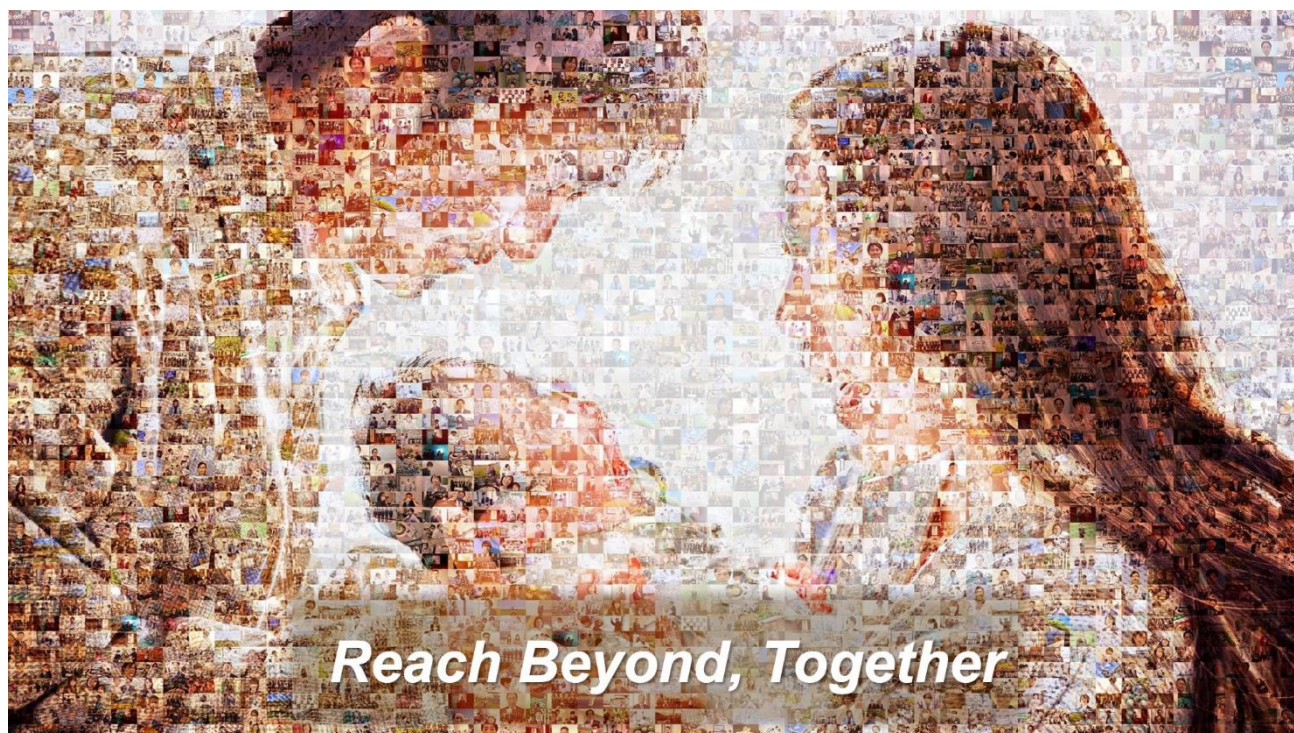
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Additionally, we believe that it is JCR's mission to create innovative platform technologies, delivering cargo technology delivery, the drugs generated through their technologies to patients and their families around the world contribute to treatments. In order to achieve this mission, rather than establishing a quantitative guidance in this midterm business plan, we will solidify our result to invest in the opportunities for growth through advancements in R&D.

We will aim to maximize value for patients under [inaudible] employees and shareholders through the creation of new innovation. The second phase of foundation will begin, and we will arise to the new challenge towards growth for patients and for their families, reach beyond and together.



This is our last slide. This mosaic artwork is made of a picture of each of our employees, team JCR, with unity in mind, we will proceed forward for the sake of our patients and their families. Thank you.

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Question & Answer

Moderator [M]: Now, we would like to take questions from the audience. The method of asking questions is shown on the screen. When it is your time to ask a question, someone will name you. Please identify yourself before asking your question.

From the Zoom participants, Mr. Yamaguchi, Citigroup, please?

Yamaguchi [Q]: This is Yamaguchi from Citi. Sorry, I was not able to attend in person. First, regarding the contract money from the previous year and this year. I understand that you cannot disclose the details, but in the previous year and at the beginning of the period, it was JPY15 billion. Actually, it was like JPY8 billion less, like JPY6.5 billion. This year, it's JPY8 billion. Am I correct to assume that the gap from the previous year was delayed into this period? I would like to understand how to interpret this year's contractor money.

Honda [A]: Thank you very much. This is Honda. The JPY15 billion forecast from the previous year, it was actually including some challenging projects that was the challenging target. Unfortunately, there was a downward revision. The contract, the revenue itself, was not achieved. For this year, this period, the target, the number is quite a certain level. We are assuming quite certain ones, not very challenging. Of course, there are some contracts that failed last year, and not all of them were delayed into this fiscal year. Some of those projects didn't go through. Also, there are new projects starting or included in this fiscal year's the forecast.

Yamaguchi [Q]: Thank you. The second question and regarding the contract manufacturing, from this year, is it from the company that you invested in, or your company suffered? I believe that there are some sales from the CDMO, the functions.

Honda [A]: Thus, for the contract manufacturing. Well, there is indeed a partner. I'm not able to disclose the details. We do not intend to enter the CDMO business from the JCR. Some other company evaluates our technology quite highly, and they actually wanted us to do some contract manufacturing. That is included in this period forecast.

Yamaguchi [Q]: Does it mean that it's the domestic one from the Kobe facility?

Honda [A]: That's right. Yes, using our manufacturing facility.

Yamaguchi [Q]: Regarding the 171, Phase I/II is going to start shortly. I understand that you will do the Phase III globally, but domestically, just like IZCARGO, is it possible that you make a filing after the Phase I/II in Japan?

Honda [M]: Sonoda will answer that.

Sonoda [A]: I cannot tell you definite things, but our policy is to conduct a Phase III. Then, based on that, we will do the global filing.

Yamaguchi [Q]: Lastly, and regarding the Angelini, the deal amount is quite a large one. You haven't made the data, so I don't think that is included in this fiscal year forecast, but the amount is very high. As a milestone, do you expect that you will get some money every year? Or will it take some more time before you receive the milestone?

Sonoda [A]: Also, this is due to the contract with a partner. Including the timeline, I am not able to discuss the details. In terms of the amount, it is different from the JCR traditional policy, but we make it more transparent.

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As for the policy of the disclosure, both companies will talk about that. The partner company wants to disclose the investment, and so we decided to disclose the amount.

Yamaguchi [Q]: Lastly, the midterm plan. So, you do not disclose any the numbers at all in this midterm plan. You don't have those numbers at all, or depending upon the timing, you may be able to disclose some numbers? Please make a comment.

Ito [A]: This is Ito, and I'd like to respond. We have a history of 48 years, and we are now in the second phase of creation. We are in the growing phase globally. Globally, we have the nature of biotech venture. In that sense, rather than having the numerical target, we want to focus on the investment in the R&D to have good results or outcomes of the R&D. For that, we want to make as much investment in R&D as possible.

On the other hand, our profit is from domestic sales and making some investments in R&D and also having the contract money. Depending upon the contract money, some profit level may fluctuate quite significantly. It is difficult to set such a numerical target in the future. It's quite difficult. By setting our target, we want to eliminate any possibility of losing concentration on the project. For this midterm plan, we are not disclosing any numbers. Thank you.

Moderator [M]: Thank you very much. Allow us to limit the number of questions per person to two. You can raise your hand as many times as the wish, but we look forward to your cooperation. Hashiguchi-san from Daiwa Securities. Please ask your questions.

Hashiguchi [Q]: Hashiguchi speaking. My first question, JR-141 is cargo Phase III, what the progress is. Page 31 of the business presentation, you are preparing to start clinical studies in new locations. Is this something that was originally planned? Or given the current circumstances, have you come out with a new plan to do clinical studies in new locations. If you could explain the background.

In relation to that, page 22. Next, the milestone, that's up to FY2027. At the current pace, if you are able to collect cases successfully at the earliest stage, when will you be able to achieve that? Of course, there may be a range. If you could shed light on that.

Moderator [M]: Matthias-san, please, if you could comment on the questions.

Schmidt [A]*: Thank you so much, Hashiguchi-san, for your question. Why did we add new locations for the clinical study? Because we want to accelerate patient enrollment. Initially, the involvement was a little bit slow because of the COVID-19 downfall and clinical sites allocated resources to anything but clinical trials. We have been able to catch up pretty well. In order to further accelerate, we added additional geographies where we believe we can find patients relatively easily. It is very difficult to forecast how our overall enrollment will go, and therefore, we rather want to stay with our initial communication that it is going to be FY2027. I hope that answers your question.

Hashiguchi [Q]: I have another question. Gene therapy joint research agreement with Takeda. Well, Takeda pharmaceutical and the vector drugs, they're not going to develop them any longer, they announced yesterday. AV vector is it what you are working on together with Takeda or something else? Or are you pursuing both with Takeda? What are you doing with Takeda? What are the circumstances? Takeda announced a decision yesterday, will that impact the project that you're doing with the Takeda going forward?

Company Representative [A]: Well, personally, I would love to share a number of things, but because we have the partner, Takeda, we're not in a position to share with you. I hope you will understand.

Hashiguchi [M]: Well, thank you. That's all for my questions.

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Moderator [M]: Thank you very much. Next from Morgan Stanley, Muraoka-san please.

Muraoka [Q]: This is Muraoka from Morgan Stanley. For the contract manufacturing, it's like JPY2.56 billion. I understand that you cannot disclose the details, but I would like to know the direction. This year, this is the number. From the next year, can we assume the similar level? Or is it only a one-time income just like AstraZeneca or will it lead to your profit? We have to make some expectation or the forecast about the profit, so please give me some hints.

Honda [A]: Thank you for your question. This is Honda again. For the contract manufacturing, the contract, this is one contract for that amount, for this period. The partner, the relationship with the partner going forward is not decided yet. From the next year, I cannot give you any specific idea whether we will have the continuous income for next year. Since we do some contract manufacturers, we are expecting a certain profit. Otherwise, we wouldn't do that. It's a meaningful significant deal for us. We can secure a certain profit from that.

Muraoka [Q]: The second question. This is the midterm plan. Today, there is a decline of the drop of the share, the stock price, like JPY20 billion down the market capitalization. We hope that you can provide good information for us.

Ito [A]: Thank you for your question. This is Ito. This time, we are not giving you any guidance. But on the other hand, from our side, we believe that it's important for us to provide various information. We say that we invest in R&D. With the results of the R&D, we want to contribute to the patients, families, as well as investors. At the proper time, we will give you information and disclose the information at the appropriate time. Thank you for your understanding.

Moderator [M]: Let's take the next question. Mitsubishi MUFG Morgan Stanley Securities, Kumagai-san please go ahead.

Kumagai [Q]: Kumagai from Mitsubishi MUFG Morgan Stanley Securities. So, you're not going to provide quantitative targets under the new midterm business plan, but what's going to be the rough number for R&D expenses? Five products are going to enter a clinical stage. Perhaps, on a qualitative basis, if you can offer something, if not quantitative?

Company Representative [A]: Not that we can share much, but clinical research will proceed for these compounds. In terms of the direction, R&D expense will rise.

Kumagai [Q]: So, IZCARGO 171 will be ready, but 441 will not be. Is that correct?

Company Representative [A]: That is correct.

Kumagai [Q]: It could be put on the normal development scheme; I think what you said is going to be the case. Domestic market sales for IZCARGO, JPY5.2 billion this year, rather soft. Through co-promotion, would there not be more sales?

Company Representative [A]: This fiscal term for IZCARGO, depending on the age of the patient, depending on the weight of the patient, when translated into sales, there could be a variance from the forecast. With respect to sales forecast, you will have to look at the number from that perspective.

As you said, with co-promotion with Sumitomo Pharma, there would be synergies generated as you suggested. More so than the forecast that we have come out with, perhaps we may be able to increase the number of prescriptions speedier than we initially thought. In April and into May, for the first month into the new fiscal year, inclusive of switches, we are seeing a larger number of prescriptions than we initially expected.

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Moderator [M]: Next question, Kawamura-san from SBI Securities.

Kawamura [Q]: This is Kawamura from SBI. Regarding the 141 global study, you are increasing the number of sites. The timing of the enrollment and also the interim result announcement timing, could you discuss that?

Moderator [M]: Matthias, please.

Schmidt [A]*: Yes. Thank you so much for your question. We would like to refrain from any comments about our interim analysis. We don't want to disclose too much on our strategy. Right now, we are basically well on track with our patient enrollment. Basically, it is calculated on a potential approval date, and that is based on 2027. If you back calculate the treatment period in the first cohort is two years, and therefore, you can easily conclude by when we will have finished the overall enrollment of our patients. Cohort B is not on the critical path, Cohort B involvement period, a treatment time is only one year as compared to Cohort A. For your calculation, use Cohort A. Last patient in plus two years plus the submission time, and then we will come to 2027 as a potential approval date.

Kawamura [Q]: Thank you very much understood. The second question is ultra-rare disease collaboration with MEDIPAL. In this area, so you were looking for the deal partners from before. MEDIPAL is a big distributor. Regarding the development, why did you decide to partner with MEDIPAL? Many of us must have expected one of the major domestic or the global companies. Please discuss why you decided to partner with MEDIPAL.

Company Representative [A]: We have been working on ultra-rare for a long time. Because this is ultra-rare, it's too small a region. In Japan, the patient number may be zero or one or two. We needed to look for a partner. It's not the money, but the mindset is important. We needed to do the partnership with some companies, which have the same understanding with us. Also, the potential of drug candidates. The partner needs to understand that potential very well. Also, the partner needs to be willing to make a big challenge for the patients.

We were looking for such companies, and we were not able to do that for a long time. Then, MEDIPAL and us working together for a long time, they have a good understanding of idea. Although MEDIPAL only has the wholesale capacity in Japan, they also want to go abroad. When it is about the ultra-rare disease, both companies thought that it's possible to deliver the therapy to each of the patients of the ultra-rare disease. Thank you for your understanding.

Moderator [M]: Thank you very much. Let's continue. Credit Suisse Securities, [Harida-san] please go ahead.

Participant [Q]: From Credit Suisse Securities, my name is [Harida]. Here's my first question. This time, J-Brain Cargo for degenerative disease, you have struck an agreement. Theoretically, J-Brain Cargo is a technology that penetrates BBB. Other than LSDs, it can be applied to other kinds of diseases. As you struck this agreement, in the nonclinical stage, have you accumulated data suggesting that this technology can work not just for LSDs but others? As you look to have more technical agreements with others? After the lump-sum payment, I think the partner will develop, and you will be responsible for the milestones. Is that the kind of arrangement that you will have with technical agreements?

Company Representative [A]: The first part of your question is whether data is available. Yes, we do have data. Regarding LSDs, because we have focused on that, we have data. Other than that, at the basic research level, we do have data regarding other diseases. Is the partner going to take the lead in development? Basically, yes, but it depends on the contract. It has to do with the specifics of the contract. I cannot disclose that.

Participant [Q]: That is understood. You will provide the technology. As you do so, how will that work? I wonder. The business model will be such that you will wait for the lump sum payment. Will you expand such arrangements?

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Company Representative [A]: Well, JCR is the one with the technology. Our partner, of course, has the expertise in the disease of focus. But we're not just waiting. The technology and know-how that we have that we can offer, there's this process of creating candidate compounds. We proceed with that rather than just waiting.

Participant [Q]: After that is done, who's going to do clinical development?

Company Representative [A]: It depends on the case, it's hard to generalize. If the partner is responsible for clinical development, of course, we will have to wait until they clinically develop the compound.

Participant [Q]: That is understood. My second question, Mycenax. Through third-party allotment, you have acquired their share last year. This year, equity loss is expected, but you said that there will be more results to come from this partnership. That is in the market. Does that mean that there is no important impairment in terms of corporate value in that regard?

Moderator [M]: Thank you for the question. Ito is responding.

Ito [A]: Mycenax, we have appreciated their technology. That is why we have decided to have an agreement and made an investment. We have commissioned Mycenax for production of investigational drugs so far. For a number of things, we have collaboration. We're asking Mycenax to produce. We're thinking of doing more of that, so we appreciate their technological prowess, strength. That remains unchanged. Equity and loss, because of the accounting treatment, that is what we have to accept. It's an investment loss in accounting terms that we have to accept.

Moderator [M]: Next from Nomura Securities, Matsubara-san please.

Matsubara [Q]: Thank you for your presentation. I have two questions regarding the contract manufacturing. How many contracts can you get in terms of the capacity, your capacity? Second point. Is it possible for you to get the deal with multiple companies, not only one company?

Sonoda [A]: Sonoda here, this is the contract manufacturing, we receive. We have the eight reactors of the 2,000 liters. If we have the full capacity operating, we have more capacity. We are not the contract manufacturing company. For Mycenax, we collaborated with Mycenax to have the flexibility of manufacturing. We want to promote the LSD drugs. The first priority for us to move forward, LSD, the projects. If we have the extra capacity, we will do the contract manufacturing. If there are good conditions, we may do that, but that's not the first priority.

Matsubara [Q]: Am I correct to assume that if the clinical studies move forward, you may not have enough capacity to receive the contract manufacturing deals, right?

Sonoda [A]: Yes, that may be the case, but it depends. If the contract manufacturing deal is quite a large one, income may be very large, so we may take that and have other products manufactured at Mycenax. That may be the possibility, but it depends.

Moderator [M]: Tsuzuki-san from Mizuho Securities, please go ahead.

Tsuzuki [Q]: This is Tsuzuki speaking, Mizuho Securities. I have one question regarding the revenue from agreements. Second, about technology investment. Our first revenue from contracts and agreements. In the last earnings announcement, I think you came up with numbers that are stretched. This time, I believe you said that the numbers are based on the concept that these are numbers that are firmly attainable. Well, I think most is to be derived from H1. In terms of contractual revenue, is that correct to understand that there could potentially be upward revision in the forecast number or the planned numbers?

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Company Representative [A]: Well, thank you for the question. Contractual revenue, when it will be posted, of course, there are partners that we have to think about. At this moment, definitively, in which quarter are we going to post the number? We cannot say. I do hope that that is understood. Of course, other than the contractual revenue that we are expecting, there could be progress in the negotiations that we're having. If there is any more to be posted, we would like to disclose that to the investor community as soon as we can.

Tsuzuki [Q]: That is understood. Now, my second question is about the licensing out of technology. I would like you to elaborate. In FY2022, R&D VHH antibody was mentioned, it's easy to process. Perhaps, it's for technology investment for FY2023, VHH antibody investment. So, JXXX Cargo, JYYY Cargo, what is the progress? Will we be able to see tangible progress by the end of FY2023? [inaudible] for different receptors. It's not J-Brain Cargo, but they're making publications and various academic conferences that was mentioned before. If you could answer that.

Moderator [M]: Sonoda to answer the VHH.

Sonoda [A]: Yes, March FY2022, we made an announcement. It was almost complete, and we are brushing up on it actually, as we speak. We are very confident about VHH. The beauty is we already have data in comparison with the human in terms of validation. We are very close to where we can actually put VHH to actual use. XXX and YYY, what's happening on that front? We're still at the basic research level. We are proceeding with 17 LSDs pipeline.

Where is going to be the focus? What's going to be the focus? That's what we're thinking hard. It's very important to come out with basic platform technology, but we need to translate that into actual drugs so that they can deliver to the patient community. 17 items were very much focused on developing them right now. In parallel with that, XXX, YYY are being worked on. When will we be able to disclose the progress? We cannot say when at this moment definitively. There are strong needs to deliver drugs, not just to the brain, but to other organs, but we would like to raise priority to work on such technologies going forward.

Moderator [M]: Next, Mizuno-san from the Tokyo Marine Asset Management.

Mizuno [Q]: This is Mizuno. Thank you for your presentation. Two questions. First Alexion and the other, Angelini, alliance with other areas other than LSDs, when did you start to market your technology for areas other than LSD?

Sonoda [A]: Sonoda here, let me clarify my understanding. You are asking about the timing of when we started the negotiation or when we announced our technology?

Mizuno [Q]: For the Alexion and Angelini, if you can give us the specific timing of your negotiation, that will great, but the timing is very similar. I want to know the timing that you started announcing your technology. I believe that after that, there was some due diligence. I just wanted to have some image of what will happen in the future. I want to know the timing that you started offering your technology.

Sonoda [A]: I understand. Well, for each case, I'm not able to give you the timing of the start of the negotiation. We are always looking for the possibility, it depends on each case. I cannot give you any average. For the Alexion and Angelini, the timing was very close.

Mizuno [Q]: Is it just coincidence? Not based upon your corporate strategy?

Sonoda [A]: Right. It was just a coincidence. Going forward, also similar partnership contracts could be made, if possible.

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Mizuno [Q]: Regarding the midterm plan, this is kind of a question and opinion. There is no quantitative target as some people asked. I understand that it's difficult for you to come up with some numbers. On the other hand, I have been covering your Company for more than a decade. Looking at that, I have some kind of expectation of what will be happening in five years or 10 years, but if the investor looks at your presentation for the first time, they will not have any image of your Company in five or 10 years. If you bring that information to the financial institution and ask for the loan, probably they will decline. Your midterm plan, you say no one left behind, but the stock market is left behind totally.

Sonoda [A]: All right. Thank you for your opinion. Yes, I listened to your opinion, and I accept that, and so we will consider that going forward. For the financing, we have a good relationship with the financial institutions that we have been dealing with. Thank you for your precious opinion. We will work on that. Thank you.

Mizuno [Q]: Sorry, I'm not concerned about your getting some financing at all. From the point of view of the stock market, your presentation should be the material for us to consider the future. Your material failed to do that. What I'm saying is that if you ask for some new investments, probably nobody will accept that. That's my understanding about your presentation. Regarding the quantitative target for like FY2028, we can calculate. For the first year, there are no specific numbers. That was not very good.

Moderator [M]: We are taking questions from the floor at this venue in person. Any questions from those of you attending in person? There seems to be none from the floor. We would like to continue to take questions from those of you on Zoom. SBI Securities, Kawamura-san, please go ahead.

Kawamura [Q]: Kawamura from SBI. This is a detailed question, but about GROWJECT and TEMCELL, I have a question. GROWJECT, because of price revision of 5% YoY, the revenue is down by 11%. Because of declining birth rate, it's going to go down. So far, it's been flat. This time, you are announcing an 11% decline. Why? For TEMCELL, there was no price revision. Why is it going to decline? What are the assumptions behind this?

Toru Ashida [A]: First of all, thank you for the question. Regarding GROWJECT, I would like to respond, Ashida speaking. Price revision impact is there, of course. A decline in birth rate is also a factor, but growth therapy patients, that patient population as a growth hormone therapy manufacturer, teachers and nurses at schools, we are continuously conducting advocacy and outreach to such people. New patients, we are always developing and cultivating. The number of patients that we're going to acquire will rise gradually. In fact, in the last five years, here in Japan, growth hormone therapy market, our market share, has been rising over the past five years. We now have a market share of 24% in growth hormone therapies in Japan. As such, even in the face of price revision, we would like to continue to develop the market for us.

Regarding revenue or sales, why negative impact? To touch upon that in the past, patients who have started growth hormone therapy, they usually initiate therapy at age two or three. In 10 or so years ago, the number of children or pediatric patients used to be relatively large compared to now. There are those patients about 10 years ago, they terminate therapy every year with increasing weight. One patient, once they are done with growth therapy, growth hormone therapy, a new patient is two or three or four of them will have to be acquired when one patient terminates. Otherwise, the performance cannot be maintained. There are patients who are terminating, and that is also considered.

Ohta [A]: From the accounting division, let me supplement. Regarding GROWJECT, and last year versus this year, wholesale versus retail, that has been an impact. There has been an impact on accounting reasons. Thank you.

Kawamura [Q]: Regarding TEMCELL, what about the situation regarding TEMCELL?

Company Representative [A]: With respect to TEMCELL, after launch, the acute GvHD treatment area, I think branding has progressed for our product. On the other hand, on the clinical scene, GvHD, prophylactic

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treatment to suppress GvHD is proceeding. Inclusive of the number of transplants, it's very hard to forecast and predict. We're being rather conservative in our forecast.

Moderator [M]: Time is running out. There are two more people who have raised their hands, so that will be end. Muraoka-san from Morgan Stanley.

Muraoka [Q]: I have only one question. 171, the Phase III will be necessary as you said, and I understand that. Still, in Japan, maybe it's possible to file with the results of the Phase I/II, you already have that track record of the 141. I'm looking for some kind of a good event that makes the stock market happy. Is it difficult to file after Phase I/II in Japan?

Company Representative [A]: Thank you for your question. Currently, I would not say that's 100% impossible. For the 141 and 171, the dosing period is different. Our plan or the design of the Phase I/II study for 171 is based upon the possible Phase III studies going forward. It will be difficult to file after Phase I/II study, but it's not completely impossible. We will look at the different options. Thank you for your comments, questions.

Muraoka [M]: Thank you. Please move forward the events that makes us happy.

Moderator [M]: Well, thank you very much. We have come to a time to close. With that, we would like to conclude questions and answers. At this moment, with that, we would like to conclude JCR Pharma's earnings results briefing session for the year ending March 2023.

Thank you very much for your attendance and participation.

[END]

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