



*Reach Beyond, Together*

# **FY2024 Third Quarter Consolidated Financial Results Conference Call**

January 31, 2025

JCR Pharmaceuticals Co., Ltd.

[Securities code]4552, Prime. TSE

[Contacts] [ir-info@jp.jcrpharm.com](mailto:ir-info@jp.jcrpharm.com)

# FY2024 Third Quarter Consolidated Financial Results

**Yoh Ito**

Senior Executive Officer

Executive Director, Corporate Strategy Division

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**FY2024 Third Quarter Consolidated Financial Results**

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**Progress of Developmental Pipelines**

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**Revision of FY2024 Consolidated Financial Forecast**

# Overview: Consolidated Financial Results

(Unit : million yen)

Consolidated	FY2023	FY2024		
	Q3 YTD	Q3 YTD	Year-on-year	
			Difference	Ratio
Net Sales	33,718	<b>25,880</b>	(7,837)	(23.2%)
Cost of Sales	8,423	<b>7,007</b>	(1,415)	(16.8%)
Gross Profit	25,295	<b>18,873</b>	(6,422)	(25.4%)
Selling, General and Administrative Expenses	17,486	<b>19,627</b>	+2,141	+12.2%
SG&A Expenses	9,127	<b>9,702</b>	+575	+6.3%
R&D Expenses	8,359	<b>9,925</b>	+1,566	+18.7%
Operating Profit	7,809	<b>(754)</b>	(8,563)	-
Non-operating Income	575	<b>200</b>	(374)	(65.1%)
Non-operating Expenses	995	<b>827</b>	(168)	(16.9%)
Ordinary Profit	7,388	<b>(1,380)</b>	(8,769)	-
Extraordinary Income	0	<b>1,065</b>	+1,064	-
Extraordinary Losses	18	<b>2</b>	(15)	(88.5%)
Profit before Income Taxes	7,371	<b>(317)</b>	(7,688)	-
Income Taxes	2,210	<b>258</b>	(1,951)	(88.3%)
Profit Attributable to Owners of Parent	5,160	<b>(576)</b>	(5,737)	-
Reference: R&D Expenses before Deducting Contribution Amount by Collaborative R&D Destinations	9,508	<b>11,121</b>	+1,613	+17.0%

## Additional Remarks

- Cost to sales ratio excluding contractual payment remained favorable
- Depreciation from the new formulation facility at Kobe Science Park Center is included in General and Administrative Expenses and is expected to be offset against the “Special suspense account for tax purpose reduction entry” (by advanced depreciation) account by fiscal year-end
- The increase in R&D Expenses was mainly due to the establishment of overseas development structures and the advancement of clinical trials
- Extraordinary Income includes from Gain on reversal of share acquisition rights and Gain on cancellation of contract

Net Sales	FY2023 Q3 YTD	FY2024 Q3 YTD	Difference
Cost of Sales Ratio	25.0%	<b>27.1%</b>	+2.1%
Cost of Sales Ratio *Excluding income from contractual payment	31.7%	<b>27.6%</b>	(4.0%)
R&D Expenses Ratio	24.8%	<b>38.3%</b>	+13.6%
Operating Profit Ratio	23.2%	<b>(2.9%)</b>	(26.1%)

# Breakdown of Net Sales (Consolidated)

(Unit: million yen)

Consolidated	FY2023	FY2024		
	Q3 YTD	Q3 YTD	Year-on-year	
			Difference	Ratio
GROWJECT®	13,995	14,177	+182	+1.3%
IZCARGO®	3,969*	4,456	+486	+12.3%
TEMCELL®HS Inj.	2,699	2,296	(402)	(14.9%)
Treatments for renal anemia	3,673	2,595	(1,078)	(29.3%)
Epoetin Alfa BS Inj. [JCR]	1,681	1,250	(430)	(25.6%)
Darbepoetin Alfa BS Inj. [JCR]	1,992	1,345	(647)	(32.5%)
Agalsidase Beta BS I.V. Infusion [JCR]	998	1,149	+150	+15.1%
<b>Total Core Products</b>	25,336	24,675	(660)	(2.6%)
Income from contractual payment	7,112	517	(6,595)	(92.7%)
Other	1,269*	688	(581)	(45.8%)
<b>Total Net Sales</b>	33,718	25,880	(7,837)	(23.2%)

## Additional Remarks

- Sales of GROWJECT® increased by 1.3% year-on-year, reflecting steady growth.
- Sales of IZCARGO® grew by 12.3% year-on-year, demonstrating strong performance
- Sales of TEMCELL®HS Inj. fell 14.9% year-on-year due to increased competition but remain steady against the full-year forecast.
- Epoetin Alfa BS Inj. [JCR] Expected to Fall Below Initial Plan
- Sales of Agalsidase Beta BS I.V. Infusion [JCR] are driven by strong performance at the distributor, Sumitomo Pharma Co., Ltd.
- Contract Revenue Includes Milestones from Joint Research; Major Revenue Expected in Q4
- The decline in other sales stems from lower contract manufacturing revenue.

\*The sales of IZCARGO® under NPS program were removed and reclassified to "Other". As such, the respective figures of FY2023 Q3 shown here are different from those published on January 26, 2024.

## “First dosing in first subject” was achieved in 3 studies in 3 products

### JR-441

BBB-penetrating heparan N-sulfatase (rDNA origin)

Indication: MPS type IIIA

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- **Japan:** Phase I study (JR-441-JP11)

### JR-446

BBB-penetrating  $\alpha$ -N-acetylglucosaminidase (rDNA origin)

Indication: MPS type IIIB

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- **Japan:** Phase I/II study (JR-446-101)

### JR-142

Long-acting growth hormone (rDNA origin)

Indication: Pediatric growth hormone deficiency

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- **Japan:** Phase III study (JR-142-301)

# Overview of Clinical or late Preclinical Pipeline

Code	Indication	Status				Milestones/Comments
		Preclinical	Phase 1	Phase 2	Phase 3	
JR-141	MPS II (Hunter syndrome)	Global Ph3				<ul style="list-style-type: none"> <li>Q3 FY2025: Enrollment completion</li> <li>~FY2027: Approval in US, EU, Brazil</li> </ul>
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed				<ul style="list-style-type: none"> <li>Extension study ongoing</li> <li>Partnering intensified</li> </ul>
JR-142	Pediatric GHD	Ph3 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph3</li> </ul>
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany)				<Ph1/2> <ul style="list-style-type: none"> <li>Patient enrollment completed</li> <li>2H FY2025: 1-year clinical data</li> </ul> <Ph1> <ul style="list-style-type: none"> <li>Oct 2024: Initiation of first dosing</li> </ul>
		Ph1 (Japan)				
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)				<ul style="list-style-type: none"> <li>Dec 2024: Initiation of first dosing in Ph1/2</li> </ul>
JR-471	Fucosidosis					—

# Revision of FY2024 Consolidated Financial Forecast

	Net Sales (Unit: million yen)	Operating Profit (Unit: million yen)	Ordinary Profit (Unit: million yen)	Profit Attributable to Owners of Parent (Unit: million yen)	Earnings Per Share (Unit: yen)
Previously announced forecasts	41,300	5,400	4,600	3,700	29.65
<b>Revised forecasts</b>	<b>39,000</b>	<b>1,400</b>	<b>750</b>	<b>2,200</b>	<b>17.77</b>
Difference	(2,300)	(4,000)	(3,850)	(1,500)	-
Ratio	(5.6%)	(74.1%)	(83.7%)	(40.5%)	-
Reference: FY2023 Results	42,871	7,531	7,264	5,507	44.13

## **Net Sales**

- While product sales remain largely on track, income from contractual payment was revised downward because an overseas licensing agreement will not be concluded for JR-171 within this fiscal year.

## **Operating Profit**

- Operating profit was revised downward to 1,400 million yen due to a decrease in gross profit resulting from lower net sales, coupled with increases in cost of sales and selling, general and administrative expenses.
  - ✓ Cost of Sales: Despite improvements in cost efficiency and a favorable product mix, higher disposal costs for manufacturing materials are expected. Accordingly, the cost of sales have increased by 700 million yen.
  - ✓ Expenses were increased by 400 million yen allocated to selling, general and administrative expenses, and 600 million yen to R&D expenses, based on results through the third quarter, etc.



# Revision of FY2024 Consolidated Financial Forecast

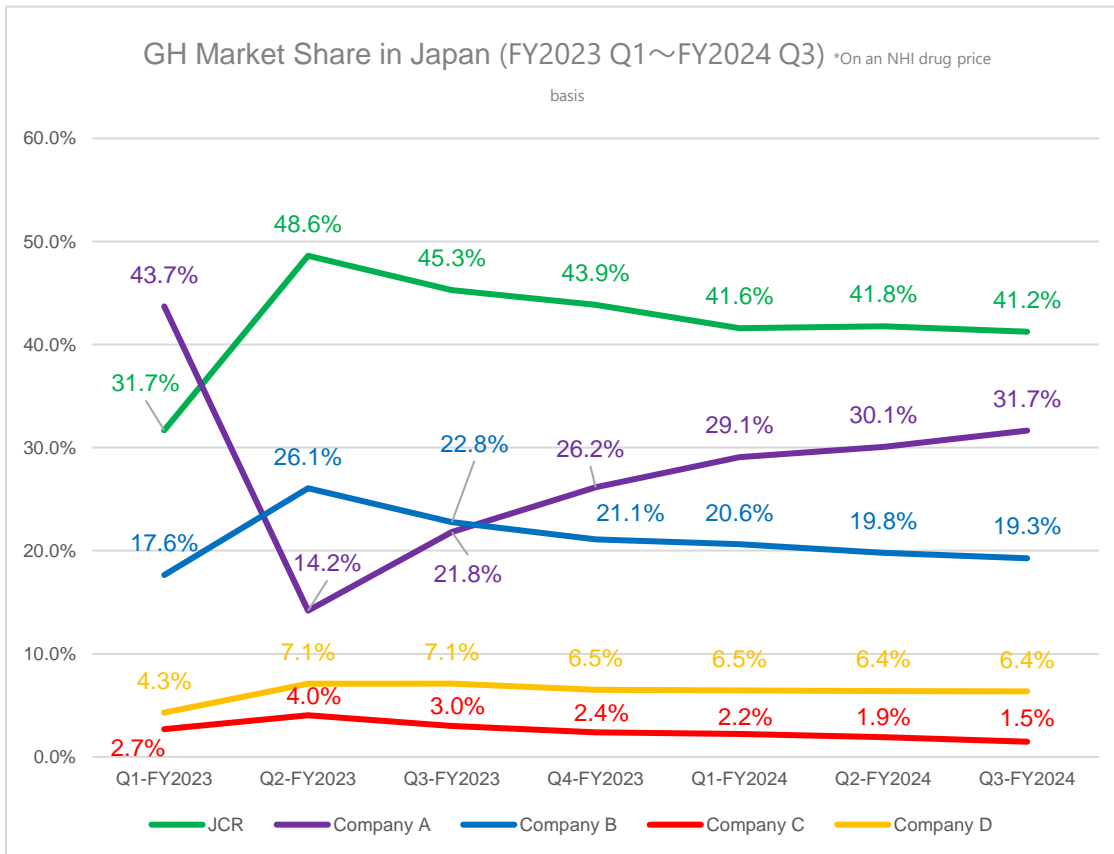
(Unit: million yen)

	Previously announced forecasts	Revised forecasts	Difference	Ratio	Reference: FY2023 Results
<b>GROWJECT®</b>	18,300	<b>18,300</b>	-	-	17,913
<b>IZCARGO®</b>	5,700	<b>5,800</b>	+100	+1.8%	5,171
<b>TEMCELL®HS Inj.</b>	2,800	<b>2,900</b>	+100	+3.6%	3,236
<b>Treatments for renal anemia</b>	4,200	<b>3,700</b>	(500)	(11.9%)	4,652
<b>Epoetin Alfa BS Inj. [JCR]</b>	2,200	<b>1,700</b>	(500)	(22.7%)	1,994
<b>Darbepoetin Alfa BS Inj. [JCR]</b>	2,000	<b>2,000</b>	-	-	2,658
<b>Agalsidase Beta BS I.V. Infusion [JCR]</b>	1,100	<b>1,100</b>	-	-	1,661
<b>Total Core Products</b>	32,100	<b>31,800</b>	(300)	(0.9%)	32,636
<b>Income from contractual payment</b>	8,100	<b>6,100</b>	(2,000)	(24.7%)	7,413
<b>Other</b>	1,100	<b>1,100</b>	-	-	2,820
<b>Total Net Sales</b>	41,300	<b>39,000</b>	(2,300)	(5.6%)	42,871

*Reach Beyond, Together*

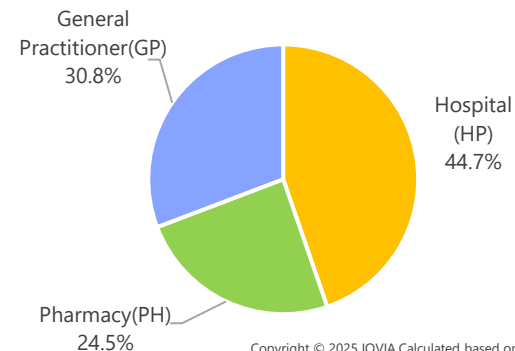


# Appendix



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## Human Growth Hormone Market in Japan



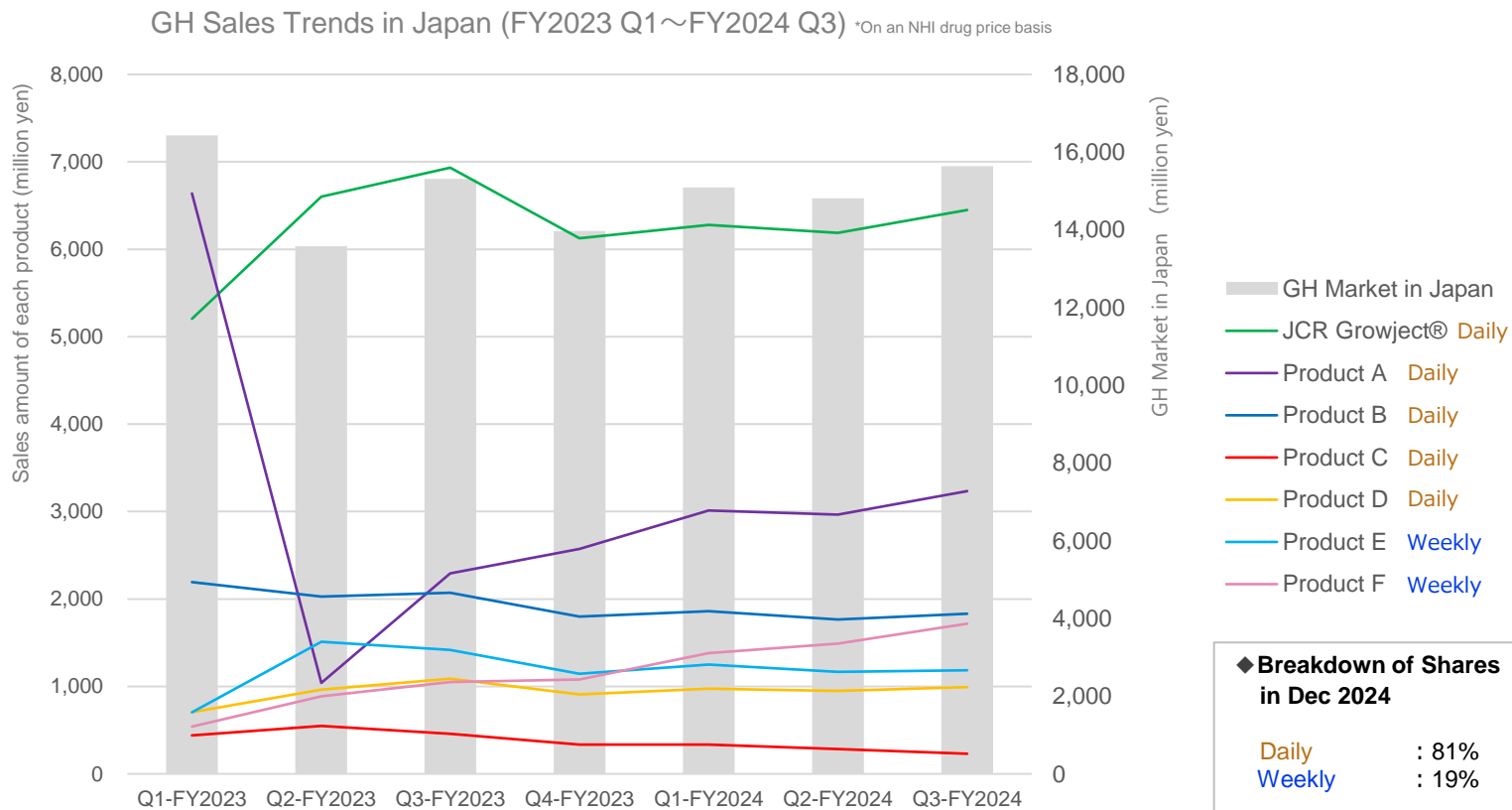
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\*Market definition by JCR Reprinted with permission

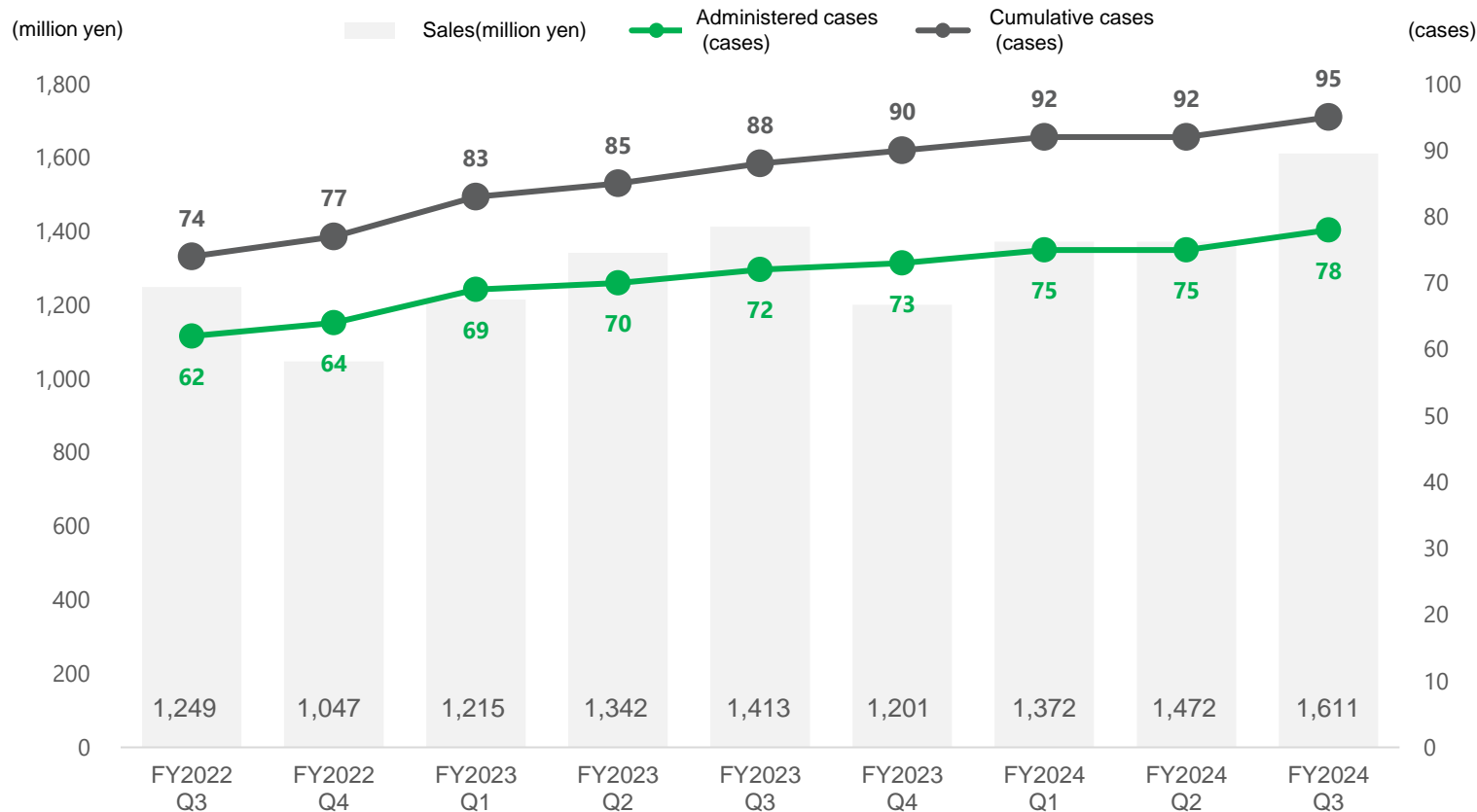
## GROWJECT® Market Share by buyer

	Dec 2024	Sales Change FY2024 Q3 (vs. FY2023 Q3) <small>*On an NHI drug price basis</small>
HP Market	33.6%	-334 million yen
PH Market	31.2%	-149 million yen
GP Market	61.1%	+250 million yen

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HP: Hospital  
GP: General Practitioner  
PH: Pharmacy





- In the third quarter financial statement, approximately 500 million yen of the depreciation at Kobe Science Park Center was recorded as SG&A expenses and approximately 100 million yen was recorded as Non-operating expenses.

Transfer of items from “construction in progress”

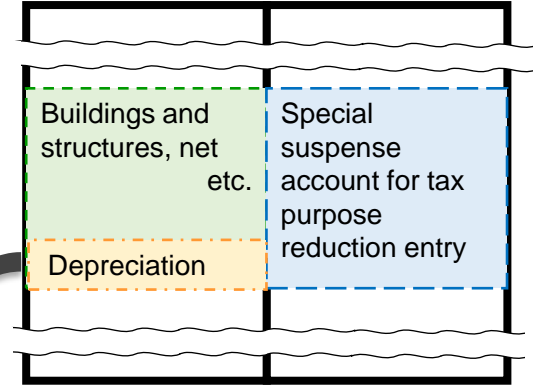
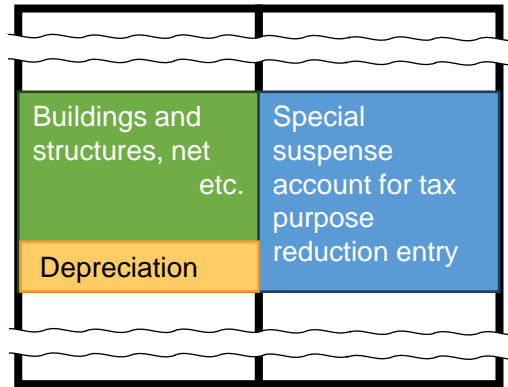
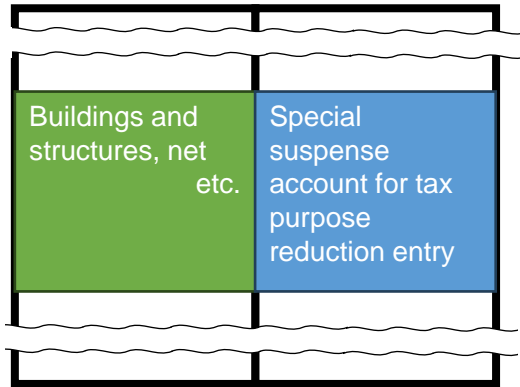
As of March 31, 2024

As of March 31, 2025 (scheduled)

- The portion subject to subsidy was transferred from the “construction in progress” account to the property, plant and equipment account.

- Depreciation (approx. 600 million yen) recorded with start of operations in Q2 FY2023

- The portion subject to subsidy will be offset against the “Special suspense account for tax purpose reduction entry” (by advanced depreciation)
- The depreciation will be recorded as Extraordinary Income.



\*Only the portion of the subsidy that is included in the balance sheet is shown.

This amount will be recorded as Extraordinary Income (Approximately 1,500 million yen)

# Abbreviations (A~G)

AAV	Adeno-Associated Virus	アデノ随伴ウイルス
ASO	Antisense oligonucleotides	アンチセンス核酸
BBB	Blood-Brain Barrier	血液脳関門
CNS	Central Nervous System	中枢神経系
CSF	Cerebrospinal fluid	脳脊髄液
CTN	Clinical Trial Notification	治験計画届
EC	European Commission	欧州委員会
EMA	European Medicines Agency	欧州医薬品庁
ERT	Enzyme Replacement Therapy	酵素補充療法
EU	European Union	欧州連合
FDA	Food and Drug Administration	米国食品医薬品局
GHD	Growth Hormone Deficiency	成長ホルモン分泌不全性低身長症



# Abbreviations (H~Z)

HS	Heparan Sulfate	ヘパラン硫酸
i.v.	Intravenous Injection	静脈注射
JBC	J-Brain Cargo®	-
LNP	Lipid nanoparticle	脂質ナノ粒子
MPS	Mucopolysaccharidosis	ムコ多糖症
NPS	Named Patient Supply	特定の患者への医薬品提供プログラム
ODD	Orphan Drug Designation	希少疾病用医薬品指定
Ph I	Phase I	臨床第 1 相試験
Ph II	Phase II	臨床第 2 相試験
Ph III	Phase III	臨床第 3 相試験
PRIME	Priority Medicines	アンメットメディカルニーズを対象とした医薬品の開発支援を強化するためのスキーム
R&D	Research and Development	研究開発
siRNA	small interfering RNA	短鎖干渉RNA
TBD	To be determined	未定

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- The figures in this document are rounded down to the nearest million yen, and percentages are rounded to the nearest whole number. As a result, there may be discrepancies in the total figures.