Reach Beyond, Together

FY2024 Third Quarter Consolidated Financial Results Conference Call

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Reach Beyond, Together

FY2024 Third Quarter Consolidated Financial Results

Yoh Ito
Senior Executive Officer
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1 FY2024 Third Quarter Consolidated Financial Results

2 Progress of Developmental Pipelines

3 Revision of FY2024 Consolidated Financial Forecast

Overview: Consolidated Financial Results

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(Unit：million yen)

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

Additional Remarks

- Cost to sales ratio excluding contractual payment remained favorable
- Depreciation from the API Plant 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%	**27.1%**	+2.1%
Cost of Sales Ratio *Excluding income from contractual payment	31.7%	**27.6%**	(4.0%)
R&D Expenses Ratio	24.8%	**38.3%**	+13.6%
Operating Profit Ratio	23.2%	**(2.9%)**	(26.1%)

On February 12 2025, Additional Remarks was corrected. Correction is indicated by underlining.

YTD: year to date

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%
Total Core Products	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%)
Total Net Sales	33,718	**25,880**	(7,837)	(23.2%)

*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.

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.

YTD: year to date

Progress of Developmental Pipelines

“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

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

JR-446

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

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

JR-142

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

- **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	• Q3 FY2025: Enrollment completion • ~FY2027: Approval in US, EU, Brazil
JR-171	MPS I (Hurler syndrome etc.)	Global Ph1/2 completed	• Extension study ongoing • Partnering intensified
JR-142	Pediatric GHD	Ph3 (Japan)	• Dec 2024: Initiation of first dosing in Ph3
JR-441	MPS IIIA (Sanfilippo syndrome type A)	Ph1/2 (Germany) Ph1 (Japan)	<Ph1/2> • Patient enrollment completed • 2H FY2025: 1-year clinical data <Ph1> • Oct 2024: Initiation of first dosing
JR-446	MPS IIIB (Sanfilippo syndrome type B)	Ph1/2 (Japan)	• Dec 2024: Initiation of first dosing in Ph1/2
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
Revised forecasts	**39,000**	**1,400**	**750**	**2,200**	**17.77**
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
GROWJECT®	18,300	**18,300**	-	-	17,913
IZCARGO®	5,700	**5,800**	+100	+1.8%	5,171
TEMCELL®HS Inj.	2,800	**2,900**	+100	+3.6%	3,236
Treatments for renal anemia	4,200	**3,700**	(500)	(11.9%)	4,652
Epoetin Alfa BS Inj. [JCR]	2,200	**1,700**	(500)	(22.7%)	1,994
Darbepoetin Alfa BS Inj. [JCR]	2,000	**2,000**	-	-	2,658
Agalsidase Beta BS I.V. Infusion [JCR]	1,100	**1,100**	-	-	1,661
Total Core Products	32,100	**31,800**	(300)	(0.9%)	32,636
Income from contractual payment	8,100	**6,100**	(2,000)	(24.7%)	7,413
Other	1,100	**1,100**	-	-	2,820
Total Net Sales	41,300	**39,000**	(2,300)	(5.6%)	42,871

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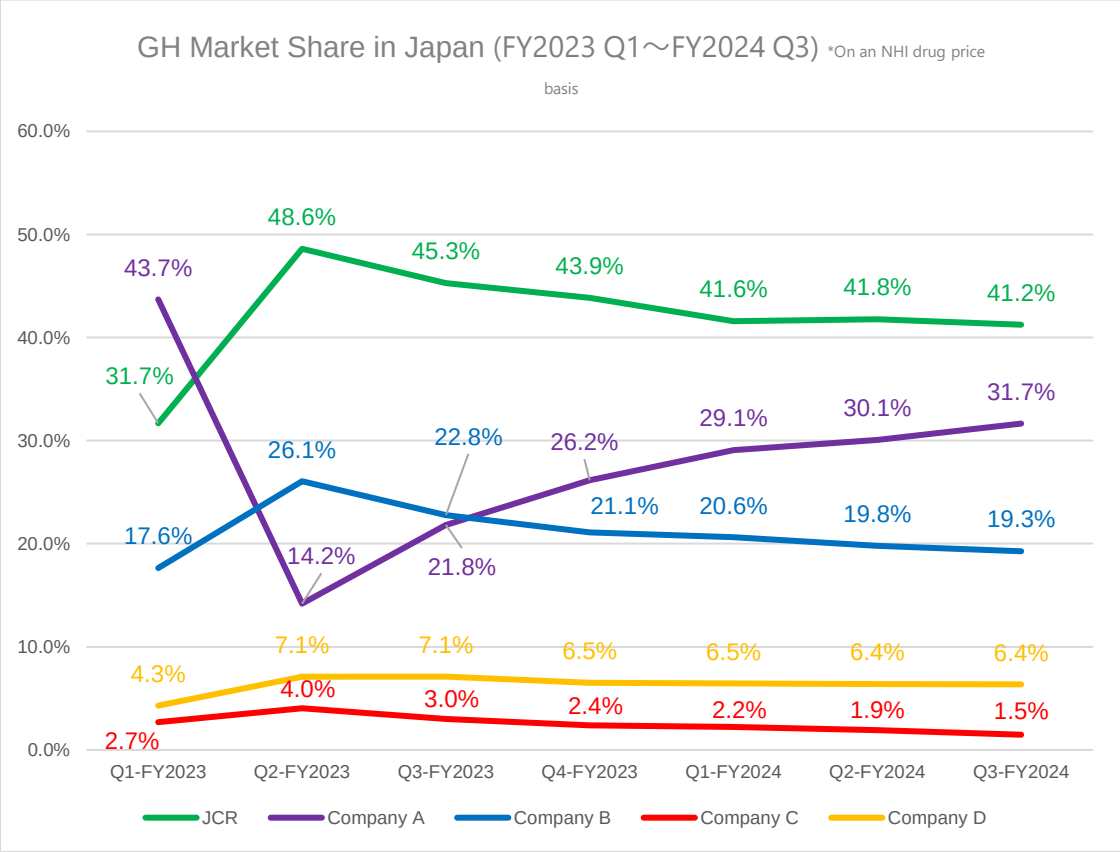
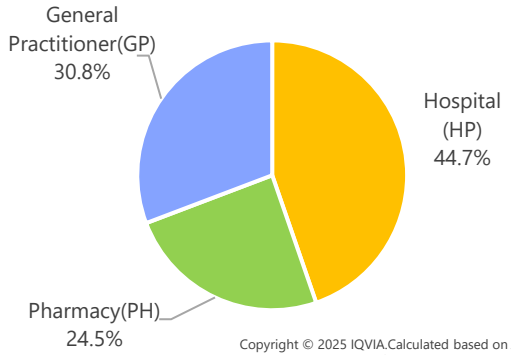
Appendix

GROWJECT® Market Share Trends in Japan (Quarterly)



■ Human Growth Hormone Market in Japan

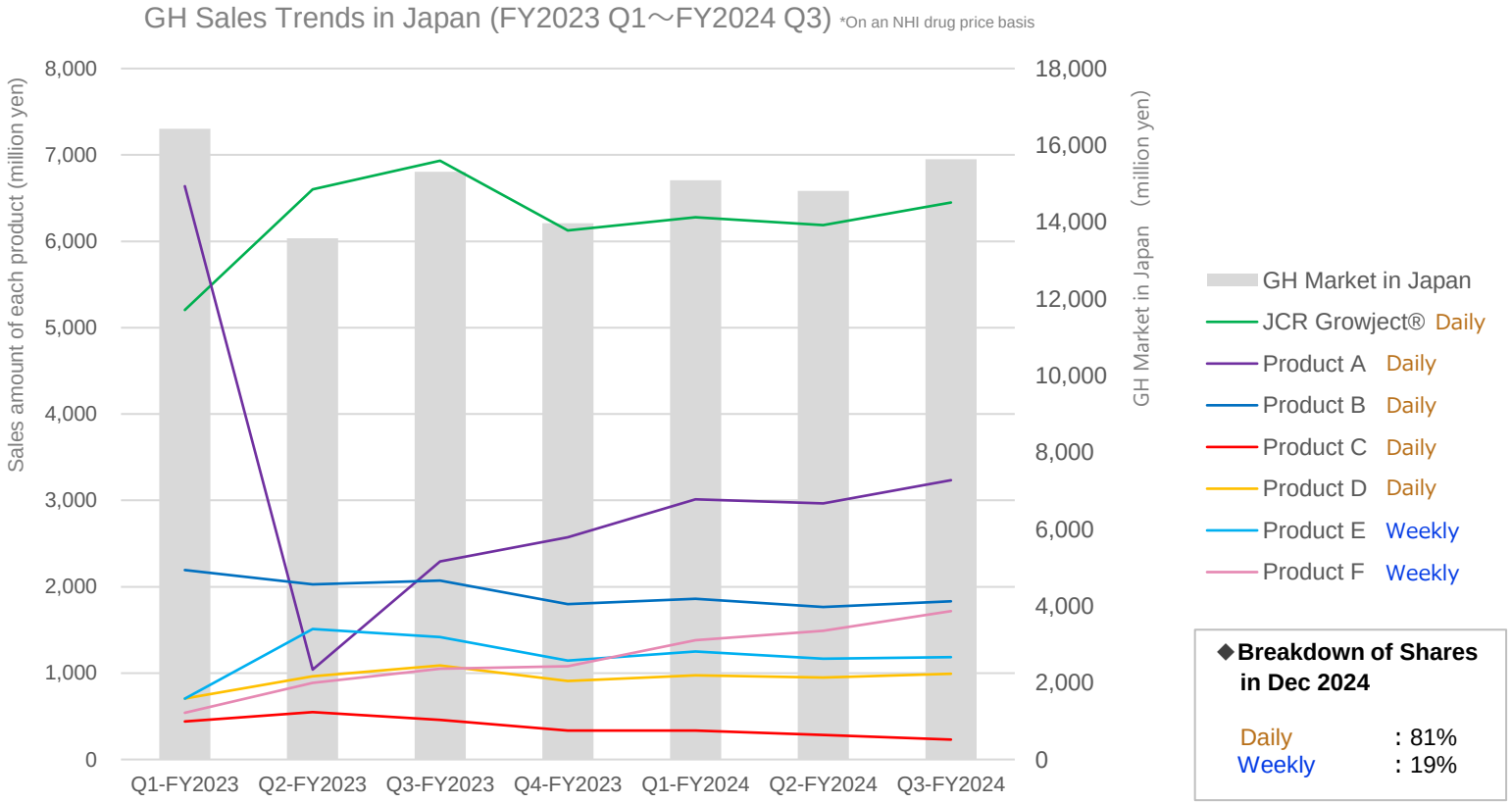


■ GROWJECT® Market Share by buyer

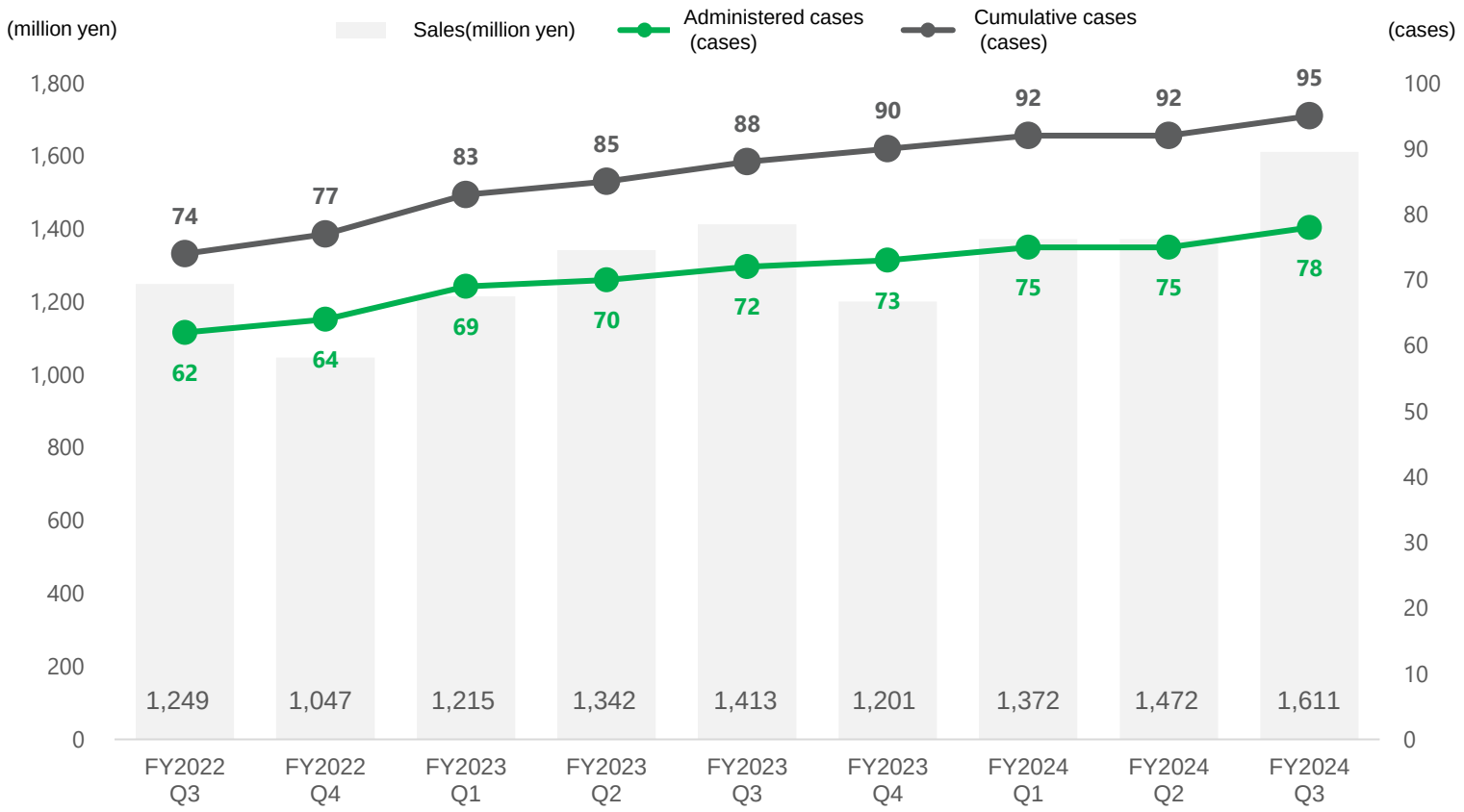
	Dec 2024	Sales Change FY2024 Q3 (vs. FY2023 Q3) *On an NHI drug price basis
HP Market	33.6%	-334 million yen
PH Market	31.2%	-149 million yen
GP Market	61.1%	+250 million yen

HP: Hospital
GP: General Practitioner
PH: Pharmacy

GROWJECT® Sales Trends in Japan (Quarterly)



IZCARGO® Prescription Status in Japan

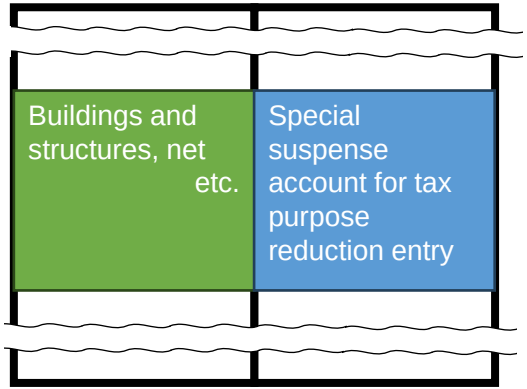


Handling of subsidies for the construction of the Kobe Science Park Center

- 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.

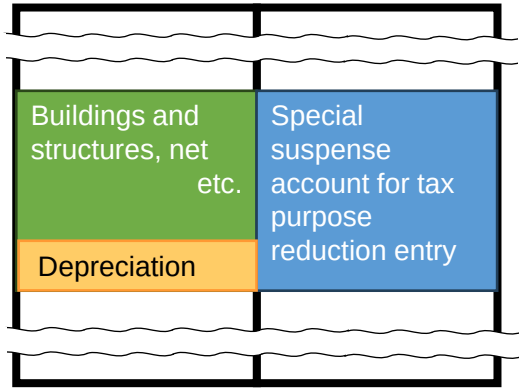
Transfer of items from "construction in progress"

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



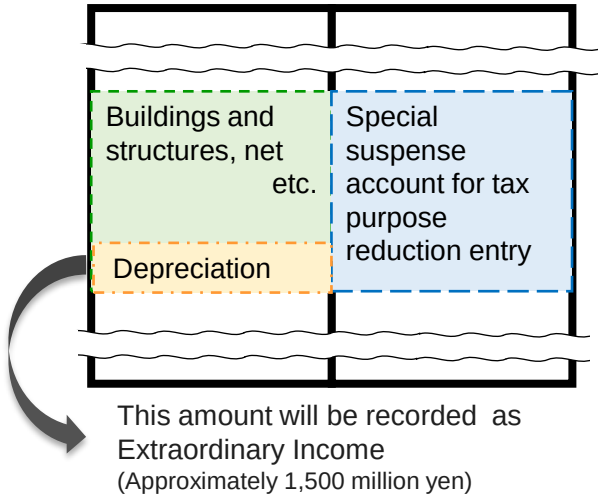
As of March 31, 2024

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



As of March 31, 2025 (scheduled)

- 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.

Abbreviations (A～G)

AAV	Adeno-Associated Virus	アデノ随伴ウイルス
API	Active Pharmaceutical Ingredient	原薬
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 Administraion	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

Disclaimer Regarding Forward-Looking Statement

- This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Company's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties. Accordingly, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

- Information concerning pharmaceuticals and medical devices (including those under development) contained herein is not intended as advertising or as medical advice.

- 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.