

Financial Summary

Consolidated Financial Results for the Three Months ended June 30, 2024 (FY2024) (Japanese standard)

July 30, 2024

Listed company name: JCR Pharmaceuticals Co., Ltd.

Listed stock exchange: Tokyo Stock Exchange

Code number: 4552 URL: <https://www.jcrpharm.co.jp/>

Representative: (Title) Representative Director, Chairman and President

(Name) Shin Ashida

Person in charge of inquiries: (Title) Senior Executive Officer, Executive Director, Corporate Strategy Division

(Name) Yoh Ito TEL: 0797(32)1995

Scheduled date to commence dividend payments: –

Preparation of supplemental information for this financial summary: Available

IR Conference: To be held (for institutional investors and analysts)

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 1Q FY2024 (April 1, 2024 to June 30, 2024)

(1) Consolidated Operating Results (Cumulative)

(Percentage shows year-on-year changes.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	million yen	%	million yen	%	million yen	%	million yen	%
Three months ended								
June 30, 2024	8,145	(24.6)	(296)	—	(257)	—	201	(87.5)
June 30, 2023	10,808	12.5	2,066	34.5	2,260	8.5	1,610	17.7

(Reference) Comprehensive income: Three months ended June 30, 2024: 441 million yen ([75.4]%)

Three months ended June 30, 2023: 1,789 million yen (30.5%)

	Earnings per share (basic)	Earnings per share (diluted)
	yen	yen
Three months ended		
June 30, 2024	1.61	1.61
June 30, 2023	12.91	12.85

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
June 30, 2024	104,165	55,674	52.4
March 31, 2024	102,226	56,475	54.2

(Reference) Shareholders' equity: As of June 30, 2024: 54,542 million yen

As of March 31, 2024: 55,365 million yen

1. Dividends

	Dividends per share				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Annual
	yen	yen	yen	yen	yen
FY2023	—	10.00	—	10.00	20.00
FY2024	—				
FY2024 (Forecast)		10.00	—	10.00	20.00

(Note) No revisions were made to the most recently announced dividend forecast.

2. Consolidated Forecasts for the Fiscal Year Ending March 31, 2025 (April 1, 2024 to March 31, 2025)

(Percentage figures for the fiscal year represent the changes from the previous year.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Year ending March 31, 2025	41,300	(3.7)	5,400	(28.3)	4,600	(36.7)	3,700	(32.8)	29.65

(Note) No revisions were made to the most recently announced financial results forecast.

*Notes

- (1) Changes in significant subsidiaries during the period (Changes in specified subsidiaries resulting in the change in consolidation scope): None
- (2) Application of specific accounting practices for preparing quarterly consolidated financial statements: None
- (3) Changes in accounting policy, changes in accounting estimates and restatements
1. Changes in accounting policy due to the revision of accounting standards, etc. : Yes
 2. Changes in accounting principles other than 1. : None
 3. Changes in accounting estimates : None
 4. Restatements : None
- (Note) For details, please refer to “2. Quarterly Consolidated Financial Statements and Important Notes (3) Notes to Quarterly Consolidated Financial Statements (Notes on changes in accounting policy)” on page 8 of the attached materials.
- (4) Number of shares outstanding (common stocks)

1. Number of shares outstanding at the end of the period (including treasury stock)	As of June 30, 2024	129,686,308 shares	As of March 31, 2024	129,686,308 shares
2. Number of shares treasury stock at the end of the period	As of June 30, 2024	4,861,414 shares	As of March 31, 2024	4,881,914 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of June 30, 2024	124,813,769 shares	As of June 30, 2023	124,782,090 shares

* Review of accompanying quarterly consolidated financial statements by certified public accountants or auditing firms:
None

* Explanation on the appropriate use of forecasts of financial results and other comments
(Note on forward-looking statements, etc.)

Forward-looking statements, such as forecasts of financial results, contained in this document are based on information currently available to the Company and certain assumption that are judged as rational. The Company does not assure the achievement of these forecasts. In addition, actual financial results may differ significantly from forecasts due to various reasons. For assumptions underlying forecasts of financial results and notes regarding the appropriate use of forecasts of financial results, please refer to “1. Overview of Financial Results, Etc., (3) Explanation on Projections such as Forecasts of Consolidated Financial Results” on page 3 of the attached material.

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1. Overview of Financial Results, Etc.

(1) Overview of Quarterly Financial Results

[1] Financial results for Q1 FY2024

Net sales amounted to 8,145 million yen (down 24.6% year on year).

Sales volume for our recombinant human growth hormone product GROWJECT® increased significantly in spite of an NHI price revision in April 2024. Sales were also brisk for IZCARGO® for I.V. infusion 10mg and certain other products. Nevertheless, decreases in income from contractual payment and contract manufacturing sales resulted in a decrease in total net sales year on year.

R&D expenses totaled 3,175 million yen (up 881 million yen, or 38.4%, year on year) reflecting proactive R&D activities.

As a result, the Company recorded an operating loss of 296 million yen (operating profit of 2,066 million yen in the same period of the previous fiscal year) and an ordinary loss of 257 million yen (ordinary profit of 2,260 million yen in the same period of the previous fiscal year), and profit attributable to owners of parent decreased 87.5% year on year to 201 million yen due to extraordinary gains resulting from contract cancellations, etc.

	Previous quarterly consolidated results (cumulative) (April 1, 2023 to June 30, 2023)	Current quarterly consolidated results (cumulative) (April 1, 2024 to June 30, 2024)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	10,808	8,145	(24.6)
Operating profit (loss)	2,066	(296)	—
Ordinary profit (loss)	2,260	(257)	—
Profit attributable to owners of parent	1,610	201	(87.5)

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2023 to June 30, 2023)	Current quarterly consolidated results (cumulative) (April 1, 2024 to June 30, 2024)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product GROWJECT®	4,222	4,649	10.1
Treatment for mucopolysaccharidosis type II IZCARGO® for I.V. Infusion	1,214	1,372	13.0
Treatment for renal anemia Epoetin Alfa BS Inj. [JCR]	1,615	907	(43.8)
Darbepoetin Alfa BS Inj. [JCR]	602	515	(14.5)
	1,012	392	(61.3)
Regenerative medicine products TEMCELL® HS Inj.	1,063	730	(31.4)
Treatment for Fabry disease Agalsidase Beta BS I.V. Infusion [JCR]	471	277	(41.2)
Income from contractual payment	1,612	15	(99.0)

[3] The Status of R&D

[Treatments for lysosomal storage disorders]

- Currently, we are focused on research and development of new drugs that employ our unique blood-brain barrier (BBB) -penetrating technology, J-Brain Cargo®, as treatments for over 17 types of lysosomal storage disorders (LSD).
- For pabinafusp alfa (development code: JR-141), our BBB-penetrating technology product for the treatment of patients with Hunter syndrome, we currently have a global Phase III clinical trial in progress. We have completed enrollment of our target number of 20 cases in cohort B, for so-called attenuated type, and we have completed enrollment for over 60% cases in cohort A, for patients with neuronopathic type.
- For lepunafusp alfa (development code: JR-171), our BBB-penetrating product for the treatment of patients with mucopolysaccharidosis type I (MPS I), we have completed our 13-week-long Phase I/II clinical trial in Japan, Brazil, and the U.S., and are conducting an extension study. For this product, our policy is to proceed with development by licensing out, rather than in-house development, and we are proceeding with licensing negotiation with a partner candidate.
- Regarding the BBB-penetrating treatment enzyme formulation for MPS IIIA (Sanfilippo syndrome type A) (development code: JR-441), we are proceeding with a Phase I/II clinical trial in Germany. In the first half of 2024, we completed enrollment of 12 cases. In December 2023, the FDA granted orphan drug designation to JR-441 in the U.S.
- As for the BBB-penetrating treatment enzyme formulation for MPS IIIB (Sanfilippo syndrome type B) (development code: JR-446), in September 2023, we entered into a licensing agreement with MEDIPAL HOLDINGS CORPORATION regarding overseas commercialization and a co-development and commercialization agreement in Japan. We submitted a clinical trial plan to the Pharmaceuticals and Medical Devices Agency in May 2024, which has been accepted, and we are currently making preparations to initiate Phase I/II clinical trial.

- With regard to our fucosidosis therapeutic (development code: JR-471), another LSD treatment that applied J-Brain Cargo[®], based on a licensing agreement concluded in October 2022, MEDIPAL HOLDINGS CORPORATION was granted the right to obtain an exclusive license with sublicensing rights for global commercialization which includes research, development, manufacturing and marketing excluding Japan. We are currently conducting research and other activities necessary to begin a clinical trial.

[Creating platform technologies]

- In addition to research that will widen the potential for application of JCR's unique BBB-penetrating technology J-Brain Cargo[®] to various modalities, we are focused on creating new platform technologies following J-Brain Cargo[®] technology. One of the results of this was our announcement in May 2024 of a new gene therapy technology using J-Brain Cargo[®]. Now being developed as a new platform technology, this gene therapy technology is able to efficiently transmit adeno-associated virus vector to the brain by modifying it with J-Brain Cargo[®] to reduce its accumulation in the liver.

[Regenerative medicine products]

- We have been developing TEMCELL[®] HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE); however, as Phase I/II clinical trial did not demonstrate the expected efficacy, we decided to discontinue this development.

[Human growth hormone product]

- We are conducting an extension study of a Phase II clinical trial of a recombinant long-acting human growth hormone (development code: JR-142). We submitted a Phase III clinical trial plan to the Pharmaceuticals and Medical Devices Agency in July 2024, which has been accepted, and we are currently making preparations to begin the clinical trial.

(2) Overview of Quarterly Financial Conditions

As of June 30, 2024, total assets amounted to 104,165 million yen (an increase of 1,939 million yen from March 31, 2024), total liabilities were 48,491 million yen (an increase of 2,740 million yen from March 31, 2024), and net assets were 55,674 million yen (a decrease of 801 million yen from March 31, 2024).

Current assets increased by 246 million yen from March 31, 2024 to 57,828 million yen due to factors including an increase in inventories, while there were decreases in cash and deposits and accounts receivable - trade, and contract assets. Non-current assets increased by 1,692 million yen from March 31, 2024 to 46,337 million yen, mainly due to an increase in property, plant and equipment. Current liabilities increased by 2,738 million yen from March 31, 2024 to 32,874 million yen, mainly due to an increase in short-term borrowings, which was partly offset by a decrease in income taxes payable. Non-current liabilities remained about level with March 31, 2024 at 15,617 million yen.

Net assets decreased by 801 million yen from March 31, 2024 to 55,674 million yen, mainly due to the payment of dividends, despite recording profit attributable to owners of parent.

As a result, the equity ratio as of June 30, 2024 was 52.4%, down 1.8 percentage points from March 31, 2024.

In order to achieve sustainable global growth, we need to secure a flexible and stable source of funds. We concluded commitment line agreements with our financial institutions for a total of 49.5 billion yen for the purpose of securing operating funds as a backup plan. Of this amount, 26.5 billion yen has been newly concluded to finance the construction of a new plant for drug product filling and finishing. The construction of this new plant has been adopted by the Ministry of Economy, Trade and Industry (METI) under the project of Establishing Biopharmaceutical Manufacturing Sites to Strengthen Vaccine Production, and the subsidy from this project will be used to construct the new plant. The purpose of the commitment line agreement is to provide the necessary funds until we receive the subsidy.

(3) Explanation on Projections such as Forecasts of Consolidated Financial Results

Looking at consolidated financial results for the three months ended June 30, 2024, sales and profits decreased year on year, but these results were in line with our initial forecasts. Accordingly, there have been no changes to the forecasts for the fiscal year ending March 31, 2025 announced on May 10, 2024.

2. Quarterly Consolidated Financial Statements and Important Notes
 (1) Quarterly Consolidated Balance Sheets

(Millions of yen)

	As of March 31, 2024	As of June 30, 2024
Assets		
Current assets		
Cash and deposits	18,756	18,337
Accounts receivable - trade, and contract assets	14,934	14,056
Merchandise and finished goods	2,111	2,404
Work in process	6,220	6,908
Raw materials and supplies	12,602	12,960
Other	2,955	3,161
Total current assets	57,581	57,828
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	14,140	13,907
Land	10,587	10,587
Construction in progress	171	2,335
Other, net	5,141	4,899
Total property, plant and equipment	30,040	31,730
Intangible assets		
Patent right	2,158	2,088
Other	1,338	1,281
Total intangible assets	3,496	3,370
Investments and other assets		
Investment securities	9,120	9,092
Other	1,991	2,148
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	11,107	11,237
Total non-current assets	44,644	46,337
Total assets	102,226	104,165
Liabilities		
Current liabilities		
Accounts payable - trade	890	857
Short-term borrowings	8,950	13,870
Income taxes payable	1,657	216
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	1,016	1,596
Provision for bonuses for directors (and other officers)	114	146
Other	5,510	4,189
Total current liabilities	30,135	32,874
Non-current liabilities		
Long-term borrowings	14,350	14,350
Provision for employee stock ownership plan	81	100
Retirement benefit liability	903	918
Other	280	248
Total non-current liabilities	15,615	15,617
Total liabilities	45,750	48,491

(Millions of yen)

	As of March 31, 2024	As of June 30, 2024
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,384	10,384
Retained earnings	37,278	36,227
Treasury shares	(2,963)	(2,952)
Total shareholders' equity	53,761	52,721
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	741	732
Deferred gains or losses on hedges	(0)	—
Foreign currency translation adjustment	731	962
Remeasurements of defined benefit plans	132	126
Total accumulated other comprehensive income	1,604	1,821
Share acquisition rights	812	812
Non-controlling interests	297	318
Total net assets	56,475	55,674
Total liabilities and net assets	102,226	104,165

(2) Quarterly Consolidated Statements of Income and Consolidated Statements of Comprehensive Income
(Quarterly Consolidated Statements of Income)

(Millions of yen)

	Three months ended June 30, 2023	Three months ended June 30, 2024
Net sales	10,808	8,145
Cost of sales	3,363	2,073
Gross profit	7,445	6,072
Selling, general and administrative expenses	5,379	6,368
Operating profit (loss)	2,066	(296)
Non-operating income		
Interest income	0	27
Dividend income	13	17
Foreign exchange gains	484	435
Other	21	24
Total non-operating income	520	505
Non-operating expenses		
Share of loss of entities accounted for using equity method	297	200
Interest expenses	19	26
Commission expenses	2	17
Depreciation	—	214
Other	6	6
Total non-operating expenses	326	466
Ordinary profit (loss)	2,260	(257)
Extraordinary income		
Gain on cancellation of contract	—	627
Total extraordinary income	—	627
Extraordinary losses		
Loss on disposal of non-current assets	0	0
Total extraordinary losses	0	0
Profit before income taxes	2,260	369
Income taxes - current	1,122	230
Income taxes - deferred	(469)	(65)
Total income taxes	653	164
Profit	1,607	204
Profit (loss) attributable to non-controlling interests	(2)	3
Profit attributable to owners of parent	1,610	201

(Quarterly Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Three months ended June 30, 2023	Three months ended June 30, 2024
Profit	1,607	204
Other comprehensive income		
Valuation difference on available-for-sale securities	68	(9)
Deferred gains or losses on hedges	-	0
Foreign currency translation adjustment	35	98
Remeasurements of defined benefit plans, net of tax	2	(6)
Share of other comprehensive income of entities accounted for using equity method	75	151
Total other comprehensive income	181	236
Comprehensive income	1,789	441
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,789	418
Comprehensive income attributable to non-controlling interests	(0)	22

(3) Notes to Quarterly Consolidated Financial Statements

(Notes on changes in accounting policy)

(Application of “Accounting Standard on Current Income Taxes,” etc.)

The Company has applied the “Accounting Standard on Current Income Taxes” (ASBJ Statement No. 27, October 28, 2022; hereinafter, the “Revised Accounting Standard of 2022”), etc. from the start of 1Q FY2024 (April 1, 2024 to June 30, 2024.)

The revision to the account classification for current income taxes (taxes on other comprehensive income) follows the transitional treatment stipulated in the proviso of paragraph 20-3 of the Revised Standard of 2022 and the transitional treatment stipulated in the proviso of paragraph 65-2 (2) of “Guidance on Accounting Standard for Tax Effect Accounting” (ASBJ Guidance No. 28, October 28, 2022; hereinafter the “Revised Guidance of 2022”). Furthermore, there is no impact on the quarterly consolidated financial statements from this change in accounting policy.

The Revised Guidance of 2022 has been applied to revisions concerning treatment in the consolidated financial statements when deferring taxes on gain or loss on the sale of the shares of subsidiaries, etc., between consolidated companies from the start of 1Q FY2024. The change in accounting policy was applied retrospectively, and the quarterly and full-year consolidated financial statements for FY2023 (April 1, 2023 to March 31, 2024) have been restated to reflect the changes after the revision. There is no impact on the full-year or quarterly consolidated financial statements for FY2023 from this change in accounting policy.

(Notes on segment information)

Segment information is not disclosed since the Group has only one segment, Pharmaceuticals.

(Notes on any significant changes in the amount of shareholders’ equity)

None

(Notes on going concern assumption)

None

(Notes on consolidated statement of cash flows)

The Company has not prepared a consolidated statement of cash flows for 1Q FY2024. Depreciation and amortization (including amortization of intangible assets) for 1Q FY2024 is as follows.

	1Q FY2023 (April 1, 2023 to June 30, 2023)	1Q FY2024 (April 1, 2024 to June 30, 2024)
Depreciation and amortization	511 million yen	826 million yen