Financial Summary
Consolidated Financial Results for the Six Months ended September 30, 2024 (FY2024)
(Japanese standard)

October 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 Corporate Officer, Executive Director, Corporate Strategy Division
(Name) Yoh Ito TEL: 0797(32)1995

Scheduled date to file Quarterly Securities Report: November 14, 2024
Scheduled date to commence dividend payments: December 6, 2024
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 2Q FY2024 (April 1, 2024 to September 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	
Six Months Ended	million yen	%	million yen	%	million yen	%	million yen	%
Sep. 30, 2024	16,657	(31.4)	(739)	—	(1,621)	—	(691)	—
Sep. 30, 2023	24,272	55.8	6,898	826.2	7,126	353.9	5,253	445.6

(Reference) Comprehensive income: Six months ended Sep. 30, 2024: 1,788 million yen ([69.6]%)
Six months ended Sep. 30, 2023: 5,877 million yen (437.4%)

	Earnings per share (basic)	Earnings per share (diluted)
Six Months Ended	yen	yen
Sep. 30, 2024	(5.53)	—
Sep. 30, 2023	42.10	41.90

(Note) "Diluted net income per share" for the first half of the fiscal year ending March 2025 is not stated because there was a net loss per share, even though there were residual shares.

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
Sep. 30, 2024	104,622	57,049	54.1
Mar. 31, 2024	102,226	56,475	54.2

(Reference) Shareholders' equity: As of Sep 30, 2024: 56,629 million yen
As of Mar. 31, 2024: 55,365 million yen

2. 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	—	10.00			
FY2024 (Forecast)			—	10.00	20.00

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

3. 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 Mar. 31, 2025	41,300	(3.7)	5,400	(28.3)	4,600	(36.7)	3,700	(32.8)	29.65

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

*Note

(1) Changes in significant subsidiaries during the period
(Changes in specified subsidiaries resulting in the change in consolidation scope): Yes
Excluded: 1 company, Mycenax Biotech Inc.

(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. Restatement : None

(Note) For details, please see "2. Quarterly Consolidated Financial Statements and Important notes (4) Notes to Quarterly Consolidated Financial Statements (Notes on Changes in accounting policies)" on page 9 of the attached document.

(4) Number of shares outstanding (common stocks)

1. Number of shares outstanding at the end of the period (including treasury stock)	As of Sep. 30, 2024	129,686,308 shares	As of Mar. 31, 2024	129,686,308 shares
2. Number of treasury stock at the end of the period	As of Sep. 30, 2024	4,189,502 shares	As of Mar. 31, 2024	4,881,914 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of Sep. 30, 2024	125,010,957 shares	As of Sep. 30, 2023	124,787,306 shares

* The quarterly financial statements are outside of the scope of quarterly review by a certified public accountant or an audit firm.

* 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 of Future Outlook, Including Consolidated Financial Forecasts" on page 3 of the attached material.

■ Table of Contents for Attached Material

1. Overview of Financial Results, Etc.

(1) Overview of Quarterly Financial Results

[1] Financial results for Q2 FY2024

Sales amounted to 16,657 million yen, a 31.4% decrease compared to the same period last year.

While our recombinant human growth hormone product "GROWJECT®" saw a revision in reimbursement prices in April 2024, sales volumes increased, and "IZCARGO® 10mg for I.V. Infusion" also continued to perform well, but product sales were almost the same as the previous year due to a decrease in sales of renal anemia treatments. However, due to a decline in contract revenue and outsourced manufacturing sales, overall revenue decreased compared to the previous year.

As a result of proactive research and development activities, R&D expenses increased by 18.8%, amounting to 6,576 million yen (an increase of 1,040 million yen year-on-year).

Consequently, the company recorded an operating loss of 739 million yen (compared to an operating profit of 6,898 million yen in the same period last year), an ordinary loss of 1,621 million yen (compared to an ordinary profit of 7,126 million yen last year), and a net loss attributable to the parent company of 691 million yen (compared to a net profit of 5,253 million yen last year).

	Previous quarterly consolidated results (cumulative) (April 1, 2023 to September 30, 2023)	Current quarterly consolidated results (cumulative) (April 1, 2024 to September 30, 2024)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	24,272	16,657	(31.4)
Operating profit (loss)	6,898	(739)	―
Ordinary profit (loss)	7,126	(1,621)	―
Profit (loss) attributable to owners of parent	5,253	(691)	―

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2023 to September 30, 2023)	Current quarterly consolidated results (cumulative) (April 1, 2024 to September 30, 2024)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product **GROWJECT®**	8,746	9,401	7.5
Treatment for mucopolysaccharidosis type II **IZCARGO® for I.V. Infusion**	2,556	2,845	11.3
Treatment for renal anemia	2,674	1,764	(34.0)
Epoetin Alfa BS Inj. [JCR]	1,046	962	(8.0)
Darbepoetin Alfa BS Inj. [JCR]	1,628	801	(50.8)
Regenerative medicine products **TEMCELL® HS Inj.**	1,901	1,521	(20.0)
Treatment for Fabry disease **Agalsidase Beta BS I.V. Infusion [JCR]**	590	714	21.0
Total	16,470	16,246	(1.4)
Income from contractual payment	7,112	15	(99.8)

[3] The Status of Research and Development (R&D)

[Lysosomal Storage Disorder (LSD) Treatments]

- We are currently focusing on the research and development of over 17 LSD treatments utilizing our proprietary blood-brain barrier (BBB) penetration technology, J-Brain Cargo®.

- For pabinafusp alfa (JR-141), a BBB-penetrating enzyme replacement therapy for Hunter syndrome, we are progressing with global Phase III clinical trials. Additionally, Cohort B, targeting patients with attenuated type, has completed the enrollment of 20 subjects, and Cohort A, targeting more neuronopathic type, has completed over 60% of its enrollment.

- For lepunafusp alfa (JR-171), a BBB-penetrating enzyme replacement therapy for mucopolysaccharidosis type I, we have completed a 13-week Phase I/II clinical trial in Japan, Brazil, and the U.S., and are continuing with extension study. This product is being developed through licensing out, and we are in discussions with potential partners.

- For JR-441, a BBB-penetrating enzyme replacement therapy for mucopolysaccharidosis type IIIA, a Phase I/II clinical trial is underway in Germany, and the planned enrollment of 12 subjects was completed in the first half of 2024. In Japan, the Phase I clinical trial notification was accepted by the the Pharmaceuticals and Medical Devices Agency(PMDA) in August 2024, and preparations for trial commencement are underway. This treatment has been designated as an orphan drug by the European Commission (EC) in January 2022 and by the U.S. Food and Drug Administration (FDA) in December 2023.

- For JR-446, a BBB-penetrating enzyme replacement therapy for mucopolysaccharidosis type IIIB, we entered into an agreement with MEDIPAL HOLDINGS CORPORATION in September 2023 for overseas commercialization and co-development and commercialization agreement in Japan. The clinical trial notification submitted in May 2024 has been accepted by the PMDA, and preparations are underway to initiate a Phase I/II clinical trial.

- For JR-471, a BBB-penetrating enzyme replacement therapy for fucosidosis, we have granted MEDIPAL HOLDINGS CORPORATION exclusive rights, including sublicensing, for the research, development, manufacturing, and commercialization of the product globally, excluding Japan, under a licensing agreement signed in October 2022. We are currently conducting necessary studies in preparation for the initiation of clinical trials.

[Creation of Platform Technologies]

- In addition to expanding the applicability of JCR's proprietary J-Brain Cargo® technology to various modalities, we are focusing on creating new platform technologies beyond J-Brain Cargo®. One of these developments was announced in May 2024, which involves a new gene therapy technology utilizing J-Brain Cargo®. This technology modifies adeno-associated virus (AAV) vectors with J-Brain Cargo® to reduce uptake by the liver and efficiently deliver the vectors to the brain. This technology is being developed as a new platform for gene therapies.

[Regenerative Medicine Products]

- We had been developing "TEMCELL® HS Injection" for the expanded indication of neonatal hypoxic-ischemic encephalopathy (JR-031HIE), but after the Phase I/II clinical trial did not demonstrate the expected efficacy, we decided to discontinue the development of this indication.

[Human Growth Hormone Products]

- We are currently conducting an extension study of a long-acting recombinant human growth hormone (JR-142) as part of a Phase II clinical trial. In July 2024, we submitted a clinical trial notification for a Phase III trial to the PMDA, and preparations for the trial are underway.

(2)Quarterly Financial Status Overview

[1] Assets, Liabilities, and Net Assets

At the end of the consolidated interim accounting period, total assets amounted to 104,622 million yen, an increase of 2,396 million yen compared to the end of the previous fiscal year. Total liabilities were 47,572 million yen, an increase of 1,822 million yen, and total net assets amounted to 57,049 million yen, an increase of 573 million yen compared to the previous fiscal year-end.
Current assets decreased by 1,274 million yen compared to the previous fiscal year-end to 56,307 million yen, primarily due to reductions in cash and deposits, as well as accounts receivable and contract assets, despite an increase in inventories. Fixed assets increased by 3,670 million yen to 48,314 million yen compared to the previous fiscal year-end. This increase was largely due to additions in tangible fixed assets related to construction in progress for the new manufacturing facility, along with higher investment in securities. Current liabilities increased by 3,998 million yen to 34,133 million yen, driven by a rise in short-term borrowings despite decreases in unpaid corporate and consumption taxes. Non-current liabilities decreased by 2,176 million yen to 13,438 million yen, mainly due to a reduction in long-term borrowings.Net assets increased by 573 million yen compared to the previous fiscal year-end to 57,049 million yen, mainly due to a decrease in treasury stock and an increase in valuation differences on available-for-sale securities, despite the recording of a net loss attributable to the parent company, dividend payments ,and decreasing share acquisition rights.

As a result, the equity ratio at the end of the consolidated interim accounting period decreased by 0.1 points compared to the previous fiscal year-end, standing at 54.1%.
To ensure our group’s sustainable global growth, it is necessary to secure flexible and stable funding options. Therefore, we have entered into a commitment line agreement with financial institutions totaling 49,500 million yen as a backup line for securing working capital. Of this, 26,500 million yen is allocated for financing the construction of a new manufacturing facility. This facility is part of the "Vaccine Production Capacity Enhancement and Biopharmaceutical Manufacturing Base Development Project" adopted by the Ministry of Economy, Trade, and Industry, and will be funded using subsidies under this project. The commitment line agreement is intended to cover necessary funds until the subsidies are received.

[2] Cash Flow Status

Cash and cash equivalents at the end of the consolidated interim accounting period decreased by 484 million yen compared to the previous fiscal year-end to 18,271 million yen.
The details of the cash flows and their primary causes are as follows:
(Cash Flow from Operating Activities)
Operating activities resulted in a cash outflow of 1,109 million yen, an increase of 4,630 million yen in expenses from the same period last year. Key factors included a reduction in accounts receivable of 2,579 million yen and depreciation expenses of 1,667 million yen. However, this was offset by a pre-tax interim net loss of 556 million yen, an increase in inventory of 1,830 million yen, a decrease in unpaid consumption taxes of 1,818 million yen, and corporate tax payments of 1,451 million yen.
(Cash Flow from Investing Activities)
Investing activities used 2,962 million yen in funds, up 1,674 million yen in outflows compared to the same period last year. This increase was mainly driven by 2,992 million yen spent on acquiring tangible fixed assets.
(Cash Flow from Financing Activities)
Financing activities generated 3,852 million yen, marking a 4,613 million yen increase in inflows from the prior year. This was primarily due to a net increase in short-term borrowings of 5,112 million yen, partly offset by 1,248 million yen in dividend payments.

(3)Explanation of Future Outlook, Including Consolidated Financial Forecasts

For the consolidated financial performance of the interim accounting period, both revenue and profit decreased compared to the same period last year.
There are no changes to the full-year forecast for the fiscal year ending March 2025, which was 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 September 30, 2024
Assets		
Current assets		
Cash and deposits	18,756	18,271
Accounts receivable - trade, and contract assets	14,934	12,354
Merchandise and finished goods	2,111	2,332
Work in process	6,220	7,642
Raw materials and supplies	12,602	12,790
Other	2,955	2,915
Total current assets	57,581	56,307
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	14,140	13,681
Land	10,587	10,587
Construction in progress	171	2,912
Other, net	5,141	4,572
Total property, plant and equipment	30,040	31,754
Intangible assets		
Patent right	2,158	2,019
Other	1,338	1,228
Total intangible assets	3,496	3,247
Investments and other assets		
Investment securities	9,120	12,084
Other	1,991	1,232
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	11,107	13,312
Total non-current assets	44,644	48,314
Total assets	102,226	104,622
Liabilities		
Current liabilities		
Accounts payable - trade	890	540
Short-term borrowings	8,950	16,262
Income taxes payable	1,657	122
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	1,016	1,178
Provision for bonuses for directors (and other officers)	114	63
Other	5,510	3,969
Total current liabilities	30,135	34,133
Non-current liabilities		
Long-term borrowings	14,350	12,150
Provision for employee stock ownership plan	81	96
Retirement benefit liability	903	931
Other	280	261
Total non-current liabilities	15,615	13,438
Total liabilities	45,750	47,572

(Millions of yen)

	As of March 31, 2024	As of September 30, 2024
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,384	10,392
Retained earnings	37,278	36,517
Treasury shares	(2,963)	(2,542)
Total shareholders' equity	53,761	53,429
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	741	2,604
Deferred gains or losses on hedges	(0)	7
Foreign currency translation adjustment	731	466
Remeasurements of defined benefit plans	132	120
Total accumulated other comprehensive income	1,604	3,199
Share acquisition rights	812	75
Non-controlling interests	297	345
Total net assets	56,475	57,049
Total liabilities and net assets	102,226	104,622

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

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Net sales	24,272	16,657
Cost of sales	5,881	4,330
Gross profit	18,391	12,326
Selling, general and administrative expenses	11,493	13,066
Operating profit (loss)	6,898	(739)
Non-operating income		
Interest income	41	68
Dividend income	13	17
Foreign exchange gains	671	—
Other	69	49
Total non-operating income	796	134
Non-operating expenses		
Share of loss of entities accounted for using equity method	507	398
Interest expenses	40	63
Commission expenses	10	41
Depreciation	—	98
Foreign exchange losses	—	404
Other	10	9
Total non-operating expenses	568	1,016
Ordinary profit (loss)	7,126	(1,621)
Extraordinary income		
Gain on reversal of share acquisition rights	—	393
Gain on cancellation of contract	—	627
Other	—	44
Total extraordinary income	—	1,065
Extraordinary losses		
Loss on disposal of non-current assets	5	0
Total extraordinary losses	5	0
Profit (loss) before income taxes	7,120	(556)
Income taxes - current	2,387	24
Income taxes - deferred	(527)	100
Total income taxes	1,860	124
Profit (loss)	5,260	(680)
Profit attributable to non-controlling interests	7	10
Profit (loss) attributable to owners of parent	5,253	(691)

(Quarterly Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Profit (loss)	5,260	(680)
Other comprehensive income		
Valuation difference on available-for-sale securities	73	1,863
Deferred gains or losses on hedges	—	8
Foreign currency translation adjustment	103	208
Remeasurements of defined benefit plans, net of tax	(0)	(12)
Share of other comprehensive income of entities accounted for using equity method	441	401
Total other comprehensive income	617	2,469
Comprehensive income	5,877	1,788
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	5,857	1,740
Comprehensive income attributable to non-controlling interests	20	48

(3) Quarterly consolidated statements of cash flows

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash flows from operating activities		
Profit (loss) before income taxes	7,120	(556)
Depreciation	1,335	1,667
Share of loss (profit) of entities accounted for using equity method	507	398
Gain on reversal of share acquisition rights	—	(393)
Increase (decrease) in retirement benefit liability	43	21
Increase (decrease) in provision for bonuses	216	162
Share-based payment expenses	71	9
Interest and dividend income	(55)	(85)
Interest expenses	40	63
Foreign exchange losses (gains)	(682)	457
Decrease (increase) in trade receivables	(9,376)	2,579
Decrease (increase) in accounts receivable - other	733	69
Decrease (increase) in inventories	(757)	(1,830)
Increase (decrease) in trade payables	(443)	(350)
Increase (decrease) in accounts payable - other	816	159
Increase (decrease) in accrued consumption taxes	1,263	(1,818)
Other, net	445	(228)
Subtotal	1,278	325
Interest and dividends received	55	85
Interest paid	(40)	(68)
Income taxes refund (paid)	2,228	(1,451)
Net cash provided by (used in) operating activities	3,521	(1,109)
Cash flows from investing activities		
Purchase of property, plant and equipment	(838)	(2,992)
Other, net	(449)	30
Net cash provided by (used in) investing activities	(1,288)	(2,962)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	(6,900)	5,112
Proceeds from long-term borrowings	8,650	300
Repayments of long-term borrowings	(750)	(300)
Redemption of bonds	(500)	—
Net decrease (increase) in treasury shares	11	15
Dividends paid	(1,249)	(1,248)
Other, net	(22)	(26)
Net cash provided by (used in) financing activities	(761)	3,852
Effect of exchange rate change on cash and cash equivalents	1,217	(264)
Net increase (decrease) in cash and cash equivalents	2,689	(484)
Cash and cash equivalents at beginning of period	13,278	18,756
Cash and cash equivalents at end of period	15,968	18,271

(4) Notes to Quarterly Consolidated Financial Statements

(Changes in Accounting Policies)

(Application of Standards for Corporate Taxes, Local Taxes, and Business Taxes)

From the start of this interim consolidated accounting period, "Accounting Standards for Corporate, Local, and Business Taxes" (Accounting Standard No. 27, October 28, 2022, hereafter referred to as the “2022 Revised Standards”) have been adopted.

For amendments related to the categorization of taxes on other comprehensive income, transitional provisions are followed as outlined in the exception of Article 20-3 of the 2022 Revised Standards and Article 65-2(2) of the “Implementation Guidance on Tax Effect Accounting” (Implementation Guidance No. 28, October 28, 2022, hereafter referred to as the “2022 Revised Guidance”).

There is no impact from this change in accounting policy on the interim consolidated financial statements.

Additionally, regarding the revised approach in the consolidated financial statements for deferred tax effects related to gains and losses on intra-group sales of subsidiary shares, the 2022 Revised Guidance has been applied from the beginning of this interim period. This change in policy has been applied retrospectively, and the interim and full-year consolidated financial statements for the previous period reflect these adjustments. There is no impact on the consolidated financial statements for the previous interim period and the previous fiscal year due to this change.

(Segment Information)

As the group operates as a single segment focused on the pharmaceutical business, segment information has been omitted.

(Significant Changes in Shareholders’ Equity)

There are no relevant items to report.

(Going Concern Assumption)

There are no relevant items to report.

3. Other

R&D Pipeline

Recombinant drug products

Code Nonproprietary Name	Status	Indication Remarks
JR-141 BBB-Penetrating Iduronate-2-sulfatase (rDNA origin)	Global: Clinical Phase III trials	Mucopolysaccharidosis II (Hunter syndrome) ERT J-Brain Cargo®
JR-171 BBB-Penetrating α-L-Iduronidase (rDNA origin)	Global: Clinical Phase I/II trials	Mucopolysaccharidosis I (Hurler syndrome, etc.) ERT J-Brain Cargo® J-MIG System®
JR-162 J-Brain Cargo® applied acid α-glucosidase (rDNA origin)	Preclinical	Pompe disease ERT J-Brain Cargo®
JR-441 BBB-Penetrating heparan N-sulfatase (rDNA origin)	Global: Clinical Phase I/II trials	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A) ERT J-Brain Cargo®
JR-443 BBB-Penetrating β-glucuronidase (rDNA origin)	Preclinical	Mucopolysaccharidosis VII (Sly's syndrome) ERT J-Brain Cargo®
JR-446 BBB-Penetrating α-N-acetylglucosaminidase (rDNA origin)	Preclinical	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B) ERT J-Brain Cargo®
JR-479 BBB-penetrating β-Hexosaminidase A (rDNA origin)	Preclinical	GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease) ERT J-Brain Cargo®
JR-471 BBB-penetrating α-L-fucosidase (rDNA origin)	Preclinical	Fucosidosis ERT J-Brain Cargo®
JR-142 Long-acting Growth hormone (rDNA origin)	Clinical Phase II trials	Pediatric Growth hormone deficiency J-MIG System®

(Note) ERT= Enzyme Replacement Therapy