

Financial Summary
Consolidated Financial Results for the Nine Months Ended December 31, 2023
(FY2023)
(Japanese standard)

January 26, 2024

Listed company name: JCR Pharmaceuticals Co., Ltd.

Listed stock exchange: Tokyo Stock Exchange

Code number: 4552 URL: <https://www.jcrpharm.co.jp/en/site/en/index.html>Representative: (Title) Representative Director, Chairman and President
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Scheduled date to file Quarterly Securities Report: February 14, 2024

Scheduled date to commence dividend payments: –

Preparation of supplemental information for this financial summary: Available

IR Conference: None

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 3Q FY2023 (April 1, 2023 to December 31, 2023)

(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	%
Nine Months Ended								
Dec. 31, 2023	33,718	26.3	7,809	57.7	7,388	39.6	5,160	44.6
Dec. 31, 2022	26,696	(33.7)	4,953	(73.0)	5,291	(71.7)	3,568	(72.4)

(Reference) Comprehensive income: Nine months ended Dec. 31, 2023: 5,949 million yen (57.6%)

Nine months ended Dec. 31, 2022: 3,774 million yen ([70.7]%)

	Earnings per share (basic)	Earnings per share (diluted)
	yen	yen
Nine Months Ended		
Dec. 31, 2023	41.35	41.16
Dec. 31, 2022	28.73	28.61

(2) Consolidated Financial Condition

	Total assets	Net assets	Equity ratio
	million yen	million yen	%
As of			
Dec. 31, 2023	102,773	55,948	53.4
Mar. 31, 2023	94,937	52,413	54.2

(Reference) Shareholders' equity: As of Dec. 31, 2023: 54,841 million yen

As of Mar. 31, 2023: 51,421 million yen

2. Dividends

	Dividends per share				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Annual
	yen	yen	yen	yen	yen
FY2022	—	10.00	—	10.00	20.00
FY2023	—	10.00	—		
FY2023 (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, 2024 (April 1, 2023 to March 31, 2024)

(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, 2024	45,400	32.2	10,500	111.0	10,000	84.6	7,300	93.5	58.71

(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): 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. : None
 2. Changes in accounting principles other than 1. : None
 3. Changes in accounting estimates : None
 4. Restatements : None
- (4) Number of shares outstanding (common stocks)

1. Number of shares outstanding at the end of the period (including treasury stock)	As of Dec. 31, 2023	129,686,308 shares	As of Mar. 31, 2023	129,686,308 shares
2. Number of treasury shares at the end of the period	As of Dec. 31, 2023	4,884,914 shares	As of Mar. 31, 2023	4,910,773 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of Dec. 31, 2023	124,791,093 shares	As of Dec. 31, 2022	124,213,046 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 assumptions 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. Qualitative information for quarterly financial statements, (3) Explanation on projections such as forecasts of consolidated financial results” on page 4 of the attached material.

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1. Qualitative information for quarterly financial statements

(1) Explanation on financial results

[1] Financial results for 3Q FY2023

Net sales amounted to 33,718 million yen (up 26.3% year on year).

Sales volumes for our recombinant human growth hormone product GROWJECT® increased significantly in spite of an NHI price revision in April 2023. Sales were also brisk for IZCARGO® for I.V. infusion 10mg and certain other products. Strong sales of our main products and an increase in income from contractual payment ensured total net sales increased year on year although there was a decrease in income due to the completion of the contract to manufacture AstraZeneca K.K.'s COVID-19 vaccine solution in Japan as planned.

All profit lines grew, as operating profit increased by 57.7% year on year to 7,809 million yen, ordinary profit increased by 39.6% to 7,388 million yen, and profit attributable to owners of parent increased by 44.6% to 5,160 million yen.

As a result of proactive R&D activities, R&D expenses totaled 8,359 million yen (up 1,941 million yen, or 30.3%, year on year).

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to December 31, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to December 31, 2023)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	26,696	33,718	26.3
Operating profit	4,953	7,809	57.7
Ordinary profit	5,291	7,388	39.6
Profit attributable to owners of parent	3,568	5,160	44.6

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to December 31, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to December 31, 2023)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product GROWJECT®	9,320	13,995	50.1
Treatment for mucopolysaccharidosis type II IZCARGO® for I.V. Infusion	3,380	4,046	19.7
Treatment for renal anemia Epoetin Alfa BS Inj. [JCR] Darbepoetin Alfa BS Inj. [JCR]	3,573 2,084 1,489	3,673 1,681 1,992	2.8 (19.4) 33.8
Regenerative medicine products TEMCELL® HS Inj.	2,560	2,699	5.4
Treatment for Fabry disease Agalsidase Beta BS I.V. Infusion [JCR]	835	998	19.5
Income from contractual payment	5,010	7,112	42.0
AZD1222 stock solution	1,931	—	(100.0)

[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, in the U.S. we received Rare Pediatric Disease (*1) designation by the U.S. Food and Drug Administration (FDA) in December 2022. In February 2022, the first patient was dosed in a global Phase III clinical trial, and we are now in the process of conducting patient enrollment.
- 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. Preparations are underway to quickly begin the global Phase III clinical trial.
- Regarding the BBB-penetrating product for MPS IIIA (Sanfilippo syndrome type A) (development code: JR-441), the Paul-Ehrlich-Institute (PEI), the regulatory authority for the Federal Republic of Germany, accepted a clinical trial application (CTA) for Phase I/II clinical trial. In October 2023, the first patient was dosed, and we are now in the process of conducting patient enrollment. In December 2023, the FDA granted orphan drug designation to JR-441 in the U.S.
- As for the BBB-penetrating product for MPS IIIB (Sanfilippo syndrome type B) (development code: JR-446), we are currently making efforts to begin a global clinical trial at an early stage during FY2024. 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 have also been successively conducting R&D into other treatments for LSDs that employ J-Brain Cargo[®], including a treatment for Pompe disease (development code: JR-162), a treatment for Sly syndrome (development code: JR-443), and a treatment for GM2 gangliosidosis (development code: JR-479). We will also develop each of these treatments globally. Furthermore, with regard to our fucosidosis therapeutic (development code: JR-471), 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.
- In May 2023 we entered into an exclusive global development and commercialization agreement with Angelini Pharma S.p.a. for the development of novel biologic therapies applying J-Brain Cargo[®] technology for the treatment of epilepsy.
- In December 2023, JCR signed a Research Collaboration, Option and License Agreement with Alexion, AstraZeneca Rare Disease ("Alexion") for the development of novel oligonucleotide therapeutics using J-Brain Cargo[®] technology. This is the second collaboration between JCR and Alexion, following the signing in March 2023 of a Research Collaboration, Option and License Agreement to develop therapeutic protein candidates using J-Brain Cargo[®] technology for neurodegenerative disease.

[Regenerative medicine products]

- We have completed a Phase I/II clinical trial of TEMCELL[®] HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE). Future development plans are currently being reviewed.

[Human growth hormone product]

- In June 2023, we received partially amended approval for an expanded indication of GROWJECT[®] in short stature due to short stature homeobox-containing gene (SHOX) deficiency without epiphyseal closure (development code: JR-401X).
- We also have completed a Phase II clinical trial of a recombinant long-acting human growth hormone (development code: JR-142). Currently, we are conducting a follow-up trial with patients who were administered the treatment. We are also preparing to start a Phase III clinical trial during FY2024.

*1 Rare Pediatric Disease Designation

This designation is intended to facilitate the development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. JCR may become eligible to receive a voucher for a priority review of a subsequent marketing application in the U.S.

(2) Overview of financial condition

As of December 31, 2023, total assets amounted to 102,773 million yen (an increase of 7,835 million yen from March 31, 2023), total liabilities were 46,824 million yen (an increase of 4,300 million yen from March 31, 2023), and net assets were 55,948 million yen (an increase of 3,534 million yen from March 31, 2023).

Current assets increased by 9,666 million yen from March 31, 2023 to 57,468 million yen, due to factors including increases in accounts receivable – trade, and contract assets, cash and deposits, and inventories, while there was a decrease in accounts receivable – other. Non-current assets decreased by 1,830 million yen from March 31, 2023 to 45,304 million yen, mainly due to a decrease in property, plant and equipment.

Current liabilities decreased by 3,847 million yen from March 31, 2023 to 31,914 million yen, mainly due to a decrease in short-term borrowings, which was partly offset by increases in income taxes payable and accrued consumption taxes. Non-current liabilities increased by 8,148 million yen from March 31, 2023 to 14,910 million yen, mainly due to an increase in long-term borrowings.

Net assets increased by 3,534 million yen from March 31, 2023 to 55,948 million yen, mainly due to recording profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 53.4% as of December 31, 2023, a decrease of 0.8 percentage points from March 31, 2023.

(3) Explanation on projections such as forecasts of consolidated financial results

Looking at consolidated financial results for the nine months ended December 31, 2023, sales and profits increased year on year.

There have been no changes to the forecasts for the fiscal year ending March 31, 2024 announced on September 28, 2023.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(Millions of yen)

	As of March 31, 2023	As of December 31, 2023
Assets		
Current assets		
Cash and deposits	13,278	18,301
Accounts receivable - trade, and contract assets	11,137	16,280
Merchandise and finished goods	1,098	1,669
Work in process	5,717	6,495
Raw materials and supplies	11,699	12,666
Other	4,870	2,055
Total current assets	47,802	57,468
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	7,128	14,387
Land	10,379	10,587
Construction in progress	13,008	121
Other, net	2,165	5,561
Total property, plant and equipment	32,681	30,657
Intangible assets		
Patent right	2,434	2,227
Other	1,217	1,381
Total intangible assets	3,652	3,609
Investments and other assets		
Investment securities	8,867	9,251
Other	1,938	1,791
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	10,800	11,038
Total non-current assets	47,135	45,304
Total assets	94,937	102,773
Liabilities		
Current liabilities		
Accounts payable - trade	1,563	1,567
Short-term borrowings	16,800	9,700
Current portion of bonds payable	500	—
Income taxes payable	33	1,950
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	974	521
Provision for bonuses for directors (and other officers)	114	86
Other	3,779	6,091
Total current liabilities	35,762	31,914
Non-current liabilities		
Long-term borrowings	5,500	13,600
Provision for employee stock ownership plan	95	81
Retirement benefit liability	924	980
Other	241	248
Total non-current liabilities	6,761	14,910
Total liabilities	42,523	46,824

(Millions of yen)

	As of March 31, 2023	As of December 31, 2023
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,384	10,384
Retained earnings	34,273	36,933
Treasury shares	(2,978)	(2,964)
Total shareholders' equity	50,740	53,414
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	555	653
Deferred gains or losses on hedges	—	0
Foreign currency translation adjustment	146	794
Remeasurements of defined benefit plans	(20)	(21)
Total accumulated other comprehensive income	681	1,426
Share acquisition rights	740	812
Non-controlling interests	251	294
Total net assets	52,413	55,948
Total liabilities and net assets	94,937	102,773

(2) Quarterly consolidated statements of income and quarterly consolidated statements of comprehensive income
(Quarterly consolidated statements of income)

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Net sales	26,696	33,718
Cost of sales	6,899	8,423
Gross profit	19,796	25,295
Selling, general and administrative expenses	14,843	17,486
Operating profit	4,953	7,809
Non-operating income		
Interest income	8	66
Dividend income	27	26
Foreign exchange gains	328	356
Other	49	124
Total non-operating income	414	575
Non-operating expenses		
Share of loss of entities accounted for using equity method	—	876
Interest expenses	33	63
Commission expenses	9	16
Other	33	38
Total non-operating expenses	76	995
Ordinary profit	5,291	7,388
Extraordinary income		
Other	—	0
Total extraordinary income	—	0
Extraordinary losses		
Loss on disposal of non-current assets	11	18
Total extraordinary losses	11	18
Profit before income taxes	5,280	7,371
Income taxes - current	233	2,113
Income taxes - deferred	1,462	85
Total income taxes	1,695	2,199
Profit	3,584	5,172
Profit attributable to non-controlling interests	15	11
Profit attributable to owners of parent	3,568	5,160

(Quarterly consolidated statements of comprehensive income)

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Profit	3,584	5,172
Other comprehensive income		
Valuation difference on available-for-sale securities	(43)	97
Deferred gains or losses on hedges	(0)	0
Foreign currency translation adjustment	226	216
Remeasurements of defined benefit plans, net of tax	8	(0)
Share of other comprehensive income of entities accounted for using equity method	—	463
Total other comprehensive income	190	776
Comprehensive income	3,774	5,949
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	3,705	5,906
Comprehensive income attributable to non-controlling interests	69	42

(3) Notes to quarterly consolidated financial statements
(Notes on going concern assumption)

None

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

None