

## Financial Summary

### Consolidated Financial Results for the Six Months ended September 30, 2023 (FY2023) (Japanese standard)

October 25, 2023

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 AshidaPerson 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, 2023

Scheduled date to commence dividend payments: December 8, 2023

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 FY2023 (April 1, 2023 to September 30, 2023)

## (1) Consolidated Operating Results (Cumulative)

(Percentage shows year-on-year changes.)

Six Months Ended	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	million yen	%	million yen	%	million yen	%	million yen	%
Sep. 30, 2023	24,272	55.8	6,898	826.2	7,126	353.9	5,253	445.6
Sep. 30, 2022	15,581	(45.1)	744	(94.5)	1,569	(88.6)	962	(89.6)

(Reference) Comprehensive income: Six months ended Sep. 30, 2023: 5,877 million yen (437.4%)

Six months ended Sep. 30, 2022: 1,093 million yen ([88.1]%)

Six Months Ended	Earnings per share (basic)		Earnings per share (diluted)	
	yen		yen	
Sep. 30, 2023	42.10		41.90	
Sep. 30, 2022	7.77		7.74	

## (2) Consolidated Financial Conditions

As of	Total assets	Net assets	Equity ratio
	million yen	million yen	%
Sep. 30, 2023	103,988	57,125	53.9
Mar. 31, 2023	94,937	52,413	54.2

(Reference) Shareholders' equity: As of Sep 30, 2023: 56,041 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				
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.)

Year ending	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
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. Restatement : None
- (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, 2023	129,686,308 shares	As of Mar. 31, 2023	129,686,308 shares
2. Number of treasury stock at the end of the period	As of Sep. 30, 2023	4,889,714 shares	As of Mar. 31, 2023	4,910,773 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of Sep. 30, 2023	124,787,306 shares	As of Sep. 30, 2022	123,933,051 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. 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 2Q FY2023

Net sales amounted to 24,272 million yen (up 55.8% 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 treatment for renal anemia and IZCARGO® for I.V. infusion 10mg. 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 826.2% year on year to 6,898 million yen, ordinary profit increased by 353.9% to 7,126 million yen, and profit attributable to owners of parent increased by 445.6% to 5,253 million yen.

As a result of proactive R&D activities, R&D expenses totaled 5,535 million yen (up 1,318 million yen, or 31.3%, year on year).

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to September 30, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to September 30, 2023)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	15,581	24,272	55.8
Operating profit	744	6,898	826.2
Ordinary profit	1,569	7,126	353.9
Profit attributable to owners of parent	962	5,253	445.6

## [2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to September 30, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to September 30, 2023)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product <b>GROWJECT®</b>	6,083	8,746	43.8
Treatment for mucopolysaccharidosis type II <b>IZCARGO® for I.V. Infusion</b>	2,118	2,581	21.9
Treatment for renal anemia <b>Epoetin Alfa BS Inj. [JCR]</b> <b>Darbepoetin Alfa BS Inj. [JCR]</b>	2,157 1,392 765	2,674 1,046 1,628	24.0 (24.8) 112.7
Regenerative medicine products <b>TEMCELL® HS Inj.</b>	1,701	1,901	11.8
Treatment for Fabry disease <b>Agalsidase Beta BS I.V. Infusion [JCR]</b>	521	590	13.1
Medical devices	50	72	44.9
Income from contractual payment	1,010	7,112	604.2
AZD1222 stock solution	1,931	—	(100.0)
Others	6	591	—

## [3] The Status of R&amp;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 (\*) 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 enrolment.
- 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 a follow-up trial. 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 trials. We are now in the process of conducting patient recruitment.

- 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<sup>®</sup>, 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<sup>®</sup> to various modalities, we are focused on creating new platform technologies following J-Brain Cargo<sup>®</sup> 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<sup>®</sup> technology for the treatment of epilepsy.

[Regenerative medicine products]

- We have completed a Phase I/II clinical trial of TEMCELL<sup>®</sup> HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE), and are currently conducting a final analysis of the observational study results, with the main objective of following up on its long-term safety and efficacy.

[Human growth hormone product]

- In June 2023, we received partially amended approval for an expanded indication of GROWJECT<sup>®</sup> in patients with short stature homeobox-containing gene (SHOX) deficiency (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.

\*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 conditions

## [1] Status of assets, liabilities and net assets

As of September 30, 2023, total assets amounted to 103,988 million yen (an increase of 9,050 million yen from March 31, 2023), total liabilities were 46,862 million yen (an increase of 4,338 million yen from March 31, 2023), and net assets were 57,125 million yen (an increase of 4,712 million yen from March 31, 2023).

Current assets increased by 10,095 million yen from March 31, 2023 to 57,898 million yen due to factors including a decrease in accounts receivable – other and increases in cash and deposits and accounts receivable – trade, and contract assets. Non-current assets decreased by 1,044 million yen from March 31, 2023 to 46,090 million yen, mainly due to a decrease in property, plant and equipment, which was partly offset by an increase in deferred tax assets.

Current liabilities decreased by 3,766 million yen from March 31, 2023 to 31,995 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 8,104 million yen from March 31, 2023 to 14,866 million yen due mainly to an increase in long-term borrowings.

Net assets increased by 4,712 million yen from March 31, 2023 to 57,125 million yen, mainly due to recording profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 53.9% as of September 30, 2023, a decrease of 0.3 percentage points from March 31, 2023.

At this point in time, the JCR Group has not felt the impact of the COVID-19 pandemic. However, the global outlook remains uncertain. In order to achieve sustainable global growth, we need to secure a flexible and stable source of funds. In the fiscal year under review, we concluded commitment line agreements with our financial institutions for a total of 23.0 billion yen for the purpose of securing operating funds as a backup plan.

## [2] Status of cash flows

Cash and cash equivalents as of September 30, 2023 was up by 2,689 million yen from the end of the previous consolidated fiscal year to 15,968 million yen. Status of each cash flows and major reasons are as stated below

## (Cash flows from operating activities)

Net cash provided by operating activities was 3,521 million yen (an increase of 4,548 million yen in net cash provided from the same period of the previous fiscal year). The main factors were the recording of profit before income taxes of 7,120 million yen, depreciation of 1,335 million yen, increase in accrued consumption taxes of 1,263 million yen, and income taxes refund of 2,228 million yen, which was partly offset by an increase in trade receivables of 9,376 million yen.

## (Cash flows from investing activities)

Net cash used in investing activities was 1,288 million yen (a decrease of 491 million yen in net cash used from the same period of the previous fiscal year). The main use of cash was 838 million yen in purchase of property, plant and equipment.

## (Cash flows from financing activities)

Net cash used in financing activities was 761 million yen (a decrease of 717 million yen in net cash used from the same period of the previous fiscal year). This was mainly attributable to dividends paid of 1,249 million yen.

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

Looking at consolidated financial results for the six months ended September 30, 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 September 30, 2023
<b>Assets</b>		
Current assets		
Cash and deposits	13,278	15,968
Accounts receivable - trade, and contract assets	11,137	20,514
Merchandise and finished goods	1,098	873
Work in process	5,717	6,448
Raw materials and supplies	11,699	11,951
Other	4,870	2,142
<b>Total current assets</b>	<b>47,802</b>	<b>57,898</b>
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	7,128	14,536
Land	10,379	10,379
Construction in progress	13,008	144
Other, net	2,165	5,904
<b>Total property, plant and equipment</b>	<b>32,681</b>	<b>30,964</b>
Intangible assets		
Patent right	2,434	2,296
Other	1,217	1,406
<b>Total intangible assets</b>	<b>3,652</b>	<b>3,703</b>
Investments and other assets		
Investment securities	8,867	8,959
Other	1,938	2,467
Allowance for doubtful accounts	(4)	(4)
<b>Total investments and other assets</b>	<b>10,800</b>	<b>11,422</b>
<b>Total non-current assets</b>	<b>47,135</b>	<b>46,090</b>
<b>Total assets</b>	<b>94,937</b>	<b>103,988</b>
<b>Liabilities</b>		
Current liabilities		
Accounts payable - trade	1,563	1,120
Short-term borrowings	16,800	9,700
Current portion of bonds payable	500	—
Income taxes payable	33	2,537
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	974	1,191
Provision for bonuses for directors (and other officers)	114	57
Other	3,779	5,393
<b>Total current liabilities</b>	<b>35,762</b>	<b>31,995</b>
Non-current liabilities		
Long-term borrowings	5,500	13,600
Provision for employee stock ownership plan	95	84
Retirement benefit liability	924	964
Other	241	217
<b>Total non-current liabilities</b>	<b>6,761</b>	<b>14,866</b>
<b>Total liabilities</b>	<b>42,523</b>	<b>46,862</b>

(Millions of yen)

	As of March 31, 2023	As of September 30, 2023
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,384	10,384
Retained earnings	34,273	38,277
Treasury shares	(2,978)	(2,967)
Total shareholders' equity	50,740	54,756
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	555	629
Foreign currency translation adjustment	146	678
Remeasurements of defined benefit plans	(20)	(21)
Total accumulated other comprehensive income	681	1,285
Share acquisition rights	740	812
Non-controlling interests	251	271
Total net assets	52,413	57,125
Total liabilities and net assets	94,937	103,988



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

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Net sales	15,581	24,272
Cost of sales	4,836	5,881
Gross profit	10,744	18,391
Selling, general and administrative expenses	9,999	11,493
Operating profit	744	6,898
Non-operating income		
Interest income	5	41
Dividend income	15	13
Foreign exchange gains	814	671
Other	25	69
Total non-operating income	861	796
Non-operating expenses		
Share of loss of entities accounted for using equity method	—	507
Interest expenses	21	40
Commission expenses	6	10
Other	8	10
Total non-operating expenses	36	568
Ordinary profit	1,569	7,126
Extraordinary losses		
Loss on disposal of non-current assets	9	5
Total extraordinary losses	9	5
Profit before income taxes	1,560	7,120
Income taxes - current	62	2,387
Income taxes - deferred	521	(527)
Total income taxes	583	1,860
Profit	976	5,260
Profit attributable to non-controlling interests	14	7
Profit attributable to owners of parent	962	5,253

(Quarterly consolidated statements of comprehensive income)

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Profit	976	5,260
Other comprehensive income		
Valuation difference on available-for-sale securities	(38)	73
Deferred gains or losses on hedges	(0)	–
Foreign currency translation adjustment	150	103
Remeasurements of defined benefit plans, net of tax	5	(0)
Share of other comprehensive income of entities accounted for using equity method	–	441
Total other comprehensive income	116	617
Comprehensive income	1,093	5,877
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,040	5,857
Comprehensive income attributable to non-controlling interests	52	20

## (3) Quarterly consolidated statements of cash flows

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from operating activities		
Profit before income taxes	1,560	7,120
Depreciation	953	1,335
Increase (decrease) in retirement benefit liability	32	43
Decrease (increase) in retirement benefit asset	6	—
Increase (decrease) in provision for bonuses	162	216
Share-based payment expenses	173	71
Interest and dividend income	(21)	(55)
Interest expenses	21	40
Foreign exchange losses (gains)	(1,517)	(682)
Decrease (increase) in trade receivables	6,996	(9,376)
Decrease (increase) in accounts receivable - other	(499)	733
Decrease (increase) in inventories	(1,175)	(757)
Increase (decrease) in trade payables	228	(443)
Increase (decrease) in accounts payable - other	(2,212)	816
Increase (decrease) in accrued consumption taxes	(313)	1,263
Share of loss (profit) of entities accounted for using equity method	—	507
Other, net	92	445
Subtotal	4,490	1,278
Interest and dividends received	21	55
Interest paid	(23)	(40)
Income taxes refund (paid)	(5,516)	2,228
Net cash provided by (used in) operating activities	(1,027)	3,521
Cash flows from investing activities		
Purchase of property, plant and equipment	(1,333)	(838)
Other, net	(446)	(449)
Net cash provided by (used in) investing activities	(1,779)	(1,288)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	—	(6,900)
Proceeds from long-term borrowings	2,750	8,650
Repayments of long-term borrowings	(2,750)	(750)
Redemption of bonds	—	(500)
Net decrease (increase) in treasury shares	8	11
Dividends paid	(1,489)	(1,249)
Other, net	1	(22)
Net cash provided by (used in) financing activities	(1,479)	(761)
Effect of exchange rate change on cash and cash equivalents	1,660	1,217
Net increase (decrease) in cash and cash equivalents	(2,625)	2,689
Cash and cash equivalents at beginning of period	30,733	13,278
Cash and cash equivalents at end of period	28,107	15,968

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

None

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

None

## 3. Other

## R&amp;D Pipeline

## Recombinant drug products

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

(Note) ERT= Enzyme Replacement Therapy

## Allogeneic regenerative medical product

Code Nonproprietary Name	Status	Indication
		Remarks
<b>JR-031HIE</b> Human mesenchymal stem cells	Clinical Phase I / II trials	Neonatal hypoxic ischemic encephalopathy
		Expanded Indication of TEMCELL® HS