

Financial Summary
Consolidated Financial Results for the Three Months ended June 30, 2023 (FY2023)
(Japanese standard)

July 26, 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
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Scheduled date to file Quarterly Securities Report: August 10, 2023

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 1Q FY2023 (April 1, 2023 to June 30, 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	%
Three Months Ended								
June30, 2023	10,808	12.5	2,066	34.5	2,260	8.5	1,610	17.7
June30, 2022	9,606	(2.1)	1,536	(48.5)	2,083	(30.5)	1,368	(10.7)

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

Three months ended June 30, 2022: 1,370 million yen (-7.2%)

	Earnings per share (basic)	Earnings per share (diluted)
	yen	yen
Three Months Ended		
June30, 2023	12.91	12.85
June30, 2022	11.06	11.02

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
	million yen	million yen	%
AS of			
June30, 2023	95,775	52,959	54.3
March 31, 2023	94,937	52,413	54.2

(Reference) Shareholders' equity: As of June 30, 2023: 51,969 million yen

As of March 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	—				
FY2023 (Forecast)		10.00	—	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 the parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Year ending March 31, 2024	36,900	7.4	5,600	12.5	5,200	(4.0)	3,800	0.7	30.56

(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 June 30, 2023	129,686,308 shares	As of March 31, 2023	129,686,308 shares
2. Number of treasury stock at the end of the period	As of June 30, 2023	4,897,814 shares	As of March 31, 2023	4,910,773 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of June 30, 2023	124,782,090 shares	As of June 30, 2022	123,762,831 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 1Q FY2023

Net sales amounted to 10,808 million yen (up 12.5% year on year).

Sales volumes for our recombinant human growth hormone product GROWJECT® and treatment for renal anemia increased significantly in spite of an NHI price revision in April 2023, while sales were also brisk for IZCARGO® for I.V. infusion 10mg. Strong sales of our main products 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 34.5% year on year to 2,066 million yen, ordinary profit increased by 8.5% to 2,260 million yen, and profit attributable to owners of parent increased by 17.7% to 1,610 million yen.

As a result of proactive R&D activities, R&D expenses totaled 2,294 million yen (up 103 million yen, or 4.7%, year on year).

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to June 30, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to June 30, 2023)	Rate of change
	Amount (millions of yen)	Amount (millions of yen)	%
Net sales	9,606	10,808	12.5
Operating profit	1,536	2,066	34.5
Ordinary profit	2,083	2,260	8.5
Profit attributable to owners of the parent	1,368	1,610	17.7

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2022 to June 30, 2022)	Current quarterly consolidated results (cumulative) (April 1, 2023 to June 30, 2023)	Rate of change
	Amount (millions of yen)	Amount (millions of yen)	%
Human growth hormone product GROWJECT®	3,134	4,222	34.7
Treatment for mucopolysaccharidosis type II IZCARGO® for I.V. Infusion	1,070	1,239	15.8
Treatment for renal anemia Epoetin Alfa BS Inj. [JCR] Darbepoetin Alfa BS Inj. [JCR]	875 660 214	1,615 602 1,012	84.5 (8.8) 371.0
Regenerative medicine products TEMCELL® HS Inj.	1,041	1,063	2.1
Treatment for Fabry disease Agalsidase Beta BS I.V. Infusion [JCR]	519	471	(9.3)
Others	—	547	—
Medical devices	21	37	69.5
Income from contractual payment	1,010	1,612	59.6
AZD1222 stock solution	1,931	—	—

[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 pabinafusup alfa (development code: JR-141), our BBB penetrating 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. Furthermore, although we had filed for marketing approval of JR-141 in Brazil with the Brazilian Health Regulatory Agency (ANVISA) in December 2020, our application was denied in August 2022. We plan to file another application using the results of the global Phase III clinical trial currently being conducted.
- For lepunafusup alfa (development code: JR-171), our BBB-penetrating product for the treatment of patients with mucopolysaccharidosis type I (MPS I), in the ongoing Phase I/II clinical trial in Japan, Brazil, and the U.S., we completed scheduled patient enrolment in March 2022, and are conducting a final analysis. 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-Institut (PEI), the regulatory authority for the Federal Republic of Germany, accepted a clinical trial application (CTA) for a Phase I/II clinical trial. We are currently finalizing the clinical trial protocol and aim to start recruitment in the first half of FY2023.
- 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.
- 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 outside Japan. We will participate from the position of licensor as the company that created this therapeutic, and help to commercialize it at an early stage.

[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.

[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), and are currently conducting analysis.

[Human growth hormone product]

- In June 2023, we received partially amended approval for an expanded indication of GROWJECT[®] in patients with short stature homeobox containing gene (SHOX) deficiency (development code: JR-401X).
- We also initiated a Phase II clinical trial of a recombinant long-acting growth hormone (development code: JR-142), have completed the scheduled statistical analysis and are preparing to start a Phase III clinical trial.

* 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

As of June 30, 2023, total assets amounted to 95,775 million yen (an increase of 838 million yen from March 31, 2023), total liabilities were 42,816 million yen (an increase of 292 million yen from March 31, 2023), and net assets were 52,959 million yen (an increase of 545 million yen from March 31, 2023).

Current assets increased by 266 million yen from March 31, 2023 to 48,069 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 increased by 571 million yen from March 31, 2023 to 47,706 million yen, mainly due to an increase in deferred tax assets.

Current liabilities decreased by 6,318 million yen from March 31, 2023 to 29,443 million yen, mainly due to a decrease in short-term borrowings. Non-current liabilities increased by 6,610 million yen from March 31, 2023 to 13,372 million yen due mainly to an increase in long-term borrowings.

Net assets increased by 545 million yen from March 31, 2023 to 52,959 million yen, mainly due to recording profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 54.3% as of June 30, 2023, an increase of 0.1 of a percentage point 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.

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

Looking at consolidated financial results for the three months ended June 30, 2023, sales and profits increased year on year, and 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, 2024 announced on May 11, 2023.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(Millions of yen)

	As of March 31, 2023	As of June 30, 2023
Assets		
Current assets		
Cash and deposits	13,278	15,331
Accounts receivable - trade, and contract assets	11,137	12,671
Merchandise and finished goods	1,098	665
Work in process	5,717	5,489
Raw materials and supplies	11,699	12,124
Other	4,870	1,785
Total current assets	47,802	48,069
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	7,128	7,037
Land	10,379	10,379
Construction in progress	13,008	13,246
Other, net	2,165	2,058
Total property, plant and equipment	32,681	32,720
Intangible assets		
Patent right	2,434	2,365
Other	1,217	1,455
Total intangible assets	3,652	3,821
Investments and other assets		
Investment securities	8,867	8,770
Other	1,938	2,398
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	10,800	11,164
Total non-current assets	47,135	47,706
Total assets	94,937	95,775
Liabilities		
Current liabilities		
Accounts payable - trade	1,563	623
Short-term borrowings	16,800	10,700
Current portion of bonds payable	500	500
Income taxes payable	33	242
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	974	1,526
Provision for bonuses for directors (and other officers)	114	143
Other	3,779	3,711
Total current liabilities	35,762	29,443
Non-current liabilities		
Long-term borrowings	5,500	12,100
Provision for employee stock ownership plan	95	88
Retirement benefit liability	924	944
Other	241	239
Total non-current liabilities	6,761	13,372
Total liabilities	42,523	42,816

(Millions of yen)

	As of March 31, 2023	As of June 30, 2023
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,384	10,384
Retained earnings	34,273	34,635
Treasury shares	(2,978)	(2,971)
Total shareholders' equity	50,740	51,109
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	555	624
Foreign currency translation adjustment	146	253
Remeasurements of defined benefit plans	(20)	(18)
Total accumulated other comprehensive income	681	859
Share acquisition rights	740	740
Non-controlling interests	251	249
Total net assets	52,413	52,959
Total liabilities and net assets	94,937	95,775

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

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Net sales	9,606	10,808
Cost of sales	2,933	3,363
Gross profit	6,672	7,445
Selling, general and administrative expenses	5,136	5,379
Operating profit	1,536	2,066
Non-operating income		
Interest income	1	0
Dividend income	15	13
Foreign exchange gains	540	484
Other	6	21
Total non-operating income	564	520
Non-operating expenses		
Share of loss of entities accounted for using equity method	—	297
Interest expenses	10	19
Commission expenses	3	2
Other	3	6
Total non-operating expenses	16	326
Ordinary profit	2,083	2,260
Extraordinary losses		
Loss on disposal of non-current assets	0	0
Total extraordinary losses	0	0
Profit before income taxes	2,083	2,260
Income taxes - current	45	1,122
Income taxes - deferred	668	(469)
Total income taxes	713	653
Profit	1,369	1,607
Profit (loss) attributable to non-controlling interests	0	(2)
Profit attributable to owners of parent	1,368	1,610

(Quarterly consolidated statements of comprehensive income)

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Profit	1,369	1,607
Other comprehensive income		
Valuation difference on available-for-sale securities	(59)	68
Deferred gains or losses on hedges	(0)	—
Foreign currency translation adjustment	58	35
Remeasurements of defined benefit plans, net of tax	2	2
Share of other comprehensive income of entities accounted for using equity method	—	75
Total other comprehensive income	1	181
Comprehensive income	1,370	1,789
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,357	1,789
Comprehensive income attributable to non-controlling interests	13	(0)

(3) Notes to quarterly consolidated financial statements
(Notes on premises as a going concern)

None

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

None