Financial Summary
Consolidated Financial Results for the Year ended June 30, 2022 (FY2022)
(Japanese standard)

July 27, 2022

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 inquires: (Title) Senior Corporate Officer, Executive Director, Administration Division
(Name) Yutaka Honda TEL: 0797(32)1995

Scheduled date to file quarterly report: August 10, 2022
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 FY2022 (April 1, 2022 to June 30, 2022)

(1) Consolidated Operating Results (Cumulative) (Percentage shows year-on-year changes.)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
Three Months Ended	million yen	%	million yen	%	million yen	%	million yen	%
June30, 2022	9,606	(2.1)	1,536	(48.5)	2,083	(30.5)	1,368	(10.7)
June30, 2021	9,813	89.4	2,984	280.3	3,000	247.6	1,532	99.8

(Reference) Comprehensive income: Three months ended June 30, 2022: 1,370 million yen (-7.2%)
Three months ended June 30, 2021: 1,476 million yen (92.3%)

	Earnings per share (basic)	Earnings per share (diluted)
Three Months Ended	yen	yen
June30, 2022	11.06	11.02
June30, 2021	12.40	12.34

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
AS of	million yen	million yen	%
June30, 2022	92,499	50,979	54.3
March 31, 2022	97,134	51,089	51.8

(Reference) Shareholders' equity: As of June 30, 2022: 50,193 million yen
As of March31, 2022: 50,316 million yen

2. Dividends

	Dividends per share				
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual
	yen	yen	yen	yen	yen
FY2021	—	10.00	—	12.00	22.00
FY2022	—				
FY2022 (Forecast)		10.00	—	10.00	20.00

(Notes) 1. No revisions were made to the most recently announced dividend forecast.
2. Breakdown of the year-end dividend for the fiscal year ended March 31, 2022
Ordinary dividend: 10.00 yen
Special dividend: 2.00yen

3. Consolidated Forecasts for the Fiscal Year Ending March 31, 2023 (April 1, 2022 to March 31, 2023)

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Year ending March 31, 2023	45,000	(11.9)	14,500	(27.3)	14,500	(29.3)	10,300	(29.0)	83.25

(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 policies, changes in accounting estimates, and restatement

1. Changes in accounting policies due to revisions to accounting standards and other regulations: Yes
2. Changes in accounting policies due to other reasons. : 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, (Changes in accounting policy)" on page 9 of the attached material.

(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, 2022	129,686,308 shares	As of March 31, 2022	129,686,308 shares
2. Number of shares treasury stock at the end of the period	As of June 30, 2022	5,919,644 shares	As of March 31, 2022	5,929,344 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of June 30, 2022	123,762,831 shares	As of June 30, 2021	123,623,198 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 FY2022

Net sales amounted to 9,606 million yen (down 2.1% year on year).

Sales volume for our recombinant human growth hormone product GROWJECT® increased, but sales were affected by the NHI price revision in April 2022. Total net sales of our main products increased year on year, although sales of treatment for renal anemia decreased significantly as a result of similar NHI price revisions, there was a substantial contribution from IZCARGO® for I.V. infusion 10mg, which was placed on the NHI reimbursement price list in May 2021. In areas other than our main products, total net sales decreased year on year, due to factors such as the completion of the contract to manufacture AstraZeneca K.K.'s COVID-19 vaccine solution in Japan as planned, while there was an increase in income from contractual payments.

Operating income decreased 48.5% year on year to 1,536 million yen, ordinary income decreased 30.5% year on year to 2,083 million yen, and profit attributable to owners of the parent decreased 10.7% year on year to 1,368 million yen, marking a decline in earnings at each of those profit levels.

As a result of proactive R&D activities, R&D expenses totaled 2,191 million yen (up 437 million yen, or 24.9%, year on year).

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to June 30, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to June 30, 2022)	Increase-decrease rate
	Amount (millions of yen)	Amount (millions of yen)	%
Net sales	9,813	9,606	(2.1)
Operating income	2,984	1,536	(48.5)
Ordinary income	3,000	2,083	(30.5)
Profit attributable to owners of the parent	1,532	1,368	(10.7)

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to June 30, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to June 30, 2022)	Increase-decrease ratio
	Amount (millions of yen)	Amount (millions of yen)	%
Human growth hormone product **GROWJECT®**	3,311	3,134	(5.3)
Treatment for mucopolysaccharidosis type II **IZCARGO® for I.V. Infusion**	224	1,070	376.8
Treatment for renal anemia	1,603	875	(45.4)
Epoetin Alfa BS Inj. [JCR]	644	660	2.5
Darbepoetin Alfa BS Inj. [JCR]	958	214	(77.6)
Regenerative medical products **TEMCELL® HS Inj.**	813	1,041	28.1
Treatment for Fabry disease **Agalsidase Beta BS I.V. Infusion [JCR]**	154	519	236.1
AZD1222 stock solution	3,671	1,931	(47.4)
Income from contractual payment	10	1,010	--

[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) technology, J-Brain Cargo®, as treatments for over 17 types of lysosomal storage disorders. Moreover, we are also focused on research to expand the possibilities for applying our J-Brain Cargo® technology to various modalities.

· For pabinafusp alfa (development code: JR-141/ IZCARGO® for I.V. infusion 10mg), our BBB-penetrating product for the treatment of patients with Hunter syndrome launched in Japan in May 2021. Furthermore, we filed for marketing approval of JR-141 in Brazil with the Brazilian Health Regulatory Agency (ANVISA) in December 2020. In other regions, JR-141 received Fast Track (*1) designation from the U.S. Food and Drug Administration (FDA) in February 2021, and PRIME (*2) designation from the European Medicines Agency (EMA) in October 2021. Moreover, in February 2022, the first patient was dosed in a global Phase III clinical trial of JR-141.

· For lepunafusp alfa (development code: JR-171), our BBB-penetrating product candidate for the treatment of patients with mucopolysaccharidosis type I (MPS I), we are currently conducting a Phase I/II clinical trial in Japan, Brazil, and the U.S., and completed scheduled patient enrolment in March 2022.JR-171 received orphan drug designation from the FDA in February 2021 and from the European Commission (EC) in March 2021. Additionally, JR-171 received Fast Track designation from the FDA in September 2021.This designation is expected to expedite clinical development in the U.S. and to enable priority review and accelerated approval.

· A treatment enzyme formulation for mucopolysaccharidosis III-A (Sanfilippo syndrome type A) (development code: JR-441) was granted orphan drug status by the European Commission (EC) in January 2022, enabling receipt of various incentives to promote development within the European Union (EU). Efforts are currently moving ahead toward starting a global clinical trial in the first half of 2023.

· We have also been successively conducting R&D into other treatments for lysosomal storage disorders that employ J-Brain Cargo®, including a treatment for Pompe disease (development code: JR-162), a treatment for Sly syndrome (development code: JR-443), a treatment for Sanfilippo syndrome type B (development code: JR-446), and a treatment for GM2 gangliosidosis (development code: JR-479). We will also develop each of these treatments globally.

[Regenerative medicine products]

· We are conducting a Phase I/II clinical trial of TEMCELL® HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE).

· In April 2022, we reached an agreement with Teijin Ltd. to terminate our contract to co-develop an allogeneic regenerative medical product using dental pulp stem cells (DPCs) for the indication of acute cerebral infarction (development code: JTR-161/JR-161).

[Human growth hormone product]

· We are conducting a Phase III clinical trial for an additional indication for 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).

*1 FDA Fast Track Designation

The FDA Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to enable early delivery of important new drugs to the patients. A drug that receives Fast Track designation may be allowed more frequent meetings with the FDA to discuss the drug's development plan, followed by priority review and an accelerated approval when relevant criteria are met.

2 EMA PRIME (PRIority MEdicines) Designation

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. Through PRIME, EMA offers early and proactive support to medicine developers to enable accelerated assessment of medicines applications and may grant eligibility for accelerated assessment.

(2) Explanation on financial status

As of June 30, 2022, total assets amounted to 92,499 million yen (a decrease of 4,634 million yen from March 31, 2022), total liabilities were 41,520 million yen (a decrease of 4,524 million yen from March 31, 2022), and net assets were 50,979 million yen (a decrease of 110 million yen from March 31, 2022).

Current assets decreased by 4,204 million yen from March 31, 2022 to 57,983 million yen, mainly due to a decrease in accounts receivable and contract assets despite an increase in cash and deposits. Non-current assets decreased by 429 million yen from March 31, 2022 to 34,516 million yen, mainly due to a decrease in deferred tax assets, despite an increase in property, plant and equipment.

Current liabilities decreased by 4,627 million yen from March 31, 2022 to 37,426 million yen, mainly reflecting a decrease in income taxes payable. Non-current liabilities increased by 103 million yen from March 31, 2022 to 4,094 million yen, mainly due to an increase in long-term borrowings.

Net assets decreased by 110 million yen from March 31, 2022 to 50,979 million yen, mainly due to the payment of dividends, despite recording profit attributable to owners of the parent.

As a result, the equity ratio was 54.3% as of June 30, 2022, an increase of 2.5 of a percentage point from March 31, 2022.

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. We have concluded commitment line agreements with our financial institutions for a total of 15.5 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, 2022, 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, 2023 announced on May 12, 2022.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(millions of yen)

	As of March 31, 2022	As of June 30, 2022
Assets		
Current assets		
Cash and deposits	30,733	32,987
Accounts receivable – trade and Contract asset	15,585	9,372
Securities	244	272
Merchandise and finished goods	2,121	1,363
Work in process	5,024	5,024
Raw materials and supplies	7,491	7,920
Other	986	1,043
Total current assets	62,188	57,983
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,086	6,286
Land	10,379	10,379
Construction in progress	8,019	8,121
Other, net	2,298	2,297
Total property, plant and equipment	26,782	27,084
Intangible assets		
Patent right	2,711	2,642
Other	249	315
Total intangible assets	2,960	2,958
Investments and other assets		
Investment securities	2,230	2,116
Other	2,976	2,361
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	5,202	4,473
Total non-current assets	34,946	34,516
Total assets	97,134	92,499
Liabilities		
Current liabilities		
Accounts payable - trade	1,324	1,352
Short-term borrowings	15,150	15,050
Income taxes payable	5,915	51
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	902	1,434
Provision for bonuses for directors (and other officers)	102	130
Other	6,663	7,411
Total current liabilities	42,054	37,426
Non-current liabilities		
Bonds payable	500	500
Long-term borrowings	2,450	2,550
Retirement benefit liability	870	874
Other	170	169
Total non-current liabilities	3,990	4,094
Total liabilities	46,045	41,520

(millions of yen)

	As of March 31, 2022	As of June 30, 2022
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,994	10,994
Retained earnings	33,241	33,124
Treasury shares	(3,600)	(3,595)
Total shareholders' equity	49,697	49,585
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	619	560
Deferred gains or losses on hedges	0	—
Foreign currency translation adjustment	30	76
Remeasurements of defined benefit plans	(32)	(29)
Total accumulated other comprehensive income	618	607
Share acquisition rights	567	567
Non-controlling interests	205	218
Total net assets	51,089	50,979
Total liabilities and net assets	97,134	92,499

(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, 2021	Three months ended June 30, 2022
Net sales	9,813	9,606
Cost of sales	2,124	2,933
Gross profit	7,688	6,672
Selling, general and administrative expenses	4.704	5,136
Operating profit	2,984	1,536
Non-operating income		
Interest income	1	1
Dividend income	16	15
Foreign exchange gains	2	540
Other	15	6
Total non-operating income	35	564
Non-operating expenses		
Interest expenses	10	10
Commission expenses	3	3
Other	5	3
Total non-operating expenses	19	16
Ordinary profit	3,000	2,083
Extraordinary losses		
Loss on disposal of non-current assets	0	0
Loss on cancellation of contracts	※1,000	―
Other	0	―
Total extraordinary losses	1,000	0
Profit before income taxes	1,999	2,083
Income taxes - current	383	45
Income taxes - deferred	79	668
Total income taxes	463	713
Profit	1,536	1,369
Profit attributable to non-controlling interests	3	0
Profit attributable to owners of the parent	1,532	1,368

(Quarterly consolidated statements of comprehensive income)

(millions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022
Profit	1,536	1,369
Other comprehensive income		
Valuation difference on available-for-sale securities	(92)	(59)
Deferred gains or losses on hedges	(0)	(0)
Foreign currency translation adjustment	30	58
Remeasurements of defined benefit plans, net of tax	2	2
Total other comprehensive income	(59)	1
Comprehensive income	1,476	1,370
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	1,460	1,357
Comprehensive income attributable to non-controlling interests	15	13

(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

(Changes in accounting policy)

(Application of Implementation Guidance on Accounting Standard for Fair Value Measurement)

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Implementation Guidance No. 31, June 17, 2021; hereinafter "Fair Value Measurement Accounting Standard Implementation Guidance") from the beginning of 1Q FY2022 (April 1, 2022 to June 30, 2022). In accordance with the transitional treatment prescribed in Paragraph 27-2 of the Fair Value Measurement Accounting Standard Implementation Guidance, the Company will prospectively apply the new accounting policies set forth in the Fair Value Measurement Accounting Standard Implementation Guidance. This has no impact on the quarterly consolidated financial statements.

(Concerning quarterly consolidated statements of income)

* Loss on cancellation of contracts

Previous quarterly consolidated results (cumulative) (April 1, 2021 to June 30, 2021)

In May 2021, we terminated an agreement concluded for first right of refusal pertaining to certain products currently in the preclinical stage of development upon mutual agreement of the parties.

This resulted in a loss on cancellation of contracts.