Financial Summary
Consolidated Financial Results for the Nine Months ended December 31, 2022 (FY2022)
(Japanese standard)

January 31, 2023

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
(Name) Shin Ashida
Person in charge of inquiries: (Title) Senior Corporate Officer, Executive Director, Administration Division
(Name) Yutaka Honda TEL: 0797(32)1995
Scheduled date to file the Securities Report: February 14, 2023
Scheduled date to commence dividend payments: －
Explanatory material for business results: Available
IR conference: None

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 3Q FY2022 (April 1, 2022 to December 31, 2022)

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of the parent	
Nine months ended	million yen	%	million yen	%	million yen	%	million yen	%
Dec. 31, 2022	26,696	(33.7)	4,953	(73.0)	5,291	(71.7)	3,568	(72.4)
Dec. 31, 2021	40,270	107.3	18,356	364.4	18,724	362.8	12,921	295.8

(Reference) Comprehensive income: Nine months ended Dec. 31, 2022: 3,774 million yen ((70.7%)),
Nine months ended Dec. 31, 2021: 12,879 million yen (296.8%)

	Earnings per share (basic)	Earnings per share (diluted)
Nine months ended	yen	yen
Dec. 31, 2022	28.73	28.61
Dec. 31, 2021	104.45	104.03

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
Dec. 31, 2022	91,728	52,309	55.9
Mar. 31, 2022	97,134	51,089	51.8

(Reference) Shareholders' equity: As of Dec. 31, 2022: 51,295 million yen
As of Mar. 31, 2022: 50,316 million yen

2. Dividends

	Dividend per share				
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual
	yen	yen	yen	yen	yen
FY2021	－	10.00	－	12.00	22.00
FY2022	－	10.00	－		
FY2022 (Forecast)				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: 2.00 yen

3. Consolidated Forecasts for the Fiscal Year Ending Mar. 31, 2023 (Apr. 1, 2022 – Mar. 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 the parent		Earnings per share
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Year ending Mar. 31, 2023	45,000	(11.9)	14,500	(27.3)	14,500	(29.3)	10,300	(29.0)	83.25

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

*Notes

(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.: Yes
2. Changes in accounting principles other than 1. : 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 Dec. 31, 2022	129,686,308 shares	As of Mar. 31, 2022	129,686,308 shares
2. Number of shares treasury stock at the end of the period	As of Dec. 31, 2022	4,912,273 shares	As of Mar. 31, 2022	5,929,344 shares
3. Average number of shares outstanding during the period	As of Dec. 31, 2022	124,213,046 shares	As of Dec. 31, 2021	123,708,453 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 3Q FY2022

Net sales amounted to 26,696 million yen (down 33.7% year on year).

Sales of our recombinant human growth hormone product GROWJECT® were affected by the National Health Insurance (NHI) price revision in April 2022, despite an increase in sales volume. 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 a decrease in income from contractual payments and the completion of the contract to manufacture AstraZeneca K.K.'s COVID-19 vaccine solution in Japan as planned.

Operating income decreased 73.0% year on year to 4,953 million yen, ordinary income decreased 71.7% year on year to 5,291 million yen, and profit attributable to owners of the parent decreased 72.4% year on year to 3,568 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 6,417 million yen (up 1,331 million yen, or 26.2%, year on year).

Furthermore, decreases in sales and profit during the nine months ended December 31, 2022 were in line with initial forecasts.

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to December 31, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to December 31, 2022)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	40,270	26,696	(33.7)
Operating income	18,356	4,953	(73.0)
Ordinary income	18,724	5,291	(71.7)
Profit attributable to owners of the parent	12,921	3,568	(72.4)

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to December 31, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to December 31,2022)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product **GROWJECT®**	9,990	9,320	(6.7)
Treatment for mucopolysaccharidosis type II **IZCARGO® for I.V. Infusion**	2,045	3,380	65.2
Treatment for renal anemia	4,755	3,573	(24.9)
Epoetin Alfa BS Inj. [JCR]	2,251	2,084	(7.4)
Darbepoetin Alfa BS Inj. [JCR]	2,504	1,489	(40.5)
Regenerative medicine products **TEMCELL® HS Inj.**	2,648	2,560	(3.3)
Treatment for Fabry disease **Agalsidase Beta BS I.V. Infusion [JCR]**	533	835	56.7
Income from contractual payments	7,667	5,010	(34.7)
AZD1222 stock solution	12,553	1,931	(84.6)

[3] Status of R&D

[Treatments for lysosomal storage disorders]

- Currently, we are focused on research and development of new drugs that apply 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/ brand name in Japan: IZCARGO® for I.V. infusion 10mg), our BBB-penetrating product for the treatment of patients with Hunter syndrome launched in Japan in May 2021. Additionally, in the U.S., we received Fast Track (*1) designation by the U.S. Food and Drug Administration (FDA) in February 2021 and Rare Pediatric Disease (*2) designation in December 2022, and in the EU, PRIME (*3) designation by the European Medicines Agency (EMA) in October 2021, respectively. In February 2022, the first patient was dosed in a global Phase III clinical trial of JR-141. 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 underway.

- For lepunafusp alfa (development code: JR-171), our BBB-penetrating product candidate for the treatment of patients with mucopolysaccharidosis type I (MPS I), in the ongoing Phase I/II clinical trials in Japan, Brazil, and the U.S., we completed scheduled patient enrolment in March 2022, and are conducting a final analysis. 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 and to enable priority review and accelerated approval in the U.S.

- A treatment enzyme formulation for mucopolysaccharidosis IIIA (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 apply 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. 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 will participate from the position of licenser as the company that created this therapeutic, and help to commercialize it at an early stage.

[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]

- In July 2022, we filed for marketing approval of an additional indication for GROWJECT® in patients with short stature homeoboxcontaining 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), and have completed the scheduled patient enrolment.

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*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 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.

*3 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) Overview of Financial Conditions

As of December 31, 2022, total assets amounted to 91,728 million yen (a decrease of 5,405 million yen from March 31, 2022), total liabilities were 39,418 million yen (a decrease of 6,626 million yen), and net assets were 52,309 million yen (an increase of 1,220 million yen).

Current assets decreased by 16,289 million yen from March 31, 2022 to 45,899 million yen, mainly due to a decrease in accounts receivable - trade and contract asset as well as a decrease in cash and deposits, despite an increase in inventories and accounts receivable - other. Non-current assets increased by 10,883 million yen from March 31, 2022 to 45,829 million yen, mainly due to an increase in property, plant and equipment and an increase in shares of subsidiaries and associates, despite a decrease in deferred tax assets.

Current liabilities decreased by 8,250 million from March 31, 2022 to 33,803 million, mainly due to decreases in income taxes payable, accounts payable-other, and short-term borrowings. Non-current liabilities increased by 1,624 million yen from March 31, 2022 to 5,614 million yen, mainly due to an increase in long-term borrowings.Net assets increased by 1,220 million yen from March 31, 2022 to 52,309 million yen, mainly due to the recording of profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 55.9% as of December 31, 2022, an increase of 4.1 percentage points 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. Accordingly, 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 nine months ended December 31, 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 December 31, 2022
Assets		
Current assets		
Cash and deposits	30,733	13,239
Accounts receivable - trade, and contract assets	15,585	11,037
Securities	244	264
Merchandise and finished goods	2,121	1,289
Work in process	5,024	5,122
Raw materials and supplies	7,491	10,668
Other	986	4,276
Total current assets	62,188	45,899
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,086	6,125
Land	10,379	10,379
Construction in progress	8,019	13,173
Other, net	2,298	2,071
Total property, plant and equipment	26,782	31,749
Intangible assets		
Patent right	2,711	2,504
Other	249	1,154
Total intangible assets	2,960	3,658
Investments and other assets		
Investment securities	2,230	2,144
Shares of subsidiaries and associates	―	6,715
Other	2,976	1,566
Allowance for doubtful accounts	△4	△4
Total investments and other assets	5,202	10,421
Total non-current assets	34,946	45,829
Total assets	97,134	91,728
Liabilities		
Current liabilities		
Accounts payable - trade	1,324	2,131
Short-term borrowings	15,150	13,150
Current portion of bonds payable	―	500
Income taxes payable	5,915	26
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	902	485
Provision for bonuses for directors (and other officers)	102	86
Other	6,663	5,428
Total current liabilities	42,054	33,803
Non-current liabilities		
Bonds payable	500	―
Long-term borrowings	2,450	4,450
Provision for employee stock ownership plan	78	72
Retirement benefit liability	870	913
Other	92	178
Total non-current liabilities	3,990	5,614
Total liabilities	46,045	39,418

(Millions of yen)

	As of March 31, 2022	As of December 31, 2022
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,994	10,384
Retained earnings	33,241	34,073
Treasury shares	△3,600	△2,979
Total shareholders' equity	49,697	50,540
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	619	575
Deferred gains or losses on hedges	0	―
Foreign currency translation adjustment	30	203
Remeasurements of defined benefit plans	△32	△24
Total accumulated other comprehensive income	618	755
Share acquisition rights	567	740
Non-controlling interests	205	273
Total net assets	51,089	52,309
Total liabilities and net assets	97,134	91,728

(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, 2021	Nine months ended December 31, 2022
Net sales	40,270	26,696
Cost of sales	6,826	6,899
Gross profit	33,444	19,796
Selling, general and administrative expenses	15,087	14,843
Operating profit	18,356	4,953
Non-operating income		
Interest income	5	8
Dividend income	28	27
Foreign exchange gains	326	328
Other	65	49
Total non-operating income	426	414
Non-operating expenses		
Interest expenses	33	33
Commission expenses	9	9
Loss on abandonment of inventories	—	20
Other	14	12
Total non-operating expenses	57	76
Ordinary profit	18,724	5,291
Extraordinary income		
Gain on sale of investment securities	0	—
Total extraordinary income	0	—
Extraordinary losses		
Loss on disposal of non-current assets	0	11
Loss on cancellation of contracts	※ 1,000	—
Other	1	—
Total extraordinary losses	1,002	11
Profit before income taxes	17,722	5,280
Income taxes - current	4,280	233
Income taxes - deferred	515	1,462
Total income taxes	4,795	1,695
Profit	12,926	3,584
Profit attributable to non-controlling interests	5	15
Profit attributable to owners of parent	12,921	3,568

(Quarterly consolidated statements of comprehensive income)

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Profit	12,926	3,584
Other comprehensive income		
Valuation difference on available-for-sale securities	(106)	(43)
Deferred gains or losses on hedges	0	0
Foreign currency translation adjustment	51	226
Remeasurements of defined benefit plans, net of tax	7	8
Total other comprehensive income	(47)	190
Comprehensive income	12,879	3,774
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	12,859	3,705
Comprehensive income attributable to non-controlling interests	20	69

(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

(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 December 31, 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.