

Financial Summary

Consolidated Financial Results for the Six Months ended September 30, 2022 (FY2022) (Japanese standard)

October 26, 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 inquiries: (Title) Senior Corporate Officer, Executive Director, Administration Division
 (Name) Yutaka Honda TEL: 0797(32)1995
 Scheduled date to file the Securities Report: November 14, 2022
 Scheduled date to commence dividend payments: December 9, 2022
 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 FY2022 (April 1, 2022 to Sep. 30, 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	
Six Months Ended	million yen	%	million yen	%	million yen	%	million yen	%
Sep. 30, 2022	15,581	(45.1)	744	(94.5)	1,569	(88.6)	962	(89.6)
Sep. 30, 2021	28,383	159.2	13,640	943.3	13,731	916.4	9,234	652.6

(Reference) Comprehensive income: Six months ended Sep. 30, 2022: 1,093 million yen ([88.1]%)
 Six months ended Sep. 30, 2021: 9,192 million yen (628.2%)

	Earnings per share (basic)	Earnings per share (diluted)
Six Months Ended	yen	yen
Sep. 30, 2022	7.77	7.74
Sep. 30, 2021	74.66	74.36

(2) Consolidated Financial Conditions

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
Sep. 30, 2022	89,387	50,878	55.8
March 31, 2022	97,134	51,089	51.8

(Reference) Shareholders' equity: As of Sep. 30, 2022: 49,879 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

(Note) 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.

*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.: 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, (4) Notes to quarterly consolidated financial statements, (Changes in accounting policy)” on page 10 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 Sep. 30, 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 Sep. 30, 2022	4,915,324 shares	As of Mar. 31, 2022	5,929,344 shares
3. Average number of shares outstanding during the period (quarterly cumulative amount)	As of Sep. 30, 2022	123,933,051 shares	As of Sep. 30, 2021	123,686,414 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 FY2022

Net sales amounted to 15,581 million yen (down 45.1% year on year).

Sales of our recombinant human growth hormone product GROWJECT® were affected by the NHI price revision in April 2022. Total net sales of our main products remained level 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 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 94.5% year on year to 744 million yen, ordinary income decreased 88.6% year on year to 1,569 million yen, and profit attributable to owners of the parent decreased 89.6% year on year to 962 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 4,216 million yen (up 696 million yen, or 19.8%, year on year).

Furthermore, decreases in sales and profit during the six months ended September 30, 2022 were in line with initial forecasts.

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to September 30, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to September 30, 2022)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	28,383	15,581	(45.1)
Operating income	13,640	744	(94.5)
Ordinary income	13,731	1,569	(88.6)
Profit attributable to owners of the parent	9,234	962	(89.6)

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2021 to September 30, 2021)	Current quarterly consolidated results (cumulative) (April 1, 2022 to September 30, 2022)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product GROWJECT®	6,689	6,083	(9.1)
Treatment for mucopolysaccharidosis type II IZCARGO® for I.V. Infusion	985	2,118	114.8
Treatment for renal anemia Epoetin Alfa BS Inj. [JCR]	3,011	2,157	(28.4)
Darbepoetin Alfa BS Inj. [JCR]	1,512	1,392	(8.0)
	1,498	765	(48.9)
Regenerative medicine products TEMCELL® HS Inj.	1,717	1,701	(0.9)
Treatment for Fabry disease Agalsidase Beta BS I.V. Infusion [JCR]	323	521	61.0
Income from contractual payments	7,557	1,010	(86.6)
AZD1222 stock solution	8,046	1,931	(76.0)

[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) penetrating 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. 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. 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 trial 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 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]

- In July 2022, we filed for marketing approval of 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), and have completed the scheduled patient enrolment.

*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) Overview of Financial Conditions

[1] Status of assets, liabilities and net assets

As of September 30, 2022, total assets amounted to 89,387 million yen (a decrease of 7,746 million yen from March 31, 2022), total liabilities were 38,509 million yen (a decrease of 7,535 million yen), and net assets were 50,878 million yen (a decrease of 210 million yen).

Current assets decreased by 7,870 million yen from March 31, 2022 to 54,317 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. Non-current assets increased by 124 million yen from March 31, 2022 to 35,070 million yen, mainly due to an increase in intangible assets, despite a decrease in deferred tax assets.

Current liabilities decreased by 9,063 million from March 31, 2022 to 32,991 million, mainly due to decreases in income taxes payable, accounts payable-other, and short-term borrowings. Non-current liabilities increased by 1,527 million yen from March 31, 2022 to 5,518 million yen, mainly due to an increase in long-term borrowings.

Net assets decreased by 210 million yen from March 31, 2022 to 50,878 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 55.8% as of September 30, 2022, an increase of 4.0 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. 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.

[2] Status of cash flows

Cash and cash equivalents stood at 28,107 million yen as of September 30, 2022, a decrease of 2,625 million yen from March 31, 2022. The status of each type of cash flow and the major reasons for changes are stated below.

(Cash flows from operating activities)

Net cash used in operating activities was 1,027 million yen, a decrease of 3,720 million yen in net cash used from the same period of the previous fiscal year. This was mainly due to income taxes paid of 5,516 million yen, a decrease in accounts payable-other of 2,212 million yen, foreign exchange gains of 1,517 million yen, and an increase in inventories of 1,175 million yen, while there was a decrease in trade receivables of 6,996 million yen and profit before income taxes of 1,560 million yen.

(Cash flows from investing activities)

Net cash used in investing activities was 1,779 million yen, an increase of 1,543 million yen in net cash used from the same period of the previous fiscal year. The main use of cash was 1,333 million yen for the purchase of property, plant and equipment.

(Cash flows from financing activities)

Net cash used in financing activities was 1,479 million yen, an increase of 548 million yen in net cash used from the same period of the previous fiscal year. This was mainly attributable to cash dividends paid of 1,489 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, 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 September 30, 2022
Assets		
Current assets		
Cash and deposits	30,733	28,107
Accounts receivable - trade, and contract assets	15,585	8,589
Securities	244	287
Merchandise and finished goods	2,121	1,469
Work in process	5,024	5,103
Raw materials and supplies	7,491	9,240
Other	986	1,519
Total current assets	62,188	54,317
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,086	6,199
Land	10,379	10,379
Construction in progress	8,019	8,116
Other, net	2,298	2,233
Total property, plant and equipment	26,782	26,928
Intangible assets		
Patent right	2,711	2,573
Other	249	939
Total intangible assets	2,960	3,512
Investments and other assets		
Investment securities	2,230	2,130
Other	2,976	2,503
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	5,202	4,629
Total non-current assets	34,946	35,070
Total assets	97,134	89,387
Liabilities		
Current liabilities		
Accounts payable - trade	1,324	1,553
Short-term borrowings	15,150	13,150
Current portion of bonds payable	—	500
Income taxes payable	5,915	93
Special suspense account for tax purpose reduction entry	11,996	11,996
Provision for bonuses	902	1,065
Provision for bonuses for directors (and other officers)	102	57
Other	6,663	4,574
Total current liabilities	42,054	32,991
Non-current liabilities		
Bonds payable	500	—
Long-term borrowings	2,450	4,450
Retirement benefit liability	870	899
Other	170	169
Total non-current liabilities	3,990	5,518
Total liabilities	46,045	38,509

(Millions of yen)

	As of March 31, 2022	As of September 30, 2022
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,994	10,384
Retained earnings	33,241	32,718
Treasury shares	(3,600)	(2,980)
Total shareholders' equity	49,697	49,183
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	619	581
Deferred gains or losses on hedges	0	—
Foreign currency translation adjustment	30	142
Remeasurements of defined benefit plans	(32)	(27)
Total accumulated other comprehensive income	618	696
Share acquisition rights	567	740
Non-controlling interests	205	257
Total net assets	51,089	50,878
Total liabilities and net assets	97,134	89,387

(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, 2021	Six months ended September 30, 2022
Net sales	28,383	15,581
Cost of sales	4,485	4,836
Gross profit	23,898	10,744
Selling, general and administrative expenses	10,258	9,999
Operating profit	13,640	744
Non-operating income		
Interest income	3	5
Dividend income	16	15
Foreign exchange gains	84	814
Other	28	25
Total non-operating income	132	861
Non-operating expenses		
Interest expenses	22	21
Commission expenses	6	6
Other	12	8
Total non-operating expenses	41	36
Ordinary profit	13,731	1,569
Extraordinary income		
Gain on sale of investment securities	0	—
Total extraordinary income	0	—
Extraordinary losses		
Loss on disposal of non-current assets	0	9
Loss on cancellation of contracts	* 1,000	—
Other	1	—
Total extraordinary losses	1,002	9
Profit before income taxes	12,729	1,560
Income taxes - current	3,311	62
Income taxes - deferred	179	521
Total income taxes	3,490	583
Profit	9,238	976
Profit attributable to non-controlling interests	4	14
Profit attributable to owners of parent	9,234	962

(Quarterly consolidated statements of comprehensive income)

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Profit	9,238	976
Other comprehensive income		
Valuation difference on available-for-sale securities	(109)	(38)
Deferred gains or losses on hedges	(0)	(0)
Foreign currency translation adjustment	58	150
Remeasurements of defined benefit plans, net of tax	5	5
Total other comprehensive income	(45)	116
Comprehensive income	9,192	1,093
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	9,176	1,040
Comprehensive income attributable to non-controlling interests	16	52

(3) Quarterly consolidated statements of cash flows

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Cash flows from operating activities		
Profit before income taxes	12,729	1,560
Depreciation	922	953
Increase (decrease) in retirement benefit liability	32	32
Decrease (increase) in retirement benefit asset	4	6
Increase (decrease) in provision for bonuses	214	162
Share-based payment expenses	177	173
Interest and dividend income	(19)	(21)
Interest expenses	22	21
Foreign exchange losses (gains)	(9)	(1,517)
Decrease (increase) in trade receivables	(13,934)	6,996
Decrease (increase) in accounts receivable - other	(39)	(499)
Decrease (increase) in inventories	(1,491)	(1,175)
Increase (decrease) in trade payables	(1,466)	228
Increase (decrease) in accounts payable - other	2,040	(2,212)
Increase (decrease) in accrued consumption taxes	(174)	(313)
Increase (decrease) in advances received	(1,105)	301
Other, net	(209)	(208)
Subtotal	(2,309)	4,490
Interest and dividends received	19	21
Interest paid	(22)	(23)
Income taxes refund (paid)	(2,435)	(5,516)
Net cash provided by (used in) operating activities	(4,747)	(1,027)
Cash flows from investing activities		
Payments into time deposits	(300)	—
Proceeds from withdrawal of time deposits	300	—
Purchase of property, plant and equipment	(4,514)	(1,333)
Proceeds from subsidy income	4,345	—
Other, net	(68)	(446)
Net cash provided by (used in) investing activities	(236)	(1,779)
Cash flows from financing activities		
Proceeds from long-term borrowings	550	2,750
Repayments of long-term borrowings	(550)	(2,750)
Net decrease (increase) in treasury shares	7	8
Dividends paid	(928)	(1,489)
Other, net	(9)	1
Net cash provided by (used in) financing activities	(930)	(1,479)
Effect of exchange rate change on cash and cash equivalents	66	1,660
Net increase (decrease) in cash and cash equivalents	(5,848)	(2,625)
Cash and cash equivalents at beginning of period	26,260	30,733
Cash and cash equivalents at end of period	20,412	28,107

(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

(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 September 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.

3. Other

R&D Pipeline

Recombinant drug products

Code Nonproprietary Name	Status	Indication
		Remarks
JR- 141 BBB-Penetrating Iduronate -2-sulfatase (rDNA origin)	Global: Phase III	Mucopolysaccharidosis II (Hunter syndrome)
		ERT J-Brain Cargo®
JR- 171 BBB-Penetrating α-L-Iduronidase (rDNA origin)	Global: Phase I/II	Mucopolysaccharidosis I (Hurler syndrome, etc)
		ERT J-Brain Cargo® J-MIG System®
JR- 162 J-Brain Cargo® - applied acid α -glucosidase (rDNA origin)	Japan: Preclinical	Pompe disease
		ERT J-Brain Cargo®
JR-441 BBB-Penetrating heparan N-sulfatase (rDNA origin)	Japan: Preclinical	Mucopolysaccharidosis III-A (Sanfilippo syndrome type A)
		ERT J-Brain Cargo®
JR-443 BBB-penetrating β-glucuronidase (rDNA origin)	Japan: Preclinical	Mucopolysaccharidosis VII (Sly's syndrome)
		ERT J-Brain Cargo®
JR-446 BBB-penetrating α-N-acetylglucosaminidase (rDNA origin)	Japan: Preclinical	Mucopolysaccharidosis III-B (Sanfilippo syndrome type B)
		ERT J-Brain Cargo®
JR-479 BBB-penetrating β-Hexosaminidase A (rDNA origin)	Japan: Preclinical	GM2 gangliosidosis (Tay-Sachs disease, Sandhoff disease)
		ERT J-Brain Cargo®
JR-401X Somatropin (rDNA origin)	Application filed	SHOX deficiency
		Expanded indication for GROWJECT®
JR-142 Long-acting Growth hormone (rDNA origin)	Japan: Phase II	Pediatric Growth hormone deficiency
		J-MIG System®

(Note) ERT= Enzyme Replacement Therapy

Allogeneic regenerative medical product

Code Nonproprietary Name	Status	Indication
		Remarks
JR- 031HIE Human mesenchymal stem cells	Japan: Phase I / II	Neonatal hypoxic ischemic encephalopathy
		Expanded Indication of TEMCELL® HS