

Financial Summary Consolidated Financial Results for the Nine Months ended December 31, 2022 (FY2021) (Japanese standard)

January 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 inquiries: (Title) Corporate Officer, Executive Director, Administration Division
 (Name) Yutaka Honda TEL: 0797(32)1995
 Scheduled date to file the Securities Report: February 14, 2022
 Scheduled date to commence dividend payments: —
 Explanatory material for business results: None
 IR conference: None

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 3Q FY2021 (April 1, 2021 to December 31, 2021)

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of the parent	
	million yen	%	million yen	%	million yen	%	million yen	%
Nine months ended								
Dec. 31, 2021	40,270	107.3	18,356	364.4	18,724	362.8	12,921	295.8
Dec. 31, 2020	19,424	7.4	3,952	83.6	4,045	86.3	3,264	80.8

(Reference) Comprehensive income: Nine months ended Dec. 31, 2021: 12,879 million yen (296.8%),
 Nine months ended Dec. 31, 2020: 3,245 million yen (90.1%)

	Net income per share (basic)	Net income per share (diluted)
Nine months ended	yen	yen
Dec. 31, 2021	104.45	104.03
Dec. 31, 2020	26.44	26.30

(Note) We conducted a 4-for-1 stock split on October 1, 2020. Calculations of "Earnings per share (basic)" and "Earnings per share (diluted)" are based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio
Nine months ended	million yen	million yen	%
Dec. 31, 2021	93,430	49,456	52.1
Mar. 31, 2021	73,784	38,557	51.3

(Reference) Shareholders' equity: As of Dec. 31, 2021: 48,693 million yen
 As of Mar. 31, 2021: 37,864 million yen

2. Dividends

	Dividend per share				
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual
	yen	yen	yen	yen	yen
FY2020	—	18.00	—	7.50	—
FY2021	—	10.00	—		
FY2021 (Forecast)				10.00	20.00

(Notes) 1. No revisions were made to the most recently announced dividend forecast.

2. We conducted a 4-for-1 stock split on October 1, 2020. The year-end dividend per share shown for the fiscal year ended March 31, 2021 reflects the impact of this stock split, and the annual dividend is presented as "—". If the stock split is assumed to have been implemented at the beginning of the previous fiscal year, the 2nd quarter-end dividend per share for the fiscal year ended March 31, 2021 would be 4.50 yen and the annual dividend per share would be 12.00 yen.

3. Breakdown of the year-end dividend for the fiscal year ended March 31, 2021:
 Ordinary dividend: 7.00 yen Commemorative dividend: 0.50 yen

3. Consolidated Forecasts for the Fiscal Year Ending Mar. 31, 2022 (Apr. 1, 2021 – Mar. 31, 2022)

(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, 2022	52,000	72.8	21,700	162.4	21,700	155.6	15,400	123.4	124.70

(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 8 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)

2. Number of shares treasury stock at the end of the period

3. Average number of shares outstanding during the period

As of Dec. 30, 2021	129,686,308 shares	As of Mar. 31, 2021	129,686,308 shares
As of Dec. 30, 2021	5,932,644 shares	As of Mar. 31, 2021	6,071,644 shares
As of Dec. 30, 2021	123,708,453 shares	As of Dec. 31, 2020	123,485,105 shares

(Note) We conducted a 4-for-1 stock split on October 1, 2020. Calculations for “Average number of shares during the period” are based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

* 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 3 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 FY2021

Net sales amounted to 40,270 million yen (up 107.3% year on year).

Net sales remained firm due to an increase in sales volume of our recombinant human growth hormone product GROWJECT®, despite being subject to the National Health Insurance (NHI) price revision in April 2021. Total net sales of our mainstay products increased year on year due to factors including a significant contribution from IZCARGO® I.V. Infusion 10mg, which was placed on the NHI reimbursement price list in May 2021, in spite of a substantial decrease in revenue in renal anemia treatments, which were also included in the NHI price revision.

In addition, total net sales increased substantially year on year. This increase was mainly because we launched sales of AstraZeneca K.K.'s COVID-19 vaccine solution in March 2021 and revenue from licensing rose year on year.

Profits increased significantly at every level, with operating income of 18,356 million yen (up 364.4%), ordinary income of 18,724 million yen (up 362.8%) and profit attributable to owners of parent of 12,921 million yen (up 295.8%).

As a result of proactive R&D activities and development activities in line with progress on clinical trials, R&D expenses totaled 5,085 million yen (up 1,309 million yen, or 34.7%, year on year).

In September 2021, JCR and Takeda Pharmaceutical Company Limited concluded an agreement to promote collaboration and commercialization of JR-141 in specific regions. JR-141 is a next-generation therapy for Hunter syndrome. With this agreement, the JCR Group has taken a further step toward becoming a global specialty pharma in the rare disease arena.

	Previous quarterly consolidated results (cumulative) (April 1, 2020 to December 31, 2020)	Current quarterly consolidated results (cumulative) (April 1, 2021 to December 31, 2021)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Net sales	19,424	40,270	107.3
Operating income	3,952	18,356	364.4
Ordinary income	4,045	18,724	362.8
Profit attributable to owners of the parent	3,264	12,921	295.8

[2] Main components of sales

	Previous quarterly consolidated results (cumulative) (April 1, 2020 to December 31, 2020)	Current quarterly consolidated results (cumulative) (April 1, 2021 to December 31, 2021)	Rate of change
	Amount (million yen)	Amount (million yen)	%
Human growth hormone product GROWJECT®	10,011	9,990	(0.2)
Treatment for mucopolysaccharidosis type II IZCARGO® for I.V. Infusion	—	2,045	—
Treatment for renal anemia Epoetin Alfa BS Inj. [JCR]	5,625	4,755	(15.5)
Darbepoetin Alfa BS Inj. [JCR]	2,598	2,251	(13.3)
	3,027	2,504	(17.3)
Regenerative medicine products TEMCELL® HS Inj. .	1,656	2,648	59.9
Treatment for Fabry disease Agalsidase Beta BS I.V. Infusion [JCR]	346	533	53.7
Income from contractual payments	1,772	7,667	332.5
AZD1222 stock solution	—	12,553	—

[3] Status of R&D

[Treatments for lysosomal storage disorders]

- In treatments for lysosomal storage disorders, a priority field for development, we are currently conducting development of new drugs that employ our unique blood-brain barrier (BBB) technology, J-Brain Cargo®.
- 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, we commenced sales 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, it was newly designated as a Fast Track (*1) by the U.S. Food and Drug Administration (FDA) in February 2021 and as a PRIME (*2) by the European Medicines Agency (EMA) in October 2021. Currently, we are preparing to commence trials for the global Phase 3 clinical trials to be conducted.
- For our BBB-penetrating product candidate for the treatment of patients with mucopolysaccharidosis type I (MPS I) (development code: JR-171), we are currently conducting a Phase I/II clinical trial in Japan, Brazil and the U.S. JR-171 received orphan drug designation from the U.S. FDA in February 2021, and the European Commission (EC) in March 2021. Additionally, JR-171 received Fast Track Designation*1 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), and a treatment for Sanfilippo syndrome type B (JR-446). We will also develop each of these treatments globally.

[Regenerative medicine products]

- Currently, 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).
- We are now conducting a Phase I/II clinical trial of 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]

- Currently, 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).
- In March 2021, we 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)

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, 2021, total assets amounted to 93,430 million yen (an increase of 19,645 million yen increase from March 31, 2021), total liabilities were 43,974 million yen (an increase of 8,747 million yen), and net assets were 49,456 million yen (an increase of 10,898 million yen).

Current assets increased by 16,975 million yen from March 31, 2021 to 65,521 million yen, mainly due to increases in cash and deposits and notes and accounts receivable – trade. Non-current assets increased by 2,670 million yen from March 31, 2021 to 27,909 million yen, mainly due to an increase in property, plant and equipment.

Current liabilities increased from March 31, 2021 by 10,945 million yen to 39,973 million yen, mainly due to increases in special suspense account for tax purpose reduction entry and short-term loans payable. Non-current liabilities totaled 4,000 million yen, a decrease of 2,198 million yen from March 31, 2021, mainly due to a decrease in long-term loans payable.

Net assets increased by 10,898 million yen from March 31, 2021 to 49,456 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 52.1% as of December 31, 2021, an improvement of 0.8 percentage points from March 31, 2021.

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, 2021, sales and profits both increased significantly year on year.

There have been no changes to the forecasts for the fiscal year ending March 31, 2022 announced on September 30, 2021.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(millions of yen)

	As of March 31, 2021	As of December 31, 2021
Assets		
Current assets		
Cash and deposits	26,260	31,300
Notes and accounts receivable - trade	8,183	17,404
Merchandise and finished goods	1,367	1,278
Work in process	3,538	5,234
Raw materials and supplies	8,649	9,232
Other	546	1,070
Total current assets	48,545	65,521
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	6,295	6,095
Land	7,663	7,663
Construction in progress	841	4,707
Other, net	2,371	2,185
Total property, plant and equipment	17,172	20,652
Intangible assets		
Patent right	2,988	2,780
Other	244	225
Total intangible assets	3,232	3,006
Investments and other assets		
Investment securities	2,572	2,425
Other	2,266	1,829
Allowance for doubtful accounts	(4)	(4)
Total investments and other assets	4,833	4,250
Total non-current assets	25,238	27,909
Total assets	73,784	93,430

(millions of yen)

	As of March 31, 2021	As of December 31, 2021
Liabilities		
Current liabilities		
Notes and accounts payable - trade	2,932	1,166
Short-term borrowings	12,850	15,050
Income taxes payable	2,646	4,542
Special suspense account for tax purpose reduction entry	3,828	11,996
Provision for bonuses	850	456
Provision for bonuses for directors (and other officers)	63	76
Other	5,855	6,686
Total current liabilities	29,028	39,973
Non-current liabilities		
Bonds payable	500	500
Long-term borrowings	4,750	2,550
Retirement benefit liability	798	847
Other	151	103
Total non-current liabilities	6,199	4,000
Total liabilities	35,227	43,974
Net assets		
Shareholders' equity		
Share capital	9,061	9,061
Capital surplus	10,941	10,994
Retained earnings	20,904	31,659
Treasury shares	(3,685)	(3,601)
Total shareholders' equity	37,222	48,113
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	691	584
Deferred gains or losses on hedges	0	0
Foreign currency translation adjustment	(18)	18
Remeasurements of defined benefit plans	(31)	(23)
Total accumulated other comprehensive income	641	580
Share acquisition rights	517	567
Non-controlling interests	174	194
Total net assets	38,557	49,456
Total liabilities and net assets	73,784	93,430

(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, 2020	Nine months ended December 31, 2021
Net sales	19,424	40,270
Cost of sales	5,811	6,826
Gross profit	13,612	33,444
Selling, general and administrative expenses	9,659	15,087
Operating profit	3,952	18,356
Non-operating income		
Interest income	6	5
Dividend income	25	28
Foreign exchange gains	64	326
Other	62	65
Total non-operating income	159	426
Non-operating expenses		
Interest expenses	30	33
Commission expenses	7	9
Other	27	14
Total non-operating expenses	65	57
Ordinary profit	4,045	18,724
Extraordinary income		
Reversal of provision for loss on guarantees	108	—
Reversal of allowance for doubtful accounts	19	—
Other	—	0
Total extraordinary income	127	0
Extraordinary losses		
Loss on disposal of non-current assets	2	0
Loss on cancellation of contracts	—	* 1,000
Other	—	1
Total extraordinary losses	2	1,002
Profit before income taxes	4,170	17,722
Income taxes - current	1,434	4,280
Income taxes - deferred	(535)	515
Total income taxes	899	4,795
Profit	3,271	12,926
Profit attributable to non-controlling interests	6	5
Profit attributable to owners of parent	3,264	12,921

(Quarterly consolidated statements of comprehensive income)

(millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Profit	3,271	12,926
Other comprehensive income		
Valuation difference on available-for-sale securities	(6)	(106)
Deferred gains or losses on hedges	(0)	0
Foreign currency translation adjustment	(36)	51
Remeasurements of defined benefit plans, net of tax	17	7
Total other comprehensive income	(25)	(47)
Comprehensive income	3,245	12,879
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	3,245	12,859
Comprehensive income attributable to non-controlling interests	0	20

(3) Notes to quarterly consolidated financial statements

(Notes on premises as a going concern)

No corresponding item existed.

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

No corresponding item existed.

(Changes in accounting policy)

(Application of Accounting Standard for Revenue Recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter "Revenue Recognition Accounting Standards"), etc. from the beginning of 1Q FY2021 (April 1, 2021 to June 30, 2021), and recognizes revenue as the amount expected to be received in exchange for promised goods or services when control of the goods or services is transferred to the customer.

As a result, a portion of commission expenses previously recorded in selling, general and administrative expenses has been deducted from net sales. In addition, a portion of sales promotion expenses previously recorded in the net amount has been included in net sales and cost of sales.

In applying the Revenue Recognition Accounting Standards, etc., the Company follows the transitional treatment set forth in the proviso of Paragraph 84 of the Revenue Recognition Accounting Standards. The cumulative effect of retroactively applying the new accounting policy to periods prior to the beginning of 1Q FY2021 has been added to or subtracted from retained earnings at the beginning of 1Q FY2021, and the new accounting policy has been applied from the beginning balance of that period. However, the Company has applied the method stipulated in Paragraph 86 of the Revenue Recognition Accounting Standards, and accordingly the new accounting policy has not been applied to contracts for which nearly the entire amount of revenue had been recognized prior to 1Q FY2021.

The resulting effects on the consolidated financial results for 3Q FY2021 are as follows: a 42 million yen increase in net sales, a 223 million yen increase in cost of sales, a 181 million yen decrease in selling, general and administrative expenses, and no impact on operating income, ordinary income, or profit before income taxes. In addition, there was no impact on the balance of retained earnings at the beginning of 1Q FY2021.

(Application of Accounting Standard for Fair Value Measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; hereinafter "Fair Value Measurement Accounting Standards") from the beginning of 1Q FY2021 (April 1, 2021 to June 30, 2021). In accordance with the transitional treatment prescribed in Paragraph 19 of the Fair Value Measurement Accounting Standards and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019), the Company will apply the new accounting policies set forth in the Fair Value Measurement Accounting Standards, etc. at a future date. This has no impact on the quarterly consolidated financial statements.

(Concerning quarterly consolidated statements of income)

* Loss on cancellation of contracts

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 contract.