

**Financial Summary**  
**Consolidated Financial Results for the Six Months Ended September 30, 2019 (2Q FY2019)**  
**(Japanese standard)**

October 31, 2019

Listed company name: JCR Pharmaceuticals Co., Ltd.

Listed stock exchange: Tokyo Stock Exchange

Code number: 4552 URL: <http://www.jcrpharm.co.jp>

Representative (Title) Representative Director, Chairman and President

(Name) Shin Ashida

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Scheduled date to file quarterly report: November 14, 2019

Scheduled date to commence dividend payments: December 10, 2019

Preparation of supplemental information for the financial summary for the quarterly financial results: Yes

Arrangement of briefing on the quarterly financial results: Yes (For institutional investors and analysts)

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for the First Six months of FY2019 Ended Sep.30, 2019 (Apr. 1, 2019 to Sep 30, 2019)

(1) Consolidated Operating Results (Cumulative)

(Percentage figures represent year-on-year changes.)

	Net Sales		Operating Income		Ordinary Income		Profit Attributable to Owners of Parent	
Six Months Ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2019	11,236	9.3	998	(48.7)	981	(51.1)	922	(33.0)
September 30, 2018	10,275	0.9	1,945	(20.5)	2,006	(18.7)	1,377	(26.8)

(Reference) Comprehensive income: Six months ended Sep. 30, 2019: 747 million yen (52.6)%,  
Six months ended Sep. 30, 2018: 1,577 million yen (18.2)%

	Net income per Share (basic)	Net Income per Share (diluted)
Six months Ended	Yen	Yen
September 30, 2019	29.95	29.77
September 30, 2018	44.76	44.50

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
As of	Million yen	Million yen	%
September 30, 2019	45,626	31,276	66.9
September 30, 2018	42,516	30,874	71.1

(Reference) Shareholders' equity

As of Sep. 30, 2019: 30,505 million yen

As of Mar. 31, 2019: 30,249 million yen

2. Dividends

	Dividend per Share				
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
FY2018	—	13.00	—	17.00	30.00
FY2019	—	15.00	—	—	—
FY2019 (Forecast)	—	—	—	15.00	30.00

(Note) No adjustment was made to the most recently announced forecast of the dividend.

3. Consolidated Forecasts for the Fiscal Year Ending Mar. 31, 2020 (Apr. 1, 2019 – Mar.31, 2020)

(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		Net Income per Share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Year ending Mar. 31, 2020	26,400	14.0	5,140	3.5	5,150	1.6	4,080	9.8	132.38

(Note) No adjustment was made to the most recently announced forecast of financial results.

\* Note

(1) There was no transfer of important subsidiary (transfer of a specific subsidiary resulting in changes in the scope of the consolidation) during the Six months ended September 30, 2019.

(2) No specific accounting process was applied to the preparation of the quarterly consolidated financial statements.

(3) Changes in accounting policy, changes in accounting estimates and retrospective restatement

1. Changes in accounting policy due to the revision of accounting standards, etc.: None
2. Changes in accounting policy other than 1: None
3. Changes in accounting estimates: None
4. Retrospective restatement: None

(4) Number of outstanding shares (common shares)

1. Number of outstanding shares as of the end of the term (including treasury stock)
2. Number of treasury stock as of the end of the term
3. Average number of shares during the term (quarterly cumulative amount)

As of Sep. 30, 2019	32,421,577 shares	As of Mar. 31, 2019	32,421,577 shares
As of Sep. 30, 2019	1,596,032 shares	As of Mar. 31, 2019	1,622,379 shares
Apr. – Sep. 2019	30,813,925 shares	Apr. – Sep. 2018	30,775,414 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 the forecasts of financial results and other comments

(Note on forward-looking statements, etc.)

The forward-looking statements such as the forecasts of financial results contained in this document are based on the information that the company currently holds and certain assumption that the company judges as rational. The company does not assure the achievement of those forecasts. In addition, actual financial results may differ significantly from forecasts due to various reasons. For the assumptions underlying the forecasts of financial results and notes for the appropriate use of the forecasts of financial results, please refer to the attached material on Page 3, “1. Qualitative information for the quarterly financial statements (3) Explanation on projections such as forecasts of consolidated financial results.”

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## 1. Qualitative information for the quarterly financial statements

### (1) Explanation on financial results

On the marketing front, the sales of our core product GROWJECT®, a recombinant human growth hormone product, increased to 6,235 million yen (up 390 million yen year on year), mainly due to increased sales volume. Sales of Epoetin Alfa BS Inj. JCR, a recombinant human erythropoietin product, and TEMCELL® HS Inj., a regenerative medical product, both increased steadily to 2,272 million yen (up 105 million yen year on year) and 1,527 million yen (up 537 million yen year on year) respectively. We recorded sales of 123 million yen for Agalsidase Beta BS I.V. Infusion [JCR], a treatment for Fabry disease launched in November 2018. Furthermore, contract income was 1,002 million yen (down 52 million yen year on year). Overall, the Group total amounted to sales of 11,236 million yen (up 960 million yen year on year).

On the profit front, gross profit was 8,063 million yen (up 783 million yen year on year), tracking the increase in net sales. However, in line with proactive research activities, R&D expenses were 3,255 million yen (up 1,430 million yen year on year). As a result, operating income was 998 million yen (down 946 million yen year on year) and ordinary income was 981 million yen (down 1,024 million yen year on year). Profit attributable to owners of parent was 922 million yen (down 454 million yen year on year).

These 2Q's increases in sales and decreases in profit were as we originally expected.

The status of R&D is as follows.

#### Treatment for lysosomal storage disorders

In treatments for lysosomal storage disorders, a priority field for development, we are currently conducting development of innovative new drugs that employ our unique blood-brain barrier (BBB) technology, J-Brain Cargo®. In particular, we have made steady progress on our BBB-penetrating therapeutic enzyme for the treatment of Hunter Syndrome (development code: JR-141). We started a Phase II clinical trial of JR-141 in Brazil in June 2018 and initiated a Phase III clinical trial in Japan in August 2018, and clinical trials have been proceeding according to plan. We have also been proceeding with preparations for global development with the reception of orphan drug designation from the US Food and Drug Administration (FDA) in October 2018, and the European Medicines Agency (EMA) in February 2019. Following on from the foregoing, we have been successively developing treatments for lysosomal storage disorders, including a therapeutic enzyme for Pompe disease (development code: JR-162), a therapeutic enzyme for Hurler syndrome (development code: JR-171), and a therapeutic enzyme for Sanfilippo syndrome type A (development code: JR-441). Going forward, we will develop each of these new treatments globally.

#### Cell therapy and regenerative medicine

In the field of cell therapy and regenerative medicine, we concluded a co-development and license agreement for an allogeneic regenerative medical product using dental pulp stem cells (DPCs) for the indication of acute cerebral infarction (development code: JTR-161/JR-161) with Teijin Limited in July 2017. We initiated Phase I/II clinical trial of JTR-161/JR-161 in February 2019, delivering the medicines to patients. Furthermore, in July 2019, we commenced Phase I/II clinical trial of TEMCELL® HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE).

As for proper expansion of treatment for epidermolysis bullosa with subcutaneous injections of TEMCELL® HS Inj., we determined that there is a necessity to further demonstrate the efficacy of TEMCELL® HS Inj. in the treatment of this disease, and we have withdrawn our application for market approval in September 2019.

#### Initiatives for core products

We received manufacturing and marketing approval for Darbepoetin Alfa BS Injection JCR, a long-acting erythropoiesis-stimulating agent that was jointly developed with Kissei Pharmaceutical Co., Ltd., on September 20, 2019.

In July 2018, we started a Phase III clinical trial for an additional indication for GROWJECT®, our human growth hormone product, in patients with short stature homeobox-containing gene (SHOX) deficiency. In May 2019, we initiated a Phase I clinical trial of a recombinant long-acting growth hormone (development code: JR-142).

(2) Explanation on financial status

(i) Status of assets, liabilities and net assets

As of September 30, 2019, total assets amounted to 45,626 million yen (an increase of 3,109 million yen from March 31, 2019), total liabilities were 14,350 million yen (an increase of 2,707 million yen from March 31, 2019), and net assets were 31,276 million yen (an increase of 401 million yen from March 31, 2019).

Current assets increased by 266 million yen from March 31, 2019 to 27,635 million yen despite a decrease in accounts receivable and owing to an increase in cash and deposits and inventories. Non-current assets increased by 2,843 million yen from March 31, 2019 to 17,990 million yen, mainly due to an increase of property, plants, and equipment related to research.

Current liabilities increased by 1,002 million yen from March 31, 2019 to 9,686 million yen, mainly due to increases in short-term loans payable. Non-current liabilities increased by 1,705 million yen from March 31, 2019 to 4,663 million yen, mainly due to an increase in line with the expansion of these research facilities. Borrowing also increased in line with the expansion of these research facilities.

Net assets increased by 401 million yen from March 31, 2019 to 31,276 million yen, due to the recording of profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 66.9% as of September 30, 2019, a decrease of 4.2 percentage point from March 31, 2019.

(ii) Status of cash flows

Cash and cash equivalents stood at 9,968 million yen as of September 30, 2019, an increase of 1,876 million yen from March 31, 2019. The status of cash flows from operating, investing and financing activities and the main reasons for changes are as follows.

(Cash flows from operating activities)

Net cash provided by operating activities was 2,949 million yen (an increase of 576 million yen from the same period of the previous fiscal year). The main contributing factors were income before income taxes of 1,098 million yen, depreciation and amortization of 658 million yen, and a decrease of account receivable of 2,098 million yen.

(Cash flows from investing activities)

Net cash used in investing activities was 3,612 million yen (an increase of 3,948 million yen from the same period of the previous fiscal year). The main source of cash was proceeds from sales and redemption of securities of 240 million yen, while cash was mainly used for the purchase of property, plant and equipment of 3,746 million yen.

(Cash flows from financing activities)

Net cash provided by in financing activities was 2,595 million yen (an increase of 3,027 million yen from the same period of the previous fiscal year). Despite the payment of cash dividends of 525 million yen, short-term loans payable of 1,000 million yen and long-term loans payable of 2,200 million yen were increased.

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

For the six months ended September 30, 2019, sales of TEMCELL<sup>®</sup> HS Inj. surpassed the initial forecast, and net sales exceeded the initial forecasts. On the profit front, R&D expenditure significantly increased year on year in line with the initial forecast for the current fiscal year, however, operating income, ordinary income, and profit attributable to owners of parent increased compared to the initial forecast due to the effects of an increase in income and the curtailing of selling, general, and administrative expenses.

In terms of the consolidated forecast for FY2019, the Company is actively undertaking R&D activities at present and maintains the previous forecasted figures due to the possibility of breakthroughs in R&D that were not initially planned for the second half of the fiscal year. However, if revisions become necessary based on future business performance trends, JCR will promptly disclose those revisions. The consolidated forecasts for the fiscal year ending March 31, 2020 are as follows.

Consolidated forecasts for the fiscal year ending March 31, 2020

	Net Sales	Operating Income	Ordinary Income	Profit Attributable to Owners of Parent	Net income per Share
Fiscal Year ending Mar.31, 2020	Million Yen 26,400	Million Yen 5,140	Million Yen 5,150	Million Yen 4,080	Yen 132.38

## 2. Quarterly consolidated financial statements and important notes

### (1) Quarterly consolidated balance sheets

(Unit: Million yen)

	As of March 31, 2019	As of September 30, 2019
<b>Assets</b>		
Current assets		
Cash and deposit	7,836	10,013
Notes and accounts receivable—trade	8,835	6,736
Securities	661	431
Merchandise and finished goods	2,281	1,696
Work in process	1,473	3,563
Raw materials and supplies	5,363	4,716
Other	917	477
Total current assets	27,368	27,635
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	4,475	4,370
Land	3,882	5,664
Construction in progress	851	1,681
Other, net	1,852	1,900
Total property, plant and equipment	11,061	13,616
Intangible assets	110	288
Investments and other assets		
Investment securities	2,941	2,640
Other	1,059	1,468
Allowance for doubtful accounts	(24)	(23)
Total investments and other assets	3,975	4,084
Total non-current assets	15,147	17,990
Total assets	42,516	45,626
<b>Liabilities</b>		
Current liabilities		
Notes and accounts payable—trade	586	966
Short-term loans payable	3,630	4,980
Income taxes payable	801	572
Provisions for bonuses	666	787
Provision for directors' bonuses	77	38
Other	2,922	2,341
Total current liabilities	8,684	9,686
Non-current liabilities		
Long-term loans payable	1,850	3,700
Net defined benefit liability	710	725
Provision for loss on guarantees	240	121
Other	157	116
Total non-current liabilities	2,957	4,663
Total liabilities	11,642	14,350

(Unit: Million yen)

	As of March 31, 2019	As of September 30, 2019
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,922	10,890
Retained earnings	13,350	13,748
Treasury stock	(3,937)	(3,871)
Total shareholders' equity	29,397	29,829
Accumulated other comprehensive income		
Foreign currency translation adjustments	149	127
Valuation difference on available-for-sale securities	773	571
Remeasurements of defined benefit plans	(71)	(23)
Total accumulated other comprehensive income	851	675
Subscription rights to shares	435	585
Non-controlling interests	189	185
Total net assets	30,874	31,276
Total liabilities and net assets	42,516	45,626

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

	(Unit: Million yen)	
	Six months ended September 30, 2018	Six months ended September 30, 2019
Net sales	10,275	11,236
Cost of sales	2,995	3,173
Gross profit	7,280	8,063
Selling, general and administrative expenses	5,335	7,064
Operating income	1,945	998
Non-operating income		
Interest income	11	7
Dividends income	14	12
Foreign exchange gains	39	—
Other	12	9
Total non-operating income	77	28
Non-operating expenses		
Interest expenses	11	10
Foreign exchange losses	—	30
Other	5	4
Total non-operating expenses	16	46
Ordinary income	2,006	981
Extraordinary income		
Reversal of provision for loss on guarantees	56	118
Other	6	—
Total extraordinary income	63	118
Extraordinary loss		
Loss on disposal of non-current assets	37	2
Loss related to voluntary recalling of products	174	—
Other	2	—
Total extraordinary loss	214	2
Profit before income taxes	1,855	1,098
Income taxes – current	552	473
Income taxes – deferred	(71)	(299)
Total income taxes	481	173
Profit	1,374	924
Profit (Loss) attributable to non-controlling interests	(3)	1
Profit attributable to owners of parent	1,377	922



(Quarterly consolidated statements of comprehensive income)

(Unit: Million yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Profit	1,374	924
Other comprehensive income		
Valuation difference on available-for-sale securities	190	(201)
Foreign currency translation adjustment	1	(22)
Remeasurements of defined benefit plans, net of tax	10	48
Total other comprehensive income	203	(176)
Comprehensive income	1,577	747
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	1,573	746
Comprehensive income attributable to non-controlling interests	4	1

## (3) Quarterly consolidated statements of cash flow

(Unit: Million yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Cash flows from operating activities		
Profit before income taxes	1,855	1,098
Depreciation and amortization	642	658
Increase (decrease) in provision for loss on guarantees	(56)	(118)
Increase (decrease) in net defined benefit liability	(2)	23
Decrease (increase) in net defined benefit asset	52	7
Increase (decrease) in provision for bonuses	147	121
Share-based compensation expenses	—	175
Interest and dividends income	(26)	(19)
Interest expenses	11	10
Foreign exchange losses (gains)	(36)	23
Decrease (increase) in notes and accounts receivable — trade	462	2,098
Decrease (increase) in accounts receivable — other	76	25
Decrease (increase) in inventories	115	(860)
Increase (decrease) in accounts payable — trade	4	379
Increase (decrease) in accounts payable — other	(84)	195
Increase (decrease) in accrued consumption taxes	(51)	(334)
Other, net	39	135
Subtotal	3,148	3,619
Interest and dividends income received	27	21
Interest expenses paid	(10)	(10)
Income taxes refund (paid)	(792)	(680)
Net cash provided by (used in) operating activities	2,372	2,949
Cash flows from investing activities		
Proceeds from sales of securities of securities	611	240
Purchase of property, plant and equipment	(276)	(3,746)
Purchase of intangible assets	—	(106)
Purchase of investment securities	(0)	—
Other, net	1	(0)
Net cash provided by (used in) investing activities	335	(3,612)
Cash flows from financing activities		
Increase (decrease) in short-term loans payable	300	1,000
Proceeds from long-term loans payable	—	2,200
Repayment of long-term loans payable	(213)	—
Repayments of lease obligations	(100)	(88)
Net decrease (increase) in treasury stock	14	10
Cash dividends paid	(432)	(525)
Other, net	—	(1)
Net cash provided by (used in) financing activities	(432)	2,595
Effect of exchange rate change on cash and cash equivalents	31	(55)
Net increase (decrease) in cash and cash equivalents	2,308	1,876
Cash and cash equivalents at beginning of period	4,850	8,091
Cash and cash equivalents at end of period	7,158	9,968

- (4) Notes for quarterly consolidated financial statements  
(Notes for going concern assumption)  
None

(Notes for any significant changes in the amount of shareholders' equity)  
None

3. Others  
R&D Pipeline  
Recombinant drug products

Code	Status (Japan)	Indication	Remarks
JR-141 BBB-penetrating iduronate-2- sulfatase (rDNA origin)	Japan: Phase III Brazil: Phase II	Hunter syndrome (lysosomal storage disease)	ERT J-Brain Cargo®
JR-162 J-Brain Cargo® -applied acid $\alpha$ -glucosidase (rDNA origin)	Preclinical	Pompe disease (lysosomal storage disease)	ERT J-Brain Cargo® J-MIG System®
JR-171 BBB-penetrating $\alpha$ -L- iduronidase (rDNA origin)	Preclinical	Hurler syndrome (lysosomal storage disease)	ERT J-Brain Cargo® J-MIG System®
JR-441 BBB-penetrating heparan N-sulfatase	Preclinical	Sanfilippo syndrome type A (lysosomal storage disease)	ERT J-Brain Cargo® J-MIG System®
JR-131 Darbepoetin Alfa (rDNA origin)	Marketing Approval received	Renal anemia	Co-development with Kissei Pharmaceutical Co., Ltd. Biosimilar
JR-401X Somatropin (rDNA origin)	Phase III	SHOX deficiency	Expanded Indication of GROWJECT®
JR-142 Long-acting human Growth hormone (rDNA origin)	Phase I	Growth disorders	Long-acting human growth hormone product J-MIG System®
JR-041 Follicle stimulating hormone (rDNA origin)	Phase I / II	Infertility	Out-licensed to ASKA Pharmaceutical Co., Ltd.

Allogeneic regenerative medical products

Code	Status (Japan)	Indication	Remarks
JR-031EB Human mesenchymal stem cells	Suspended (Application withdrawn)	Epidermolysis bullosa	Expanded Indication of TEMCELL® HS Inj. Regenerative Medical Product
JR-031HIE Human mesenchymal stem cells	Phase I / II	Neonatal Hypoxic Ischemic Encephalopathy	Expanded Indication of TEMCELL® HS Inj. Regenerative Medical Product
JTR-161 / JR-161 Dental pulp stem cells (DPCs)	Phase I / II	Acute cerebral infarction	Co-development with Teijin Limited Regenerative Medical Product