

Financial Summary
Consolidated Financial Results for the Three Months Ended June 30, 2019 (1Q FY2019)
(Japanese standard)

July 25, 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
Person in charge of inquiries (Title) Corporate Officer, Executive Director Administration Division
(Name) Akihiro Haguchi TEL: 0797(32)8591
Scheduled date to file quarterly report: August 9, 2019
Scheduled date to commence dividend payments: -
Preparation of supplemental information for the financial summary for the quarterly financial results: None
Arrangement of briefing on the quarterly financial results: None

(Fractions smaller than one million yen omitted)

1. Consolidated Financial Results for 1Q FY2019 (Apr. 1, 2019 to June 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	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Three Months Ended June 30, 2019	5,155	10.2	461	(14.6)	467	(18.7)	369	30.8
June 30, 2018	4,677	6.6	539	(11.4)	574	(8.6)	282	(43.0)

(Reference) Comprehensive income: Three months ended June 30, 2019: 243 million yen ((29.1)%), Three months ended June 30, 2018: 343 million yen ((30.8)%)

	Net income per Share (basic)	Net Income per Share (diluted)
	Yen	Yen
Three Months Ended June 30, 2019	12.00	11.93
June 30, 2018	9.19	9.14

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
	Million yen	Million yen	%
As of June 30, 2019	41,658	30,600	72.0
March 31, 2019	42,516	30,874	71.1

(Reference) Shareholders' equity; As of Jun. 30, 2019: 29,977 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	-				
FY2019 (Forecast)		15.00	-	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.

Those of the quarter represent the changes on a year-on-year basis.)

	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
The second quarter (cumulative)	10,900	6.1	640	(67.1)	630	(68.6)	500	(63.7)	16.23
Year ending Mar. 31, 2020	26,400	14.0	5,140	3.5	5,150	1.6	4,080	9.8	132.47

(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 Three months ended June 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)	As of June 30, 2019	32,421,577 shares	As of Mar. 31, 2019	32,421,577 shares
2. Number of treasury stock as of the end of the term	As of June 30, 2019	1,614,412 shares	As of Mar. 31, 2019	1,622,379 shares
3. Average number of shares during the term (quarterly cumulative amount)	As of June 30, 2019	30,802,499 shares	As of June 30, 2019	30,761,381 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 2, "1. Qualitative information for the quarterly financial statements (3) Explanation on projections such as forecasts of consolidated financial results."

○ Table of Contents for Attached Material

1.	Qualitative information for the quarterly financial statements	2
(1)	Explanation on financial results	2
(2)	Explanation on financial status.....	3
(3)	Explanation on projections such as forecasts of consolidated financial results	3
2.	Quarterly consolidated financial statements and important notes.....	4
(1)	Quarterly consolidated balance sheets	4
(2)	Quarterly consolidated statements of income and quarterly consolidated statements of comprehensive income	6
	(Quarterly consolidated statements of income)	6
	(Quarterly consolidated statements of comprehensive income)	7
(3)	Notes for quarterly consolidated financial statements	8
	(Notes for going concern assumption)	8
	(Notes for any significant changes in the amount of shareholders' equity)	8

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 3,143 million yen (up 254 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 1,193 million yen (up 80 million yen year on year) and 712 million yen (up 169 million yen year on year). Moreover, sales of 65 million yen were recorded for Agalsidase Beta BS I.V. Infusion [JCR], a treatment for Fabry disease launched in November 2018. Overall, the Group total amounted to sales of 5,155 million yen (up 477 million yen year on year).

On the profit front, gross profit was 3,548 million yen (up 452 million yen year on year), tracking the increase in net sales. Selling, general and administrative (SG&A) expenses were higher (up 530 million yen year on year), including R&D expenditures of 1,279 million yen (up 453 million yen year on year). The higher SG&A expenses also reflected an increase in selling expenses associated with the increase in net sales. As a result, operating income was 461 million yen (down 78 million yen year on year) and ordinary income was 467 million yen (down 107 million yen year on year). Profit attributable to owners of parent rose 86 million yen year on year to 369 million yen. This increase reflected the absence in the three months ended June 30, 2019 of a loss on a voluntary recall related to medical devices that was recorded in the same period of the previous fiscal year.

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. Furthermore, JR-141 received orphan drug designation from the US Food and Drug Administration (FDA) in October 2018 and from 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) and a therapeutic enzyme for Hurler syndrome (development code: JR-171). Moreover, in September 2018, we initiated development of a BBB-penetrating therapeutic enzyme for the treatment of Sanfilippo syndrome type A (development code: JR-441). JR-441 is a new drug candidate to which J-Brain Cargo® is applied. 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) with Teijin Limited in July 2017. We initiated Phase I/II clinical trials of JTR-161 in October 2018. Also, in March 2019, we filed an application for additional marketing approval for TEMCELL® HS Inj. allogeneic bone marrow-derived mesenchymal stem cells for the indication of epidermolysis bullosa (development code: JR-031EB), which is currently the subject of an investigator initiated trial at the Osaka University Hospital. Furthermore, in July 2019, we commenced Phase I/II clinical trials of TEMCELL® HS Inj. for the additional indication of neonatal hypoxic ischemic encephalopathy (HIE) (development code: JR-031HIE).

Initiatives for core products

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). In September 2018, we filed an application for marketing approval for a proposed biosimilar to darbepoetin alfa, a long-acting erythropoiesis-stimulating agent (development code: JR-131), which we are jointly developing with Kissei Pharmaceutical Co., Ltd.

In addition to the foregoing, on the technology front, we have established manufacturing technologies for gene therapies. Looking ahead, we will promote the application of these technologies, along with our BBB penetration technology J-Brain Cargo®, to the development of new drugs and drug licensing activities.

(2) Explanation on financial status

As of June 30, 2019, total assets amounted to 41,658 million yen (a decrease of 858 million yen from March 31, 2019), total liabilities were 11,058 million yen (a decrease of 584 million yen from March 31, 2019), and net assets were 30,600 million yen (a decrease of 273 million yen from March 31, 2019).

Current assets decreased by 704 million yen from March 31, 2019 to 26,664 million yen, mainly due to a decrease in notes and accounts receivable-trade, which was partly offset by an increase in cash and deposits. Non-current assets decreased by 153 million yen from March 31, 2019 to 14,994 million yen, mainly due to decreases in property, plant and equipment and investment securities.

Current liabilities decreased by 197 million yen from March 31, 2019 to 8,486 million yen, mainly due to decreases in accounts payable-other and income taxes payable, which were partly offset by an increase in provision for bonuses. Non-current liabilities decreased by 386 million yen from March 31, 2019 to 2,571 million yen, mainly due to a decrease in long-term loans payable.

Net assets decreased by 273 million yen from March 31, 2019 to 30,600 million yen. This decrease was mainly due to the payment of dividends, despite the recording of profit attributable to owners of parent.

As a result, the equity ratio was 72.0% as of June 30, 2019, an increase of 0.9 percentage point from March 31, 2019.

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

Looking at consolidated financial results for the three months ended June 30, 2019, we posted higher earnings on higher net sales, which was largely in line with our initial forecasts. Accordingly, there have been no changes to the forecasts for the six months ending September 30, 2019 and the year ending March 31, 2020 announced on May 10, 2019.

2. Quarterly consolidated financial statements and important notes

(1) Quarterly consolidated balance sheets

(Unit: Million yen)

	As of March 31, 2019	As of June 30, 2019
Assets		
Current assets		
Cash and deposit	7,836	8,069
Notes and accounts receivable-trade	8,835	7,468
Securities	661	644
Merchandise and finished goods	2,281	1,423
Work in process	1,473	3,173
Raw materials and supplies	5,363	4,809
Other	917	1,075
Total current assets	27,368	26,664
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	4,475	4,396
Land	3,882	3,882
Construction in progress	851	765
Other, net	1,852	1,776
Total property, plant and equipment	11,061	10,820
Intangible assets	110	255
Investments and other assets		
Investment securities	2,941	2,699
Other	1,059	1,242
Allowance for doubtful accounts	(24)	(24)
Total investments and other assets	3,975	3,917
Total non-current assets	15,147	14,994
Total assets	42,516	41,658
Liabilities		
Current liabilities		
Notes and accounts payable-trade	586	795
Short-term loans payable	3,630	3,980
Income taxes payable	801	239
Provisions for bonuses	666	1,055
Provision for directors' bonuses	77	96
Other	2,922	2,319
Total current liabilities	8,684	8,486
Non-current liabilities		
Long-term loans payable	1,850	1,500
Provision for loss on guarantees	240	230
Net defined benefit liability	710	719
Other	157	121
Total non-current liabilities	2,957	2,571
Total liabilities	11,642	11,058

(Unit: Million yen)

	As of March 31, 2019	As of June 30, 2019
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,922	10,913
Retained earnings	13,350	13,195
Treasury stock	(3,937)	(3,918)
Total shareholders' equity	29,397	29,252
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	773	595
Foreign currency translation adjustments	149	158
Remeasurements of defined benefit plans	(71)	(28)
Total accumulated other comprehensive income	851	725
Subscription rights to shares	435	432
Non-controlling interests	189	190
Total net assets	30,874	30,600
Total liabilities and net assets	42,516	41,658

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

(Unit: Million yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Net sales	4,677	5,155
Cost of sales	1,581	1,607
Gross profit	3,096	3,548
Selling, general and administrative expenses		
Total selling, general and administrative expenses	2,556	3,087
Operating income	539	461
Non-operating income		
Interest income	5	3
Dividends income	14	12
Foreign exchange gains	20	-
Other	3	4
Total non-operating income	43	20
Non-operating expenses		
Interest expenses	5	5
Foreign exchange losses	-	7
Loss on redemption of securities	1	-
Other	1	1
Total non-operating expenses	8	13
Ordinary income	574	467
Extraordinary income		
Reversal of provision for loss on guarantees	8	9
Total extraordinary income	8	9
Extraordinary loss		
Loss related to voluntary recalling of products	172	-
Loss on disposal of non-current assets	0	-
Other	-	0
Total extraordinary loss	172	0
Profit before income taxes	410	476
Income taxes – current	233	191
Income taxes – deferred	(105)	(85)
Total income taxes	127	106
Profit	282	370
Profit attributable to non-controlling interests	0	0
Profit attributable to owners of parent	282	369

(Quarterly consolidated statements of comprehensive income)

(Unit: Million yen)

	Three months ended June 30, 2018	Three months ended June 30, 2019
Quarterly net profit	282	370
Other comprehensive income		
Valuation difference on available-for-sale securities	68	(178)
Foreign currency translation adjustment	(13)	8
Remeasurements of defined benefit plans, net of tax	5	43
Total other comprehensive income	60	(126)
Comprehensive income	343	243
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	343	243
Comprehensive income attributable to non-controlling interests	0	0

(3) Notes for quarterly consolidated financial statements

(Notes for going concern assumption)

None

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

None