Financial Summary Consolidated Financial Results for the Six Months Ended Sep. 30, 2018 (2Q FY2018) (Japanese standard)

October 25, 2018

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 inquires (Title) Corporate Officer, Executive Director Administration Division

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Scheduled date to file quarterly report: November 13, 2018

Scheduled date to commence dividend payments: December 10, 2018

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 Six Months Ended Sep. 30, 2018 (Apr. 1, 2018 to Sep. 30, 2018)

(1) Consolidated Operating Results (Cumulative)

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

		Net Sales		Operating Income		Operating Income		Ordinary Ir	ncome	Profit Attribut Owners of P	
Six N	Ionths Ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%		
Sep. 3	30, 2018	10,275	0.9	1,945	-20.5	2,006	-18.7	1,377	-26.8		
Sep. 3	30, 2017	10,187	19.4	2,447	78.5	2,469	81.2	1,881	84.1		

(Reference) Comprehensive income: Six months ended Sep. 30, 2018: 1,577 million yen (-18.2%), Six months ended Sep. 30, 2017: 1,929 million yen (136.3%)

	Net Income per Share	Net Income per Share
	(basic)	(diluted)
Six Months Ended	Yen	Yen
Sep. 30, 2018	44.76	44.50
Sep. 30, 2017	59.85	59.49

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
As of	Million yen	Million yen	%
Sep. 30, 2018	39,305	28,688	71.8
Mar. 31, 2018	38,398	27,528	70.3

(Reference) Shareholders' equity; As of Sep. 30, 2018: 28,205 million yen, As of Mar. 31, 2018: 26,999 million yen

2. Dividends

2. 2.1.1441145									
		Dividend per Share							
	1st quarter	2nd quarter	3rd quarter	Year-end	Annual				
	Yen	Yen	Yen	Yen	Yen				
FY2017	-	12.00	-	14.00	26.00				
FY2018	-	13.00							
FY2018 (Forecast)			-	13.00	26.00				

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

3. Consolidated Forecasts for the Fiscal Year Ending Mar. 31, 2019 (Apr. 1, 2018 – Mar. 31, 2019)

(Percentage figures represent changes from the previous year.)

							Profit Attrib	outable	Net
	Net Sale	S	Operating Ir	ncome	Ordinary Ir	come	to Owner	s of	Income
							Paren	t	per Share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Year ending Mar. 31, 2019	21,900	6.3	4,290	13.3	4,360	13.4	3,200	4.2	104.05

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

- * Note
- (1) There was no transfer of important subsidiaries (transfer of a specific subsidiary resulting in changes in the scope of the consolidation) during the six months ended Sep. 30, 2018.
- (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)

As of Sep.	32,421,577	As of Mar.	32,421,577
30, 2018	shares	31, 2018	shares
As of Sep.	1,632,131	As of Mar.	1,665,930
30, 2018	shares	31, 2018	shares
AprSep.	30,775,414	AprSep.	31,444,365
2018	shares	2017	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

An overview of the six months ended September 30, 2018 is as follows.

On the marketing front, sales for one of our main products, GROWJECT®, a recombinant human growth hormone product, increased to 5,845 million yen (up 243 million yen year on year). Sales of GROWJECT® were driven by increased sales volume, which outweighed a reduction in drug prices. Sales of Epoetin Alfa BS Inj. JCR, a recombinant human erythropoietin product, and TEMCELL® HS Inj., a regenerative medical product, both increased steadily to 2,166 million yen (up 68 million yen year on year) and to 989 million yen (up 403 million yen year on year), respectively. Revenue from licensing amounted to 1,054 million yen (down 570 million yen year on year), mainly because a portion of revenue from licensing that was expected to be recorded in the second half was brought forward to the first half. As a result, sales in the Pharmaceutical business segment amounted to 10,083 million yen (up 132 million yen year on year). Sales in the medical devices and laboratory equipment business were 192 million yen (down 44 million yen year on year). Overall, the group total amounted to sales of 10,275 million yen (up 88 million yen year on year).

Turning to profit, gross profit was 7,280 million yen (down 227 million yen year on year), mainly reflecting the year-on-year decrease in revenue from licensing. Despite undertaking efficient corporate management, selling, general and administrative expenses, including R&D expenditures of 1,824 million yen (up 12 million yen year on year), were higher (up 274 million yen year on year). As a result, operating income was 1,945 million yen (down 502 million yen year on year) and ordinary income was 2,006 million yen (down 463 million yen year on year). In addition, we recorded estimated expenses of 174 million yen for the voluntary recall of certain products in the medical devices and laboratory segment, as an extraordinary loss. Due to this impact, profit attributable to owners of parent amounted to 1,377 million yen (down 504 million yen year on year).

On the research and development front, 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 homeoboxcontaining gene (SHOX) deficiency. Moreover, on September 28, 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). JR-131 is being jointly developed with Kissei Pharmaceutical Co., Ltd. Moreover, in treatments for lysosomal storage diseases, a priority field for development, we obtained marketing approval for Agalsidase Beta BS I.V. Infusion [JCR] for Fabry disease (development code: JR-051) on September 21, 2018. JR-051 is Japan's first enzyme replacement therapy for lysosomal storage disorders. Also, we are conducting development of innovative new drugs that employ our unique blood-brain barrier (BBB) technology, J-Brain Cargo[®]. In June 2018, we started a Phase II clinical trial of a BBB-penetrating therapeutic enzyme for the treatment of Hunter Syndrome (development code: JR-141) in Brazil. The Phase III clinical trial of JR-141 was initiated in August in Japan. Following on from the foregoing, 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. We are successively developing treatments for 15 types of lysosomal storage diseases, including a therapeutic enzyme for Pompe disease (development code: JR-162) and a therapeutic enzyme for Hurler syndrome (development code: JR-171). We are considering global marketing for all of our therapeutic products for lysosomal storage diseases. Clinical development in the United States will be undertaken by JCR USA, Inc., a joint venture company we established with MEDIPAL HOLDINGS CORPORATION in the United States in January 2018.

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.

(2) Explanation on financial status

(i) Status of assets, liabilities and net assets

As of September 30, 2018, total assets amounted to 39,305 million yen (an increase of 906 million yen from March 31, 2018), total liabilities were 10,617 million yen (a decrease of 252 million yen from March 31, 2018) and net assets were 28,688 million yen (an increase of 1,159 million yen from March 31, 2018).

Current assets increased by 1,317 million yen from March 31, 2018 to 24,148 million yen, mainly due to an increase in cash and cash deposits, which was partly offset by decreases in notes and accounts receivable-

trade and inventories. Non-current assets decreased by 410 million yen from March 31, 2018 to 15,156 million yen, mainly due to a decrease in property, plant and equipment.

Current liabilities increased by 410 million yen from March 31, 2018 to 7,515 million yen, mainly reflecting an increase in short-term loans payable. Non-current liabilities decreased by 663 million yen from March 31, 2018 to 3,101 million yen, mainly due to decreases in long-term loans payable and long-term lease obligations.

Net assets increased by 1,159 million yen from March 31, 2018 to 28,688 million yen. This was due to the recording of profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 71.8% as of September 30, 2018, an increase of 1.5 percentage points from March 31, 2018.

(ii) Status of cash flows

Cash and cash equivalents stood at 7,158 million yen as of September 30, 2018, an increase of 2,308 million yen from March 31, 2018. 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 2,372 million yen (an increase of 542 million yen from the same period of the previous fiscal year). The main contributing factors were income before income taxes of 1,855 million yen and depreciation and amortization of 642 million yen, which were partly offset by income taxes paid of 792 million yen.

(Cash flows from investing activities)

Net cash provided by investing activities was 335 million yen (an increase of 1,743 million yen from net cash used of 1,407 million yen in the same period of the previous fiscal year). The main source of cash was proceeds from sales and redemption of securities of 611 million yen, while cash was mainly used for the purchase of property, plant and equipment of 276 million yen.

(Cash flows from financing activities)

Net cash used in financing activities was 432 million yen (a decrease of 1,079 million yen from the same period of the previous fiscal year). This was mainly due to the repayment of long-term loans payable of 213 million yen and cash dividends paid of 432 million yen. These cash outflows were partly offset by a net increase in short-term loans payable of 300 million yen.

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

For the six months ended September 30, 2018, sales of mainstay products such as GROWJECT[®], a recombinant human growth hormone, surpassed the initial forecast, and a portion of revenue from licensing that was initially expected to be recorded from the third quarter onward was realized in the six months ended September 30, 2018, as announced on September 27, 2018. Consequently, net sales and profits for the six months ended September 30, 2018 exceeded the initial forecasts.

There have been no changes to the consolidated forecasts for the fiscal year ending March 31, 2019 announced on May 11, 2018. 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, 2019 are as follows.

Consolidated forecasts for the fiscal year ending March 31, 2019

	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
Fiscal Year ending Mar. 31, 2019	21,900	4,290	4,360	3,200	104.05

Quarterly consolidated financial statements and important notes Quarterly consolidated balance sheets

		(Millions of yen)
	As of March 31, 2018	As of September 30, 2018
Assets		
Current assets		
Cash and deposit	4,895	7,203
Notes and accounts receivable-trade	7,103	6,640
Securities	1,217	851
Merchandise and finished goods	1,759	1,834
Work in process	1,790	2,119
Raw materials and supplies	5,474	4,900
Other	592	599
Total current assets	22,831	24,148
Non-current assets		
Property, plant and equipment		
Buildings and structrues, net	4,755	4,614
Land	3,882	3,882
Construction in progress	-	31
Other, net	2,215	2,006
Total property, plant and equipment	10,853	10,534
Intangible assets	112	99
Investments and other assets		
Investment securities	3,194	3,227
Other	1,429	1,320
Allowance for doubtful accounts	-22	-24
Total investments and other assets	4,600	4,522
Total non-current assets	15,567	15,156
Total assets	38,398	39,305
Liabilities		
Current liabilities		
Notes and accounts payable-trade	585	590
Short-term loans payable	2,893	3,530
Income taxes payable	887	646
Provisions for bonuses	560	708
Provision for directors' bonuses	80	40
Other	2,097	1,999
Total current liabilities	7,105	7,515
Non-current liabilities		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Long-term loans payable	2,500	1,950
Provision for loss on guarantees	315	258
Net defined benefit liability	641	674
Other	307	218
Total non-current liabilities	3,764	3,101
1 otal non-current madmides	3,704	10,617

(Millions	of ven)
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	As of March 31, 2018	As of September 30, 2018
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,947	10,930
Retained earnings	10,469	11,414
Treasury stock	-4,042	-3,960
Total shareholders' equity	26,435	27,446
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	462	653
Foreign currency translation adjustments	169	163
Remeasurements of defined benefit plans	-67	-57
Total accumulated other comprehensive income	563	758
Subscription rights to shares	344	293
Non-controlling interests	185	189
Total net assets	27,528	28,688
Total liabilities and net assets	38,398	39,305

(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, 2017	Six months ended September 30, 2018
Net sales	10,187	10,275
Cost of sales	2,679	2,995
Gross profit	7,508	7,280
Selling, general and administrative expenses		
Total selling, general and administrative expenses	5,060	5,335
Operating income	2,447	1,945
Non-operating income		
Interest income	10	11
Dividends income	14	14
Foreign exchange gains	7	39
Other	10	12
Total non-operating income	42	77
Non-operating expenses		
Interest expenses	12	11
Other	6	5
Total non-operating expenses	19	16
Ordinary income	2,469	2,006
Extraordinary income		
Reversal of provision for loss on guarantees	9	56
Other	0	6
Total extraordinary income	10	63
Extraordinary loss		
Loss on disposal of non-current assets	1	37
Loss related to voluntary recalling of products	-	174
Other		2
Total extraordinary loss	1	214
Profit before income taxes	2,478	1,855
Income taxes – current	712	552
Income taxes – deferred	-116	-71
Total income taxes	596	481
Profit	1,881	1,374
Profit attributable to non-controlling interests	0	-3
Profit attributable to owners of parent	1,881	1,377

(Quarterly consolidated statements of comprehensive income)

		(Millions of yen)
	Six months ended September 30, 2017	Six months ended September 30, 2018
Quarterly net profit	1,881	1,374
Other comprehensive income		
Valuation difference on available-for-sale securities	31	190
Foreign currency translation adjustment	-6	1
Remeasurements of defined benefit plans, net of tax	21	10
Total other comprehensive income	47	203
Comprehensive income	1,929	1,577
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	1,928	1,573
Comprehensive income attributable to non-controlling interests	0	4

(3) Quarterly consolidated statements of cash flow

	Six months ended September 30, 2017	Six months ended September 30, 2018
Cash flows from operating activities		•
Income before income taxes	2,478	1,855
Depreciation and amortization	652	642
Increase (decrease) in provision for loss on guarantees	-9	-56
Increase (decrease) in net defined benefit liability	28	-2
Decrease (increase) in net defined benefit asset	20	52
Increase (decrease) in provision for bonuses	109	147
Share-based compensation expenses	77	-
Interest and dividends income	-24	-26
Interest expenses	12	11
Foreign exchange losses (gains)	-2	-36
Decrease (increase) in notes and accounts receivable-trade	-693	462
Decrease (increase) in accounts receivable-other	268	76
Decrease (increase) in inventories	-1,417	115
Increase (decrease) in accounts payable-trade	18	4
Increase (decrease) in accounts payable-other	70	-84
Increase (decrease) in accrued consumption taxes	126	-51
Other, net	53	39
Subtotal	1,770	3,148
Interest and dividends income received	24	27
Interest expenses paid	-12	-10
Income taxes (paid) refund	48	-792
Net cash provided by (used in) operating activities	1,830	2,372
Cash flows from investing activities		·
Purchase of securities	-611	_
Proceeds from sales and redemption of securities	-	611
Purchase of property, plant and equipment	-310	-276
Purchase of investment securities	-448	-0
Other, net	-37	1
Net cash provided by (used in) investing activities	-1,407	335
Cash flows from financing activities		
Increase (decrease) in short-term loans payable	1,600	300
Repayment of long-term loans payable	-16	-213
Repayments of lease obligations	-105	-100
Net decrease (increase) in treasury stock	-2,609	14
Cash dividends paid	-379	-432
Net cash provided by (used in) financing activities	-1,511	-432
Effect of exchange rate change on cash and cash equivalents	2	31
Net increase (decrease) in cash and cash equivalents	-1,087	2,308
=		
Cash and cash equivalents at beginning of period Cash and cash equivalents at end of period	5,464 4,377	4,850 7,158

(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

(Additional information)

(Application of "Partial Amendments to Accounting Standard for Tax Effect Accounting, etc.") The Company has adopted "Partial Amendments to Accounting Standard for Tax Effect Accounting, etc." (Accounting Standards Board of Japan (ASBJ) Statement No. 28, February 16, 2018) from the beginning of the three months ended June 30, 2018. In accordance with this change, deferred tax assets are presented in "investments and other assets."

3. Others

R&D Pipeline Recombinant drug products

Code	Status	Indication	
Nonproprietary Name	(Japan)	Remarks	
JR-051	Marketing	Fabry disease (lysosomal storage disease)	
Alpha-galactosidase A (rDNA origin)	approval received	Enzyme replacement therapy (ERT) Biosimilar	
JR-141		Hunter syndrome (lysosomal storage disease)	
BBB-Penetrating Iduronate-2- sulfatase (rDNA origin)	Japan: Phase III Brazil: Phase II	ERT J-Brain Cargo [®]	
JR-162		Pompe disease (lysosomal storage disease)	
J-Brain Cargo® applied acid alpha-glucosidase (Blood Brain Barrier passage) (rDNA origin) Preclinical	ERT J-Brain Cargo® J-MIG System®		
JR-171 BBB-Penetrating acid alpha-L-Iduronidase (rDNA origin) Preclinical		Hurler syndrome (lysosomal storage disease)	
	Preclinical	ERT J-Brain Cargo® J-MIG System®	
JR-441 BBB-Penetrating Preclinical heparan N-sulfatase		Sanfilippo syndrome type A (lysosomal storage disease)	
	Preclinical	ERT J-Brain Cargo [®] J-MIG System [®]	
JR-131 Application for	Renal anemia		
Darbepoetin Alfa (rDNA origin)	marketing approval filed	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 Growth hormone (rDNA origin)		Growth disorders	
	Preclinical	Long-acting human growth hormone product J-MIG System®	
JR-041		Infertility	
Follicle stimulating hormone (rDNA origin)		Out-licensed to ASKA Pharmaceutical Co., Ltd.	

Allogeneic regenerative medical product

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Code	Status Indication			
Nonproprietary Name	(Japan)	Remarks		
JTR-161 / JR-161 Dental pulp stem cells (DPCs)	Phase I / II	Acute cerebral infarction		
		Co-development with Teijin Limited		