Financial Summary Consolidated Financial Results for the Nine Months Ended Dec. 31, 2018 (3Q FY2018) (Japanese standard)

January 31, 2019

Listed company name: JCR Pharmaceuticals Co., Ltd.

Listed stock exchange: Tokyo Stock Exchange

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

(Title) Representative Director, Chairman and President Representative

(Name) Shin Ashida

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Scheduled date to file quarterly report: February 14, 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 Q3 FY2018 (Apr. 1, 2018 to Dec. 31, 2018)

(1) Consolidated Operating Results (Cumulative)

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

	Net Sales Operating Income		Ordinary Income		Profit Attributable to Owners of Parent			
Nine Months Ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Dec. 31, 2018	15,528	1.8	2,522	- 23.6	2,616	- 21.8	1,867	- 24.8
Dec. 31, 2017	15,248	16.4	3,302	77.7	3,344	72.4	2,483	75.3

(Reference) Comprehensive income: Nine months ended Dec. 31, 2018: 2,005 million yen (-23.1%), Nine months ended Dec. 31, 2017: 2,607 million yen (86.5%)

	Net Income per Share (basic)	Net Income per Share (diluted)
Nine Months Ended	Yen	Yen
Dec. 31, 2018	60.66	60.30
Dec. 31, 2017	79.58	79.08

(2) Consolidated Financial Position

	Total Assets	Net Assets	Equity Ratio
As of	Million yen	Million yen	%
Dec. 31, 2018	39,523	28,863	71.4
Mar. 31, 2018	38,398	27,528	70.3

(Reference) Shareholders' equity; As of Dec. 31, 2018: 28,235 million yen, As of Mar. 31, 2018: 26,999 million yen

2. Dividends

2. Dividends										
		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 Attri	butable	Net
	Net Sales		Operating Income		Ordinary Income		to Owners of		Income
			1 0		_		Parent		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 nine months ended Dec. 31, 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 Dec. 31, 2018	32,421,577 shares	As of Mar. 31, 2018	32,421,577 shares
As of Dec. 31, 2018	1,630,431 shares	As of Mar. 31, 2018	1,665,930 shares
Apr Dec. 31,2018	30,780,291 shares	Apr Dec. 2017	31,210,967 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 nine months ended December 31, 2018 is as follows.

On the marketing front, sales for one of our main products, GROWJECT®, a recombinant human growth hormone product, increased to 9,051 million yen (up 275 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 3,462 million yen (up 289 million yen year on year) and to 1,554 million yen (up 440 million yen year on year), respectively. Moreover, Agalsidase Beta BS I.V. Infusion [JCR] for Fabry disease (development code: JR-051) was launched in November 2018 as Japan's first treatment for lysosomal storage disorders, with sales amounting 40 million yen. On the other hand, revenue from licensing amounted to 1,056 million yen (down 568 million yen year on year). As a result, sales in the Pharmaceutical business segment amounted to 15,282 million yen (up 367 million yen year on year). Sales in the medical devices and laboratory equipment business were 245 million yen (down 88 million yen year on year). Overall, the group total amounted to sales of 15,528 million yen (up 279 million yen year on year).

Turning to profit, gross profit was 10,920 million yen (down 72 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 2,972 million yen (up 145 million yen year on year), were higher (up707 million yen year on year). As a result, operating income was 2,522 million yen (down 780 million yen year on year) and ordinary income was 2,616 million yen (down 727 million yen year on year). In addition, we recorded estimated expenses of 178 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 1,867 million yen (down 616 million yen year on 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, as mentioned above, we launched sales of Agalsidase Beta BS I.V. Infusion [JCR]. Also, 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 the Phase III clinical trial in Japan was initiated in August, with registration of patients completed in December. Furthermore, JR-141 received orphan drug designation from the US Food and Drug Administration in October. Moreover, the report on results of Phase I/II clinical trials conducted in Japan was published as an academic paper in the electronic journal of the American Society of Gene and Cell Therapy. 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 disorders, including a therapeutic enzyme for Pompe disease (development code: JR-162) and a therapeutic enzyme for Hurler syndrome (development code: JR-171), and will develop them 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 our effort to expand the application for TEMCELL® HS Inj. allogenic bone marrow-derived mesenchymal stem cells for the indication of epidermolysis bullosa, which is currently the subject of an investigator initiated trial at the Osaka University Hospital, we received designation for the product as an orphan regenerative medical product by the Ministry of Health, Labour and Welfare on October 1, 2018, and we are now making preparations aimed at filing an application for marketing approval during FY2018.

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. Furthermore, 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), which we are jointly developing with Kissei Pharmaceutical Co., Ltd.

(2) Explanation on financial status

As of December 31, 2018, total assets amounted to 39,523 million yen (an increase of 1,124 million yen from March 31, 2018), total liabilities were 10,659 million yen (a decrease of 210 million yen from March 31, 2018) and net assets were 28,863 million yen (an increase of 1,334 million yen from March 31, 2018).

Current assets increased by 1,980 million yen from March 31, 2018 to 24,812 million yen, mainly due to increases in cash and cash deposits and inventories, which were partly offset by decrease in notes and accounts receivable-trade. Non-current assets decreased by 856 million yen from March 31, 2018 to 14,711 million yen, mainly due to decreases in property, plant and equipment and investment securities.

Current liabilities increased by 475 million yen from March 31, 2018 to 7,581 million yen, mainly reflecting an increase in short-term loans payable. Non-current liabilities decreased by 686 million yen from March 31, 2018 to 3,078 million yen, mainly due to decreases in long-term loans payable and long-term lease obligations.

Net assets increased by 1,334 million yen from March 31, 2018 to 28,863 million yen. This was mainly due to the recording of profit attributable to owners of parent, despite the payment of dividends.

As a result, the equity ratio was 71.4% as of December 31, 2018, an increase of 1.1 percentage points from March 31, 2018.

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

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

Quarterly consolidated financial statements and important notes Quarterly consolidated balance sheets

.,,	(Millions o		
	As of March 31, 2018	As of December 31, 2018	
Assets			
Current assets			
Cash and deposit	4,895	6,888	
Notes and accounts receivable-trade	7,103	6,771	
Securities	1,217	839	
Merchandise and finished goods	1,759	2,262	
Work in process	1,790	1,713	
Raw materials and supplies	5,474	5,638	
Other	592	698	
Total current assets	22,831	24,812	
Non-current assets			
Property, plant and equipment			
Buildings and structrues, net	4,755	4,539	
Land	3,882	3,882	
Construction in progress	-	154	
Other, net	2,215	2,01	
Total property, plant and equipment	10,853	10,58	
Intangible assets	112	9.	
Investments and other assets			
Investment securities	3,194	2,88	
Other	1,429	1,17	
Allowance for doubtful accounts	-22	-24	
Total investments and other assets	4,600	4,03	
Total non-current assets	15,567	14,71	
Total assets	38,398	39,52	
Liabilities		57,0 2	
Current liabilities			
Notes and accounts payable-trade	585	1,02	
Short-term loans payable	2,893	3,53	
Income taxes payable	887	10	
Provisions for bonuses	560	32	
Provision for directors' bonuses	80	6	
Other	2,097	2,54	
Total current liabilities	7,105	7,58	
Non-current liabilities	7,103	7,50	
Long-term loans payable	2,500	1,95	
Provision for loss on guarantees	315	1,93	
Net defined benefit liability	641	68	
Other	307	19	
Total non-current liabilities	3,764	3,078	
Total liabilities	10,870	10,65	

(Millions of yen)

		(Millions of yell)
	As of March 31, 2018	As of December 31, 2018
Net assets		
Shareholders' equity		
Capital stock	9,061	9,061
Capital surplus	10,947	10,930
Retained earnings	10,469	11,503
Treasury stock	-4,042	-3,956
Total shareholders' equity	26,435	27,539
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	462	577
Foreign currency translation adjustments	169	170
Remeasurements of defined benefit plans	-67	-51
Total accumulated other comprehensive income	563	695
Subscription rights to shares	344	437
Non-controlling interests	185	190
Total net assets	27,528	28,863
Total liabilities and net assets	38,398	39,523

(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 31,2017	Nine months ended December 31, 2018
Net sales	15,248	15,528
Cost of sales	4,255	4,607
Gross profit	10,993	10,920
Selling, general and administrative expenses		
Total selling, general and administrative expenses	7,690	8,397
Operating income	3,302	2,522
Non-operating income		
Interest income	14	15
Dividends income	25	25
Foreign exchange gains	8	32
Insurance income	11	39
Other	10	21
Total non-operating income	70	134
Non-operating expenses		
Interest expenses	20	16
Loss on redemption of securities	-	19
Other	8	4
Total non-operating expenses	29	40
Ordinary income	3,344	2,616
Extraordinary income		
Reversal of provision for loss on guarantees	14	66
Other	0	6
Total extraordinary income	15	72
Extraordinary loss		
Loss on disposal of non-current assets	20	37
Loss related to voluntary recalling of products	-	178
Other	-	2
Total extraordinary loss	20	218
Profit before income taxes	3,339	2,471
Income taxes – current	813	539
Income taxes – deferred	42	72
Total income taxes	856	612
Profit	2,483	1,859
Profit attributable to non-controlling interests	0	-7
Profit attributable to owners of parent	2,483	1,867
·		

(Quarterly consolidated statements of comprehensive income)

		(Millions of yen)
	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Quarterly net profit	2,483	1,859
Other comprehensive income		
Valuation difference on available-for-sale securities	82	114
Foreign currency translation adjustment	8	14
Remeasurements of defined benefit plans, net of tax	32	16
Total other comprehensive income	123	145
Comprehensive income	2,607	2,005
(Comprehensive income attributable to)		
Comprehensive income attributable to owners of parent	2,607	1,999
Comprehensive income attributable to non-controlling interests	0	5

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

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

(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."