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August 9, 2019

Summary of Consolidated Financial Results for the First Six Months of the Fiscal Year Ending December 31, 2019 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: <https://www.raqualia.com/>
Representative: Naoki Tani, President and CEO
Contact: Kiichiro Kawada, Director and Executive Vice President (TEL) +81-52-446-6100
Scheduled date of filing of quarterly securities report: August 9, 2019
Scheduled date of dividend payment: —
Supplementary documents for quarterly results: Yes
Quarterly results briefing: Yes (for institutional investors and analysts)

(Amounts are rounded down to the nearest million yen.)

1. Consolidated financial results for the first six months of the fiscal year ending December 31, 2019 (January 1, 2019 to June 30, 2019)

(1) Consolidated operating results (cumulative)

(Percentage figures represent changes from the same period of the previous fiscal year.)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	million yen	%	million yen	%	million yen	%	million yen	%
First six months ended June 30, 2019	545	22.4	(302)	-	(307)	-	(310)	-
June 30, 2018	445	(3.8)	(558)	-	(569)	-	(596)	-

Note: Comprehensive income Six months ended June 30, 2019: (280) million yen [-%]
Six months ended June 30, 2018: (627) million yen [-%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First six months ended June 30, 2019	yen (15.19)	yen -
June 30, 2018	(29.32)	-

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
June 30, 2019	4,095	3,951	96.0
December 31, 2018	4,052	3,857	94.9

Reference: Equity As of June 30, 2019: 3,932 million yen As of December 31, 2018: 3,844 million yen

2. Dividends

	Annual dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	yen	yen	yen	yen	yen
Fiscal year ended December 31, 2018	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2019	-	0.00			
Fiscal year ending December 31, 2019 (forecast)			-	0.00	0.00

Note: Revisions to the forecast of dividends most recently announced: None

3. Forecasts of consolidated financial results for the fiscal year ending December 31, 2019 (January 1, 2019 to December 31, 2019)

(Percentage figures represent year-on-year changes)

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent		Earnings per share (Basic)
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Fiscal year ending December 31, 2019	2,022	171.6	187	-	195	-	153	-	7.52

Note: Revisions to the forecasts of results most recently announced: None

* As the Company conducts performance management on an annualized basis, forecasts of results over a six-month period are omitted.

*** Notes**

- (1) Changes in significant subsidiaries during the first six months ended June 30, 2019 (changes in specified subsidiaries resulting in the change in scope of consolidation): None
- (2) Application of special accounting for preparing quarterly consolidated financial statements: None
- (3) Changes in accounting policies, changes in accounting estimates, and restatements of prior financial statements
 - a. Changes in accounting policies due to the revisions to accounting standards and other regulations: None
 - b. Changes in accounting policies due to other reasons: None
 - c. Changes in accounting estimates: None
 - d. Restatements of prior financial statements: None
- (4) Number of issued shares (common shares)

- a. Total number of issued shares at the end of the period (including treasury shares)

As of June 30, 2019	20,669,162 shares
As of December 31, 2018	20,388,389 shares

- b. Total number of treasury shares at the end of the period

As of June 30, 2019	50 shares
As of December 31, 2018	50 shares

- c. Average number of outstanding shares during the period (cumulative from the beginning of the fiscal year)

For the first six months ended June 30, 2019	20,416,921 shares
For the first six months ended June 30, 2018	20,349,554 shares

* **Quarterly financial results reports are exempt from quarterly review conducted by certified public accountants or an audit corporation.**

*** Appropriate use of financial forecasts and other special remarks**

(Caution concerning forward-looking statements)

Forward-looking statements provided in this document, including financial forecasts, are based on the information currently available to the Company and certain assumptions considered reasonable. Such statements are included without any guarantee as to their future achievement. Actual results, etc. may differ materially from the forecasts depending on various factors.

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1. Qualitative information regarding settlement of accounts for the first six months

(1) Qualitative information regarding consolidated operating results

1) Financial results

During the first six months ended June 30, 2019, the Group continued to show a steady overall performance. This is attributable to the milestone payment related to licensed-out programs received as well as the royalty income related to pet drug products and human drug product that has exceeded the Group's expectations.

As for tegoprazan (RQ-00000004/CJ-12420/brand name in South Korea (registered trademark in South Korea): K-CAB®; "tegoprazan"), which is the Group's first human drug product, licensee CJ HealthCare Corporation (South Korea) ("CJ HealthCare (South Korea)") started selling it in South Korea in March 2019 and posted steady sales growth.

The sales of the EP4 antagonist (GALLIPRANT®, grapiprant, RQ-00000007, AT-001; "GALLIPRANT®") licensed for pain management for pets remained strong. This achievement came from successful joint marketing promotions between Elanco Animal Health (U.S.) ("Elanco (U.S.)"), which is the animal drug division of Eli Lilly and Company, and Aratana Therapeutics Inc. (U.S.) ("Aratana (U.S.)"), which is the Group's licensee. Furthermore, in Europe, Elanco (U.S.) started selling GALLIPRANT® in March 2019 and generated steady results.

Meanwhile, Aratana (U.S.) has steadily increased the sales of our Ghrelin receptor agonist (ENTYCE®, capromorelin, RQ-00000005, AT-002), which has an indication for anorexia management for dogs, and constantly received inquiries from veterinary clinics and other customers.

Regarding the serotonin 5-HT_{2A} and dopamine D₂ receptor blocker (ziprasidone) licensed as a treatment for schizophrenia, Meiji Seika Pharma Co., Ltd. has started Phase III clinical trials in Japan.

In our industry-academia-government collaboration activities, we aim to bring our drug discovery research activities to the next level in several programs, starting with the collaborative research with a national university corporation, Nagoya University ("Nagoya University"), on new drugs for heart failure.

Meanwhile, at the 32nd Annual Symposium on the Etiology, Pathogenesis, and Treatment of Parkinson Disease and Other Movement Disorders held in Phoenix, Arizona, U.S., in April 2019, Dr. Leslie J. Cloud and others from the Parkinson's and Movement Disorders Center of Virginia Commonwealth University made a poster presentation on the research results of the 5-HT₄ partial agonist (RQ-00000010). Of the evaluation trials regarding the efficacy and safety of RQ-00000010 for the gastroparesis and constipation, complications of Parkinson's disease patients, the results of the single dose study were presented and it was reported that the safety and tolerability of the drug were confirmed.

Furthermore, in May 2019, the Company started collaborative research on treatment drug for retinal vein occlusion (RVO) with the Molecular Pharmacology, Biofunctional Evaluation of Gifu Pharmaceutical University (Hideaki Hara, Professor and Vice President).

Meanwhile, RaQualia Innovations Inc., established in December 2018, has started specific initiatives to provide ventures and academia in the life science field with support for developing technologies and formulating intellectual property strategies.

Accordingly, financial results for the first six months, the reporting period, were as follows. Business revenue for the period was 545 million yen (up 22.4% year on year), operating loss totaled 302 million yen (compared with operating loss of 558 million yen a year earlier), ordinary loss totaled 307 million yen (compared with ordinary loss of 569 million yen a year earlier), and loss attributable to owners of parent was 310 million yen (compared with loss attributable to owners of parent of 596 million yen a year earlier). Total business expenses were 848 million yen (down 15.6% year on year). This total mainly consists of cost of business expenses (130 million yen, a 284.4% increase from the same quarter last year), research and development expenses (430 million yen, a 28.7% decrease from the same quarter last year) and other selling, general and administrative expenses (287 million yen, a 21.8% decrease from the same quarter last year).

2) Research and development activities

Research and development expenses of the entire Group during the first six months were 430 million yen. The main components of these activities were as follows:

(A) RaQualia's research and development and collaborative research

Exploratory and discovery phase

In a research project to evaluate a CRHR2 antagonist, the Company has discovered lead compounds and started an investigation of preclinical efficacy. The project has been carried out to create new mechanism-based drugs for heart failure in collaboration with the Department of Cardiology of the Faculty of Internal Medicine, Graduate School of Medicine, Nagoya University (under the supervision of Professor Toyooki Murohara and Associate Professor Mikito Takefuji).

The Company started collaborative research on treatment drug for RVO; retinal vein occlusion with Molecular Pharmacology, Biofunctional Evaluation of Gifu Pharmaceutical University (Hideaki Hara, Professor and Vice President).

For the first six months, there were no material changes other than what is stated above.

Preclinical development phase

For the first six months, there were no material changes to the preclinical development phase.

Clinical development phase

For the first six months, there were no material changes to the clinical development phase.

(B) Status of development at licensee corporation

a) Potassium-competitive acid blocker (RQ-00000004, tegoprazan)

The compound is under development by CJ HealthCare (South Korea). It obtained approval for the production and distribution of the compound for an indication for gastro-esophageal reflux disease (GERD) in July 2018, and started selling it in March 2019. To pursue additional indications, clinical trials have been conducted in South Korea. In addition, Shandong Luoxin Pharmaceutical Group (China), a licensee of CJ HealthCare (South Korea), started Phase III clinical trials in October 2018 in China. Furthermore, CJ HealthCare (South Korea) concluded a sub-license agreement with Vimedimex Medi-Pharma JSC (Vietnam) in December 2018, and with Laboratorios Carnot (Mexico) in February 2019.

b) EP4 antagonist (GALLIPRANT[®], RQ-00000007, AT-001, grapiprant, animal drug)

The compound was developed for pain management for pets by Aratana (U.S.). In January 2017, the Company started selling it in the U.S. through Aratana (U.S.) and Elanco (U.S.), posting steady sales growth. The Company also started selling the compound in Europe in March 2019.

c) EP4 antagonist (RQ-00000007, AAT-007, grapiprant)

The compound was licensed out to AskAt Inc. Ningbo NewBay Medical Technology Co., Ltd., which is a subsidiary in charge of clinical development for the sublicensee Ningbo Tai Kang Medical Technology Co., Ltd. in China, began Phase I clinical trials for the compound in the field of cancer in China in June 2019.

For the first six months, there were no material changes other than what is stated above.

(2) Qualitative information regarding consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of June 30, 2019 were 4,095 million yen, an increase of 43 million yen (up 1.1%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 260 million yen, an increase in accounts receivable - trade of 69 million yen and a decrease in investment securities of 264 million yen.

Liabilities

Total liabilities as of June 30, 2019 were 143 million yen, a decrease of 51 million yen (down 26.4%) from the end of the previous fiscal year. This is mainly attributable to a decrease in accounts payable - other of 53 million yen.

Net assets

Total net assets as of June 30, 2019 were 3,951 million yen, an increase of 94 million yen (up 2.5%) from the end of the previous fiscal year. This is mainly attributable to increases in capital stock and legal capital surplus of 368 million yen resulting from exercise of share acquisition rights, the recording of loss attributable to owners of parent of 310 million yen, an increase in valuation difference on available-for-sale securities of 29 million yen and an increase in share acquisition

rights of 6 million yen.

Consequently, the equity ratio was 96.0% (up 1.1 percentage points from the end of the previous fiscal year.)

2) Analysis of cash flows

The balance of cash and cash equivalents (“net cash”) as of June 30, 2019 amounted to 1,997 million yen (compared with 2,159 million yen a year earlier), an increase of 168 million yen from the end of the previous fiscal year.

The respective cash flows in the first six months and the factors thereof are as follows.

Cash flows from operating activities

Net cash used in operating activities was 391 million yen (up 1,792.3% year on year). This is mainly attributable to the recording of loss before income taxes of 301 million yen and depreciation of 68 million yen, a cash outflow from increases in notes and accounts receivable - trade of 69 million yen and prepaid expenses of 102 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 220 million yen (compared with 352 million yen used a year earlier). This is mainly attributable to the proceeds from sales of investment securities of 301 million yen, purchase of property, plant and equipment of 58 million yen, and purchase of intangible assets of 21 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 366 million yen (up 329.4% year on year). This is primarily due to the proceeds from issuance of shares resulting from exercise of share acquisition rights of 362 million yen and proceeds from issuance of share acquisition rights of 4 million yen.

(3) Qualitative information regarding consolidated earnings forecasts

There has been no change to the figures of the consolidated earnings forecasts for the fiscal year ending December 31, 2019 contained in the “Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2018 (JGAAP)” announced on February 8, 2019. The Company carefully examines business revenue and business expenses whenever necessary, and in the case that any revisions are made to the expected earnings forecasts due to changes made to the estimated amounts for the fiscal year under review, the Company will make relevant announcements immediately.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2018	As of June 30, 2019
Assets		
Current assets		
Cash and deposits	1,671,346	1,932,295
Accounts receivable - trade	680	69,871
Securities	168,193	75,603
Supplies	6,498	5,780
Advance payments - trade	8,737	4,615
Prepaid expenses	71,937	174,239
Other	34,858	25,729
Total current assets	1,962,252	2,288,135
Non-current assets		
Property, plant and equipment		
Buildings, net	88,268	82,898
Tools, furniture and fixtures, net	226,666	219,833
Leased assets, net	2,860	2,516
Total property, plant and equipment	317,795	305,248
Intangible assets		
Trademark right	4,533	4,170
Software	28,420	27,427
Other	1,032	1,032
Total intangible assets	33,985	32,631
Investments and other assets		
Investment securities	1,716,580	1,451,732
Long-term prepaid expenses	10,035	6,228
Other	11,652	11,618
Total investments and other assets	1,738,267	1,469,578
Total non-current assets	2,090,049	1,807,458
Total assets	4,052,302	4,095,594

(Thousands of yen)

	As of December 31, 2018	As of June 30, 2019
Liabilities		
Current liabilities		
Accounts payable - trade	–	169
Lease obligations	741	741
Accounts payable - other	98,618	45,613
Accrued expenses	47,805	52,102
Income taxes payable	14,237	11,144
Deposits received	3,089	5,902
Total current liabilities	164,492	115,673
Non-current liabilities		
Lease obligations	2,409	2,038
Asset retirement obligations	11,838	11,886
Deferred tax liabilities	16,474	14,160
Total non-current liabilities	30,722	28,086
Total liabilities	195,214	143,760
Net assets		
Shareholders' equity		
Capital stock	2,793,458	2,085,055
Capital surplus	2,983,241	2,274,838
Retained earnings	(1,890,201)	(414,565)
Treasury shares	(21)	(21)
Total shareholders' equity	3,886,476	3,945,307
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(41,901)	(12,484)
Total accumulated other comprehensive income	(41,901)	(12,484)
Share acquisition rights	12,512	19,012
Total net assets	3,857,087	3,951,834
Total liabilities and net assets	4,052,302	4,095,594

(2) Consolidated statement of income and consolidated statement of comprehensive income
Consolidated statement of income (cumulative)

(Thousands of yen)

	First six months ended June 30, 2018	First six months ended June 30, 2019
Business revenue	445,822	545,637
Business expenses		
Cost of business revenue	33,957	130,536
Research and development expenses	603,098	430,110
Other selling, general and administrative expenses	367,734	287,684
Total business expenses	1,004,790	848,331
Operating loss	(558,968)	(302,693)
Non-operating income		
Interest income	4,573	4,311
Interest on securities	13,915	18,033
Subsidy income	855	–
Gain on valuation of compound financial instruments	–	4,600
Other	2,905	645
Total non-operating income	22,248	27,590
Non-operating expenses		
Foreign exchange losses	30,083	23,623
Loss on valuation of compound financial instruments	1,390	–
Share issuance cost	1,024	8,926
Total non-operating expenses	32,498	32,549
Ordinary loss	(569,218)	(307,651)
Extraordinary income		
Gain on sales of investment securities	–	5,727
Total extraordinary income	–	5,727
Extraordinary losses		
Loss on redemption of investment securities	14,292	–
Total extraordinary losses	14,292	–
Loss before income taxes	(583,510)	(301,924)
Income taxes - current	13,395	8,269
Income taxes - deferred	(165)	(144)
Total income taxes	13,230	8,125
Loss	(596,741)	(310,050)
Profit attributable to non-controlling interests	–	–
Loss attributable to owners of parent	(596,741)	(310,050)

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First six months ended June 30, 2018	First six months ended June 30, 2019
Loss	(596,741)	(310,050)
Other comprehensive income		
Valuation difference on available-for-sale securities	(30,431)	29,416
Total other comprehensive income	(30,431)	29,416
Comprehensive income	(627,172)	(280,633)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(627,172)	(280,633)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First six months ended June 30, 2018	First six months ended June 30, 2019
Cash flows from operating activities		
Loss before income taxes	(583,510)	(301,924)
Depreciation	51,819	68,585
Interest income	(4,573)	(4,311)
Interest income on securities	(13,915)	(18,033)
Foreign exchange losses (gains)	28,559	27,324
Subsidy income	(855)	-
Loss (gain) on valuation of compound financial instruments	1,390	(4,600)
Share issuance cost	1,024	8,926
Loss (gain) on sales of investment securities	-	(5,727)
Loss (gain) on redemption of investment securities	14,292	-
Decrease (increase) in notes and accounts receivable - trade	447,902	(69,190)
Decrease (increase) in inventories	453	717
Increase (decrease) in notes and accounts payable - trade	16,342	169
Decrease (increase) in advance payments	175,447	4,122
Decrease (increase) in prepaid expenses	(103,619)	(102,521)
Increase (decrease) in accounts payable - other	(18,317)	(28,049)
Decrease (increase) in consumption taxes refund receivable	(14,984)	4,551
Increase (decrease) in accrued consumption taxes	(13,907)	-
Other, net	(7,110)	18,734
Subtotal	(23,561)	(401,225)
Interest and dividend income received	18,579	22,778
Proceeds from subsidy income	855	-
Income taxes paid	(16,554)	(12,896)
Net cash provided by (used in) operating activities	(20,681)	(391,343)
Cash flows from investing activities		
Proceeds from redemption of securities	113,040	-
Purchase of property, plant and equipment	(153,904)	(58,687)
Purchase of intangible assets	-	(21,408)
Purchase of investment securities	(516,583)	-
Proceeds from sales of investment securities	-	301,439
Proceeds from redemption of investment securities	210,860	-
Other, net	(6,313)	(433)
Net cash provided by (used in) investing activities	(352,901)	220,909
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	85,262	362,042
Proceeds from issuance of share acquisition rights	-	4,412
Repayments of lease obligations	-	(370)
Net cash provided by (used in) financing activities	85,262	366,083
Effect of exchange rate change on cash and cash equivalents	(26,172)	(27,291)
Net increase (decrease) in cash and cash equivalents	(314,493)	168,358
Cash and cash equivalents at beginning of period	2,473,916	1,829,540
Cash and cash equivalents at end of period	2,159,422	1,997,899

(4) Notes to quarterly consolidated financial statements

Notes on premise of going concern

No items to report.

Notes on significant changes in the amount of shareholders' equity

No items to report.

Segment information, etc.

[Segment information]

- I. For the first six months ended June 30, 2018 (January 1, 2018 to June 30, 2018)
This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.
- II. For the first six months ended June 30, 2019 (January 1, 2019 to June 30, 2019)
This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.