August 10, 2018

Summary of Consolidated Financial Results for the First Six Months of the Fiscal Year Ending December 31, 2018 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: http://www.raqualia.com/
Representative: Naoki Tani, President and CEO
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Scheduled date of filing of quarterly securities report: August 10, 2018
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, 2018 (January 1, 2018 to June 30, 2018)

(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	
First six months ended	million yen	%	million yen	%	million yen	%	million yen	%
June 30, 2018	445	(3.8)	(558)	—	(569)	—	(596)	—
June 30, 2017	463	—	(352)	—	(300)	—	(287)	—

Note: Comprehensive income Six months ended June 30, 2018: (627) million yen [–%]
Six months ended June 30, 2017: (319) million yen [–%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First six months ended	yen	yen
June 30, 2018	(29.32)	—
June 30, 2017	(14.99)	—

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
June 30, 2018	4,609	4,345	94.0	212.66
December 31, 2017	5,064	4,887	96.2	240.00

Reference: Equity As of June 30, 2018: 4,333 million yen As of December 31, 2017: 4,870 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, 2017	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2018	—	0.00			
Fiscal year ending December 31, 2018 (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, 2018 (January 1, 2018 to December 31, 2018)

(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, 2018	1,388	(2.2)	(698)	—	(680)	—	(686)	—	(33.84)

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

* As the Company manages financial results annually, forecasts of results over a six-month period are omitted.

*** Notes**

(1) Changes in significant subsidiaries during the first six months ended June 30, 2018 (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, 2018	20,376,192 shares
As of December 31, 2017	20,295,236 shares

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

As of June 30, 2018	50 shares
As of December 31, 2017	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, 2018	20,349,554 shares
For the first six months ended June 30, 2017	19,159,051 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.

Contents of attachment

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, 2018, the Japanese economy continued to gradually expand thanks to solid export growth, strong consumer spending, labor-saving-oriented corporate capital investment, etc. However, uncertainty surrounding the Japanese economy began to rise due to the increased cost burden of companies and individuals as a result of a rise in crude oil prices for the first time in three and half years, in addition to worsening economic disputes between the U.S. and China, concerns about a downturn in the European economy, growing geopolitical risks in the Middle East and other factors.

In the pharmaceutical sector, domestic pharmaceutical companies actively sought to buy or sell mainly long-listed drug products or businesses, pursuing business restructuring, with a focus on products whose patents had expired. The movements toward becoming specialty pharmaceutical companies specializing in the fields of specific disease and establishing carve-out ventures have a non-negligible effect on the licensing-out activities of drug discovery venture companies such as the Group.

Against this backdrop, the Group pushed ahead with research and development and sales activities, aiming to continuously generate compounds developed as pharmaceuticals, to expand its research and development portfolio, and to license out developed compounds.

During the period under review, the Company decided to postpone the establishment of a joint venture company with ZTE Coming Biotech Co., Ltd. (headquartered in China; "ZTE Biotech (China)") which was initially scheduled for May 2018. The aim of this joint venture company is to engage in clinical development of 5-HT_4 partial agonist (RQ-00000010) and 5-HT_{2B} antagonist (RQ-00310941; hereinafter "RQ-941") in China. The reason for this postponement is the organizational review of the ZTE Group to deal with sanctions imposed as a result of a false report on the issue of the illegal export of telecommunications equipment to North Korea and Iran by ZTE Corporation ("ZTE"), a major company of the ZTE Group. The Group will continue to cooperate with ZTE Biotech (China) in its efforts to establish a joint venture company by the end of 2018.

In addition, at "Digestive Disease Week (DDW) 2018" held in Washington, D.C., the U.S., in June 2018, the Company made a poster presentation on the results of Phase I clinical trials of RQ-941 in the U.K. While they were short-duration trials (two weeks) on a small number of patients, the results suggested RQ-941's potential as a drug to improve IBS-like symptoms of IBD and treat IBS. The Group will work to improve the value of RQ-941 with a new mechanism of action and actively implement licensing activities while aiming to contribute to medical care by placing a new drug originally developed by the Group on the market as soon as possible.

Accordingly, financial results for the first six months, the reporting period, were as follows. Business revenue for the period was 445 million yen (down 3.8% year on year), operating loss totaled 558 million yen (compared with operating loss of 352 million yen a year earlier), ordinary loss totaled 569 million yen (compared with ordinary loss of 300 million yen a year earlier), and loss attributable to owners of parent was 596 million yen (compared with loss attributable to owners of parent of 287 million yen a year earlier). Total business expenses were 1,004 million yen (up 23.1% year on year). This total mainly consists of research and development expenses (603 million yen, a 53.3% increase from the same quarter last year) and other selling, general and administrative expenses (367 million yen, a 22.4% increase from the same quarter last year). Phase I clinical trial expenses incurred in the U.K. and royalty payments under the patent license agreement are recorded under the research and development expenses and other selling, general and administrative expenses, respectively. In the first six months, interest on securities of 13 million yen, foreign exchange losses of 30 million yen, and loss on redemption of investment securities of 14 million yen were recognized.

2) Research and development activities

Research and development expenses of the entire Group during the first six months were 603 million yen. The main components of these activities were as follows:

i. RaQualia's research and development and collaborative research

Exploratory and discovery phase

In a project to evaluate a selective sodium channel blocker compound for indications such as inflammatory pain, the Company has discovered lead compounds and has been carrying out investigation of preclinical efficacy.

The Company also conducts collaborative research with pharmaceutical companies, etc. In March 2018, the Company received a lump-sum payment associated with a milestone achievement in collaborative research with Asahi Kasei Pharma Corporation ("Asahi Kasei Pharma") and concluded a license agreement with them. Asahi Kasei Pharma will perform development of curative medicines using this compound as an active ingredient.

The Company continued collaborative research with two companies.

Company	Start date	Content
Interprotein Corporation	February 2013	Collaboration on a specific protein-protein interaction (PPI) inhibitor for pain treatments
XuanZhu Pharma Co., Ltd.	December 2015	Collaboration on a specific ion channel target for pain treatments

Preclinical development phase

(a) Ghrelin receptor agonist (RQ-00433412)

The compound is under development for cancer-related anorexia/cachexia syndrome. The Company has completed investigation of preclinical efficacy and has not detected any inadequacy for moving on to the next stage of performing preclinical development study.

(b) TRPM8 blocker compounds (RQ-00434739)

The compound is under development for neuropathic pain (chemotherapy-induced cold allodynia). The Company has completed investigation of preclinical efficacy and has not detected any inadequacy for moving on to the next stage of performing preclinical development study.

(c) Motilin receptor agonist (RQ-00201894)

The compound is under development for gastroparesis, functional dyspepsia and post-operative ileus. The Company has completed the preclinical studies, including in vivo pharmacology studies, metabolism and pharmacokinetics studies, toxicity studies (GLP) and safety pharmacology studies (GLP), which were the prerequisite studies for Phase I clinical trials. So far, the Company has not detected any inadequacy for moving on to the next clinical development stage.

Clinical development phase

(a) 5-HT_4 partial agonist (RQ-00000010)

The compound is under development for gastroparesis, functional dyspepsia and chronic constipation. In August 2016, Virginia Commonwealth University, Parkinson's and Movement Disorders Center ("VCU") of the United States, a research partner of the Company, launched investigator-initiated clinical trials of the compound. These trials, while obtaining a research grant from The Michael J. Fox Foundation for Parkinson's Research, are currently under way as a clinical research program aimed to examine the safety and efficacy of the compound for managing gastroparesis, a complication of Parkinson's disease patients. The joint venture company formed with ZTE Biotech (China) is scheduled to carry out relevant development mainly in China.

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

The compound is under development for gastro-esophageal reflux disease (RE/NERD), and the Company completed the Phase I clinical trials in Japan, following those in the U.S. Utilizing data on clinical trials in South Korea where development has been underway, we will continue consultations toward licensing out the compound.

(c) 5-HT_{2B} antagonist (RQ-00310941)

Regarding this compound under development for irritable bowel syndrome with diarrhea (IBS-D) as a target indication, the Phase I clinical trials (for healthy adults and patients) and the preparation of a clinical trial summary report have been completed in the U.K. The joint venture company formed with ZTE Biotech (China) is scheduled to carry out relevant development mainly in China.

ii. Status of development at licensee corporation

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

The compound is under development primarily for gastro-esophageal reflux disease (RE/NERD) by CJ HealthCare Corporation (South Korea) ("CJ HealthCare (South Korea)"), and that company applied to South Korea's Ministry of Food and Drug Safety ("MFDS") for approval in August 2017. After it passes the new-drug approval procedure and gets listed in that country's National Health Insurance Service drug price list, it is scheduled to be launched in

December 2018. In addition, development continued smoothly in China.

(b) Serotonin 5-HT_{2A} and dopamine D_2 receptor blocker (ziprasidone)
The compound is under development for schizophrenia by Meiji Seika Pharma Co., Ltd., and is undergoing Phase III clinical trials in Japan. The agent has been marketed in 75 countries by Pfizer Inc. (U.S.), and accepted as a first-choice drug in its class according to guidelines for the treatment of mental disorders in the United States.

(c) EP4 antagonist (Galliprant®, RQ-00000007, AT-001, grapiprant, animal drug)
The compound was developed for pain management for pets by our licensee, Aratana Therapeutics Inc. (U.S.) ("Aratana (U.S.)"). In January 2017, the Company started selling it in the U.S. through Aratana (U.S.) and Elanco Animal Health (U.S.) ("Elanco (U.S.)"). The Company also obtained approval for sale of this compound from the European Medicines Agency (EMA) in January 2018, and started to make relevant preparations for its sale in Europe.

(d) Ghrelin receptor agonist (Entyce®, RQ-00000005, AT-002, capromorelin, animal drug)
The compound was developed for anorexia management for pets by Aratana (U.S.) and was launched for sale in October 2017 by Aratana (U.S.). While continuing the program to develop the compound as a cat anorexia management drug, Aratana (U.S.) launched long-term toxicity studies on cats in December 2016.

(e) EP4 antagonist (RQ-00000007, AAT-007, grapiprant)
Preparations are currently underway at a licensee of AskAt Inc. ("AskAt") for implementing clinical trials.

(f) EP4 antagonist (RQ-00000008, AAT-008)
Preparations are currently underway at a licensee of AskAt for implementing clinical trials.

(g) Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076, AAT-076)
Preparations are currently underway at a licensee of AskAt for implementing clinical trials.

(h) Selective sodium channel blocker (no compound code disclosed)
The compound was licensed out to Maruho Co., Ltd. ("Maruho") in December 2017. Maruho will carry out development of curative medicines using this compound as an active ingredient.

(i) P2X7 receptor antagonist (RQ-00466479, AKP-23494954)
This compound was created through joint research with Asahi Kasei Pharma and licensed out when the research moved to the preclinical development phase in March 2018. Asahi Kasei Pharma will carry out relevant development to create a new therapeutic agent for neuropathic pain treatment using this compound as an active ingredient.

(2) Qualitative information regarding consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of June 30, 2018 were 4,609 million yen. The major components were 1,947 million yen in cash and deposits, 324 million yen in property, plant and equipment, and 1,863 million yen in investment securities.

Liabilities

Total liabilities as of June 30, 2018 were 263 million yen. The major components were 153 million yen in accounts payable - other and 46 million yen in accrued expenses.

Net assets

Total net assets as of June 30, 2018 were 4,345 million yen. The major components were 2,786 million yen in capital stock, 2,975 million yen in capital surplus, negative 1,382 million yen in retained earnings, and negative 46 million yen in valuation difference on available-for-sale securities. The equity ratio was 94.0%.

2) Analysis of cash flows

The balance of cash and cash equivalents (hereafter "cash") as of June 30, 2018 amounted to 2,159 million yen (compared with 2,002 million yen a year earlier), a decrease of 314 million yen compared with the beginning of the fiscal year under review.

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 20 million yen (compared with 260 million yen used a year earlier). This is mainly attributable to the recording of loss before income taxes of 583 million yen, increase in prepaid expenses of 103 million yen, decrease in advance payments - trade of 175 million yen, and decrease in notes and accounts receivable - trade of 447 million yen.

Cash flows from investing activities

Net cash used in investing activities was 352 million yen (compared with 1,023 million yen provided a year earlier). This is mainly attributable to the proceeds from redemption of securities of 113 million yen, proceeds from redemption of investment securities of 210 million yen, purchase of investment securities of 516 million yen, and purchase of property, plant and equipment of 153 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 85 million yen (compared with 0 million yen provided a year earlier). This is attributable to the proceeds from issuance of shares resulting from exercise of subscription rights to shares.

(3) Qualitative information regarding consolidated earnings forecasts

There has been no change to the figures contained in the "Summary of Consolidated Financial Results for the Fiscal Year ended December 31, 2017 (JGAAP)" announced on February 9, 2018. 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, 2017	As of June 30, 2018
Assets		
Current assets		
Cash and deposits	2,268,024	1,947,491
Accounts receivable - trade	448,738	835
Securities	328,957	221,931
Supplies	5,153	4,699
Advance payments - trade	189,743	14,296
Prepaid expenses	62,150	165,151
Other	19,631	33,748
Total current assets	3,322,398	2,388,154
Non-current assets		
Property, plant and equipment		
Buildings, net	100,442	94,490
Tools, furniture and fixtures, net	115,237	226,795
Leased assets, net	–	3,203
Total property, plant and equipment	215,680	324,489
Intangible assets		
Trademark right	4,945	4,498
Software	4,383	7,397
Other	626	626
Total intangible assets	9,955	12,522
Investments and other assets		
Investment securities	1,503,443	1,863,611
Long-term prepaid expenses	2,126	9,046
Other	10,584	12,019
Total investments and other assets	1,516,154	1,884,676
Total non-current assets	1,741,790	2,221,688
Total assets	5,064,188	4,609,843

(Thousands of yen)

	As of December 31, 2017	As of June 30, 2018
Liabilities		
Current liabilities		
Accounts payable - trade	1,984	18,326
Lease obligations	–	741
Accounts payable - other	63,365	153,316
Accrued expenses	43,997	46,027
Income taxes payable	20,691	12,980
Accrued consumption taxes	13,907	–
Advances received	1,101	–
Deposits received	3,716	6,144
Other	–	951
Total current liabilities	148,763	238,488
Non-current liabilities		
Lease obligations	–	2,779
Deferred tax liabilities	15,730	10,912
Asset retirement obligations	11,743	11,791
Total non-current liabilities	27,474	25,483
Total liabilities	176,237	263,972
Net assets		
Shareholders' equity		
Capital stock	2,741,249	2,786,007
Capital surplus	2,931,032	2,975,790
Retained earnings	(785,652)	(1,382,393)
Treasury shares	(21)	(21)
Total shareholders' equity	4,886,607	4,379,381
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(15,826)	(46,258)
Total accumulated other comprehensive income	(15,826)	(46,258)
Subscription rights to shares	17,168	12,747
Total net assets	4,887,950	4,345,870
Total liabilities and net assets	5,064,188	4,609,843

(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, 2017	First six months ended June 30, 2018
Business revenue	463,568	445,822
Business expenses		
Cost of business revenue	122,793	33,957
Research and development expenses	393,335	603,098
Other selling, general and administrative expenses	300,328	367,734
Total business expenses	816,458	1,004,790
Operating loss	(352,889)	(558,968)
Non-operating income		
Interest income	1,625	4,573
Interest on securities	22,142	13,915
Subsidy income	44,072	855
Other	672	2,905
Total non-operating income	68,513	22,248
Non-operating expenses		
Foreign exchange losses	14,581	30,083
Loss on valuation of compound financial instruments	1,250	1,390
Share issuance cost	–	1,024
Other	100	–
Total non-operating expenses	15,931	32,498
Ordinary loss	(300,308)	(569,218)
Extraordinary income		
Gain on sales of investment securities	7,710	–
Gain on bargain purchase	3,278	–
Total extraordinary income	10,989	–
Extraordinary losses		
Loss on sales of investment securities	199	–
Loss on redemption of investment securities	–	14,292
Total extraordinary losses	199	14,292
Loss before income taxes	(289,518)	(583,510)
Income taxes - current	2,140	13,395
Income taxes - deferred	(4,516)	(165)
Total income taxes	(2,376)	13,230
Loss	(287,141)	(596,741)
Profit attributable to non-controlling interests	–	–
Loss attributable to owners of parent	(287,141)	(596,741)

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First six months ended June 30, 2017	First six months ended June 30, 2018
Loss	(287,141)	(596,741)
Other comprehensive income		
Valuation difference on available-for-sale securities	(31,923)	(30,431)
Total other comprehensive income	(31,923)	(30,431)
Comprehensive income	(319,064)	(627,172)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(319,064)	(627,172)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First six months ended June 30, 2017	First six months ended June 30, 2018
Cash flows from operating activities		
Loss before income taxes	(289,518)	(583,510)
Depreciation	39,243	51,819
Interest income	(1,625)	(4,573)
Interest income on securities	(22,142)	(13,915)
Foreign exchange losses (gains)	12,086	28,559
Subsidy income	(44,072)	(855)
Loss (gain) on valuation of compound financial instruments	1,250	1,390
Gain on bargain purchase	(3,278)	–
Loss (gain) on sales of investment securities	(7,489)	–
Loss (gain) on redemption of investment securities	–	14,292
Decrease (increase) in notes and accounts receivable - trade	67,766	447,902
Decrease (increase) in inventories	(1,594)	453
Increase (decrease) in notes and accounts payable - trade	9,379	16,342
Decrease (increase) in advance payments	(1,331)	175,447
Decrease (increase) in prepaid expenses	(104,766)	(103,619)
Increase (decrease) in accounts payable - other	(28,537)	(18,317)
Decrease (increase) in consumption taxes refund receivable	8,725	(14,984)
Increase (decrease) in accrued consumption taxes	–	(13,907)
Other, net	35,257	(6,085)
Subtotal	(330,647)	(23,561)
Interest and dividend income received	28,574	18,579
Proceeds from subsidy income	44,072	855
Income taxes paid	(2,296)	(16,554)
Net cash provided by (used in) operating activities	(260,296)	(20,681)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	340,462	–
Proceeds from redemption of securities	–	113,040
Purchase of property, plant and equipment	(47,281)	(153,904)
Purchase of intangible assets	(940)	–
Purchase of investment securities	(170,000)	(516,583)
Proceeds from sales of investment securities	886,886	–
Proceeds from redemption of investment securities	15,000	210,860
Other, net	(259)	(6,313)
Net cash provided by (used in) investing activities	1,023,867	(352,901)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	–	85,262
Proceeds from issuance of subscription rights to shares	60	–
Purchase of treasury shares	(21)	–
Net cash provided by (used in) financing activities	38	85,262
Effect of exchange rate change on cash and cash equivalents	(5,777)	(26,172)
Net increase (decrease) in cash and cash equivalents	757,831	(314,493)
Cash and cash equivalents at beginning of period	1,244,490	2,473,916
Cash and cash equivalents at end of period	2,002,321	2,159,422

(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.

Additional information

The Company resolved at the meeting of its Board of Directors held on January 29, 2018 to establish a joint venture company with ZTE Biotech (China) and it concluded an agreement relating to the establishment of the joint venture company on the same date.

However, due to various factors, the Company decided to postpone the date of establishment, May 2018 (Plan), as stated in the above-mentioned agreement relating to the establishment of the joint venture company, as follows:

1.Date of establishment

December 2018 (Plan)

2.Reason to postpone the date of establishment

Due to the effects of sanctions by the U.S. on ZTE, a major company of the ZTE Group, various procedures, internal and external, of the ZTE Group take time. While the Company checked with ZTE Biotech (China) for the status and schedule of the application for establishment originally planned in June 2018, as of now, the Company has not yet received a reply regarding the date of establishment.

Segment information, etc.

[Segment information]

I. For the first six months ended June 30, 2017 (January 1, 2017 to June 30, 2017)

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, 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.