August 10, 2017

Summary of Consolidated Financial Results for the First Six Months of the Fiscal Year Ending December 31, 2017 (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, 2017
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, 2017 (January 1, 2017 to June 30, 2017)

(1) Consolidated operating results (cumulative)

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
First six months ended	million yen	%	million yen	%	million yen	%	million yen	%
June 30, 2017	463	—	(352)	—	(300)	—	(287)	—
June 30, 2016	—	—	—	—	—	—	—	—

Note: Comprehensive income Six months ended June 30, 2017: (319) million yen [–%]
Six months ended June 30, 2016: – million yen [–%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First six months ended	yen	yen
June 30, 2017	(14.99)	—
June 30, 2016	—	—

* Year-on-year changes are not presented as the Company began preparing quarterly consolidated financial statements in the first quarter ended March 31, 2017.

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
June 30, 2017	3,829	3,661	95.2
December 31, 2016	—	—	—

Reference: Equity As of June 30, 2017: 3,644 million yen As of December 31, 2016: – million yen

* Year-on-year changes are not presented as the Company began preparing quarterly consolidated financial statements in the first quarter ended March 31, 2017.

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, 2016	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2017	—	0.00			
Fiscal year ending December 31, 2017 (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, 2017 (January 1, 2017 to December 31, 2017)

(Percentage figures represent year-on-year changes)

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent		Earnings per share (Basic)
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Fiscal year ending December 31, 2017	1,176	—	(791)	—	(777)	—	(778)	—	(40.45)

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

* As the Company manages financial results annually, forecasts of results for the first six months ended June 30, 2017 are omitted.

* Year-on-year changes are not presented as the Company began preparing quarterly consolidated financial statements in the first quarter ended March 31, 2017.

*** Notes**

(1) Changes in significant subsidiaries during the first six months ended June 30, 2017 (changes in specified subsidiaries resulting in the change in scope of consolidation): Yes

Newly included: 1 company TMRC Co., Ltd.

During the first quarter ended March 31, 2017, the Company made TMRC Co., Ltd. (TMRC) a wholly owned subsidiary company by share exchange. In conjunction with this, the Company began preparing quarterly consolidated financial statements in the first quarter ended March 31, 2017.

(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, 2017	19,246,450 shares
As of December 31, 2016	18,767,200 shares

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

As of June 30, 2017	50 shares
As of December 31, 2016	— 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, 2017	19,159,051 shares
For the first six months ended June 30, 2016	18,767,200 shares

*** Summary of quarterly financial results is not required to be subjected to quarterly reviews.**

*** 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, 2017, the Japanese economy was on a moderate recovery track with a revival centered on export-oriented companies, against a backdrop of global economic recovery. Meanwhile, the outlook for the Japanese economy remained uncertain amid concerns over U.S. monetary policies, political turmoil in Europe and potential deceleration of the Chinese economy and other emerging economies.

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 Company.

Against this backdrop, the Company 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.

As for the status at our licensees, Aratana Therapeutics Inc. (U.S.) ("Aratana (U.S.)") started, in January 2017, to sell Galliprant®, a pain management compound for dog osteoarthrosis, together with Elanco Animal Health (U.S.) ("Elanco (U.S.)," an animal pharmaceutical division of Eli Lilly and Company), and steadily increased the number of sales contracts. With regard to Entyce®, a ghrelin receptor agonist licensed out to Aratana (U.S.), it was announced that discussions on production transfer were held with the Center for Veterinary Medicine ("CVM") of the U.S. Food and Drug Administration ("FDA"). Necessary application documents for the production of Entyce® will be submitted again in accordance with the agreement with CVM. If these documents are accepted, Entyce® will be launched by fall 2017. In addition, Phase III clinical trials of potassium-competitive acid blocker, tegoprazan, licensed out to CJ HealthCare Corporation (South Korea) ("CJ HealthCare (South Korea)") continued smoothly in the country. As for a second generation (atypical) antipsychotic drug, ziprasidone, licensed out to Meiji Seika Pharma Co., Ltd., Phase III clinical trials are progressing smoothly in Japan.

As for industry-academia-government collaboration, our project was adopted as "2015 New Collaboration Business to Promote Commercial and Service Competitiveness (new collaboration business)" by the Ministry of Economy, Trade and Industry and "New Aichi Grant for Research, Development and Creation" in 2016 by Aichi Prefecture. Subsidy income for the second quarter ended June 30, 2017 amounted to 44 million yen.

Accordingly, financial results for the first six months, the reporting period, were as follows. Business revenue for the period was 463 million yen, operating loss totaled 352 million yen, ordinary loss totaled 300 million yen, loss attributable to owners of parent was 287 million yen and comprehensive income was negative 319 million yen. Total business expenses were 816 million yen, of which 122 million yen in royalty payments was recorded under cost of business revenue. Moreover, research and development expenses were 393 million yen and other selling, general and administrative expenses totaled 300 million yen. In the first six months, interest on securities of 22 million yen, subsidy income of 44 million yen, foreign exchange losses of 14 million yen, gain on sales of investment securities of 7 million yen, and gain on bargain purchase of 3 million yen were recognized.

2) Research and development activities

Research and development expenses of the Company during the first six months were 393 million yen. The main components of these activities were as follows:

i. RaQualia's research and development and collaborative research

Exploratory and discovery phase

The Company discovered two promising candidate compounds suitable for external medical preparations and continued conducting exploratory toxicity studies in a project to evaluate a selective sodium channel blocker compound for indications such as inflammatory pain and neuropathic pain. In addition, the Company explored new lead compounds used for oral medications and discovered several candidate compounds.

The Company continued collaborative research with three 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
Asahi Kasei Pharma Corporation	January 2016	Collaboration on a specific ion channel target for pain treatments

Note: The joint research agreement with EA Pharma Co., Ltd. expired on April 30, 2017. However, the compounds generated through this joint research continue to be under development by EA Pharma Co., Ltd., and the Company's rights remain valid even after the expiration of the said agreement.

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 lleus. 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.

(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)

For the compound, which is under development for irritable bowel syndrome with diarrhea (IBS-D), the Company launched the Phase I clinical trials for the first administration of the compound to human (involving healthy adults and patients) in July 2015 in U.K., which is currently ongoing.

(d) Anti-MRSA antibacterial agent (dalbavancin)

The Company is continuing activities for the licensing-out of this agent in Japan.

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 (South Korea), and is undergoing Phase III clinical trials in South Korea. In addition, preparations are under way to start its development 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 83 countries by Pfizer Inc. in the U.S., and is listed as a first-line drug in the U.S. Treatment Guidelines.

(c) EP4 antagonist (Galliprant®, RQ-00000007, AT-001, grapiprant, animal drug)

The compound was developed for pain management for pets by our licensee, Aratana (U.S.). In January 2017, the Company started selling it in the U.S. through Aratana (U.S.) and Elanco (U.S.). In Europe, the compound is now under application with the European Medicines Agency (EMA) for approval for sales and approval is expected to be obtained in 2017.

(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.). Regarding this compound, it was announced that discussions on production transfer were held with the CVM of the FDA. Necessary application documents for the production of Entyce® will be submitted again in accordance with the agreement with CVM. If these documents are accepted, Entyce® will be launched by fall 2017.

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. (Japan) for implementing clinical trials.

(f) Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076, AAT-076)

Preparations are currently underway at a licensee of AskAt, Inc. (Japan) for implementing clinical trials.

(2) Qualitative information regarding consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of June 30, 2017 were 3,829 million yen. The major components were 1,900 million yen in cash and deposits, 219 million yen in property, plant and equipment, and 1,169 million yen in investment securities.

Liabilities

Total liabilities as of June 30, 2017 were 168 million yen. The major components were 53 million yen in accounts payable - other and 43 million yen in accrued expenses.

Net assets

Total net assets as of June 30, 2017 were 3,661 million yen. The major components were 2,237 million yen in capital stock, 2,427 million yen in capital surplus, negative 1,014 million yen in retained earnings, and negative 5 million yen in valuation difference on available-for-sale securities. The equity ratio was 95.2%.

2) Analysis of cash flows

The balance of cash and cash equivalents (hereafter "cash") as of June 30, 2017 amounted to 2,002 million yen, an increase of 757 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 260 million yen. This is mainly attributable to the recording of loss before income taxes of 289 million yen, increase in prepaid expenses of 104 million yen, depreciation of 39 million yen, and decrease in notes and accounts receivable - trade of 67 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 1,023 million yen. This is mainly attributable to the proceeds from withdrawal of time deposits of 340 million yen, proceeds from sales of investment securities of 886 million yen, purchase of investment securities of 170 million yen, and purchase of property, plant and equipment of 47 million yen.

Cash flows from financing activities

Net cash provided by financing activities is mainly attributable to the proceeds from issuance of subscription rights to shares.

(3) Qualitative information regarding consolidated earnings forecasts

There has been no change to the figures contained in the "Record of Non-operating Income and Revisions of Consolidated and Non-consolidated Business Forecasts for the Fiscal Year Ending December 31, 2017" announced on May 11, 2017. 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 June 30, 2017
Assets	
Current assets	
Cash and deposits	1,900,069
Securities	112,251
Supplies	8,719
Advance payments - trade	206,568
Prepaid expenses	160,334
Other	27,486
Total current assets	2,415,431
Non-current assets	
Property, plant and equipment	
Buildings, net	107,607
Tools, furniture and fixtures, net	111,621
Total property, plant and equipment	219,229
Intangible assets	
Trademark right	5,392
Software	5,599
Other	626
Total intangible assets	11,618
Investments and other assets	
Investment securities	1,169,899
Long-term prepaid expenses	2,755
Other	11,051
Total investments and other assets	1,183,706
Total non-current assets	1,414,554
Total assets	3,829,985
Liabilities	
Current liabilities	
Accounts payable - trade	9,379
Accounts payable - other	53,900
Accrued expenses	43,206
Income taxes payable	10,274
Advances received	13,500
Deposits received	5,209
Total current liabilities	135,471
Non-current liabilities	
Asset retirement obligations	11,696
Deferred tax liabilities	21,226
Total non-current liabilities	32,922
Total liabilities	168,394
Net assets	
Shareholders' equity	
Capital stock	2,237,588
Capital surplus	2,427,371
Retained earnings	(1,014,671)
Treasury shares	(21)
Total shareholders' equity	3,650,266
Accumulated other comprehensive income	
Valuation difference on available-for-sale securities	(5,739)
Total accumulated other comprehensive income	(5,739)
Subscription rights to shares	17,064
Total net assets	3,661,591
Total liabilities and net assets	3,829,985

(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
Business revenue	463,568
Business expenses	
Cost of business revenue	122,793
Research and development expenses	393,335
Other selling, general and administrative expenses	300,328
Total business expenses	816,458
Operating loss	(352,889)
Non-operating income	
Interest income	1,625
Interest on securities	22,142
Subsidy income	44,072
Other	672
Total non-operating income	68,513
Non-operating expenses	
Foreign exchange losses	14,581
Loss on valuation of compound financial instruments	1,250
Other	100
Total non-operating expenses	15,931
Ordinary loss	(300,308)
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
Total extraordinary losses	199
Loss before income taxes	(289,518)
Income taxes - current	2,140
Income taxes - deferred	(4,516)
Total income taxes	(2,376)
Loss	(287,141)
Profit attributable to non-controlling interests	–
Loss attributable to owners of parent	(287,141)

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

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

(3) Consolidated statement of cash flows

(Thousands of yen)

	First six months ended June 30, 2017
Cash flows from operating activities	
Loss before income taxes	(289,518)
Depreciation	39,243
Interest income	(1,625)
Interest income on securities	(22,142)
Foreign exchange losses (gains)	12,086
Subsidy income	(44,072)
Loss (gain) on valuation of compound financial instruments	1,250
Gain on bargain purchase	(3,278)
Loss (gain) on sales of investment securities	(7,489)
Decrease (increase) in notes and accounts receivable - trade	67,766
Decrease (increase) in inventories	(1,594)
Increase (decrease) in notes and accounts payable - trade	9,379
Decrease (increase) in advance payments	(1,331)
Decrease (increase) in prepaid expenses	(104,766)
Increase (decrease) in accounts payable - other	(28,537)
Decrease (increase) in consumption taxes refund receivable	8,725
Other, net	35,257
Subtotal	(330,647)
Interest and dividend income received	28,574
Proceeds from subsidy income	44,072
Income taxes paid	(2,296)
Net cash provided by (used in) operating activities	(260,296)
Cash flows from investing activities	
Proceeds from withdrawal of time deposits	340,462
Purchase of property, plant and equipment	(47,281)
Purchase of intangible assets	(940)
Purchase of investment securities	(170,000)
Proceeds from sales of investment securities	886,886
Proceeds from redemption of investment securities	15,000
Other, net	(259)
Net cash provided by (used in) investing activities	1,023,867
Cash flows from financing activities	
Proceeds from issuance of subscription rights to shares	60
Purchase of treasury shares	(21)
Net cash provided by (used in) financing activities	38
Effect of exchange rate change on cash and cash equivalents	(5,777)
Net increase (decrease) in cash and cash equivalents	757,831
Cash and cash equivalents at beginning of period	1,244,490
Cash and cash equivalents at end of period	2,002,321

(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

During the first quarter ended March 31, 2017, the Company made TMRC a wholly owned subsidiary company following a share exchange on February 3, 2017. In conjunction with this, as of June 30, 2017, capital surplus increased by 189,783 thousand yen.

Additional information

Significant changes in the scope of consolidation

During the first quarter ended March 31, 2017, the Company made TMRC a wholly owned subsidiary company following a share exchange on February 3, 2017. In conjunction with this, TMRC is included in the scope of consolidation from the first quarter ended March 31, 2017.

Significant matters forming the basis of preparing the quarterly consolidated financial statements

1. Scope of consolidation
   Number of consolidated subsidiaries: 1
   Name of consolidated subsidiary: TMRC Co., Ltd.
2. Balance sheet date of consolidated subsidiary
   The balance sheet date of the consolidated subsidiary is the same as the consolidated balance sheet date.
3. Accounting policies
   (1) Valuation bases and methods of significant assets
      1) Securities
         i) Held-to-maturity securities
            Stated at amortized cost (straight-line method).
         ii) Available-for-sale securities
            Securities with readily determinable fair value
            Stated at fair value based on the market price as of the consolidated balance sheet date (valuation differences are recognized in net assets and the cost of sales is calculated by the moving-average method).
            Note however that available-for-sale securities denominated in foreign currencies are translated into Japanese yen using the spot exchange rate as of the consolidated balance sheet date and the translation differences are treated as valuation differences. Valuation differences are recognized in net assets.
      2) Derivatives
         Stated at fair value.
      3) Inventories
         Supplies
         Stated at cost using the last purchase cost method (balance sheet amounts are determined based on the method of writing down book value in accordance with decreased profitability of assets).
   (2) Depreciation and amortization of significant depreciable and amortizable assets
      1) Property, plant and equipment
         Depreciated by the declining balance method.
         Note however that facilities attached to buildings acquired on and after April 1, 2016, and buildings are depreciated by the straight-line method.
         The main useful lives are as follows:
         Facilities attached to buildings 8 to 15 years
         Tools, furniture and fixtures 4 to 6 years
      2) Intangible assets
         Amortized by the straight-line method.
         Software for internal use is amortized by the straight-line method over the internally estimated useful life (5 years).
      3) Long-term prepaid expenses
         Amortized by the straight-line method.
   (3) Criteria for translating assets or liabilities denominated in foreign currencies into Japanese currency
      Monetary claims and liabilities denominated in foreign currencies are translated into Japanese yen using the spot exchange rate as of the consolidated balance sheet date, and translation differences are included in gains or losses.
   (4) Scope of cash and cash equivalents in consolidated statements of cash flows
      Cash and cash equivalents consist of cash on hand, demand deposits, and short-term investments that are readily convertible to known amounts of cash and subject to insignificant risk of change in value and due within three months from the date of acquisition.
   (5) Other significant matters for preparing the consolidated financial statements
      Accounting for consumption taxes
      Consumption taxes and local consumption taxes are accounted for based on the tax exclusion method.

Application of Implementation Guidance on Recoverability of Deferred Tax Assets

Effective from the first quarter ended March 31, 2017, the Company has applied "Implementation Guidance on Recoverability of Deferred Tax Assets" (ASBJ Guidance No. 26, March 28, 2016).

Segment information, etc.

[Segment information]

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.