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Summary of Non-consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2016 (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
Contact: Hirobumi Takeuchi, Executive Director (TEL) +81-52-446-6100
Scheduled date of filing of quarterly securities report: May 13, 2016
Scheduled date of dividend payment: —
Supplementary documents for quarterly results: None
Quarterly results briefing: None

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

1. Non-consolidated financial results for the first three months of the fiscal year ending December 31, 2016 (January 1, 2016 to March 31, 2016)

(1) Non-consolidated operating results (cumulative)

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

	Net sales		Operating income		Ordinary income		Profit	
	million yen	%	million yen	%	million yen	%	million yen	%
First three months ended								
March 31, 2016	604	—	119	—	94	—	88	—
March 31, 2015	12	—	(460)	—	(427)	—	(412)	—

	Earnings per share (Basic)	Earnings per share (Diluted)
	yen	yen
First three months ended		
March 31, 2016	4.73	—
March 31, 2015	(27.78)	—

* The financial figure that the Company presents as business revenues in the statement of income is displayed above as net sales.

(2) Non-consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
March 31, 2016	4,826	4,550	94.1	241.87
December 31, 2015	4,752	4,514	94.8	239.96

Reference: Equity As of March 31, 2016: 4,539 million yen As of December 31, 2015: 4,503 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, 2015	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2016	—				
Fiscal year ending December 31, 2016 (forecast)		0.00	—	0.00	0.00

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

3. Forecasts of non-consolidated financial results for the fiscal year ending December 31, 2016 (January 1, 2016 to December 31, 2016)

(Percentage figures represent changes from the previous year.)

	Net sales		Operating income		Ordinary income		Profit		Earnings per share (Basic)
	million yen	%	million yen	%	million yen	%	million yen	%	yen
Fiscal year ending December 31, 2016	950	552.9	(819)	—	(799)	—	(805)	—	(42.95)

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 ending June 30, 2016 are omitted.

*** Notes**

- (1) Application of special accounting for preparing quarterly non-consolidated financial statements: None
- (2) 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
- (3) Number of issued shares (common shares)

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

As of March 31, 2016	18,767,200 shares
As of December 31, 2015	18,767,200 shares

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

As of March 31, 2016	— shares
As of December 31, 2015	— shares

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

For the first three months ended March 31, 2016	18,767,200 shares
For the first three months ended March 31, 2015	14,857,200 shares

*** Status of review procedures for quarterly reports**

This Summary of Quarterly Financial Results is exempt from the external auditor's review procedures for quarterly non-consolidated financial statements under the Financial Instruments and Exchange Act. However, review procedures for quarterly non-consolidated financial statements under the said Act are completed at the time of disclosure of this Summary of Quarterly Financial Results.

*** 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 three months

(1) Qualitative information regarding non-consolidated operating results

1) Overall trend

During the first three months, the Japanese yen's fast-paced appreciation against other major currencies began to adversely affect export-oriented companies' financial results, while the performance of the Chinese economy, until recently, a driving force behind the world economy, deteriorated. Thus, the Japanese economy is expected to experience challenging conditions going forward.

In the country's pharmaceutical sector, initiatives are now under way to rein in medical expenses in response to an aging society, as evidenced by the fact that the Ministry of Health, Labour and Welfare set a target of raising the volume-based market share of generic drugs to 80% or over by the end of fiscal 2020. In the fiscal 2016 National Health Insurance drug price revision, the average drug price was reduced by a significant 6.47%, meaning that the Japanese pharmaceutical industry is now faced with a challenging business environment. Consequently, individual pharmaceutical companies have been increasing their efforts in the selection process for compounds developed as pharmaceuticals. This situation has a non-negligible effect on the licensing 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.

On the business side, the Company's licensed partner Aratana Therapeutics Inc. (headquartered in the State of Kansas, U.S. and hereafter "Aratana (U.S.)") filed an application with the Food and Drug Administration of the U.S. (hereafter "FDA") for animal drug approval of the EP4 antagonist (hereafter "Galliprant®") and the Ghrelin receptor agonist ("hereafter "Entyce®").

As for Galliprant®, continuously under development at Aratana (U.S.) as a pain treatment drug for dog osteoarthritis, approval was obtained from the FDA in March 2016 with an application filed with the European Medicines Agency (EMA) for European region approval. Meanwhile, with regard to Entyce®, under development at Aratana (U.S.) as a treatment drug for dog anorexia, an application was filed with the FDA Center for Veterinary Medicine in March 2016 for animal drug approval. Thanks to the above-mentioned progress in its development activities, the Company recorded 592 million yen in milestone revenues in the first three months.

In the area of collaboration with academia, the Company relocated its entire drug discovery research division to the Higashiyama Campus of Nagoya University in the year ended December 31, 2015, marking a full-scale launch of research activities based on academic-industrial collaboration. Currently, multiple joint research activities are under way in such collaboration with Nagoya University.

Accordingly, financial results for the first three months, the reporting period, were as follows. Business revenue for the period was 604 million yen (business revenue of 12 million yen a year ago), operating income totaled 119 million yen (operating loss of 460 million yen a year earlier), ordinary income totaled 94 million yen (ordinary loss of 427 million yen a year earlier) and profit was 88 million yen (loss of 412 million yen a year earlier). Total business expenses were 484 million yen (an increase of 2.5% year on year), of which 117 million yen in royalty payments was recorded under cost of business revenue. Moreover, research and development expenses were 219 million yen (a decrease of 22.6% year on year) and other selling, general and administrative expenses totaled 148 million yen (down 22.0% year on year).

2) Research and development activities

Research and development expenses of the Company during the first three months were 219 million yen (down 22.6% year on year). The main components of these activities were as follows:

<RaQualia's research and development and collaborative research>

Exploratory and discovery phase

The Company continued to examine a suitable administration method for a compound discovered 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 and discovered several candidate compounds.

In a project to develop TRPM8 blocker compounds primarily for indications such as neuropathic pain, the Company continued an investigation of preclinical efficacy for clinical development candidates.

The Company continued collaborative research with four companies.

Company	Start date	Content
Ajinomoto Pharmaceuticals Co., Ltd. (Note)	October 2012	A specific ion channel target for gastrointestinal treatments
Interprotein Corporation	February 2013	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: Effective April 1, 2016, EA Pharma Co., Ltd. was established through the splitting off of a portion of Eisai Co., Ltd.'s gastrointestinal disease treatment business and its subsequent succession by Ajinomoto Pharmaceuticals Co., Ltd.

Preclinical development phase

(a) Ghrelin receptor agonist (RQ-00433412)

The compound is under development for an anorexia and cancerous cachexia. The Company has completed investigation of preclinical efficacy and is considering moving on to the next stage of performing preclinical development study.

(b) Motilin receptor agonist (RQ-00201894)

The compound is under development for GI motility disorders. The Company has completed the preclinical studies, including 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-HT₄ partial agonist (RQ-00000010)

The compound is under development for functional gastrointestinal disorders (FGID). The Company obtained IND approval from the U.S. Food and Drug Administration (FDA) to conduct investigator-initiated clinical trials at Virginia Commonwealth University (VCU) which the final preparations for conducting trials are currently under way.

(b) Acid pump antagonist (RQ-00000004, tegoprazan)

The compound is under development for gastro-esophageal reflux disease (GERD), and the Company completed the Phase I clinical trials in Japan, following those in the U.S., and finished preparing a clinical trial summary report in accordance with the guidelines. As a result of conducting clinical trials of the compound, we confirmed the favorable safety, tolerability and pharmacokinetic profiles and achieved results that revealed excellent pharmacological nature. Specifically, the compound showed significant strong gastric acid secretion inhibitive activity immediately after dosing, and the effect lasted for many hours (24-hour pH \geq 4 Retention time ratio = 90%). We will continue with our activities toward licensing out the compound.

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

For the compound, which is under development for diarrhea-predominant irritable bowel syndrome (IBS), 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)

In December 2010, the Company and Durata Therapeutics, Inc. (currently Allergan Inc.) entered into an agreement on the transfer of dalbavancin-related rights held by the former. Pursuant to the provisions of this rights transfer agreement, the Company re-acquired, effective June 23, 2015, dalbavancin-related rights that apply in Japan. The Company is now in the process of having consultations with the view to licensing out the agent in Japan. This agent was put on the U.S. market as a drug to treat acute bacterial skin and skin structure infections (ABSSSI) under the trademark of DALVANCETM. In Europe, in March 2015, we obtained regulatory approval for the distribution of this agent under the trademark of XYDALBATM.

<Status of development at licensee corporation>

(a) Acid pump antagonist (RQ-00000004, tegoprazan)

The compound is under development for gastro-esophageal reflux disease (GERD) by CJ Healthcare Corporation in South Korea, and is undergoing Phase III clinical trials in South Korea. In addition, preparations are under way to start its development in China at licensee corporation of CJ Healthcare Corporation.

(b) Serotonin 5-HT_{2A} and dopamine D₂ 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 already 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 is under development for pain management for pets by Aratana (U.S.). Following favorable results of clinical trials with dogs in the U.S., Aratana has obtained manufacturing and marketing approval with the FDA, and thereby the preparation for the commencement of sales this fall is underway. In February 2016, Aratana (U.S.) is proceeding with an application for an animal drug approval with European regulator.

(d) Ghrelin receptor agonist (Entyce®, RQ-00000005, AT-002, capromorelin, animal drug)

The compound is under development for anorexia management for pets by Aratana (U.S.). Following favorable results of clinical trials with dogs, Aratana (U.S.) is proceeding with an application for an animal drug approval with the FDA.

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

The compound was licensed out to AskAt, Inc., which concluded a license agreement with RMX Pharmaceutical Technology Co., Ltd. (China), a pharmaceutical venture company, in the field of pain treatments in China. Going forward, the development of the compound will be proceeded in China.

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

The compound was licensed out to AskAt, Inc., which concluded a license agreement with RMX Pharmaceutical Technology Co., Ltd. (China), a pharmaceutical venture company, in the field of pain treatments in China. Going forward, the development of the compound will be proceeded in China.

(2) Qualitative information regarding non-consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of March 31, 2016 were 4,826 million yen. The major components were 1,046 million yen in cash and deposits, 703 million yen in securities, and 1,811 million yen in investment securities.

Liabilities

Total liabilities as of March 31, 2016 were 275 million yen. The major components were 112 million yen in accounts payable - trade, 76 million yen in accounts payable - other, and 46 million yen in accrued expenses.

Net assets

Total net assets as of March 31, 2016 were 4,550 million yen. The major components were 9,806 million yen in capital stock, 5,090 million yen in capital surplus, negative 10,332 million yen in retained earnings, and negative 24 million yen in valuation difference on available-for-sale securities. The equity ratio was 94.1%.

2) Analysis of cash flows

The balance of cash and cash equivalents (hereafter “cash”) as of March 31, 2016 amounted to 1,437 million yen (compared with 1,718 million yen used a year earlier), a decrease of 805 million yen compared with the end of the previous fiscal year.

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

Cash flows from operating activities

Net cash used in operating activities was 420 million yen (compared with 722 million yen used a year earlier). This is mainly attributable to the recording of income before income taxes of 92 million yen, increase in notes and accounts receivable - trade of 504 million yen and increase in notes and accounts payable - trade of 112 million yen.

Cash flows from investing activities

Net cash used in investing activities was 351 million yen (compared with 454 million yen provided a year earlier). This is mainly attributable to the purchase of investment securities of 216 million yen and the purchase of securities of 200 million yen.

Cash flows from financing activities

There was no increase or decrease in cash resulting from financing activities.

(3) Qualitative Information Regarding Earnings Forecasts

There has been no change to the full-year earnings forecasts since the announcement of “Record of Non-Operating Income Due to Receipt of Grant and Revisions of Non-consolidated Business Forecasts for the Current Full Year” on April 28, 2016, as the expected earnings results remain in line with the announced forecasts.

2. Quarterly non-consolidated financial statements

(1) Non-consolidated balance sheet

(Thousands of yen)

	As of December 31, 2015	As of March 31, 2016
Assets		
Current assets		
Cash and deposits	1,840,239	1,046,369
Accounts receivable - trade	72,866	576,950
Securities	503,037	703,879
Supplies	7,148	5,068
Advance payments - trade	179,368	208,951
Prepaid expenses	65,488	137,970
Other	39,639	52,440
Total current assets	2,707,787	2,731,629
Non-current assets		
Property, plant and equipment		
Buildings, net	129,853	125,744
Tools, furniture and fixtures, net	131,437	128,074
Total property, plant and equipment	261,290	253,819
Intangible assets		
Trademark right	2,306	2,188
Software	8,213	7,651
Other	3,708	3,954
Total intangible assets	14,228	13,793
Investments and other assets		
Investment securities	1,751,779	1,811,326
Long-term prepaid expenses	5,479	4,460
Other	11,545	11,360
Total investments and other assets	1,768,805	1,827,147
Total non-current assets	2,044,324	2,094,760
Total assets	4,752,112	4,826,390
Liabilities		
Current liabilities		
Accounts payable - trade	-	112,577
Accounts payable - other	123,405	76,600
Accrued expenses	57,067	46,625
Income taxes payable	15,071	4,985
Deposits received	4,663	6,178
Total current liabilities	200,207	246,967
Non-current liabilities		
Asset retirement obligations	11,555	11,578
Deferred tax liabilities	25,985	17,184
Total non-current liabilities	37,540	28,763
Total liabilities	237,748	275,730
Net assets		
Shareholders' equity		
Capital stock	9,806,225	9,806,225
Capital surplus	5,090,225	5,090,225
Retained earnings	(10,421,274)	(10,332,496)
Total shareholders' equity	4,475,176	4,563,954
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	28,170	(24,708)
Total valuation and translation adjustments	28,170	(24,708)
Subscription rights to shares	11,017	11,413
Total net assets	4,514,364	4,550,659
Total liabilities and net assets	4,752,112	4,826,390

(2) Non-consolidated statement of income**Non-consolidated statement of income (cumulative)**

(Thousands of yen)

	First three months ended March 31, 2015	First three months ended March 31, 2016
Business revenue	12,500	604,600
Business expenses		
Cost of business revenue	–	117,630
Research and development expenses	283,276	219,217
Other selling, general and administrative expenses	189,934	148,054
Total business expenses	473,211	484,902
Operating income (loss)	(460,711)	119,697
Non-operating income		
Interest income	838	1,658
Interest on securities	33,846	13,675
Dividend income	186	–
Gain on sales of securities	1,075	–
Gain on valuation of compound financial instruments	2,676	9,710
Other	155	1,090
Total non-operating income	38,779	26,134
Non-operating expenses		
Foreign exchange losses	5,123	51,513
Total non-operating expenses	5,123	51,513
Ordinary income (loss)	(427,055)	94,318
Extraordinary income		
Gain on sales of investment securities	22,838	–
Total extraordinary income	22,838	–
Extraordinary losses		
Loss on redemption of investment securities	6,000	2,000
Total extraordinary losses	6,000	2,000
Income (loss) before income taxes	(410,216)	92,318
Income taxes - current	2,508	336
Income taxes - deferred	–	3,203
Total income taxes	2,508	3,540
Profit (loss)	(412,724)	88,778

(3) Non-consolidated statement of cash flows

(Thousands of yen)

	First three months ended March 31, 2015	First three months ended March 31, 2016
Cash flows from operating activities		
Income (loss) before income taxes	(410,216)	92,318
Depreciation	6,796	19,162
Interest income	(838)	(1,658)
Interest income on securities	(33,846)	(13,675)
Dividend income	(186)	–
Foreign exchange losses (gains)	5,068	37,865
Loss (gain) on sales of securities	(1,075)	–
Loss (gain) on valuation of compound financial instruments	(2,676)	(9,710)
Loss (gain) on sales of investment securities	(22,838)	–
Loss (gain) on redemption of investment securities	6,000	2,000
Decrease (increase) in notes and accounts receivable - trade	20,000	(504,083)
Decrease (increase) in inventories	707	2,080
Increase (decrease) in notes and accounts payable - trade	–	112,577
Decrease (increase) in advance payments	(63,702)	(29,583)
Decrease (increase) in prepaid expenses	(196,711)	(73,005)
Increase (decrease) in accounts payable - other	(1,920)	(18,036)
Other, net	(32,044)	(20,466)
Subtotal	(727,484)	(404,215)
Interest and dividend income received	23,466	1,628
Income taxes paid	(18,865)	(1,892)
Payments for extra retirement payments	–	(15,693)
Net cash provided by (used in) operating activities	(722,883)	(420,172)
Cash flows from investing activities		
Purchase of securities	(320,950)	(200,000)
Proceeds from sales of securities	50,854	–
Proceeds from redemption of securities	500,000	100,000
Purchase of property, plant and equipment	(3,078)	(21,344)
Purchase of intangible assets	(192)	(495)
Purchase of investment securities	(60,301)	(216,720)
Proceeds from sales of investment securities	138,168	–
Proceeds from redemption of investment securities	150,000	100,000
Payments into time deposits	–	(112,690)
Net cash provided by (used in) investing activities	454,501	(351,250)
Cash flows from financing activities		
Net cash provided by (used in) financing activities	–	–
Effect of exchange rate change on cash and cash equivalents	(4,242)	(34,295)
Net increase (decrease) in cash and cash equivalents	(272,624)	(805,718)
Cash and cash equivalents at beginning of period	1,991,558	2,243,276
Cash and cash equivalents at end of period	1,718,933	1,437,558

(4) Notes to quarterly non-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.

Significant subsequent event

Reduction of capital stock and legal capital surplus as well as appropriation of retained earnings

The Company's 8th Ordinary General Meeting of Shareholders held on March 30, 2016 passed a resolution for reduction of capital stock and legal capital surplus as well as appropriation of retained earnings, which came into effect on May 1, 2016.

- 1) Purpose of reduction of capital stock and legal capital surplus as well as appropriation of retained earnings
For eliminating the loss carried forward and of retained earnings restore the financial position to enable it to distribute dividends from retained earnings and implement shareholder return measures, such as purchase of treasury stock, in the future, as well as ensuring the flexibility and mobility of the capital policy going forward.
- 2) Outline of the reduction of capital stock
 - i) Amount of capital stock to be reduced
Capital stock of 9,806,225,500 yen will be reduced by 7,568,637,328 yen to 2,237,588,172 yen.
 - ii) Method of reduction of capital stock
Reduction of capital without compensation, whereby the total number of shares issued shall not be changed but part of capital stock will be reduced and transferred to other capital surplus, will be implemented.
- 3) Outline of the reduction of legal capital surplus
 - i) Amount of legal capital surplus to be reduced
Legal capital surplus of 5,090,225,500 yen will be reduced by 2,852,637,329 yen to 2,237,588,171 yen.
 - ii) Method of reduction of legal capital surplus
Legal capital surplus will be reduced and transferred to other capital surplus.
- 4) Outline of the appropriation of retained earnings
Pursuant to provisions of Article 452 of the Companies Act, the entire amount of other capital surplus, after the abovementioned resolution takes effect, of 10,421,274,657 yen will be transferred to retained earnings brought forward to cover the loss.
 - i) Items and amounts of surplus to be reduced
Other capital surplus: 10,421,274,657 yen
 - ii) Items and amounts of surplus to be increased
Retained earnings brought forward: 10,421,274,657 yen
- 5) Schedule
 - i) Date of resolution of the Board of Directors: February 12, 2016
 - ii) Date of resolution of the Ordinary General Meeting of Shareholders: March 30, 2016
 - iii) Initial date of public notice for creditors to make objections: March 31, 2016
 - iv) Final due date for creditors to make objections: April 30, 2016
 - v) Effective date: May 1, 2016
- 6) Other significant matters
Regarding the reduction of capital stock and legal capital surplus as well as appropriation of retained earnings, these actions are accounting transfers within the "Net Assets section" in the balance sheet, and therefore, they will not change the Company's net assets and will not affect the Company's financial results.