November 10, 2016

Summary of Non-consolidated Financial Results for the First Nine 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
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Scheduled date of filing of quarterly securities report: November 11, 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 nine months of the fiscal year ending December 31, 2016 (January 1, 2016 to September 30, 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	
First nine months ended	million yen	%	million yen	%	million yen	%	million yen	%
September 30, 2016	638	—	(475)	—	(542)	—	(548)	—
September 30, 2015	58	—	(1,518)	—	(1,467)	—	(1,493)	—

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months ended	yen	yen
September 30, 2016	(29.24)	—
September 30, 2015	(98.45)	—

Note: 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
September 30, 2016	4,085	3,865	94.3	205.24
December 31, 2015	4,752	4,514	94.8	239.96

Reference: Equity As of September 30, 2016: 3,851 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	—	0.00	—		
Fiscal year ending December 31, 2016 (forecast)				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 fiscal 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	660	354.2	(845)	—	(910)	—	(917)	—	(48.91)

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, 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: Yes

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 September 30, 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 September 30, 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 nine months ended September 30, 2016	18,767,200 shares
For the first nine months ended September 30, 2015	15,167,969 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.

Contents of attachment

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

(1) Qualitative information regarding non-consolidated operating results

1) Overall trend

During the first nine months ended September 30, 2016, the Japanese economy began to experience the effects from an appreciation of the yen against the U.S. dollar as U.K. voters decided to leave the European Union and the world economy slowed down, as shown by capital spending deceleration mainly in China and emerging Asian countries. Meanwhile, the Japanese economy displayed signs of improvement in some respects, as both public works funded by public investment and housing capital spending exceeded earlier expectations.

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, in investigator-initiated clinical trials of the Company's 5-HT_4 partial agonist (compound code: RQ-00000010 or "RQ-10") that were conducted by Virginia Commonwealth University, Parkinson's and Movement Disorders Center ("VCU") of the United States, the compound began to be prescribed to Parkinson's disease patients. Meanwhile, in a project for TRPM8 blocker compounds primarily for indications such as neuropathic pain, the Company completed the investigation of preclinical efficacy for clinical development candidates (compound code: RQ-00434739), and its Board of Directors meeting held in September 2016 approved moving on to a preclinical phase.
In the area of collaboration with academia, the Company entered into an agreement on collaborative research for a retinopathy treatment drug with the Molecular Pharmacology, Biofunctional Evaluation of Gifu Pharmaceutical University (Hideaki Hara, Professor and Vice President) as well as an agreement on collaborative research for a non-alcoholic steatohepatitis (NASH) treatment drug with the Department of Molecular Medicine and Metabolism, Research Institute of Environmental Medicine of Nagoya University (Takayoshi Suganami, Professor).

Accordingly, financial results for the first nine months, the reporting period, were as follows. Business revenue for the period was 638 million yen (business revenue of 58 million yen a year earlier), operating loss totaled 475 million yen (operating loss of 1,518 million yen a year earlier), ordinary loss totaled 542 million yen (ordinary loss of 1,467 million yen a year earlier) and loss was 548 million yen (loss of 1,493 million yen a year earlier). Total business expenses were 1,114 million yen (a decrease of 29.3% year on year), of which 117 million yen in royalty payments was recorded under cost of business revenue. Moreover, research and development expenses were 593 million yen (a decrease of 42.5% year on year) and other selling, general and administrative expenses totaled 403 million yen (down 26.1% year on year).

2) Research and development activities

Research and development expenses of the Company during the first nine months were 593 million yen (down 42.5% year on year). The main components of these activities were as follows:

A. 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 completed the investigation of preclinical efficacy for clinical development candidates (RQ-00434739), and its Board of Directors meeting held in September 2016 approved moving on to a preclinical phase.

The Company continued collaborative research with four companies.

Company	Start date	Content
EA Pharma Co., Ltd. (Note)	October 2012	Collaboration on a specific ion channel target for gastrointestinal treatments
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: Effective April 1, 2016, EA Pharma Co., Ltd. was established as a new company that resulted from the integration of a portion of Eisai Co., Ltd.'s gastrointestinal disease treatment business and Ajinomoto Pharmaceuticals Co., Ltd., which was the successor company in the integration.

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 has not detected any inadequacy for 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 *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 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 VCU and it was decided that a research grant would be awarded by The Michael J. Fox Foundation for the said investigator-initiated clinical trials. The trials began in August 2016 at VCU.

(b) Potassium-competitive acid blocker (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. 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 diarrhea-predominant irritable bowel syndrome (D-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)

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 DALVANCE™. In Europe, in March 2015, we obtained regulatory approval for the distribution of this agent under the trademark of XYDALBA™.

B. 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 (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.

(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 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 was developed for pain management for pets by Aratana Therapeutics Inc. (headquartered in the State of Kansas, U.S. and hereafter "Aratana (U.S.)"), a licensed partner of the Company. Following favorable results of clinical trials with dogs in the U.S., Aratana (U.S.) has obtained manufacturing and marketing approval with the FDA. The preparation for the commencement of sales in fall 2016 is currently underway by Aratana (U.S.) and Elanco Animal Health, a division of Eli Lilly and Company. In Europe, the compound is now under application with the European Medicines Agency (EMA) for approval for sales with approval expected to be obtained in 2017.

(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.) has obtained manufacturing and marketing approval with the FDA. Preparations are underway for the commencement of sales coinciding with the North American Veterinary Community Conference slated for February 2017.

(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 non-consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of September 30, 2016 were 4,085 million yen. The major components were 1,379 million yen in cash and deposits, 206 million yen in securities, and 1,869 million yen in investment securities.

Liabilities

Total liabilities as of September 30, 2016 were 219 million yen. The major components were 68 million yen in accounts payable - trade, 51 million yen in accounts payable - other, and 40 million yen in accrued expenses.

Net assets

Total net assets as of September 30, 2016 were 3,865 million yen. The major components were 2,237 million yen in capital stock, 2,237 million yen in capital surplus, negative 548 million yen in retained earnings, and negative 74 million yen in valuation difference on available-for-sale securities. The equity ratio was 94.3%.

2) Analysis of cash flows

The balance of cash and cash equivalents (hereafter "cash") as of September 30, 2016 amounted to 1,282 million yen (compared with 1,728 million yen a year earlier), a decrease of 960 million yen compared with the end of the previous fiscal year.

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

Cash flows from operating activities

Net cash used in operating activities was 410 million yen (compared with 1,766 million yen used a year earlier). This is mainly attributable to the recording of loss before income taxes of 544 million yen, decrease in notes and accounts receivable - trade of 72 million yen, increase in prepaid expenses of 53 million yen and increase in notes and accounts payable - trade of 68 million yen.

Cash flows from investing activities

Net cash used in investing activities was 470 million yen (compared with 697 million yen provided a year earlier). This is mainly attributable to the purchase of investment securities of 376 million yen, payments into time deposits of 323 million yen and proceeds from redemption of securities of 300 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

As for the non-consolidated earnings forecasts, please refer to "Change in the Date Scheduled for Aratana Therapeutics Inc. to Launch EP4 Antagonist Galliprant® in the U.S. and Revisions of Non-consolidated Business Forecasts for the Current Full Year" announced on November 4, 2016.

2. Matters regarding summary information (Notes)

Changes in accounting policies, changes in accounting estimates, and restatements of prior financial statements

Changes in accounting policies

(Application of Practical Solution on a Change in Depreciation Method Due to Tax Reform 2016)

Following the revision to the Corporation Tax Act, the Company has applied the "Practical Solution on a Change in Depreciation Method Due to Tax Reform 2016" (ASBJ PITF No. 32, June 17, 2016) from the second quarter ended June 30, 2016, and changed the depreciation method for facilities attached to buildings and structures acquired on or after April 1, 2016 from the declining balance method to the straight line method.

These changes have no impact on the Company's profit and loss.

3. Quarterly non-consolidated financial statements

(1) Non-consolidated balance sheet

(Thousands of yen)

	As of December 31, 2015	As of September 30, 2016
Assets		
Current assets		
Cash and deposits	1,840,239	1,379,131
Accounts receivable - trade	72,866	–
Securities	503,037	206,608
Supplies	7,148	5,939
Advance payments - trade	179,368	210,726
Prepaid expenses	65,488	119,405
Other	39,639	40,558
Total current assets	2,707,787	1,962,369
Non-current assets		
Property, plant and equipment		
Buildings, net	129,853	117,865
Tools, furniture and fixtures, net	131,437	106,588
Total property, plant and equipment	261,290	224,453
Intangible assets		
Trademark right	2,306	5,163
Software	8,213	6,908
Other	3,708	1,804
Total intangible assets	14,228	13,876
Investments and other assets		
Investment securities	1,751,779	1,869,998
Long-term prepaid expenses	5,479	3,522
Other	11,545	10,890
Total investments and other assets	1,768,805	1,884,411
Total non-current assets	2,044,324	2,122,741
Total assets	4,752,112	4,085,111
Liabilities		
Current liabilities		
Accounts payable - trade	–	68,256
Accounts payable - other	123,405	51,559
Accrued expenses	57,067	40,442
Income taxes payable	15,071	4,433
Advances received	–	13,500
Deposits received	4,663	5,299
Total current liabilities	200,207	183,490
Non-current liabilities		
Asset retirement obligations	11,555	11,625
Deferred tax liabilities	25,985	24,644
Total non-current liabilities	37,540	36,270
Total liabilities	237,748	219,761
Net assets		
Shareholders' equity		
Capital stock	9,806,225	2,237,588
Capital surplus	5,090,225	2,237,588
Retained earnings	(10,421,274)	(548,770)
Total shareholders' equity	4,475,176	3,926,405
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	28,170	(74,712)
Total valuation and translation adjustments	28,170	(74,712)
Subscription rights to shares	11,017	13,657
Total net assets	4,514,364	3,865,350
Total liabilities and net assets	4,752,112	4,085,111

(2) Non-consolidated statement of income

Non-consolidated statement of income (cumulative)

(Thousands of yen)

	First nine months ended September 30, 2015	First nine months ended September 30, 2016
Business revenue	58,031	638,600
Business expenses		
Cost of business revenue	–	117,630
Research and development expenses	1,031,180	593,227
Other selling, general and administrative expenses	545,578	403,268
Total business expenses	1,576,759	1,114,126
Operating loss	(1,518,727)	(475,526)
Non-operating income		
Interest income	1,001	8,978
Interest on securities	64,728	38,161
Dividend income	186	–
Foreign exchange gains	13,482	–
Gain on sales of securities	1,165	–
Gain on valuation of compound financial instruments	–	11,470
Subsidy income	–	19,843
Other	952	1,437
Total non-operating income	81,516	79,891
Non-operating expenses		
Foreign exchange losses	–	147,142
Loss on valuation of compound financial instruments	21,957	–
Loss on redemption of securities	1,530	–
Share issuance cost	6,400	–
Total non-operating expenses	29,887	147,142
Ordinary loss	(1,467,098)	(542,777)
Extraordinary income		
Gain on sales of investment securities	52,842	–
Total extraordinary income	52,842	–
Extraordinary losses		
Special retirement expenses	37,042	–
Loss on redemption of investment securities	6,000	2,000
Office transfer expenses	30,466	–
Total extraordinary losses	73,509	2,000
Loss before income taxes	(1,487,764)	(544,777)
Income taxes - current	5,489	1,010
Income taxes - deferred	–	2,983
Total income taxes	5,489	3,993
Loss	(1,493,254)	(548,770)

(3) Non-consolidated statement of cash flows

(Thousands of yen)

	First nine months ended September 30, 2015	First nine months ended September 30, 2016
Cash flows from operating activities		
Loss before income taxes	(1,487,764)	(544,777)
Depreciation	31,714	58,136
Interest income	(1,001)	(8,978)
Interest income on securities	(64,728)	(38,161)
Dividend income	(186)	–
Foreign exchange losses (gains)	(13,417)	99,581
Loss (gain) on sales of securities	(1,165)	–
Loss (gain) on valuation of compound financial instruments	21,957	(11,470)
Loss (gain) on redemption of securities	1,530	–
Share issuance cost	6,400	–
Subsidy income	–	(19,843)
Loss (gain) on sales of investment securities	(52,842)	–
Loss (gain) on redemption of investment securities	6,000	2,000
Extra retirement payment	37,042	–
Office transfer expenses	30,466	–
Decrease (increase) in notes and accounts receivable - trade	12,946	72,866
Decrease (increase) in inventories	8,674	1,208
Increase (decrease) in notes and accounts payable - trade	–	68,256
Decrease (increase) in advance payments	(76,274)	(31,358)
Decrease (increase) in prepaid expenses	(80,041)	(53,916)
Decrease (increase) in consumption taxes refund receivable	(25,637)	–
Increase (decrease) in accounts payable - other	(61,640)	(25,820)
Other, net	(36,117)	10,819
Subtotal	(1,744,087)	(421,459)
Interest and dividend income received	51,137	25,142
Income taxes paid	(24,827)	(1,892)
Payments for extra retirement payments	(37,042)	(32,440)
Proceeds from subsidy income	–	19,843
Payments for removal expenses	(4,807)	–
Other, net	(6,400)	–
Net cash provided by (used in) operating activities	(1,766,027)	(410,805)
Cash flows from investing activities		
Payments into time deposits	–	(323,570)
Purchase of securities	(620,950)	(200,000)
Proceeds from sales of securities	50,854	–
Proceeds from redemption of securities	1,357,256	300,000
Purchase of property, plant and equipment	(195,175)	(30,422)
Purchase of intangible assets	(3,863)	(1,150)
Purchase of investment securities	(478,784)	(376,905)
Proceeds from sales of investment securities	441,987	61,160
Proceeds from redemption of investment securities	150,000	100,000
Other, net	(4,201)	81
Net cash provided by (used in) investing activities	697,122	(470,807)

(Thousands of yen)

	First nine months ended September 30, 2015	First nine months ended September 30, 2016
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	803,610	–
Proceeds from issuance of subscription rights to shares	15,450	–
Net cash provided by (used in) financing activities	819,060	–
Effect of exchange rate change on cash and cash equivalents	(13,112)	(79,284)
Net increase (decrease) in cash and cash equivalents	(262,957)	(960,897)
Cash and cash equivalents at beginning of period	1,991,558	2,243,276
Cash and cash equivalents at end of period	1,728,601	1,282,379

(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

For the first nine months ended September 30, 2016 (January 1, 2016 to September 30, 2016)

1. Dividends

No items to report.

2. Significant changes in the amount of shareholders' equity

The Company resolved at the 8th Ordinary General Meeting of Shareholders held on March 30, 2016 to conduct a reduction of capital without compensation in order to offset the deficit, which went into effect on May 1, 2016. As a result, in the second quarter ended June 30, 2016, capital stock decreased by 7,568,637,000 yen and capital surplus by 2,852,637,000 yen with capital stock standing at 2,237,588,000 yen and capital surplus at 2,237,588,000 yen as of September 30, 2016.

Significant subsequent event

No items to report.