February 8, 2019

Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2018 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: https://www.raqualia.com/
Representative: Naoki Tani, President and CEO
Contact: Kiichiro Kawada, Director and Executive Vice President (TEL) +81-52-446-6100
Scheduled date of general meeting of shareholders: March 25, 2019
Scheduled date of dividend payment: —
Scheduled date of filing of securities report: March 26, 2019
Supplementary documents for financial results: Yes
Financial results briefing: Yes (for institutional investors and analysts)

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

1. Consolidated financial results for the fiscal year ended December 31, 2018 (January 1, 2018 to December 31, 2018)

(1) Consolidated operating results

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

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
Fiscal year ended	million yen	%	million yen	%	million yen	%	million yen	%
December 31, 2018	744	(47.5)	(1,075)	–	(1,064)	–	(1,104)	–
December 31, 2017	1,419	–	(150)	–	(80)	–	(58)	–

Note: Comprehensive income Fiscal year ended December 31, 2018: (1,130) million yen [–%]
Fiscal year ended December 31, 2017: (100) million yen [–%]

	Earnings per share (Basic)	Earnings per share (Diluted)	Profit/equity	Ordinary profit/ total assets	Operating profit/ net sales
Fiscal year ended	yen	yen	%	%	%
December 31, 2018	(54.23)	–	(25.3)	(23.4)	(144.4)
December 31, 2017	(2.99)	–	(1.3)	(1.7)	(10.6)

Reference: Share of (profit) loss of entities accounted for using equity method:
Fiscal year ended December 31, 2018: – million yen
Fiscal year ended December 31, 2017: – million yen

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
December 31, 2018	4,052	3,857	94.9	188.57
December 31, 2017	5,064	4,887	96.2	240.00

Reference: Equity As of December 31, 2018: 3,844 million yen As of December 31, 2017: 4,870 million yen

(3) Consolidated cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	million yen	million yen	million yen	million yen
December 31, 2018	(403)	(368)	99	1,829
December 31, 2017	(307)	533	1,007	2,473

2. Dividends

	Annual dividends per share					Total cash dividends (Total)	Dividend payout ratio (Consolidated)	Ratio of dividends to net assets (Consolidated)
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total			
	yen	yen	yen	yen	yen	million yen	%	%
Fiscal year ended December 31, 2017	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended December 31, 2018	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending December 31, 2019 (forecast)	–	0.00	–	0.00	0.00		–	

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

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

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

Note: As the Company conducts performance management on an annualized basis, forecasts of results over a six-month period are not presented.

*** Notes**

(1) Changes in significant subsidiaries during the fiscal year ended December 31, 2018 (changes in specified subsidiaries resulting in the change in scope of consolidation): 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 December 31, 2018	20,388,389 shares
As of December 31, 2017	20,295,236 shares

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

As of December 31, 2018	50 shares
As of December 31, 2017	50 shares

c. Average number of outstanding shares during the period

For the fiscal year ended December 31, 2018	20,368,732 shares
For the fiscal year ended December 31, 2017	19,423,317 shares

(Reference) Overview of non-consolidated financial results

Non-consolidated financial results for the fiscal year ended December 31, 2018 (January 1, 2018 to December 31, 2018)

(1) Non-consolidated operating results

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

	Net sales		Operating profit		Ordinary profit		Profit	
Fiscal year ended	million yen	%	million yen	%	million yen	%	million yen	%
December 31, 2018	738	(45.8)	(1,001)	–	(991)	–	(1,029)	–
December 31, 2017	1,362	93.2	(114)	–	(44)	–	(27)	–

	Earnings per share (Basic)	Earnings per share (Diluted)
Fiscal year ended	yen	yen
December 31, 2018	(50.56)	–
December 31, 2017	(1.42)	–

(2) Non-consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
December 31, 2018	4,147	3,961	95.2	193.69
December 31, 2017	5,091	4,917	96.2	241.47

Reference: Equity As of December 31, 2018: 3,949 million yen As of December 31, 2017: 4,900 million yen

*** Financial results reports are exempt from audit 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.

(Method of accessing supplementary documents for financial results and details of financial results briefing)

The Company plans to hold a financial results briefing for institutional investors and securities analysts on Thursday, February 14, 2019.

The Company plans to post the documents used at the briefing on its website promptly after the briefing is held.

Contents of attachment

1. Overview of consolidated operating results and others

(1) Overview of consolidated operating results for the fiscal year under review

1) Consolidated operating results for the fiscal year under review

Overall trend

During the fiscal year under review, the long-term recovery of the Japanese economy continued due to solid exports and growth in capital investment for labor-saving-oriented purposes, although unusually hot weather conditions and natural disasters cast a shadow on consumer spending. In addition, mounting concern about overseas risks, such as intensified trade friction between the U.S. and China, fears of a downturn in Europe, and geopolitical risks in the Middle East and elsewhere, led in turn to an uneasy sense that business conditions may have peaked.

In the pharmaceutical sector, employment became more fluid within the pharmaceutical industry as cross-border business restructuring progressed, driven by a rise in further restructuring among "Mega Pharma" (the largest pharmaceutical companies), and by intensified buying and selling activity at the product portfolio and business level among domestic pharmaceutical firms. 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. As a result, during the fiscal year under review, CJ HealthCare Corporation (South Korea) ("CJ HealthCare (South Korea)"), to which the Company had licensed out tegoprazan (RQ-00000004/CJ-12420/brand name in South Korea (registered trademark in South Korea): K-CAB®; "tegoprazan"), obtained approval for the production and distribution of the compound from South Korea's Ministry of Food and Drug Safety ("MFDS") in July 2018.

The above-mentioned approval by MFDS deemed tegoprazan to have an indication for gastro-esophageal reflux disease (GERD) including non-erosive reflux disease (NERD). This marked the world's first-ever approval obtained for a potassium-competitive acid blocker (P-CAB) for an indication for NERD. In addition, development is proceeding satisfactorily at the Shandong Luoxin Pharmaceutical Group in China ("Luoxin Pharma (China)"), which is a licensee of CJ HealthCare (South Korea), and Phase III clinical trials began in October 2018 in China. Also, with regard to the 5-HT_{2B} antagonist (RQ-00310941) being developed by the Group, Phase I clinical trials in the U.K. was completed in the second quarter of 2018, and suggested its potential for improving irritable bowel syndrome with diarrhea-like (IBS-D) symptoms in inflammatory bowel disease (IBD), and as a treatment for IBS-D.

In relation to the ion channel drug discovery that is one of the strengths of the Group, the P2X7 receptor antagonist (RQ-00466479, AKP-23494954) that was created through collaborative research with Asahi Kasei Pharma Corporation ("Asahi Kasei Pharma") achieved a milestone in March 2018, and moved to the preclinical phase, resulting in the conclusion of a license agreement with Asahi Kasei Pharma. Development of the compound by Asahi Kasei Pharma is progressing steadily. Furthermore, with respect to compounds created through collaborative research on a specific ion channel target for digestive treatments with EA Pharma Co., Ltd. ("EA Pharma"), in addition to achieving certain milestones in March 2018, the development on a selective sodium channel blocker licensed to Maruho Co., Ltd. ("Maruho") in December 2017 is proceeding steadily.

In terms of contribution to revenue, the EP4 antagonist (GALLIPRANT®, grapiprant, RQ-00000007, AT-001, "GALLIPRANT®") licensed for pain management for pets, recorded steady growth in sales in the U.S. In addition to the results achieved by joint marketing promotions between Elanco Animal Health (U.S.) ("Elanco (U.S.)"), which is the animal drug division of Eli Lilly and Company, and Aratana Therapeutics Inc. (U.S.) ("Aratana (U.S.)"), which is the Group's licensee, in terms of development, the Group received approval from the European Commission in January 2018 for the production and distribution of animal drugs in Europe. Our Ghrelin receptor agonist (ENTYCE®, capromorelin, RQ-00000005, AT-002, "ENTYCE®"), which has an indication for anorexia management for dogs, is strengthening its foothold as a result of growing sales by our licensee, Aratana (U.S.). Moreover, the serotonin 5-HT_{2A} and dopamine D_2 receptor blocker (ziprasidone), which is being developed by Meiji Seika Pharma Co., Ltd. ("Meiji Seika Pharma") as a treatment for schizophrenia, continues to undergo Phase III clinical trials in Japan.

On the other hand, with regard to the establishment of the joint venture planned between the Group and ZTE Coming Biotech Co., Ltd. (China) ("ZTE Biotech (China)"), as a result of ZTE Corporation - a major company of the ZTE Group to which ZTE Biotech (China) belongs - being subjected to U.S. government sanctions banning it from trading with U.S. companies, not only

were these plans delayed, but it also became very challenging to obtain the financing that would be required for the future development of drugs. Accordingly, we suspended the establishment of the joint venture and terminated the agreement with ZTE Biotech (China).

For the 5-HT_4 partial agonist (RQ-00000010) and 5-HT_{2B} antagonist (RQ-00310941), we continue to search for new partners not only in China but globally, and are working on new activities.

In its collaborative research activities, in August 2018, the Company terminated a collaborative research agreement with XuanZhu Pharma Co., Ltd. (China) on sodium channel Nav 1.7 selective blocker compound. Both parties have agreed to individually pursue research and development, based on research results attributed to each of them. Going forward, we will work on further initiatives with the aim of maximizing project value based on the results of this collaborative research.

In our industry-academia-government collaboration activities, the Company made the decision to establish the RaQualia Pharma Industry-Academia Collaborative Research Center in February 2018 at a national university corporation, Nagoya University ("Nagoya University"). The three departments and laboratories at Nagoya University that had hitherto been set up by the Group were integrated into two new departments ("Department of Pharmacology" and "Department of Pharmaceutical Sciences").

In addition to raising the recognition of the Group at Nagoya University, the Center is intended to facilitate ongoing collaborative research aimed at new drug discovery in conjunction with the University, which owns a variety of existing technologies as well as the seeds of new technologies. By doing so, we aim to further accelerate our drug discovery research activities at Nagoya University, and to increase expectations with regard to the discovery of compound candidates for medicinal drugs.

In December 2018, the Company established a wholly owned subsidiary, RaQualia Innovations Inc. This company will search both in Japan and overseas for possible clinical applications and potential commercialization for the seeds of new drugs and businesses based on the superior basic research created by academia and startups. As well as seeking to extend the business opportunities available to the Group, it will attempt to promote and develop drug discovery activities within academia in central Japan, including Nagoya University itself.

Accordingly, financial results for the fiscal year ended December 31, 2018, the reporting period, were as follows. Business revenue for the period was 744 million yen (down 47.5% year on year), operating loss totaled 1,075 million yen (compared with operating loss of 150 million yen a year earlier), ordinary loss totaled 1,064 million yen (compared with ordinary loss of 80 million yen a year earlier), and loss attributable to owners of parent was 1,104 million yen (compared with loss attributable to owners of parent of 58 million yen a year earlier). Total business expenses were 1,819 million yen (up 15.9% year on year). This total mainly consists of research and development expenses (1,074 million yen, a 26.6% increase from the same period last year) and other selling, general and administrative expenses (655 million yen, a 14.7% increase from the same period last year).

Research and development activities

Research and development expenses of the Group during the fiscal year ended December 31, 2018 were 1,074 million yen. The main components of these activities were as follows:

<RaQualia's research and development and collaborative research>

(A) Exploratory and discovery phase

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

The Company continued collaborative research with one company.

Company	Start date	Content
Interprotein Corporation	February 2013	Collaborative research on a specific protein-protein interaction (PPI) inhibitor for pain treatments

(B) Preclinical development phase

a) 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.

b) 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.

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.

(C) Clinical development phase

a) 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 the U.S. and Japan. The Company is utilizing data on clinical trials in South Korea as part of activities currently under way aimed at licensing out the compound.

b) 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.

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

Regarding the 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.

<Status of development at licensee corporation>

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

The compound is under development for gastro-esophageal reflux disease (GERD) by CJ HealthCare (South Korea), and that company obtained approval for the production and distribution of the compound in South Korea in July 2018. Clinical trial proceeds for additional indications. In addition, Luoxin Pharma (China), which is a licensee in China of CJ HealthCare (South Korea), began the Phase III clinical trials in China in October 2018. In addition, CJ HealthCare (South Korea) concluded a sub-licensing agreement with Vimedimex Medi-Pharma JSC (Vietnam) in December 2018.

b) Serotonin 5-HT_{2A} and dopamine D_2 receptor blocker (ziprasidone)

The compound is under development for schizophrenia by Meiji Seika Pharma, and is undergoing Phase III clinical trials in Japan. The agent has been marketed in 79 countries by Pfizer Inc. (U.S.), and accepted as a first-choice drug in its class according to treatment guidelines in the United States.

c) EP4 antagonist (GALLIPRANT®)

The compound was developed for pain management for pets by Aratana (U.S.). In January 2017, the Company started selling it in the U.S. through Aratana (U.S.) and Elanco Animal Health (U.S.) and has steadily increased its sales. The Company also obtained approval for production and distribution of the compound in Europe in January 2018, and expects to commence its sale in the first half of fiscal 2019.

d) Ghrelin receptor agonist (ENTYCE®)

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.). The Company is gradually increasing its recognition. While continuing the program to develop the compound as a cat anorexia management drug, Aratana (U.S.) completed long-term toxicity studies on cats in February 2018 and has carried out pivotal studies.

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

In September 2018, RMX BioPharma Co., Ltd. (China), a licensee in China of AskAt Inc. ("AskAt"), launched clinical trials in China with pain as a target indication. In addition, at Kyn Therapeutics Inc. (U.S.), which is a licensee in the U.S. of AskAt, clinical trial as a cancer immunotherapeutic began in October 2018.

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

g) Development candidate compound for a specific ion channel target (no compound code disclosed)
The compound was created through collaborative research with EA Pharma that started in October 2012 and the Company achieved certain milestones in March 2018. Currently, EA Pharma is carrying out development to create a new therapeutic agent for digestive treatment using the compound as an active ingredient.

h) Selective sodium channel blocker (no compound code disclosed)
The compound was licensed out to Maruho in December 2017. Currently, Maruho is carrying out development of curative medicines using the compound as an active ingredient.

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

2) Outlook for the fiscal year ending December 31, 2019

Looking ahead to the next fiscal year (the fiscal year ending December 31, 2019), on the business front, the Company will work steadily to secure profits by licensing out development compounds and managing alliances. On the research and development front, the Company will promote alliances and collaborative research with pharmaceutical companies and others through the advancement of projects at the exploratory and development phases, and thus enhance its corporate value.

On the revenue front, under the out-licensing agreement entered into by and between the Company and Aratana (U.S.), the Company will obtain from Aratana (U.S.) a certain amount of milestone payment if certain terms of the agreement are attained, and it will also obtain royalty corresponding to Aratana's sales of GALLIPRANT® and ENTYCE® in the U.S. As for tegoprazan, licensee CJ HealthCare (South Korea) is currently preparing for sales in South Korea and for a clinical trial process in regions in which the Company has granted license and is also renegotiating the license agreement. If the terms of the agreement are attained, the Company will obtain a certain amount of milestone payments and also royalties for the sale of tegoprazan by CJ Health after launch in South Korea. In addition, while considering in-house development of medicinal drug compound candidates, including those in the exploratory and discovery phase, the Company aims to partner with pharmaceutical companies via out-licensing agreements.

As for the outlook of consolidated financial results for the fiscal year ending December 31, 2019, the Company forecasts business revenue of 2,022 million yen, operating profit of 187 million yen, ordinary profit of 195 million yen and profit attributable to owners of parent of 153 million yen.

The forecast figures presented above are based on the information currently available to the Group 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. In the case where the Group acknowledges the need to revise the financial forecast, it will disclose such information promptly.

(2) Overview of consolidated financial position for the fiscal year under review

1) Status of assets, liabilities and net assets

Assets

Total assets as of December 31, 2018 were 4,052 million yen. The major components were 1,671 million yen in cash and deposits, 317 million yen in property, plant and equipment, and 1,716 million yen in investment securities.

Liabilities

Total liabilities as of December 31, 2018 were 195 million yen. The major components were 98 million yen in accounts payable - other and 47 million yen in accrued expenses.

Net assets

Total net assets as of December 31, 2018 were 3,857 million yen. The major components were 2,793 million yen in capital stock, 2,983 million yen in capital surplus, and negative 1,890 million yen in retained earnings. The equity ratio was 94.9%.

2) Overview of cash flows for the fiscal year under review

The balance of cash and cash equivalents ("cash") as of December 31, 2018 amounted to 1,829 million yen, a decrease of 644 million yen compared with the beginning of the fiscal year under review. The respective cash flows in the fiscal year under review and the factors thereof are as follows.

Cash flows from operating activities

Net cash used in operating activities was 403 million yen (up 31.4% year on year). This is mainly attributable to the recording of loss before income taxes of 1,078 million yen, depreciation of 125 million yen, decrease in notes and

accounts receivable - trade of 448 million yen, and decrease in advance payments of 181 million yen.

Cash flows from investing activities

Net cash used in investing activities was 368 million yen (compared with 533 million yen provided a year earlier). This is mainly attributable to the proceeds from sales of investment securities of 203 million yen, proceeds from redemption of investment securities of 323 million yen, purchase of investment securities of 785 million yen, and purchase of property, plant and equipment of 213 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 99 million yen (down 90.2% year on year). This is primarily due to the proceeds from issuance of shares resulting from exercise of share acquisition rights of 99 million yen.

(Reference) Trend in cash flow-related indicators

	Fiscal year ended December 31, 2014	Fiscal year ended December 31, 2015	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Equity ratio (%)	89.6	94.8	93.9	96.2	94.9
Market value equity ratio (%)	125.3	132.7	184.9	941.8	541.9
Interest-bearing debt to cash flow ratio (years)	–	–	–	–	–
Interest coverage ratio (factor)	–	–	–	–	–

Equity ratio: equity / total assets

Market value equity ratio: market capitalization / total assets

Interest-bearing debt to cash flow ratio: interest-bearing debt / cash flow

Interest coverage ratio: cash flow / paid interest

Notes: 1. Figures are obtained from the non-consolidated financial statements for the fiscal year ended December 31, 2015 and the fiscal year ended December 31, 2016 and from the consolidated financial statements for other fiscal years.

2. Interest-bearing debt to cash flow ratio and interest coverage ratio are not provided since operating cash flow was a minus figure.

(3) Basic policy on profit distribution and dividends for fiscal years 2018 and 2019

The Group is a bio venture company specializing in drug discovery research. Therefore, looking forward, the Company must continually conduct research and development activities. In view of this, we have decided to concentrate on securing internal reserves and to attach priority on securing funds for the continuation of research and development activities without paying dividends. Therefore, because we presently remain in a situation where we continue to record a loss, we have not carried out profit distributions. We also plan not to carry out profit distributions in that fiscal year.

Nevertheless, we consider the distribution of profits to shareholders to be an important management issue, and we intend to make future profit distributions a continual consideration.

2. Basic rationale for selecting the accounting standard

The Group has adopted Japanese accounting standards to ease the cost, etc., of parallel disclosure of reporting under both Japanese accounting standards and international financial reporting standards (IFRS).

As for the future, we intend to further the consideration on application of IFRS in light of the change in the ratio of foreign shareholders and trends in the application of IFRS by domestic sector peer companies.

3. Consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2017	As of December 31, 2018
Assets		
Current assets		
Cash and deposits	2,268,024	1,671,346
Accounts receivable - trade	448,738	680
Securities	328,957	168,193
Supplies	5,153	6,498
Advance payments - trade	189,743	8,737
Prepaid expenses	62,150	71,937
Other	19,631	34,858
Total current assets	3,322,398	1,962,252
Non-current assets		
Property, plant and equipment		
Buildings	142,462	142,731
Tools, furniture and fixtures	488,193	676,694
Leased assets	—	3,432
Accumulated depreciation	(414,975)	(505,062)
Total property, plant and equipment	215,680	317,795
Intangible assets		
Trademark right	4,945	4,533
Software	4,383	28,420
Other	626	1,032
Total intangible assets	9,955	33,985
Investments and other assets		
Investment securities	1,503,443	1,716,580
Long-term prepaid expenses	2,126	10,035
Other	10,584	11,652
Total investments and other assets	1,516,154	1,738,267
Total non-current assets	1,741,790	2,090,049
Total assets	5,064,188	4,052,302

(Thousands of yen)

	As of December 31, 2017	As of December 31, 2018
Liabilities		
Current liabilities		
Accounts payable - trade	1,984	–
Lease obligations	–	741
Accounts payable - other	63,365	98,618
Accrued expenses	43,997	47,805
Income taxes payable	20,691	14,237
Accrued consumption taxes	13,907	–
Advances received	1,101	–
Deposits received	3,716	3,089
Total current liabilities	148,763	164,492
Non-current liabilities		
Lease obligations	–	2,409
Asset retirement obligations	11,743	11,838
Deferred tax liabilities	15,730	16,474
Total non-current liabilities	27,474	30,722
Total liabilities	176,237	195,214
Net assets		
Shareholders' equity		
Capital stock	2,741,249	2,793,458
Capital surplus	2,931,032	2,983,241
Retained earnings	(785,652)	(1,890,201)
Treasury shares	(21)	(21)
Total shareholders' equity	4,886,607	3,886,476
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(15,826)	(41,901)
Total accumulated other comprehensive income	(15,826)	(41,901)
Share acquisition rights	17,168	12,512
Total net assets	4,887,950	3,857,087
Total liabilities and net assets	5,064,188	4,052,302

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

Consolidated statement of income

(Thousands of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Business revenue	1,419,195	744,517
Business expenses		
Cost of business revenue	149,534	89,411
Research and development expenses	848,516	1,074,619
Other selling, general and administrative expenses	571,555	655,596
Total business expenses	1,569,607	1,819,627
Operating loss	(150,411)	(1,075,109)
Non-operating income		
Interest income	3,541	9,004
Interest on securities	35,271	32,215
Foreign exchange gains	700	–
Subsidy income	44,072	855
Other	1,078	3,143
Total non-operating income	84,665	45,218
Non-operating expenses		
Foreign exchange losses	–	32,841
Share issuance cost	12,919	1,408
Loss on valuation of compound financial instruments	1,810	710
Other	100	–
Total non-operating expenses	14,829	34,960
Ordinary loss	(80,575)	(1,064,851)
Extraordinary income		
Gain on sales of investment securities	17,647	4,577
Gain on bargain purchase	3,278	–
Total extraordinary income	20,926	4,577
Extraordinary losses		
Loss on sales of investment securities	199	–
Loss on redemption of investment securities	–	17,919
Total extraordinary losses	199	17,919
Loss before income taxes	(59,848)	(1,078,193)
Income taxes - current	2,982	26,686
Income taxes - deferred	(4,707)	(331)
Total income taxes	(1,725)	26,355
Loss	(58,122)	(1,104,548)
Profit attributable to non-controlling interests	–	–
Loss attributable to owners of parent	(58,122)	(1,104,548)

Consolidated statement of comprehensive income

(Thousands of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Loss	(58,122)	(1,104,548)
Other comprehensive income		
Valuation difference on available-for-sale securities	(42,010)	(26,075)
Total other comprehensive income	(42,010)	(26,075)
Comprehensive income	(100,132)	(1,130,624)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(100,132)	(1,130,624)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of changes in equity

Fiscal year ended December 31, 2017

(Thousands of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	2,237,588	2,237,588	(727,530)	—	3,747,646
Changes of items during period					
Increase by share exchanges		189,783			189,783
Issuance of new shares	503,661	503,661			1,007,322
Purchase of treasury shares				(21)	(21)
Loss attributable to owners of parent			(58,122)		(58,122)
Net changes of items other than shareholders' equity					
Total changes of items during period	503,661	693,444	(58,122)	(21)	1,138,961
Balance at end of current period	2,741,249	2,931,032	(785,652)	(21)	4,886,607

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Valuation difference on available-for-sale securities	Total accumulated other comprehensive income		
Balance at beginning of current period	26,183	26,183	14,785	3,788,615
Changes of items during period				
Increase by share exchanges				189,783
Issuance of new shares				1,007,322
Purchase of treasury shares				(21)
Loss attributable to owners of parent				(58,122)
Net changes of items other than shareholders' equity	(42,010)	(42,010)	2,383	(39,626)
Total changes of items during period	(42,010)	(42,010)	2,383	1,099,335
Balance at end of current period	(15,826)	(15,826)	17,168	4,887,950

Fiscal year ended December 31, 2018

(Thousands of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	2,741,249	2,931,032	(785,652)	(21)	4,886,607
Changes of items during period					
Issuance of new shares	52,208	52,208			104,417
Loss attributable to owners of parent			(1,104,548)		(1,104,548)
Net changes of items other than shareholders' equity					
Total changes of items during period	52,208	52,208	(1,104,548)		(1,000,131)
Balance at end of current period	2,793,458	2,983,241	(1,890,201)	(21)	3,886,476

	Accumulated other comprehensive income		Share acquisition rights	Total net assets
	Valuation difference on available-for-sale securities	Total accumulated other comprehensive income		
Balance at beginning of current period	(15,826)	(15,826)	17,168	4,887,950
Changes of items during period				
Issuance of new shares				104,417
Loss attributable to owners of parent				(1,104,548)
Net changes of items other than shareholders' equity	(26,075)	(26,075)	(4,656)	(30,732)
Total changes of items during period	(26,075)	(26,075)	(4,656)	(1,030,863)
Balance at end of current period	(41,901)	(41,901)	12,512	3,857,087

(4) Consolidated statement of cash flows

(Thousands of yen)

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Cash flows from operating activities		
Loss before income taxes	(59,848)	(1,078,193)
Depreciation	85,785	125,588
Interest income	(3,541)	(9,004)
Interest income on securities	(35,271)	(32,215)
Foreign exchange losses (gains)	7,463	(25,606)
Loss (gain) on valuation of compound financial instruments	1,810	710
Subsidy income	(44,072)	(855)
Gain on bargain purchase	(3,278)	–
Loss (gain) on sales of investment securities	(17,448)	(4,577)
Loss (gain) on redemption of investment securities	—	17,919
Decrease (increase) in notes and accounts receivable - trade	(380,972)	448,058
Decrease (increase) in inventories	1,972	(1,345)
Increase (decrease) in notes and accounts payable - trade	1,984	(1,984)
Decrease (increase) in advance payments	15,493	181,006
Decrease (increase) in prepaid expenses	(6,282)	(9,786)
Increase (decrease) in accounts payable - other	(19,930)	11,004
Decrease (increase) in consumption taxes refund receivable	18,123	(13,800)
Increase (decrease) in accrued consumption taxes	–	(13,907)
Other, net	48,144	(7,487)
Subtotal	(389,870)	(414,477)
Interest and dividend income received	40,659	41,401
Proceeds from subsidy income	44,072	855
Income taxes paid	(2,296)	(31,775)
Net cash provided by (used in) operating activities	(307,434)	(403,997)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	340,462	–
Purchase of securities	(110,049)	–
Proceeds from redemption of securities	–	113,040
Purchase of property, plant and equipment	(87,509)	(213,337)
Purchase of intangible assets	(940)	(7,797)
Purchase of investment securities	(719,750)	(785,276)
Proceeds from sales of investment securities	1,096,847	203,747
Proceeds from redemption of investment securities	15,000	323,567
Other, net	(259)	(2,001)
Net cash provided by (used in) investing activities	533,800	(368,057)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	996,382	99,741
Proceeds from issuance of share acquisition rights	10,960	–
Purchase of treasury shares	(21)	–
Repayments of lease obligations	–	(555)
Net cash provided by (used in) financing activities	1,007,321	99,185
Effect of exchange rate change on cash and cash equivalents	(4,260)	28,493
Net increase (decrease) in cash and cash equivalents	1,229,426	(644,375)
Cash and cash equivalents at beginning of period	1,244,490	2,473,916
Cash and cash equivalents at end of period	2,473,916	1,829,540

(5) Notes to consolidated financial statements

Notes on premise of going concern

No items to report.

Significant matters forming the basis of preparing the consolidated financial statements

1. Scope of consolidation

   Number of consolidated subsidiaries: 2

   Name of consolidated subsidiaries: TMRC Co., Ltd., RaQualia Innovations Inc.

   Among the companies above, RaQualia Innovations Inc. has been included in the scope of consolidation because it was newly established in the fiscal year under review.

2. Balance sheet date of consolidated subsidiaries

   The balance sheet date of the consolidated subsidiaries 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) 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) Accounting for deferred assets

   Share issuance cost

   The whole amount is treated as expenses when incurred.

   (4) 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.

   (5) 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.

   (6) 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.

Segment information, etc.

Segment information

This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.

Per share information

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Net assets per share (Yen)	240.00	188.57
Basic earnings (loss) per share (Yen)	(2.99)	(54.23)

Notes: 1. Diluted earnings per share are not described here because, although there are potentially dilutive shares, basic loss per share was recorded.

2. The basis for calculation of net assets per share is as follows:

	As of December 31, 2017	As of December 31, 2018
Total net assets (Thousands of yen)	4,887,950	3,857,087
Amount to be deducted from total net assets (Thousands of yen)	17,168	12,512
[Share acquisition rights included therein] (Thousands of yen)	[17,168]	[12,512]
Amount of net assets at the end of period related to common shares (Thousands of yen)	4,870,781	3,844,575
Number of common shares at the end of period used in calculation of net assets per share (Shares)	20,295,186	20,388,339

3. The basis for calculation of basic loss per share is as follows:

	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018
Amount of loss attributable to owners of parent (Thousands of yen)	(58,122)	(1,104,548)
Amount not attributable to common shareholders (Thousands of yen)	–	–
Amount of loss attributable to owners of parent related to common shares (Thousands of yen)	(58,122)	(1,104,548)
Average number of outstanding common shares during the period (Shares)	19,423,317	20,368,732
Summary of potential shares that are not included in calculation of diluted earnings per share due to a lack of dilution effect	3rd series share options; 5th series share options; 7th series share options (134,209 common shares)	———

Significant subsequent event

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

The Company resolved at the Board of Directors meeting held on February 8, 2019, to propose a reduction of capital stock and legal capital surplus as well as appropriation of retained earnings at the 11th Ordinary General Meeting of Shareholders to be held on March 25, 2019.

(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 2,793,458,488 yen will be reduced by 892,842,971 yen to 1,900,615,517 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 2,983,241,487 yen will be reduced by 892,842,971 yen to 2,090,398,516 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 1,785,685,942 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: 1,785,685,942 yen

ii) Items and amounts of surplus to be increased
Retained earnings brought forward: 1,785,685,942 yen

(5) Schedule

i) Date of resolution of the Board of Directors: February 8, 2019

ii) Date of resolution of the Ordinary General Meeting of Shareholders: March 25, 2019

iii) Initial date of public notice for creditors to make objections: March 26, 2019

iv) Final due date for creditors to make objections: Late April 2019 (scheduled)

v) Effective date: May 1, 2019 (scheduled)

(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. These are, however, subject to approval at the general meeting of shareholders scheduled for March 25, 2019.