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February 14, 2020

Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2019 (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 26, 2020
Scheduled date of dividend payment: —
Scheduled date of filing of securities report: March 27, 2020
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, 2019 (January 1, 2019 to December 31, 2019)

(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	
	million yen	%	million yen	%	million yen	%	million yen	%
Fiscal year ended December 31, 2019	1,702	128.7	(15)	—	21	—	5	—
December 31, 2018	744	(47.5)	(1,075)	—	(1,064)	—	(1,104)	—

Note: Comprehensive income Fiscal year ended December 31, 2019: 55 million yen [–%]
 Fiscal year ended December 31, 2018: (1,130) 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, 2019	0.26	0.26	0.1	0.5	(0.9)
December 31, 2018	(54.23)	—	(25.3)	(23.4)	(144.4)

Reference: Share of (profit) loss of entities accounted for using equity method:

Fiscal year ended December 31, 2019: – million yen
 Fiscal year ended December 31, 2018: – 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, 2019	4,836	4,620	95.3	219.97
December 31, 2018	4,052	3,857	94.9	188.57

Reference: Equity As of December 31, 2019: 4,608 million yen As of December 31, 2018: 3,844 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, 2019	(530)	216	695	2,200
December 31, 2018	(403)	(368)	99	1,829

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, 2018	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended December 31, 2019	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending December 31, 2020 (forecast)	–	0.00	–	0.00	0.00		–	

3. Forecasts of consolidated financial results for the fiscal year ending December 31, 2020 (January 1, 2020 to December 31, 2020)

(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, 2020	2,129	25.0	70	–	85	296.4	13	161.6	0.67

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, 2019 (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, 2019	20,950,142 shares
As of December 31, 2018	20,388,389 shares

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

As of December 31, 2019	50 shares
As of December 31, 2018	50 shares

- c. Average number of outstanding shares during the period

For the fiscal year ended December 31, 2019	20,588,848 shares
For the fiscal year ended December 31, 2018	20,368,732 shares

(Reference) Overview of non-consolidated financial results

Non-consolidated financial results for the fiscal year ended December 31, 2019 (January 1, 2019 to December 31, 2019)

(1) Non-consolidated operating results

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

	Net sales		Operating profit		Ordinary profit		Profit	
	million yen	%	million yen	%	million yen	%	million yen	%
Fiscal year ended December 31, 2019	1,688	128.7	62	–	92	–	79	–
December 31, 2018	738	(45.8)	(1,001)	–	(991)	–	(1,029)	–

	Earnings per share (Basic)	Earnings per share (Diluted)
Fiscal year ended December 31, 2019	yen 3.86	yen 3.85
December 31, 2018	(50.56)	–

(2) Non-consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
December 31, 2019	5,008	4,799	95.6	228.50
December 31, 2018	4,147	3,961	95.2	193.69

Reference: Equity As of December 31, 2019: 4,787 million yen As of December 31, 2018: 3,949 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 Wednesday, February 19, 2020.

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.....	2
(1) Overview of consolidated operating results for the fiscal year under review.....	2
(2) Overview of consolidated financial position for the fiscal year under review.....	5
(3) Overview of cash flows for the fiscal year under review.....	5
(4) Outlook for the fiscal year ending December 31, 2020.....	6
2. Basic rationale for selecting the accounting standard.....	6
3. Consolidated financial statements and significant notes thereto.....	7
(1) Consolidated balance sheet.....	7
(2) Consolidated statement of income and consolidated statement of comprehensive income.....	9
Consolidated statement of income.....	9
Consolidated statement of comprehensive income.....	9
(3) Consolidated statement of changes in equity.....	10
(4) Consolidated statement of cash flows.....	12
(5) Notes to consolidated financial statements.....	13
Notes on premise of going concern.....	13
Segment information, etc.....	13
Per share information.....	13
Significant subsequent event.....	14

1. Overview of consolidated operating results and others

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

Overall trend

With the backdrop of policies to control social security expenses in developed countries, during the fiscal year under review the pharmaceutical sector saw a series of corporate acquisitions in both Japan and overseas, as well as M&A at the product portfolio and business level. Pharmaceutical companies also worked to improve their competitiveness by selecting candidate compounds for medicinal drugs more rigorously, and by moving forward with the rebuilding of product portfolios. Such industry trends as these had no small impact on the licensing activities of drug discovery startups, like the Group, that operate a drug discovery research business.

Under such business environment, the Group pushed ahead with activities on generating development candidate compounds as pharmaceuticals by utilizing collaborative research and industry-academia collaboration and expanding its research and development portfolio, as well as promoting out-licensing activities of our own compounds under development.

With regard to business activities during the fiscal year under review, CJ HealthCare Corporation (South Korea, “CJ HealthCare (South Korea)”) began selling the potassium-competitive acid blocker tegoprazan (RQ-00000004/CJ-12420/brand name in South Korea (registered trademark in South Korea): K-CAB®; “tegoprazan”) in South Korea in March 2019. This is the first human drug product of the Group to come onto the market.

In addition, in November 2019 we concluded an agreement with CJ HealthCare (South Korea) to broaden our global partnership with the aim of maximizing the value of tegoprazan by accelerating its worldwide expansion. As a result, in addition to expecting progress by CJ HealthCare (South Korea) in US and European development, we are also strengthening our cooperative relationship with CJ HealthCare (South Korea) in relation to expanding tegoprazan in Japan.

Regarding the serotonin 5-HT_{2A} and dopamine D₂ receptor blocker (ziprasidone) licensed as a treatment for schizophrenia, Meiji Seika Pharma Co., Ltd. (“Meiji Seika Pharma”) carried out Phase III clinical trials of ziprasidone in Japan enrolling patients with an acute exacerbation of schizophrenia. Meiji Seika Pharma reported that findings of the study indicated no particular safety issues, but also indicated no statistically-significant difference in comparison with the placebo group in the primary endpoint. Currently Meiji Seika Pharma is conducting a detailed analysis and evaluation of the results obtained from this trial, and is considering future development plans and strategies.

With regard to the pet drug products that form the income platform of the Group, performance in the fiscal year under review remained strong. Sales of the EP4 antagonist (GALLIPRANT®/grapiprant/RQ-00000007/AT-001; “GALLIPRANT®”) increased steadily in the U.S., in addition to which sales in Europe began in March 2019, with favorable sales growth achieved in all regions. In addition, the Ghrelin receptor agonist (ENTYCE®/capromorelin/RQ-00000005/AT-002; “ENTYCE®”) also recorded steady sales in the U.S.

Moreover, Aratana Therapeutics Inc. (U.S., “Aratana (U.S.)”), a licensee for GALLIPRANT® and ENTYCE®, became the subsidiary of GALLIPRANT® co-promoter Elanco Animal Health Inc. (U.S., “Elanco (U.S.)”) in July 2019, so that sales of both drugs are being expanded by Elanco (U.S.).

In terms of development candidate compounds created through collaborative research with pharmaceutical companies, development by Asahi Kasei Pharma Corporation (“Asahi Kasei Pharma”) and EA Pharma Co., Ltd. (“EA Pharma”) is proceeding, and a certain milestone income was achieved during the fiscal year under review.

As for collaborative research activities, the Group and ASKA Pharmaceutical Co., Ltd. began collaborative research targeted at a specific ion channel in July 2019. In addition, the Group began collaborative research on new themes with Epigeneron, Inc., Nagoya City University and Gifu Pharmaceutical University.

With regard to the business activities of subsidiaries, at TMRC Co., Ltd., the retinoic acid receptor alpha agonist (Tamibarotene/TM-411/SY-1425) licensed to Syros Pharmaceuticals Inc. (U.S.) progressed steadily in its combined Phase II clinical trial, and favorable follow-up data was disclosed at the European Hematology Association in October 2019. RaQualia Innovations Inc. engaged in activities including providing technology development support and support for drawing up intellectual property strategy to startups and academia in the life science field, as well as building relationships and structuring projects.

Furthermore, we set up our first overseas location by opening a U.S. branch in San Diego, California, where an innovation ecosystem for pharmaceutical companies and biotechnology startups has developed.

Accordingly, financial results for the fiscal year ended December 31, 2019, the reporting period, were as follows. Business revenue for the period was 1,702 million yen (up 128.7% year on year), operating loss totaled 15 million yen (compared with operating loss of 1,075 million yen a year earlier), ordinary profit totaled 21 million yen (compared with ordinary loss of 1,064 million yen a year earlier), and profit attributable to owners of parent was 5 million yen (compared with loss attributable to owners of parent of 1,104 million yen a year earlier). Total business expenses were 1,718 million yen (down 5.5% year on year). In terms of the breakdown of this total, royalty payments of 231 million yen (up 175.7% year on year) were posted to cost of business expenses of 262 million yen (up 193.9% year on year), in addition to which research and development expenses were 864 million yen (down 19.6% year on year) and other selling, general and administrative expenses came to 591 million yen (down 9.7% year on year).

With 12 years having passed since the Company was established as a drug discovery startup, we are cementing our unique position, supported by a stable business platform based on royalty income from drug products sold in the market. The Group aims to use its R&D-centric approach to achieve further advances in future.

Research and development activities

Research and development expenses of the Group during the fiscal year ended December 31, 2019 were 864 million yen. The main components of these activities were as follows:

<RaQualia's research and development and collaborative research>

(A) Exploratory and discovery phase

- a) 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.
- b) The Company continued collaborative research with three companies.

Company	Start date	Content
Interprotein Corporation	February 2013	Collaborative research on a specific protein-protein interaction (PPI) inhibitor for pain treatments
ASKA Pharmaceutical. Co., Ltd.	July 2019	Collaborative research with respect to drug discovery research targeting at a specific ion channel
Epigeneron, Inc.	September 2019	Collaborative research for the creation of drugs for treating idiopathic pediatric nephrotic syndrome

- c) In a research project to evaluate a corticotropin-releasing hormone receptor 2 (CRHR2) antagonist, the Company has discovered multiple development candidate compounds and started an investigation of preclinical efficacy. The project has been carried out to create new mechanism-based drugs for heart failure in collaboration with the Department of Cardiology of the Faculty of Internal Medicine, Graduate School of Medicine, Nagoya University (under the supervision of Professor Toyooki Murohara and Associate Professor Mikito Takefuji).

(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 anything preventing it from moving on to the next stage of preclinical development study.

b) Ghrelin receptor agonist (RQ-00433412)

The compound is under development for cancer-related anorexia/cachexia syndrome and constipation resulting from spinal cord injury. The Company has completed investigation of preclinical efficacy and has not detected anything preventing it from moving on to the next stage of 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. The Company has not detected anything preventing it from moving on to the next clinical development phase.

(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. A license for clinical development after Phase II in the U.S. and Europe was granted to CJ HealthCare (South Korea) in November 2019. Going forward, development in the U.S. will be restarted by CJ HealthCare (South Korea).

b) 5-HT₄ 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)

The compound is under development for irritable bowel syndrome with diarrhea (IBS-D) as a target indication, and the Phase I clinical trials have been completed in the U.K.

<Status of development at licensee corporation>

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

Sales of the compound developed by CJ HealthCare (South Korea) in South Korea as an indication for gastro-esophageal reflux disease (GERD) began in March 2019, and additional approval was received in South Korea as an indication for gastric ulcers.

With regard to the status of development in other regions, in addition to CJ HealthCare (South Korea) proceeding with development in the U.S., it was announced in December 2019 that the primary endpoint had been achieved in Phase III clinical trials in China conducted by Shandong Luoxin Pharmaceutical Group Stock Co., Ltd., which is a Chinese sub-licensee of CJ HealthCare (South Korea).

b) Serotonin 5-HT_{2A} and dopamine D₂ receptor blocker (ziprasidone)

The compound is under development for treatment for schizophrenia. Meiji Seika Pharma carried out Phase III clinical trials of ziprasidone in Japan enrolling patients with an acute exacerbation of schizophrenia. In September 2019, Meiji Seika Pharma reported that findings of the study indicated no particular safety issues, but also indicated no statistically-significant difference in comparison with the placebo group in the primary endpoint. Currently Meiji Seika Pharma is considering future development plans and strategies based on the results obtained from this trial.

c) EP4 antagonist (GALLIPRANT®)

The compound was developed for pain management for pets by Aratana (U.S.). The company started selling the compound in the U.S. in January 2017, and then in Europe in March 2019 as well. Elanco (U.S.) is now the primary seller of the compound, upon Aratana (U.S.) having become its subsidiary in July 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 the U.S. in October 2017. Elanco (U.S.) has become the primary seller of the compound, upon Aratana (U.S.) having become its subsidiary in July 2019. While continuing the development of the compound as a cat anorexia management drug, Elanco (U.S.) has been carrying out pivotal studies.

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

AskAt Inc. ("AskAt") licensee Ikena Oncology Inc. (U.S., name changed from Kyn Therapeutics Inc. in December

2019), began Phase Ib clinical trials as a cancer immunotherapy for patients with colorectal cancer in October 2018, and Phase Ib/II clinical trials aimed at non-small cell lung cancer in December 2018.

Also, the compound licensed by AskAt to RMX BioPharma Co., Ltd. (China) entered Phase I clinical trials in China in September 2018 as an indication for pain management, while in relation to the compound licensed to Ningbo Tai Kang Medical Technology Co., Ltd. (China), that company's subsidiary, Ningbo NewBay Medical Technology Co., Ltd. (China), began Phase I clinical trials in China in June 2019 in the field of oncology.

- f) Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076, AAT-076)**
RMX BioPharma Co., Ltd. (China), a licensee of AskAt, started Phase I clinical trials for pain indication in China in October 2019.
- g) CB2 agonist (RQ-00202730/AAT-730)**
In September 2019, AskAt and Oxford Cannabinoid Technologies Ltd. (U.K.) concluded a license agreement and a business partnership agreement regarding the compound.
- h) Development candidate compound for a specific ion channel target (no compound code disclosed)**
Development on this compound, which was created through collaborative research with EA Pharma, is proceeding smoothly at EA Pharma.
- i) Selective sodium channel blocker (no compound code disclosed)**
Development on this compound, which was licensed to Maruho Co., Ltd., is currently under way for initiation of Phase I clinical trials.
- j) P2X7 receptor antagonist (RQ-00466479, AKP-23494954)**
Development on this compound, which was created through collaborative research with Asahi Kasei Pharma and licensed in March 2018, is proceeding smoothly for the target indication of neuropathic pain.

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

Assets

Total assets as of December 31, 2019 were 4,836 million yen, an increase of 784 million yen (up 19.4%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 502 million yen, an increase in accounts receivable - trade of 746 million yen, a decrease in securities of 142 million yen and a decrease in investment securities of 242 million yen.

Liabilities

Total liabilities as of December 31, 2019 were 215 million yen, an increase of 20 million yen (up 10.6%) from the end of the previous fiscal year. This is mainly attributable to an increase in accounts payable - trade of 34 million yen.

Net assets

Total net assets as of December 31, 2019 were 4,620 million yen, an increase of 763 million yen (up 19.8%) from the end of the previous fiscal year. This is mainly attributable to increases in capital stock and legal capital surplus of 708 million yen resulting from exercise of share acquisition rights, the recording of profit attributable to owners of parent of 5 million yen and an increase in valuation difference on available-for-sale securities of 49 million yen.

Consequently, the equity ratio was 95.3% (up 0.4 percentage points from the end of the previous fiscal year.)

(3) Overview of cash flows for the fiscal year under review

The balance of cash and cash equivalents ("cash") as of December 31, 2019 amounted to 2,200 million yen, an increase of 370 million yen (up 20.3%) from the end of the previous fiscal year.

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 530 million yen, an increase of 126 million yen (up 31.4% year on year). This is mainly attributable to the recording of income before income taxes of 27 million yen and depreciation of 140 million yen, a cash outflow from an increase in notes and accounts receivable - trade of 746 million yen, and a cash inflow from an increase in notes and accounts payable - trade of 34 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 216 million yen, a year-on-year increase of 584 million yen (compared with net cash of 368 million yen used a year earlier). This is mainly attributable to the proceeds from sales of investment securities of 301 million yen, purchase of property, plant and equipment of 70 million yen, and purchase of intangible assets of 23 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 695 million yen, an increase of 596 million yen (up 601.6% year on year). This is primarily due to the proceeds from issuance of shares resulting from exercise of share acquisition rights of 692 million yen and proceeds from issuance of share acquisition rights of 4 million yen.

(Reference) Trend in cash flow-related indicators

	Fiscal year ended December 31, 2015	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019
Equity ratio (%)	94.8	93.9	96.2	94.9	95.3
Market value equity ratio (%)	132.7	184.9	941.8	541.9	580.9
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.

(4) Outlook for the fiscal year ending December 31, 2020

Looking ahead to the next fiscal year (the fiscal year ending December 31, 2020) on the business activities, in addition to steadily promoting improvements in profitability through licensing of compounds under development and alliance management, we will strengthen our cooperative relationship with CJ HealthCare (South Korea) in relation to expanding tegoprazan in Japan, based on the agreement we concluded with CJ HealthCare (South Korea) to broaden our global partnership.

On the research and development front, in addition to proceeding with projects based on our own drug discovery research and development at both the exploratory and discovery stage and the development stage, we will continue to work on raising corporate value by promoting collaborative research with academia and pharmaceutical companies, amongst others.

On the revenue front, we expect strong performance in terms of royalty income from tegoprazan, sales of which have begun in South Korea, and the pet drug products that form the income platform of the Group. In addition, we anticipate some income associated with licensing of the compounds under development and milestone achievement of licensed compounds.

With 12 years having passed since the Company was established as a drug discovery startup, we are cementing our unique position, supported by a stable business platform based on royalty income from drug products sold in the market. The Group aims to use its R&D-centric approach to achieve further advances in future.

As for the outlook of consolidated financial results for the fiscal year ending December 31, 2020, the Company forecasts business revenue of 2,129 million yen, operating profit of 70 million yen, ordinary profit of 85 million yen and profit attributable to owners of parent of 13 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. 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, 2018	As of December 31, 2019
Assets		
Current assets		
Cash and deposits	1,671,346	2,174,200
Accounts receivable - trade	680	747,267
Securities	168,193	26,006
Supplies	6,498	5,500
Advance payments - trade	8,737	5,952
Prepaid expenses	71,937	69,231
Other	34,858	38,988
Total current assets	1,962,252	3,067,147
Non-current assets		
Property, plant and equipment		
Buildings	142,731	142,731
Tools, furniture and fixtures	676,694	742,190
Leased assets	3,432	3,432
Accumulated depreciation	(505,062)	(639,472)
Total property, plant and equipment	317,795	248,881
Intangible assets		
Trademark right	4,533	5,129
Software	28,420	26,805
Other	1,032	550
Total intangible assets	33,985	32,485
Investments and other assets		
Investment securities	1,716,580	1,474,270
Long-term prepaid expenses	10,035	2,199
Other	11,652	11,576
Total investments and other assets	1,738,267	1,488,047
Total non-current assets	2,090,049	1,769,413
Total assets	4,052,302	4,836,561

(Thousands of yen)

	As of December 31, 2018	As of December 31, 2019
Liabilities		
Current liabilities		
Accounts payable - trade	–	34,297
Lease obligations	741	741
Accounts payable - other	98,618	67,183
Accrued expenses	47,805	50,423
Income taxes payable	14,237	20,235
Advances received	–	6,875
Deposits received	3,089	3,318
Total current liabilities	164,492	183,074
Non-current liabilities		
Lease obligations	2,409	1,667
Asset retirement obligations	11,838	11,934
Deferred tax liabilities	16,474	19,236
Total non-current liabilities	30,722	32,839
Total liabilities	195,214	215,914
Net assets		
Shareholders' equity		
Capital stock	2,793,458	2,254,943
Capital surplus	2,983,241	2,444,726
Retained earnings	(1,890,201)	(99,172)
Treasury shares	(21)	(21)
Total shareholders' equity	3,886,476	4,600,476
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(41,901)	7,906
Total accumulated other comprehensive income	(41,901)	7,906
Share acquisition rights	12,512	12,265
Total net assets	3,857,087	4,620,647
Total liabilities and net assets	4,052,302	4,836,561

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

(Thousands of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019
Business revenue	744,517	1,702,973
Business expenses		
Cost of business revenue	89,411	262,804
Research and development expenses	1,074,619	864,251
Other selling, general and administrative expenses	655,596	591,862
Total business expenses	1,819,627	1,718,919
Operating loss	(1,075,109)	(15,945)
Non-operating income		
Interest income	9,004	9,184
Interest on securities	32,215	34,995
Gain on valuation of compound financial instruments	–	4,170
Subsidy income	855	335
Other	3,143	710
Total non-operating income	45,218	49,396
Non-operating expenses		
Foreign exchange losses	32,841	104
Share issuance cost	1,408	11,762
Loss on valuation of compound financial instruments	710	–
Total non-operating expenses	34,960	11,867
Ordinary profit (loss)	(1,064,851)	21,583
Extraordinary income		
Gain on sales of investment securities	4,577	5,728
Total extraordinary income	4,577	5,728
Extraordinary losses		
Loss on redemption of investment securities	17,919	–
Total extraordinary losses	17,919	–
Profit (loss) before income taxes	(1,078,193)	27,311
Income taxes - current	26,686	20,030
Income taxes - deferred	(331)	1,937
Total income taxes	26,355	21,968
Profit (loss)	(1,104,548)	5,343
Profit attributable to non-controlling interests	–	–
Profit (loss) attributable to owners of parent	(1,104,548)	5,343

Consolidated statement of comprehensive income

(Thousands of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019
Profit (loss)	(1,104,548)	5,343
Other comprehensive income		
Valuation difference on available-for-sale securities	(26,075)	49,807
Total other comprehensive income	(26,075)	49,807
Comprehensive income	(1,130,624)	55,151
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(1,130,624)	55,151
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of changes in equity

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
Profit 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
Profit 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

Fiscal year ended December 31, 2019

(Thousands of yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	2,793,458	2,983,241	(1,890,201)	(21)	3,886,476
Changes of items during period					
Issuance of new shares	354,327	354,327			708,655
Capital reduction	(892,842)	892,842			–
Deficit disposition		(1,785,685)	1,785,685		–
Profit attributable to owners of parent			5,343		5,343
Net changes of items other than shareholders' equity					–
Total changes of items during period	(538,514)	(538,514)	1,791,029	–	713,999
Balance at end of current period	2,254,943	2,444,726	(99,172)	(21)	4,600,476

	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	(41,901)	(41,901)	12,512	3,857,087
Changes of items during period				
Issuance of new shares		–		708,655
Capital reduction		–		–
Deficit disposition		–		–
Profit attributable to owners of parent		–		5,343
Net changes of items other than shareholders' equity	49,807	49,807	(247)	49,560
Total changes of items during period	49,807	49,807	(247)	763,560
Balance at end of current period	7,906	7,906	12,265	4,620,647

(4) Consolidated statement of cash flows

(Thousands of yen)

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019
Cash flows from operating activities		
Profit (loss) before income taxes	(1,078,193)	27,311
Depreciation	125,588	140,050
Interest income	(9,004)	(9,184)
Interest income on securities	(32,215)	(34,995)
Foreign exchange losses (gains)	(25,606)	10,635
Loss (gain) on valuation of compound financial instruments	710	(4,170)
Subsidy income	(855)	(335)
Share issuance cost	1,408	11,762
Loss (gain) on sales of investment securities	(4,577)	(5,728)
Loss (gain) on redemption of investment securities	17,919	–
Decrease (increase) in notes and accounts receivable - trade	448,058	(746,587)
Decrease (increase) in inventories	(1,345)	998
Increase (decrease) in notes and accounts payable - trade	(1,984)	34,297
Decrease (increase) in advance payments	181,006	2,784
Decrease (increase) in prepaid expenses	(9,786)	2,705
Increase (decrease) in accounts payable - other	11,004	(7,186)
Decrease (increase) in consumption taxes refund receivable	(13,800)	(4,793)
Increase (decrease) in accrued consumption taxes	(13,907)	–
Other, net	(8,896)	30,880
Subtotal	(414,477)	(551,554)
Interest and dividend income received	41,401	44,324
Proceeds from subsidy income	855	335
Income taxes paid	(31,775)	(23,953)
Net cash provided by (used in) operating activities	(403,997)	(530,848)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	–	10,000
Proceeds from redemption of securities	113,040	–
Purchase of property, plant and equipment	(213,337)	(70,663)
Purchase of intangible assets	(7,797)	(23,714)
Purchase of investment securities	(785,276)	–
Proceeds from sales of investment securities	203,747	301,440
Proceeds from redemption of investment securities	323,567	–
Other, net	(2,001)	(858)
Net cash provided by (used in) investing activities	(368,057)	216,204
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	99,741	692,234
Proceeds from issuance of share acquisition rights	–	4,412
Repayments of lease obligations	(555)	(741)
Net cash provided by (used in) financing activities	99,185	695,905
Effect of exchange rate change on cash and cash equivalents	28,493	(10,595)
Net increase (decrease) in cash and cash equivalents	(644,375)	370,666
Cash and cash equivalents at beginning of period	2,473,916	1,829,540
Cash and cash equivalents at end of period	1,829,540	2,200,206

(5) Notes to consolidated financial statements**Notes on premise of going concern**

No items to report.

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, 2018	Fiscal year ended December 31, 2019
Net assets per share (Yen)	188.57	219.97
Basic earnings (loss) per share (Yen)	(54.23)	0.26
Diluted earnings per share	—	0.26

Notes: 1. Diluted earnings per share of fiscal year ended December 31, 2018 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, 2018	As of December 31, 2019
Total net assets (Thousands of yen)	3,857,087	4,620,647
Amount to be deducted from total net assets (Thousands of yen)	12,512	12,265
[Share acquisition rights included therein] (Thousands of yen)	[12,512]	[12,265]
Amount of net assets at the end of period related to common shares (Thousands of yen)	3,844,575	4,608,382
Number of common shares at the end of period used in calculation of net assets per share (Shares)	20,388,339	20,950,092

3. The basis for calculation of basic earnings (loss) per share and diluted earnings per share is as follows:

	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019
Basic earnings (loss) per share		
Amount of profit (loss) attributable to owners of parent (Thousands of yen)	(1,104,548)	5,343
Amount not attributable to common shareholders (Thousands of yen)	—	—
Amount of profit (loss) attributable to owners of parent related to common shares (Thousands of yen)	(1,104,548)	5,343
Average number of outstanding common shares during the period (Shares)	20,368,732	20,588,848
Diluted earnings per share		

Adjustment on profit attributable to owners of parent (Thousands of yen)	-	-
Increase in number of common shares (Shares)	-	27,951
[Share acquisition rights included therein (Shares)]	-	(27,951)
Summary of potential shares that are not included in calculation of diluted earnings per share due to a lack of dilution effect	-----	-----

Significant subsequent event

No items to report.