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February 12, 2021

Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2020 (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
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Scheduled date of general meeting of shareholders: March 25, 2021
Scheduled date of dividend payment: —
Scheduled date of filing of securities report: March 30, 2021
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, 2020 (January 1, 2020 to December 31, 2020)

(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, 2020	1,107	(35.0)	(486)	—	(527)	—	(606)	—
December 31, 2019	1,702	128.7	(15)	—	21	—	5	—

Note: Comprehensive income Fiscal year ended December 31, 2020: (610) million yen [–%]
 Fiscal year ended December 31, 2019: 55 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, 2020	(28.97)	—	(14.1)	(11.6)	(43.9)
December 31, 2019	0.26	0.26	0.1	0.5	(0.9)

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

Fiscal year ended December 31, 2020: – million yen
 Fiscal year ended December 31, 2019: – 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, 2020	4,251	4,011	94.1	190.88
December 31, 2019	4,836	4,620	95.3	219.97

Reference: Equity As of December 31, 2020: 3,999 million yen As of December 31, 2019: 4,608 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, 2020	(289)	225	(6)	2,061
December 31, 2019	(530)	216	695	2,200

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, 2019	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended December 31, 2020	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending December 31, 2021 (forecast)	–	0.00	–	0.00	0.00		–	

3. Forecasts of consolidated financial results for the fiscal year ending December 31, 2021 (January 1, 2021 to December 31, 2021)

(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, 2021	2,738	147.3	420	–	427	–	343	–	16.41

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, 2020 (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, 2020	20,951,642 shares
As of December 31, 2019	20,950,142 shares

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

As of December 31, 2020	50 shares
As of December 31, 2019	50 shares

- c. Average number of outstanding shares during the period

For the fiscal year ended December 31, 2020	20,950,654 shares
For the fiscal year ended December 31, 2019	20,588,848 shares

(Reference) Overview of non-consolidated financial results

Non-consolidated financial results for the fiscal year ended December 31, 2020 (January 1, 2020 to December 31, 2020)

(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, 2020	1,099	(40.2)	(512)	–	(550)	–	(654)	–
December 31, 2019	1,688	128.7	62	–	92	–	79	–

	Earnings per share (Basic)	Earnings per share (Diluted)
Fiscal year ended December 31, 2020	yen (31.26)	yen –
December 31, 2019	3.86	3.85

(2) Non-consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	million yen	million yen	%	yen
December 31, 2020	4,367	4,141	94.6	197.12
December 31, 2019	5,008	4,799	95.6	228.50

Reference: Equity As of December 31, 2020: 4,129 million yen As of December 31, 2019: 4,787 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 17, 2021.

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.....	6
(3) Overview of cash flows for the fiscal year under review.....	6
(4) Outlook for the fiscal year ending December 31, 2021.....	7
2. Basic rationale for selecting the accounting standard.....	7
3. Consolidated financial statements and significant notes thereto.....	8
(1) Consolidated balance sheet.....	8
(2) Consolidated statement of income and consolidated statement of comprehensive income.....	10
Consolidated statement of income.....	10
Consolidated statement of comprehensive income.....	10
(3) Consolidated statement of changes in equity.....	11
(4) Consolidated statement of cash flows.....	13
(5) Notes to consolidated financial statements.....	14
Notes on premise of going concern.....	14
Segment information, etc.....	14
Per share information.....	15
Significant subsequent event.....	16

1. Overview of consolidated operating results and others

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

Overall trend

During the fiscal year ended December 31, 2020, the Japanese economy was in a difficult situation due to stagnation in global economic activity, restrictions on movement, and so forth under the impact of the global novel coronavirus disease (“COVID-19”) pandemic and related states of emergency declared by governments in various countries. Over the second half of the fiscal year, a second wave of the COVID-19 pandemic swept the world, bringing concerns of the risk of an economic downturn domestically and internationally.

In the pharmaceutical industry, sales activities have been hindered by suppression of medical examinations for patients and refraining from visiting customers, among others. Business development activities have also been hindered in various ways, such as people refraining from taking domestic business trips and a virtual prohibition of international travel in line with movement restrictions, as well as closure of clinical testing facilities. Such industry trends as these had no small impact on the business development activities of drug discovery startups, like the Group, that operate a drug discovery research business.

Under such 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 in the development stages.

With regard to business activities for the fiscal year under review, sales of pet drug products were strong overall. Sales of GALLIPRANT® (generic name: grapiprant)—a drug for osteoarthritis in dogs—struggled in the first quarter ended March 31, 2020, soon after the start of the COVID-19 pandemic, as a result of a temporary impact on logistics and product supplies in major cities in the U.S., where COVID-19 infections soared, and a reduction in channel inventory carried out by the Company’s licensee Elanco Animal Health Inc. (U.S., “Elanco (U.S.)”). From the second quarter ended June 30, 2020, onward, sales in the U.S. followed a recovery trend and performed strongly. GALLIPRANT® sales in regions outside of the U.S. performed favorably. It was launched in Latin America during the first quarter and in Japan in the fourth quarter ended December 31, 2020, making a steady start in both cases.

Sales of ENTYCE® (generic name: capromorelin)—a treatment for anorexia in dogs—continued to record steady growth in the U.S.

Capromorelin received approval from the U.S. Food and Drug Administration (FDA, “FDA”) Center for Veterinary Medicine (CVM) in October 2020 as a treatment for managing weight loss in cats with chronic kidney disease.

Regarding human drug products, sales of K-CAB® (generic name: tegoprazan)—a drug for gastro-esophageal reflux disease marketed by the Company’s licensee HK inno.N Corporation (South Korea, “HK inno.N (South Korea)”)—in South Korea performed well overall. During the first quarter, the Company’s royalty income floundered partly due to the impact of inventory adjustments; however, growth expanded from the second quarter, leading to a sharp increase in the Company’s royalty income. With regard to the global development of tegoprazan, HK inno.N (South Korea) submitted an Investigational New Drug (IND) application to the FDA and obtained approval in June 2020 for conducting trials in the U.S. This company is currently preparing to start the Phase I clinical trials. In China, HK Inno.N (South Korea)’s Chinese licensee Shandong Luoxin Pharmaceutical Group Co., Ltd. (China, “Luoxin Pharma (China)”), completed Phase III clinical trials for the target indication of erosive gastro-esophageal reflux disease and filed an application for new drug approval to the local Chinese authority. After that, notice of acceptance was received from the authority.

In addition, HK inno.N (South Korea) announced in November 2020 that it had concluded sub-licensing agreements with Metro Pharma Phils Inc. (Philippines), Monos Pharma LLC (Mongolia), and United Italian Trading Corporation (Pte) Ltd. (Singapore). Meanwhile, in Japan, the Company is examining all possibilities regarding conducting Phase II clinical trials, including building a cooperative relationship with HK inno.N (South Korea).

Regarding “ion channel drug discovery,” in which the Group aims to develop strengths, the Group has been making steady progress on four programs: a P2X7 receptor antagonist (RQ-00466479/AK1780) discovered through collaborative research with Asahi Kasei Pharma Corporation (“Asahi Kasei Pharma”), a compound discovered through collaborative research with EA Pharma Co., Ltd. (“EA Pharma”), a selective sodium channel blocker licensed to Maruho Co., Ltd. (“Maruho”), and a collaborative research project with ASKA Pharmaceutical Co., Ltd. (“ASKA Pharmaceutical”). Some of the programs have seen their clinical trials delayed by the closure of clinical trial facilities due to COVID-19, while others have seen progress stall on licensing negotiations. However, in November 2020, the Company achieved the first milestone on the collaborative research project with ASKA Pharmaceutical.

Regarding the retinoic acid receptor alpha agonist (Tamibarotene/TM-411/SY-1425, “Tamibarotene”) licensed to Syros Pharmaceuticals Inc. (U.S., “Syros (U.S.)”) by the Company’s consolidated subsidiary TMRC Co., Ltd., Syros (U.S.) reported the new data of a combined Phase II clinical trial at the 62nd Annual Meeting and Exposition of the American Society of Hematology (ASH) in December 2020. Syros (U.S.) and the research team commented that combined administration of tamibarotene with azacitidine exhibited a high response rates, rapid onset of responses, and clinically meaningful durability, and was well tolerated in RARA-positive newly diagnosed acute myeloid leukemia (AML) patients who are difficult to treat with standard chemotherapy. Based on consultation with the FDA, Syros (U.S.) has announced plans to begin Phase III clinical trials for indication of myelodysplastic syndrome (MDS) in the first quarter of 2021. It also announced the start of a new Phase II clinical trial for AML of a combination of Tamibarotene, azacitidine, and Venetoclax (another company’s AML treatment drug) in the fourth quarter of 2021.

There has been a slightly negative impact on activities for the licensing of candidate compounds for medicinal drugs and collaborative research as opportunities for face-to-face meetings have decreased due to COVID-19, but business development activities have steadily progressed while utilizing web conferencing. The Group started collaborative research for new treatments for COVID-19 with Nagasaki University in September 2020. In October 2020, the Company concluded a basic agreement on industry-academia collaboration with Gifu Pharmaceutical University.

Meanwhile, the Company’s consolidated subsidiary, RaQualia Innovations Inc. has been working since its establishment in December 2018 to build a universe of pre-clinical compounds emerging from researchers within academia, provide optimal solutions for maximizing bioventure business value and promote collaboration. As a result, the said subsidiary has achieved some success in supporting technology development leveraging the Company’s drug discovery platform, drawing up of intellectual property strategy, and proposing exit strategies. Nevertheless, the Company decided to dissolve the said subsidiary as of January 22, 2021, as its operations were deemed too difficult to continue given the recent management environment. The impact of this decision on the Group’s consolidated financial results is negligible.

Accordingly, financial results for the fiscal year ended December 31, 2020, the reporting period, were as follows. Business revenue for the period was 1,107 million yen (down 35.0% year on year), operating loss totaled 486 million yen (compared with operating loss of 15 million yen a year earlier), ordinary loss totaled 527 million yen (compared with ordinary profit of 21 million yen a year earlier), and loss attributable to owners of parent was 606 million yen (compared with profit attributable to owners of parent of 5 million yen a year earlier).

Total business expenses were 1,593 million yen (down 7.3% year on year). In terms of the breakdown of this total, royalty payments of 134 million yen (down 41.7% year on year) were posted to cost of business revenue of 138 million yen (down 47.5% year on year), in addition to which research and development expenses were 932 million yen (up 7.9% year on year) and other selling, general and administrative expenses came to 522 million yen (down 11.6% year on year).

Research and development activities

Research and development expenses of the Group during the fiscal year ended December 31, 2020 were 932 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) Project of selective sodium channel blocker
In a project to evaluate a selective sodium channel blocker for indications such as inflammatory pain and neuropathic pain, the Company has discovered lead compounds and has been carrying out characterization of such compounds.

- b) Collaborative research with companies
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) Collaborative research with academia

In a research project to evaluate a corticotropin-releasing hormone receptor 2 (CRHR2) antagonist (compound code: RQ-00490721), the Company has discovered multiple development candidates and started characterization of such compounds. 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 Toyoaki Murohara and Associate Professor Mikito Takefuji).

(B) Preclinical development phase

a) TRPM8 blocker (RQ-00434739)

The compound is under development for neuropathic pain (chemotherapy-induced cold allodynia). The Company has completed characterization of the compound 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 started manufacturing APIs necessary to start preclinical 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. Furthermore, in June 2020, the Company licensed tegoprazan to HK inno.N (South Korea) for all non-licensed countries and regions (emerging and developing countries) except Japan. In Japan, the Company is examining all possibilities regarding conducting Phase II clinical trials, including building a cooperative relationship with HK inno.N (South Korea).

b) 5-HT₄ partial agonist (RQ-00000010)

The compound is under development for gastroparesis, functional dyspepsia and chronic constipation. Virginia Commonwealth University Parkinson's and Movement Disorders Center of the United States, a research partner of the Company, completed investigator-initiated clinical trials of the compound.

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

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

<Status of development at licensee corporation>

a) tegoprazan (registered trademark in South Korea: K-CAB®, development code: RQ-00000004/IN-12420)

Tegoprazan has already been approved and sold as a drug for gastro-esophageal reflux disease, etc., in South Korea, and in March 2020 the compound received additional approval in South Korea for "Combination antibiotic therapy for *Helicobacter pylori* eradication in patients with peptic ulcer and chronic atrophic gastritis."

HK inno.N (South Korea) submitted an Investigational New Drug (IND) application to the FDA for tegoprazan and obtained approval in June 2020 for conducting trials.

Meanwhile, HK Inno.N (South Korea)'s Chinese licensee Luoxin Pharma (China) completed Phase III clinical trials for the target indication of erosive gastro-esophageal reflux disease, and filed an application for new drug approval to the local Chinese authority. After that, notice of approval was received from the authority.

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

Regarding this compound which was licensed out as a treatment for schizophrenia, Meiji Seika Pharma Co., Ltd. is considering the development plan and strategy.

c) EP4 antagonist (GALLIPRANT®)

This compound is currently being sold as a pain management for dogs by Elanco (U.S.). Since its launch in the U.S. in January 2017, the compound has been launched in over 20 countries around the world and sales began in Japan in October 2020.

d) Ghrelin receptor agonist (ENTYCE®)

The compound was being sold in the U.S. by Elanco (U.S.) as a treatment for anorexia in dogs. It received approval from the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) in October 2020 as ELURA®, a treatment for managing weight loss in cats with chronic kidney disease.

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

AskAt Inc. ("AskAt") licensee Ikena Oncology Inc. (U.S.) is conducting Phase I and Phase II clinical trials in the U.S. as a cancer immunotherapy.

In addition, AskAt licensee Shanghai Haihe Biopharma Research and Development Co., Ltd. (China, "Haihe (China)") completed Phase I clinical trials in China for the indication of pain, and Ningbo Tai Kang Medical Technology Co., Ltd. (China), another AskAt licensee, is conducting Phase I clinical trials in China in the area of oncology.

- f) **Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076, AAT-076)**
AskAt licensee Haihe (China) is conducting Phase I clinical trials in China for the indication of pain.
- g) **CB2 agonist (RQ-00202730/AAT-730)**
AskAt licensee Oxford Cannabinoid Technologies Ltd. (U.K.) is conducting preclinical development in the U.S.
- 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 at EA Pharma.
- i) **Selective sodium channel blocker (no compound code disclosed)**
The compound was licensed to Maruho, which is proceeding with development of a therapeutic agent using the compound as an active ingredient.
- j) **P2X7 receptor antagonist (RQ-00466479, AK1780)**
Development on this compound, which was created through collaborative research with Asahi Kasei Pharma, is proceeding smoothly for the target indication of neuropathic pain at Asahi Kasei Pharma.

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

Assets

Total assets as of December 31, 2020 were 4,251 million yen, a decrease of 585 million yen (down 12.1%) from the end of the previous fiscal year. This is mainly attributable to a decrease in cash and deposits of 780 million yen, a decrease in accounts receivable - trade of 216 million yen, an increase in securities of 693 million yen, and a decrease in investment securities of 436 million yen.

Liabilities

Total liabilities as of December 31, 2020 were 240 million yen, an increase of 24 million yen (up 11.2%) from the end of the previous fiscal year. This is mainly attributable to a decrease in accounts payable - other of 14 million yen and an increase in lease obligations of 43 million yen.

Net assets

Total net assets as of December 31, 2020 were 4,011 million yen, a decrease of 609 million yen (down 13.2%) from the end of the previous fiscal year. This is mainly attributable to the recording of loss attributable to owners of parent of 606 million yen.

Consequently, the equity ratio was 94.1% (down 1.2 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, 2020 amounted to 2,061 million yen, a decrease of 138 million yen (down 6.3%) 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 289 million yen, a decrease of 241 million yen (down 45.5% year on year). This is mainly attributable to the recording of loss before income taxes of 527 million yen and depreciation of 124 million yen, and a cash inflow from a decrease in trade receivables of 216 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 225 million yen, an increase of 9 million yen (up 4.3% year on year). This is mainly attributable to the proceeds from sales of investment securities of 387 million yen, purchase of property, plant and equipment of 150 million yen, and purchase of intangible assets of 6 million yen.

Cash flows from financing activities

Net cash used in financing activities was 6 million yen, a decrease of 702 million yen (compared with net cash of 695 million yen provided a year earlier). This is mainly attributable to repayments of lease obligations of 7 million yen.

(Reference) Trend in cash flow-related indicators

	Fiscal year ended December 31, 2016	Fiscal year ended December 31, 2017	Fiscal year ended December 31, 2018	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Equity ratio (%)	93.9	96.2	94.9	95.3	94.1
Market value equity ratio (%)	184.9	941.8	541.9	580.9	492.8
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, 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, 2021

As of the fiscal year ended December 31, 2020, because operating profit and cash flows from operating activities for the four most recent fiscal years were negative (business performance standard), operating profit for the fiscal year in which the Company made the listing application was negative, and operating profit for nine consecutive fiscal years after the share listing was negative (standard for recorded profit), the Company expects its shares to be designated as an issue entering the grace period pertaining to delisting.

For details, please refer to “Notice Regarding the Possibility of the Company’s Shares Being Designated as “Issue Entering the Grace Period Pertaining to Delisting” announced today.

For the next fiscal year (the fiscal year ending December 31, 2021), the Company expects to receive steady royalty income from tegoprazan—a gastro-esophageal reflux disease treatment, GALLIPRANT®—a drug for osteoarthritis in dogs, and ENTYCE®—a treatment for anorexia in dogs. The Company also expects to earn lump-sum income associated with out-licensing and milestone income associated with development progress of out-licensed development compounds.

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, the Company will continue to work on raising corporate value by promoting collaborative research with academia and pharmaceutical companies, amongst others.

As for the outlook of consolidated financial results for the fiscal year ending December 31, 2021, the Company forecasts business revenue of 2,738 million yen, operating profit of 420 million yen, ordinary profit of 427 million yen and profit attributable to owners of parent of 343 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.

In the current situation, where there is no clear prediction regarding when COVID-19 will be brought under control, it is difficult at this time to forecast the impact on the Group’s financial results. If it should become necessary to revise the forecasts due to factors such as the spread of COVID-19 or changes in the business environment, the Group will announce the revision 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).

The Group does not have plans to adopt IFRS as of the end of the fiscal year under review; however, our policy is to respond appropriately to the situation in Japan and overseas with regard to adoption trends by other companies in the industry.

3. Consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2019	As of December 31, 2020
Assets		
Current assets		
Cash and deposits	2,174,200	1,394,128
Accounts receivable - trade	747,267	530,818
Securities	26,006	719,418
Supplies	5,500	6,540
Advance payments - trade	5,952	36,412
Prepaid expenses	69,231	50,243
Other	38,988	96,671
Total current assets	3,067,147	2,834,232
Non-current assets		
Property, plant and equipment		
Buildings	142,731	153,242
Tools, furniture and fixtures	742,190	871,764
Leased assets	3,432	49,069
Accumulated depreciation	(639,472)	(741,109)
Total property, plant and equipment	248,881	332,967
Intangible assets		
Trademark right	5,129	4,439
Software	26,805	27,927
Other	550	639
Total intangible assets	32,485	33,005
Investments and other assets		
Investment securities	1,474,270	1,037,601
Long-term prepaid expenses	2,199	10
Deferred tax assets	-	2,959
Other	11,576	10,457
Total investments and other assets	1,488,047	1,051,029
Total non-current assets	1,769,413	1,417,002
Total assets	4,836,561	4,251,235

(Thousands of yen)

	As of December 31, 2019	As of December 31, 2020
Liabilities		
Current liabilities		
Accounts payable - trade	34,297	41,830
Lease obligations	741	18,281
Accounts payable - other	67,183	52,666
Accrued expenses	50,423	49,868
Income taxes payable	20,235	20,882
Advances received	6,875	–
Deposits received	3,318	3,133
Total current liabilities	183,074	186,662
Non-current liabilities		
Lease obligations	1,667	27,238
Asset retirement obligations	11,934	12,031
Deferred tax liabilities	19,236	14,173
Total non-current liabilities	32,839	53,443
Total liabilities	215,914	240,106
Net assets		
Shareholders' equity		
Share capital	2,254,943	2,255,401
Capital surplus	2,444,726	2,445,184
Retained earnings	(99,172)	(706,157)
Treasury shares	(21)	(21)
Total shareholders' equity	4,600,476	3,994,407
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	7,906	4,809
Total accumulated other comprehensive income	7,906	4,809
Share acquisition rights	12,265	11,912
Total net assets	4,620,647	4,011,129
Total liabilities and net assets	4,836,561	4,251,235

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

(Thousands of yen)

	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Business revenue	1,702,973	1,107,301
Business expenses		
Cost of business revenue	262,804	138,012
Research and development expenses	864,251	932,451
Other selling, general and administrative expenses	591,862	522,915
Total business expenses	1,718,919	1,593,379
Operating loss	(15,945)	(486,078)
Non-operating income		
Interest income	9,184	3,593
Interest on securities	34,995	28,144
Gain on valuation of compound financial instruments	4,170	810
Subsidy income	335	1,500
Other	710	613
Total non-operating income	49,396	34,660
Non-operating expenses		
Interest expenses	-	436
Foreign exchange losses	104	75,645
Share issuance costs	11,762	154
Total non-operating expenses	11,867	76,237
Ordinary profit (loss)	21,583	(527,654)
Extraordinary income		
Gain on sales of non-current assets	-	750
Gain on sales of investment securities	5,728	8,430
Total extraordinary income	5,728	9,180
Extraordinary losses		
Impairment loss	-	2,542
Loss on sales of investment securities	-	348
Loss on redemption of investment securities	-	6,575
Total extraordinary losses	-	9,466
Profit (loss) before income taxes	27,311	(527,941)
Income taxes - current	20,030	84,469
Income taxes - deferred	1,937	(5,425)
Total income taxes	21,968	79,044
Profit (loss)	5,343	(606,985)
Profit attributable to non-controlling interests	-	-
Profit (loss) attributable to owners of parent	5,343	(606,985)

Consolidated statement of comprehensive income

(Thousands of yen)

	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Profit (loss)	5,343	(606,985)
Other comprehensive income		
Valuation difference on available-for-sale securities	49,807	(3,096)
Total other comprehensive income	49,807	(3,096)
Comprehensive income	55,151	(610,082)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	55,151	(610,082)
Comprehensive income attributable to non-controlling interests	-	-

(3) Consolidated statement of changes in equity

Fiscal year ended December 31, 2019

(Thousands of yen)

	Shareholders' equity				
	Share capital	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 current of 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

Fiscal year ended December 31, 2020

(Thousands of yen)

	Shareholders' equity				
	Share capital	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	2,254,943	2,444,726	(99,172)	(21)	4,600,476
Changes of items during period					
Issuance of new shares	458	458			916
Profit (loss) attributable to owners of parent			(606,985)		(606,985)
Net changes of items other than shareholders' equity					-
Total changes of items during period	458	458	(606,985)	-	(606,068)
Balance at end of current period	2,255,401	2,445,184	(706,157)	(21)	3,994,407

	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 current of period	7,906	7,906	12,265	4,620,647
Changes of items during period				
Issuance of new shares		-		916
Profit (loss) attributable to owners of parent		-		(606,985)
Net changes of items other than shareholders' equity	(3,096)	(3,096)	(352)	(3,449)
Total changes of items during period	(3,096)	(3,096)	(352)	(609,518)
Balance at end of current period	4,809	4,809	11,912	4,011,129

(4) Consolidated statement of cash flows

(Thousands of yen)

	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Cash flows from operating activities		
Profit (loss) before income taxes	27,311	(527,941)
Depreciation	140,050	124,255
Impairment loss	-	2,542
Interest income	(9,184)	(3,593)
Interest income on securities	(34,995)	(28,144)
Interest expenses	-	436
Foreign exchange losses (gains)	10,635	67,613
Loss (gain) on valuation of compound financial instruments	(4,170)	(810)
Subsidy income	(335)	(1,500)
Share issuance costs	11,762	154
Loss (gain) on sales of investment securities	(5,728)	(8,081)
Loss (gain) on sales of non-current assets	-	(750)
Loss (gain) on redemption of investment securities	-	6,575
Decrease (increase) in trade receivables	(746,587)	216,449
Decrease (increase) in inventories	998	(1,040)
Increase (decrease) in trade payables	34,297	7,532
Decrease (increase) in advance payments - trade	2,784	(30,459)
Decrease (increase) in prepaid expenses	2,705	18,988
Increase (decrease) in accounts payable - other	(7,186)	(23,102)
Decrease (increase) in consumption taxes refund receivable	(4,793)	(55,544)
Other, net	30,880	2,120
Subtotal	(551,554)	(234,298)
Interest and dividends received	44,324	36,753
Interest paid	-	(436)
Subsidies received	335	1,500
Income taxes paid	(23,953)	(92,726)
Net cash provided by (used in) operating activities	(530,848)	(289,208)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	10,000	-
Purchase of property, plant and equipment	(70,663)	(150,151)
Proceeds from sales of property, plant and equipment	-	750
Purchase of intangible assets	(23,714)	(6,199)
Purchase of investment securities	-	(106,933)
Proceeds from sales of investment securities	301,440	387,515
Proceeds from redemption of investment securities	-	100,309
Other, net	(858)	185
Net cash provided by (used in) investing activities	216,204	225,475
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	692,234	409
Proceeds from issuance of share acquisition rights	4,412	-
Repayments of lease obligations	(741)	(7,370)
Net cash provided by (used in) financing activities	695,905	(6,961)
Effect of exchange rate change on cash and cash equivalents	(10,595)	(68,196)
Net increase (decrease) in cash and cash equivalents	370,666	(138,890)
Cash and cash equivalents at beginning of period	1,829,540	2,200,206
Cash and cash equivalents at end of period	2,200,206	2,061,316

(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, 2019	Fiscal year ended December 31, 2020
Net assets per share (Yen)	219.97	190.88
Basic earnings (loss) per share	0.26	(28.97)
Diluted earnings per share	0.26	—

Notes: 1. Diluted earnings per share of fiscal year ended December 31, 2020 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, 2019	As of December 31, 2020
Total net assets (Thousands of yen)	4,620,647	4,011,129
Amount to be deducted from total net assets (Thousands of yen)	12,265	11,912
[Share acquisition rights included therein (Shares)] (Thousands of yen)	[12,265]	[11,912]
Amount of net assets at the end of period related to common shares (Thousands of yen)	4,608,382	3,999,216
Number of common shares at the end of period used in calculation of net assets per share (Shares)	20,950,092	20,951,592

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

	Fiscal year ended December 31, 2019	Fiscal year ended December 31, 2020
Basic earnings (loss) per share		
Amount of profit (loss) attributable to owners of parent (Thousands of yen)	5,343	(606,985)
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)	5,343	(606,985)
Average number of outstanding common shares during the period (Shares)	20,588,848	20,950,654
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

(Dissolution and liquidation of a subsidiary)

The Board of Directors resolved at a meeting held on January 22, 2021 to dissolve the Company's consolidated subsidiary, RaQualia Innovations Inc.

1. Reason for dissolution

RaQualia Innovations Inc., the Company's consolidated subsidiary, has been working since its establishment to build a universe of pre-clinical compounds emerging from researchers within academia, provide optimal solutions for maximizing bioventure business value and promote collaboration. As a result, the said subsidiary has achieved some success in supporting technology development leveraging the Company's drug discovery platform, drawing up of intellectual property strategy, and proposing exit strategies. Nevertheless, the Board of Directors resolved to dissolve the said subsidiary as of January 22, 2021, as its operations were deemed too difficult to continue given the recent management environment.

2. Overview of the dissolving subsidiary

Company	RaQualia Innovations Inc.
Location	1-3-2 Kyobashi, Chuo-ku, Tokyo, Japan
Business description	Pharmaceutical research and development support business
Share capital	5 million yen
Ratio of investments in capital	100%

3. Schedule for dissolution and liquidation

- (1) January 22, 2021 Resolution on dissolution by the Company's Board of Directors
- (2) January 22, 2021 Resolution on dissolution by an extraordinary meeting of shareholders of RaQualia Innovations Inc.
- (3) January 22, 2021 Date of dissolution
- (4) March 31, 2021 (planned) Completion of liquidation

4. Status of the subsidiary (as of December 31, 2020)

Total assets	76 million yen
Total liabilities	102 million yen

5. Impact of the dissolution on profit and loss

Since the loans made to the subsidiary are currently unrecoverable due to its insolvent status, the Company will write off receivables held against the subsidiary to the amount of its net capital deficit in conjunction with its dissolution. Since this debt write-off is for a consolidated subsidiary, there is no impact on the Company's consolidated financial results. The impact of the subsidiary's dissolution and liquidation on the consolidated financial results is negligible.