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May 14, 2021

Summary of Consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2021 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: <https://www.raqualia.com/>
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Scheduled date of filing of quarterly securities report: May 14, 2021
Scheduled date of dividend payment: —
Supplementary documents for quarterly results: Yes
Quarterly results briefing: Yes

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

1. Consolidated financial results for the first three months of the fiscal year ending December 31, 2021 (January 1, 2021 to March 31, 2021)

(1) Consolidated operating results (cumulative)

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

	Net sales		Operating profit		Ordinary profit		Profit attributable to owners of parent	
	million yen	%	million yen	%	million yen	%	million yen	%
First three months ended March 31, 2021	655	430.7	149	—	268	—	188	—
March 31, 2020	123	(64.5)	(273)	—	(267)	—	(328)	—

Note: Comprehensive income Three months ended March 31, 2021: 206 million yen [-%]
 Three months ended March 31, 2020: (366) million yen [-%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First three months ended March 31, 2021	9.00 yen	9.00 yen
March 31, 2020	(15.66)	—

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
March 31, 2021	4,628	4,218	90.9
December 31, 2020	4,251	4,011	94.1

Reference: Equity As of March 31, 2021: 4,206 million yen As of December 31, 2020: 3,999 million yen

2. Dividends

	Annual dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	yen	yen	yen	yen	yen
Fiscal year ended December 31, 2020	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2021	—				
Fiscal year ending December 31, 2021 (forecast)		0.00	—	0.00	0.00

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

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

(Percentage figures represent year-on-year changes)

	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: Revisions to the forecasts of results most recently announced: None

* As the Company conducts performance management on an annualized basis, forecasts of results over a six-month period are omitted.

*** Notes**

(1) Changes in significant subsidiaries during the first three months ended March 31, 2021 (changes in specified subsidiaries resulting in the change in scope of consolidation): None

(2) Application of special accounting for preparing quarterly consolidated financial statements: Yes

Note: For more details, please refer to the section of “(4) Notes to quarterly consolidated financial statements (Application of special accounting for preparing quarterly consolidated financial statements)” of “2. Quarterly consolidated financial statements and significant notes thereto” on page 9 of the attached material.

(3) 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: Yes

c. Changes in accounting estimates: None

d. Restatements of prior financial statements: None

Note: For more details, please refer to the section of “(4) Notes to quarterly consolidated financial statements (Changes in accounting policies)” of “2. Quarterly consolidated financial statements and significant notes thereto” on page 9 of the attached material.

(4) Number of issued shares (common shares)

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

As of March 31, 2021	20,941,642 shares
As of December 31, 2020	20,941,642 shares

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

As of March 31, 2021	50 shares
As of December 31, 2020	50 shares

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

For the first three months ended March 31, 2021	20,951,592 shares
For the first three months ended March 31, 2020	20,950,317 shares

*** Quarterly financial results reports are exempt from quarterly review 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. For the suppositions that form the assumptions for earnings forecasts and cautions concerning the use thereof, please refer to the section of “(3) Qualitative information regarding consolidated earnings forecasts” of “1. Qualitative information regarding settlement of accounts for the first three months” on page 4 of the attached material.

As it is currently difficult to anticipate the impact of the spread of the novel coronavirus disease (COVID-19), it is not factored into financial forecasts. If any revisions to financial forecasts are deemed necessary going forward, the Company will promptly disclose them.

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

The Company plans to hold a briefing for the first three months as follows;

[Streaming date]	May 21, 2021 (Friday) 10:30 to 11:30 a.m. (Japan Time)
[Briefing format]	Online (Vimeo)
[How to apply]	Please use the URL below. Deadline for applications is May 16, 11:59 p.m. (Japan Time)
[URL]	https://www.raqualia.co.jp/ir/join.html (Japanese only)
[Details]	Briefing and Q&A for the first three months ended March 31, 2021
(Note)	Due to the system adopted for video streaming, there is a limit of first 500 streaming recipients.

The Company plans to post the video of this briefing on its website promptly after the briefing is held, in addition to the presentation materials for the quarterly results to be used on the day of the briefing.

Contents of attachment

1. Qualitative information regarding settlement of accounts for the first three months	2
(1) Qualitative information regarding consolidated operating results	2
(2) Qualitative information regarding consolidated financial position.....	4
(3) Qualitative information regarding consolidated earnings forecasts.....	4
2. Quarterly consolidated financial statements and significant notes thereto.....	5
(1) Consolidated balance sheet.....	5
(2) Consolidated statement of income and consolidated statement of comprehensive income.....	7
Consolidated statement of income (cumulative).....	7
Consolidated statement of comprehensive income (cumulative)	7
(3) Consolidated statement of cash flows.....	8
(4) Notes to quarterly consolidated financial statements.....	9
Notes on premise of going concern	9
Notes on significant changes in the amount of shareholders' equity.....	9
Application of special accounting for preparing quarterly consolidated financial statements.....	9
Changes in accounting policies	9
Additional information	9
Segment information, etc.....	9
Significant subsequent event	9

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

(1) Qualitative information regarding consolidated operating results

1) Financial results

During the first three months ended March 31, 2021, the financial market in Japan was active due to monetary easing. However, the spread of novel coronavirus disease (“COVID-19”) mutants has made the economic prospects extremely severe. In the pharmaceutical industry, although many companies are facing declining business performance due to COVID-19, developments of new mRNA vaccines and drugs for COVID-19 have been active.

Under such conditions, the Group achieved the following financial results during the first three months.

Regarding licensed-out drug products, development progressed steadily as a whole despite a delay due to COVID-19. As a result, the Company received milestone payment from Asahi Kasei Pharma Corporation (headquarters: Chiyoda-ku, Tokyo, “Asahi Kasei Pharma”) and Maruho Co., Ltd. (headquarters: Kita-ku, Osaka, “Maruho”) in the period under review.

With regard to the P2X7 receptor antagonist (AK1780/RQ-00466479) licensed to Asahi Kasei Pharma, a license agreement for the P2X7 receptor antagonist was concluded between Asahi Kasei Pharma and Eli Lilly and Company (headquarters: Indianapolis, Indiana, U.S., “Lilly (U.S.)”). As a result, it means the Company has licensed it to Lilly (U.S.) through Asahi Kasei Pharma. P2X7 receptors have been implicated in neuroinflammation, a driving force in chronic pain conditions. Lilly (U.S.) will work on global development for the P2X7 receptor antagonist. If the P2X7 receptor antagonist is successfully commercialized, Asahi Kasei Pharma would be eligible for up to US\$180 million in potential sales milestones, as well as tiered royalties ranging from the mid-single to low-double digits.

With regard to the selective sodium channel blocker licensed to Maruho, pre-defined results were achieved, and as a result, the Company received milestone payment. This compound, of which Maruho is carrying out development, is expected to become a drug that relieves symptoms including pain and itching by selectively blocking particular sodium channel functions.

A new drug application (NDA) for tegoprazan (brand name in South Korea (registered trademark in South Korea): K-CAB[®], “tegoprazan”), a drug for gastro-esophageal reflux disease, which the Company licensed to HK inno.N Corporation (headquarters: Seoul, South Korea, “HK inno.N (South Korea)”) and was sublicensed to Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (China), has been accepted by the Chinese authority. HK inno.N (South Korea) anticipates that tegoprazan will be launched in China in the first quarter of 2022.

The financial results of marketed drug products were as follows:

Regarding human drug products, strong sales were seen as in the previous fiscal year in tegoprazan licensed to HK inno.N (South Korea). Sales from external prescriptions recorded an increase of 54.1% compared with the same period of the previous fiscal year.

With regard to pet drug products, solid sales were seen in the EP4 antagonist (grapiprant/brand name: GALLIPRANT[®]; “GALLIPRANT[®]”), which has been marketed as a drug for osteoarthritis in dogs, and the Ghrelin receptor agonist (capromorelin/brand name: ENTYCE[®]), which has an indication for anorexia management for dogs, both of which were licensed to Elanco Animal Health Inc. (headquarters: Indiana, U.S., “Elanco (U.S.)”). The sales recorded an increase of 56.2% compared with the same period of the previous fiscal year. Elanco (U.S.) announced that it started selling ELURA[™] (capromorelin/RQ-0000005/AT-002), a ghrelin receptor agonist, in the U.S. as a drug for the management of weight loss in cats with chronic kidney disease (CKD).

With regard to the business activities of subsidiaries, at TMRC Co., Ltd., the Phase II combination clinical trial has progressed well for the retinoic acid receptor alpha agonist (Tamibarotene/TM-411/SY-1425) licensed to Syros Pharmaceuticals Inc. (headquarters: Cambridge, Massachusetts, U.S., “Syros (U.S.)”). Thus, Syros (U.S.) announced in February 2021 that it will start Phase III clinical trials in the U.S.

A new management system including a change of Representative Director was adopted as shareholder proposals were approved and adopted at the 13th Ordinary General Meeting of Shareholders held on March 25, 2021. Currently, the Company is making efforts to accelerate the improvement of our corporate value under the new management system.

In the Company’s securities report for the fiscal year ended December 31, 2020, which was submitted on March 30, 2021, the shares of the Company fell under two delisting criteria, the criteria pertaining to business performance and the criteria pertaining to recorded profit. As a result, the shares of the Company entered a grace period relating to delisting criteria on the same date. As the section transfer criteria and delisting criteria, which are not included in the criteria for maintaining listing for the new market segments, will be deleted on June 30, 2021, the Company’s status of having entered a grace period on April 30, 2021 will be annulled.

This is explained by Tokyo Stock Exchange, Inc. in its news release “Partial Revision of the Enforcement Rules for Securities Listing Regulations in Accordance with the Development of Listing Rules for Cash Equity Market Restructuring (second set of revisions)” announced on April 30, 2021.

Accordingly, operating results for the first three months, the reporting period, were as follows. Business revenue for the period was 655 million yen (up 430.7% year on year), operating profit totaled 149 million yen (compared with operating loss of 273 million yen a year earlier), ordinary profit totaled 268 million yen (compared with ordinary loss of 267 million yen a year earlier), and profit attributable to owners of parent was 188 million yen (compared with loss attributable to owners of parent of 328 million yen a year earlier).

Business revenue mainly consists of millstone income of 516 million yen (compared with – million yen a year earlier) and sales royalty income of 135 million yen (up 56.2% year on). On the other hand, total business expenses were 506 million yen (up 27.6% year on year). This total mainly consists of cost of business revenue (41 million yen, a 61.2% increase from the same period of the previous fiscal year), research and development expenses (255 million yen, a 14.4% increase from the same period of the previous fiscal year) and other selling, general and administrative expenses (209 million yen, a 41.8% increase from the same period of the previous fiscal year). A main reason for an increase of other selling, general and administrative expenses is that cost for the Ordinary General Meeting of Shareholders associated with shareholder proposals was 60 million yen, more than double that of ordinary years.

2) Research and development

Research and development expenses of the entire Group during the first three months were 255 million yen. For the first three months, there were no material changes to the research and development activities.

(2) Qualitative information regarding consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of March 31, 2021 were 4,628 million yen, an increase of 377 million yen (up 8.9%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 640 million yen and a decrease in securities of 379 million yen.

Liabilities

Total liabilities as of March 31, 2021 were 410 million yen, an increase of 170 million yen (up 70.8%) from the end of the previous fiscal year. This is mainly attributable to an increase in accounts payable - other of 99 million yen and an increase in income taxes payable of 29 million yen.

Net assets

Total net assets as of March 31, 2021 were 4,218 million yen, an increase of 206 million yen (up 5.2%) from the end of the previous fiscal year. This is mainly attributable to the recording of profit attributable to owners of parent of 188 million yen and an increase in valuation difference on available-for-sale securities of 18 million yen.

Consequently, the equity ratio was 90.9% (down 3.2 percentage points from the end of the previous fiscal year.)

2) Analysis of cash flows

The balance of cash and cash equivalents (“net cash”) as of March 31, 2021 amounted to 2,041 million yen (compared with 2,430 million yen a year earlier), a decrease of 19 million yen (down 1.0%) from the end of the previous fiscal year.

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

Cash flows from operating activities

Net cash provided by operating activities was 52 million yen (down 60.9% year on year). This is mainly attributable to the recording of profit before income taxes of 271 million yen, a cash outflow from an increase in trade receivables of 99 million yen, a cash outflow from an increase in prepaid expenses of 199 million yen, and income taxes paid of 48 million yen.

Cash flows from investing activities

Net cash used in investing activities was 154 million yen (compared with net cash of 105 million yen provided a year earlier). This is mainly attributable to payments into time deposits of 207 million yen, purchase of property, plant and equipment of 53 million yen, and proceeds from sales of investment securities of 110 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 6 million yen (compared with net cash of 0 million yen used a year earlier). This is mainly attributable to proceeds from short-term borrowings of 10 million yen and repayments of lease obligations of 3 million yen.

(3) Qualitative information regarding consolidated earnings forecasts

There has been no change to the figures of the consolidated earnings forecasts for the fiscal year ending December 31, 2021 contained in the “Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2020 (JGAAP)” announced on February 12, 2021. The Company will make an announcement on its earnings forecasts when the business plan has been finalized under the new management system.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2020	As of March 31, 2021
Assets		
Current assets		
Cash and deposits	1,394,128	2,035,009
Accounts receivable - trade	530,818	630,252
Securities	719,418	339,969
Work in process	-	1,050
Supplies	6,540	14,905
Advance payments - trade	36,412	42,900
Prepaid expenses	50,243	249,621
Other	96,671	14,842
Total current assets	2,834,232	3,328,551
Non-current assets		
Property, plant and equipment		
Buildings, net	78,501	77,195
Tools, furniture and fixtures, net	208,278	240,788
Leased assets, net	46,187	44,123
Total property, plant and equipment	332,967	362,107
Intangible assets		
Trademark right	4,439	4,257
Software	27,927	31,486
Other	639	639
Total intangible assets	33,005	36,383
Investments and other assets		
Investment securities	1,037,601	887,792
Long-term prepaid expenses	10	237
Deferred tax assets	2,959	2,959
Other	10,457	10,240
Total investments and other assets	1,051,029	901,229
Total non-current assets	1,417,002	1,299,720
Total assets	4,251,235	4,628,272

(Thousands of yen)

	As of December 31, 2020	As of March 31, 2021
Liabilities		
Current liabilities		
Accounts payable - trade	41,830	44,946
Lease obligations	18,281	17,586
Short-term borrowings	–	10,000
Accounts payable - other	52,666	152,274
Accrued expenses	49,868	50,617
Income taxes payable	20,882	50,317
Advances received	–	2,337
Deposits received	3,133	8,201
Other	–	21,387
Total current liabilities	186,662	357,668
Non-current liabilities		
Lease obligations	27,238	24,864
Asset retirement obligations	12,031	12,055
Deferred tax liabilities	14,173	15,587
Total non-current liabilities	53,443	52,507
Total liabilities	240,106	410,176
Net assets		
Shareholders' equity		
Share capital	2,255,401	2,255,401
Capital surplus	2,445,184	2,445,184
Retained earnings	(706,157)	(517,579)
Treasury shares	(21)	(21)
Total shareholders' equity	3,994,407	4,182,985
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	4,809	23,198
Total accumulated other comprehensive income	4,809	23,198
Share acquisition rights	11,912	11,912
Total net assets	4,011,129	4,218,096
Total liabilities and net assets	4,251,235	4,628,272

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

(Thousands of yen)

	First three months ended March 31, 2020	First three months ended March 31, 2021
Business revenue	123,537	655,610
Business expenses		
Cost of business revenue	25,760	41,529
Research and development expenses	223,749	255,977
Other selling, general and administrative expenses	147,413	209,059
Total business expenses	396,922	506,566
Operating profit (loss)	(273,385)	149,043
Non-operating income		
Interest income	2,268	359
Interest on securities	8,314	5,319
Foreign exchange gains	–	111,683
Gain on valuation of compound financial instruments	5,880	–
Subsidy income	1,500	1,972
Other	172	2,404
Total non-operating income	18,136	121,738
Non-operating expenses		
Interest expenses	–	398
Foreign exchange losses	12,457	–
Loss on valuation of compound financial instruments	–	2,040
Share issuance costs	78	–
Other	1	–
Total non-operating expenses	12,536	2,438
Ordinary profit (loss)	(267,785)	268,343
Extraordinary income		
Gain on sales of non-current assets	750	–
Gain on sales of investment securities	4,768	3,382
Total extraordinary income	5,518	3,382
Profit (loss) before income taxes	(262,267)	271,726
Income taxes	65,859	83,148
Profit (loss)	(328,127)	188,578
Profit attributable to non-controlling interests	–	–
Profit (loss) attributable to owners of parent	(328,127)	188,578

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First three months ended March 31, 2020	First three months ended March 31, 2021
Profit (loss)	(328,127)	188,578
Other comprehensive income		
Valuation difference on available-for-sale securities	(38,111)	18,388
Total other comprehensive income	(38,111)	18,388
Comprehensive income	(366,239)	206,967
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(366,239)	206,967
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First three months ended March 31, 2020	First three months ended March 31, 2021
Cash flows from operating activities		
Profit (loss) before income taxes	(262,267)	271,726
Depreciation	24,985	32,324
Interest income	(2,268)	(359)
Interest income on securities	(8,314)	(5,319)
Interest expenses	–	398
Foreign exchange losses (gains)	9,896	(89,487)
Loss (gain) on valuation of compound financial instruments	(5,880)	2,040
Subsidy income	(1,500)	(1,972)
Share issuance costs	78	–
Loss (gain) on sales of non-current assets	(750)	–
Loss (gain) on sales of investment securities	(4,768)	(3,382)
Decrease (increase) in trade receivables	623,813	(99,434)
Decrease (increase) in inventories	377	(9,415)
Increase (decrease) in trade payables	(8,025)	3,116
Decrease (increase) in advance payments - trade	(289)	(6,488)
Decrease (increase) in prepaid expenses	(158,409)	(199,431)
Increase (decrease) in accounts payable - other	(14,667)	94,680
Decrease (increase) in consumption taxes refund receivable	871	74,146
Other, net	(4,951)	31,845
Subtotal	187,930	94,987
Interest and dividends received	12,762	4,653
Interest paid	–	(398)
Income taxes paid	(67,906)	(48,698)
Subsidies received	1,500	1,972
Net cash provided by (used in) operating activities	134,285	52,516
Cash flows from investing activities		
Payments into time deposits	–	(207,380)
Purchase of property, plant and equipment	(6,918)	(53,557)
Proceeds from sales of property, plant and equipment	750	–
Purchase of intangible assets	(902)	(4,757)
Proceeds from sales of investment securities	112,926	110,923
Net cash provided by (used in) investing activities	105,855	(154,771)
Cash flows from financing activities		
Proceeds from short-term borrowings	–	10,000
Proceeds from issuance of shares resulting from exercise of share acquisition rights	110	–
Repayments of lease obligations	(185)	(3,068)
Net cash provided by (used in) financing activities	(75)	6,931
Effect of exchange rate change on cash and cash equivalents	(9,919)	75,425
Net increase (decrease) in cash and cash equivalents	230,145	(19,898)
Cash and cash equivalents at beginning of period	2,200,206	2,061,316
Cash and cash equivalents at end of period	2,430,352	2,041,418

(4) Notes to quarterly consolidated financial statements

Notes on premise of going concern

No items to report.

Notes on significant changes in the amount of shareholders' equity

No items to report.

Application of special accounting for preparing quarterly consolidated financial statements

(Calculation of tax expenses)

Tax expenses are calculated by multiplying the profit before income taxes by the reasonably estimated effective tax rates after the application of tax effect accounting to the profit before income taxes for the fiscal year including the quarter under review. Income taxes is the amount inclusive of income taxes - deferred.

Changes in accounting policies

(Change in methodology for calculating tax expenses)

Tax expenses were calculated in the same method as that used in year-end closing of accounts. However, the Company has adopted the consolidated tax payment system starting from the period under review, aiming to perform quarterly closing of accounts quickly and efficiently. Accordingly, the calculation method has been changed starting from the period under review. With the changed calculation method, tax expenses are calculated by multiplying the profit before income taxes for the quarter by the reasonably estimated effective tax rates after the application of tax effect accounting to the profit before income taxes for the fiscal year.

As the effect of this change on quarterly consolidated financial statements is immaterial, no retrospective application has been performed.

Additional information

(Application of tax effect accounting for transition from consolidated taxation system to group tax sharing system)

As for items regarding the transition to the group tax sharing system introduced in the "Act Partially Amending the Income Tax Act" (Act No. 8 of 2020) and items revised on non-consolidated taxation system in connection with the transition to the group tax sharing system, the Company and its consolidated subsidiaries have not applied the provisions of paragraph 44 of the "Guidance on Accounting Standard for Tax Effect Accounting" (Accounting Standards Board of Japan (ASBJ) Guidance No. 28, February 16, 2018) as allowed by the provisions of paragraph 3 of the "Tax Effect Accounting for the Transition from the Consolidated Taxation System to the Group Tax Sharing System" (ASBJ PITF No. 39, March 31, 2020). Accordingly, amounts of deferred tax assets and deferred tax liabilities are determined in accordance with the provisions of the tax law before revision.

(Accounting estimates amid the spread of COVID-19)

The Group has determined the accounting estimates for impairment accounting of non-current assets, etc. based on information available when preparing the consolidated financial statements. The effects of the spread of COVID-19 on the Group are limited at the present time and the Group has determined that there will not be a significant impact on the estimates for the fiscal year under review.

(Liquidation of consolidated subsidiaries)

Dissolution of the Company's consolidated subsidiary, RaQualia Innovations Inc. was resolved on January 22, 2021, and the liquidation was completed as of April 1, 2021. The liquidation has an immaterial impact on the consolidated business results.

Segment information, etc.

[Segment information]

- I. For the first three months ended March 31, 2020 (January 1, 2020 to March 31, 2020)
This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.
- II. For the first three months ended March 31, 2021 (January 1, 2021 to March 31, 2021)
This information is omitted because the Group consists of a single business segment dealing with research and development of pharmaceutical and related businesses.

Significant subsequent event

No items to report.