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November 11, 2022

Summary of Consolidated Financial Results for the First Nine Months of the Fiscal Year Ending December 31, 2022 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: <https://www.raqualia.com/>
Representative: Hirobumi Takeuchi, President and CEO
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Scheduled date of filing of quarterly securities report: November 11, 2022
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 nine months of the fiscal year ending December 31, 2022 (January 1, 2022 to September 30, 2022)

(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 nine months ended September 30, 2022	1,904	17.3	501	367.6	676	183.8	467	175.9
September 30, 2021	1,623	183.0	107	—	238	—	169	—

Note: Comprehensive income
 Nine months ended September 30, 2022: 443 million yen [126.9%]
 Nine months ended September 30, 2021: 195 million yen [—%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months ended September 30, 2022	yen 22.28	yen 22.27
September 30, 2021	8.08	8.08

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
September 30, 2022	5,849	5,246	89.5
December 31, 2021	5,234	4,788	91.3

Reference: Equity As of September 30, 2022: 5,237 million yen As of December 31, 2021: 4,777 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, 2021	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2022	—	0.00	—		
Fiscal year ending December 31, 2022 (forecast)				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, 2022 (January 1, 2022 to December 31, 2022)

(Percentage figures represent year-on-year changes)

Fiscal year ending December 31, 2022	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
	2,605	(6.2)	420	(40.6)	420	(51.3)	342	(54.7)	16.34

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

*** Notes**

(1) Changes in significant subsidiaries during the first nine months ended September 30, 2022 (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: Yes

b. Changes in accounting policies due to other reasons: None

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 September 30, 2022	20,976,681 shares
As of December 31, 2021	20,955,142 shares

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

As of September 30, 2022	50 shares
As of December 31, 2021	50 shares

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

For the first nine months ended September 30, 2022	20,966,836 shares
For the first nine months ended September 30, 2021	20,952,322 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 nine months” on page 3 of the attached material.

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

The Company plans to hold a financial results briefing on Wednesday, November 16, 2022.

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

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

(1) Qualitative information regarding consolidated operating results

1) Financial results

During the third quarter of the fiscal year ending December 31, 2022, the Japanese economy showed a moderate recovery trend due to increased consumer spending and corporate capital investment, etc. However, the seventh wave of COVID-19, rapid yen depreciation, rising prices, and worsening global economic conditions, among other factors, continued to cast a shadow over the economy. In the pharmaceutical industry, there are growing concerns about the impact on business of the yen's depreciation against the dollar and rising prices of commodities and energy, such as increased procurement costs of APIs and raw materials and increased overseas clinical trial costs denominated in dollars.

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

Regarding human drug products, sales of K-CAB[®] (generic name: tegoprazan)—a drug for gastro-esophageal reflux disease marketed by HK inno.N Corporation (headquarters: Osong, South Korea, “HK inno.N”)—in South Korea continued to perform well, with sales in the third quarter of the fiscal year from external prescriptions of 31.6 billion won, an increase of 12.5% compared with the same period of the previous fiscal year, and cumulative sales from external prescriptions of 92.2 billion won year to date for 2022. Furthermore, in July 2022, HK inno.N received manufacturing and marketing approval in South Korea for the product as a maintenance treatment for patients with cured erosive gastro-esophageal reflux disease. As a result, there are now five indications for which the product has received manufacturing and marketing approval in South Korea: erosive gastro-esophageal reflux disease, non-erosive gastro-esophageal reflux disease, gastric ulcer, adjuvant therapy for *Helicobacter pylori* eradication, and maintenance treatment for patients with cured erosive gastro-esophageal reflux disease.

Global expansion of tegoprazan is also progressing well. During the first nine months of the fiscal year, the product has been marketed in China under the trade name 泰欣贊[®] (Taixinzan), and preparations are underway for its launch in Mongolia and the Philippines. In addition, the product is under review or in preparation for approval in 29 other countries, including Indonesia, Thailand, and Mexico.

With regard to pet drugs, sales were strong for GALLIPRANT[®] (generic name: grapiprant), which is a drug for osteoarthritis in dogs, and ENTyce[®] (generic name: capromorelin), which has an indication for anorexia management for dogs, and ELURA[®] (generic name: capromorelin), which has an indication for weight loss management in cats with chronic kidney disease, all of which were licensed to Elanco Animal Health Inc. (headquarters: Indiana, U.S., “Elanco”). In particular, GALLIPRANT[®] has become one of Elanco's most profitable products, with sales continuing to grow in the U.S., the world's largest pet drug market, five years after its launch in 2017.

For the cyclooxygenase inhibitor (COX-2 inhibitor, RQ-00317076/AAT-076), which was licensed out to AskAt Inc. (headquarters: Nagoya, Aichi, “AskAt”), AskAt has entered into a license and development support agreement with Velo-1, Inc. (headquarters: Tennessee, U.S.). As a result, the Company received a lump-sum payment from AskAt.

Licensed programs are in the pre-clinical development stage or later at licensee companies. As for programs in preparation for licensing, pre-clinical studies for the ghrelin receptor agonist, developed in-house by the Company, are progressing. In addition, we are preparing for clinical development and searching for potential partners with the aim of launching tegoprazan in Japan as soon as possible. Furthermore, as for programs in the discovery research stage, collaborative research with ASKA Pharmaceutical Co., Ltd. is progressing steadily. In parallel, the Group has been promoting internal projects to generate development candidate compounds. During the first nine months of the fiscal year, the Company entered into a joint research agreement with STAND Therapeutics Co., Ltd. (headquarters: Minato, Tokyo, “STAND”) and started a joint research project to discover new drugs for intractable and rare diseases by utilizing the Company's ion channel drug discovery technology and STAND's intracellular antibody production technology.

In addition, clinical trials for the treatment of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) are underway in the U.S. by Syros Pharmaceuticals Inc. (headquarters: Massachusetts, U.S., “Syros”) for a retinoic acid receptor alpha agonist (tamibarotene, TM-411/SY-1425), which was discovered by consolidated subsidiary TMRC Co., Ltd. and licensed to Syros.

Accordingly, financial results for the first nine months, the reporting period, were as follows. Business revenue for the period was 1,904 million yen (up 17.3% year on year), operating profit totaled 501 million yen (up 367.6% year on year), ordinary profit totaled 676 million yen (up 183.8% year on year), and profit attributable to owners of parent was 467 million yen (up 175.9% year on year).

Total business expenses were 1,403 million yen (down 7.4% year on year). This total mainly consists of cost of business revenue (167 million yen, a 37.5% decrease from the same period of the previous fiscal year), research and development expenses (840 million yen, a 7.6% increase from the same period of the previous fiscal year) and other selling, general and administrative expenses (394 million yen, a 15.3% decrease from the same period of the previous fiscal year).

2) Research and development activities

Research and development expenses of the Group during the first nine months were 840 million yen. For the first nine 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 September 30, 2022 were 5,849 million yen, an increase of 615 million yen (up 11.8%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 1,207 million yen, a decrease in accounts receivable - trade, and contract assets of 718 million yen, a decrease in securities of 112 million yen, and an increase in leased assets of 170 million yen.

Liabilities

Total liabilities as of September 30, 2022 were 603 million yen, an increase of 157 million yen (up 35.3%) from the end of the previous fiscal year. This is mainly attributable to an increase in lease obligations of 189 million yen and a decrease in accounts payable - other of 32 million yen.

Net assets

Total net assets as of September 30, 2022 were 5,246 million yen, an increase of 458 million yen (up 9.6%) from the end of the previous fiscal year. This is mainly attributable to the recording of profit attributable to owners of parent of 467 million yen.

Consequently, the equity ratio was 89.5% (down 1.8 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 September 30, 2022 amounted to 3,355 million yen (compared with 2,209 million yen a year earlier), an increase of 1,115 million yen (up 49.8%) from the end of the previous fiscal year.

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

Cash flows from operating activities

Net cash provided by operating activities was 952 million yen (up 69.7% year on year). This is mainly attributable to the recording of profit before income taxes of 673 million yen and depreciation of 108 million yen, a cash inflow from a decrease in trade receivables of 718 million yen, and income taxes paid of 183 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 57 million yen (compared with net cash of 487 million yen used a year earlier). This is mainly attributable to payments into time deposits of 200 million yen, purchase of investment securities of 351 million yen, proceeds from sale of investment securities of 315 million yen, and proceeds from redemption of investment securities of 210 million yen.

Cash flows from financing activities

Net cash used in financing activities was 11 million yen (down 65.5% year on year). This is mainly attributable to proceeds from long-term borrowings of 13 million yen and repayments of lease obligations of 27 million yen.

(3) Qualitative information regarding consolidated earnings forecasts

At the present time, there are no changes to the full-year consolidated earnings forecasts for the fiscal year ending December 31, 2022 presented in “Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2021 (JGAAP)” published on February 14, 2022.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2021	As of September 30, 2022
Assets		
Current assets		
Cash and deposits	2,345,306	3,552,852
Accounts receivable - trade	1,205,401	–
Accounts receivable - trade, and contract assets	–	486,980
Securities	313,807	201,531
Work in process	–	1,210
Supplies	10,547	7,967
Advance payments to suppliers	15,939	91,146
Prepaid expenses	90,382	166,891
Other	22,390	85,749
Total current assets	4,003,775	4,594,329
Non-current assets		
Property, plant and equipment		
Buildings, net	70,479	64,602
Tools, furniture and fixtures, net	180,500	141,866
Leased assets, net	48,409	218,977
Total property, plant and equipment	299,389	425,445
Intangible assets		
Trademark right	3,839	4,012
Software	29,227	22,295
Other	731	731
Total intangible assets	33,799	27,039
Investments and other assets		
Investment securities	887,932	794,721
Other	9,300	8,400
Total investments and other assets	897,233	803,122
Total non-current assets	1,230,422	1,255,607
Total assets	5,234,197	5,849,936

(Thousands of yen)

	As of December 31, 2021	As of September 30, 2022
Liabilities		
Current liabilities		
Accounts payable - trade	45,996	69,924
Current portion of long-term borrowings	–	2,620
Lease obligations	21,547	50,536
Accounts payable - other	112,768	80,379
Accrued expenses	63,004	49,248
Income taxes payable	80,405	77,099
Accrued consumption taxes	37,475	–
Deposits received	28,884	5,140
Other	10,442	16,975
Total current liabilities	400,524	351,924
Non-current liabilities		
Long-term borrowings	–	9,825
Lease obligations	17,520	177,798
Asset retirement obligations	12,129	12,197
Deferred tax liabilities	16,018	5,235
Other	–	46,709
Total non-current liabilities	45,668	251,766
Total liabilities	446,193	603,691
Net assets		
Shareholders' equity		
Share capital	2,256,920	2,265,545
Capital surplus	2,446,703	2,455,328
Retained earnings	49,631	516,802
Treasury shares	(21)	(21)
Total shareholders' equity	4,753,234	5,237,654
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	23,919	100
Total accumulated other comprehensive income	23,919	100
Share acquisition rights	10,850	8,490
Total net assets	4,788,004	5,246,245
Total liabilities and net assets	5,234,197	5,849,936

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

(Thousands of yen)

	First nine months ended September 30, 2021	First nine months ended September 30, 2022
Business revenue	1,623,136	1,904,302
Business expenses		
Cost of business revenue	268,927	167,984
Research and development expenses	780,550	840,102
Other selling, general and administrative expenses	466,478	394,992
Total business expenses	1,515,956	1,403,080
Operating profit	107,179	501,222
Non-operating income		
Interest income	1,352	491
Interest on securities	16,154	11,664
Foreign exchange gains	127,264	182,461
Subsidy income	5,785	–
Other	2,817	388
Total non-operating income	153,373	195,005
Non-operating expenses		
Interest expenses	905	4,253
Commitment fees	–	4,083
Share issuance costs	120	287
Loss on valuation of compound financial instruments	2,820	4,220
Loss on valuation of derivatives	8,760	6,896
Settlement package	9,600	–
Other	–	0
Total non-operating expenses	22,207	19,740
Ordinary profit	238,345	676,486
Extraordinary income		
Gain on sale of investment securities	3,382	10,268
Gain on redemption of investment securities	2,267	4,203
Total extraordinary income	5,650	14,472
Extraordinary losses		
Retirement benefits for directors (and other officers)	–	17,800
Total extraordinary losses	–	17,800
Profit before income taxes	243,996	673,159
Income taxes	74,662	205,986
Profit	169,333	467,172
Profit attributable to non-controlling interests	–	–
Profit attributable to owners of parent	169,333	467,172

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First nine months ended September 30, 2021	First nine months ended September 30, 2022
Profit	169,333	467,172
Other comprehensive income		
Valuation difference on available-for-sale securities	26,096	(23,819)
Total other comprehensive income	26,096	(23,819)
Comprehensive income	195,430	443,353
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	195,430	443,353
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First nine months ended September 30, 2021	First nine months ended September 30, 2022
Cash flows from operating activities		
Profit before income taxes	243,996	673,159
Depreciation	103,842	108,291
Interest income	(1,352)	(491)
Interest income on securities	(16,154)	(11,664)
Foreign exchange losses (gains)	(98,967)	(111,358)
Subsidy income	(5,785)	–
Loss (gain) on valuation of compound financial instruments	2,820	4,220
Interest expenses	905	4,253
Commitment fees	–	4,083
Share issuance costs	120	287
Loss (gain) on valuation of derivatives	8,760	6,896
Loss (gain) on sale of investment securities	(3,382)	(10,268)
Loss (gain) on redemption of investment securities	(2,267)	(4,203)
Retirement benefits for directors (and other officers)	–	17,800
Settlement package	9,600	–
Decrease (increase) in trade receivables	349,495	718,421
Decrease (increase) in inventories	(5,326)	1,370
Increase (decrease) in trade payables	53,866	23,928
Decrease (increase) in advance payments to suppliers	12,573	(75,207)
Decrease (increase) in prepaid expenses	(84,250)	(63,032)
Increase (decrease) in accounts payable - other	(5,017)	(37,092)
Increase (decrease) in accrued expenses	(2,614)	(13,755)
Increase (decrease) in income taxes payable - factor based tax	(5,293)	(26,251)
Decrease (increase) in accounts receivable - other	12,045	–
Decrease (increase) in consumption taxes refund receivable	51,770	(47,231)
Increase (decrease) in accrued consumption taxes	–	(37,475)
Increase (decrease) in deposits received	3,308	(23,744)
Other, net	2,708	48,224
Subtotal	625,403	1,149,158
Interest and dividends received	15,581	15,893
Interest paid	(905)	(4,278)
Subsidies received	5,785	–
Commitment fees paid	–	(7,000)
Income taxes paid	(74,694)	(183,182)
Payments of retirement benefits for directors (and other officers)	–	(17,800)
Settlement package paid	(9,600)	–
Net cash provided by (used in) operating activities	561,570	952,791
Cash flows from investing activities		
Payments into time deposits	(317,510)	(200,000)
Proceeds from withdrawal of time deposits	–	110,130
Purchase of securities	(100,000)	–
Purchase of property, plant and equipment	(82,303)	(25,968)
Purchase of intangible assets	(12,983)	(745)
Purchase of investment securities	(200,649)	(351,856)
Proceeds from sale of investment securities	110,923	315,249
Proceeds from redemption of investment securities	115,065	210,512
Other, net	424	–
Net cash provided by (used in) investing activities	(487,032)	57,321

(Thousands of yen)

	First nine months ended September 30, 2021	First nine months ended September 30, 2022
Cash flows from financing activities		
Proceeds from short-term borrowings	10,000	–
Repayments of short-term borrowings	(10,000)	–
Proceeds from long-term borrowings	–	13,100
Repayments of long-term borrowings	–	(655)
Proceeds from issuance of shares resulting from exercise of share acquisition rights	1,855	4,040
Repayments of lease obligations	(8,571)	(27,600)
Net cash provided by (used in) financing activities	(6,716)	(11,114)
Effect of exchange rate change on cash and cash equivalents	80,641	116,195
Net increase (decrease) in cash and cash equivalents	148,462	1,115,193
Cash and cash equivalents at beginning of period	2,061,316	2,240,661
Cash and cash equivalents at end of period	2,209,778	3,355,854

(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. However, in cases where calculations using said estimated effective tax rate yield a result that is notably lacking rationality, tax expenses are calculated by multiplying profit (loss) before income taxes by the statutory effective tax rate, taking into consideration the recoverability of deferred tax assets.

Income taxes is the amount inclusive of income taxes - deferred.

Changes in accounting policies

(Application of accounting standard for revenue recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020) and relevant ASBJ regulations from the beginning of the first quarter of the fiscal year under review, and it has recognized revenue at the time the control of promised goods or services is transferred to the customer at the amount expected to be received upon exchange of said goods or services.

The Group earns revenues (upfront payments, milestone-related revenues, royalty income, etc.) from licensing agreements that allow third parties to research, develop, manufacture and sell pharmaceuticals and other products and to use their technologies.

With regard to upfront payments and milestone-related revenues, when performance obligations are satisfied at a point in time, contractual performance obligations are deemed to be satisfied at the time when development, marketing, and other rights are granted, or at the time when the contractually stipulated milestone is achieved. These revenues are recognized as business revenue at the point when contractual performance obligations are deemed to be satisfied.

Royalty income is consideration based on license agreements, etc., calculated based on the sales revenue of the contract partner, etc. This income is recognized as business revenue with consideration to the point in time at which it is incurred.

The application of the Accounting Standard for Revenue Recognition and its guidance is subject to the transitional treatment provided in the proviso to paragraph 84 of the Accounting Standard for Revenue Recognition. The cumulative effect of the retrospective application assuming the new accounting policy had been applied to periods prior to the start of the first quarter ended March 31, 2022, was added to or subtracted from the opening balance of retained earnings of the first quarter ended March 31, 2022, and thus the new accounting policy is applied from such opening balance; provided, however, that the new accounting policy is not retrospectively applied to contracts where recognitions of nearly all the revenue amounts for periods prior to the start of the first quarter ended March 31, 2022, are subject to the previous treatment by applying the method provided for in paragraph 86 of the Accounting Standard for Revenue Recognition. Furthermore, by applying the method set forth in item (1) of the supplementary provisions of paragraph 86 of the Accounting Standard for Revenue Recognition, modifications to contracts carried out prior to the beginning of the first quarter of the fiscal year under review were accounted for based on the contractual terms after all contract modifications were reflected. Consequently, this cumulative effect was added to or deducted from the opening balance of retained earnings of the first quarter of the fiscal year under review.

As a result, there was no effect on the quarterly consolidated financial statements for the first nine months of the fiscal year under review. In addition, there was no effect on the opening balance of retained earnings.

In accordance with the transitional treatment provided for in paragraph 89-2 of the Accounting Standard for Revenue Recognition, figures for the previous fiscal year have not been restated in accordance with the new approach to presentation.

(Application of accounting standard for fair value measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019) and relevant ASBJ regulations from the beginning of the first quarter of the fiscal year under review, and it has applied the new accounting policy provided for by the Accounting Standard for Fair Value Measurement, etc. prospectively in accordance with the transitional measures provided for in paragraph 19 of the Accounting Standard For Fair Value Measurement, and paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019).

Note that there was no effect on the quarterly consolidated financial statements.

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" (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 quarterly 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 accounting estimates.

Segment information, etc.

[Segment information]

- I. For the first nine months ended September 30, 2021 (January 1, 2021 to September 30, 2021)
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 nine months ended September 30, 2022 (January 1, 2022 to September 30, 2022)
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.