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November 10, 2023

Summary of Consolidated Financial Results for the First Nine Months of the Fiscal Year Ending December 31, 2023 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: <https://www.raqualia.com/en/>
Representative: Hirobumi Takeuchi, President and CEO
Contact: Hidefumi Sugiyama, General Manager, Finance & Accounting Dept. (TEL) +81-52-446-6100
Scheduled date of filing of quarterly securities report: November 10, 2023
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, 2023 (January 1, 2023 to September 30, 2023)

(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, 2023	1,495	(21.5)	(108)	—	(36)	—	(117)	—
September 30, 2022	1,904	17.3	501	367.6	676	183.8	467	175.9

Note: Comprehensive income
 Nine months ended September 30, 2023: (79) million yen [–%]
 Nine months ended September 30, 2022: 443 million yen [126.9%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months ended September 30, 2023	yen (5.45)	yen —
September 30, 2022	22.28	22.27

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
September 30, 2023	6,968	6,235	89.1
December 31, 2022	6,257	5,496	87.7

Reference: Equity As of September 30, 2023: 6,207 million yen As of December 31, 2022: 5,488 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, 2022	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2023	—	0.00	—		
Fiscal year ending December 31, 2023 (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, 2023 (January 1, 2023 to December 31, 2023)

(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, 2023	2,799	(4.1)	260	(69.9)	242	(73.2)	183	(74.7)	8.74

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, 2023 (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 10 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 10 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, 2023	21,616,781 shares
As of December 31, 2022	20,977,181 shares

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

As of September 30, 2023	50 shares
As of December 31, 2022	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, 2023	21,601,715 shares
For the first nine months ended September 30, 2022	20,966,836 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 4 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 via live webcast on Wednesday, November 15, 2023. 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, 2023, the Japanese economy continued to show modest recovery due to the ongoing normalization of economic activities after the COVID-19 pandemic. According to the Bank of Japan's quarterly short-term economic survey (September survey), business sentiment among large enterprises in the non-manufacturing sector rose for the sixth consecutive quarter on the back of a recovery in inbound demand, while business confidence among large enterprises in the manufacturing sector improved for the second consecutive quarter.

In the pharmaceutical industry, there have been discussions in various forums about issues such as worsening drug lag/drug loss and insecurity in the supply of pharmaceuticals, especially generics. At the September 20 meeting of the Special Committee on Drug Prices of the Central Social Insurance Medical Council (Chuikyo), opinions were once again heard from industry associations in preparation for the next reform of the National Health Insurance (NHI) drug price system in April 2024. In addition to industry associations including new drug manufacturers, generic drug manufacturers, overseas drug manufacturers and drug wholesalers, the SAMURAI Biotech Association, an industry association mainly comprised of drug discovery ventures, was also present. A lively Q&A session was held, with exchanges between members from the treatment side and the payment side, and with recommendations made to promote both innovation and the sustainability of the universal health insurance system, as well as for the rapid introduction of innovative new drugs.

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 gastroesophageal reflux disease marketed by the Company's licensee, HK inno.N Corporation (headquarters: Osong, South Korea, "HK inno.N")—in South Korea continued to increase steadily. Cumulative sales from January to September this year (external prescription data) totaled 114.1 billion won (approximately 11.4 billion yen at 0.10 yen to the won, an increase of 18.7% year on year), with the market share of anti-ulcer drugs in South Korea reaching 13%.

Global expansion of tegoprazan is also progressing steadily. The Company has executed exclusive license agreements with HK inno.N for the development, marketing, and manufacturing of tegoprazan with sublicensing rights. As of the end of the first nine months ended September 30, 2023, in 35 countries outside of South Korea, the companies that have entered into the license agreements with HK inno.N (the "sublicensee companies") are engaged in development, manufacturing, and marketing in their respective countries and regions. During the third quarter under review, sales of the product were launched in Indonesia and Singapore. With this launch, tegoprazan is now being marketed in seven countries: South Korea, China, Mongolia, the Philippines, Mexico, Indonesia, and Singapore. In China, which was the second country following South Korea, product sales of tegoprazan were launched in 2022 and it is currently sold in 31 provinces and administrative regions. Moreover, in Peru, a sublicensee company received marketing approval for four indications including erosive gastro-esophageal reflux disease. The filings for approval are under review by local regulatory authorities in 20 and more countries, including Argentina.

With regard to pet drugs, sales were steady for GALLIPRANT[®] (generic name: grapiprant) for osteoarthritis in dogs, ENTyce[®] (generic name: capromorelin) for anorexia management for dogs, and ELURA[®] (generic name: capromorelin) for weight loss management in cats with chronic kidney failure, all of which were licensed to Elanco Animal Health Inc. (headquarters: Indiana, U.S.).

Other licensed programs are also in the pre-clinical or later development stage at licensee and sublicensee companies. In the third quarter under review, regarding the cannabinoid CB2 receptor agonist (RQ-00202730/AAT-730/OCT461201) assigned by the Company to AskAt Inc. (headquarters: Nagoya, Aichi, "AskAt") and further licensed by AskAt to Oxford Cannabinoid Technologies Ltd. (headquarters: London, U.K., "OCT"), OCT initiated Phase I clinical trials in the U.K. OCT plans to pursue further clinical development with chemotherapy-induced peripheral neuropathy (CIPN) as the primary indication.

For pre-licensing programs, the Company has conducted business development activities aimed at acquiring further licensees through a flexible combination of face-to-face meetings and online conferences. For tegoprazan, the Company has the rights to develop, manufacture, and market the product in Japan, and has been in discussions with potential licensee companies since the previous quarter. For the ghrelin receptor agonist, which the Company is developing in-house with the aim of securing a large license agreement, the Company has continued to conduct pre-clinical studies and manufacture active pharmaceutical ingredients (APIs) for clinical trials.

In the discovery research stage, the Company is focusing on discovery research programs to generate development compounds, and is also working to strengthen its drug discovery research capabilities, which are central to its growth strategy. Focusing on four areas, "modality," "drug target," "disease area," and "basic technology," the Company is aiming to establish a next-generation in-house drug discovery value chain through synergy effects from existing technologies and new initiatives. In addition to its own independent research, it has been strengthening its collaboration with startups and drug discovery venture companies.

Clinical trials for the treatment of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) are underway by Syros Pharmaceuticals Inc. (headquarters: Massachusetts, U.S., “Syros”) in the U.S. for a retinoic acid receptor alpha agonist (tamibarotene, AM80/TM-411/SY-1425), licensed by the Company’s consolidated subsidiary TMRC Co., Ltd. to Syros.

Accordingly, financial results for the first nine months, the reporting period, were as follows. Business revenue for the period was 1,495 million yen (down 21.5% year on year), operating loss totaled 108 million yen (compared with operating profit of 501 million yen a year earlier), ordinary loss totaled 36 million yen (compared with ordinary profit of 676 million yen a year earlier), and loss attributable to owners of parent was 117 million yen (compared with profit attributable to owners of parent of 467 million yen a year earlier).

Total business expenses were 1,603 million yen (up 14.3% year on year). This mainly consists of cost of business revenue (189 million yen, a 12.8% increase year on year), research and development expenses (934 million yen, an 11.2% increase year on year) and other selling, general and administrative expenses (479 million yen, a 21.4% increase year on year).

2) Research and development activities

Research and development expenses of the Group during the first nine months were 934 million yen, an increase of 94 million yen (up 11.2% year on year). This is mainly attributable to an increase in clinical development expenses of 46 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, 2023 were 6,968 million yen, an increase of 710 million yen (up 11.4%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 319 million yen, a decrease in accounts receivable - trade, and contract assets of 133 million yen, an increase in prepaid expenses of 189 million yen, and an increase in tools, furniture and fixtures of 115 million yen.

Liabilities

Total liabilities as of September 30, 2023 were 732 million yen, a decrease of 27 million yen (down 3.7%) from the end of the previous fiscal year. This is mainly attributable to an increase in lease liabilities of 87 million yen and a decrease in accounts payable - other of 131 million yen.

Net assets

Total net assets as of September 30, 2023 were 6,235 million yen, an increase of 738 million yen (up 13.4%) from the end of the previous fiscal year. This is mainly attributable to an increase in share capital and capital surplus of 786 million yen due to capital increase through third-party allotment, and the recording of loss attributable to owners of parent of 117 million yen.

Consequently, the equity ratio was 89.1% (up 1.4 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, 2023 amounted to 3,915 million yen (compared with 3,355 million yen a year earlier), an increase of 236 million yen (up 6.4%) 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 used in operating activities was 405 million yen (compared with net cash of 952 million yen provided a year earlier). This is mainly attributable to the recording of loss before income taxes of 37 million yen and depreciation of 120 million yen, a cash inflow from a decrease in trade receivables of 133 million yen, cash outflows from an increase in prepaid expenses of 172 million yen and a decrease in accounts payable - other of 137 million yen, and income taxes paid of 119 million yen.

Cash flows from investing activities

Net cash used in investing activities was 268 million yen (compared with net cash of 57 million yen provided a year earlier). This is mainly attributable to payments into time deposits of 100 million yen, the purchase of property, plant and equipment of 189 million yen, the purchase of investment securities of 160 million yen, and proceeds from redemption of investment securities of 200 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 812 million yen (compared with net cash of 11 million yen used a year earlier). This is mainly attributable to proceeds from long-term borrowings of 50 million yen, proceeds from issuance of shares of 782 million yen, and repayments of lease liabilities of 32 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, 2023 presented in “Summary of Consolidated Financial Results for the Fiscal Year Ended December 31, 2022 (JGAAP)” published on February 14, 2023.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2022	As of September 30, 2023
Assets		
Current assets		
Cash and deposits	3,675,450	3,994,878
Accounts receivable - trade, and contract assets	602,311	468,712
Securities	250,599	170,737
Work in process	978	1,685
Supplies	7,522	6,070
Advance payments to suppliers	89,820	83,938
Prepaid expenses	108,633	297,808
Other	86,777	143,063
Total current assets	4,822,094	5,166,894
Non-current assets		
Property, plant and equipment		
Buildings, net	62,642	60,996
Tools, furniture and fixtures, net	119,093	234,511
Leased assets, net	209,288	287,899
Total property, plant and equipment	391,024	583,407
Intangible assets		
Trademark right	4,268	4,784
Software	19,984	28,486
Other	72	72
Total intangible assets	24,325	33,344
Investments and other assets		
Investment securities	987,962	1,100,259
Long-term prepaid expenses	24,073	74,012
Other	8,172	10,219
Total investments and other assets	1,020,208	1,184,491
Total non-current assets	1,435,559	1,801,242
Total assets	6,257,653	6,968,136

(Thousands of yen)

	As of December 31, 2022	As of September 30, 2023
Liabilities		
Current liabilities		
Accounts payable - trade	128,066	71,478
Current portion of long-term borrowings	2,620	12,620
Lease liabilities	42,887	60,705
Accounts payable - other	206,209	74,511
Accrued expenses	60,479	54,635
Income taxes payable	30,957	13,808
Deposits received	18,922	6,864
Other	3,635	43,168
Total current liabilities	493,778	337,792
Non-current liabilities		
Long-term borrowings	9,170	42,205
Lease liabilities	167,661	237,098
Asset retirement obligations	12,222	12,296
Provision for share awards	60,590	62,431
Provision for share awards for directors (and other officers)	14,498	19,031
Deferred tax liabilities	2,750	21,975
Total non-current liabilities	266,893	395,037
Total liabilities	760,671	732,829
Net assets		
Shareholders' equity		
Share capital	2,265,697	2,664,763
Capital surplus	2,455,480	2,854,546
Retained earnings	773,021	655,383
Treasury shares	(21)	(21)
Total shareholders' equity	5,494,178	6,174,672
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(5,569)	33,017
Total accumulated other comprehensive income	(5,569)	33,017
Share acquisition rights	8,372	27,617
Total net assets	5,496,981	6,235,307
Total liabilities and net assets	6,257,653	6,968,136

(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, 2022	First nine months ended September 30, 2023
Business revenue	1,904,302	1,495,493
Business expenses		
Cost of business revenue	167,984	189,420
Research and development expenses	840,102	934,434
Other selling, general and administrative expenses	394,992	479,715
Total business expenses	1,403,080	1,603,570
Operating profit (loss)	501,222	(108,077)
Non-operating income		
Interest income	491	711
Interest on securities	11,664	4,777
Foreign exchange gains	182,461	111,674
Gain on valuation of compound financial instruments	–	3,260
Subsidy income	–	2,600
Other	388	9,770
Total non-operating income	195,005	132,793
Non-operating expenses		
Interest expenses	4,253	4,629
Commitment fees	4,083	5,859
Share issuance costs	287	3,930
Loss on valuation of compound financial instruments	4,220	–
Loss on valuation of derivatives	6,896	46,761
Other	0	0
Total non-operating expenses	19,740	61,180
Ordinary profit (loss)	676,486	(36,464)
Extraordinary income		
Gain on sale of investment securities	10,268	–
Gain on redemption of investment securities	4,203	–
Total extraordinary income	14,472	–
Extraordinary losses		
Loss on redemption of investment securities	–	649
Retirement benefits for directors (and other officers)	17,800	–
Total extraordinary losses	17,800	649
Profit (loss) before income taxes	673,159	(37,113)
Income taxes	205,986	80,524
Profit (loss)	467,172	(117,637)
Profit attributable to non-controlling interests	–	–
Profit (loss) attributable to owners of parent	467,172	(117,637)

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First nine months ended September 30, 2022	First nine months ended September 30, 2023
Profit (loss)	467,172	(117,637)
Other comprehensive income		
Valuation difference on available-for-sale securities	(23,819)	38,586
Total other comprehensive income	(23,819)	38,586
Comprehensive income	443,353	(79,051)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	443,353	(79,051)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First nine months ended September 30, 2022	First nine months ended September 30, 2023
Cash flows from operating activities		
Profit (loss) before income taxes	673,159	(37,113)
Depreciation	108,291	120,509
Interest income	(491)	(711)
Interest income on securities	(11,664)	(4,777)
Foreign exchange losses (gains)	(111,358)	(98,034)
Subsidy income	–	(2,600)
Loss (gain) on valuation of compound financial instruments	4,220	(3,260)
Interest expenses	4,253	4,629
Commitment fees	4,083	5,859
Share issuance costs	287	3,930
Loss (gain) on valuation of derivatives	6,896	46,761
Loss (gain) on sale of investment securities	(10,268)	–
Loss (gain) on redemption of investment securities	(4,203)	649
Retirement benefits for directors (and other officers)	17,800	–
Decrease (increase) in trade receivables	718,421	133,599
Decrease (increase) in inventories	1,370	744
Increase (decrease) in trade payables	23,928	(56,588)
Decrease (increase) in advance payments to suppliers	(75,207)	5,882
Decrease (increase) in prepaid expenses	(63,032)	(172,678)
Decrease (increase) in long-term prepaid expenses	97	(41,505)
Increase (decrease) in accounts payable - other	(37,092)	(137,816)
Increase (decrease) in accrued expenses	(13,755)	(5,843)
Increase (decrease) in income taxes payable - factor based tax	(26,251)	(16,539)
Decrease (increase) in consumption taxes refund receivable	(47,231)	(41,045)
Increase (decrease) in accrued consumption taxes	(37,475)	–
Increase (decrease) in deposits received	(23,744)	(12,057)
Increase (decrease) in provision for share awards	38,553	1,840
Increase (decrease) in provision for share awards for directors (and other officers)	8,156	4,532
Other, net	1,417	14,135
Subtotal	1,149,158	(287,496)
Interest and dividends received	15,893	11,259
Interest paid	(4,278)	(4,715)
Subsidies received	–	2,600
Commitment fees paid	(7,000)	(19,212)
Income taxes paid	(183,182)	(119,368)
Income taxes refund	–	11,826
Payments of retirement benefits for directors (and other officers)	(17,800)	–
Net cash provided by (used in) operating activities	952,791	(405,107)
Cash flows from investing activities		
Payments into time deposits	(200,000)	(100,000)
Proceeds from withdrawal of time deposits	110,130	–
Purchase of property, plant and equipment	(25,968)	(189,449)
Purchase of intangible assets	(745)	(16,730)
Purchase of investment securities	(351,856)	(160,000)
Proceeds from sale of investment securities	315,249	–
Proceeds from redemption of investment securities	210,512	200,000
Other, net	–	(2,592)
Net cash provided by (used in) investing activities	57,321	(268,771)

(Thousands of yen)

	First nine months ended September 30, 2022	First nine months ended September 30, 2023
Cash flows from financing activities		
Proceeds from long-term borrowings	13,100	50,000
Repayments of long-term borrowings	(655)	(6,965)
Proceeds from issuance of shares	–	782,614
Proceeds from issuance of shares resulting from exercise of share acquisition rights	4,040	188
Proceeds from issuance of share acquisition rights	–	19,362
Repayments of lease liabilities	(27,600)	(32,750)
Net cash provided by (used in) financing activities	(11,114)	812,449
Effect of exchange rate change on cash and cash equivalents	116,195	98,030
Net increase (decrease) in cash and cash equivalents	1,115,193	236,601
Cash and cash equivalents at beginning of period	2,240,661	3,679,304
Cash and cash equivalents at end of period	3,355,854	3,915,905

(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

On January 5, 2023, the Company received payment for capital increase through third-party allotment from CVI Investments, Inc. As a result, share capital and capital surplus each increased 393,125 thousand yen. Moreover, including increases due to the issuance of share acquisition rights (stock options) and the issuance of new shares as restricted stock-based compensation for directors, share capital and capital surplus each increased 399,065 thousand yen during the first nine months ended September 30, 2023, resulting in share capital of 2,664,763 thousand yen and capital surplus of 2,854,546 thousand yen as of September 30, 2023.

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 implementation guidance on accounting standard for fair value measurement)

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, June 17, 2021) 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 Implementation Guidance on Accounting Standard for Fair Value Measurement prospectively in accordance with the transitional measures provided for in paragraph 27-2 of the Implementation Guidance on Accounting Standard for Fair Value Measurement.

Note that there was no effect of the application of the Implementation Guidance on Accounting Standard for Fair Value Measurement on the quarterly consolidated financial statements.

Additional information

(Application of practical solution on the accounting and disclosure under the group tax sharing system)

The Company and its consolidated subsidiaries have transitioned from the consolidated taxation system to the group tax sharing system from the first quarter of the fiscal year under review. Accordingly, the treatment of accounting and disclosure for corporation tax, regional corporation tax, and tax effect accounting is in accordance with the "Practical Solution on the Accounting and Disclosure under the Group Tax Sharing System" (PITF No. 42, issued on August 12, 2021; hereinafter "PITF No. 42"). In addition, the change in accounting policy with the application of PITF No. 42 in accordance with paragraph 32(1) of PITF No. 42 is considered to have no impact.

(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 estimates for the fiscal year under review.

Segment information, etc.

[Segment information]

- I. 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.
- II. For the first nine months ended September 30, 2023 (January 1, 2023 to September 30, 2023)
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.