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November 12, 2021

Summary of Consolidated Financial Results for the First Nine 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: November 12, 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 nine months of the fiscal year ending December 31, 2021 (January 1, 2021 to September 30, 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 nine months ended September 30, 2021	1,623	183.0	107	—	238	—	169	—
September 30, 2020	573	(19.0)	(600)	—	(615)	—	(698)	—

Note: Comprehensive income
 Nine months ended September 30, 2021: 195 million yen [—%]
 Nine months ended September 30, 2020: (703) million yen [—%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months ended September 30, 2021	yen 8.08	yen 8.08
September 30, 2020	(33.35)	—

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
September 30, 2021	4,502	4,208	93.2
December 31, 2020	4,251	4,011	94.1

Reference: Equity As of September 30, 2021: 4,197 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	—	0.00	—		
Fiscal year ending December 31, 2021 (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, 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	2,246	102.9	61	–	184	–	118	–	5.65

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, 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 8 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 8 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, 2021	20,955,142 shares
As of December 31, 2020	20,951,642 shares

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

As of September 30, 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 nine months ended September 30, 2021	20,952,322 shares
For the first nine months ended September 30, 2020	20,950,500 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.

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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

In the pharmaceutical industry during the first nine months ended September 30, 2021, initiatives have been active for the development of new drugs, and competition for developing new vaccines and drugs for COVID-19 has been accelerating. Under such conditions, the Group achieved the following financial results during the first nine months.

The financial results of marketed drug products were as follows:

Regarding human drug products, strong sales of the drug for gastro-esophageal reflux disease (tegoprazan/brand name: K-CAB[®]) licensed to HK inno.N Corporation (headquarters: Seoul, South Korea) continue to be seen from the first half of the fiscal year under review.

With regard to pet drug products, sales increased by 11.1% year on year as sales of the EP4 antagonist (grapiprant/brand name: GALLIPRANT[®]), which has been marketed as a drug for osteoarthritis in dogs, remained strong although sales of the Ghrelin receptor agonist (capromorelin/brand name: ENTYCE[®]), which has an indication for anorexia management for dogs, were sluggish. These drugs are licensed to Elanco Animal Health Inc. (headquarters: Indiana, U.S.).

Regarding licensed-out drug products, for the retinoic acid receptor alpha agonist (tamibarotene/TM-411/SY-1425) licensed to Syros Pharmaceuticals Inc. (headquarters: Massachusetts, U.S.) by the Company's consolidated subsidiary TMRC Co., Ltd. ("TMRC"), the Phase II clinical trial (SELECT-AML-1) of a combination with venetoclax and azacitidine for RARA-positive newly diagnosed unfit patients with acute myeloid leukemia (AML) started, and TMRC received a milestone payment.

In addition, in the third quarter ended September 30, 2021, the Company concluded a license agreement with Xgene Pharmaceutical Co. Ltd. (headquarters: Hong Kong, China, CEO: Gene Hsu, Ph.D.) regarding a TRPM8 blocker with the aim of developing a drug for the treatment of chronic pain. Under the terms of the agreement, the Company received an upfront payment as consideration.

As for other collaborative research projects, collaborative research with ASKA Pharmaceutical Co., Ltd. is progressing steadily. In parallel, the Group has been promoting internal research projects to generate development candidate compounds.

Accordingly, financial results for the first nine months, the reporting period, were as follows. Business revenue for the period was 1,623 million yen (up 183.0% year on year), operating profit totaled 107 million yen (compared with operating loss of 600 million yen a year earlier), ordinary profit totaled 238 million yen (compared with ordinary loss of 615 million yen a year earlier), and profit attributable to owners of parent was 169 million yen (compared with loss attributable to owners of parent of 698 million yen a year earlier).

Total business expenses were 1,515 million yen (up 29.1% year on year). This total mainly consists of cost of business revenue (268 million yen, a 176.4% increase from the same period of the previous fiscal year), research and development expenses (780 million yen, a 15.6% increase from the same period of the previous fiscal year) and other selling, general and administrative expenses (466 million yen, a 16.0% 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 activities

Research and development expenses of the Group during the first nine months were 780 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, 2021 were 4,502 million yen, an increase of 251 million yen (up 5.9%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 1,142 million yen, a decrease in accounts receivable – trade of 349 million yen and a decrease in securities of 508 million yen.

Liabilities

Total liabilities as of September 30, 2021 were 294 million yen, an increase of 54 million yen (up 22.5%) from the end of the previous fiscal year. This is mainly attributable to an increase in accounts payable – trade of 53 million yen.

Net assets

Total net assets as of September 30, 2021 were 4,208 million yen, an increase of 197 million yen (up 4.9%) from the end of the previous fiscal year. This is mainly attributable to the recording of profit attributable to owners of parent of 169 million yen.

Consequently, the equity ratio was 93.2% (down 0.9 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, 2021 amounted to 2,209 million yen (compared with 2,310 million yen a year earlier), an increase of 148 million yen (up 7.2%) 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 561 million yen (compared with net cash of 95 million yen used a year earlier). This is mainly attributable to the recording of profit before income taxes of 243 million yen and depreciation of 103 million yen, and a cash inflow from a decrease in trade receivables of 349 million yen.

Cash flows from investing activities

Net cash used in investing activities was 487 million yen (compared with net cash of 246 million yen provided a year earlier). This is mainly attributable to payments into time deposits of 317 million yen and purchase of investment securities of 200 million yen.

Cash flows from financing activities

Net cash used in financing activities was 6 million yen (compared with net cash of 0 million yen used a year earlier). This is mainly attributable to repayments of lease obligations of 8 million yen.

(3) Qualitative information regarding consolidated earnings forecasts

At the present time, there are no changes to the figures in “Notice Concerning Revision to Full-Year FY12/21 Consolidated Earnings Forecast” announced on June 30, 2021.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2020	As of September 30, 2021
Assets		
Current assets		
Cash and deposits	1,394,128	2,536,445
Accounts receivable - trade	530,818	181,323
Securities	719,418	211,360
Supplies	6,540	11,866
Advance payments - trade	36,412	23,838
Prepaid expenses	50,243	134,493
Other	96,671	38,092
Total current assets	2,834,232	3,137,419
Non-current assets		
Property, plant and equipment		
Buildings, net	78,501	72,718
Tools, furniture and fixtures, net	208,278	208,935
Leased assets, net	46,187	39,994
Total property, plant and equipment	332,967	321,648
Intangible assets		
Trademark right	4,439	4,035
Software	27,927	31,095
Other	639	639
Total intangible assets	33,005	35,770
Investments and other assets		
Investment securities	1,037,601	995,348
Long-term prepaid expenses	10	172
Deferred tax assets	2,959	2,959
Other	10,457	9,445
Total investments and other assets	1,051,029	1,007,926
Total non-current assets	1,417,002	1,365,345
Total assets	4,251,235	4,502,764

(Thousands of yen)

	As of December 31, 2020	As of September 30, 2021
Liabilities		
Current liabilities		
Accounts payable - trade	41,830	95,696
Lease obligations	18,281	17,494
Accounts payable - other	52,666	46,602
Accrued expenses	49,868	47,254
Income taxes payable	20,882	20,614
Deposits received	3,133	6,442
Other	–	9,889
Total current liabilities	186,662	243,994
Non-current liabilities		
Lease obligations	27,238	19,453
Asset retirement obligations	12,031	12,104
Deferred tax liabilities	14,173	18,676
Total non-current liabilities	53,443	50,234
Total liabilities	240,106	294,229
Net assets		
Shareholders' equity		
Share capital	2,255,401	2,256,920
Capital surplus	2,445,184	2,446,703
Retained earnings	(706,157)	(536,824)
Treasury shares	(21)	(21)
Total shareholders' equity	3,994,407	4,166,779
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	4,809	30,906
Total accumulated other comprehensive income	4,809	30,906
Share acquisition rights	11,912	10,850
Total net assets	4,011,129	4,208,535
Total liabilities and net assets	4,251,235	4,502,764

(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, 2020	First nine months ended September 30, 2021
Business revenue	573,550	1,623,136
Business expenses		
Cost of business revenue	97,312	268,927
Research and development expenses	675,005	780,550
Other selling, general and administrative expenses	402,002	466,478
Total business expenses	1,174,320	1,515,956
Operating profit (loss)	(600,770)	107,179
Non-operating income		
Interest income	3,428	1,352
Interest on securities	23,092	16,154
Foreign exchange gains	–	127,264
Subsidy income	1,500	5,785
Gain on valuation of compound financial instruments	2,250	–
Other	522	2,817
Total non-operating income	30,793	153,373
Non-operating expenses		
Interest expenses	–	905
Foreign exchange losses	45,201	–
Share issuance costs	78	120
Loss on valuation of compound financial instruments	–	2,820
Loss on valuation of derivatives	–	8,760
Settlement package	–	9,600
Other	0	–
Total non-operating expenses	45,279	22,207
Ordinary profit (loss)	(615,256)	238,345
Extraordinary income		
Gain on sales of non-current assets	750	–
Gain on sales of investment securities	8,430	3,382
Gain on redemption of investment securities	–	2,267
Total extraordinary income	9,180	5,650
Extraordinary losses		
Loss on sales of investment securities	348	–
Loss on redemption of investment securities	5,778	–
Total extraordinary losses	6,127	–
Profit (loss) before income taxes	(612,203)	243,996
Income taxes	86,449	74,662
Profit (loss)	(698,652)	169,333
Profit attributable to non-controlling interests	–	–
Profit (loss) attributable to owners of parent	(698,652)	169,333

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First nine months ended September 30, 2020	First nine months ended September 30, 2021
Profit (loss)	(698,652)	169,333
Other comprehensive income		
Valuation difference on available-for-sale securities	(4,599)	26,096
Total other comprehensive income	(4,599)	26,096
Comprehensive income	(703,252)	195,430
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(703,252)	195,430
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First nine months ended September 30, 2020	First nine months ended September 30, 2021
Cash flows from operating activities		
Profit (loss) before income taxes	(612,203)	243,996
Depreciation	86,405	103,842
Interest income	(3,428)	(1,352)
Interest income on securities	(23,092)	(16,154)
Foreign exchange losses (gains)	40,648	(98,967)
Subsidy income	(1,500)	(5,785)
Loss (gain) on valuation of compound financial instruments	(2,250)	2,820
Interest expenses	–	905
Share issuance costs	78	120
Loss (gain) on valuation of derivatives	–	8,760
Settlement package	–	9,600
Loss (gain) on sales of non-current assets	(750)	–
Loss (gain) on sales of investment securities	(8,081)	(3,382)
Loss (gain) on redemption of investment securities	5,778	(2,267)
Decrease (increase) in trade receivables	615,409	349,495
Decrease (increase) in inventories	959	(5,326)
Increase (decrease) in trade payables	5,950	53,866
Decrease (increase) in advance payments - trade	(17,698)	12,573
Decrease (increase) in prepaid expenses	(53,806)	(84,250)
Increase (decrease) in accounts payable - other	(30,030)	(5,017)
Decrease (increase) in accounts receivable - other	4,238	12,045
Decrease (increase) in consumption taxes refund receivable	(31,850)	51,770
Other, net	(11,837)	(1,890)
Subtotal	(37,058)	625,403
Interest and dividends received	30,321	15,581
Interest paid	–	(905)
Subsidies received	1,500	5,785
Income taxes paid	(90,013)	(74,694)
Settlement package paid	–	(9,600)
Net cash provided by (used in) operating activities	(95,249)	561,570
Cash flows from investing activities		
Payments into time deposits	–	(317,510)
Purchase of securities	–	(100,000)
Purchase of property, plant and equipment	(84,387)	(82,303)
Proceeds from sales of property, plant and equipment	750	–
Purchase of intangible assets	(4,115)	(12,983)
Purchase of investment securities	(106,933)	(200,649)
Proceeds from sales of investment securities	387,515	110,923
Proceeds from redemption of investment securities	53,775	115,065
Other, net	185	424
Net cash provided by (used in) investing activities	246,788	(487,032)
Cash flows from financing activities		
Proceeds from short-term borrowings	–	10,000
Repayments of short-term borrowings	–	(10,000)
Proceeds from issuance of shares resulting from exercise of share acquisition rights	110	1,855
Repayments of lease obligations	(555)	(8,571)
Net cash provided by (used in) financing activities	(445)	(6,716)
Effect of exchange rate change on cash and cash equivalents	(41,248)	80,641
Net increase (decrease) in cash and cash equivalents	109,844	148,462
Cash and cash equivalents at beginning of period	2,200,206	2,061,316
Cash and cash equivalents at end of period	2,310,051	2,209,778

(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 first quarter ended March 31, 2021, aiming to perform quarterly closing of accounts quickly and efficiently. Accordingly, the calculation method has been changed starting from the first quarter ended March 31, 2021. 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.

Segment information, etc.

[Segment information]

- I. For the first nine months ended September 30, 2020 (January 1, 2020 to September 30, 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 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.

Significant subsequent event

No items to report.