Disclaimer: This translation is prepared and provided for readers' convenience only. This summary does not constitute any guarantee, and the Company will not compensate any losses and/or damage stemming from actions taken based on these statements. In the case that there is any discrepancy between the Japanese and English versions, the Japanese version is assumed to be correct.

November 8, 2019

Summary of Consolidated Financial Results for the First Nine Months of the Fiscal Year Ending December 31, 2019 (JGAAP)

Listed company's name: RaQualia Pharma Inc.
Listed on: Tokyo Stock Exchange (TSE)
Stock code: 4579
URL: https://www.raqualia.com/
Representative: Naoki Tani, President and CEO
Contact: Kiichiro Kawada, Director and Executive Vice President (TEL) +81-52-446-6100
Scheduled date of filing of quarterly securities report: November 8, 2019
Scheduled date of dividend payment: —
Supplementary documents for quarterly results: None
Quarterly results briefing: None

(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, 2019 (January 1, 2019 to September 30, 2019)

(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	
First nine months ended	million yen	%	million yen	%	million yen	%	million yen	%
September 30, 2019	708	32.9	(534)	-	(527)	-	(531)	-
September 30, 2018	532	(12.1)	(835)	-	(818)	-	(844)	-

Note: Comprehensive income Nine months ended September 30, 2019: (499) million yen [–%]
Nine months ended September 30, 2018: (839) million yen [–%]

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months ended	yen	yen
September 30, 2019	(25.94)	-
September 30, 2018	(41.47)	-

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio
As of	million yen	million yen	%
September 30, 2019	3,896	3,743	95.6
December 31, 2018	4,052	3,857	94.9

Reference: Equity As of September 30, 2019: 3,724 million yen As of December 31, 2018: 3,844 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, 2018	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2019	-	0.00	-		
Fiscal year ending December 31, 2019 (forecast)				0.00	0.00

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

3. Forecasts of consolidated financial results for the fiscal year ending December 31, 2019 (January 1, 2019 to December 31, 2019)

(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, 2019	1,756	135.9	(84)	-	(82)	-	(106)	-	(5.13)

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 nine months ended September 30, 2019 (changes in specified subsidiaries resulting in the change in scope of consolidation): None

(2) Application of special accounting for preparing quarterly consolidated financial statements: None

(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: None

c. Changes in accounting estimates: None

d. Restatements of prior financial statements: None

(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, 2019	20,678,142 shares
As of December 31, 2018	20,388,339 shares

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

As of September 30, 2019	50 shares
As of December 31, 2018	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, 2019	20,504,524 shares
For the first nine months ended September 30, 2018	20,362,125 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

During the first nine months ended September 30, 2019, the Group continued to show a solid performance. This is attributable to the milestone payment related to licensed-out programs received as well as the steady royalty income related to pet drug products and human drug product.

As for tegoprazan (RQ-00000004/CJ-12420/brand name in South Korea (registered trademark in South Korea): K-CAB®; "tegoprazan"), which is the Group's first human drug product, licensee CJ HealthCare Corporation (South Korea) ("CJ HealthCare (South Korea)") started selling it in South Korea in March 2019 for erosive esophagitis and non-erosive reflux disease, and received approval for an additional indication for gastric ulcer in South Korea in July 2019. CJ HealthCare (South Korea) has been promoting in sub-licensing activities geared to expanding tegoprazan's global sales channels. In September 2019, it concluded a sub-license agreement with leading Indonesian company PT Kalbe Farma Tbk (Indonesia, "Kalbe (Indonesia)"), and achieved favorable market growth.

The sales of the EP4 antagonist (GALLIPRANT®, grapiprant, RQ-00000007, AT-001; "GALLIPRANT®") licensed for pain management for pets steadily increased in the U.S. and Europe. This achievement came from successful marketing promotion by Elanco Animal Health Inc. (U.S., "Elanco (U.S.)"). Furthermore, with respect to Ghrelin receptor agonist (ENTYCE®, capromorelin, RQ-00000005, AT-002; "ENTYCE®"), which has an indication for anorexia management for dogs, Elanco (U.S.) added ENTYCE® to its commercial portfolio, and consequently posted steady sales growth.
Elanco (U.S.) has been building a new sales structure, which has involved making Aratana Therapeutics Inc. (U.S., "Aratana (U.S.)"), the licensee of GALLIPRANT® and ENTYCE® of the Group, a subsidiary in July 2019.

With respect to licensing-out activities, the Group and CJ HealthCare (South Korea) reached a basic agreement to expand their global partnership in September 2019. By the end of November 2019, the Group and CJ HealthCare (South Korea) will conclude a license agreement granting CJ HealthCare (South Korea) the rights for development, sales and manufacturing of tegoprazan in North America and Europe.

Regarding the serotonin 5-HT2A and dopamine D2 receptor blocker (ziprasidone) licensed as a treatment for schizophrenia, Meiji Seika Pharma Co., Ltd. ("Meiji Seika Pharma") carried out Phase III clinical trials of ziprasidone in Japan enlisting patients with an acute exacerbation of schizophrenia. In September 2019, Meiji Seika Pharma reported that findings of the study indicated no particular safety issues, but also indicated no statistically-significant difference in comparison with the placebo group in the primary endpoint. Meiji Seika Pharma is conducting detailed analysis and assessment of the results observed in the study, and continuing consideration on future development plans and development strategies.

For the medicinal drug compound candidates created through collaborative research targeting at a specific ion channel conducted between the Group and EA Pharma Co., Ltd. ("EA Pharma"), certain milestones were achieved in September 2019. Currently, EA Pharma is carrying out development to create a new therapeutic agent for digestive treatment using the compound as an active ingredient.

Regarding the collaborative research and industry-academia-government collaboration activities, in July 2019, the Group and ASKA Pharmaceutical. Co., Ltd. have concluded a collaborative research agreement regarding drug discovery research targeting at a specific ion channel, with the aim of creating new drugs. In addition, the Group and Nagoya City University's Graduate School of Pharmaceutical Sciences, Department of Biomedical Science (Hitomi Tsuiji, Lecturer) have concluded a collaborative research agreement geared to creating new drugs for treating amyotrophic lateral sclerosis (ALS), and have embarked on the initial phase of discovery research in that regard. In September 2019, the Group and Epigeneron, Inc. concluded an agreement regarding collaborative research with an option to commercialize. It involves initiating drug discovery research from the exploratory phases to identify novel drug target molecules for the creation of drugs for treating idiopathic pediatric nephrotic syndrome.

Accordingly, financial results for the first nine months, the reporting period, were as follows. Business revenue for the period was 708 million yen (up 32.9% year on year), operating loss totaled 534 million yen (compared with operating loss of 835 million yen a year earlier), ordinary loss totaled 527 million yen (compared with ordinary loss of 818 million yen a year earlier), and loss attributable to owners of parent was 531 million yen (compared with loss attributable to owners of parent of 844 million yen a year earlier). Total business expenses were 1,242 million yen (down 9.2% year on year). This total mainly consists of cost of business expenses (165 million yen, a 196.4% increase from the same quarter last year), research and development expenses (638

million yen, a 21.4% decrease from the same quarter last year) and other selling, general and administrative expenses (437 million yen, a 12.4% decrease from the same quarter last year).

2) Research and development activities

Research and development expenses of the entire Group during the first nine months were 638 million yen. The main components of these activities were as follows:

(A) RaQualia's research and development and collaborative research

Exploratory and discovery phase

a) In a research project to evaluate a CRHR2 antagonist, the Company has discovered multiple development candidate compounds and started an investigation of preclinical efficacy. The project has been carried out to create new mechanism-based drugs for heart failure in collaboration with the Department of Cardiology of the Faculty of Internal Medicine, Graduate School of Medicine, Nagoya University (under the supervision of Professor Toyoaki Murohara and Associate Professor Mikito Takefuji).

b) The Company started collaborative research on treatment drug for RVO; retinal vein occlusion with the Molecular Pharmacology, Biofunctional Evaluation Gifu Pharmaceutical University (Hideaki Hara, Professor and Vice President).

c) The Company started collaborative research with respect to drug discovery research targeting at a specific ion channel, with the aim of creating new drugs with ASKA Pharmaceutical. Co., Ltd.

d) The Company started collaborative research geared to creating new drugs for treating amyotrophic lateral sclerosis (ALS), in conjunction with Lecturer Hitomi Tsuiji of Nagoya City University's Graduate School of Pharmaceutical Sciences, Department of Biomedical Science.

e) The Company and Epigeneron, Inc. concluded an agreement regarding collaborative research with an option to commercialize. It involves initiating drug discovery research from the exploratory phases to identify novel drug target molecules for the creation of drugs for treating idiopathic pediatric nephrotic syndrome. The Company is now preparing to initiate the collaborative research.

For the first nine months, there were no material changes other than what is stated above.

Preclinical development phase

For the first nine months, there were no material changes to the preclinical development phase.

Clinical development phase

For the first nine months, there were no material changes to the clinical development phase.

(B) Status of development at licensee corporation

a) Potassium-competitive acid blocker (tegoprazan)

The compound was developed by CJ HealthCare (South Korea) and was launched for sale in South Korea in March 2019. In addition, clinical trials have been conducted in South Korea to pursue additional indications. CJ HealthCare (South Korea) concluded a sub-license agreement with Vimedimex Medi-Pharma JSC (Vietnam) in December 2018, with Laboratorios Carnot (Mexico) in February 2019, and with Kalbe (Indonesia) in September 2019.

b) Serotonin 5-HT2A and dopamine D2 receptor blocker (ziprasidone)

The compound is under development for treatment for schizophrenia. Meiji Seika Pharma carried out Phase III clinical trials of ziprasidone in Japan enlisting patients with an acute exacerbation of schizophrenia. In September 2019, Meiji Seika Pharma reported that findings of the study indicated no particular safety issues, but also indicated no statistically-significant difference in comparison with the placebo group in the primary endpoint. Meiji Seika Pharma is conducting detailed analysis and assessment of the results observed in the study, and continuing consideration on future development plans and development strategies.

c) EP4 antagonist (GALLIPRANT®)

The compound was developed for pain management for pets by Aratana (U.S.). The Company started selling the compound in the U.S. in January 2017, and started selling it in Europe in March 2019. Elanco (U.S.) has been the primary seller of the compound since September 2019, upon Aratana (U.S.) having become its subsidiary in July 2019.

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

The compound was licensed out to AskAt Inc. ("AskAt"). The sublicensee in China began Phase I clinical trials for the compound in the field of cancer in June 2019.

e) CB2 agonist (RQ-00202730/AAT-730)

The compound was licensed out to AskAt. In September 2019, AskAt and Oxford Cannabinoid Technologies Ltd. (U.K.) concluded a license agreement and a business partnership agreement regarding the compound.

f) Development candidate compound for a specific ion channel target (no compound code disclosed)

The compound was created through collaborative research with EA Pharma. Development efforts have been continued at EA Pharma even after expiration of the collaborative research agreement. Such efforts are proceeding smoothly. In September 2019, predetermined milestones stipulated in the collaborative research agreement were achieved.

For the first nine months, there were no material changes other than what is stated above.

(2) Qualitative information regarding consolidated financial position

1) Analysis of assets, liabilities and net assets

Assets

Total assets as of September 30, 2019 were 3,896 million yen, a decrease of 155 million yen (down 3.8%) from the end of the previous fiscal year. This is mainly attributable to an increase in cash and deposits of 105 million yen and a decrease in investment securities of 262 million yen.

Liabilities

Total liabilities as of September 30, 2019 were 153 million yen, a decrease of 41 million yen (down 21.4%) from the end of the previous fiscal year. This is mainly attributable to an increase in advances received of 13 million and a decrease in accounts payable - other of 54 million yen.

Net assets

Total net assets as of September 30, 2019 were 3,743 million yen, a decrease of 113 million yen (down 3.0%) from the end of the previous fiscal year. This is mainly attributable to increases in capital stock and legal capital surplus of 371 million yen resulting from exercise of share acquisition rights, the recording of loss attributable to owners of parent of 531 million yen and an increase in valuation difference on available-for-sale securities of 31 million yen.

Consequently, the equity ratio was 95.6% (up 0.7 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, 2019 amounted to 1,859 million yen (compared with 2,119 million yen a year earlier), an increase of 29 million yen (up 1.6%) 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 544 million yen, an increase of 303 million yen (up 126.2%) year on year. This is mainly attributable to the recording of loss before income taxes of 522 million yen and depreciation of 101 million yen, a cash outflow from increases in notes and accounts receivable - trade of 59 million yen and prepaid expenses of 60 million yen, and a cash inflow from an increase in notes and accounts payable - trade of 3 million yen.

Cash flows from investing activities

Net cash provided by investing activities was 226 million yen, a year-on-year increase of 429 million yen (compared with net cash of 203 million yen used a year earlier). This is mainly attributable to the proceeds from sales of investment securities of 301 million yen, purchase of property, plant and equipment of 62 million yen, and purchase of intangible assets of 21 million yen.

Cash flows from financing activities

Net cash provided by financing activities was 375 million yen, an increase of 275 million yen (up 276.0%) year on year. This is primarily due to the proceeds from issuance of shares resulting from exercise of share acquisition rights of 371

million yen and proceeds from issuance of share acquisition rights of 4 million yen.

(3) Qualitative information regarding consolidated earnings forecasts

There has been no change to the figures contained in the “Revisions to full-year FY12/19 consolidated earnings forecasts” announced on September 6, 2019. The Company carefully examines business revenue and business expenses whenever necessary, and in the case that any revisions are necessary to the expected earnings forecasts due to changes made to the estimated amounts for the fiscal year under review, the Company will make relevant announcements immediately.

2. Quarterly consolidated financial statements and significant notes thereto

(1) Consolidated balance sheet

(Thousands of yen)

	As of December 31, 2018	As of September 30, 2019
Assets		
Current assets		
Cash and deposits	1,671,346	1,777,015
Accounts receivable - trade	680	60,006
Securities	168,193	82,149
Work in process	–	10,381
Supplies	6,498	5,646
Advance payments - trade	8,737	8,291
Prepaid expenses	71,937	132,819
Other	34,858	33,900
Total current assets	1,962,252	2,110,212
Non-current assets		
Property, plant and equipment		
Buildings, net	88,268	80,213
Tools, furniture and fixtures, net	226,666	200,798
Leased assets, net	2,860	2,345
Total property, plant and equipment	317,795	283,357
Intangible assets		
Trademark right	4,533	3,989
Software	28,420	28,252
Other	1,032	1,032
Total intangible assets	33,985	33,275
Investments and other assets		
Investment securities	1,716,580	1,454,309
Long-term prepaid expenses	10,035	4,195
Other	11,652	11,385
Total investments and other assets	1,738,267	1,469,890
Total non-current assets	2,090,049	1,786,523
Total assets	4,052,302	3,896,735

(Thousands of yen)

	As of December 31, 2018	As of September 30, 2019
Liabilities		
Current liabilities		
Accounts payable - trade	–	3,402
Lease obligations	741	741
Accounts payable - other	98,618	44,392
Accrued expenses	47,805	51,626
Income taxes payable	14,237	5,026
Advances received	–	13,500
Deposits received	3,089	8,173
Total current liabilities	164,492	126,862
Non-current liabilities		
Lease obligations	2,409	1,853
Asset retirement obligations	11,838	11,910
Deferred tax liabilities	16,474	12,862
Total non-current liabilities	30,722	26,627
Total liabilities	195,214	153,489
Net assets		
Shareholders' equity		
Capital stock	2,793,458	2,090,500
Capital surplus	2,983,241	2,280,283
Retained earnings	(1,890,201)	(636,351)
Treasury shares	(21)	(21)
Total shareholders' equity	3,886,476	3,734,410
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(41,901)	(9,941)
Total accumulated other comprehensive income	(41,901)	(9,941)
Share acquisition rights	12,512	18,777
Total net assets	3,857,087	3,743,246
Total liabilities and net assets	4,052,302	3,896,735

(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, 2018	First nine months ended September 30, 2019
Business revenue	532,790	708,168
Business expenses		
Cost of business revenue	55,808	165,415
Research and development expenses	812,961	638,883
Other selling, general and administrative expenses	499,662	437,907
Total business expenses	1,368,432	1,242,206
Operating loss	(835,641)	(534,037)
Non-operating income		
Interest income	7,564	6,957
Interest on securities	22,902	26,464
Gain on valuation of compound financial instruments	–	6,080
Subsidy income	855	–
Other	2,999	629
Total non-operating income	34,321	40,131
Non-operating expenses		
Foreign exchange losses	14,704	23,583
Loss on valuation of compound financial instruments	1,450	–
Share issuance cost	1,408	10,460
Other	–	1
Total non-operating expenses	17,563	34,045
Ordinary loss	(818,883)	(527,951)
Extraordinary income		
Gain on sales of investment securities	4,577	5,728
Total extraordinary income	4,577	5,728
Extraordinary losses		
Loss on redemption of investment securities	14,303	–
Total extraordinary losses	14,303	–
Loss before income taxes	(828,609)	(522,223)
Income taxes - current	16,038	9,828
Income taxes - deferred	(165)	(216)
Total income taxes	15,872	9,612
Loss	(844,481)	(531,836)
Profit attributable to non-controlling interests	–	–
Loss attributable to owners of parent	(844,481)	(531,836)

Consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	First nine months ended September 30, 2018	First nine months ended September 30, 2019
Loss	(844,481)	(531,836)
Other comprehensive income		
Valuation difference on available-for-sale securities	5,142	31,960
Total other comprehensive income	5,142	31,960
Comprehensive income	(839,339)	(499,875)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(839,339)	(499,875)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated statement of cash flows

(Thousands of yen)

	First nine months ended September 30, 2018	First nine months ended September 30, 2019
Cash flows from operating activities		
Loss before income taxes	(828,609)	(522,223)
Depreciation	86,262	101,937
Interest income	(7,560)	(6,957)
Interest income on securities	(22,902)	(26,464)
Foreign exchange losses (gains)	10,715	27,345
Subsidy income	(855)	–
Loss (gain) on valuation of compound financial instruments	1,450	(6,080)
Share issuance cost	1,408	10,460
Loss (gain) on sales of investment securities	(4,577)	(5,728)
Loss (gain) on redemption of investment securities	14,303	–
Decrease (increase) in notes and accounts receivable - trade	447,881	(59,326)
Decrease (increase) in inventories	(376)	(9,530)
Increase (decrease) in notes and accounts payable - trade	(1,984)	3,402
Decrease (increase) in advance payments	168,139	445
Decrease (increase) in prepaid expenses	(62,918)	(60,881)
Increase (decrease) in accounts payable - other	(19,748)	(38,385)
Decrease (increase) in consumption taxes refund receivable	(13,310)	(3,029)
Increase (decrease) in accrued consumption taxes	(13,907)	–
Other, net	(5,133)	31,900
Subtotal	(251,722)	(563,116)
Interest and dividend income received	29,245	34,412
Proceeds from subsidy income	855	–
Income taxes paid	(19,064)	(15,630)
Net cash provided by (used in) operating activities	(240,687)	(544,334)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	–	10,000
Proceeds from redemption of securities	113,040	–
Purchase of property, plant and equipment	(155,141)	(62,947)
Purchase of intangible assets	–	(21,813)
Purchase of investment securities	(625,719)	–
Proceeds from sales of investment securities	203,747	301,440
Proceeds from redemption of investment securities	266,882	–
Other, net	(6,475)	(433)
Net cash provided by (used in) investing activities	(203,666)	226,245
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	99,741	371,162
Proceeds from issuance of share acquisition rights	–	4,412
Repayments of lease obligations	–	(555)
Net cash provided by (used in) financing activities	99,741	375,018
Effect of exchange rate change on cash and cash equivalents	(9,551)	(27,305)
Net increase (decrease) in cash and cash equivalents	(354,163)	29,624
Cash and cash equivalents at beginning of period	2,473,916	1,829,540
Cash and cash equivalents at end of period	2,119,752	1,859,165

(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.

Segment information, etc.

[Segment information]

I. For the first nine months ended September 30, 2018 (January 1, 2018 to September 30, 2018)
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, 2019 (January 1, 2019 to September 30, 2019)
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

Capital increase through exercise of share acquisition rights

During the period from the end of the first nine months ended September 30, 2019 to October 31, 2019, payment and issuance of new shares were carried out in line with the exercise of 15th series share acquisition rights with exercise price amendment clause, which were issued on March 25, 2019, as shown below.

Exercise date	Number of share acquisition rights exercised (Units)	Number of shares issued (Shares)	Exercise price (Yen)	Total amount of exercise price (Thousands of yen)	Increase in capital stock (Thousands of yen)	Increase in legal capital surplus (Thousands of yen)
October 25, 2019	50	50,000	1,252.2	62,610	31,930	31,930
October 28, 2019	10	10,000	1,210.3	12,103	6,176	6,176
October 29, 2019	20	20,000	1,201.2	24,024	12,262	12,262
October 31, 2019	25	25,000	1,197.0	29,925	15,275	15,275
Total	105	105,000	–	128,662	65,643	65,643

As a result, as of October 31, 2019, the total number of issued common shares is 20,783,142, capital stock is 2,156,143 thousand yen and capital surplus is 2,345,926 thousand yen.

The above figures do not include the number of shares issued upon exercise of share acquisition rights between November 1, 2019 and the filing date of this quarterly securities report.