



February 16, 2012

**Summary of Business Report  
for the Fourth Fiscal Year ended December 31, 2011**

RaQualia Pharma Inc. (4579, Osaka Stock Exchange, Growth Market) today reported financial results for the fourth fiscal year ended December 31, 2011.

# Summary of Business Report

## The Fourth Fiscal Year

Period from January 1, 2011  
to December 31, 2011

### 1. Status of the Company

#### (1) Status of Operations

##### 1) Progress and Results

###### Overall Trend

The Great East Japan Earthquake and subsequent accident at the nuclear power plant in Fukushima had a significant impact on the Japanese economy, resulting in considerable economic deterioration in the ensuing weeks and months. Moreover, the financial problems in Europe triggered a global credit crisis and rise of the Japanese yen, trends that kept economic conditions in Japan difficult.

In the pharmaceutical industry, the government made headway in implementing its policy to curtail medical expenditures by lowering regulated drug prices and promoting the use of generic medicines. Concurrently, pharmaceutical companies faced the so-called “2010 problem,” the consecutive expiration of patents for blockbuster drugs. Companies are attempting to cope with these challenges by investing significant resources in the development of new drugs with potential to emerge as revenue sources in future years.

Amidst these circumstances, the Company proactively implemented research and development, marketing and sales activities with a view toward continuously exploiting and developing new drugs, expanding its R&D portfolio of multiple projects, and licensing development compounds created from such efforts.

On the business front, the Company entered into two new licensing agreements, the first with Meiji Seika Kaisha, Ltd. (currently Meiji Seika Pharma Co., Ltd.) for the commercialization of Ziprasidone (RQ-00000003) in Japan in March 2011, and the second with CJ CheilJedang Corporation (Republic of Korea) for the commercialization of 5-HT<sub>4</sub> Partial Agonist (RQ-00000010) in July 2011. The Company recognized business revenue (as one-time income upon the execution of contracts).

The business revenue for the current fiscal year was ¥684 million (down by 42.3% compared to the previous year). Operating loss totaled ¥1,916 million (¥1,345 million for the previous year), ordinary loss totaled ¥1,906 million (¥1,295 million for the previous year), and current net loss was ¥1,916 million (¥1,307 million for the previous year). Total business expenses were ¥2,600 million (up by 2.7% compared with the previous year). Within this total, cost of business revenue accounted for ¥11 million (down by 88.8% from the previous year), Research and development expenses were ¥1,660 million (up by 0.5% from the previous year), and other selling, general and administrative expenses were ¥928 million (up by 19.4% from the previous year).

## **Research and Development Activities**

Research and Development expenses incurred through the Company's Research and Development activities for the fiscal year under review came to ¥1,660 million.

The main components of these activities were:

### **i. Exploratory and discovery phase**

In projects to develop a CB<sub>2</sub> agonist and 5-HT<sub>2B</sub> antagonist, agents mainly used for indications such as irritable bowel syndrome (IBS), and a Motilin receptor agonist mainly used for indications such as functional dyspepsia (FD), we completed identifying several compounds and proceeded with the investigation to confirm efficacy and initial safety assessments.

In the T-type (Cav3.2) calcium channel blocker program, we focused on optimizing activity of lead compounds used for indications such as neuropathic pain, to discover compounds sufficiently qualified for pharmacological evaluation. In parallel we also explored applications to other indications.

In projects on a TRPM8 blocker, we evaluated the characteristic efficacy and safety of selected potential candidate compounds towards identification of a development candidate. However, safety concerns linked to pharmacokinetics properties led us to return search new development compounds.

In projects to develop a sodium channel blocker incorporating a Nav1.3, a Nav1.7 and a Nav1.8 useful for indications such as inflammatory pain and neuropathic pain, we continued to implement optimization and evaluate characteristics of compounds.

In the project to develop an N-type calcium channel blocker we discovered a family of compounds and commenced evaluations for their optimization.

In projects focused on specific ion channels, we continued its collaborative research with Eli Lilly and Company (United States) effective from December 2010 with a view towards exploring and discovering development compounds with high levels of efficacy and safety.

### **ii. Development phase**

#### **a) EP4 Antagonist (RQ-00000007 and RQ-00000008)**

These development compounds have significant potential for indications such as chronic inflammatory pain, acute pain, inflammation, autoimmune diseases, allergies, cancer, and other diseases. During the fiscal year under review we carried out additional studies to investigate pharmacological effects on these indications, including collaborative studies with research laboratories specializing in the evaluation of the anticancer effects in animal models.

We also performed pharmacokinetics studies and toxicity studies in preparation for clinical trials of these indications for RQ-00000007. Likewise, we carried out the safety pharmacological studies required for the commencement of clinical trials of RQ-00000008.

#### **b) 5-HT<sub>4</sub> Partial Agonist (RQ-00000009)**

In order to support development for Alzheimer's disease, we completed the evaluation on intracerebral acetylcholine levels in a rodent animal model.

c) 5-HT4 Partial Agonist (RQ-00000010)

Completed several non-clinical studies applicable to potential gastrointestinal indications such as gastro-esophageal reflux disease (GERD), including toxicity studies required to commence a Phase I clinical trial. In the current fiscal year, we prepared the investigator's brochure and clinical protocols, manufactured the agents, and conduct other works for starting a Phase I clinical trial.

d) Acid Pump Antagonist (RQ-00000004)

Completed clinical part of a Phase I clinical trial in the US. During the year, we completed a clinical study report and submitted it to the US Food and Drug Administration (FDA).

## **2) Capital investments**

Capital investments made during the current fiscal year amounted to ¥16 million in total. The major components of capital investments went towards software improvements and replacement of analytical equipment for enhancing business capacity.

The Company did not make remove or sell any significant property and equipment during the current fiscal year.

## **3) Fund procurement status**

The Company listed its stocks on the Growth Section of the Osaka Securities Exchange in July 2011. In floating its shares, the Company increased its shareholders' equity by a public offering of 4,000,000 shares of ordinary stock (the paid-in amount per share was ¥1,480). The Company raised funds amounting to ¥5,920 million in total.

## (2) Changes in assets and profit/loss

(In thousands of yen)

Item	First Fiscal year (February 2008 to December 2008)	Second Fiscal year (January 2009 to December 2009)	Third Fiscal year (January 2010 to December 2010)	Current (Fourth) Fiscal year (January 2011 to December 2011)
Business revenue	—	—	1,186,759	684,202
Ordinary loss	(2,903,476)	(2,638,527)	(1,295,839)	(1,906,429)
Net loss	(2,899,748)	(2,642,327)	(1,307,679)	(1,916,269)
Net loss per share (in yen)	(4,207,536.19)	(2,642,327.53)	(261,094.08)	(172.85)
Total assets	6,690,678	4,111,171	4,460,773	8,379,143
Net assets	6,522,251	3,879,923	4,191,144	8,174,470
Net assets per share (in yen)	(2,889,749.00)	(5,532,076.52)	180,902.28	616.14

Notes:

1. Because the Company was founded on February 19, 2008, the duration of the first fiscal year was approximately 11 months, from February 19, 2008 through December 31, 2008.
2. The amounts stated in the Table above are rounded down to the nearest thousand yen, except for the net loss per share and net asset per share, which are shown in yen, rounded off to the third decimal point.
3. The current net loss per share was calculated based on the average number of outstanding shares issued during the fiscal year.
4. On January 28, 2011, one ordinary share of the Company was split into 400 shares. The net loss per share for the fourth term was calculated as if the share split had been effected at the beginning of the fiscal year.

## (3) Status of material parent companies and subsidiaries

N/A

#### **(4) Issues to Address**

For RaQualia, an R&D-oriented company pursuing the discovery and creation of new pharmaceutical products, we believe that the achievements in the following three areas will lead to enhanced corporate value: (i) the discovery and creation of promising development compounds; (ii) the escalation of development compounds to clinical trials, the next step towards licensing arrangements; and (iii) the identification of optimal parties as the licensees to which licenses are granted. In recognition of these factors, the Company has defined the following as issues to address.

##### **1) Reinforce our system for promoting licensing**

The Company believes that it will be critical to continue to strengthen its exploitation of potential licensees based on its business strategy, in order to establish optimal licensing arrangements for the development compounds it owns. The Company will be adopting the following measures to address these issues.

- To achieve successful licensing arrangements, the Company will execute effective selection of appropriate licensees and determine the best timing for product launches for customers. Thus, the Company is committed to reinforcing its capabilities in collecting and analyzing customer information.
- The Company strives to employ talented individuals with experience and expertise in licensing activities at pharmaceutical companies, to provide internal education through the OJT approach, and to retain outside advisors with in-depth experience. By doing so, the Company will gain and maintain optimized marketing and sales activities.
- The Company will allocate significant management resources to its Licensing Department to achieve efficient contact and engagement with the management, development leaders, research leaders, relevant personnel, and licensing departments of licensee candidates.

##### **2) Reinforce our system for promoting projects**

The Company flexibly leverages a combination of outside resources to obtain high-quality information both promptly and efficiently, in order to enhance the value of the development compounds in the Company's portfolio. Our main challenge, to this end, is to develop and improve our project promotion system. The Company has implemented the following measures to address these issues.

- The Company continues to research and assess potential collaboration partners in order to retain high-quality outsourced talent in every area of the development businesses. Through close collaboration with these partners, we strive to carry out higher-quality development activities.
- The Company will obtain information on the business needs of individual pharmaceutical companies, our potential customers, by working closely with specialists with in-depth expertise in each area, while making our best efforts to develop strategies for individual diseases and indications, and enhancing the respective values of relevant development compounds. As part of our project promotion strategy, we are committed to developing and implementing development plans to obtain trial results at lower cost

and within shorter time frames, in order to satisfy key budgetary and scheduling requirements for the licensing of individual development compounds.

- Regarding technical matters involving pertinent issues in our development programs, including clinical trials, CMC (activities related to chemical and manufacturing management and quality control in applications for drug development and drug approval), examination of toxicity, pharmaceutical affairs, and project management, we will reinforce our development system by proactively engaging outside specialists and fostering internal human resources, as well as new recruits.

### **3) Reinforce our research and development portfolio**

To create new development compounds, the Company believes that it will be critical to incorporate new projects into our existing research and development portfolio. We have implemented the following measures to address these challenges:

- We strive to discover new target molecules and increase the number of projects by leveraging our own unique assessment system and related database.
- We strive to utilize collaborative research efforts with collaboration partners, in particular outside research laboratories, and to add projects outside the areas of pain disease and gastrointestinal disease, areas in which we have a substantial inventory of pharmacology models.
- We will develop new projects aiming at new indications by utilizing our existing R&D portfolio.

### **4) Further improve our systems for compliance with regulations under the Pharmaceutical Affairs Law**

In the context of drug R&D, it is essential to create drugs that demonstrate effectiveness, safety, and quality in accordance with the standards established by competent regulators for pharmaceutical affairs in each country and jurisdiction. From our inception, RaQualia has been strongly aware of the importance of its systems for complying with these regulations. As such, we have carried out our businesses by developing and updating SOPs (Standard Operating Procedures) and training and educating our employees on these standards. We will continue collecting the latest information on the standards mentioned above and reinforcing our compliance systems accordingly.

### **5) Improve our financial strength**

The Company has incurred an operating loss and operating cash outflow every year, from the first fiscal year to the fourth. Progress in R&D has continued steadily over the same period, but the Company expects R&D expenditures to continue rising. To meet these funding requirements, we will obtain revenue via licensing the growing number of development compounds we are producing through exploratory and discovery efforts, pre clinical trials, and initial clinical trials. We continue to contemplate the development of diverse routes for fundraising, including the use of the public finance system and other measures, to improve our financial strength in support of our business.

**(5) Main businesses** (as of December 31, 2011)

The Company has defined its main business as the licensing of intellectual property related to research and development of drugs and development compounds.

**(6) Main sales offices and factories** (as of December 31, 2011)

Name	Location
Head Office	5-2 Taketoyo, Aichi, Japan

**(7) Status of employees** (as of December 31, 2011)

Number of employees	Changes from the previous year	Average age	Average years of service
81	Increase of 2	43.7 years old	3.2 years

Notes:

1. The number of employees represents the full-time working employees and does not include any temporary workers (any employees contracted via a manpower service company).
2. The Company is now in its fourth year of operations. Since operations in the first year began in July 2008, the average number of years under employment is as stated in table above.

## Non-Consolidated Balance Sheet

(As of December 31, 2011)

(In thousands of yen)

Item	Amount	Item	Amount
(Assets)		(Liabilities)	
Current assets	7,783,270	Current liabilities	204,673
Cash and deposits	7,672,312	Accounts payable-other	99,295
Accounts receivable-trade	1,355	Accrued Expenses	76,911
Raw materials and supplies	45,112	Income taxes payable	22,569
Advance Payment-trade	31,927	Deposits received	5,897
Prepaid expenses	13,842	<b>Total liabilities</b>	<b>204,673</b>
Other	18,720	(Net assets)	
Noncurrent assets	595,873	Shareholders' equity	8,203,675
Property, plant and equipment	68,333	Capital stock	8,489,850
Buildings	41,876	Capital surplus	3,773,850
Structures	16,666	Legal Capital surplus	3,773,850
Machinery and equipment	385	Retained earnings	(4,060,024)
Tools, furniture and fixtures	9,403	Other retained earnings	(4,060,024)
Intangible assets	26,009	Retained earnings brought forward	(4,060,024)
Right of trademark	2,334	Valuation and translation adjustments	(29,205)
Software	23,470	Valuation difference on available-for-sale securities	(29,205)
Other	203		
Investments and other assets	501,531	<b>Total net assets</b>	<b>8,174,470</b>
Investment securities	427,515		
Long-term prepaid expenses	4,589		
Guaranty deposited	69,427	<b>Total liabilities and net assets</b>	<b>8,379,143</b>
<b>Total assets</b>	<b>8,379,143</b>		

Notes: Amounts less than ¥1,000 are rounded down.

## Non-Consolidated Statements of Operations

(January 1, 2011 to December 31, 2011)

(In thousands of yen)

Item	Amount	
Business revenue		684,202
Business expenses		
Cost of business revenue	11,429	
Research and development expenses	1,660,952	
Other selling, general and administrative expenses	928,431	2,600,814
Operating loss		(1,916,612)
Non-operating income		
Interest income	2,214	
Interest on securities	759	
Subsidy income	43,164	
Other	9,405	55,543
Non-operating expense		
Share issuance cost	22,820	
Foreign exchange losses	8,321	
Going public expenses	5,920	
Miscellaneous loss	8,298	45,360
Ordinary loss		(1,906,429)
loss before income taxes		(1,906,429)
Income taxes-current	9,840	9,840
Net loss		(1,916,269)

Notes: Amounts less than ¥1,000 are rounded down.

## Non-Consolidated Statements of Changes in Net Assets

(January 1, 2011 to December 31, 2011)

(In thousands of yen)

	Shareholders' equity			
	Capital stock	Capital surplus	Retained earnings	Total shareholders' equity
		Legal capital surplus	Other retained earnings Retained earnings brought forward	
Balance as of December 31, 2010	5,529,850	813,850	(2,143,755)	4,199,944
Changes of items during the period				
Issuance of new shares	2,960,000	2,960,000		5,920,000
Net loss			(1,916,269)	(1,916,269)
Net changes of items other than shareholders' equity				
Total changes of items during the period	2,960,000	2,960,000	(1,916,269)	4,003,730
Balance as of December 31, 2011	8,489,850	3,773,800	(4,060,024)	8,203,675

	Variance and translation adjustments		Total net assets
	Valuation difference on available-for-sale securities	Total valuation and translation adjustments	
Balance as of December 31, 2010	(8,800)	(8,800)	4,191,144
Changes of items during the period			
Issuance of new shares			5,920,000
Net loss			(1,916,269)
Net changes of items other than shareholders' equity	(20,405)	(20,405)	(20,405)
Total changes of items during the period	(20,405)	(20,405)	3,983,325
Balance as of December 31, 2011	(29,205)	(29,205)	8,174,470

Notes: Amounts less than ¥1,000 are rounded down.

## 1. Notes to matters relating to significant accounting policies

### (1) Valuation basis and method for assets

#### 1) Other securities - those without fair value

The cost method is applied by using the moving average approach. However, other securities denominated in foreign currencies are translated into Japanese yen at the prevailing spot rate of foreign exchange at the end of the fiscal year and translation differences are accounted for as valuation adjustments. Moreover, the valuation adjustments are recognized directly into net assets in full.

#### 2) Inventories – Raw materials and supplies

The last cost method is applied (the method to write down the values included in the balance sheet based on the lowering of productivity)

### (2) Depreciation methods used for tangible fixed assets

#### 1) Property, plant and equipment (excluding lease assets)

They are depreciated by using the declining-balance method; provided that building (excluding any ancillary equipment, etc. they contain) are depreciated by using the straight line method.

Main useful lives are as follows:

Tools, furniture and fixtures: two to four years

#### 2) Intangible assets (excluding lease assets)

They are amortized mainly by using the straight-line method.

Moreover, software for own use is amortized using a straight-line method over the period determined based on its potential internal use (5 years).

#### 3) Long-term prepaid expenses

They are amortized mainly by using the straight-line method.

### (3) Accounting for deferred assets

#### Share issuance cost

They are charged to expenses in full when they are paid.

### (4) Other basis for presentation of financial statements

#### Accounting for consumption taxes

Consumption taxes and local consumption taxes are excluded from the transaction amounts.

(5) Changes in accounting policies

Adoption of Accounting Standard for Asset Retirement Obligations

Effective from the fiscal year under review, the Company has adopted "Accounting Standard for Asset Retirement Obligations" (ASBJ Statement No.18, March 31, 2008) and "Guidance on Accounting Standard for Asset Retirement Obligations" (ASBJ Guidance No.21, March 31, 2008). Such changes will not have any effect on profit and loss.

**2. Notes to non-consolidated statements of changes in net assets**

(1) Matters concerning the classes and the number of outstanding shares issued

Class of shares of stock	Number of shares as of December 31, 2010	Increase in the number of shares during the fiscal year	Decrease in the number of shares during the fiscal year	Number of shares as of December 31, 2011
Common stock	23,168	13,244,032	-	13,267,200

Notes:

The increase in the number of outstanding shares issued was due to the increase of 9,244,032 via split of shares (1: 400) and increase of 4,000,000 via the issuance of new shares upon the new listing.

**3. Notes to information per share**

(1) Net assets per share ¥616.14

(2) Net loss per share (¥172.85)