RaQualia Pharma Inc.
4579 TSE JASDAQ

27-Sept.-16

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Realizing stable earnings is in sight from the acquisition of royalty income; aiming to leap forward to the next stage through industry-academia collaborations

RaQualia Pharma Inc. <4579> (hereafter, also “the Company”) is a drug discovery and development-type biotech venture company that was established when the central research laboratory of Pfizer’s Japanese subsidiary became independent of Pfizer. Unlike typical pharmaceutical manufacturers, its business model is to generate earnings by creating the development compounds that become the seeds for new drugs and licensing-out the resulting technologies and patents to pharmaceutical manufacturers. The Company’s strengths include its superiority in ion channel drug discovery that has a high barrier to entry, while it specializes in indications for the gastrointestinal and pain fields.

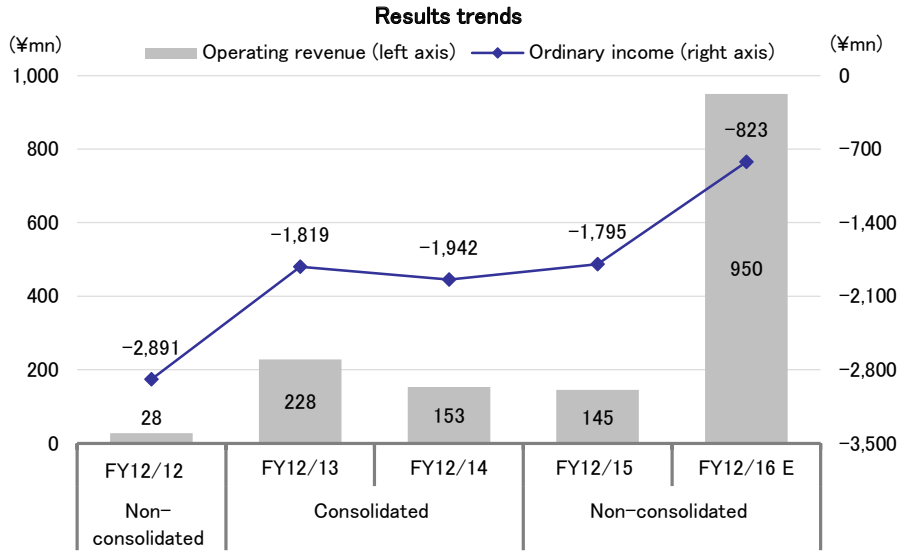
In the last few years, a situation has continued at the Company in which it has failed to achieve its results targets. The main reason for this is that, there have continuously been cases in which the timing of lump-sum payments from licensing agreements deviated greatly from the Company’s expectations due to the licensee companies’ circumstances. However, it has reached a turning point in 2016. The background to this is that due to the steady progress it has made in the portfolio that is has already licensed out, the likelihood of it obtaining milestone income is increasing, and in addition the market launches of animal drugs are drawing closer. Therefore, a path can be seen in which the Company stably generates high royalty income, which will become a pillar of its operating revenue in the future.

The Company’s operating revenue forecast for FY12/16 is ¥950mn, and it seems likely that it will achieve this based on the Q1 results and the Q4 forecast for milestone income. Royalty income will be generated from FY12/17 onwards and operating revenue is expected to stably exceed ¥1bn. On the other hand, as operating costs are trending downward, it would seem that the Company is only a short step from achieving the profit-loss breakeven point in FY12/18.

As the operating loss will continue for the time being, it is considered highly likely that the Company will need to raise funds to stably manage its operations. But on this point also, at FISCO we think that it might be changing its previous stance. Since the past, the Company has been highly aware of the importance of improving shareholder value, but its fund raising has often invited a situation in which this value is diluted. But as the prospect of obtaining stable revenue is now in sight, its options for fund raising in the future are widening and this is expected to translate into measures that will be even more aware of shareholder value.

Check Point

- It has a leading drug discovery infrastructure even among domestic bio-ventures
- The two animal drug programs have already received new drug approval and are expected to generate royalty income
- Announced the Odyssey 2018 mid-term business plan



■ Viewpoint for investing in the Company

It has a leading drug discovery infrastructure even among domestic bio-ventures

The Company was founded when it was spun-out of Pfizer of the United States in 2008. It inherited an extensive library of compounds and possesses a leading drug discovery infrastructure even when compared to other domestic bio-venture companies. Its ability to generate pharmaceutical candidate compounds from this infrastructure is its strength and appeal to pharmaceutical manufacturers, and at the same time is the biggest motivation for investing in the Company.

In the last few years, the Company has continually failed to achieve its results forecast. This was because the licensing-out to pharmaceutical manufacturers of the compounds the Company developed did not proceed according to plan. In 2014 and 2015, it planned to license -out products such as its potassium-competitive acid blocker / P-CAB (RQ-4 / tegoprazan) and 5-HT$_4$ partial agonist (RQ-10), and its targets in its business plan incorporated the income from the resulting lump-sum payments. However, these plans did not develop as expected. Licensing-out deals are greatly affected by the situations at the pharmaceutical-manufacturer licensees, such as the current state of their drug portfolios and future plans. The evaluations of the licensing-out candidates themselves, such as of RQ-4 and RQ-10, have not changed at all. Rather, their licensing-out was delayed due to the situations at the licensees, and the Company's results over the last few years have been due to this situation continuing.

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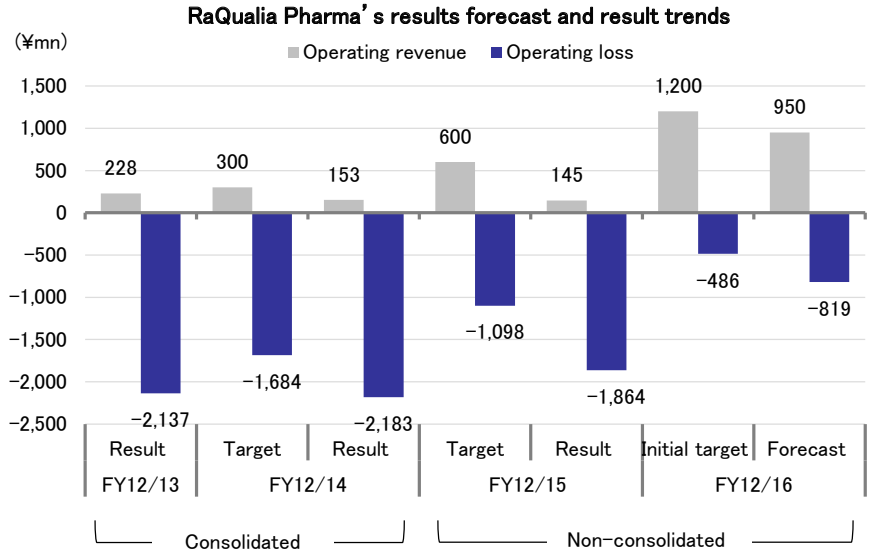


Note: The targets and the initial targets are the initial values in the 2014-2016 mid-term business plan. The forecasts are the initial values in the 2016-2018 mid-term business plan.

Source: Prepared by FISCO from the Company's financial results briefing materials, financial results summary, etc.

But the Company has reached a major turning point in 2016. From the elimination of income in the form of lump-sum payments from licensing out, which includes risks that the Company cannot control, and instead the accumulation of income that it is highly likely to obtain – specifically, milestone income from the progress made in the development of compounds that it has already licensed-out, research-collaboration income from its joint-research partners, and royalty income as a percentage of sales following a market launch – it has reached a situation in which the profit-loss breakeven point and then becoming profitable is in sight.

The background to the Company becoming able to set income targets toward achieving profitability that do not incorporate lump-sum payments income, which include unstable elements, is the progress it has made in development. As will be explained in more detail later, this spring it consecutively received approval from the FDA in the United States for 2 animal drugs, and it plans to launch them in the United States in the second half of 2016 and the first half of 2017 respectively. In addition, it is making steady progress in the clinical trials of the multiple compounds it has already licensed-out and is expected to receive milestone income for these compounds. In terms of joint research, the Company is utilizing its extensive compound library and its advanced new compound discovery capabilities and can be expected to obtain research-collaboration income as a result of these efforts.

The Company is still aiming to obtain lump-sum payments income in the same way as it has done up to the present time, but this has become purely an upside factor in the current mid-term business plan. That is to say, the situation is that not only has the possibility of the Company stably generating income greatly increased, there is also the possibility of upside in terms of results exceeding income targets.

The Company's income items

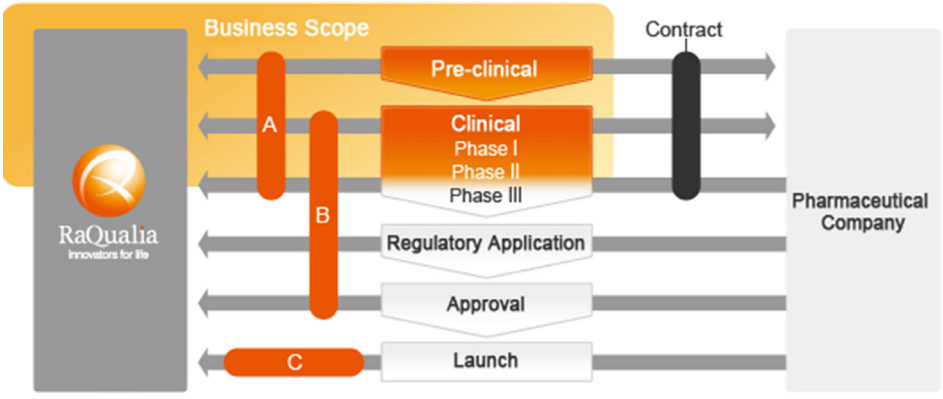
Lump-sum payments income	Income received when it licenses-out a compound it has discovered to a pharmaceutical company that will undertake its development
Milestone income	Income received when milestones are reached as the clinical trials are progressed after licensing out
Royalty income	Income received as a fixed percentage of sales after a product market launch
Research-collaboration income	In accordance with the conditions of the research collaboration agreement, income received as recompense for the research findings provided by the Company up to the time of the start of the collaborative research, and also income received as recompense for the work conducted during the collaborative research period.

Source: Prepared by FISCO from the Company's homepage

As described above, the stability of the Company's results is set to greatly improve in the future, and also, depending on the circumstances, results can be expected to exceed targets. Moreover, as is described below, it has established a foundation through industry-academia collaborations on which to generate seeds for a major leap forward in the future. From these and other factors, at FISCO we think that there may be sufficient room to once again consider investing in the Company.

In terms of the viewpoint for investment, the important points are also its intellectual property strategy and lifecycle management. This is because for the Company, which employs a business model of generating income by licensing-out the rights to new drug candidate compounds, a complete portfolio will result in it assuredly obtaining income, so the intellectual property itself is the product and the essence of the Company. For each portfolio, the Company is acquiring substance patents and usages patents for its main markets, including Japan, the United States, Europe, and China. It also conducts lifecycle management for its intellectual property in order to prevent the entry of generics, to extend the royalty income period to the greatest extent possible, and to continuously secure income. The stability and completeness of its intellectual property strategy and lifecycle management should help investors feel a sense of security about investing in the Company.

The Company's income model



Source: Reproduced from the Company's homepage

■ Status of the licensing-out candidates in the pipeline

8 candidates in the pipeline for the gastrointestinal, pain, and antibacterial fields

The business model is for the Company itself to discover pharmaceutical-candidate compounds and then license them out to pharmaceutical manufacturers at the stages when they have been evaluated to a certain extent, such as the pre-clinical trial stage and the phase I clinical trials stage. The Company receives lump-sum payments when it licenses-out its compounds. The success or failure of this licensing-out of course depends on the potential of the compound itself, but it also depends on other factors, such as the conditions at the licensees of pharmaceutical manufacturers, and the needs of the pharmaceutical market. As the licensor, the Company cannot influence these factors by its own efforts, and as previously described, in the past this has been the major reason why its results have repeatedly failed to achieve its targets.

As of August 2016, the Company had in its pipeline 5 programs for the gastrointestinal field, 2 programs for the pain field, and 1 program for the antibacterial field. Of these, it had already licensed out for specific regions some of the programs for the gastrointestinal field, and it is aiming to also license them out for the remaining regions.

■ Status of the licensing-out candidates in the pipeline

List of licensing-out candidates in the pipeline

	Program	Compound code	Main indication	Licensee	Agreement region	Exploratory research – pre-clinical	Clinical trials			Remarks
							P-I	P-II	P-III	
Human drugs	Dalbavancin	RQ-00000002	MRSA		Japan		Preparations underway			Approved by the U.S. FDA in May 2014, market launched in the United States in July 2014.
	Potassium-competitive acid blocker	RQ-00000004	Gastroesophageal reflux disease	CJ Healthcare	Japan, Global excluding Asia		Completed			Assumption is that it will be launched for Japan, Europe, and the United States. Completed P-I in Japan (FY12/15), received an allowance for an use patent in Japan.
	5-HT_4 partial agonist	RQ-00000010	Gastroparesis, functional GI disorder, functional constipation	CJ Healthcare	Japan, Global excluding Asia			Being investigated		Launched an investigator-initiated clinical trial for Parkinson's disease patients at Virginia Commonwealth University in the U.S. Investigating conducting a global P-II by the Company.
	5-HT_{2B} antagonist	RQ-00310941	Functional gastrointestinal disorders, irritable bowel syndrome (IBS)		Japan, global		Underway			Started P-I clinical trials in the U.K. in July 2015, which are currently underway.
	Motilin receptor agonist	RQ-00201894	Gastroparesis, Functional GI disorder, Postoperative ileus		Japan, global	Pre-clinical stage completed				Completed Pre-clinical stage. P-I clinical trials are being investigated.
	Ghrelin receptor agonist	RQ-00433412	Loss of appetite associated with cancer / cachexia syndrome		Japan, global	Pre-clinical stage				Transferred to the pre-clinical stage and pre-clinical trials are being investigated.
	TRPM8 blocker	RQ-00434739	Neuropathic pain (chemotherapy-induced cold allodynia)		Japan, global	Pre-clinical stage				Transferred to the pre-clinical stage and pre-clinical trials are being investigated.
	Selective sodium channel blocker	-	Neuropathic pain		Japan, global	Research stage				

Source: Prepared by FISCO from Company materials, interviews, etc.

(1) Potassium-competitive acid blocker / P-CAB (RQ-4, International Nonproprietary Name (INN) : tegoprazan)

The potassium-competitive acid blocker / P-CAB (RQ-4 / tegoprazan) is mainly indicated for gastroesophageal reflux disease (GERD) and as a next-generation drug, it is expected to replace the current mainstream treatment of proton pump inhibitors (the leading examples of which are Pariet® from Eisai Co, Ltd. <4523> and Takepron® from Takeda Pharmaceutical Company Limited <4502> (hereafter, Takeda)). In the development of P-CAB, Takeda is the top runner having already released TAKECAB® in February 2015, with the Company's product next in line.

TAKECAB® has sold steadily since its launch, and in FY3/15, which was the first fiscal year of its launch (2 months), it achieved sales of ¥3.2bn, and in its second year, FY3/16, sales of ¥8.4bn. The launch of TAKECAB® can be said to have established a sequence of H2 blocker ⇒ proton pump inhibitor ⇒ P-CAB, which in turn can be said to be advantageous for the Company's licensing-out of tegoprazan.

The Company has already licensed-out tegoprazan to CJ Healthcare Corporation of South Korea for South Korea, Taiwan, China, and the Southeast Asia region (details are provided below). Therefore, it is currently mainly aiming to license it out in Japan and in the global market for regions outside of its agreement with CJ Healthcare; namely, the major pharmaceutical markets of the United States and Europe and the markets of emerging countries outside of the Asia region. The current situation is that by FY12/15, phase I clinical trials have been completed in the United States and Japan, and in January 2016, "tegoprazan" was acquired as the pharmaceutical's International Nonproprietary Name (INN).

Development status for the potassium-competitive acid blocker / P-CAB (RQ-4 / tegoprazan)

March 2013	Granted substance patent in the United States
October 2013	Granted use patent in the United States
June 2014	Started phase I clinical trials in Japan
December 2014	Granted use patent in Japan
June 2015	Granted use patent in Japan
August 2015	Completed phase I clinical trials in Japan, completed the comprehensive report
January 2016	Obtained "tegoprazan" as the pharmaceutical's International Nonproprietary Name (INN)
May 2016	Granted use patent in Japan

Source: Prepared by FISCO from Company materials, etc.

The scale of tegoprazan's potential market is considered to be large. For example, the scale of the global proton pump inhibitor market is said to be approximately ¥2 trillion. At the current time, the Company is aiming to license it out in the domestic market, so understanding the domestic proton pump inhibitor market would seem to be useful in order to get a picture of tegoprazan's potential market. According to the relevant financial documents from the main manufacturers for FY15, Takeda recorded total sales of ¥49.7bn for Takepron® and TAKECAB® combined, Daiichi Sankyo Company, Limited <4568> ¥82.4 billion for Nexium®, and Eisai ¥30.4bn for Pariet®.

Sales of the main proton pump inhibitors in the domestic market

(unit: ¥100mn)

Company name	Product name	Sales		
		FY13	FY14	FY15
Takeda	Takepron®	676	525	413
	TAKECAB®	-	32	84
Daiichi Sankyo	Nexium®	542	693	824
Eisai	Pariet®	473	371	304

Source: Prepared by FISCO from each company's published materials

The Company has been granted various patents for P-CAB, but the patent granted on May 25, 2016 (release on the same day) is particularly interesting. It was granted the patent application for the use of P-CAB in Japan, but in terms of the scope of the patent for P-CAB, the Company was granted the rights not only for tegoprazan discovered by itself, but also for all P-CAB (in other words, other company's products also) to improve the occurrence of Phase III contractions of interdigestive migrating contractions (IMC) indicated for GERD, functional indigestion, abdominal bloating, gastrointestinal motility abnormalities such as discomfort and constipation, and for gastrointestinal functions regulating agents and gastrointestinal motility activating agents to improve symptoms.

To explain this more simply, with regards to Takeda's forerunner product of TAKECAB®, in the event of marketing by Takeda in which it appeals to this product's expression of efficacy for the occurrence of the IMC Phase III contractions described above, this would infringe on the Company's patent. It is considered that Takeda will act to avoid a patent infringement, so although the Company will not immediately acquire the intellectual property-related benefits of being granted this patent, it is expected to prove advantageous for its licensing-out of tegoprazan domestically that the Company is aiming for. In addition, it is not impossible that it will receive intellectual property income in the future from patent infringements by other companies, including Takeda.

(2) 5-HT$_4$ partial agonist (RQ-10)

RQ-10 is a compound indicated for conditions including gastroparesis, functional GI disorder, and chronic constipation. This drug targets one of the serotonin receptors (5-HT$_4$) and has the same pharmacological action as Mosapride, which has already been launched under the brand name of Gasmotin® by Sumitomo Dainippon Pharma Co., Ltd. <4506>. The Company has licensed it out to CJ Healthcare of South Korea for the South Korea, Taiwan, China, India, and the Southeast Asia markets. It is aiming to also license it out for the global market, including in Japan and the other regions outside of the agreement with CJ Healthcare (the status of the development by CJ Healthcare is described below).

The Company completed phase I clinical trials in June 2013 in the United Kingdom, in which RQ-10 demonstrated very strong efficacy and safety. An investigator-initiated clinical trial for Parkinson's disease patients is also being carried out at Virginia Commonwealth University in the United States. In April 2016, the Michael J. Fox Foundation for Parkinson's Research decided to award this trial a research grant totally $868,000 over three years. This research grant is only to assist the above-described investigator-led clinical trial so it will not affect the Company's results, but it is thought that the progress made in this trial will have a positive effect on the licensing-out of RQ-10, so it can be evaluated as a positive development for the Company.

Status of the development of the 5-HT$_4$ partial agonist (RQ-10)

June 2013	Completed phase I clinical trials in the United Kingdom
February 2014	Granted a substance patent in the United States
May 2014	Concluded a joint research agreement with Virginia Commonwealth University in the United States for Parkinson's disease patients
April 2016	The Michael J. Fox Foundation for Parkinson's Research decided to award a research grant to the investigator-led clinical trial
August 2016	Started the investigator-led clinical trial (start of administration of the drug to Parkinson's disease patients)

Source: Prepared by FISCO from Company materials, etc.

Income from RQ-10 is expected to be first in the form of lump-sum payments from licensing-out from Japan and globally. After that, the Company will receive milestone income in accordance with the progress made in its development, and it will then receive royalty income once it is market launched as a new drug. In terms of estimating market scale, the sales of Gasmotin® would seem to be of reference. Sales of this drug have been trending downward in recent years following the appearance of generics, but in FY11 it recorded sales of ¥21.2bn.

(3) 5-HT$_{2B}$ antagonist (RQ-00310941)

5-HT$_{2B}$ is one type of gastrointestinal hormone serotonin (5-HT) receptor, and this compound (RQ-941) has the medicinal effect of suppressing the activity of 5-HT$_{2B}$, which is expected to reduce visceral pain and normalize gastrointestinal motility. The joint research conducted with Gunma University has indicated that the compound controls abnormal defecation but does not have an excessive effect on normal intestine functions, and therefore it is expected to be indicated for irritable bowel syndrome (IBS). The Company, based on the results of the evaluation in the pre-clinical trials (in-vivo pharmacology study, pharmacokinetic study, toxicity study, and safety pharmacology study), decided it was possible to proceed to the clinical trials stage and began phase I clinical trials in the United Kingdom in July 2015, which are currently ongoing.

Development status of the 5-HT$_{2B}$ antagonist (RQ-00310941)

June 2012	Granted a substance patent in the United States
2013-2014	Completed the pharmacology study, safety pharmacology study, and pharmacokinetic study
August 2014	Granted a substance patent in Japan
May 2015	Granted a substance patent in Europe
June 2015	Granted a substance patent in China
July 2015	Started phase I clinical trials (currently ongoing as of August 2016)
April 2016	Granted a substance patent in South Korea

Source: Prepared by FISCO from Company materials, etc.

The Company has been granted a substance patent for RQ-941 from five major patent offices (Japan, United States, Europe, China, and South Korea). Up until now, it has focused on the development of tegoprazan and RQ-10, but the Company completed tegoprazan's phase I clinical trials in Japan in July 2015, so at FISCO we think that in the current fiscal year, the development of RQ-941 will in particular be expedited. The background to this is considered to be that it might be possible to expand the indication of RQ-941 to a drug to improve abdominal symptoms resulting from autoimmune conditions such as ulcerative colitis and Crohn's disease. One possible timing for its licensing-out would seem to be when the phase I clinical trials, which are currently underway, are completed. But the Company itself has not incorporated this point into its results targets in its mid-term business plan. Therefore, should it license it out, the resulting lump-sum payments income would be an upside factor for results to exceed targets.

(4) Motilin receptor agonist (RQ-00201894)

RQ-894 is a compound that acts on and has a medicinal effect on Motilin receptor, which is one of the gastrointestinal hormones, and it has been confirmed that it is highly effective for activating motility in cases of gastric motor dysfunction. Its targeted indications include for gastroparesis, functional GI disorder, and postoperative ileus. Currently, there is no Motilin receptor agonist that has received manufacturing and marketing approval. Therefore, should the Company's compound be market launched, it may become a ground-breaking new drug.

The current state of development is that the Company has completed the pre-clinical trials necessary to carry out the phase I clinical trial (in-vivo pharmacology study, pharmacokinetic study, toxicity study, and safety pharmacology study), and from their findings, it evaluated that there are no problems for its further development. Going forward, the Company is investigating whether to advance to the clinical stage or to attempt to license it out at the current stage.

Development status of the Motilin receptor agonist (RQ-00201894)

January 2014	Granted a substance patent in the United States
May 2014	Granted a substance patent in China
October 2014	Granted a substance patent in Japan
2014	Completed the pre-clinical trials
March 2015	Granted a substance patent in Europe
October 2015	Granted a substance patent in South Korea

Source: Prepared by FISCO from Company materials, etc.

(5) Dalbavancin

Dalbavancin is an antibiotic mainly indicated for Methicillin-Resistant Staphylococcus Aureus (MRSA) that the Company acquired the development, manufacturing, and marketing rights for Japan from Pfizer. In December 2010, it transferred the rights to Durata Therapeutics Inc. (currently, Allergan plc) of the United States, but following negotiations with Allergan, it was decided that the Company would once again acquire the rights for Japan as of June 23, 2015, in accordance with the provisions of the rights-transfer agreement. Going forward, the Company is aiming to license out Dalbavancin to pharmaceutical manufacturers that will carry out its development, manufacturing, and marketing in Japan.

Dalbavancin has already been launched in the United States in July 2014 (product name, DALVANCE®), while in March 2015, new-drug approval was also acquired for it in Europe (product name, XYDALBATM). For its development within Japan, it would seem that the Company intends to provide support based on the overseas clinical development and information applications being conducted by Allergan plc.

The goal is for Dalbavancin to be a replacement drug for Vancomycin. A feature of Dalbavancin is its long half-life (it maintains its medicinal effect over a long period of time). Compared to Vancomycin, which must be taken twice a day, it has the major advantage that it only needs to be taken once per week. Furthermore, there are great expectations for Dalbavancin in the United States due to the emergence of Vancomycin-Resistant Staphylococcus Aureus (VRSA), and although presently VRSA has not been confirmed in Japan, the Vancomycin Intermediate Staphylococcus Aureus (VISA) variation of MRSA has been reported. Essentially, the medical conditions that Dalbavancin is indicated for are limited, so there should not be excessive expectations for it, with the forecast being annual sales within Japan in the range of ¥2bn to ¥3bn. But it is possible that its sales will exceed this forecast if the conditions that Dalbavancin is indicated for are expanded to include, for example, pneumonia and septicemia.

■ Status of the licensed programs

The two animal drug programs have already received new drug approval and are expected to generate royalty income

As of August 2016, the Company had already licensed out 4 human drug programs, including P-CAB, and 2 animal drug programs, and as a whole it is making steady progress. In particular, both of the two animal drug programs have already received new drug approval in the United States, and going forward they are expected to transition to the stage of stably generating revenue in the form of royalty income.

■ Status of portfolios already licensed-out

Status of the licensed programs (human drugs)

	Program	Compound code	Main indication	Licensee	Agreement region	Exploratory research – pre-clinical	Clinical trials			Remarks
							P-I	P-II	P-III	
Human drugs	Ziprasidone	RQ-00000003	Schizophrenia, Bipolar disorder	Meiji Seika Pharma	Japan				Underway	Launched in Europe and the United States. Meiji Seika Pharma has started P-III in March 2015.
	Potassium-competitive acid blocker	RQ-00000004	Gastroesophageal reflux disease	CJ Healthcare	South Korea, China, Taiwan, and Southeast Asia				Underway	CJ has started P-III in South Korea. Added Southeast Asian rights in November 2014. CJ has sub-licensed Chinese right to Luoxin in China.
	5-HT$_4$ partial agonist	RQ-00000010	Gastroparesis, Functional GI disorder	CJ Healthcare	South Korea, China, Taiwan, India, and Southeast Asia		Being planned			
	EP4 antagonist	RQ-00000007	Chronic inflammation, Pain, acute pain, etc.	Maruishi Pharmaceutical	Japan, South Korea, China, and Taiwan	Being planned				Injection only (oral agent being developed by AskAt Inc.)

Source: Prepared by FISCO from Company materials, interviews, etc.

(1) 5-HT2A/D2 antagonist (RQ-3 / Ziprasidone)

Ziprasidone is a drug indicated for schizophrenia and bipolar disorder and is already being sold by Pfizer in 83 countries and regions, including the United States and Europe. The Company acquired the rights for it in Japan from Pfizer and has licensed it out to Meiji Seika Pharma, Co., Ltd. Meiji Seika Pharma started phase III clinical trials in March 2015, which are currently ongoing. Going forward, if steady progress is made in the phase III clinical trials, the outlook is that the application for regulatory approval as a new drug will be made in the spring of 2019.

In terms of the impact on the Company's results, first it will obtain milestone income on reaching milestones such as applying for regulatory approval as a new drug and the market launch. After the market launch, it will receive royalty income according to sales. On considering the sales scales of existing drugs, it has the potential to grow to be a drug with annual sales in excess of ¥10bn.

(2) Potassium-competitive acid blocker / P-CAB (RQ-4 / tegoprazan)

As previously described, tegoprazan has already been licensed-out to CJ Healthcare of South Korea for South Korea, Taiwan, China, and the Southeast Asia region. CJ Healthcare is currently conducting phase III clinical trials in South Korea, and the present situation is that it expects to apply for new-drug regulatory approval during 2017, toward a market launch at the end of 2018. In July 2014, CJ Healthcare announced that tegoprazan had been adopted in the South Korean project "Full Cycle New Drug Development Business Challenges." This is a national new drug development project that will invest 1.06 trillion won up to 2020. If we were to estimate from this situation and the development status up to the present time, we anticipate that this product will be smoothly market launched.

In terms of its impact on the Company's income, it will receive milestone income from the progress made in the development and royalty income after the market launch. However, it is necessary to be aware that the scale of South Korea's pharmaceutical market is considerably smaller than that of the Japanese market, and annual sales by CJ Healthcare in its South Korean domestic market are expected to be in the region of ¥5bn.

CJ Healthcare also has the rights to launch the product onto the Chinese market, but it has concluded an exclusive collaboration agreement for the Chinese market with Shandong Luoxin Pharmaceutical Group Stock Co., Ltd. (hereafter, Luoxin Pharma) of China. In other words, CJ Healthcare is sub-licensing-out the product to Luoxin Pharma. In the future during the progress made in the development for the China market, not only CJ Healthcare, but also the Company will receive milestone income. Further, after it is market launched, the agreement stipulates that both CJ Healthcare and the Company will receive a fixed percentage of sales in the Chinese market as royalty income, so a mechanism is in place in which the Company can receive the benefits of the launch in the Chinese market. According to IMS GMM (Global Market Measurement), the market for drugs to inhibit gastric acid in mainland China grew by 25% from 2010 to 2014, with annual sales in 2014 reaching U.S.$2.6bn. So sales after its launch onto the Chinese market are expected to be on a scale several times those of the South Korean market.

(3) 5-HT$_4$ partial agonist (RQ-10)

The Company has also licensed-out RQ-10 to CJ Healthcare for South Korea, Taiwan, China, India, and Southeast Asia. CJ Healthcare is currently focusing on developing tegoprazan, so it has not yet started developing this compound.

(4) EP4 antagonist (RQ-7 / grapiprant) <novel human drug>

Grapiprant is a compound whose main indications are for acute and chronic inflammatory pain, and in Japan it has been licensed-out to Maruishi Pharmaceutical Co., Ltd. Maruishi Pharmaceutical is presently at the pre-clinical trials stage and is constructing a development strategy and development plan. The Company's policy is to provide support for the planning of Maruishi Pharmaceutical based on its own medical and R&D findings.

(5) EP4 antagonist (RQ-7/ grapiprant, animal drug) and ghrelin receptor agonist (RQ-5 / capromorelin, animal drug)

The Company has licensed out to Aratana Therapeutics, Inc. (hereafter, Aratana) of the United States grapiprant, which is indicated for acute and chronic pain in pets, and capromorelin, which is indicated for loss of appetite and weight loss in pets. Aratana is continuing to steadily develop these product and it received manufacturing and marketing approval from the FDA of the United States in March 2016 for grapiprant and in May 2016 for capromorelin. Based on this, Aratana plans to market launch grapiprant in the fall of 2016 under the product name Galliprant®, and capromorelin in February 2017 under the product name Entyce®. In February 2016, it also applied for regulatory approval for Galliprant² in Europe, and the application is currently being reviewed by the authorities.

Status of the licensed programs (animal drugs)

	Program	Compound code	Main indication	Licensee	Agreement region	Exploratory research to pre-clinical	Clinical trials		Market launched	Remarks
							Search for dosage	Large scale		
Animal drugs	Ghrelin receptor agonist	RQ-00000005	Weight loss, loss of appetite	Aratana Therapeutics,	Global			Completed	February 2017	Completed end of 2015, approval obtained in May 2016. Scheduled for market launch in February 2017
	EP4 antagonist	RQ-00000007	Osteoarthritis	Aratana Therapeutics,	Global (excluding injection type in Japan and East Asia)			Completed	Fall of 2016	Began large-scale clinical trials in May 2014. Submitted NADA to FDA in January 2015 and obtained approval in March 2016. Scheduled for market launch in fall of 2016.

Source: Prepared by FISCO from Company materials, interviews, etc.

In addition, it should be noted that Aratana has made significant progress with Galliprant®. In April of this year, Aratana announced that it had concluded a global strategic partnership agreement for Galliprant® with Elanco Animal Health (hereafter, Elanco), which is the animal drugs division of Eli Lilly and Company. Through this partnership, Elanco obtained the exclusive global development, manufacturing, and marketing rights to Galliprant® other than in the United States, and the rights for its joint development and marketing with Aratana in the United States. At FISCO, we expect that the addition of Elanco's development capabilities and marketing network will not only accelerate the drug's development, but also expand the potential scale of global sales and maximize the value of Galliprant®. This will in turn result in greater royalty income for the Company.

The impact on the Company's income has been milestone income from the two drugs on the application for regulatory approval, and thereafter, another milestone income is expected upon market launch. Royalty income will also be subsequently received in proportion to sales.

In terms of the annual sales of these animal drugs (U.S. sales only), Aratana itself expects them to be in the range of ¥2.5bn to ¥8bn when converted into Japanese yen, and annual sales of ¥5bn would seem to be realistic targets for both Galliprant® and Entyce®. While Aratana has the global marketing rights for these two drugs, at the present time it would seem to be aiming just for market launches in Europe in addition to the United States. In the future, should sales in Europe get on track, the annual sales of these 2 drugs in this region could each be around ¥5bn, and their total combined sales could reach a scale of ¥20bn. Moreover, globally there are few drugs such as Entyce® that are indicated for loss of appetite in animals, and among veterinarians in Japan, there are even some who would use it from personal imports. So not only the sales after the market launch, but also its reputation among the vets and pet owners who actually use it will be the focus of much attention.

■ Status of joint research and industry-academia collaborations

Strengths are its compound library and ion channel drug discovery technologies

(1) Joint research with other companies

The Company's strengths are its extensive compound library and ion channel drug discovery technologies, which are very appealing to major pharmaceutical companies. The objective of joint research is to search for compounds that will become pharmaceutical candidates, and it takes place in the initial stage within pharmaceutical R&D as a whole. But as the joint research agreements describe the milestone income to be paid at each development stage and the royalty income to be paid after the compound's market launch as a new drug, if a promising compound is discovered from the results of the search, it can be expected to contribute to the Company's income.

Status of joint research with other companies

Name of joint research partner	Target	Compound	Indication	Details of agreement	Date agreement was concluded
Ajinomoto Pharmaceutical (currently, EA Pharma)	Ion channels	Being identified	Gastrointestinal	Joint research in the gastrointestinal field targeting a specific ion channel	October 2012
Interprotein	Interaction between specific proteins	Being identified	Pain	Joint research in the pain field targeting interaction between specific proteins	February 2013
XuanZhu Pharma Co., Ltd	Ion channels	Being identified	Pain	Joint research in the pain field targeting a specific ion channel	December 2015
Asahi Kasei Pharma	Ion channels	Being identified	Pain	Joint research in the pain field targeting a specific ion channel	January 2016

Source: Prepared by FISCO from Company materials

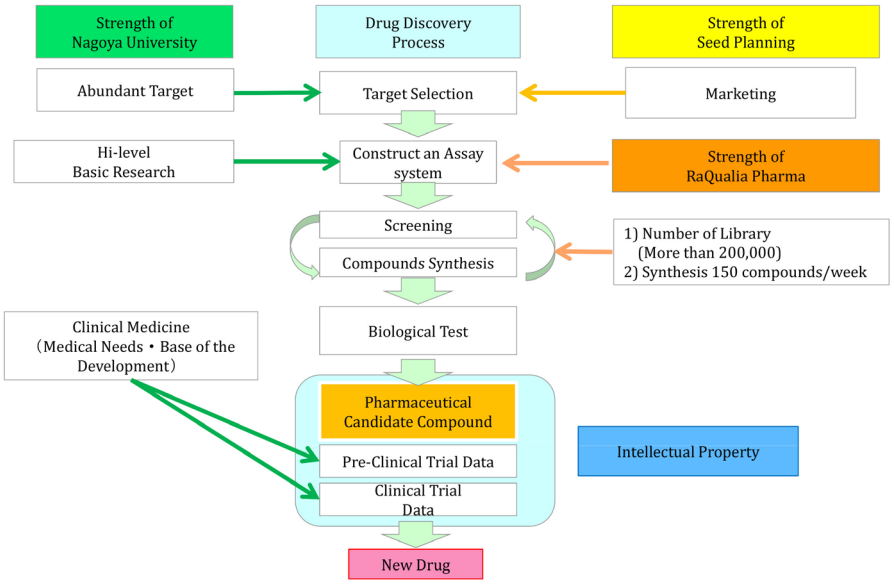
Currently, the Company has concluded joint research agreements with EA Pharma Co., Ltd. (named Ajinomoto Pharmaceuticals Co., Ltd. at the time the agreement was concluded), Interprotein Corporation, Asahi Kasei Pharma Co. Ltd., and XuanZhu Pharma Co., Ltd. of China. Other than with Interprotein, the targets of all of this joint research is the Company's specialist field of ion channels. This is its third agreement with Asahi Kasei Pharma, and both of the previous two agreements achieved certain goals and were completed on the payment of milestone income.

(2) Industry-academia collaborations

In the last few years, the Company has focused on industry-academia collaborations. In particular, it has been deepening its cooperation with the local Nagoya University. In April 2014, the Company established a division of analytical study on pharmacological efficacy within the University's Research Institute of Environmental Medicine as a forum for industry-academia study. Then in April 2015, they established academic-industrial research collaboration courses on "the science of medicine and analytical chemistry" and "Chemical advances and the creation of new medicines." In August of the same year, the Company transferred its scientific research department to the University's Higashiyama campus. In terms of the result of this series of academia-industrial research collaborations with Nagoya University, the Company plans to generate income from licensing-out compounds to domestic and overseas pharmaceutical companies and bio-venture companies.

The Company summarized the above-described initiatives into the business theme of "Discover innovative drug candidates from the seeds of academia with the aim of monetizing them through licensing-out." It applied for the the new business partnership between different fields by Chubu Bureau of Economy, Trade and Industry (METI), and in July 2015, it was certified for the first program in 2015 for the Chubu region." Through this certification, the Company can receive subsidies and also various kinds of support from government institutions, including low-interest loans and special provisions for credit guarantees. For this initiative, it is collaborating with Seed Planning, Inc., that will be responsible for researching market potential and conducting marketing, which is expected to increase the business possibilities.

New drug discovery through the industry-academia collaboration with Nagoya University



Source: Reproduced from the Company's briefing materials

At FISCO, we think the Company's industry-academia collaborations can be expected to produce results not only in terms of drug discovery, but also in terms of generating various synergy effects. Toward achieving the main objective of drug discovery, through establishing the three previously described institutions within Nagoya University (the division of analytical study on pharmacological efficacy, the drug science and analytical chemistry course, and the new drug frontier chemistry course), the Company is able to utilize Nagoya University's strengths, which are its abundance of targets and its high-level basic research capabilities. In the event that a company progresses development through joint research with a university and the discovered compound grows to be an intellectual property license product, the attribution of rights can be determined flexibly between the university and the company. Further, as it has been determined that intellectual property created by researchers employed at the expense of a company can be attributed to that company, it can also continue to conduct research independently in-house. On the other hand, in conjunction with the establishment of these three facilities, the Company has transferred the base of activities for its researchers to Nagoya University, which has greatly reduced facilities costs within its operating costs. In addition, participating in university-sponsored corporate research seminars and briefings held jointly with companies, and also internships programs and other such programs, can be expected to have positive effects in the future for the recruitment and training of talented young researchers. In such ways, it seems that the Company receives many and various benefits from its collaboration with Nagoya University, and at FISCO we think it will be worth keeping a close watch on the progress it makes in its industry-academia collaborations.

(3) Collaboration with AskAt Inc. as a business partner

The Company and AskAt Inc. are business partners, and they have concluded an agreement in which the Company transfers intellectual property to AskAt, and in return it will receive royalties as a fixed percentage of sales in the future.

In terms of the intellectual property transferred to AskAt as of August 2016, the EP4 antagonist (RQ-8/AAT-008) in the pain field is at the pre-clinical stage, while the EP4 antagonist (RQ-7/AAT-007) and the COX-2 inhibitor (RQ-00317076/AAT-076) are at the phase II clinical trials stage. In addition, the 5-HT_4 partial agonist (RQ-9/AAT-009), which is to be indicated for conditions of the central nervous system, has completed phase I clinical trials. Each of these programs seems to be progressing steadily and so in the future we will be paying attention to their further development and licensing-out.

■ Results outlook

Announcement of the Odyssey 2018 mid-term business plan

(1) Overall results outlook

On February 24, 2016, the Company announced Odyssey 2018, its mid-term business plan, which in addition to its FY12/16 results forecast, includes its results targets up to FY12/18. Subsequently on May 18, 2016, it announced revisions to some of its FY12/16 results forecasts.

For FY12/16, the Company is forecasting operating revenue (net sales) of ¥950mn (up 552.9% year-on-year (YOY)), an operating loss of ¥819mn, an ordinary loss of ¥823mn, and a net loss of ¥832mn. Also for FY12/18, which is the final fiscal year of the mid-term business plan, it is targeting operating revenue of ¥1,200mn, an operating loss of ¥128mn, an ordinary loss of ¥130mn, and a net loss of ¥136mn.

FY12/16 results forecast and the results targets in the mid-term business plan

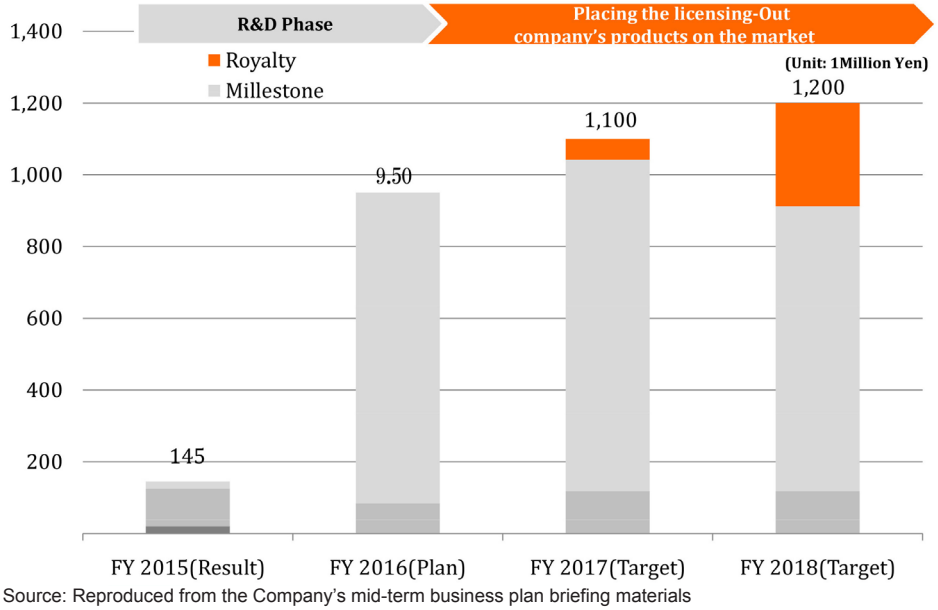
(unit: ¥mn)

	FY12/15	FY12/16		FY12/17	FY12/18
	Result	1H	Full fiscal year forecast	Target	Target
Operating revenue	145	617	950	1,100	1,200
Operating costs	2,010	790	1,769	1,703	1,328
Operating income	-1,864	-173	-819	-603	-128
Ordinary income	-1,795	-235	-823	-604	-130
Net income	-1,854	-241	-832	-610	-136

Source: Prepared by FISCO from the Company's mid-term business plan briefing materials, etc.

The Company has announced the breakdown of the operating revenue target described above. We consider the following three points to be important: 1) lump-sum payments income are not incorporated into the targets; 2) the recording of royalty income following the market launch of products by licensees are included in the targets; 3) milestone income, which will constitute the core part of operating revenue in the coming three years, is limited to compounds that it has already licensed-out in the past. On considering these three points as a whole, at FISCO we evaluate the targets in the business plan as conservative and think that it is fully possible that the Company will achieve them.

Breakdown of the operating revenue target



Source: Reproduced from the Company's mid-term business plan briefing materials

Although lump-sum payments income has not been incorporated into the targets, it is highly likely that the Company will obtain this income. Its policy is to focus even more on licensing-out its main compounds (including tegoprazan, RQ-10, Dalbavancin, and the 5-HT_{2B} antagonist). The reason why it did not include lump-sum payments income in the targets in its current mid-term business plan is thought to be because it reflected on its experiences of the last few years (of not recording this income as expected). But above all, at FISCO we think that even if it does not rely on this income, it is very probable that it will achieve the profit-loss breakeven point solely from other (milestone and royalty) income that it is highly likely to obtain. The lump-sum payments income that may be generated in the future will act as an upside factor for revenue to exceed the target.

(2) Details of operating revenue

At FISCO, we think that the Company configured the breakdown of operating revenue (sales) in the mid-term business plan based on the following schedule of events.

List of events generating operating revenue (FY12/16 result and forecasts)

	Time period	Event	Type of revenue
Result	January 2016	Aratana applied for regulatory approval of the EP4 antagonist (RQ-7, product name, Galliprant®) in the United States (⇒ received approval in March 2016)	Milestone
	February 2016	Aratana applied for regulatory approval of the EP4 antagonist in Europe	Milestone
	March 2016	Concluded a joint research agreement with Asahi Kasei Pharma	Research-collaboration income
	March 2016	Aratana received approval for the EP4 antagonist in the United States	
	March 2016	Aratana applied for regulatory approval of the ghrelin receptor agonist (RQ-5, product name, Entyce®) in the United States (⇒ received approval in May 2016)	Milestone
Scheduled	Fall of 2016	Aratana is scheduled to launch Galliprant®	Milestone, royalty
	February 2017	Aratana is scheduled to launch Entyce®	Milestone, royalty
	2017	CJ Healthcare is scheduled to apply for new-drug regulatory approval for P-CAB (RQ-4 / tegoprazan) in South Korea	Milestone
	End of 2018	CJ Healthcare is scheduled to launch P-CAB (RQ-4 / tegoprazan) in South Korea	Milestone, royalty
	Spring of 2019	Meiji Seika Pharma is scheduled to apply for new-drug regulatory approval for Ziprasidone in Japan	Milestone

Source: Prepared by FISCO from the Company's briefing materials, interviews, etc.

In FY12/16, up to Q2 the Company had already received milestone income from Aratana of the United States following its application for new-drug regulatory approval for two animal drugs. It has not published the exact amount, but it is considered that a fairly large portion of its Q2 operating revenue of ¥617mn was milestone income from Aratana. In 2H also, Aratana is scheduled to market launch Galliprant® in the fall of 2016, so the Company is expected to receive milestone income at this time. From this milestone income from Aratana and the research-collaboration income from Asahi Kasei Pharma, at FISCO we think it is extremely likely that it will achieve its operating revenue forecast for the current full fiscal year.

For FY12/17, the Company is targeting operating revenue of ¥1,100mn, of which, approximately ¥700mn will be milestone income. In terms of the specific breakdown of this milestone income, it is thought that it will mainly take the form of payments from Aratana following the launch of Entyce® and from CJ Healthcare on its application for regulatory approval of P-CAB as a new drug. The royalty income will be from the two animal drugs market launched by Aratana. At FISCO, we think the Company has set cautious targets because the market launches in Europe are lagging behind those in the United States and also it is difficult to forecast sales of animal drugs. Aratana has indicated that it expects annual sales from each of the animal drugs of around ¥5bn for both the United States and European markets. Therefore, it is possible that at their peak periods, the total size of the market for the two drugs will be ¥20bn.

For FY12/18, the main milestone income is expected to be from Meiji Seika Pharma's application for regulatory approval for Ziprasidone as a new drug. Ziprasidone is a pharmaceutical that is already on the market in Europe and the United States, so it is considered that there is little possibility of it being dropped (the development cancelled) only in Japan, where it is currently undergoing phase III clinical trials. Royalty income is forecast to rapidly expand in the range of 400% YOY from the income from Aratana's animal drugs, following the acceleration in sales growth in conjunction with the greater awareness of these products.

Breakdown of operating revenue from FY12/16 to FY12/18
(the amounts in the breakdown are estimates by FISCO)

Operating revenue items	2016 forecast		2017 forecast		2018 forecast	
	Amount	Details	Amount	Details	Amount	Details
Lump-sum payments	0		0		0	
Milestone income	880	Aratana's application for regulatory approval of two animal drugs and market launch of one drug	900	Aratana's market launch of one animal drug and CJ's application for regulatory approval of tegoprazan	800	CJ's market launch of tegoprazan
Royalty	0		70	Aratana's two animal drugs	270	Aratana's two animal drugs
Research-collaboration income	70	Asahi Kasei Pharma	130		130	
Total	950		1,100		1,200	

Source: Prepared by FISCO from Company materials, interviews, etc.

(3) Breakdown of operating costs

On the other hand, operating costs in the FY12/15 results were ¥2,010mn, and the Company is aiming to reduce this to ¥1,328mn in FY12/18. The breakdown of the main cost items is as follows.

a) Labor costs
In FY12/15, the Company solicited voluntary retirement from employees and implemented a review to reduce employee salaries in January 2016. This has greatly reduced personnel costs in FY12/16, and going forward it is expected to maintain these costs at this level.

b) R&D costs
In FY12/16 and FY12/17, the Company is expected to record R&D costs of close to ¥500mn from the phase I clinical trials of the 5-HT_{2B} antagonist (RQ-00310941) in the United Kingdom and in the exploratory field for its industry-academia joint research. However, in FY12/18, the 5-HT_{2B} antagonist phase I clinical trials will be completed and the Company plans to greatly reduce these costs.

c) Payments of royalties
Within the milestone income and royalty income that the Company receives, it is contracted to pay part of it to Pfizer, which can be seen to be spot costs commensurate to income. The payment of royalties for milestone income will increase slightly in FY12/16 and FY12/17, but as only royalty income is expected to be recorded in FY12/18, it is thought that this payment amount will fall considerably.

Breakdown of operating costs

(unit: ¥mn)

	FY12/15 result	FY12/16 forecast	FY12/17 target	FY12/18 target
Labor costs	766	568	551	552
R&D costs	577	435	492	265
Royalty payments	0	195	133	38
Administrative costs	280	264	207	206
Facilities costs	189	162	164	161
Other costs	198	145	156	106
Total operating costs	2,010	1,769	1,703	1,328

Source: Prepared by FISCO from the Company's mid-term business plan briefing materials

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Simplified balance sheet

(unit: ¥mn)

	FY12/12	FY12/13	FY12/14	FY12/15	FY12/16 Q2
Current assets	5,089	4,363	3,261	2,707	2,470
Cash and deposits	4,889	4,035	1,891	1,840	1,143
Accounts receivable-trade	9	59	20	72	514
Inventory	47	47	8	7	8
Non-current assets	411	2,284	1,940	2,044	2,110
Tangible non-current assets	101	7	85	261	238
Intangible non-current assets	20	11	12	14	13
Investments and other assets	288	2,265	1,843	1,768	1,858
Assets, total	5,501	6,648	5,202	4,752	4,581
Current liabilities	183	232	261	200	404
Account payable-other	90	141	118	123	234
Non-current liabilities	7	669	108	37	27
Shareholder's equity	5,298	4,466	4,621	4,475	4,233
Capital stock	8,489	8,627	8,952	9,806	2,237
Capital surplus	3,773	3,911	4,236	5,090	2,237
Retained earnings	-6,965	-8,073	-8,566	-10,421	-241
Subscription rights to shares	-	33	10	11	12
Total net assets	5,310	5,746	4,831	4,514	4,149
Total liabilities and net assets	5,501	6,648	5,202	4,752	4,581

Note: FY12/13 and FY12/14 only are consolidated results. The results for all other fiscal years are non-consolidated.
Source: Prepared by FISCO from the Company's financial results summary

Statement of cash flow

(unit: ¥mn)

	FY12/12	FY12/13	FY12/14	FY12/15	FY12/16 Q2
Net cash provided by (used in) operating activities	-2,728	-2,179	-2,081	-2,116	-671
Net cash provided by (used in) investing activities	3,741	951	-796	665	-163
Net cash provided by (used in) financing activities	-	309	761	1,701	0
Effects of exchange rate change on cash and cash equivalents	4	63	84	0	-62
Net increase (decrease) in cash and cash equivalents	1,012	-854	-2,030	251	-897
Cash and cash equivalents at beginning of period	3,877	4,889	4,035	1,991	2,243
Cash and cash equivalents at end of period	4,889	4,035	2,004	2,243	1,345

Note: FY12/13 and FY12/14 only are consolidated results. The results for all other fiscal years are non-consolidated.
Source: Prepared by FISCO from the Company's financial results summary

■ Fund raising

Will its proactive IR activities have positive effects on its fund raising?

For the Company, which is still only on the way to stably securing revenue, raising the funds necessary for its operations is an important issue. Its basic policy is to maintain ¥3.5bn at the end of each fiscal year as the balance of funds for operations. In the FY12/15 results, it raised funds of around ¥1.7bn during the fiscal year, and its balance of cash and cash equivalents and of highly liquid investment securities at the end of the period was approximately ¥4.3bn.

As previously described, the Company's target in the mid-term business plan is for the operating loss to be reduced to ¥128mn in FY12/18, at which time profitability will be in sight. But it should be noted that it is highly likely that it will raise funds again during the plan's three years.

In terms of its specific method of raising funds in the future, the Company is considering selling the shares it holds in Aratana (it holds 103,088 shares, and the closing price on July 23 was U.S.$6.52). But it seems that the core of its fund raising will be funding from external parties, such as capital increases from third-party allocation of shares and public offerings, and from project financing.

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At FISCO, we consider it highly likely that the Company will carry out fund raising. But as previously described, the prospect for it stably obtaining revenue, including royalty income, is now in sight, and so it may be that the Company is changing its former stance on fund raising. Although from the past the Company has set improving shareholder value as an important management target, the reality is that shareholder value has been impaired as it has been diluted by the fund raising. But going forward, the Company will be able to raise funds in the form of them being backed by the income that it is highly likely to acquire, of royalty income and milestone income from already licensed-out programs, and it can be expected to do everything it can to avoid any adverse impact on shareholder value. We also think that the option of project financing is precisely as a consequence of the Company being aware of this point.

The Company is currently proactively conducting IR activities both domestically and overseas. Domestically, it regularly holds dialogues with both institutional and individual investors, while overseas, in June of this year it visited institutional investors in Singapore and in September it plans to visit institutional investors in the United States and Hong Kong. Its aim is to increase awareness of the fact that it has established a path to stably generating revenue in its current mid-term business plan, and these steady IR activities can be expected to have a positive effect on the Company's fund raising.

■ Company outline

Its predecessor was the central research laboratory of the global pharmaceutical major Pfizer's Japanese subsidiary

(1) History

The predecessor to the Company was the central research laboratory of the Japanese subsidiary of the global pharmaceutical major Pfizer, Inc., of the United States. This research laboratory served as Pfizer's exploratory research base and carried out drug discovery research, mainly in the areas of pain and gastrointestinal disease. However, in 2007 the decision was taken to close it. Following this decision, the head of the laboratory at that time and some of its employees decided to conduct an employee buyout (EBO) and to continue as an independent drug discovery business, which resulted in the foundation of the Company. It listed on the Osaka Securities Exchange JASDAQ Growth Market in July 2011.

(2) Business model

The Company is a research and development-type drug discovery company and it has a different business model than conventional pharmaceutical companies, as it specializes only on R&D and does not have its own MR and plants. In its business model, it generates revenue by licensing-out the novel candidate compounds (licenses for technologies and patents) it discovers to the pharmaceutical companies that will be responsible for commercializing and selling them.

Normally, drug research and development goes through three major stages; exploratory research to find candidate compounds, pre-clinical development to confirm its safety and efficacy in animal testing, and clinical development to assess its safety and efficacy in humans. After the developer applies for its regulatory approval as a new drug, the regulatory authorities approve it to be launched on the market. In addition, the clinical research is divided into three phrases; phase I, II and III. The Company's business area is from the exploratory research stage to phase II of clinical development.

The Company's business area

Source: Reproduced from the Company's homepage

In terms of its specific sources of income, the Company has four types: "lump-sum payments," which it receives upon licensing-out pharmaceutical candidate compounds to pharmaceutical manufacturers; "milestone income," which it receives for each milestone reached in the progress made in the clinical research after the licensing-out; "royalty income," which it receives as a certain percentage of sales following the market launch of a compound as a new drug; and "research-collaboration income," which it receives from its joint-research partners. Royalty income can be positioned as the most stable of these four types, with the royalty rate being determined by each individual agreement (generally in the pharmaceutical industry, the rate is from 7% to 10%).

(3) Characteristics and strengths

The Company has two main strengths. The first is its technologies for ion channels drug discovery. While ion channels drug discovery is very difficult and the barriers to entry are high, it is new and next-generation drug-discovery technologies and there are expectations for this area from the drug efficacy and market potential of its products. Its second strength is that it has a complete infrastructure for drug discovery with a library of about 380,000 compounds and expertise in screening robots and analysis.

Ion channels drug discovery signifies a new generation of drugs. Ion channels have selectivity as each ion channel limits the substances that pass through. They are known as the potassium channel or the sodium channel. Utilizing this characteristic of selectivity makes possible new drugs that use a different approach to that of current therapies, such as drugs that act strongly on a specific location or disease. In terms of the indicated treatment areas for these drugs, effective new drugs are expected for pain and for circulatory organs, and gastrointestinal conditions. But on the other hand, there remain a number of issues to be resolved, such as the question of how to separate the side effects, and there also remain many challenges in terms of the drug discovery process itself. For these reasons, it is not easy to enter this field.

While there are various hurdles that the Company must clear for its ion channels drug discovery, it also possesses solutions to these problems, such as an extensive library of compounds, utilization of screening robots to increase their efficacy, the joint research with universities, government research institutes and major pharmaceutical companies, and its own expertise in refining and analysis. These factors serve as its competitive advantages over other companies in the same business.

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Problems for ion channels drug discovery and RaQualia Pharma's competitive advantages

Issues related to the Ion Channel Drug Development	Our Superiority
Many matters unsolved Because it is a relatively new area of study, there are many unsolved matters such as physiology and involvement in clinical conditions	**Implementation of collaborative studies with universities, public Research organizations, pharmaceutical companies, etc.**
Limitations of existing methods Because the natural ligand does not exist, natural biologically active substances will not be a clue	**Abundant compound library and establishment of the automated compound refining and analyzing system**
Difficult to explore As the existing HTS method can only do the indirect observation, cumbersome measurement systems to measure living cells are essential	**A collaborative development of an ion channel activity measuring instrument with Hamamatsu Photonics K.K.**

Note: Ligands are materials that differentially bind to specific receptors

Source: Prepared by FISCO from Company materials

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