COMPANY RESEARCH AND ANALYSIS REPORT

RaQualia Pharma Inc.

4579

TSE JASDAQ Growth

26-Apr-2017

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Summary

Looking to record an operating profit in FY12/19 from the steady progress made in market launches of animal drugs and clinical development

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.

1. The FY12/16 results confirmed the potential contribution to earnings of animal drugs in terms of content

The FY12/16 results did not achieve their initial forecasts, but the main reason for this was that in the United States, the market launch of an animal drug was postponed from the fall of 2016 to January 2017, and therefore no milestone payment could be recorded. This animal drug was launched in January 2017 and royalty payments can be expected from it in the future. At FISCO, we think that the most important message to be taken from the FY12/16 results is that the likelihood that animal drugs will make an important contribution to the Company's earnings in the future has risen even higher.

2. In human drugs, is making steady progress in clinical development and two drugs are expected to be market launched in 2019 and 2020

Overall, steady progress continues to be made in the clinical development of the compounds in the licensed-out programs. In the development of P-CAB for gastroesophageal reflux disease being undertaken by CJ Healthcare Corporation of South Korea, the phase III clinical trial will be completed in 2017 and it is expected to be market launched in 2019. The development of Ziprasidone for schizophrenia being advanced by Meiji Seika Pharma Co., Ltd, is also progressing as scheduled, which is for the phase III clinical trial to be completed in 2018, the application for regulatory approval to be made in 2019, and the market launch in 2020.

3. Made a wholly-owned subsidiary of TMRC, a drug discovery venture specializing in the cancer area

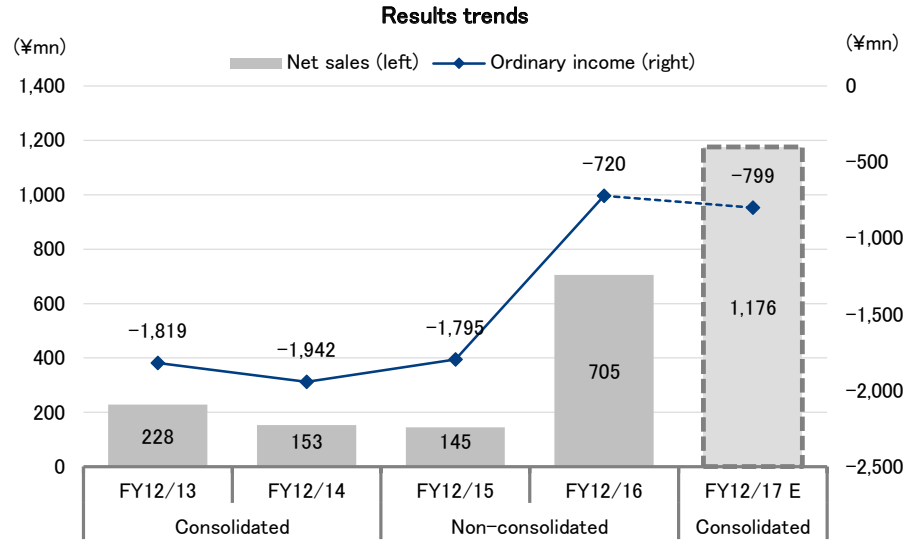
The Company made a wholly owned subsidiary of TMRC Co., Ltd., on February 3, 2017, for objectives that included to establish a system for the horizontal expansion of the development area and to acquire the results of collaborative research with academia. TM-411, which TMRC has licensed-out to U.S. Syros Pharmaceuticals, Inc. (hereafter, Syros) is currently in phase II trials as an indication for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). What is extremely interesting is that Syros is aiming for new drug approval for TM-411 as a precision medicine (personalized medicine) for AML and MDS. Precision medicine is a field that is attracting a lot of attention as a new medical concept that results in improved treatment efficacy.

4. Has clearly indicated that it is targeting an operating profit in FY12/19

The Company has announced the rolling results targets up to FY12/19 in Odyssey 2018, its mid-term business plan, and it is targeting an operating profit in FY12/19. This target can be read as indicating the Company's increased confidence that it will stably acquire earnings in the future from the current situation, of the market launches of animal drugs and the steady progress being made in the development of human drugs. The results targets in the current mid-term business plan were formulated based on business revenue from the licensed-out programs, including royalty payments and milestone payments, so at FISCO we think that the likelihood it will achieve its targets is high.

Key Points

- Outlook is for two animal drugs to be market launched in 2017 and for two human drugs to be launched in 2019 and 2020
- Made a subsidiary of TMRC, from which differentiation can be expected in the precision medicine area
- Expects to record an operating profit in FY12/19



Source: Prepared by FISCO from the Company's financial results

Company profile

Became independent from the research laboratory of Pfizer's Japanese subsidiary Business model specializing in R&D for new drugs

1. History and business model

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, 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.

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 in 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 manufacturing 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 development is divided into three phases; phase I, II, and III. The Company's business area is from the exploratory research stage to phase II of clinical development.

While the Company's business area is up to phase II, its earnings structure is fundamentally to acquire earnings after licensing-out. In other words, while the period up to phase II is the Company's business area, it is only after a compound is licensed-out to a pharmaceutical company that its business activities become monetized. The compounds that the Company licenses-out as drug candidates are then further clinically developed by the licensee company, and finally are marked launched as a new drug. Up to this final point, the Company itself continues activities for the drug candidate through teamwork with the licensee company. So while the Company sets its business area as "producing" the compounds that will become drug candidates, another important part of the Company's business is supporting the "nurturing" of the drug candidate by the licensee company.

The Company's business scope

Source: Prepared by FISCO from Company website

The Company has four specific sources of income. These are "upfront payments," which it receives upon licensing-out pharmaceutical candidate compounds to pharmaceutical manufacturers; "milestone payments," which it receives for each milestone reached in the progress made in the clinical research after the licensing-out; "royalty payments," which it receives as a certain percentage of sales following the market launch of a compound as a new drug; and "research cooperation revenue," which it receives from its joint-research partners. Royalty payments 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%).

RaQualia's revenue items

Upfront payments	Revenue received from licensing IP rights for development compounds to the pharmaceutical companies
Milestone payments	Revenue received when each agreed milestone event is achieved
Royalty payments	Revenue received at a set percentage of sales after the product is launched on the market
Research cooperation revenue	Revenue received as consideration for providing RaQualia's research results at the beginning of joint research, based on the terms of the joint research, and revenue received as consideration for services provided during the joint research.

Source: Prepared by FISCO from the Company's website

Strengths are its ion channel drug discovery technologies and its drug discovery infrastructure that is top-class among domestic bio-ventures

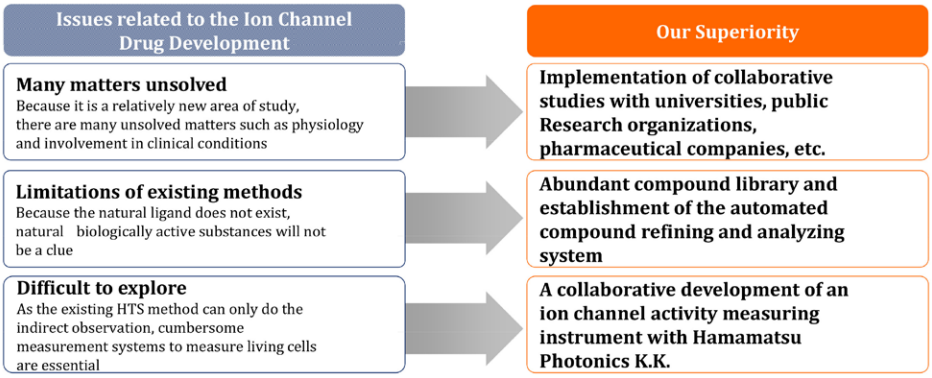
2. Advantages and strengths

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 entails 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, screening robots, and expertise in 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, the 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.

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



*Ligands are materials that differentially bind to specific receptors
Source: Prepared by FISCO from the Company materials

Results trends

Forecasts were downwardly revised due to the postponement of the market launch of a new animal drug. But results exceeded the revised forecasts from an unscheduled milestone payment.

1. Summary of the FY12/16 results in the Company's FY12/16 results, business revenue (net sales) was ¥705mn (up 384.7% year on year (YoY)), the operating loss was ¥759mn (loss of ¥1,864mn in the previous fiscal year), the ordinary loss was ¥720mn (loss of ¥1,795mn), and the net loss was ¥728mn (loss of ¥1,854mn).

Summary of the FY12/16 results

(¥mn)

	FY12/15	FY12/16		
	Results	Full year initial forecast	Full year revised forecast	Full year results
Business revenue	145	950	660	705
Operating expenses	2,010	1,769	1,505	1,465
Operating income	-1,864	-819	-845	-759
Ordinary income	-1,795	-819	-910	-720
Profit	-1,854	-825	-917	-728

Source: Prepared by FISCO from the Company's financial results

In November 2016, the Company announced downwardly revised results forecasts based on a change to the market-launch date of Galliprant®, which is an EP4 antagonist that it licensed-out to Aratana Therapeutics Inc. (hereafter, Aratana), one of its licensee companies. Business revenue was downwardly revised from the initial forecast of ¥950mn to ¥660mn, and the operating loss forecast was changed from ¥819mn to ¥845mn. In the FY12/16 results, both business revenue and the operating loss were slightly better than these revised forecasts due to the recording of a milestone payment for Entyce®, which is another drug that the Company licenses-out to Aratana (further details below).

The part that the business revenue exceeded the forecast and the improvement in the extent of the operating loss (and also in the income items below it) was because the scheduled completion of a clinical trial was pushed back from FY12/16 to FY12/17. Therefore, one part of the clinical trial expenses were carried forward to the next fiscal period, and as a result, the FY12/16 operating expenses were reduced more than expected and the extent of the improvement in the operating loss grew.

The animal drug Galliprant® was market launched in January 2017 Start of trials of Entyce® for cats

2. Details of business revenue

The initial forecasts assumed that Galliprant® would be market launched (for dogs in the U.S. market) in the fall of 2016. But as explained above, the market-launch date was postponed until January 2017, and therefore the milestone payment that would have be paid on its launch and that was incorporated into the FY12/16 results forecasts was not recorded. This lead to the forecasts being downwardly revised during the period.

Meanwhile, in December 2016, Aratana began long-term toxicity tests toward expanding the indication of Entyce® to cats. The Company recorded a milestone payment for this in FY12/16, but in the initial forecast and the November revised forecasts, it was assumed that this milestone payment would be recorded in 2017, so this also became a factor pushing-up the results above the Company's revised forecasts.

List of events and scheduled events generating business revenue

	Time period	Event	Type of revenue
FY12/16	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 for the EP4 antagonist in Europe	Milestone
	March 2016	Concluded a joint research agreement with Asahi Kasei Pharma	Research cooperation revenue
	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	Milestone
	May 2016	Aratana received approval for Entyce® in the United States	
	December 2016	Aratana started long-term toxicity tests toward the indication of Entyce® for cats	Milestone
FY12/17 onward	January 2017	Aratana launched Galliprant® for dogs in the United States	Milestone, royalty
	2017	CJ Healthcare is scheduled to apply for new-drug regulatory approval for P-CAB (RQ-4 / tegoprazan) in South Korea	Milestone
	Second half of 2017	Aratana is scheduled to launch Entyce® for dogs	Milestone, royalty
	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 materials and interviews

At FISCO, we do not think it is necessary to feel disappointed or concerned about the Company's FY12/16 results. The fact that a licensed-out drug missed its original market-launch date is nothing more than this launch of Galliprant® being postponed by around three months. It was launched as per the revised scheduled in January 2017 and the Company received the milestone payment from this launch, and in the future it will receive royalty payments as a percentage of the net sales of Galliprant®. It goes without saying that what investors should be paying attention to is not the delay in the recording of the milestone payment, but how Galliprant® sells in the future.

The Company is working on Odyssey 2018, the three-year, mid-term business plan formulated and announced in February 2016 for the period FY12/16 to FY12/18. At FISCO, we noted in the previous report (August 30, 2016) that the most important point for Odyssey 2018 is that it has greatly improve the stability of the Company's results.

Although the FY12/16 results did not achieve their initial forecasts, they did not affect at all from the improved stability of the results, which can be described as a feature of Odyssey 2018. Rather, the current situation is that Galliprant® was marked launched in accordance with the revised plan and that the indication of Entyce® for cats is set to occur faster than scheduled. So at FISCO, we think that at the very least the expectations have been further raised for the contributions to earnings in the future of these two animal drugs. Also, as is explained below, the market launches as new drugs of the compounds that are candidates for human drugs are steadily growing closer.

Medium- to long-term growth strategy

Outlook is for two animal drugs to be market launched in 2017 And then two human drugs to be launched in 2019 and 2020

1. Status of the licensed-out program

Up to the present time, the Company has four programs for licensing-out human drugs and has already licensed-out two programs for animal drugs. The licensed-out programs generate most of the Company's business revenue. On entering-into a licensing-out agreement, it receives an upfront payment and then milestone payments from the licensee pharmaceutical company on the occasion of the various milestones. These are when certain progress is made in the clinical development, the application for regulatory approval for manufacturing and sales, and the market launch. These two payments have been the Company's sources of revenue up to the present time, but the outlook is that it will start recording royalty payments from market launches, which is the ultimate goal of any drug discovery company, from FY12/17 on the market launches of the animal drugs.

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

The Company has licensed-out to 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 developed these products and 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 decided to market launch grapiprant under the product name Galliprant®, and capromorelin under the product name Entyce®.

Aratana has concluded agreements for a strategic partnership for Galliprant® with Elanco Animal Health (hereafter, Elanco), which functions as Eli Lilly and Company's animal drugs division. The details of the agreement are that Elanco has acquired the exclusive rights to develop, manufacture, and sell Galliprant® worldwide other than in the United States, and the right to jointly sell it with Aratana in the United States. At FISCO, we think that this strategic partnership is an extremely positive development for the Company. This is because in addition to Elanco's development capabilities and global sales network, we can expect the drug's development to be accelerated and the sales scale to be maximized. It goes without saying that this will also maximize the royalty payments received by the Company.

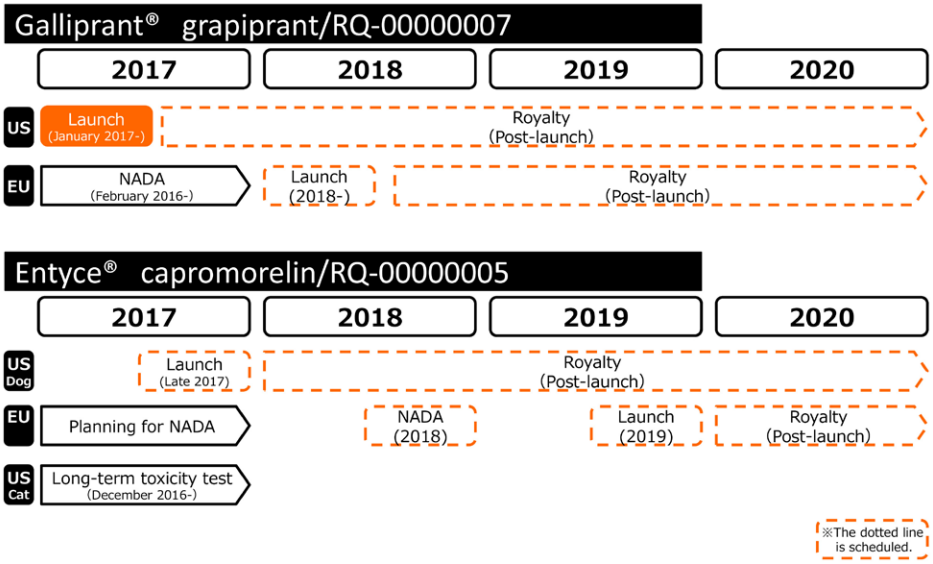
It was initially announced that Galliprant® would be market launched in the fall of 2016, but this was postponed to early in 2017. It was subsequently launched as scheduled in January 2017 in the United States, and the Company received a milestone payment as a result. In the future, it will receive royalty payments as a certain percentage of the net sales of Galliprant® which are expected to be recorded from FY12/17 onwards.

It was initially announced that Entyce® would be market launched in February 2017, but this was subsequently postponed to the second half of 2017. The same as for Galliprant®, the Company will receive a milestone payment on the market launch of Entyce® and then royalty payments after that, although it seems it will substantively contribute to the Company's earnings from FY12/18 onwards.

Medium- to long-term growth strategy

It was decided that both Galliprant® and Entyce® would be launched in the United States market, so a point to pay attention to going forward will be their launches in the European market. The application for regulatory approval for Galliprant® was completed in February 2016, and it is expected to be launched in Europe in 2018. Currently, preparations are underway to apply for regulatory approval for Entyce®, with the application scheduled for 2018 toward its planned market launch in 2019. Aratana also started the scheduled toxicity tests for Entyce® in December 2016 to expand its indication to cats.

Animal drugs' development roadmap



Source: From Company's mid-term business plan materials

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 for each would seem to be realistic. Aratana has the worldwide rights for these two drugs, and at the present time in the United States, it would seem to be targeting expanding their total sales to ¥10bn. Looking toward their market launches in Europe in the future, should sales in Europe get on track, then annual sales from each of these two drugs in each region may reach ¥5bn, for total net sales on a scale of ¥20bn.

Medium- to long-term growth strategy

The features and market potential of Galliprant®

Indication	Osteoarthritis in Companion Animal
Advantage	A first-in-class EP4 antagonist Galliprant® is designed to lower gastrointestinal problems or kidney problems associated with NSAIDs.
Progress	Launched in January 2017(USA, Dog) Application for an animal drug approval has been submitted to EMA
License	Licensed exclusive worldwide rights to Aratana Aratana partner with Elanco Animal Health for commercialization in global markets.

Topix

Jan 2016 Application for an animal drug approval has been submitted to FDA
Feb 2016 Application for an animal drug approval has been submitted to EMA
Mar 2016 Approval (USA)
Apr 2016 Aratana announced strategic partnership with Elanco Animal Health
Jan 2017 Launched (USA)

Launched in January 2017
10 million dogs in the USA are annually treated for OA

Source: From Company's mid-term business plan materials

(2) Potassium-competitive acid blocker / P-CAB (RQ-4, nonproprietary name: tegoprazan)

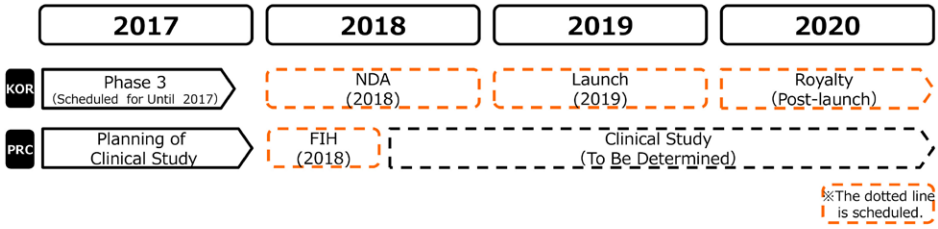
Potassium-Competitive Acid Blocker (abbreviated to P-CAB)/ (RQ-4/tegoprazan) is a next-generation new drug mainly indicated for gastroesophageal reflux disease that is expected to replace the current mainstream treatment of Proton Pump Inhibitors (abbreviated to PPI. Leading examples of PPI are Nexium® from Daiichi Sankyo Company, Limited <4568> 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.

The Company has already licensed out P-CAB (International Nonproprietary Name (INN), tegoprazan) to CJ Healthcare of South Korea for South Korea, Taiwan, China, and the Southeast Asia Region (its licensing-out for other regions, including Japan, has not yet been completed, and in this respect it is a candidate for licensing-out programs). CJ Healthcare is conducting phase III clinical trials in South Korea that it currently expects to complete during 2017.

After that, CJ Healthcare is expected to quickly move to the preparing to apply for regulatory approval as a new drug, but as yet the timing of this application has not been decided. In the case of it narrowing down its indications and prioritizing a speedy market launch, it is considered that it will apply for regulatory approval in 2017 followed by its launch as a new drug in 2018. Conversely, more time would be required in the case that it applies for regulatory approval for a number of indications, which is likely to entail an application for regulatory approval in 2018 followed by its launch as a new drug in 2019. This timing is outside of the Company's control, but as seen from the conservative results targets in its mid-term business plan, it would seem to be assuming the latter case, of an application for regulatory approval in 2018.

In terms of its impact on the Company's income, it will receive milestone payments from the progress made in the development and royalty payments 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. However, at FISCO we expect that not only will it receive various types of revenue from CJ Healthcare, but that in addition, this will lead to the licensing-out of tegoprazan in Japan, Europe, and the United States also.

P-CAB's development roadmap



Licensee	CJ HealthCare Corporation
Indication	Reflux Esophagitis
Progress	Korea(KOR): Phase 3 in on going. First NDA is Scheduled in 2018, Launch is Scheduled in 2019. China(PRC): Planning for Clinical Study.
Reference	Market Size(KOR)※;50billion yen (500billion won) Market Size(PRC)※;260billion yen (2billion 600million USD)

※An in-company investigation

Source: From Company's mid-term business plan materials

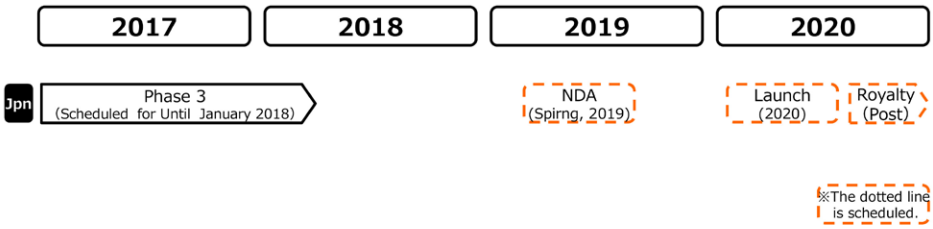
(3) 5-HT2A/D2 antagonist (RQ-3 / Ziprasidone)

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 phase III trials will be completed in January 2018 and 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 receive milestone payments on the application for regulatory approval as a new drug and the market launch. It will also receive royalty payments as a percentage of sales following the market launch. The scale of Japan's market for schizophrenia treatments is estimated to be around ¥160bn. Abilify from Otsuka Pharmaceutical (Otsuka Holdings <4578>) and second generation (atypical) schizophrenia treatments have significant market shares, but a feature of Ziprasidone is that it has less side effects, such as causing weight gain and elevated blood glucose values, while having the same efficacy as the existing second generation schizophrenia treatments. It is expected to be prescribed not only as a single drug, but also in combination with Abilify. Considering factors such as the market scale and the expected directions for usage, it may grow to become a drug with annual sales in excess of ¥10bn.

Medium- to long-term growth strategy

Ziprasidone's development roadmap



Licensee	Meiji Seika Pharma Co., Ltd.
Indication	Schizophrenia, Bipolar disorder
Progress	Phase 3 is on going in Japan. NDA is Scheduled on spring 2019, Launch is Scheduled in 2020.
Reference	The Number of Patients (Jpn) ※1 ;7.13 million, Internal Number of Inpatients; 1.74 million. Market Size (Jpn) ※2 ; 160 Billion Yen

※1 : MHLW investigation in 2011、※2 : An in-company investigation
Source: From Company's mid-term business plan materials

(4) 5-HT4 partial agonist (RQ-10)

RQ-10 is a compound indicated for conditions including gastroparesis, functional GI disorder, and chronic constipation. The Company has licensed it out to CJ Healthcare of South Korea for the South Korea, Taiwan, China, India, and the Southeast Asia markets. However, the current situation is that CJ Healthcare has not started the development of RQ-10, as it is focusing exclusively on the development of tegoprazan.

(5) EP4 antagonist (RQ-7/grapiprant) <new human-use 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. for the rights for a human drug administered as an injection. 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.

Focusing on the trends in the global development of tegoprazan (P-CAB)

2. Status of the candidates for licensing-out programs

As of March 2017, the Company's pipeline contained five programs in the gastrointestinal disease area, two programs in the pain area, and one program for an antibacterial drug. It goes without saying that the potential of a compound will determine whether or not it is licensed-out, but it is also necessary to be aware of other factors that affect this decision, such as the situations at the pharmaceutical manufacturers and the needs of the pharmaceutical market (marketability).

Medium- to long-term growth strategy

List of licensing-out candidates in the programs

	Program	Compound code	Target	Area	Pre-clinical	Clinical studies			Remarks
						P-I	P-II	P-III	
Human drugs	Potassium-competitive acid blocker	RQ-00000004	GERD	Japan, global excluding Asia		Completed			P-I completed in the United States and Japan (FY12/15), granted a new patent in Japan and South Korea
	5-HT4 partial agonist	RQ-00000010	Gastroparesis, functional dyspepsia, functional constipation	Japan, global excluding Asia		Completed			Completed P-I clinical trial in UK. Investigator initiated clinical trial collaboration with Virginia Commonwealth University (VCU) for Parkinson's disease is underway.
	5-HT2B antagonist	RQ-00310941	Gastrointestinal field, IBS	Japan, global		Underway			P-I has been underway in the UK since June 2015. Scheduled to be completed in the second half of 2017.
	Motilin receptor agonist	RQ-00201894	Gastrointestinal disease	Japan, global	Completed				Pre-clinical trial completed. The subsequent P-I is being considered.
	Ghrelin receptor agonist	RQ-00433412	Loss of appetite associated with cancer	Japan, global	Pre-clinical trial is being considered				Investigation of efficacy has been completed, pre-clinical trial is being considered
	TRPM8 blocker	RQ-00434739	Pain field	Japan, global	Pre-clinical trial is being considered				In August 2016, decided to move to the pre-clinical development stage.
	Selective sodium channel blocker	-	Pain field	Japan, global	Discovery				
	Dalbavancin	RQ-00000002	MRSA infection	Japan		Is being considered.			Approved by the U.S. FDA in May 2014, launched in the United States in July 2014, and was approved by the European Commission in March 2015.

Source: Prepared by FISCO from Company materials

The details of the main license-out candidate programs are as follows.

(1) Potassium-competitive acid blocker / P-CAB (RQ-4, nonproprietary name: tegoprazan)

As previously explained, tegoprazan has been licensed-out to CJ Healthcare of South Korea for South Korea, Taiwan, China and the Southeast Asia region, and the Company's aim is to license it out in the global market, of Japan and the other regions not covered by the agreement with CJ Healthcare.

The Company completed phase I clinical trials of tegoprazan in Japan in August 2015. During the same period, CJ Healthcare commenced phase III trials in South Korea, and the Company has been searching for possibilities for global development while watching how these trials develop. As previously mentioned, CJ Healthcare's phase III trials are expected to be completed in the first half of 2017, and at FISCO, we expect that this will become a demand driver and activate the licensing-out activities.

Also, the Company was granted patent rights on May 25, 2016, for tegoprazan, a gastrointestinal function regulating agent and gastrointestinal motility activating agent that improves symptoms of GERD, functional indigestion, abdominal bloating, discomfort and constipation due to gastrointestinal motility abnormalities by phase III contractions in interdigestive migrating contractions (IMC). This patent covers all P-CAB in Japan. To explain this more simply, with regard 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 aim of licensing-out of tegoprazan domestically.

Development status for the P-CAB

March 2013	Granted substance patent in the United States
October 2013	Granted usage patent in the United States
June 2014	The Company started phase I clinical trials in Japan
December 2014	Granted usage patent in Japan
June 2015	Granted new usage 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
May 2016	Granted usage patent in Japan

Source: Prepared by FISCO from the Company's results briefing materials

PPI are currently the mainstream drugs indicated for gastroesophageal reflux disease and the market scale worldwide is said to be ¥2 trillion. P-CAB is a next generation new drug expected to replace PPI. As mentioned above, among P-CAB, the Company's tegoprazan is positioned next in line after Takeda's TAKECAB® (INN, Vonoprazan) which is the top-runner that has already been launched. Currently in the domestic market, Takeda's PPI Takepron®, Daiichi Sankyo's Nexium®, and Eisai's <4523> Pariet® are each recording major sales. However, TAKECAB® has also achieved steady growth since its launch, and it was announced that its cumulative net sales up to FY16 3Q were ¥24.7bn, and further growth is expected in the future.

Sales of the main PPI and P-CAB in the domestic market

Company	Drug type	Product name	Sales (¥100mn)		
			FY2013	FY2014	FY2015
Takeda	PPI	Takepron	676	525	413
	P-CAB	TAKECAB	-	32	84
Daiichi Sankyo	PPI	Nexium	542	693	824
Eisai	PPI	Pariet	473	371	304

Source: Prepared by FISCO from each company materials

(2) 5-HT4 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-HT4) 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>.

Targeting the markets of South Korea, Taiwan, China, India and East Asia, it has been licensed-out to CJ Healthcare of South Korea, but the situation is that its development at CJ Healthcare has been temporarily stopped. The Company is aiming to license it out in global markets, of Japan and regions other than those covered by the agreement with CJ Healthcare.

The Company completed phase I clinical trials in May 2013 in the United Kingdom, in which RQ-10 demonstrated very strong efficacy and safety. A doctor-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. These clinical trials seem to be proceeding smoothly, with the administration of the drug to the Parkinson's disease patients participating in the trial starting in August 2016.

Viewed as a whole, it seems that the doctor-initiated trials in VCU for RQ-10 are at the most advanced stage of development. The Company's policy is to use the results of these trials at VCU to open-up the way to strengthening its activities for licensing-out. As previously mentioned, as the phase I trials in the UK have been completed, in the case that it targets the European and United States markets, it is considered that one positive point will be that it will be able to use the results of these phase I trials to immediately begin Phase II trials.

The sales of Gasmotin® would seem to be of reference when considering market scale in the future. Sales of this drug have been declining in recent years on the appearance of generics, but at their peak in FY11, it achieved net sales of ¥21.2bn.

Development status of the 5-HT$_4$ partial agonist (RQ-10)

Indications	Gastro paresis, Functional Dyspepsia, Chronic Constipation
Advantage	Efficacy and the safety that are stronger than existing 5-HT$_4$ Partial Agonist are expected.
Progress	Completed Phase Ⅰ Clinical Study in UK
Licensing	Intellectual property of Korea and East Asia to CJ Health Care(CJHC)

Topix

May 2013	Completed Phase Ⅰ Clinical Trial in UK(RaQualia)
May 2014	Investigator Initiated Clinical Trial Collaboration with Virginia Commonwealth University(VCU) Parkinson's and Movement Disorders Center
August 2016	The First Dosing of RQ-00000010 at Virginia Commonwealth University Initiated

Mosapride's sales amount of peak tops is 21.2 billion yen(Japan). As RQ-10, efficacy and the safety that are stronger than Mosapride is expected.

Source: From Company's mid-term business plan materials

(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 tests, and safety pharmacology study), decided it was possible to proceed to the clinical trials stage and began phase I clinical trials in the UK in July 2015, which are currently ongoing.

Medium- to long-term growth strategy

Development status of the 5-HT2B antagonist (RQ-00310941)

June 2012	Granted a substance patent in the United States
2013	Completed the safety pharmacology study and pharmacokinetic study
2014	Completed the pharmacology 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 March 2017)
April 2016	Granted a substance patent in South Korea

Source: prepared by FISCO from Company materials

A major feature of the phase I trials in the UK is that after the evaluation of aspects such as safety, tolerability, and pharmacokinetics in healthy adults, the trial was designed with only a small number of patients. On entering this year, efforts to recruit trial subjects (patients) were accelerated, and the target for the completion of the phase I trials has been set as the second half of 2017. The Company has been granted a substance patent for RQ-941 from five major patent offices (Japan, United States, Europe, China, and South Korea). The possibility of expanding the indication of RQ-941 to a drug to improve abdominal symptoms resulting from autoimmune conditions, such as ulcerative colitis and Crohn's disease, is considered to be another positive factor. One possible timing for its licensing-out would seem to be when the phase I clinical trials, which are currently underway, are completed.

Made a subsidiary of TMRC, from which differentiation can be expected in the precision medicine area

3. Made a wholly-owned subsidiary of TMRC

(1) Background to TMRC being made a wholly-owned subsidiary

On February 3, 2017, the Company made a wholly owned subsidiary of TMRC through a share exchange. TMRC is a drug discovery venture company founded in January 2002 that specializes in the cancer area. The Company's objectives and motives in making TMRC a wholly-owned subsidiary include that 1) the Company's R&D is focused on the gastrointestinal disease and pain areas, so making a subsidiary of TMRC, which specializes in the cancer area, will lead to a pure expansion of its business area, 2) it can be expected to acquire the findings of joint research with academia and to accelerate the development of treatments, and 3) there are hopes for the future potential of TM-411 (INN: tamibarotene) that TMRC licenses-out to Syros.

(2) Status of TMRC's program and development

TMRC's current development program is for TM-411. This is a retinoic acid receptor (retinoid) created by Professor Emeritus Koichi Shudo of the Graduate School of Pharmaceutical Sciences, the University of Tokyo, and it is a drug that has demonstrated superior chemical stability, safety, and differentiation inducing activity than existing drugs. Within Japan, Toko Pharmaceutical Industrial Co., Ltd. conducted clinical trials and in April 2005, received approval for it as a treatment for "recurrent or refractory acute promyelocytic leukemia (APL)," and then in June of the same year, it was launched by Nippon Shinyaku <4516> as "Amnolake 2mg tablets."

TMRC licensed-in TM-411 in 2004. In 2014 in Japan, it licensed it out to Ohara Pharmaceutical Co., Ltd., and in 2015 in the United States to Syros, and both these licensee companies have been advancing its clinical development. Within this development, the greatest expectations are for the development being advanced at Syros for treatments for acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Syros is aiming to acquire new-drug approval for TM-411 as a precision medicine for AML and MDS.

Medium- to long-term growth strategy

Precision medicine is a new concept that contrasts with traditional medical treatment. Medical treatments (and drug development) up until recently were designed assuming an average patient, and particularly for anticancer drugs, the situation has been that "they are very effective for some patient groups, but have practically no effects for others." In contrast to this, precision medicine entails analyzing the genetic information that differs in each individual for prevention and treatment. Syros, based on the "Gene Control Platform" it developed, from among all the subjects, selected 25% of the AML and MDS patients with a stronger expression of the retinoic acid receptor (RARα) on which TM-411 acts. It is currently conducting the phase II trials for its development as a new drug for this group, for which it is expected to demonstrate strong efficacy.

Precision medicine has been attracting a lot of attention, such as from the announcement of the "Precision Medicine Initiative" in the State of the Union address by former U.S. President Obama in January 2015. Precision medicine narrows down the patient group to those patients for which the treatment is expected to be particularly effective, so it is anticipated it will demonstrate high cost performance compared to conventional treatments. Moreover, it is also being expected to benefit the low- and middle-income groups. The societal demand is expected to add a sense of urgency to the approval of new drugs. Personalized medicine is a similar concept, but this is targeted at the wealthy as it narrows down the target patient to the level of a single individual. At FISCO, we think that precision medicine has the potential to become a bigger market for pharmaceutical manufacturers than personalized medicine.

TMRC /TM-411's development status

Compound Code	Indication	Territory	Dev. Stage	Licensee
TM-411	Acute myelogenous leukemia (AML)	USA	PII	Syros Pharmaceutical, Inc.
	Myelodysplastic syndrome (MDS)	USA	PII	Syros Pharmaceutical, Inc.
	Breast cancer (BC)	USA	PII (prep.)	Syros Pharmaceutical, Inc.
	Neuroblastoma (NB)	Japan	PI	Ohara Pharmaceutical Co., Ltd.
	Acute promyelocytic leukemia (APL)	China	NDA Submitted	Toko Pharmaceutical Industries Co., Ltd.
	Neutropenia (NP)	USA	Non-clinical	Under negotiation

Source: From Company's mid-term business plan materials

(3) Contribution to earnings from the consolidation of TMRC

The Company used a share exchange to make TMRC a subsidiary, issuing and delivering 479,250 new shares. If calculated as ¥450 per share, this corresponds to around ¥216mn. It is expected that goodwill be generated from this, but at the time of writing of this report, the amount had not been confirmed or announced.

The earnings from TMRC are explained briefly in the press release dated December 12, 2016 (Japanese only), on making TMRC a wholly-owned subsidiary. TMRC's revenue is mainly from the supply of investigational drugs and milestone payments from Syros, its licensee company, but it does not receive milestone payments every year. In addition, it is estimated that TMRC will pay royalties to Toko Pharmaceutical Industrial from licensing-in TM-411. In this situation, the Company published a press release on April 14, 2017, on the outlook for the consolidated results, and announced the combined medium-term revised forecasts for both companies. The figures are described in detail in the "Future Outlook" section, but the point to focus on here is that compared to at the time of acquisition, the view has changed on when TMRC will become profitable, with the timing being moved forward.

Making steady progress in the collaborative R&D with Nagoya University

4. Status of industry-academia collaborations

For the Company, which is a drug discovery venture, an issue that can be said to relate to its continued existence is how to secure drug discovery seeds (drug-candidate compounds). For this issue, the Company's strategy is to advance collaborations with academia (universities), and it is particularly focusing on its collaboration with Nagoya University that utilizes this university's geographical proximity.

In April 2014, the Company established a Division of Analytical Study on Efficacy Pharmacology within Nagoya University's Research Institute of Environmental Medicine as a forum for industry-academia study. Then in February 2015, they concluded an agreement to establish academic-industrial research collaboration laboratories on "Laboratory of Medical Chemistry" and "Laboratory of Pharmaceutical Sciences & Analytical Chemistry." In August of the same year, the Company transferred its R&D center 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. In FY16, the Company conducted eight collaborative research projects with Nagoya University, and recruited within the University three times a year for new research themes.

Research Collaboration with Nagoya University

Theme	Collaboration party
Exploration of selective blockers targeting DNA polymerase eta	Research Institute of Environmental Medicine
Exploration of selective blockers targeting specific enzymes for treatment of refractory neuroblastoma	Graduate School of Medicine
Exploration of selective blockers targeting connective tissue growth factors (CTGF) for treatment of malignant mesothelioma	Graduate School of Medicine
Exploration of small molecule compounds inducing the secretion of cytokines and growth factors from adipose-derived stem cells	Graduate School of Medicine
Antibody production by gene transfer method using chickens	Graduate School of Bioagricultural Sciences
Exploration of selective blockers targeting specific proteins for treatment of cardiac failure	Graduate School of Medicine
Exploration of small molecule compounds that regulate circadian rhythms	Institute of Transformative Bio-Molecules (ITbM)
Exploration of treatment of non-alcoholic steatohepatitis (NASH)	Research Institute of Environmental Medicine

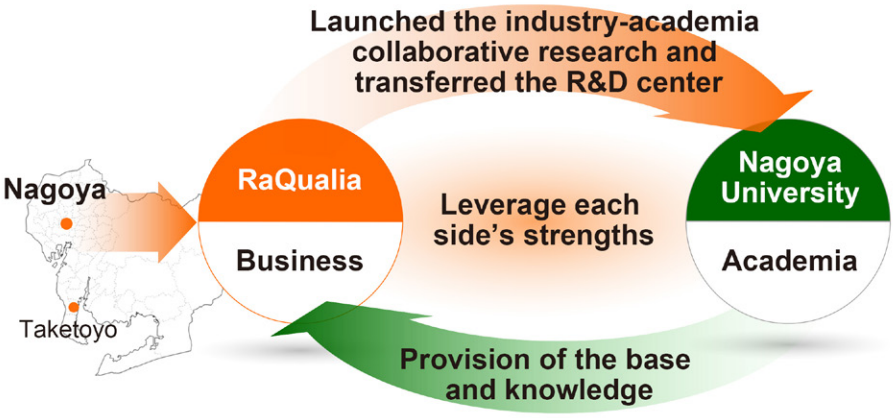
Source: Prepared by FISCO from the Mid-term business plan

The Company's above-described initiatives were certified for one of the new business partnership between different fields by Chubu Bureau of Economy, Trade and Industry (METI) (the first program in 2015 for the Chubu region) in July 2015. 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.

Medium- to long-term growth strategy

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 Efficacy Pharmacology, laboratory of Medical Chemistry, and Laboratory of Pharmaceutical Sciences & Analytical Chemistry), 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 regulated 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 expenses. 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.

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



Source: Prepared by FISCO from the Company's results briefing materials

Business outlook

Probability has increased that it will become profitable in FY12/19

1. The rolling targets in Odyssey 2018

In February 2016, the Company formulated and published Odyssey 2018, its three-year, mid-term business plan for FY12/16 to FY12/18. This is a rolling plan in which the Company reviews and revises the results targets every year, and in February 2017, it revised the previous targets so they reflected the FY12/16 results, the changes to the development and sales schedules of the animal drugs, and the state of progress of each development program.

While the new results targets have been downwardly revised for FY12/17 and FY12/18 compared to the previous targets, in the targets newly formulated for FY12/19, the Company announced that it is aiming for an operating profit and it is clear that it considers its profit structure will reach a major turning point.

Also, due to TMRC being made a subsidiary as previously described, the plan is to shift to consolidated results from FY12/17. After TMRC became a subsidiary on February 3, 2017, the Company carefully reviewed the results forecasts on a consolidated basis, and on April 14 published a press release indicating the consolidated results forecasts, while it also revised the mid-term plan's targets to on a consolidated basis.

At FISCO, we evaluate that the current revision to the mid-term plan's results forecasts is clearly an "upward revision." On comparing the consolidated and non-consolidated results forecasts, the TMRC results can be read as showing a loss from the income items in FY2/17, but showing profitability in FY12/18 and then an increase in profits in FY12/19. As previously mentioned, TMRC already receives a certain level of earnings from milestone payments from its licensee company and from supplying investigational drugs, and if its licensee company makes steady progress with the development of TM-411, a profitable earnings structure for TMRC and an increase in profits will come into sight. RaQualia Pharma itself is also expected to achieve profitability in FY12/19, such as from the royalty payments for the animal drugs. At FISCO, we expect that the earnings stability of the RaQualia Pharma Group will be solidified from both the parent company and the subsidiary becoming profitable.

The revised results targets in Odyssey 2018

(¥mn)

	FY12/15 result	Odyssey 2018			
		FY12/16 result	FY12/17 forecast	FY12/18 target	FY12/19 target
Business revenue	145	705	1,176	1,291	1,688
Operating expenses	2,010	1,465	1,968	1,554	1,559
Operating income	-1,864	-759	-791	-263	128
Ordinary income	-1,795	-720	-799	-265	127
Profit	-1,854	-728	-800	-271	121

Note: the results are non-consolidated up to FY12/16 and consolidated from FY12/17
Source: Prepared by FISCO from the mid-term business plan

Following on from the two animal drugs, market launches of two human drugs are expected

2. Detailed breakdown of the business revenue (non-consolidated basis)

The Company's business revenue on a non-consolidated basis up to the present time has been comprised of the upfront payments received at the time of licensing-out, the milestone payments it receives alongside the development progress made in the licensing-out programs, and the research-collaboration income from the collaborative research. Following the launch of an animal drug by Aratana, from FY12/17 it will receive royalty payments as a fixed percentage of this drug's net sales. Not only do royalty payments tend to be large, they also have the quality of being stable payments received each year during the period when the relevant patent is effective, so can be said to be the ultimate goal for a drug discovery venture such as the Company. From the prospect of the recording of the royalty payments, the Company's earnings structure can be evaluated as having moved to the next stage.

Breakdown of the business revenue target

(¥mn)	FY12/16 Result	FY12/17 Plan	FY12/18 Target	FY12/19 Target
Business revenue	705	1,100	1,200	1,400
Operating expenses	1,465	1,860	1,486	1,386
Operating profit	−759	−760	−286	13
Profit item	Upfront payment on the licensing-out of new program Upfront payment by right geographic or indication expansion Upfront payment or research cooperation revenue by collaboration research Milestone payment by stepping up to the next development stage Royalty			
Breakdown of business revenue	Milestone Research cooperation revenue Aratana Asahi Kasei Pharma Xuan Zhu	Milestone Research cooperation revenue Royalty Aratana Asahi Kasei Pharma CJ Healthcare Asahi Kasei Pharma Xuan Zhu Aratana	Milestone Research cooperation revenue Royalty Aratana Asahi Kasei Pharma Xuan Zhu Aratana	Milestone Research cooperation revenue Royalty CJ Healthcare Meiji Seika Pharma Asahi Kasei Pharma Xuan Zhu Aratana

Source: Prepared by FISCO from the Mid-term business plan

(1) FY12/17

On a non-consolidated basis, business revenue is forecast to be ¥1,100mn. The main point to pay attention to in FY12/17 is the prospect of the Company receiving its first ever royalty payment from Aratana's market launch of Galliprant® in January 2017. Fundamentally, the Company will receive a royalty payment every fiscal quarter. In addition to the monetary amount, there is also the uncertainty regarding the timing of the payment, and it is possible that the forecasts will change in the future after the Company conducts a review.

In terms of the other business revenue, the Company will also receive milestone payments, mainly from the market launches of Galliprant® and Entyce® (scheduled for the second half of 2017), and from CJ Healthcare on the completion of the phase III trials of tegoprazan (P-CAB). It is also expected to record research cooperation revenue and milestone payments from Asahi Kasei Pharma and Xuan Zhu.

Conversely, operating expenses are forecast to increase 27.0% YoY to ¥1,860mn, including due to expenses for the 5-HT2B antagonist (RQ-941) phase I clinical trials in the United Kingdom, and the payment of royalties arising from milestone payments. As a result, the operating loss is expected to remain basically unchanged, at ¥760mn.

(2) FY12/18

The business revenue target is ¥1,200mn. At FISCO, we estimate that the source of earnings in FY12/18 will mainly be royalty payments from Galliprant® and Entyce® from the expected higher sales of these two drugs. We also think that the Company will receive milestone payments from Aratana from the development for the European market (where it is currently applying for regulatory approval) and also from the development to expand the indication to cats.

Operating expenses are forecast to be ¥1,486mn, which is an approximately 20% decline on the previous fiscal period. At FISCO, we estimate that this will mainly be due to the end of expenses for the 5-HT$_{2B}$ antagonist (RQ-941) phase I clinical trials. The Company will pay royalties arising from the milestone payment, so operating expenses will not decrease sharply. But even so, it is aiming to greatly reduce the operating loss in the previous fiscal period to ¥286mn.

(3) FY12/19

On a non-consolidated basis, the business revenue target is ¥1,400mn. It is thought that the royalty payments from Aratana for the two animal drugs will continue to be the core of earnings. Milestone payments are expected to increase in FY12/19, mainly from CJ Healthcare on the market launch of tegoprazan (P-CAB) and from Meiji Seika Pharma on the application for regulatory approval for Ziprasidone.

The Company anticipates that the same as in FY12/18, the extent of the reduction in operating expenses will be moderate as it will pay royalties arising from milestone payments. However, as a result of the increase in business revenue, it is aiming to convert the previous operating loss to an operating profit and record operating income of ¥13mn.

At FISCO, we evaluate that it is highly likely that the Company will achieve both the results forecasts and the mid-term business plan's results target. We consider that the major difference between the current mid-term results targets and the previous ones is that these are highly reliable. The reasons we think this are first that royalty payments, which are the most stable form of revenue and also which can be expected to increase in scale, are set to steadily and significantly increase from FY12/17 onwards. Another point to focus on is that the Company is highly likely to obtain milestone payments as there are several drugs that are approaching their market launches from the steady progress being made by the licensee companies in their respective clinical trials. One risk factor is timing, such as the postponement of the market launch that was seen in the Aratana case. But as long as this does not result in the dropping (cancellation) of the drug's development, it is not necessary to be excessively concerned about a time delay, as the drug will still be market launched.

Financing

Aiming to both improve shareholder value and stabilize management by raising funds

Although the Company is clearly on a path to becoming profitable, it is also a fact that it still in the process of securing stable earnings, so acquiring the funds necessary for business management remains an important issue. As its basic policy, the Company aims to maintain a balance of funds of ¥3bn for business management at the end of each fiscal year. Also, it has not changed its previous fundamental stance on fund raising.

In order to raise funds for the future, the Company prioritizes raising funds from business revenue for working capital and reducing operating expenses. When it raises funds from shareholders and the markets, its basic policy is to do so by obtaining the understanding of the shareholders or markets through telling a clear equity story that indicates how the fund raising will lead to an increase in shareholder value.

At FISCO, we think that the Company's approach to fundraising can be praised. As previously mentioned, we consider its approach to be persuasive from the viewpoint of feasibility from the previous mentioned prospects for the recording of stable revenue, including from royalty payments. The Company is actively conducting IR activities in Japan and overseas, and within Japan, it regularly holds dialogues with institutional and individual investors. Overseas also, it has visited institutional investors in the United States, Hong Kong, and Singapore. We can expect that these steady IR activities will have a positive impact on its fundraising.

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