Medium-Term Management Plan Gaia 2021 (2019 - 2021) (Revised)

Previous announcement: February 8, 2019

This time: September 6, 2019 (TSE JASDAQ Growth: 4579)

RaQualia Pharma Inc.

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Company Overview

(As of the date of submission)

私たちは創薬を通じて健康と幸せに貢献し、人々の心に陽をもたらします

We will bring people hope, health and happiness with innovative new medicines

Company Name

RaQualia Pharma Inc.

President and CEO

Naoki Tani

Business Summary

Discovery and development of pharmaceutical compounds
Licensing of intellectual properties for pharmaceutical compounds

Employees(Consolidated)

67

Establishment

February 19, 2008

Capital Fund

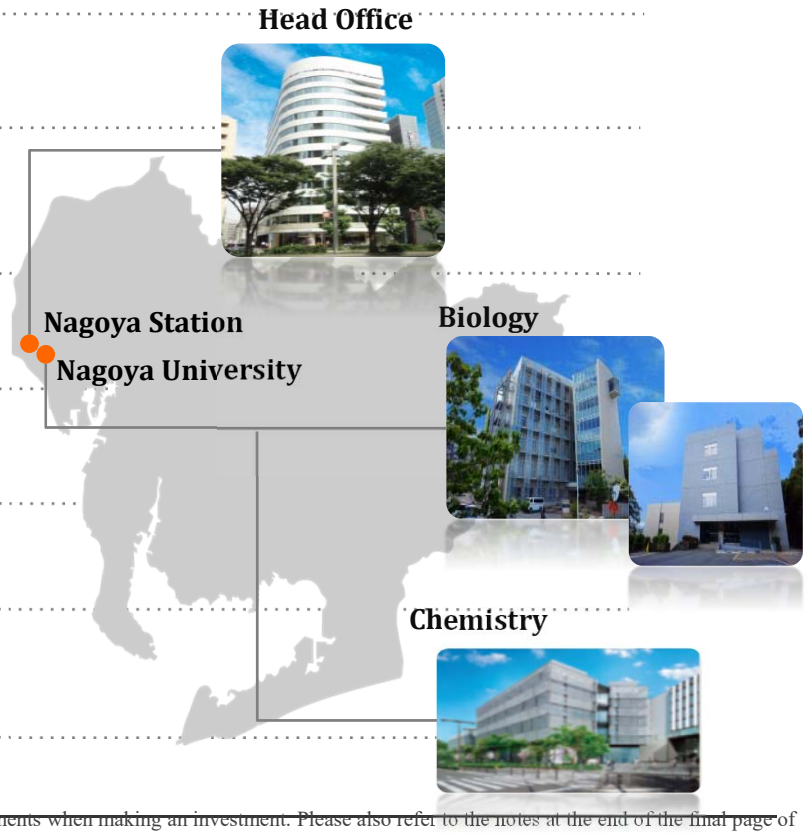
2.09 billion JPY

Outstanding Shares

20,678,142

Subsidiary

TMRC Co,Ltd
Raqualia Innovations Inc.



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RaQualia Pharma's History and Future Growth

Feb. 2008
Establishment

Jul. 2008
Spin-out
from Pfizer

Jul. 2011
Initial public offering
JASDAQ: 4579

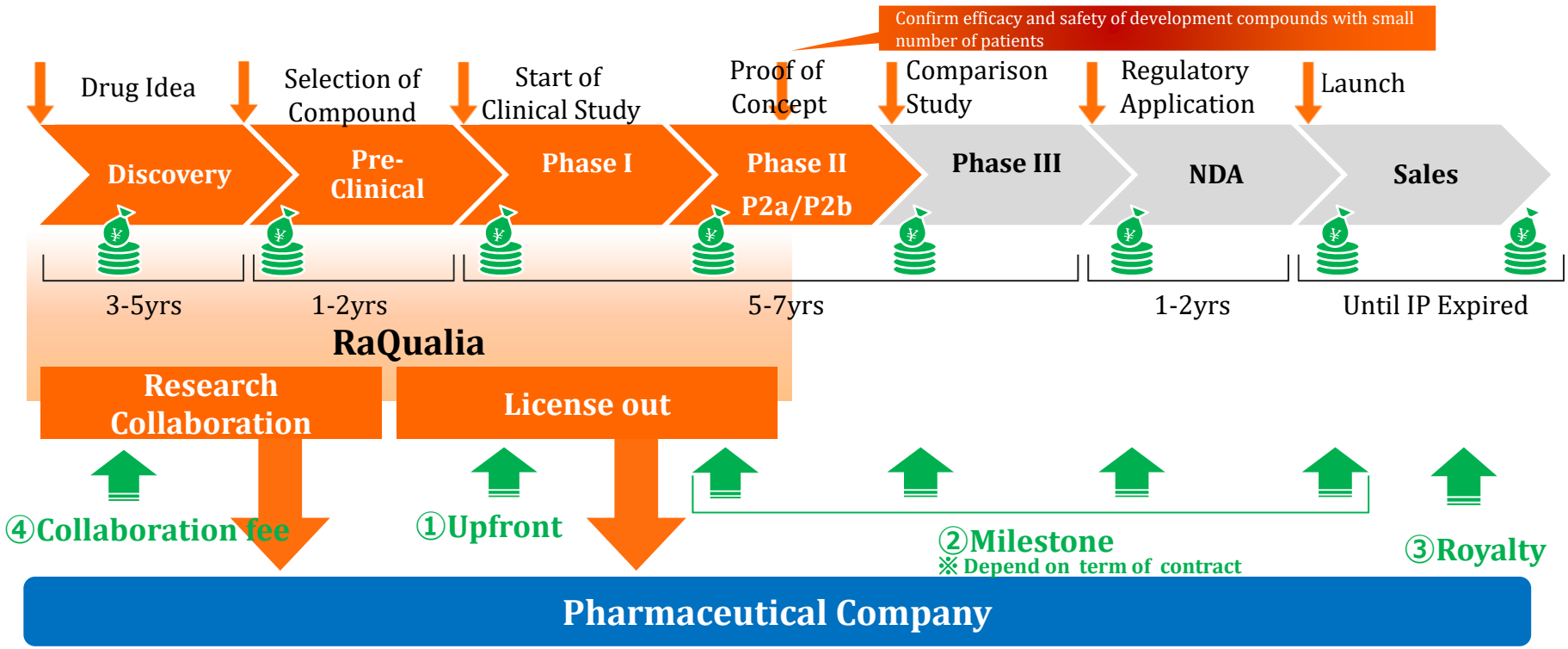
2014-2015
Drug Discovery and
Research Division relocated
to Nagoya University

2017
Launched two pet
phamaceuticals

2019
Launched human pharmaceutical

Establis hment → Growth → Develop ment → Further Growth

Business Domain and Strategy



Business Model	• RaQualia primarily generates its revenue (upfront, milestone payments and royalty income) by licensing development and commercialization rights to pharmaceutical companies for compounds that it has discovered. • RaQualia also projects revenue from research collaboration activities with academia.

Review of the Medium-Term Management Plan "Odyssey 2018"

■ Launched Pet pharmaceuticals in U.S. and Obtained Approval in Europe and Launching near in the future

- Our licensee Aratana Therapeutics, Inc. (U.S.: "Aratana") launched GALLIPRANT® in U.S. for the treatment of pain and inflamed associated with Osteoarthritis("OA") in dogs. [January 2017]
- Aratana launched ENTYCE® in U.S. for the treatment of the appetite stimulation in dogs. [Oct. 2017]
- Aratana received marketing authorization in Europe("EU") for GALLIPRANT®, a drug for the treatment of pain associated with Dog Osteorthritis. [January 2018]

■ Preparing for the Launch of Human Pharmaceuticals

- Our licensee CJ HealthCare Corporation (Korea: "CJ") filed an application for tegoprazan, a treatment for gastroesophageal reflux disease, with the Korean Food Safety Board (MFDS:Ministry of Food and Drug Safety) .[Aug. 2017]
- CJ obtained Korean approval for tegoprazan.[July 2018]
- Shandong Luoxin Pharmaceutical Group (China), a CJ sublicense partner, started Phase 3 trials of tegoprazan in China.[Oct. 2018]

■ Shift to Drug Discovery Research and Actively Promote Industry-Academia Collaboration

- Completed of Phase 1 trials for 5-HT_4 partial agonist (RQ-00000010) and 5-HT_{2B} antagonist (RQ-00310941) in U.K..
- Collaboration in ion channel drug discovery progresses. Out-licensed to Maruho Co., Ltd. (Japan) and Asahi Kasei Pharma Co., Ltd. (Japan). Jointly developed with EA Pharma Co., Ltd. (Japan: ※ Former Ajinomoto Pharmaceuticals Co., Ltd.) is also steadily developing compounds.
- Established the RaQualia Pharma Industry-Academia Collaboration Research Center within Nagoya University. [April 2018]

■ Subsidiaries

- Acquisition of 100% Ownership of TMRC Co., Ltd. [Feb. 2017]; The results of the initial phase 2 trials (combination use of multiple drugs) of TM-411 are favorable. [Dec. 2018]
- Established RaQualia Innovations Inc. [Dec. 2018] Explore commercialization of "seeds of new drugs" and "seeds of business" produced by academia and startup companies in Japan and overseas.

Business Summary for FY2018

Operating revenues were revised downward to 743 million JPY from 1,388 million JPY

- Decided to terminate the agreement to establish a Joint Venture company with ZTE Coming Biotech Co., Ltd.. (China)
- Multiple milstone revenues are delayed to the next fiscal year or thereafter.
- Operating loss for FY2018 was 1,075 million JPY.

Sales trend of Pet Pharmaceuticals is Strong

- **GALLIPRANT®**; Sustained strong sales performance in U.S. with royalty income.
- **ENTYCE®** ; Steady sales performance in U.S..

Concrete Results of Joint Research with Partner Companies and Joint Patent Applications with Nagoya University

- Achieved milestone for P2X7 antagonist (RQ-00466479/AKP-23494954) developed in collaboration with Asahi Kasei Pharma and progressed to the pre-clinical phase. Newly signed a licensing agreement.
- Achieved milestone and recorded milestone revenue for compounds created through joint research with EA Pharma targeting specific ion channels in the gastrointestinal field.
- Steady development of selective Sodium Channel Blockers licensed to Maruho.
- Joint Patent Application with Nagoya University for Heart Failure treatments and drugs.

Business Summary for FY2018

Steady progress toward the launch of human pharmaceuticals

- CJ obtained approval from South Korea for the drug for gastroesophageal reflux disease.
- CJ sublicense partner Shandong Luoxin Pharmaceutical Group (China) began Phase 3 clinical trials for tegoprazan in China.
- Our licensee Meiji Seika Pharma is currently conducting Phase 3 clinical trials of Ziprasidone (a serotonin 5-HT_{2A} and dopamin D_2 inhibitor) in Japan.

Industry-academia collaboration

- The investigator-initiated trial (IIT) of 5-HT_4 partial agonists (RQ-00000010), funded by the Michael J. Fox Foundation, is underway at the University of Virginia Commonwealth.
- Steady progress in joint research with Nagoya University on new heart failure treatments and drugs for the treatment of non-alcoholic fatteness (NASH).
- Started studying glaucoma treatment with Gifu University of Pharmacy.

Others

- TMRC's Phase 2 TM-411 AML trials (combination with multiple drugs);the initial data were favorable.
- Established RaQualia Innovations Inc. to collaborate with academia, startup companies, etc. to create a "new platform".
- Continuously strengthen intellectual property: Announced acquisition of four new patents.

Major events in FY2019

Launched the Human Pharmaceutical in South Korea, and Further Business Alliance with CJ

- In July 2018,tegoprazan was approved in South Korea and launched in March 2019.
- CJ will be developing sub-licensees in Southeast Asia and Rest Of World.

Pet Pharmaceuticals: Moving to a Growth Phase

- GALLIPRANT®; U.S. sales steady expansion and launched in March 2019 in EU.
- ENTYCE®; Sales is solid in U.S. ; Pivotal trials in cats is on going

Major events in FY2019

Steady clinical trials in alliance partners

- In September 2019, Meiji Seika Pharma announced that Phase 3 clinical trials to assess the safety and efficacy of Ziprasidone (serotonin 5-HT_{2A} and dopamine D_2 antagonist) for the treatment of patients with acute schizophrenia in Japan did not meet its primary endpoint. Meiji Seika Pharma plans to analyze and evaluate the results obtained from this study in detail and to consider future development plans and strategies.
- P2X7 antagonist (RQ-00466479/AKP-23494954) is in the preclinical stage at Asahi Kasei Pharma. Expecting further progress
- Compounds created through collaborative research targeting ion channels with EA Pharma are continuing to be developed at EA Pharma
- Selective Sodium Channel Blocker is under development in Maruho

Subsidiaries

- Steady progress in Phase 2 clinical studies of TM-411(AML) (combination with multiple drugs)
- RaQualia Innovations;expanding information gathering activities from biotech ventures and academia

Others

- Further Progress in Ion Channel Drug Discovery
- Continuous Strengthening of Intellectual Property: Life Cycle Management (LCM) Strategy

Positioning of the New Medium-Term Management Plan "Gaia"

Period	Name	Main measures
FY2016 ~ FY2018	「Odyssey」 (journey of the return)	・ Launch of two pet pharmaceuticals ・ Preparing for the launch of human pharmaceuticals
FY2019 ~ FY2021	「Gaia」 (Estate god, creation)	・ **Launch of human pharmaceuticals** ・ **To accelerate overseas business operation**

Gaia (Ara Pacific Museum, Rome)

In Greek Mythology

・After Chaos, wide-bosomed "Gaia (Earth)" arose to be the everlasting seat of the immortals who possess Olympus above.[Hesiod's Theogony]

With creativity such as the "Gaia"(Mother God)
Evolution of "Global" Scale!

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Results and Future Performance Targets (Overview)

[Consolidated] (Unit: Millions of yen)	FY2017 (Result)	FY2018 (Initial plan)	FY12/18 (Results)	FYE 2019 (Plan)	FYE 2020 (Target)	FYE 2021 (Target)
Operating revenues	**1,419**	**1,388**	**744**	**1,756**	**2,129**	**2,240**
Operating profit(loss)	**△150**	**△698**	**△1,075**	**△84**	**237**	**229**
Ordinary profit(loss)	**△80**	**△680**	**△1,064**	**△82**	**245**	**237**
Profit attributable to owners of the	**△58**	**△686**	**△1,104**	**△106**	**174**	**161**

Further growth and Stability

Licensed

GALLIPRANT® US(Market) EU(Market)	**K-CAB®** Korea (Market) China (Phase 3)	**P2X7 receptor antagonist** Worldwide (Pre-clinical)
ENTYCE® Dog:US (Market) Cat: Pivotal Study	**Ziprasidone** Japan (Phase 3)	**Selective Sodium Channel Blockers** Worldwide (Pre-clinical)

Expect milestone by development stage
Expect royalty after launch in market

License Candidate

TRPM8-Blockers (worldwide) Pre-clinical	**Motilin receptor agonist** (worldwide) Phase 1 plannnig	**5-HT$_4$ partial agonists** (worldwide) Phase 1 completed: UK
Ghrelin Receptor Agonist (worldwide) Pre-clinical	**tegoprazan** (Japan,US,EU) Phase 1 completed: Japan,US	**5-HT$_{2B}$ antagonists** (worldwide) Phase 1 completed: UK

Ready for license activity
Expect Upfront payment

Overview of expenses

(Unit: Million yen)	FY2017 (Results)	FY2018 (Plan)	FY2018 (Results)	FYE2019 (Plan)	FYE2020 (Target)	FYE2021 (Target)
1. Cost of Goods	149	150	89	272	247	327
2. SG & A	1,420	1,936	1,730	1,568	1,644	1,683
Personnel	580	567	607	625	604	671
R & D	296	628	451	267	351	350
Administrative	259	296	255	273	254	255
Facility related	164	181	204	235	223	225
Others	119	151	213	168	212	182
Total (1+2)	1,569	1,968	1,819	1,840	1,892	2,011

FY2019	Royalty Payment, etc： Increase the royalty payment based on Milestone and Royalty revenues. Administrative： Increase in depreciation expenses due to capital investment.
FY2020	Royalty Payment, etc：Increase the royalty payment based on Milestone and Royalty revenues.
FY2021	Royalty Payment, etc ：Increase the royalty payment based on Milestone and Royalty revenues.

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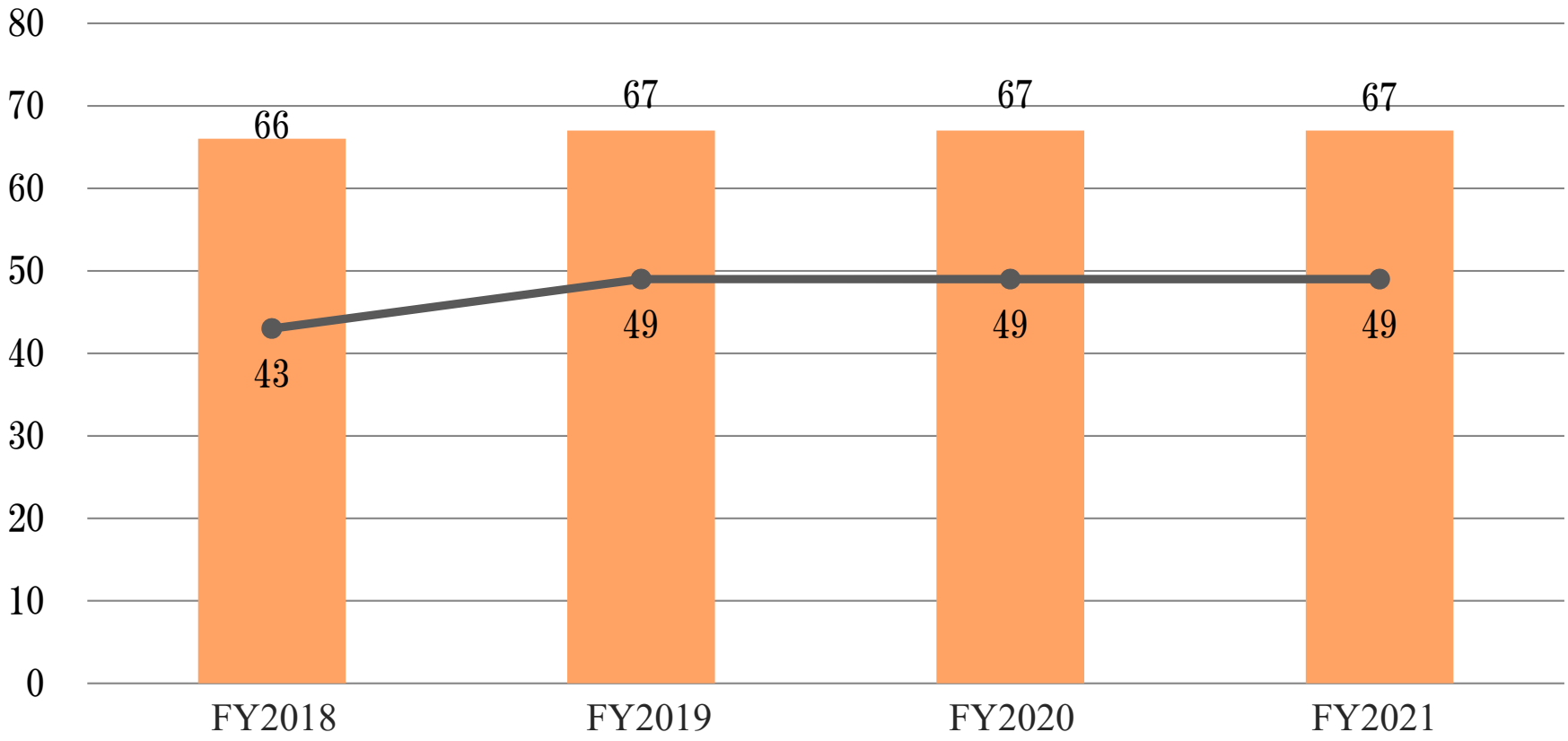
Personnel plan



※. Including those on a consolidated basis and those on leave

Fundraising strategy

Basic Principle

- Maintain fund balance at the level of 3.0 billion JPY at each fiscal year end by continuing cost reduction measures implemented the year before last.
- Running costs should be basically covered by business revenue and cost reduction measures.
- Devote budget surplus to Discovery research activities with the aim of enhancing the value of existing programs and monetizing the achievements.
- Propose and implement financing strategies with a convincing equity story based on shareholder value.

Estimation（cash and deposits, investment securities etc.）

- Estimated fund balance at the end of FY2018 (approx. 3.5 billion JPY)

Financing Methods

- Allocation of new stocks to a third party for stable investors
- Public stock offerings
- Consider a new way of financing (e.g. financing per project)
- Financing with effective use of assets held (Consider selling Aratana stocks: 103,088 shares)
- Debt

Propose and implement financing strategies with a convincing equity story based on shareholder value

Strengths and Attractiveness

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Drug Development Capability

Maximize the infrastructure that is in the highest class among biotechnology venture companies in Japan and aim to create development compounds

Hardware

- **Compound Library**
  - Continue to expand rich compounds

Number Owned
380,000

- **Synthesis & Analysis**
  - Establishment of the automation system

Synthesis
150/week possible

- **Screening**
  - SCARA Robot System
  - QPatch

High Through-put Screening

Software

- **Abundant researchers who have advanced techniques**
- **Research with expertise on the fields of "GI" and "Pain"**
- **Implementing collaborative studies in the field of ion channel drug development with multiple pharmaceutical companies**

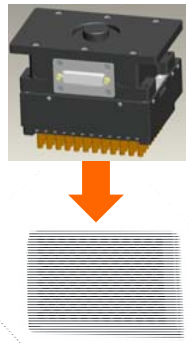
Based on the rich resources, we will efficiently conduct the exploratory research and development and aim to create development compound

Ion Channel Drug Development (Our Superiority)

The field where other companies cannot easily imitate and follow up

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 cellsare essential	A collaborative development of an ion channel activity measuring instrument with Hamamatsu Photonics K.K.

FDSS/μCELL
(Hamamatsu Photonics)



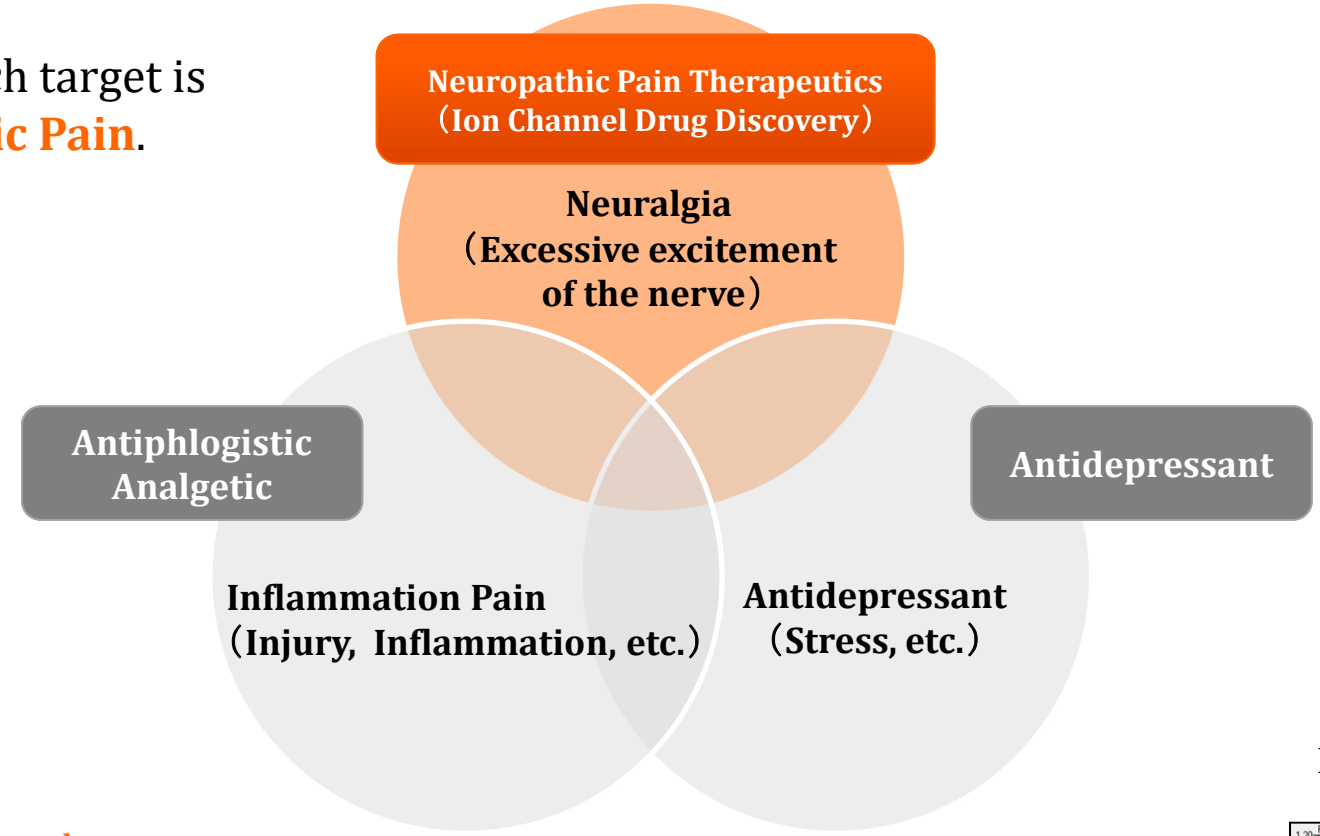
It able to analyzed at the same time 96 compound.

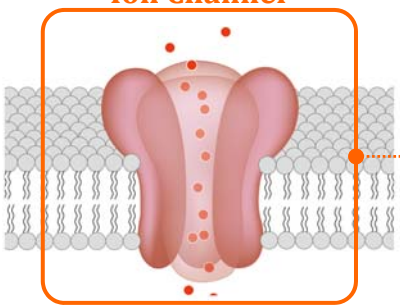
QPatch HTX
(Sophion Bioscience)

Autopatch systems
It able to HTS.
(7,000 data point/day)
It able to giga seal.

Ion Channel

Our Research target is **Neuropathic Pain**.

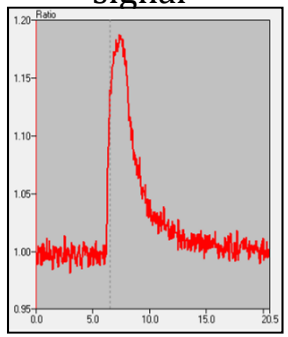




About Ion Channel

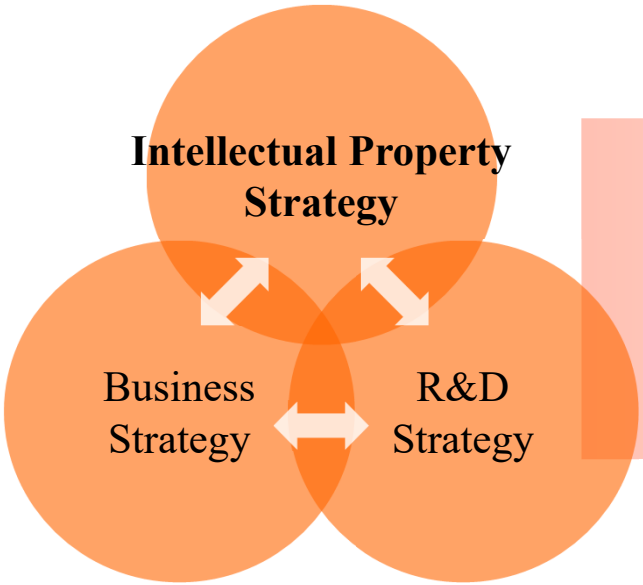
The generic name of a membrane protein passing an ion to the inside and outside of the cell. It take an important duty to regulate the release of the neurotransmitter.

Fluorescence signal



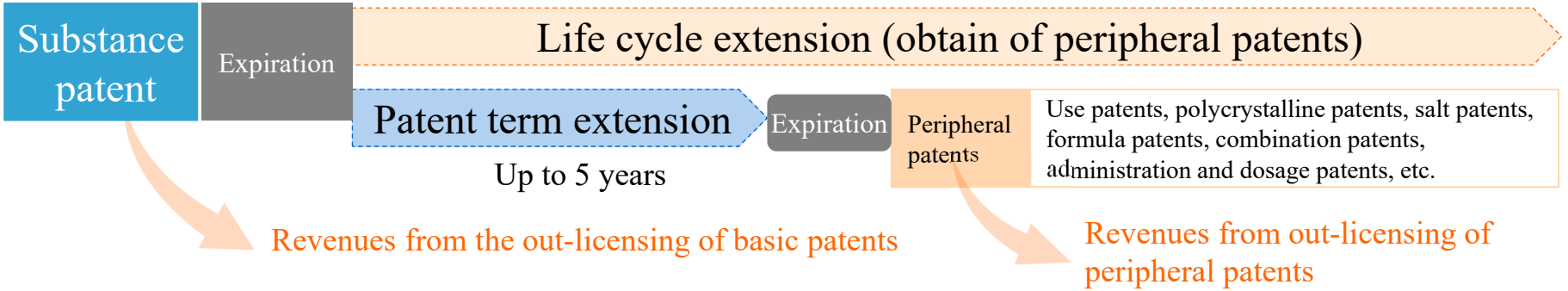
IP(Intellectual Property) strategy

Intellectual property in our products
- Building a high-value intellectual property portfolio



Anticipated Program Benefits

- Prompt patent application
- Steady acquisition of rights
- Creation of intellectual property tailored to customer needs
- IP-based licensing proposals
- Extending the life cycle of intellectual property



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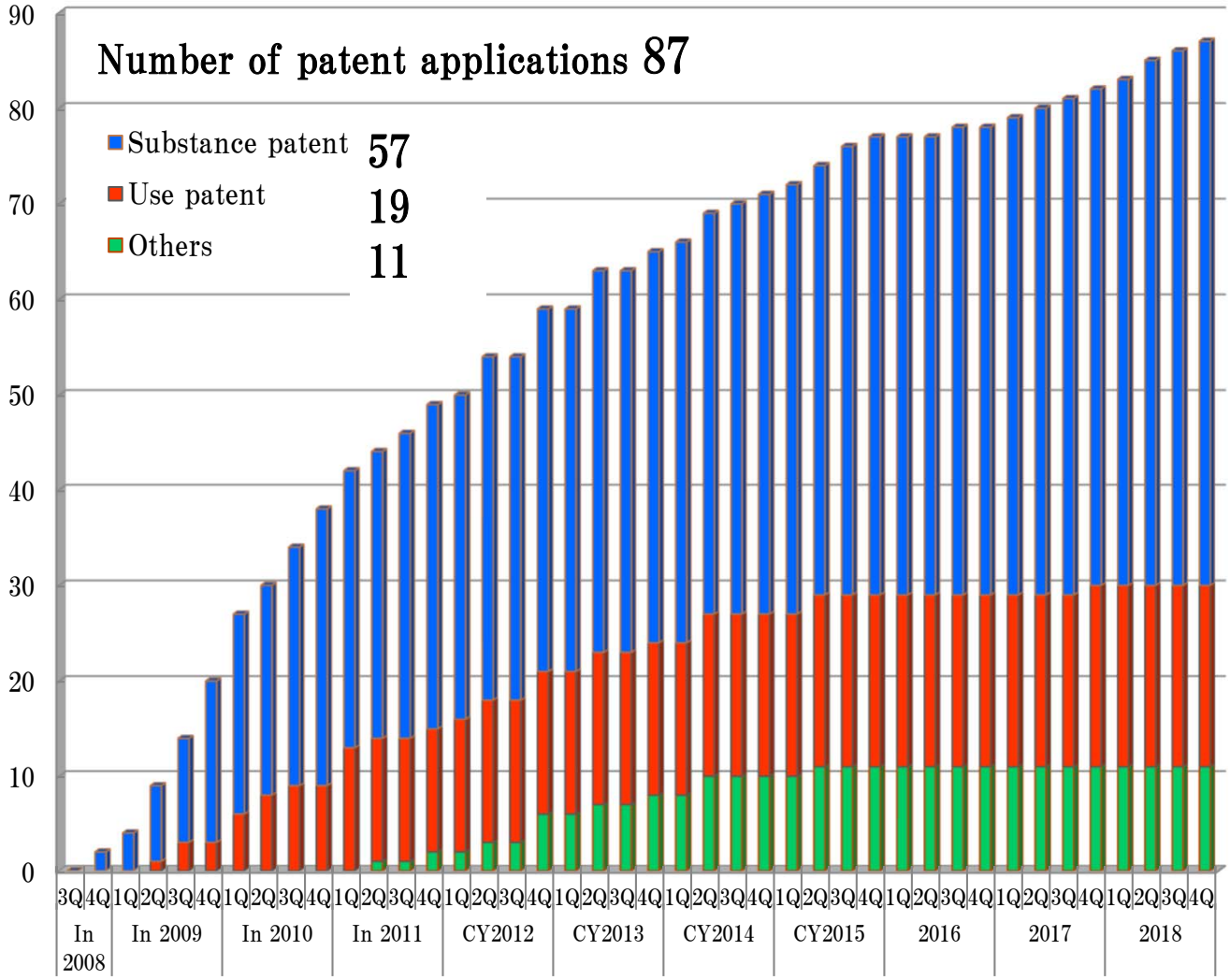
Patent Applications

(excluding the number of trans



Major Programs

Major Derived Programs

(As of the date of submis

Project	Compound	Primary indication	Implementation Region	Search	Pre-clinical	Clinical trials			Application	Approval	Marketing
						Phase1	Phase2	Phase3			
Potassium competitive acid blocker(P-CAB)	RQ-00000004 (tegoprazan)	Gastroesophageal Reflux Disease	Korea	○	○	○	○	○	○	○	○ Marketing
			China	○	○	○	○	○ On going			
			Vietnam						○ Preparing		
			Latin America						○ Preparing		
Ziprasidone	RQ-00000003 (ziprasidone)	schizophrenia	Japan	○	○	○	○	○ On going			

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Major Derived Programs

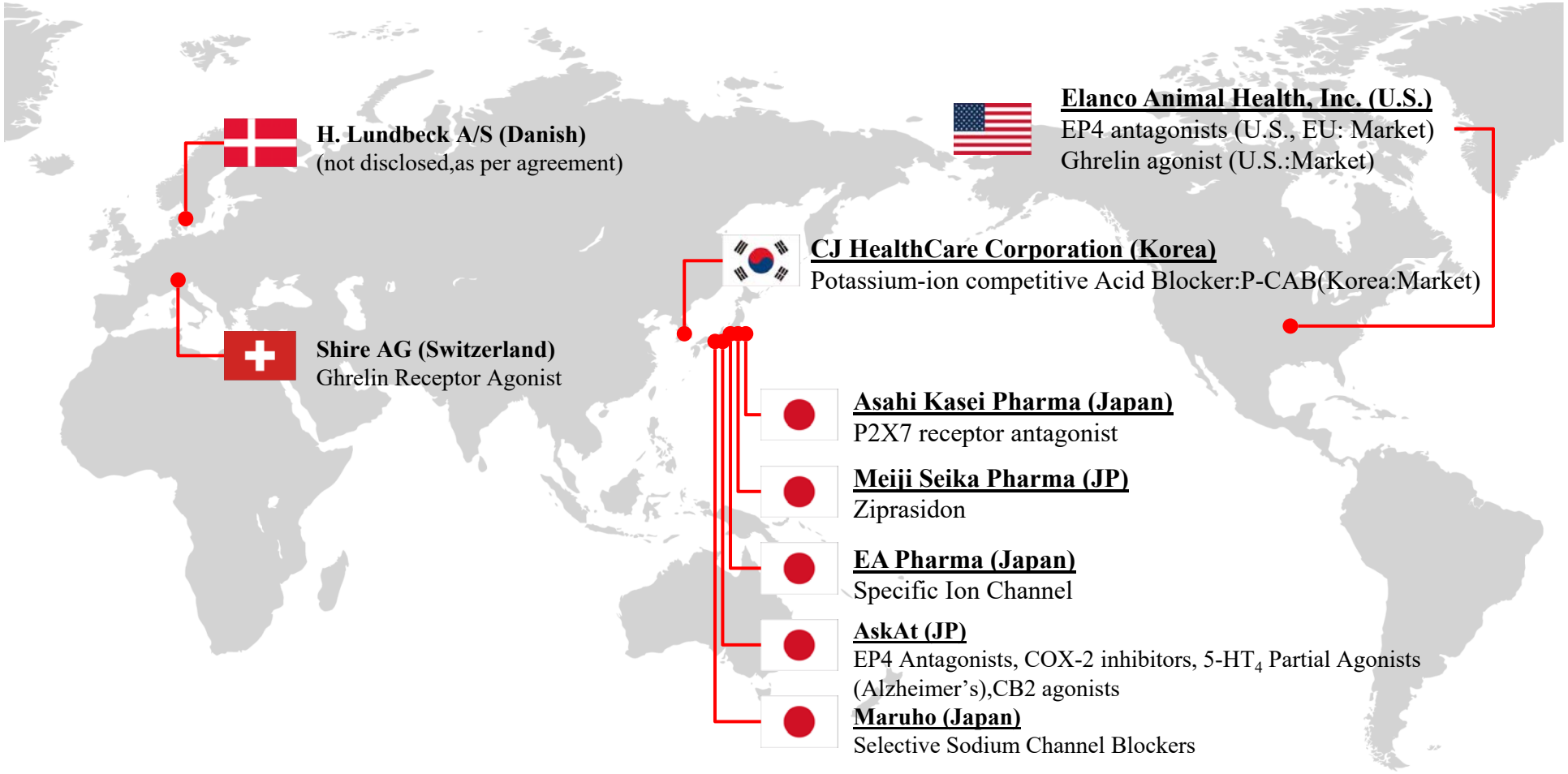
(As of the date of submission)

EP4 Antagonist	grapiprant RQ-00000007	Osteoarthritis	Worldwide (Human)	Phase 2 in progress:U.S. Phase 1 in pogress:China	AskAt Inc.
		Autoimmune Disorders Allergies, Cancer	Worldwide (Human)	Phase 1b in progress:U.S. Phase 1 in progress:China	
	RQ-00000008	Osteoarthritis Autoimmune Disorders	Worldwide (Human)	Pre-Clinical Completed	
		Pain	Worldwide (Animals)	Pre-Clinical Completed	
5-HT4 Partial Agonist	RQ-00000009	Alzheimer's	Worldwide	Phase 1 Completed: U.S.	
Cyclooxygenase-2 (COX-2) Inhibitor	RQ-00317076	Acute Pain	Worldwide	Phase2aCompleted: U.S.	
Selective Sodium Channel Blocker	Undisclosed	Pain, Itch	Worldwide	Undisclosed	Maruho Corporation
P2X7 Receptor Antagonist	RQ-00466479	Neuropathic Pain	Worldwide	Pre-Clinical Stage	Asahi Kasei Pharma
Specific Ion Channels	Undisclosed	Gastrointestinal Tract	Worldwide	Undisclosed	EA Pharma

Licensed-out program

(As of the date of submission)

- **13 licensing and joint research agreements reached 9 companies in 5 countries**



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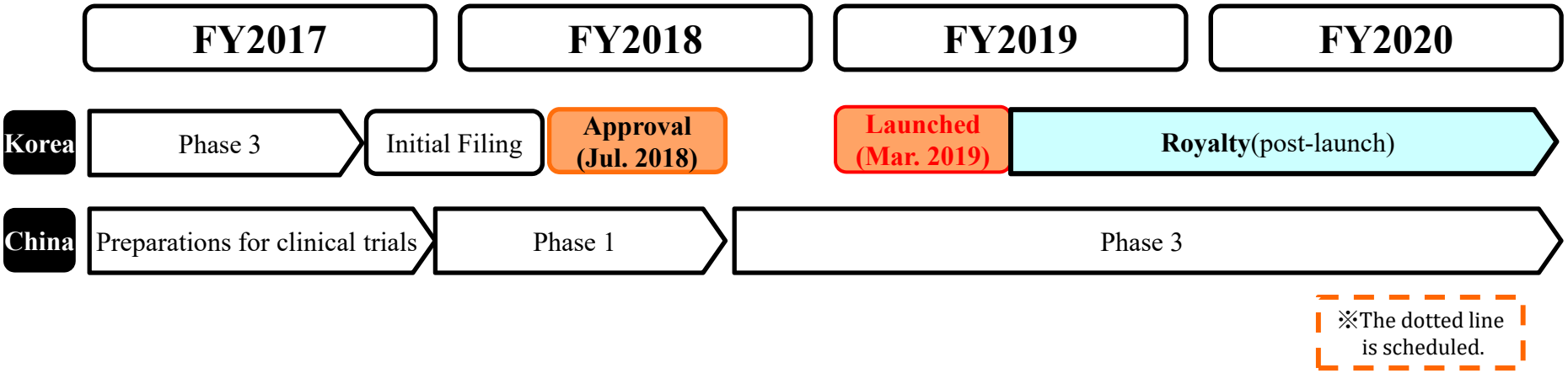
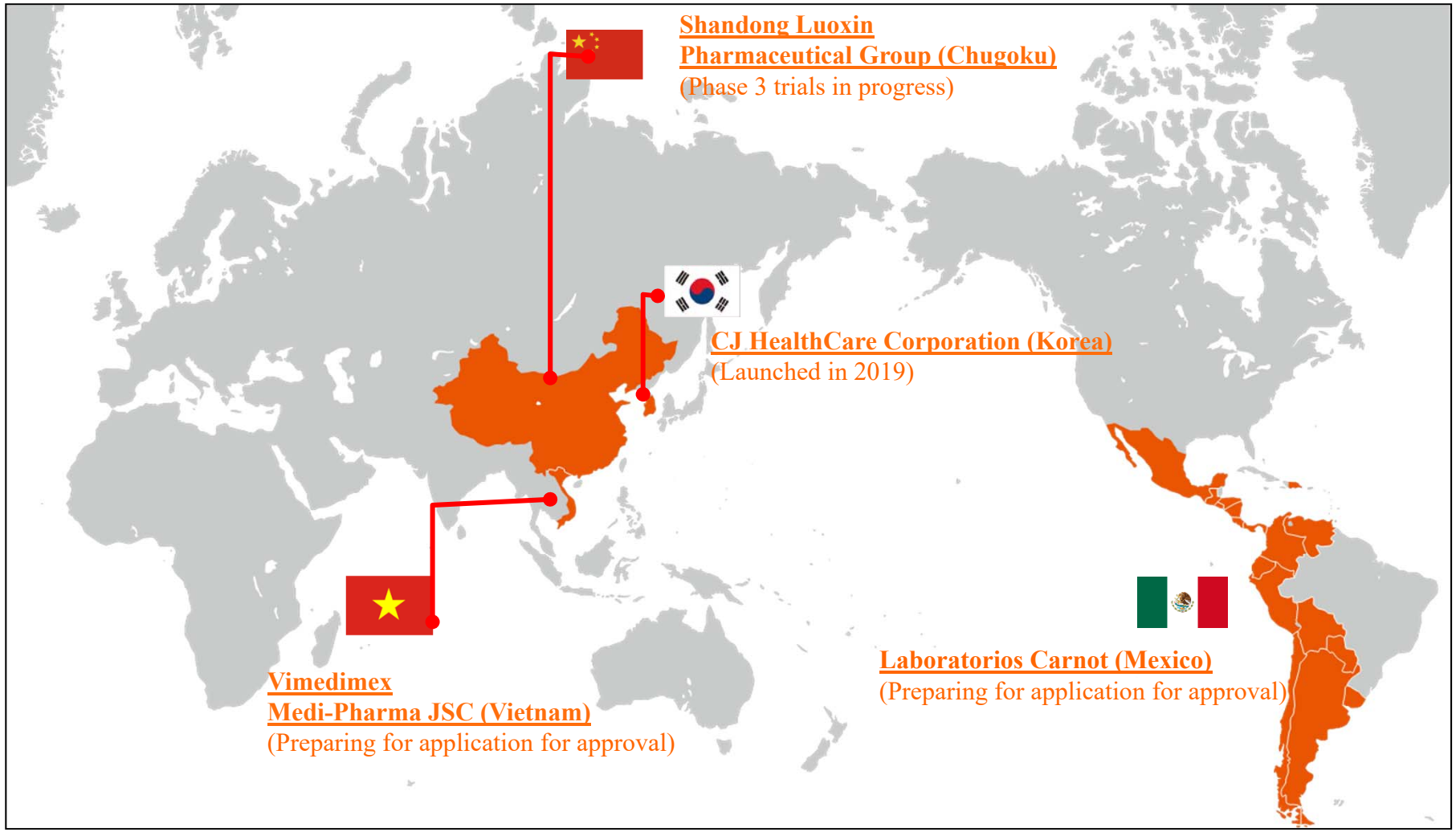
Roadmap for Developing tegoprazan



Out-licensing partner	**CJ HealthCare Corporation**
Indication	Non-erosive gastroesophageal reflux (NERD) Erosive Esophagitis:(EE) Gastric ulcer (GU)
Development status	Korea: Launched in March 2019 China: Phase 3 in progress (from October 2018)
Reference Information	Market size (Korea); ※ of approx. 50 billion JPY (approx. 500 billion won) Market size (China); ※ of approx. 260 billion JPY (approx. 2.6 billion USD)

※ Our research

Developments in tegoprazan (States of sublicensees)



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Major Pipelines: Pet pharmaceuticals

(As of the date of submission)

- **GALLIPRANT®** was launched in U.S. in January 2017 by Aratana Therapeutics Inc.(U.S."Aratana") and its strategic partner, Elanco Animal Health (*). GALLIPRANT® is intended to control pain and inflammation associated with Osteoarthritis("OA") in dogs.GALLIPRANT® was approved in January, 2018 and launched in March 2019 in EU.

- **ENTYCE®** was developed by Aratana as an appetite stimulation drug for dogs. The product was granted FDA approval in May 2016 and was launched in October 2017. Aratana has started a long-term toxicity test for ENTYCE® for use in cats in February 2018 and pivotal study is on going.

Project	Compound (Generic name)	Out-licensing partner	Primary indication	Pilot Testing	Pivotal Corp. Testing	Application	Approval	Sales
EP4 antagonists GALLIPRANT®	RQ-00000007 (grapiprant)	Elanco	Dog OA (U.S.)					Start of sales (Jan.2017: U.S.)
			Dog OA (EU)					Start of sales (Mar. 2019, EU)
Ghrelin receptor Aggregate Drugs ENTYCE®	RQ-00000005 (capromorelin)	Elanco	Appetite Stimulation: Dog					Start of sales (Oct.2017: U.S.)
			Appetite Stimulation: Cat		On going			

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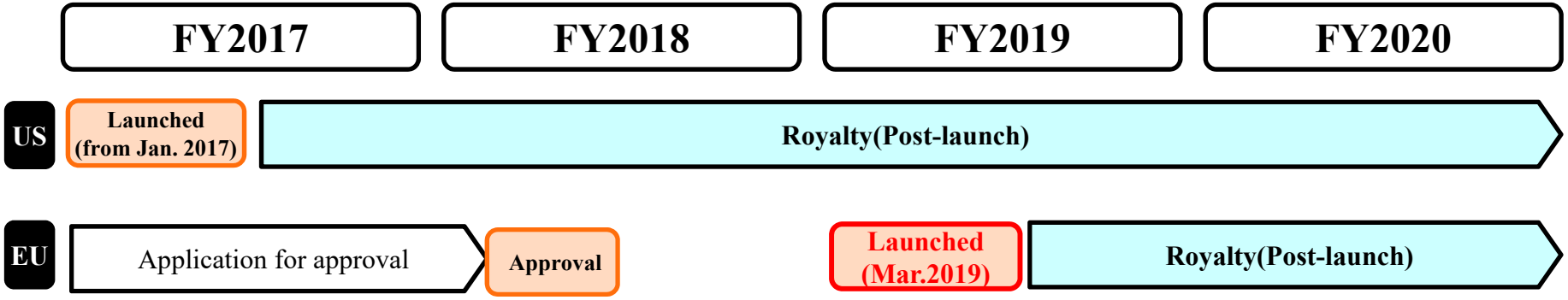
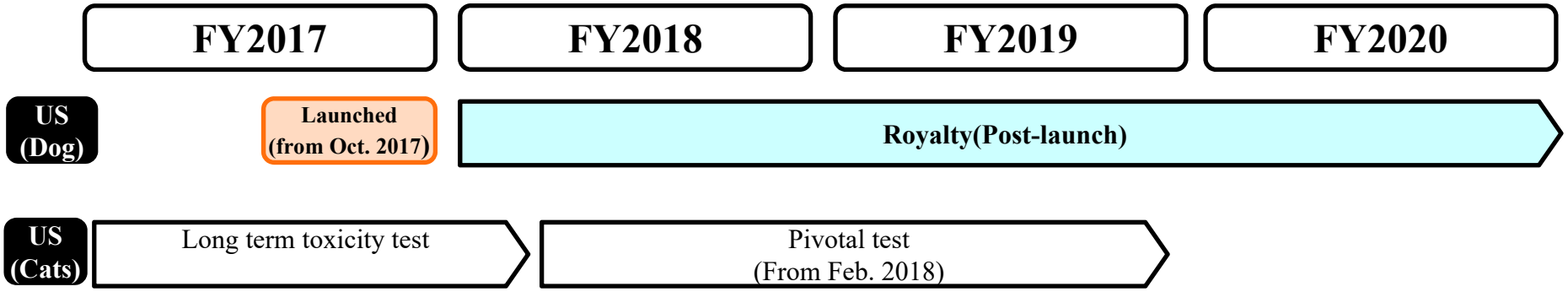
Pet Pharmaceuticals Development Roadmap

GALLIPRANT® grapiprant/RQ-00000007



ENTYCE® capromorelin/RQ-00000005



※The dotted line is scheduled.

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EP4 antagonists: GALLIPRANT®

- **Steady sales growth in U.S.**
- **Leading brand in nonsteroidal anti-inflammatory analgesic (NSAIDs)**

Indication	Dog Osteoarthritis (chronic inflammatory pain)
Features	The first EP4 antagonist in the world. Than conventional NSAIDs in areas such as gastrointestinal and kidney disorder.
Development status	・ U.S.: on sale (January 2017~) ・ Europe: received marketing authorization in January 2018 and on sale(March 2019~)
Status of out-licensing	・ Out-licensed worldwide rights for pet pharmaceuticals to Aratana ・ Aratana signed a strategic alliance with Elanco, a spin-off from Eli Lilly and Company, and Elanco acquired Aratana in July 2019.

Ghrelin receptor agonist: ENTYCE®

➢ **About half of the 25,000 U.S. veterinary clinics ordered ENTYCE®**

Indication	Appetite Stimulation (weight loss)
Features	The world's first ghrelin-agonist First FDA Approval for Anorexia An easy-to-drink oral solution that can be used both acutely and chronic.
Development status	・ U.S.: on sale (October 2017~) ・ U.S.: Pivotal Study underway due to sluggish cat appetite
Status of out-licensing	・ Out-licensed worldwide rights for pet pharmaceuticals to Aratana ・ Elanco acquired Aratana in July 2019.

Derivation Preparation Program

(As of the date of submission)

- Potassium-ion-competitor acid blocker:Completed Clinical study report on P-CAB (tegoprazan/RQ-00000004) for Phase 1 (Dec. 2016)
- Completed Clinical study report on 5-HT_4 partial agonist (RQ-00000010) for Phase 1(Oct. 2017)
- Completed Clinical study report on 5-HT_{2B} antagonist (RQ-00310941) for Phase 1 (Apr. 2018)
- Completed Pre-clinical trials on motilin-agonist (RQ-00201894) ; Phase 1 clinical trials are under consideration
- Pre-clinical trials are under consideration for the ghrelin-agonist (RQ-00433412) and TRPM8 blocker (RQ-00434739)

Project	Compound	Primary indication	Search	Pre-clinical	Clinical trials			Appli-cation	Approval	Marketing	Implementation Region
					Phase 1	Phase 2	Phase 3				
Potassium-ion competitor acid blocker (P-CAB)	RQ-00000004 (tegoprazan)	Gastroesophageal Reflux Disease (GERD)			Completed of Phase 1						U.S. Japan
5-HT_4 partial agonist	RQ-00000010	Gastroparesis Functional Dyspepsia Chronic Constipation			Completed of Phase 1						U.K.
5-HT_{2B} antagonist	RQ-00310941	D-IBS IBD-Remission Stage Syndrome			Completed of Phase 1						U.K.
Motilin agonist	RQ-00201894	Gastroparesis Functional Dyspepsia Post-Operatiue Ileus			Under consideration						Japan
Ghrelin receptor agonist	RQ-00433412	Cancer-Related Anorexia/Cachexia Syndrome		Under consideration							Japan
TRPM8-Blocker	RQ-00434739	Neuropathic pain (cold allodynia induced by chemotherapy)		Under consideration							Japan

Patent news

Date	Target	Region	Details
August 6, 2019	New applications for potassium-ion competitive acid blockers (P-CAB)	Europe	Use patent
July 23, 2019	Nav1. 7 and Nav1. 8 Sodium-blocking agents (amides)	Japan	Substance patent
April 9, 2019	Ghrelin Receptive Aggregate (Serine Derivative)	South Korea	Substance patent
November 5, 2018	Selective Sodium channel blockers (Amide derivatives)	Europe	Substance patent
June 12, 2018	Selective TRPM8 blockers (Azaspiro derivative)	United States	Substance patent
February 13, 2018	Selective Sodium channel blockers (Pyrazolopyridine derivative)	United States	Substance patent
February 13, 2018	Ghrelin receptor agonist (Serine derivatives)	Europe	Substance patent

Industry-government-academia collaboration

Our Mission on Industry-Academia – Government Collaboration

■ **Vision**

"We seek to bring people health and happiness through innovative new medications."

■ Based on the basic/clinical technologies and knowledge of **Nagoya University**, we are engaged in generating "innovative drug candidates" to address unmet medical needs. Working jointly with academia from the early stage of programs drives creating a one-stop and economical "drug discovery platform."

■ We aim to deliver innovative drug candidates with newly obtained intellectual properties through the collaboration, and to license those programs to pharmaceutical companies and bio ventures around the world.

■ We see Silicon Valley in the USA as an exemplar of our goal of becoming a leading hub for innovative drug discovery platform centered around **Nagoya University** (the Chubu area).

Certified business plan by Ministry of Economy, Trade and Industry

"Drug discovery business which raises revenue by licensing out drug candidates created from drug seeds of academia such as Nagoya university"

Frame work

Sales destination (Licensee)

Pharmaceutical companies

Bio Ventures etc

in domestic and global

Support menu

Grant

Collaboration Parties

Drug seeds/ R&D activities

Nagoya University (Nagoya Aichi)
- Drug seeds
- R&D activities (basic research・Clinical)

Market research / consulting

Seed Planning, Inc. (Bunkyo Tokyo)
- Evaluation of seeds
- Consult on market strategy for drug candidate

R&D activities / Management of IP / Licensing activities

Core Company: RaQualia Pharma Inc. (Nagoya Aichi)
- Selection of drug seeds from Academia
- R&D on new drug candidates
- Creation & management of intellectual properties
- Licensing activities for new drug candidates

Status of Industry-Academia-Government Collaboration

Search for selective inhibitors of specific enzymes for the development of drugs for refractory neuro blastoma(May.2015)

Kenji Kadomatsu,Professor of Biochemistry, Nagoya University Graduate School of Medicine

Exploration of selective inhibitors for specific protein for the purpose of development of heart failure drugs (Oct.2015)

Mitsuhito Takefuji,Assistant Professor of Cardiology Science Nagoya University Graduate School of Medicine

Search for a drug to treat nonalcoholic steatohepatitis (NASH)(Sep.2016~ ;Renewal in Oct.2018)

Takayoshi Suganami, Professor of Research Institute of Environmental Medicine Nagoya University (in the field of Molecular Metabolism)

Development of a New Drug for Treatment of Mutant KRAS Lung Cancer Using Cellular Aging (Jan.2018)

Mitsuo Sato, Professor of Nagoya University Graduate School of Medicine

Elucidation of the Mechanism of TRPM8 Blocker (RQ-00434739) at the Core (July. 2018)

Makoto Sawada , Professor of Research Institute of Environmental Medicine Nagoya University(in the field of Brain Function)

Exploration of drugs for the treatment of retinal vein occlusion (RVO) (May 2019)

Hideaki_Hara, Professor of Molecular Pharmacology, Gifu Pharmaceutical University

Initial exploratory research aimed at the creation of new therapeutic agents for ALS (ALS) (July.2019)

Mr.Hitomi Tsukiji, Hospital Eco-Chemical Sector, Graduate School of Pharmacy, Nagoya City University

Subsidiaries

TMRC Co., Ltd.: Development of TM-411

- Acute Myeloid Leukemia（AML）/Myelodysplastic Syndrome（MDS）: Following single agent Phase 2 study, combination Phase 2 study with 5-Azacitizine (Celgene) or Daratumumab, anti-CD38 antibody (J&J) is undergoing to elucidate efficacy and safety. The AML initial data are favorable.
- Breast Cancer(BC) : Plan to initiate clinical trial upon achieve POC in AML/MDS
- Neuroblastoma(NB) : Combination PI/II study with decitabine is started following single PI study.
- Acute Promyelocytic Leukemia（APL/China）: Combination therapy with arsenic trioxide in relapsed/refractory APL patients is at pre-registration for Import Approval in China.
- Neutropenia : In the course of out-license activity to expand the indication other than cancer

Indication	Out-licensing partner	Search / Pre-clinical / Clinical trials (Phase 1 / Phase 2 / Phase 3) / Appli-cation / Approval / Marketing	Contract Region
Acute Myeloid Leukemia: AML	Syros Pharmaceutical, Inc. (U.S.)	Phase 2 in progress	U.S.
Myelodysplastic Syndromes: MDS	Syros Pharmaceutical, Inc. (U.S.)	Phase 2 in progress	U.S.
Breast Cancer: BC	Syros Pharmaceutical, Inc. (U.S.)	Preparing for Phase 2	U.S.
Neuroblastoma: NB	OHARA Pharmaceutical Co.,	Phase 1/2 in progress	Japan
Acute Promyelocytic Leukemia: APL	TOKO Pharmaceutical CO.,	In progress	China
Neutropenia: NP	Out-licensiy negotiations in progress	Completed all pre-clinical testing	Asia

RaQualia Innovations Inc.

Company Name

RaQualia Innovations Inc.

Business Summary

1) Build a universe of drug candidate emerging from Academia researchers
2) Provide optimal solutions for maximizing bio venture business value
3) Support to develop orphan drugs for children
4) Establish fund to accelerate above business to going forward

Establishment

December 7, 2018

Capital

500Million JPY (Funding total 10Million JPY)

Representative Director

Kiichiro Kawada (RaQualia Pharma Inc. Executive Director & CFO)

Notes on Business Projections

- Materials and information provided in this document include forward-looking statements. These statements are based on the current expectations, projections and assumptions involving risks, and contain uncertainties that could cause the actual results to be substantially different from such statements.

- Such risks and uncertainties include general conditions of domestic and global economy such as general industry and market conditions, interest rate, changes in exchange rates. Particularly, risks and uncertainties exist in forward-looking statements related to products (R&D programs and compounds). Risks and uncertainties of products include, but not limited to, technical progress, acquisition of patents by competitors, completion of clinical trials, claims and concerns regarding safety and efficacy of products, approval by regulatory authority, health-care insurance reforms within and outside Japan, tendency to contain medical expenses, laws and regulations of the government affecting businesses within and outside Japan, challenges associated with new product development.

- The Company does not undertake to update or revise any forward-looking statements contained in this document, whether as a result of new information, future events, or otherwise.

Note: This document has not been prepared for the solicitation of investments. In making any investments, investors are kindly required to base their decisions on their own judgments. Please be sure to read the notes at the end of this paper, without fail.

RaQualia
innovators for life

Contact Information

Please use our website.
https://www.raqualia.co.jp/(Link)

RaQualia Pharma Inc.