RaQualia
innovators for life

JPX
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Business Plan
Odyssey 2018
January 1, 2017-December 31, 2019

May 11th, 2017
Tokyo Stock Exchange(TSE) 4579

RaQualia Pharma Inc.

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Company Overview

As of Announcement date

Company Name

RaQualia Pharma Inc.

President and CEO

Naoki Tani

Business Summary

Discovery and development of pharmaceutica
Licensing of intellectual properties for pharma

Employees(Consolidated)

57

Establishment

February 19, 2008

Capital Fund

2.23 billion yen

Outstanding Shares

19,246,450



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Company Name	**RaQualia Pharma Inc.**
Security ID Code	**4579　(JASDAQ Growth)**
URL	**http://www.raqualia.com**

【Contact】

President and CEO	**Naoki Tani**
Director and Executive Vice President	**Kiichiro Kawada**
Telephone	**+81-52-446-6100**

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(1)Previous Fiscal Year's Summary

■ Business revenue totaled 705 million yen (384.7% increase over the previous year)

- Business revenue for the period was 705 million yen including milestone payments from a licensed partner triggered by manufacturing and sales approval in the USA and Europe.

- Total business expenses were 1,465 million yen and accumulated operating loss totaled 759 million yen as a result of implementation of voluntary retirement program, salary and cost reduction and postponement of conclusion of a clinical trial.

- Due to sharp appreciation of the yen, accumulated foreign exchange losses regarding foreign currency deposits and receivables in foreign currency were 55 million yen, with the result that net loss was 728 million yen for the period.

■ Steady progress of Discovery research projects

- Three collaborative research activities for ion channel targets are proceeding as planned.

- TRPM8 blocker project for treatment of neuropathic pain advanced to preclinical research.

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(2) Business Highlight for FY2016

In-house development/Academia-industry collaboration

- Continued Phase I clinical trial for 5-HT_{2B} antagonist (RQ-00310941) with therapeutic potential for treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) in the UK.

- Investigator-initiated clinical trial for RQ-00000010 is underway for Parkinson's disease patients at Virginia Commonwealth University, while obtaining a grant from the Michael J. Fox Foundation for the project.

- Started research collaborations with Nagoya University for treatment of Non-Alcoholic Steatohepatitis (NASH) and with Gifu Pharmaceutical University for treatment of retinal diseases respectively.

Ongoing clinical trials conducted by a licensed partner (Animal drugs)

- Galliprant® (grapiprant/RQ-00000007) – Launched in January 2017 following approval with the FDA.
- Galliprant® (grapiprant/RQ-00000007) – Application for approval is under evaluation by the EMA.
- Entyce® (capromorelin/RQ-00000005) – Preparation for launching is underway following approval with the FDA.

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(3) Business Highlight for FY2016

■ Ongoing clinical trials conducted by licensed partners (Development)

- Potassium-competitive acid blocker (tegoprazan/RQ-00000004) :
  CJ HealthCare Corporation is conducting a Phase III clinical trial in Korea and preparation for clinical development in China is underway.

- Ziprasidone (serotonin 5-HT_{2A} and dopamine D_2 receptor antagonist):
  Meiji Seika Pharma Co., Ltd. is conducting a Phase III clinical trial in Japan.

■ Others

- Sustained strong intellectual property rights: 9 new patents were granted.

- Adopted as an eligible project for “New Aichi Creation Research and Development Grant in 2016”.

- Received 19 million yen as a first-year grant money from METI (the new business partnership support program).

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(4) Basic Policy and Outline of Mid-Term Business Plan①

【Basic Policy of the Mid-Term Business Plan】

- **Realization of Corporate Vision**

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

- **Propose and implement practical measures to ensure business stability and increase shareholder value.**

【Outline of the Mid-Term Business Plan】

- **Establish and strengthen a drug discovery platform aimed at accelerating licensing-out**
  - Continue and strengthen innovative drug discovery collaboration with academia
  - Promote collaborative research with external organizations to generate new drug development candidates.
  - Constantly deliver new drug candidates utilizing in-house assays.

- **Establish an effective licensing-out framework by re-examining development strategy**
  - Ensure receipt of milestones and royalties through robust alliance management in the medium- and long-term.
  - Concentrate management resources on establishing an effective licensing-out framework for existing pipelines.

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(5) Basic Policy and Outline of Mid-Term Business Plan②

【Outline of the Mid-Term Business Plan】

- **Establish an effective business framework with the concentration of management resources and continue cost-reduction efforts**
  - Re-examine fixed expenses and continue cost-cutting efforts

- **Management stability and business continuity**
  - Consider and implement financing strategies to secure business continuity during the period without steady income
  - Promote strategic capital (operational) alliances
  - Consider and implement merit-based incentive programs for employees

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(6)Measures to increase Shareholder value①

Promptly monetize key licensed-out programs through robust alliance management

- Support Aratana Therapeutics, Inc. in its launch of animal drugs (RQ-5: Ghrelin receptor agonist) in Europe and the United States.
- Support Aratana Therapeutics, Inc. in its launch of animal drugs (RQ-7: EP4 antagonist) in Europe.
- Support CJ HealthCare Corporation in its ongoing Phase III clinical trial and a new-drug application for RQ-4 (Potassium-competitive acid blocker/tegoprazan).
- Support Meiji Seika Pharma Co., Ltd. in its ongoing Phase III clinical trial and a new-drug application for ziprasidone.

Accelerate drug discovery through research collaboration with academia (Nagoya University) and business partners

- Promote research collaboration with Nagoya University on specific research themes and access to public funding.
- Speed up collaborative research with EA Pharma Co., Ltd/Asahi Kasei Pharma Corporation/XuanZhu Pharma Co., Ltd. toward the advancement of development compounds.
- Seek for new collaboration partners focused on ion channel drug discovery

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(7)Measures to Increase Shareholders Value②

Promote in-house development of GI programs with the aim of monetizing the achievements via licensing-out

- License out RQ-4 (Potassium-competitive acid blocker/tegoprazan) for the Japan, Europe and the United States.
- Advance the investigator-initiated clinical trial for RQ-10 (5-HT_4 partial agonist) at VCU and License out for the Japan, Europe and the United States.
- Improve the program value of 5-HT_{2B} antagonist through in-house development
- License out motilin receptor agonist at the early stage of development.
- Consider and Initiate pre-clinical studies for ghrelin receptor agonist/TRPM8 blocker.
- Activate research initiatives with Chinese partners for GI programs.

Consider and implement financing strategies to secure business continuity during the period without steady income

- Maintain fund balance at the level of 3.0billion yen at each fiscal year end.
- Running costs should be basically covered by business revenue and cost reduction measures.
- Propose and implement financing strategies with a convincing equity story based on shareholder value.

Strengthen intellectual property strategies

- Implement intellectual property strategies with the objective of monetizing patents

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(1) Our Mission on Industry-Academia Collaboration

Vision

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

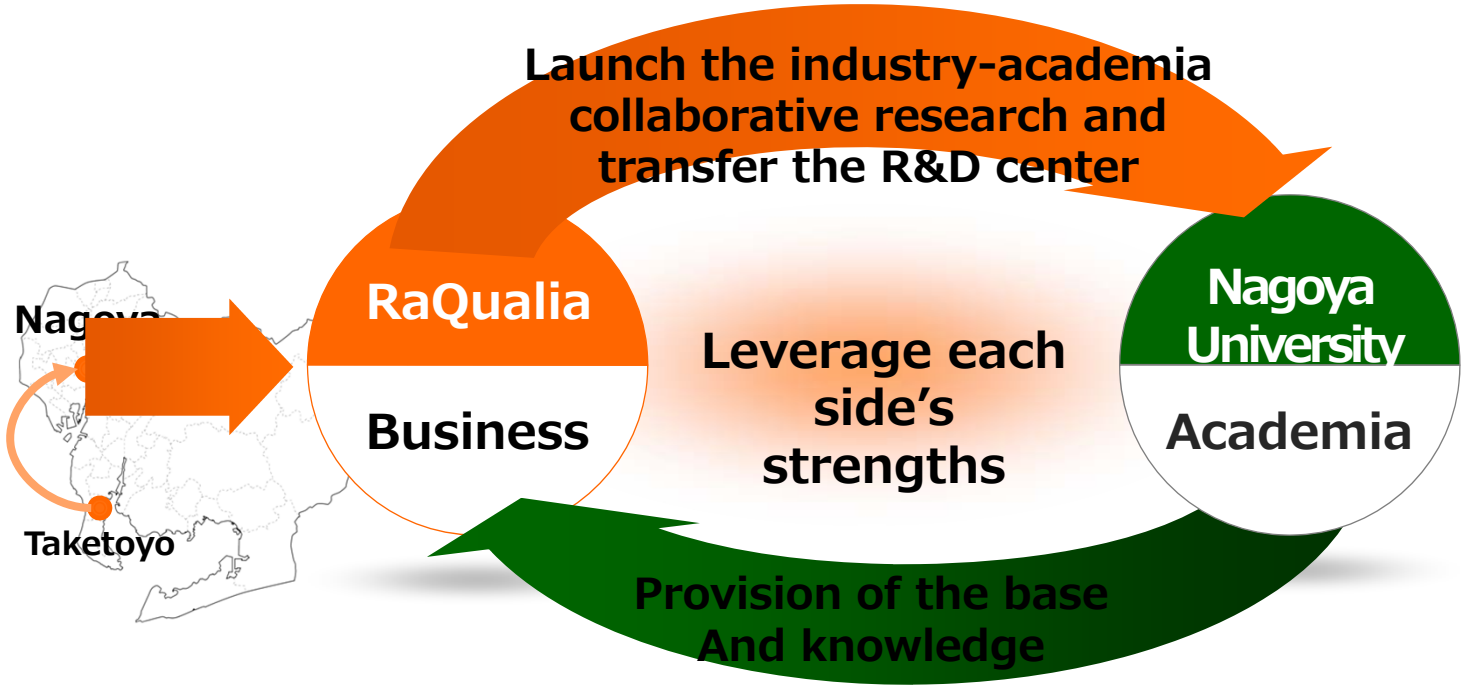
- Based on the basic/clinical technologies and knowledge of Nagoya University, we are engaged in generating "innovative drug candidates" to address unmet medical needs. Working jointly with academia from the early stage of programs drives creating a one-stop and economical "drug discovery platform."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

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(2) Acceleration of Drug Discovery Research by the Industry-Academia-Government Collaboration

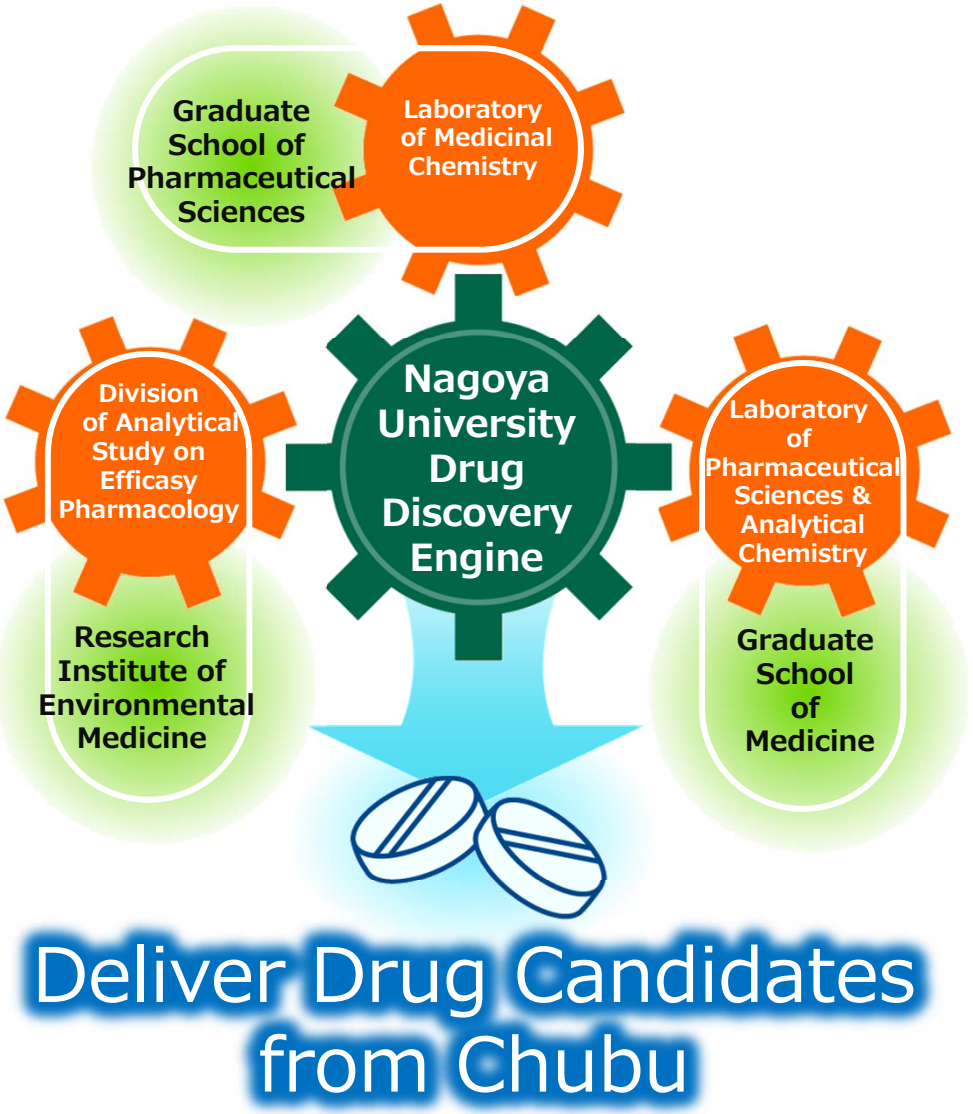
- 3 Research Laboratories establish in Nagoya University from 2014 through 2015.
- Completed transfer the R&D center.



Capitalize on the collaboration with academia and accelerate the drug discovery research

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(3)Roles of Research Laboratories at Nagoya University



The Industry-Academia Collaborative Research

Division of Analytical Study on Efficacy Pharmacology

1. Evaluate drug efficacy and mechanism of action
2. Study pharmacological effect

Laboratory of Medicinal Chemistry

1. Design candidate compounds and study synthetic chemistry
2. Explore and optimize new drug candidates

Laboratory of Pharmaceutical Sciences & Analytical Chemistry

1. Explore, examine and practice
2. Perform risk analysis on drug candidates and seek solutions
3. Develop a drug discovery platform that provides compounds quickly

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(4)2016 Achievement – News on Research Collaboration with Nagoya University①

Faculty of Genome Dynamics, RIeM

- Exploration of selective blockers targeting DNA Polymerase eta

Department of Biochemistry, Graduate School of Medicine

- Exploration of selective blockers targeting specific enzymes for treatment of refractory neuroblastoma.

Department of Pathology and Biological Responses, Graduate School of Medicine

- Exploration of selective blockers targeting connective tissue growth factors (CTGF) for treatment of malignant mesothelioma

Department of Nephrology, Internal Medicine, Graduate School of Medicine

- Exploration of small molecule compounds inducing the secretion of cytokines and growth factors from adipose-derived stem cells

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(5)2016 Achievement – News on Research Collaboration with Nagoya University②

Graduate School of Bioagricultural Sciences

- Antibody production by gene transfer method using chicken

Department of Cardiovascular Medicine

- Exploration of selective blockers targeting specific proteins for treatment of cardiac failure

Institute of Transformative Bio-Molecules (ITbM)

- Exploration of small molecule compounds that regulate circadian rhythms

Exploration of small molecule compounds that regulate circadian rhythms

- Research for a non-alcoholic steatohepatities(NASH) treatment drug

Initiation of 8 collaborative research projects and Offering New Research Subject with Nagoya University (3times per year)

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(6)METI New Drug Discovery Business Framework

"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

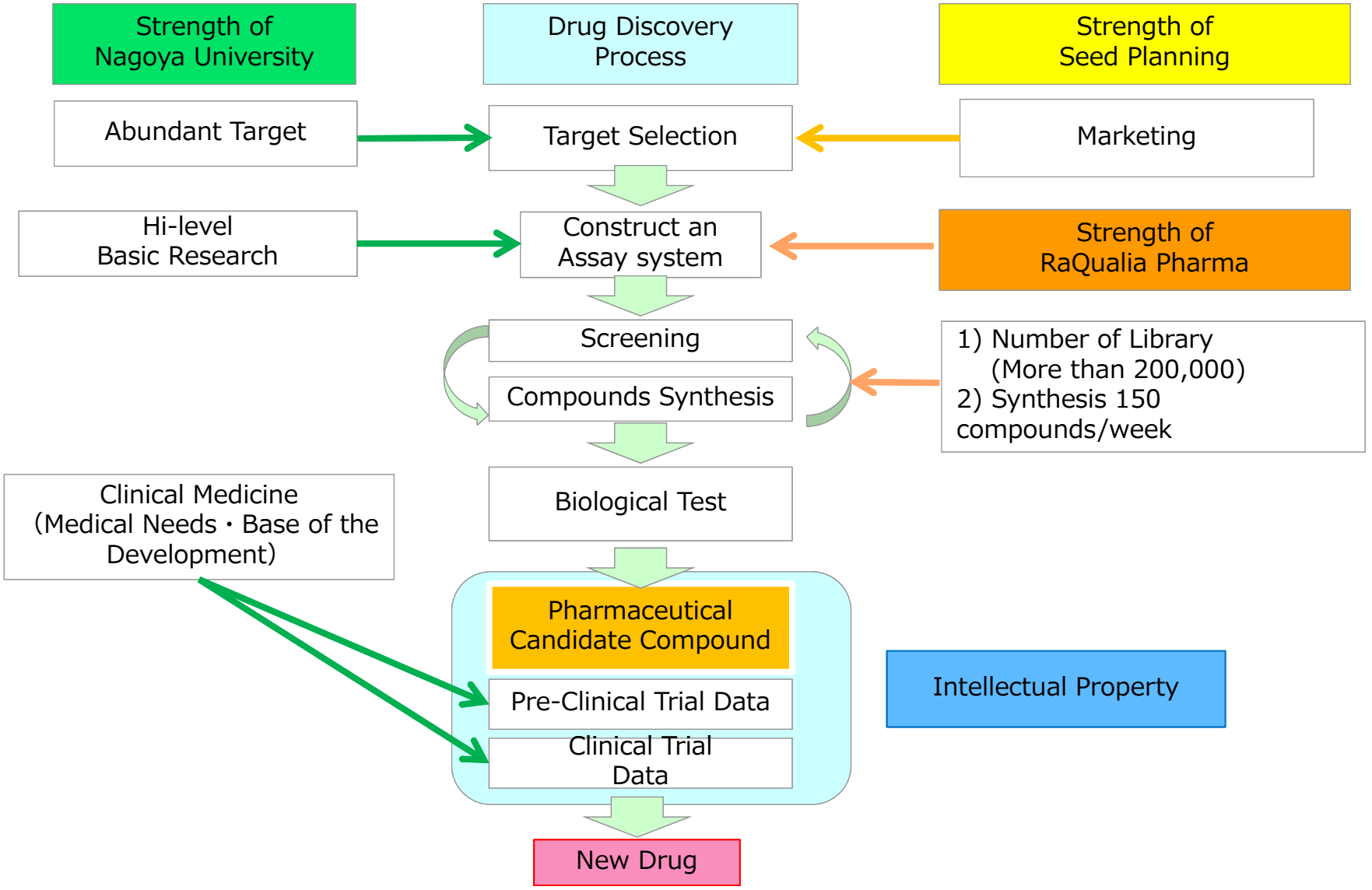
Core Company：RaQualia Pharma Inc. (Nagoya Aichi)
- Selection of drug seeds from Academia
- R & D on new drug candidates
- Creation & management of intellectual properties
- Licensing activities for new drug candidates

Received a subsidy 19 million yen of the first year in 2016.
Aim the continued subsidies received.

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(7) To Provide a Process of Drug Discovery Process more Efficient than heretofore.



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(1) This Term's Earnings Forecast and Future Earnings Targets (Summary)

(Unit ; 1 million yen)	Full FY 2016 (Result)	Full FY 2017 (Plan)	Full FY 2018 (Target)	Full FY 2019 (Target)
Operating Revenue	705	1,176	1,291	1,688
Operating Income	(759)	(791)	(263)	128
Ordinary Income	(720)	(777)	(265)	127
Current Term Net Income	(728)	(778)	(271)	121

Profit

Royalty

- Upfront payment by license out of new program
- Upfront payment by right geographic or indication expansion
- Upfront payment or study cooperation money by collaboration research
- Milestone payment by step up to the next development stage

Cost

- Active investment in R&D to industry-academia collaboration
- Cost effective capital investment

※Unconsolidated: Full FY 2016
Consolidated: Full FY 2017, Full FY 2018, Full FY 2019

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(2)Outline of Business Expense

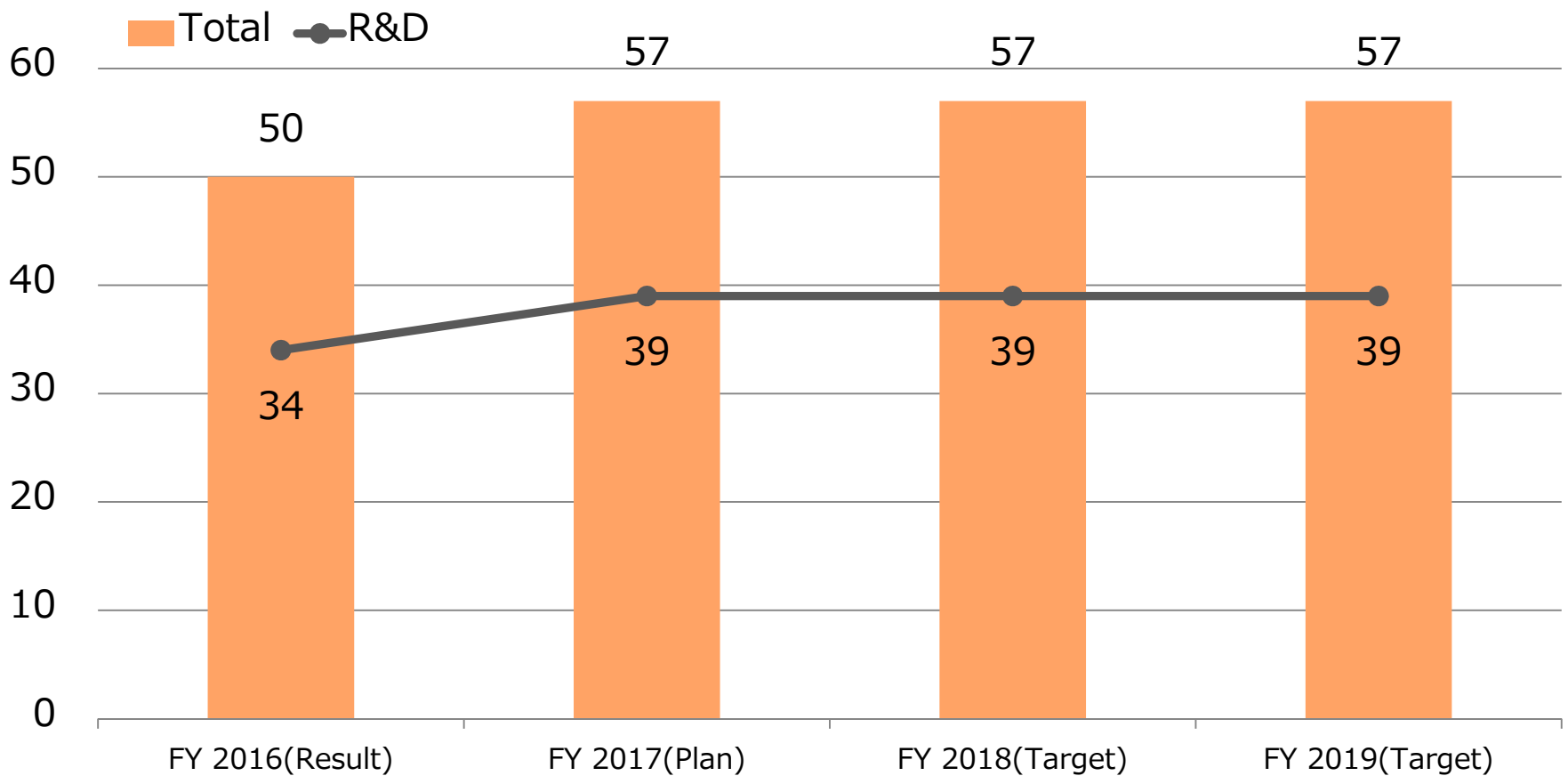
(Unit ; 1 Million yen)	FY 2016 (Result)	FY 2017 (Plan)	FY 2018 (Target)	FY 2019 (Target)
Business Expense	1,465	1,968	1,554	1,559
Personal	534	567	558	557
R&D	277	628	318	308
Royalty Payment, etc	117	145	121	153
Administrative Control	249	296	254	254
Facility Related	155	181	179	182
Others	133	151	124	105

Fiscal Year Ending December 31, 2017	R&D : Phase 1 Clinical trial（RQ-941） Royalty Payment, etc : Temporary Increase with the Milestone. Administrative Control : Phase 1 Clinical trial Ancillary Expense（RQ-941）
Fiscal Year Ending December 31, 2018	Royalty Payment, etc : Temporary increase with the Milestone, and Payment with the royalty.
Fiscal Year Ending December 31, 2019	Royalty Payment, etc : Payment with the royalty.

※Unconsolidated: Full FY 2016
Consolidated: Full FY 2017, Full FY 2018, Full FY 2019

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(3) Trend of the Manpower Planning and Research and Development Capacity



The scale of the Research and Development Department's personnel will be maintained at 30-40 people

※Unconsolidated: Full FY 2016
Consolidated: Full FY 2017, Full FY 2018, Full FY 2019

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(4)Financing Plan

Basic Principle

- Maintain fund balance at the level of 3.0 billion yen 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.

Actual (cash and deposits, investment securities etc.)

- Actual fund balance at the end of FY2016: 3.4 billion yen

Financing Methods

- Public stock offerings (domestic/global)
- Allocation of new stocks to a third party
- Consider a new way of financing (e.g. financing per project)
- Financing with effective use of assets held (Consider selling PETX stocks: 103,088

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

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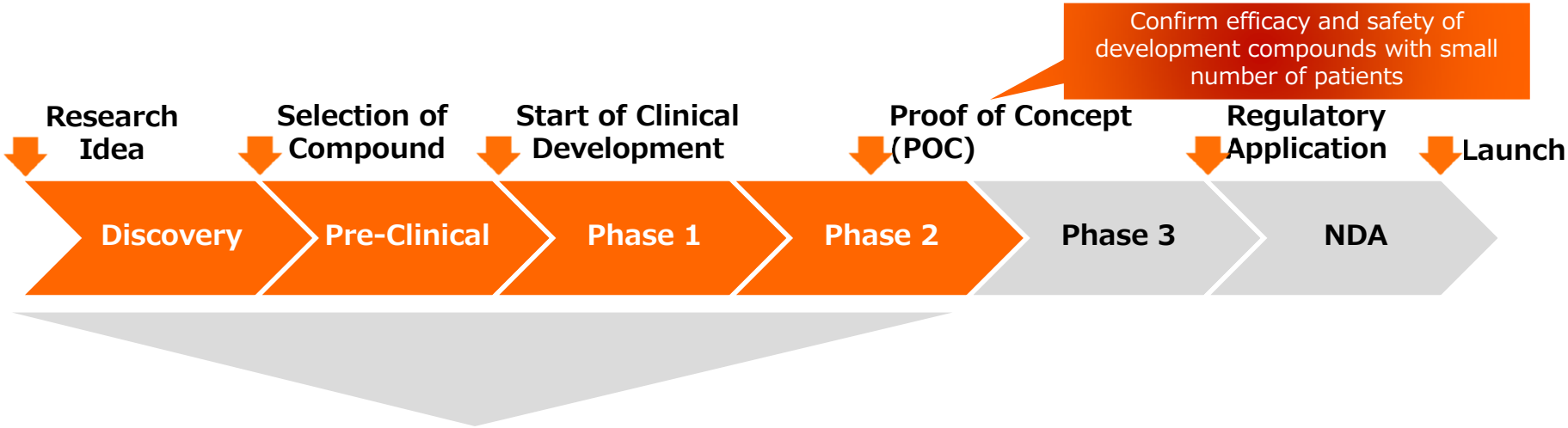
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(1)Business Domain and Strategy



Business Domain	Our business focus extends from discovery research to proof of concept (POC)
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.

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(2)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**

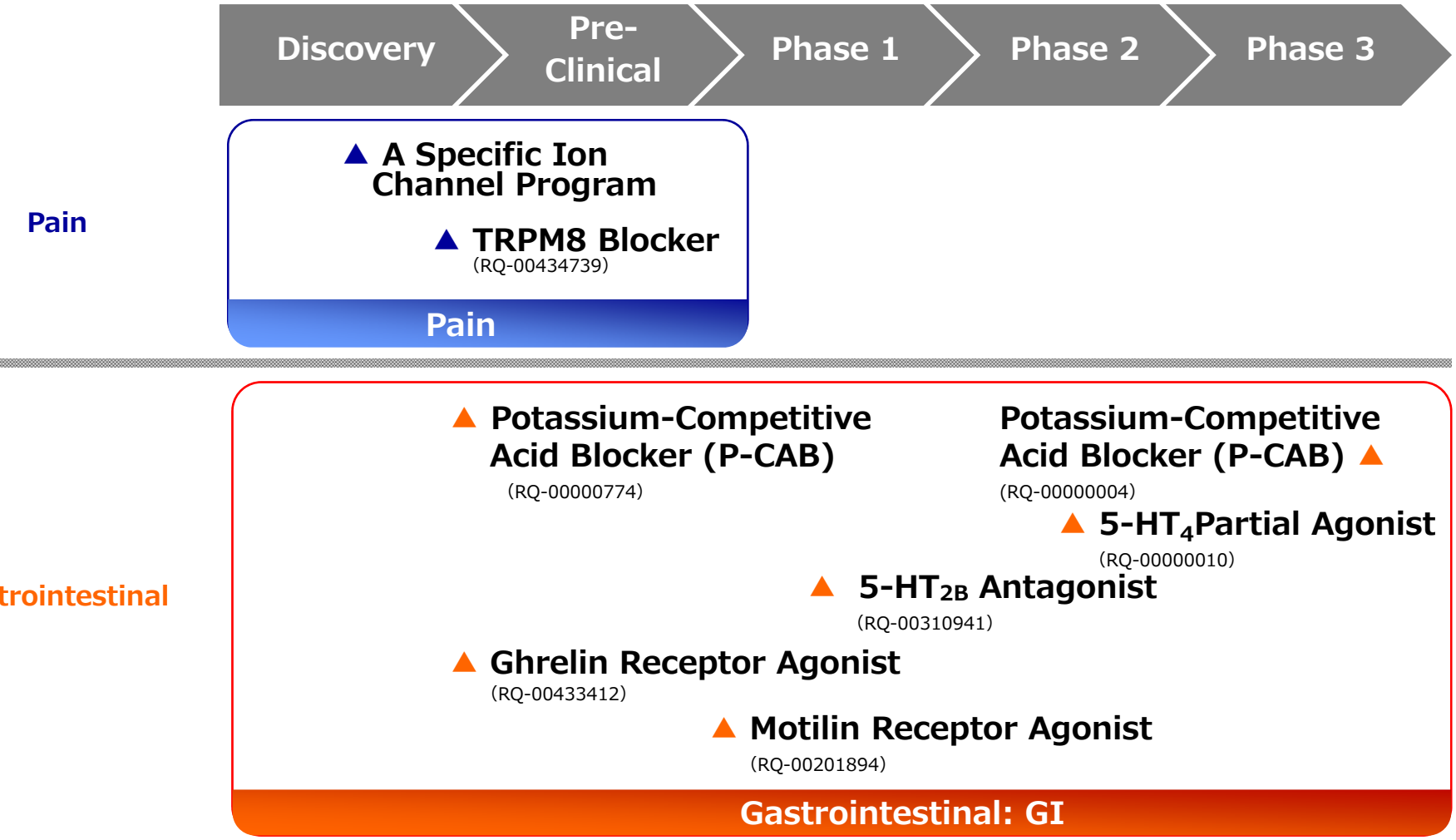
Based on the rich resources, we will efficiently conduct the exploratory research and development and aim to create development compound

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(3)Licensing Out Preparation Program Situation

As of Announcement date



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(4) Licensing Out Preparation Program : Pain

As of Announcement date

- TRPM8 Blocker （RQ-00434739） has completed investigation of preclinical efficacy and has not detected any inadequacy for moving on to next stage of performing preclinical development study.
- Selective Sodium Channel Blocker has continued to examine a suitable administration method.

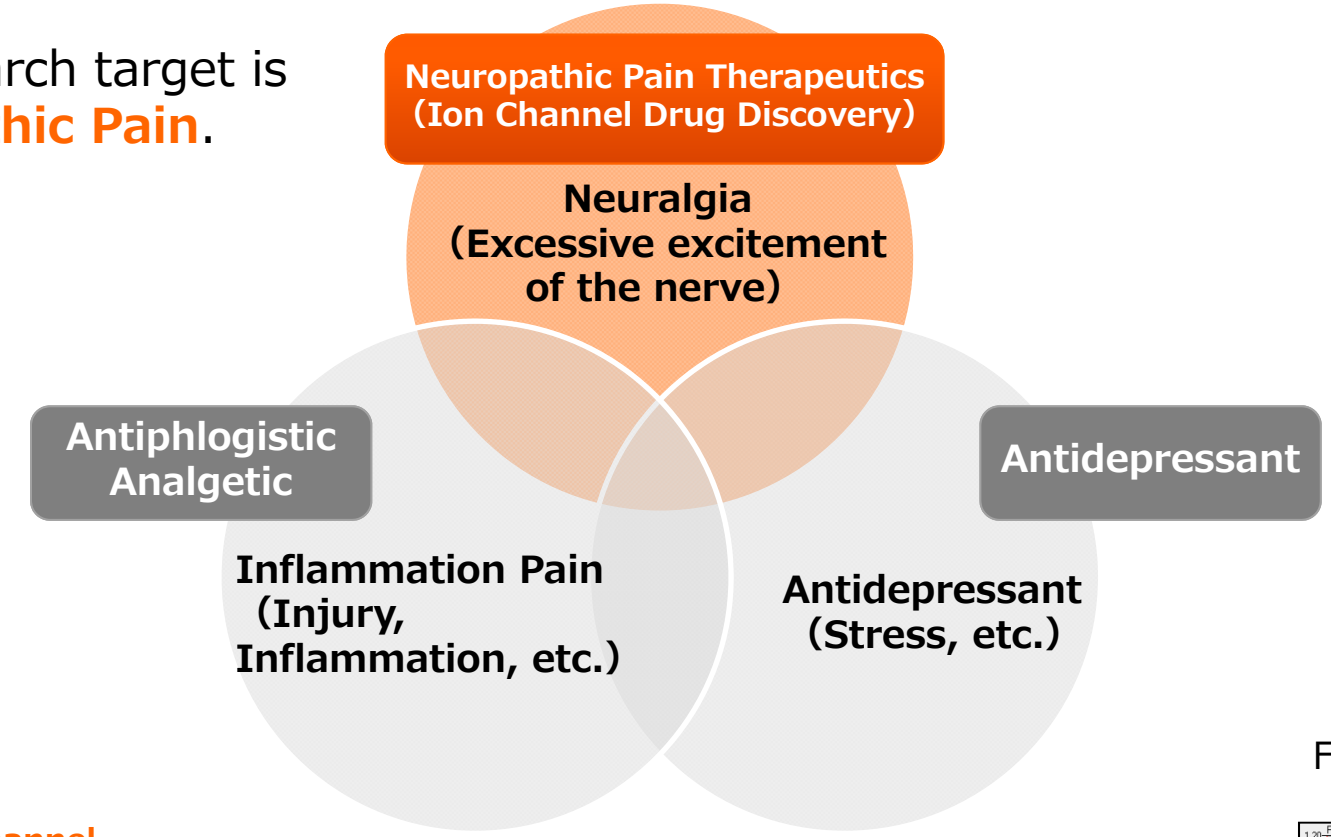
Project	Compound	Indication	Discovery	Pre-Clin,	Clinical Studies P1	Clinical Studies P2	Clinical Studies P3	NDA	Approval	Sales	Area
TRPM8 Blocker	RQ-00434739	Neuropathic pain		On Planning							Japan
Selective Sodium Channel Blocker	–	Neuropathic pain	Discovery								Japan

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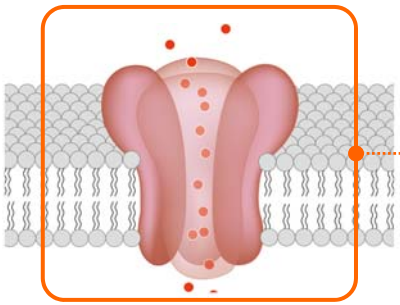
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(5)About Ion Channel

Our Research target is **Neuropathic Pain**.



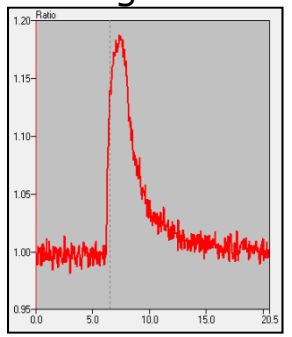
Ion Channel



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



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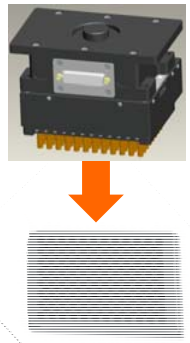
(6) Ion Channel Drug Development (Our Superiority)

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.

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(7)Research Collaboration Program

As of Announcement date

- Collaboration on a specific ion-channel target for gastrointestinal treatments with EA Pharma is on going.
- Collaboration on a specific ion-channel in the pain treatments with Asahi Kasei Pharma is on going.
- Collaboration on a specific ion-channel in the pain treatments with XuanZhu Pharma is on going.
- Collaboration in a specific protein-protein interaction(PPI) inhibitor for pain treatments with Interprotein is on going.

Project	Compound	Indication	Discovery	Pre-Clin	Clinical Studies P1	Clinical Studies P2	Clinical Studies P3	NDA	Approval	Sales	Licensee	Territory
Ion Channel	On Identity Test	Gastrointestinal	● On-going								EA Pharma	Japan
	On Identity Test	Pain	● On-going								Asahi Kasei Pharma	Japan
	On Identity Test	Pain	● On-going								XuanZhu Pharma	China
protein-protein interaction inhibitor	On Identity Test	Pain	● On-going								Interprotein	Japan

※Formed EA Pharma Co., Ltd through a merger between Eisai Co., Ltd. GI unit and Ajinomoto Pharmaceuticals Co., Ltd. since April 1, 2016.

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(8)Licensing Out Preparation Program : Gastrointestinal

As of Announcement date

- Completed a Phase I clinical study for Potassium-Competitive Acid Blocker (tegoprazan/RQ-00000004) in Japan
- Planning of global Phase II clinical study for 5-HT_4 Partial Agonist (RQ-00000010)
- Phase1 clinical study for 5-HT_{2B} Antagonist （RQ-00310941） is on going in United Kingdom since July, 2015.
- Completed non-clinical studies for Motilin Receptor Agonist （RQ-00201894）.
- Ghrelin Receptor Agonist （RQ-00433412） is advanced to Pre-clinical Stage and is preparing Pre-clinical studies.

Project	Compound	Indication	Discovery	Pre-Clin	Clinical Studies P1	Clinical Studies P2	Clinical Studies P3	NDA	Approval	Sales	Territory
Potassium-Competitive Acid Blocker (P-CAB)	RQ-00000004 (tegoprazan)	RE/NERD			Completed						USA Japan
5-HT_4 Partial Agonist	RQ-00000010	Gastroparesis FD Chronic Constipation				On planning					UK
5-HT_{2B} Antagonist	RQ-00310941	IBS-D			On going						UK
Motilin Receptor Agonist	RQ-00201894	Gastroparesis FD Post - operative Ileus		Completed Pre-Clinical							Japan
Ghrelin Receptor Agonist	RQ-00433412	Anorexia associated with cancer	On Planning								Japan

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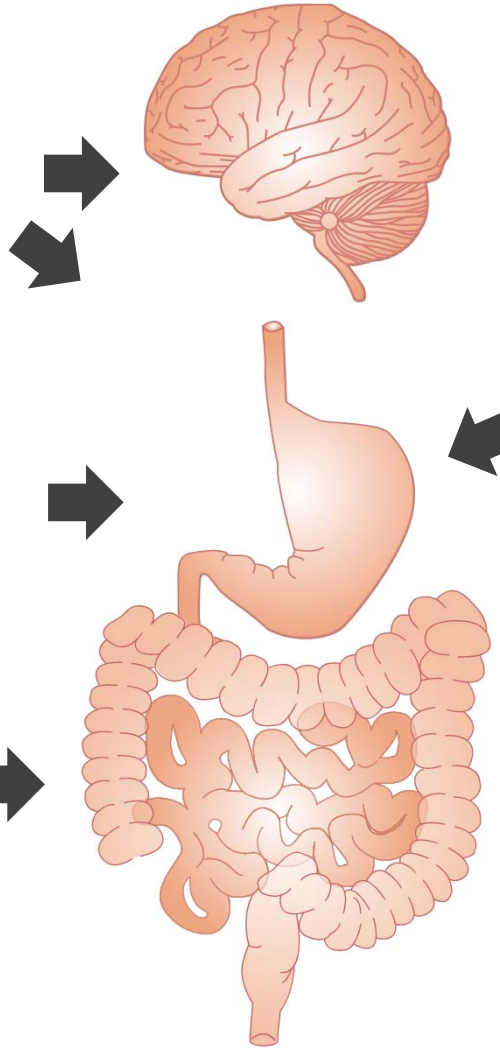
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(9)Gastrointestinal Franchise

Increase in Appetite and Gastrointestinal Motility
- Ghrelin Receptor Agonist
  (RQ-00000005)
  (RQ-00433412)

Restoration of Impaired Upper Gastrointestinal Motility in the Inter-digestive State
- Motilin Receptor Agonist
  (RQ-00201894)

Attenuation of Visceral Hypersensitivity and Excessive Colonic Motility
- 5-HT_{2B} Antagonist
  (RQ-00310941)



Suppression of Gastric Acid Secretion
- Potassium-competitive acid blocker
  (RQ-00000004)

Acceleration of Gastrointestinal Motility
- 5-HT_4 Partial Agonist
  (RQ-00000010)

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(10) Potassium-competitive acid blocker: tegoprazan/RQ-00000004

Indications	Gastroesophageal reflux, Peptic ulcer, etc
Advantage	RQ-4 suppress gastric acid strongly earlier than existing Proton pump inhibitor(PPI)
Progress	On going Phase Ⅲ Clinical Study in Korea Completed Phase Ⅰ Clinical Study in Japan
Licensing	Intellectual property of Korea and East Asia to CJ Health Care(CJHC) CJHC contracts Sub-license agreement in China with Luoxin Pharma

Topix

March 2013　Receive a patent allowance for Compound Patent in USA
May 2015　Start Phase Ⅲ Clinical trial in Korea(CJHC)
June 2015　Receive a Patent Allowance for new usage patent in Japan
July 2015　Completed Phase Ⅰ Clinical trial in Japan(RaQualia)
January 2016　The compound named “tegoprazan” as International Nonproprietary Name

The market scale of the target sector 2 trillion yen.
RQ-4 aim at recapture of the market share from PPI.

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(11)5-HT_4 Partial Agonist : RQ-00000010

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.

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(12)Other Gastrointestinal Program

1

5-HT_{2B} Antagonist（RQ-00310941）:On going Phase 1 in UK

- 5-HT_{2B} antagonist is involved in gastrointestinal motility and perception. This compound with high activity and selectivity has the potential to be an effective drug for treating IBS-D.
- Phase I clinical trial is underway in UK.

2

Motilin Receptor Agonist（RQ-00201894）: Completed Pre-Clinical

- Motilin has a critical role as a gastrointestinal hormone in maintaining homeostasis in gastrointestinal motility. This compound with high activity and high selectivity has the potential to be an effective drug for treating gastroparesis, post-operative ileus and functional dyspepsia.
- The company will decide whether to progress into a Phase I clinical trial or to license at this stage.

3

Ghrelin Receptor Agonist（RQ-00433412）: Planning Pre-Clinical

- Ghrelin, a gut hormone, plays a role in promoting appetite. This compound with high activity and selectivity has the potential to be an effective drug for treating cancer-related anorexia and cachexia.
- Pre-clinical study is under consideration.

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(13) Licensing Out Preparation Program : Other

As of Announcement date

- The Company is now in the process of having consultations with the view to licensing out the agent in Japan. This agent was put on the U.S. market as a drug to treat acute bacterial skin and skin structure infections(ABSSSI) under the trademark of DALVANCE™. In Europe, in the March 2015, we obtained regulatory approval for the distribution of this agent under the trademark of XYDALBA™.

Project	Compound	Indication	Discovery	Pre-Clin	Clinical Studies P1	Clinical Studies P2	Clinical Studies P3	NDA	Approval	Sales	Territory
Glycopeptide anti-MRSA antibiotic	Dalbavancin	Acute Bacterial Skin, Skin Structure Infections		On Planning							Japan

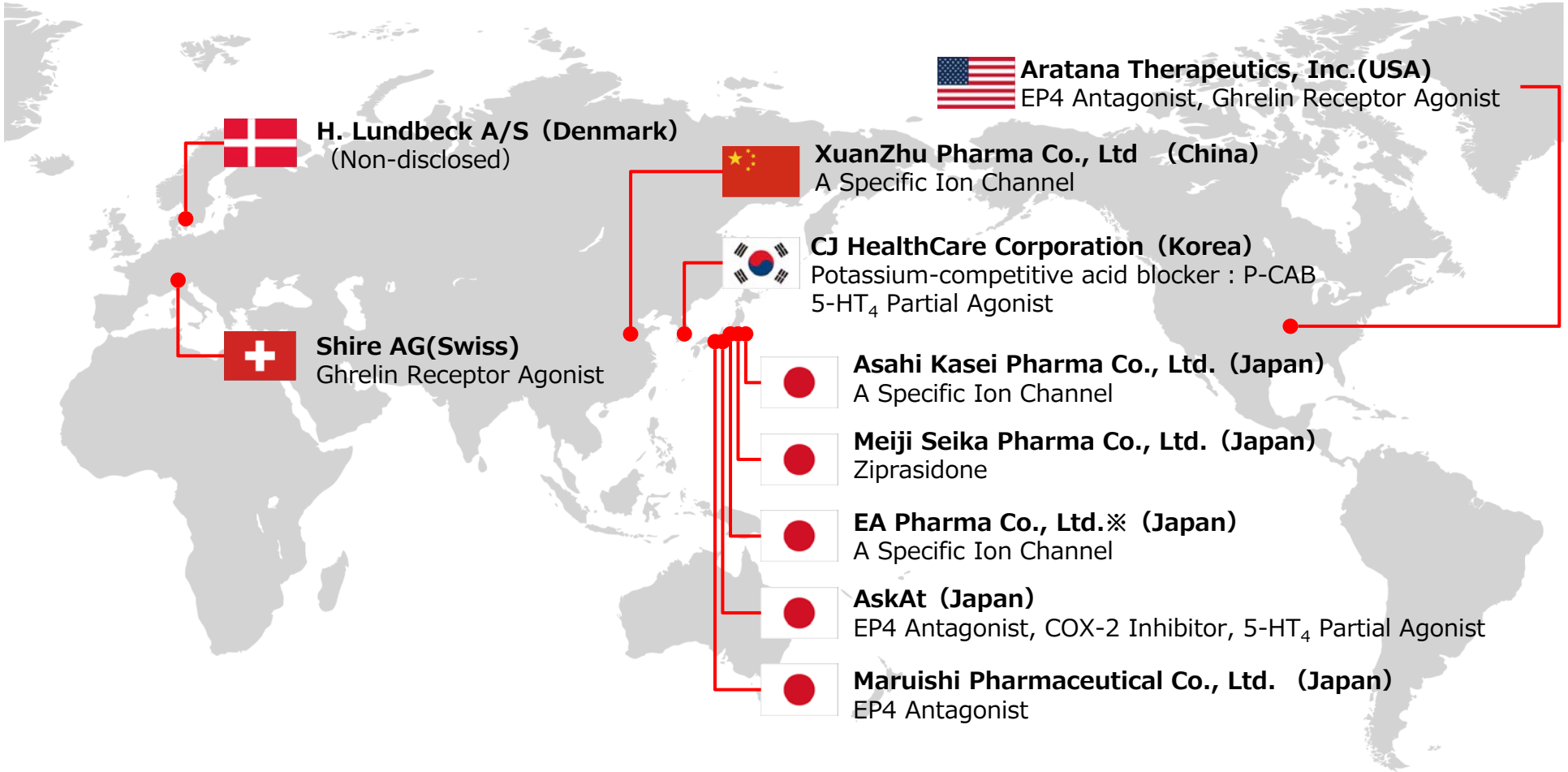
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(14)Licensed Out Program

As of Announcement date

Conclude 14 licensing agreement and Collaborative Research Contract with 10 companies in 6 countries of the world.



Aratana Therapeutics, Inc.(USA)
EP4 Antagonist, Ghrelin Receptor Agonist

H. Lundbeck A/S（Denmark）
（Non-disclosed）

XuanZhu Pharma Co., Ltd （China）
A Specific Ion Channel

CJ HealthCare Corporation（Korea）
Potassium-competitive acid blocker : P-CAB
5-HT_4 Partial Agonist

Shire AG(Swiss)
Ghrelin Receptor Agonist

Asahi Kasei Pharma Co., Ltd.（Japan）
A Specific Ion Channel

Meiji Seika Pharma Co., Ltd.（Japan）
Ziprasidone

EA Pharma Co., Ltd.※（Japan）
A Specific Ion Channel

AskAt（Japan）
EP4 Antagonist, COX-2 Inhibitor, 5-HT_4 Partial Agonist

Maruishi Pharmaceutical Co., Ltd. （Japan）
EP4 Antagonist

※Formed EA Pharma Co., Ltd through a merger between Eisai Co., Ltd. GI unit and Ajinomoto Pharmaceuticals Co., Ltd. since April 1, 2016.

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(15)Key Licensed Out Program Status

As of Announcement date

Program	Compound	Licensee	Territory
5-HT_{2A}/D_2 Antagonist	Ziprasidone	Meiji Seika Pharma	Jpn
Potassium-competitive acid blocker : P-CAB	RQ-00000004 (tegoprazan)	CJ HealthCare	Korea, China, Taiwan Southeast Asia
	RQ-00000774		
Ghrelin Receptor Agonist	RQ-00000005 (capromorelin)	Aratana Therapeutics	Global(Animal)
EP4 Antagonist	RQ-00000007 (grapiprant)	Aratana Therapeutics	Global(Animal)
		Maruishi Pharmaceuticals	Jpn, Korea, China, Taiwan(i.v. formulation)
		AskAt	Global (Other than the above)
	RQ-00000008	AskAt	Global
5-HT_4 Partial Agonist	RQ-00000009	AskAt	Global
	RQ-00000010	CJ HealthCare	Korea, China, Taiwan, India and Southeast Asia
COX-2 Inhibitor	RQ-00317076	AskAt	Global

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(16)Pipeline Situation : Human Domain

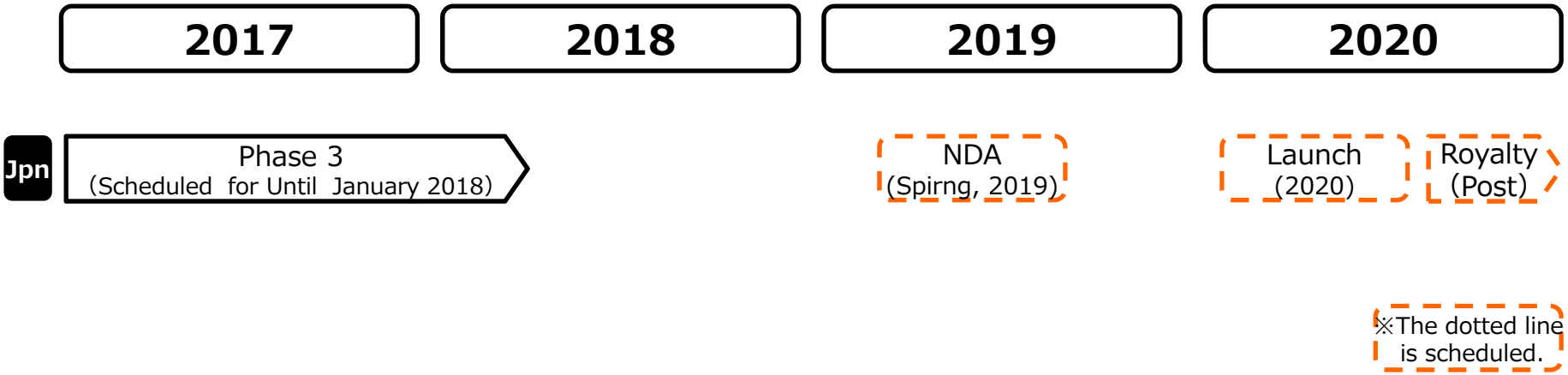
As of Announcement date

Projcet	Compound	Licensee	Indication	Discovery	Pre-Clin	Clinical Studies P1	Clinical Studies P2	Clinical Studies P3	NDA	Approval	Sales
Ziprasidone	RQ-00000003	Meiji Seika Pharma	Schizophrenia, Bipolar disorder					On going (March, 2015 : Jpn)			
Potassium-competitive acid blocker (P-CAB)	RQ-00000004 (tegoprazan)	CJ HealthCare	RE/NERD					On going (May, 2015 : Jpn)			
	RQ-00000774	CJ HealthCare	RE/NERD			On Planning					
EP4 Antagonist	RQ-00000007 (grapiprant)	AskAt	Autoimmune Disease, Allergy, Oncology				On Planning (Cancer : USA)				
		AskAt	Osteoarthritis				Completed P2a				
		Maruishi Pharmaceticals	Postoperative pain (i.v. formulation)			On Planning					
5-HT_4 Partial Agonist	RQ-00000010	CJ HealthCare	Gastroparesis, Functional dyspepsia			On Planning					
COX-2 Inhibitor	RQ-00317076	AskAt	Acute Pain				Completed P2a				

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(17)Development Roadmap: Ziprasidone

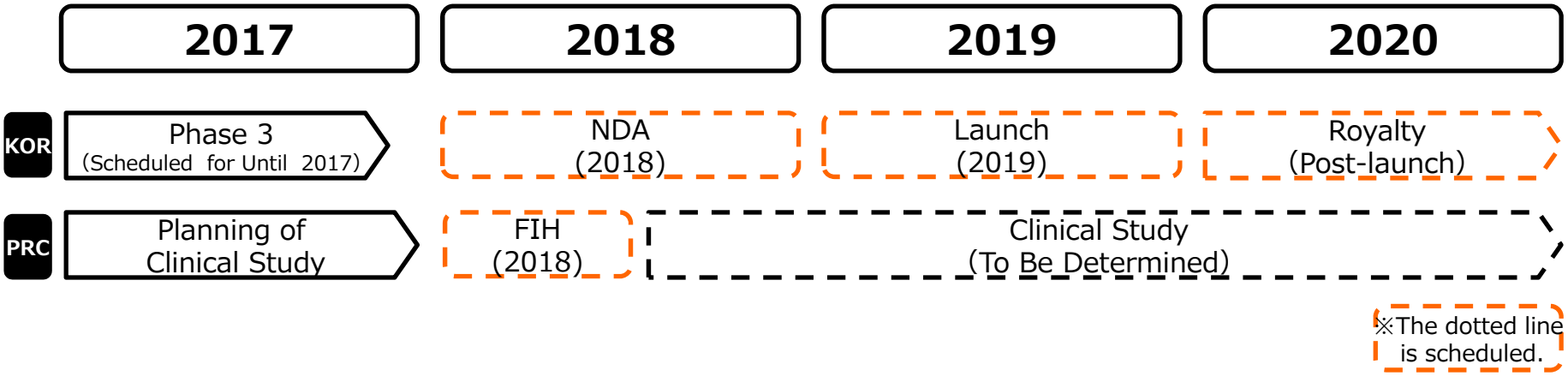


Licensee	Meiji Seika Pharma Co., Ltd.
Indication	Schizophrenia, Bipolar disorder
Progress	Phase 3 is on going in Japan. NDA is Scheduled on spring 2019, Launch is Scheduled in 2020.
Reference	The Number of Patients（Jpn）※1 ;7.13 million, Internal Number of Inpatients; 1.74 million. Market Size（Jpn）※2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

※1 : MHLW investigation in 2011、※2 : An in-company investigation

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(18) Development Roadmap: Potassium-competitive acid Blocker



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

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(19) 16)Pipeline Situation : Animal Drug

As of Announcement date

- Galliprant® was launched in the USA in January 2017 by Aratana Therapeutics Inc. and its strategic partner, Elanco Animal Health (*). Galliprant® is intended to control pain and inflammation associated with OA in dogs. Aratana submitted an application for approval with the EMA in February 2016.

- Entyce® was developed by Aratana as an appetite stimulation drug for dogs. The product was granted FDA approval in May 2016, expected to be launched in late 2017. Aratana has started a long-term toxicity test for Entyce® for use in cats since December 2016.

Project	Compound	Licensee	Indication	Discovery	Long-term toxicity test	Clinical Studies: Dose-finding	Clinical Studies: Large-scale	NADA	Approval	Sales
EP4 Agonist Galliprant®	RQ-00000007 (grapiprant)	Aratana Therapeutics	Osteoarthritis (USA)							Launch (January 2017 : USA)
			Osteoarthritis (Europe)					Application for approval (February 2016 : Europe)		
Ghrelin Receptor Agonist Entyce®	RQ-00000005 (capromorelin)	Aratana Therapeutics	Weight loss, Anorexia: Dog						Approval (May 2016 : USA)	
			Weight loss, Anorexia: Cat	On going (December 2016 : USA)						

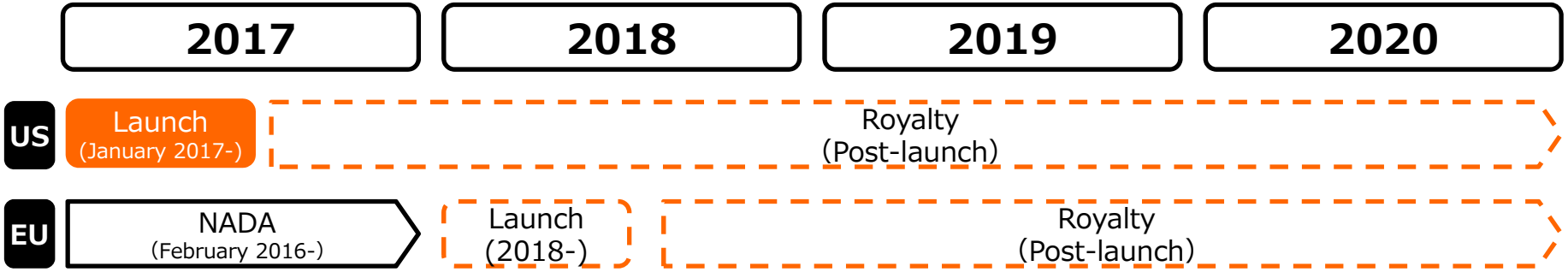
※Eli Lilly and Company's Animal Drug Division

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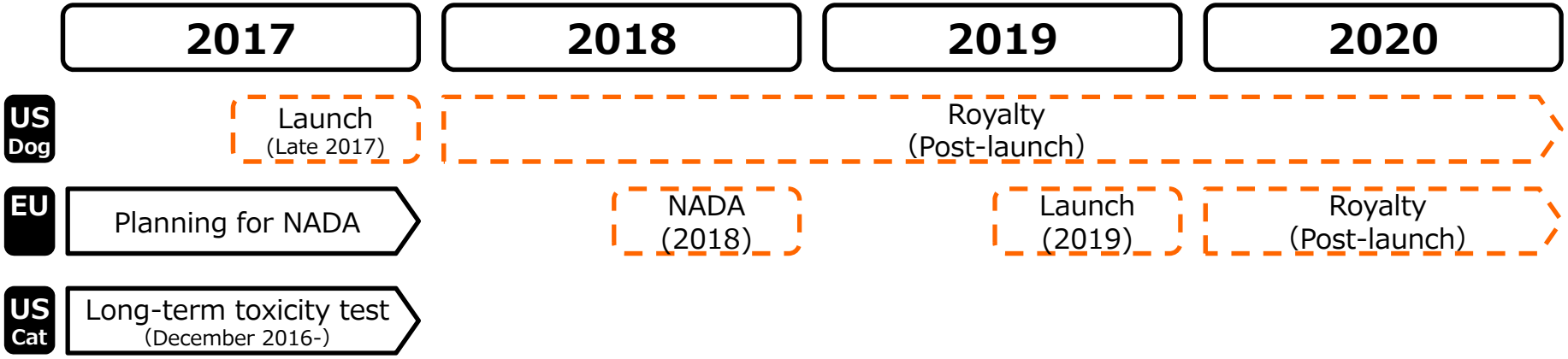
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(20)Development Roadmap: Animal Drug

Galliprant® grapiprant/RQ-00000007



Entyce® capromorelin/RQ-00000005



※The dotted line is scheduled.

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(21)EP4 Agonist : Galliprant®/grapiprant/RQ-00000007

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

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(22)Ghrelin Receptor Agonist : Entyce®/capromorelin/RQ-00000005

Indication	Weight loss, Anorexia in Companion Animal
Advantage	A first-of-its-kind therapeutic to treat inappetence in dogs Entyce® is an oral liquid prescription drug that can be used both for acute and chronic inappetent conditions.
Progress	NADA Approval (USA, Dog) Start of Long-term toxicity test (USA, Cat)
License	Licensed exclusive worldwide rights to Aratana

Topix

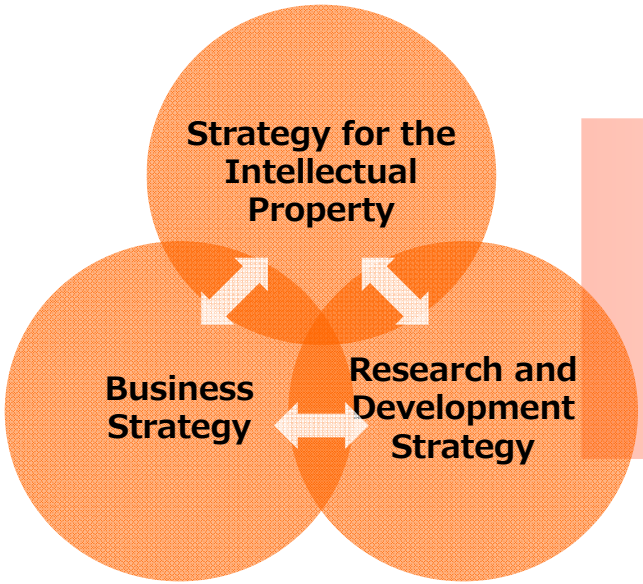
Jun 2015	Aratana announced positive results of pivotal field study
Jul 2015	Aratana announced positive results of preliminary test for cats
Mar 2016	NADA submitted for approval with FDA (USA)
May 2016	Approval (USA)
Dec 2016	Start long-term toxicity test in cats (USA)

4 million dogs in the USA are annually treated for inappetence
Commercial availability scheduled in late 2017

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(23)Strategy for the Intellectual Property

The intellectual property equals our product.
— Construction of a highly-valued intellectual property portfolio



Expected Effects

- Prompt application for patent
- Solid acquisition of right
- Creation of the intellectual property tailored to customers' needs
- License proposals based on the intellectual property
- Extension of the life cycle by the intellectual property

Compound Patent | Expiration | **Extension of the life cycle (Acquisition of the Use Patents)**

Extension of the patent term | Expiration

Up to 5 years

Earnings by licensing a basic patent

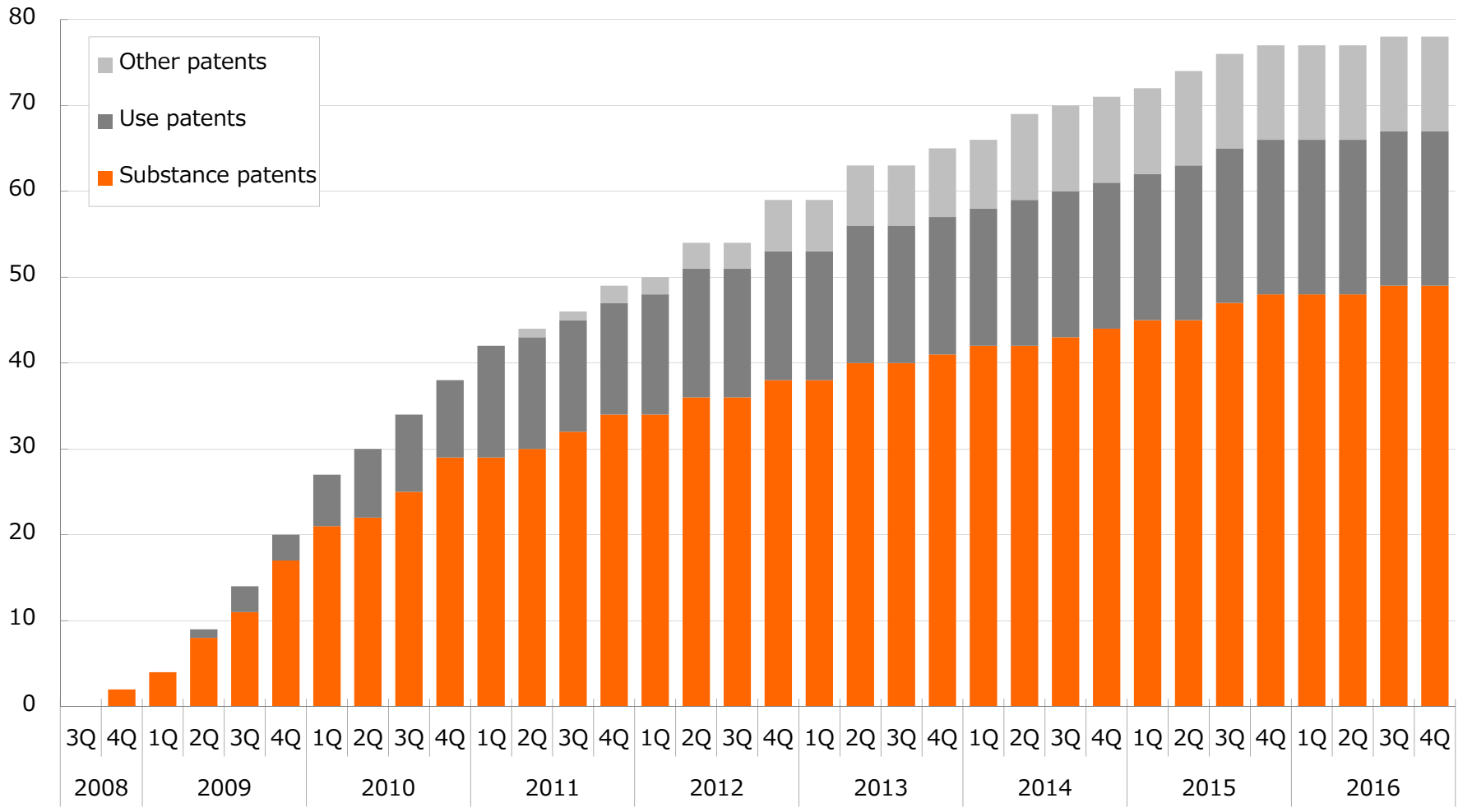
Use Patents	Patent on use, patent on crystal polymorphism, patent on base, process patent, patent on drug formulation, patent on combined treatment, patent on dosage and administration etc.

Earnings by licensing Use Patents

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(24)Intellectual Property Status



※Exclude the numbers of individual country applications

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(25)Intellectual News : January 2016-

Date	Subject	Territory	Patent Type
6th October	Ghrelin Receptor Agonist (Serin Derivatives)	Japan	Substance
5th October	T-type Calcium Channel/ Voltage-Gated Sodium Channel Blocker	USA	Substance
23rd September	Sodium Channel Blocker (Pyrrolopyridine Derivatives)	China	Substance
25th July	Sodium Channel Blocker (Arylamide Derivatives)	China	Substance
7th July	Sodium Channel Blocker (Aryl Amide Derivatives)	Europe	Substance
25th May	Potassium-competitive acid Blocker	Japan	Use
20th April	5-HT_{2B} Antagonist	Korea	Substance
18th February	Potassium-competitive acid Blocker	Korea	Use
17th February	T-type Calcium Channel/ Voltage-Gated Sodium Channel Blocker	Korea	Substance

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Business Plan Overview

About Industry-Academia-Government Collaboration

Business Forecast and Projections

Policy / Measures Toward the Stable Income-Earning

About Acquisition of Shares of TMRC through a Simplified Equity Swap (Making TMRC a Wholly Owned Subsidiary)

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Acquisition of 100% Ownership of TMRC Inc., Ltd.

Overview of TMRC Inc., Ltd.

- Established : January 25, 2002; President and CEO: Hisao Ekimoto; Location: Shinjuku-ku, Tokyo; Capital Fund: 10 million yen; Employees: 4; Number of shares issued: 5,325

Description of business

- TMRC is a biopharmaceutical company, specializing in development of anti-cancer products.

Purpose and background of acquisition

- Purpose: Actively promote collaborative research on therapeutic drugs based on novel mechanism of action proposed by academia centering on cancer and/or rare disease.
- Consider and decide on acquisition of 100% ownership of TMRC, which has an affinity to RaQualia's corporate value, with an aim to expand its business to cancer and rare disease areas.
- By acquiring 100% ownership, RaQualia will build a drug discovery platform to incorporate the results of collaborative research with academia and accelerate development of therapeutic drugs.
- Estimated future revenue from development and commercialization of TM-411 (generic name: tamibarotene), which is under development at Syros Pharmaceuticals, Inc. (Massachusetts, USA), will contribute to stabilization of financial base of RaQualia (business sustainability/improvement of corporate value).
- Financial method of acquisition is stock-for-stock. RaQualia and TMRC will take over their own employees and suppliers while operating as different companies.

Summary of acquisition

- Effective date : February 3, 2017
- Stock swap ratio : 1 (RQ) : 90 (TMRC)
- Number of shares delivered : Common stock (RQ) : 479,250

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About TMRC – Pipeline, Development Status and Strategy

About TM-411

- TM-411 is a retinoic acid derivative (retinoid) invented by Dr. Koichi Shudo of Faculty of Pharmaceutical Sciences at University of Tokyo. The compound exhibits stronger differentiation activity with improved stability and safety than currently available retinoid agents.
- Developed by Toko Pharmaceuticals, TM-411 was approved for relapsed/refractory acute promyelocytic leukemia (APL) in Japan in April 2005 and launched under the trade name of Amnolake Tablet® 2mg in June 2005. The product is available from Nippon Shinyaku Co., Ltd.

Status of TM-411 and strategic objectives

- Syros Pharmaceutical aims at approval of TM-411(SY-1425) as “Precision Medicine” by screening about 25% of AML/MDS patients who strongly express RARα on which TM-411(SY-1425) acts, using its Gene Control Platform.
- Ohara Pharmaceutical looks to establish a Proof-of-Concept (POC) for pediatric solid tumor as a combination therapy with TM-411 and epigenetic agonist.
- Toko Pharmaceutical Industries aims at import approval in China for the combination therapy with TM-411 and arsenic trioxide for ATRA-resistant refractory APL.
- License negotiation is underway for neutropenia with an aim to expand indications other than cancer.

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

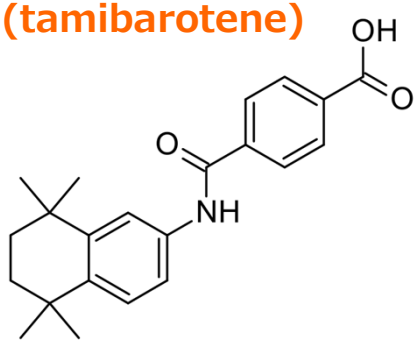
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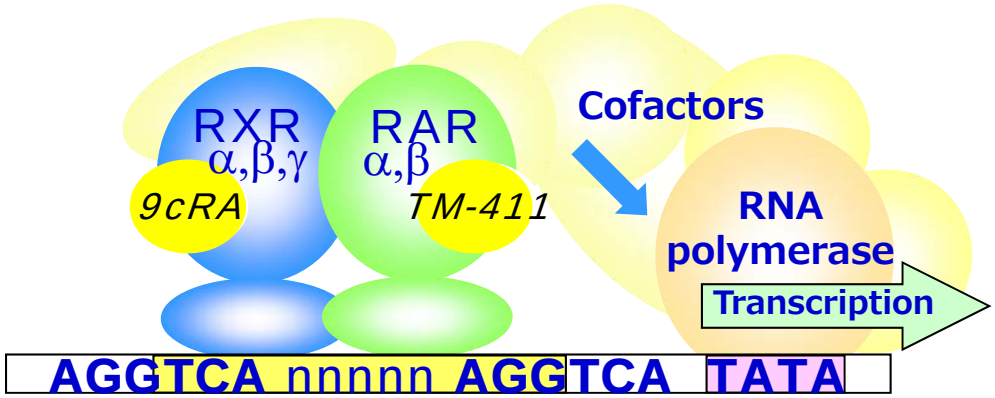
Mechanism of action (TM-411)

MOA of TM-411

- TM-411 strongly binds to retinoic acid receptor (RARα), a type of nuclear receptor, and forms/activates homodimers or heterodimers with RAR or rexinoid receptor (RXR). The activated receptor binds to retinoic acid response element (RARE) and regulates the transcription of the downstream gene.

TM-411(tamibarotene)





Major functions regulated by retinoids

- Cell proliferation
- Differentiation
- Cell death (apoptosis)
- Development/morphogenesis

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.
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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.

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