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RaQualia Pharma

Company Name
RaQualia Pharma Inc.

Head Office
Meieki Southside Square, 1-21-19 Meieki Minami, Nakamura-ku, Nagoya City

Listed On
Tokyo Stock Exchange, Growth Market

Fiscal Year-End
Dec

Established
2008-02-19

Exchange Listing
2011-07-20

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Research Coverage Report by **Shared Research Inc.**

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Executive summary

Business overview

RaQualia Pharma Inc. is an R&D-focused drug discovery company. It primarily conducts exploratory research into small molecule compounds to discover the "seeds" of new drugs and out-licenses development and marketing rights to pharmaceutical companies and others. The company covers the drug discovery stage from exploratory research through early clinical development (Phase II clinical trials). It develops new drugs targeting various fields, including pain, gastrointestinal disorders, cancer, and immunological disorders. The company receives operating revenue from companies that in-license its products in the form of upfront payments, milestone payments, post-launch royalties, and joint development cooperation payments. Licensees have already launched four products, providing the company with stable long-term royalty revenue, its main source of earnings. In FY12/25, operating revenue was JPY4.0bn (+28.1% YoY), comprising royalty revenue (56.3%) and upfront and milestone payments and research collaboration payments (43.6%).

The company started as an independent entity when US-based Pfizer Inc. (NYSE: PFE; ranked third in terms of pharmaceuticals sales globally in 2024) decided to close its central research laboratory in Japan as part of a global research restructuring in 2007. The research lab spun off from Pfizer through an employee buyout, and RaQualia was established in July 2008, after Pfizer transferred its intellectual property rights covering a number of projects in the exploratory or development stages in June 2008. When RaQualia out-licenses rights for some compounds transferred from Pfizer, it pays royalties to Pfizer and records them under operating expenses.

RaQualia has four products already commercialized by licensees (K-CAB® [generic name: tegoprazan], GALLIPRANT®, ENTYCE™, and ELURA™), 13 programs already out-licensed, and seven at the pre-out-licensing stage. Human drug tegoprazan is a potassium-competitive acid blocker (P-CAB)*, with the main indication of gastroesophageal reflux disease (GERD)*[2]. In September 2010, the company reached an out-licensing agreement for marketing in South Korea, China (including Hong Kong), and Taiwan with South Korea's CJ Healthcare Corporation (currently HK inno.N Corporation [KOSDAQ: 195940]). Since 2019, the company has gradually expanded the licensed territories and in December 2025, it granted global rights including Japan to HK inno.N.

* P-CAB: Potassium-competitive acid blockers act differently than the proton pump inhibitors (PPIs) used in existing therapies. While PPIs inhibit gastric acid secretion after being activated by acid in the body, P-CABs do not require acid activation. Instead they inhibit the binding of potassium ions necessary for gastric acid secretion, with a rapid and beneficial impact.
*[2] Gastroesophageal reflux disease (GERD): A disease whereby stomach contents, in particular stomach acid, flow back into the esophagus (food pipe), causing characteristic symptoms such as heartburn. Non-erosive reflux disease (NERD) is a condition in which damage to the esophageal mucosa cannot be confirmed by endoscopy, despite symptoms such as heartburn and acid reflux caused by reflux of stomach acid and stomach contents.

HK inno.N has launched tegoprazan under the brand name K-CAB® in South Korea and aims to roll out the drug to 100 countries by 2028. HK inno.N and its sublicensees are working on development, manufacturing, and sales of tegoprazan in 57 countries. As of end-FY12/25, tegoprazan had been launched in South Korea, China, Mongolia, the Philippines, Indonesia, Singapore, Mexico, Peru, Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador, Panama, Malaysia, India, and Thailand; was under regulatory review in Vietnam and five Central and South American countries; and was under preparation for approval filing in the US. The company is preparing to start Phase III clinical trials or submit regulatory applications in Canada, Brazil, South Africa, six Eastern European countries, and Middle Eastern and North African regions. Under the licensing agreement with HK inno.N, RaQualia receives milestone payments based on development progress or a percentage of the revenue that HK inno.N earns from the sublicensee.

In December 2025, the company out-licensed to HK inno.N exclusive development, manufacturing, and marketing rights for tegoprazan in Japan, including the right to grant sublicenses, and raised approximately JPY1.4bn from HK inno.N through a third-party allotment of shares, expanding its capital and business alliance with the licensee. By strengthening the capital relationship with HK inno.N, the company aims to accelerate joint research centered on tegoprazan and its commercialization in Japan, enhancing the value of the overall drug discovery pipeline and reinforcing the medium- to long-term earnings base. The company plans to allocate the funds raised to R&D investment and partial repayment of

JPY2.8bn in syndicated bank borrowings, thereby strengthening its drug discovery research platform, expanding its pipeline, and improving its financial position. Under the agreement, the company will not receive an upfront payment, but will be entitled to milestone payments tied to commercialization progress, royalties based on product sales, and a portion of revenues that HK inno.N receives from its sublicensees.

GALLIPRANT®, ENTYCE™, and ELURA™ are drugs for pets. In December 2010, the company out-licensed worldwide rights to the three drugs to US-based Elanco Animal Health, Inc. (NYSE: ELAN) a former subsidiary of US-based Eli Lilly and Co. (NYSE: LLY). GALLIPRANT® revenue reached USD100mn (roughly JPY12.5bn) in FY12/21, becoming Elanco's tenth blockbuster drug.

RaQualia obtained approval for ELURA™, a weight loss management drug for cats with CKD, in Europe in 2023 and launched it as Eluracat™ in France in August 2024. It obtained approval in Japan in February 2024 and launched the drug domestically in November 2024. The company plans to expand ELURA™ into other markets, having already secured approvals in the UK, several European countries, Brazil, and Canada. While the pet drug market is smaller than the human pharmaceuticals market, the absence of regulated drug prices in Japan and other regions allows the company to maintain or increase prices more easily. Shared Research thinks this pricing flexibility supports stable royalty revenue and earnings.

In March 2024, the company acquired all shares in FIMECS, Inc. (unlisted) and made it a subsidiary (see the "Business" section below). FIMECS advances the research and development of new pharmaceuticals using targeted protein degradation (TPD) inducers, a new modality in drug discovery. Based on its unique drug discovery platform technology RaPPIDS™, it conducts joint research with Astellas Pharma Inc. (TSE Prime: 4503) and may receive milestone payments according to progress with development and royalties after product launch. The company expects to strengthen its drug discovery value chain, increase its earnings through a hybridized business model, and strengthen its presence in the field of cancer by making FIMECS a subsidiary.

In March 2021, the company expanded its target indications beyond its traditional focus on pain and gastrointestinal diseases to include neurological diseases. It also expanded target areas to fields with significant unmet medical needs, continuously generating new drug candidates, including in oncology, a key focus of subsidiary FIMECS, and metabolic and endocrine diseases, supporting collaboration with HK inno.N. It previously shifted to in-house development of new drug candidates through the proof of concept (POC) stage, aiming to secure higher upfront and milestone payments and higher royalty rates. However, achieving POC typically requires substantial investments ranging from JPY2.0 to JPY JPY5.0bn. Accordingly, under the medium-term management plan through FY12/28, the company now focuses on generating new pipeline assets at the preclinical stage and pursuing early out-licensing, rather than conducting large-scale clinical development in-house.

* Unmet medical needs: Medical needs involving diseases for which effective remedies are not yet available. This includes serious illnesses such as cancer, dementia, and multiple sclerosis as well as those that are not life-threatening but require innovative drugs to improve quality of life, such as insomnia and migraines.
*[2] Proof of concept (POC): The hypothesis (clinical concept) that a new drug candidate substance under development can be a potential therapeutic agent for a disease (in terms of its usefulness and efficacy) is tested and validated through administration to humans. In the drug discovery process, Phase II of a three-stage clinical trial is used to demonstrate whether or not the candidate substance demonstrates a therapeutic effect during administration to a small number of patients, as measured using appropriate benchmarks.

The company has successfully out-licensed five drug discovery research programs targeting ion channels. Ion channels are membrane proteins that allow ions to pass into and out of cells. They are expressed in a variety of cells, and the type of ions that can pass through depend on the type of channels. Ion channels play key roles in maintaining cell function and regulating diverse physiological processes. Modulating ion channels could help treat a wide range of diseases, but because these channels are widely expressed in vital organs such as the heart and brain, drugs that act on unintended channels can cause life-threatening adverse reactions, including cardiotoxicity and neurotoxicity. Few companies have entered the market due to the significant difficulty of designing and screening compounds targeting ion channels, and such drugs account for under 10% of all drugs.

RaQualia says it is the only company in the world to have out-licensed five drugs in the ion channel area, demonstrating its strong technological capabilities in small-molecule drug discovery. Building on its advanced expertise in addressing

highly challenging targets, the company has expanded its research scope beyond conventional approaches by incorporating targeted protein degradation (TPD) technology of its subsidiary FIMECS and small-molecule drugs targeting mRNA through joint research with Veritas In Silico, evolving into a next-generation drug discovery company. To mitigate less favorable contract terms in early-stage out-licensing, the company leverages highly regarded novel modalities, including FIMECS's TPD technology, attracting strong interest from major pharmaceutical companies even at the preclinical stage, securing partnerships on favorable terms.

Earnings trends

In FY12/25, operating revenue was JPY4.0bn (+28.1% YoY), operating profit was JPY484mn (a loss of JPY213mn in FY12/24), recurring profit was JPY438mn (a loss of JPY362mn), and net income attributable to owners of the parent was JPY273mn (a loss of JPY495mn). Operating revenue reached a record high, supported by strong royalty revenue from tegoprazan and pet drugs, while other income, including upfront payments and milestone payments related to sales and research, increased 49.4% YoY but fell short of the initial forecast by JPY207mn. R&D expenses fell short of the initial forecast because commissioned studies were delayed and the company reduced operating expenses through thorough cost control. As a result, all profit categories turned positive.

For FY12/26, RaQualia forecasts operating revenue of JPY4.0bn (flat YoY), operating profit of JPY165mn (-65.9% YoY), recurring profit of JPY86mn (-80.4% YoY) and a net loss attributable to owners of the parent of JPY63mn (profit of JPY273mn in FY12/25). The company expects operating revenue to be driven by steady royalty revenue from global expansion of tegoprazan sales, along with upfront and milestone payments and research collaboration payments including payments including those received at subsidiaries. It forecasts standalone revenue for RaQualia at JPY3.0bn (+2.2% YoY), and revenue for subsidiaries FIMECS Inc. at JPY1.0bn (-6.0% YoY). It expects total operating expenses of JPY3.8bn (+9.1% YoY).

The company revised the numerical targets of its medium-term management plan for the three-year period from FY12/26 to FY12/28 in conjunction with its FY12/25 earnings announcement. For FY12/28, the final year of the plan, the company projects operating revenue of JPY4.7bn, operating profit of JPY909mn, recurring profit of JPY864mn, and net income of JPY676mn. The company expects further expansion in global tegoprazan sales, with royalty income from US sales beginning to contribute to earnings. Over the three-year period, the company forecasts cumulative operating revenue of JPY12.8bn and plans to allocate JPY7.2bn to exploratory research and JPY300mn to preclinical and clinical trials. The company plans to pay dividends while strengthening its financial base and will consider share repurchases flexibly.

Strengths and weaknesses

Shared Research thinks the company has the following three strengths.

1) An advanced small-molecule drug discovery platform based on pharmaceutical-grade research processes, cultivated through ion channel drug discovery

2) Several hundred patents held

3) Strong drug discovery capability driven by the proprietary TPD (targeted protein degradation) platform RaPPIDS™ held by subsidiary FIMECS

We think it has the following three weaknesses.

1) Constraints on earnings growth due to reliance on specific drug discovery modalities

* Drug discovery modality refers to the method of drug discovery, i.e., what kind of drug to make from what sources and by what method. Traditionally, most drugs have been small molecule drugs synthesized from chemical substances with molecular weights of under 500 Daltons. Currently there is a range of modalities including proteins (hormones, biological materials), antibody drugs, nucleic acid drugs, middle molecule drugs, and regenerative medicine.

2) Milestone payments and royalties depend on partners' development progress and business strategies, creating uncertainty in the timing of monetization and weakening the medium- to long-term earnings outlook

3) Difficulty in recruiting and training researchers due to high degree of specialization

Key financial data

Income statement	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24	FY12/25	FY12/26
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Company forecast
Operating revenue	**705**	**1,419**	**745**	**1,703**	**1,107**	**2,776**	**2,918**	**1,901**	**3,108**	**3,980**	**3,980**
YoY	384.7%	101.2%	-47.5%	128.7%	-35.0%	150.7%	5.1%	-34.8%	63.5%	28.1%	28.1%
Operating expenses	**1,465**	**1,570**	**1,820**	**1,719**	**1,593**	**2,068**	**2,052**	**2,239**	**3,321**	**3,496**	**3,814**
YoY	-27.1%	7.1%	15.9%	-5.5%	-7.3%	29.8%	-0.8%	9.1%	48.4%	5.3%	14.8%
Operating profit	**-760**	**-150**	**-1,075**	**-16**	**-486**	**708**	**866**	**-337**	**-213**	**484**	**165**
YoY	-	-	-	-	-	-	22.4%	-	-	-	-
Operating profit margin	-	-	-	-	-	25.5%	29.7%	-	-	12.2%	4.1%
Recurring profit	**-721**	**-81**	**-1,065**	**22**	**-528**	**864**	**904**	**-293**	**-362**	**438**	**86**
YoY	-	-	-	-	-	-	4.7%	-	-	-	-
Recurring profit margin	-	-	-	1.3%	-	31.1%	31.0%	-	-	11.0%	2.2%
Net income	**-728**	**-58**	**-1,105**	**5**	**-607**	**756**	**723**	**-324**	**-495**	**273**	**-63**
YoY	-	-	-	-	-	-	-4.3%	-	-	-	-
Net margin	-	-	-	0.3%	-	27.2%	24.8%	-	-	6.9%	-
Per-share data (split-adjusted; JPY)											
Shares issued (year-end; 000)	18,767	20,295	20,388	20,950	20,952	20,955	20,977	21,623	21,839	24,459	
EPS (JPY)	-38.8	-3.0	-54.2	0.3	-29.0	36.1	34.5	-15.0	-22.9	11.5	-2.6
EPS (fully diluted; JPY)	-	-	-	0.3	-	36.0	34.5	-	-	11.4	
Dividend per share (JPY)	-	-	-	-	-	-	-	-	-	-	-
Book value per share (JPY)	201	240	189	220	191	228	262	282	254	280	
Balance sheet (JPYmn)											
Cash and cash equivalents	1,428	2,268	1,671	2,174	1,394	2,345	3,675	3,715	3,340	3,241	
Total current assets	**1,806**	**3,322**	**1,962**	**3,067**	**2,834**	**4,004**	**4,822**	**4,957**	**4,539**	**5,682**	
Tangible fixed assets	249	216	318	249	333	299	391	574	529	436	
Investments and other assets	1,951	1,516	1,738	1,488	1,051	897	1,020	1,311	685	662	
Intangible assets	13	10	34	32	33	34	24	30	3,902	3,733	
Total assets	**4,019**	**5,064**	**4,052**	**4,837**	**4,251**	**5,234**	**6,258**	**6,872**	**9,655**	**10,514**	
Short-term debt	-	-	1	1	18	22	46	77	582	591	
Total current liabilities	**190**	**149**	**164**	**183**	**187**	**401**	**494**	**389**	**1,187**	**1,275**	
Long-term debt	-	-	2	2	27	18	177	291	2,870	2,311	
Total fixed liabilities	**41**	**27**	**31**	**33**	**53**	**46**	**267**	**362**	**2,897**	**2,343**	
Total liabilities	**231**	**176**	**195**	**216**	**240**	**446**	**761**	**752**	**4,085**	**3,618**	
Shareholders' equity	3,773	4,871	3,845	4,608	3,999	4,777	5,489	6,095	5,543	6,848	
Total net assets	**3,788**	**4,888**	**3,857**	**4,621**	**4,011**	**4,788**	**5,497**	**6,120**	**5,571**	**6,896**	
Total interest-bearing debt	-	-	3	2	46	39	222	368	3,452	2,902	
Cash flow statement (JPYmn)											
Cash flows from operating activities	-681	-307	-404	-531	-289	366	1,480	-719	181	-354	
Cash flows from investing activities	-441	534	-368	216	225	-279	-48	-135	-3,666	124	
Cash flows from financing activities	-	1,007	99	696	-7	-16	-30	793	2,982	378	
Financial ratios											
ROA (RP-based)	-16.4%	-1.8%	-23.4%	0.5%	-11.6%	18.2%	15.7%	-4.5%	-4.4%	4.3%	
ROE	-17.6%	-1.3%	-25.3%	0.1%	-14.1%	17.2%	14.1%	-5.6%	-8.5%	4.4%	
Equity ratio	93.9%	96.2%	94.9%	95.3%	94.1%	91.3%	87.7%	88.7%	57.4%	65.1%	

Source: Shared Research based on company data

Notes: 1. Figures may differ from company materials due to differences in rounding methods.

2. Operating expenses include cost of operating revenue, R&D expenses, and other SG&A expenses.

Recent updates

Assignee terminates license agreement for CB2 agonist

2026-02-20

RaQualia Pharma Inc. announced its assignee, AskAt Inc. (unlisted), has terminated a license agreement with Oxford Cannabinoid Technologies Ltd. (LON: OCTP; OCT). This agreement had been related to the CB2 agonist for which RaQualia previously assigned intellectual property rights to AskAt.

AskAt terminated the September 2019 license agreement with OCT concerning the CB2 agonist (compound codes: RQ-00202730, AAT-730, and OCT461201). In November 2015, RaQualia assigned the intellectual property rights for the agonist to AskAt, becoming entitled to receive royalty income representing a portion of the revenue AskAt would generate from commercialization of the agonist.

In July 2023, OCT initiated a Phase I clinical trial in the UK for the CB2 agonist, primarily targeting chemotherapy-induced peripheral neuropathy (CIPN), and planned to push forward with clinical development. RaQualia announced AskAt terminated the agreement due to OCT's breach of contract. As the termination does not affect the compound's development potential, AskAt is seeking a new partner to continue clinical development. RaQualia continues to collaborate with AskAt, supporting development and out-licensing of the agonist.

RaQualia stated this matter will have no impact on its results for FY12/26.

Company makes an announceemnt regarding patent review in Japan for IRAK-M degradation inducer (heterocyclic compound)

2026-01-26

RaQualia Pharma Inc. has announced that it received notification of a patent grant in Japan for a substance patent application (application number: 2021-535473) covering its IRAK-M degradation inducer (heterocyclic compound) developed by its consolidated subsidiary FIMECS.

A decision to grant a patent establishes patent rights in the relevant country, as it reflects the country's patent office's determination that the invention is patentable. Once the patent fee is paid, the patent is registered.

The compound group for which the company received the patent grant comprises multiple novel compounds that induce degradation of IRAK-M protein, including FIM-001, which FIMECS is advancing in preclinical development. The substance patent covers FIM-001 and related compounds, thereby strengthening intellectual property rights for FIM-001 in Japan.

This application forms part of national phase entries based on an international filing, with examinations currently underway in other countries and regions. The patent offices in China, South Korea, Taiwan, Hong Kong, Russia, Australia, and Mexico have already granted the patent or issued grant decisions. Among the company's core markets—Japan, the US, and Europe—the Japan Patent Office was the first to issue a patent grant decision.

IRAK-M is known as a protein that negatively regulates innate immune signaling and has been reported to contribute to cancer immune suppression. FIMECS-developed IRAK-M protein degraders that selectively bind to IRAK-M and induce its degradation, thereby activating anti-tumor immune responses. The company has confirmed anti-tumor effects in multiple animal cancer models, including models resistant to immune checkpoint inhibitors, which have become the mainstream of cancer immunotherapy in recent years.

The compound group was generated using FIMECS's proprietary drug discovery platform, RaPPIDS™. The company plans to continue drug discovery research and development using RaPPIDS™, strengthen and expand its intellectual property, and build a foundation for pipeline development, including FIM-001, targeting future commercialization and collaborations.

According to RaQualia, the patent decision will have no impact on its FY12/26 results. The company expects the IRAK-M protein degraders (heterocyclic compounds) will contribute to medium- to long-term enhancement of its corporate value as research and development further progresses.

Patent review in the US for TRPV4 antagonist (pyrimidin-4(3H)-one derivative)

2026-01-23

RaQualia Pharma Inc. has announced it received notification of a patent grant in the US for its TRPV4 antagonist (pyrimidin-4(3H)-one derivative) substance patent application (application number: 17/921,203).

US Patent and Trademark Office (USPTO) has granted a patent for pyrimidin-4(3H)-one derivatives, a novel class of compounds with TRPV4 antagonistic properties. This patent follows a grant in China, Japan, and Europe, further strengthening its intellectual property rights in the US.

The company's TRPV4 antagonist acts specifically on TRPV4 ion channel receptors and has demonstrated high efficacy in multiple animal models of pain, inflammation, and ocular diseases. Since 2016, the company has conducted industry–academia collaborative research on ocular diseases with Gifu Pharmaceutical University. In April 2021, it established a joint research course at the university. Collaborative research involving the Laboratory of Pharmacological Evaluation led to a 2023 publication suggesting that TRPV4-targeted therapies could provide new treatment options for retinal vascular disorders, and the research group presented a TRPV4 antagonist as a small-molecule drug discovery approach for posterior segment diseases at the 45th Annual Meeting of the Japanese Society for Ocular Pharmacology in 2025.

This patent grant highlights the company's expertise in ion channel drug discovery. RaQualia Pharma stated it will continue efforts aiming to strengthen its intellectual property portfolio. The company is confident the pyrimidin-4(3H)-one derivatives will contribute to its corporate value in the medium to long term through future development and related activities.

The company does not expect this patent decision will impact its consolidated results for FY12/26.

RaQualia Pharma announces filing of an application for marketing approval of the gastric acid secretion inhibitor tegoprazan in the US

2026-01-13

RaQualia Pharma Inc. announced the filing an application for marketing approval of the gastric acid secretion inhibitor tegoprazan in the US.

HK inno.N Corporation (KOSDAQ: 195940), the company's licensee, and US-based Sebela Pharmaceuticals Inc., the sublicensee, announced that Braintree Laboratories, an unlisted division of Sebela, submitted an application to the US Food and Drug Administration (FDA) for approval of the gastric acid secretion inhibitor tegoprazan. RaQualia out-licensed tegoprazan to Sebela via HK inno.N for the treatment of erosive esophagitis (EE) and non-erosive reflux disease (NERD) as well as for maintenance therapy following EE healing.

Tegoprazan is a novel gastric acid suppressant developed by RaQualia, classified as a potassium-competitive acid blocker (P-CAB), a new class of drugs with a distinct mechanism of action. Unlike proton pump inhibitors (PPIs), the first-line therapy for gastroesophageal reflux disease, P-CABs suppress gastric acid secretion more rapidly and with longer duration.

Launched by HK inno.N as K-CAB® tablets since 2019, tegoprazan has become a blockbuster product in South Korea, with cumulative domestic sales (out-of-hospital prescriptions) reaching KRW705.4bn (approximately JPY70.5bn, at JPY0.11/KRW) by 2024, maintaining the top share in the Korean gastric acid secretion inhibitor market. HK inno.N has developed, manufactured, and/or sold tegoprazan in 55 countries, including Japan, and tegoprazan products are marketed in 19 countries.

In September 2010, RaQualia entered into an exclusive license agreement with CJ HealthCare Corporation (now HK inno.N), including sublicensing rights, concerning the development, manufacturing, and sales of tegoprazan in East Asia. In November 2019, the parties entered into an additional agreement covering North America and Europe. In December 2021, HK inno.N entered into a sublicense agreement with Braintree, a gastrointestinal therapeutics-focused company and a division of Sebela Pharmaceuticals, granting exclusive development, manufacturing, and marketing rights for tegoprazan in the US and Canada.

In April 2025, Sebela announced it achieved all primary and secondary endpoints in both the NERD trial and the healing phase of the EE trial. In August 2025, Sebela also reported favorable results from the ongoing maintenance therapy study following EE healing. On January 9, 2026, Braintree filed the application for approval of tegoprazan to the US FDA, with

approval expected in January 2027. The global market for peptic ulcer therapeutics totals approximately JPY2.0tn, with the US accounting for an estimated 20%. In North America, proton pump inhibitors (PPIs) serve as the primary existing treatment for GERD; however, approximately 40% of patients experience insufficient relief from heartburn symptoms or continue to exhibit esophageal mucosal damage, highlighting limitations of PPI therapy. The company expects tegoprazan to address these unmet needs as a new treatment option for GERD.

Under its license agreement with HK inno.N, RaQualia is entitled to receive a portion of the revenue that HK inno.N earns from sublicensees. Although the company will not receive an upfront payment from this filing, RaQualia considers the submission for marketing approval in the US—one of its key markets—to represent an important milestone in the business development of tegoprazan and to contribute to the medium- to long-term enhancement of the group's corporate value.

Patent review in Europe for TRPV4 antagonist (pyrimidin-4(3H)-one derivative)

2026-01-08

RaQualia Pharma Inc. has announced it received notification of a patent grant in Europe for its TRPV4 antagonist (pyrimidin-4(3H)-one derivative) substance patent application.

European Patent Office has granted a patent for pyrimidin-4(3H)-one derivatives, a novel class of compounds with TRPV4 antagonistic properties. This patent is the company's third related to TRPV4 antagonists, following an earlier grant in China and Japan, and further strengthens its intellectual property rights in Europe.

The company's TRPV4 antagonist acts specifically on TRPV4 ion channel receptors and has demonstrated high efficacy in multiple animal models of pain, inflammation, and ocular diseases. Since 2016, the company has conducted industry–academia collaborative research on ocular diseases with Gifu Pharmaceutical University. In April 2021, it established a joint research course at the university. Collaborative research involving the Laboratory of Pharmacological Evaluation led to a 2023 publication suggesting that TRPV4-targeted therapies could provide new treatment options for retinal vascular disorders, and the research group presented a TRPV4 antagonist as a small-molecule drug discovery approach for posterior segment diseases at the 45th Annual Meeting of the Japanese Society for Ocular Pharmacology in 2025.

This patent grant highlights the company's expertise in ion channel drug discovery. RaQualia Pharma stated it will continue efforts aiming to strengthen its intellectual property portfolio. The company is confident the pyrimidin-4(3H)-one derivatives will contribute to its corporate value in the medium to long term through future development and related activities.

The company does not expect this patent decision will impact its consolidated results for FY12/26.

Trends and outlook

Quarterly trends and results

Earnings (cumulative)	FY12/24				FY12/25				FY12/25	
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1–Q4	Q1	Q1–Q2	Q1–Q3	Q1–Q4	% of forecast	FY forecast
Operating revenue	649	1,411	2,369	3,108	965	1,536	2,311	3,980	102.4%	3,888
YoY	75.1%	39.1%	58.4%	63.5%	48.8%	8.9%	-2.5%	28.1%		25.1%
Operating expenses	604	1,565	2,397	3,321	872	1,726	2,656	3,496	92.8%	3,769
YoY	26.0%	50.9%	49.5%	48.4%	44.4%	10.3%	10.8%	5.3%		13.5%
Operating expense ratio	93.1%	110.9%	101.1%	106.9%	90.4%	112.4%	114.9%	87.8%		-
Cost of operating revenue	61	227	397	626	222	389	547	712		
YoY	1.9%	85.6%	109.5%	155.4%	267.3%	71.4%	37.9%	13.8%		
Cost ratio	9.3%	16.1%	16.7%	20.1%	23.0%	25.3%	23.7%	17.9%		
R&D expenses	359	833	1,255	1,704	385	782	1,237	1,600	94.1%	1,700
YoY	33.8%	38.0%	34.3%	24.1%	7.3%	-6.1%	-1.5%	-6.1%		-0.2%
R&D expense ratio	55.4%	59.0%	53.0%	54.8%	39.9%	50.9%	53.5%	40.2%		
Other SG&A expenses	185	506	745	991	265	555	872	1,184		
YoY	21.8%	62.1%	55.2%	59.6%	43.6%	9.7%	17.1%	19.5%		
Other SG&A expense ratio	28.5%	35.8%	31.4%	31.9%	27.4%	36.1%	37.7%	29.8%		
Operating profit	45	-154	-27	-213	93	-190	-345	484	409.9%	118
YoY	-	-	-	-	109.2%	-	-	-		-
Operating profit margin	6.9%	-	-	-	9.6%	-	-	12.2%		3.0%
Recurring profit	-77	-278	-231	-362	29	-291	-427	438	599.9%	73
YoY	-	-	-	-	-	-	-	-		-
Recurring profit margin	-	-	-	-	3.0%	-	-	11.0%		1.9%
Net income	-78	-324	-340	-495	-5	-355	-569	273	-	-71
YoY	-	-	-	-	-	-	-	-		-
Net margin	-	-	-	-	-	-	-	6.9%		-

Earnings (quarterly)	FY12/24				FY12/25			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Operating revenue	649	762	958	738	965	571	775	1,669
YoY	75.1%	18.5%	99.1%	81.9%	48.8%	-25.2%	-19.1%	126.1%
Operating expenses	604	961	831	924	872	854	930	840
YoY	26.0%	72.2%	46.9%	45.6%	44.4%	-11.2%	11.8%	-9.1%
Operating expense ratio	93.1%	126.1%	86.7%	125.2%	90.4%	149.7%	119.9%	50.4%
Cost of operating revenue	61	166	170	229	222	167	158	165
YoY	1.9%	164.8%	153.0%	311.5%	267.3%	0.2%	-6.9%	-28.0%
R&D expense ratio	9.3%	21.8%	17.7%	31.0%	23.0%	29.2%	20.4%	9.9%
R&D expenses	359	474	423	449	385	397	455	363
YoY	33.8%	41.4%	27.6%	2.4%	7.3%	-16.1%	7.6%	-19.1%
R&D expense ratio	55.4%	62.1%	44.1%	60.8%	39.9%	69.6%	58.7%	21.7%
Other SG&A expenses	185	321	239	247	265	290	317	313
YoY	21.8%	100.3%	42.4%	74.6%	43.6%	-9.7%	32.6%	26.8%
R&D expense ratio	28.5%	42.1%	24.9%	33.4%	27.4%	50.8%	40.9%	18.7%
Operating profit	45	-199	127	-186	93	-283	-155	828
YoY	-	-	-	-	109.2%	-	-	-
Operating profit margin	6.9%	-	13.3%	-	9.6%	-	-	49.6%
Recurring profit	-77	-200	46	-130	29	-321	-135	865
YoY	-	-	-	-	-	-	-	-
Recurring profit margin	-	-	4.8%	-	3.0%	-	-	51.8%
Net income	-78	-246	-16	-155	-5	-350	-214	842
YoY	-	-	-	-	-	-	-	-
Net margin	-	-	-	-	-	-	-	50.5%

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

Full-year FY12/25 results (out February 13, 2026)

Earnings summary

FY12/25 results (January–December 2025)

- Operating revenue: JPY4.0bn (+28.1% YoY)
- Operating profit: JPY484mn (a loss of JPY213mn in FY12/24)
- Recurring profit: JPY438mn (a loss of JPY362mn)
- Net income attributable to owners of the parent: JPY273mn (a loss of JPY495mn)

- R&D expenses: JPY1.6bn (-6.1% YoY)

Operating revenue increased 28.1% YoY, reaching a record high and achieving 102.4% of the full-year FY12/25 operating revenue forecast. All profit categories turned positive, supported by higher-than-expected operating revenue and lower operating expenses.

Factors behind higher revenue and profit

Revenue reached a record high in FY12/25, and the company turned profitable. Royalty revenue increased 15.3% YoY to JPY2.2bn, exceeding expectations, driven by steady growth in royalties from four launched products, particularly higher royalties from strong tegoprazan sales in South Korea and its global expansion. Other income, including upfront and milestone payments and research collaboration payments, increased 49.4% YoY to JPY1.7bn but fell short of expectations.

Cost of operating revenue totaled to JPY712mn (+13.8% YoY), R&D expenses declined to JPY1.6bn (-6.1% YoY), while other SG&A expenses increased to JPY1.2bn (+19.5% YoY). R&D expenses decreased and fell short of the initial forecast due in part to timing differences in commissioned studies of ghrelin receptor agonists and IRAK-M degradation inducers. However, no significant delays occurred in development schedules. Operating expenses totaled JPY3.5bn, with the increase limited to 5.3% YoY, reflecting thorough cost control. Operating profit reached JPY484mn, up from a loss of JPY213mn in FY12/24. EBITDA totaled JPY965mn (+421.6% YoY), with cash generation—a key management focus—improving significantly.

Non-operating income totaled JPY70mn (+3.4% YoY), driven by JPY26mn in derivative valuation gains, JPY17mn in interest income, and JPY7mn in dividend income. Non-operating expenses totaled JPY116mn (-46.4% YoY), including JPY41mn in foreign exchange losses and JPY59mn in interest expenses. As a result, the company recorded net non-operating expense.

Breakdown of operating revenue

Earnings (cumulative)	FY12/24				FY12/25			
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1-Q4	Q1	Q1–Q2	Q1–Q3	Q1-Q4
Operating revenue	649	1,411	2,369	3,108	965	1,536	2,311	3,980
YoY	75.1%	39.1%	58.4%	63.5%	48.8%	8.9%	-2.5%	28.1%
Royalties	551	998	1,493	1,944	614	1,073	1,703	2,242
YoY	57.4%	36.3%	24.6%	21.2%	11.4%	7.5%	14.1%	15.3%
% of total	85.0%	70.7%	63.0%	62.6%	63.6%	69.9%	73.7%	56.3%
Other (upfront and milestone payments)	97	413	876	1,163	351	462	607	1,737
YoY	385.0%	46.5%	194.9%	292.0%	261.9%	11.9%	-30.7%	49.4%
% of total	15.0%	29.3%	37.0%	37.4%	36.4%	30.1%	26.3%	43.6%
R&D expenses	359	833	1,255	1,704	385	782	1,237	1,600
YoY	33.8%	38.0%	34.3%	24.1%	7.3%	-6.1%	-1.5%	-6.1%
Operating profit	45	-154	-27	-213	93	-190	-345	484
YoY	-	-	-	-	109.2%	-	-	-326.7%
Operating profit margin	6.9%	-	-	-	9.6%	-	-	12.2%
Earnings (quarterly)	**FY12/24**				**FY12/25**			
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Operating revenue	649	762	958	738	965	571	775	1,669
YoY	75.1%	18.5%	99.1%	81.9%	48.8%	-25.2%	-19.1%	126.1%
Royalties	551	447	495	451	614	459	630	539
YoY	57.4%	17.0%	6.2%	11.1%	11.4%	2.7%	27.3%	19.5%
% of total	85.0%	58.6%	51.6%	61.1%	63.6%	80.4%	81.3%	32.3%
Other (upfront and milestone payments)	97	316	463	287	351	111	145	1,130
YoY	385.0%	20.6%	-	-	261.9%	-64.9%	-68.7%	293.7%
% of total	15.0%	41.4%	48.3%	38.9%	36.4%	19.5%	18.7%	67.7%
R&D expenses	359	474	423	449	385	397	455	363
YoY	34.0%	41.4%	27.6%	2.4%	7.3%	-16.1%	7.6%	-19.1%
Operating profit	45	-199	127	-186	93	-283	-155	828
YoY	-	-	-	-	109.2%	-	-	-
Operating profit margin	6.9%	-	13.3%	-	9.6%	-	-	49.6%

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

	Preclinical trials	Phase I	Phase II	Phase III
Out-licensed	5-HT4 agonist (gastrointestinal motility disorders; veterinary use) to Vectibix	Tegoprazan (Japan) (gastroesophageal reflux disease, etc.)	COX-2 inhibitor (pain; veterinary use) to AskAt	
	Pet drugs using four compounds to Velovia	TRPM8 blocker (pain) to Xgene Pharmaceutical	EP4 receptor antagonist (pain) to AskAt	
	EP4 receptor antagonist (osteoarthritis and other diseases) to AskAt	CB2 agonist (chemotherapy induced peripheral neuropathy) to AskAt/OCT	COX2 inhibitor (pain) to AskAt	
		EP4 receptor antagonist (cancer/cancer immunology) to AskAt		
		5-HT4 partial agonist (Alzheimer's disease) to AskAt		
	Phase not disclosed			
	Selective sodium channel blocker (pain) to Hisamitsu	P2X7 receptor antagonist (—) to Asahi Kasei Pharma / Eli Lilly		
	Preclinical trials	**Phase I**	**Phase II**	**Phase III**
Pre-out-licensing	5-HT4 agonist (gastroparesis and other diseases)	5-HT4 agonist (functional dyspepsia, etc.)		
	Ghrelin receptor agonist (constipation, cachexia, anorexia)	5-HT2B agonist (irritable bowel syndrome with diarrhea [IBS-D])		
	TRPM8 blocker (Japan) (chronic pain)			
	IRAK-M degradation inducer (cancer/cancer immunology) from FIMECS			

Source: Shared Research based on company data (as of February 2026)
Note: In addition to the above, the following programs are in the clinical stage as pre-out-licensing programs: a selective sodium channel blocker (analgesic/antipruritic) and tamibarotene (cancer).

Brisk royalties from four commercialized products

Pet drugs

Revenue from GALLIPRANT® (generic name: grapiprant), a treatment for osteoarthritis in dogs; ENTYCE® (capromorelin), a treatment for anorexia in dogs; and ELURA® (capromorelin), a treatment for weight management in cats with chronic kidney disease (CKD), continued to perform well.

Royalty income from pet pharmaceuticals comes mainly from GALLIPRANT®, which became a blockbuster with annual revenue of over JPY10.0bn in 2021. Sales of GALLIPRANT® remained strong, with no signs of peaking. The company is seeking regulatory approval and expanding sales of the three commercialized pet pharmaceuticals in new countries and regions.

Tegoprazan sales in South Korea

Revenue from GERD treatment K-CAB® (tegoprazan) in South Korea by licensee HK inno.N continued to be robust, with prescription revenue outside hospitals amounting to roughly JPY24.0bn (+10.7% YoY; at JPY0.11/KRW). HK inno.N continues to lead the peptic ulcer drug market in South Korea with a share of 15%.

More than 60 generic drugmakers in South Korea had challenged the scope of RaQualia's extended substance patent rights for gastric acid secretion inhibitor tegoprazan through negative patent scope confirmation trials*. Following the Intellectual Property Trial and Appeal Board's decision in its favor in the first-instance trial, the company also won all cases in the appeal trial equivalent to the second instance. In November 2025, the company won all of the cases in the Supreme Court (third instance). As a result, the exclusive marketing rights for K-CAB® tablets through 2031 are now more firmly protected.

Development of tegoprazan in countries around the world

RaQualia has an exclusive license agreement with HK inno.N to develop, market, and manufacture tegoprazan, including sublicense rights. HK inno.N and its sublicensees, partner companies in respective countries that have obtained licenses or product exports from HK inno.N, are advancing tegoprazan-related business activities. HK inno.N aims to expand tegoprazan's reach to 100 countries by 2028 and to achieve annual global sales of KRW3.0tn (about JPY330.0bn at JPY0.11/KRW) for tegoprazan products by 2030, and is actively working toward these goals. As of end-FY12/25, tegoprazan was available or in preparation in 57 countries worldwide.

In January 2025, HK inno.N signed a license agreement with Southern XP IP Pty Ltd (unlisted), granting Southern XP exclusive distribution and marketing rights for tegoprazan in Australia and New Zealand. Southern XP, an Australian

pharmaceutical company with over 20 years of operational experience, specializes in pharmaceutical approval filings and distribution across the region.

In April 2025, HK inno.N signed an amendment to its April 2024 license agreement with Tabuk Pharmaceutical Manufacturing Company (unlisted) to expand the licensed territory in the Middle East and North Africa. The amendment added six countries—Egypt, Sudan, Ethiopia, Morocco, Yemen, and Libya—bringing the total to 16.

Following marketing approval for the drug by India's Central Drugs Standard Control Organization (CDSCO) to HK inno.N's partner, Dr. Reddy's Laboratories (NSE: DRREDDY), the company received a lump-sum milestone payment of USD4.0mn (approximately JPY620mn, at JPY155/USD) from HK inno.N. India's peptic ulcer drug market was estimated at about JPY167.2bn in 2024, ranking fourth globally after China, the US, and Japan.

As of end-FY12/25, tegoprazan is marketed in 19 countries: South Korea, China, Mongolia, the Philippines, Indonesia, Singapore, Mexico, Peru, Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador, Malaysia, Panama, Thailand, and India. Through HK inno.N, RaQualia receives royalties based on a portion of the revenue HK inno.N earns from sublicensees, such as sales royalties. Regulatory approval processes are underway in Southeast Asia and Central and South America, and applications have been in preparation in Brazil and the Middle East.

Favorable trial results in the US

In April 2025, Braintree Laboratories (unlisted), a division of its sublicensee Sebela Pharmaceuticals Inc. in the US through HK inno.N, reported favorable results from the ongoing US Phase III clinical trial (the TRIUMpH trial). The TRIUMpH trial is being conducted as a pivotal study for erosive esophagitis (EE) and non-erosive reflux disease (NERD). Tegoprazan met all primary and secondary endpoints in both the EE and NERD studies. Braintree filed a new drug application (NDA) in January 2026 and expects approval in early 2027.

Braintree also reported favorable maintenance therapy results at the end of up to eight weeks of initial treatment in EE patients who achieved complete healing in the TRIUMpH trial.

Insurance coverage in China

In China, H. pylori eradication therapy was included in the National Reimbursement Drug List (NRDL). The company expects revenue contribution to fully materialize from 2H FY12/26 following this reimbursement listing, reflecting an approximately six-month lag between local sales growth and royalty recognition.

Out-licensing of tegoprazan in Japan and expansion of the capital and business alliance

On December 12, 2025, RaQualia announced that it has out-licensed to HK inno.N Corporation exclusive rights, including sublicensing rights, for the development and commercialization of the gastric acid secretion inhibitor tegoprazan in Japan, and that it will strengthen its capital and business alliance through the issuance of new shares through a third-party allotment.

The company has identified domestic commercialization of tegoprazan as its top priority for FY12/25. It believes out-licensing tegoprazan in Japan is directly related to maintaining and enhancing corporate value. It held discussions with multiple candidates with the aim of concluding a contract in FY12/25. It recognized delays in initiating development could postpone market entry and negatively affect profitability, and in light of this, factored development timing heavily into its decision-making.

Based on these considerations, the company decided to expand its partnership with HK inno.N by granting it exclusive development, manufacturing, and marketing rights to tegoprazan in Japan. The agreement includes no upfront payment; instead, the company retains the right to receive sales royalties, a share of the revenue HK inno.N earns from its partners, and milestone payments tied to future development and commercialization progress.

The company states it selected HK inno.N as its domestic out-licensing partner primarily because of the latter's emphasis on rapid commercialization. The company recognizes the competing drug TAKECAB® (generic name: vonoprazan) could lose patent protection in the early 2030s and believes launching the product before generic entry is critical to securing a sufficient period of market exclusivity in the Japanese market. For this reason, the company decided to initiate clinical development early in Japan and sign an out-licensing contract within 2025. Consequently, it decided to out-license tegoprazan to HK inno.N, leveraging the partner's product knowledge and development expertise. Under the agreement, HK inno.N will bear the development costs for late-stage clinical trials in Japan. In parallel with an equity alliance through

a third-party allotment, the company plans to establish a framework with HK inno.N to accelerate development. (see "Medium-term business plan".)

Development structure in Japan

The company granted HK inno.N exclusive rights to develop, manufacture, and commercialize tegoprazan in Japan. HK inno.N is preparing to commence Phase III clinical trials while exploring a sales partnership (sublicensing) with pharmaceutical companies in Japan. The company supports these efforts, including introducing potential partners. It has established a scheme under which it receives a portion of revenue that HK inno.N earns from sublicensees.

Out-licensed and pre-out-licensing programs

For the out-licensed programs, including the P2X7 receptor antagonist, TRPM8 blocker, and 5-HT4 agonist for animal health, RaQualia's licensees and sublicensees are advancing development in preclinical and later stages.

The company confirmed that Eli Lilly has removed the P2X7 receptor antagonist from its pain-relief development pipeline. Based on clinical trial results to date, the company recognizes that there is a low possibility that Eli Lilly will resume development in the pain area. However, the license agreement remains in effect, and Eli Lilly has not terminated development of the P2X7 receptor antagonist, continuing internal reviews of future development options. Xgene is conducting a Phase I clinical trial for the TRPM8 antagonist. The company is closely monitoring progress in this study.

For pre-out-licensing programs, RaQualia completed preclinical trials for its ghrelin receptor agonist program and is conducting business development activities, aiming to secure licensing agreements.

The company has also actively engaged in other pre-out-licensing activities through flexible in-person meetings and online conferences with potential partners. The company suggests it began negotiating specific terms for the IRAK-M degradation inducer.

Exploratory programs

In the exploratory research phase, RaQualia is concentrating on research programs aimed at creating new development compounds. By enhancing its next-generation drug discovery value chain through synergies of existing and new technologies, the company advances a critical development strategy to target previously unexplored drug opportunities, including genes and proteins once considered undruggable. The company seeks to enhance technologies and pipelines, approaching from four perspectives: modality, drug discovery targets, disease areas, and foundational technologies.

In May 2025, RaQualia confirmed favorable results from the joint research with D. Western Therapeutics Institute, Inc. (TSE Growth: 4576, DWTI). The partners continue joint research and validating results, with plans to explore possibilities for collaboration in the next phase. The company is conducting joint research with Veritas In Silico Inc. (TSE Growth: 130A) to develop breakthrough small-molecule drugs targeting messenger RNAs (mRNA). The company expanded the scope of target genes covered under joint research and, leveraging the expertise of both parties, conducted screening for multiple genes. As a result, it obtained several small-molecule compounds that could serve as starting points for drug discovery aimed at generating development candidates.

The company is developing targeted protein degradation inducers—a novel drug discovery modality—primarily through FIMECS, which became a consolidated subsidiary in March 2024. FIMECS and Astellas Pharma Inc. (TSE Prime: 4503) are jointly developing compounds targeting multiple proteins for cancer treatment, leveraging the proprietary RaPPIDS™ drug discovery platform, which was specifically designed for targeted protein degradation.

Milestone payments and a new science-driven management structure at FIMECS

In March 2025, FIMECS completed a predefined phase of its joint research project for the same program, advancing to the next stage of research. As a result, FIMECS received JPY200mn from Astellas. In November 2025, the company agreed with Astellas to add two new drug discovery targets to the research collaboration and will receive an upfront payment of JPY400mn. If Astellas identifies a development candidate and achieves commercialization of a new pharmaceutical product, FIMECS may receive milestone payments exceeding JPY15.0bn in total, tied to development progress, regulatory filing and approval, and sales, as well as royalties at a single-digit rate on product sales.

In FY12/25, FIMECS achieved profitability for the first time since its establishment, in its eighth year. FIMECS's core strengths lie in its proprietary capability to identify novel E3 ligase-binding molecules and create orally available targeted

protein degradation (TPD) drugs, which the industry considers challenging. Major pharmaceutical companies strongly recognize these technological advantages, and this recognition drives new partnerships and strengthens the company's negotiating leverage.

From March 2026, Mr. Gamo, CSO and one of the founders of the company, assumed the role of representative director and CEO of FIMECS. By shifting to a management structure with deep scientific expertise, FIMECS will transition from a technology provider to a more strategic business model, focusing on out-licensing its own pipeline assets and pursuing large-scale partnerships.

Capital and business alliance with HK inno.N

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. A total of 2,592,100 common shares were allocated to HK inno.N, representing 10.62% of voting rights after the issuance. HK inno.N made the payment on April 18, 2025.

Through the partnership, RaQualia aims to strengthen its financial base through investment from HK inno.N and to establish a strategic alliance between the two companies. In cumulative Q3, the company advanced preparations to launch the joint research project for tegoprazan, including obtaining study data and holding discussions to formulate the project plan (see "Medium-term business plan" for collaboration expansion in December 2025).

Absorption-type merger (simplified and short-form merger) of TMRC Co., Ltd.

RaQualia merged with TMRC through a simplified, short-form absorption-type merger to streamline group operations, reduce costs, and improve administrative efficiency. Under the merger, the company remained the surviving country, and TMRC was dissolved. The company and TMRC signed the merger agreement on October 17, 2025, and the merger took effect on January 1, 2026. Because the merger was being conducted with a wholly owned subsidiary, the company issued no new shares and paid no consideration for the merger.

FY12/26 company forecast

	FY12/24			FY12/25			FY12/26
(JPYmn)	1H results	2H results	FY results	1H results	2H results	FY results	FY forecast
Operating revenue	**1,411**	**1,697**	**3,108**	**1,536**	**2,444**	**3,980**	**3,980**
YoY	39.1%	91.2%	63.5%	8.9%	44.1%	28.1%	0.0%
Operating expenses	**1,565**	**1,756**	**3,321**	**1,726**	**1,771**	**3,496**	**3,814**
YoY	50.9%	46.2%	48.4%	10.2%	0.9%	5.3%	9.1%
Cost of revenue	227	399	626	389	323	712	
YoY	85.6%	224.8%	155.4%	71.4%	-19.1%	13.8%	
R&D expenses	833	871	1,704	782	818	1,600	
YoY	38.0%	13.3%	24.1%	-6.1%	-6.2%	-6.1%	
R&D expense ratio	59.0%	51.4%	54.8%	50.9%	33.5%	40.2%	
SG&A expenses	506	486	991	554	630	1,184	
YoY	62.1%	57.1%	59.6%	9.6%	29.8%	19.5%	
SG&A ratio	35.8%	28.6%	31.9%	36.1%	25.8%	29.8%	
Operating profit	**-154**	**-59**	**-213**	**-190**	**674**	**484**	**165**
YoY	-	-	-	-	-	-	-65.9%
Operating profit margin	-	-	-	-	27.6%	-	4.1%
Recurring profit	**-278**	**-84**	**-362**	**-291**	**729**	**438**	**86**
YoY	-	-	-	-	-	-	-80.4%
Recurring profit margin	-	-	-	-	29.8%	-	2.2%
Net income	**-324**	**-171**	**-495**	**-355**	**628**	**273**	**-63**
YoY	-	-	-	-	-	-	-
Net margin	-	-	-	-	25.7%	-	-

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

Full-year FY12/26 consolidated earnings forecast (out February 13, 2026)

- Operating revenue: JPY4.0bn (flat YoY)
- Operating profit: JPY165mn (-65.9% YoY)
- Recurring profit: JPY86mn (-80.4% YoY)
- Net loss attributable to owners of the parent: JPY63mn (vs. JPY273mn profit in FY12/25)
- EPS (Earnings Per Share): -JPY2.58 (vs. JPY11.53)

The company expects operating revenue from steady royalty income from global expansion of tegoprazan sales, along with upfront and milestone payments and research collaboration payments, including those received at subsidiaries. It forecasts standalone revenue for RaQualia at JPY3.0bn (+2.2% YoY), and revenue for subsidiary FIMECS at JPY1.0bn (-6.0% YoY). It expects total operating expenses of JPY3.8bn (+9.1% YoY).

The company expects operating revenue will remain flat, projecting continued growth in royalty income while conservatively estimating milestone and upfront payments due to high uncertainty. It projects lower operating profit and a net loss, as it expects to record R&D expenses carried over from FY12/25. The company does not view the expected net loss as overly concerning, prioritizing the maintenance of positive EBITDA, reflecting underlying cash generation excluding goodwill amortization. The company plans to review R&D spending priorities in line with revenue progress, maintaining flexible cost control. The company has made steady progress toward medium- to long-term growth, supported by out-licensing of tegoprazan rights in Japan, as well as by profitability and the overhaul of the management structure at its subsidiary FIMECS.

In FY12/25, the company raised approximately JPY1.4bn through a third-party allotment to HK inno.N, improving its equity ratio to 65.1% (+7.7pp YoY). Under its new medium-term management plan through FY12/28, it targets available funds of approximately JPY19.0bn, including cash on hand and stock acquisition rights. It plans to allocate these funds flexibly to exploratory research as well as strategic investments, including M&A and the acquisition of new modalities.

Key catalysts

	Indication	Country/ region	Development phase	FY12/26	FY12/27–FY12/28	Licensee, partner
Tegoprazan	Gastroesophageal reflux disease and other diseases	US	Phase III	Under regulatory review	Obtain approval and launched	HK inno.N / Sebela, Braintree
		Japan	Phase I	Conduct late-stage clinical trials		HK inno.N
		Europe	Preclinical trials	Signed license-out agreement	Conduct late-stage clinical trials	HK inno.N, partner
TRPM8 blocker	Chronic pain	Worldwide	Phase I	Progressed in clinical trials (Phase I to Phase II)		Xgene
Ghrelin receptor agonist	Constipation, cachexia	Worldwide	Preclinical trials	Out-licensing	Conduct clinical trials	Partner
IRAK-M degradation inducer	Cancer (cancer immunity)	Worldwide	Preclinical trials	Prepare for clinical development and out-licensing	Conduct clinical trials	Partner
Existing joint research programs	Cancer	Worldwide	Research	Progress in joint research (milestone payments)		Astellas, HK inno.N
New joint research programs	TBD	Worldwide	Research	Sign a new contract	Sign a new contract	Partner
P2X7 receptor antagonist	TBD	Worldwide	Not disclosed	Revise the development plan and resume development		Asahi Kasei Pharma, Lilly

Source: Shared Research based on company data

Difference between initial company forecasts and results

Results vs. initial forecast	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24	FY12/25
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.
Operating revenue (initial forecast)	950	1,100	1,388	2,022	2,129	2,738	2,605	2,799	4,535	3,888
Operating revenue (results)	705	1,419	745	1,703	1,107	2,776	2,918	1,901	3,108	3,980
Results vs. initial forecast	**-25.8%**	**29.0%**	**-46.4%**	**-15.8%**	**-48.0%**	**1.4%**	**12.0%**	**-32.1%**	**-31.5%**	**2.4%**
Operating profit (initial forecast)	-819	-760	-698	187	70	420	420	260	313	118
Operating profit (results)	-760	-150	-1,075	-16	-486	708	866	-337	-213	484
Results vs. initial forecast	**-**	**-**	**-**	**-**	**-**	**68.5%**	**106.2%**	**-**	**-168.2%**	**309.9%**
Recurring profit (initial forecast)	-819	-761	-680	195	85	427	420	242	290	73
Recurring profit (results)	-721	-81	-1,065	22	-528	864	904	-293	-362	438
Results vs. initial forecast	**-**	**-**	**-**	**-88.9%**	**-**	**102.3%**	**115.3%**	**-**	**-224.7%**	**499.9%**
Net income (initial forecast)	-825	-767	-686	153	13	343	342	183	236	-71
Net income (results)	-728	-58	-1,105	5	-607	756	723	-324	-495	273
Results vs. initial forecast	**-**	**-**	**-**	**-96.5%**	**-**	**120.3%**	**111.5%**	**-**	**-309.8%**	**-**

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

Through FY12/20, its results significantly fell short of its initial forecasts.

In FY12/21, the company booked an operating profit for the first time since its founding in 2008. Brisk sales of the four products on the market (tegoprazan [K-CAB®], GALLIPRANT®, ENTYCE™, and ELURA™) generated strong royalty revenue. Milestone payments for out-licensed programs and upfront payments for new license agreements also contributed to profitability. The significant difference between the initial recurring profit and net income forecasts and actual results is due to JPY146mn in forex gains stemming from yen depreciation.

In FY12/22, in addition to rising royalty revenue from the above four commercialized drugs, the company received a milestone payment accompanying the launch of a Phase II clinical trial on a P2X7 receptor antagonist and upfront payment from a new pet drug license agreement, aided by yen weakness, booking its second consecutive operating profit.

In FY12/23, the company lowered its earnings forecast on December 8, 2023, due to expected delays in finalizing the licensing agreement for the development, manufacture, and sale of tegoprazan in Japan, and the postponement of the approval and launch of ELURA™, a weight loss treatment for cats with CKD, in Europe until FY12/24. The company estimated these delays would negatively impact earnings by JPY900mn.

For FY12/24, the company lowered its earnings forecast in December 2024. It postponed its out-licensing agreement for the development, manufacture, and sales rights of the gastric acid secretion inhibitor tegoprazan in Japan to FY12/25. Additionally, no progress was made on new joint research agreements at FIMECS Inc. or licensing negotiations at TMRC Co. Ltd. However, royalty revenue from HK inno.N and Elanco's veterinary pharmaceuticals remained strong, while milestone payments, research collaboration payments, and option fees related to veterinary drugs contributed to increased other income.

In FY12/25, operating revenue reached a record high, supported by strong royalty revenue from tegoprazan and pet drugs, while other income, including upfront and milestone payments related to sales and research, increased 49.4% YoY but fell short of the initial forecast by JPY207mn due to the absence of upfront payment of tegoprazan. R&D expenses fell short of the initial forecast because commissioned studies were delayed and the company reduced operating expenses through thorough cost control. As a result, all profit categories turned positive.

Medium-term business plan

Revision of targets using a rolling approach

The company has shifted to a rolling update approach and released a new medium-term management plan covering FY12/26–FY12/28 along with the announcement of its full-year FY12/25 earnings results.

For FY12/26, it targets operating revenue of JPY4.0bn (flat YoY) and operating profit of JPY165mn (-65.9% YoY). For FY12/27, it expects operating revenue of JPY4.2bn (+4.3% YoY) and operating profit of JPY279mn (+69.1% YoY), followed by JPY4.7bn (+12.9% YoY) in operating revenue and JPY909mn (+225.8% YoY) in operating profit for FY12/28. The company projects a three-year operating revenue CAGR of 5.6% and an EBITDA CAGR of 13.9%, assuming an exchange rate of JPY150/USD for FY12/26–FY12/28. To remain responsive to changes in the business environment, it will update the plan annually on a rolling basis.

Targets by FY12/28

	FY12/21	FY12/22	FY12/23	FY12/24	FY12/25	FY12/26	FY12/27	FY12/28	3-year
(JPYmn)	Results	Results	Results	Results	Results	Forecasts	Targets	Targets	CAGR
Operating revenue	**2,776**	**2,918**	**1,901**	**3,108**	**3,980**	**3,980**	**4,152**	**4,686**	
YoY	150.7%	5.1%	-34.8%	63.5%	28.1%	0.0%	4.3%	12.9%	5.6%
Operating expenses	**2,068**	**2,052**	**2,538**	**3,321**	**3,496**	**3,814**	**3,872**	**3,777**	
YoY	29.8%	-0.8%	23.7%	30.9%	5.3%	9.1%	1.5%	-2.5%	2.6%
Operating expense ratio	74.5%	70.3%	133.5%	106.9%	87.8%	95.8%	93.3%	80.6%	
Operating profit	**708**	**866**	**-337**	**-213**	**484**	**165**	**279**	**909**	
YoY	-	22.4%	-	-	-	-65.9%	69.1%	225.8%	-
Operating profit margin	25.5%	29.7%	-	-	12.2%	4.1%	6.7%	19.4%	
Recurring profit	**864**	**904**	**-293**	**-362**	**438**	**86**	**212**	**864**	
YoY	-	4.7%	-	-	-	-80.4%	146.5%	307.5%	-
Recurring profit margin	31.1%	31.0%	-	-	11.0%	2.2%	5.1%	18.4%	
Net income	**756**	**723**	**-324**	**-495**	**273**	**-63**	**54**	**676**	
YoY	-	-4.3%	-	-	-	-	-	-	-
Net margin	27.2%	24.8%	-	-	6.9%	-	1.3%	14.4%	
EBITDA	**849**	**1,013**	**464**	**185**	**965**	**685**	**824**	**1,426**	
YoY	-	19.3%	-54.2%	-60.1%	421.6%	-29.0%	20.3%	73.1%	13.9%

Source: Shared Research based on company data

Progress on the previous medium-term plan

As of end-FY12/25, the company made solid progress under its previous medium-term management plan covering FY12/25–FY12/27. In FY12/25, revenue reached a record high and the company returned to profitability, indicating tegoprazan royalties have become a stable revenue base.

The company is continuing compound development and is integrating FIMECS's business into its corporate group. In its development strategy, the company has revised the approach for the ghrelin receptor agonist, now aiming to secure a partnership agreement prior to initiating clinical trials. It is pursuing out-licensing activities for FIMECS' IRAK-M degradation inducer.

While the company signed an option agreement related to a veterinary drug in FY12/24, it did not achieve its goal of concluding one licensing agreement per year from programs under preparation for out-licensing, including tegoprazan (Japan), nor one joint research agreement annually from FIMECS's platform business. In FY12/25, the company committed to out-licensing tegoprazan in Japan and signing a new agreement at FIMECS. Ultimately, it out-licensed tegoprazan to HK inno.N and expanded its agreement with Astellas Pharma.

Targets and progress under the previous medium-term management plan covering FY12/25–FY12/27

		Progress in FY12/25
Operating revenue	Operating profit for all fiscal years	Achieved operating profit
	Total operating revenue of JPY11.1bn	Operating revenue of JPY4.0bn
Research	Developing two candidate compounds	Initiatives underway
	Advancing research on platform and pipeline programs through collaboration between RaQualia and FIMECS	
Development	Out-licensing of ghrelin receptor agonist and IRAK-M degradation inducer and initiation of clinical trials by licensee	Initiatives underway
	Initiation of preclinical trials of new pipeline programs	
Out-licensing	One out-licensing agreement per year from its pre-out-licensing program including tegoprazan (Japan)	Achieved out-licensing of tegoprazan in Japan
	One joint research agreement per year in FIMECS' platform business	Expanded agreement with Astellas Pharma

Source: Shared Research based on company data

Targets for FY12/28 under the new medium-term management plan

Revenue	• Operating profit for three consecutive fiscal years from FY12/26 through FY12/28 • Cumulative operating revenue of JPY12.8bn over the three-year period through FY12/28
Research	• Discover three development candidate compounds by FY12/28 • Advance platform and pipeline development through collaboration between RaQualia and FIMECS • Advance pipeline development through joint research with HK inno.N
Development	• Out-license ghrelin receptor agonists and IRAK-M degradation inducers, initiating clinical trials at licensees • Initiate preclinical studies for new development programs
Out-licensing	• Enter into one license agreement per year from programs under preparation for out-licensing • Enter into one joint research agreement per year in FIMECS' platform business

Source: Shared Research based on company data

Targets under the new medium-term management plan

Operating revenue forecast: total of JPY12.8bn

FY12/26

The company expects royalty income to increase steadily, driven by the expansion of tegoprazan's global rollout, and expects to receive upfront and milestone payments and research collaboration payments, including from new agreements at FIMECS. The company forecasts operating revenue of JPY4.0bn (flat YoY), consisting of JPY3.0bn (+2.2% YoY) in standalone revenue from RaQualia and JPY1.0bn (-6.0% YoY) from subsidiary FIMECS.

FY12/27

The company expects royalties will increase YoY, driven by the expansion of tegoprazan's sales area. While it anticipates milestone payments and research collaboration payments from within the group, it expects a YoY decline in upfront and milestone payments from new agreements. The company forecasts operating revenue of JPY4.2bn (+4.3% YoY), consisting of JPY2.9bn (-3.2% YoY) in standalone revenue from RaQualia and JPY1.3bn (+26.5% YoY) from subsidiary FIMECS.

FY12/28

Following FY12/26 and FY12/27, the company projects royalties will increase YoY, driven by the expansion of tegoprazan's sales area. While it anticipates upfront and milestone payments and research collaboration payments, it

conservatively assumes contributions from new agreements and milestone payments. The company forecasts operating revenue of JPY4.7bn (+12.9% YoY), consisting of JPY3.2bn (+12.4% YoY) in standalone revenue from RaQualia and JPY1.5bn (+14.0% YoY) from subsidiary FIMECS.

Status and allocation of funds

Fund	Use: investment aiming to enhance corporate value	Use: shareholder return
Estimated operating revenue from FY12/26 to FY12/28: JPY12.8bn	Exploratory investment, including personnel expenses for three years to expand research areas: JPY7.2bn	Dividend: to be implemented in line with efforts to strengthen the financial base
Cash and cash equivalents as of end-FY12/25: JPY3.8bn	Preclinical and clinical trials, including personnel expenses for three years to enhance project value: JPY300mn	Acquisition of own shares: consider flexibly
Borrowing capacity (commitment line): JPY500mn	Capex (expanding existing facilities, investment in AI and digital transformation)	
Received payment from HK inno.N: JPY1.4bn	Strategic investment (acquisition of drug discovery technologies and pipeline programs)	
Equity financing (share subscription rights): JPY490mn		

Source: Shared Research based on company data

Growth strategy: Transforming undruggable targets into druggable ones

To maximize corporate value as a drug discovery venture, the company continuously discovers innovative drug candidates and strengthens its portfolio in disease areas with high unmet medical needs, where existing treatments remain insufficient.

Drug discovery faces its greatest challenge in druggability. Of approximately 25,000 human genes, around 3,000 are associated with diseases, yet only about 500 represent druggable targets that conventional approaches, such as small molecules or antibodies, can modulate. The company targets the remaining undruggable space—disease-related genes and proteins for which drug discovery has remained extremely difficult—leveraging its advanced small-molecule drug discovery platform and developing novel modalities, including mRNA-targeted small molecules, intrabodies, and targeted protein degradation (TPD) technology through its subsidiary FIMECS. Through this approach, the company aims to open up previously untapped areas of drug discovery.

To enhance the pipeline of new drug candidates and strengthen the underlying drug discovery research capabilities, the company is advancing the following four initiatives.

- Strengthening partnerships: The company will strengthen its capital and business alliance with HK inno.N, accelerating the commercializaiton of tegoprazan, conducting joint research, and strengthening its financial base.
- Strengthening the drug discovery research platform: The company will expand investment in new modalities, building on its proven small-molecule drug discovery capabilities.
- Expanding the R&D portfolio: During the medium-term management period, the company will focus on generating new development candidates.
- Strengthening the business model: The company will adopt a hybrid business model, combining growth in royalty income with revenue generation at the research stage.

Four key initiatives to enhance corporate value and shareholder value

Strengthening partnerships	Improved growth potential (PER) and profitability (ROE)
Strengthening the drug discovery research platform	Improved growth potential (PER)
Expanding R&D portfolio	Improved growth potential (PER)
Strengthening the business model	Improved growth potential (PER) and profitability (ROE)

Source: Shared Research based on company data

Establishing drug discovery value chain through open innovation

The company thinks it must organically combine basic technologies with drug discovery technologies if it is to continually create its development pipeline, and thus has a policy of actively working in collaboration with startups, drug discovery ventures, and academia to solve problems. Creating a drug development pipeline by combining its own technologies is possible with a plentiful supply of funds and human resources, but carries the risk of being limited by existing technologies and frameworks. Relationships of trust and ensuring rights are protected are important in open innovation between multiple companies and collaborations with academia, but this approach allows the application of technologies that a company does not own. The company seeks to establish a next-generation in-house drug discovery value chain by

harnessing synergies between its own existing technologies and strengthened collaboration with startups and drug discovery ventures (see the “Business” section below).

- 1) Initiatives to expand drug discovery targets: Joint research with Veritas In Silico Inc. (TSE Growth: 130A; VIS)
- 3) Initiatives to expand modalities: Joint research with STAND Therapeutics Co., Ltd.
- 4) Initiatives to maximize value of pipeline: Joint research with D. Western Therapeutics Institute (TSE Growth: 4576; DWTI)

Capital and business alliance with HK inno.N

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. A total of 2,592,100 common shares were allocated to HK inno.N, representing 10.62% of voting rights after the issuance. HK inno.N made the payment on April 18, 2025.

The alliance aimed to establish a strategic partnership. Through this alliance, the company seeks to strengthen its financial base and generate synergies across broad areas, including R&D, to maximize corporate value. The funds raised will primarily be used for capital investment and R&D investment, key drivers of the company’s growth strategy such as below.

- R&D expenses related to the development of exploratory-stage candidates, including collaborative research and outsourcing
- R&D expenses aimed at enhancing the value of existing compounds at the preclinical stage or later, including the ghrelin receptor agonist (covering activities such as API manufacturing, preclinical studies, and clinical trials)
- Investment in infrastructure

Expanded capital and business alliance with HK inno.N, including out-licensing of tegoprazan in Japan

In December 2025, the company announced it had out-licensed to HK inno.N exclusive rights, with sublicensing rights, for the development and commercialization in Japan of tegoprazan, a gastric acid secretion inhibitor. At the same time, the company stated it would strengthen its capital and business alliance with HK inno.N through the issuance of new shares via a third-party allotment. As a result of the third-party allotment, HK inno.N will hold approximately 16.0% of the company’s issued shares, remaining the largest shareholder.

The company has identified domestic commercialization of tegoprazan as its top priority for FY12/25 as it believes doing so is directly related to maintaining and enhancing corporate value. It held discussions with multiple candidates with the aim of concluding a contract in FY12/25. It recognized delays in initiating development could postpone market entry and negatively affect profitability, hence prioritizing development timing in its considerations.

Since entering into the partnership agreement in March 2025, the company has held repeated discussions with HK inno.N regarding potential future business collaboration and joint research. They share a common focus on the commercialization of tegoprazan in Japan and the ongoing generation of innovative pharmaceuticals beyond tegoprazan. Consequently, both parties determined to further strengthen their cooperative relationship by expanding the scope of the partnership.

The company will grant HK inno.N exclusive development, manufacturing, and marketing rights in Japan to commercialize human pharmaceuticals containing tegoprazan as the active ingredient. HK inno.N will advance efforts to conduct late-stage clinical trials. The agreement includes no upfront payment; instead, the company retains the right to receive sales royalties, a share of the revenue HK inno.N earns from its partners, and milestone payments tied to future development and commercialization progress. Although HK inno.N does not have a sales network in Japan, it may sublicense the product to a Japanese pharmaceutical company.

The company states it selected HK inno.N primarily because of its commitment to rapid commercialization. The company recognizes the competing drug TAKECAB® (generic name: vonoprazan) could lose patent protection in the early 2030s and believes launching tegoprazan before generic entry is critical to securing a sufficient period of market exclusivity in the Japanese market. For this reason, the company prioritized an early start to clinical development in Japan and, by prioritizing contract execution within 2025, decided to out-license tegoprazan to HK inno.N, which has product knowledge and development expertise in tegoprazan. Under the agreement, HK inno.N will bear the development costs for late-stage clinical trials in Japan.

Overview of December 2025 expansion of alliance

The main terms of the expanded alliance are as below, under which an amendment to the license agreement grants HK inno.N exclusive rights to develop, manufacture, and market tegoprazan in Japan. In addition, the company and HK inno.N will examine and discuss measures to further enhance both parties' corporate value.

- RaQualia's grant to HK inno.N of exclusive rights to develop, manufacture, and market tegoprazan in Japan
- Value enhancement for development compounds
- Joint research
- Other R&D initiatives
- Value enhancement for development compounds
- Joint research
- Other R&D initiatives

Overview of the new share issuance

Number of shares to be issued	1,555,900 ordinary shares
Issuance price per share	JPY907 per share
Payment due date	January 29, 2026
Total proceeds	JPY1.4bn
Total amount to be paid in	JPY1.4mn
Estimated issuance expenses	JPY9mn
Estimated net proceeds	JPY1.4mn
Method	Third-party allotment
Planned allottee	HK inno.N Corporation
Amounts of increase in capital stock and capital surplus	Capital stock: JPY705.6mn, Capital reserve : JPY705.6mn

Source: Shared Research based on company data

Use of funds raised through the third-party allotment

The estimated net proceeds from the third-party allotment total JPY1.4bn. The company plans to allocate JPY842mn to R&D, consistent with the previous capital and business alliance, and use the full amount for joint research with HK inno.N. The company plans to apply the remaining JPY559mn toward partial repayment of bank borrowings of JPY2.8bn under a syndicated loan.

1) Strengthening drug discovery infrastructure (JPY284mn): R&D investment in new modalities, including targeted protein degradation (TPD) and small molecules targeting mRNA, as well as related platform technologies

2) Initiatives aimed at expanding the development pipeline (JPY267mn): R&D investment in exploratory studies to create new development pipelines through joint research with HK inno.N, including the purchase of consumables and costs related to various experimental studies

3) Strengthening facilities for experimental research (JPY291mn): capital expenditure to improve operational efficiency and increase the probability of search activities

4) Repayment of a syndicated loan (JPY559mn)

Use of proceeds and scheduled timing of expenditure

Use	Amount (JPYmn)	Scheduled timing of expenditure	
Strengthening drug discovery infrastructure (a technology platform that supports the advancement of joint research projects with HK inno.N)	284	Feb 2026–Dec 2028	FY12/26: JPY80mn, FY12/27: JPY80mn, FY12/28: JPY124mn
Initiatives aimed at expanding the development pipeline (creation of a new development pipeline through joint research with HK inno.N)	267	Feb 2026–Dec 2028	FY12/26: JPY118mn, FY12/27: JPY90mn, FY12/28: JPY58mn
Strengthening facilities for experimental research (procurement of experimental research equipment that contributes to the advancement of joint research projects with HK inno.N)	291	Feb 2026–Dec 2028	FY12/26: JPY70mn, FY12/27: JPY101mn, FY12/28: JPY120mn
Repayment of a syndicated loan	559	Mar 2026–Mar 2027	FY12/26: JPY500mn, FY12/27: JPY59mn
Total	1,402		

Source: Shared Research based on company data

In expanding the capital and business alliance, HK inno.N, Mr. Yuichi Kakinuma, a major shareholder and Audit & Supervisory Committee member of the company, and the company agreed on the following matters.

- Dispatching directors and an observer: From March 2026 onward, HK inno.N will nominate two director candidates to the company. One observer will attend the Board meetings until the directors assume office and in the event of a vacancy.
- Granting preemptive rights: In the event of issuances of shares or similar securities (excluding public offerings, stock splits, and stock options for officers and employees), HK inno.N may subscribe on a preferential basis to newly issued shares or similar securities in proportion to its ownership stake.
- Effective date and termination conditions: The agreement will take effect upon completion of payment and will automatically terminate if the shares held by HK inno.N or Mr. Kakinuma fall below 5% of the issued shares.

Business

Business overview

Predecessor was Pfizer's central research laboratory in Japan

RaQualia Pharma Inc. is an R&D-focused drug discovery company. It primarily conducts exploratory research into small molecule compounds ("seeds") for new drugs, and out-licenses development and marketing rights to pharmaceutical and other companies. The company got its start when US-based Pfizer Inc. (NYSE: PFE; ranked third in terms of pharmaceutical sales worldwide in 2023) decided to close its central research laboratory in Japan as part of a global research restructuring in 2007. The research lab spun off from Pfizer through an employee buyout, and RaQualia was established in July 2008. Pfizer held 19% of the company's shares at its inception, but reduced its stake after the company's initial public offering (IPO), and as of end-December 2025 it held 3.04%.

Pfizer transferred intellectual property to the company covering six exploratory programs, six development programs, and Japanese rights to three products already approved and marketed in the US: GEODON® (ziprasidone), Dalvance® (dalbavancin), and ERAXIS® (anidulafungin)*. Under development at that time were tegoprazan and GALLIPRANT® (grapiprant), which the company continued developing and has already launched. Some compounds transferred from Pfizer are among the pre-out-licensing and out-licensed programs in the development pipeline. The company will pay royalties to Pfizer and record them as cost of operating revenue when licensing out certain compounds transferred from Pfizer.

* Programs transferred from Pfizer that are currently in RaQualia's development pipeline include a potassium-competitive acid blocker (tegoprazan), EP4 receptor antagonist (grapiprant), ghrelin receptor agonist (capromorelin), 5-HT_4, CB2, and 5-HT_{2B}, as well as those at a stage of research where the compound candidate has not yet been determined. Convinced of its value, the company was committed to developing tegoprazan, which it took over after Pfizer decided to withdraw from gastrointestinal diseases in 2007. Tegoprazan has been a key driver of the company's growth.

Earnings structure

In general, biotech company's revenue can be broken down based on drug development stage into: 1) upfront payments received when a contract is signed; 2) development milestone payments tied to predetermined achievements such as clinical trial initiation and application filings; 3) research collaboration payments when conducting joint research, and 4) royalty payments based on a percentage of sales from launched products, while one-time sales milestone payments are triggered when cumulative sales exceed predetermined thresholds.

Licensees have already launched four products, providing the company with stable long-term royalty revenue, its main source of earnings. In FY12/25, operating revenue was JPY4.0bn (+28.1% YoY), comprising royalty revenue (56.3%), as well as upfront and milestone payments, research collaboration payments, and other income (43.6%).

Types of company revenue

Upfront payment	Revenue received upon signing out-licensing or R&D cooperation contract
	Compensation for value and potential of new drug candidate the company has developed
Development milestone payment	Relatively short- to medium-term revenue generated in line with R&D progress at out-licensees
	Received when key barriers are crossed in process of transforming new drug candidate into a new drug such as moving to the next phase of clinical trials
Sales milestone payment	Revenue received after product launch when product sales reach predetermined thresholds
Royalty revenue	Revenue based on product sales at out-licensee
	Rate increases progressively with sales, depending on contract terms
Research collaboration payment	Revenue from partners when conducting joint research aimed at generating new drug candidates through early-stage alliances. Consideration for the company's drug discovery technologies

Source: Shared Research based on company data

Revenue by region

	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24	FY12/25
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.
Total	705	1,419	745	1,703	1,107	2,776	2,918	1,901	3,108	3,980
YoY	384.7%	101.2%	-47.5%	128.6%	-35.0%	150.7%	5.1%	-34.8%	63.5%	28.1%
US	646	818	278	761	549	1,004	1,142	1,091	1,129	861
YoY	-	26.5%	-66.0%	173.8%	-27.8%	82.7%	13.8%	-4.5%	3.5%	-23.7%
% of total	91.6%	57.6%	37.3%	44.7%	49.6%	36.2%	39.1%	57.4%	36.3%	21.6%
Japan	50	471	349	196	28	1,187	742	6	711	1,067
YoY	-52.6%	841.1%	-25.8%	-43.7%	-85.9%	4175.6%	-37.5%	-99.2%	-	50.2%
% of total	7.1%	33.2%	46.8%	11.5%	2.5%	42.8%	25.4%	0.3%	22.9%	26.8%
Asia	9	131	121	746	530	585	1,034	801	1,256	2,051
YoY	-77.5%	1355.0%	-7.8%	517.9%	-28.9%	10.3%	76.8%	-22.6%	56.8%	63.4%
% of total	1.3%	9.2%	16.2%	43.8%	47.9%	21.1%	35.4%	42.1%	40.4%	51.5%
Europe	-	-	-	-	-	-	-	-	-	-
YoY	-	-	-	-	-	-	-	-	-	-
% of total	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	4	12	-
YoY	-	-	-	-	-	-	-	-	249.5%	-
% of total	-	-	-	-	-	-	-	0.2%	0.4%	-

Source: Shared Research based on company data
Note: Revenue is based on customer location, and classified by country or region

Potential revenue from out-licensing products

As of end-FY12/25, potential revenue from milestone and royalty payments from out-licensed programs totaled JPY80.0bn. Development milestone payments are capped at JPY20.0bn, of which the company earned JPY5.3bn by end-FY12/25. Potential sales milestone payments exceed JPY60.0bn, with no revenue recorded to date. Royalties have no upper limit; the company earned JPY10.5bn by end-FY12/25.

Business territory

Drug discovery from exploratory research to early clinical development

RaQualia is a drug discovery company that uses leading-edge technology with the aim of developing drugs for diseases with high unmet medical needs. The stages of drug discovery on which it focuses range from exploratory research of target molecules to early clinical development. When conducting development, the company aims to reduce R&D expenses and risk by advancing programs through early clinical trials (up to Phase II), where efficacy and safety can be broadly assessed. The company broadened its targets from pain and gastrointestinal diseases to include neurological diseases in FY12/21, and added oncology in FY12/24.

Neurological diseases: Newly added to the company's disease coverage, these involve damage to the brain, spinal cord, and nerves. A wide range of conditions comes under this category due to the number of bodily functions controlled by the nerves. Typical examples include cerebrovascular disease, Alzheimer's, epilepsy, and Parkinson's disease, as well as migraine and tension headaches.

The company has traditionally aimed at out-licensing at the preclinical stage, and many of the out-licensing deals to date have been in the early development stages. However, due to the low likelihood of market launch for pipeline drugs in the early development stage, upfront, milestone, and royalty payment rates tend to be lower. In FY12/21, the company shifted toward developing new drug candidate compounds until the proof of concept (POC) stage (which confirms the usefulness and efficacy of a new drug candidate compound under development through administration to humans) in a bid to enhance the value of its future pipelines. POC demonstration entails carrying on clinical trials until the Phase II stage, and requires more R&D spending than previously. The company plans to fund clinical trials through a combination of equity financing and commitment credit lines.

Following FIMECS' FY12/24 conversion into a subsidiary, the company adopted a hybrid business model and is now reconsidering early out-licensing, particularly during basic and exploratory research, as a strategic option. It also revised the development plan for its ghrelin receptor agonist, now aiming to secure a collaboration agreement before initiating clinical trials. The company has not scheduled clinical trials for the compound.

Making the undruggable druggable

The human genome includes approximately 25,000 genes, of which around 3,000 are associated with disease. Currently, only about 500 of these are considered druggable targets. The company focuses on neuroscience and oncology, areas with high unmet medical needs, and aims to develop innovative drugs by targeting previously intractable disease-related genes through a reinforced drug discovery value chain.

*"Druggable" refers to the potential for modulating the function of target molecules, such as receptors, using compounds or antibodies. Target druggability significantly affects the likelihood of generating viable drug candidates.

Drug development process

Generally, R&D into drugs goes through several stages. Exploratory research looks for new compounds ("seeds") on which drugs will be based; nonclinical studies confirm the efficacy and safety of the compounds discovered through experiments on animals; clinical trials confirm efficacy and safety of administration to humans (healthy individuals and patients). Phase I clinical trials check for safety and adverse reactions in a small number of healthy individuals. Phase II clinical trials evaluate efficacy and safety and help determine appropriate dosages and dosing regimens in a limited patient population. Phase III clinical trials compare efficacy and safety with existing drugs using large numbers of patients.

Time required and success rates

Before a new drug is launched, applications are filed with regulatory authorities in individual countries based on huge volumes of trial data regarding its quality, efficacy, and safety. The drug is marketed following reviews and approval by experts. The process involves a long R&D period of roughly 10 to 15 years, and expenditure of tens of billions to hundreds of billions of yen. Few development pipelines succeed, as development may be halted during the long R&D period due to risks such as changes in the business environment and failure to obtain sought-after data. The difficulty of drug development continues to increase and likelihood of success has declined over time. The Japan Pharmaceutical Manufacturers Association puts the probability of success at 1 in 23,000 currently, versus 1 in 13,000 20 years ago.

Typical drug discovery processes and company's business territory

	Process		Duration	Details	RaQualia's business territory
Research	Exploratory (basic) research		3–5 years	Development of therapeutic concepts, compound synthesis and evaluation	✔
Development	Preclinical (nonclinical) studies		2–3 years	Evaluation of efficacy and safety mainly in animals	✔
	Clinical trials	Phase I	3–7 years	Evaluation of efficacy and safety in humans	✔
		Phase II			
		Phase III			
	Approval filing		approx. 1 year	Application and regulatory review	
	Time until launch		Total 9-16 years		

Source: Shared Research based on company data

Success rates in new drug development

	2000–2004	2005–2009	2010–2014	2015–2019
Preclinical trial launch	1:2,158	1:3,213	1:3,748	1:3,740
Clinical trial launch	1:3,653	1:8,698	1:9,622	1:10,301
Regulatory approval (own company)	1:12,888	1:31,064	1:24,553	1:22,749
Number of approvals (own company)	36	21	29	24

Source: Shared Research based on MHLW, Pharmaceutical Industry Vision 2021

RaQualia's drug discovery modality (methodology)

Expertise in small molecule drug development

The company primarily engages in R&D into small molecule compounds, which comprised its entire development pipeline as of FY12/22. The company got its start through an employee buyout of the central research laboratory in Japan

of US-based Pfizer. When it was established in 2008, RaQualia took over research equipment and some research programs from Pfizer, the world's largest pharmaceutical company by revenue in 2021. As a result, less than two years after its founding, the company succeeded in out-licensing tegoprazan, its potassium-competitive acid blocker.

Building on Pfizer's expertise, which had focused on compound synthesis and design, the company established an internal structure to conduct experiments with the 100–150 compounds it synthesizes every week. It assigns an eight-digit compound code (starting with 00000001) for all the compounds it researches, develops, and evaluates. The number of digits in the codes demonstrates the company's ongoing exploratory research aimed at finding the seeds of new drugs using its vast stores of data. The compound database it uses on a daily basis numbers approximately 800,000, including a library of about 300,000 compounds used for screening.

World's shortest research cycle: two weeks

The company uses a robotics system called SCARA (Selective Compliance Assembly Robot Arm) which allows it to evaluate 10,000 compounds a day from its vast compound library. New compounds that will become the seeds of new drugs are synthesized by analyzing multidimensional data, with designs based on empirical rules and computational methods according to an efficient synthesis plan based on accumulated expertise. Synthetic samples (including impurities) synthesized by company chemists are delivered promptly to pharmacologists in solution form with purity guaranteed through the company's CAP (Centralized Analysis & Purification) system that automates the purification, weighing, dissolution, and dispensing processes. The company says using CAP increases the SCARA robotic system's efficiency by roughly 10 times, enabling it to supply 200 compounds per week.

All information concerning compounds is managed using two-dimensional barcodes in a database and used for the structure-activity relationship (SAR)* research. Barcode-controlled 384-hole plates conduct rapid, accurate pharmacological, safety, metabolic, and other studies. Results are promptly recorded in a database and reported to design and synthesis staff. This research cycle takes two weeks, which the company says is the fastest in the world.

* Structure-activity relationship: Refers to the statistical relationship between the structure of a chemical substance and its biological (pharmacological or toxicological) activity. In the drug discovery process, researchers conduct studies aimed at making predictions about the efficacy of structurally similar compounds.

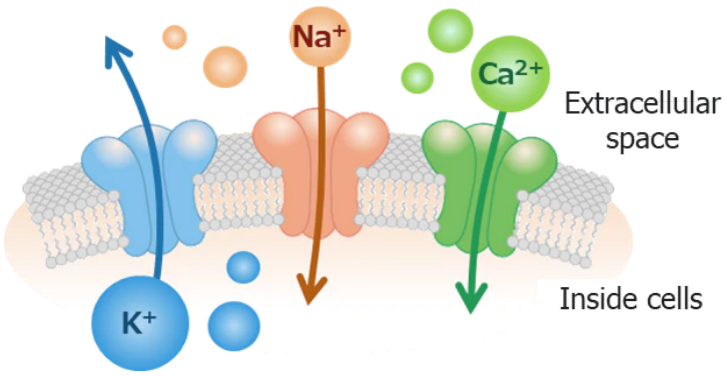
Ion channel drug discovery

The company has already out-licensed five drug discovery programs targeting ion channels. Ion channels are membrane proteins which allow the passage of ions across cell membranes. Expressed in a range of cells, each has a specific ion that can pass through it; examples include the sodium channel, calcium channel, potassium channel, and chloride ion channel.

Ion channels are vital for the maintenance of cell functions and deeply involved in a variety of physiological phenomena. There are over 100 types. Modulating ion channels may offer therapeutic potential across a wide range of diseases; however, selective blocking is essential to avoid serious adverse effects, as simultaneous inhibition of different ion channels in distinct tissues can lead to unintended outcomes. Ion channels are widely expressed in vital organs such as the heart and brain, increasing the risk of life-threatening adverse reactions, including cardiotoxicity and neurotoxicity. Compound design expertise and systems enabling constant high throughput screening* to evaluate compounds are necessary, so this is a niche territory where few companies operate. Consequently, drugs targeting ion channels account for under 10% of all drugs, and RaQualia is the only company in the world to have out-licensed five drugs in the area.

* High throughput screening (HTS) is a technology used to select useful drug candidates from a vast number of compounds rapidly and efficiently. Fast, efficient screening requires a systematic approach covering all processes, including compound storage, structural diversity, solution preparation, plate preparation, assay technology, robotic assays, measurement methodologies, data processing, and database building.

Ion channel mechanism



Source: Company data

Key physiological phenomena involving ion channels

Nerve signaling	➡	**Cognition, memory, five senses**	➡	**Psychiatric and neurological disorders**
Myocardial contraction	➡	Arrhythmia	➡	**Cardiovascular disease**
Skeletal muscle contraction	➡	Quadriplegia, muscle atrophy	➡	**Muscular disorders**
Hormone secretion	➡	Blood sugar, diuresis	➡	**Metabolic and urological diseases**

Source: Shared Research based on company data

Researchers originally involved when the company was under the Pfizer umbrella are conducting a large number of drug discovery research programs targeting ion channels based on advanced technology and abundant experience. To improve screening efficiency, the company teamed up with Hamamatsu Photonics K.K. (TSE Prime: 6965) to develop a voltage-gated ion channel assay system (EFS-FRET Assay System). The system acquires about 1,000 data points per day, enabling highly accurate, low-cost ion channel assays. It enables the company to conduct electrophysiological* research in-house, allowing it to distinguish its assays.

* Electrophysiology refers to both a branch of physiology and an experimental technique that elucidates the electrical properties of nerves, the brain, muscles, and other tissues or cells, and their effects on the body. The interior of cell membranes in living cells maintains an electrically charged state against the outside, and stimuli and information received by sensory cells and nerve cells from outside the cells change the membrane's potential. Neurophysiology in particular focuses on electrophysiological research, and conducts molecular-level research on ion channels and receptors.

The company has a track record of collaborative research in ion channel drug discovery with companies in Japan and overseas, which has resulted in some out-licensed programs.

- Eli Lilly & Company (US): 2010–2014
- Ajinomoto Pharmaceuticals Co., Ltd. (currently EA Pharma Co., Ltd., Japan): 2012–2017
- Asahi Kasei Pharma Corporation (Japan): 2013–2018
- XuanZhu Pharma Co., Ltd. (China): 2015–2018
- ASKA Pharmaceutical Co., Ltd. (Japan): Since 2019–2023

Development candidate compounds created by the company and licensees

Program	Compound code	Main indications	Licensee	Development stage
P2X7 receptor antagonist	RQ-00466479/AK1780	-	Asahi Kasei Pharma	Joint research in 2013
				Eli Lilly running Phase II trials
Selective sodium channel blocker	Not disclosed	Analgesic and antipruritic	Maruho	Out-licensed in 2017
				Not disclosed
Specific ion channel target	Not disclosed	Specific gastrointestinal disorders	EA Pharma	Joint research in 2012
				Not disclosed
TRPM8 blocker	RQ-00434739	Chronic pain	Xgene	Out-licensed in 2021
				Xgene (Hong Kong) running Phase I trials
Sodium channel blocker	RQ-00350215	Chronic pain	Hisamitsu	Out-licensed in 2021
				Not disclosed

Source: Shared Research based on company data (as of December 2024)

The TRPM8 blocker and sodium channel blocker programs were out-licensed in FY12/21, and are drug discovery programs targeting ion channels.

Expanding coverage to neurological diseases

The company has decided to shift the direction of in-house development from a line-up focused mainly on pain and gastrointestinal diseases to include neurological diseases. From FY12/22 onward, RaQualia plans to focus on areas with significant unmet medical needs including neurodegenerative, genetic, and rare diseases, and continue to discover new drugs by searching for target molecules and collaborating with academia in its disease models. The company has long pursued research on pain, a disorder associated with the nervous system. With growing demand for treatments of nervous system diseases among rare diseases, the company determined its technology and facilities were well suited to this field.

Patent expiry management

Aims to extend life of patents

RaQualia applies for basic patents (substance patents) and obtains rights in major countries around the world on an ongoing basis. While the regions and expiry dates differ, the company has several hundred patents, with some effective until around 2040. After filing for a basic patent, the company aims to extend the effective life of patents by seeking extensions and applying for peripheral patents. Compound patents are effective for 20 years, which may be extended by as much as five years, and filing for peripheral patents (such as use patents and manufacturing process patents) can extend exclusivity for a further 20 years. The company has extended the life of patents that Pfizer originally applied for until the mid-2030s via extensions and peripheral patent applications. The aim is to ensure revenue over the long term by delaying the launch of lower-priced generic drugs with the same ingredients and efficacy after the basic patent for a new drug has expired.

Examples of patent types

Patent	Coverage	Example
Substance patent	Substance structure only	Compound as indicated in chemical formula X
Process patent	Substance manufacturing method	Method of producing substance C through reaction of substance A and substance B
Use patent	Uses and target diseases	Agents for treating specific diseases containing substance A
Dosage and administration patent	Dosage and administration method	Administering xx mg per dose x times daily
Formulation patent	Formulation technology	Compressed solid preparation containing substance A, disintegrant B, and binder C
Compound in combination patent	Multiple active ingredients	Pharmaceutical composition containing substance A and substance B
Crystal patent	Substance crystal structure	Crystal of substance A (definition of diffraction angle)

Source: Shared Research based on company data

Trying new modality

Drugs can be broadly classified into two categories: chemically synthesized small molecule drugs and biopharmaceuticals made from biological materials. Small molecule drugs are generally less expensive to produce because they have smaller molecules, a fixed chemical structural formula, and are easy to mass produce. Biopharmaceuticals have active ingredients derived from proteins, such as growth hormones, insulin, or antibodies, and are manufactured from cells, yeast, or bacteria. The molecules of biopharmaceuticals are large and complex, and their

properties and characteristics depend on the manufacturing process, boosting costs. Biopharmaceuticals launched as new drugs tend to be more expensive, and the market is also larger.

When the Ministry of Health, Labour and Welfare puts a new prescription drug on the national health insurance (NHI) price list, the price of the newly developed drug is based on a comparison with drugs already in use with similar efficacy (comparable drug method). If the new drug is more effective or novel, a premium is added, boosting the price. If there is no comparable drug with similar efficacy, the price is based on costs such as raw materials and manufacturing (cost accounting method). There are more existing drugs in the company's main therapeutic areas of pain and gastrointestinal diseases than neurodegenerative diseases, genetic diseases, and rare diseases, which have significant unmet medical needs. This means the price at time of launch for the former tends to be low, as does royalty revenue.

In its medium-term plan up to FY12/24, the company mentioned conducting tests of new modality concepts. Its strength lies in small molecule drug discovery. It plans to try out new modalities involving collaborations with university start-ups and others for drugs challenging to develop with the technology and expertise it has accumulated thus far. The company is engaged in initiatives such as protein structure analysis using cryo-electron microscopy and informatics-driven drug discovery for a structural biological approach to ion channels.

Collaboration with drug discovery start-ups and others

Using AI to look for treatments for intractable and rare diseases

In May 2022, the company and Socium Inc. (unlisted) signed a joint research agreement to look for indications for RaQualia's compounds to treat intractable and rare diseases. Socium's intractable and rare disease program has a database of gene expression patterns for all intractable and rare diseases registered at the Intractable Disease Information Center. Socium can estimate compounds' possible indications based on their gene expression pattern. Estimating indications based on gene expression patterns can identify novel indications in a few months that could not be predicted from the conventional pharmacological mode of action of the compound. The company thinks this will help maximize the value of the compound.

Disease-focused approach using new modality (intracellular antibodies)

In August 2022, RaQualia entered into an agreement with STAND Therapeutics (unlisted) to explore the possibility of applying STAND's technologies to drug discovery, and began collaborating with STAND with the aim of discovering treatments for intractable and rare diseases. Many target molecules of drugs and other medical therapies exist within cells; however, because antibodies cannot function within cells as they become unstable and aggregate in the cytosol, antibody drugs until now have focused on targets in the extracellular space. By utilizing STAND's technology to generate intracellular antibodies that can function within cells, the company believes it can stabilize antibody drugs by attaching stabilizing peptide tags to them and have them approach target molecules in the intracellular space without aggregating.

Aims at mRNA-targeted small-molecule anti-cancer drug discovery

In December 2022, the company announced a joint research agreement with Veritas In Silico Inc. (TSE GRT: 130A, VIS) to discover breakthrough small-molecule drugs targeting messenger RNAs (mRNA). VIS has proprietary platform technologies specialized in mRNA-targeted drug discovery. Through joint research over multiple years, the company and Veritas In Silico will target a number of genes associated with cancer specified by the company and identify target structures on corresponding mRNA; identify hit compounds by high-throughput screening; identify lead compounds by synthesizing analogues (hit expansion); and determine development candidate compounds through lead optimization.

Looking for compounds targeting ion channels to treat eye diseases

In December 2022, the company announced a joint research agreement with D. Western Therapeutics Institute, Inc. (TSE Growth: 4576, DWTI). The partners will use their respective technologies, resources, and expertise in pharmaceutical R&D in joint research aimed at discovering and developing therapeutic agents for specific optic nerve disorders. The company will draw on its ion channel drug discovery technology to synthesize a group of compounds that target specific ion channels. DWTI will verify the compounds' potential as therapeutic agents for eye diseases through pharmacological tests and other methods using its evaluation technology in the field of ophthalmology. Technological achievements and intellectual property obtained from the joint research will be jointly owned by the company and DWTI, and after the research program finishes, the partners plan to hold discussions on the next stage of collaboration.

Structural biology analysis of ion channels

The company announced it has partnered with leadXpro AG (unlisted), a Swiss company with expertise in membrane protein biochemistry, to accelerate drug discovery research targeting membrane proteins, a challenging area for drug development. RaQualia has a strong track record in ion channel drug discovery targeting membrane proteins and aims to accelerate drug discovery projects in this area through collaboration with leadXpro. leadXpro is a biotech company specializing in membrane protein structure-based drug discovery with expertise in structural biology, ligand design*1, and biophysical characterization of membrane proteins. By using structural biology techniques such as cryogenic electron microscopy*2 to observe how ligands bind to proteins at the atomic level, the company believes it is possible to logically design drug candidates (i.e., improve drug activity and selectivity) and accelerate drug discovery research.

*1 A ligand is a substance that binds specifically to a particular receptor, such as an amino acid, protein, or small molecule. Drug development involves identifying receptors that are targets for specific diseases and developing drugs that exert therapeutic effects through interactions with ligands or selective actions of ligand-based drugs.

*2 Cryogenic electron microscopy is a device used to observe and analyze the three-dimensional structure of biomolecules such as proteins by irradiating them with an electron beam while cooled with liquid nitrogen to -196℃.

Joint research and technologies held by startups and drug discovery companies

	Proprietary technologies	Start date	Joint research overview
Socium	Proprietary database of intractable and rare diseases and AI drug discovery platform	May 2022	Exploratory research on the applicability of the company's compounds to intractable and rare diseases
STAND	Proprietary technology (STAND technology) to generate antibodies in cells and approach target molecules	August 2022	Feasibility study on the application of STAND technology for drug discovery targeting intractable and rare diseases
Veritas In Silico	Informatics technology to find target substructures on mRNA	December 2022	Discovery of small-molecule drugs targeting mRNA
DWTI	Expertise in ophthalmic drug discovery (glaucoma drug: Glanatec®)	December 2022	Discovery of treatments for ophthalmic diseases
LeadXpro	Technology for structural analysis of membrane proteins using cryo-electron microscopy	December 2022	3D structural analysis of membrane proteins

Source: Shared Research based on company materials

Business model change

To a hybridized business model

M&A aiming to raise corporate value and shareholder value

In February 2024, the company announced it would acquire all shares in FIMECS, Inc. (unlisted) and make it a subsidiary, because it needs to create a new source of earnings to follow tegoprazan and pet drugs. FIMECS advances the research and development of new pharmaceuticals using targeted protein degradation (TPD) inducers, a new modality in drug discovery. Based on its unique drug discovery platform technology RaPPIDS™, it conducts joint research with Astellas Pharma Inc. (TSE Prime: 4503) and may receive milestone payments according to progress with development and royalties after product launch. The company expects to strengthen its drug discovery value chain, increase its earnings through a hybridized business model, and strengthen the cancer disease area by making FIMECS a subsidiary.

Synergies expected from M&A

Management resources	• Acquire pipelines • Acquire skilled personnel • New corporate cultures and innovation engines
Increased growth potential	• Strengthen drug discovery value chain • Acquire new modalities • Further advance into cancer disease area
Increased profitability	• Increase earnings opportunities • Expand into platform businesses

Source: Shared Research based on company data

Taking on untouched drug discovery targets

Existing small molecule drugs treat diseases by binding to disease-related proteins, which are the drug discovery targets, and inhibiting their function. Proteins with structures that prevent binding have been considered “undruggable” (impossible to discover drugs to treat the condition). However, new modalities and application of new technologies such as informatics and AI in drug discovery have opened up the possibility of creating new candidate drugs that target disease-related proteins that were previously believed to be “undruggable.”

Founded in 2018, FIMECS is a drug discovery bio-venture engaged in research and development of new pharmaceuticals using targeted protein degradation (TPD) inducers, a new modality in drug discovery. TPD works by directly breaking down “undruggable” target proteins. The human body naturally breaks down and removes unnecessary proteins through metabolism, but TPD stimulates the breaking down of the target protein by bringing E3 ligase, an enzyme that adds ubiquitin to mark the target protein to help break it down.

Based on its unique E3 ligase binding molecule and drug discovery platform technology RaPPIDS™, it aims to create innovative medicines for diseases that have been considered extremely difficult to treat using medications (“undruggable”). FIMECS has established a technology to identify the optimal E3 ligase for each target from over 600 known E3 ligases and acquire novel E3 ligase binders by improving and evolving RaPPIDS™.

Platform-type business model enables revenue generation from early-stage of the development

The company operates as a pipeline-type drug discovery company, developing drug candidate compounds, conducting preclinical and clinical trials in-house, and licensing out these programs. It generates revenue through upfront and milestone payments, as well as royalties based on a percentage of sales from launched products. In contrast, FIMECS follows a platform-type model.

Platform-type biotech companies provide their proprietary technology at the exploratory stage and license it out prior to preclinical trials, generating revenue through upfront payments and research collaboration fees. Licensees are responsible for conducting preclinical studies and subsequent development. Platform-type companies earn milestone payments based on development progress and receive royalties based on a percentage of sales from launched products. In contrast with pipeline-type companies, platform-type companies avoid development risk but tend to receive smaller upfront and milestone payments, and royalties. However, they generate more stable income from the early stages of product development. Through the acquisition of FIMECS, RaQualia aims to establish a hybrid model that combines platform- and pipeline-type approaches.

In 2022, FIMECS entered into a research collaboration agreement with Astellas Pharma Inc. (TSE Prime: 4503) on multiple targets. Based on this agreement, FIMECS received an upfront payment of JPY500mn and research funding. After identifying candidate compounds, Astellas Pharma will lead development, and FIMECS will receive milestone payments based on the progress in each target program. Furthermore, after commercialization, FIMECS may receive single-digit sales milestone payments and royalties at a single-digit rate based on sales revenue. In FY12/25, FIMECS recorded operating revenue of JPY600mn from upfront and milestone payments and JPY452mn from research collaboration payments.

FIMECS is also advancing several first-in-class new drug development programs targeting proteins associated with cancer diseases as its main in-house pipeline. The most advanced program, the IRAK-M program (compound code: FIM-001), aims to develop a new cancer immunotherapy based on the mechanism of action of immune suppression relief and is currently in the preclinical stage.

FIMECS' pipeline

Target	Target disease	Research stage	Partner
IRAK-M	Non-small cell lung cancer, pancreatic cancer, other	Preclinical studies	
TRIB1	Cancer	Exploratory	
Undisclosed	Undisclosed	Exploratory	Astellas Pharma
Undisclosed	Undisclosed	Exploratory	Astellas Pharma

Source: Shared Research based on FIMECS website (as of December 2024)

Reason for the acquisition

RaQualia is focused on enhancing corporate and shareholder value by reinforcing its growth foundation, while aiming to improve profitability through the signing of large contracts. In pursuit of growth enhancement, updating the drug discovery value chain and M&A are positioned as key strategies. By making FIMECS a subsidiary, RaQualia expects business expansion in the following three areas:

1. Enhancing the drug discovery value chain to improve growth potential and competitiveness

Traditionally, RaQualia has specialized in drug discovery research of small molecules targeting ion channels and GPCRs, generating many drug candidate compounds. Since 2022, aiming to establish the next-generation in-house drug discovery value chain from four perspectives: modality, drug discovery target, disease area, and core technology, RaQualia has been advancing collaborations with several startups and drug discovery companies. Acquiring FIMECS's RaPPIDS™ platform technology to venture into new modalities, such as targeted protein degradation (TPD) inducers, allows targeting molecules and disease areas previously considered undruggable. The acquisition of FIMECS is expected to significantly advance the strengthening of RaQualia's next-generation in-house drug discovery value chain.

*The human body eliminates unnecessary proteins through natural intracellular degradation systems. Targeted protein degraders (TPDs) are small molecules that harness these systems to selectively eliminate disease-related proteins. By inducing degradation, TPDs inhibit protein function through a mechanism of action distinct from that of conventional enzyme inhibitors or receptor antagonists.

2. Adopt a hybridized business model: Increase its earnings through platform business

The company is a "pipeline-type" drug discovery company, which discovers new drug candidate compounds and develops them in-house, and undertakes the later stages of clinical development by out-licensing, through joint research, or independently. FIMECS is a "platform-type" drug discovery company, which focuses on exploratory research, with technology that it out-licenses and ability to create drug discovery seeds. The company that in-licenses its technology undertakes development from the preclinical studies stage onward. The earnings structure of platform-type companies is based on joint research from the exploratory research stage to obtain upfront payments, research collaboration payments, and milestone payments early on, as well as royalty revenue. For pipeline-type companies on the other hand, exploratory research through to out-licensing is an investment phase, and the investment recovery phase comes after out-licensing in the form of upfront and milestone payments and royalty revenue. By making FIMECS a subsidiary, the company has hybridized its business model so it can earn revenue from the exploratory research stage.

FIMECS currently conducts joint research with Astellas Pharma on multiple targets, which may generate development milestone payments based on progress, as well as royalties and sales milestone payments. The interest in targeted protein degradation inducers is particularly high abroad, with similar companies in the US (e.g., Arvinas [NASDAQ: ARVN], C4 Therapeutics [NASDAQ: CCCC], Kymera Therapeutics [NASDAQ: KYMR], Nurix Therapeutics [NASDAQ: NRIX]) building their platforms and securing substantial contracts from the early stages of collaboration. FIMECS plans to continuously acquire new joint research partners both domestically and internationally around its core platform technology, RaPPIDS™, expecting further expansion of revenue opportunities.

3. Further strengthening and expansion in the oncology field

RaQualia has developed marketed pharmaceuticals such as the gastric acid secretion inhibitor tegoprazan (brand name: K-CAB®) and the dog osteoarthritis treatment grapiprant (brand name: GALLIPRANT®). While many of its out-licensed programs are being developed by pharmaceutical companies and belong mainly to the pain and gastrointestinal disease areas, the company has initiated exploratory research targeting cancer as part of strengthening its drug discovery value

chain. The company's subsidiary TMRC is engaged in the research, development, and licensing of cancer therapeutics using retinoic acid receptor alpha agonists. The acquisition of FIMECS, adding pipelines including the IRAK-M program, will strengthen the group's pipeline targeting cancer.

Consideration and method for the acquisition

RaQualia plans to acquire all issued shares of FIMECS from the current shareholders on March 26, 2024, making FIMECS a consolidated subsidiary. The consideration for the acquisition consists of an upfront payment (the closing consideration) paid at the time of the share acquisition and payments based on future revenues earned by FIMECS (the earn-out consideration).

1. Closing consideration

RaQualia will pay a closing consideration of JPY4.5bn in cash to the sellers on March 26, 2024. In March 2024, the company decided to borrow a syndicated loan of JPY3.5bn (loan period: seven years) to fund the share acquisition.

2. Earn-out consideration

From FY12/24 to FY12/28, based on contract upfront payments, milestone payments, royalty revenue, and revenue from commissioned work generated from contracts with third parties, an amount calculated using a predetermined calculation method will be paid to the sellers.

This arrangement mitigates the risk of RaQualia paying a large one-time consideration by avoiding payment of the entire consideration at the time of the acquisition execution, instead paying part of it as earn-out consideration based on the revenue of FIMECS. It also serves as an incentive for some sellers involved in FIMECS's operations to continue contributing to research and development activities and revenue expansion.

Proprietary drug discovery platform RaPPIDS™

FIMECS possesses Rapid Protein Proteolysis Inducer Discovery System (RaPPIDS™), a proprietary platform technology specialized in targeted protein degradation (TPD). This system, based on diversity-oriented synthesis (DOS), enables the efficient identification of TPD candidates.

The large molecular size of TPD molecules generally limits oral administration. To develop orally available TPD compounds, FIMECS accumulates proprietary expertise in design and optimization. In addition, FIMECS has identified novel E3 ligase-binding molecules through data-driven experiments, without being limited to known E3 ligases, establishing multiple proprietary E3-binding molecules.

Approach to undruggable targets

RaPPIDS™ enables an approach that targets undruggable disease-related proteins that conventional small molecules and antibodies cannot effectively modulate, degrading and eliminating causative proteins by leveraging the body's natural protein degradation mechanism (the ubiquitin–proteasome system). The company expects this approach will lead to the development of breakthrough therapeutics that act on proteins associated with cancer, which traditional methods have struggled to target effectively.

Key features of RaPPIDS™

1. Proprietary discovery of novel E3 ligase binders (phenotypic-first approach)

In TPD development, binders that link E3 ligases to target proteins, thereby inducing degradation signals, play a critical role. RaPPIDS™ adopts a proprietary phenotypic-first approach, identifying candidates based on degradation activity, enabling the discovery of novel binders without being limited to known E3 ligases (such as cereblon). The company has identified two novel E3 ligases and developed proprietary binders for them, enabling the design of more potent and diverse TPD compounds.

2. Expertise in designing orally available TPD

TPD compounds consist of two different linked molecules, increasing molecular weight and making oral administration difficult. RaPPIDS™ addresses this issue by combining molecular design and optimization technologies, enabling the creation of orally available TPD compounds.

3. High-throughput synthesis and evaluation system

RaPPIDS™ integrates automated synthesis technology with a high-throughput evaluation system, enabling the synthesis and evaluation of 1,000–1,500 compounds per week. The company leverages this system to accumulate large-scale drug discovery data in a short period, applying it to machine learning (AI) to improve discovery efficiency.

4. Hybrid business model including joint research

RaPPIDS™ supports the company's in-house pipeline development and joint research with external partners such as pharmaceutical companies. For example, the company has obtained milestone payments tied to R&D progress on the platform and the addition of new targets from its collaboration with Astellas Pharma, demonstrating the platform's drug discovery capability, practicality, and competitiveness.

Competitive advantages of RaPPIDS™

High productivity	RaPPIDS™ accelerates compound development by enabling the synthesis of more than 1,500 compounds per week and utilizing a high-throughput evaluation system that directly detects intracellular protein degradation.
Screening approach to identify novel E3-binding molecules	The system helps identify novel and optimal E3 ligase-binding molecules using proprietary technology, enabling the development of compounds with superior properties across a wide range of diseases.
Proprietary novel E3 ligase-binding molecules	The system has facilitated the identification of multiple E3 ligase-binding molecules that enable the degradation of various target proteins, potentially allowing tissue-specific degradation and reducing adverse events.
Capability to create oral therapeutics	The system addresses low bioavailability, a key challenge in TPD, accumulating specialized expertise to develop orally available compounds.

Source: Shared Research based on company data

Pipeline overview

Ample pipeline based on pharmaceutical company standard research processes and operating procedures

The company took over the expertise and methodology in drug discovery R&D from its predecessor, the Pfizer central research laboratory, and has continued with the research projects it inherited. Accordingly, it has a large number of "seeds," and has been able to create a series of candidate compounds. It has advanced technological capabilities based on its standard operating procedures (SOP) equivalent to those of pharmaceutical companies, and is engaged in difficult drug discovery targeting ion channels, and has out-licensed five projects at an early stage. The company has four products already commercialized (tegoprazan, GALLIPRANT®, ENTYCE™, and ELURA™), and an ample pipeline: 15 project compounds already out-licensed, including ion channel projects, and seven at the pre-out-licensing stage.

It also had 12 programs in its exploratory research pipeline at the beginning of FY12/26, and in addition to in-house research, it is conducting joint research with other companies and academia. In March 2018, the company signed an agreement with Nagoya University to establish the RaQualia Pharma Industry-Academia Collaborative Research Center (RARC) and set up two joint research divisions—the pharmacological analysis division and the drug discovery science division—within the university, which houses the Department of Pharmacology and the Department of Pharmaceutical Sciences. It conducts research aimed at discovering drug candidate compounds and aims to accelerate drug discovery with industry-academia collaboration. The company thinks it can continually discover innovative compounds as development candidates by always having 7–10 exploratory research programs underway.

Out-licensed pipeline (human)

Out-licensed programs (human)

Program name	Generic nameCompound code	Key indication	Out-licensing region	Development stage
Tegoprazan (potassium-competitive acid blocker [P-CAB]; K-CAB®)	RQ-00000004 (tegoprazan)	GERD	South Korea	On market (Mar 2019)
			China	On market (Apr 2022)
			Philippines	On market (Oct 2022)
			Mongolia	On market (Oct 2022)
			Mexico	On market (May 2023)
			Indonesia	On market (July 2023)
			Singapore	On market (Sep 2023)
			Peru	On market (Oct 2023)
			Chile	On market (Sep 2024)
			Colombia	On market (Oct 2024)
			Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador	On market (Dec 2024)
			Malaysia, Panama, India, Thailand	On market (FY12/25)
			Paraguay, Ecuador, Russia	Approved, preparations underway
			Vietnam, 5 countries in Central and South America, the US	Application under review
			Canada, Brazil, South Africa and 6 countries including Eastern Europe region, Middle East and North Africa	Phase III underway, application preparations underway
			Japan	Out-licensed (December 2025)
Acute myeloid leukemia (AML)	Phase II complete (US) , Development discontinued	EP4 receptor antagonist		RQ-00000007 (grapiprant)
Phase I complete (China)				Cancer
		Phase I underway (China)		RQ-00000008
	5-HT4 partial agonist	RQ-00000009	Alzheimer's disease	Worldwide
COX-2 inhibitor	RQ-00317076	Pain	Worldwide	Phase IIa complete (US)
Phase I underway (China)				CB2 agonist
Selective sodium channel blocker	Not disclosed	Analgesic and antipruritic	Worldwide	Not disclosed
P2X7 receptor antagonist	RQ-00466479 AK1780	Neuropathic pain	Worldwide	Phase II complete (US and others)
Specific ion channel target	Not disclosed	Gastroenterology	Worldwide	Not disclosed
TRPM8 blocker	RQ-00434739	Chronic pain	Worldwide, except Japan	Phase I underway (Australia)
Sodium channel blocker	RQ-00350215	Chronic pain	Worldwide	Phase I underway
IRAK-M degradation inducer	FIM-001	Cancer	Worldwide	Preclinical trials ongoing

Source: Shared Research based on company data (as of February 2026)

Potassium-competitive acid blocker: P-CAB (generic name: tegoprazan)

Characteristics of tegoprazan

Tegoprazan is primarily used to treat gastroesophageal reflux disease (GERD)* and serves as an alternative to conventional proton pump inhibitors (PPIs). The company initiated preclinical trials upon its establishment, having received tegoprazan as a development candidate from Pfizer and with many Pfizer researchers involved in tegoprazan transferring to the company.

*GERD: A disease whereby stomach contents, in particular stomach acid, flow back into the esophagus (food pipe), causing characteristic symptoms such as heartburn. GERD can be classified as non-erosive reflux disease (NERD) or erosive esophagitis (EE). NERD is a condition in which damage to the esophageal mucosa cannot be confirmed by endoscopy, despite symptoms such as heartburn and acid reflux.

GERD is a condition in which stomach contents, especially gastric acid, reflux into the esophagus and cause symptoms such as heartburn. The primary symptoms are acid regurgitation* and heartburn, which often occurs during fasting or at night. Tegoprazan and the existing drug vonoprazan (brand name: TAKECAB®) primarily differ in their mechanisms of acid secretion inhibition and speed of onset. According to the company, tegoprazan provides acid suppression comparable to vonoprazan and superior to PPIs.

In South Korea, tegoprazan and PPIs are approved to treat NERD, whereas vonoprazan is not approved for this indication in Japan. Intragastric pH is used as an indicator of onset of action. Tegoprazan raises intragastric pH above 4 within one

hour, whereas vonoprazan takes approximately four hours to reach the same level. PPIs require activation by gastric acid and therefore generally do not take effect on the first day of administration. While gastrin*2 levels tend to increase with vonoprazan, the elevation is less pronounced with tegoprazan and PPIs.

* Acid regurgitation is a symptom of the backward flow of stomach acid into the esophagus, followed by downward flow that causes a sour or bitter sensation in the mouth and throat.
*2 Gastrin is a hormone secreted mainly from cells in the pyloric antrum of the stomach. Under normal conditions, it temporarily rises after meals and promotes gastric acid secretion. When abnormally secreted, causing extreme hyperacidity, if the serum gastrin level is maintained at an elevated level over an extended period, this increases the risk of developing peptic ulcers and neuroendocrine tumor development and should be carefully monitored. Medication is sometimes discontinued due to high gastrin levels.

Frontrunner was Takeda Pharmaceutical's TAKECAB®

Vonoprazan (brand name: TAKECAB®) is a potassium-competitive acid blocker (P-CAB) launched by Takeda Pharmaceutical Company Limited (TSE Prime: 4502) in February 2015, and has a different action than the then-mainstream treatment, PPIs. PPIs are activated by acid in the body, and inhibit gastric acid secretion. Vonoprazan does not require activation by acid, and is fast acting and effective at preventing gastric acid secretion by inhibiting the binding of potassium ions needed for secretion (source: Takeda).

P-CABs have largely replaced PPIs and histamine H2 receptor antagonists (H2RAs, H2 blockers). In 2021, despite a 4.1% reduction in the NHI price of TAKECAB®, its revenue on an NHI price basis totaled JPY111.1bn (+13.5% YoY), ranking third among domestic prescription drugs. In FY12/25, revenue rose to JPY125.3bn (+4.4% YoY), placing fifth among domestic prescription drugs. P-CABs have continued to achieve YoY revenue growth for 10 years since launch, whereas most drugs typically peak five to six years after market entry. TAKECAB® was listed on February 1, 2015 at an NHI price of JPY160.12 for a 10mg tablet and JPY240.20 for a 20mg tablet. As of April 1, 2026, the prices had decreased to JPY91.6 for a 10mg tablet and JPY136.7 for a 20mg tablet, including orally disintegrating formulations.

Maintained No. 1 market share in South Korea following out-licensing

In June 2010, following the completion of Phase I trials in the US, the company entered a strategic alliance in gastrointestinal diseases with South Korea-based CJ HealthCare Corporation (KOSDAQ: 195940, now HK inno.N). Under this alliance, the company granted exclusive out-licensing rights with a sublicense option for development, manufacturing, and sales of tegoprazan in East Asia, including South Korea, China (including Hong Kong), and Taiwan. The geographic regions covered gradually increased from 2019, and currently HK inno.N has been granted rights to cover the entire world except Japan.

HK inno.N gained marketing approval for the company's out-licensed drug tegoprazan for South Korea in July 2018, and launched it as K-CAB® tablets in March 2019. Revenue of K-CAB® in South Korea in 2025 (non-hospital prescription data) remained brisk, totaling KRW217.9bn (+10.7% YoY, roughly JPY24.0bn converted at JPY0.11/KRW). From 2019 to 2025, total prescriptions reached KRW923.3bn (JPY101.6bn), with a CAGR of 39.2%. As of end-December 2025, the product held the top market share in South Korea for gastrointestinal disease treatments at 15%.

K-CAB® for sale in South Korea

Source: HK inno.N homepage

Expanding market share in South Korea through broadened indications and OD tablets

In February 2022, HK inno.N gained manufacturing and marketing approval for orally disintegrating K-CAB® tablets, and launched sales in May 2022. These can be taken by elderly who have trouble swallowing tablets, those with restricted fluid intake, or those unable to drink water because they are away from home. The company expects improved dosing convenience and expanded patient population will boost HK inno.N's earnings and be reflected in royalty revenue.

In July 2022, HK inno.N obtained approval for K-CAB® as maintenance therapy for healed erosive esophagitis. This makes K-CAB® the most widely indicated P-CAB marketed in South Korea. The five indications for which tegoprazan received marketing approval in South Korea are erosive esophagitis, NERD, gastric ulcer, adjuvant therapy for Helicobacter pylori eradication, and maintenance therapy for healed erosive esophagitis. Following its approval for health insurance coverage in January 2023, a new formulation used in maintenance therapy for erosive esophagitis was launched. The new formulation contains half of the tegoprazan volume of existing medicines, and maintains the condition of the patient once healed. This means tegoprazan is the only P-CAB marketed in South Korea able to be used in all stages from the onset of erosive esophagitis to the post-treatment stage.

Global expansion of tegoprazan

The company granted HK inno.N the global rights to out-license tegoprazan, including the right to sublicense. HK inno.N aims to expand tegoprazan into 100 countries by 2028. HK inno.N and its sublicensees are engaged in global business activities related to tegoprazan, with the product marketed in 19 countries and entered 57 countries as of end-FY12/25.

HK inno.N's sales expansion plans

HK inno.N has gradually expanded its licensed territories and, since 2019, holds global rights excluding Japan. Since its establishment in 2008, RaQualia carried on with and invested in R&D into tegoprazan, one of Pfizer's development programs. Under its global strategy, HK inno.N has started acquiring marketing approval in countries around the world under its global sales strategy. The company believes it is on the cusp of a long-term period where it can recoup its investment.

In China, tegoprazan has been marketed by sublicensee Luoxin Pharmaceuticals since 2022, making it the second country after South Korea to launch the product. Luoxin sells tegoprazan across 31 provinces and administrative regions. Luoxin has received regulatory approval from the National Medical Products Administration (NMPA) to conduct clinical trials on an injectable formulation and has also obtained marketing approval for a combination therapy targeting Helicobacter pylori infections.

In May 2022, HK inno.N's sublicensee Metro received marketing approval for four indications in the Philippines, including erosive esophagitis, and launched sales in November 2022. The peptic ulcer medicine market in the country is over USD60mn (about JPY7.5bn), making it the fourth largest market in Southeast Asia. Metro has successfully marketed proton pump inhibitors (PPIs) in the Philippines and has sales infrastructure and marketing expertise in the field of peptic

ulcers, so the company hopes it will be able to make quick inroads in the market with tegoprazan. As of March 2023, in addition to being on sale in South Korea, China, and the Philippines, tegoprazan has been rolled out to 36 countries, where it is in the development, awaiting approval, or preparing to launch stage. It has received approval in Mongolia, and product supply has begun, with plans to put the drug on sale during FY12/23.

Royalty revenue expected to increase due to expansion of sales territories

As of end-June 2025, HK Inno.N's sublicensees are advancing the development, manufacture, and sale of tegoprazan in 53 countries excluding South Korea. In January 2025, HK Inno.N announced the signing of a sublicense agreement in Australia and New Zealand, expanding tegoprazan's reach to 48 countries. In May 2025, HK inno.N announced the signing of a regional expansion agreement with its sublicensee Tabuk, increasing the number of covered countries in the Middle East and North Africa to 16.

As of end-June 2025, tegoprazan is marketed in 17 countries: South Korea, China, Mongolia, the Philippines, Mexico, Indonesia, Singapore, Malaysia, Peru, Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador, and Panama. Under the licensing agreement with HK inno.N, RaQualia receives milestone payments based on development progress or a percentage of the revenue that HK inno.N earns from the sublicensee.

The company says the global peptic ulcer market is potentially worth JPY2tn, and HK inno.N aims to roll out tegoprazan to 100 countries by 2028. The largest market is North America at JPY400bn, followed by China at JPY310bn. Assuming a global market share of 10% for tegoprazan and a royalty rate of 5%, the company could potentially receive annual royalty payments of JPY10bn.

Estimate of company royalties

Potential global market size	×	Share captured	×	Royalty rate	=	Maximum royalties company can receive
JPY2bn		15% in South Korea		Generally 1–10%		

Source: Shared Research based on company data

Development status and market size for HK inno.N by key country/region

Country/region	Licensee*	Sales and development status	Market (JPYmn)
South Korea	HK inno.N	Launched in 2019, maintaining No. 1 market share	120,000
China	Luoxin	Launched in April 2022	450,000
Philippines	MPPI	Launched in October 2022	5,000
Mongolia	Monos	Launched in October 2022	-
Mexico	Carnot	Launched in May 2023	66,000
Indonesia	Kalbe	Launched in July 2023	50,000
Singapore	UITC	Launched in September 2023	50,000
Peru	Carnot	Launched in October 2023	66,000
Thailand, Vietnam, Malaysia	Pond's, Lyhn farma, Pharmaniaga	Malaysia: launch scheduled in Q2 2025; Thailand: approved, preparing for launch; Vietnam: under regulatory review	50,000
15 Central and South American countries including Argentina	Carnot	8 Central and South American countries including Chile: Launched; 2 countries: Approved; 5 countries: Under review	66,000
Brazil	Eurofarma	Filing in preparation	88,000
US, Canada	Braintree	Phase III completed, filing in preparation	460,000
7 countries including India	Dr.Reddy	India: Approved / preparing for launch; Others: P3 ongoing / In preparation	140,000

Source: Shared Research based on company data (as of August 2025)
* The out-license partners include sublicensees of HK inno.N.
*² Market size is based on HK inno.N materials (September 2022). Exchange rate: JPY0.1/KRW

Growth potential for peptic ulcer drug market in China

According to Scientific Reports, in 2020 there were 58mn GERD patients in China (4.2% of the population), with an estimated market size of JPY350bn. The mainstream treatments are conventional PPIs and H2RAs (H2 blockers), with treatment costs per patient of JPY6,000. With the entry of P-CAB, prescription costs per patient in Japan and South Korea have risen to JPY14,000 and JPY20,000 respectively, and the company thinks prescription costs per patient in China will also increase as PPIs and H2RAs are replaced. Furthermore, due to the adoption of Western dietary habits and the aging of the population, GERD patients are also increasing, and the market is likely to expand as their share in the population grows.

GERD patient numbers and peptic ulcer drug market size

Country/region	No. of patients (% of population)	Market size (JPYmn)	Treatment costs per patient	Mainstream treatment
China	58mn (4.2%)	350,000	JPY6,000	PPI, H2RA
US	67mn (21.0%)	450,000	JPY6,700	PPI, H2RA
South Korea	3mn (5.8%)	60,000	JPY20,000	PPI, H2RA, P-CAB
Japan	17mn (14.0%)	250,000	JPY14,000	PPI, H2RA, P-CAB

Source: Shared Research based on company data
Note: Calculated at JPY0.1/KRW, JPY19.6/CNY, JPY125/USD

Sales plans in China

Luoxin Pharmaceutical is selling tegoprazan under the brand name Tai Xin Zan® in China. After receiving Category 1 approval in China, designating it an innovative drug, on April 13, 2022, it launched the drug just 15 days later, on April 28. In addition to selling it at major hospitals and retail drugstores in China, it is also selling it over the internet via online medical services, and is targeting revenue of CNY1.0bn (roughly JPY19.6bn converted at JPY19.6/CNY) in 2023, and CNY3.0bn in the longer term (roughly JPY58.8bn). In Q2 FY12/22, the company received a milestone payment of JPY300mn, and is set to receive further royalty payments based on a percentage of sales from launched products. Because Luoxin is a sublicensee, royalty revenue will come through HK inno.N, so the company expects a time lag of about six months.

Favorable topline data from the Phase III clinical trial in the US

In November 2019, the company signed an agreement with HK inno.N to expand their partnership to include North America and Europe. In December 2021, HK inno.N signed a licensing agreement with Braintree Laboratories, a gastrointestinal drug specialist and division of US-based Sebela Pharmaceuticals Inc. (both unlisted), granting Braintree exclusive rights to develop, manufacture, and market the product in the US and Canada.

In April 2025, the company announced favorable topline results from the ongoing US Phase III TRIUMpH trial initiated by Braintree in October 2022. The TRIUMpH trial serves as a pivotal study for regulatory submission and targets both erosive esophagitis (EE) and non-erosive reflux disease (NERD). Tegoprazan met all primary and secondary endpoints in both the EE and NERD studies. In the EE study, tegoprazan demonstrated statistically significant superiority over lansoprazole—a proton pump inhibitor (PPI) used as a comparator—in terms of healing rates at both two and eight weeks, among the overall patient population as well as in patients with moderate to severe disease. In the NERD study, tegoprazan was shown to completely resolve symptoms of heartburn and acid reflux.

In the TRIUMpH trial, treatment-related adverse events occurred in fewer than 3% of patients in each study and were generally mild and transient. Serious treatment-related adverse events occurred in fewer than 2% of patients in each trial. Safety and tolerability were comparable across tegoprazan, lansoprazole, and placebo. Mean serum gastrin levels for both tegoprazan and lansoprazole remained within the normal range (0–180pg/mL) throughout the treatment period.

Braintree plans to complete the EE study in Q3 FY12/25 and to submit a New Drug Application (NDA) to the US FDA in Q4 FY12/25, seeking approval for both EE and NERD. While PPIs remain the first-line therapy for gastroesophageal reflux disease (GERD), approximately 40% of US patients experience incomplete symptom relief with PPI therapy. Sebela expects tegoprazan to capture a 20–25% market share in the US, with peak revenue projected at JPY140.0bn.

Out-licensing of tegoprazan in Japan

Could become best in class

The existing drug TAKECAB®, approved for erosive esophagitis, has not received approval for NERD in Japan. In Japan, NERD accounts for 60% of GERD cases (source: Osaka City Medical Association, "Pathophysiology and treatment of gastroesophageal reflux disease and related disorders" [2016]). Gastrin levels tend to rise less with tegoprazan than with vonoprazan (TAKECAB®). Shared Research thinks that, if approved in Japan, tegoprazan has a high probability of replacing TAKECAB®. The company says there were some 17mn GERD patients in Japan as of 2020 (14% of the population) with a market size of JPY250bn.

Extended negotiations for out-licensing tegoprazan in Japan

The company retains the rights for Japan for tegoprazan, which was out-licensed to HK inno.N in September 2010. It had planned to complete pharmacological studies as part of Phase I clinical trials in FY12/23 and out-license in FY12/24

onward. However, having been approached by a licensee candidate, the company decided not to conduct its own pharmacological studies and out-license in FY12/23 so that the product could go on sale as soon as possible. It began negotiations with the licensee candidate in FY12/23 and expected to conclude an agreement by end-2023, but the following issues have required more time to resolve.

In the negotiations with the licensee candidate for tegoprazan in Japan, RaQualia identified three discussion points: 1) accelerating development and reducing the risk, 2) ensuring the supply of APIs and formulations, and 3) potential drug price cuts.

The company leverages overseas clinical trial information through frequent consultation with its partners, HK Inno.N and Braintree to address the first issue. HK inno.N, currently marketing in countries including Korea and China, will supply APIs and formulations to the company. These two issues were resolved early in 2023. However, discussions on the third issue persist. To maintain price elasticity in anticipation of future drug price reductions, negotiations with licensee candidates continue. The discussions focus on key terms such as license fees and supply costs. The company missed its initial target of signing an agreement in FY12/24, as the prospective licensee had not reached a final decision.

Use of South Korean and US data

The company is working to maximize the value of tegoprazan. It is aiming at rapid and efficient development and approval in Japan using South Korean data and is getting ready to launch clinical pharmacological studies. RaQualia is investigating the study protocol based on advice from medical experts and is in discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) concerning the trial. Tegoprazan has already been approved in South Korea for erosive esophagitis, non-erosive reflux disease (NERD), gastric ulcers, and adjuvant therapy for Helicobacter pylori eradication. The company thinks it needs to evaluate ethnic differences between Japanese and Korean people to use South Korean data when filing for approval in Japan.

Out-licensing of tegoprazan in Japan and expansion of the capital and business alliance with HK inno.N

On December 12, 2025, RaQualia Pharma Inc. announced that it has out-licensed to HK inno.N Corporation exclusive rights, including sublicensing rights, for the development and commercialization of the gastric acid secretion inhibitor tegoprazan in Japan, and that it will strengthen its capital and business alliance through the issuance of new shares through a third-party allotment.

The company has identified domestic commercialization of tegoprazan as its top priority for FY12/25 because it believes domestic out-licensing of tegoprazan directly maintains and enhances corporate value. It held discussions with multiple candidates with the aim of concluding a contract in FY12/25. It recognized delays in initiating development could postpone market entry and negatively affect profitability, prioritizing development timing in its considerations.

Based on these considerations, the company decided to expand its partnership with HK inno.N by granting it exclusive development, manufacturing, and marketing rights to tegoprazan in Japan to further strengthen the relationship. The agreement includes no upfront payment; instead, the company retains the right to receive sales royalties, a share of the revenue HK inno.N earns from its partners, and milestone payments tied to future development and commercialization progress.

The company states that it selected HK inno.N primarily because of its emphasis on rapid commercialization. The company recognizes the competing drug TAKECAB® (generic name: vonoprazan) could lose patent protection in the early 2030s and believes launching the product before generic entry is critical to securing a sufficient period of market exclusivity in the Japanese market. For this reason, the company prioritized an early start to clinical development in Japan and, by emphasizing contract execution within 2025, decided to out-license tegoprazan to HK inno.N, which has product knowledge and development expertise in tegoprazan. Under the agreement, HK inno.N will bear the development costs for late-stage clinical trials in Japan. In parallel with an equity alliance through a third-party allotment, the company plans to establish a framework with HK inno.N to accelerate development. (see “Medium-term business plan”.)

EP4 receptor antagonist (RQ-00000007, grapiprant)

Grapiprant is an EP4 receptor antagonist originally developed by Pfizer and later transferred to RaQualia. It is the same compound as GALLIPRANT®, which is already marketed as a pet drug. In January 2013, the company transferred the intellectual property rights for grapiprant to AskAt Inc. (a wholly-owned subsidiary at the time) in return for a set percentage of royalties AskAt receives. AskAt has been developing grapiprant since the IP transfer, mainly for the

indications of cancer and pain. In December 2017, AskAt concluded a licensing agreement with Arrys Therapeutics (unlisted, a subsidiary of Ikena) for global rights to grapiprant, excluding China and Taiwan. Subsequently, Ikena took over rights from Arrys and has been conducting clinical trials.

Ikena started a US expansion phase I clinical trial (Phase Ib) in October 2018, targeting patients with unresectable or advanced microsatellite stable colorectal cancer. However, in November 2022, Ikena announced it had suspended in-house development and was considering alternative strategic plans. In September 2023, AskAt announced the cancellation of its worldwide license agreement for the EP4 receptor antagonist in cancer immunology, reflecting a shift in its R&D strategy. An investigator-initiated clinical trial that began in September 2021 is ongoing at the University of Texas MD Anderson Cancer Center to evaluate concurrent treatment with grapiprant and Halaven® (eribulin) for metastatic inflammatory breast cancer since September 2021.

In addition, Chinese licensee 3D Medicines Co., Ltd. (unlisted) concluded Phase I trials of grapiprant for pain management. Another licensee in China, Ningbo NewBay Medical Technology Development Co., Ltd. (unlisted), is conducting Phase I clinical trials for oncological applications.

CB2 agonist (RQ-00202730)

The CB2 agonist is a compound the company discovered after inheriting the theme from Pfizer. The human body contains cannabinoid receptors, CB1 and CB2, with CB1 highly expressed in the central nervous system and CB2 predominantly expressed in the immune system. According to the company, CB2 receptors play a critical role in modulating chemotherapy-induced peripheral neuropathy (CIPN), which occurs as an adverse reaction to certain anticancer drugs and reduces quality of life through symptoms such as pain and numbness. Because the company's CB2 agonist selectively targets CB2, it is expected to avoid CB1-mediated central nervous system adverse reactions. The global CIPN market is worth about USD1.6bn (roughly JPY241.5bn at JPY150/USD), and is expected to grow to USD2.4bn (roughly JPY355.5bn) by 2027.

In November 2015, the company entered into an agreement with AskAt to transfer rights related to CB2 agonists. Under this agreement, the company transferred intellectual property rights related to CB2 agonists to AskAt while retaining the right to receive royalty income at a specified rate based on revenue generated by AskAt from these agonists.

In January 2023, UK-based sublicensee Oxford Cannabinoid Technologies Ltd. (LSE: OCTP; OCTP), via AskAt, submitted an application for a clinical trial to the UK Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC). After receiving approval, OCTP initiated a Phase I clinical trial in the UK targeting CIPN, beginning patient dosing in July 2023. As of December 2024, OCTP was conducting a single-dose clinical trial.

In February 2026, AskAt announced the termination of its sublicense agreement with OCT. According to AskAt, OCT breached the agreement, and the termination did not result from development-related issues. AskAt will continue developing CB2 agonists while seeking a new partner. The company will further strengthen its collaboration with AskAt, continuing to provide development and licensing support.

P2X7 receptor antagonist (RQ-00466479)

The company created a P2X7 receptor antagonist through joint research with Asahi Kasei Pharma (a license agreement signed in March 2018). Phase I clinical trials targeting peripheral neuropathic pain have been completed. Eli Lilly, with whom Asahi Kasei Pharma has a license agreement, will take over global development from Phase II. Based on the licensing agreement with Asahi Kasei Pharma, the company will receive royalty payments based on a certain percentage of Asahi Kasei Pharma's earnings. With the start of Phase II by Eli Lilly in November 2022, RaQualia achieved the development milestone and received an upfront payment of USD4mn (JPY500mn based on JPY125/USD translation).

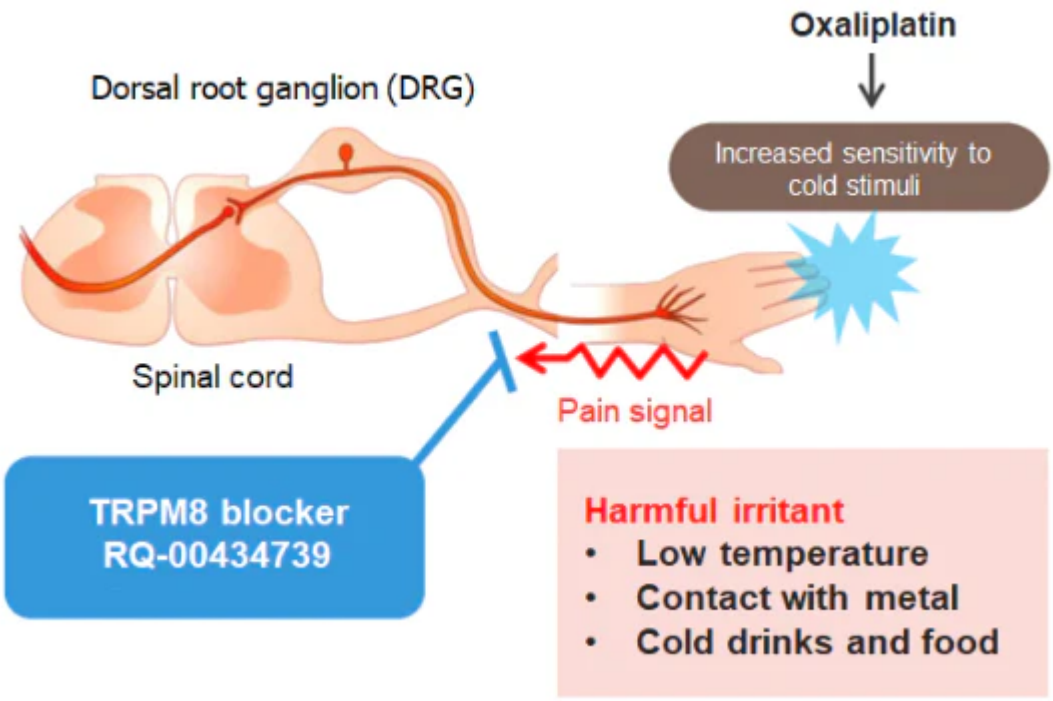
In August 2024, sublicensee Eli Lilly announced the results of Phase II clinical trials conducted in the US for three diseases (knee pain due to osteoarthritis, chronic low back pain, and diabetic neuropathic pain). Although the safety profile of the investigational drug was favorable with no major concerns, its efficacy did not meet the primary endpoints. Eli Lilly is currently reviewing future development plans.

TRPM8 blocker (RQ-00434739)

The TRPM8 blocker is a program RaQualia created. TRPM8 is a temperature-sensitive ion channel activated by cold stimuli under 28°C or by menthol (mint) and its involvement has been suggested in a variety of chronic disorders, including chronic pain. In-house discovered selective TRPM8 blocker (azaspiro derivative) demonstrated a different mechanism of

action in animal models of chronic pain from existing drugs, and the company hopes it will be a breakthrough drug. For example, about 90% of patients who receive cancer treatment using oxaliplatin are susceptible to cold pain. The company's TRPM8 blocker blocks TRPM8 (the cold receptor) directly, suppressing the transmission of pain signals.

TRPM8 blocker and pain mechanisms



Source: Company data

In September 2021, RaQualia entered a licensing agreement with Hong Kong-based Xgene Pharmaceutical Co. Ltd. (unlisted), granting it exclusive global rights (excluding Japan) to develop, manufacture, and sell the TRPM8 blocker. Xgene has moved to the preclinical study phase in its quest to develop a pain therapy, and In March 2024, it received approval to begin Phase I clinical trials from the Australian Therapeutic Goods Administration (TGA). The company is set to receive milestone payments as research moves through development stages and royalties based on sales if the product is launched (specific target conditions and amounts have not been disclosed).

In May 2024, Xgene initiated a Phase I clinical trial in Australia without a one-time payment at initiation. The trial involves a dose-escalation study in healthy volunteers to evaluate the tolerability and pharmacokinetics of a TRPM8 blocker to gather critical data. Xgene will advance to Phase II clinical trials targeting cancer-related and neuropathic pain in China and the US.

Sodium channel blocker (RQ-00350215)

Sodium channels, along with other ion channels such as potassium channels, control the generation and transmission of nerve action potentials, and are deeply involved in neurotransmission. The company hopes the sodium channel blocker it developed will become a breakthrough new drug for chronic pain (that existing drugs to not provide sufficient analgesic effect for) by selectively blocking the function of specific sodium channels involved in pain signal transmission.

In December 2021, RaQualia entered a licensing agreement with Hisamitsu Pharmaceutical Co., Inc., (TSE Prime: 4530) granting it exclusive worldwide development, manufacturing, and marketing rights. Although the out-licensing occurred in the early development stage, the company received JPY600mn as an upfront payment and may receive up to JPY3.0bn in milestone payments as development progresses. Further, if drugs containing the sodium channel blocker the company developed are approved and launched, it has the right to receive sales royalties with a royalty rate in the range of 5–10%, and milestone payments in line with revenue to a maximum of over JPY10bn. Hisamitsu Pharmaceutical plans to develop transdermal medication (one of its strengths) for pain containing the sodium channel blocker RaQualia developed, starting with the preclinical trial phase.

In October 2024, the company received a milestone payment of JPY100mn from Hisamitsu upon achieving a pre-determined target. Although the company has not disclosed its development status, Shared Research believes a Phase I clinical trial has commenced.

The company has additional projects underway, though the development stages remain undisclosed. It has out-licensed a compound targeting a specific ion channel for gastrointestinal indications to EA Pharma. In December 2017, the company out-licensed a selective sodium channel blocker for analgesic and anti-pruritic indications to Maruho and received a milestone payment in March 2021 upon achieving a pre-determined target. However, it terminated the license agreement in December 2024.

Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076)

The company discovered a cyclooxygenase-2 (COX-2) inhibitor from a compound with a different type of chemical structure from existing COX-2 inhibitors.

In January 2013, the company signed an agreement to transfer all intellectual property rights, related data, and the drug substance for RQ-00317076 to AskAt in return for a percentage of the revenue AskAt earns from RQ-00317076 as royalties. AskAt has positioned RQ-00317076 as a third-generation COX-2 inhibitor. In early-stage Phase II clinical trials conducted in the US targeting postoperative pain, RQ-00317076 was shown to have superior efficacy, more rapid response, and longer-lasting effect, as well as higher safety and tolerability compared with ibuprofen, the standard treatment. As of FY12/22, AskAt's China-based licensee 3D Medicines Co., Ltd. (unlisted) was conducting a Phase I clinical trial of the drug for human use.

In July 2022, AskAt entered into a license agreement with US-based Velo-1 for global rights to RQ-00317076 as a drug for animals, as well as a two-year development support agreement with Velo-1. Signing of these agreements meant RQ-00317076 was being developed not only for human use, but also for animals. RQ-00317076 has lower risk of adverse effects when used in dogs compared with existing NSAIDs, and AskAt believes it is a promising compound for treating acute pain, e.g., postoperative pain, and chronic pain associated with osteoarthritis.

Tamibarotene (TM-411) (retinoic acid receptor alpha agonist: anticancer agent)

Tamibarotene is a selective retinoic acid receptor alpha (RARα) agonist. In February 2004, TMRC obtained exclusive development and marketing rights in Japan and overseas for tamibarotene as an anticancer drug. In April 2005, licensee Toko Pharmaceutical Industries Co., Ltd (unlisted) received manufacturing and marketing approval in Japan and launched the drug as an orphan drug* (for rare diseases) for acute promyelocytic leukemia (APL). The drug is sold by Nippon Shinyaku Co., Ltd (TSE Prime: 4516) as Amnolake® tablets.

> * Orphan drugs are drugs used to treat rare diseases, and they are called so because they are often not actively developed, i.e., ignored or rarely adopted by pharmaceutical companies, due to their limited market and accompanying difficulty in recouping development costs.

Generic name	Tamibarotene
Mechanism of action	TM-411 has a high affinity for RAR alpha, and inhibits leukemia cell differentiation and cancer cell proliferation by regulating gene expression. The inhibitory effect includes suppression of IL-6 production and IL-6R expression, enhancement of IGFBP-3 expression, and suppression of VEGF-dependent angiogenesis, and may be applicable to a range of cancer tumors.
	Meanwhile, it acts on hematopoietic stem cells (CDK-activating kinase [CAK]-RAR alpha) in the bone marrow to promote differentiation into neutrophils via progenitor cells, induces granule formation and reactive oxygen species (ROS), and displays antibacterial activity.
	It is expected to be more effective when used in combination with the G-CSF preparations used to treat neutropenia.
Indications	Myelodysplastic syndrome, acute myelogenous leukemia, breast cancer, childhood cancers, acute promyelocytic leukemia, neuroblastoma, and neutropenia.
Administration	Oral (tablets, capsules)
Licensor	Toko Pharmaceutical Industry, Chemfizz

Source: Shared Research based on company data

Former consolidated subsidiary TMRC was established in January 2002 as a contract research organization (CRO) specializing in cancer. In February 2004, TMRC obtained exclusive manufacturing and marketing rights in Japan and overseas for tamibarotene (TM-411) as an antineoplastic (anticancer) drug. In March 2009, TMRC spun off its CRO business, established a subsidiary, and transferred all shares of the subsidiary to Sugi Medical Co., Ltd (unlisted, a subsidiary of Sugi Holdings Co., Ltd [TSE Prime: 7649]). In February 2017, TMRC became a wholly-owned subsidiary of

RaQualia. On January 1, 2026, RaQualia absorbed TMRC through a simplified short-form merger, reducing costs while streamlining and improving administrative operations to enhance group operational efficiency.

Out-licensed to US-based Syros Pharmaceuticals

In September 2015, TMRC granted development and marketing rights in Europe and North America for tamibarotene as a cancer therapy to US-based Syros Pharmaceuticals, Inc. (NASDAQ: SYRS) in exchange for rights to receive milestone payments in accordance with development progress and sales royalties after launch. Syros aims to file a new drug application for tamibarotene as a precision medicine* for RAR alpha gene (RARA)-positive patients. RARA is expressed as a biomarker in patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML). Syros has been conducting clinical trials targeting MDS and AML in the US.

* Precision medicine: Also known as cancer gene therapy, it is cutting-edge medicine that entails analyzing cancer at the genetic level to provide the optimal treatment for that particular cancer. It is most advanced in the field of oncology, but can be used for all diseases. It is a kind of tailor-made, personalized medicine that entails analyzing cancer cell genes using a next-generation sequencer (a device for high-speed, large-scale decoding of the base sequences that represent the order in which the bases that make up DNA are bound together) to find the cancer-causing genetic mutation. It uses a molecular targeted drug designed to be effective against that particular gene mutation.

Analysis shows approximately 50% of MDS patients and 30% of AML patients have RAR alpha overexpression. When tamibarotene is used in combination with an anticancer agent, tamibarotene binds to RAR alpha, controlling the expression of differentiation factor genes, for an anti-tumor effect inducing cancer cell death. A patent review regarding the use of tamibarotene with anticancer drugs in Japan was conducted in July 2023.

Tamibarotene received fast-track designation from the US Food and Drug Administration for higher-risk myelodysplastic syndrome (HR-MDS) in January 2023, and for acute myeloid leukemia (AML) in April 2024. Companies whose drug candidates obtain fast-track designation can hold more frequent meetings to discuss development plans with the FDA, and may be eligible for priority and fast-track review if the plan can be supported by clinical data.

RaQualia is entitled to receive milestone payments from Syros in line with the development stages and royalties once tamibarotene is launched on the market. Tamibarotene has received orphan drug designation* for MDS and AML in the US and for AML in Europe. In addition, in July 2022 the company obtained a use patent (jointly filed with the National Institute of Advanced Industrial Science and Technology [AIST]) for tamibarotene as a growth inhibitor for cancer stem cells*[2] in Europe. In August 2022, Syros announced the European Medical Agency (EMA) indicated it was in favor of granting orphan drug designation to tamibarotene for MDS.

* Orphan drug designation: A system designed to support development of drugs for life-threatening, rare diseases that affect only a small number of people (diseases that affect less than 200,000 [inclusive] patients in the US; less than five [exclusive] patients out of 10,000 persons in Europe; and less than 50,000 [exclusive] patients in Japan). Drugs that have obtained orphan drug designation enjoy various benefits, including preferential treatment in approval review, development funding, and guaranteed time-limited first mover advantage (market exclusivity) from the start of sales.
*[2] Cancer stem cells are cancer cells that have the characteristics of stem cells (i.e., self-renewal ability to divide and produce identical cells and multilineage differentiation ability to differentiate into various types of cells). They are malignant cells that self-renew and serve as the source of cancer cells. Cancer stem cells are either 1) normal stem cells that have become cancerous or 2) cells that have differentiated to some degree and become cancer stem cells through long-term inflammation. The former is often seen in childhood cancers such as osteosarcoma and hematologic cancers, and is thought to be the cause of disease recurrence and metastasis, as its slow cell division makes it difficult to respond to radiotherapy and anticancer drugs.

Clinical trial results from Syros

Syros conducted a Phase III clinical trial (SELECT-MDS-1) of tamibarotene administered in combination with azacitidine, the standard treatment for high-risk MDS, targeting previously untreated high-risk MDS patients. Patient enrollment necessary for analyzing the primary endpoint was completed during Q1 FY12/24. The company initially planned to release pivotal data by mid-Q4 and subsequently submit an NDA. However, in November 2024, Syros announced that the trial failed to meet its primary endpoint, the complete response (CR) rate, and that it would discontinue the trial while conducting a detailed analysis of the clinical trial data to determine the next steps.

In December 2022, Syros published data from the safety lead-in phase of the Phase II clinical trial (SELECT-AML-1), which studied the combination therapy consisting of tamibarotene, venetoclax, and azacitidine. The trial was conducted in AML patients, including elderly individuals, who are ineligible for standard chemotherapy. The trial then progressed to the randomized phase, and the results of this phase were announced in December 2023. In August 2024, an interim analysis, including a non-binding futility analysis, was conducted using data from 51 patients enrolled in the Phase II clinical trial. The analysis concluded the probability of demonstrating superiority in the final analysis with data from 80 patients was low, leading Syros to decide to halt new patient enrollment. No new safety concerns were identified in the combination therapy of tamibarotene, venetoclax, and azacitidine. Syros presented these findings at the 12th Annual Meeting of the Society of Hematologic Oncology (SOHO) in September 2024.

*A futility analysis is a statistical assessment used to predict trial outcomes based on prespecified hypotheses and evaluation criteria, helping to determine whether the trial should continue.

Regarding MDS, Syros completed patient enrollment necessary for the primary endpoint analysis during Q1 FY12/24 for the Phase III clinical trial evaluating the combination therapy of tamibarotene and azacitidine. In November 2024, Syros announced the trial failed to meet its primary endpoint, the complete response (CR) rate. Syros also disclosed its decision to discontinue the trial while conducting a detailed analysis of the clinical trial data to determine the next steps. Additionally, the company stated the failure to meet the primary endpoint in the Phase III clinical trial constitutes a default event under its existing secured loan agreement. Syros returned the rights to tamibarotene, and the company is evaluating the drug's future potential.

Separately, a clinical research/investigator-initiated clinical trial of tamibarotene for pancreatic cancer and upper urinary tract cancer (led by Nagoya University) has been underway since March 2023, as a Japan Agency for Medical Research and Development (AMED) project. RaQualia has rights for Asia, and aims to out-license rights for treatment of MDS in Japan and China and pancreatic cancer in Japan as development in the US progresses.

Out-licensed pipeline (pet drugs)

Three products on the market

Two of the pet drugs the company has already launched, EP4 receptor antagonist grapiprant and ghrelin receptor agonist capromorelin, are compounds inherited from Pfizer. In December 2010, it granted US-based Aratana Therapeutics Inc. (acquired by Elanco in 2019) an exclusive global license with sublicensing rights to develop, market, and manufacture veterinary drugs. The three products on the market are currently sold by Elanco.

Out-licensed programs (veterinary)

Program name	Generic name/compound code	Key indication	Rollout area	Development stage
EP4 antagonist GALLIPRANT®	RQ-00000007 (grapiprant)	Osteoarthritis in dogs	US	On market
			Europe	On market
			Japan	On market
Ghrelin receptor agonist ENTYCE™	RQ-00000005 (capromorelin)	Anorexia in dogs	US	On market
Ghrelin receptor agonist ELURA™		Weight loss in cats with CKD	US	On market
			Europe	Approved, on market
			Japan	Approved, preparing for launch
COX-2 inhibitor	RQ-00317076	Pain	—	Exploratory research completed
EP4 receptor antagonist	RQ-00000008	Osteoarthritis, etc.	Worldwide	Preclinical trial ongoing
5-HT4 agonist	RQ-00000010	Intestinal motility disorder (dogs, cats)	Worldwide (veterinary)	POC trial ongoing
Four specific compounds	Not disclosed	Under evaluation	Worldwide	Under evaluation

Source: Shared Research based on company data (as of November 2024)

GALLIPRANT® (EP4 receptor antagonist, generic name: grapiprant)

This compound was launched in the US in January 2017 as GALLIPRANT® for osteoarthritis in dogs by US-based Elanco and is now being sold in over 20 countries around the world by Elanco (US). The nonsteroidal anti-inflammatory analgesic and first-in-class (breakthrough)* drug was launched in Japan in October 2020, and sales are growing steadily. Sales reached USD100mn (roughly JPY12.5bn) in FY12/21, becoming Elanco's tenth blockbuster drug.

* A first-in-class (breakthrough) drug is one that is highly novel and useful, and groundbreaking in that it significantly changes existing treatments. It often has a new chemical structure or therapeutic concept. Best-in-class (improved) drugs compensate for shortcomings of first-in-class drugs and have a clear advantage over existing drugs.

ENTYCE™ and ELURA™ (ghrelin receptor agonist, generic name: capromorelin)

Elanco sells ENTYCE™ in the US as a treatment for anorexia in dogs. It is also sold under the brand name ELURA™ in the US as a drug for the management of weight loss in cats with chronic kidney disease (CKD). Elanco filed for approval in Europe in March 2022. The company received an associated milestone payment of JPY115mn in Q1 FY12/22. The company receives milestone payments as set out in its contract and royalties in line with sales when there is progress such as expanding sales territories. The company said sales of ENTYCE™ and ELURA™ were tracking well due to the absence of similar products.

The company filed for approval of ELURA™ in March 2022 in Europe, and the Committee for Veterinary Medicinal Products (CVMP) of the European Medical Agency (EMA) indicated it was in favor of approval in May 2023. Approval was granted in 2023; the product was launched in August 2024 in France and the company received a milestone payment. In February 2024, Elanco obtained manufacturing and marketing approval for ELURA™ from Japan's Ministry of Agriculture, Forestry, and Fisheries and launched the product in November. The company will not receive an upfront payment for the launch.

Potential for ELURA™

According to the company, over 30% of cats aged 10 and over and over 9% overall (roughly 648,000 cats) in Japan have CKD. Cats with CKD may show ongoing weight loss and reduced life expectancy due to loss of appetite and repeated vomiting as the disease progresses. Over 80% of the cats with CKD that were administered ELURA™ for 56 days gained weight. In 2022, there are 74.1mn pet cats in the US and 56.6mn in Europe, so the company thinks the potential market is significant (source: Global Market Insights Research Inc. [unlisted]).

Cyclooxygenase-2 (COX-2) inhibitor (RQ-00317076)

RaQualia's in-house discovered cyclooxygenase-2 (COX-2) inhibitor has a different type of chemical structure than those of existing COX-2 inhibitors. In January 2013, the company signed an agreement to transfer all intellectual property rights, related data, and the drug substance for RQ-00317076 to AskAt, in return for a percentage of the revenue that AskAt earns from RQ-00317076 as royalties. AskAt had been developing RQ-00317076 as a human drug, but in July 2022, signed a

license agreement with US-based Velo-1 for global rights to the drug for use in animals, as well as a two-year development support agreement with Velo-1. Signing of these agreements signaled the start of RQ-00317076 development as an animal drug. RQ-00317076 has lower risk of adverse effects when used in dogs compared with existing NSAIDs, and AskAt believes it is a promising compound for treating acute pain, e.g., postoperative pain, and chronic pain associated with osteoarthritis.

New licensing agreement

5-HT4 agonist (RQ-00000010)

In April 2023, the company signed an option and license agreement with Vetbiolix SAS (unlisted) for the development of a veterinary drug targeting gastrointestinal motility disorders in dogs and cats, based on its proprietary 5-HT$_4$ agonist RQ-00000010 (RQ-10). Under the agreement, the company granted Vetbiolix an exclusive, global, and sublicensable option to license RQ-10 for development, manufacturing, and commercialization. In December 2024, the company received an option fee following Vetbiolix's exercise of the option. The company is entitled to receive milestone payments based on RQ-10's development progress, as well as sales-based royalties from product revenue or sublicensing income earned by Vetbiolix following market launch.

Four development compounds

In April 2024, the company entered into an option and license agreement with US-based Velovia Pharma, LLC (unlisted) for the development of veterinary drugs containing the company's four pipeline compounds. Based on the terms of the agreement, the company granted Velovia option for the exclusive rights to evaluate, develop, manufacture, and sell veterinary drugs containing its four pipeline compounds. If Velovia exercises its option right for one or more of the compounds, the company is entitled to receive option exercise fees as well as milestone payments based on Velovia's subsequent development progress. Further, if veterinary drugs containing the compounds reach the market, the company may receive sales royalties and sales milestone payments based on product sales from Velovia.

Royalty revenue stable for pet drugs, as not affected by drug price revisions

In Japan, the Ministry of Health, Labour and Welfare (MHLW) sets uniform nationwide prices (NHI prices) for human prescription drugs. However, in the distribution chain, pharmaceutical wholesalers sell drugs to medical institutions and insurance pharmacies at wholesale prices that are different from the NHI prices. To reduce the burden on the insurance scheme, the MHLW surveys sales prices and volumes for each individual drug, and revises (lowers) prices based on its findings every year (every second year until April 2018). On the five occasions leading up to the April 2024 round of price revisions, the price was cut by 1.18% on a medical fee basis and reduced and by 5.51% on a drug fee basis on average. Expensive drugs are covered by public insurance and are thought to have a significant impact on the insurance budget, leading to this arrangement for stepwise reductions. This means it is difficult for pharmaceutical companies to generate expected profits for drugs that they launch following prolonged periods of development and massive investments.

The market for pet drugs for which the company receives royalty revenue is smaller than that for human drugs, but there is no similar NHI drug price system either in Japan or overseas. This enables prices to be maintained or lifted, and Shared Research thinks royalty revenue, which is a percentage of sales, tends to be stable and resilient to downward pressure as a result.

Pet drugs versus human drugs

	Pet drugs	Human drugs
Curtailing medical expenses/price revisions	Basically deregulated treatment with no price-setting system. Manufacturers have the right to set prices.	In countries with national drug price systems, the government (insurers in countries without such systems) influences price setting.
Generic drugs	A small number of companies enter market with slightly lower prices once patent expires. Japanese government provides little administrative guidance to promote generics.	Many companies enter market with lower prices once patent expires. Japanese government promotes use of generics.
Consumer behavior	Pet owners (consumers) have strong focus on brand/quality, and tend to keep using the same product after patent expiry.	Price is an important consideration, and consumers tend to shift to low-priced generic products after patent expiry.

Source: Shared Research based on company data

Pre-out-licensing programs

The company has six pre-out-licensing programs (i.e., pipelines in preparation for out-licensing). Of these, the company has out-licensed a TRPM8 blocker outside Japan.

Pre-out-licensing programs

Program name	Generic name/compound code	Key indication	Target market	Development stage
5-HT4 agonist	RQ-00000010	Gastroparesis, functional dyspepsia, and chronic constipation	Worldwide (human)	Phase I complete
5-HT2B agonist	RQ-00310941	Irritable bowel syndrome with diarrhea (IBS-D)	Worldwide	Phase I complete (UK)
Motilin receptor agonist	RQ-00201894	gastroparesis, functional dyspepsia, and post-operative ileus	Worldwide	Preclinical trials complete
Ghrelin receptor agonist	RQ-00433412	Cancer-related anorexia/cachexia syndrome, constipation from spinal cord injury	Worldwide	Preclinical trials ongoing
IRAK-M degradation inducer	FIM-001	Cancer (non-small cell lung cancer, pancreatic cancer, other)	—	Preclinical trials ongoing
TRPM8 blocker	RQ-00434739	Pain	Japan	Preclinical trials ongoing

Source: Shared Research based on company data (as of December 2025)

5-HT4 agonist (RQ-00000010)

This compound is under development for target indications of gastrointestinal dysmotility including gastroparesis, functional dyspepsia, and chronic constipation. Phase I clinical trials in the UK of healthy individuals and patients have been completed. In addition to moving forward with out-licensing activities, the company is looking into the next stage of development, Phase II clinical trials.

Ghrelin receptor agonist (RQ-00433412)

The compound is under development for the target indication of cancer-related anorexia and cachexia syndrome and constipation resulting from spinal cord injury. The company originated the compound after its establishment. The manufacturing of APIs for preclinical study has been completed, and an outsourced preclinical study began in Q4 FY12/21. The company initially planned to out-license worldwide rights in 2024 after completing preclinical studies by end-FY12/23. As of end-FY12/24, the studies were nearly complete, having taken longer than expected. The company is awaiting final reports from part of the studies. It has already manufactured APIs for clinical trials and is prepared to initiate subsequent clinical studies. The company remains committed to concluding a license-out agreement before the start of clinical trials.

Cancer cachexia is a complication seen in about 50% of patients with advanced cancer at the time of initial diagnosis and 80% at the terminal stage, contributing to 30% of cancer-related deaths. The main symptoms are weight loss, skeletal muscle loss, and anorexia. It calls for aggressive treatment because it can weaken the effect of chemotherapy, exacerbate side-effects, interrupt treatment, and ultimately impact survival rates; however, current treatment options remain limited. The ghrelin receptor agonist works on the hypothalamus to increase appetite, stimulate the release of growth hormone from the pituitary gland, and increase muscle mass and body weight.

Approximately 60% of patients with spinal cord injury experience defecation disorders due to autonomic dysfunction. Chronic constipation affects 10–15% of the population, with an even higher prevalence among the elderly. Existing laxatives may cause diarrhea, driving demand in clinical settings for more manageable bowel movement therapies. The company's ghrelin receptor agonists, orally available small-molecule compounds that mimic the action of the hormone ghrelin, demonstrate high biological activity, promoting bowel movements, and increasing body weight. These compounds share a mechanism of action with ENTYCE™ and ELURA™, which the company markets as veterinary drugs, directly stimulating the sacral defecation center to enhance colonic motility and promote spontaneous defecation.

TRPM8 (RQ-00434739)

TRPM8 is a temperature-sensitive ion channel activated by cold stimuli under 28°C or menthol (mint) and its involvement has been suggested in a variety of chronic disorders, including chronic pain. The company discovered a selective TRPM8 blocker (azaspiro derivative) that demonstrated a different mechanism of action in animal models of chronic pain and cystitis than existing drugs, and hopes it will be a breakthrough new drug in the pain and urological disease fields. RaQualia entered an agreement with Hong Kong-based Xgene, granting it exclusive global (excluding Japan) development, manufacturing, and marketing rights for its TRPM8 blocker in September 2021 (see TRPM8 blocker in the out-licensed pipeline (human) section). The company still holds the rights in Japan.

Motilin receptor agonist (RQ-00201894)

The compound is under development for the target indication of gastrointestinal dysmotility including gastroparesis, functional dyspepsia, and post-operative ileus, and the preclinical studies required for Phase I clinical trials have been

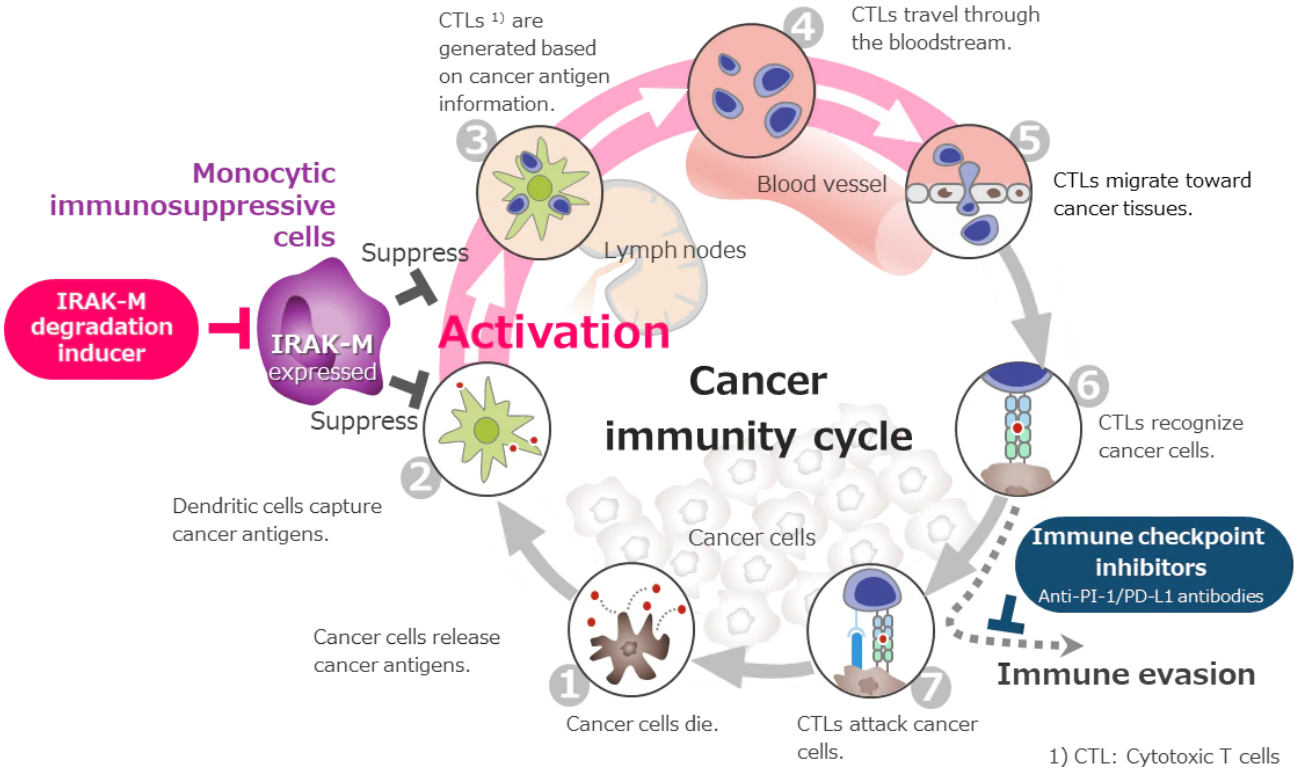
completed. In addition to moving forward with licensing activities, the company is considering conducting Phase I clinical trials, the next development phase.

IRAK-M degradation inducer (FIM-001)

A targeted protein degradation inducer developed by FIMECS, FIM-001 serves as a cancer immunotherapy that operates by degrading IRAK-M to disrupt immunosuppressive mechanisms. It inhibits a novel systemic immunosuppressive mechanism through a pathway distinct from that of immune checkpoint inhibitors (see below). For this reason, the company believes the investigational drug may help overcome resistance (a condition in which the drug becomes ineffective due to mutations in the drug's target protein) to immune checkpoint inhibitors.

Preclinical studies and out-licensing activities are ongoing for the primary target indications of non-small cell lung cancer and pancreatic cancer. Annual incidence is approximately 180,000 cases in the US and 110,000 in Japan for non-small cell lung cancer, and 49,000 in the US and 32,000 in Japan for pancreatic cancer.

Target and mechanism of action of IRAK-M degradation-inducing agents



Source: The company materials.

Exploratory and discovery phase pipeline

As of the beginning of FY12/25, the company had 11 discovery-stage programs, focusing on oncology and neurological disorders through novel modalities such as TPDs.

Beginning of 2024: nine programs	Small molecule compound	TPD	Other new modalities	Total
Cancer	0	0	1	1
Neurological diseases	4	0	1	5
Ocular diseases	2	0	0	2
Other diseases	1	0	0	1
Beginning of 2025: 11 programs	**Small molecule compound**	**TPD**	**Other new modalities**	**Total**
Cancer	0	4	1	5
Neurological diseases	2	0	2	4
Ocular diseases	2	0	0	2
Other diseases	0	0	0	0

Source: Shared Research based on company data

Drug discovery research targeting specific ion channel

The company has been conducting joint research with ASKA Pharmaceutical Co., Ltd. (unlisted; subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. [TSE Prime: 4886]) since July 2019, with the goal of developing new drugs targeting specific ion channels (main indication undisclosed). After extensive discussions on the future development based on the results achieved to date, the two companies have agreed to terminate the joint research agreement in June 2023. Upon termination of the agreement, the research results of the joint research will belong to RaQualia and the company will continue to develop new drugs independently.

RaQualia is also conducting joint research with Gifu Pharmaceutical University for the main indication of retinal vein occlusion (details not disclosed). By constantly conducting seven to ten programs in exploratory and discovery phases, the company thinks it will be able to continue to create groundbreaking development compounds.

Market and value chain

Global drug market

According to US-based IQVIA Holding Inc. (NYSE: IQV), global prescription drug sales in 2023 totaled USD1.6tn (JPY239.9tn, converted at JPY150.0/USD). It forecasts global market growth of USD2.3tn (JPY345tn) in 2028, with a five-year CAGR of 5–8%. In Japan, prescription drug sales totaled USD72.3bn (JPY10.8tn) in 2023, reflecting a five-year CAGR of -3.0%.

Global drug sales

(USDbn)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	5-year CAGR
US	389.4	430.6	455.4	464.7	492.8	521.0	544.6	588.9	645.9	727.4	8.1%
YoY	13.6%	10.6%	5.8%	2.0%	6.0%	5.7%	4.5%	8.1%	9.7%	12.6%	
Japan	85.4	78.8	89.1	84.8	84.2	87.9	87.4	86.7	74.8	72.3	-3.0%
YoY	-5.8%	-7.7%	13.1%	-4.8%	-0.7%	4.4%	-0.6%	-0.8%	-13.7%	-3.3%	
China	111.4	120.5	122.6	127.7	136.7	150.5	148.5	171.4	162.8	160.8	3.3%
YoY	14.5%	8.2%	1.7%	4.2%	7.0%	10.1%	-1.3%	15.4%	-5.0%	-1.2%	
Europe	266.2	238.5	244.5	258.5	273.7	281.8	298.4	334.7	327.9	360.1	5.6%
YoY	3.1%	-10.4%	2.5%	5.7%	5.9%	3.0%	5.9%	12.2%	-2.0%	9.8%	
Central and South America	65.1	74.7	86.9	97.9	59.8	60.5	56.3	68.7	76.5	83.5	6.9%
YoY	-10.2%	14.7%	16.3%	12.7%	-38.9%	1.2%	-6.9%	22.0%	11.4%	9.2%	
Other	138.4	160.9	142.8	145.7	156.0	163.3	164.9	188.8	192.1	195.5	4.6%
YoY	4.5%	16.3%	-11.2%	2.0%	7.1%	4.7%	1.0%	14.5%	1.7%	1.8%	
Worldwide	1,055.9	1,104.0	1,141.3	1,179.3	1,203.2	1,265.0	1,300.1	1,439.2	1,480.0	1,599.6	5.9%
YoY	6.2%	4.6%	3.4%	3.3%	2.0%	5.1%	2.8%	10.7%	2.8%	8.1%	

Source: Shared Research based on Japan Pharmaceutical Manufacturers Association (JPMA) DATA BOOK 2025 (data sourced from IQVIA World Review)
Note: 5-year CAGR s are five years to 2023

According to the Ministry of Health, Labour and Welfare's 2023 Pharmaceutical Production Statistics, the domestic pharmaceutical market rose 2.7% YoY to JPY13.1tn (excluding foreign exchange effects), while domestic prescription drug shipments increased 4.5% YoY to JPY12.4tn. The domestic pharmaceutical market has returned to growth in recent years, supported by increased vaccine imports in response to the COVID-19 pandemic. This recovery occurred despite a prior downturn driven by annual NHI drug price revisions introduced in 2018 and the promotion of lower-cost generics aimed at curbing rising public healthcare expenditures resulting from Japan's aging population.

Pharmaceutical market in Japan

(JPYbn)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	5-year CAGR
Pharmaceutical market in Japan	9,652.1	10,616.7	10,393.6	9,992.7	9,866.6	11,787.4	11,629.4	11,650.9	12,747.7	13,092.8	5.8%
YoY	-1.9%	10.0%	-2.1%	-3.9%	-1.3%	19.5%	-1.3%	0.2%	9.4%	2.7%	

Source: Shared Research based on Statistics of Production by Pharmaceutical Industry, Ministry of Health, Labour and Welfare
* Pharmaceutical market size = domestic production value - export value + import value

(JPYbn)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Drug											
Domestic production	6,894	6,590	6,748	6,624	6,721	6,908	9,486	9,305	9,180	9,982	10,033
YoY	-1.2%	-4.4%	2.4%	-1.8%	1.5%	2.8%	37.3%	-1.9%	-1.3%	8.7%	0.5%
Import	3,077	3,188	4,022	3,945	3,438	3,148	2,753	2,853	3,093	3,414	3,773
Export	130	126	154	176	167	189	443	513	563	649	713
Internal shipping							11,224	10,897	11,203	11,823	12,360
YoY								-2.9%	2.8%	5.5%	4.5%
Medical devices											
Domestic production	1,905	1,989	1,946	1,915	1,990	1,949	2,568	2,426	2,602	2,583	2,675
YoY	0.5%	4.4%	-2.2%	-1.6%	4.0%	-2.1%	31.8%	-5.5%	7.2%	-0.7%	3.6%
Import	1,301	1,369	1,425	1,556	1,650	1,620	2,723	2,637	2,815	2,918	3,322
Export	530	572	623	584	619	668	1,009	991	1,003	1,094	1,126
Internal shipping							3,986	3,935	4,233	4,186	4,549
YoY								-1.3%	7.6%	-1.1%	8.7%
Quasi-drug											
Domestic production	925	923	922	947	951	1,000	1,343	1,405	1,400	1,407	1,425
YoY	15.6%	-0.2%	-0.2%	2.7%	0.5%	5.1%	34.4%	4.6%	-0.4%	0.5%	1.3%
Regenerative medicine											
Domestic production							6	6	7	7	11
YoY								0.0%	25.5%	-2.9%	58.2%

Source: Shared Research based on Statistics of Production by Pharmaceutical Industry, Ministry of Health, Labour and Welfare

Peptic ulcer drug market

Global Industry Analysts, Inc. forecasts the market for peptic ulcer drugs will grow at a CAGR of 2.6% from USD4.9bn (JPY0.7tn converted at JPY150.0/USD) in 2020 to USD5.9bn (JPY0.9tn) in 2027. It projects the market for PPIs that suppress gastric acid secretions to reach USD4.2bn (JPY0.6tn, CAGR of 2.5%) in 2027.

Potential market of main target diseases

Disease	Number of patients	Market size	Region	Existing therapies	RaQualia's development pipeline
GERD	58mn (US), 17mn (Japan)	JPY2tn JPY450bn JPY250bn	Worldwide US Japan	H2RA, PPI, vonoprazan	Tegoprazan
Pain	50mn (US), 23mn (Japan)	JPY2.4tn JPY300bn	Worldwide Japan	Pregabalin, duloxetine, celecoxib, etc.	EP4 receptor antagonist , COX-2 inhibitor, TRPM8 blocker, P2X7 receptor antagonist, sodium channel blocker
Cancer immunity	Approx. 12% of cancer patients respond to cancer immunotherapy	JPY10tn	Worldwide	Nivolumab, pembrolizumab, etc.	EP4 antagonist
Chronic constipation	42mn (US)	JPY660bn JPY60bn	Worldwide Japan	Linaclotide, lubiprostone, etc.	5-HT_4 partial agonist
Gastroparesis	80,000-400,000	JPY200bn	Worldwide	Metoclopramide, etc.	5-HT_4 partial agonist, motilin receptor agonist
Irritable bowel syndrome	5-20% of Japanese/Western adults	JPY100bn	Worldwide	Rifaximin, ramosetron, etc.	5-HT_{2B} agonist
Cancer cachexia	Over 20% of cancer patients develop cachexia	JPY200bn	Worldwide	Anamorelin	Ghrelin receptor agonist
Constipation associated with spinal cord injury	300mn	Over JPY20bn	Worldwide	Laxatives	Ghrelin receptor agonist
Myelodysplastic syndrome	60,000-170,000 (US), 20,000 new cases annually (US, Europe)	JPY100bn	Worldwide	Azacitidine, etc.	Tamibarotene
Acute myeloid leukemia	160,000 (worldwide), 25,000 new cases annually (US, Europe), 7,000 (Japan)	JPY1tn	Worldwide	Azacitidine, venetoclax, etc.	Tamibarotene

Source: Shared Research based on company data

Japanese drug market

According to IQVIA, prescription drug sales in Japan in 2024 reached JPY11.5tn (+2.0% YoY), the tenth consecutive year above JPY10tn. Sales of antacids, flatulence agents, and ulcer agents were not disclosed as the product did not rank among the top 10 therapeutic categories. Sales of Takeda's antiulcer drug TAKECAB® were JPY120.1bn (+3.9% YoY), the fourth highest among domestic drugs.

Prescription drug sales in Japan

(JPYmn)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Prescription drug sales in Japan	6,455,972	6,698,087	6,775,152	7,056,186	7,203,310	7,745,509	7,696,972	8,047,859	8,254,290	8,851,647
YoY	0.0%	3.8%	1.2%	4.1%	2.1%	7.5%	-0.6%	4.6%	2.6%	7.2%
Antacids, flatulence/ulcer agents	391,242	400,632	383,713	392,301	395,660	418,112	408,593	422,148	427,027	446,651
YoY	-1.0%	2.4%	-4.2%	2.2%	0.9%	5.7%	-2.3%	3.3%	1.2%	4.6%
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Prescription drug sales in Japan	8,873,623	9,481,578	9,547,314	9,846,641	9,983,426	10,597,934	10,623,980	10,514,878	10,337,471	10,625,631
YoY	0.2%	6.9%	0.7%	3.1%	1.4%	6.2%	0.2%	-1.0%	-1.7%	2.8%
Antacids, flatulence/ulcer agents	429,890	434,997	408,604	418,289	397,394	389,788	376,365	377,550	349,783	351,329
YoY	-3.8%	1.2%	-6.1%	2.4%	-5.0%	-1.9%	-3.4%	0.3%	-7.4%	0.4%
	2020	2021	2022	2023	2024					
Prescription drug sales in Japan	10,371,733	10,599,031	10,939,481	11,280,631	11,503,713					
YoY	-2.4%	2.2%	3.2%	3.1%	2.0%					
Antacids, flatulence/ulcer agents	347,142	351,640	331,675	278,425	-					
YoY	-1.2%	1.3%	-5.7%	-16.1%	-					

Source: Shared Research based on IQVIA data
Note: Figures may differ from company materials due to differences in rounding methods.

Impact of Japan's NHI drug price revisions

The Ministry of Health, Labour and Welfare (MHLW) sets uniform nationwide prices (NHI prices) for human drugs. The price of a newly developed drug is based on a comparison with drugs already in use with similar efficacy (comparable drug method). If the new drug is more effective or novel, a premium is added, boosting the price. If there is no comparable drug with similar efficacy, the price is based on costs such as raw materials and manufacturing (cost accounting method).

However, the distribution process involves free price competition. Medical institutions and insurance pharmacies charge drug costs based on NHI prices, but the prices of drugs sold from drug companies to wholesalers and wholesalers to medical institutions and insurance pharmacies are freely set wholesale prices, resulting in differences from the NHI price (i.e., drug-price margins). To reduce the insurance benefit burden, the MHLW surveys sales prices and volumes for each individual drug, and revises (lowers) prices based on its findings every year (every second year until April 2018). Expensive drugs are covered by public insurance and are thought to have a significant impact on the insurance budget, leading to this arrangement for stepwise reductions. On the five occasions leading up to the April 2024 price revisions, the price was cut by 1.18% on a medical fee basis and reduced and by 5.51% on a drug fee basis on average.

Japan's arrangements to set NHI drug prices make it difficult for pharmaceutical companies to generate expected profits after launching drugs following extended periods of development and massive investments. The April 2022 drug price revisions featured a cut of 1.35% on a medical fee basis and a cut of 6.69% on a drug fee basis. This acted to shrink the domestic drug market by over JPY600bn in FY2022.

According to an August 2022 survey by MHLW, there were shortages, suspended shipments, or limited shipments for 28.2% of drugs overall and 41.0% of generic drugs due to a sharp rise in demand during the pandemic and steep cost increases due to the Russia-Ukraine war and yen weakness. As a consequence, in the off-year price revisions for FY2023, the ministry took limited extraordinary measures to reassess unprofitable products, resulting in price hikes to 1,100 relevant items. In the FY2023 revisions, prices were cut for 48% of all listed drugs (9,300) items, maintained for 46% (9,000), and raised for 6% (1,100).

The April 2024 NHI drug price revision called for cuts of 0.97% on a medical fee basis and 4.67% on a drug fee basis, with the expectation of a JPY120.0bn reduction in healthcare spending. The 2024 price revision reviewed the drug reimbursement price system to resolve the issue of drug lag and loss and ensure a stable supply. It overhauled the Drug Price Standard, including the way drugs are evaluated for early adoption in Japan and the way premiums such as innovation premium, value premium (for usefulness), pediatric premium (to encourage development of pediatric drugs), and repricing for market expansion are calculated by doing away with corporate indicators and increasing the number of items for evaluation. To ensure stable supply, price revisions reflected the reassessment of unprofitable products and the evaluation of the supply system for generic drugs.

The 2025 NHI drug price revision, the third interim-year revision, differs from the previous two in that price adjustments were determined by drug category. In earlier revisions, all products with a price divergence exceeding 0.625× the average were uniformly subject to revision. The 2025 revision classifies drugs into five categories: products eligible for the premium to promote the creation of new drugs, new drugs not eligible for the premium, long-listed products, generic drugs, and others. Pricing adjustments were relaxed for all categories except long-listed products, for which the scope of

revision was expanded. A total of 9,320 products, accounting for 53% of all listed drugs, were subject to revision, with projected medical cost savings of JPY246.6bn. However, due to the reduced number of applicable products and a narrower divergence rate, the overall cost reduction is expected to be smaller than in the previous two interim-year revisions.

NHI price revisions and average deviation

	1994	1996	1998	2000	2002	2004	2006	2008	2010
NHI price revisions (drug fee basis)	-6.6%	-4.4%	-9.7%	-7.0%	-6.3%	-4.2%	-6.7%	-5.2%	-5.75%
NHI price revisions (medical fee basis)	-2.0%	-1.3%	-2.7%	-1.6%	-1.3%	-0.9%	-1.6%	-1.1%	-1.23%
Average deviation	17.8%	13.1%	9.5%	7.1%	6.3%	8.0%	6.9%	8.4%	8.4%
	2012	**2014**	**2016**	**2018**	**2019**	**2020**	**2022**	**2023**	**2024**
NHI price revisions (drug fee basis)	-6.00%	-5.64%	-5.57%	-7.48%	-4.35%	-4.38%	-6.69%	-4.00%	-4.67%
NHI price revisions (medical fee basis)	-1.26%	-1.22%	-1.22%	-1.65%	-0.93%	-0.99%	-1.35%	-0.83%	-0.97%
Average deviation	8.2%	8.8%	9.1%	7.2%	8.0%	8.0%	7.0%	6.0%	5.2%

Source: Shared Research based on MHLW "NHI drug price revisions"
Note: Figures for FY2019 include the consumption tax revision.

Global pet drug market

Global Market Insights Research Inc. (unlisted) estimates the global pet drug market at USD43.3bn (JPY6.5tn, at JPY150/USD) in 2024 and USD46.3bn (JPY6.9tn) in 2025, and forecasts it will reach USD78.9bn (JPY11.8tn) by 2032, with a CAGR of approximately 6.1%. The market continues to expand as pets are increasing (estimated at 522mn dogs and 445mn cats) due to growth in emerging economies and a burgeoning middle class. Although the market for pet drugs is smaller than that of human pharmaceuticals, the company can maintain or increase prices more easily in the absence of regulated drug prices in Japan and elsewhere.

Number of pet dogs and cats (in thousands)

Number of pet dogs			Number of pet cats	
US	69,929	1	US	74,059
China	27,400	2	China	53,100
Russia	12,520	3	Russia	17,800
Japan	12,000	4	Brazil	12,466
Philippines	11,600	5	France	11,480
India	10,200	6	Germany	8,200
Argentina	9,200	7	UK	8,000
UK	9,000	8	Italy	7,400
France	7,570	9	Ukraine	7,350
South Africa	7,400	10	Japan	7,300

Source: Shared Research based on The Hollard Insurance Company Pty Ltd., A Guide to Worldwide Pet Ownership

Changes to drug discovery modalities

Traditionally, small molecule compounds accounted for the bulk of drug discovery in the pharmaceutical industry, but starting in the 1990s, biopharmaceuticals (made from antibodies, enzymes, hormones, and other substances) produced using biotechnology started being approved. Currently modalities span a diverse range including middle molecule drugs, antibody drugs, nucleic acid drugs, gene therapies, and regenerative medicine.

Difference between small molecule drugs and biopharmaceuticals

Small molecule drugs have a molecular weight of under 500 Daltons, stable chemical structures, and are produced by chemical synthesis. Manufacturing and development costs are comparatively low, and there is a wide variety of dosage forms, not just tablets. Biopharmaceuticals have large molecular weights ranging from several thousand to 150,000 Daltons, complex structures, and are nonuniform. They are made from cells and microorganisms, and manufacturing and development costs are much higher than small molecule drugs. Because they are proteins that are broken down by digestive enzymes if taken orally, they are mainly administered by injection.

Biopharmaceuticals are made within cells using genetic recombination technology. The manufacturing process is extremely complicated, and slight variations in temperature, oxygen concentration, agitation speed, and cell density can affect the quality. Establishing manufacturing methods requires advanced technology and significant costs. While

chemically synthesized small molecule drugs entail about 50 in-process tests, biopharmaceuticals require about 250. In some cases, culture methods have not been established for biopharmaceuticals, and in other cases, overseas companies may hold the patents even if the culture method has been established, and Japan has a lack of specialists. Regulators demand compliance with exacting quality control standards (good manufacturing practice or GMP) and stipulated standards, to constantly maintain the safety and efficacy of products during mass production.

Characteristics of small molecule drugs, medium molecule drugs, and biopharmaceuticals

Type of drug		Small molecule drugs	Medium molecule drugs, biopharmaceuticals		
			Peptide	Nucleic acid	Antibody
Shape (image)					
Molecular weight		100–500	100–10,000	Up to 10,000	About 100,000 or more
Manufacturing method		Chemical synthesis	Chemical synthesis/culture	Chemical synthesis/culture	Culture
Target molecule	Protein	○	○		○
	Nucleic acid (DNA/RNA)	○		○	○
Target molecule location	Intracellular	○	○	○	
	Extracellular	○	○	○	○
Administration route	Oral	○			
	Other	○	○	○	○

Source: Shared Research based on company data

The advantage of biopharmaceuticals is their ability to target molecules that are difficult for small molecule drugs, but their disadvantage is that they are difficult to administer orally. The share of small molecule drugs in FDA approvals was 64.0% in 2024, and remained the most common.

Number of approvals by FDA (US)

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
New Molecular Entities (NMEs)	28	47	34	25	33	25	19	11	15	31	18	18	16	21	20
% of total	96.6%	88.7%	87.2%	83.3%	94.3%	92.6%	79.2%	64.7%	71.4%	86.1%	90.0%	81.8%	88.9%	87.5%	76.9%
Biologics License Applications (BLAs)	1	6	5	5	2	2	5	6	6	5	2	4	2	3	6
% of total	3.4%	11.3%	12.8%	16.7%	5.7%	7.4%	20.8%	35.3%	28.6%	13.9%	10.0%	18.2%	11.1%	12.5%	23.1%
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**
New Molecular Entities (NMEs)	15	24	33	25	30	33	15	34	42	38	40	36	22	34	32
% of total	71.4%	80.0%	84.6%	92.6%	73.2%	73.3%	68.2%	73.9%	71.2%	79.2%	75.5%	72.0%	59.5%	61.8%	64.0%
Biologics License Applications (BLAs)	6	6	6	2	11	12	7	12	17	10	13	14	15	21	18
% of total	28.6%	20.0%	15.4%	7.4%	26.8%	26.7%	31.8%	26.1%	28.8%	20.8%	24.5%	28.0%	40.5%	38.2%	36.0%

Source: Shared Research based on company data
Note: New Molecular Entities (NMEs) are drugs containing new active ingredients and refer to small molecule drugs. Biologics License Applications (BLAs) are for new biopharmaceuticals.

Competition

The Ministry of Economy Trade and Industry (METI) categorizes biotech start-ups into three broad groups. RaQualia can be classified as a pipeline-type as it is involved in the exploratory research, preclinical study, and early clinical trial stages. It looks for seed compounds and its development pipeline is based on its core ion channel drug discovery technology.

Types of biotech start-up business model

Business model		Japanese company example
Drug discovery platform technology-type (platform-type)	Has technology to create drug discovery seeds, which it out-licenses	PeptiDream, Carna Biosciences, Sosei Group
Drug discovery pipeline-type (pipeline-type)	Integrated from seed exploration through in-house development and sales	NanoCarrier, RaQualia
Pipeline acquisition-type (in-licensing-type)	Acquires promising pipeline drugs through corporate acquisitions or in-licensing	Solasia Pharma

Source: Shared Research based on Ministry of Economy, Trade and Industry, 2017, "Business models and financing activities of biotech startups" and company data
Note: The drug discovery pipeline model employs a variety of strategies, such as partial out-licensing for particular indications and selling territories, and development and sales through alliances.

Latest full-year results from biotech start-ups

Stock code	Company	Latest full-year results			Key characteristics
		Revenue (JPYmn)	Operating profit margin (%)	ROE (%)	
4579	RaQualia	3,108	-6.9%	-8.5%	Predecessor was Pfizer's central research laboratory in Japan. Business focuses on revenue from out-licensing new development compounds. Expanding from pain and gastrointestinal diseases to include neurological diseases.
2160	GNI Group	23,612	5.9%	3.1%	Vertically integrated company based in China, involved in drug discovery, clinical development, and manufacturing through sales. Has a leading share in idiopathic pulmonary fibrosis drugs in China. Has R&D locations in US and China.
4565	Nxera Pharma (former Sosei Group)	28,835	-18.8%	-7.2%	A biotech start-up engaged in membrane protein GPCR-targeted drug discovery. The mainstay of its business is a UK acquisition, Heptares. Acquired the pharmaceutical business in Japan and the Asia-Pacific region (excluding China) from Switzerland-based Idorsia and will also conduct late-stage clinical trials and commercialization.
4571	NANO MRNA (former NanoCarrier)	136	-637.9%	-20.4%	Biotech start-up focused on oncology. Aims at new drugs with few adverse reactions using its ultrafine micellar nanoparticle technology.
4572	Carna Biosciences	636	-326.3%	-68.6%	Revenue stable. Sells kinase proteins and provides early stage drug discovery support services such as screening under contract. Also engaged in drug discovery using BTK inhibitors.
4582	SymBio	2,453	-158.1%	-70.9%	Main focus on oncology, hematology, and rare diseases. In-licenses drug candidate compounds which it develops and commercializes.
4587	PeptiDream	46,677	45.2%	30.9%	Biopharmaceutical company using proprietary Peptide Discovery Platform System to produce specialty peptide drug candidates, which it creates with major drug companies and licenses technology for. Many alliances with major overseas drug companies. Moved into radiopharmaceuticals by M&A.
4597	Solasia Pharma	316	-615.7%	-128.1%	Biotech venture that in-licenses development rights for candidate substances and uses in clinical development, focusing on cancer. Re-out-licenses drug candidates it has in-licensed and developed, and sells pharmaceutical products. Fabless operations. Outsources manufacturing to overseas companies.
4883	Modalis	0	-	-54.0%	Biotech start-up that creates therapeutic drugs for rare genetic disorders through drug discovery using unique non-cleaving genome editing technology. Has research base in US.

Source: Shared Research based on company data

(JPYmn)	RaQualia (4579)			GNI group (2160)			Nxera Pharma (4565)		
	FY12/22 Cons.	FY12/23 Cons.	FY12/24 Cons.	FY12/22 IFRS, Cons.	FY12/23 IFRS, Cons.	FY12/24 IFRS, Cons.	FY12/22 IFRS, Cons.	FY12/23 IFRS, Cons.	FY12/24 IFRS, Cons.
Revenue	2,918	1,901	3,108	17,419	26,011	23,612	15,569	12,766	28,835
Gross profit	2,686	1,670	2,482	14,745	22,431	18,037	14,643	9,664	21,219
R&D expenses	1,249	1,373	1,704	2,545	2,558	2,812	7,454	10,075	11,816
SG&A expenses (excluding R&A expense)	572	621	991	10,966	15,293	15,772	4,377	9,965	16,015
Operating profit	866	-337	-213	1,378	13,109	1,402	3,436	-9,526	-5,423
Pre-tax recurring profit	904	-293	-362	768	12,613	238	645	-10,680	-4,662
Net income	723	-324	-495	-868	9,504	-10	382	-7,193	-4,838
ROE	14.1%	-5.6%	-8.5%	2.0%	29.6%	3.1%	0.7%	-11.5%	-7.2%
ROA (RP-based)	15.7%	-4.5%	-4.4%	2.4%	26.2%	0.4%	1.1%	-8.3%	-3.0%
Operating profit margin	29.7%	-17.7%	-6.9%	7.9%	50.4%	5.9%	22.1%	-74.6%	-18.8%
Total assets	6,258	6,872	9,655	33,907	63,394	71,943	99,417	157,198	151,498
Net assets	5,497	6,120	5,571	19,811	36,053	39,714	57,936	66,810	68,518
Equity ratio	87.7%	88.7%	57.4%	61.8%	54.2%	50.7%	58.3%	42.5%	45.2%
Operating CF	1,480	-719	181	393	6,549	-3,164	9,952	-5,273	-7,718
Investing CF	-48	-135	-3,666	-4,116	-9,843	-10,361	1,043	-63,791	-4,763
Financial CF	-30	793	2,982	-646	10,687	694	-4,887	48,329	-6,854
Cash and deposits	3,675	3,715	3,340	11,049	21,633	10,115	66,557	49,065	32,268
Interest-bearing debt	222	368	3,452	537	3,699	7,206	1,753	73,973	67,900
Net debt	-3,453	-3,347	112	-10,512	-17,934	-2,909	-64,804	24,908	35,632
	NANO MRNA (4571)			Carna Biosciences (4572)			SymBio (4582)		
	FY03/22 Cons.	FY03/23 Cons.	FY03/24 Cons.	FY12/22 Cons.	FY12/23 Cons.	FY12/24 Cons.	FY12/22 Cons.	FY12/23 Cons.	FY12/24 Cons.
Revenue	264	202	136	1,387	1,626	636	10,008	5,590	2,453

Gross profit	223	160	111	1,215	1,451	466	7,600	4,411	1,873
R&D expenses	1,924	1,121	647	1,882	1,903	1,886	2,555	2,638	3,379
SG&A expenses (excluding R&A expense)	360	285	328	2,485	2,568	2,542	5,636	5,223	2,371
Operating profit	-2,061	-1,246	-864	-1,270	-1,117	-2,076	1,964	-812	-3,877
Pre-tax recurring profit	-1,925	-1,105	-750	-1,279	-1,126	-2,081	2,000	-736	-3,690
Net income	-1,882	-1,311	-780	-1,350	-1,153	-2,179	1,179	-1,963	-3,833
ROE	-29.1%	-27.0%	-20.4%	-34.0%	-30.7%	-68.6%	14.6%	-26.1%	-70.9%
ROA (RP-based)	-25.7%	-17.0%	-13.8%	-26.4%	-26.1%	-58.4%	19.2%	-7.9%	-56.2%
Operating profit margin	-780.6%	-616.3%	-637.9%	-91.6%	-68.7%	-326.3%	19.6%	-14.5%	-158.1%
Total assets	7,136	5,784	5,071	4,266	4,350	2,772	10,433	8,170	4,968
Net assets	5,567	4,253	3,421	3,642	3,878	2,475	8,506	7,210	4,198
Equity ratio	77.6%	73.5%	67.2%	85.0%	89.1%	89.3%	77.6%	84.9%	78.1%
Operating CF	-1,753	-1,087	-585	-708	-1,677	-1,375	1,614	-195	-3,417
Investing CF	-244	1,208	793	-126	-11	-13	-47	-377	-4
Financial CF	1,146	0	4	367	1,182	567	628	680	708
Cash and deposits	3,545	2,812	2,078	3,379	2,889	2,108	6,283	6,517	3,964
Interest-bearing debt	1,150	0	0	300	183	61	0	0	0
Net debt	-2,395	-2,812	-2,078	-3,079	-2,706	-2,047	-6,283	-6,517	-3,964
	PeptiDream (4587)			**Solasia Pharma (4597)**			**Modalis (4883)**		
	FY12/22	**FY12/23**	**FY12/24**	**FY12/22**	**FY12/23**	**FY12/24**	**FY12/22**	**FY12/23**	**FY12/24**
	IFRS, Cons.	**IFRS, Cons.**	**IFRS, Cons.**	**IFRS, Cons.**	**IFRS, Cons.**	**IFRS, Cons.**	**Cons.**	**Cons.**	**Cons.**
Revenue	26,852	28,712	46,677	1,092	617	316	41	0	0
Gross profit	18,113	17,218	34,504	662	337	185	-	-	-
R&D expenses	2,915	3,155	4,003	883	403	414	1,862	2,103	1,092
SG&A expenses (excluding R&A expense)	6,218	7,256	9,110	2,250	1,073	1,721	242	268	245
Operating profit	8,980	6,773	21,114	-2,470	-1,139	-1,951	-2,063	-2,371	-1,338
Pre-tax recurring profit	6,653	4,353	20,889	-2,492	-1,135	-1,961	-1,996	-2,352	-1,303
Net income	7,554	3,036	15,015	-2,548	-1,112	-1,941	-2,703	-2,392	-1,318
ROE	26.3%	8.4%	30.9%	-97.1%	-49.0%	-128.1%	-63.8%	-111.9%	-54.0%
ROA (RP-based)	14.6%	6.5%	25.8%	-79.4%	-42.3%	-109.2%	-43.4%	-91.2%	-45.6%
Operating profit margin	33.4%	23.6%	45.2%	-226.1%	-184.6%	-615.7%	-5094.3%	-	-
Total assets	63,865	69,464	92,770	3,134	2,229	1,362	3,130	2,026	3,692
Net assets	32,041	40,350	56,762	2,662	1,875	1,156	2,941	1,380	3,548
Equity ratio	50.2%	58.1%	61.2%	84.9%	84.1%	84.9%	93.4%	66.8%	95.5%
Operating CF	-83	12,421	23,845	-2,074	-359	-1,033	-1,896	-2,254	-1,432
Investing CF	-27,377	1,303	8,371	-418	0	0	-186	-40	-188
Financial CF	20,789	264	-2,995	2,571	275	1,180	64	1,216	3,045
Cash and deposits	5,248	19,508	48,118	803	728	886	2,933	1,883	3,575
Interest-bearing debt	21,048	22,221	20,154	37	33	25	0	413	0
Net debt	15,801	2,713	-27,964	-766	-695	-861	-2,933	-1,471	-3,575

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods. Pre-tax profit for companies that use IFRS is shown as recurring profit.

Strengths and weaknesses

Strengths

An advanced small-molecule drug discovery platform based on pharmaceutical-grade research processes, cultivated through ion channel drug discovery

The company took over drug discovery R&D expertise and methodologies from its predecessor, Pfizer's central research laboratory in Japan, following an employee buyout, and carried on with its research programs. It is able to create numerous drug candidates from its compound library, which includes hundreds of thousands of compounds. Advanced technological capabilities based on pharmaceutical company standard research processes and operating procedures have enabled it to discover drugs targeting ion channels with the potential to treat a wide range of diseases. It has already out-licensed five ion channel projects at an early stage.

Ion channels are membrane proteins that allow ions to pass into and out of cells, widely expressed in vital organs such as the heart and brain. More than 100 types exist, each permitting specific ions to pass and contributing to the maintenance of cellular function and a wide range of physiological processes. While modulating ion channels offers potential to treat a broad range of diseases, non-selective blockade may cause severe adverse reactions, including cardiotoxicity and neurotoxicity. Ion channel drug discovery is significantly difficult as compound design expertise and systems enabling constant screening to evaluate compounds are necessary. As a result, drugs that target ion channels account for under 10% of all prescription drugs. According to the company, this is a niche territory with few companies operating in it, and RaQualia is the only company in the world to have out-licensed five programs in the area.

As of end-FY12/25, the company had an extensive development pipeline, with four commercialized products and 13 out-licensed programs (including those targeting ion channels), most of which involve small molecule drugs. Recently, the company has significantly expanded its research scope, building on its strong foundation in advanced small-molecule drug discovery targeting highly challenging targets. It has incorporated the targeted protein degradation (TPD) technology of its subsidiary FIMECS and is advancing the development of small-molecule drugs targeting mRNA through joint research with Veritas In Silico, positioning itself as a next-generation drug discovery company that extends beyond conventional frameworks. The value of biotech companies is generally considered to be the sum total of its pipeline programs. Shared Research thinks RaQualia's corporate value is also strongly backed by its alliances with major companies in Japan and overseas and joint research outcomes in both commercialized products and out-licensed projects, in addition to its ability to generate a series of candidate compounds.

Several hundred patents held

The company applies for basic patents (substance patents) and obtains rights in major countries around the world on an ongoing basis. It has several hundred patents (including peripheral patents) in various regions with different expiry dates (some effective until as late as 2040). After filing for a basic patent, the company aims to extend its life cycle of a compound it has created by seeking extensions and peripheral patents. Compound patents are effective for 20 years, and may be extended by up to five years, and peripheral patents (such as use patents and manufacturing process patents) can extend the exclusive period for a further 20 years. The company has extended patents that Pfizer originally applied for until the mid-2030s via extensions and peripheral patent applications.

Patent expirations are a matter of life and death for drug companies. Pfizer's major restructuring came about after its failure to develop a successor for its hyperlipidemia drug Lipitor® (which generated more than JPY1tn in revenue worldwide), despite investing JPY80bn. RaQualia's strategy aims to ensure revenue over the long term by delaying the launch of lower-priced generic drugs with the same ingredients and efficacy after the patent for a new drug has expired. In addition to obtaining strong patents with broad coverage, the timing of filing patent applications is important to avoid gaps. Some former Pfizer patent experts have come over to the company and are managing patent life cycles using pharmaceutical company expertise. This is a strength for the company.

More recently, in litigation with generic manufacturers over the South Korean substance patent for its main product tegoprazan, the Supreme Court dismissed the generic manufacturers' appeal in November 2025, finalizing the company's complete victory. Through this outcome, the company secured exclusive marketing rights through 2031, directly supporting stable earnings through the company's intellectual property strategy.

Strong discovery capability driven by the proprietary TPD (targeted protein degradation) platform RaPPIDS™ of its subsidiary FIMECS

The company holds a strong competitive advantage in TPD drug discovery capabilities through its subsidiary FIMECS. FIMECS has Rapid Protein Proteolysis Inducer Discovery System (RaPPIDS™), a proprietary platform specialized in TPD. This highly productive system directly detects target protein degradation and evaluates binders using a high-throughput platform, synthesizing up to 1,500 compounds per week with automated synthesis technology.

While TPD compounds generally have large molecular sizes, limiting oral administration, FIMECS has developed orally available TPD compounds, accumulating specialized expertise to overcome this challenge. In addition, FIMECS identifies novel E3 ligase binders through an experimental approach without relying solely on known E3 ligases, establishing multiple proprietary binders.

This development speed and technological capability have earned strong recognition from major pharmaceutical companies. In joint research with Astellas Pharma, FIMECS completed predefined research activities for a specific program, advanced to the next research stage, and received an upfront payment of JPY200mn. The parties also agreed to add two new targets, generating an additional upfront payment of JPY400mn, contributing to the company's consolidated performance. FIMECS continuously generates new drug candidates across a range of disease targets, functioning as a key driver of the group's hybrid business model.

Weaknesses

Constraints on earnings growth due to reliance on specific drug discovery modalities

Small molecule drugs are generally less expensive to produce than biopharmaceuticals because they have a fixed chemical structural formula and are easy to mass-produce. In contrast, biopharmaceuticals contain active ingredients

derived from proteins such as growth hormones, insulin, or antibodies and rely on manufacturing processes using cells, yeast, or bacteria. As a result, they are large and structurally complex molecules, making manufacturing and quality control more difficult. Consequently, they tend to be priced higher, and the market size is often relatively large.

As of end-FY12/25, the company had an extensive development pipeline, with four commercialized products and 13 out-licensed programs (including those targeting ion channels), most of which involve small molecule drugs. The chances of launching a new drug are said to be one in 30,000. While small molecule drugs benefit from a well-established drug discovery process, developing a candidate compound takes about 72 months, placing a significant burden on time and cost. In addition, compared with biopharmaceuticals, small molecule drugs may face constraints in target scope and market size.

In light of these conditions, the company advances into new modality drug discovery while maintaining small molecule drug discovery as its foundation, aiming to create synergies between existing and emerging technologies. Under its medium-term management plan through FY12/28, the company aims to strengthen efforts to expand small molecule drug discovery technologies and advance new modality drug discovery, having made FIMECS a subsidiary and conducting ongoing joint research with VIS and STAND. The company positions these new modalities as derivatives of small molecules, sharing similarities with conventional small-molecule drugs in manufacturing processes and quality control. Shared Research surmises establishing sophisticated platform technologies will take time.

Milestone payments and royalties depend on partners' development progress and business strategies, creating uncertainty in the timing of monetization and weakening the medium- to long-term earnings outlook

The company's revenue comes from: 1) upfront payments received when a contract is signed; 2) milestone payments that depend on pipeline progress such as launching clinical trials; 3) research collaboration payments when conducting joint research, and 4) royalty payments received based on a percentage of sales from launched products. As the company does not have its own sales network, its revenue depends heavily on partners' development and commercialization strategies. While this issue is common among drug discovery startups, the company has faced repeated delays beyond initial expectations in monetizing its key pipeline programs.

For example, in out-licensing tegoprazan in Japan, which is performing strongly in South Korea and other regions, the company sought a domestic partner for many years. In December 2025, it shifted its approach and granted exclusive development, manufacturing, and commercialization rights in Japan to its existing partner, HK inno.N. Under this agreement, the company did not receive an upfront payment; instead, HK inno.N will conduct late-stage clinical trials in Japan, generate revenue from sublicensees, and share a portion of the revenue with the company. As a result, full revenue contribution from the Japanese market will likely begin after 2030, requiring a long-term approach.

In the US, although the company expects to obtain approval for tegoprazan in early 2027 through a partner, factors such as prescription restrictions in the initial year will delay royalty contributions, with full impact on performance expected from 2028. This structure creates a significant time lag between business progress and cash inflows.

The company maintains a high burn rate, investing approximately JPY2.4–JPY2.5bn annually in R&D on a consolidated basis. In its initial forecast for FY12/26, the company made highly conservative assumptions about upfront payments, reflecting limited control over the timing of revenue recognition. This high level of uncertainty represents a structural weakness in managing cash flow while sustaining substantial upfront investment.

Difficulty in recruiting and training specialist researchers

The company mainly hires researchers with abundant R&D experience in pharmaceutical companies. It intends to recruit researchers with PhD in a bid to stand shoulder to shoulder with the world's top companies. Researchers in biopharmacology have high levels of expertise and focus on specific disease areas. As the company expands beyond its traditional focus on pain and gastrointestinal diseases, it needs to recruit researchers with experience in neurological diseases and cancers, as well as in metabolic and endocrine disease research to support joint research with HK inno.N.

According to the School Basic Survey conducted by the Ministry of Education, Culture, Sports, Science and Technology, the number of students entering PhD programs (typically five years) in Japan peaked in FY2003 and declined until the downward slide reached a nadir in FY2015. The number of entrants in FY2024 reached 15,744, increasing for the second consecutive year and showing signs of recovery. The share of working professionals among PhD entrants rose from approximately 20% in FY2003 to around 40% in FY2024. A survey by the National Institute of Science and Technology

Policy also shows health-related fields (including medicine, dentistry, and pharmacy) account for about 60% of working professionals enrolled in doctoral programs, with this share increasing YoY.

However, research in biopharmaceutical drug discovery remains dominated by overseas research institutions, with a limited number of researchers in Japan. According to Science and Technology Indicators 2024 published by the National Institute of Science and Technology Policy, using the most recent available data for each country, the US had the highest number of PhD graduates at 95,000, followed by China at 82,000 and Germany at 28,000. Japan is gradually developing highly skilled talent, primarily among working professionals pursuing doctoral degrees, but the overall number remains limited on a global scale. Shared Research believes recruiting and developing specialized researchers that align with the company's expanding development needs will be critical to its future growth.

Historical results and financial statements

Income statement

Income statement	FY12/15	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.
Operating revenue	**146**	**705**	**1,419**	**745**	**1,703**	**1,107**	**2,776**	**2,918**	**1,901**	**3,108**
YoY	-5.5%	384.7%	101.2%	-47.5%	128.7%	-35.0%	150.7%	5.1%	-34.8%	63.5%
Gross profit	146	588	1,270	655	1,440	969	2,456	2,686	1,656	2,482
YoY	-3.9%	303.9%	116.1%	-48.4%	119.8%	-32.7%	153.3%	9.4%	-38.4%	49.9%
Gross profit margin	100.0%	83.3%	89.5%	88.0%	84.6%	87.5%	88.4%	92.1%	87.1%	79.9%
Operating expenses	**2,010**	**1,465**	**1,570**	**1,820**	**1,719**	**1,593**	**2,068**	**2,052**	**2,239**	**3,321**
YoY	-11.7%	-27.1%	7.1%	15.9%	-5.5%	-7.3%	29.8%	-0.8%	9.1%	48.4%
Cost of operating revenue	-	118	150	89	263	138	321	232	245	626
YoY	-	-	27.1%	-40.2%	193.9%	-47.5%	132.4%	-27.8%	5.8%	155.4%
R&D expenses	1,302	796	849	1,075	864	932	1,127	1,249	1,373	1,704
YoY	-12.0%	-38.9%	6.6%	26.6%	-19.6%	7.9%	20.9%	10.8%	9.9%	24.1%
R&D expense ratio	895.2%	112.9%	59.8%	144.3%	50.7%	84.2%	40.6%	42.8%	72.2%	54.8%
SG&A expenses	708	551	572	656	592	523	620	572	621	991
YoY	-10.9%	-22.1%	3.7%	14.7%	-9.7%	-11.6%	18.6%	-7.9%	8.6%	59.6%
SG&A ratio	486.4%	78.2%	40.3%	88.1%	34.8%	47.2%	22.3%	19.6%	32.7%	31.9%
Operating profit	**-1,865**	**-760**	**-150**	**-1,075**	**-16**	**-486**	**708**	**866**	**-337**	**-213**
YoY	-	-	-	-	-	-	-	22.4%	-	-
Operating profit margin	-	-	-	-	-	-	25.5%	29.7%	-	-
Non-operating income	99	94	85	45	49	35	177	77	88	68
Interest income	4	13	4	9	9	4	2	1	3	5
Interest on securities	78	52	35	32	35	28	21	13	7	3
Foreign exchange gains	14		1			-	146	44	52	39
Gain on valuation of compound financial instruments		8			4	1	0		3	-
Gain on sale of securities	1									
Subsidy income		20	44	1	0	2	6			
Dividend received	0									
Reversal of allowance for investment loss										
Other	1	2	1	3	1	1	3	6		
Non-operating expenses	29	55	85	35	12	76	21	39	44	216
Interest expenses						0	1	6	7	43
Commitment fees								6	9	7
Foreign exchange losses		55		33	0	76	-			
Syndicated loan fees										141
Share issuance expenses	6		13	1	12	0	0	16	4	1
Loss on valuation of derivatives						-	10	-	25	22
Settlement package						-	10			
Loss on valuation of compound financial instruments	21		2	1				11		2
Loss on redemption of securities	2									
Other	-	-	0	-	-	-	-	-	-	-
Recurring profit	**-1,795**	**-721**	**-81**	**-1,065**	**22**	**-528**	**864**	**904**	**-293**	**-362**
YoY	-	-	-	-	-	-	-	4.7%	-	-
Recurring profit margin	-	-	-	-	1.3%	-	31.1%	31.0%	-	-
Extraordinary gains	66		21	5	6	9	17	14	-	9
Gain on sale of fixed assets						1	-			
Gain on sale of investment securities	66		18	5	6	8	14	10		9
Gain on redemption of investment securities							2	4		
Extraordinary losses	119	2	0	18		9		68	1	6
Impairment losses						3				
Loss on sales of investment securities			0			0				6
Loss on redemption of investment securities	6	2				7		50	1	
Retirement benefits for officers								18	-	
Special retirement expenses	69									
Office relocation expenses	43									
Loss on cancellation of lease contract										
Other	-	-	-	-	-	-	-	-	-	-
Income taxes	6	5	-2	26	22	79	125	128	30	137
Implied tax rate	-0.3%	-0.7%	2.9%	-2.4%	80.4%	-15.0%	14.2%	15.0%	-10.1%	-38.4%
Net income attributable to owners of the parent	**-1,854**	**-728**	**-58**	**-1,105**	**5**	**-607**	**756**	**723**	**-324**	**-495**
YoY	-	-	-	-	-	-	-	-4.3%	-	-
Net margin	-	-	-	-	0.3%	-	27.2%	24.8%	-	-

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

In June 2008, the company received intellectual property rights from Pfizer covering a number of projects that were in the exploratory or development stages. When the company out-licenses rights for compounds transferred from Pfizer, it pays a certain percentage of the revenue it receives (upfront, milestone, and royalty payments) as royalties to Pfizer and record them under operating expenses.

The bulk of the upfront, milestone, and royalty payments the company receives from out-licensing is in US dollars, so it books foreign exchange gains or losses each fiscal year depending on currency fluctuations, which affect earnings.

Balance sheet

Balance sheet	FY12/15	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.
Assets										
Cash and deposits	1,840	1,428	2,268	1,671	2,174	1,394	2,345	3,675	3,715	3,340
Notes and accounts receivable	73	58	449	1	747	531	1,205	602	603	689
Securities	503	9	329	168	26	719	314	251	50	2
Inventories	7	7	5	6	6	7	11	9	148	168
Advances paid	179	205	190	9	6	36	16	90	67	27
Prepaid expenses	65	56	62	72	69	50	90	109	188	194
Other	40	43	20	35	39	97	22	87	186	120
Total current assets	**2,708**	**1,806**	**3,322**	**1,962**	**3,067**	**2,834**	**4,004**	**4,822**	**4,957**	**4,539**
Buildings and structures	140	141	142	143	143	153	154	154	158	159
Tools, furniture, and fixtures	394	452	488	677	742	872	944	964	1,125	1,371
Lease assets				3	3	49	60	255	398	434
Accumulated depreciation	-273	-344	-415	-505	-639	-741	-859	-982	-1,107	-1,435
Total tangible fixed assets	**261**	**249**	**216**	**318**	**249**	**333**	**299**	**391**	**574**	**529**
Trademark	2	6	5	5	5	4	4	4	5	4
Software	8	7	4	28	27	28	29	20	26	33
Goodwill										3,865
Other	4	0	-	1	1	1	1	0	0	0
Total intangible assets	**14**	**13**	**10**	**34**	**32**	**33**	**34**	**24**	**30**	**3,902**
Investment securities	1,752	1,937	1,503	1,717	1,474	1,038	888	988	1,231	547
Long-term prepaid expenses	5	3	2	10	2	0	0	24	64	15
Deferred tax assets						3	-		6	78
Other	12	11	11	12	12	10	9	8	11	45
Investments and other assets	**1,769**	**1,951**	**1,516**	**1,738**	**1,488**	**1,051**	**897**	**1,020**	**1,311**	**685**
Total fixed assets	**2,044**	**2,213**	**1,742**	**2,090**	**1,769**	**1,417**	**1,230**	**1,436**	**1,915**	**5,117**
Total assets	**4,752**	**4,019**	**5,064**	**4,052**	**4,837**	**4,251**	**5,234**	**6,258**	**6,872**	**9,655**
Liabilities										
Notes and accounts payable			2		34	42	46	128	54	59
Short-term debt	-	-	-	1	1	18	22	46	77	582
Accounts payable–other	123	126	63	99	67	53	113	206	159	194
Accrued expenses	57	40	44	48	50	50	63	60	54	69
Income taxes payable	15	1	21	14	20	21	80	31	20	28
Consumption taxes payable			14			-	37			
Deferred tax liabilities		1							-	186
Advances received		14	1		7					
Deposits	5	3	4	3	3	3	29	19	4	19
Other	-	5	-	-	-	-	10	4	22	50
Total current liabilities	**200**	**190**	**149**	**164**	**183**	**187**	**401**	**494**	**389**	**1,187**
Long-term debt	-	-	-	2	2	27	18	177	291	2,870
Asset retirement obligations	12	12	12	12	12	12	12	12	12	15
Deferred tax liabilities	26	29	16	16	19	14	16	3	-	
Other	-	-	-	-	-	-	-	75	59	13
Total fixed liabilities	**38**	**41**	**27**	**31**	**33**	**53**	**46**	**267**	**362**	**2,897**
Total liabilities	**238**	**231**	**176**	**195**	**216**	**240**	**446**	**761**	**752**	**4,085**
Net assets										
Capital stock	9,806	2,238	2,741	2,793	2,255	2,255	2,257	2,266	2,668	2,721
Capital surplus	5,090	2,238	2,931	2,983	2,445	2,445	2,447	2,455	2,857	2,910
Retained earnings	-10,421	-728	-786	-1,890	-99	-706	50	773	449	-46
Share subscription rights	11	15	17	13	12	12	11	8	26	27
Total net assets	**4,514**	**3,788**	**4,888**	**3,857**	**4,621**	**4,011**	**4,788**	**5,497**	**6,120**	**5,571**
Total liabilities and net assets	**4,752**	**4,019**	**5,064**	**4,052**	**4,837**	**4,251**	**5,234**	**6,258**	**6,872**	**9,655**
Working capital	80	65	452	7	718	496	1,170	483	697	798
Total interest-bearing debt	-	-	-	3	2	46	39	222	368	3,452
Net debt	-1,840	-1,428	-2,268	-1,668	-2,172	-1,349	-2,306	-3,453	-3,347	112

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

As of end-FY12/24, total assets increased JPY2.8bn YoY to JPY9.7bn, up 40.5% from end-FY12/23. The rise was primarily driven by a JPY3.9bn increase in intangible assets, reflecting higher goodwill following the full acquisition of FIMECS in March 2024. This was partially offset by a JPY374mn decrease in cash and deposits and a JPY684mn decline in investment securities.

Total liabilities rose by JPY3.3bn to JPY4.1bn, up 443.6% YoY, mainly due to a JPY2.6bn increase in long-term borrowings, a JPY500mn rise in the current portion of long-term borrowings, and a JPY185mn increase in contract liabilities.

Total net assets declined JPY549mn to JPY5.6bn, down 9.0% YoY, primarily reflecting a JPY495mn net loss attributable to owners of the parent and a JPY162mn decrease in valuation difference on marketable securities, partially offset by a JPY105mn increase in capital stock and capital surplus through a third-party allotment.

As a result, the equity ratio declined 31.3pp YoY to 57.4%.

Cash flow statement

Cash flow statement	FY12/15	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24
(JPYmn)	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.	Cons.
Cash flows from operating activities (1)	-2,117	-681	-307	-404	-531	-289	366	1,480	-719	181
Pre-tax profit	-1,848	-723	-60	-1,078	27	-528	881	851	-294	-358
Depreciation	53	80	86	126	140	124	142	148	176	198
Impairment losses						3	-			
Gain and loss on sale and disposal of fixed assets						-1	-			
Change in working capital	-51	15	-377	445	-711	223	-674	687	-214	-78
Cash flows from investing activities (2)	666	-441	534	-368	216	225	-279	-48	-135	-3,666
Purchase of intangible/tangible fixed assets	-200	-37	-88	-221	-94	-156	-105	-32	-222	-116
Proceeds from sale of intangible/tangible fixed assets						1	-			
Free cash flow (1+2)	-1,451	-1,122	226	-772	-315	-64	87	1,432	-854	-3,485
Cash flows from financing activities	1,702	-	1,007	99	696	-7	-16	-30	793	2,982
Net change in short-term borrowings						-	-			
Net change in long-term borrowings	-	-	-	-	-	-	-	12	40	2,970
Proceeds from issuance of, and redemption of, bonds	-	-	-	-	-	-	-	-	-	-
Proceeds from share issuance exercising share subscription rights	1,686		996	100	692	0	2	4	4	0
Proceeds from issuance of share subscription rights	15		11		4				783	80
Repayments of lease obligations				-1	-1	-7	-18	-45	-52	-68
Change in cash and cash equivalents	252	-999	1,229	-644	371	-139	179	1,439	-15	-523
Cash and cash equivalents (year-end)	2,243	1,244	2,474	1,830	2,200	2,061	2,241	3,679	3,665	3,142

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

Cash flows from operating activities

Cash inflows from operating activities increased by JPY899mn YoY, turning from an outflow of JPY718mn in FY12/23 to an inflow of JPY180mn in FY12/24. This improvement was primarily driven by a pre-tax loss of JPY357mn, depreciation of JPY198mn, amortization of goodwill of JPY203mn, a JPY73mn decrease in advance payments, and a JPY74mn decrease in consumption taxes receivable.

Cash flows from investing activities

Cash outflows from investing activities increased JPY3.5bn YoY, rising from JPY135mn in FY12/23 to JPY3.7bn in FY12/24. This was mainly due to a JPY3.9bn outflow for the acquisition of shares in a subsidiary following a change in the scope of consolidation, and a JPY200mn outflow for payments into time deposits. These were partially offset by inflows of JPY100mn from withdrawal of time deposits, JPY258mn from sales of investment securities, and JPY200mn from distributions from investment partnerships.

Cash flows from financing activities

Cash inflows from financing activities increased JPY2.2bn YoY, rising from JPY793mn in FY12/23 to JPY3.0bn in FY12/24. This was primarily due to an inflow of JPY3.4bn from long-term borrowings and JPY79mn from share issuance. These were partially offset by outflows of JPY387mn for repayments of long-term borrowings and JPY68mn for lease obligation repayments.

Historical performance

Q3 Cumulative FY12/25 results (out November 14, 2025)

Earnings summary

Cumulative Q3 FY12/25 results (January–September 2025)

- Operating revenue: JPY2.3bn (-2.5% YoY)
- Operating loss: JPY345mn (a loss of JPY27mn in cumulative Q3 FY12/24)
- Recurring loss: JPY427mn (a loss of JPY231mn)
- Net loss attributable to owners of the parent: JPY569mn (a loss of JPY340mn)
- R&D expenses: JPY1.2bn (-1.5% YoY)

Operating revenue declined 2.5% YoY, while the company recorded an operating loss. Progress toward the full-year FY12/25 operating revenue forecast reached 59.4%. RaQualia did not disclose progress rates for profit categories below operating profit, as each recorded a loss. The company considers losses to be within expectations and progress to be broadly in line with the forecast.

Factors behind lower revenue and profit

Royalty income increased to JPY1.7bn (+14.1% YoY), driven by steady growth in royalties from four launched products, including tegoprazan, and a significant YoY increase in royalties from tegoprazan's global sales. Particularly, royalty income generated in China increased YoY, and the company views the increase as driven by a structural rise in demand rather than temporary factors.

Other income declined 30.7% YoY to JPY607mn, including upfront payments, milestone payments, and research collaboration payments. In cumulative Q3 FY12/24, the company recorded milestone payments related to the launch of Eluracat™ in France. In cumulative Q3 FY12/25, the company did not record any large milestone payments and primarily recorded research collaboration payments from FIMECS.

In Q3 (July–September), royalty revenue increased to JPY630mn (+27.3% YoY), but other income declined to JPY145mn (-68.7% YoY), as it recorded no upfront or milestone payments. Royalties from sublicensees in a given period may not align with local sales revenue for the same period because revenue recognition takes time to finalize. Shared Research estimates quarterly research collaboration payments at around JPY100–150mn, with fluctuations depending on research progress.

Total operating expenses increased to JPY2.7bn (+10.8% YoY), and the operating loss widened to JPY345mn (a loss of JPY27mn in cumulative Q3 FY12/24). Cost of operating revenue totaled to JPY547mn (+37.9% YoY), R&D expenses declined to JPY1.2bn (-1.5% YoY), while other SG&A expenses increased to JPY872mn (+17.1% YoY). Cost of operating revenue increased YoY, reflecting higher external royalty payments in line with growth in license revenue, as well as higher operating costs following the consolidation of FIMECS as a subsidiary from Q2 FY12/24. Despite clinical trial preparation costs recorded in advance in Q2, the company has maintained R&D expenses under appropriate control relative to the full-year forecast.

Non-operating income totaled JPY66mn (+183.6% YoY), driven by JPY31mn in derivative valuation gains and JPY13mn in interest income. Non-operating expenses totaled JPY148mn (-35.0% YoY), including JPY87mn in foreign exchange losses and JPY45mn in interest expenses. As a result, the company recorded net non-operating expense. Recurring loss totaled JPY427mn (a loss of JPY231mn in cumulative Q3 FY12/24), and net loss was JPY569mn (a loss of JPY340mn).

Brisk royalties from four commercialized products

Pet drugs

Revenue from GALLIPRANT® (generic name: grapiprant), a treatment for osteoarthritis in dogs; ENTYCE® (capromorelin), a treatment for anorexia in dogs; and ELURA® (capromorelin), a treatment for weight management in cats with chronic kidney disease (CKD), continued to perform well.

Royalty income from pet pharmaceuticals comes mainly from GALLIPRANT®, which became a blockbuster with annual revenue of over JPY10.0bn in 2021. Sales of GALLIPRANT® remained strong, showing no signs of peaking. The company is seeking regulatory approvals and expanding sales for three commercialized pet pharmaceuticals in new countries and regions.

Tegoprazan sales in South Korea

Revenue from GERD treatment K-CAB® (tegoprazan) in South Korea by licensee HK inno.N continued to be robust, with prescription revenue outside hospitals amounting to KRW160.8bn (+13.1% YoY; roughly JPY17.7bn at JPY0.11/KRW). HK inno.N continues to lead the peptic ulcer drug market in South Korea with a share of 15%.

On November 20, 2025, the Supreme Court of Korea dismissed a generic manufacturer's appeal in a patent dispute in the Korean market concerning a trial for confirmation of scope of rights. This ruling finalized the company's complete win and confirmed the legal validity of the substance patent, which remains effective through 2031. As for development progress, the company completed a Phase III clinical trial in South Korea for the prevention of NSAID-induced ulcers, which would represent the sixth indication. HK inno.N plans to file an application for approval for NSAID-induced ulcers with the South Korea Ministry of Food and Drug Safety (MFDS) within 2025.

*For gastric acid secretion inhibitor tegoprazan, RaQualia holds a substance patent in South Korea (patent number 1088247) covering its marketed product K-CAB® tablets. The patent term had been extended to 2031 under the patent term extension system for pharmaceuticals. More than 60 Korean generic manufacturers filed actions for a negative scope confirmation trial, disputing the scope of the extended patent rights. Some South Korean generics makers sought to launch K-CAB® generic products in 2026, right after the original patent expired. To that end, they filed trials claiming the extended patent rights did not cover three later-approved indications—gastric ulcer, combination therapy for Helicobacter pylori eradication, and maintenance therapy—and only covered the initially approved indications of erosive esophagitis (EE) and non-erosive reflux disease (NERD). In 2024, the Intellectual Property Trial and Appeal Board upheld the company's position, ruling that the extended patent rights also applied to the later-approved indications. In August 2025, the Patent Court, serving as the court of second instance, also ruled in the company's favor, thereby ensuring that K-CAB® tablets' exclusive sales rights remain firmly protected through 2031.

Development of tegoprazan in countries around the world

RaQualia has an exclusive license agreement with HK Inno.N to develop, market, and manufacture tegoprazan, including sublicense rights. HK inno.N and partner companies in respective countries that have received licenses or product exports from HK inno.N (sublicensees) are advancing tegoprazan-related business activities. HK inno.N aims to expand tegoprazan's reach to 100 countries by 2028 and to achieve annual global sales of KRW3.0tn for tegoprazan products by 2030, and is actively working toward these goals. As of end-cumulative Q3, tegoprazan was available or in preparation in 54 countries worldwide.

RaQualia announced Dr. Reddy's Laboratories (NSE: DRREDDY), a sublicensee of HK inno.N, has launched a tegoprazan product in India. Marketed under the brand name PCAB, the drug was approved for three indications—erosive esophagitis (EE), non-erosive esophagitis (NERD), and gastric ulcer. India's peptic ulcer drug market was estimated at about JPY167.2bn in 2024, ranking fourth globally after China, the US, and Japan.

Sales of tegoprazan began in India during Q3. As of end-cumulative Q3 FY12/25, tegoprazan is marketed in 18 countries: South Korea, China, Mongolia, the Philippines, Indonesia, Singapore, Mexico, Peru, Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador, Malaysia, Panama, and India. Through HK inno.N, RaQualia receives royalties based on a portion of the revenue HK inno.N earns from sublicensees, such as sales royalties.

Regulatory approval processes are underway in Southeast Asia and Central and South America, and applications have been filed in Brazil and the Middle East.

Favorable trial results in the US

In April 2025, HK inno.N announced Braintree Laboratories (unlisted), a division of its sublicensee Sebela Pharmaceuticals Inc. in the US, reported favorable results from the ongoing US Phase III clinical trial (the TRIUMpH trial). The TRIUMpH trial is being conducted as a pivotal study for erosive esophagitis (EE) and non-erosive reflux disease (NERD). Tegoprazan met all primary and secondary endpoints in both the EE and NERD studies.

Braintree also reported favorable maintenance therapy results at the end of up to eight weeks of initial treatment in EE patients who achieved complete healing in the TRIUMpH trial. Sebela plans to submit an application to the US FDA for approval for EE and NERD in Q4 FY12/25. If development proceeds smoothly, Sebela expects to obtain approval between late 2026 and early 2027 and to launch sales during 2027. The company anticipates that a full-scale contribution to royalty income will begin from 2028 onward.

Out-licensed and pre-out-licensing programs

For the out-licensed programs, including the P2X7 receptor antagonist, TRPM8 blocker, and 5-HT4 agonist for animal health, RaQualia's licensees and sublicensees are advancing development in preclinical and later stages.

The company confirmed that Eli Lilly has removed the P2X7 receptor antagonist from its pain-relief development pipeline. Based on clinical trial results to date, the company recognizes that there is a low possibility that Eli Lilly will resume development in the pain area. However, the license agreement remains in effect, and Eli Lilly has not terminated development of the P2X7 receptor antagonist, continuing internal reviews of future development options. Xgene is conducting a Phase I clinical trial for the TRPM8 antagonist. The company is closely monitoring progress in this study.

For pre-out-licensing programs, RaQualia completed preclinical trials for its ghrelin receptor agonist program and is conducting business development activities, aiming to secure licensing agreements. For tegoprazan, the company retained development, manufacturing, and sales rights in Japan and was continuing negotiations as of Q3 with the goal of concluding a licensing contract by the end of the year. (The company out-licensed the Japan rights to HK Inno.N in December 2025). In the US, the company recognizes that successful contract negotiations will not depend solely on the results of the US Phase III clinical trial because some counterparties already assume clinical success in their negotiation conditions. The company is prioritizing early market entry over maximizing contract terms, and it is advancing discussions under a conventional licensing model in which partner companies bear development costs, as well as co-development and other options.

The company has also actively engaged in other pre-out-licensing activities through flexible in-person meetings and online conferences with potential partners. The company suggests it began negotiating specific terms for the IRAK-M degradation inducer.

Exploratory programs

In the exploratory research phase, RaQualia is concentrating on research programs aimed at creating new development compounds. By enhancing its next-generation drug discovery value chain through synergies of existing and new technologies, the company advances a critical development strategy to target previously unexplored drug opportunities, including genes and proteins once considered undruggable. The company seeks to enhance technologies and pipelines, approaching from four perspectives: modality, drug discovery targets, disease areas, and foundational technologies.

The company is developing targeted protein degradation inducers—a novel drug discovery modality—primarily through FIMECS, which became a consolidated subsidiary in March 2024. FIMECS and Astellas Pharma Inc. (TSE Prime: 4503) are jointly developing compounds targeting multiple proteins for cancer treatment, leveraging the proprietary RaPPIDS™ drug discovery platform, which was specifically designed for targeted protein degradation.

Capital and business alliance with HK Inno.N

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. A total of 2,592,100 common shares were allocated to HK inno.N, representing 10.62% of voting rights after the issuance. HK inno.N made the payment on April 18, 2025.

Through the partnership, RaQualia aims to strengthen its financial base through investment from HK inno.N and to establish a strategic alliance between the two companies. In cumulative Q3, the company advanced preparations to launch the joint research project for tegoprazan, including obtaining study data and holding discussions to formulate the project plan.

Absorption-type merger (simplified and short-form merger) of TMRC Co., Ltd.

RaQualia decided to merge with TMRC through a simplified, short-form absorption-type merger to streamline group operations, reduce costs, and improve administrative efficiency. Under the merger, the company will remain the surviving country, and TMRC will be dissolved. The company and TMRC signed the merger agreement on October 17, 2025, and planned to make the merger effective on January 1, 2026. Because the merger is being conducted with a wholly owned subsidiary, the company will issue no new shares and pay no consideration for the merger.

Outlook at the time of the cumulative Q3 earnings announcement

As of end-cumulative Q3, progress toward full-year FY12/25 operating revenue forecast reached 59.4%. RaQualia did not disclose progress rates for profit categories below operating profit, as each recorded a loss. The company projects that royalty revenue, which continues to grow, will exceed the FY12/24 result of JPY1.9bn. The company aims to increase other income to achieve the full-year forecasts. At the time of the cumulative Q3 earnings announcement, it maintained the full-year forecast.

The company needs an additional JPY1.0bn in revenue to meet the full-year forecast and believes it is still on track. It expects an upfront payment from Astellas Pharma Inc. via its subsidiary FIMECS in Q4 and revenue from the out-licensing of tegoprazan in Japan in Q4.

1H FY12/25 results (out August 14, 2025)

Earnings summary

1H FY12/25 results (January–June 2025)

- Operating revenue: JPY1.5bn (+8.9% YoY)
- Operating loss: JPY190mn (a loss of JPy154mn in 1H FY12/24)
- Recurring loss: JPY291mn (a loss of JPY278mn)
- Net loss attributable to owners of the parent: JPY355mn (a loss of JPY324mn)
- R&D expenses: JPY782mn (-6.1% YoY)

1H progress toward the full-year FY12/25 forecast reached 39.5% for operating revenue. The company did not disclose progress rates for profit categories below operating profit, as each recorded a loss. The company considers losses within expectations and progress broadly in line with the forecast.

Factors behind higher revenue and lower profit

Royalty income from four launched products increased, and global sales of tegoprazan continued to expand steadily. Royalty income increased to JPY1.1bn (+7.5% YoY), exceeding JPY1.0bn for the first time in 1H. Other income, including upfront and milestone payments and research collaboration payments, totaled JPY462mn (+11.9% YoY).

In Q2 (April–June), royalty revenue increased 2.7% YoY to JPY459mn but fell QoQ, partly because results excluded royalties in China and other regions. Upfront payments and milestone payments were absent, and other revenue declined to JPY111mn (-64.9% YoY). Royalties from sublicensees in a given period may not align with local sales revenue for the same period because revenue recognition takes time to finalize. The recognition period is gradually shortening. Shared Research estimates quarterly research collaboration payments at around JPY100–150mn, with fluctuations depending on research progress.

R&D expenses decreased to JPY782mn (-6.1% YoY) as costs for the ghrelin receptor agonist program ceased, and some R&D expenses were reclassified as cost of operating revenue. Meanwhile, expenses increased for GMP production of the IRAK-M degradation inducer (FIM-01) and for exploratory research. Cost of operating revenue expanded to JPY389mn (+71.4% YoY), reflecting higher royalty payments to external parties. SG&A expenses rose to JPY555mn (+9.7% YoY), driven by higher personnel expenses from wage increases and litigation costs in South Korea*. Total operating expenses increased to JPY1.7bn (+10.3% YoY), and the operating loss widened to JPY190mn (a loss of JPY154mn in 1H FY12/24).

Non-operating income included JPY32mn from derivative valuation gains and JPY8mn from interest income. However, RaQualia also recorded non-operating expenses such as JPY105mn in foreign exchange losses and JPY30mn in interest expenses, resulting in a net non-operating loss. Recurring loss totaled JPY291mn (a loss of JPY278mn in 1H FY12/24), and interim net loss came to JPY355mn (a loss of JPY324mn).

*For gastric acid secretion inhibitor tegoprazan, the company holds a substance patent in South Korea (patent number 1088247) covering its marketed product K-CAB® tablets. The patent term had been extended to 2031 under the patent term extension system for pharmaceuticals. More than 60 Korean generic manufacturers filed actions for a negative scope confirmation trial, disputing the scope of the extended patent rights. Some South Korean generics makers sought to launch K-CAB® generic products in 2026, right after the original patent expired. To that end, they filed trials claiming the extended patent rights did not cover three later-approved indications—gastric ulcer, combination therapy for Helicobacter pylori eradication, and maintenance therapy—and only covered the initially approved indications of erosive esophagitis (EE) and non-erosive reflux disease (NERD). In 2024, the Intellectual Property Trial and Appeal Board upheld the company's position, ruling that the extended patent rights also applied to the later-approved indications. In August 2025, the Patent Court, serving as the court of second instance, also ruled in the company's favor, thereby ensuring that K-CAB® tablets' exclusive sales rights remain firmly protected through 2031. Some plaintiffs have appealed to the Supreme Court (third instance), and the litigation is ongoing. However, in certain earlier cases, the Supreme Court has already dismissed appeals for failure to proceed with hearings, thereby finalizing judgments in the company's favor.

Pipeline

Brisk royalties from four commercialized products

Pet drugs

Revenue from GALLIPRANT® (generic name: grapiprant), a treatment for osteoarthritis in dogs, ENTYCE® (generic name: capromorelin), a treatment for anorexia in dogs, and ELURA® (generic name: capromorelin), a treatment for weight management in cats with chronic kidney disease (CKD), continues to perform well. Royalty income from pet pharmaceuticals comes mainly from GALLIPRANT®, which became a blockbuster with annual revenue of over JPY10.0bn in 2021. These pet pharmaceuticals are also progressing in obtaining approvals and expanding sales into new countries and regions.

Development of tegoprazan in countries around the world

Revenue from GERD treatment K-CAB® in South Korea by licensee HK inno.N continued to be robust, with revenue from prescriptions outside hospitals amounting to KRW104.7bn (+14.3% YoY; roughly JPY11.5bn at JPY0.11/KRW) in 1H FY12/25. In 2024, the South Korean anti-ulcer drug market expanded to approximately JPY151.0bn, 1.7x the 2019 level. HK inno.N continues to lead the anti-ulcer drug market in South Korea with a share of 15%.

The company holds an exclusive license agreement with HK Inno.N to develop, market, and manufacture tegoprazan, including sublicense rights. HK inno.N and its global partner companies that have received licenses or product exports from HK inno.N (sublicensees) are advancing tegoprazan-related business activities. HK inno.N aims to expand tegoprazan's reach to 100 countries by 2028 and to achieve annual global sales of KRW3.0tn for tegoprazan products by 2030, and is actively working toward these goals. As of end-1H, tegoprazan was available or in preparation in 54 countries worldwide.

Sales of tegoprazan began in Malaysia and Panama during Q2. As of end-1H FY12/25, tegoprazan is marketed in 17 countries: South Korea, China, Mongolia, the Philippines, Mexico, Indonesia, Singapore, Peru, Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, El Salvador, Malaysia, and Panama. Through HK inno.N, RaQualia receives royalties based on a portion of the revenue HK inno.N earns from sublicensees, such as sales royalties. The approval process is ongoing in Southeast Asia and Central and South America, alongside continued clinical development in the US, Canada, and other regions. In May 2025, Dr. Reddy's Laboratories (NSE: DRREDDY), a sublicensee, obtained marketing approval from the Central Drugs Standard Control Organization (CDSCO) in India.

In April 2025, HK inno.N signed an amendment to its April 2024 license agreement with Tabuk Pharmaceutical Manufacturing Company (unlisted) to expand the licensed territory in the Middle East and North Africa. The amendment

added six countries—Egypt, Sudan, Ethiopia, Morocco, Yemen, and Libya—bringing the total to 16. The company expects Tabuk, a leading Saudi Arabian pharmaceutical company with a strong sales network and marketing capabilities in the region, to drive market penetration and further expansion of tegoprazan in the Middle East and North Africa.

In April 2025, HK inno.N announced that Braintree Laboratories (unlisted), a division of its sublicensee Sebela Pharmaceuticals Inc. in the US, reported favorable results from the ongoing US Phase III clinical trial (the TRIUMpH trial). The TRIUMpH trial is being conducted as a pivotal study for erosive esophagitis (EE) and non-erosive reflux disease (NERD). In the trial, tegoprazan met all primary and secondary endpoints in both the EE and NERD studies. Braintree plans to complete the EE study in Q3 FY12/25 and submit a US FDA marketing application in Q4 FY12/25, seeking approval for both EE and NERD indications.

In China, sublicensee Luoxin Pharmaceutical is developing the injectable formulation of tegoprazan (LX22001). Healthy adults received the drug in a Phase I clinical trial that began in August 2024. The trial is proceeding smoothly and is scheduled for completion in November 2025. Hospitals in China commonly use injectable formulations during surgery and hospitalization. Available options include H2 receptor antagonists (H2 blockers) and proton pump inhibitors (PPIs). The market for injectable gastric acid secretion inhibitors is estimated at around JPY200.0bn. Successful development would create the world's first P-CAB injectable formulation. By diversifying into dosage forms that address local clinical needs, the company expects to drive medium- to long-term revenue growth.

Out-licensed and pre-out-licensing programs

For the out-licensed programs, including the P2X7 receptor antagonist, TRPM8 blocker, and 5-HT4 agonist for animal health, RaQualia's licensees and their sublicensees are advancing development in preclinical and later stages.

For pre-out-licensing programs, the company completed preclinical trials for its ghrelin receptor agonist program and conduct business development activities, aiming to secure licensing agreements. For tegoprazan, for which the company retains development, manufacturing, and sales rights in Japan, negotiations with potential partners continued from Q1 FY12/25. The company has also pursued other pre-out-licensing programs through in-person meetings and online conferences flexibly with potential partners.

In the exploratory research phase, RaQualia is concentrating on research programs aimed at creating new development compounds. By enhancing its next-generation drug discovery value chain through synergies of existing and new technologies, the company advances a critical development strategy to target previously unexplored drug opportunities, including genes and proteins once considered undruggable. The company seeks to enhance technologies and pipelines, approaching from four perspectives: modality, drug discovery targets, disease areas, and foundational technologies.

The company is developing targeted protein degradation inducers—a novel drug discovery modality—primarily through FIMECS, which became a consolidated subsidiary in March 2024. FIMECS and Astellas Pharma Inc. (TSE Prime: 4503) are jointly developing compounds targeting multiple proteins for cancer treatment, leveraging the proprietary RaPPIDS™ drug discovery platform, which was specifically designed for targeted protein degradation.

In May 2025, RaQualia confirmed favorable results from the joint research with D. Western Therapeutics Institute, Inc. (TSE Growth: 4576, DWTI). Since December 2022, RaQualia leveraged its ion channel drug discovery technology to synthesize a group of compounds targeting specific ion channels, while DWTI applied its ophthalmological evaluation technologies to conduct pharmacological and efficacy testing to assess the therapeutic potential of these compounds for eye diseases. The compounds selected through the partnership demonstrated favorable pharmacological activity in animal models of retinal disorders. The partners continue joint research and validating results, with plans to explore possibilities for collaboration in the next phase.

The company is conducting joint research with Veritas In Silico Inc. (TSE GRT: 130A) to develop breakthrough small-molecule drugs targeting messenger RNAs (mRNA). In 1H, the company expanded the scope of target genes covered under joint research and, leveraging the expertise of both parties, conducted screening for multiple genes. As a result, it obtained several small-molecule compounds that could serve as starting points for drug discovery aimed at generating development candidates.

On April 11, 2025, consolidated subsidiary TMRC canceled its license agreement with Syros Pharmaceuticals Inc. (NASDAQ: SYRS) on the retinoic acid receptor α agonist (tamibarotene/AM80/TM-411/SY-1425) following discussions on business strategy.

Capital and business alliance with HK Inno.N

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. A total of 2,592,100 common shares were allocated to HK inno.N, representing 10.62% of voting rights after the issuance. HK inno.N made the payment on April 18, 2025.

The alliance aimed to establish a strategic partnership. Through this alliance, the company seeks to strengthen its financial base and generate synergies across broad areas, including R&D, to maximize corporate value. The funds raised will primarily be used for capital investment and R&D investment, key drivers of the company's growth strategy such as below.

- R&D expenses related to the development of exploratory-stage candidates, including collaborative research and outsourcing
- R&D expenses aimed at enhancing the value of existing compounds at the preclinical stage or later, including the ghrelin receptor agonist (covering activities such as API manufacturing, preclinical studies, and clinical trials)
- Investment in infrastructure

Outlook at the time of the 1H earnings announcement

As of end-1H, progress against the full-year FY12/25 forecast was 39.5% for operating revenue. According to the company, performance was largely in line with initial expectations, and the company maintained its full-year forecast at the time of the 1H announcement.

In FY12/25, the company expects royalty revenue to exceed the FY12/24 result of JPY1.9bn, with royalty revenue continuing to grow steadily. By adding other revenue streams—including the out-licensing fee for tegoprazan in Japan, upfront payments from FIMECS, milestone payments from Astellas Pharma, and research collaboration payments—the company aims to achieve its full-year forecast.

Global rollout of tegoprazan is progressing smoothly. In Q2, the company obtained approvals in Ecuador and India and is preparing to launch sales. Challenges remain in Europe and Japan. HK inno.N is working to secure an out-license in Europe, while RaQualia is doing so in Japan. The Phase III clinical trial in the US completed in August 2025, produced favorable results, and is scheduled for regulatory filing in Q4. The results indicated the potential for tegoprazan to become a breakthrough treatment option for gastroesophageal reflux disease (GERD). Based on these outcomes, HK inno.N is stepping up efforts in Europe with the aim of securing an out-license in 2H. In Japan, concerns about the probability of success have eased in light of the US results, and the company has begun discussions with new potential licensees in addition to those already in negotiations.

At end-1H, cash on hand totaled approximately JPY4.2bn, reflecting JPY1.0bn obtained through the capital and business alliance with HK inno.N. Even if upfront payments and other revenue streams fall short of expectations and the company posts a full-year net loss, it believes additional financing will not be immediately necessary.

Q1 FY12/25 results (out May 15, 2025)

Earnings summary

Q1 FY12/25 results (January–March 2025)

- Operating revenue: JPY965mn (+48.8% YoY)
- Operating profit: JPY93mn (+109.2% YoY)
- Recurring profit: JPY29mn (a loss of JPY77mn in Q1 FY12/24)
- Net loss attributable to owners of the parent: JPY5mn (a loss of JPY78mn)
- R&D expenses: JPY385mn (+7.3% YoY)

Q1 progress toward the full-year FY12/25 forecast reached 24.8% for operating revenue, 78.9% for operating profit, and 40.0% for recurring profit.

Factors behind higher revenue and profits

Royalty income from four launched products, along with the steady global expansion of tegoprazan, resulted in royalty revenue of JPY614mn (+11.4% YoY). Other income, including upfront and milestone payments, totaled JPY351mn

(+261.9% YoY). Other income includes research collaboration payments and JPY200mn in milestone payments—both from Astellas Pharma to FIMECS—for achieving an initial target in their joint research.

Total operating expenses were JPY872mn (+44.4% YoY), including the cost of operating revenue at JPY222mn (+267.3% YoY), R&D expenses at JPY385mn (+7.3% YoY), and other SG&A expenses at JPY265mn (+43.6% YoY). Operating expenses increased primarily due to the consolidation of FIMECS starting in Q2 FY12/24. R&D expenses at RaQualia on a standalone basis declined YoY due to the absence of preclinical trial costs for its ghrelin receptor agonist. Progress toward the full-year plan stood at 23.1% for operating expenses and 22.7% for R&D expenses.

Operating profit rose 109.2% YoY, with an operating profit margin of 9.6% YoY (+2.7pp), driven by higher revenue despite increased operating expenses. Non-operating income included JPY4mn in interest income and JPY22mn in derivative valuation gains. Non-operating expenses totaled JPY14mn in interest expenses and JPY73mn in foreign exchange losses. As a result, the company recorded recurring profit but posted a net loss due to corporate income tax and other factors.

Pipeline

Brisk royalties from four commercialized products

Pet drugs

Sales of GALLIPRANT® (generic name: grapiprant), a treatment for osteoarthritis in dogs, ENTYCE™ (generic name: capromorelin), a treatment for anorexia in dogs, and ELURA™ (generic name: capromorelin), a treatment for weight management in cats with chronic kidney disease (CKD), continue to perform well.

Development of tegoprazan in countries around the world

Sales of GERD treatment K-CAB® in South Korea by licensee HK inno.N continued to be robust, with sales from prescriptions outside hospitals amounting to KRW51.4bn (+13.7% YoY; roughly JPY5.1bn at JPY0.10/KRW) in Q1 FY12/25. HK inno.N continues to lead the anti-ulcer drug market in South Korea with a share of 15%. In China, where sales had significantly undershot the initial forecast through FY12/24, revenue expanded steadily and posted strong growth in FY12/25.

The company holds an exclusive license agreement with HK Inno.N to develop, market, and manufacture tegoprazan, including sublicense rights. HK Inno.N aims to expand tegoprazan's reach to 100 countries by 2028 and is actively pursuing this goal. As of end-Q1, tegoprazan was available or in preparation in 48 countries worldwide. HK Inno.N's sublicensees are advancing the development, manufacturing, and sales of tegoprazan.

HK Inno.N signed a license agreement with Southern XP IP Pty Ltd (unlisted), granting Southern XP exclusive distribution and marketing rights for tegoprazan in Australia and New Zealand. Southern XP, an Australian pharmaceutical company with over 20 years of operational experience, specializes in pharmaceutical approval filings and distribution across the region. Under the license agreement between RaQualia and HK Inno.N, RaQualia retains the right to receive a portion of the revenue that Southern XP pays to HK Inno.N.

As of end-Q1 FY12/25, tegoprazan is marketed in 15 countries: South Korea, China, the Philippines, Mongolia, Mexico, Indonesia, Singapore, Peru, Chile, and the seven newly added countries. RaQualia receives sales-based royalties and milestone payments for development progress from HK inno.N and its sublicensees. The approval process is ongoing in Southeast Asia and Central and South America, alongside continued clinical development in the US, Canada, and other regions.

Out-licensed and pre-out-licensing programs

For the out-licensed programs, RaQualia's partners and its sublicensees are advancing development in the preclinical or later stages.

For pre-out-licensing programs, the company completed preclinical trial for its ghrelin receptor agonist program to secure large-scale licensing agreements. The company is currently in negotiations under a confidentiality agreement to out-license its ghrelin receptor agonist. It is currently conducting stability testing of the active pharmaceutical ingredient (API) for trial use, as clinical trials are expected to be carried out by the licensee. For tegoprazan, for which the company retains development, manufacturing, and sales rights in Japan, negotiations with potential partners continued from FY12/24. The

company has also flexibly pursued other pre-out-licensing programs through in-person meetings and online conferences with potential partners.

In the exploratory research phase, RaQualia is concentrating on research programs aimed at creating new development compounds. The company seeks to enhance technologies and pipelines by leveraging synergies between existing technologies and new initiatives, approached from four perspectives: modality, drug discovery targets, disease areas, and foundational technologies. By enhancing its next-generation drug discovery value chain through synergies of existing and new technologies, the company advances a critical development strategy to target previously unexplored drug opportunities, including genes and proteins once considered undruggable.

The company is developing targeted protein degradation inducers—a novel drug discovery modality—primarily through FIMECS, which became a consolidated subsidiary in March 2024. FIMECS and Astellas Pharma Inc. (TSE Prime: 4503) are jointly developing compounds targeting multiple proteins for cancer treatment, leveraging the proprietary RaPPIDS™ drug discovery platform, which was specifically designed for targeted protein degradation. In Q1, FIMECS achieved an early-stage milestone for one of its programs and received a lump-sum payment.

Both companies plan to identify a development candidate. FIMECS expects to receive up to JPY15.0bn in milestone payments related to development, regulatory filings and approvals, and commercialization. In addition, the company may earn royalty income equivalent to a single-digit percentage of product revenue.

In March 2025, RaQualia signed an exclusive global licensing agreement with Nissan Chemical Corporation (TSE Prime: 4021) for some of Nissan Chemical's proprietary know-how in neurological disorders. Under the agreement, the company received a sublicensable exclusive license to globally research, develop, and sell certain neurological disease-related expertise of Nissan Chemical to advance new drug candidates.

Capital and business alliance with HK Inno.N

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. A total of 2,592,100 common shares were allocated to HK inno.N, representing 10.62% of voting rights after the issuance. The transaction raised approximately JPY1.0bn and aimed to establish a strategic partnership. Through this alliance, the company seeks to strengthen its financial base and generate synergies across broad areas, including R&D, to enhance corporate value. The company does not intend to pursue all programs jointly with HK inno.N, but instead plans to move forward with those that are mutually beneficial and subject to agreement by both parties. The funds raised will primarily be used for capital expenditures and R&D investment, key drivers of the company's growth strategy.

Use of proceeds

- R&D expenses related to the development of exploratory-stage candidates, including collaborative research and outsourcing
- R&D expenses aimed at enhancing the value of existing compounds at the preclinical stage or later, including the ghrelin receptor agonist (covering activities such as API manufacturing, preclinical studies, and clinical trials)
- Capital expenditures

Use	Amount (JPYmn)	Scheduled timing of expenditure	
Strengthening the drug discovery research platform, with a focus on new modalities	341	May 2025—Dec 2027	R&D investment in new modalities—including targeted protein degraders (TPDs) and small molecules targeting mRNA—as well as related foundational technologies.
Expansion of the development pipeline	426		R&D investment to enhance the value of selected programs from the company's pipeline—such as ghrelin receptor agonists and IRAK-M degradation inducers—through data acquisition and the implementation or preparation of preclinical and clinical trials.
Upgrading laboratory facilities	250		Capital investment to improve operational efficiency and increase success rates in exploratory research activities.
Total	1,017		

Source: Shared Research based on company data

Revision of exercise price for the 16th series of share subscription rights

In April 2025, in connection with a capital and business alliance with HK inno.N involving a new share issuance, the company revised the exercise price of its 16th series of share subscription rights—originally issued in January 2023 to CVI Investments, Inc.—from JPY1,556 to JPY397 per share. The revised price matches the issue price of the new shares allocated to HK inno.N. As of April 17, 2025, 12,500 units of the 16th series of share acquisition rights remained

unexercised. Following the revision, the maximum amount of funds that can be raised declined from JPY1.9bn to approximately JPY496mn.

Outlook at the time of the Q1 earnings announcement

In April 2025, Braintree announced favorable topline results from the Phase III clinical trial of tegoprazan, which has been ongoing in the US since October 2022. The pivotal trial, designed to generate data for regulatory submission, targeted both erosive esophagitis (EE) and non-erosive reflux disease (NERD). The trial met all primary and secondary endpoints for both EE and NERD. Safety and tolerability were comparable to those of placebo and lansoprazole, a proton pump inhibitor (PPI) used as a comparator. Based on these results, Braintree plans to complete the trial in Q3 FY12/25 and submit a regulatory filing in Q4.

In May 2025, HK inno.N announced the signing of a regional expansion agreement with its sublicensee Tabuk, bringing the total number of covered countries in the Middle East and North Africa to 16. With this expansion, tegoprazan had entered 54 countries as of end-May 2025.

In April 2025, the company's subsidiary TMRC ended its agreement with Syros concerning tamibarotene. Under the terms of the agreement, data and related materials have been returned, and the company is currently reviewing future options.

Full-year FY12/24 results (out February 14, 2025)

Earnings summary

Full-year FY12/24 results (January–December 2024)

- Operating revenue: JPY3.1bn (+63.5% YoY)
- Operating loss: JPY213mn (a loss of JPY337mn in FY12/23)
- Recurring loss: JPY362mn (a loss of JPY293mn)
- Net loss attributable to owners of the parent: JPY495mn (a loss of JPY324mn)
- R&D expenses: JPY1.7bn (+24.1% YoY)

The company revised its full-year FY12/24 forecast on December 13, 2024. For FY12/24, the company achieved 99.1% of its revised full-year operating revenue forecast. This figure includes the results of FIMECS from Q2, following its consolidation.

Difference between initial forecasts and results

Operating revenue fell JPY1.4bn short of the initial forecast due primarily to the postponement of a license-out agreement for the development, manufacturing, and sale of tegoprazan in Japan, which deferred expected upfront payments of JPY1.0bn to FY12/25. In addition, operating revenue declined JPY400mn compared with the forecast, as FIMECS's new joint research contracts and TMRC's license negotiations did not progress as planned.

Operating expenses were JPY853mn below the initial forecast, reflecting a JPY679mn reduction in clinical development preparation costs and JPY174mn in lower expenses associated with a decline in cost of operating revenue and postponed contracts.

Factors behind higher operating revenue and lower profits

During FY12/24, royalties from four launched products, along with the steady global expansion of tegoprazan, resulted in royalty revenue of JPY1.9bn (+21.2% YoY). Other income, including upfront and milestone payments, totaled JPY1.2bn (+291.6% YoY). The company received option fee payments from Vetbiolix and milestone payments for the sodium channel blocker from Hisamitsu Pharmaceutical in Q4.

Total operating expenses were JPY3.3bn (+48.4% YoY), comprising cost of operating revenue at JPY626mn (+155.4% YoY), R&D expenses at JPY1.7bn (+24.1% YoY), and other SG&A expenses at JPY991mn (+159.6% YoY). Personnel and R&D expenses increased primarily due to the inclusion of FIMECS. The rise in R&D expenses was driven by higher clinical development preparation costs for the ghrelin receptor agonist and IRAK-M degradation inducer. These increased costs resulted in an operating loss of JPY213mn. The company recorded non-operating income of JPY39mn in foreign exchange gains and JPY5mn in interest income. Meanwhile, non-operating expenses included JPY43mn in interest expenses, JPY141mn in syndicated loan fees, and JPY22mn in loss on valuation of derivatives, resulting in a recurring loss and a net loss.

Pipeline

Brisk royalties from four commercialized products

Pet drugs

Sales of GALLIPRANT® (generic name: grapiprant), a treatment for osteoarthritis in dogs, ENTYCE™ (generic name: capromorelin), a treatment for anorexia in dogs, and ELURA™ (generic name: capromorelin), a treatment for weight management in cats with chronic kidney disease (CKD), continue to perform well. In Europe, ELURA™ was launched in France in August 2024 following approval in 2023, securing a milestone payment for RaQualia. In February 2024, Elanco Japan obtained manufacturing and marketing approval from Japan's Ministry of Agriculture, Forestry, and Fisheries for ELURA™, launching the product in November 2024.

Development of tegoprazan in countries around the world

Sales of GERD treatment K-CAB® in South Korea by licensee HK inno.N continued to be robust, with sales from prescriptions outside hospitals amounting to KRW196.9bn (+24.4% YoY; roughly JPY21.7bn at JPY0.11/KRW) in FY12/24. HK inno.N's continues to lead the anti-ulcer drug market in South Korea with a share of 15%.

The company holds an exclusive license agreement with HK Inno.N to develop, market, and manufacture tegoprazan, including sublicense rights. HK Inno.N aims to expand tegoprazan's reach to 100 countries by 2028 and is actively pursuing this goal. As of end-FY12/24, tegoprazan was available or in preparation in 46 countries worldwide. HK Inno.N's sublicensees are advancing the development, manufacture, and sale of tegoprazan.

During FY12/24, tegoprazan was newly launched in Chile, Colombia, the Dominican Republic, Nicaragua, Honduras, Guatemala, and El Salvador. As of end-FY12/24, tegoprazan is marketed in 15 countries: South Korea, China, the Philippines, Mongolia, Mexico, Indonesia, Singapore, Peru, Chile, and the seven newly added countries. Under the licensing agreement with HK inno.N, RaQualia receives milestone payments based on development progress or a percentage of the revenue that HK inno.N earns from the sublicensee.

In China, tegoprazan has been marketed since 2022 by sublicensee Luoxin Pharmaceuticals and is now sold in 31 provinces and administrative regions. Luoxin has received regulatory approval from the National Medical Products Administration for clinical trials on an injectable formulation and has obtained marketing approval for combination therapy targeting Helicobacter pylori infections. In the US, sublicensee Brainree is conducting a Phase III clinical trial. In January 2025, HK. Inno.N signed a sublicense agreement in Australia and New Zealand, expanding tegoprazan's reach to 48 countries.

Out-licensed and pre-out-licensing programs

For the out-licensed programs, RaQualia's partners and its sublicensees are advancing development in the preclinical or later stages.

In FY12/24, licensee Xgene commenced a Phase I clinical trial for the TRPM8 blocker in Australia, triggering a milestone payment. In December 2024, Vetbiolix exercised an option for a 5-HT4 agonist to develop veterinary pharmaceuticals, resulting in option fee payments and rights to milestone payments for development progress and royalty payments after product launch. Hisamitsu Pharmaceutical achieved a development milestone for a sodium channel blocker patch, leading to a milestone payment. The company and Maruho agreed to terminate their license contract for a sodium channel blocker in December 2024 following discussions on future development.

In April 2024, RaQualia signed an option and license agreement with Velovia Pharma for four development compounds targeting gastrointestinal, metabolic, and fibrotic diseases for veterinary use. If options are exercised, RaQualia is eligible to receive option fees, milestone payments, and sales royalties upon commercialization. If Velovia Pharma launches pet drugs containing the compounds, RaQualia is also eligible to receive sales royalties and sales-based milestone payments.

For pre-out-licensing programs, the company has accelerated business development efforts to secure large-scale licensing agreements. It is finalizing preclinical studies for its in-house developed ghrelin receptor agonist, while strategically shifting toward securing partnerships before entering clinical trials. The company has completed preclinical studies and is currently preparing the final report, including data verification, while actively pursuing out-licensing discussions under confidentiality agreements with multiple companies.

The company retains the development, manufacturing, and sales rights for tegoprazan in Japan. It decided to defer internal clinical development and prioritize out-licensing activities to enable an earlier market launch, and is currently in negotiations with potential partners. Although the company initially aimed to conclude a license agreement in FY12/24, this has been deferred to FY12/25. In parallel, it is also advancing other pre-out-licensing programs through in-person meetings and online discussions with prospective partners.

Exploratory and joint research

In the exploratory research phase, RaQualia is concentrating on research programs aimed at creating new development compounds. The company seeks to enhance technologies and pipelines by leveraging synergies between existing technologies and new initiatives, approached from four perspectives: modality, drug discovery targets, disease areas, and foundational technologies. By enhancing its next-generation drug discovery value chain through synergies of existing and new technologies, the company advances a critical development strategy to target previously unexplored drug opportunities, including genes and proteins once considered undruggable.

The company is developing targeted protein degradation inducers, a novel drug creation modality, primarily through FIMECS, which became a consolidated subsidiary in March 2024. FIMECS's RaPPIDS™ drug discovery platform strengthens the company and group's foundational technology while generating revenue through ongoing joint development efforts.

RaQualia entered an agreement with STAND Therapeutics (unlisted) to leverage STAND's technology for generating intracellular antibodies functional within cells, advancing drug discovery efforts. Additionally, the company conducts joint research with Veritas In Silico Inc. (TSE GRT: 130A) to develop breakthrough small-molecule drugs targeting messenger RNAs (mRNA). Through these initiatives, the company expanded its focus to include cancer. In 2023, RaQualia established a new research base at Shonan Health Innovation Park to advance drug discovery using new modalities.

Tamibarotene

Regarding the retinoic acid receptor α agonist (tamibarotene), which was out-licensed from subsidiary TMRC Co., Ltd. to Syros Pharmaceuticals Inc. (NASDAQ: SYRS), clinical trials are underway in the US targeting myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML).

In August 2024, an interim analysis of the SELECT-AML-1 trial for tamibarotene in combination with venetoclax and azacitidine indicated a low likelihood of the investigational drug demonstrating superiority in the final analysis, prompting Syros to halt new patient enrollment.

In Q1, Syros completed the patient enrollment required for the primary endpoint analysis in the Phase III clinical trial (SELECT-MDS-1) for tamibarotene and azacitidine. In November 2024, Syros announced that the trial did not meet its primary endpoint of complete response (CR) rate and that it would discontinue the trial.

News and topics

RaQualia announces expanded capital and business alliance with HK inno.N, including out-licensing of tegoprazan in Japan and issuance of new shares through third-party allotment

2025-12-15

On December 12, 2025, RaQualia Pharma Inc. announced that it has out-licensed to HK inno.N Corporation (KOSDAQ: 195940) exclusive rights, including sublicensing rights, for the development and commercialization of the gastric acid secretion inhibitor tegoprazan in Japan, and that it will strengthen its capital and business alliance through the issuance of new shares through a third-party allotment.

Through the expansion of the alliance, the company aims to raise funds through a third-party allotment to HK inno.N, the planned allottee, and to further strengthen its strategic partnership with HK inno.N. HK inno.N is the licensee of tegoprazan, an acid suppressant developed by the company, and the first company to commercialize it globally as a pharmaceutical product. As strategic partners in the compound's global business development, HK inno.N. and the company have worked closely together since the tegoprazan development stage and built a strong relationship of trust over many years.

On March 21, 2025, the company entered into a capital and business alliance agreement with HK inno.N and issued new shares through a third-party allotment. Through this alliance, the company aimed to strengthen its financial base and, by deepening collaboration with HK inno.N, generate synergies across a wide range of areas, including R&D, thereby maximizing corporate value.

Overview of December 2025 expansion of alliance

The main terms of the expanded alliance are as below, under which an amendment to the license agreement grants HK inno.N exclusive rights to develop, manufacture, and market tegoprazan in Japan. In addition, the company and HK inno.N will examine and discuss measures to further enhance both parties' corporate value.

1. RaQualia's grant to HK inno.N of exclusive rights to develop, manufacture, and market tegoprazan in Japan

2. Value enhancement for development compounds

3. Joint research

4. Other R&D initiatives

Following execution of the alliance agreement in March 2025, RaQualia and HK inno.N have held repeated discussions on ongoing business collaboration and joint research and confirmed shared goals of commercializing tegoprazan in Japan and continuously developing innovative pharmaceuticals beyond tegoprazan.

Developed by the company, tegoprazan is a global pharmaceutical product with development and marketing rights granted in 54 countries worldwide and sales launched in 18 countries as of November 14, 2025. However, clinical development has not yet commenced in Japan, where the compound originated, because the company's limited development resources as the domestic rights holder required it to secure a development partner, and identifying a partner capable of conducting costly late-stage clinical trials took time, while the company simultaneously allocated resources to strengthen drug discovery research and continuously build an attractive development pipeline in a rapidly changing pharmaceutical industry.

In FY12/25, the company positioned domestic commercialization of tegoprazan as its top priority and advanced negotiations toward executing an agreement within the fiscal year, as domestic out-licensing of tegoprazan is critical to maintaining and enhancing corporate value. Delays in clinical development would postpone the launch, shorten the period of market exclusivity, and make it difficult to maximize peak sales. The basic patent term (20 years from the filing date) continues to run down, raising the risk of expiry and earlier entry by competing products.

Based on the above, the two companies decided to expand the scope of their alliance to further strengthen their cooperative relationship. The expanded alliance includes granting HK inno.N exclusive rights in Japan to develop, manufacture, and commercialize human pharmaceuticals containing tegoprazan as the active ingredient, along with its advancement of initiatives toward conducting late-stage clinical trials. While no upfront payment is associated with the grant of exclusive rights for Japan, the company will receive milestone payments tied to commercialization progress, sales royalties, and a portion of revenues HK inno.N receives from sublicensees.

The company will work to strengthen its research infrastructure to create innovative pharmaceuticals following tegoprazan, thereby enhancing medium- to long-term shareholder value for the group, and will further accelerate drug discovery R&D to realize its mission of bringing light to life through the power of innovation.

The company expects this fundraising to have a minimal impact on results in FY12/25, and has maintained its earnings forecast. As a result of the allotment, HK Inno.N will become the largest shareholder, holding approximately 16.0% of the company's issued shares.

Overview of the new share issuance

Number of shares to be issued	1,555,900 ordinary shares
Issuance price per share	JPY907 per share
Payment due date	January 29, 2026
Total proceeds	JPY1.4bn
Total amount to be paid in	JPY1.4bn
Estimated issuance expenses	JPY9.0mn
Estimated net proceeds	JPY1.4bn
Method	Third-party allotment
Planned allottee	HK inno.N Corporation
Amounts of increase in capital stock and capital reserve	Capital stock: JPY705.6mn, capital reserve : JPY705.6mn

Source: Shared Research based on company data

Use of proceeds and scheduled timing of expenditure

Use	Amount (JPYmn)	Scheduled timing of expenditure	
1. Strengthening drug discovery infrastructure (a technology platform that supports the advancement of joint research projects with HK inno.N)	284	Feb 2026–Dec 2028	FY12/26: JPY80mn, FY12/27: JPY80mn, FY12/28: JPY124mn
2. Initiatives aimed at expanding the development pipeline (creation of a new development pipeline through joint research with HK inno.N)	267	Feb 2026–Dec 2028	FY12/26: JPY118mn, FY12/27: JPY90mn, FY12/28: JPY58mn
3. Strengthening facilities for experimental research (procurement of experimental research equipment that contributes to the advancement of joint research projects with HK inno.N)	291	Feb 2026–Dec 2028	FY12/26: JPY70mn, FY12/27: JPY101mn, FY12/28: JPY120mn
4. Repayment of a syndicated loan	559	Mar 2026–Mar 2027	FY12/26: JPY500mn, FY12/27: JPY59mn
Total	1,402		

Source: Shared Research based on company data

RaQualia Pharma receives milestone payment following marketing approval of tegoprazan in India

2025-12-15

RaQualia Pharma Inc. announced the receipt of a milestone payment following the marketing approval of tegoprazan, a gastric acid secretion inhibitor, in India.

The company out-licensed tegoprazan, a gastric acid secretion inhibitor, to HK inno.N Corporation (KOSDAQ: 195940). Following marketing approval for the drug by India's Central Drugs Standard Control Organization (CDSCO) to HK inno.N's partner, Dr. Reddy's Laboratories (NSE: DRREDDY), the company expects to receive a lump-sum milestone payment.

Tegoprazan is a novel gastric acid suppressant developed by the company, classified as a potassium-competitive acid blocker (P-CAB), a new class of drugs with a distinct mechanism of action. Unlike proton pump inhibitors (PPIs), the first-line therapy for gastroesophageal reflux disease, P-CABs suppress gastric acid secretion more rapidly and with longer duration. Launched by HK inno.N as K-CAB® tablets since 2019, tegoprazan has become a blockbuster product in South Korea, with cumulative domestic sales (out-of-hospital prescriptions) reaching KRW705.4bn (approximately JPY77.6bn, at

JPY0.11/KRW) by 2024, maintaining the top share in the Korean gastric acid secretion inhibitor market. HK inno.N has entered into license agreements for tegoprazan in 54 countries, and tegoprazan products are marketed in 18 countries.

In 2022, HK inno.N and Dr. Reddy's Laboratories entered into an export agreement covering seven countries, including India, South Africa, and Eastern Europe. Since then, Dr. Reddy's Laboratories advanced clinical development, obtained marketing approval from CDSCO in May 2025 for the 50mg PCAB formulation for three indications—erosive esophagitis (EE), non-erosive reflux disease (NERD), and gastric ulcer—and began sales in September 2025.

India's peptic ulcer drug market was valued at about KRW1.52tr (approx. JPY167.2bn) in 2024, ranking fourth globally after China, the US, and Japan. Around 38% of India's population suffers from gastroesophageal reflux disease (GERD), underscoring the growing importance of effective treatment. Dr. Reddy's Laboratories aims to influence the treatment practice for peptic ulcer treatment in India with the launch of the 50mg formulation in September 2025.

Under its license agreement with HK inno.N, RaQualia is entitled to receive a portion of the revenue that HK inno.N earns from sublicensees. Although product launch in India was not set as a milestone, contractual adjustments resulted in the recognition of the marketing approval milestone payment. As a result, the company will receive a lump-sum payment of USD4.0mn (JPY620mn at JPY155/USD) from HK inno.N and record it as operating revenue in Q4 FY12/25.

Patent grant for the combination use of tamibarotene and anticancer drugs in the US

2025-11-28

RaQualia Pharma Inc. announced that it had received a decision to grant a patent in the US for the use of tamibarotene (AM80), which had previously been under examination.

The decision involves patent application number 18/010,686, which RaQualia filed in the US concerning the use of tamibarotene (AM80), a compound for which the company's consolidated subsidiary TMRC Co., Ltd. holds the rights. A decision to grant a patent leads to the establishment of patent rights in the relevant country, as it signifies the country's patent office has determined the invention to be patentable. Once the patent fee is paid, the application proceeds to registration.

The patent covers inventions related to combination therapies comprising retinoids and anticancer agents, as well as a method for selecting cancer patients likely to benefit from combination therapy with tamibarotene—a synthetic retinoid—and anticancer drugs. In cancers that are resistant to anticancer drug therapy—such as pancreatic cancer—attention has turned to cancer-associated fibroblasts (CAFs)*1, a principal component of the stroma*2 that forms the tumor microenvironment, as research has shown they play a role in diminishing the efficacy of anticancer drugs. There are two types of CAFs: tumor-promoting CAFs (which support cancer cells) and tumor-suppressive CAFs (which inhibit cancer progression). The protein Meflin*3 has been identified as a functional marker specific to tumor-suppressive CAFs.

*1 Cancer-associated fibroblasts (CAFs) are fibroblasts within the tumor stroma that secrete factors that promote cancer malignancy, including cancer cell proliferation, invasion, and metastasis.
*2 The stroma refers to the non-cancerous tissue surrounding cancer cells.
*3 Meflin is a protein identified by a research team at Tokai National University Organization, Graduate School of Nagoya University as a specific marker for undifferentiated mesenchymal stem cells—cells with the potential to differentiate into bone, cartilage, adipose tissue, and other lineages—as well as fibroblasts.

Through this invention, it has been found that retinoids, including tamibarotene, enhance the expression of the Meflin gene and convert tumor-promoting CAFs (which support cancer cells) into tumor-suppressive CAFs (which inhibit cancer progression). It has also been found that in cancer patients with malignant tumors characterized by stromal infiltration of CAFs, combination therapy with retinoids and conventional anticancer drugs improved therapeutic efficacy. RaQualia Pharma expects the invention to enable the provision of more effective cancer treatments for patients with malignant tumors resistant to anticancer therapies, such as pancreatic cancer.

With this decision to grant, the company has strengthened its intellectual property rights in the US, following South Korea and Japan. According to the company, although it expects no impact on FY12/25 consolidated results, it believes that this

patent will contribute to enhancing corporate value over the medium to long term through future development efforts involving tamibarotene.

FIMECS adds new targets to ongoing research collaboration with Astellas

2025-11-27

RaQualia Pharma Inc. announced that its consolidated subsidiary FIMECS, Inc. agreed with Astellas Pharma Inc. to add two new targets to their ongoing research collaboration.

FIMECS will receive an upfront payment of JPY400mn from Astellas Pharma under the terms of the agreement.

In 2022, FIMECS entered into a collaborative research agreement with Astellas Pharma to develop targeted protein degradation (TPD) drugs. Since then, FIMECS has utilized its proprietary RaPPIDS™ platform to work with Astellas Pharma on discovering TPD targets for oncology. In May 2024, one of these programs achieved its initial objectives, and in March 2025, the same program completed the predefined joint research plan. Based on this progress, the parties agreed to advance the program to the next stage.

If the two companies identify a development candidate compound and commercialize a new pharmaceutical product, FIMECS may receive milestone payments exceeding JPY15.0bn based on progress in development, regulatory filing and approval, and commercialization. FIMECS may also receive single-digit royalties on product revenue.

RaQualia has already incorporated the impact of this agreement into its consolidated earnings forecast for FY12/25. The company believes the collaboration, including the potential for further progress, will contribute significantly to the group's medium- to long-term growth potential and corporate value.

Favorable rulings in all Supreme Court (third-instance) appeals in South Korea

2025-11-21

RaQualia Pharma Inc. announced it won all of the Supreme Court (third-instance) cases in South Korea concerning substance patents for the gastric acid secretion inhibitor tegoprazan.

More than 60 South Korean generic-drug manufacturers filed negative patent scope confirmation trials, and RaQualia contested these trials to defend the extended scope of its substance patent (South Korea Patent No. 1088247) for the gastric acid secretion inhibitor tegoprazan, marketed in South Korea as K-CAB® tablets. Following the Intellectual Property Trial and Appeal Board's decision in its favor in the first-instance trial, and in the appeal trial equivalent to the second instance, the company won all of the cases in the Supreme Court (third instance).

Tegoprazan, discovered by RaQualia and developed in South Korea by partner HK inno.N Corporation (KOSDAQ: 195940), is marketed locally as K-CAB® tablets for acid-related disorders such as GERD, with substance patents extended to 2031 under South Korea's patent term extension system.

However, some South Korean generics makers sought to launch K-CAB® generic products in 2026, right after the original patent expired. To that end, they filed trials claiming the extended patent rights did not cover three later-approved indications—gastric ulcer, combination therapy for Helicobacter pylori eradication, and maintenance therapy—and only covered the initially approved indications of erosive esophagitis and non-erosive esophagitis. In 2024, the Intellectual Property Trial and Appeal Board upheld RaQualia's position, ruling that the extended patent rights also applied to the later-approved indications. The Patent Court, serving as the court of second instance, also ruled in the company's favor.

Some plaintiffs appealed to the Supreme Court (third instance), and litigation continued. However, the Supreme Court dismissed all appeals and finalized the rulings. This decision fully established exclusive marketing rights for K-CAB® tablets in South Korea through 2031 and strengthened RaQualia's market advantage under strong legal protection. It also secures the royalties the company receives. The company views the latest favorable ruling as a result of its intellectual property strategy and believes it will serve as a solid foundation for future growth.

According to RaQualia, this development has minimal impact on results for FY12/25.

Absorption-type merger (simplified and short-form merger) of wholly owned subsidiary TMRC Co., Ltd.

2025-10-17

RaQualia Pharma Inc. announced that, on October 17, 2025, its Board of Directors resolved to merge with its wholly owned subsidiary, TMRC Co., Ltd.

The company decided to merge with TMRC through a simplified, short-form absorption-type merger to streamline group operations, reduce costs, and improve administrative efficiency. Under the merger, the company will remain the surviving country, and TMRC will be dissolved. Because the merger is being conducted with a wholly owned subsidiary, the company will issue no new shares and pay no consideration for the merger.

- Date of Board resolution for merger agreement: October 17, 2025
- Date of merger agreement execution: October 17, 2025
- Scheduled date of merger (effective date): January 1, 2026

The company expects the merger to have minimal impact on earnings for FY12/25.

Launch of gastric acid secretion inhibitor tegoprazan in India

2025-09-17

RaQualia Pharma Inc. announced that Dr. Reddy's Laboratories (NSE: DRREDDY), a sublicensee of HK inno.N Corporation (KOSDAQ: 195940), has launched sales in India of tegoprazan, a gastric acid secretion inhibitor out-licensed by RaQualia to HK inno.N.

Tegoprazan is a novel gastric acid suppressant developed by the company, classified as a potassium-competitive acid blocker (P-CAB), a new class of drugs with a distinct mechanism of action. Unlike proton pump inhibitors (PPIs), the first-line therapy for gastroesophageal reflux disease, P-CABs suppress gastric acid secretion more rapidly and with longer duration.

Launched by HK inno.N as K-CAB® tablets since 2019, tegoprazan has become a blockbuster product in South Korea, with cumulative domestic sales (out-of-hospital prescriptions) reaching KRW705.4bn (approximately JPY77.6bn, at JPY0.11/KRW) by 2024, maintaining the top share in the Korean gastric acid secretion inhibitor market. HK inno.N has entered into license agreements for tegoprazan in 53 countries, and with the launch in India, tegoprazan products are now marketed in 18 countries.

In 2022, HK inno.N and Dr. Reddy's Laboratories entered into an export agreement covering seven countries, including India, South Africa, and Eastern Europe. Since then, Dr. Reddy's Laboratories advanced clinical development, obtained marketing approval from the Central Drugs Standard Control Organization (CDSCO) in India, and commercialized the product. Marketed under the brand name PCAB, the 50mg formulation was approved for three indications—erosive esophagitis (EE), non-erosive esophagitis (NERD), and gastric ulcer—as of May 2025.

India's peptic ulcer drug market was valued at about KRW1.52tr (approx. JPY167.2bn) in 2024, ranking fourth globally after China, the US, and Japan. Around 38% of India's population suffers from gastroesophageal reflux disease (GERD), underscoring the growing importance of effective treatment. Dr. Reddy's Laboratories aims to influence the treatment practice for peptic ulcer treatment in India with the launch of the 50mg formulation in September 2025.

Under its license agreement with HK inno.N, RaQualia is entitled to receive a portion of the revenue that HK inno.N earns from sublicensees. Although the company will not receive an upfront payment from this expansion, RaQualia expects it to enhance operating revenue and corporate value over the medium to long term.

Favorable rulings in all appeal trials concerning tegoprazan gastric acid secretion inhibitor patent litigation

2025-08-15

RaQualia Pharma Inc. announced it won all cases in a South Korean appeal trial over substance patents for tegoprazan, a gastric acid secretion inhibitor sold locally as K-CAB® tablets.

More than 60 generic drugmakers in South Korea had challenged the scope of RaQualia's extended substance patent rights (South Korea Patent No. 1088247) for gastric acid secretion inhibitor tegoprazan through negative patent scope confirmation trials*. Following the Intellectual Property Trial and Appeal Board's decision in its favor in the first-instance trial, the company also won all cases in the appeal trial equivalent to the second instance. As a result, the exclusive marketing rights for K-CAB® tablets through 2031 are now more firmly protected.

*A negative patent scope confirmation trial is a South Korean trial system in which a third party seeks confirmation that the technology or actions it uses or implements do not fall within the scope of an existing patent. This system is used as a means of preventing disputes or resolving them early by clarifying the scope of rights in advance when necessary. In South Korea, the trial system involves an administrative trial by the Intellectual Property Trial and Appeal Board, followed by proceedings at the Patent Court, a judicial body specializing in intellectual property litigation. Decisions by the Patent Court can be appealed to the Supreme Court, which serves as the final instance in South Korea's three-tier judicial system.

Tegoprazan, discovered by RaQualia and developed in South Korea by partner HK inno.N Corporation (KOSDAQ: 195940), is marketed locally as K-CAB® tablets for acid-related disorders such as GERD, with substance patents extended to 2031 under South Korea's patent term extension system.

However, some South Korean generics makers sought to launch K-CAB® generic products in 2026, right after the original patent expired. To that end, they filed trials claiming the extended patent rights did not cover three later-approved indications—gastric ulcer, combination therapy for Helicobacter pylori eradication, and maintenance therapy—and only covered the initially approved indications of erosive esophagitis and non-erosive esophagitis. In 2024, the Intellectual Property Trial and Appeal Board upheld the company's position, ruling that the extended patent rights also applied to the later-approved indications. The Patent Court, serving as the court of second instance, has now also ruled in the company's favor, thereby ensuring that K-CAB® tablets' exclusive commercialization rights remain firmly protected through 2031.

Some plaintiffs have appealed to the Supreme Court (third instance), and the litigation is ongoing. However, in certain earlier cases, the Supreme Court has already dismissed appeals for failure to proceed with hearings, thereby finalizing judgments in the company's favor. These judicial decisions to date strongly support the validity of the company's intellectual property rights and have significantly bolstered its position. The company views the latest favorable ruling as a result of its intellectual property strategy and believes it will serve as a solid foundation for future growth.

Launched by HK inno.N as K-CAB® tablets since 2019, tegoprazan has become a blockbuster product in South Korea, with cumulative domestic sales (out-of-hospital prescriptions) reaching KRW705.4bn (approximately JPY70.54bn, at JPY0.10/KRW) by 2024, maintaining the top share in the country's gastric acid secretion inhibitor market. HK inno.N has entered into license agreements for tegoprazan in 54 countries, with products currently marketed in 17 of them. Under its license agreement with HK inno.N, the company is entitled to receive a portion of revenue as royalties, which the latest favorable ruling ensures will be preserved.

According to RaQualia, this development has no impact on results for FY12/25.

RaQualia announces favorable results and completion of US Phase III TRIUMpH trial for gastric acid secretion inhibitor tegoprazan

2025-08-08

RaQualia Pharma Inc. announced the completion of a Phase III clinical trial for tegoprazan, a gastric acid suppressant, in the US, reporting favorable results.

The company announced Braintree Laboratories (unlisted), a division of US-based Sebela Pharmaceuticals Inc.—the sublicensee of gastric acid suppressant tegoprazan, out-licensed via licensee HK inno.N Corporation (KOSDAQ: 195940)—obtained favorable results and completed a Phase III clinical trial (TRIUMpH trial) in the US.

The TRIUMpH trial is a pivotal US Phase III clinical study targeting both EE (erosive esophagitis) and NERD (non-erosive reflux disease). On April 23, 2025 (local time), Sebela Pharmaceuticals announced the study met all primary and

secondary endpoints in both the healing phase for EE and the NERD study. The company later confirmed maintenance therapy following EE healing (treatment with medication to sustain the healed state) also yielded favorable results.

In the TRIUMpH trial, the study evaluated the efficacy of maintenance therapy in EE patients who had achieved complete healing following up to eight weeks of initial treatment. Patients received 100mg or 50mg of tegoprazan, or 15mg of lansoprazole (a proton pump inhibitor), once daily for 24 weeks. Tegoprazan demonstrated non-inferiority to lansoprazole at both doses and showed statistically superior results across all patients (LA grades A–D) for the primary endpoint: maintenance of healing at 24 weeks. In particular, among patients with moderate to severe disease (LA grades C–D), both tegoprazan groups showed improvement versus lansoprazole, with the 100mg group demonstrating statistical superiority. Tegoprazan also achieved non-inferiority to lansoprazole in the proportion of days without 24-hour heartburn symptoms.

LA grade refers to a scale used in endoscopic assessment of mucosal damage (inflammation) in gastroesophageal reflux disease (GERD), also known as the Los Angeles Classification. The scale consists of four grades, from A (mildest) to D (most severe), based on the extent of mucosal damage. Grade C indicates mucosal breaks that extend across at least two mucosal folds but involve less than 75% of the esophageal circumference. Grade D indicates mucosal breaks involving at least 75% of the circumference.

In the TRIUMpH trial, the incidence of individual adverse events remained below 3%, with most events being mild and transient. The incidence of serious adverse events was under 1%, and the overall incidence of adverse reactions was comparable across the tegoprazan, PPI, and placebo groups. Mean serum gastrin levels remained within the normal range (0–180 pg/mL) throughout the treatment period. Based on these results, Sebela Pharmaceuticals plans to submit a New Drug Application to the US FDA in Q4 FY12/25 for tegoprazan, targeting both EE and NERD.

Tegoprazan is a novel gastric acid suppressant created by the company, classified as a potassium-competitive acid blocker (P-CAB), a new class of drugs with a distinct mechanism of action. Unlike proton pump inhibitors (PPIs), the first-line therapy for gastroesophageal reflux disease, P-CABs suppress gastric acid secretion more rapidly and with longer duration. Marketed in South Korea by HK inno.N under the brand name K-CAB® since 2019, tegoprazan has become a major product, with cumulative domestic (outpatient) sales reaching KRW705.4bn (approximately JPY70.5bn at JPY0.11/KRW) by 2024. It holds the top share in South Korea's gastric acid suppressant market. HK inno.N has entered into license agreements for tegoprazan in 54 countries, and the product is currently marketed in 16 of them.

In September 2010, the company entered into an exclusive license agreement with CJ HealthCare Corporation (now HK inno.N Corporation) for the development, manufacturing, and commercialization of tegoprazan in East Asia, including sublicensing rights. In November 2019, the two parties expanded the agreement to include North America and Europe. In December 2021, HK inno.N signed a license agreement with Braintree Laboratories—a gastrointestinal specialty division of US-based Sebela Pharmaceuticals—granting exclusive rights to develop, manufacture, and commercialize tegoprazan in the US and Canada.

The global market for peptic ulcer treatments is estimated at approximately JPY2.0tn, with the US accounting for roughly 20% of that total. In North America, PPIs are currently the primary treatment for gastroesophageal reflux disease. However, around 40% of patients continue to experience heartburn symptoms or esophageal mucosal damage despite PPI therapy, highlighting the limitations of existing treatment options. The company expects tegoprazan to serve as a new therapeutic option and help address these unmet medical needs.

Under its license agreement with HK inno.N, the company retains the right to receive a portion of revenue earned by HK inno.N from its partners. While the company will not receive an upfront payment from HK inno.N in connection with this development, it believes further development of tegoprazan will contribute to enhancing the group's medium- to long-term corporate value.

Patent grant for the combination use of tamibarotene and anticancer drugs in South Korea

2025-08-05

RaQualia Pharma Inc. announced that it had received a decision to grant a patent in South Korea for the use of tamibarotene (AM80), which had previously been under examination.

The decision involves patent application number 10-2023-7000437, which RaQualia filed in South Korea concerning the use of tamibarotene (AM80), a compound for which the company's consolidated subsidiary TMRC Co., Ltd. holds the rights. A decision to grant a patent leads to the establishment of patent rights in the relevant country, as it signifies the country's patent office has determined the invention to be patentable. Once the patent fee is paid, the application proceeds to registration.

The patent covers inventions related to combination therapies comprising retinoids and anticancer agents, as well as a method for selecting cancer patients likely to benefit from combination therapy with tamibarotene—a synthetic retinoid—and anticancer drugs. In cancers that are resistant to anticancer drug therapy—such as pancreatic cancer—attention has turned to cancer-associated fibroblasts (CAFs)*1, a principal component of the stroma*2 that forms the tumor microenvironment, as research has shown they play a role in diminishing the efficacy of anticancer drugs. There are two types of CAFs: tumor-promoting CAFs (which support cancer cells) and tumor-suppressive CAFs (which inhibit cancer progression). The protein Meflin*3 has been identified as a functional marker specific to tumor-suppressive CAFs.

*1 Cancer-associated fibroblasts (CAFs) are fibroblasts within the tumor stroma that secrete factors that promote cancer malignancy, including cancer cell proliferation, invasion, and metastasis.
*2 The stroma refers to the non-cancerous tissue surrounding cancer cells.
*3 Meflin is a protein identified by a research team at Nagoya University Graduate School as a specific marker for undifferentiated mesenchymal stem cells—cells with the potential to differentiate into bone, cartilage, adipose tissue, and other lineages—as well as fibroblasts.

Through this invention, it has been found that retinoids, including tamibarotene, enhance the expression of the Meflin gene and convert tumor-promoting CAFs (which support cancer cells) into tumor-suppressive CAFs (which inhibit cancer progression). It has also been found that in cancer patients with malignant tumors characterized by stromal infiltration of CAFs, combination therapy with retinoids and conventional anticancer drugs improved therapeutic efficacy. RaQualia Pharma expects the invention to enable the provision of more effective cancer treatments for patients with malignant tumors resistant to anticancer therapies, such as pancreatic cancer.

With this decision to grant, the company has strengthened its intellectual property rights in South Korea, following Japan. According to the company, although it expects no impact on FY12/25 consolidated results, it believes that this patent will contribute to enhancing corporate value over the medium to long term through future development efforts involving tamibarotene.

Patent review in Japan for TRPV4 antagonist (pyrimidin-4(3H)-one derivative)

2025-05-20

RaQualia Pharma Inc. has announced it received notification of a patent grant in Japan for its TRPV4 antagonist (pyrimidin-4(3H)-one derivative) substance patent application (application number: 2022-566153).

The Japan Patent Office has granted a patent for pyrimidin-4(3H)-one derivatives, a novel class of compounds with TRPV4 antagonistic properties. This patent is the company's second related to TRPV4 antagonists, following an earlier grant in China, and further strengthens its intellectual property rights in Japan.

The company's TRPV4 antagonist acts specifically on TRPV4 ion channel receptors and has demonstrated high efficacy in multiple animal models of pain, inflammation, and ocular diseases. Since 2016, the company has conducted industry–academia collaborative research on ocular diseases with Gifu Pharmaceutical University. In April 2021, it established a joint research course at the university. Collaborative research involving the Laboratory of Pharmacological Evaluation, led

by Professor Masamitsu Shimazawa, resulted in a 2023 publication suggesting TRPV4-targeted therapies could provide new treatment options for retinal vascular disorders in retinal diseases.

This patent grant highlights the company's expertise in ion channel drug discovery. RaQualia Pharma stated it will continue efforts aiming to strengthen its intellectual property portfolio. The company does not expect this patent decision will impact its consolidated results for FY12/25. However, the company is confident the pyrimidin-4(3H)-one derivatives will contribute to its corporate value in the medium to long term through future development and related activities.

Favorable results from joint research with DWTI on eye disease treatment

2025-05-16

RaQualia Pharma Inc. announced favorable results from the joint research with D. Western Therapeutics Institute, Inc. (TSE Growth: 4576, DWTI).

The company has been conducting this joint research with DWTI since December 2022, aimed at discovering and developing therapeutic agents for eye diseases.

RaQualia leveraged its ion channel drug discovery technology to synthesize a group of compounds targeting specific ion channels, while DWTI applied its ophthalmological evaluation technologies to conduct pharmacological and efficacy testing to assess the therapeutic potential of these compounds for eye diseases. The compounds selected through the partnership demonstrated favorable pharmacological activity in animal models of retinal disorders. The partners continue joint research and validating results, with plans to explore possibilities for collaboration in the next phase. The company and DWTI will jointly own any technological achievements and intellectual property arising from the joint research.

This development does not affect the company's earnings forecast for FY12/25, but the company believes it will contribute to strengthening its R&D portfolio over the medium to long term.

Sublicense expansion of tegoprazan in Middle East and North Africa

2025-05-07

RaQualia Pharma Inc. announced the expansion of its sublicense for the gastric acid secretion inhibitor tegoprazan within the Middle East and North Africa (MENA) region.

On May 7, 2025, RaQualia Pharma Inc. announced the expansion of a sublicense agreement between HK inno.N (KOSDAQ: 195940), the licensee, and Tabuk Pharmaceutical Manufacturing Company (unlisted, "Tabuk"), a leading pharmaceutical company based in Saudi Arabia in the Middle East and North Africa (MENA) region.

In April 2024, HK inno.N signed a license agreement with Tabuk, granting exclusive rights to sell tegoprazan in 10 MENA countries. Under the renewed agreement, the licensed territory has been expanded to include six additional countries—Egypt, Sudan, Ethiopia, Morocco, Yemen, and Libya—bringing the total to 16. Due to Tabuk's strong market presence, RaQualia anticipates significant acceleration in the deployment of tegoprazan in MENA. With the addition of these markets, tegoprazan is now set to enter 54 countries globally.

Developed by RaQualia, tegoprazan is a gastric acid secretion inhibitor with a novel mechanism of action and is classified as a potassium-competitive acid blocker (P-CAB). Unlike proton pump inhibitors (PPIs), the current standard treatment for gastroesophageal reflux disease (GERD), P-CABs like tegoprazan provide more rapid and sustained acid suppression, positioning them as next-generation therapies. First launched globally in South Korea in 2019 under the brand name K-CAB® by HK inno.N, tegoprazan has led the out-of-hospital prescription market for gastric acid secretion inhibitors for five consecutive years. Sales in South Korea totaled KRW196.9bn (JPY19.7bn at JPY0.10/KRW) in 2024.

Global rollout continues to accelerate, with the drug now marketed in 15 countries. In April 2025, Phase III clinical trials in the US for both erosive esophagitis (EE) and non-erosive reflux disease (NERD) met all primary and secondary endpoints.

Under its license agreement with HK inno.N, RaQualia is entitled to receive a portion of the revenue that HK inno.N earns from sublicensees. Although the company will not receive an upfront payment from this expansion, RaQualia expects the development to enhance corporate value over the medium- to long-term.

Favorable topline results for the Phase III (TRIUMpH) clinical trial

2025-04-24

Raqualia Pharma Inc. announced positive topline results from the US Phase III TRIUMpH trial of tegoprazan, a gastric acid secretion inhibitor.

On April 24, 2025, HK inno.N Corporation (KOSDAQ: 195940), the licensee of tegoprazan, announced favorable topline results for the TRIUMpH trial, which is being conducted in the US by Braintree Laboratories (unlisted), a subsidiary of sublicensee Sebela Pharmaceuticals Inc. (unlisted).

The TRIUMpH clinical trial is a pivotal Phase III study being conducted in the US targeting both erosive esophagitis (EE) and non-erosive reflux disease (NERD). Tegoprazan met all primary and secondary endpoints in both study parts. In the EE study, the drug demonstrated statistically significant superiority over PPI (lansoprazole) in healing rates at both two and eight weeks, across the overall patient population and among those with moderate to severe symptoms. In the NERD study, tegoprazan was confirmed to be effective in fully relieving heartburn and acid reflux symptoms.

Treatment-related adverse events occurred in fewer than 3% of patients in each study and were generally mild and transient. Serious treatment-related adverse events were observed in less than 2% of cases and occurred at comparable rates among the tegoprazan, PPI, and placebo groups. Mean serum gastrin levels remained within the normal range (0–180 pg/ml) for both tegoprazan and PPI groups during the treatment period. Braintree plans to complete the EE study in Q3 FY2025 and submit a New Drug Application (NDA) to the US FDA in Q4 FY2025 seeking approval for both EE and NERD indications.

In September 2010, Raqualia entered into an exclusive license agreement with CJ HealthCare Corporation (now HK inno.N), covering development, manufacturing, and sales rights for tegoprazan in East Asia, including sublicensing rights. In November 2019, the partnership was expanded to include North America and Europe. In December 2021, HK inno.N signed an exclusive sublicense agreement with Braintree, a gastrointestinal drug specialist and division of US-based Sebela, covering development, manufacturing, and marketing rights in the US and Canada.

Raqualia estimates the global market for peptic ulcer treatments at approximately JPY2.0tn, with the US accounting for around 20%. In North America, gastroesophageal reflux disease (GERD; classified as EE and NERD) is primarily treated using PPIs; however, around 40% of patients continue to experience heartburn or mucosal damage, indicating the limitations of current therapies. Tegoprazan is expected to address these unmet needs as a new treatment option for GERD.

Under its license agreement with HK inno.N, Raqualia is entitled to receive a portion of the revenue HK inno.N earns from sublicensees. Although no milestone payment was triggered in connection with this announcement, Raqualia expects tegoprazan's further progress to contribute to long-term value creation.

Termination of license agreement between TMRC and Syros Pharmaceuticals

2025-04-11

RaQualia Pharma Inc. announced consolidated subsidiary TMRC canceled its license agreement with Syros Pharmaceuticals Inc. (NASDAQ: SYRS) on the retinoic acid receptor α agonist (tamibarotene).

In September 2015, TMRC signed a license agreement granting Syros Pharmaceuticals development and marketing rights for tamibarotene for cancer treatment in North America and Europe. Under this agreement, Syros conducted clinical trials, including the Phase III SELECT-MDS-1 trial targeting HR-MDS patients with overexpression of the RARA gene. On November 12, 2024, Syros announced it would discontinue the trial, citing failure to meet the primary endpoint of complete remission (CR) rate. On February 28, 2025, Syros announced plans to scale down its operations, limit spending, voluntarily delist from NASDAQ, and deregister its common stock with the SEC.

Both parties agreed to terminate the license agreement for tamibarotene following discussions on business strategy. Syros will return development and marketing rights to TMRC without compensation.

The company expects the conclusion of the agreement to have no impact on earnings for FY12/25. TMRC will consider further development of tamibarotene based on clinical trial data provided by Syros.

Other information

History

Feb 2008	Company established in Chita, Aichi to conduct R&D into pharmaceuticals
Jul 2008	Accompanying the closure of Pfizer's central research laboratory in Japan, RaQualia's business launched with the transfer of some employees and purchase of laboratory equipment
Sep 2010	Reached out-licensing agreement for marketing potassium-competitive acid blocker (P-CAB) in South Korea, China including Hong Kong, and Taiwan with South Korea's CJ CheilJedang Corporation (currently HK inno.N Corporation)
Dec 2010	Reached agreement to grant global rights to commercialize EP4 receptor antagonist and ghrelin receptor agonist as veterinary drugs to US-based Aratana Therapeutics Inc. (currently Elanco Animal Health Inc.)
Jul 2011	Listed shares on Osaka Securities Exchange JASDAQ Growth market (currently Tokyo Stock Exchange Growth)
Feb 2014	Signed agreement with Nagoya University to establish joint industry-academia research department
Sep 2014	Biological Research Department, Drug Discovery Research Division was moved to the premises of Nagoya University
Nov 2014	Signed out-licensing agreement with CJ HealthCare Corporation (currently HK inno.N Corporation) for marketing P-CAB in Southeast Asia
Aug 2015	Scientific Research Department, Drug Discovery Research Division was moved to the premises of Nagoya University
Jan 2017	Aratana Therapeutics, Inc. (currently Elanco Animal Health Inc.) began marketing EP4 receptor antagonist (GALLIPRANT®, pet drug) in the US
Dec 2017	Out-licensed selective sodium channel blocker to Maruho Co., Ltd.
Mar 2018	Signed out-licensing agreement with Asahi Kasei Pharma for P2X7 receptor antagonist targeting peripheral neuropathic pain
Mar 2019	CJ CheilJedang Corporation (currently HK inno.N Corporation) began marketing P-CAB (tegoprazan, K-CAB®) in South Korea
Mar 2019	Aratana Therapeutics, Inc. (currently Elanco Animal Health Inc.) began marketing ghrelin receptor agonist (ELURA™, pet drug) in the US
Nov 2019	Signed agreement with CJ CheilJedang Corporation (currently HK inno.N Corporation) on expanding global partnership
Sep 2021	Signed out-licensing agreement with Hong Kong-based Xgene Pharmaceutical Co. Ltd covering TRPM8 blocker
Dec 2021	Signed out-licensing agreement with Hisamitsu Pharmaceutical Co., Inc., covering sodium channel blocker
Apr 2022	Listed on Growth market under new Tokyo Stock Exchange classifications
Jan 2023	Established a new research facility at Shonan Health Innovation Park in Fujisawa, Kanagawa Prefecture
Apr 2023	Entered into an option and license agreement with Vetbiolix SAS to develop veterinary pharmaceuticals based on 5-HT4 agonists
Mar 2024	Acquired all shares in FIMECS, Inc., making it a wholly owned consolidated subsidiary
March 2025	Signed a capital and business alliance agreement with HK inno.N
January 2026	Absorbed and merged with TMRC

Source: Shared Research based on company data

Predecessor was Pfizer's central research laboratory in Japan

The company was established as an independent entity following the closure of Pfizer Inc.'s central research laboratory in Japan, part of a global research restructuring in 2007. Pfizer Inc. (NYSE: PFE), ranked third globally in pharmaceutical sales in 2023, allowed the research lab to spin off through an employee buyout. RaQualia was founded in July 2008, following the transfer of intellectual property rights from Pfizer in June 2008, covering multiple projects in the exploratory and development stages. Pfizer held 19% of the company's shares at its inception, but reduced its stake after the company's initial public offering (IPO), and as of end-December 2024 it held about 3.40%. When RaQualia out-licenses compounds originally transferred from Pfizer, it pays royalties to Pfizer, which are recorded under cost of operating revenue.

New R&D base established at Shonan iPark

The company conducts drug discovery research primarily at the RaQualia Industry-Academia Collaborative Research Center located on the premises of the Higashiyama Campus of Nagoya University. In January 2023, the company opened a new research center at Shonan Health Innovation Park (Fujisawa, Kanagawa Prefecture; Shonan iPark) and commenced research activities there. Established in April 2018, Shonan iPark is Japan's first pharma-led science park, where more than 2,000 people from over 150 companies and organizations (as of January 2023), including pharmaceutical companies, experts and researchers in next-generation medicine and AI, startups, and administrative agencies, form an ecosystem. The Park hosts a variety of networking events, and the company seeks opportunities to collaborate with companies conducting cutting-edge clinical trials or possessing advanced technologies for novel modalities, target search, and AI-driven drug discovery, further enhancing its drug discovery value chain and portfolio.

Top management and corporate governance

Form of organization and capital structure	
Form of organization	Company with Audit & Supervisory Committee
Controlling shareholder and parent company	None
Directors and Audit & Supervisory Committee members	
Number of directors under Articles of Incorporation	12
Number of directors	8
Directors' term of office under Articles of Incorporation	1 year
Chairperson of Board of Directors	President
Number of outside directors	6
Number of independent outside directors	4
Number of Audit & Supervisory Committee members under Articles of Incorporation	3
Number of Audit & Supervisory Committee members	3
Number of outside directors on Audit and Supervisory Committee	3
Other	
Participation in electronic voting platform	In place
Providing convocation notice in English	In place
Implementation of measures regarding director incentives	Performance-linked compensation system
Eligible for stock option	Employees (consolidated)
Disclosure of directors' compensation	None
Policy to determine amount and calculation method of remuneration	In place
Corporate takeover defenses	None

Source: Shared Research based on company data (as of March 2026)

Corporate governance

RaQualia Pharma employs a company with Audit & Supervisory Committee structure, and has a board of directors, an Audit & Supervisory Committee, and a corporate internal audit office. The board of directors has seven members (including four outside directors). To strengthen the board's monitoring functions, the company chooses outside board members who are familiar with the pharmaceutical industry and corporate management. Furthermore, the company has an executive officer system to separate the management and execution functions and strengthen and invigorate execution.
In March 2023, the company established a nomination and remuneration committee to enhance the fairness, transparency, and objectivity of procedures related to the nomination and remuneration of directors and strengthen corporate governance. In March 2026, the company established a Sustainability Committee, overseeing deliberation of ESG-related basic policies, identification of material issues, company-wide initiatives, and progress management.

Top management

At the ordinary general meeting of shareholders held in March 2021, a shareholder resolution for a management renewal put forth by current board member Yuichi Kakinuma (the largest shareholder with an 11% stake), was adopted with the approval an overwhelming majority (about 85%) of individual shareholders. Mr. Kakinuma had three concerns: that the company's initial forecast was lowered for three consecutive years starting in FY12/19, that the existing pipeline development program was halted, and that the company was unable to out-license its new pipeline. In addition, in 2017, former president Naoki Tani had pledged that the company would have a market capitalization of JPY100bn in 2020, but as of end-2020 it was significantly below this figure, at about JPY20bn.

In February 2025, the company announced the resignation of former Representative Director Hirofumi Takeuchi. The resignation was formally approved at the General Meeting of Shareholders held on March 25, 2025. Prior to this, in January 2025, Masaki Sudo was appointed as the new Representative Director. Sudo brings extensive experience and expertise in drug discovery research and has contributed to company-wide strategy formulation and execution as Director and Executive Officer in charge of corporate management. His responsibilities have included oversight of human resources, general affairs, medium-term management planning, and investor relations. As of end-December 2025, he held 30,232 shares of the company.

Masaki Sudo, Representative Director (born July 29, 1971)

1996	Apr	Joined Teijin Ltd.
1999	Sep	Joined Pfizer Japan (currentPfizer Japan Inc.)
2004	Apr	Senior Research Scientist, Department of Chemical Research, Central Research Laboratories, Pfizer Japan
2006	Apr	Principal Research Scientist, Department of Chemical Research, Central Research Laboratories, Pfizer Japan
2008	Jul	Principal Researcher, Department of Research, the company
2012	Oct	Executive officer, Chemical Research division, Drug Discovery department, the company
2016	Apr	Associate Professor (special appointment), Institute of Transformative Bio-Molecules, Nagoya University
2018	Jul	Visiting Professor, Nagoya University
	Jul	Head of Business Planning Office, Stem Cell & Device Laboratory,
2020	Jan	General Manager, Business Development department, Stem Cell & Device Laboratory, Inc.
2021	Jun	Stem Cell & Device Laboratory, Inc. as General Manager, Business Strategy department, the company
	Oct	Executive Officer, the company (administration and management)
2022	Mar	Director, the company
2023	Mar	Director, TMRC Co., Ltd.
	Apr	Executive Officer, the company
2025	Jan	Representative Director, the company
	Mar	Representative director, TMRC Co., Ltd.
2026	Mar	Director, FIMECS (current)

Source: Shared Research based on company data

Dividends

The company sees returning profits to shareholders as an important management issue, but it has continued to make upfront investments since its establishment and recorded net losses, so has not yet paid a dividend. In FY12/21, it posted operating profit for the first time and will consider paying a dividend in the future if it is able to maintain business profits, depending on the strength of its financial position. The company plans to consider share repurchases flexibly.

Top shareholders

Top shareholders	Shares held (shares)	Shareholding ratio
KOREA SECURITIES DEPOSITORY-SAMSUNG	2,594,100	10.61%
Yuichi Kakinuma	2,384,700	9.75%
Pfizer Japan Inc.	743,000	3.04%
Mitsubishi UFJ Morgan Stanley Securities Co., Ltd.	294,807	1.21%
SBC Co., Ltd.	251,300	1.03%
Advanced Media, Inc.	223,800	0.92%
The Tokyo Tanshi Co., Ltd.	221,500	0.91%
Takahiro Tanago	169,500	0.69%
Ikuyoshi Koumoto	157,000	0.64%
Nomura Securities Co., Ltd.	156,798	0.64%
Total	7,196,505	29.42%

Source: Shared Research based on company data (as of December 31, 2025)
Note: Shareholding ratio is calculated excluding 181 treasury shares.

The company reported 24,458,673 issued shares as of end-FY12/25. Of the shares held by KOREA SECURITIES DEPOSITORY-SAMSUNG (nominee), HK inno.N holds 2,592,100 shares as the beneficial shareholder.

Number of employees

	FY12/15	FY12/16	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21	FY12/22	FY12/23	FY12/24
Number of employees (consolidated)	-	-	60	63	68	70	67	65	67	85
Number of employees (parent)	64	50	55	58	62	64	62	62	64	64
Average age	44.1	44.8	45.5	45.5	46.3	47.3	46.5	47.5	46.4	48.2
Average years of service	5.9	6.6	7.0	6.9	7.4	8.1	8.7	10.7	8.9	10.4
Average annual salary (JPY'000)	8,124	7,242	7,391	7,408	7,237	7,510	7,369	7,033	7,264	7,427

Source: Shared Research based on company data; omissions reflect undisclosed data.

In FY12/24, consolidated employees increased following the consolidation of FIMECS in March 2024. Roughly 50 of the parent's 64 employees were involved in research and development, and over 10 were involved in out-licensing and other business development and management duties. Females accounted for 13.6% of management positions (+8.9pp YoY).

About Shared Research Inc.

We offer corporate clients comprehensive report coverage, a service that allows them to better inform investors and other stakeholders by presenting a continuously updated third-party view of business fundamentals, independent of investment biases. Shared Research can be found on the web at https://sharedresearch.jp.

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