Business Overview

ASKA Pharmaceutical

Aiming to enhance corporate value as a specialty pharma company seeking to address unmet medical needs

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ASKA Pharmaceutical, a core subsidiary of the Group, operates the pharmaceutical business as a specialty pharma company focused on obstetrics and gynecology (Ob/Gyn), internal medicine, and thyroid disorders. In FY2024, despite the continued impact of drug price revisions and other cost-containment measures in healthcare, overall performance remained solid, with net sales reaching a record ¥56.6 billion. Specialty areas, particularly Ob/Gyn, continued to drive growth. Sales of RELUMINA, an uterine fibroids and endometriosis agent, totaled ¥10.5 billion, while sales of DroEthi, a dysmenorrhea agent, totaled ¥7.5 billion, bringing total Ob/Gyn sales to ¥28.1 billion. As a result, we maintained our leading position in this segment in Japan in FY2024, a position first achieved in the second half of FY2022. In addition, RIFXIMA, a hepatic encephalopathy agent (internal medicine), and THYRADIN, a hypothyroidism agent, continued to receive strong support from healthcare professionals and contributed to the Company's robust performance.

In the overseas business, the Company made Hataphar of Vietnam a consolidated subsidiary and began a partnership with MedChoice Pharma of the Philippines. Through these alliances, we are expanding our presence in Southeast Asia, where medical needs are increasing in line with population growth and economic development. We are also making steady progress in drug discovery research and clinical development with an eye to the future. In addition to our existing focus on internal medicine, Ob/Gyn, and urology, we have begun addressing unmet medical needs by targeting ion channels. Several new drug candidates, particularly in the area of women's health, have already entered clinical trials, strengthening our pipeline to support longer-term growth.

Looking ahead, we will work to drive deeper penetration of existing products and accelerate the uptake of new ones. In Ob/Gyn, in addition to RELUMINA and DroEthi, we aim to establish Slinda—the first oral progestin-only contraceptive approved in Japan—in the market at an early stage. In thyroid disorders, where only about 1 million of an estimated 2.4 million patients requiring treatment are currently being treated, we will step up awareness initiatives to expand treatment opportunities. As the leading company in both Ob/Gyn and thyroid disorders in Japan, we will continue to promote accurate understanding of diseases and treatments across society.

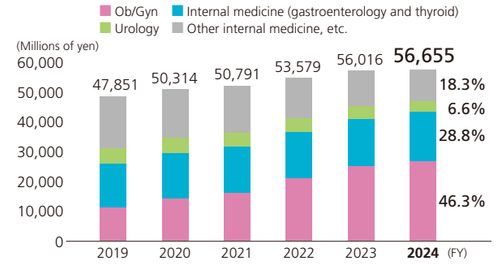
Overseas, we are working to bring high-value-added products to market, including through the planned launch of a new Hataphar factory in FY2026. Leveraging more than a century of experience in pharmaceutical development and marketing in Ob/Gyn in Japan, we aim to drive global growth. As a leading company in women's health, we will continue to address unmet medical needs ahead of competitors and contribute to solving social issues.

Trend in Net Sales

The pharmaceutical business—which focuses on the three fields of internal medicine, Ob/Gyn, and urology—achieved record high sales of ¥56,655 million (up 1.1% year on year) in FY2024. Sales of mainstay products increased despite the impact of NHI drug price revisions, and growth remained stable overall. Growth in the Ob/Gyn field was driven by steady sales growth for RELUMINA, up 6.3% year on year to ¥10,531 million, and for DroEthi, up 22.5% year on year to ¥7,502 million. Sales also grew in the internal medicine area, as sales of THYRADIN rose 3.2% year on year to ¥8,113 million, and sales of RIFXIMA increased 10.1% year on year to ¥6,455 million.

In FY2025, we expect to contribute to higher sales and profit for the Group as a whole, as the pharmaceutical business continues to expand amid stronger sales of mainstay products and increased uptake of Slinda, launched in June 2025.

Net Sales at Pharmaceutical Business



Note: Amounts are rounded down to the nearest million yen.

Strengths

Leading company in the Ob/Gyn field

Leading company in the thyroid field

Expertise in hormones cultivated over a century

Business Climate

Market environment

The domestic pharmaceutical industry continues to experience challenging conditions in the form of annual drug price revisions and government policies to curb medical expenditure. Even under these conditions, though, we expect to achieve sustainable growth in the Ob/Gyn field.

Size of Ob/Gyn Market

Source: Fuji Keizai Co., Ltd., *Data Book for Prescription Drugs 2024, No. 4* — Obstetrics & Gynecology. Unauthorized reproduction prohibited

Risks

- Drug price reductions as part of the government's push to lower medical costs (annual drug price revisions leading to a decline in profits)
- Uncertainties and high costs involved in R&D (new drug development requires substantial time and money, with risks including clinical trial failures and approval delays)
- Intensifying competition as pharmaceutical products go off-patent (falling drug prices due to patent expirations, and market share contraction due to an increase in generic drugs)

Opportunities

- **Support from government policy**
  Basic Policy on Economic and Fiscal Management and Reform, Basic Policy on Gender Equality and Empowerment of Women, etc.
- **Women's advancement in society and changes in lifestyle**
  Medical needs that change according to life stages, amid an increase in the number of female employees and promotion of women to managerial positions
- **Advances in medical technology and improved access to medical care for women's diseases**
  Diversification in treatment choices, improved access to health information through social media and online medical care, improvement in women's health literacy

Strategies

- **Enhance corporate value by strengthening efforts in specialty areas**
  - Pursue greater uptake of 22 pharmaceutical products that accommodate women's lifestyles, including RELUMINA, DroEthi, and Slinda
  - Contribute to addressing women's health issues through various initiatives including dissemination of information about women's health
  - Enhance recognition of RIFXIMA as an essential therapeutic drug for hepatic encephalopathy
  - Contribute to raising awareness and treatment of thyroid-related diseases
- **Continuously create new drugs through advanced drug discovery**
  - Expand R&D pipeline and hasten development of drug candidates by leveraging in-house drug discovery technologies such as ion channel
  - Further strengthen the development portfolio by licensing in drug discovery seeds
- **Develop overseas businesses**
  - Strengthen collaboration with our consolidated subsidiary Hataphar of Vietnam and get business up and running early
  - Promote collaboration with MedChoice Pharma of the Philippines
- **Provide new value to achieve total healthcare**
  - Promote femtech business, including through the development of corporate training videos
  - Create new business opportunities through corporate venture capital

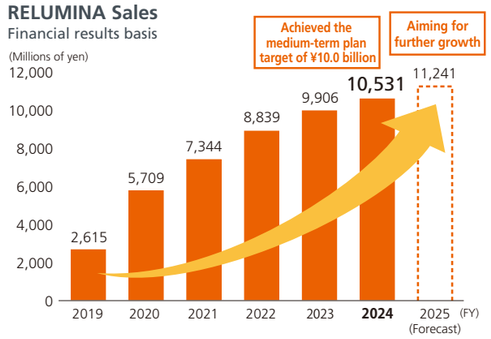
FY2024 Initiatives

❶ Uterine Fibroid and Endometriosis Treatment

We launched RELUMINA in 2019 as the first oral GnRH antagonist agent for the treatment of uterine fibroids in roughly 20 years, and its market share has since grown rapidly.

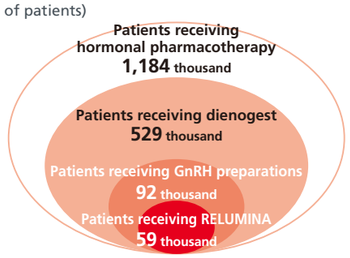
RELUMINA has evolved into an extremely key growth driver, with sales topping ¥10,000 million in FY2024.

RELUMINA Sales
Financial results basis



Following approval for the additional indication of endometriosis, RELUMINA is now making deeper inroads into that market. It continues contributing to endometriosis treatment, particularly in severe cases and those where uterine fibroids are also present.

Reality of Treatment for Endometriosis
(Number of patients)



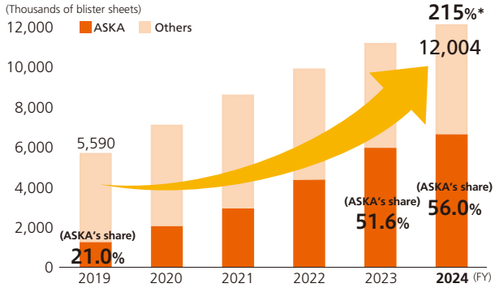
Source: Intage Inc., *Claims (Receipt) Data, FY2024* (includes duplicate cases due to complications). Estimated figures for April 2024–March 2025

Promote penetration of RELUMINA for the treatment of endometriosis

❷ Dysmenorrhea Treatments

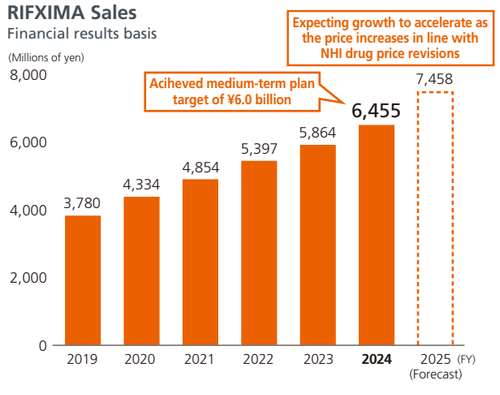
The dysmenorrhea market is rapidly expanding due to factors such as women's advancement in the workforce and increased health literacy. In this area, we have three products in our LEP formulation lineup: FREWELL (authorized generic), Jemina (co-promotion with Nobelpharma Co., Ltd.), and DroEthi (generic drug) launched in June 2022 for which we have the sole sales rights. As such, we provide a range of options for people suffering from dysmenorrhea. The combined market share of the three formulations is 56.0%, and we expect this to continue to grow in line with market expansion. In addition to the provision of pharmaceutical products, we also operate Health Lab Mint+ for Women's health as an initiative to support women's health. We continue striving to contribute to women's health through dissemination of a variety of information.

LEP Market



Notes: In-house analysis based on Encise Data (Unauthorized reproduction prohibited) *FY2019 = 100%

RIFXIMA Sales
Financial results basis



TOPICS Launch of Oral Contraceptive Slinda (June 2025)

Slinda is Japan's first progestin-only oral contraceptive. It can be used by women at risk of thrombosis, which is a contraindication for estrogen-containing oral contraceptives, and offers women a new option for planned contraception.

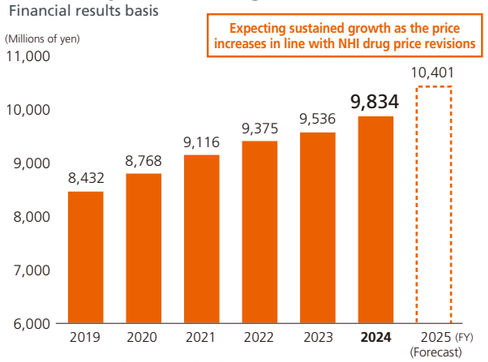
❸ Hepatic Encephalopathy Treatment

Hepatic encephalopathy is a condition in which liver function is significantly reduced, which can give rise to psychoneurological symptoms such as loss of consciousness. It is a rare disease with fewer than 50,000 patients, and as such RIFXIMA is designated as an orphan drug. In addition, the *Evidence-Based Clinical Practice Guidelines for Liver Cirrhosis* strongly recommend RIFXIMA for treating hepatic encephalopathy. We are working to raise awareness of these guidelines with the aim of promoting the penetration of RIFXIMA. In March 2024, we additionally applied for dosage and administration approval for RIFXIMA as an agent for the treatment of hepatic encephalopathy in children. We will continue to address unmet medical needs so that we can contribute to society.

❹ Thyroid Disease Treatments

Abnormal thyroid function can cause a variety of physical and mental symptoms. Thyroid disease is a common disorder among women and is said to be related to menstrual disorders and infertility. Through a wide range of activities to raise disease awareness among medical professionals and the general public, we seek to improve our ability to identify patients in need of treatment at an early stage. In addition to activities to provide information, a longer period of treatment (drug administration) due to longer life expectancy has also contributed to sales growth of roughly 2–3% each year. We will work to ensure stable supply through daily production, stocking, and business continuity planning (BCP) so that we can continue to deliver pharmaceuticals to patients even in the event of an emergency. In doing so, we will fulfill our mission as a leading company in the thyroid area.

Sales of Thyroid Disease Agents*
Financial results basis



*THYRADIN, MERCAZOLE, PROPACIL

❺ Development Pipeline

We conduct drug discovery research and clinical development centered on our three priority areas of internal medicine, Ob/Gyn, and urology, while actively pursuing licensing activities and business alliances.

In addition, the Company has introduced fundamental drug discovery technology for ion channels as a novel drug discovery platform, enabling it to take on the challenge of addressing unmet medical needs in new areas, in addition to its priority areas.

In clinical development, in the Ob/Gyn area we received manufacturing and marketing approval in May 2025 for LF111 (drospirenone), which we have been developing for the indication of contraception. We launched LF111 in June 2025 as Slinda. AKP-022 (relugolix combination tablets), which we are developing as a successor to RELUMINA, is an agent that combines relugolix with estrogen and progestin. Development is under way with the hope of allowing for treatment durations longer than six months, by suppressing the bone loss that is associated with RELUMINA monotherapy. In March 2025, we initiated a Phase III clinical trial of LPRI-CF113 (drospirenone), a continuously administered progestin agent we licensed in to develop as a treatment for dysmenorrhea. AKP-SMD106 is a non-pharmacological therapy using an app, and a specified clinical trial is ongoing for premenstrual syndrome and premenstrual dysphoric disorder. AKP-009 (ludaterone), a next-generation androgen receptor modulator discovered in-house, is currently the subject of a Phase II clinical trial for benign prostatic hyperplasia in the urology field. We are also preparing to develop the drug as a treatment for polycystic ovary syndrome in the Ob/Gyn field.

R&D Status (As of September 30, 2025)

Development code (generic name) / Indication		Research[1]	Non-clinical[1]	Phase I	Phase II	Phase III	Application	Approval
AKP-022 (relugolix combination tablet)	Uterine fibroids					Phase III ongoing		
AKP-022 (relugolix combination tablet)	Endometriosis					Phase III ongoing		
LPRI-CF113 (drospirenone)	dysmenorrhea				Phase I/II ongoing			
AKP-SMD106 (digital therapeutics app)	Premenstrual syndrome/Premenstrual dysphoric disorder (PMS/PMDD)				Specified clinical trial ongoing			
AKP-009[2] (ludaterone acetate)	Polycystic ovary syndrome (PCOS)				Preparing clinical trials			
Theme B	Ob/Gyn							
MCN-009 (digital therapeutics app)	Irritable bowel syndrome (IBS)					Phase III ongoing		
Theme C	Internal medicine							
AKP-009[3] (ludaterone acetate)	Benign prostatic hyperplasia				Phase II ongoing			
AKP-021 (mPGES-1 inhibitor agent)	Urology			Phase I ongoing				
AKP-017 (intransnasal testosterone)	Urology			Preparing clinical trials				

1. Details of research are not disclosed because it is non-clinical.
2. AKP-009 for PCOS is Theme A
3. Terminated an agreement with KYORIN Pharmaceutical Co., Ltd. regarding joint development and commercialization of AKP-009 for benign prostatic hyperplasia

Overseas Business Development

Vision for Our Overseas Business

In Southeast Asia, a region that has experienced rapid economic growth in recent years, we aim to actively contribute to local government efforts to enhance healthcare environments. We support local pharmaceutical partners in expanding their product portfolios and upgrading production systems to meet international standards. This is achieved by leveraging our world-class pharmaceutical production technology, advanced quality control expertise, proprietary pharmaceutical supply system, and technology transfers. Through these efforts, we have established strategic partnerships with companies in Vietnam and the Philippines, generating synergies that maximize the strengths of both parties. Looking ahead, we plan to further strengthen collaboration with our strategic partners to build on our contributions to healthcare improvement in Southeast Asia. We also aim to leverage the experience and networks we have developed in the region to create value in Europe, the United States, and other global markets. We remain committed to expanding our activities across Southeast Asia, becoming actively involved in more countries, and contributing to the enhancement of healthcare infrastructure and sustainable social development throughout the region.

To build a highly profitable structure with the aim of expanding it throughout Southeast Asia

Expansion into Vietnam

As part of our overseas expansion, primarily in Southeast Asia, we view Vietnam, a market that continues to experience strong economic growth, as a key strategic market. In January 2021, we acquired a 24.9% stake in Ha Tay Pharmaceutical Joint Stock Company ("Hataphar"), a major local pharmaceutical company, initiating a collaboration through a capital alliance. We continued to increase our shareholding, and by February 2025, we had acquired 40% of the shares, making Hataphar a consolidated subsidiary from FY2025.

Since commencing our collaboration with Hataphar, we have undertaken a range of joint initiatives, including the construction of a new factory compliant with PIC/S GMP (a stringent, internationally recognized manufacturing standard ratified by developed countries such as Japan, the U.S., and those in Europe), regulatory filings in Vietnam for products developed in-house, and the outsourcing of manufacturing for our products. Currently, we have seconded five personnel, including the manager of the new factory, to Hataphar as we actively work to strengthen that company's manufacturing and development capabilities.

Going forward, the two companies aim to further expand their business by leveraging synergies, using the new PIC/S GMP-compliant factory to support growth in Vietnam.

Expansion into the Philippines

In April 2025, we acquired a 21% stake in FTS Ambrose Holdings, marking the first step toward building a strategic partnership with the its wholly owned subsidiary, MedChoice Pharma, a Philippine pharmaceutical company. MedChoice Pharma is a branded generic[1] specialty pharmaceutical company in the Philippines, focusing on specific therapeutic areas and chronic diseases. It possesses strong brand equity built on a proven track record, along with excellent sales and marketing capabilities. The company handles a wide range of pharmaceuticals in endocrinology and central nervous system disorders and is particularly notable for its high market share in thyroid agents. As MedChoice Pharma is also focusing on Ob/Gyn as a future growth area, we view it as a potential collaborator in that field and in thyroid diseases, where our presence is already strong. The Philippines had a population of approximately 112.72 million as of 2024[2] and even within the fast-growing Southeast Asian region, represents a particularly promising market, with average GDP growth of 5-6%.[2] We plan to leverage our partnership with MedChoice Pharma as a foothold for expanding in the Philippines and aim to use it to further develop our overseas presence, alongside our collaborative businesses with Hataphar in Vietnam.

1. Off-patent (generic) drugs that are given a brand name by a manufacturer, with claims of superior quality and effectiveness.
2. Source: Japan External Trade Organization (JETRO)

Message from International Business Division Director

In 2019, the International Business Division began cultivating new markets with the aim of making it a key pillar supporting the growth of our company. We identified the rapidly growing Southeast Asian market as a target and have been actively pursuing business opportunities in the region, guided by local market conditions and growth trends. These efforts advanced further in 2020, when we commenced an initial collaboration with our strategic partner, the Vietnamese pharmaceutical company Hataphar, to build a new factory. Since then, we have transitioned to a collaborative structure encompasing research, finance, procurement, and sales activities. In February 2025, Hataphar became a consolidated subsidiary. In April 2025, we also began collaborating with Philippine pharmaceutical company MedChoice Pharma, acquiring a 21% capital stake.

Going forward, we will work to enhance Hataphar's profitability and strengthen its foundations to support further growth. At the same time, we aim to solidify our presence by deepening collaboration with MedChoice Pharma, starting with joint initiatives in the thyroid field.

We will continue to identify and evaluate new growth opportunities across Southeast Asia.

Hiroyasu Nishioka
Managing Member of the Board of Directors
International Business Division Director
ASKA Pharmaceutical Co., Ltd.