Business Conditions

ASKA Pharmaceutical

Striving to enhance corporate value while addressing unmet medical needs in a timely fashion

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President, Representative Director
ASKA Pharmaceutical Co., Ltd.

Working to consolidate our status as a specialty pharma company

Earnings at ASKA Pharmaceutical, the main subsidiary of ASKA Pharmaceutical Holdings, were broadly in line with plan in FY2023. We achieved record net sales of ¥56 billion, fueled in large part by our businesses in specialty areas, particularly Ob/Gyn products. In our current medium-term management plan, we set the goal of achieving more than ¥20 billion in annual sales in the Ob/Gyn field, with the aim of attaining the No. 1 share of net sales in this market in Japan. We reached that target two years ahead of schedule, owing in large part to sales growth of the uterine fibroid and endometriosis agent RELUMINA. This solid business performance also reflected the high regard medical professionals have for our products, including RIFXIMA, an agent for the treatment of hepatic encephalopathy (an area of high unmet medical need), and the hypothyroidism agent THYRADIN.

Our next challenge is to lay the foundations for further growth by consolidating our position as a highly competitive specialty pharma company in Japan. To that end, we are working to flesh out our pipeline. As we seek to solidify our position as a market-leading company, we will respond to demand by launching new drugs in the near future, including Japan's first progesterone-only pill[1] (POP) and a successor to RELUMINA. Overseas expansion is another challenge. In January 2024, we strengthened our alliance with leading Vietnamese pharmaceutical company Ha Tay Pharmaceutical Joint Stock Company (Hataphar) by executing a capital increase. Through this alliance with Hataphar, we seek first to expand our share of the fast-growing Vietnamese market before deploying our products into neighboring countries in Southeast Asia.

1. Progesterone-only pill, a contraceptive pill that contains no estrogen, only progesterone. Such pills have a reduced risk of thrombosis and other side effects relative to traditional low-dose birth control pills.

Increase proposals on material issues from employees

Since assuming the role of president in 2021, I have worked to communicate the medium-to long-term vision of "creating new value as a leading company in female healthcare" both inside and outside the company. I have worked especially hard to explain to our employees the relationship between this vision and the company's day-to-day operations, sharing with them my plans for achieving sustainable growth. In the course of recent dialogue between management and employees, I have been struck by the growing number of employees who think deeply about how they can contribute to the 11 material issues identified by the Group, evidence that their horizons spread beyond near-term business performance. At each such dialogue session, employees contribute multiple ideas on how ASKA Pharmaceutical can fulfill its role as a leading company in the very important area of contributing to women's health. This has given rise to a cycle in which we collate the ideas that have been presented and take the initiative in pursuing those deemed worthy of action.

Looking back over the past 10 years, I have observed a growing awareness of the importance to society of addressing women's health issues, as evidenced by the 2016 enactment of the Act on the Promotion of Women's Active Engagement in Professional Life, and the government's annual release of a Basic Policy on Gender Equality and Empowerment of Women. As a result, I think that expectations of ASKA Pharmaceutical have been rising year by year. In the healthcare field, Femtech is garnering significant attention as a technology-based approach to addressing women's health issues. Against this backdrop, ASKA Pharmaceutical aspires to be a total healthcare company capable of supporting women's health not just through its pharmaceutical products, but across the entire spectrum from prevention through testing and diagnosis, treatment, and prognosis.

The economic cost of women's illnesses is substantial, with menstrual symptoms alone costing the economy approximately ¥570.0 billion annually. Meanwhile, around two million women in Japan are diagnosed with uterine fibroids, but the patient population is probably much larger when including women without a formal diagnosis from a medical institution. We accordingly think it important to raise awareness in this regard.

Since 2020, we have been running Health Lab Mint+ for Women's health, mainly utilizing a dedicated website to disseminate the knowledge we have amassed over the years about diseases and health concerns unique to women. Our efforts have been very well received, leading us to recognize anew the importance of such educational activities. In FY2023, we established the Femtech Business Promotion Unit and began selling Mint+ Femknowledge training videos to companies, with the goal of spreading knowledge about women's health and encouraging the creation of work environments that are positive for everyone.

Strengthening capabilities in new drug development with a view to raising our ROE to 8%

For pharmaceutical companies such as ASKA Pharmaceutical, ongoing investment in R&D is the key to realizing sustainable growth. For the past several years, our R&D expenditure to sales ratio has remained around 10%. The development of new drugs not only is very costly, but also naturally involves risk. Among the drug candidates in our pipeline, some will fall short of expectations even if they proceed to clinical trials, such that development is ultimately discontinued. Even allowing for this risk, we will continue to invest proactively in R&D to support our future growth. We also need to channel more management resources into drug discovery research, the process furthest upstream within the scope of R&D. We plan to scour the global market in search of seeds for drug discovery, with an eye to monetizing the intellectual property thus generated.

In addition to boosting our new drug development capabilities in this manner and increasing our exposure to new drugs, we seek also to improve operational efficiency through the use of ICT and enhance our profitability. In our current medium-term management plan, we set the goal of achieving the 8% ROE (return on equity) that shareholders and investors generally expect of listed companies. We have achieved that goal already, ahead of schedule. Looking ahead, we look to grow the operating profit margin and ROE to levels closer to the average for multinational new drug manufacturers.

Over the past year or so, ASKA Pharmaceutical Holdings has sought to implement management that is conscious of cost of capital and share price, through such means as successfully implementing our growth strategy and strengthening shareholder returns. In March 2024, our PBR (price-to-book ratio) rose above 1x, and it is currently[2] around 1.1x. Our first goal is to raise the PBR further to the pharmaceutical industry average of 1.5x. To that end, we need to create more opportunities to convey to investors the potential we see in our main subsidiary ASKA Pharmaceutical to realize our vision of becoming a total healthcare company with a strong foundation as a specialty pharma company through active investment in R&D and new businesses.

2. As of September 2024

Continuing to make investments drawing out the value of human resources to realize our vision

We believe that human capital is key to ASKA Pharmaceutical building on its century-long history and continuing to enhance corporate value while realizing the vision of becoming a total healthcare company. Fostering our human resources is especially important, and to that end we have put together a training program that is linked to the human resources system and designed to enable employees to further their knowledge base voluntarily in response to changes in the external environment. To instill in our employees an attitude of autonomous growth and a willingness to take on challenges, we provide all employees with an e-learning system that features a book summary app and training videos enabling participation regardless of time and place. From FY2024, we also resumed the overseas training that had been interrupted for four years during the COVID-19 pandemic.

In a comparison of per-capita spending on employee education and training with that of listed companies in general, ASKA Pharmaceutical's spending is approximately three times the listed company average. Significantly, this was not a target set beforehand, but rather the numerical consequence of our investments in human resources.

Looking ahead, one of our main focus areas will be the cultivation of the next generation of leaders. The pharmaceutical and healthcare industry is entering a phase in which it is difficult to achieve growth simply by piggybacking expanding markets and social trends. We believe that growth can only be ensured by acting independently to create new markets and trends, thereby leading the industry. For this very reason, we consider it a priority to develop the kind of human resources capable of defining a clear vision and future direction and building the necessary business and organizational framework. We have established our own Next-Generation Leader Development Program, under which we plan to provide not just desktop learning, but also opportunities to gain practical experience, such as through secondment to companies overseas.

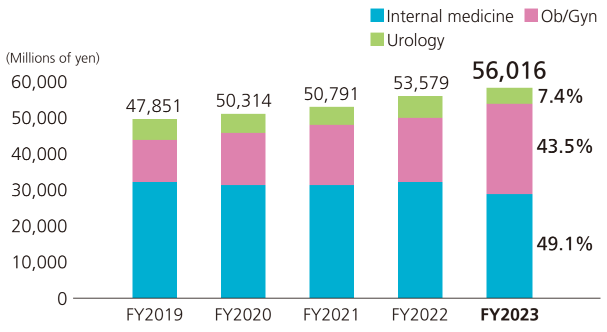
As our operating environment is changing by the day, the role that society expects us to fill should also be changing, at least little by little. We think opportunities for dialogue with stakeholders are a key means of detecting those changes. Our goal to become a leading company in supporting women's health makes it all the more important to accurately identify unmet medical needs and to take the initiative in addressing them. We will remain active in this respect, even if it means taking on challenges beyond the scope of conventional wisdom. Please look forward to our continued success.

Business Conditions

Performance in FY2023

The pharmaceutical business, which focuses on the three priority areas of internal medicine, Ob/Gyn, and urology, remained strong overall despite the impact of NHI drug price revisions. Net sales increased to ¥56,016 million (up 4.5% year on year). By product, in the Ob/Gyn field, sales of RELUMINA (relugolix), a uterine fibroid and endometriosis agent, increased to ¥9,906 million (up a solid 12.1% year on year), while sales of DroEthi, a dysmenorrhea agent for which we acquired manufacturing and marketing approval as the only company in June 2022, again grew strongly, rising 66.8% year on year to ¥6,125 million. In addition, in the area of internal medicine, sales of our key product THYRADIN, a hypothyroidism agent, increased to ¥7,862 million (up 1.7% year on year). Sales of RIFXIMA, a hepatic encephalopathy agent for which we are working to increase recognition for having been included in clinical practice guidelines, rose to ¥5,864 million (up 8.7% year on year). In the urology field, sales of LEUPRORELIN, an endometriosis, uterine fibroid, and prostate cancer agent, decreased to ¥4,430 million (down 11.4% year on year). As a specialty pharma company focusing on the three areas of internal medicine, Ob/Gyn, and urology, we will continue to actively expand our pipeline by further promoting drug discovery and alliances.

Net Sales in the Pharmaceutical Business



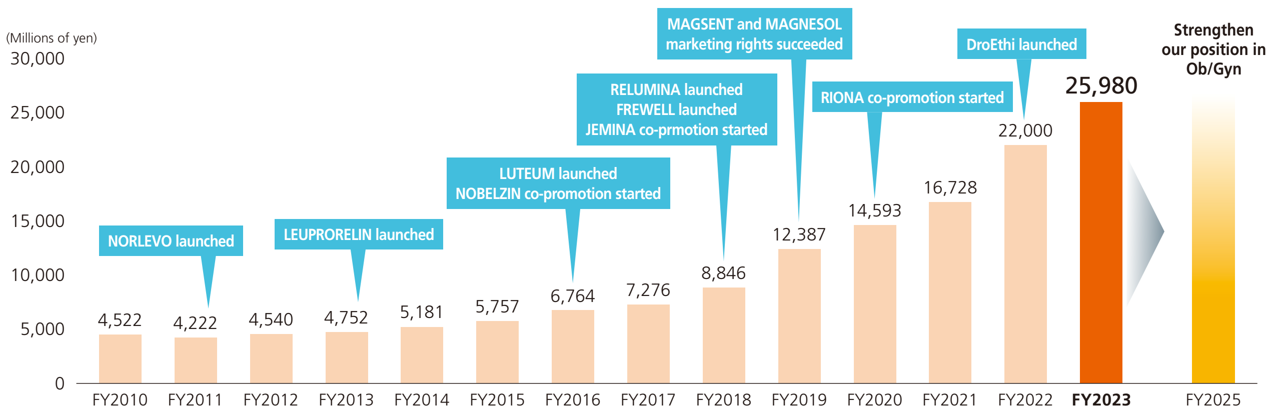
Note: Amounts are rounded down to the nearest million yen.

Major Initiatives

❶ Strengthening Our Position in the Ob/Gyn Field

ASKA Pharmaceutical has attained the No. 1 position in the Ob/Gyn market in Japan. As a leading company in this field, we approach various issues according to women's life stages. We support women's health and lives with a wide variety of pharmaceuticals for dysmenorrhea, uterine fibroids and endometriosis, among other conditions, while also working to advance Femtech with a view to supporting women's health more broadly, beyond pharmaceuticals. Additionally, as we strive to become a total healthcare company, we are strengthening collaboration with other companies. One such initiative has been the launch of training videos on women's health based on the concept of "what workers should know about sex," with the aim of improving health literacy among all people working in companies and organizations. We also established a corporate venture capital fund, ASKA Innovation Investment Limited Partnersahip, jointly with Future Venture Capital Co., Ltd. This fund will enable us to accelerate collaboration with venture and start-up companies, creating new value as we work to solve women's health issues.

Sales of ASKA Pharmaceutical's Ob/Gyn Products



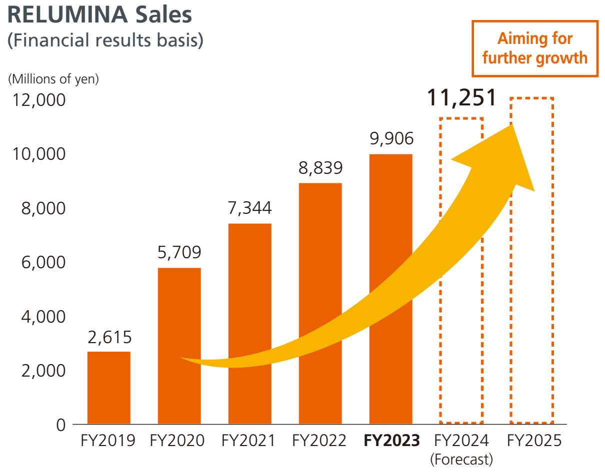
Attained No. 1 domestic market share in field of Ob/Gyn*

* Company estimate

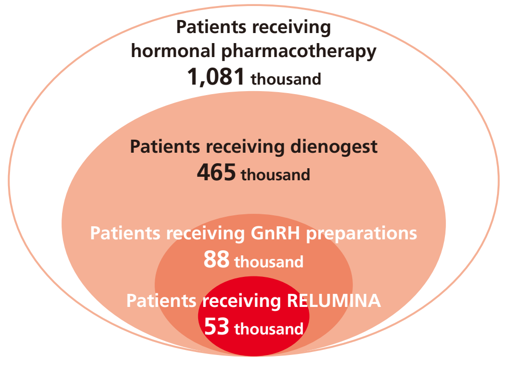
Endometriosis and Uterine Fibroid Agent

We launched RELUMINA in 2019 as the first oral GnRH antagonist agent for the treatment of uterine fibroids in 20 years. Since then, the switch from the standard injectable formulation of comparable drugs with similar efficacy is progressing steadily. In December 2021, it received approval for an additional indication as an endometriosis agent. We are working to promote the penetration of RELUMINA as a treatment for endometriosis as well as for the treatment of uterine fibroids with the aim of providing a new option in pharmaceuticals for endometriosis. In FY2023, sales increased significantly to ¥9,906 million (up 12.1% year on year). By accelerating the penetration of RELUMINA for the uterine fibroid and endometriosis agent, we plan to significantly increase sales to ¥11,251 million (up 13.6% year on year) in FY2024.

RELUMINA Sales
(Financial results basis)



Reality of Treatment for Endometriosis



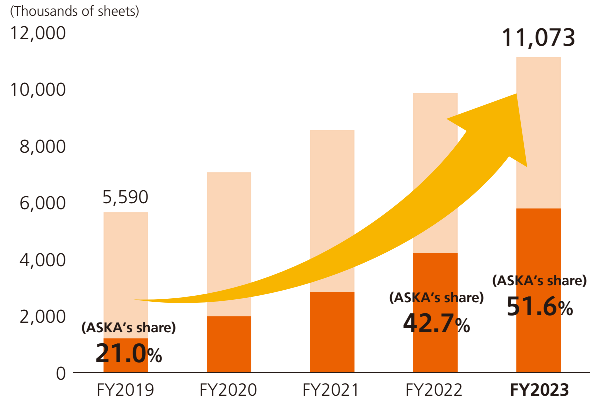
Note: Intage Receipt Data in FY2023 (with duplication due to complications) Confirmed figures for April-December 2023, estimated figures for January-March 2024

Promote penetration of RELUMINA for the treatment of endometriosis

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 lineup: FREWELL (authorized generic), Jemina (a co-promotion with Nobelpharma Co., Ltd.), and DroEthi (a 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 LEP[1] formulations (pharmaceuticals) is 51.6%, 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[1] Market

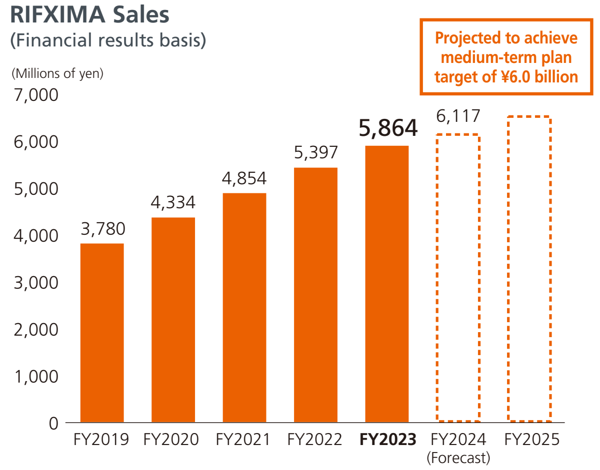


Notes: In-house analysis based on data from Encise Inc. (unauthorized reproduction prohibited).
Jemina tablets are co-promoted with Nobelpharma Co., Ltd.
1. Low dose estrogen progestin

❷ 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 Clinical Practice Guidelines for 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.

RIFXIMA Sales
(Financial results basis)

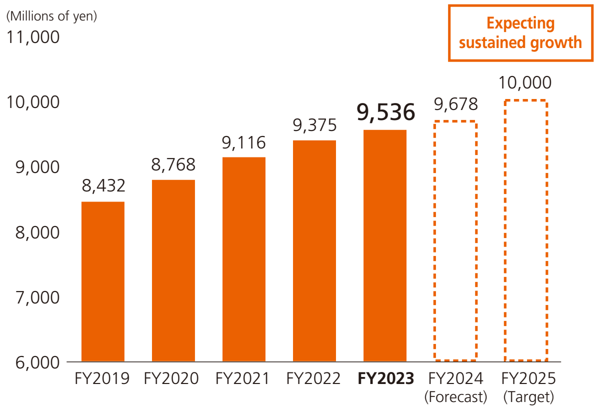


Business Conditions

❸ Thyroid Disease Treatments

Abnormal thyroid function can cause a variety of physical and mental symptoms. Thyroid disease is a common disorder among women and 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 the 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) measures 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[2]
(Financial results basis)



2. THYRADIN, MERCAZOLE, PROPACIL

❹ Development Pipeline

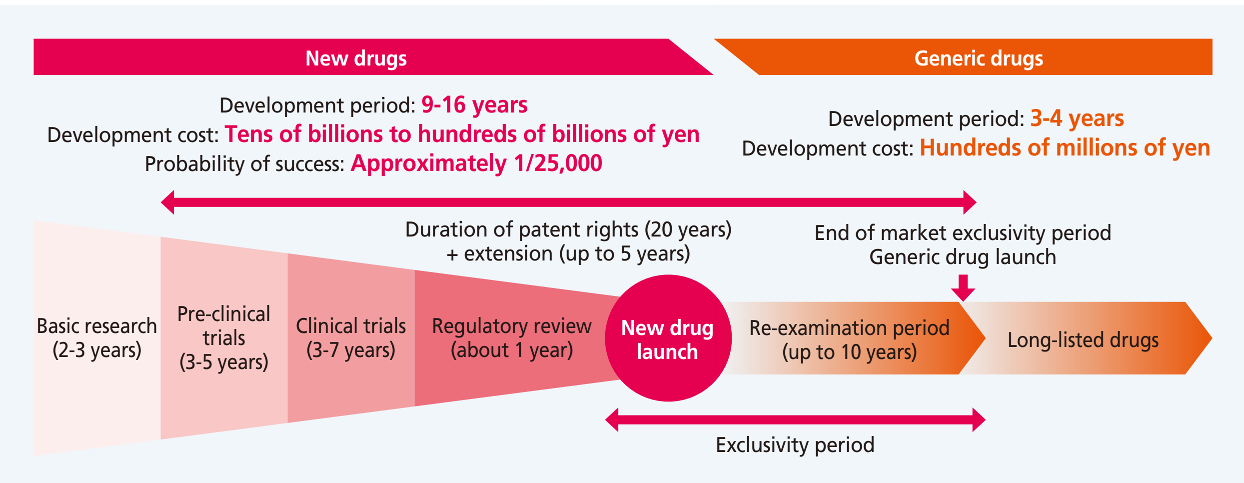
In addition to performing drug discovery research and clinical development centered on our three priority areas of internal medicine, Ob/Gyn, and urology, we are proactively engaged in licensing activities and business alliances. In the area of clinical development, in March 2024 L-105 (rifaximin) received approval for a partial change in manufacturing and marketing for the pediatric indication of improvement of hyperammonemia in hepatic encephalopathy. Furthermore, in June 2024 we filed for manufacturing and marketing approval for LF111 (drospirenone), which we have been developing for the indication of contraception.

Three clinical trials are currently under way. AKP-009 (ludaterone), which we are developing jointly with Kyorin Pharmaceutical Co., Ltd., is in Phase II trials and an additional Phase I trial is under way. Phase III trials have begun for TRM-270, an adhesion barrier being jointly developed with Toray Industries, Inc. The candidates of the trials are in the fields of gastroenterology and Ob/Gyn. A Phase I/II study of AKP-022 (relugolix combination tablets) was initiated in July 2023 in patients suffering uterine fibroids.

Among candidates undergoing preparations for development, we aim to initiate clinical trials soon on AKP-017 (transnasal testosterone). We also have multiple candidates at the pre-clinical stage, some stemming from our own technologies and some from the acquisition of drug discovery seeds through open innovation.

In terms of licensing and alliance activities, ASKA Pharmaceutical signed an agreement with SUSMED for joint research, development, and post-launch marketing of digital therapeutics in the Ob/Gyn field in September 2023. Also, in March 2024 ASKA Pharmaceutical and Red Arrow Therapeutics signed a joint research agreement to develop a new treatment for preeclampsia. In May 2024, ASKA Pharmaceutical entered into a license agreement with Takeda Pharmaceutical to additionally acquire exclusive development and marketing rights in Japan for the relugolix combination tablet in-licensed from Takeda for the treatment of endometriosis, with the aim of maximizing product value. We continue working to flesh out the pipeline by pursuing drug discovery and research in this manner.

Pharmaceutical Company Business Model (Prescription Pharmaceuticals)



R&D Status (As of August 31, 2024)

Development code (generic name)	Indication	Research[3]	Non-clinical[3]	Phase I	Phase II	Phase III	Application	Approval
LF111 (drospirenone)	Contraception							Filed
(Option agreement)	PMS/PMDD[4] drugs under development at Renascience Inc.				Investigator-initiated Phase II ongoing			
AKP-022 (Relugolix combination tablet)	Uterine fibroids					Phase I/II completed		
AKP-022 (Relugolix combination tablet)	Endometriosis				Preparing for development			
Theme A	Ob/Gyn							
Theme B	Ob/Gyn							
TRM-270 (adhesion barrier)	Gastroenterology and Ob/Gyn					Phase III ongoing		
Theme C	Internal medicine							
AKP-009 (ludaterone acetate)	Benign prostatic hyperplasia				Phase IIa completed[5]			
AKP-017 (transnasal testosterone)	Urology			Preparing for development				
AKP-021 (mPGES-1 inhibitor agent)	Urology							

3. Details of research are not disclosed because it is non-clinical.
4. PMS: Premenstrual syndrome/PMDD: Premenstrual dysphoric disorder
5. After receiving the results of the additional Phase I clinical trial, we are again conducting a Phase I clinical trial to reconfirm the data.

❺ International Business Development

The International Business Division is focusing on expanding its operations in the Southeast Asian region, where growth is expected due to population increase and economic development, with Ha Tay Pharmaceutical (Hataphar, Hanoi Vietnam), a company with which we have formed a strategic partnership, as one of the major pillars. Following an initial investment in January 2021, which brought our rights in Hataphar to 24.9%. We increased our ownership to 34.9% in March 2024 through additional capital subscription, taking steady steps toward deepening the partnership.

Through our joint project with Hataphar, the new factory constructed in Hoa Lac High-Tech Park in Hanoi obtained WHO-GMP[6] certification from the Drug Administration of Vietnam under the Ministry of Health in June 2024. Currently, we have dispatched key personnel, including the factory head, and are steadily preparing for the acquisition of PIC/S-GMP[7] certification from the Japanese authorities. At the same time, we are promoting various initiatives to strengthen formulation development, expand our product portfolio, and explore new markets in the ASEAN region and beyond, all in preparation for the launch of new products from the new factory.

We will accelerate these collaborative activities, promote Hataphar's market expansion, and leverage this to advance our global expansion efforts.

6. WHO GMP: Standards for manufacturing control and quality control of pharmaceuticals, mainly ratified by emerging countries.
7. PIC/S GMP: Standards for manufacturing control and quality control of pharmaceuticals, ratified by most developed countries under international standards.

Hataphar High-Tech Pharmaceutical Factory (new factory)

❻ Progress in Femtech Business

The term "Femtech," blending the words "female" and "technology," refers to products and services that use technology to solve various health issues that women face in their various life stages.

Femtech is gradually gaining traction in Japan, with support from government measures including Ministry of Economy, Trade and Industry initiatives to promote women's participation in the workforce through the use of Femtech, and the Basic Policy on Gender Equality and Empowerment of Women.

Established in April 2023, ASKA Pharmaceutical's Femtech Business Promotion Unit develops products and services addressing women's diverse health issues and concerns. In October 2023, we started to sell training videos on women's health to companies and organizations, as the first service offering from the Femtech Business Promotion Unit. Through these videos, the unit aims to encourage men and women to gain mutual understanding regarding the female-specific symptoms that can prevent women from performing at their best. Looking forward, the Femtech Business Promotion Unit seeks to continue engaging in activities that contribute to women's health and workplace wellbeing.