

# Manufactured Capital and Intellectual Capital Strategies

## Overview and Plans for Strengthening Manufactured Capital and Intellectual Capital

Based on its corporate philosophy of "Contribute toward the improvement of people's health and progress in society through the development of innovative products," the ASKA Pharmaceutical Holdings Group positions manufactured capital and intellectual capital as the foundation for sustainable growth. When it comes to manufactured capital, the Group ensures a stable supply of high-quality pharmaceuticals through compliance with GMP standards, the introduction of advanced systems including a Manufacturing Execution System (MES), Laboratory Information Management System (LIMS), and Quality Assurance System (QAS), as well as human resource development. By balancing efficiency and quality, the Group provides reliable products that prioritize patients' health and safety.

Intellectual capital refers to intellectual property resulting from R&D, such as patents and trademarks. It is a source of competitive advantage and social value. We are harnessing

our expertise in the Ob/Gyn and endocrinology fields to promote industry-government-academia collaboration, the introduction of AI technology, and our CVC fund. At our research facility in the Shonan Health Innovation Park, we are engaged in drug discovery research that utilizes open innovation, which in FY2024 yielded results including the introduction of a technology for ion channel drug discovery and preparations for clinical trials investigating AKP-009 for the new indication of polycystic ovary syndrome.

We plan to accelerate collaboration both domestically and internationally in order to create innovative products that address women's health issues and unmet medical needs. We aim to enhance our corporate capital by combining user-oriented value creation with flexible manufacturing, thereby increasing our corporate value over the medium to long term and contributing to a sustainable society.

## Innovative Drug Discovery Division

### Tackling cutting-edge drug discovery research through open innovation and the introduction of technology for ion channel drug discovery

In the two years or so since my July 2023 appointment as a division director, the Innovative Drug Discovery Division has worked to bolster the existing drug discovery research platform in obstetrics and gynecology, one of the Group's three priority areas, while also introducing ion channel drug discovery as a new platform. In addition to the small molecule drug discovery that we have been addressing to date, the division is also actively embracing new modalities such as antibodies and mid-size molecules through open innovation. By incorporating AI into our research, we are also pursuing efficiency gains in the selection of new drug discovery targets and generation of new development candidates.

To achieve the Group's goal of making a "contribution to women's health," the Innovative Drug Discovery Division is focusing on drug discovery research for health conditions specific to women, such as menstrual disorders, endometriosis, infertility, and menopause-related disorders. Furthermore, by combining ASKA Pharmaceutical's experience in endocrine hormone research amassed over many years with its ion channel drug discovery platform, we will take on the challenge of addressing unmet medical needs in new disease areas.



**Shuzo Watanabe**  
Corporate Officer  
Innovative Drug Discovery  
Division Director  
ASKA Pharmaceutical Co., Ltd.

## FY2024 Initiatives

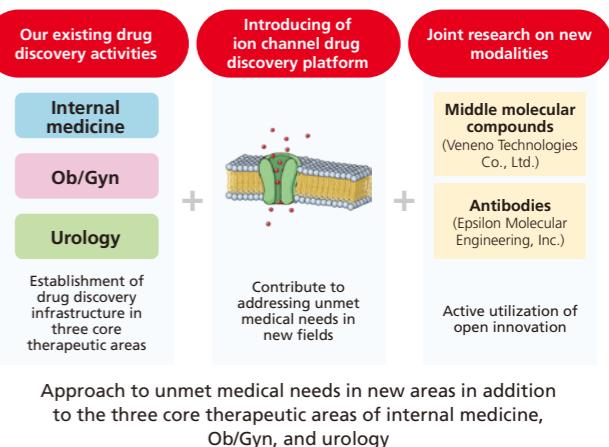
One of our goals in FY2024 was to enhance our portfolio at the discovery research stage. To that end, we solicited proposals from academia for collaborative research on drug discovery seeds and technologies supporting drug discovery research. Through advertisements on our website and information sessions held at multiple universities, we received a total of 20 applications, three of which led to collaborative research projects. We also secured meetings with many venture companies through our exhibit at BioJapan, one of Japan's largest partnering events, and through similar partnering events in Europe and the United States. One such meeting led to the start of collaborative

research into new ion channel therapeutics. This research leverages Veneno Technologies' technology for creating medium-sized compounds (disulfide-rich peptides) that act selectively on ion channels, and our own technology for ion channel drug discovery.

Through research aimed at expanding our development pipeline, we discovered that AKP-009 (currently in a Phase II clinical trial for benign prostatic hyperplasia) also has potential as a treatment for polycystic ovary syndrome (PCOS). We have resolved to initiate a clinical trial investigating AKP-009 for this new indication.

## Open Innovation at Shonan Health Innovation Park

The Innovative Drug Discovery Division closed its Kawasaki Research Center in April 2020 and relocated to the Shonan Health Innovation Park (Shonan iPark), where we continue to work daily on drug discovery research geared toward creating new medicines. As of March 2025, Shonan iPark was home to 190 companies and organizations and more than 2,500 people—not only from the pharmaceutical industry, but also from next-generation medicine, cellular agriculture, AI, and government—and constitutes one of Japan's largest drug discovery ecosystems. Shonan iPark frequently holds science seminars as well as partnering and other business events in order to promote open innovation. By integrating ideas and technologies obtained through these exchanges with our own technologies, we aim to create innovative new drugs formed from new perspectives.



## Business Development Division

### Leveraging intellectual capital to offer new choices for women and pursuing collaborative innovation

In addressing the needs of society, Business Development Division members are engaged in creating products and services that leverage intellectual capital in such forms as relationships of trust with medical professionals, scientific knowledge, regulatory response, and collaboration with domestic and international partners.

One such initiative was our launch of the oral contraceptive, Slinda. This drug is widely used overseas and recommended in WHO guidelines, but had yet to be launched in Japan. By in-licensing this drug from an overseas partner and developing it for domestic use, ASKA Pharmaceutical is providing a new treatment option for women unsuited to the use of traditional contraceptives.

Another initiative is our effort to make the emergency contraceptive, NORLEVO, available over the counter. There has been a long-standing campaign to improve access to this drug, as it prevents unintended pregnancies. We have been working tirelessly on laying the groundwork for an OTC switch, in conjunction with a range of stakeholders including regulatory authorities, physicians, and pharmacists. It is our hope that these efforts will contribute, even if only a little, to greater acceptance of "Sexual and Reproductive Health and Rights (SRHR)," which support women's right to self-determination concerning health and reproduction.

A further example, but one from a completely different perspective, is our work on developing digital therapeutics (DTx\*). We look forward to the day when we can deliver a new treatment modality—that of treating illness with an app—to patients, and to this end, we are collaborating with start-ups to incorporate external innovation and expand our reach into new fields.

\*Software or apps developed based on medical evidence; a new form of treatment that supports disease management and treatment.



**Junko Komatsu**  
Corporate Officer  
Business Development  
Division Director  
ASKA Pharmaceutical Co., Ltd.

## FY2024 Initiatives

The mission of the Business Development Division is to optimize ASKA Pharmaceutical's portfolio and enhance asset value, thereby contributing to the Company's medium- to long-term growth strategy.

The Business Development Division comprises the Business Development Department, the Medical Affairs Department, and the Portfolio Management Department. It focuses on forging ASKA's future through initiatives such as (1) optimizing product value by building evidence, (2) acquiring new products through licensing and alliance activities in Japan and overseas, (3) optimizing the portfolio by strengthening our presence in

the Ob/Gyn field and planning strategies for new fields, and (4) investing in start-ups.

In FY2024, we achieved a major milestone by acquiring two potential drug candidates for the pipeline targeting endometriosis and dysmenorrhea, both of which are expected to become mainstay products. We also took on a new challenge of generating evidence using real-world data (RWD) collected from actual clinical practice, and made strategic investments in three startups focused on women's health issues and digital medicine. These initiatives demonstrate our fresh thinking and are contributing to the Group's sustainable growth.

## Manufactured Capital and Intellectual Capital Strategies

### Development Division

The Development Division comprises the Development Planning Department, which formulates development strategies, and the Clinical Development Department, which conducts clinical trials in line with those strategies. Each department brings their expertise to achieve the Development Division's vision of being an organization that continuously develops new drugs as "One Team." Currently, five clinical trials are underway in the Ob/Gyn field and two trials are ongoing in other fields, all at varying stages. In each trial, a clinical team directed by the Development Planning Department and a study team, which is directed by the Clinical Development Department are working in tandem as "One Team" to advance development with the goal of winning regulatory approval.

As yet, the Group has only ever conducted clinical trials in Japan. However with an eye to licensing out products to overseas companies, the Development Planning Department will work even more closely with the Innovative Drug Discovery Division and Business Development Division on potential development strategies, and the Clinical Development Department lays the groundwork for conducting trials overseas.

While there will no doubt be new challenges going forward, it is my hope that the individuals in the Development Division and the division itself will surmount these challenges and grow further.



**Masaya Takanashi**  
Corporate Officer  
Development Division Director  
ASKA Pharmaceutical Co., Ltd.

### FY2024 Initiatives

For the Development Division, the biggest topic in FY2024 was the filing for regulatory approval of a contraceptive agent that had advanced to Phase III clinical trials. Slinda is believed to reduce the incidence of thrombosis, a risk associated with existing contraceptives, and it is already sold overseas. In FY2024, we consulted with the Pharmaceuticals and Medical Devices Agency on six trials, as the number of drug candidates increased and some existing candidates advanced to the next stage of development. Our arguments evidently proved persuasive for many of these projects, enabling us proceed with clinical trials. We

held two consultations regarding the relugolix combination tablet AKP-022, which we have positioned as a successor to RELUMINA. As a result, we were able to initiate a large-scale Phase III clinical trial in patients with uterine fibroids, and simultaneously proceeding with preparations for a Phase III clinical trial for endometriosis. This drug can be administered over a long period, and our hope is to bring it to patients in need as soon as possible.

The Development Division will continue working on pharmaceuticals that contribute not only to women's health but also to the whole society.

### Production Division

ASKA Pharmaceutical's Production Division has three bases: the Iwaki Factory, which is responsible for pharmaceutical manufacturing; the Head Office, which oversees the supply chain; and the Shonan Research Center, which undertakes pharmaceutical development and industrialization. We have instituted rigorous production control in order to ensure a stable supply of top-quality pharmaceuticals while also reducing costs.

The Iwaki Factory consistently produces high-quality products using GMP-compliant manufacturing processes, while the Head Office's Supply Chain Management Department is responsible for supply chain optimization through supply/demand adjustments and logistics management. The Shonan Research Center's CMC Departments are charged with enhancing formulation and analytical technologies, supporting a smooth transition from product development to commercial production. Under this arrangement, we are confident that each site can fulfill their role while also working together even more closely.

Environmental considerations constitute another important pillar of our business activities. We are actively engaged in initiatives for realizing a sustainable society, including reducing CO<sub>2</sub> emissions, installing energy-saving equipment, and properly disposing of waste.

Through these Production Division initiatives, ASKA Pharmaceutical will continue supporting people's health and lifestyles by fulfilling its quality, safety, and environmental responsibilities and providing a stable supply of pharmaceuticals that have earned the trust of society.



**Toshitaka Nakajima**  
Corporate Officer  
Production Division Director  
ASKA Pharmaceutical Co., Ltd.

### FY2024 Initiatives

In FY2024, the Production Division focused on lowering manufacturing costs, ensuring stable supply, developing new products, and reducing environmental impact. In terms of lowering manufacturing costs, Iwaki Factory achieved its target annual manufacturing cost ratio through cost reductions for additives and packaging materials, process improvements, a review of unprofitable products, and price optimization for active pharmaceutical ingredients and other materials. To ensure stable supply, we maintained stable inventories of core products by adjusting production plans as needed and obtaining second-source approval for active pharmaceutical ingredients. We

renovated the First Formulation Building and Second Formulation Building, strengthening production capacity and setting the stage for increasing output of new products. The CMC Departments worked steadily on filing for regulatory approval of the oral contraceptive Slinda and on the supply of investigational drugs for clinical trials, thereby advancing development. The Production Division also supported Vietnamese subsidiary Hataphar in obtaining GMP certification, thereby strengthening the Group's global supply network. Moreover, we worked to reduce CO<sub>2</sub> emissions through solar power generation, use of thinner packaging materials, and material recycling.

### ASKA's History: The Meaning of Animal Memorialization

#### "In an ideal society nothing should be thrown away"

Back in the early Showa Era, when it traded as Teikokusha, the Company was engaged in manufacturing foodstuffs and active pharmaceutical ingredients. At this time, the Company's founder, Yasohachi Yamaguchi, decided he could not abide the thought of animal organs being treated as waste (almost entirely discarded with only a small amount going toward fertilizer production) in resource-poor Japan, and embarked on a journey of mass-producing innovative hormone preparations with a strong commitment to creating valuable medicines from discarded organs.

In this manner, the concept of sustainability has underpinned the Company's operations right from the outset. In September 1930, Yasohachi Yamaguchi erected an animal-themed memorial tower on the grounds of the Omiya-cho Headquarters Factory (currently Omiya-cho, Saiwai-ku, Kawasaki-shi, Kanagawa), then the Company's main research and production facility. The spirit thus enshrined, namely, that "in an ideal society nothing should be thrown away," continues to inspire the Company to this day.

#### SUSTAINABLE DEVELOPMENT GOALS



Inscription on animal memorial tower  
(Currently located at the Iwaki Factory)



Animal memorial tower  
(Currently located at the Iwaki Factory)

#### Summary of text:

*Gist is dismissive. For many years, the Teikoku Hormone Research Institute has manufactured effective pharmaceuticals using animal organs that have been discarded by slaughterhouses. Converting waste into products that contribute to medicine is a momentous achievement akin to turning iron into gold, or a dead serpent into a living dragon, and the very embodiment of the idea that nothing should be thrown away in an ideal society. Moreover, humbly offering up the bodies of animals that have avoided a needless death constitutes an extraordinarily good deed that brings the state of perfect enlightenment sought in Buddhism closer. In the sutra known as the Kegon-kyo, making an offering means letting go of attachments and promising them to the world in a solemn and sacred manner. Animals, too, can part with their beloved bodies, entering the Pure Land and attaining enlightenment.*

Erected by Yasohachi Yamaguchi at the Teikoku Hormone Research Institute on Autumnal Equinox Day in September 1930.

### DX Initiatives

#### Message from Division Director in Charge of DX Promotion

The ASKA Pharmaceutical Holdings Group is employing digital transformation (DX) in the pursuit of sustainable growth, with the aim of enhancing operational efficiency and improving the quality of operations across all processes from drug discovery through to production, logistics, and sales.

Since FY2018, we have been strengthening our IT platform to support DX, progressively improving the IT infrastructure by integrating backbone systems, strengthening cybersecurity, and enabling remote work. This has enabled us to operate more flexibly and efficiently, and to respond nimbly to rapid changes in the operating environment.

Since FY2022, we have been using BI tools<sup>1</sup> to visualize and analyze internal data, enabling us to make quick and accurate decisions. We are also actively utilizing generative AI and RPA<sup>2</sup> to automate routine tasks and reduce workloads.

In FY2024, we focused also on developing DX human resources, appointing a DX Promotion Manager in each department and introducing a training and development program to improve employees' IT skills and ideas and insights regarding IT. In August 2025, the ASKA Pharmaceutical Holdings Group was recognized by the Ministry of Economy, Trade and Industry as a "DX-Certified Operator," evaluated as having established systems that meet or exceed specific standards in areas such as digital strategies aligned with management vision, organizational structure, IT governance, and human resource development.

We will take these initiatives further as we strive to improve the IT literacy and digital skills of all employees and undertake Company-wide digital transformation in pursuit of further growth.

1. Business Intelligence tools, used for collecting, analyzing, and visualizing corporate data from ERP and backbone systems
2. Robotic Process Automation: Automation of routine tasks using software robots



**Kiyohiko Tamura**  
Executive Corporate Officer in charge of DX Promotion  
Group Business Management Division Director  
ASKA Pharmaceutical Holdings Co., Ltd.



# Manufactured Capital and Intellectual Capital Strategies

## Intellectual Property Strategy

### Basic Principles

The ASKA Pharmaceutical Holdings Group positions intellectual property as an essential element of its business activities, based on its corporate philosophy of "Contribute toward the improvement of people's health and progress in society through the development of innovative products." We appropriately protect and utilize intellectual property resulting from our R&D to enhance corporate value, also respecting the intellectual property rights of third parties and engaging in fair competition in accordance with relevant laws and regulations. We seek to maximize the value of our pharmaceutical and animal health products by strategically

applying for and obtaining intellectual property rights following multifaceted analysis of both our own intellectual property and that of other companies. We are also actively engaged in open innovation through collaborations with industry, government, and academia, creating new value by leveraging our collective strengths. We seek to create and share high-value-added intellectual property that meets society's needs, by reflecting feedback from medical professionals, patients, and production site employees in our product development.

### Intellectual Property Activities

#### (1) Formulation and Promotion of Intellectual Property Strategy

The ASKA Pharmaceutical Holdings Group aims to create valuable products in the fields of medicine and animal health by formulating and promoting a strategy governing the intellectual property created through our R&D activities. We see intellectual property as an important asset from the standpoint of carving out a competitive advantage and enhancing corporate value. We seek to maximize the added-value of our products by obtaining and utilizing patent, utility model, design, trademark and other rights, and strategically managing the entire process from creation of the intellectual property to applying for, acquiring, and utilizing the intellectual property rights. We are also working

to optimize our intellectual property portfolio by using multifaceted analysis of both our own intellectual property and that of other companies to identify our technological uniqueness and advantages. As we expand our operations internationally, we seek to stabilize our business and strengthen our competitiveness in overseas markets by going about our activities in accordance with each country's intellectual property systems and regulations. We view intellectual property as a management resource and will be endeavoring to strengthen tie-ins with our R&D strategy as we build an intellectual infrastructure that supports sustainable growth.

#### (2) Improving Product Value through User-focused Business Activities

The Group's business activities are informed by the voices of medical professionals and patients who use our products, as well as those of our manufacturing personnel. We ask ourselves about the kind of value we can provide to society, seeking to enhance the quality of life (QOL) of as many people as possible through initiatives related to product R&D, product improvement, and product supply. We are proactive in taking on board feedback from the field. This enables us to create products that accurately address needs, and the knowledge and technology thus gained results in the creation of new intellectual property. We do not rely

solely on our own know-how but have adopted a multifaceted approach to problem-solving in collaboration with external research institutions, medical institutions, and other companies. With intellectual property created in this manner, we are not looking at simply acquiring rights; we think our products' reliability and market competitiveness stem from this intellectual property. We will continue to create value that reflects the needs of users, integrating our intellectual property strategy into the development of products needed by society.

#### (3) Co-creation of Intellectual Property through Open Innovation

The Group is actively engaged in open innovation through industry-government-academia collaboration, in order to deliver valuable drugs and products to society as quickly as possible. Even in areas where it would be difficult for us to go it alone due to the increasing sophistication of technologies and diversification of medical needs, we are working to create new value via collaborations that go beyond industry, nationality, and corporate size considerations. In the priority field of women's health in particular, we engage in co-creation of intellectual property by sharing our research

findings and knowledge with partner companies. Intellectual property generated through co-creation enhances our competitiveness, as it is properly protected and managed and contributes to our product differentiation and international expansion. Moreover, new perspectives gained through this kind of technology exchange foster a culture of innovation within the Company. Going forward, we will continue using intellectual property-based collaborations with diverse parties, with a view to creating new value and making a sustainable contribution to society.