

ASKA HD REPORT 2021

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ASKA Pharmaceutical Holdings Co., Ltd.

Total Healthcare Company
with a Strong Foundation
as a Specialty Pharma Company

For a Healthy Tomorrow and Future.

In April 2021, we transitioned to a holding company structure and made a new start as ASKA Pharmaceutical Holdings Co., Ltd.

Amid major changes in the economy, society and the operating environment in the pharmaceutical industry, we have selected a holding company structure centered on our existing businesses as it will enable us to develop related businesses spanning the entire healthcare market.

Based on the drug discovery capabilities we have cultivated over a 100-year history, we will continue taking on new challenges to contribute to the improvement of people's health and progress in society.

Corporate Philosophy

Contribute toward the improvement of people's health and progress in society through the development of innovative products

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Editorial Policy

ASKA Pharmaceutical Holdings Co., Ltd. issues the *ASKA HD Report* to communicate messages from management on the Company's management strategies and priority issues. It also includes comprehensive information on the Company's environmental, social and governance (ESG) initiatives and finances. Information based on the seven core subjects of ISO 26000, the international standard for social responsibility, and its classifications is presented on the Company's website.

ASKA HD Report 2021 introduces the initiatives of ASKA Pharmaceutical, ASKA Animal Health and ASKA Pharma Medical under the theme of elucidating what is entailed in ASKA Holdings' aim of becoming a total healthcare company. In producing this report, we have integrated the opinions and inquiries of our stakeholders to provide a thorough overview.

Note on Forward-Looking Statements

Information on the Group's business outlook and other forward-looking statements presented in this report are based on the judgment of the Group's management based on various information at the time of publication. Please be aware that actual results may differ significantly from the current outlook due to changes in market trends, economic conditions or other factors.

In our quest to provide highly specialized products and services, we will implement management in which contribution to society and Group growth are one and the same.

Takashi Yamaguchi

President, Representative Director
ASKA Pharmaceutical Holdings Co., Ltd.



Transition to a Holding Company Structure in Consideration of a Rapidly Changing Environment

In April 2021, we took a new step forward as ASKA Pharmaceutical Holdings. The context for our introduction of a holding company structure was the 5-to-10-year cycle of substantial change in the business environment of the pharmaceutical industry. Especially in recent years, global trends have been accelerating and becoming harder to predict. The prolonged COVID-19 pandemic and the new, off-year revisions of National Health Insurance (NHI) drug prices that began in fiscal 2021 are now having a major impact on the industry in Japan. In response to these rapid changes, we have selected a holding company structure so we can make

flexible decisions based on risks and opportunities for our entire Group.

This new structure will clearly separate management and execution to further accelerate the development of each business. I want all our stakeholders to be aware of our strong determination to take on new challenges toward the goal of maximizing Group value. In addition, under the holding company structure, each operating company will maintain a healthy sense of tension as it strives to improve its performance with capabilities backed by a high level of expertise.

Aiming to Become a Total Healthcare Company

Our new challenge is to expand our business beyond prescription pharmaceuticals to related fields and overseas markets, thus making a broader contribution to people's health and quality of life. ASKA Pharmaceutical, the core company of the Group, currently specializes in the three areas of internal medicine, Ob/Gyn and urology with a focus on hormone preparations and is working to strengthen its competitiveness as a specialty pharma company. Expanding our focus from this core company, we have established ASKA Animal Health, which conducts research and development, manufacturing, and sales of veterinary medicines and feed additives, and ASKA Pharma Medical, which contributes to testing and preventive medicine using the latest hormone measurement technology. Going forward, we aim to become a total healthcare company covering areas from prevention, testing and diagnostics to treatment and prognosis. The businesses conducted by the three Group companies have all been built upon research and development platforms in specialized fields, production technologies and information provision capabilities that have been cultivated over periods ranging from decades to a century. We believe that other companies cannot easily enter these fields. We will use our transition to a holding company structure as an opportunity to draw up a scenario for generating synergies and further raising our competitive advantage in the industry by stepping up strategic collaboration and cooperation among the three companies.

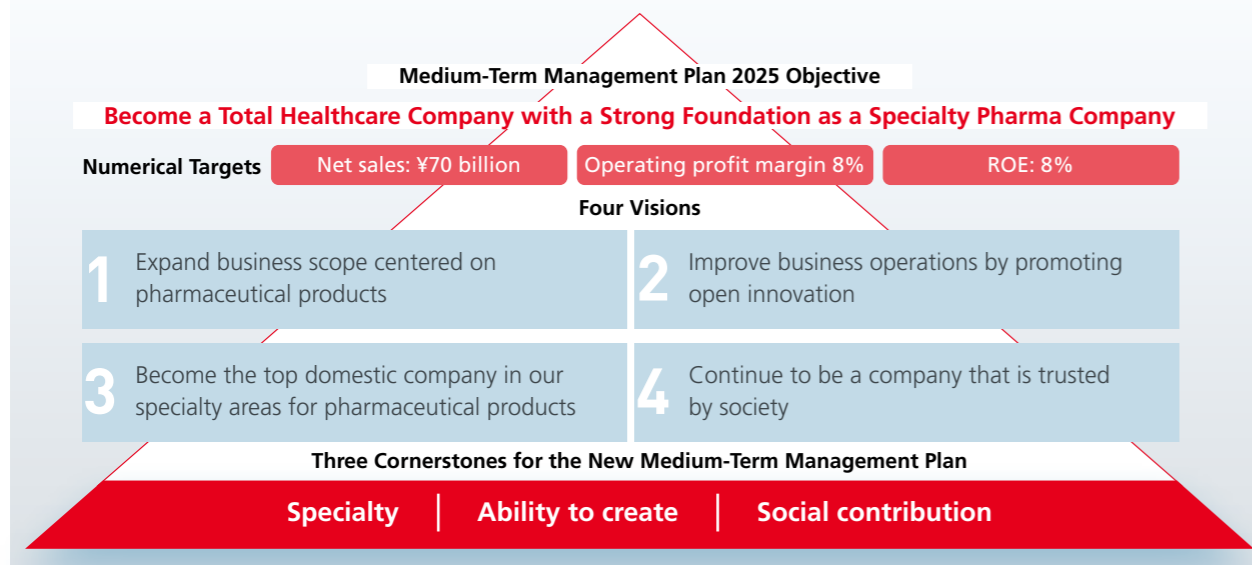
We believe that the kinds of social contributions that only a pharmaceutical company can make will be important to the process of realizing our goal of becoming a total

healthcare company with a strong foundation as a specialty pharma company. Some examples include addressing people's desire to maintain and improve their health and raise their quality of life; easing the difficulties unique to women facing ever-expanding opportunities to play an active role in society; ensuring both production efficiency and safety for farmers working in the fields of livestock and fishery products; and maintaining the health of companion animals, who can be said without exaggeration to be considered virtually family members these days. The ASKA Pharmaceutical Holdings Group takes pride in being able to challenge these themes and stay attuned to the concerns of numerous people and medical professionals as it clearly sets forth a path to resolving them. We will continue to carry out management in which contribution to society and Group growth are one and the same.

Another focus for growing sustainably as a total healthcare company will be global expansion. We are proactively developing capital alliances and technical support capabilities with local companies in the high-potential Asian market.

We will also work to cultivate and popularize new products for which we expect growth, such as pharmaceuticals and supplements for companion animals. In the future, we will continue to target multifaceted growth by rethinking our approaches in ways such as out-licensing original products that have undergone clinical trials and approval reviews overseas, then reimporting them into Japan.

Foundation for Achieving ASKA Pharmaceutical Holdings' Medium-Term Management Plan 2025



We have formulated ASKA Pharmaceutical Holdings Medium-Term Management Plan 2025 (hereafter, "Medium-Term Management Plan 2025"), with fiscal 2025 as its final year. We view these five years as a period for solidifying the foundation of our holding company system. To begin with, we will foster an organizational culture of confidence and pride by reminding employees of each Group company of the extent of their business's positive impact on society. In such a culture, I want each employee to improve their core competencies, leading to higher work quality and lively interchange within the Group. We are also reviewing some aspects of our human resource development system and training programs as we flexibly

address changes in people's lifestyles and ways of doing business caused by the COVID-19 pandemic.

The three cornerstones of the foundation for carrying out Medium-Term Management Plan 2025 are specialty, ability to create, and social contribution. Our prescription pharmaceutical business centered on hormone preparations, which is the Group's core business, is something only we can offer. Reaffirming this strength, we have made "specialty" the first cornerstone for raising the level of our new drug creation and business development capabilities. The second, "ability to create," refers to our human resources and organizations that enable the continuous creation of new drugs and rollout of business overseas. For the third, "social contribution," I consider it important to remember that our products and services protect the health of humans and animals, thereby providing indispensable support for everyday life, and to take that fact seriously in our approach to work each day. These three cornerstones of our foundation will support the Group's framework for responding to expected changes in the environment of the medical and healthcare industry over the medium to long term. Based on this foundation, Medium-Term Management Plan 2025 was designed with four visions¹ and seven strategies.¹

In the five years starting from fiscal 2021, we will further develop the alliance activities that we have been conducting since the previous medium-term management plan. Since April 2020, we have stepped up open innovation with companies inside and outside our industry at our new research base at Shonan Health Innovation Park (Fujisawa City, Kanagawa Prefecture). In addition to creating new drugs in our specialty areas of internal medicine, Ob/Gyn and urology, we will collaborate with



various companies in the fields of veterinary medicine and healthcare to develop services and products that

make a significant contribution to health.

1. ▶ See pages 8-11 for details.

Strengthening ESG Management

Medium-Term Management Plan 2025 has set promotion of ESG management as a key measure for realizing our Corporate Philosophy of "Contribute toward the improvement of people's health and progress in society through the development of innovative products." In April 2021, we began by establishing the ESG Committee in tandem with the transition to a holding company structure. The committee will play a central role in appropriately examining, identifying and addressing the material issues to be dealt with by the entire Group. At the same time, we will strive to continue putting our Corporate Philosophy into practice, improve corporate value over the medium to long term and build relationships of trust with our stakeholders.

From the perspective of the environment—the "E" in ESG—we are working toward specific numerical targets we have set for reducing energy consumption, promoting reduction of waste emissions and reuse, and controlling emissions of substances that affect air and water quality in our production and all other business activities. For the element of society (S), we intend to continue the unique activities of each of our businesses based on their approach of contributing to society. Examples include

contributing to people's health and quality of life with hormone-related substances. In particular, we recognize that one of our most important duties to society is to utilize our treatments in the Ob/Gyn field and the information communication capabilities of Mint+ Health Lab for Women, a new organization we established in 2020, to support women's health and productive lifestyles in accordance with their life stages. Moreover, in keeping with our commitment to providing pharmaceuticals for which needs are high regardless of the size of the market, we want to address unmet medical needs for diseases for which no effective treatment has yet been found.

For corporate governance (G), we have set up functions within ASKA Pharmaceutical Holdings to control governance throughout the Group and established a structure that enables us to conduct business operations under a unified policy. We are also focusing on recruiting and training human resources with an emphasis on diversity, and during Medium-Term Management Plan 2025 we will promote the creation of workplaces in which diverse human resources can play an active role regardless of age or attributes.

What We Should Do in the "Age of Choice"

The present times have been called the "VUCA² Age." With advances in technology and the rapid increase in digital data generated by individuals and businesses, the world has become more complex and the future harder to predict. In this environment, I view these days of various viewpoints and interpretations depending on the individual as an "Age of Choice." In today's Japan, many paths are available whenever an individual or company takes some action. Naturally, a company such as ours will not be able to fulfil its responsibilities to its shareholders if we only make choices where success is likely but strong growth cannot be expected. In other words, important situations require us to make various choices, including decisions to take risks appropriately and boldly in line with clear objectives and strategies.

For individuals, on the other hand, it has become very difficult to make the right choice in today's society, which is inundated with a jumble of good and bad information. People are becoming more likely to take too many risks

or to make choices based on erroneous information. If such a choice involves pharmaceuticals or vaccines, it can threaten health or, in the worst case, life. Therefore, companies such as ours must fulfill their role of encouraging the proper selection and use of pharmaceuticals based on high ethical standards. For this reason, I am convinced that each employee's awareness and confidence backed by expertise will be of greater value than ever.

For the next five years, we will take on challenges toward the vision set forth in Medium-Term Management Plan 2025. We would appreciate receiving your evaluation of our progress on the plan's measures and our achievements each year, and feedback on how you see our position as we move forward as the years go by. We ask all our stakeholders for their continued understanding and support.

2. VUCA: An acronym for Volatility, Uncertainty, Complexity and Ambiguity. The term expresses the current perception of an age of social and economic circumstances in the face of unpredictable forces.

Value Creation Process

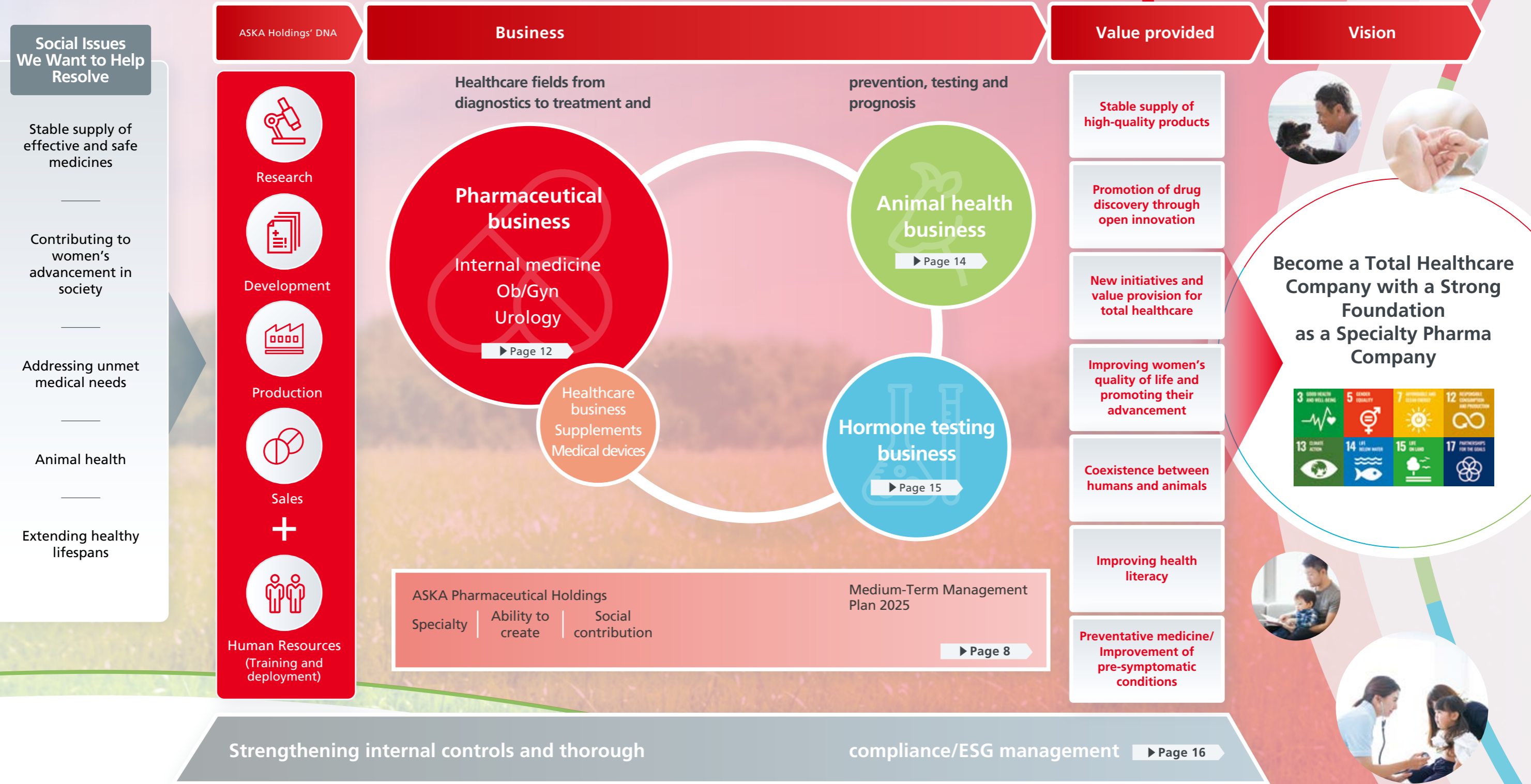
ASKA Pharmaceutical Holdings aims to become a total healthcare company with a strong foundation as a specialty pharma company through its pharmaceutical business, animal health business, and hormone testing business, using a value chain imbued with ASKA's DNA, the source of its growth for over 100 years. Through the value we create, we will fulfill the pharmaceutical industry's responsibilities toward contributing to the resolution of social issues.



Corporate Philosophy: Contribute toward the improvement

of people's health and progress in society through the development of innovative products

Value creation cycle



In conjunction with the inauguration of ASKA Pharmaceutical Holdings, we have formulated ASKA Pharmaceutical Holdings' Medium-Term Management Plan 2025. Looking ahead five years to FY2025, we have set forth four visions and will carry out seven strategies in our aim to become a total healthcare company.

Review of ASKA PLAN 2020

Although we fell short of the targets of our previous medium-term management plan due to factors including a drastic reform of Japan's National Health Insurance (NHI) drug pricing system and major changes in the market for generics and other products, net sales reached a record high of ¥55.1 billion in FY2020, the final year of the plan. In addition, due to our profit structure reforms we were able to significantly increase the sales ratio of brand-name drugs from 25.0% in FY2015 to 46.8% in FY2020. At the same time, we improved the cost of sales ratio from 60.3% in FY2015 to 54.0% in FY2020 by conducting structural reforms. We worked to enhance our human resources by revising our personnel system and hiring mid-career employees, among other measures. We concentrated our research functions at Shonan Health Innovation Park to strengthen our drug discovery functions through open innovation. Under our new structure, we will continue to work on two of the plan's four challenges: strengthening the new drug development business, particularly by restructuring drug discovery functions; and increasing product value and optimizing as well as maximizing profit through post-marketing product development.

External Changes

- ◆ Shrinking domestic prescription pharmaceutical market
- ◆ Impact of the COVID-19 pandemic
- ◆ Advancement of women in society
- ◆ Drastic reform of the drug pricing system (annual NHI price revisions, etc.)
- ◆ Pharmaceutical quality issues
- ◆ Advancement in medical technologies and expansion of medical needs

R&D	Sales and Marketing	Manufacturing and Distribution
<ul style="list-style-type: none"> ■ Diversification of research styles ■ Increasingly complex clinical trial strategy <ul style="list-style-type: none"> • Thorough priority management of portfolios • Aggregate and distribute research resources • Review of development portfolio • Online clinical trial follow-up 	<ul style="list-style-type: none"> ■ Review of sales strategy ■ Accelerating digitalization ■ Changing customer needs <ul style="list-style-type: none"> • Online conferences and lectures • Establishment of an online support system 	<ul style="list-style-type: none"> ■ Visualization of the supply chain ■ Review suppliers globally ■ Establishment of a flexible and robust production system ■ Stable supply and quality assurance

Responding to anticipated medium-to-long-term changes in the business environment

ASKA Pharmaceutical Holdings' Medium-Term Management Plan 2025

Four Visions

- 1 Expand business scope centered on pharmaceutical products
- 2 Improve business operations by promoting open innovation (from R&D to production and sales)
- 3 Become the top domestic company in our specialty areas for pharmaceutical products
- 4 Continue to be a company that is trusted by society

The Foundation for Formulating the New Medium-Term Management Plan

Specialty

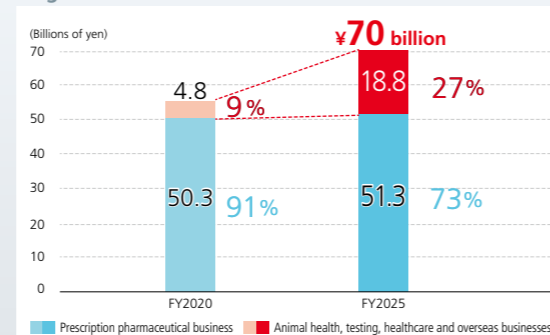
Ability to create

Social contribution

7 Strategies

- Net sales: ¥70 billion
- Operating profit margin: 8%
- ROE: 8%

Targeted Net Sales



Sustainable Growth and Seven Strategies

Under the new holding company structure, we will build an organization for continuing to take on challenges amid drastic changes in our operating environment. Based on the technologies and track record that ASKA Pharmaceutical has cultivated over many years, we will conduct our business activities more broadly, more deeply and more quickly.

1 Enhance Corporate Value by Strengthening Initiatives in the Specialty Areas

Specialty Social contribution

We consider Ob/Gyn, thyroid and unmet medical needs to be our three specialty areas and aim to increase corporate value by concentrating our resources to invest in these areas.

Becoming a Leader in the Ob/Gyn Field

ASKA Pharmaceutical has already established a solid position in the Ob/Gyn field. We will further enhance our expertise as a leader in the field to contribute to society by supporting the creation of an environment in which women can play an active role.

To that end, our top priority is to further expand our lineup of Ob/Gyn products for women ranging from puberty to their reproductive years, menopause and old age. In addition to popularizing our pharmaceuticals, we will conduct activities in various formats to raise awareness of women's health and illnesses.

Japan's Ob/Gyn market is projected to grow to

¥82.6 billion* in FY2025, and the Group is stepping up its efforts for uterine fibroids and endometriosis with the aim of more than ¥20 billion in overall sales.

* Fuji Keizai Co., Ltd., Ethical Drug Data Book No. 4
Forecast for 2021 is ¥73.9 billion.

Ob/Gyn Field Growth Factors

- Penetration of RELUMINA and other products into the uterine fibroid and endometriosis market
 - ▶ See page 13 for more information on RELUMINA.
- Jemina Tablets and Riona Tablets co-promotion
- Expansion of lineup through in-licensing, etc.
- Dissemination of accurate information through disease awareness activities

Ob/Gyn Products by Life Stage

Early childhood	Puberty	Reproductive age	Menopause	Old age
		<ul style="list-style-type: none"> ■ Oral contraception: LF111, ANGE, NORLEVO 	<ul style="list-style-type: none"> ■ Menopause: HOLIN 	
		<ul style="list-style-type: none"> ■ Iron deficiency anemia: Riona (Co-promotion) 		
		<ul style="list-style-type: none"> ■ Menstrual disorders: PLANOVAR 		
		<ul style="list-style-type: none"> ■ Dysmenorrhea: Jemina (Co-promotion), Pyridoxamine ■ Endometriosis: RELUMINA*, LEUPRORELIN ■ Uterine fibroids: Frewell (AG), Ulipristal 		
		<ul style="list-style-type: none"> ■ Infertility: HMG Intramuscular Injection, LUTEUM, uFSH Injection, SEXOVID, GONATROPIN 		
		<ul style="list-style-type: none"> ■ Miscarriage, Premature birth, Childbirth: Magsent, RITODRINE, MAGNESOL, ATONIN-O 		
		<ul style="list-style-type: none"> ■ STD/Infection: Cervical dysplasia drugs, Rapid SP Chlamydia (Co-promotion) 		

Legend: Under development (blue), New products (yellow), In-licensed products (orange), Option agreement (purple), Existing products (grey)

* An additional indication has been applied for RELUMINA for endometriosis

Contributing to Medical Care by Responding to Unmet Medical Needs

RIFXIMA is listed as "Recommendation: Strong" and "Evidence level: A" in *Evidence-Based Clinical Practice Guidelines for Liver Cirrhosis 2020*.* In addition to disseminating the latest information on the guidelines, we are focusing on activities to raise awareness of the disease. We are also proceeding with clinical

trials for the additional indications of pediatric hepatic encephalopathy and Crohn's disease, and aim for sales of ¥6 billion in FY2025 and to make it a growth driver in the field of internal medicine.

* *Evidence-Based Clinical Practice Guidelines for Liver Cirrhosis 2020* (Revised Third Edition), edited by The Japanese Society of Gastroenterology and The Japan Society of Hepatology (Published by Nankodo Co., Ltd.)

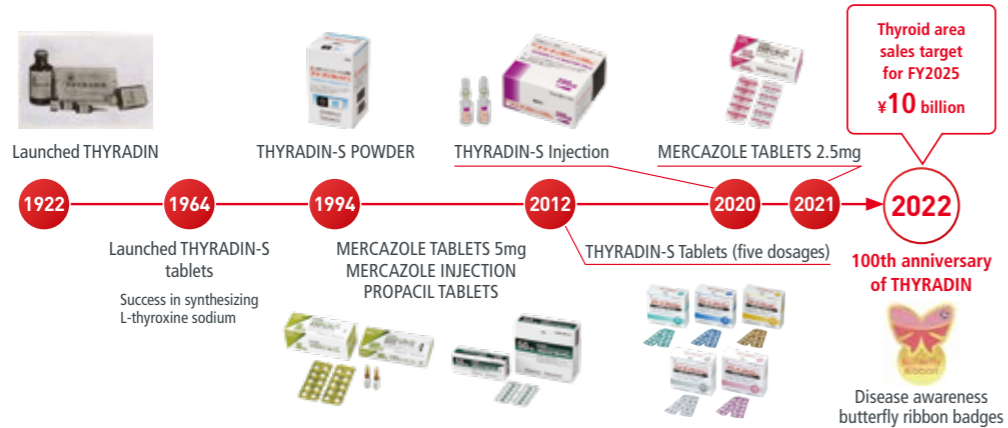
Further Enhancing a 100-Year Track Record in the Thyroid Area

We are expanding our product lineup in the thyroid area, which includes the hypothyroidism treatment THYRADIN that we launched in 1922 and the hyperthyroidism treatments MERCAZOLE and PROPACIL. The market for thyroid disease treatments continues to expand as medical advances improve

testing accuracy to identify potential patients. Based on 100 years of research and results in this area, we will contribute to medical care by providing a stable supply of treatments and extensive information with the aim of sales of ¥10 billion in FY2025.

Initiatives in the Thyroid Area

- Secure stable supply
- Continue to raise awareness of diseases
- Cooperate with related academic societies
- Respond to medical needs (wide-ranging product lineup)
- Strengthen the testing business of ASKA Pharma Medical



2 Continuously Create New Drugs through Advanced Drug Discovery

Specialty Ability to create

Expanding the Pipeline and Strengthening Alliances

In 2020, we relocated our entire research center to the Shonan Health Innovation Park and restructured our drug discovery functions as the new Shonan Research Institute. The Shonan Health Innovation Park brings together pharmaceutical companies, drug discovery venture companies and support services, medical device manufacturers and others with the aim of proactively conducting drug discovery through open innovation.

As of May 2021, we have applied for manufacturing and marketing approval for TAK-385 (relugolix) for

the treatment of endometriosis in the Ob/Gyn field, aiming for a 2022 launch. We also plan to move three projects at the preclinical stage to clinical trials as soon as possible, including RIFXIMA for pediatric hepatic encephalopathy and Crohn's disease, and will work to expand our pipeline.

In research and development, we will expedite drug discovery and promote out-licensing and in-licensing of products by strengthening alliances with companies outside the Group.

Development Pipeline (As of May 2021)

Changes from the previous report

Development code (Generic name)	Indication	Phase I	Phase II	Phase III	Application	Approval
CDB-2914 (ulipristal acetate)	Uterine fibroids				Filed	
TAK-385 (relugolix)	Endometriosis				Filed	
LF111 (drospirenone)	Contraception		Phase III Ongoing			
L-105 (rifaximin)	Hepatic encephalopathy (pediatrics)			Phase III Ongoing		
L-105 (rifaximin)	Crohn's disease		Phase I Completed			
AKP-009 (ludaterone acetate)	Benign prostatic hyperplasia		Phase II Ongoing			

3 Overseas Operations

Ability to create

We will work to capture new markets, with an initial focus on establishing a business in the growing Asian market. Our diverse joint projects include manufacturing and sales with the Vietnamese pharmaceutical company Ha Tay Pharmaceutical (Vietnam's second-largest pharmaceutical company in terms of sales), with which we have entered a strategic partnership through a capital tie-up in 2020. As the first initiative for this project, we have started preparations for a new factory that conforms with PIC/S GMP, with



Image of completed factory in Vietnam (Start of construction in November 2021, start of operation scheduled in July 2023)

plans to establish a pharmaceutical supply system that meets international standards in FY2023. We will also further reinforce the partnership between the two companies through dynamic interaction.

In China, we took our first step in East Asia by signing an exclusive license agreement with Harbin Pharmaceutical Group Co., Ltd. (China's tenth-largest pharmaceutical company in terms of sales) for our original drug ALTAT, a treatment for gastritis and gastric ulcers. Going forward, we will proactively work to roll out products in East Asia and contribute to the improvement of healthcare in Asia.

Message from the Head of the International Business Division

Hiroyasu Nishioka

Director, Executive Corporate Officer, Head of International Business Division, In charge of Production Division ASKA Pharmaceutical Co., Ltd.



All members of the International Business Division are working to start and expand business overseas to contribute to the Group's "ability to create" in the hope of growing into a business division that supports the company's performance by FY2025. From our base at Ha Tay Pharmaceutical in Vietnam, we will first expand our business throughout Vietnam, then to other ASEAN countries and Southeast Asia. Going forward, we will aim to secure steady profits from our products, especially in East Asia.

4 Provide New Value to Realize "Total Healthcare"

Specialty Ability to create Social contribution

The Group will engage in a wide range of healthcare businesses that work cooperatively with each other, encompassing animal as well as human health.

ASKA Animal Health conducts business centered on veterinary medicines and ASKA Pharma Medical conducts business centered on testing.

▶ See page 14 for ASKA Animal Health and page 15 for ASKA Pharma Medical

In addition, ASKA Pharmaceutical's healthcare business develops and sells supplements and testing equipment.

5 Improve Operational Efficiency, Cut Costs, and Reinforce Our Financial Base

Ability to create

To drive our various initiatives leading up to FY2025 and achieve results, we will further improve operational efficiency, cut costs and reinforce our financial base.

We will improve the operating profit margin by increasing the sales ratio of brand-name products and reviewing selling, general and administrative (SG&A) expenses. We also intend to achieve a stable supply of high-quality products and reduce the cost of sales ratio to 50% or lower in FY2025.

To improve operational efficiency, we will upgrade our IT environment and roll it out to sales, R&D and production sites, in addition to conducting initiatives utilizing digital transformation (DX), including the introduction of robotic process automation (RPA).

6 Foster an Organizational Culture that Emphasizes thorough Compliance and Accountability

Social contribution

To be a company that continues to be trusted, not just by our business partners but by a wide range of stakeholders, we will instill thorough compliance throughout the Group. We will also re-examine our domestic and overseas supply chains to ensure that we maintain a stable supply of high-quality products. By separating management and execution through our holding company structure, we will strengthen our supervisory functions for business execution.

▶ See page 17 for more information on Corporate Governance

7 Develop Human Resources to Realize Growth Strategies

Specialty Ability to create

To reliably implement our various strategies for FY2025 and achieve our targets, the human resources who put them into practice must play an active role. To respond to the diversification of our business and alliance partners, as well as diversification in our business itself, we will promote and develop human resources with competencies in global business and IT.

▶ See page 18 for more information on Human Resources

Message

We will take a new step forward toward our next 100 years.

Sohta Yamaguchi
President and Representative Director
ASKA Pharmaceutical Co., Ltd.

ASKA Pharmaceutical Co., Ltd. celebrated its 100th anniversary in 2020 and inaugurated a holding company structure in April 2021. As we took this new step forward, I was appointed President and Representative Director. I can feel your expectations as well as the magnitude of this responsibility.

ASKA Pharmaceutical's history began with research and development focused on the potential of hormone preparations, and today we contribute to the medical community as a specialty pharma company emphasizing the three areas of internal medicine, obstetrics and gynecology (Ob/Gyn), and urology. We intend to remain an industry pioneer, generating innovations for unresolved issues in our three core areas and exploring potential markets.

Japan's pharmaceutical industry is facing the challenge of annual reductions in National Health Insurance (NHI) drug prices due to cutbacks in medical expenditures as part of reforms of the social security system. Therefore, from fiscal 2021, we will reduce manufacturing costs and utilize digital transformation (DX) to improve operating efficiency company-wide. At the same time, we are focusing on new drug development to address unmet medical needs and offer new treatment methods, and have set a target of increasing the proportion of new drugs to 70% of total sales by fiscal 2025. In addition to in-house development, we will promote joint research and alliance activities in Japan and overseas to expand our unique development pipeline. We are also rolling out our business to overseas markets, mainly in Asia.

We will harness management resources that contain our unique DNA, and in so doing continue to take on challenges that go beyond the conventions of the past.



Initiatives in Core Areas

RELUMINA Tablets (Relugolix): Therapeutic Effects on Uterine Fibroids and Outlook

Development History

RELUMINA Tablets 40 mg are a uterine fibroid treatment developed by ASKA Pharmaceutical following a licensing and development agreement for the compound relugolix, which was created by Takeda Pharmaceutical Company Limited. Because female sex hormones promote the growth of uterine fibroids, a drug that suppresses the secretion of these hormones (a GnRH¹ antagonist) is used for treatment. Conventional formulations for GnRH antagonists are injections and nasal spray, which cause a transient increase in the female sex hormones that promote uterine fibroid growth at the initial stage of administration. Therefore, a formulation that can be taken orally and does not increase female sex hormones was sought. RELUMINA was developed to address this need, and after its efficacy and safety were confirmed in clinical comparison studies with conventional injections the product was launched in March 2019.



Market Potential

Uterine fibroids are growths that are unique to women and have a high rate of incidence, with approximately 2 million patients at present in Japan. In addition to surgery, various drug treatments are used, and an estimated 120,000⁴ patients are being treated with a GnRH antagonist.

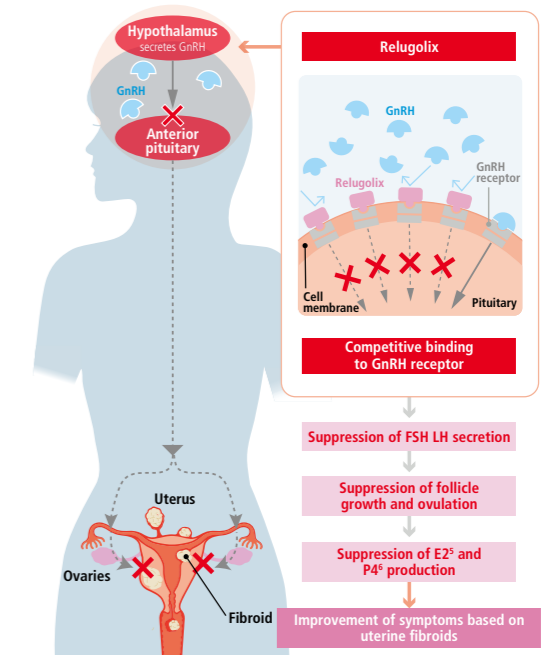
An estimated 55,000 of these patients have been prescribed RELUMINA, which has grown to account for about 46% of the GnRH antagonist market in less than two years after its launch. We will continue to provide information so that RELUMINA can be of use to more patients for the treatment of uterine fibroids.

Evaluation by Medical Practitioners

Since RELUMINA can be administered orally and improves symptoms quickly, it has been positively evaluated for the treatment of uterine fibroids, including preoperative administration. This is demonstrated by the product's adoption at all 82 university hospitals in Japan, and the steady switchover from the conventional injections and nasal sprays mentioned above.

Mechanism of Action

RELUMINA is a GnRH antagonist that directly blocks the action of a hormone (GnRH) secreted from the hypothalamus. When the action of GnRH is blocked by RELUMINA, the secretion of hormones that control follicle growth and ovulation (FSH² and LH³) from the pituitary gland is suppressed. As a result, there is no transient increase in the blood level of female sex hormones secreted from the ovaries, which quickly drops to the same level as menopausal women. This mechanism of action causes uterine fibroids to shrink and temporarily stops menstruation, improving symptoms such as menorrhagia, anemia and pain caused by uterine fibroids.



1. Gonadotropin-releasing hormone
2. Follicle-stimulating hormone
3. Luteinizing hormone
4. As of 2020
5. Estradiol
6. Progesterone

Outlook

In January 2021, an application for the additional indication of endometriosis was submitted for RELUMINA, and approval is expected in the first half of 2022. Endometriosis has attracted attention as a disease that causes menstrual pain and infertility, with an estimated 800,000 patients in Japan. Endometriosis is often associated with uterine fibroids, and the number of patients with both is estimated to be about 200,000. We forecast annual sales of RELUMINA of ¥10 billion or more during the period of the Medium-Term Management Plan.

ASKA Animal Health

Message

Through our two areas of business, we aim to create a society where people and animals can coexist.

ASKA Animal Health Co., Ltd. operates under the corporate philosophy of "contributing to the creation of a society where humans and animals can coexist by protecting animal health and food safety." The animal health business of ASKA Pharmaceutical, which celebrated its 100th anniversary in 2020, was spun off as a separate company in 2013.

We conduct business in the two areas of veterinary medicines and animal feed additives. By maintaining or improving the productivity of the livestock and fishery products that underpin Japan's food self-sufficiency, and by conducting research, development, manufacturing, import and sales of veterinary medicines and other products that are useful for maintaining the health of dogs, cats and other companion animals, we contribute to the operations of farmers and veterinary professionals, as well as the peace of mind of animal owners. Efforts in the field of livestock and fisheries focus on our strengths in breeding, immunity and nutrition. We work to improve livestock and fishery productivity using hormone preparations for breeding and amino acids, which are our main products. As a member of the ASKA Pharmaceutical Holdings Group, we will work for the development of the Group and the realization of a vibrant society based on the Group's Corporate Philosophy to "Contribute toward the improvement of people's health and progress in society through the development of innovative products."

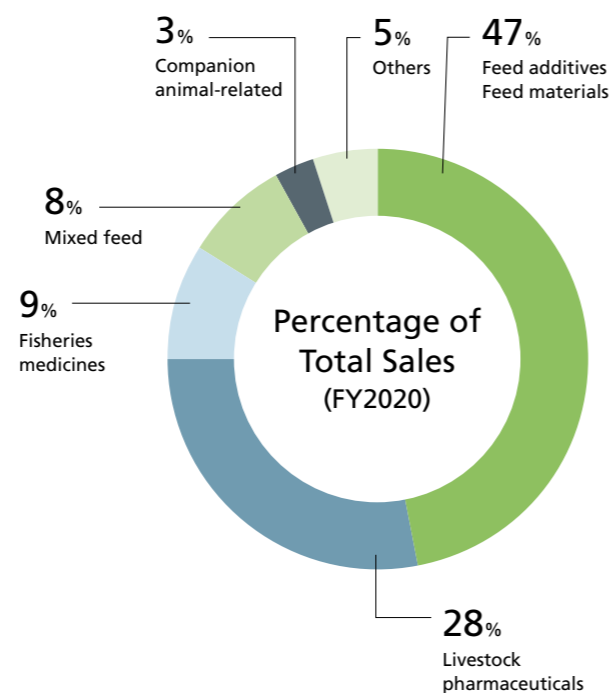
Fumiyoshi Yamaguchi
President and Representative Director
ASKA Animal Health Co., Ltd.



Initiatives

To successfully carry out the Medium-Term Management Plan by fiscal 2025, we will launch and cultivate five or more new products in the fields of livestock, fisheries and companion animals, and conduct measures with a view to the rapidly growing overseas market. As a company that contributes to a sustainable society by meeting the needs of the veterinary medicines, feed, livestock and fishery industries, we aim to exceed ¥6 billion in sales in fiscal 2025.

As we accelerate the development of products that meet the needs of the veterinary medicines, feed, livestock and fishery industries, we will also further the development of a system for continuous and stable supply, and the training or acquisition of human resources who will be responsible for the future of ASKA Animal Health. We will also create synergies and maximize value by sharing technologies and know-how among Group companies and by encouraging personnel exchanges.



ASKA Pharma Medical

Message

We will contribute to a vibrant, healthy society using our unique technologies.

Based on its corporate philosophy of "contributing to the creation of a vibrant, health society through the latest measurement technologies," ASKA Pharma Medical Co., Ltd. conducts operations with a focus on the testing business. As a member of the ASKA Pharmaceutical Holdings Group, we leverage our advanced technologies and extensive know-how to contribute to a wide range of fields including basic research, clinical research and diagnostics, centered on measurement of steroid hormones and other bioactive substances. We will provide strong support for pharmaceutical development and clinical research utilizing a liquid chromatography-tandem mass spectrometry (LC-MS/MS) measurement method with improved accuracy and sensitivity that was developed using our original technology.

Furthermore, to play an important part in "becoming a total healthcare company with a strong foundation as a specialty pharma company," which is the vision of ASKA Pharmaceutical Holdings Medium-Term Management Plan 2025, we intend to expand into a wide range of new testing businesses including preventive medicine, businesses related to improving pre-symptomatic conditions and self-medication, in addition to our conventional hormone measurement business for research organizations. Through its sincere commitment to meeting diversifying needs for testing, ASKA Pharma Medical aims to offer new value and maximize corporate value.

Junichi Saito
President and Representative Director
ASKA Pharma Medical Co., Ltd.



Initiatives

As new business initiatives, we are focusing on hair hormone measurement and thyroid disease testing.

In the hair hormone measurement business, we have established a method for measuring the various steroid hormones in hair and adopted it in a cohort study* and other research as a non-invasive, highly convenient measurement method. In addition, in collaboration with ASKA Pharmaceutical, we have developed a hair hormone level measurement kit for androgenetic alopecia (AGA).

In the thyroid disease testing business, we are working on the development of biomarkers in the area of thyroid disease, which is one of the Group's strengths.

* An observational research method for studying the relationship between disease factors and onset

Endogenous Hormone Microanalysis (Steroid hormones, thyroid hormones, etc.)

Our Technologies

- ✓ High sensitivity analysis of steroid hormones
- ✓ Multi item simultaneous analysis of steroid hormones
- ✓ Analysis of a wide range of matrices

Study sample commissioned business

Hair growth diagnostics

Thyroid disease testing business

Collaboration with ASKA Pharmaceutical's Healthcare Business



Establishing a structure for the entire Group to contribute to creating a sustainable society for our next 100 years

Atsushi Maruo

Executive Director, Representative Director
ASKA Pharmaceutical Holdings Co., Ltd.

Today, environmental, social and governance (ESG) initiatives are indispensable for improving corporate value and an important yardstick for evaluating companies. This section introduces the ESG management policy of the ASKA Pharmaceutical Holdings Group and its system for carrying it out.

Start of a New Medium-Term Management Plan and Strengthening ESG Management

In 2020, ASKA Pharmaceutical celebrated its 100th anniversary. In April 2021, we established ASKA Pharmaceutical Holdings Co., Ltd. and announced our aim to become a total healthcare company in the inaugural ASKA Pharmaceutical Holdings Medium-Term Management Plan 2025. Specifically, Group companies will work together to tackle a series of issues in the healthcare field from prevention, testing and diagnostics to treatment and management of prognosis. To achieve sustainable growth for the next 100 years under our new structure, it will be crucial for us to proactively address non-financial issues such as ESG in parallel with financial targets for sales and profits. ASKA Pharmaceutical Holdings has set forth a Corporate Philosophy of "Contribute toward the improvement of people's health and progress in society through the development of innovative products." To swiftly make this corporate philosophy a reality, we will work as a group to strengthen ESG management.

Looking at each of the elements of ESG, starting with the environment, we hold regular Group-wide meetings on the topic of overall environmental management of our efforts to reduce our environmental impact. We are especially focused on the issues of conserving energy and reducing emissions of chemicals, greenhouse gases, wastes and other substances at ASKA Pharmaceutical's Iwaki Factory. For society, our core prescription pharmaceuticals business is based on the stable supply of high-quality, innovative products. In addition to providing pharmaceuticals, we conduct awareness-raising activities, particularly in the Ob/Gyn field, with the intention of contributing to women's advance in society and diversification. For governance, we will strive for appropriate cooperation with our various stakeholders.

Establishing an ESG Promotion System

The objective of the ESG Committee we established in April 2021 is to formulate ESG strategies and promote and assess activity plans so that the entire Group can contribute to creating a sustainable society. Based on discussions at Group companies and across the Group, the ESG Committee identifies material issues and formulates action plans. The important point here is for each employee to have a deep understanding of these material issues and to carry out independent activities. To that end, we will step up our activities by setting KPIs for resolving issues in each department.

The new market segments of the Tokyo Stock Exchange will come into effect in April 2022. Our Group meets the standards for maintaining its listing on the Prime Market, but a higher level of governance will be required of such companies going forward. We are already working to improve the functions of the Board of Directors by establishing independent nomination and compensation committees and having outside directors account for half of the members of the Board of Directors, among other measures. However, to achieve further growth we must incorporate diverse perspectives and values through methods such as promoting greater diversity in our core personnel. We also intend to step up our initiatives for sustainability and will steadily collect and analyze data for effective information disclosure, especially regarding risks related to climate change.

While continuing to conduct business activities based on what makes sense for society, we will work to enhance corporate governance and continuously improve corporate value and shareholder value in order to meet the various expectations of our stakeholders.



ASKA Pharmaceutical Holdings (the "Company") aims for sustainable growth and improvement of corporate value over the medium to long term for itself and its subsidiaries (the "Group") and is continuously working to build and strengthen the best and most effective corporate governance structure as the basis for achieving this aim.

Basic Principles

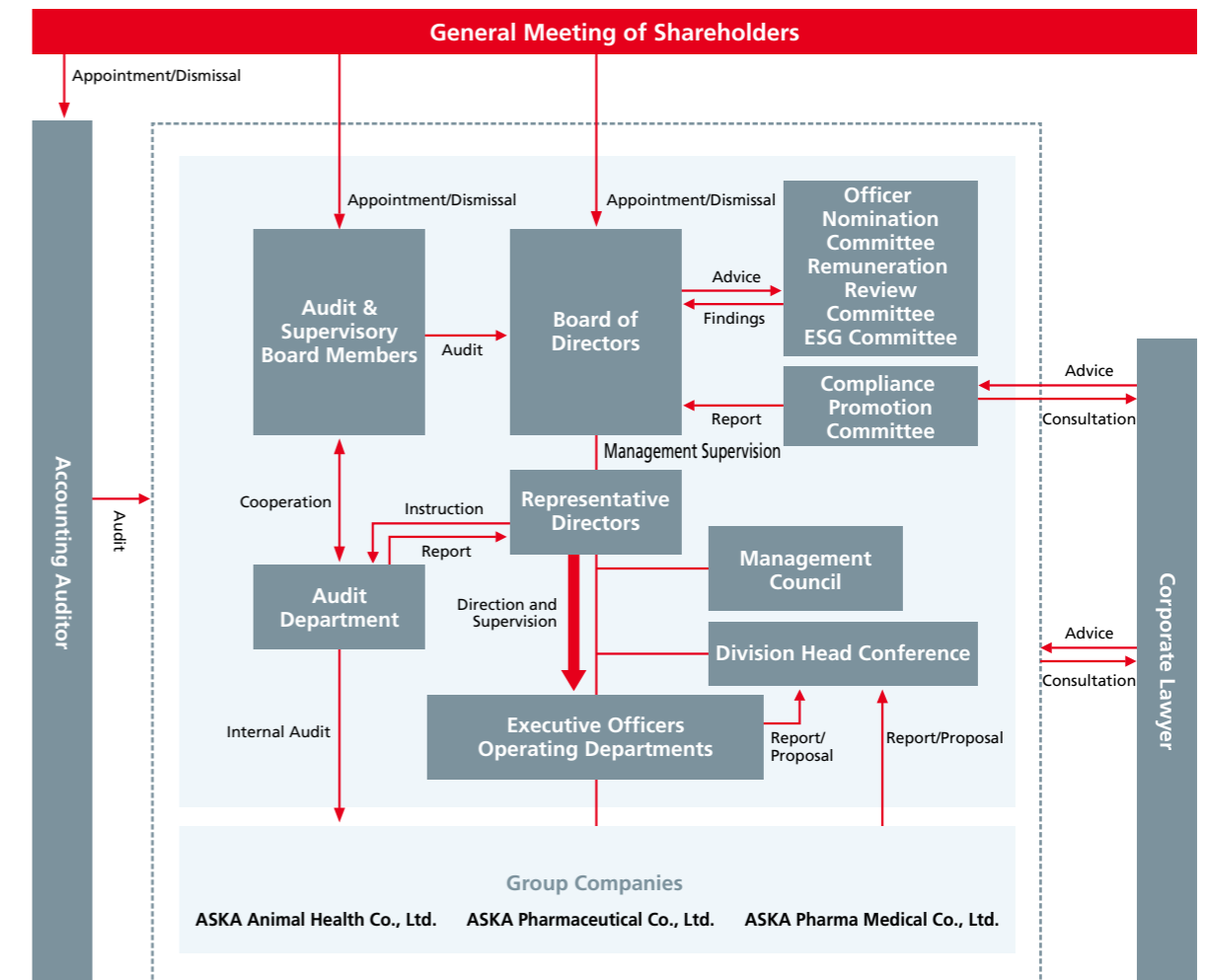
We always pursue and continually work to enhance the best corporate governance in line with the following basic principles.

1. We will strive to effectively secure the rights of shareholders and will ensure shareholder equality.
2. We will strive to cooperate fully with stakeholders and will foster a corporate culture and climate that respects the ethics of sound business practices.
3. We will appropriately disclose the Company's financial, management, and other information to ensure transparency.
4. The Board of Directors will establish an environment where bold management decisions are made based on corporate strategies and will conduct highly effective supervision of directors.
5. We will engage in constructive dialogue with shareholders.

The full text of the Basic Principles is available on the Company's website.
<https://www.aska-pharma-hd.co.jp/english/invest/governance/>

Corporate Governance Structure

Under the Company's executive officer system, executive officers execute business and directors concentrate on management and supervision functions.



Compliance

Basic Principles

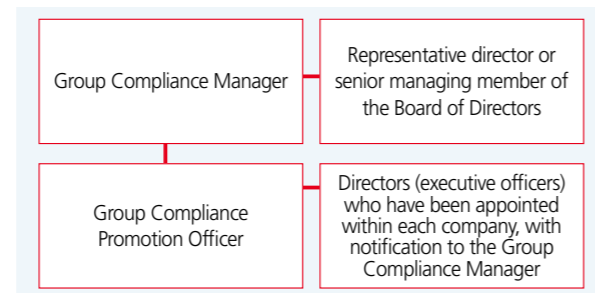
For ASKA Pharmaceutical to continue to exist and to grow and develop as a company trusted by society, it has established internal regulations based on voluntary industry standards such as the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice, in addition to compliance with statutes, laws and regulations. We have formulated the ASKA Pharmaceutical Corporate Code of Conduct and a Compliance Program, which outline the principles of conduct to be put into practice based on our corporate philosophy, and we are working to instill corporate ethics and strictly observe compliance. To complement the program, a Code Compliance Manual is posted on the company intranet to make it commonly known among employees.

The ASKA Pharmaceutical Holdings Group has established a Compliance Promotion Department to serve as a contact point for compliance, and to centrally manage our initiatives in accordance with voluntary industry standards and internal standards as well as general corporate compliance. The structure we have created facilitates the prompt handling of cases, and the formulation of measures to prevent violations, and other measures. This means that officers and employees can engage in corporate activities with peace of mind. To increase employee awareness of compliance, we are

conducting compliance education for each job level while working to grasp the level of employee awareness through questionnaire surveys and identify points for improvement. In fiscal 2020, we conducted interviews with each department of the Group based on the results of the compliance awareness survey and worked for more thorough compliance by understanding the current situation, identifying problems, and conducting training and problem solving based on actual conditions.

With the transition to a holding company structure in April 2021, the Group Compliance Promotion Committee has been established to supervise the Group in recognizing and responding to risks that will have a significant impact on Group management and promoting a compliance system that thoroughly complies with laws and corporate ethics.

Group Compliance Promotion System



Human Resources

Basic Principles

Based on the idea that the Group's most important asset is its human resources, we consider the skills and abilities of our employees to be human capital and strive to maximize those strengths. The Group looks for four qualities in its ideal human resources.

Act with pride and reliability	A person who can act reliably based on pride in the Group and high ethical standards
Respond to change from a high-level perspective	A person who can understand changes inside and outside the company from a high-level perspective to change direction flexibly and with a sense of urgency
Take on new challenges from independent growth	A person who can use independent learning to grow and take new actions unconstrained by the past
Respect diversity and collaborate as a team	Human resources who can incorporate new perspectives through diverse communication and reflect them in organizational and individual growth

To develop human resources with these four qualities, we are creating an environment that addresses willingness to learn independently by introducing voluntary training in addition to level-specific training. We would like every one of our human resources to pursue diverse careers, aspire to personal growth and acquire high-level knowledge and skills.

Developing Human Resources

Education and Training

The Group offers a variety of programs for education and training including mandatory Group-wide training, level-specific training, elective training, selective training and career design training.

To turn new university graduates who enter the company into well-adjusted working adults during their first three years, ASKA Pharmaceutical will enhance its education and training for young employees. To support the acquisition of knowledge and skills in anticipation of the personal growth of all employees according to their

assigned departments and individual characteristics, ASKA Pharmaceutical will overhaul its systems with the aim of promoting independent learning by each individual.

Furthermore, in addition to offering working styles geared toward advancing employees' careers in their current posts, ASKA Pharmaceutical has proactively introduced inter-departmental job rotation and an in-house recruiting system to promote career development in the form of change in occupation within the company.

Environment

Basic Principles

The Group considers initiatives to deal with environmental problems to be its natural mission and in keeping with its Corporate Philosophy as a corporate entity that contributes to society and earns its trust. We have established and implemented the following basic environmental policies to protect the environment and continuously reduce the environmental impact of all our business activities.

1. We will establish an environmental management system.
2. We will comply with environmental laws and regulations and other requirements.
3. We will strive to continuously reduce the environmental impact from research and development, production, sales and other business activities.
4. We will conduct environmentally friendly facility planning and technology and product development.

Reduction of CO₂ Emissions

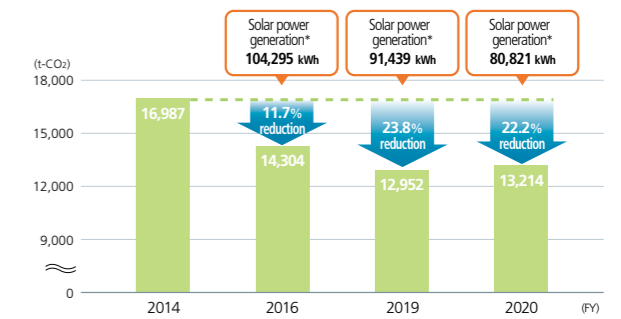
The Group considers climate change to be one of the most important issues for global environmental conservation, and is working to reduce its greenhouse gas emissions. ASKA Pharmaceutical is promoting the deployment of eco-friendly vehicles for its commercial vehicles and is using hybrid vehicles in all cases except for 4WD vehicles in cold regions. At its head office building, ASKA Pharmaceutical reduced CO₂ emissions by 3.6% compared with the previous year by switching to LED lighting and through other energy-saving efforts. The research institute has been relocated to the Shonan Health Innovation Park, which generates its own energy from high-efficiency in-house power generation and solar power. At the Iwaki Factory, although the amount of energy used increased due to the start of operation of a new building for

5. We will strive to improve environmental communication as a corporate citizen.
6. We will strive to educate employees and raise their awareness about the environment.

To effectively practice environmental management, the Group also holds regular Group-wide meetings on the topic of overall environmental management. Discussion at the FY2020 meeting covered the previous fiscal year's results under the medium-term environmental plan and the goals for the current fiscal year. We believe that information sharing and exchange of opinions among the attendees help to promote environmental measures throughout the Group.

formulations, the manufacture of new products and other factors, efforts to improve the efficiency of cogeneration system operation and the manufacturing process significantly reduced CO₂ emissions per unit of energy.

CO₂ Emissions Volume



* ASKA Pharmaceutical Iwaki Factory

Society

Basic Principles

In addition to providing excellent pharmaceuticals and treatments as a Group-wide business activity, the Group also recognizes the various issues involved in the development of a healthier society as a member of society and the local community, and believes it has a role to play in helping to resolve those issues.

The Group conducts wide-ranging communication with society and makes an active contribution as a good corporate citizen as well as through its business activities. Based on our Corporate Philosophy, we will continue to strive for growth and development as a Group that earns the trust of society.

Activities as a Corporate Citizen

As a good corporate citizen, the Group conducts initiatives that contribute to the local community. Initiatives at ASKA Pharmaceutical include co-sponsoring public lectures with Women's Health Action, the Marunouchi Career School and other organizations to support women's healthcare. In addition, ASKA Pharmaceutical participates as a supporting company in the activities of a project to reform working styles for women* based on its agreement with the project's concept of realizing a society in which women can work

comfortably by promoting an accurate understanding of women's bodies and physiology and improving the health literacy of society in general.

In addition, the company continued its registration as a Barrier-Free Mindsets Support Corporation and worked to raise awareness under this program established by the Tokyo Metropolitan Government.

* Sponsored by Nikkei BP Intelligence Group

Company Overview

Company name	ASKA Pharmaceutical Holdings Co., Ltd.
Founded	April 1, 2021
Capital	¥1,197.9 million
Number of employees	781 (Consolidated)
Representative	Takashi Yamaguchi President and Representative Director
Address	5-1 Shibaura 2-chome, Minato-ku, Tokyo 108-8532
Businesses	Business management of Group companies and related operations
Group companies	ASKA Pharmaceutical Co., Ltd. ASKA Animal Health Co., Ltd. ASKA Pharma Medical Co., Ltd.
Equity-method affiliates	NeoASKA Pharma Private Limited (India) Ha Tay Pharmaceutical Joint Stock Company (Vietnam) Japan Glass Industry Co., Ltd.

Websites

IR Site (Shareholders and Investors)
<https://www.aska-pharma-hd.co.jp/english/invest/strategy/message.html>



Mint+ Health Lab for Women (Japanese only)
<https://www.aska-pharma.co.jp/mint/>



ASKA Pharmaceutical Co., Ltd. (Japanese only)
<https://www.aska-pharma.co.jp/>



ASKA Animal Health Co., Ltd. (Japanese only)
<https://www.aska-animal.co.jp/>



ASKA Pharma Medical Co., Ltd. (Japanese only)
<https://www.ap-med.co.jp/>



Executives (As of June 24, 2021)

Directors

Takashi Yamaguchi	President, Member of the Board of Directors, Representative Director
Atsushi Maruo	Senior Managing Member of the Board of Directors, Representative Director "Assistant to the President"
Sohta Yamaguchi	Senior Managing Member of the Board of Directors, Representative Director President and Representative Director of ASKA Pharmaceutical Co., Ltd.
Yasunori Yoshimura	Member of the Board of Directors (Outside)
Michizo Yamanaka	Member of the Board of Directors (Outside)
Tsutomu Harino	Member of the Board of Directors (Outside)

Audit & Supervisory Board Members

Ikuo Kumano	Audit & Supervisory Board Member
Yuichiro Fukui	Audit & Supervisory Board Member
Takao Kimura	Outside Audit & Supervisory Board Member
Keiko Fukuchi	Outside Audit & Supervisory Board Member

Corporate Officers

Kazuhiko Kato	Executive Corporate Officer In charge of New Business Development
Kunihiro Gunji	Corporate Officer In charge of Audit and Legal Affairs & Regulatory Compliance
Junichi Saito	Corporate Officer In charge of Special Appointments, President and Representative Director of ASKA Pharma Medical Co., Ltd.
Kiyohiko Tamura	Corporate Officer Division Director Group Business Management Division
Fumiyoshi Yamaguchi	Corporate Officer In charge of Special Appointments, President and Representative Director of ASKA Animal Health Co., Ltd.

Investor Information (As of April 1, 2021)

Shares issued	Number of shareholders
30,563,199	7,792

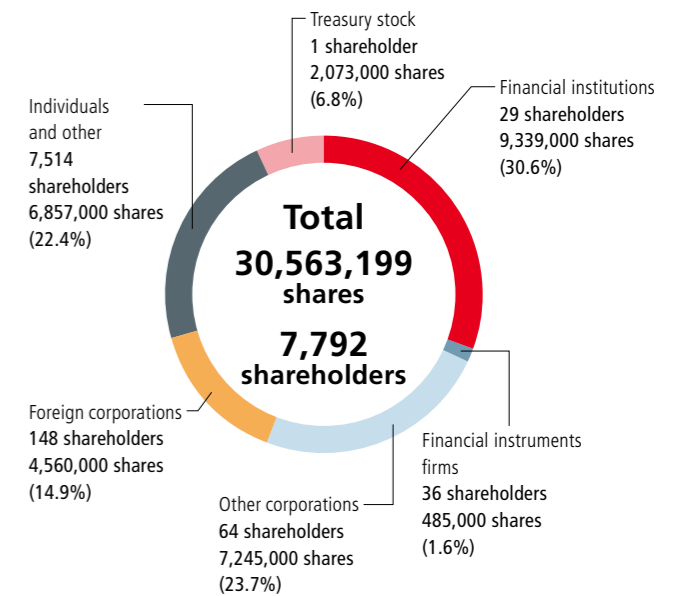
Major Shareholders (As of April 1, 2021)

Shareholder	Shares owned (Thousands)	Shareholding ratio (%)
Takeda Pharmaceutical Company Limited	2,204	7.7
The Master Trust Bank of Japan, Ltd. (Trust Account)	1,968	6.9
Custody Bank of Japan, Ltd. (Trust Account)	1,197	4.2
Zeria Pharmaceutical Co., Ltd.	1,128	3.9
MUFG Bank, Ltd.	1,100	3.8
Takashi Yamaguchi	871	3.0
ASKA Pharmaceutical Holdings Employee Shareholders' Association	540	1.8
Yamaguchi Co., Ltd.	536	1.8
Aioi Nissay Dowa Insurance Co., Ltd.	530	1.8
Nippon Life Insurance Company	522	1.8

Notes:

- ASKA Pharmaceutical Co., Ltd., a wholly owned subsidiary, owns 2,073,600 shares of the Company, but because it is a shareholder that falls within the scope of Article 67 of the Enforcement Regulations of the Companies Act of Japan, it is excluded from the list of major shareholders and the calculation of the shareholding ratio.
- The shares held in note 1 were acquired by the Company on May 14, 2021 by paying dividends in kind.

Distribution of Shares (As of April 1, 2021)



Dividend Policy

ASKA views return of profit to shareholders as one of its main management responsibilities. Distribution of profit is conducted based on maintaining stable dividend payments, and on an overall appraisal of earnings, funds required for the medium and long term, and the Company's financial position.

