

November 16, 2021

**Consolidated Financial Results for  
the Second Quarter of the Year Ending in  
March 31, 2022 (FY2021)**

**Presentation for Investors**



**Stock code : 4886 (TSE)**

**ASKA Pharmaceutical Holdings Co., Ltd.**

# Forward Looking Statement

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- The forward-looking statements contained in this presentation are based the Company's assumptions and beliefs in the light of information currently available to it and involves known and unknown risks and uncertainties.
- Accordingly, there is a possibility that actual results and development programs may differ largely from these forecasts, due to a variety of factors.
- This report contains information on Pharmaceuticals Products (including those under development), and the content of this report is not intended for medical promotion or medical advice.

# Financial Results Summary for 2Q FY2021



**Atsushi Maruo**, Member of the Board of Directors  
**ASKA Pharmaceutical Holdings Co., Ltd.**

# Consolidated Statements of Income

\*The figures announced as ASKA Pharmaceutical Co., Ltd.

(Millions of yen)	*FY2020 Apr - Sep Actual	FY2021 Apr - Sep Actual	Actual +/-	Growth +/-
Net sales	27,403	28,477	1,074	3.9%
Cost of sales	14,563	15,051	488	3.4%
Gross profit	12,840	13,426	586	4.6%
Selling, general and administrative expenses	10,894	10,768	(126)	(1.2%)
Operating profit	1,946	2,657	711	36.5%
Ordinary profit	1,952	2,743	791	40.5%
Profit attributable to owners of parent	1,552	(2,796)	(4,348)	—

# Net Sales by Business (Consolidated)

\*The figures announced as ASKA Pharmaceutical Co., Ltd.

(Millions of yen)	*FY2020 Apr - Sep Actual	FY2021 Apr - Sep Actual	Breakdown	Actual +/-	Growth +/-
Pharmaceutical drugs	25,128	25,619	90.0%	491	2.0%
Animal health drugs	2,232	2,791	9.8%	559	25.0%
Others	42	66	0.2%	24	57.1%
<b>Total</b>	<b>27,403</b>	<b>28,477</b>	<b>100.0%</b>	<b>1,074</b>	<b>3.9%</b>

# Sales of Main Products

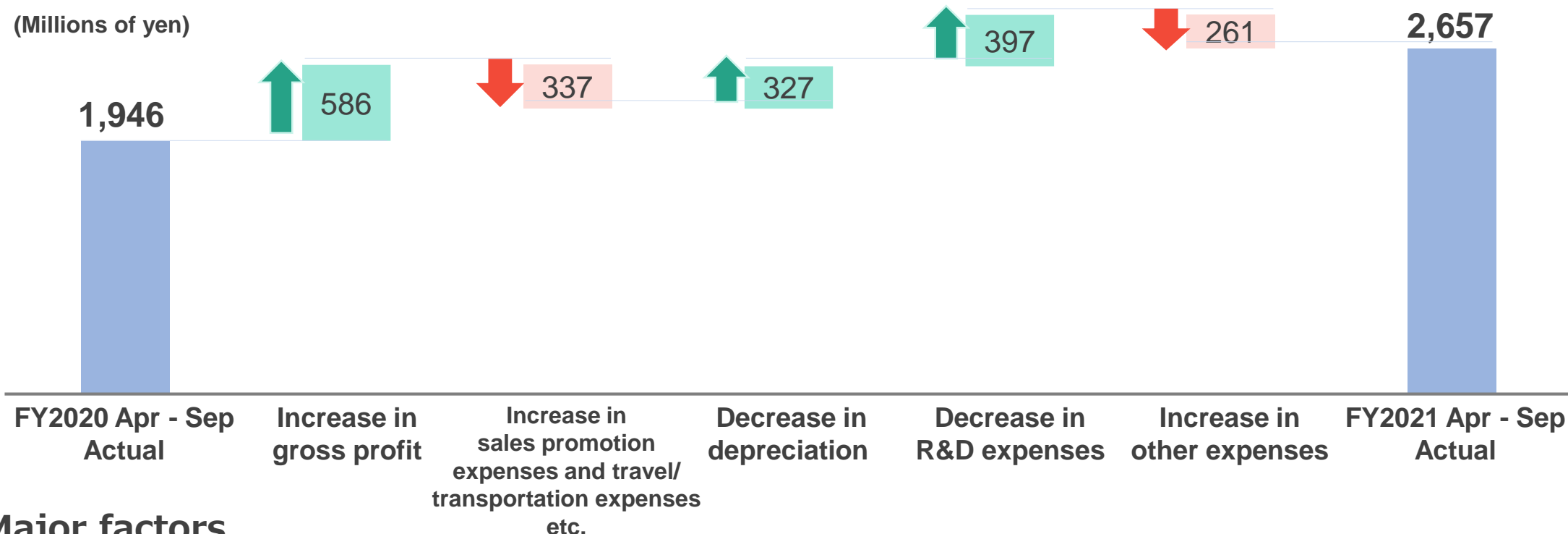
Area	Products (generic name)	FY2020 Apr - Sep	FY2021 Apr - Sep		FY2021		Reference Pre-revision
		Actual	Actual	YOY (%)	Forecast	YOY (%)	Forecast
Internal Medicine	*1, *2 CANDESARTAN (candesartan)	6,117	6,259	102.3%	11,651	94.5%	10,605
	THYRADIN (levothyroxine)	3,579	3,790	105.9%	7,365	102.2%	7,279
	RIFXIMA (rifaximin)	2,176	2,464	113.2%	5,170	119.3%	5,301
	MERCAZOLE (thiamazole)	698	751	107.5%	1,435	102.4%	1,466
	*1 AMLODIPINE (amlodipine)	632	555	87.7%	1,091	84.3%	1,102
	LIPIDIL (fenofibrate)	590	452	76.8%	788	71.9%	716
Obstetrics and Gynecology	RELUMINA (2019.3-) (relugolix)	2,519	3,703	147.0%	7,694	134.8%	7,257
	*1 FREWELL (2018.12-) (norethindrone/ethinylestradiol)	1,355	1,667	123.0%	3,006	101.8%	2,655
	ANGE (levonorgestrel/ethinylestradiol)	453	446	98.4%	905	99.6%	1,016
	*3 MAGSENT (2020.3-) (magnesium sulfate)	466	467	100.3%	794	87.5%	700
	LUTEUM (progesterone)	238	298	125.2%	615	109.6%	615
Urology	*1, *4 LEUPRORELIN (leuprorelin)	2,274	2,520	110.8%	4,439	98.6%	3,919
	*1 BICALUTAMIDE (bicalutamide)	515	-	-	-	-	-

\* 1 Generic drugs \* 3 Total value of magnesium sulfate preparation

\* 2 Including combination drugs \* 4 1.88mg formulation is for gynecological indications only, but combined with 3.75mg formulation

(Millions of yen)

# Analysis of Operating Profit (YOY)



## Major factors

- Gross profit increased due to higher net sales.
- Operating expenses increased in comparison to the previous year, which had decreased due to the COVID-19 pandemic and consequent activity decrease. Depreciation and R&D expenses decreased as originally expected. As a result, the total marketing, general and administrative expenses decreased overall compared to the previous second quarter.

# Consolidated Balance Sheet

**End of FY2020** (Millions of yen)

Current assets <b>39,932</b>	Current liabilities <b>16,737</b>
Property, plant and equipment <b>12,675</b>	Non-current liabilities <b>21,334</b>
Intangible assets <b>11,893</b>	Net assets <b>44,510</b>
Investments and other assets <b>18,081</b>	

**Total assets 82,582 million yen**

**End of FY2021** (Millions of yen)

Current assets <b>40,451</b> (+519)	Current liabilities <b>16,124</b> (-613)
Property, plant and equipment <b>12,347</b> (-328)	Non-current liabilities <b>20,380</b> (-954)
Intangible assets <b>5,689</b> (-6,204)	Net assets <b>41,790</b> (-2,720)
Investments and other assets <b>19,807</b> (+1,726)	

**Total assets 78,295 (-4,286) million yen**

<b>Assets</b>	
Cash and deposits	-397
Notes and accounts receivable	1,698
Property, plant and equipment	-328
Intangible assets	-6,204
<b>Liabilities / Net Assets</b>	
Notes and accounts payable-trade (Include electronically recorded obligations-operating)	-280
Long-term loans	-1,149
Retained earnings	-1,871



# FY2022 Forecast (Consolidated)

(Millions of yen)	FY2020 Actual	FY2021 Forecast (update)	YOY Actual +/-	YOY % +/-
Net sales	55,181	54,500	(681)	(1.2%)
Operating profit	3,609	3,500	(109)	(3.0%)
Ordinary profit	3,092	3,600	508	16.4%
Profit attributable to owners of parent	2,713	(2,600)	(5,313)	-

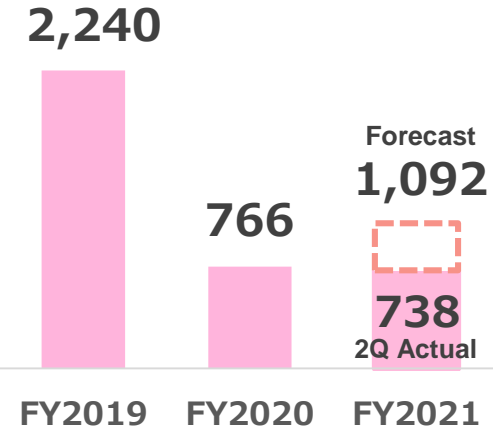
## Major factors

- Sales, operating profit, and ordinary profit are expected to exceed initial forecasts and are expected to be equivalent to FY2020 levels for the same quarter.
- Corrected as Net Loss due to the recording of an extraordinary loss (6,882 million yen) for the discontinuation of CDB-2914 “ulipristal”.

# Reference information

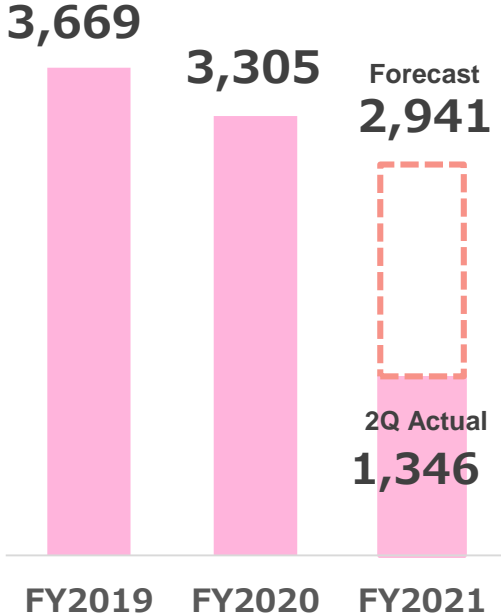
## Capital Expenditures

(Including intangible assets, consolidated basis)  
(Millions of yen)



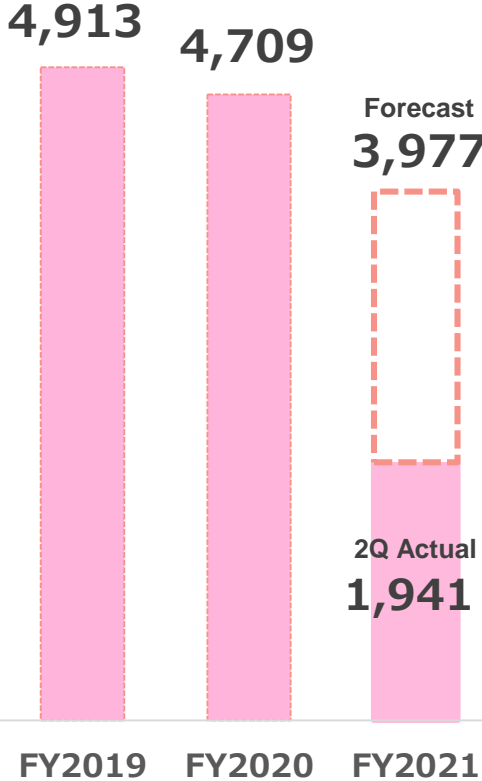
## Depreciation and Amortization

(Millions of yen)



## R&D expenses

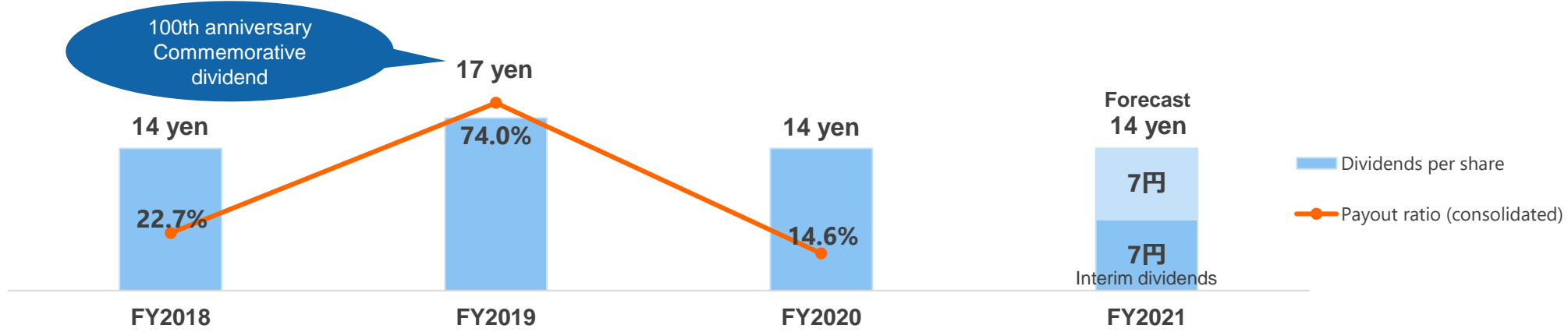
(Millions of yen)



# Reference information

## Shareholder Returns

Following the policy of ASKA Pharmaceutical Co., Ltd., ASKA Pharmaceutical Holdings' basic policy is to continue paying a stable and continuous dividends in order to provide appropriate return on profit for shareholders.



## Strategic stockholdings

From the viewpoint of capital efficiency, ASKA Pharmaceutical Holdings Co., Ltd. will examine the appropriateness of continuing to hold certain strategic stocks, and will reduce certain stocks if it's significance is determined to be not necessarily sufficient.

## Other

The source of dividends for the end of the second quarter of the year ending in March 31, 2022 "interim dividend" is "other capital surplus".

# Overview of the 2Q FY2021 Interim Annual Report

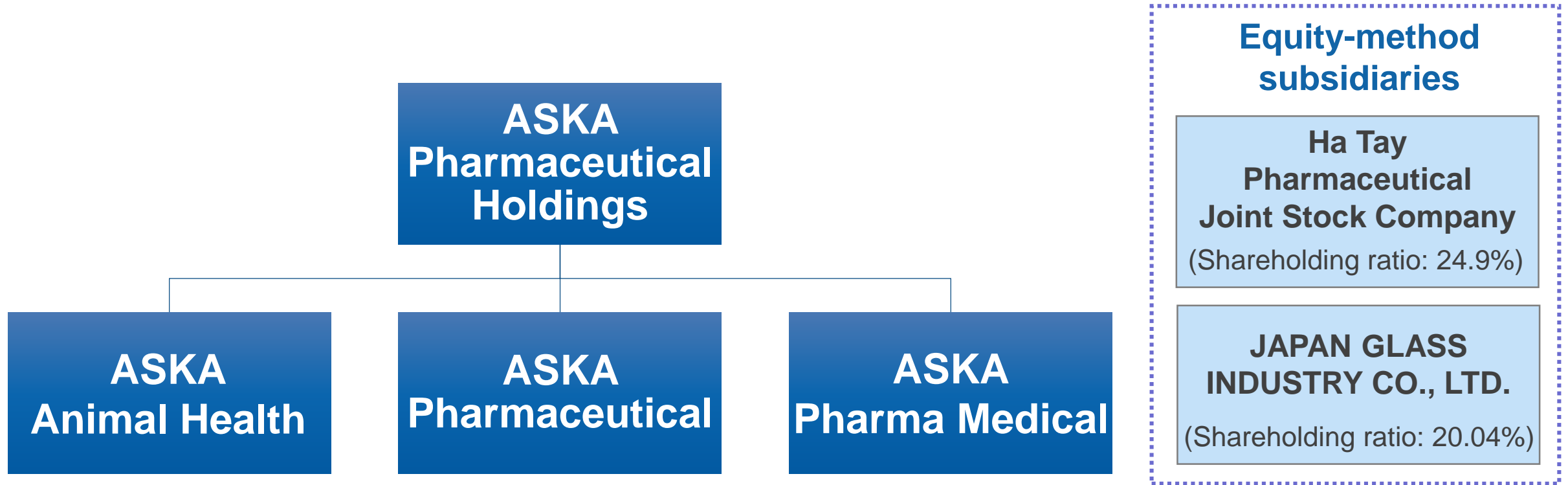


**Takashi Yamaguchi, President, Representative Director**  
**ASKA Pharmaceutical Holdings Co., Ltd.**

# ASKA Pharmaceutical Holdings Co., Ltd.

- ✓ Transition to a Holding Company structure
- ✓ Medium-term management plan 2025 objectives
- ✓ Overview of each subsidiary

# ASKA Pharmaceutical Holdings Co., Ltd.



Building upon our strong presence within the areas of endocrine hormone research and within our specialty therapeutic areas, ASKA will not only focus on pharmaceutical products, but also expand its horizons to overseas healthcare businesses in the areas of Prevention, Testing, Diagnostics, and Treatment, as well as Prognosis.

# Transition to a holding company structure

**"Become a Total Healthcare Company with  
a Strong Foundation as  
a Specialty Pharma Company"**

The Medium-Term Management Plan 2025 Numerical Targets  
**Net sales: 70 billion yen, Operating profit rate: 8%, ROE: 8%**

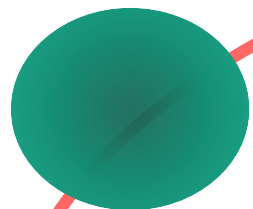
Based on this foundation, The Medium-Term Management Plan 2025 was designed with four visions and seven strategies.

Three foundation cornerstones to carry out the Medium-Term Management Plan 2025  
**Specialty      Ability to create      Social contribution**

# Overview of each subsidiary (Net sales for 2Q FY2021)

## Animal Health Drugs

(ASKA Animal Health)



**Net sales**  
**¥2,791 million**  
**9.8%**

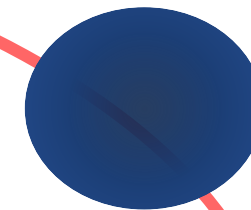


ASKA Pharmaceutical Holdings Co., Ltd.

**Net sales**  
**¥28,477 million**

## Others

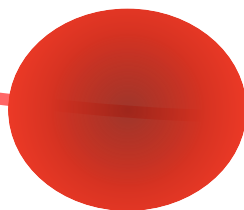
(ASKA Pharma Medical etc.)



**Net sales**  
**¥66 million**  
**0.2%**

## Pharmaceutical Drugs

(ASKA Pharmaceutical)



**Net sales**  
**¥25,619 million**  
**90.0%**



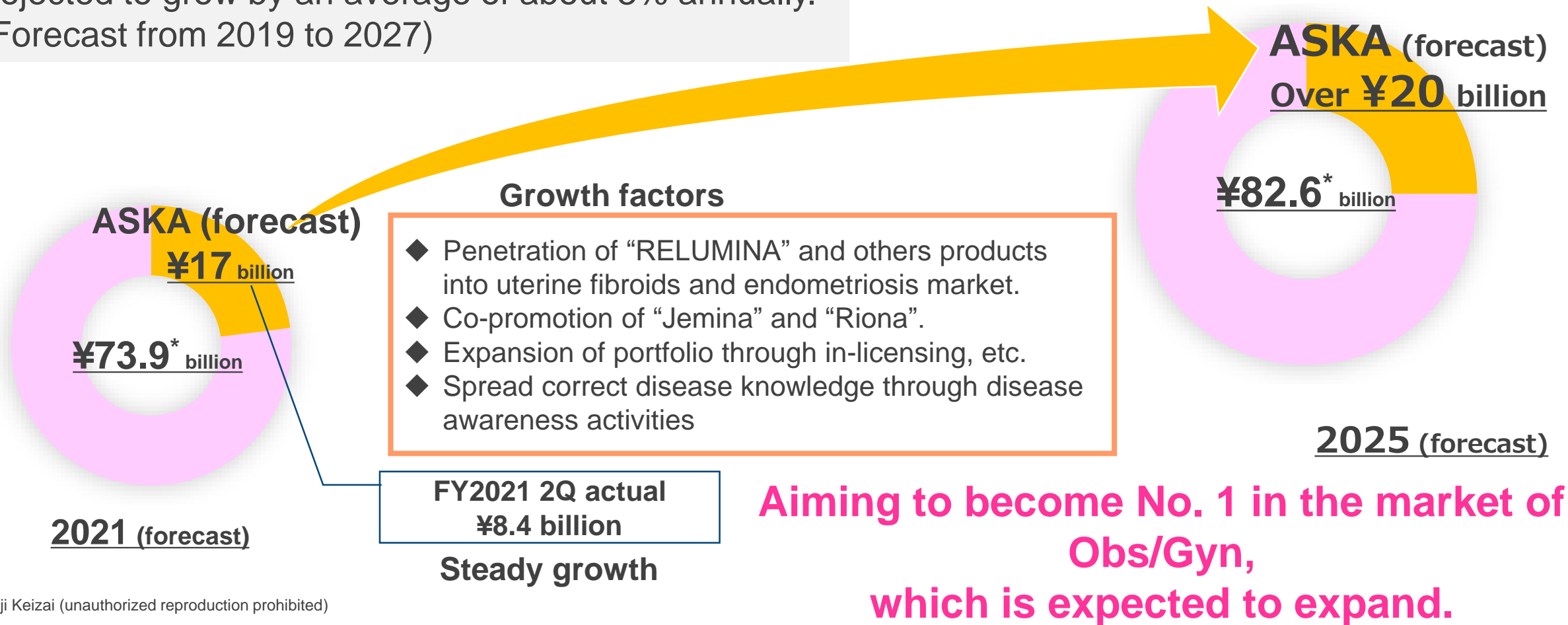
# ASKA Pharmaceutical Co., Ltd.

## ■ Major Initiatives

- ✓ **Strengthening the Specialty Therapeutic Areas**
- ✓ **Engaging in alliance activities and development pipeline**
- ✓ **Global Expansion**

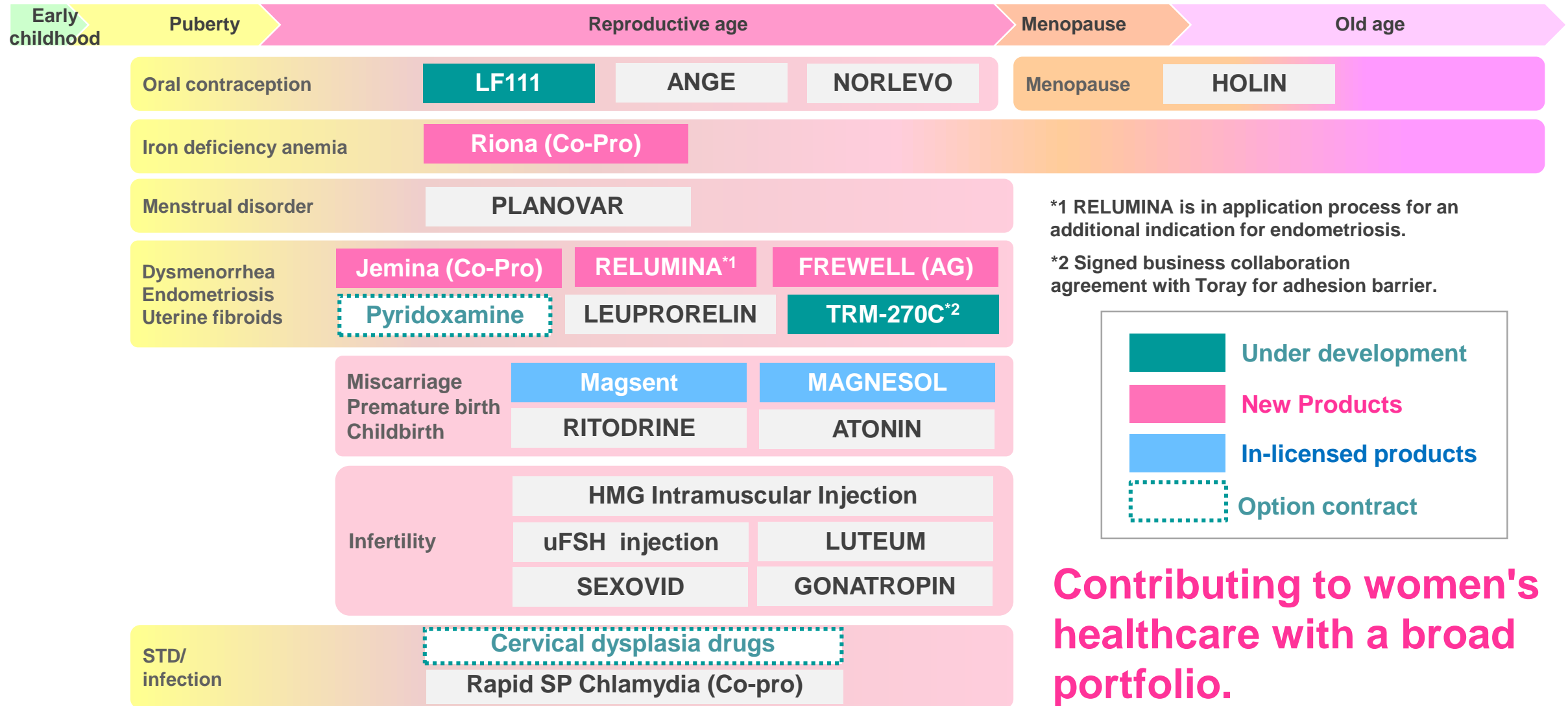
# Prediction of the Obs/Gyn market and ASKA's Numerical Targets

The obstetrics and gynecology (Obs/Gyn) market is projected to grow by an average of about 3% annually. (Forecast from 2019 to 2027)



\*Fuji Keizai (unauthorized reproduction prohibited)

# Obs/Gyn Products by Life Stage



\*1 RELUMINA is in application process for an additional indication for endometriosis.

\*2 Signed business collaboration agreement with Toray for adhesion barrier.

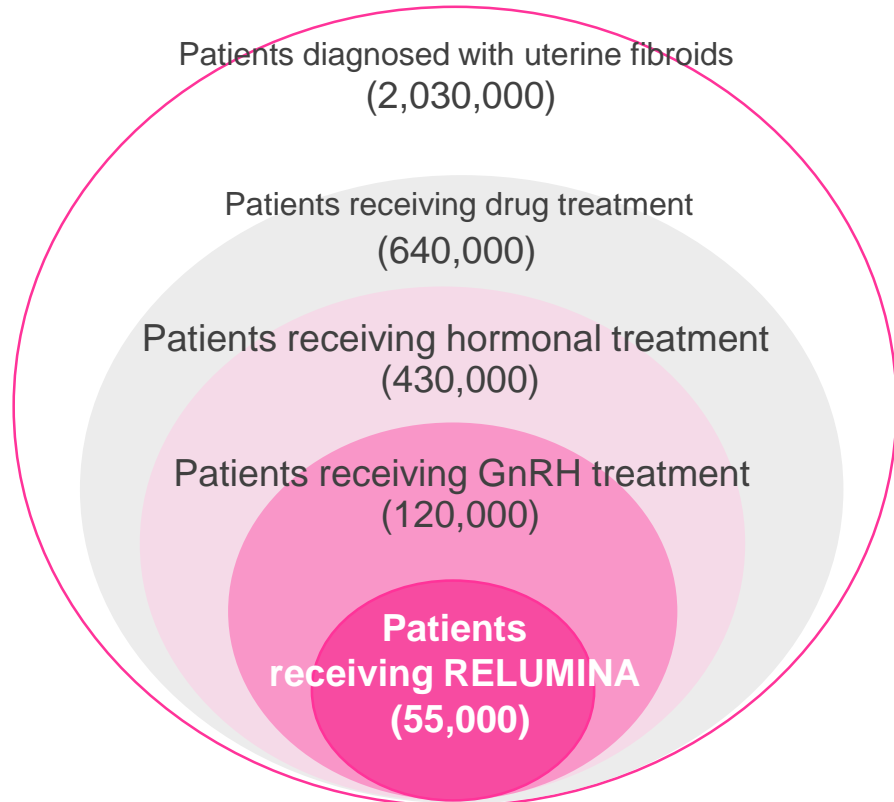
- Under development
- New Products
- In-licensed products
- Option contract

**Contributing to women's healthcare with a broad portfolio.**

# Growth Driver – The Potential of RELUMINA (relugolix)-

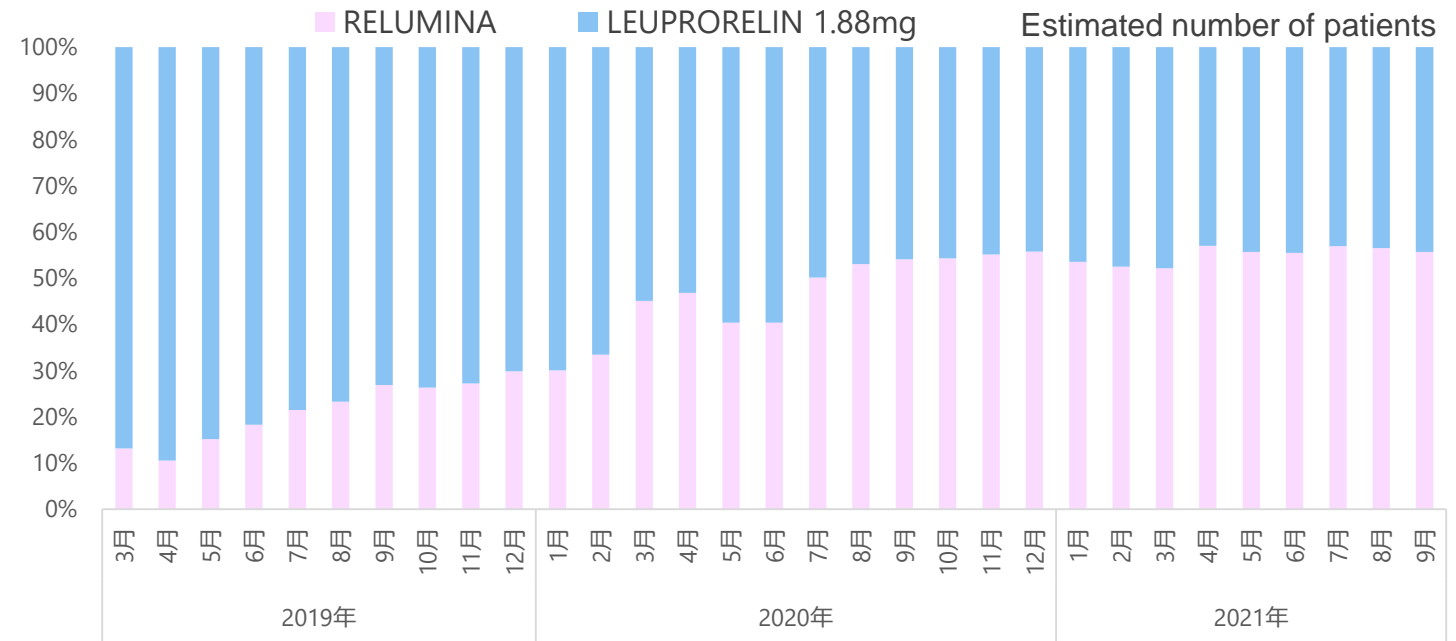
## Uterine fibroids treatment status

(Enlarged estimation from electronic receptacle data)



Source: JMDC2020 Research Inc.  
(unauthorized reproduction prohibited)

## Market share of uterine fibroid therapeutic agents



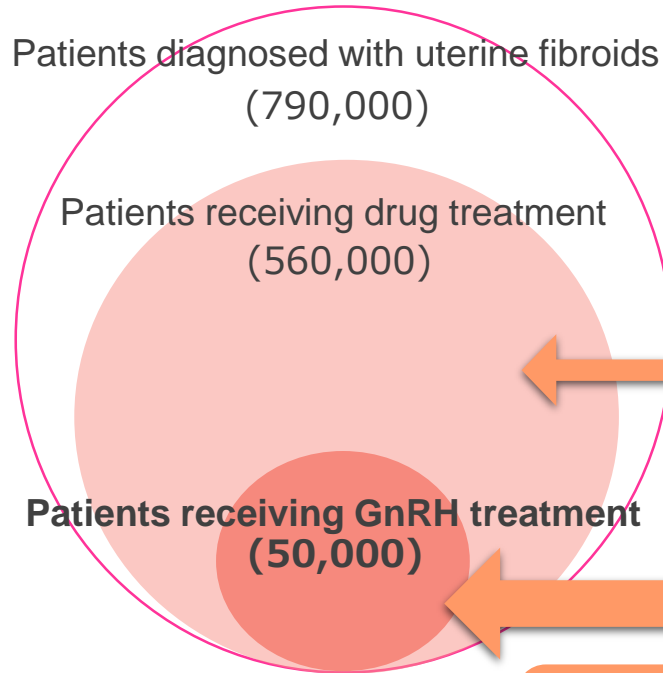
Source: Encise Inc. (unauthorized reproduction prohibited)

- ✓ RELUMINA is the first oral GnRH antagonist tablet in Japan.
- ✓ Establish its position as a standard treatment for uterine fibroids.

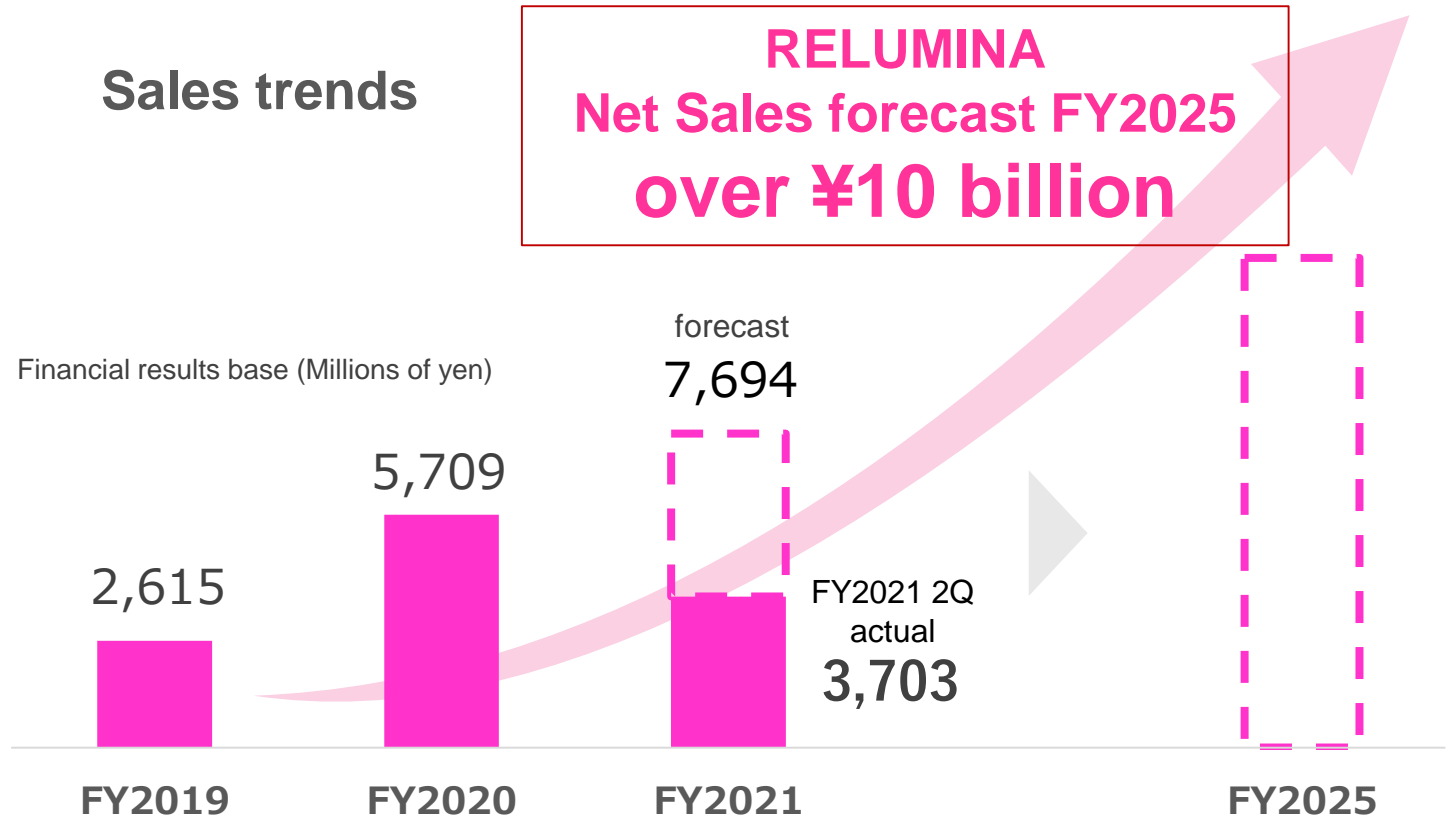
# Growth Driver – The Potential of RELUMINA (relugolix)-

## Endometriosis treatment status

(Enlarged estimation from electronic receptacle data)



## Sales trends



**Contributing to women's healthcare by adding the indication of endometriosis\*.**

\*Applied in January 2021

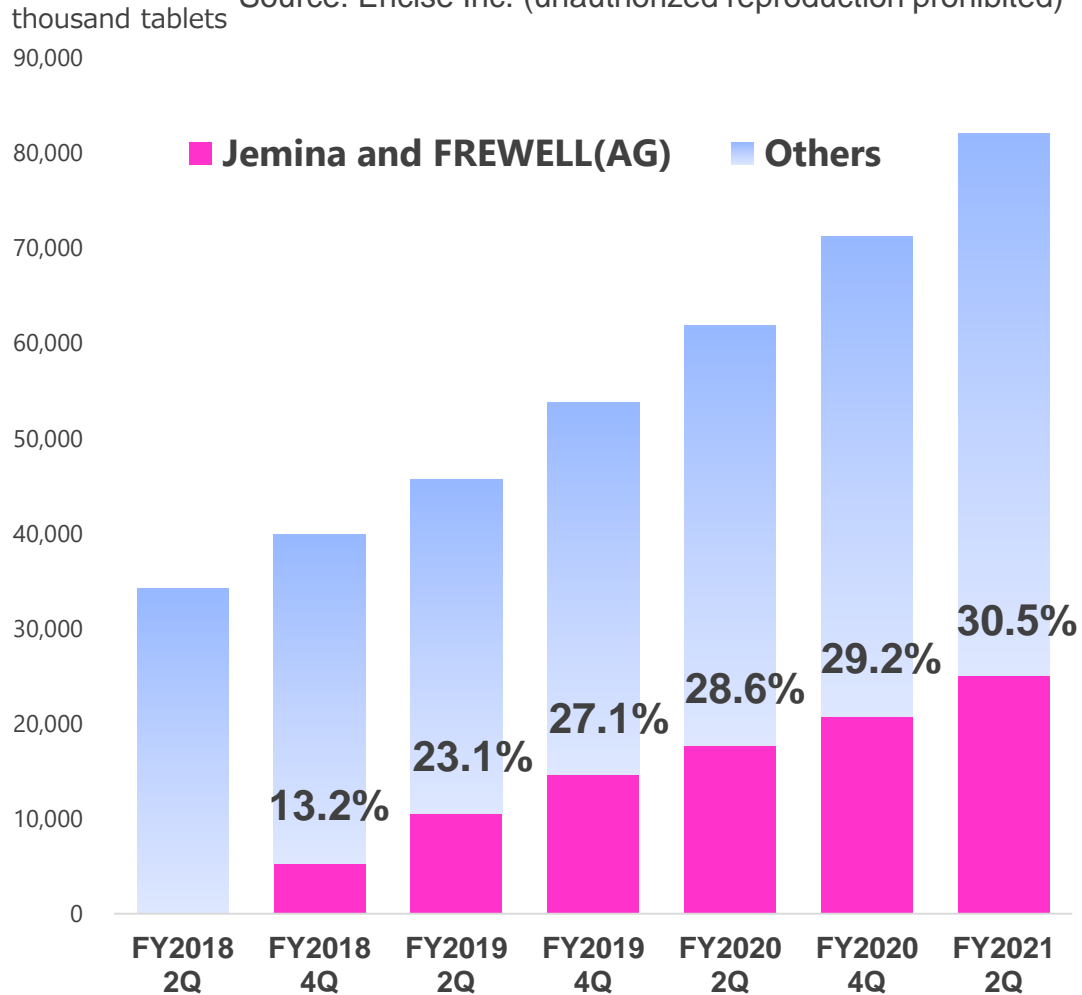
Source: JMDC2020 Research Inc.  
(unauthorized reproduction prohibited)

# Sustained Growth of LEP\* Formulations (Jemina and FREWELL)

\*Low-dose Estrogen/Progestin combination

## LEP market continues to expand

Source: Encise Inc. (unauthorized reproduction prohibited)



### Expansion factors

- ✓ Increasing number of women are controlling menstrual pain as women advance into society.
- ✓ Increasing interest in women's health and increasing access to information.

#### Jemina



Co-promotion with Nobelpharma Co., Ltd.

#### FREWELL (AG)



- ✓ Supporting women's health who suffer from dysmenorrhea.
- ✓ Contribute to women's healthcare.

# Responding to Unmet Medical Needs by RIFXIMA

## Clinical Practice Guidelines for Cirrhosis 2020

Strength of recommendation:

**Strongly recommended**

Evidence level:

**A**

Applicable partial summary:

**Because RIFXIMA is an effective treatment for hepatic encephalopathy, It has been recommended as a "basic therapeutic agent".**

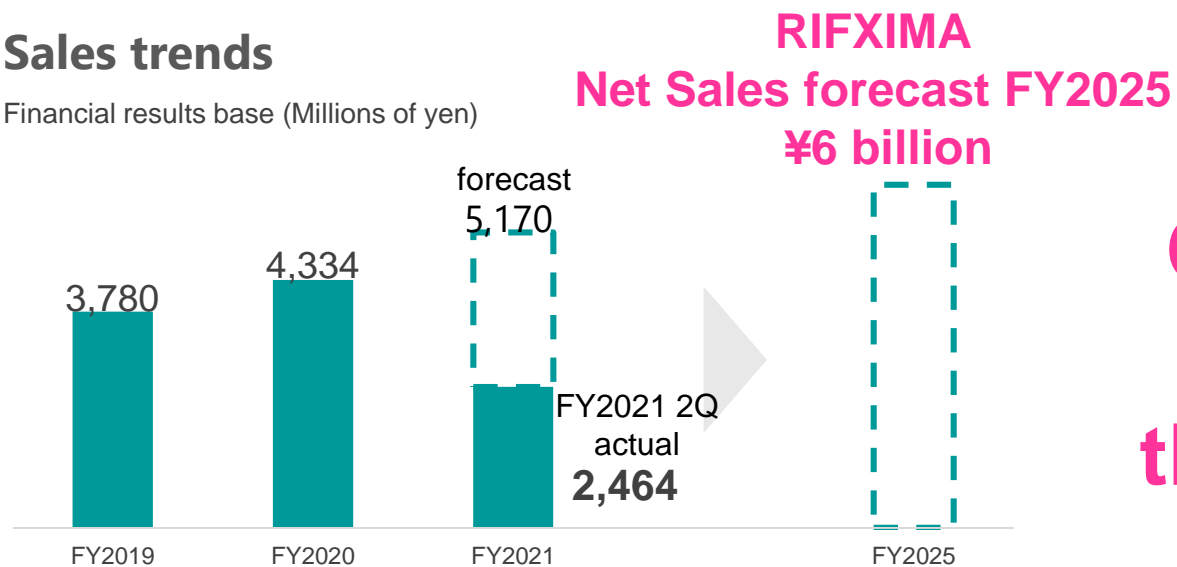
## Initiatives of RIFXIMA

- ✓ Awareness-raising activities for asymptomatic hepatic encephalopathy\*.
- ✓ Further penetration into the 28,000 patients (estimated) of hepatic encephalopathy.

\* Hepatic encephalopathy patients with few clinical symptoms **which may be** diagnosed for the first time by a neurological test. May progress to symptomatic hepatic encephalopathy

## Sales trends

Financial results base (Millions of yen)



**Contribution to the treatment of hepatic encephalopathy through guideline penetration.**

# Initiatives of the Thyroid Area

## Responsibilities as a Leading Company

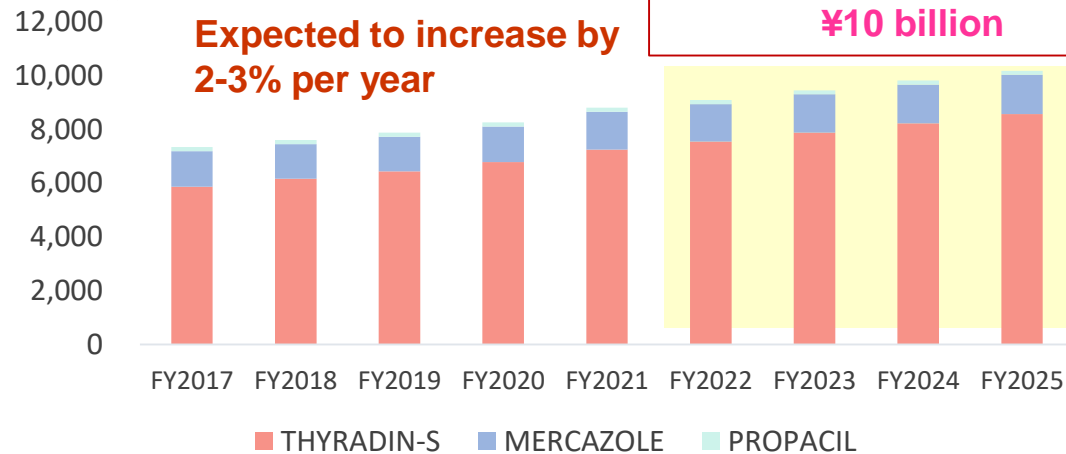
- ✓ Continue to raise awareness of diseases.
- ✓ Securing of a stable supply.
- ✓ Respond to medical needs. (Launch half-dose MERCAZOLE tablets and THYRADIN-S Injection)
- ✓ Promote thyroid testing in collaboration with clinical test companies.

## Initiatives of the Thyroid Area

- ✓ Considering a new project to coincide with the 100th anniversary of the birth of THYRADIN in 2022.
- ✓ Continuous patient contribution.

## Sales trends

(Millions of yen)



**Thyroid Drugs  
Net Sales forecast FY2025  
¥10 billion**



Disease awareness  
Butterfly ribbon  
badges

**Promote awareness-raising activities for thyroid diseases and contribute to the treatment of potential patients**



# Drug Discovery Promotion (Alliance Activities)



Option agreement regarding the treatment for cervical dysplasia.



Co-development and option agreement in the field of gynecology.

Adopted for CiCLE business by AMED





Joint research agreement on drug discovery research.  
Aim to create new drugs targeting ion channels.



Joint R&D agreement for drug discovery.  
Aim to create an aptamer drug targeting hormone receptors.

# Development Pipeline

## R&D Status (as of November 2021)

Development code (generic name) Indication	Ph I	Ph II	Ph III	Application	Approval
TAK-385 (relugolix) Endometriosis 					<b>Filed</b>
LF111 (drospirenone) Contraception			<b>Ph II Completed</b>		
(option agreement) Under development at Renascience Inc. Treatment for PMS/PMDD			<b>Investigator-initiated clinical Ph II trial Ongoing</b>		
(option agreement) Under development at KinoPharma, Inc. Treatment for Cervical Dysplasia			<b>Ph I/II Ongoing in Korea</b>		
L-105 (rifaximin) Hepatic encephalopathy (pediatrics) 				<b>Ph II/III Ongoing</b>	
AKP-009 (ludaterone acetate) Benign prostatic hyperplasia			<b>Ph IIa Completed*</b>		

\* Additional Ph I trial at a higher dose started.

Note: Approval application for CDB-2914 (ulipristal) has been withdrawn.

### TAK-385 (Relugolix Combination Tablet)

Uterine fibroid

Licensing agreement with Takeda Pharmaceutical Company Limited.

**Preparing development**

### TRM-270C (Adhesion Barrier)

Surgery in obstetrics and gynecology as well as in gastroenterology procedures.

Signed business collaboration agreement with Toray Industries, Inc.

**Preparing development**

# New Development

## Relugolix Combination Tablet (TAK-385)

Licensing agreement with Takeda Pharmaceutical Company Limited.

September 27, 2021

### Summary

- ✓ Entered into a license agreement for exclusive development and commercialization for uterine fibroids in Japan.
- ✓ Combination of relugolix, estradiol-INN and norethindrone acetate-INN.
- ✓ Expected to be used for a long term treatment.
- ✓ The number of patients with uterine fibroids is estimated to be around 2 million in Japan.
- ✓ Other companies have already obtained approval in Europe and in the United States.

**Proposing a New Option for  
Uterine Fibroid Treatment.**

# New Development

## Adhesion Barrier\* (TRM-270C)

Signed business collaboration agreement with Toray Industries, Inc.

### Summary

October 5, 2021

- ✓ **Jointly develop the Product to obtain a marketing approval.**
- ✓ **Commercialization exclusively for Japan.**
- ✓ **Use during medical procedures such as laparotomies and laparoscopies in obstetrics and gynecology as well as in gastroenterology procedures.**
- ✓ **It has a laminated structure that comprises anti-adhesive layers as well as supportive layers. Different properties provides the necessary flexibility and adhesiveness to target organs.**
- ✓ **The market size of adhesion barrier is estimated to be around 13-14 billion yen per year in Japan.**

\* When tissues are sutured together in surgery, it is normal for the sutured tissues to adhere and heal spontaneously. However, during the healing process after surgery, postoperative adhesion can occur, whereby tissues that should be separated, can adhere to one another. These postoperative adhesions can cause complications such as, small bowel obstruction, secondary infertility, and chronic pelvic pain. Adhesion barriers are applied to areas effected by surgeries to prevent such adhesions.

**Improve the prognoses of patients who undergo surgery in obstetrics and gynecology as well as gastroenterology interventions.**

# Business Development in Asia

## Vietnam

Equity-method affiliate

## Ha Tay Pharmaceutical Joint Stock Company (Hataphar)

- ✓ Two members of ASKA were appointed as directors of Hataphar, and participate in management.
- ✓ Support the construction for a new factory compatible with PIC/S GMP.
  - ⇒ Due to the impact of Hanoi city lockdown, construction is scheduled to start in December 2021.
- ✓ Start personnel exchange.
  - ⇒ One of ASKA employees is seconded to Hataphar's head office.



Image of new factory

Scheduled to start operation in 2023

In addition to factory construction support and personnel exchange, we are planning to expand our products into Vietnam

## China

## Out-licensed ASKA's original Product "Altat\*" to China

\* H<sub>2</sub> receptor antagonist

Harbin Pharmaceutical Group Co.,Ltd.

⇒ Signed a license agreement of exclusive development and commercialization in China.

Considering out-licensing other products to other Asian markets as well as China.

# ASKA Animal Health Co., Ltd.

# Overview of ASKA Animal Health Co., Ltd.

## Business

Manufacture and sale of animal health products, feed, feed additives and raw materials, etc.

## Vision

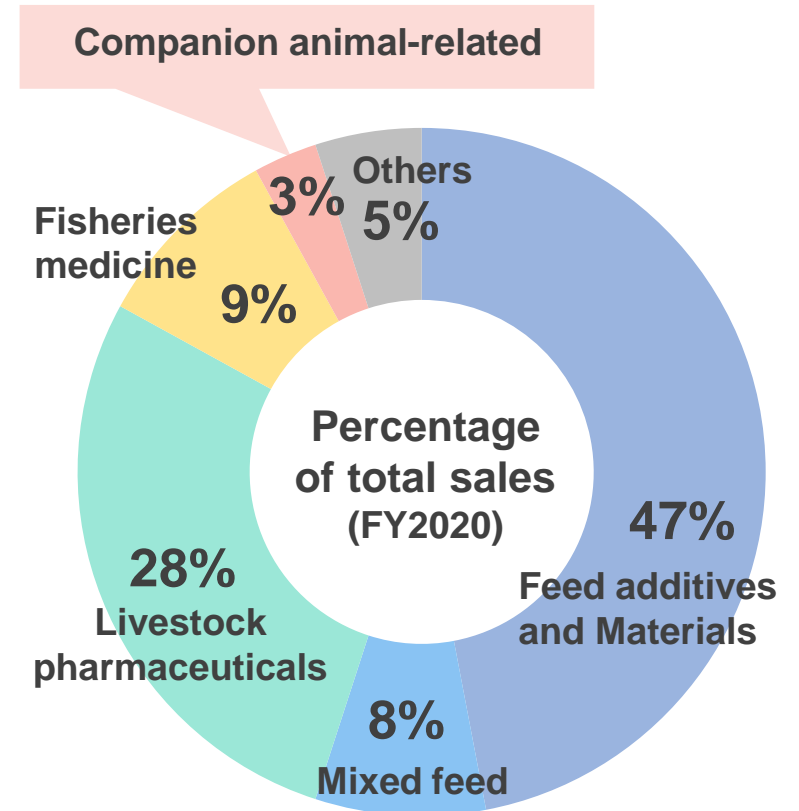
Become the one and only company that supports the health of companion animals with strengths in animal reproduction, immunology and nutrition regarding livestock and fisheries.

## Initiatives

Launch new products.

- ✓ Companion animal drugs, feed supplements.
- ✓ Feed additives for industrial animal products.

- ✓ Launch and foster important products as well as new products in the livestock and fishery field
- ✓ Launch and foster new companion animal products



# Major Initiatives for 2Q FY2021

## Launched three new mixed feed products in April 2021

Mixed feed for *Dermanyssus gallinae* control  
**WAKUMOHATE**



Nucleic acid-containing yeast feed  
**NUCLEOFORCE LIVESTOCK**  
**NUCLEOFORCE AQUA**

Yeast activity feed for ruminant  
**VISTACERE**



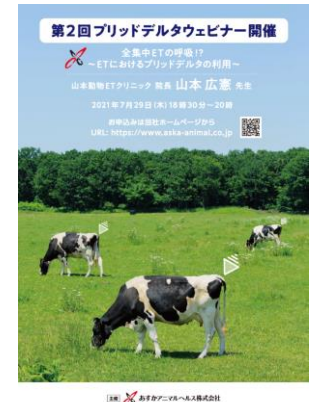
✓ "PRIDDELTA\*" web lecture held in July 2021  
with over 400 participants

\* Hormonal preparation for cattle breeding

✓ "THYLOBLOCK\*" market penetration

\* hyperthyroidism treatment for cats

Create synergies



Contribute to create a society where people and animals can coexist.



# ASKA Pharma Medical Co., Ltd.

# Overview of ASKA Pharma Medical Co., Ltd.

## Business

Clinical testing and biological testing

## Priority Targets

Expansion of business through hair-growth diagnostics and thyroid disease testing

## Initiatives

Expanding hormone microanalysis as a business

Hair-growth diagnostics

Thyroid disease business

Research specimen commissioned business

Endogenous hormone microanalysis  
(Steroid hormones, thyroid hormones, etc.)

### Owned patent

- ✓ Analysis of steroid hormones
- ✓ New microanalysis of estradiol in vivo
- ✓ Differentiation between prostate cancer and benign prostate hyperplasia
- ✓ High-sensitivity analysis of steroid hormones
- ✓ High-sensitivity analysis of estrones
- ✓ Adenoma differentiation for primary aldosteronism and analysis for 18-oxocortisol and 18-hydroxycortisol
- ✓ Ultra high-sensitivity analysis of estrogen

"ASKA Pharma Medical" for hormone mass spectrometry.

## Initiatives of Major Themes for 2Q FY2021

Hair-growth diagnostics

**Collaboration with ASKA  
Pharmaceutical's healthcare business**

Launched hair-growth hormone analysis kit.

Thyroid disease business

**Collaboration with ASKA  
Pharmaceutical's sales headquarters**

Strengthening sales force and promote research specimen business.

Study sample  
commissioned business

**Signed a business alliance with  
the company of NDTs**

Increased in contract inspection items

Create  
synergies

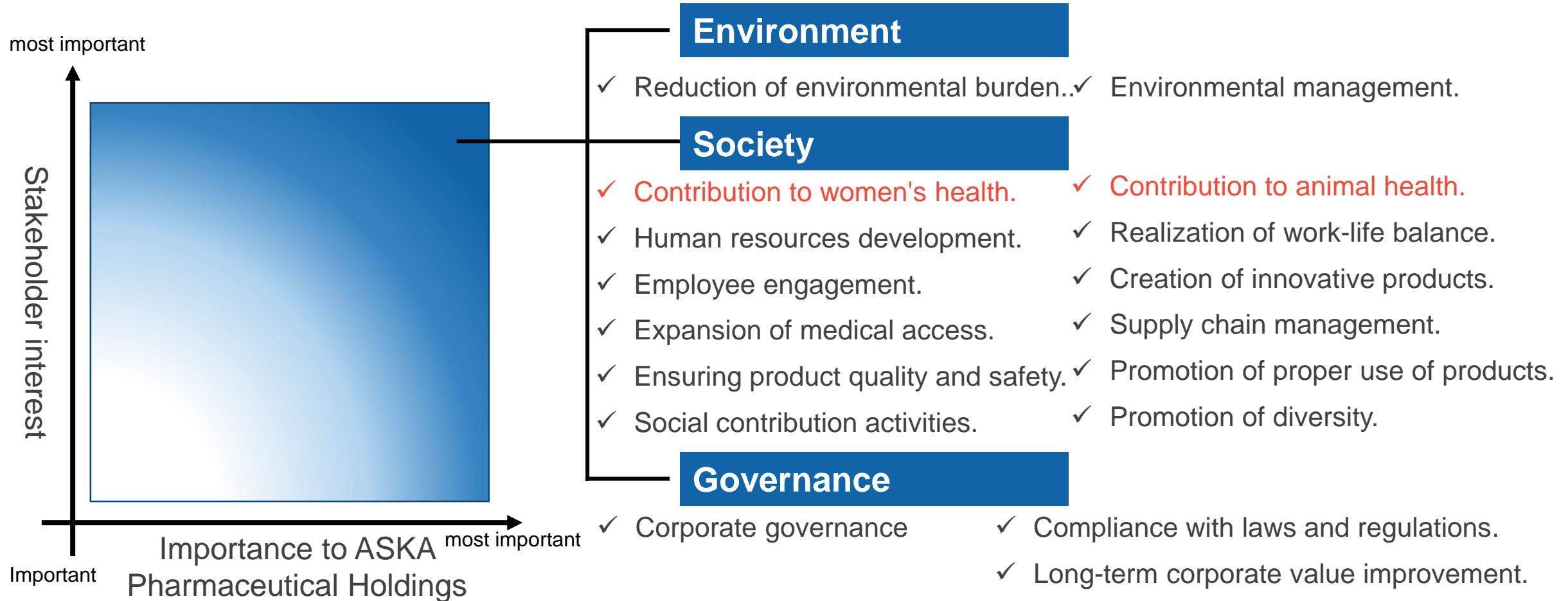
Outside  
Collaboration

**Contributing to the creation of a vibrant, healthy society  
through the latest measurement technologies.**

# Promote ESG Management

# Promote ESG Management and Identify Materiality

**We have established an ESG committee and identified 17 materialities from the perspective of relevance to our business and social contribution.**



# Promote ESG Management and Contribute to SDGs



**Contributing to SDGs by promoting ESG management.**

**ASKA Pharmaceutical Holdings Group  
Corporate Message**

**For a Healthy Tomorrow and Future.**



**ASKA Pharmaceutical Holdings Co., Ltd.**

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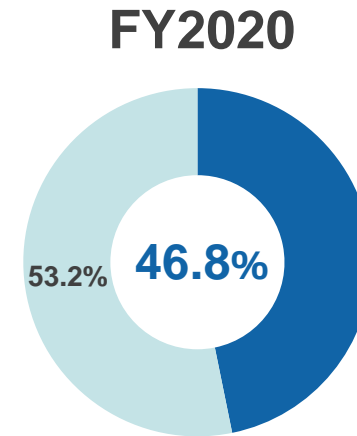
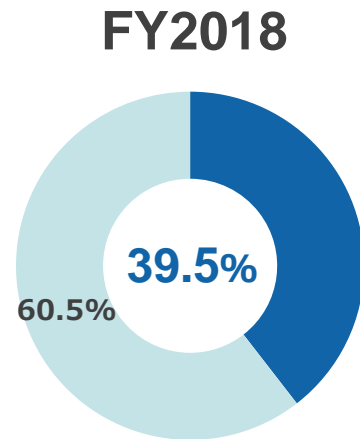
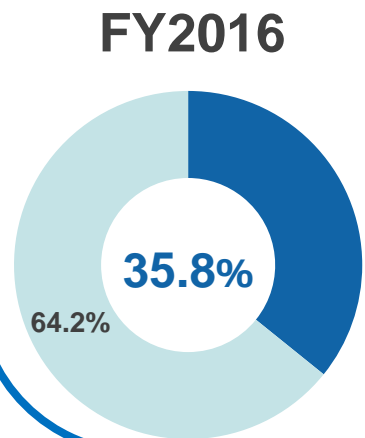
# Appendix



# Transition to a New Drug-Based Business

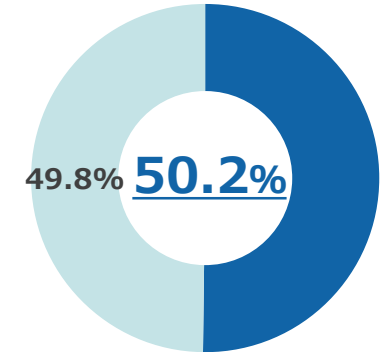
## Sales Proportion of Brand-name Drugs

Previous medium-term management plan period (ASKA PLAN 2020)



■ Brand-name drugs  
■ Generic drugs

## FY2021 2Q



**Aim to increase the ratio of brand-name drugs.**

# Development of AKP-009

## Outline of clinical trial

Ph II clinical trial (randomized, double-blind, parallel-controlled trial with placebo control).

Target: Patients with benign prostatic hyperplasia Number of cases: Approximately 100.

Number of drug administrations: Once daily.

Evaluation parameters items: Safety / Efficacy: Rate of change from baseline in prostate volume at 12 weeks of administration.

## Test results

No significant dose correlation was found statistically, and no significant difference was found between the active groups and the placebo group.

## Countermeasure

Based on the results of the Ph II clinical study, a higher dose study was considered in order to confirm the maximum effect of the drug, and an additional Ph I study will be in September 2021.

# Initiative for a Healthy Management

## Acquired “Gold Prize” certificate for Health Management. (ASKA Pharmaceutical Co., Ltd.)

Received from Health and Productivity Management Declaration Council in Tokyo



Following the silver prize certificate, we addressed six items as STEP2.

1. Health checkups / Prevention of disease progression.
2. Health management / Health management and safety and hygiene activities.
3. Mental health care measures.
4. Prevention of overwork.
5. Infectious disease prevention measures.
6. Health management.

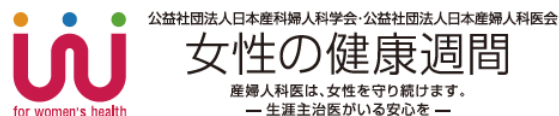
**As an excellent health management company, we will continue our efforts for health management and health promotion.**



# CSR Activities in FY2021

## ASKA Pharmaceutical contribute to Women's Health Issues through a number of projects:

(Women's Health Week Event)



なりたい自分をデザインする  
**丸の内キャリア塾**  
Marunouchi Career Academy

(Marunouchi Career Academy)



(Comfortable Menstruation Project)



\*1 : <https://special.nikkeibp.co.jp/atclh/DRS/20/seirikaiteki/>

\*2 : <https://whasympo.com/>

# Social Contribution Activity



"Health Lab for Women Mint+", which provides information on women's body and health, has started new activities for the younger generation as it has launched the website "Mint+ teens" for young people.

## Inquiries

### Corporate Planning Department

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