

May 19, 2020

Financial Results for FY2019

 ASKA Pharmaceutical Co., Ltd.

Stock Code :4514

FORWARD LOOKING STATEMENT

- 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 involve known and unknown risks and uncertainties.
- Accordingly, there is a possible that actual results and development programmes may differ largely from these forecasts, due to a variety of factors.
- This report contains information on Pharmaceuticals Products (including those under development), but the content of this report is not intended for medical promotion or advice to patients.

Full Year 2019*

Consolidated Financial Summary

ASKA Pharmaceutical Co., Ltd.

Atsushi Maruo

Executive Director, Representative Director

*Refers to April 1st 2019 to March 31st 2020

Consolidated Statements of Income

Millions of yen	FY2018	FY2019	Actual +/-	Growth +/-
Net sales	46,706	52,542*	5,836	12.5%
Cost of sales	27,814	28,525	709	2.6%
Gross profit	18,890	24,016	5,126	27.1%
Selling, general and administrative expenses	17,107	22,509	5,401	31.6%
Operating profit	1,782	1,507	△275	△15.5%
Ordinary profit	1,980	1,715	△264	△13.4%
Profit attributable to owners of parent Co.	1,744	649	△1,094	△62.8%

*Put a current exchange rate and the ref (1 US dollar = 107.68 yen, BI May 19th 2020)
(1 Euro = 118.07 yen, BI May 19th 2020)

Net Sales by Business (Consolidated)

Millions of yen	FY2018	FY2019	Breakdown	Actual +/-	Growth +/-
Ethical drugs	41,757	47,851	91.1%	6,094	14.6%
Drugs for animal	4,669	4,502	8.5%	△166	△3.6%
Others	278	187	0.4%	△91	△32.8%
Total	46,706	52,542	100.0%	5,836	12.5%

Sales of Main Products

The "Accounting Standard for Revenue Recognition" was adopted in FY2019.

Millions of yen

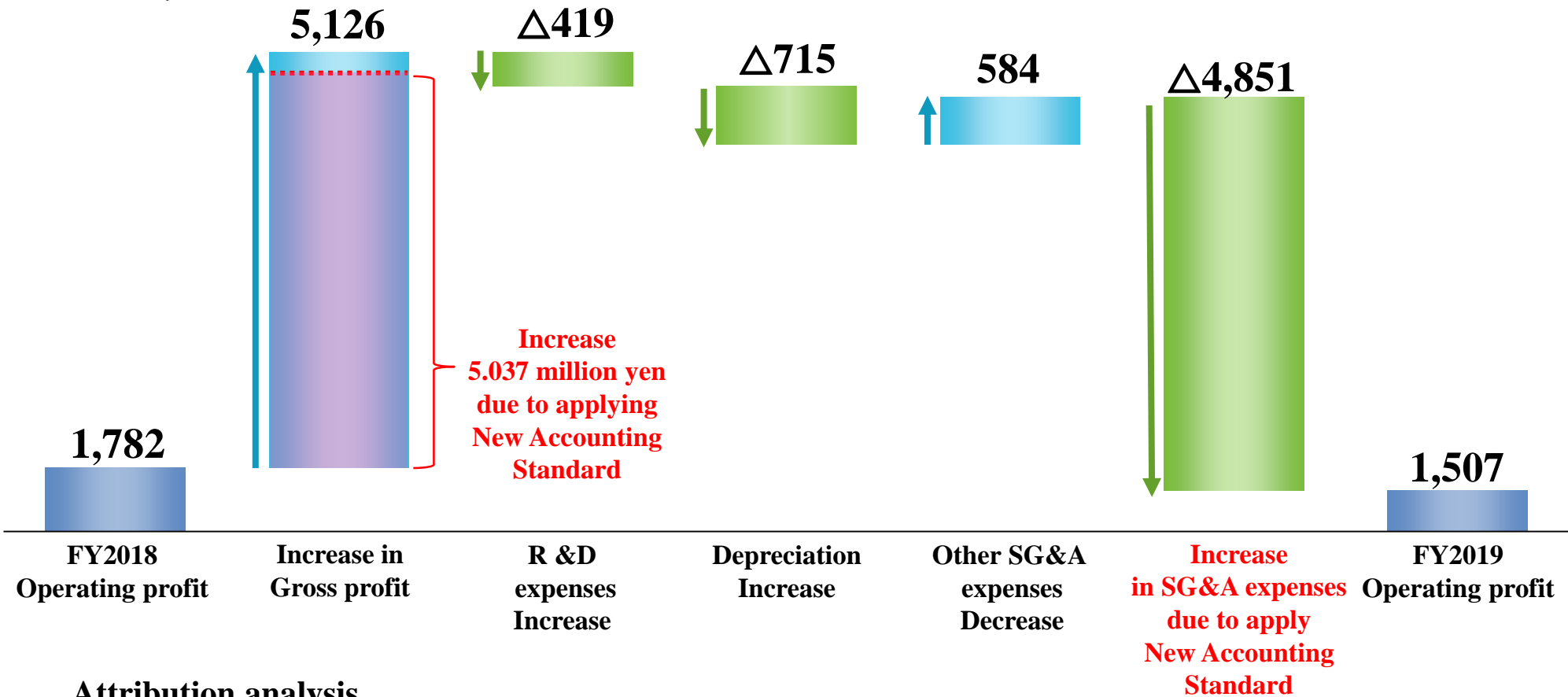
Area	Products	FY2018	FY2019		FY2020	
		Actual	Actual	YOY (%)	Forecast	YOY (%)
Internal Medicine	* 1 * 2 CANDESARTAN	11,924	13,224	110.9%	11,486	86.9%
	THYRADIN	5,657	6,893	121.9%	7,169	104.0%
	RIFXIMA	2,478	3,780	152.5%	4,829	127.7%
	* 1 AMLODIPINE	1,390	1,437	103.4%	1,184	82.4%
	MERCAZOLE	1,159	1,380	119.1%	1,383	100.2%
	LIPIDIL	1,803	1,370	76.0%	1,294	94.5%
Obstetrics and Gynecology	RELUMINA (2019.3~)	363	2,615	720.4%	5,921	226.4%
	* 1 FREWELL (2018.12~)	668	2,248	336.5%	2,469	109.8%
	ANGE	835	1,009	120.9%	958	94.9%
	LUTEUM	392	514	131.1%	519	101.0%
	NORLEVO	1,294	217	16.8%	180	82.9%
	* 3 Magsent (2020.3~)	-	55	-	878	1583.7%
Urology	* 1 * 4 LEUPRORELIN	4,167	4,794	115.1%	3,639	75.9%
	* 1 BICALUTAMIDE	1,221	1,258	103.0%	1,060	84.3%

* 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

Analysis of Increase and decrease in Operating Profit (YOY)

Millions of yen



Attribution analysis

- Although gross profit increased, operating profit decreased due to an increase in depreciation expenses resulting from the start of depreciation of distributorship and an increase in R&D expenses resulting from progress of candidates in their development stage.

Consolidated Balance Sheet

End of FY2018

Millions of yen

Current assets 37,829	Current liabilities 18,002
Property, plant and equipment 13,573	Long-term liabilities 20,735
Intangible assets 15,332	Net assets 43,456
Investments and other assets 15,458	

Total assets ¥82.194 million

End of FY2019

Millions of yen

Current assets 37,326 (Δ503)	Current liabilities 17,127 (Δ874)
Property, plant and equipment 13,539 (Δ34)	Long-term liabilities 21,537 (+801)
Intangible assets 13,584 (Δ1,748)	Net assets 41,573 (Δ1,882)
Investments and other assets 15,789 (+330)	

Total assets ¥80.239 million
(Δ1,954)

Assets	
Cash and deposits	Δ3,688
Notes and accounts receivable	2,770
Property, plant and equipment	Δ34
Intangible assets	Δ1,748
Liabilities/Net Assets	
Notes and accounts payable	Δ1067
Loans payable	Δ49
Retained earnings	Δ1,070

FY2020 Forecast (Consolidated)

Millions of yen	FY2019 Results	FY2020 Forecast	YOY Actual +/-	YOY +/- %
Net sales	52,542	53,000	458	0.9%
Operating profit	1,507	2,000	493	32.7%
Ordinary profit	1,715	1,900	185	10.8%
Profit attributable to owners of parent Co.	649	1,500	851	131.1%

Factors

- Net sales are expected to increase due to growth in sales of new products in the field of obstetrics and gynecology, such as RELUMINA and Magcent, as well as of RIFXIMA in gastroenterology.
- Profit attributable to owners of parent Co. is expected to increase significantly, as there are no extraordinary losses related to the relocation of the research center that occurred in 2019 financial year.
- The impact of COVID-19 on performance is not taken into account.

Reference

Capital Expenditures

(Millions of yen)

2,619

1,934

619

FY2018

FY2019

FY2020
Forecast

Depreciation

(Millions of yen)

2,491

3,669

3,299

FY2018

FY2019

FY2020
Forecast

R&D expenses

(Millions of yen)

4,493

4,913

4,575

FY2018

FY2019

FY2020
Forecast

Overview of FY2019 and FY2020 Major Initiatives

ASKA Pharmaceutical Co., Ltd.

Takashi Yamaguchi

President, Representative Director

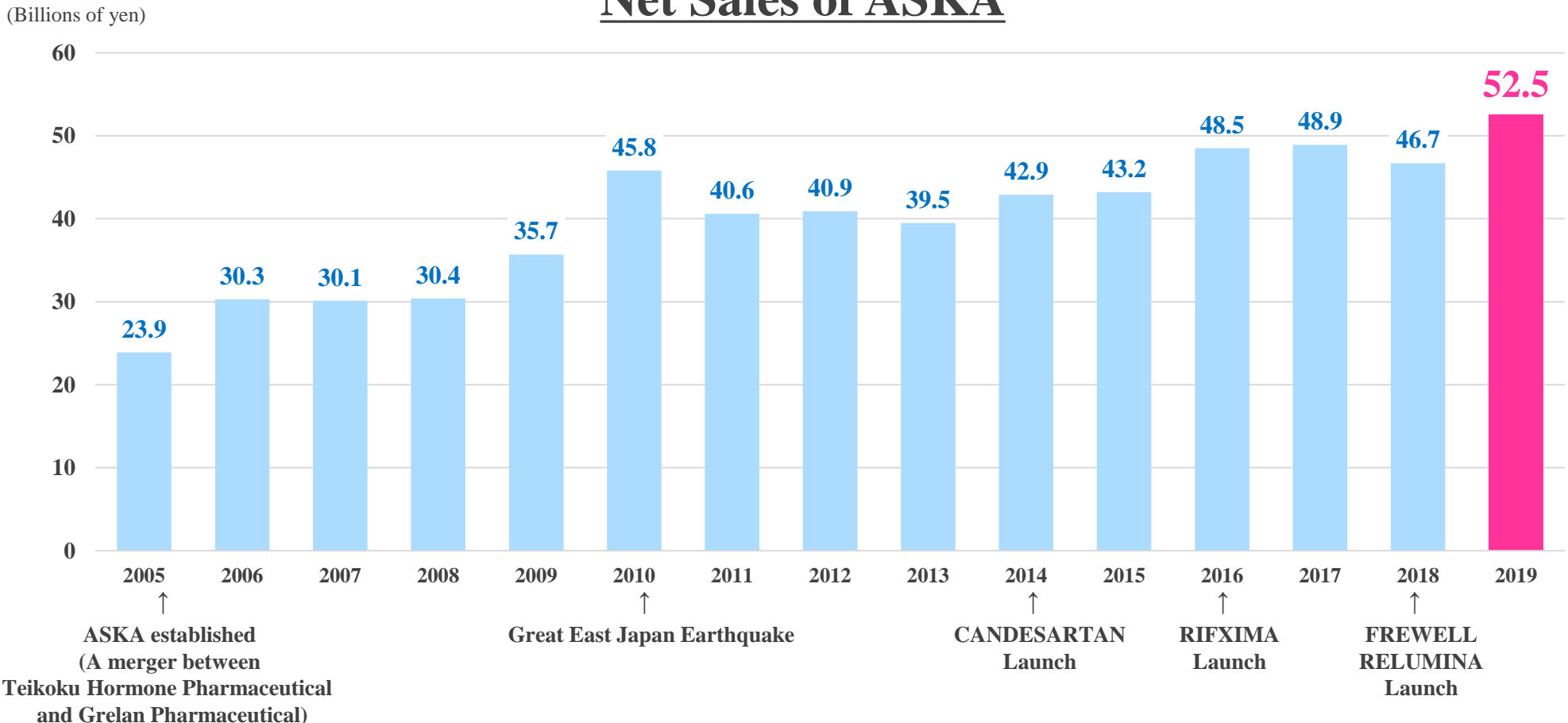
Today's Content

- **FY2019 Overview**
- **ASKA Objectives**
- **Contributing to Women's Healthcare**
- **Initiatives in Other Priority Areas**
- **Research and Development Update**

Overview of FY2019

Major Achievements in FY2019 ①

Net Sales of ASKA



Achieved Sales of ¥50 Billion for the First Time
Since the Founding of the Company

Major Achievements in FY2019 ②

Active Licensing Activities



**Co-research Agreement with RaQualia
for Ion Channel Drug Discovery**



**Option Agreement with Renasience
in the Field of Gynecology**



**Option Agreement with KinoPharma
for the Treatment of Cervical Dysplasia**



**Licensing Agreement with INSUD PHARMA
for Drospirenone in Women's Health**

ASKA Objectives

Core Values Provided by the Whole ASKA Organization

Sales and Medical Activities

- Gathering information on medical needs
- Providing highly specialized information

Spread and contribute to treatment options

R&D

- Drug discovery in new fields
- Product introductions and out-licensing activities

Continuous development for new drugs

Production

- Construction and enhancement of production systems, mainly at the Iwaki factory

Responsibilities for a stable supply chain

Structure

- Corporate development through transition to a holding company structure

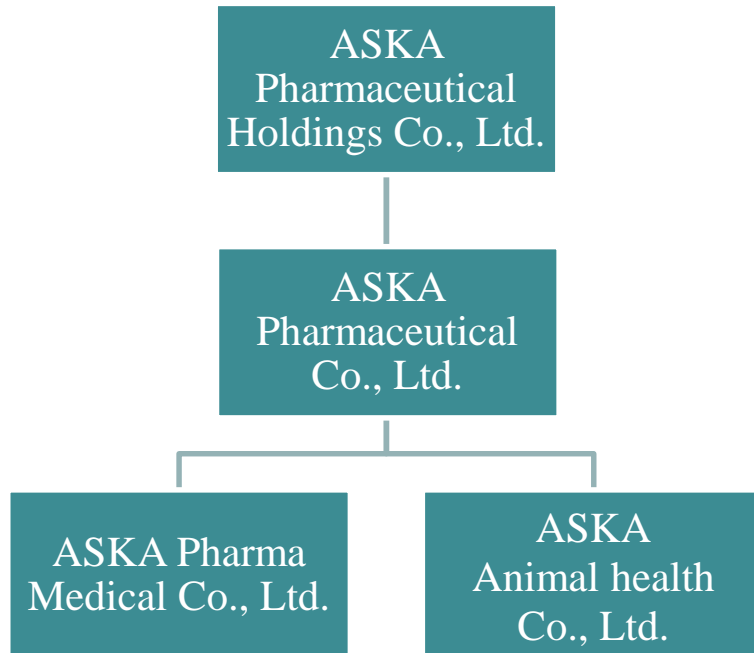
Adapting to diversified medical needs



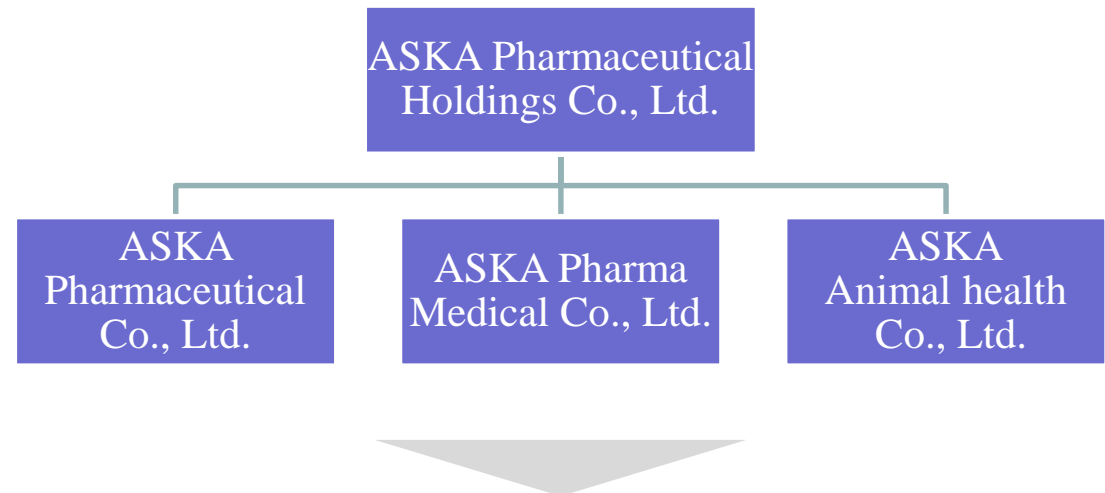
Through the development and spread of drugs that improve QOL,
Supporting Women's Health and Social Advancement

Establishment of ASKA Pharmaceutical Holdings Co., Ltd.

<Step1: From April 1, 2021 >



<Step2: Scheduled for Early Transition>



Aiming to Become
a "Total Healthcare Company"

[Summary of the share transfer]

Ordinary general meeting of shareholders to approve transfer of shares: June 25, 2020

Current ASKA stock is delisted on March 30, 2021.

Planned date of establishment of holding company: April 1, 2021 ("effective date")

Planned listing: April 1, 2021

[N.B.]

The schedule of the share transfer may be changed due to the necessity for the proceedings of the share transfer or for any other reason. The shares of the newly established holding company are scheduled to be listed on the first section of the Tokyo Stock Exchange. In addition, since ASKA Pharmaceuticals Ltd will become a wholly-owned subsidiary of the holding company through this share transfer, it is scheduled to be delisted prior to the listing of the holding company. As for the final date of delisting, it is subject to change because it is determined based on the rules of the Tokyo Stock Exchange.

Objectives of the Holdings Structure

① Enhancement of Businesses Related to Healthcare Field

Attempt to develop associated businesses by comprehensively recognizing healthcare as a frameworks of series phases from prevention to examination, diagnosis and treatment.

② Separating between Administration and Business Execution

We will aim to establish a system that clarifies roles and responsibilities of our group companies to appropriately and promptly respond to business environmental changes.

③ Maximized Group Value

Considering the characteristics of each business and emphasizing strategic ties among our group companies, the company will execute an optimal strategy from the perspective of the whole group.

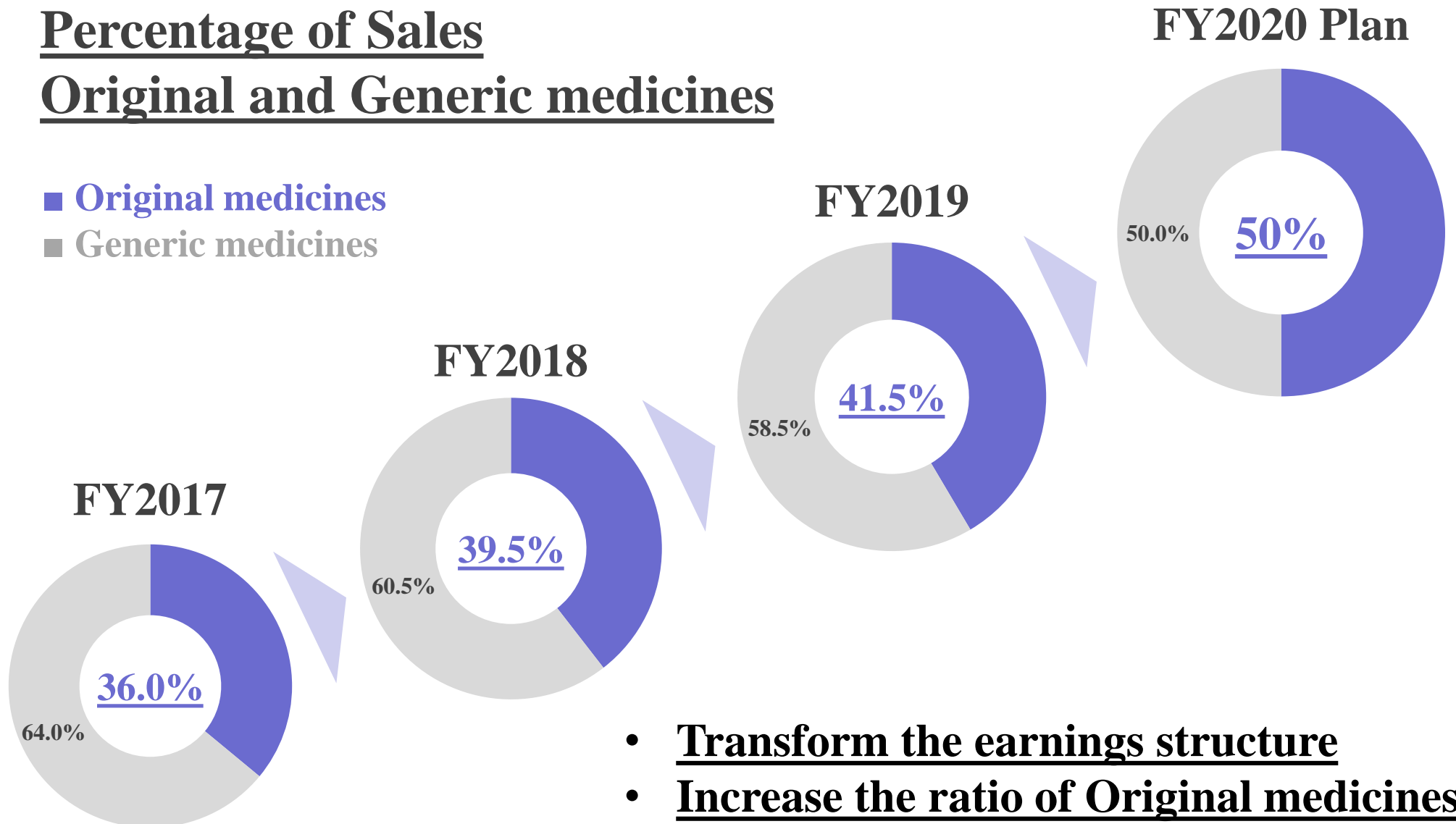
④ Enhancement of Group Governance

**Governance functions for the group as a whole will be allocated to the Holdings Company.
Business operations will be conducted under unified corporate policies.**

Transformation into an Innovative Drug-Based Business

Percentage of Sales Original and Generic medicines

- Original medicines
- Generic medicines



- Transform the earnings structure
- Increase the ratio of Original medicines

ASKA PLAN 2020

"ASKA PLAN 2020" Medium-Term Management Strategy

Consolidated	FY2016	FY2017	FY2018	FY2019	FY2020	Next Medium-Term Management Plan
	Actual	Actual	Actual	Actual	Forecast	Target
Net sales (billions of yen)	48.5	48.9	46.7	52.5	53	70
Rate of operating profit	3.7%	5.8%	3.8%	2.8%	3.8%	10.0%
ROE	7.8%	5.8%	4.1%	1.5%	3.6%	8.0%

Formulating the next medium-term plan

Scheduled to Be Announced by the End of FY2020

- Target for the next medium-term management plan

Net sales: ¥70 billion, Rate of operating income: 10%, ROE: 8%

- Elements for achieving ¥70 billion

Launched: RELUMINA (Uterine fibroids), FREWELL, and RIFXIMA

Under development: Ulipristal, RELUMINA (Endometriosis), AKP-009, etc.

Initiatives for SDGs



SUSTAINABLE DEVELOPMENT GOALS

SDGs

2030

Since its establishment, ASKA Pharmaceutical has been continuously working on contributing to women's health care through manufacturing of pharmaceuticals, focusing on THYRADIN, that are indispensable to the world and the provision of a wide range of obstetric and gynecological products.

Considering the role that a pharmaceutical company should play in the future, contributing to SDG activities.

At present

2020



Established

1920

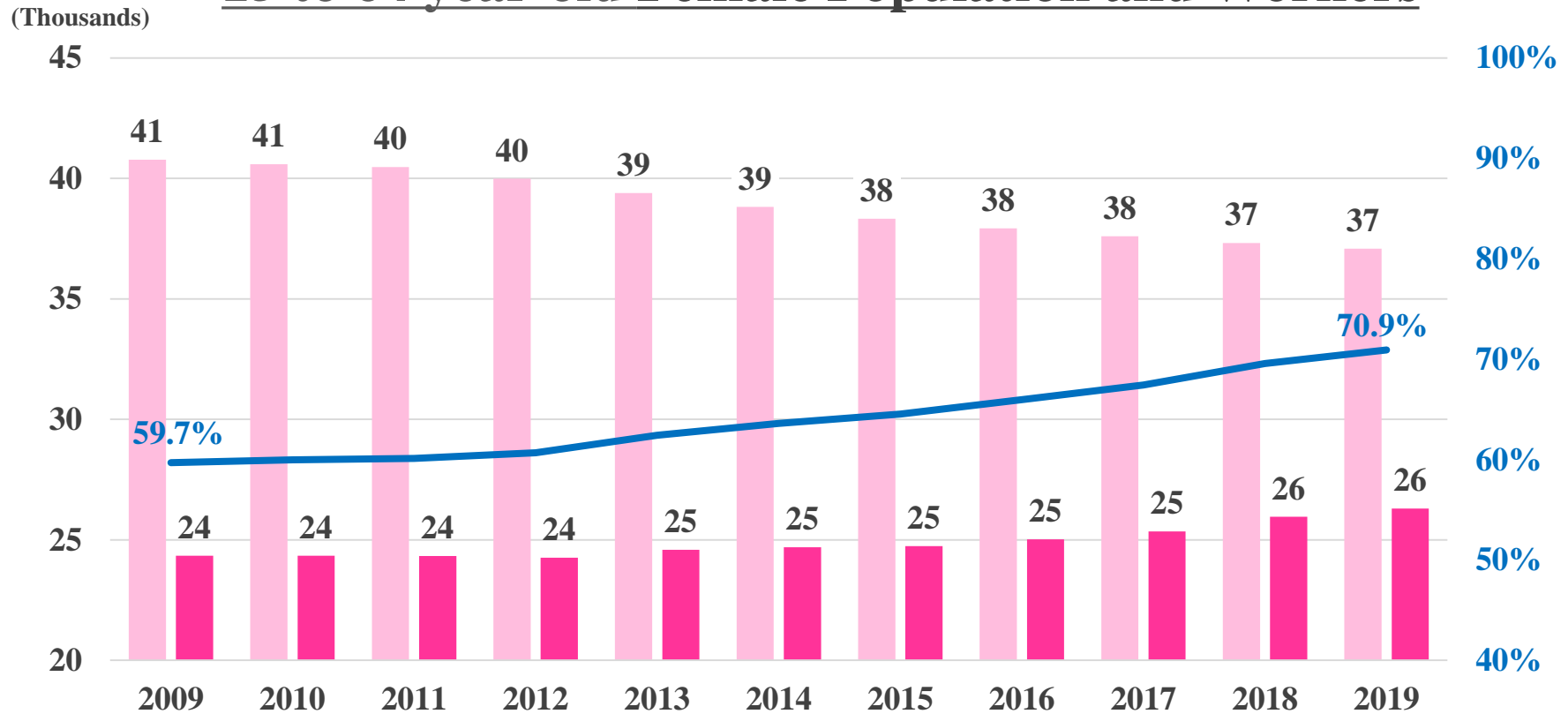
Contribution items of ASKA

- 3. Good Health and Well-being
- 5. Gender Equality
- 7. Affordable and Clean Energy
- 12. Responsible Consumption and Production
- 13. Climate Action
- 17. Partnerships

Contributing to Women's Healthcare

Number of Female Workers

15 to 64 year-old Female Population and Workers

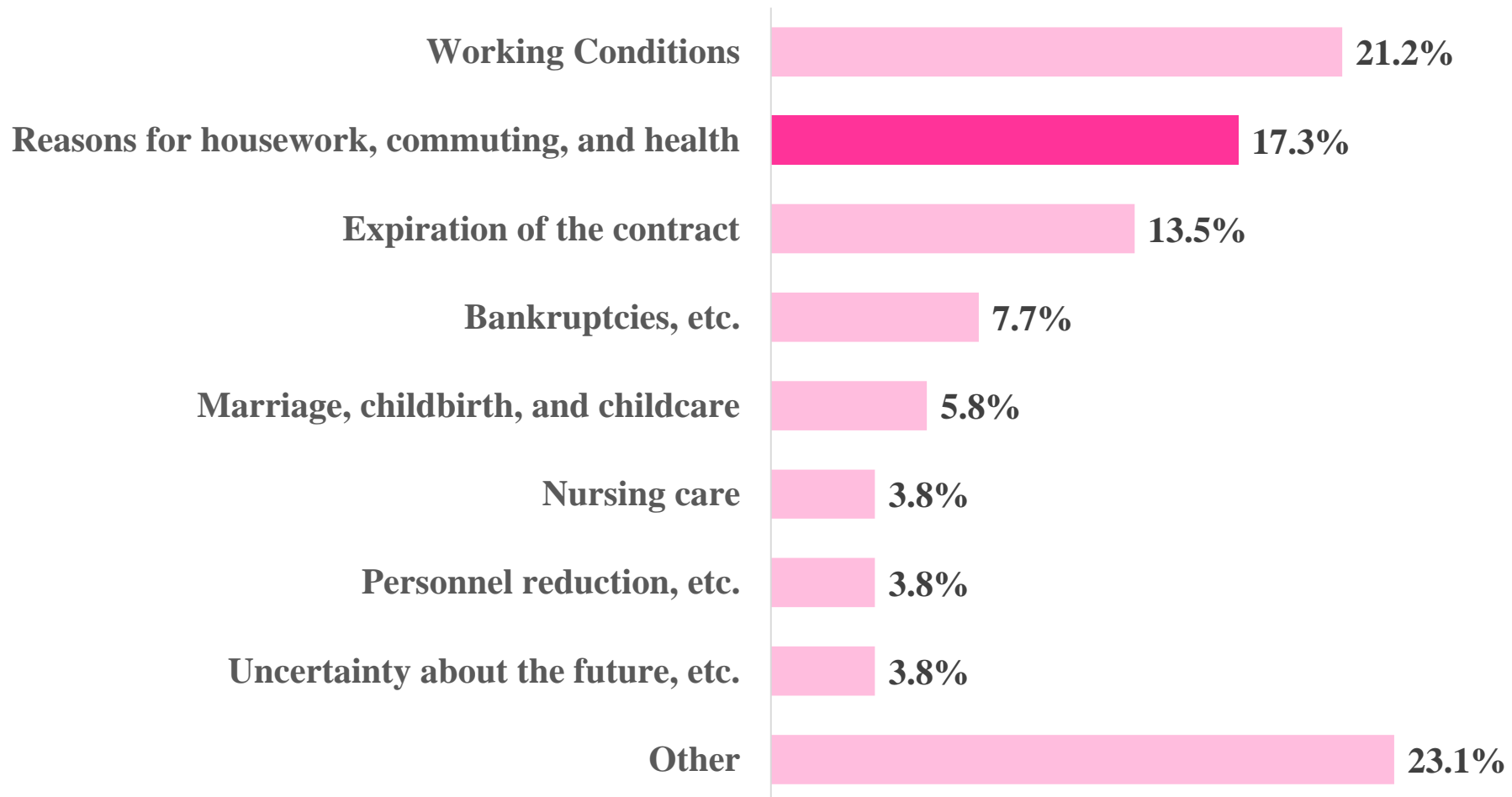


Source: Labour Force Survey 2019, Statistics Bureau, Ministry of Internal Affairs and Communications.

Female population
 No. of female employees
 Rate of female workers

The Number of Female Workers Has Increased by About 1,960,000 over for the Past 10 Years

Reasons for Women's Turnover in Employment (2019)



Source: Labour Force Survey 2019, Statistics Bureau, Ministry of Internal Affairs and Communications.

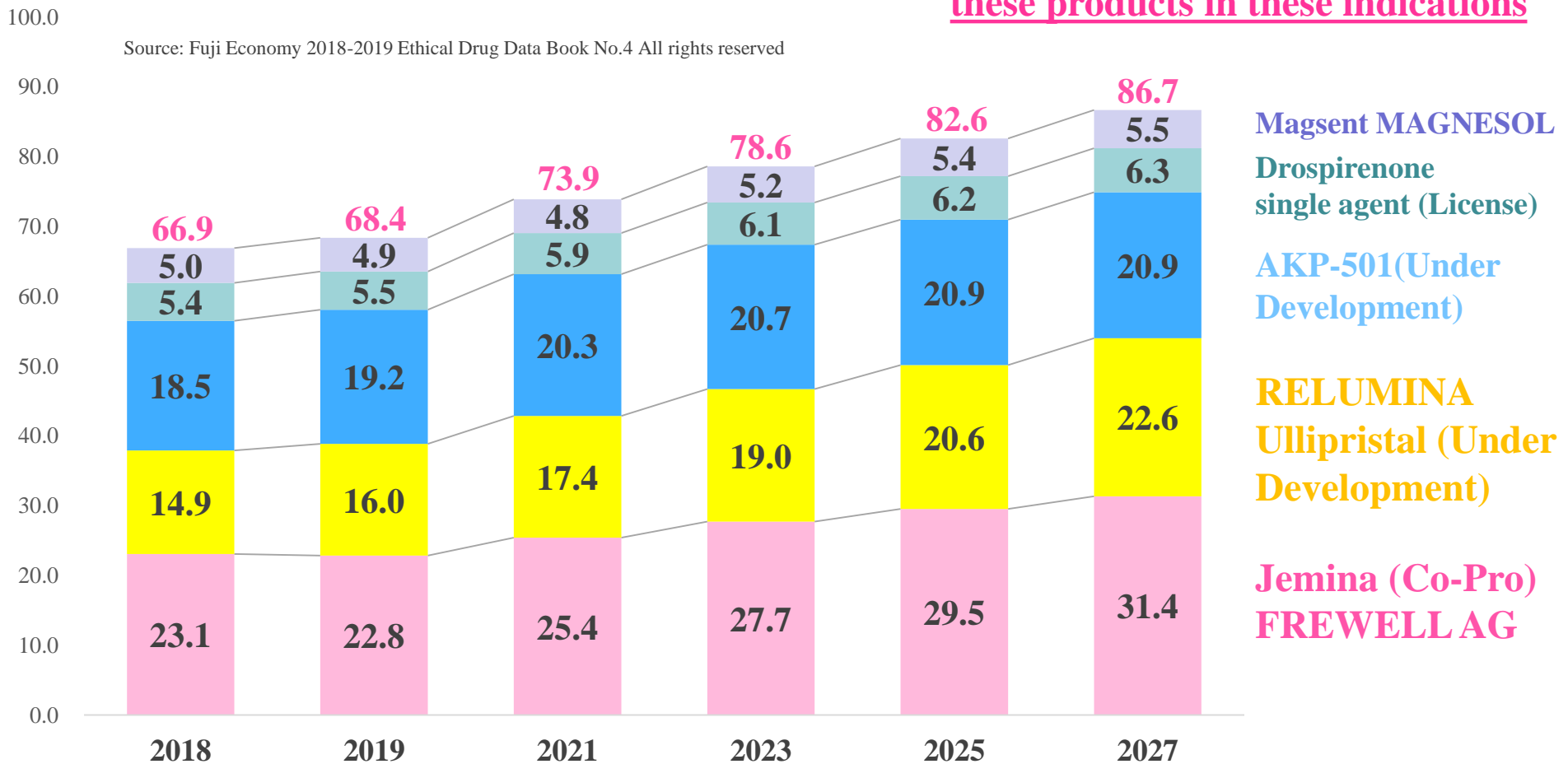
On the Other Hand, Many Women Have No Choice but to Leave for Health Reasons, etc.

Projections of Ob/Gyn Market Expansion by Indication

(Billions of yen)

We will launch and expand these products in these indications

Source: Fuji Economy 2018-2019 Ethical Drug Data Book No.4 All rights reserved



Magsent MAGNESOL
Drospirenone
single agent (License)

**AKP-501(Under
Development)**

RELUMINA
Ullipristal (Under
Development)

Jemina (Co-Pro)
FREWELLAG

- Menopause/Menstrual disorders
- Infertility
- Imminent premature birth /Labor pains

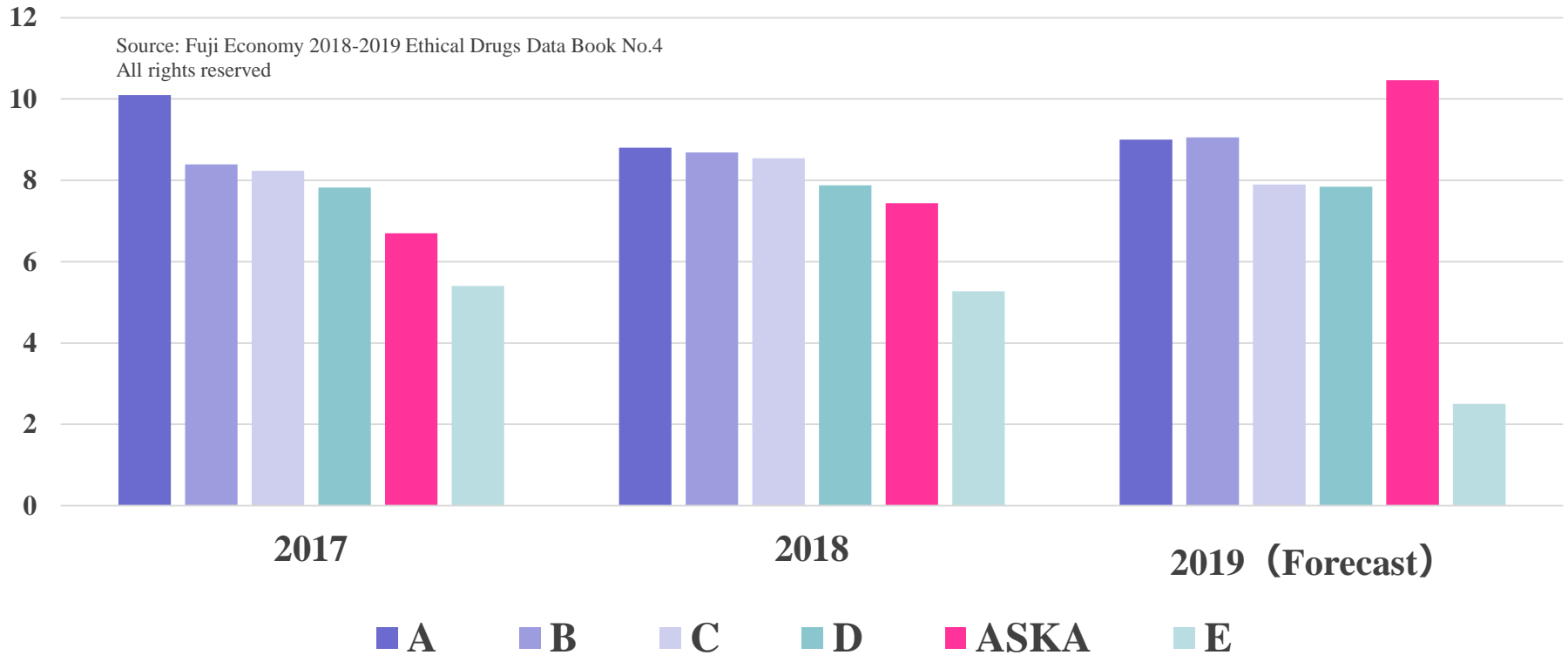
- Uterine fibroids/Endometriosis
- Oral contraception (including EC)

Transition of Sales in the Field of Ob/Gyn

Sales in Ob/Gyn by Major Companies by Fuji Economic Forecast Manufacturer

(Billions of yen)

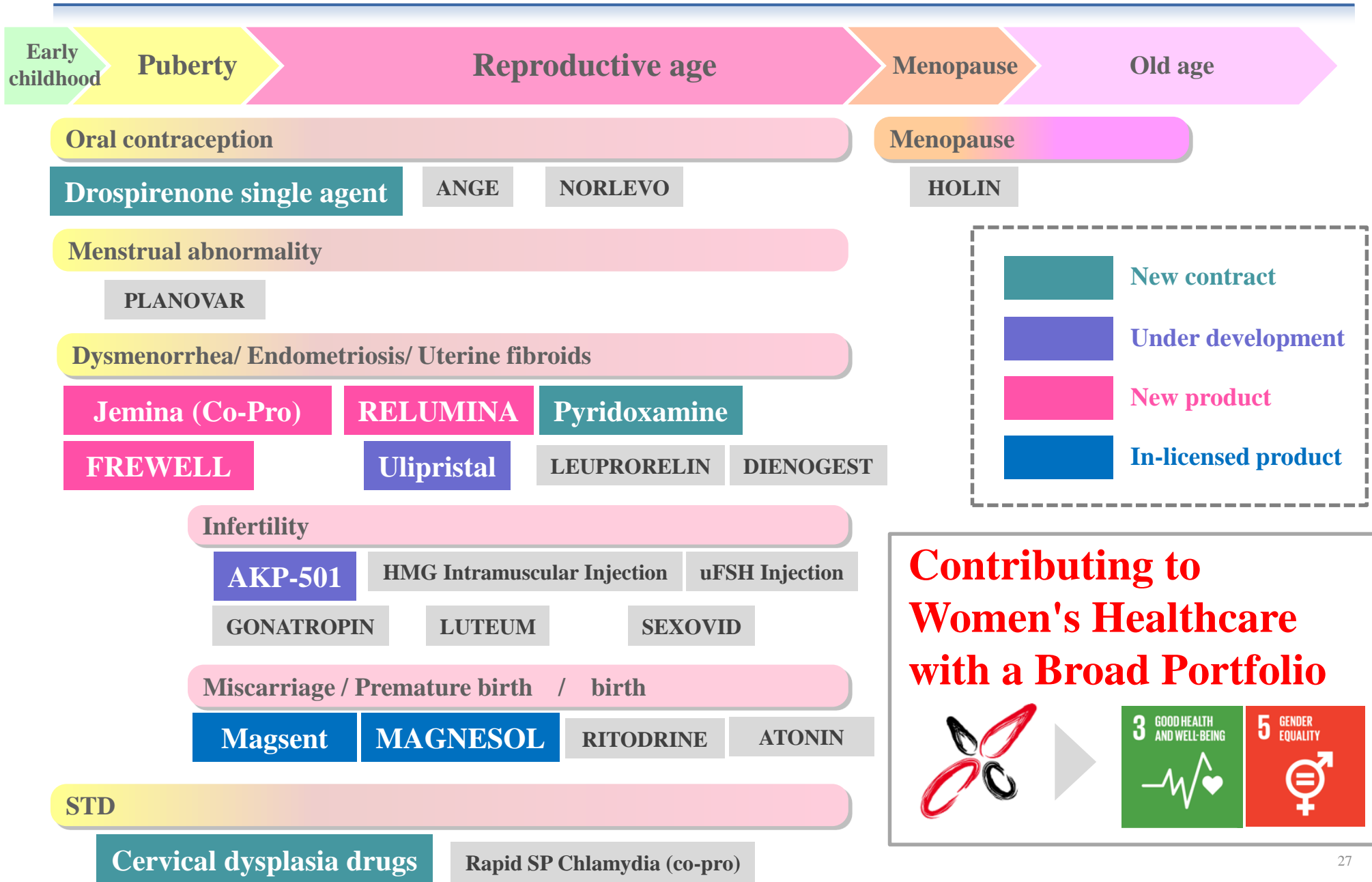
Source: Fuji Economy 2018-2019 Ethical Drugs Data Book No.4
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*ABCDE are other Ob/Gyn companies

ASKA Aims to Become Leader in the Field of Ob/Gyn

Gynecological Products by Life Stage

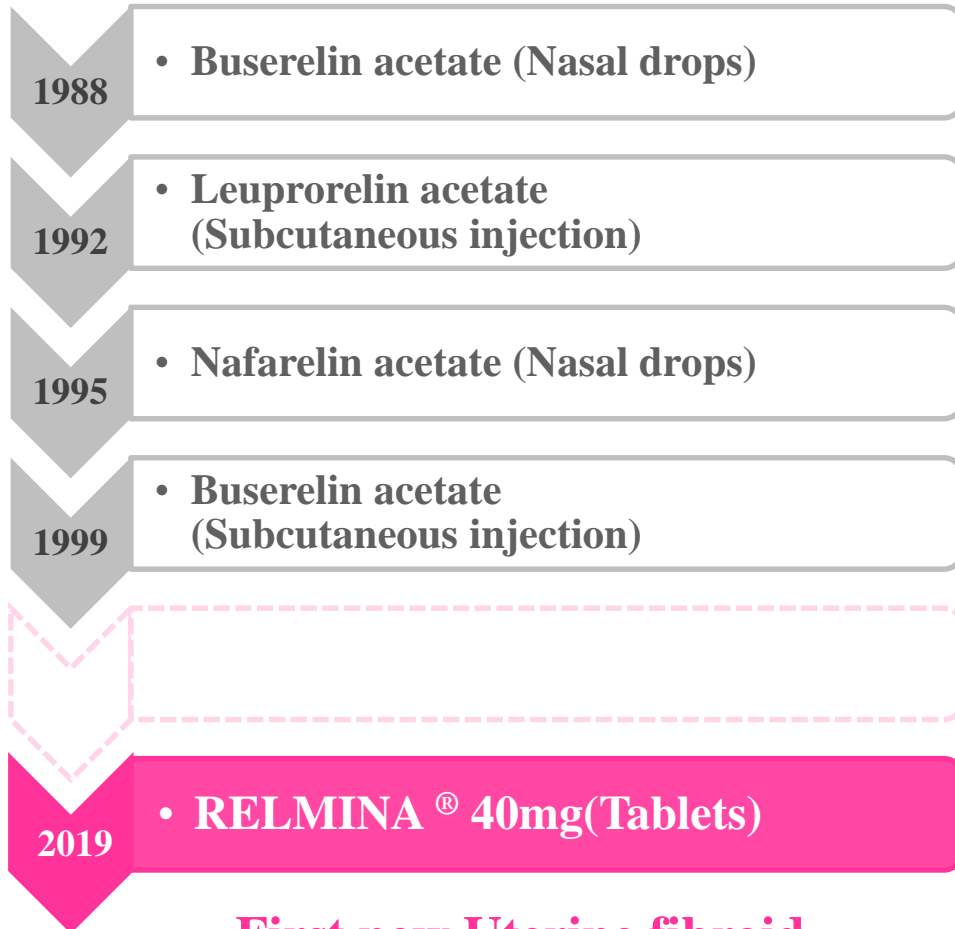


Contributing to Women's Healthcare with a Broad Portfolio



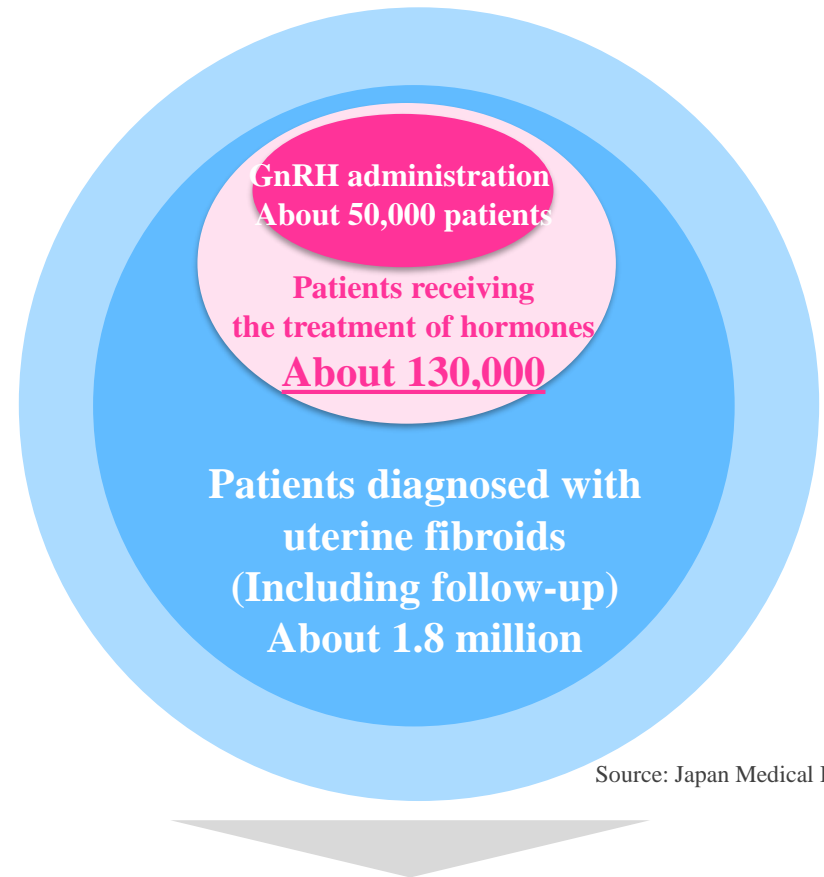


Release year of the treatment of Uterine fibroids(GnRH)



First new Uterine fibroid treatment in 20 years

Uterine fibroid market

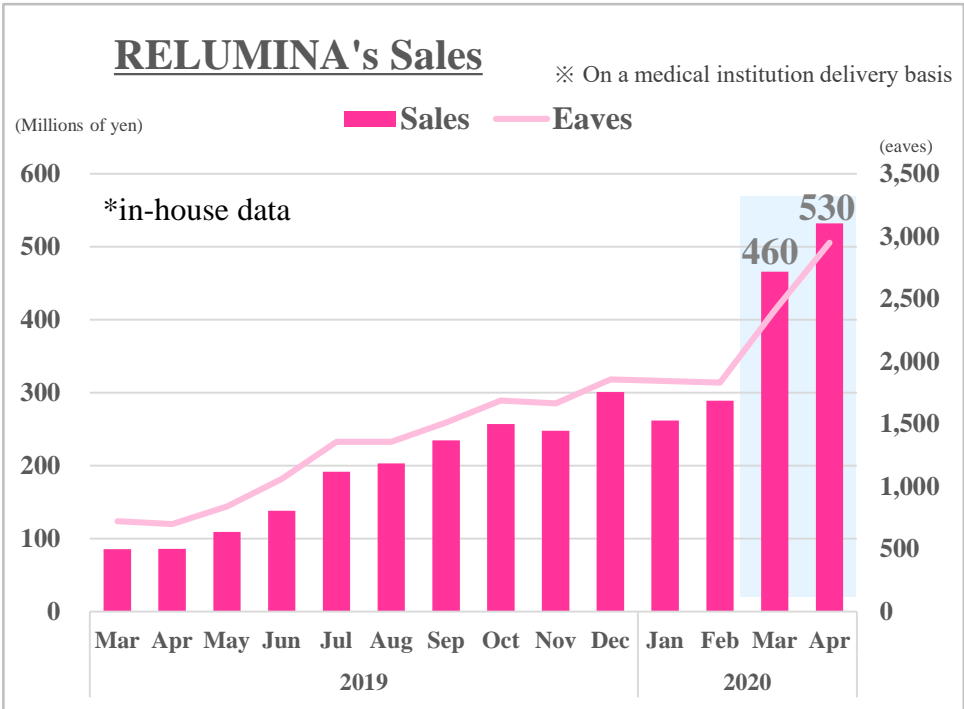


Source: Japan Medical Data Center

We will not only aim for the GnRH market but also the market of other treatments for Uterine fibroids



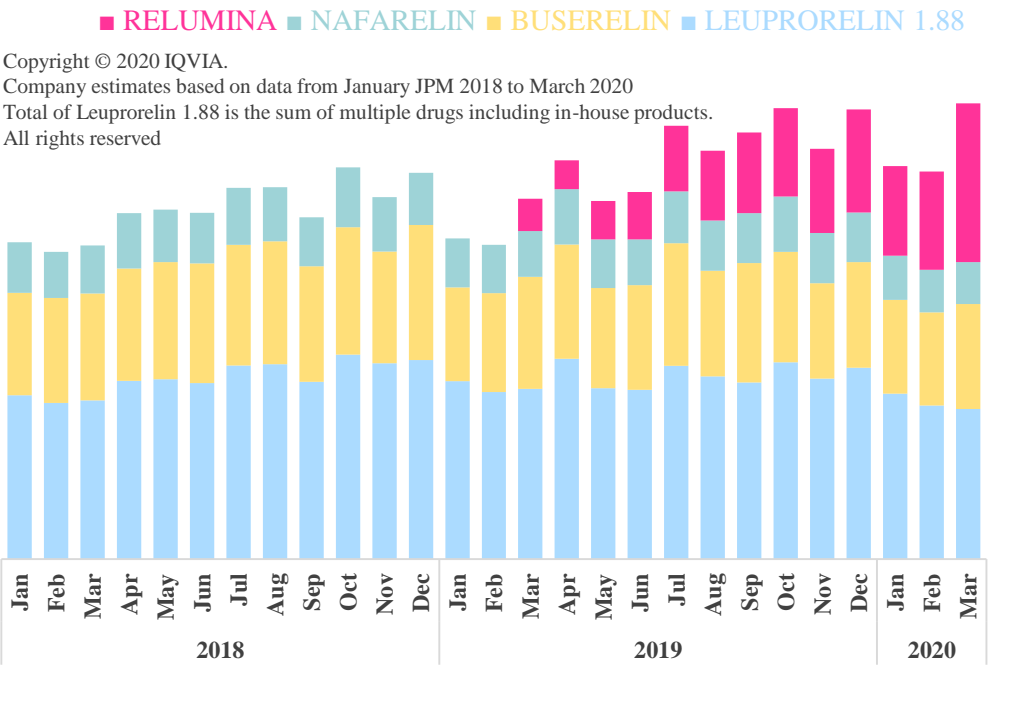
March 2020: Release from Prescription Length Limit



Increased sales and number of adoption RELUMINA after March 2020

Estimated Number of Cases of Uterine Fibroids

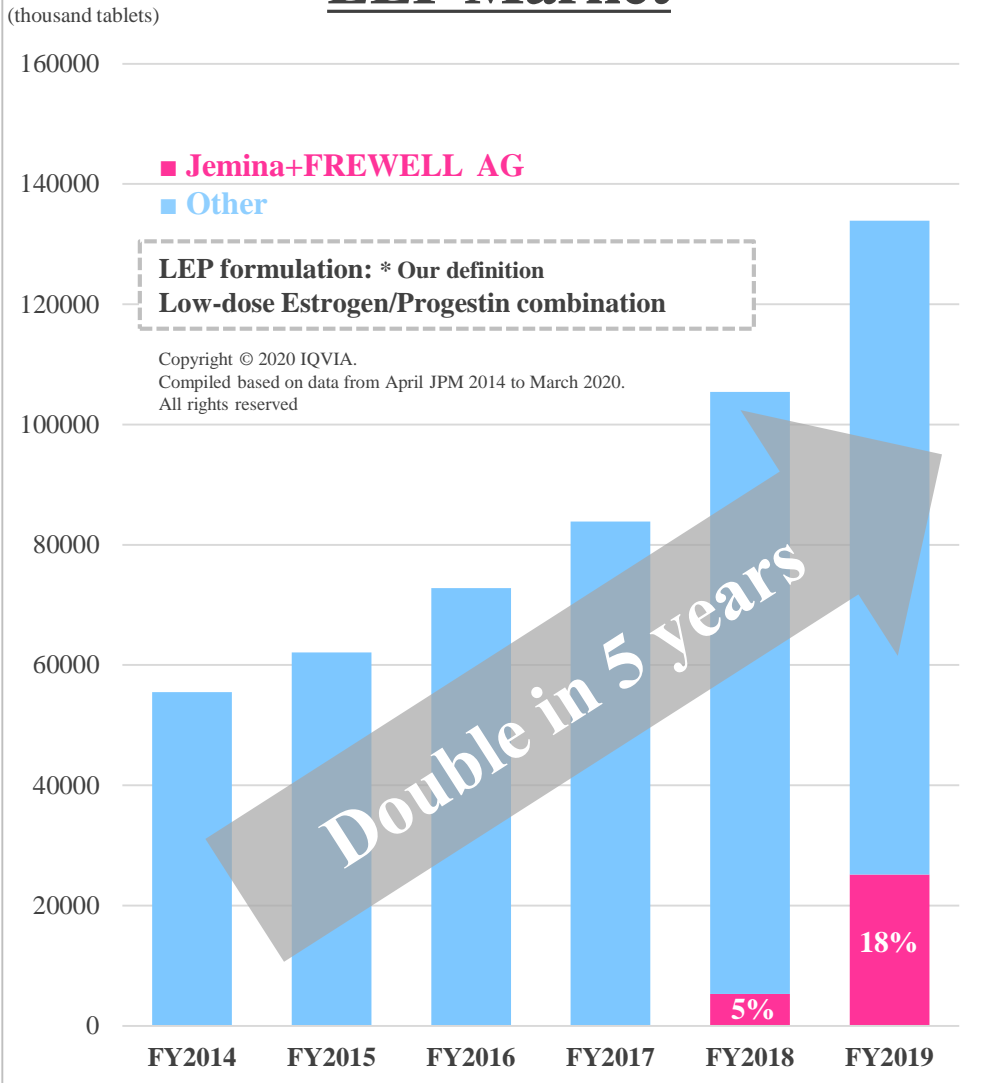
※ Estimates based on quantity



GnRH marketplace expected acceleration of the switch from other medicines after the release from prescription length limit

LEP Formulation (Jemina, FREWELL)

Continue to Expand LEP Market



Increasing Need for LEP Formulations



Launched by Nobel Pharma in October 2018

Jemina® Tablets

Co-promotion

Proposal for New Administration Methods (Continuous Administration)



Launched in December 2018

FREWELL® Tablets LD/ULD"ASKA"

Authorized Generics*

*The generic medicines which be authorized to make in the same way as original makers

Reduction of Drug Costs and Burden on Patients

Initiatives in Other Priority Areas

Internal Medicine Field

Contributing to Unmet Medical Needs



RIFXIMA

Key Drug for Hepatic Encephalopathy

1

Switching from existing antibacterial agent

- All-Drug Use Investigation
- Distribution control items

2

Combination with existing treatments

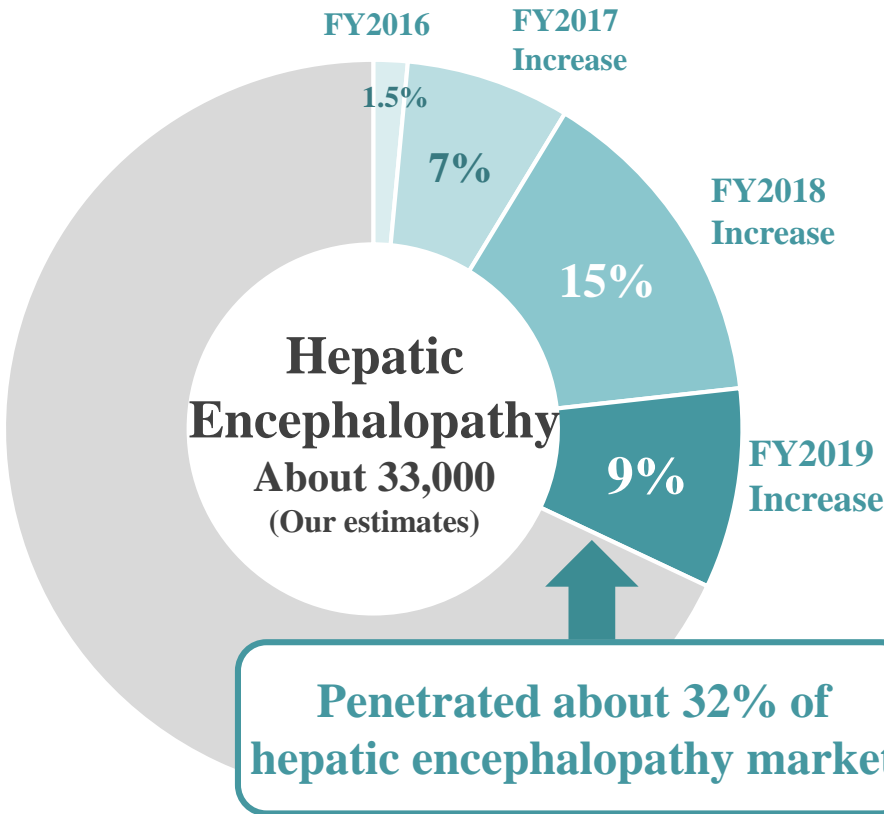
- Release from the prescription day limit
- Release from All-Drug Use Investigation

3

Position as Core Drug

4

Aim for further market penetration



Treatment of
Hepatic Encephalopathy
Aim at Further Penetration

Initiatives in the Thyroid Area

Toward the 100th anniversary of THYRADIN in 2022...



Scheduled for release in late June

『THYRADIN®-S I.V. INJECTION 200µg』

[Indications]

- Myxoedema coma
- Hypothyroidism (Limited to cases in which treatment with oral levothyroxine sodium is not appropriate)

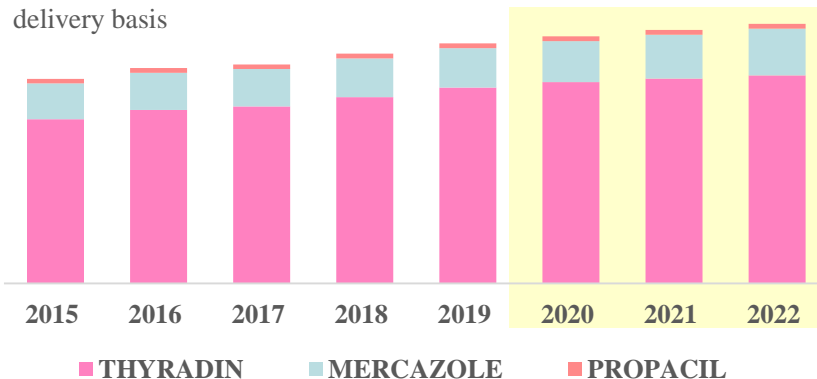
Developed as “Unapproved medicine / Off-label medicine with high medical needs” by ASKA in response to a request from the MHLW



Trends in the sales of thyroid products

On a medical institution delivery basis

2% to 3% increase per year



Core medicines

- THYRADIN-S Powder/Tablets
- MERCAZOLE Injection 10mg

<Basic medicines>

For long-term widespread use in the healthcare field due to the high need for insurance medical care

A pharmaceutical product with established efficacy and safety and a stable supply to the market on an ongoing basis.

Drugs for which NHI drug pricing measures have been implemented due to the need to ensure their availability.






Status of Research and Development
Expansion of Development Pipeline and
Enhancement of Drug Discovery Research

Development Pipeline

R&D Status (as of May 2020)

 Changes from the previous report

Development code (Generic name) Indication	PhI	PhII	PhIII	Filed	Approved
AKP-015 (levothyroxine sodium) Myxedematous coma/Hypothyroidism					Approved
CDB-2914 (Ulipristal) Uterine fibroids				Filed	
TAK-385 (Relugolix) Endometriosis				PhIII Ongoing	
AKP-501 (Folitropin gamma) Infertility		PhI Completed			
L-105 (Rifaximin) Hepatic encephalopathy (Children)				PhII/III Ongoing	
L-105 (Rifaximin) Crohn's disease			PhI Completed		
AKP-009 Benign prostatic hyperplasia			PhII Ongoing		

AKP-009 (New Androgen Receptor Modulator)

Focus on Development of In-house Products

AKP-009: Newly developed prostatic atrophic drug

Proposed indication: Urination disorder associated with benign prostatic hyperplasia

Domestic development: Phase II trials initiated December 2019)

<Target Product Profile>

Expected to be more effective than existing products for “Greater prostatic atrophy effect” and “Better urinary function improvement effect”

<Summary of Phase II trial>

Design	A Double-Blind, Placebo-Controlled, Parallel-Group Study
Target	Patient with benign prostatic hyperplasia
Dosage and administration method	Oral injection of 2.5 m g, 5mg, 10 mg (once a day)
Administration period	12 weeks
Number of cases	105 (planned)
Primary endpoint	Safety and efficacy Rate of change in prostatic volume from baseline at 12 weeks of administration
Scheduled completion of the test	November, 2020

Targeting the urination disorders treatment market
Value circa 100 billion yen

Dutasteride's patent has expired

Expected to Be
the Next Novel Drug

Relocation to Shonan iPark

Purpose

Enhance the New Drug Business Concentrating on Strengthening its Innovative Development

Current Status

- Advanced Drug Discovery Research Department moved already in June 2019 and conducted research at Shonan iPark. Promoting collaboration with Shonan iPark resident companies.
- Completed relocation from Kawasaki Research Center in March 2020. Expanding research activities at Shonan iPark from April 2020.

Anticipated Program Benefits

- A large number of researchers and organizations have accumulated and active exchange with industry, academia and government and diverse researchers will be enhanced
- Efficiently promote advanced drug discovery research, using the latest equipment and technologies
- Collaboration with Shonan iPark companies such as drug discovery support ventures and bio-ventures from academia

Global and Regional Expansion

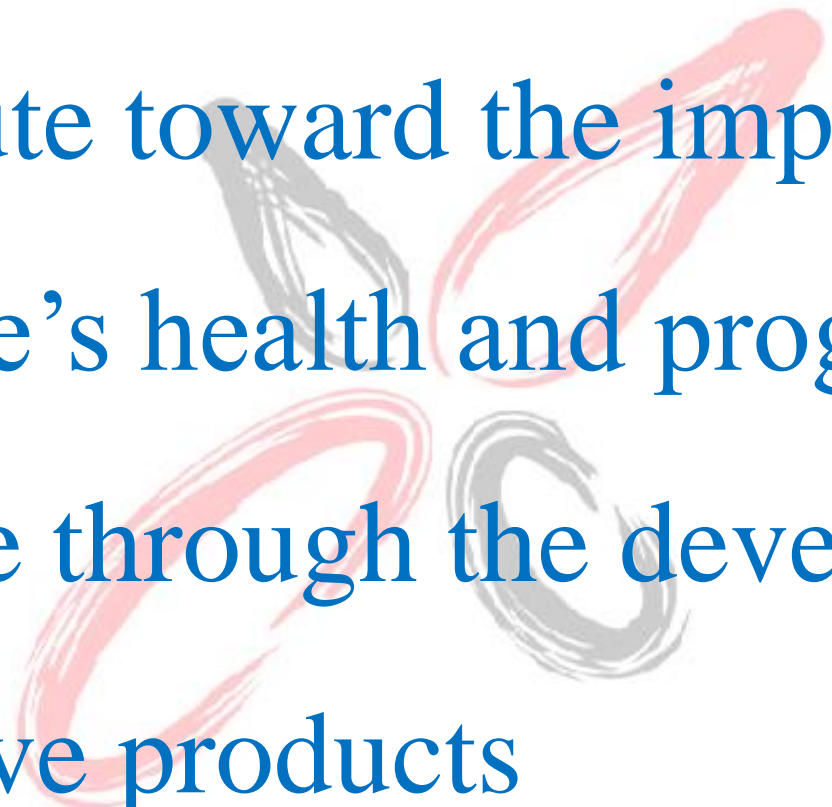
**As a result of the spread of COVID-19 worldwide,
International activities have been put on hold**

100th Anniversary



Advance further with all the alliances

- ASKA will reach its 100th anniversary on June 16, 2020.
 - Since our founding in 1920, the Company has consistently focused on drug discovery.
 - We have continued to create and provide pharmaceuticals of value to patients.
 - The past 100 years will be linked to the future.
 - Based on our corporate philosophy of "Contribute toward the improvement of people's health and progress in medicine through the development of innovative products", ASKA Pharmaceutical will continue to be a firm that contributes to people's lives.
- Advance further with all the alliances



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

あすか製薬株式会社

ASKA Pharmaceutical Co., Ltd.

Contact Information

Corporate Planning Department

Tel : +81-3-5484-8366

e-mail : kouhou@aska-pharma.co.jp

