

November 18, 2020

Financial Results of the Second Quarter, FY2020

 ASKA Pharmaceutical Co., Ltd.

Stock Code :4514

FORWARD LOOKING STATEMENT

- The forward-looking statements contained in this presentation are based on 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 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 medical advice.

The First Half of FY2020*

Consolidated Financial Summary

ASKA Pharmaceutical Co., Ltd.

Atsushi Maruo

Executive Director, Representative Director

*Refers to April 1st 2020 to March 31st 2021

Consolidated Statements of Income

Millions of yen	FY2019 Apr-Sep	FY2020 Apr-Sep	Actual +/-	Growth +/-
Net sales	26,582	27,403	+ 820	+ 3.1%
Cost of sales	14,492	14,563	+ 70	+ 0.5%
Gross profit	12,089	12,840	+ 750	+ 6.2%
Selling, general and administrative expenses	11,343	10,894	- 449	- 4.0%
Operating profit	746	1,946	+ 1,199	+ 160.7%
Ordinary profit	869	1,952	+ 1,082	+ 124.5%
Profit attributable to owners of parent	577	1,552	+ 975	+ 168.9%

* Put a current exchange rate and the ref (1 US dollar = 103.83 yen, as of Nov 18th 2020)
(1 Euro = 123.06 yen, as of Nov 18th 2020)

Net Sales by Business (Consolidated)

Millions of yen	FY2019 Apr-Sep	FY2020 Apr-Sep	Breakdown	Actual +/-	Growth +/-
Ethical drugs	24,177	25,128	91.7%	+ 951	+ 3.9%
Animal Health	2,319	2,232	8.1%	- 86	- 3.7%
Others	86	42	0.2%	- 44	- 51.0%
Total	26,582	27,403	100.0%	+ 820	+ 3.1%

Sales of Main Products

Millions of yen

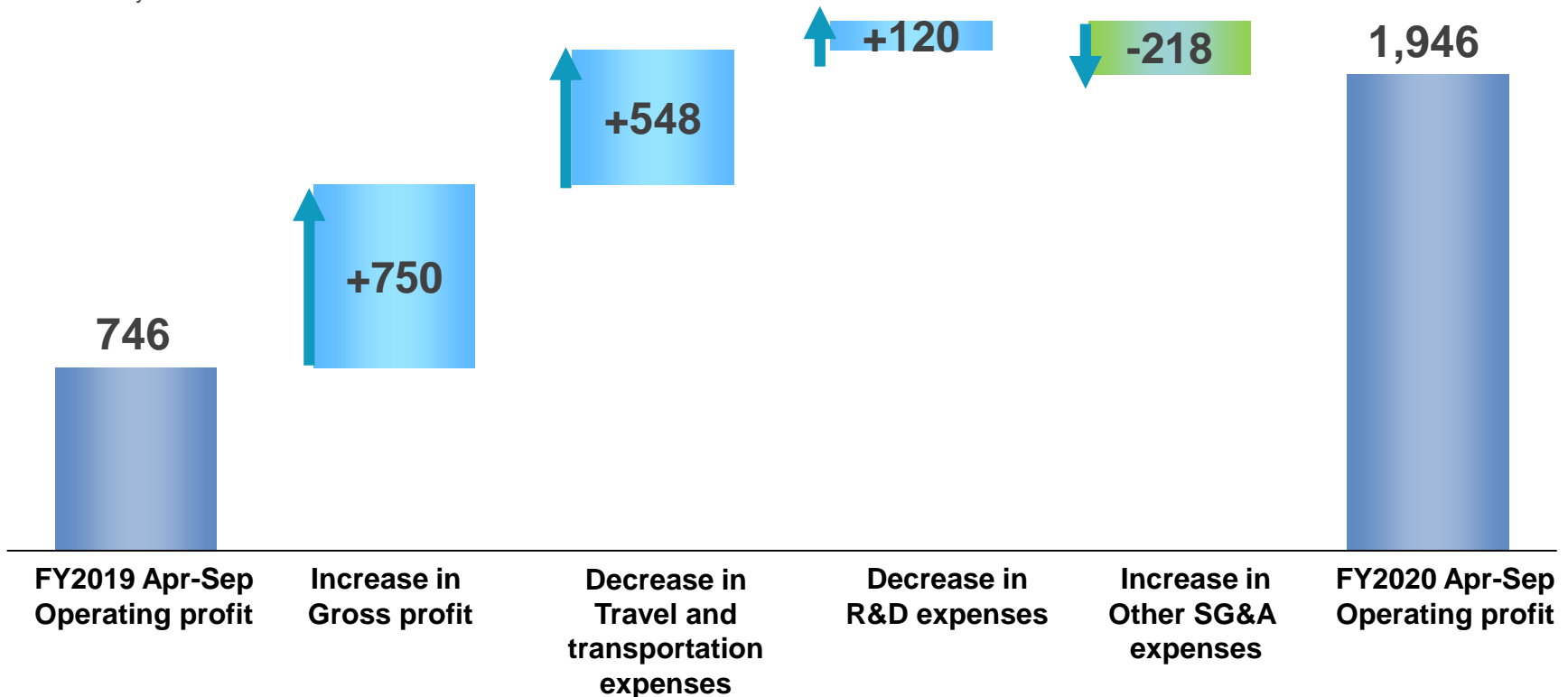
Area	Products	FY2019 Apr-Sep	FY2020 Apr-Sep		FY2020	
		Actual	Actual	YOY (%)	Forecast	YOY (%)
Internal Medicine	*1 *2 CANDESARTAN	6,878	6,117	88.9%	11,486	86.9%
	THYRADIN	3,433	3,579	104.3%	7,169	104.0%
	RIFXIMA	1,845	2,176	117.9%	4,829	127.7%
	MERCAZOLE	700	698	99.7%	1,383	100.2%
	*1 AMLODIPINE	790	632	80.0%	1,184	82.4%
	LIPIDIL	777	590	75.9%	1,187	94.5%
Obstetrics and Gynecology	RELUMINA (2019.3~)	865	2,519	291.1%	5,921	226.4%
	*1 FREWELL	1,012	1,355	133.9%	2,469	109.8%
	*4 Magsent (2020.2~)	—	466	—	878	1583.7%
	ANGE	538	453	84.1%	958	94.9%
	LUTEUM	246	238	96.9%	519	101.0%
Urology	*1 *3 LEUPRORELIN	2,472	2,274	92.0%	3,639	75.9%
	*1 BICALUTAMIDE	692	515	74.5%	1,060	84.3%

* 1 Generic Drugs * 3 1.88mg formulation is for gynecological indications only, but combined with 3.75mg formulation

* 2 Including combination drugs * 4 Total value of magnesium sulfate preparation

Analysis of Increase and Decrease in Operating Profit (YOY)

Millions of yen



Attribution analysis

- Gross profit increased due to growth in "RELUMINA" after the lifting of length of prescription restrictions, steady increase in main products such as "RIFXIMA", and recording of a lump-sum milestone payment related to the Agreement with Kyorin Pharmaceutical.
- Reduction in expenses due to reduction of direct sales activities due to the spread of the novel coronavirus

Consolidated Balance Sheet

End of FY2019

Millions of yen

Current assets 37,326	Current liabilities 17,127
Property, plant and equipment 13,539	Non-current liabilities 21,537
Intangible assets 13,584	Net assets 41,573
Investments and other assets 15,789	

Total assets ¥ 80,239 million

End of 2Q FY2020

Millions of yen

Current assets 37,809 (+483)	Current liabilities 15,702 (-1,425)
Property, plant and equipment 13,165 (-373)	Non-current liabilities 20,672 (-864)
Intangible assets 12,561 (-1,022)	Net assets 43,070 (+1,496)
Investments and other assets 15,908 (+119)	

Total assets ¥ 79,445 million
(-793)

Assets

- Cash and deposits +1,057
- Notes and accounts receivable-trade -652
- Property, plant and equipment -373
- Intangible assets -1,022

Liabilities/Net Assets

- Notes and accounts payable-trade -34
- Loans payable -1,449
- Retained earnings +1,267

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	649	1,500	+ 851	+ 131.1%

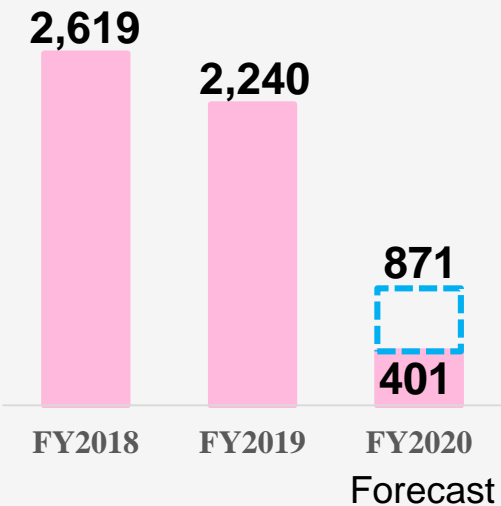
Factors

- Sales are expected to increase due to growth in “RELUMINA”, contributions from “RIFXIMA” and “Magsent”, as well as the recording of a lump-sum milestone payment.
- In terms of profits, operating income, ordinary income, and net income are all expected to increase respectively due to an increase in sales.

Reference

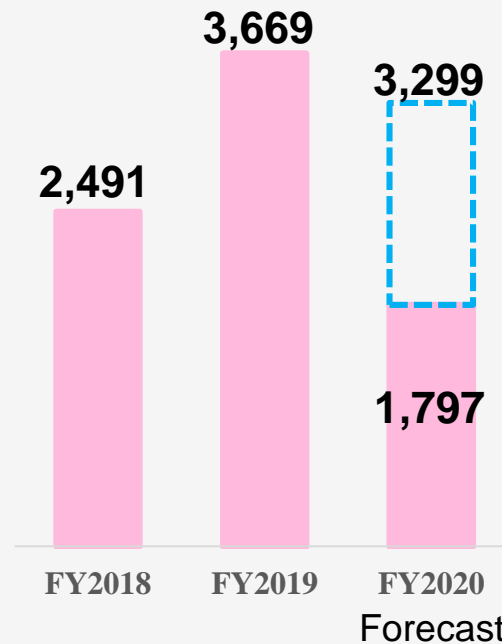
Capital Expenditures

(Millions of yen)



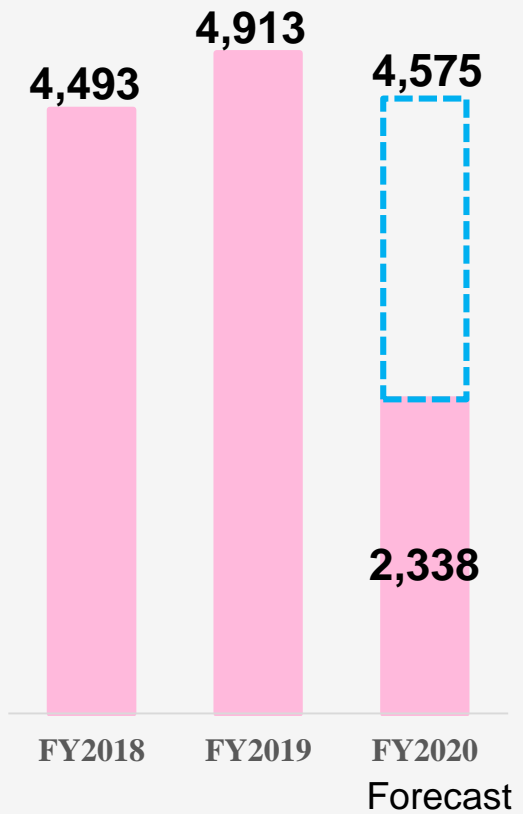
Depreciation

(Millions of yen)



R&D expenses

(Millions of yen)



Overview of the First Half of FY2020 Interim Annual Report

ASKA Pharmaceutical Co., Ltd.

Takashi Yamaguchi

President, Representative Director

Founding 100th Year



Advance further with all the alliances

Advertised in the Nikkei
(June 16, 2020)



ASKA reached its 100th anniversary on June 16, 2020.

Since our founding in 1920, the Company has consistently focused on drug discovery.

The Company has 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

Today's Content

- **Overview of the First Half of FY2020**
- **Initiatives for Major Themes in FY2020**
 - **Contribution to Women's Health Care**
 - **Initiatives in Internal Medicine**
 - **Research and Development**
 - **Global Expansion**

Overview of the First Half of FY2020

The Impact and Response to the Novel Coronavirus

From the viewpoint of preventing the spread of the novel coronavirus (COVID-19), the Company has taken numerous measures such as: the promotion of working from home, flexible commuting, self-restriction of business activities and travel, development of a Web friendly environment, and the correct utilization of electronic signatures.

In the second quarter of the fiscal year under review, the impact to business performance was minimal and the Company has maintained a stable supply chain.

Sales

- Slight impact on sales, up 3.1% YoY due to penetration of new drugs
- Continue activities by utilizing Web interviews and Webinars to prevent infection among healthcare professionals

R&D

- No significant effects have been observed regarding R&D activities at the present time.
- Enrollment delay has occurred in some clinical trials due to patients refraining from visits to clinics.

Production

- Maintain a stable supply system in production by a strict response
- We will continue to ensure a stable supply chain with appropriate risk assessment.

Initiatives and Achievements in the First Half of FY2020

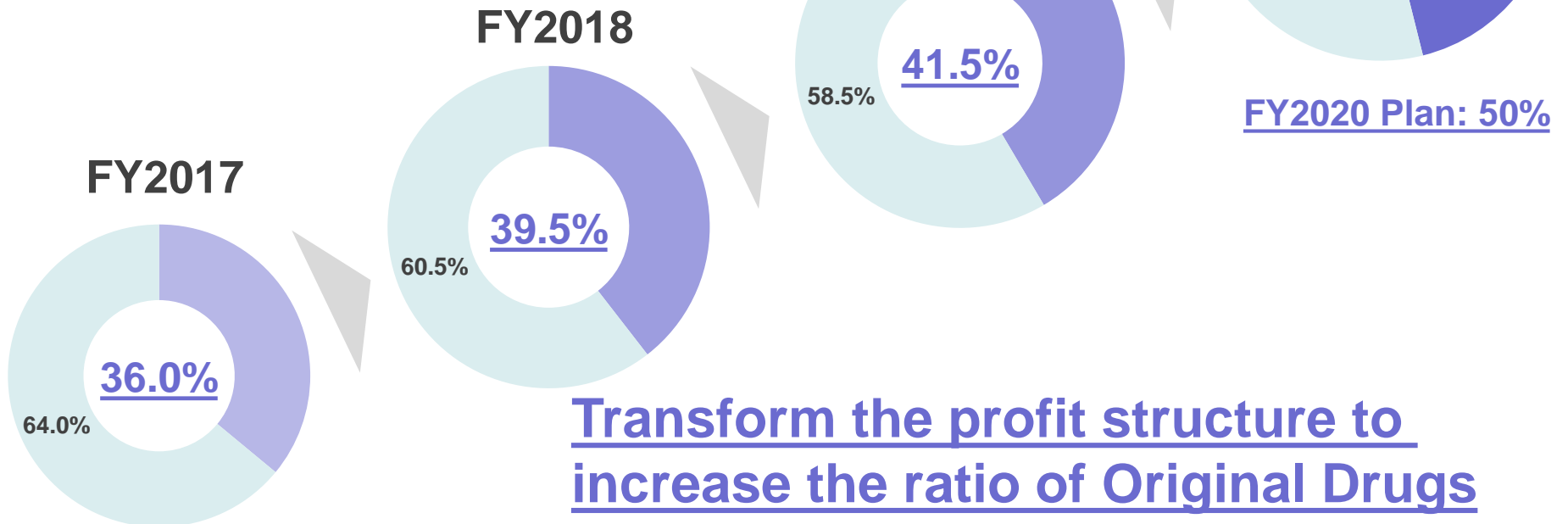
- **Growth of New Products such as RELUMINA[®] and RIFXIMA[®]**
- **Joint Development and Commercialization Agreement for AKP-009 with Kyorin Pharmaceutical**
- **Shares Transfer Agreement with Hataphar**
- **Co-promotion agreement for Riona[®] Tablets with Torii Pharmaceutical**

* Promotion of iron deficiency anemia within gynecology and obstetrics (Indication as in the application)

Transformation into New Drug-Based Business

Percentage of Sales Original and Generic Drugs

- Original Drugs
- GE Drugs



Update of Alliance Activities



Licensing Agreement for Drospirenone



Preparing for Phase I/ II clinical trials in Japan



Option Agreement regarding the Treatment for Cervical Dysplasia



Kino Pharma is conducting a Phase I Clinical Trial in Korea



Co-Development and Option agreement in the Field of Gynecology



Phase II trial initiated by physicians

* Adopted for CiCLE business by AMED



Joint Research Agreement on drug discovery research



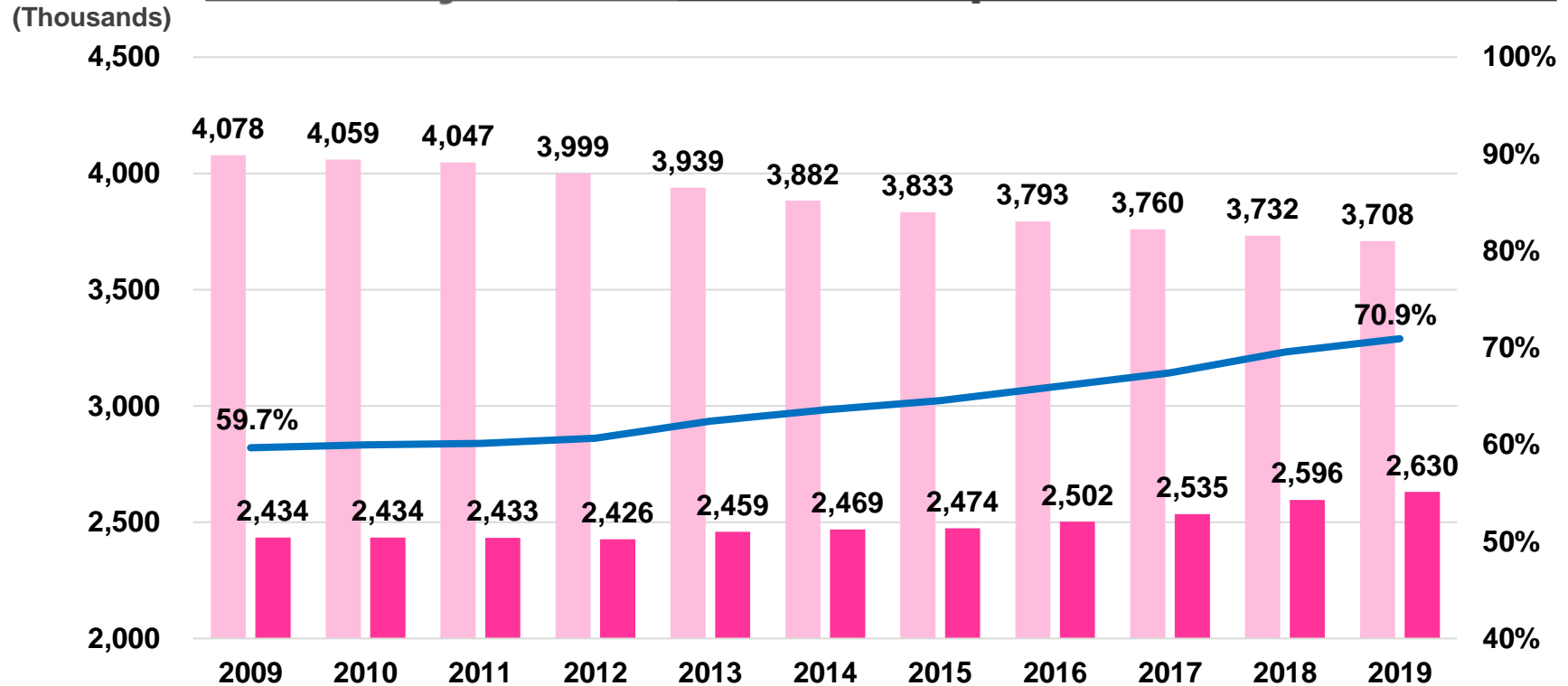
Establishment of a new screening system targeting ion channels

Initiatives for Major Themes in FY2020

Contribution to Women's Health Care

Trends in Female Workforce * Previous bulletin

15 to 64 year-old Female Population and Workers



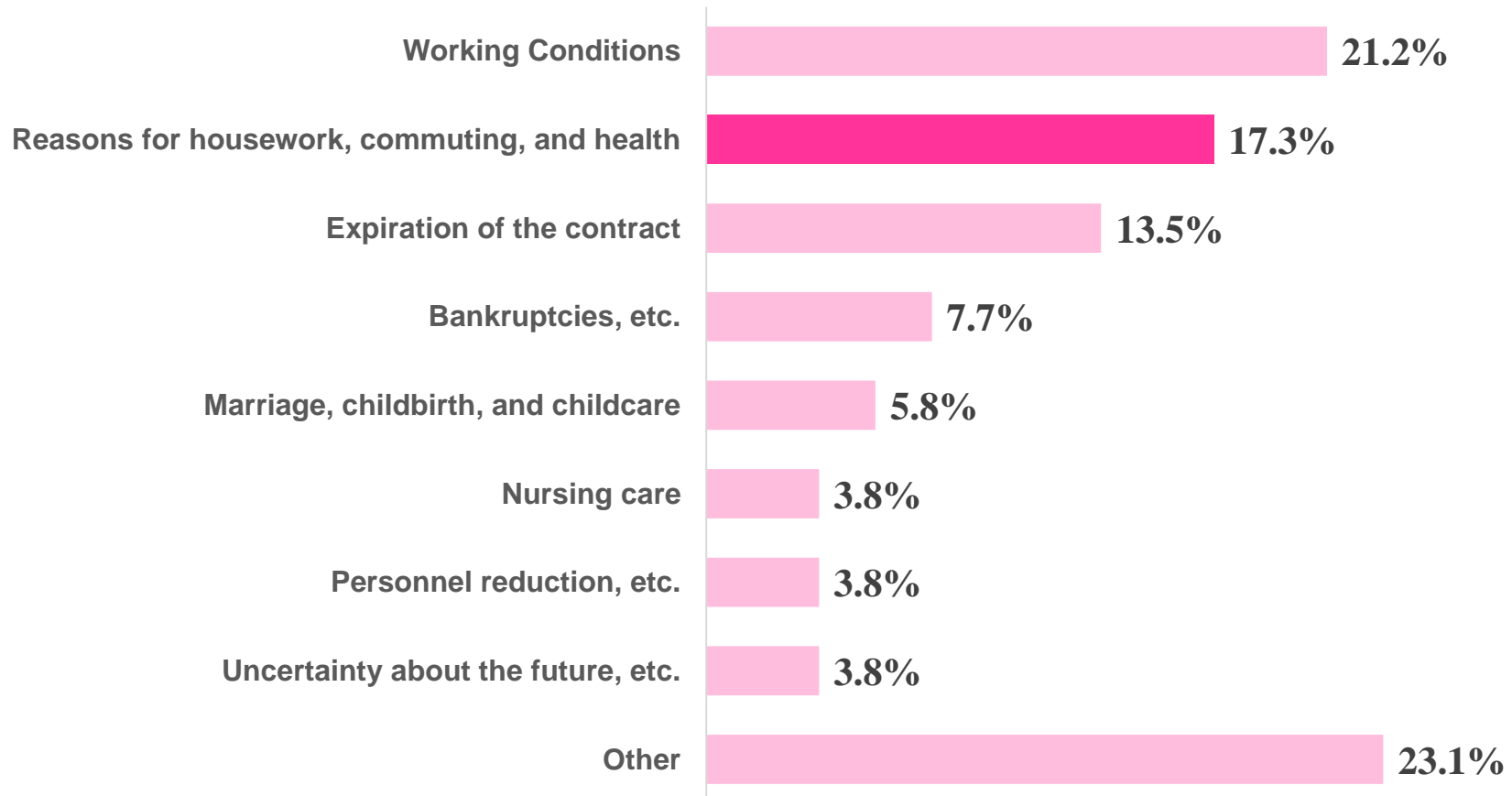
Source: Labor Force Survey 2019, Statistics Bureau, Ministry Of Internal Affairs and Communications

■ Female population
 ■ Number 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)

* Previous bulletin

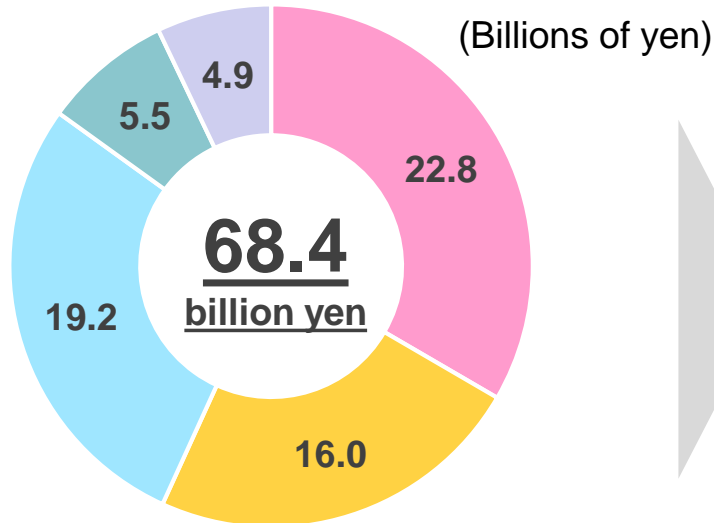


Source: Labour Force Survey 2019, Statistics Bureau, Ministry of Internal Affairs and Communications.

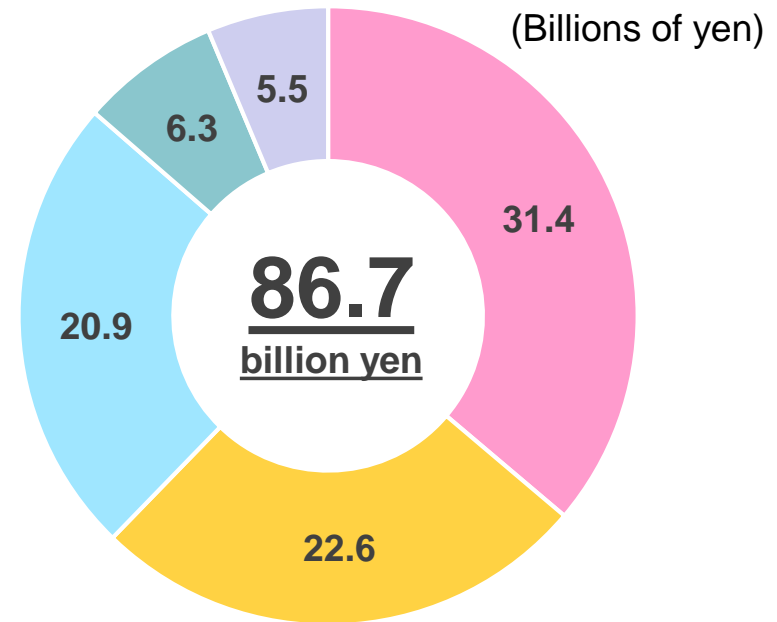
On the other hand, many women have no choice but to leave for health reasons, etc.

Prediction of the Ob/Gyn market

In 2019 (Expected)

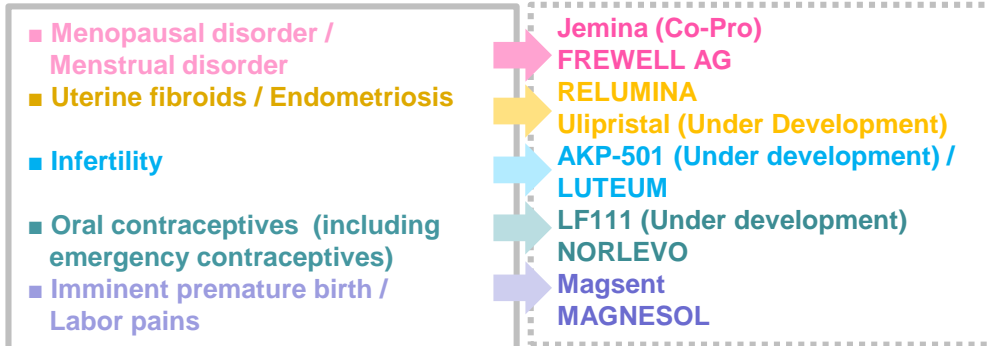


In 2027 (Predicted)



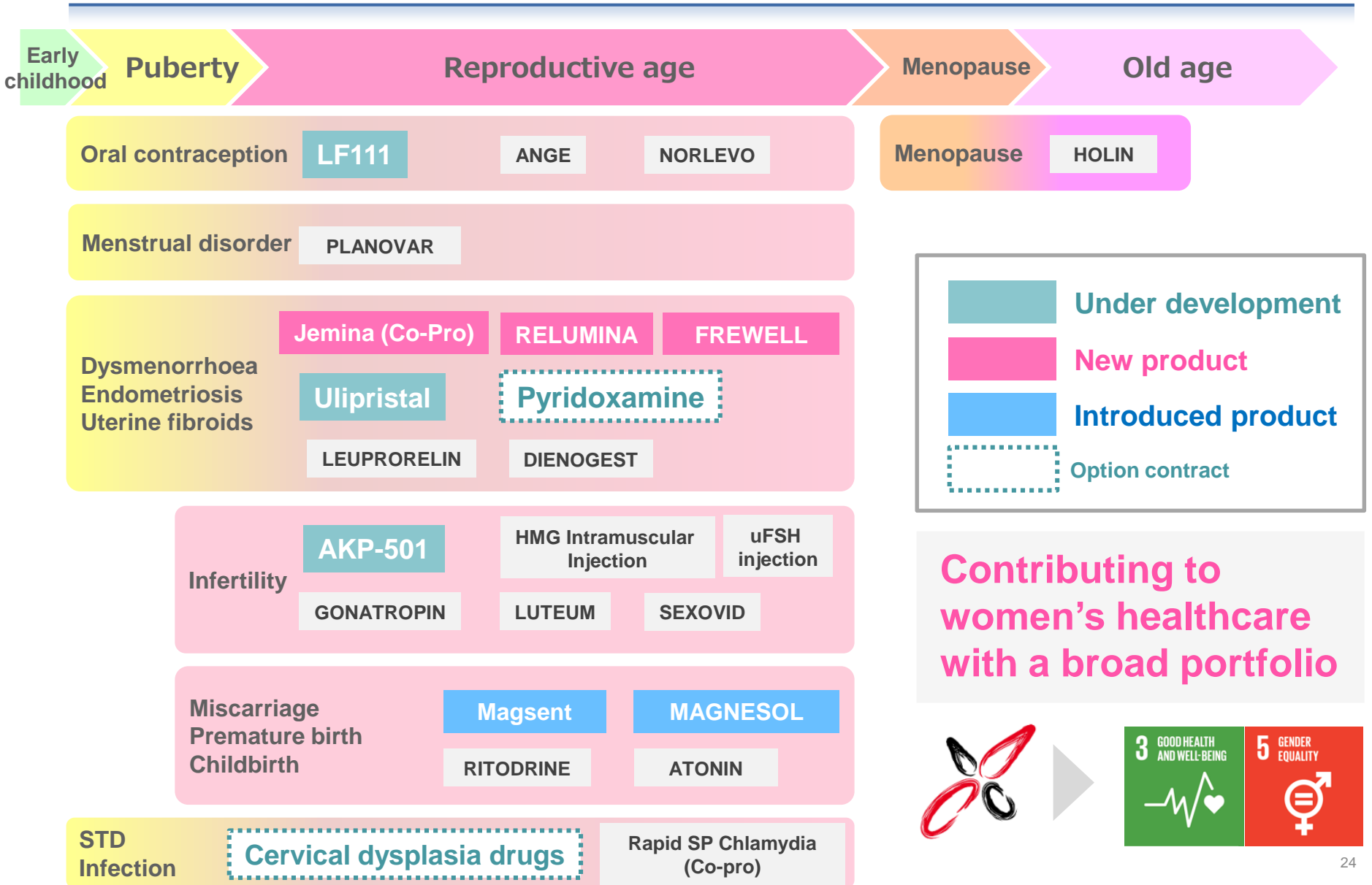
Therapeutic areas

Our products



Healthcare needs in the field of Ob/ Gyn predicted to expand

Obstetrics and Gynecology Products by Life Stage

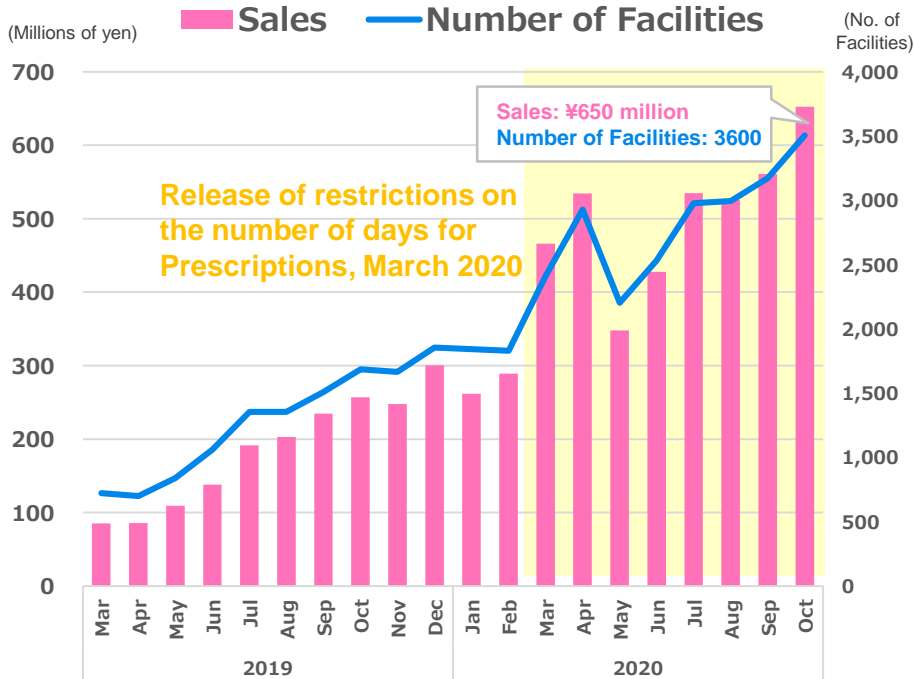




RELUMINA

RELUMINA's Sales

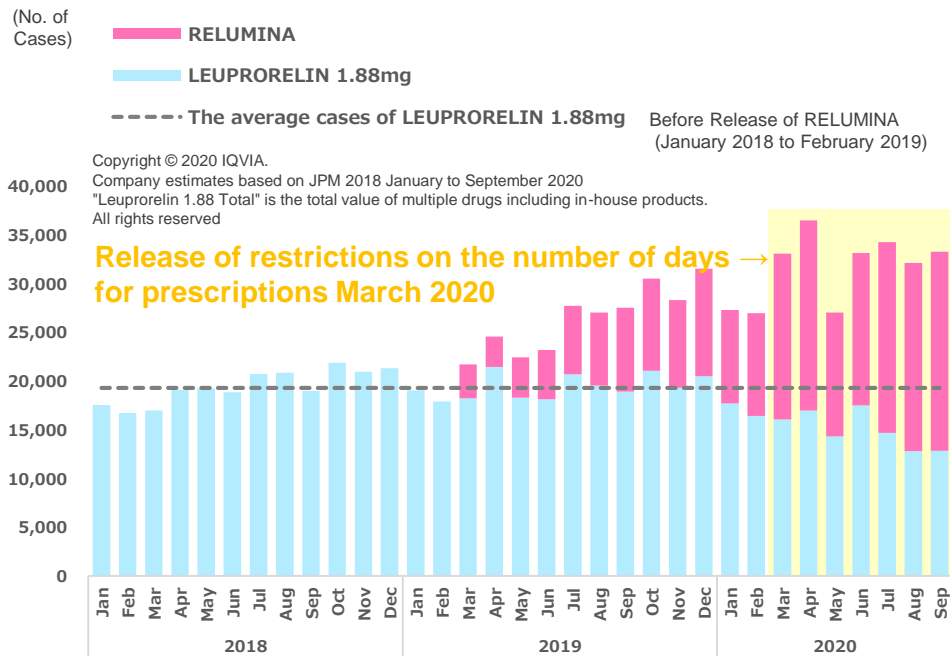
* Drug Price Basis



After the release of the restriction on the number of days for prescription, increase in sales and number of Prescribers for RELUMINA

Estimated Number of Cases of Uterine Fibroids

*Estimates from Units



Acceleration of switch from LEUPRORELIN 1.88mg after March 2020



RELUMINA

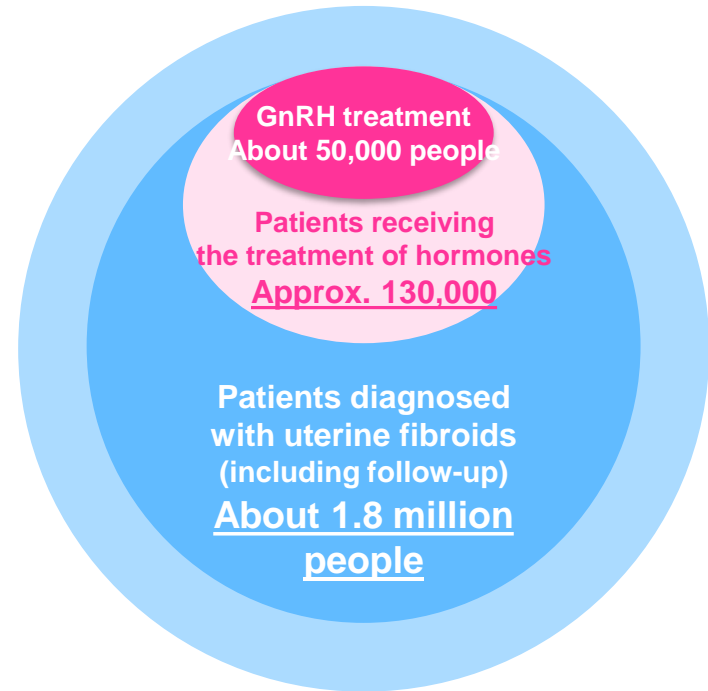
Reasons for selecting RELUMINA (excerpt from physician feedback)

- Oral formulations are preferred over other dosage forms
- Symptoms associated with uterine fibroids can be relieved quickly
- Flare-up phenomena* can be avoided
- Suitable before surgery
- Cases of enlarged myoma
- Patients with uncontrolled bleeding

➔ Approx. 20,000 people take RELUMINA
(as of September 2020)

* As female hormone secretion increases transiently during the early phase of administration, symptoms such as abnormal genital bleeding or lower abdominal pain occur

Uterine fibroids market

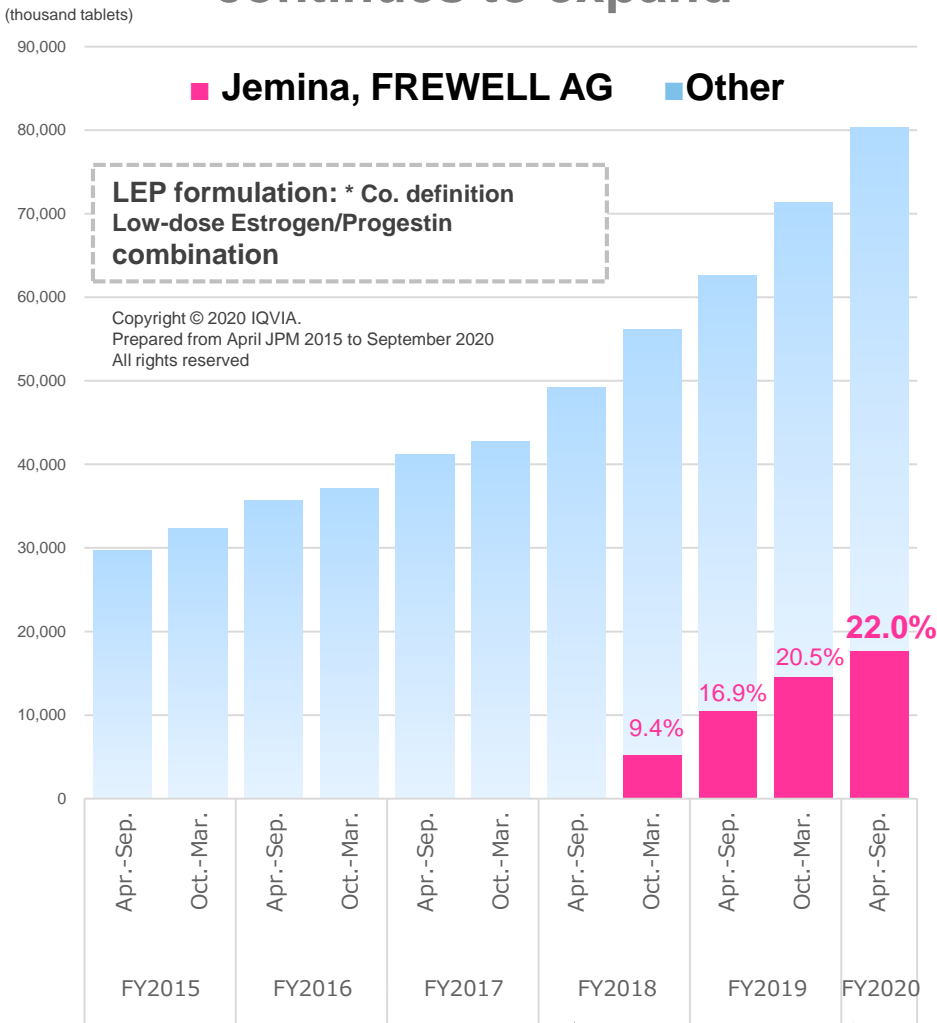


Source: Japan Medical Data Center

We expect further
switching from
GnRH and other hormonal agents

LEP Preparations (Jemina, FREWELL)

LEP market continues to expand



The popularity of LEP preparations for dysmenorrhea is accelerating.

Launched by Nobelpharma in October 2018

Jemina® Tablets

Co-promotion



Launched in December 2018

FREWELL® Tablets LD/ULD"ASKA"

Authorized Generic*



Contribute to the treatment of dysmenorrhea through the provision of new drugs and Authorized Generics(AG) information

Internal Medicine



RIFXIMA



Revised version of Clinical Practice Guidelines for Cirrhosis.

Published in November 2020 *First revision after the launch of RIFXIMA

(applicable partial summary)

Because RIFXIMA is an effective treatment for hepatic encephalopathy, as is synthetic disaccharides, It has been recommended as a “basic therapeutic agent”.

Strength of recommendation:

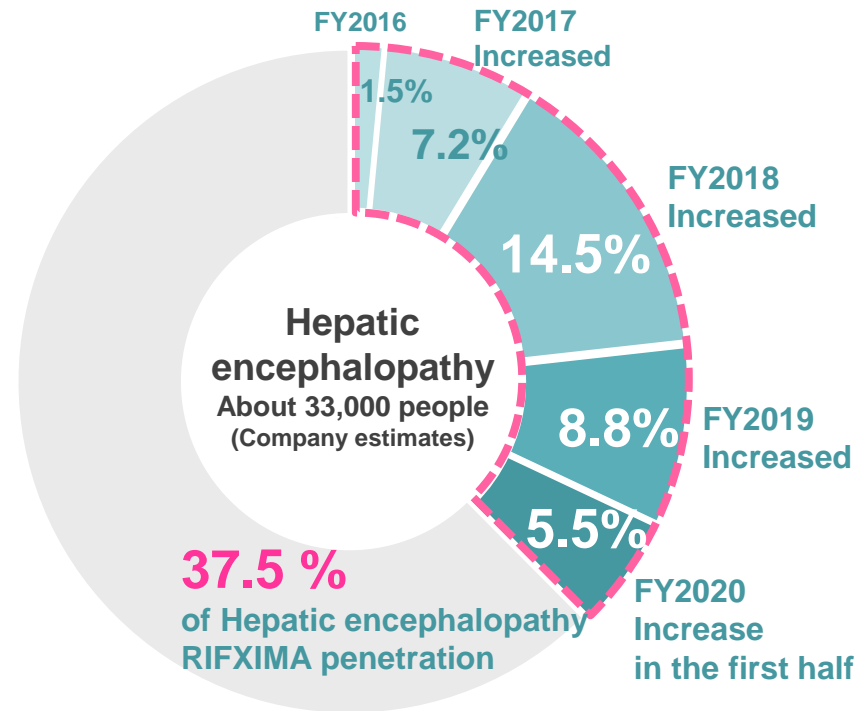
Strongly recommended

* Top grade

Evidence level: **A**

* Top grade

We will complete providing information to Board Certified Gastroenterologist and to Board Certified Hepatologist



ASKA aims to further contribute as the First-line treatment for hepatic encephalopathy

Initiatives in the Thyroid Area

Launched on June 29, 2020

『THYRADIN®-S I.V. INJECTION 200μg』

[Indications]

- Myxoedema coma
- Hypothyroidism

(Limited to cases in which treatment with oral levothyroxine sodium is not appropriate)

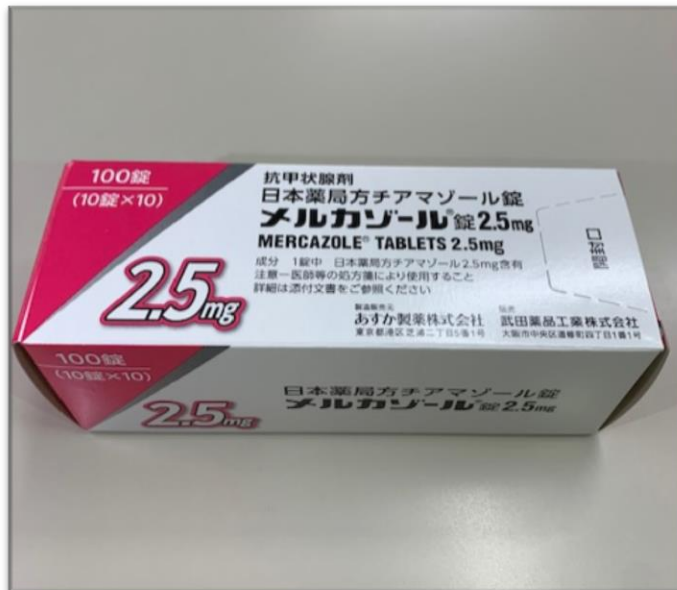
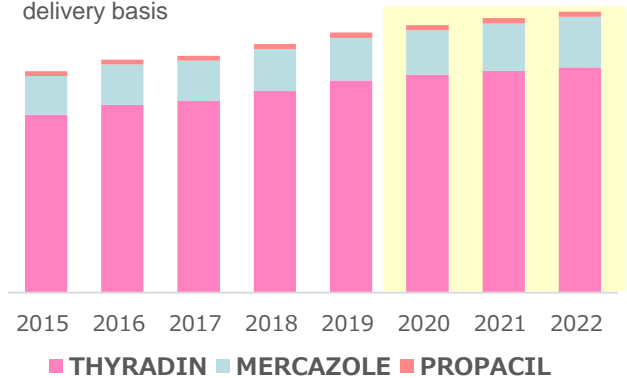
Developed as “Unapproved medicine / Off-label medicine with high medical needs” by ASKA in response to a request from the MHLW



Trends in the sales of thyroid products

On a medical institution delivery basis

2% to 3% increase per year



Approved for marketing on August 17, 2020

『MELCAZOLE® TABLETS 2.5 mg』

* Scheduled for release in February 2021

[Indication]

- Hyperthyroidism

Half-dose products that meet the high needs of medical institutions

Research and Development

Development Pipeline

R&D Status (as of November 2020)

 Changes from the previous report

Development code (Generic name) Indication	PhI	PhII	PhIII	Application	Approval
CDB-2914 (Ulipristal) Uterine fibroids					Filed
TAK-385 (Relugolix) Endometriosis				PhIII Completed	
AKP-501 (Foliotropin gamma) Infertility		PhI Completed			
LF111 (Drospirenone) Contraception		Ph/II Started			
L-105 (Rifaximin) Hepatic encephalopathy (Children)				PhII/III Ongoing	
L-105 (Rifaximin) Crohn's disease		PhI Completed			
AKP-009 Benign Prostatic Hyperplasia			PhII Ongoing		

In-house AKP-009 (new androgen-receptor modulators)



Agreement concluded for Joint Development and Commercialization with Kyorin Pharmaceutical

* September 30, 2020 press release

AKP-009 [A Novel prostatic hyperplasia drug from ASKA R&D]

Prospective indication: Urinary dysfunction associated with benign prostatic hyperplasia
Domestic development timeline: Phase II trials (scheduled for Q4 2019 to Q4 2020)

~ Product Feature ~

Expectations “A high prostate atrophy effect” and “Increase efficacy for voiding function”

 The contract agreement with Kyorin Pharmaceutical is for the treatment in urology. It is expected that this will lead to an effective and efficient joint drug development.

Progress in the Development Pipeline

Licensed from
Takeda Pharmaceutical

RELUMINA

PhIII completed

Planned Indication: Improvement of pain for endometriosis

Market: Approx. 2.6 million patients (10% of menstrual women)

- It can be administered orally, and it is expected to improve patient's QOL and symptoms by promptly lowering their sex hormone (estrogen and progesterone) levels

License agreement with
Insud Pharma (Spain)

LF111

(Drospirenone)

PhI/II started

Planned Indication: Contraception

Market: Approx. 4.7 million sheets for oral contraceptives per year

- Under development as the first luteinizing hormone single-agent oral contraceptives in Japan
- It does not contain estrogen and can be used in women who are at risk for thromboembolism.
- Exclusive Rights for the Development and Distribution in Japan and sub-licensing in Korea

▶ **Expanding the development pipeline by promoting in-house drug discovery and drug introduction activities**

Global Expansion

Global Expansion

Concluded a stock transfer agreement with Ha Tay Pharmaceutical Joint Stock Company (Know as Hataphar)

Completed a 24.9% share transfer agreement with Hataphar, the second largest commercial company in the Vietnamese pharmaceutical industry as a strategic partner

Synergies between ASKA Pharmaceutical's development and manufacturing technologies and Hataphar's local sales capabilities will lead to significant growth in the two companies' business operations.



Signing ceremony (August 18, 2020)

[Overview of Hataphar]

Year of founding: 1965

Headquarter location: Hanoi, Vietnam

Net sales: ¥9.8 billion (FY2019)

Net income: ¥430 million (FY2019)

Net assets: ¥1.5 billion (FY2019)

Total assets: ¥3.54 billion (FY2019)

* 1VND=0.0048JPY

New Medium-Term Management Plan (FY2021-FY2025)

▶ In progress for announcement within FY2020

[Reference] **Non-Financial Information (ESG) Topics**

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

Social Contribution Activity

知ることは、
自分を守ること。

Through ASKA's long experience and knowledge regarding Female Hormones, the Company has established a new organization of "Health Lab Mint+ for Women's health" to support women who suffer from and experience female specific symptoms, on the occasion of our 100th year anniversary

Health
Lab
Mint+

女性のための健康ラボ Mint+

ASKA mint +

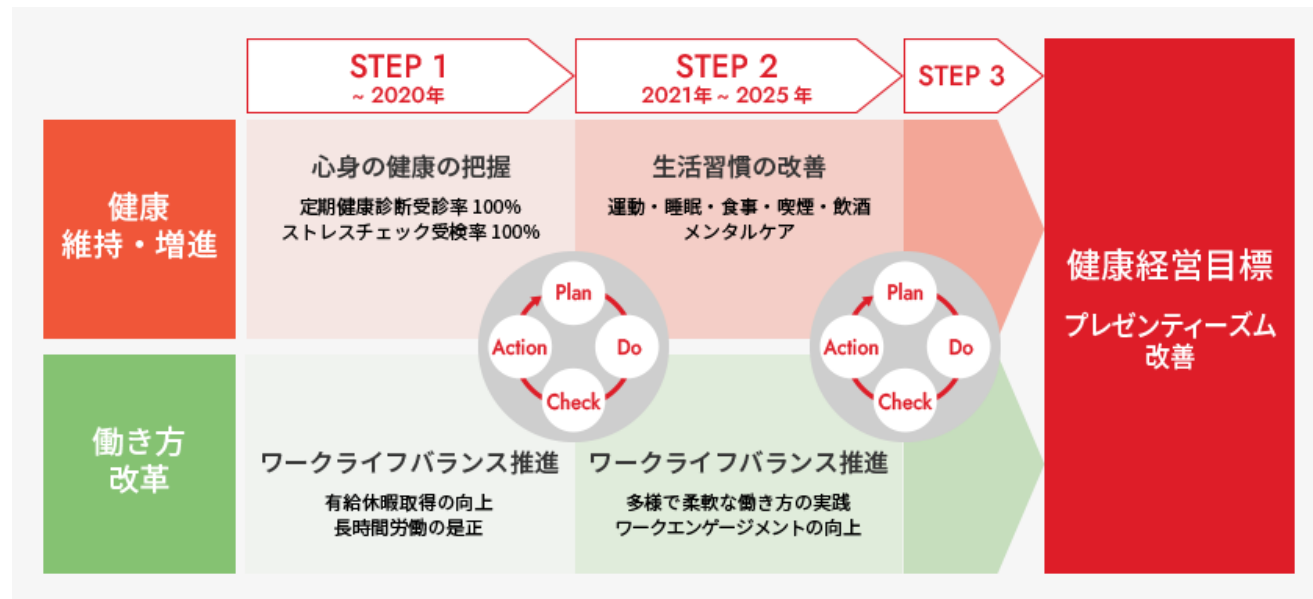
Search

*Japanese only



Health Management Initiative

ASKA has been recognized as one of the “White 500”:
 A Certified Health & Productivity Management Outstanding
 Organizations Recognition Program, conducted jointly by the Ministry
 of Economy Trade and Industry and the the Nippon Kenko Kaigi, for
 two consecutive years.



Our HP: ASKA’s Health Management

<https://www.aska-pharma.co.jp/csr/sustainability/health.html#anc2> * Japanese only

“女性からだ会議® 大賞2020” Excellence Prize

What is the “女性からだ会議® 大賞2020”?

A project sponsored by “Thinkparl” which introduces and awards Companies as well as Organizations which commit to working on women’s health, preventive measures and activities to fight cancer.



[女性からだ会議® 大賞2020 Grand Prize].
POLA CO., LTD.

[女性からだ会議® 大賞2020 Special Prize].
Rakuten Medical, Inc.

[女性からだ会議® 大賞2020 Excellence Prizes]

ASKA Pharmaceutical Co., Ltd.
AVEX MANAGEMENT Inc.
Suntory Holdings Limited
ALL NIPPON AIRWAYS CO., LTD.
Japan Airlines Co., Ltd.
Nomura Securities Co., Ltd.
FUJITSU LIMITED
Yahoo Japan Corporation

Participation in the “3rd Shonan Meeting”

Participating in the “3rd Shonan Meeting”, focusing on providing solutions for social issues concerning perinatal depression

The Shonan Meeting began as **a consortium of private-sector companies seeking to create businesses for pre-symptomatic conditions**. It is facilitated by Shonan iPark and supported by Kanagawa Prefecture (ME-BYO Industry Research Group), Fujisawa City, and Kamakura City

Duration	October 2020-February 2021
Hosted by	Shonan iPark
Sponsored by	Janssen Pharmaceutical K.K.,
Supported by	Kanagawa Prefecture (ME-BYO Industry Research Group), Fujisawa City, and Kamakura City
Participants (8 companies)	ASKA Pharmaceutical co., Ltd. , Aflac Life Insurance Co., Ltd. , MTI Ltd. , GUNZE LIMITED , Genequest Inc. , Mitsubishi Tanabe Pharma Corporation , IBM Japan, Ltd. , HYPER CUBE Ltd.

[About Perinatal Depression]

- Perinatal depression is a condition experienced by patients worldwide, affecting 10 to 15% of women with children
- In Japan, the highest cause of death among perinatal women is suicide from perinatal depression



Co-sponsorship in “女性のための働き方改革！「生理快適プロジェクト」”



女性のための働き方改革！

生理快適
プロジェクト

A project supported by Multi-companies,
“The realization of a society in which women can work comfortably”
Sponsored by NIKKEI BP INTELLIGENCE GROUP

Web article series
Webinar for media
Webinar for working women


↓ Targets of SDGs committed by “生理快適プロジェクト” ↓



Project HP: <https://special.nikkeibp.co.jp/atclh/DRS/20/seirikaiteki/>

Web article : <https://doors.nikkei.com/atcl/column/19/092400212/>

* Japanese only



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

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