

November 10, 2023

**Consolidated Financial Results for
the Second Quarter of the Year Ending
March 31, 2024 (FY2023)**

Presentation for Investors



Securities code : 4886 (TSE)

ASKA Pharmaceutical Holdings Co., Ltd.

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 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.
- This translation is provided solely as a reference material. In the case of any discrepancy between the two versions, the original Japanese version shall prevail.

Financial Results Summary for 2Q FY2023



Atsushi Maruo,

Senior Managing Member of the Board of Directors, Representative Director

ASKA Pharmaceutical Holdings Co., Ltd.

FY2023 2Q (Consolidated) Highlight

Net sales

✓ **31.6 billion yen, up 4.9% YOY**

The pharmaceuticals business remained strong, with record-high sales.

Cost of sales

✓ **16.4 billion yen, improved 0.6 percentage points YOY**

The product mix improved due to growth in Brand-name drugs such as RELUMINA, THYRADIN, and RIFXIMA.

SG&A expenses

✓ **12.1 billion yen, up 0.4 percentage points YOY**

Impacted by an increase in business activity expenses due to the normalization of economic activities.

Operating profit

✓ **3.0 billion yen, up 6.1% YOY**

Despite increases in R&D, SG&A, and other expenses, the increased sales and gross profit boosted profits.

Full-year forecast

✓ **Revised upward, as announced on September 25, 2023**

Revised upward due to a record of sales of investment securities (extraordinary income).

Consolidated Statements of Income

(Millions of yen)	FY2022 Apr - Sep Actual	FY2023 Apr - Sep Actual	Actual +/-	Growth +/-
Net sales	30,172	31,648	1,475	4.9%
Cost of sales	15,870	16,461	590	3.7%
Gross profit	14,301	15,186	884	6.2%
Selling, general and administrative expenses	11,422	12,130	708	6.2%
Operating profit	2,879	3,055	176	6.1%
Ordinary profit	2,987	3,096	108	3.6%
Profit attributable to owners of parent	2,346	4,129	1,783	76.0%

* Put a current exchange rate and the reference: (1 US dollar = 150.07 yen, as of Nov 6th 2023)
(1 Euro = 160.82 yen, as of Nov 6th 2023)

Consolidated Net Sales by Business

(Millions of yen)	FY2022 Apr - Sep Actual	FY2023 Apr - Sep Actual	Breakdown	Actual +/-	Growth +/-
Pharmaceutical business	26,851	28,404	89.7%	1,553	5.8%
Animal health business	3,234	3,162	10.0%	-71	-2.2%
Other businesses	86	80	0.3%	-5	-6.6%
Total	30,172	31,648	100.0%	1,475	4.9%

Sales of Main Products (ASKA Pharmaceutical Co., Ltd.)

(Millions of yen)

Area	Category	Products (generic name)	FY2022 Apr - Sep	FY2023 Apr - Sep		FY2023		Reference	Notes
			Actual	Actual	YOY	Revised Forecast	YOY	Previous Forecast	
Internal Medicine	AG	CANDESARTAN * 1 (candesartan)	5,477	4,952	-9.6%	9,438	-12.0%	9,268	The NHI drug price decreased, but sales on a quantity basis maintained.
	Brand-name	THYRADIN (levothyroxine)	3,921	4,000	2.0%	7,823	1.2%	7,833	Progressed as expected
	Brand-name	RIFXIMA (rifaximin)	2,757	2,997	8.7%	5,671	5.1%	5,578	Sales grew as the guideline penetration increased
	Brand-name	MERCAZOLE (thiamazole)	761	776	1.9%	1,515	1.9%	1,513	Progressed as expected
	Generic	AMLODIPINE (amlodipine)	465	430	-7.4%	844	-6.2%	844	Progressed as expected
Obstetrics and Gynecology	Brand-name	RELUMINA (relugolix)	4,524	5,186	14.6%	10,234	15.8%	10,128	Continued penetration activities for endometriosis
	Generic	DroEthi (drospirenone/ethinylestradiol)	1,279	2,909	127.4%	5,370	46.3%	4,165	Progressed significantly more than expected.
	AG	FREWELL (norethisterone/ethinylestradiol)	1,765	1,663	-5.8%	3,329	-4.6%	3,407	Increased sales volume but less than initially expected
	Brand-name	LUTEUM (progesterone)	569	876	53.8%	1,462	16.9%	1,363	Sales grew due to lifting of shipping restrictions, external factors, etc.
	Brand-name	ANGE (levonorgestrel/ethinylestradiol)	420	367	-12.6%	713	-9.0%	799	Decreased due to shift to other companies' products
	Brand-name	MAGSENT * 2 (magnesium sulfate)	309	355	14.9%	711	13.4%	750	The NHI price increase reflected in its figure
Urology	Generic	LEUPRORELIN * 3 (leuprorelin)	2,619	2,321	-11.4%	4,494	-10.1%	4,828	Continued switch to other products from the initial forecast

* 1 Including compounding agents

* 3 1.88mg formulation is for gynecological indications only but combined with 3.75mg formulation

* 2 Total value of magnesium sulfate preparation

Sales of Major Business Field (ASKA Animal Health Co., Ltd.)

(Millions of yen)

Business field	FY2022 Apr - Sep	FY2023 Apr - Sep		FY2023	
	Actual	Actual	YOY	Forecast	YOY
Feed additives and materials, Mixed feed	2,062	1,873	-9.1	3,484	-16.1%
Veterinary pharmaceuticals	1,081	1,189	10.0	2,415	1.9%

Key factors

- ✓ Market conditions for feed additives remained uncertain, although there were trends toward a bottoming out of the market.
- ✓ Sales of veterinary drugs remained steady, centering on TRILOSTANE TABLETS "ASKA," launched last year, and hormone agents.

Consolidated Balance Sheet

End of FY2022

(Millions of yen)

Current assets 53,759	Current liabilities 17,650
	Non-current liabilities 14,954
Property, plant and equipment 10,796	Net assets 54,533
Intangible assets 4,465	
Investments and other assets 18,117	

Total assets 87,138

End of 2Q FY2023

(Millions of yen)

Current assets 59,644 (+5,884)	Current liabilities 20,036 (+2,386)
	Non-current liabilities 13,262 (-1,691)
Property, plant and equipment 10,649 (-147)	Net assets 58,621 (+4,087)
Intangible assets 3,615 (-849)	
Investments and other assets 18,011 (-105)	

Total assets 92,120 (+4,782)

Assets

(Millions of yen)

Cash and deposits	+2,941
Accounts receivable - trade	+2,126
Inventories	+899
Intangible assets	-849

Liabilities/Net assets

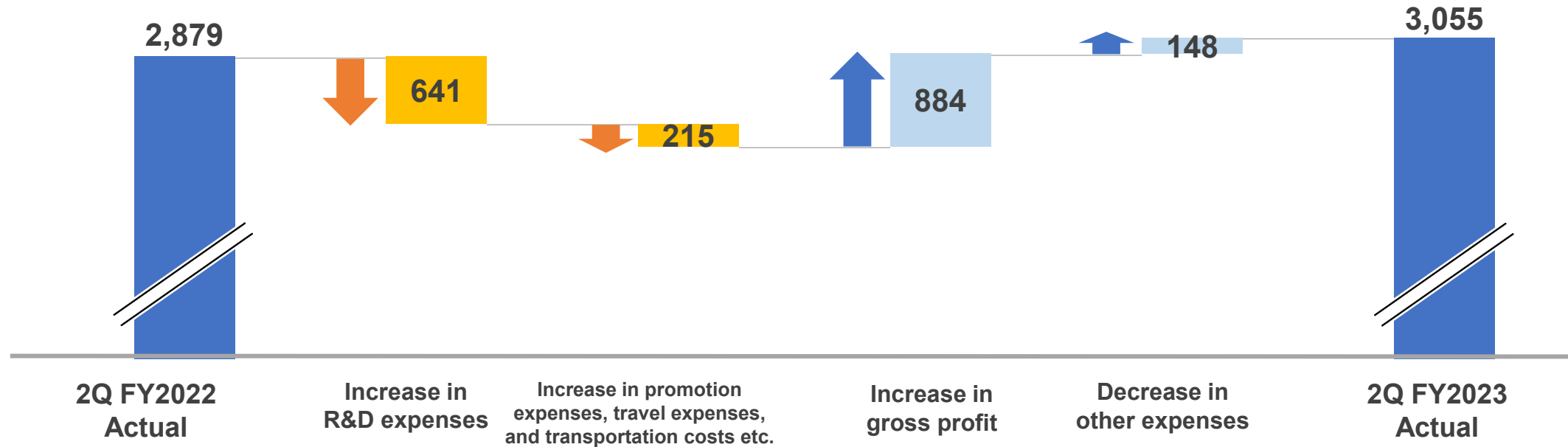
Notes and accounts payable – trade, Electronically recorded obligations - operating	+1,587
Income taxes payable	+730
Retirement benefit liability	+145
Short/long-term borrowings	-2,298
Retained earnings	+3,903

Analysis of key factors

Assets:	Increase in cash and deposits, accounts receivable - trade, inventories decrease in intangible assets due to amortization of distributorship
Liabilities/	Increase in notes and accounts payable – trade, electronically recorded obligations – operating, income taxes payable, and retirement
Net assets:	benefit liability, Decrease in short/long-term borrowings, Increase in retained earnings

Analysis of Operating Profit (YOY)

(Millions of yen)



Key factors

- ❑ R&D expenses increased due to progress in clinical trials and aggressive discovery research
- ❑ Promotion expenses etc. increased as economic activities normalized
- ❑ Increase in profit due to increased gross profit with higher net sales

Consolidated FY2023 Performance Forecast

Revised on September 25, 2023

(Millions of yen)	FY2022 Actual	FY2023 Previous Forecast	FY2023 Revised Forecast	YOY Actual +/-	YOY Growth +/-
Net sales	60,461	62,000	62,000	1,538	2.5%
Operating profit	5,108	5,400	5,400	291	5.7%
Ordinary profit	5,232	5,500	5,500	267	5.1%
Profit attributable to owners of parent	4,238	4,400	6,200	1,961	46.3%

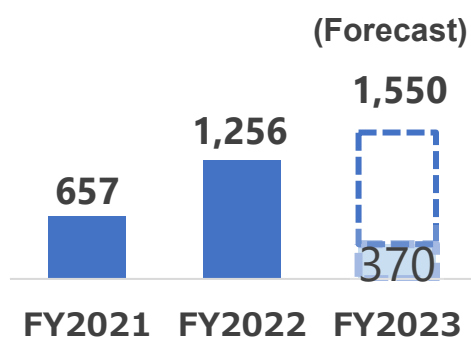
Analysis of Major factors

- Profit attributable to owners of parent was revised upward because an extraordinary income is expected to be recorded due to the sale of investment securities.

Capital Expenditures, Depreciation and R&D expenses

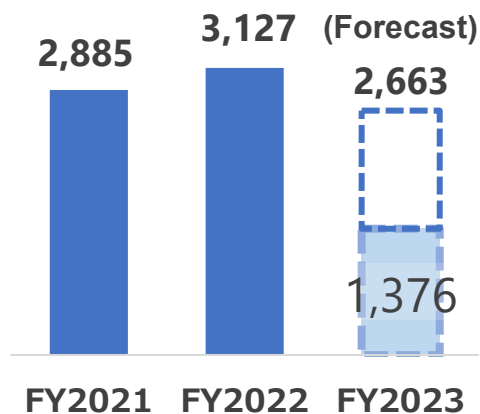
Capital Expenditures

(Tangible and software transfer basis)
(Millions of yen)



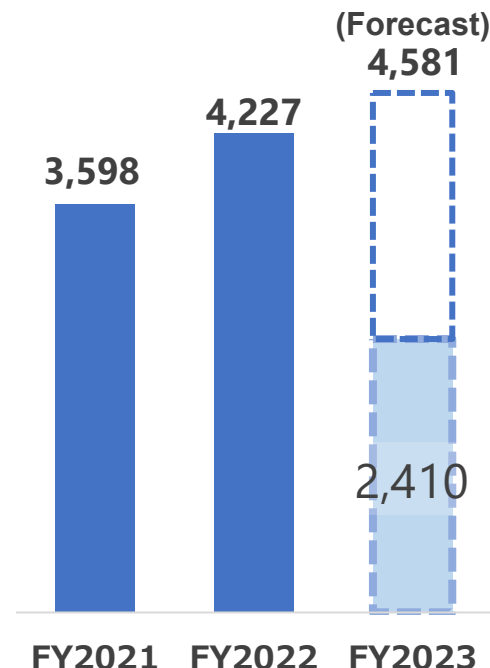
Depreciation

(Tangible/intangible total)
(Millions of yen)



R&D expenses

(Millions of yen)



Key factors

- Capital expenditures:** Expected to exceed the previous year due to planned partial renovation of Iwaki factory, etc.
- Depreciation:** Expected to be lower than the previous year due to a decrease in depreciation expenses for production facilities and mission-critical systems
- R&D expenses:** Expected to exceed the previous year due to aggressive discovery researches and progress in clinical trials.

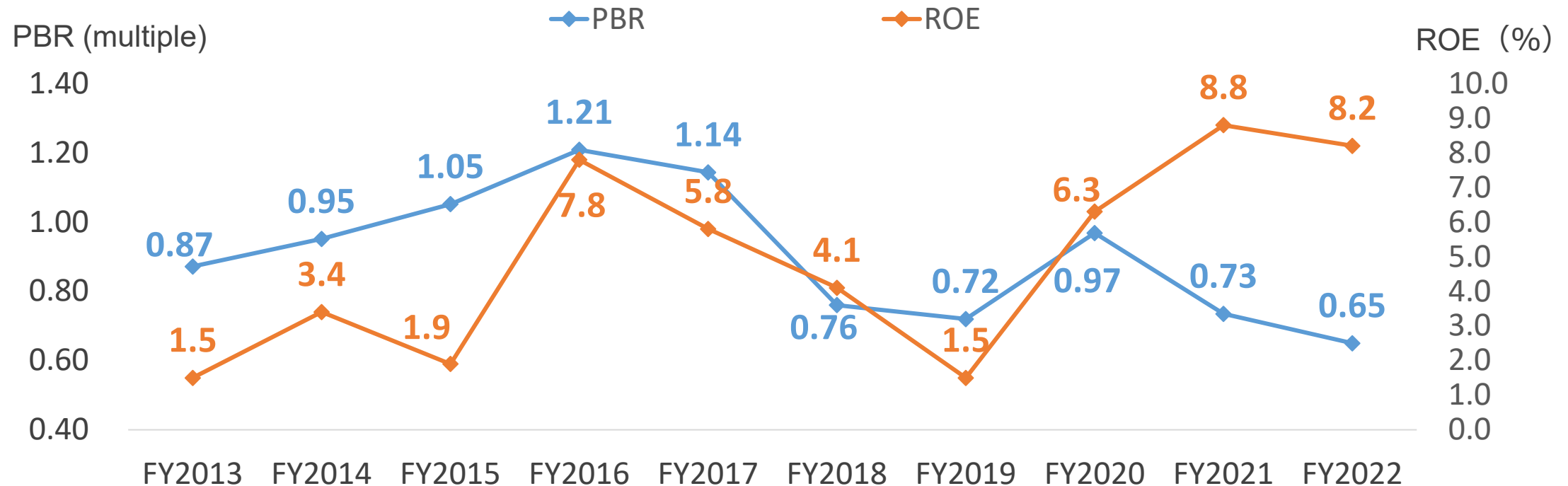
About Action to Implement Management That Is Conscious of Cost of Capital and Share Price

Business Environment under Headwinds

The business environment remains challenging due to policies to curb healthcare costs, such as annual NHI drug price revisions, drug quality/supply issues, increasing difficulty in drug discovery, changing international circumstances, including the Russian-Ukrainian crisis, global supply chain disruptions, and rising costs associated with soaring energy, raw materials, wages, and other costs.

Despite facing an uncertain future and challenges ahead, we aim for growth by capitalizing on external changes.

PBR and ROE



In the light of PBR being below 1x, we assessed the current situation and discussed improvement policies and detailed initiatives at the board meeting several times.

* PBRs for FY2013-FY2022 are calculated based on the year-end share price.
PBRs and ROEs up to FY2020 are those of ASKA Pharmaceutical Co., Ltd.
PBRs and ROEs after FY2021 are those of ASKA Pharmaceutical Holdings Co., Ltd.

Assessment of Current Status and Policy for Improvement

Assessment of Current Status

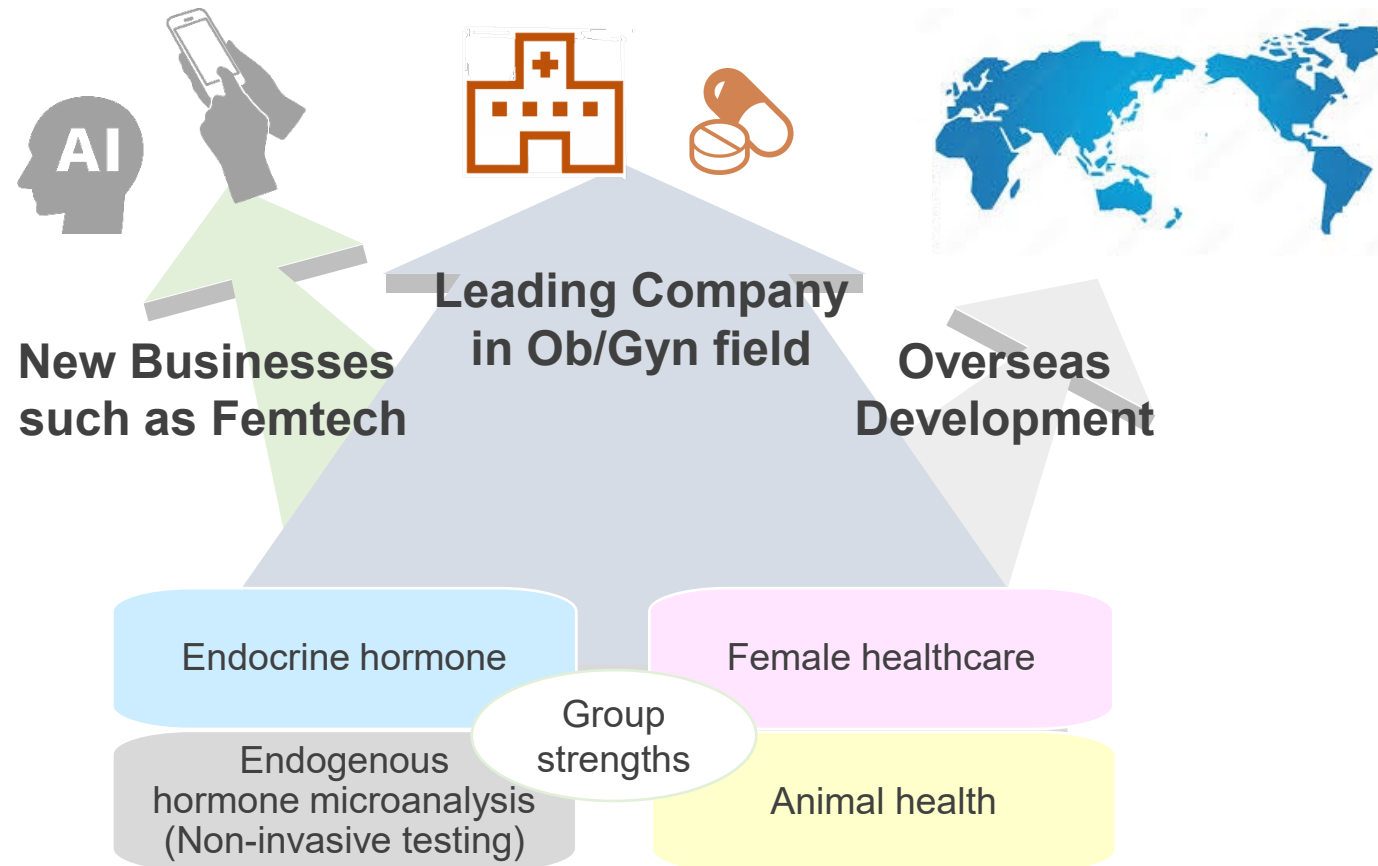
- ✓ The Company's ROE has increased to the 8% level for three consecutive fiscal years of profit growth and has exceeded the 8% target for FY2025, the final year of the Medium-Term Management Plan.
- ✓ On the other hand, PBR has been below 1x since FY2018. We assess that the feasibility of the growth strategy was not fully understood, the external communication was not sufficient, and the Company did not disclose specific cash allocation. This was due to the Company's lack of clear direction for growth strategy and shareholder returns.

Policy for Improvement

To improve market valuation, we will continue to strengthen IR activities to communicate our growth strategy by holding financial results briefings and pipeline briefings. Moreover, we will consider optimal cash allocation and take action to implement management that is conscious of the cost of capital and our share price to enhance the feasibility of the growth strategy and meet the expectations of our shareholders. We will continue to reduce cross-shareholdings as a percentage of net assets to less than 20% by the end of March 2024.

Details of Initiatives 1) Growth Strategy

Toward Total Healthcare Company



Implementation of Growth Strategy

- **Pharmaceutical business**
Further strengthening our position as a leading company in the Ob/Gyn field
- **Establish new businesses**
In the peripheral area of pharmaceutical, such as Femtech, as a total healthcare company
- **Overseas development**
With a focus on the growing Southeast Asian market

Details of Initiatives 1) Growth Strategy

Cash allocation for future growth

FY2020-2022

FY2023-2025

(Historical breakdown)

Operating CF 12.7 billion	Growth investment Strengthen management base	6.7 billion
	Debt repayment Others	4.5 billion
	Shareholder return*	1.6 billion
Sale of tangible assets 10.3 billion	Increase in cash on hand assets	10.2 billion



Source of funds		Investment direction	Objectives	Distribution
Operating CF* 20 billion	Growth investment	Pharmaceutical business	Expand pipeline by strengthening R&D and BD	15 billion + X
		New field	Femtech, CVC, Digital Health Testing, Animal Health (CA)	
		Overseas development	Establish business in Southeast Asia	
		M&A	Acquisition of competencies necessary for growth	
Cash from sale of cross-shareholdings 3 billion	Strengthen management base		Renewal and expansion of production facilities	3-4 billion
			Digital transformation	
			Investment in human capital	
Fundraising (+X)	Shareholder return		Dividends, share buybacks	3-4 billion

*Dividend + Share buyback

*Assumed operating profit + depreciation
+Research and development expenses (except tangible assets)

✓ Maintain Equity ratio of over 50%

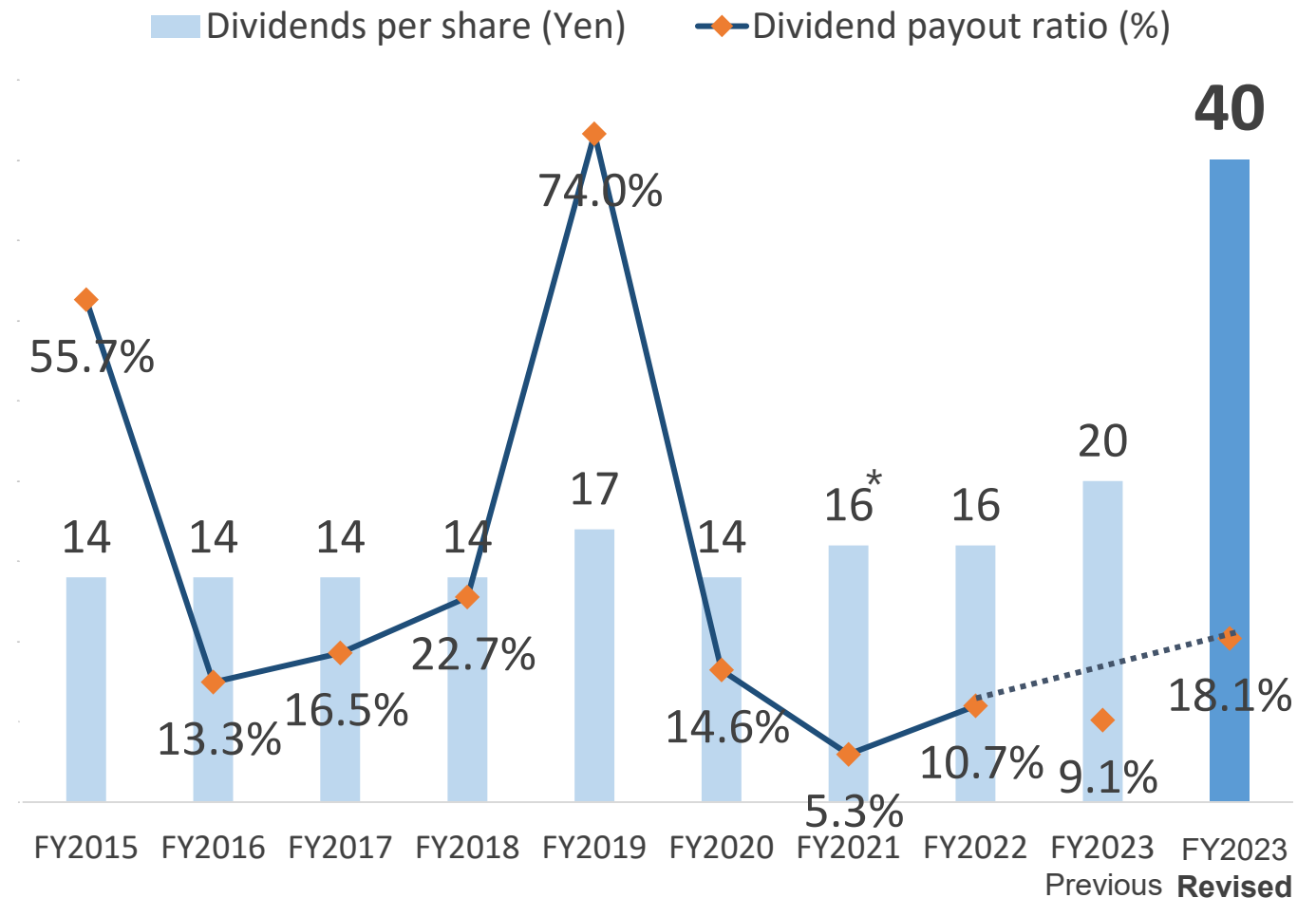
Details of Initiatives 2) Strengthen Shareholder Returns

◆ Revised Shareholder Return Policy

- ✓ We plan to increase the annual dividend payment to 40 yen per share, considering the solid performance and the extraordinary income from sale of investment securities in FY2023.
- ✓ Starting from FY2024, we will maintain stable profit distribution by indicating a consolidated dividend payout ratio of **30%** as performance-linked profit distribution, with a minimum annual dividend per share of **30 yen**.

◆ Consideration of Share Repurchase

- ✓ We will consider flexible measures, taking into account growth investment, dividend level, cash on hand and share price level, and other factors.



*The interim dividend for FY2021 was paid from other capital surplus and is excluded from the dividend payout ratio.

Details of Initiatives 3) Strengthen IR Activities

- ◆ Strengthen financial results briefings for individual/institutional investors
- ◆ Continue constructive dialogue with shareholders and investors (IR meetings)
- ◆ Create new opportunities for dialogue, such as small meetings and pipeline briefings
- ◆ Report to the Board of Directors on opinions obtained at IR meetings, etc., as appropriate, and conduct reviews
- ◆ Enhance information disclosure by expanding our website information and availability in English



Financial results briefing
for institutional investors
(Webcasts in May and November)



IR seminars for individual investors
(Held in February and August 2023)

IR meetings with analysts
and institutional investors:
78 times; total of 98
participants

IR meetings
(Actual in FY2022)

FY2023 Interim Report



Takashi Yamaguchi,

President, Member of the Board of Directors, Representative Director

ASKA Pharmaceutical Holdings Co., Ltd.

About Action to Implement Management That Is Conscious of Cost of Capital and Share Price

Details of initiatives to swiftly achieve a PBR of above 1x

1. Growth strategy (implementation of growth strategy, optimal cash allocation)
2. Strengthen shareholder returns (dividend payout ratio of 30% from FY2024)
3. Strengthen IR activities
(Creation of dialogue opportunities, expansion of information disclosures)

In addition to the above three initiatives, actively promote governance and ESG management, etc., to implement management that is conscious of cost of capital and share price.

Adapt to different environmental changes and utilize them to promote corporate growth

ASKA Pharmaceutical Holdings Co., Ltd.

FY2023 Interim Report

The Goals of the Medium-Term Management Plan 2025

**"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 below foundation, The Medium-Term Management Plan 2025 was
designed with four visions and seven strategies.

Specialty

Ability to create

Social contribution

Interim Summary: 3rd Year of the Medium-Term Management Plan 2025

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

3rd year of the Plan

2Q FY2023 Actual

Net sales: 31.6 billion yen
Operating profit rate: 9.7 %

FY2023 Target: Net sales 62.0 billion yen

Steady Progress Toward Achievement of the Medium-Term Management Plan

The Accomplishments of Operating Companies

ASKA Pharmaceutical

- Co-founded a Corporate Venture Capital Fund “ASKA Innovation Fund”
- Newly established the Femtech Business Promotion Unit
- Filed an Application for Partial Change of Manufacturing and Marketing Approval for L-105 (rifaximin for pediatric patients)
- Initiated the domestic phase I/II clinical trial of relugolix combination tablet (AKP-022)
- Signed an agreement with SUSMED for joint development and marketing of therapeutic apps in Ob/Gyn field.

ASKA Animal Health

- L-histidine hydrochloride was designated as a new feed additive and is being prepared for marketing for aquaculture.

ASKA Pharma Medical

- Expansion of non-invasive testing business (launch of male hormone test kit and stress hormone test kit)

Each company achieved certain results that paved the way for the next steps.

ASKA Pharmaceutical Co., Ltd.

■ Main initiatives

- Specialty Areas
- Development Pipeline
- Overseas Business Development

ASKA Pharmaceutical Co., Ltd.

■ Main initiatives

- Specialty Areas
- Development Pipeline
- Overseas Business Development

Changes in the Environment Surrounding Women (Examples)

Changes in the political environment

- ✓ Establishment of the Headquarters for Creating a Society in which All Women Shine in the Cabinet Secretariat, and formulation of the Women's Version of the Framework Policy
- ✓ Establishment of gynecology-specific disease treatment and management fee, and insurance coverage of infertility treatment

Changes in the social environment

- ✓ Increase in the number of female employees and promotion of women to managerial positions through promotion of women's activities
- ✓ Increased awareness of health literacy through increased attention to women's specific health issues and increased exposure in the media and social media, etc.

Changes in the technological environment

- ✓ Development of pharmaceuticals and advances in medical technology related to diseases specific to women, such as treatment of dysmenorrhea and infertility
- ✓ Changes in access to medical care, including improved access to health information and expansion of online medical care due to the widespread use of the Internet

Obstetrics and Gynecology (Ob/Gyn) market is expanding in response to various changes in the environment surrounding women.

Ob/Gyn market in 2010: 49.5 billion yen*1 → Ob/Gyn market in FY2026 (forecast): 100 billion yen*2

*1 Fuji Keizai Corporation 2018-2019 Ethical Drugs Databook No.4 All rights reserved.

*2 Fuji Keizai Corporation, "Trend Analysis and Future Projections for Obstetrics and Gynecology Related Markets after 1 Year of Insurance Coverage in 2023," All rights reserved.

Contribute to Solving Health Issues for All Kinds of Women

**Actively engage in activities as a leading company
in the field of obstetrics and gynecology**

Health – Mibyou^{*1} - Disease

Mint⁺*2

Femtech

**Pharma-
ceuticals**

Providing care for women's health during all stages of health, mibyou^{*1} and disease

*1. Mibyou refers to a pre-symptomatic state.

*2. Mint⁺ disseminates information on women's health.

Our Ob/Gyn Pharmaceutical Products by Life Stage

Early childhood	Puberty	Sexual maturity	Menopause	Old age
	Contraception	<div style="display: flex; justify-content: space-around;"> <div style="background-color: #0056b3; color: white; padding: 2px 5px;">Drospirenone (LF111)</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">ANGE</div> <div style="background-color: #0056b3; color: white; padding: 2px 5px;">NORLEVO</div> </div>	Menopause	<div style="background-color: #e67e22; color: white; padding: 2px 5px;">HOLIN</div>
	Iron deficiency anemia	<div style="background-color: #e67e22; color: white; padding: 2px 5px;">Riona (Co-Pro*)</div>		
	STD/infection	<div style="background-color: #e67e22; color: white; padding: 2px 5px;">Rapid SP Chlamydia (Co-pro*)</div>		
	Uterine fibroids Endometriosis Dysmenorrhea Menstrual disorder	<div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">RELUMINA</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">LEUPRORELIN</div> <div style="background-color: #0056b3; color: white; padding: 2px 5px;">AKP-022</div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 5px;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">Jemina (Co-Pro)</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">FREWELL (AG)</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">DroEthi</div> </div> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 5px;"> <div style="background-color: #0056b3; color: white; padding: 2px 5px;">PMS/PMDD drugs</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">PLANOVAR</div> <div style="background-color: #0056b3; color: white; padding: 2px 5px;">TRM-270</div> </div>		
	Imminent miscarriage/ premature birth, labor induction	<div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">Magsent</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">MAGNESOL</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">Methyl-ergometrine</div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 5px;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">RITODRINE</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">ATONIN</div> </div>		
	Infertility	<div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">HMG</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">uFSH</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">SEXOVID</div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 5px;"> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">LUTEUM</div> <div style="background-color: #e67e22; color: white; padding: 2px 5px;">GONATROPIN</div> </div>		

Our Ob/Gyn drugs under development
LF111
AKP-022
TRM-270

Expands the lineup and contributes to women's healthcare

Now on sale

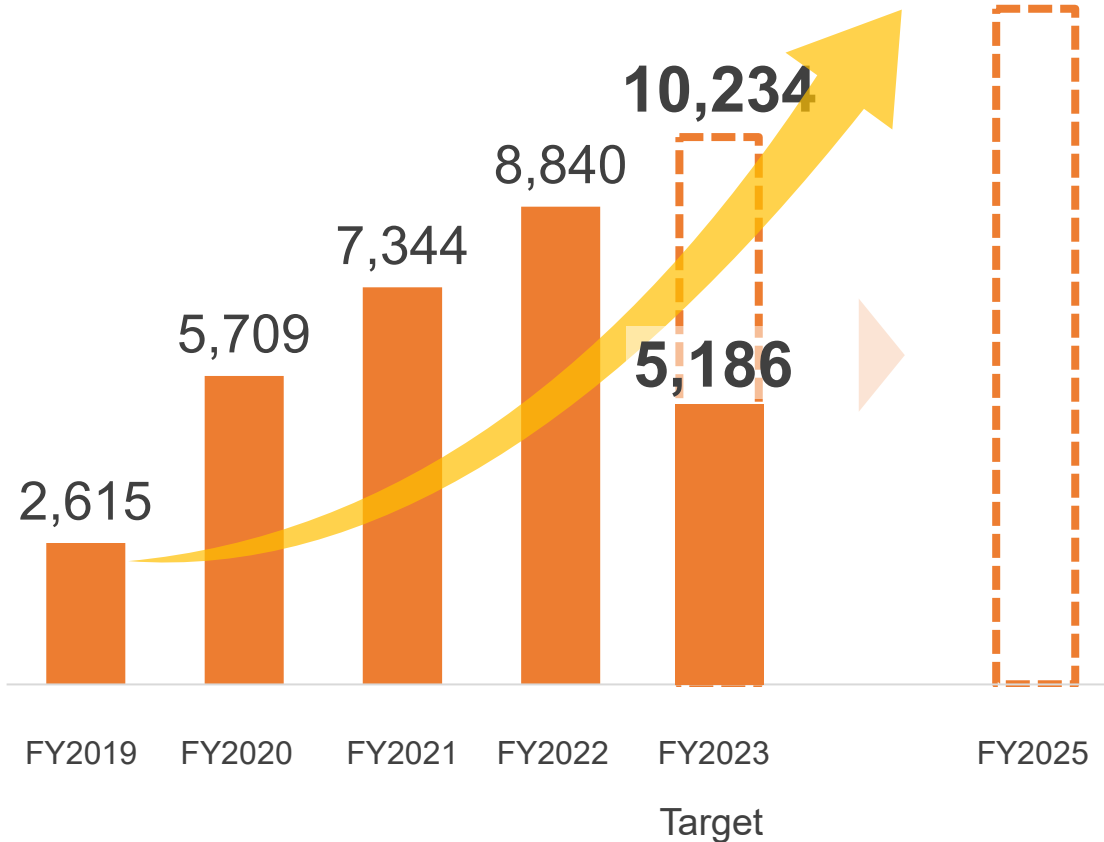
Under development

* Mainly in the field of obstetrics and gynecology

Growth Driver - RELUMINA (relugolix)

RELUMINA sales trend

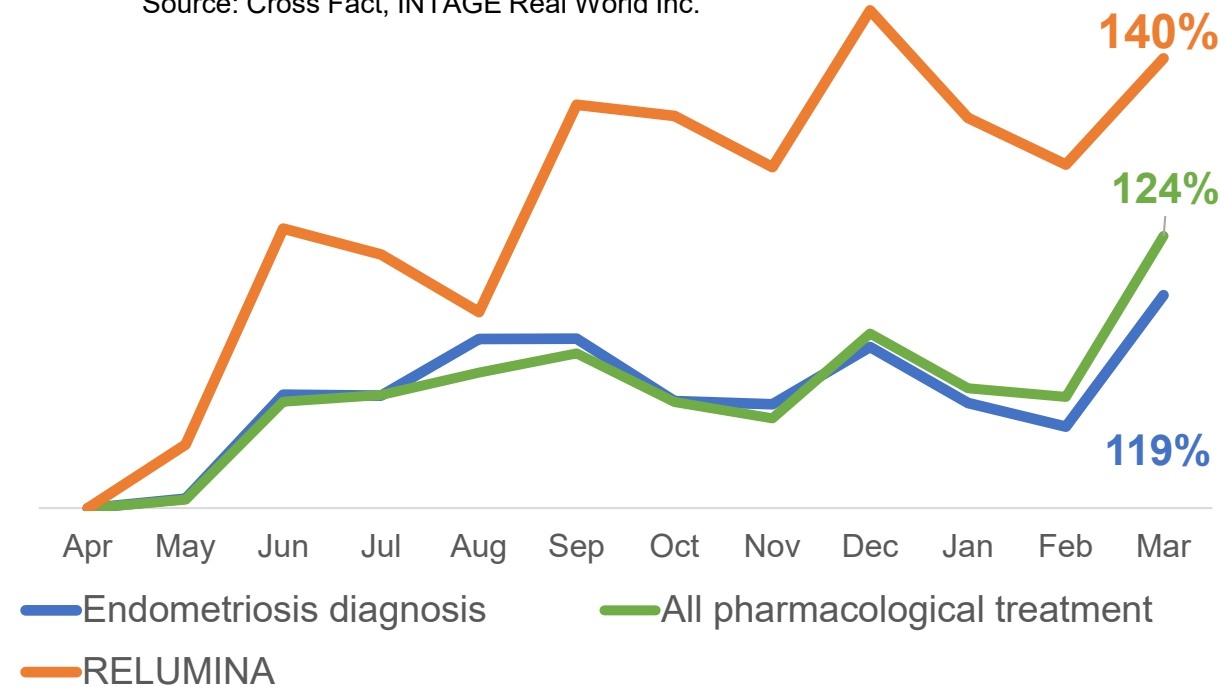
Financial results base (millions of yen)



Growth rate of endometriosis-related figures in FY2022

*Calculated with April 2022 as 100%.

Source: Cross Fact, INTAGE Real World Inc.



Promote market penetration of RELUMINA in the treatment of endometriosis.

LEP*1 market continues to expand

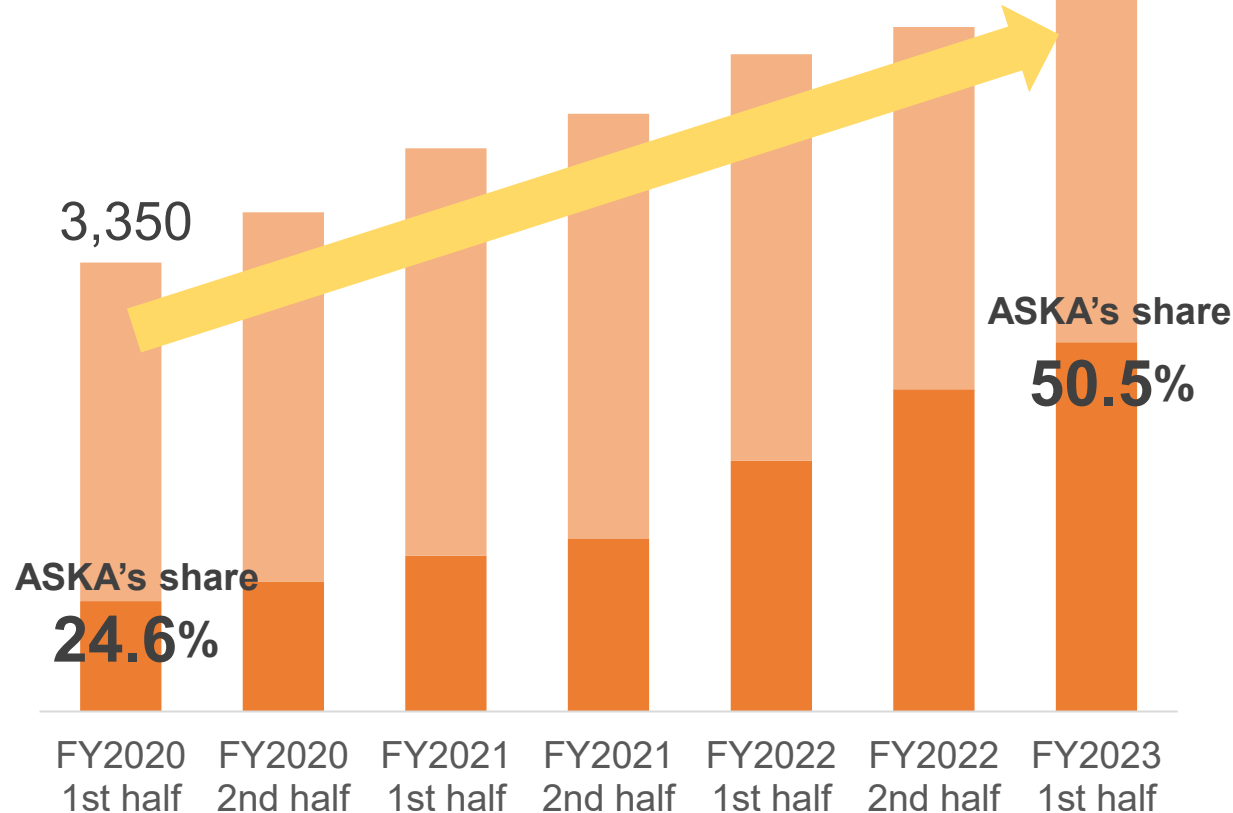
LEP market trend

(Thousands of sheets)

■ ASKA products ■ Competitors' products **161%*2**

5,460

In-house analysis based on date of Encise Inc.
(unauthorized reproduction prohibited)



Our LEP*3 formulations

Jemina® tablets

FREWELL® COMBINATION TABLETS

DroEthi® COMBINATION TABLETS

Current situation

Jemina, FREWELL

✓ Sales volume is increasing along with the growth of the market.

DroEthi

✓ The significant increase has contributed to the gains in market share.

Contributes to dysmenorrhea treatment

*1 Low-dose Estrogen/Progestin combination

*2 Calculated with the first half of 2020 as 100%

*3 Jemina tablets are co-promoted with Nobelpharma Co., Ltd.

Contribute to the Peripheral Pharmaceutical Fields with Femtech

Signed an agreement for joint development and marketing of therapeutic applications in the field of obstetrics and gynecology



* Japanese version only

SUSMED

Sustainable Medicine

2023年9月25日

あすか製薬株式会社

サスメド株式会社

各 位

産婦人科領域における治療用アプリの共同研究開発及び販売に関する契約を締結

あすか製薬株式会社（本社：東京都港区、代表取締役社長：山口 惣大、以下「あすか製薬」）とサスメド株式会社（本社：東京都中央区、代表取締役社長：上野 太郎、以下「サスメド」）は、産婦人科領域における治療用アプリの共同研究開発及び販売に関する契約を締結しました。

Develop as therapeutic applications
Aim for insurance coverage

Address women's health issues through new approaches in addition to traditional methods

ASKA Pharmaceutical launches
“Training Videos on Women's Health”

Press Release



ASKA Pharmaceutical Launches “Training Videos on Women's Health”

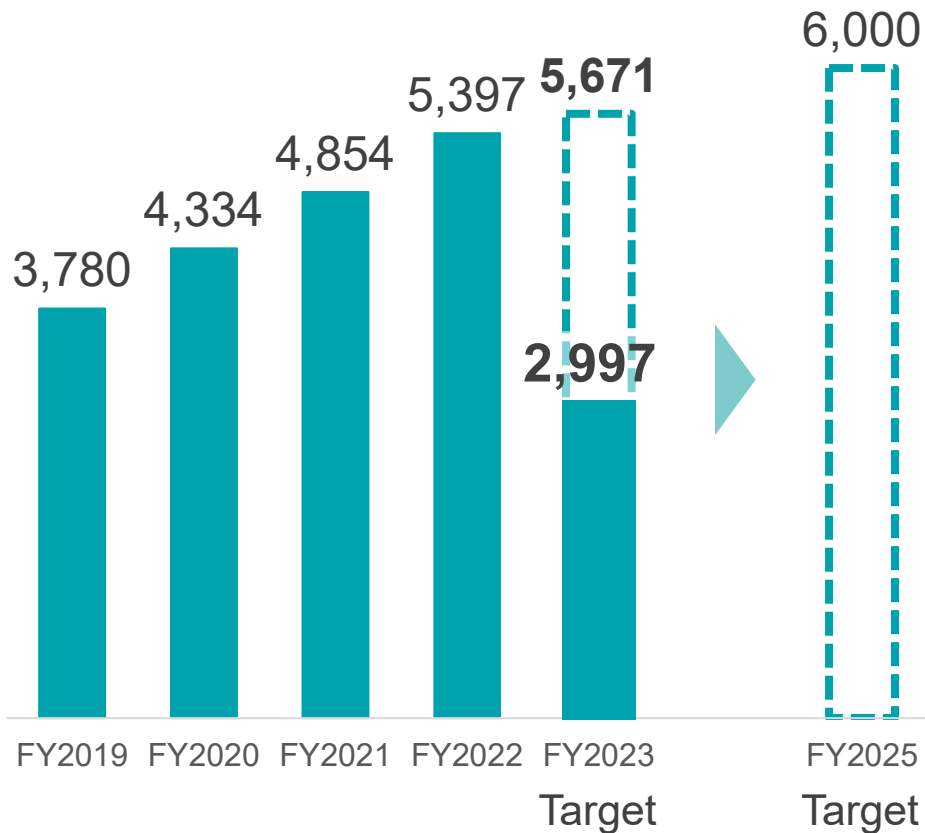
TOKYO, September 21, 2023 - ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo; President: Sohta Yamaguchi; hereinafter “ASKA”), a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd., established the Femtech Business Promotion Unit in April of this year to make a broad contribution to women's healthcare. ASKA is pleased to announce that it will start selling “training videos on women's health” as the first step of the Unit.

Improve health literacy in companies
Contribute to the realization of health management

RIFXIMA (rifaximin) Contributes to Unmet Medical Needs

RIFXIMA sales trend

Financial results base (millions of yen)



Further growth projected

Clinical Practice Guidelines for Liver Cirrhosis 2020

Published in November 2020

Strength of recommendation:
Strongly recommended

Evidence level:
A

Ongoing efforts to disseminate the guidelines

Clinical Practice Guidelines for Liver Cirrhosis
(Renewal of Annual Review)

* Published domestic long-term clinical data

< Effective penetration activities through face-to-face and web interviews >

Contribution to unmet medical needs
Pediatric indication for hepatic encephalopathy
Filed application in June

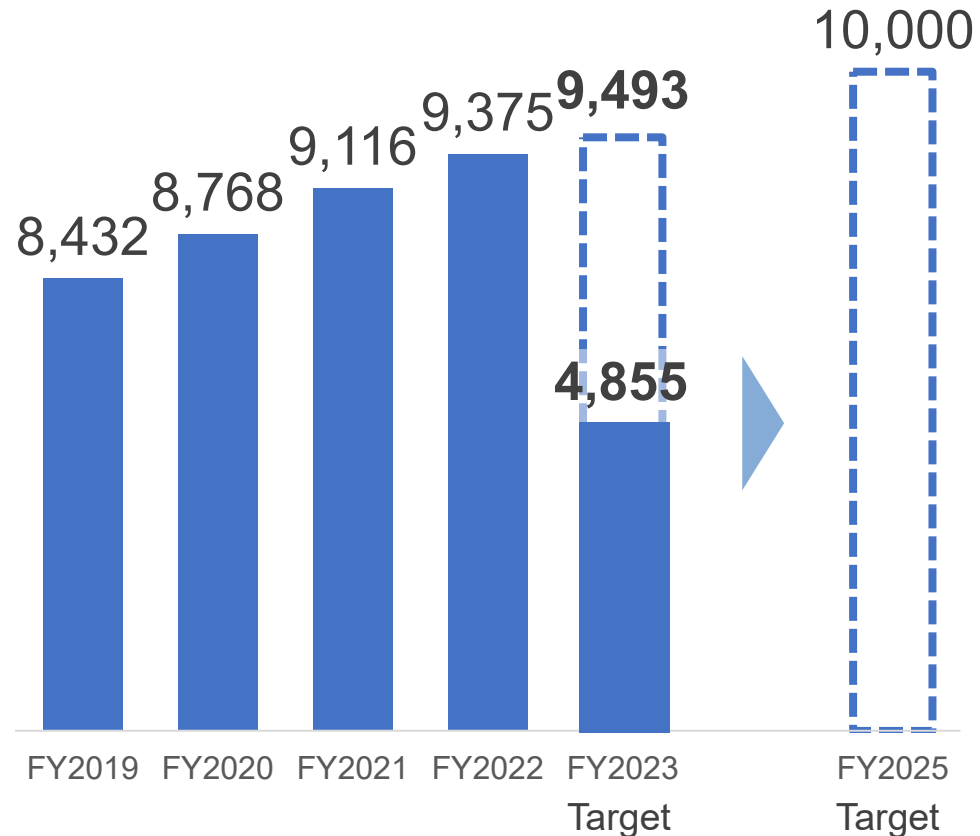
**Establishes itself as the standard treatment
for hepatic encephalopathy**

A Leading Company for Thyroid Treatment

Sales trend of three thyroid products*

Financial results base (millions of yen)

Sustainable
growth projected



Over 95% share

of the domestic market for the thyroid treatment

Thyroid disease awareness efforts

- ✓ Raise public awareness about thyroid testing
- Proposed thyroid testing to companies promoting health management
- Provided thyroid information to health checkup centers

Mission of ASKA Pharmaceutical

Promote disease awareness and contribute to treatment
Maintain stable supply as basic pharmaceuticals

* THYRADIN, MERCAZOLE, PROPACIL

ASKA Pharmaceutical Co., Ltd.














■ Main initiatives

- Specialty Areas
- Development Pipeline
- Overseas Business Development

Development Pipeline

R&D Status (as of November 2023)

 Changes from the previous financial results briefing

Development code (generic name) Indication	Research ^{*1}	Non-clinical ^{*1}	Ph I	Ph II	Ph III	Application	Approval
LF111 (drospirenone) Contraception							
							
(Option agreement) Treatment for PMS/PMDD ^{*2}							
							
AKP-022 (Relugolix combination tablet) Uterine fibroids							
							
							
Theme A / Ob/Gyn							
Theme B / Ob/Gyn							
TRM-270 (adhesion barrier) (Gastroenterology and Ob/Gyn)							
							
L-105 (rifaximin) Hepatic encephalopathy (pediatrics)							
							
							
Theme C / Internal Medicine							
AKP-009 (Iudaterone acetate) Benign prostatic hyperplasia							
							
						Ph IIa Completed^{*3}	
AKP-017 (transnasal testosterone)							
							
						Preparing clinical trials	
AKP-021 / mPGES-1 inhibitor agent							
							

*1 Details of research are not disclosed because it is non-clinical. *2 Premenstrual syndrome / premenstrual dysphoric disorder

*3 After receiving the results of the additional Phase I study, we are again conducting a Phase I study to reconfirm the data.

Development Pipeline - Summary of Characteristics

✓ **LF111**

Progesterone only oral contraceptive. Under development **with the expectation of reducing the risk of thrombosis.**

✓ **AKP-022**

Combines estrogen and progesterone with relugolix. Under development **with the expectation that long-term administration for 6 months or longer will be possible.**

✓ **TRM-270**

Under development **with the expectation that it will be an Adhesion Barrier with good maneuverability,** with a special focus on handling in laparoscopic surgery and robot-assisted surgery.

ASKA Pharmaceutical Co., Ltd.

■ Main initiatives

- Specialty Areas
- Development Pipeline
- Overseas Business Development

Vietnam - Collaboration with Hataphar -



Construction progress of a new plant (in compliance with PIC/S GMP)

- Initiated preparations for GMP acquisition for the start of commercial production
- Dispatch of new plant manager from ASKA in September
- Increased the number of seconded employees from 2 to 5

Reinforcement of support for plant operation

Deepening Collaboration

Aim to strengthen the alliance through further financial incorporation

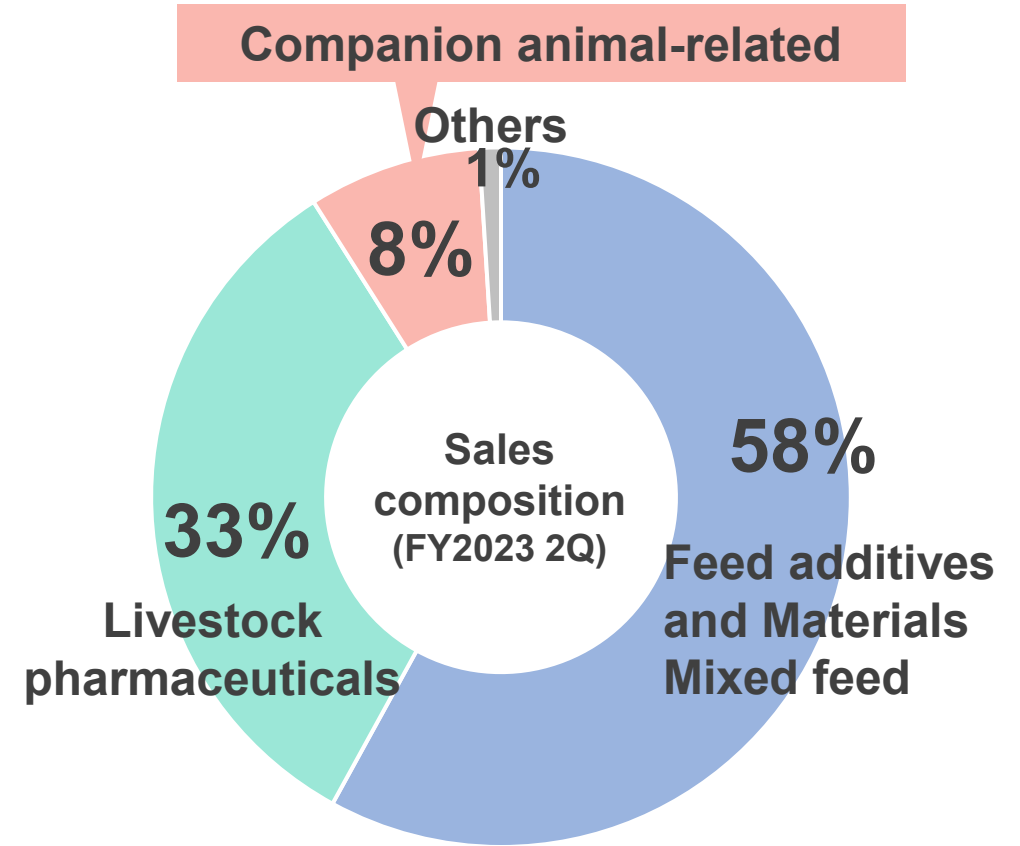
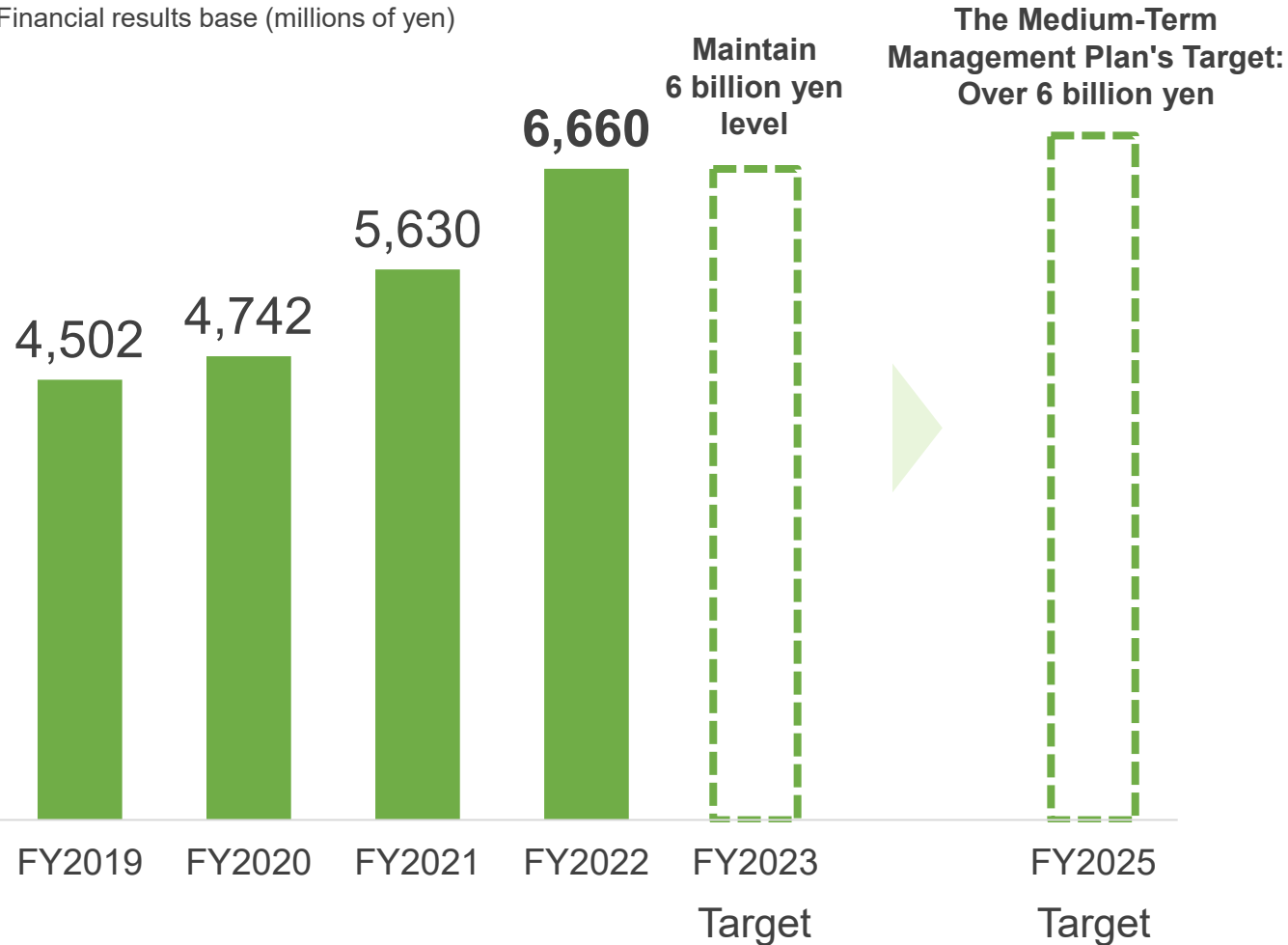
Aim to achieve further growth and increase corporate value of both companies

ASKA Animal Health Co., Ltd.

ASKA Animal Health - FY2023 Target and Sales Composition -

Sales trend of ASKA Animal Health

*Financial results base (millions of yen)



Promotes market penetration and the development of pharmaceuticals for companion animals

ASKA Animal Health - Circumstances and Initiatives

Key Initiatives for 2Q FY2023

Sales activities focused on products such as veterinary pharmaceuticals to improve profit margins

- Focuses on TRILOSTAN TABLETS “ASKA,” a treatment for canine hyperadrenocorticism, launched in November 2022
- Promotes market penetration of TRILOSTAN TABLETS “ASKA” by continuing to hold academic conference exhibitions, webinars, etc.
- Prepares for the launch of L-histidine hydrochloride, a feed for aquaculture (to be launched in November)

Outlook for Feed Additives

- Market conditions for feed additives remains uncertain, although there are trends toward a bottoming out of the market.

Contributes to the creation of a society where humans and animals can coexist

ASKA Pharma Medical Co., Ltd.

ASKA Pharma Medical - Main Initiatives

Strength of ASKA Pharma Medical: Endogenous hormone microanalysis technologies

Main initiative: expansion of non-invasive testing business

Launched in April 2023
Target: male menopausal disorder



Hair hormone level measurement kit
Dihydrotestosterone

Launched in July 2023
Target: Stress



Hair/nail stress hormone level test kit
Cortisol

Under development

Test kits for
companion animals

To be launched in FY2024

Contributes to the creation of a vibrant, healthy society
through the latest measurement technologies

ASKA Pharmaceutical Holdings - Group Strengths -

Sources of Growth

Specializing in endocrine R&D for a long time

Over **100** years

Developed and launched various products

ASKA Pharmaceutical

A Leading Company in Ob/Gyn field

Top sales in Ob/Gyn field*
*In-house estimate: in 2nd half of FY2022

ASKA Pharmaceutical

A Leading Company in Thyroid field

Over 95% share of the domestic market for the thyroid treatment

ASKA Animal Health

Product lineup

**Feed additives
Industrial animal/
Companion animal
pharmaceuticals**

Launched various products

ASKA Pharma Medical

Measurement technologies

**Endogenous hormone
microanalysis technologies**

Expansion of non-invasive testing businesses

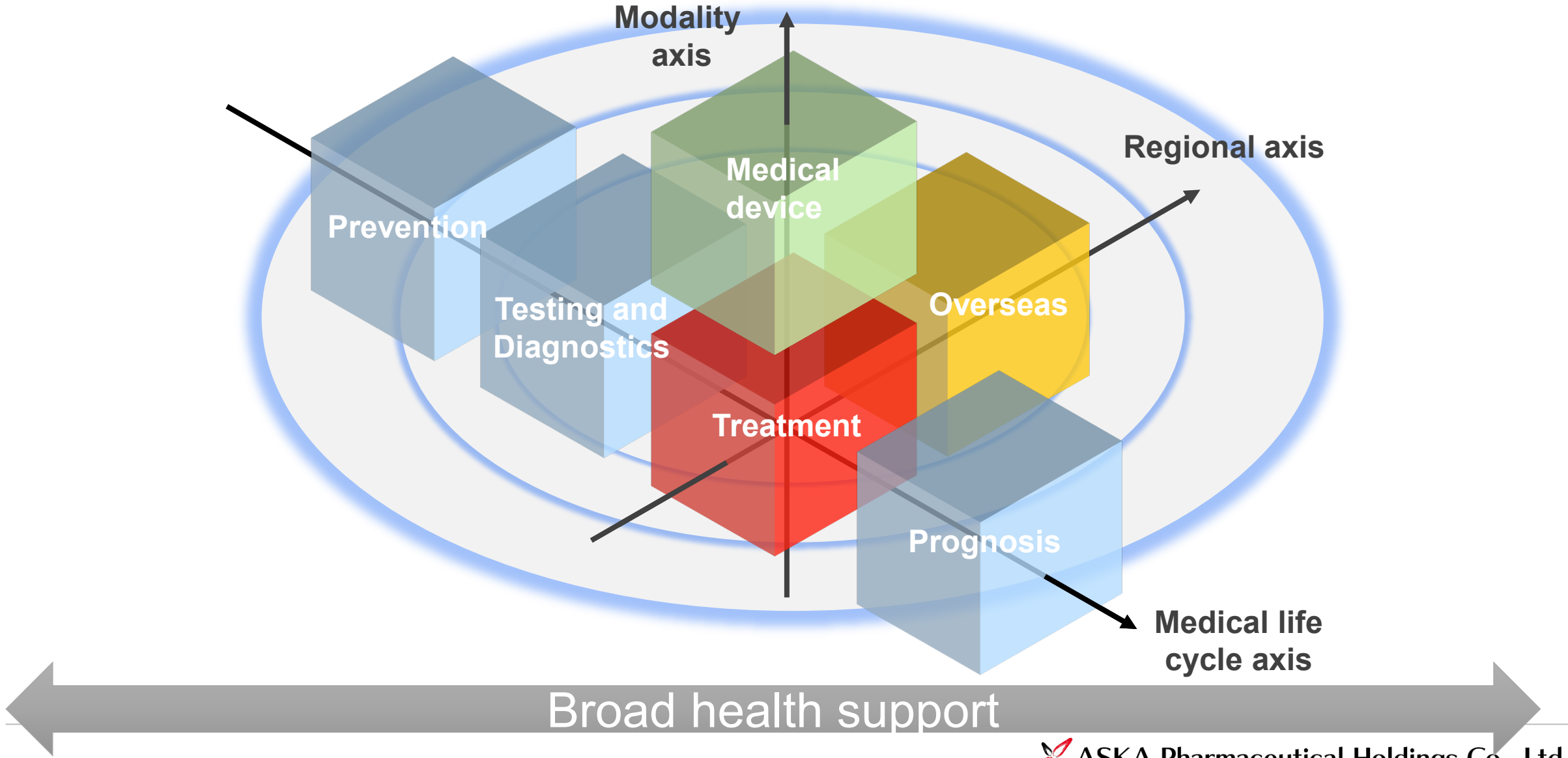
ASKA Pharmaceutical Holdings

Synergy Creation

**Intensifying inter-
group cooperation**

Cooperation and collaboration in various fields

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



**ASKA Pharmaceutical Holdings Group
Corporate Message**

For a Healthy Tomorrow and Future.

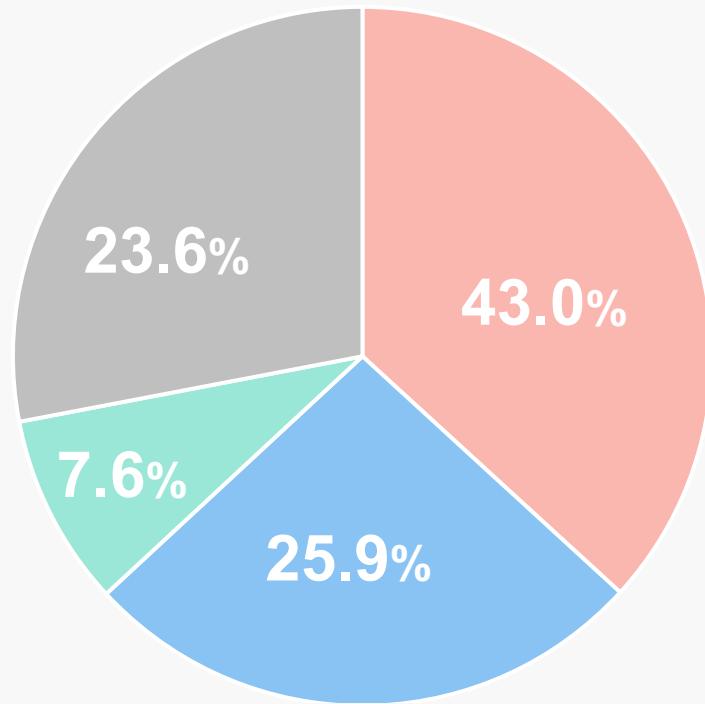


ASKA Pharmaceutical Holdings Co., Ltd.

Appendix

Sales Ratio by Area and Sales Proportion of Brand-name Drugs

Sales Ratio by Area (2Q FY2023)



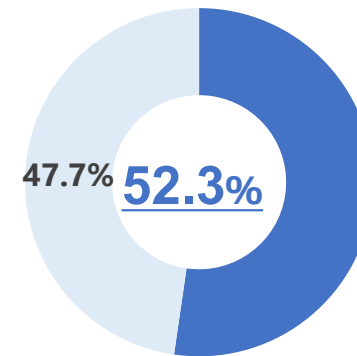
- Obstetrics and Gynecology
- Internal medicine (Gastroenterology and thyroid)
- Urology
- Others

The total may not add up to 100 because the figures are rounded to the second decimal place.

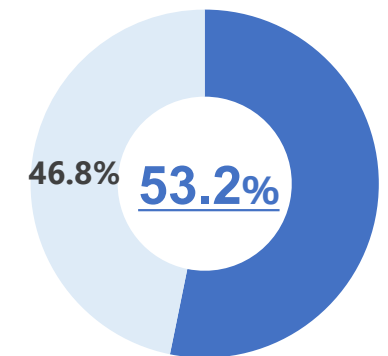
Sales Proportion of Brand-name Drugs

- Brand-name drugs
- Generic drugs

2Q FY2022

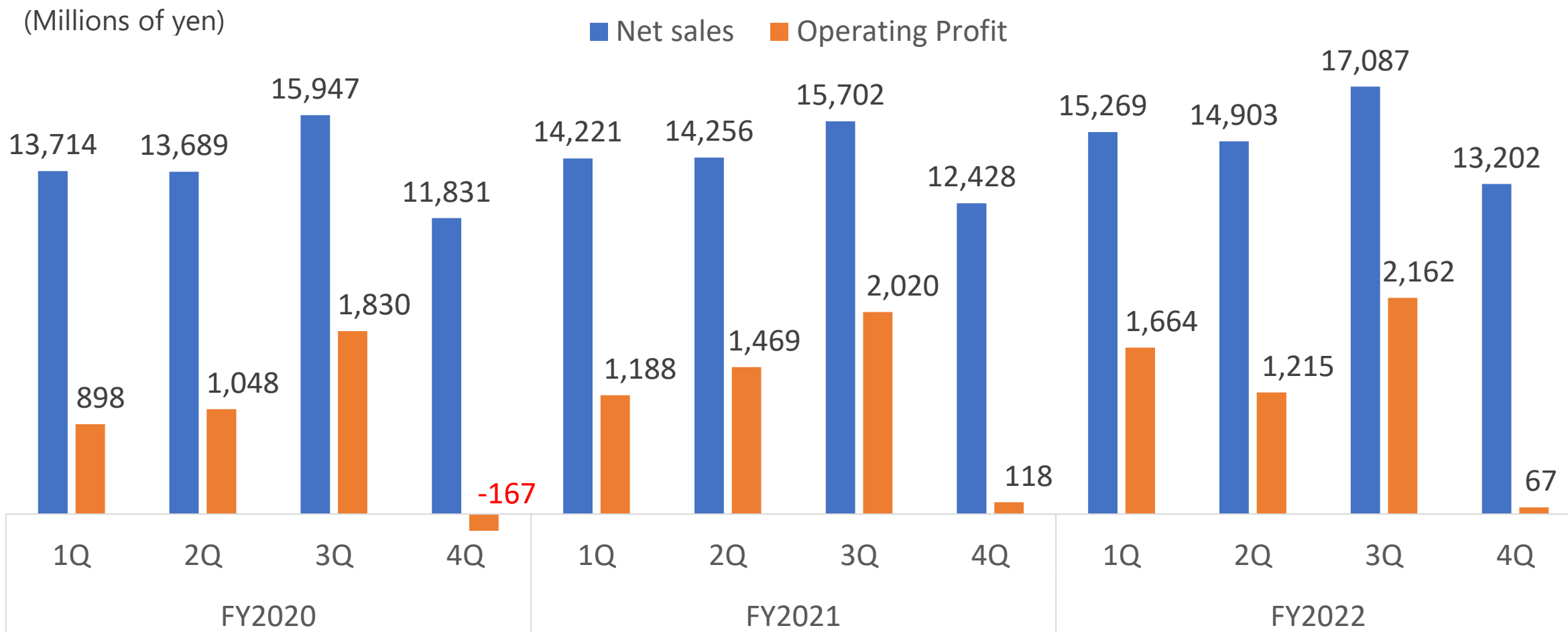


2Q FY2023



Aims to increase the ratio of brand-name drugs
(Numerical target in The Medium-Term Management Plan 2025: 70%)

Net Sales/Operating Profit by Quarter



Both sales and profits tend to be low in 4Q due to restrained purchases and expenses incurred before NHI drug price revisions.

Increase in the Number of Menstrual Cycles due to Changes in Life Events

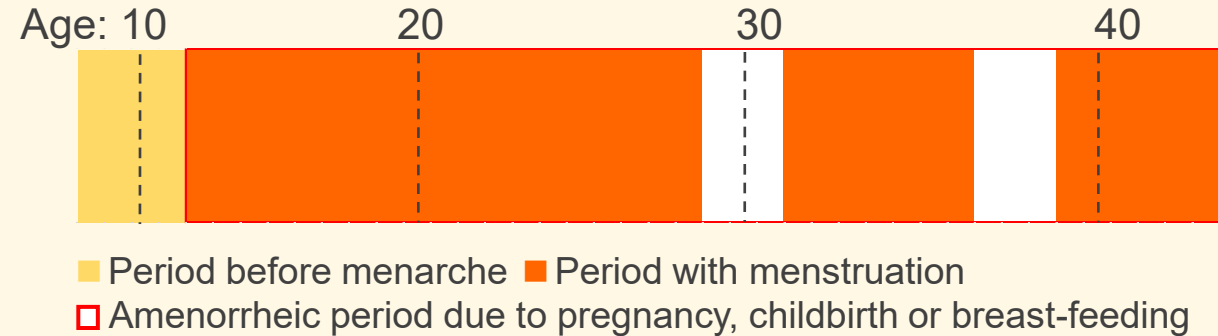
Women today experience their first menstruation earlier, tend to marry later, and experience fewer childbirths than women in past generations. The increase in the number of menstrual cycles (MCs) experienced in women's lifetime is considered a factor for the increase in dysmenorrhea and other menstrual problems.

Number of MCs experienced by women today

Number of lifetime MCs: **Approx. 450**

Number of lifetime childbirths: **Approx. 2**

Menstrual periods of women today

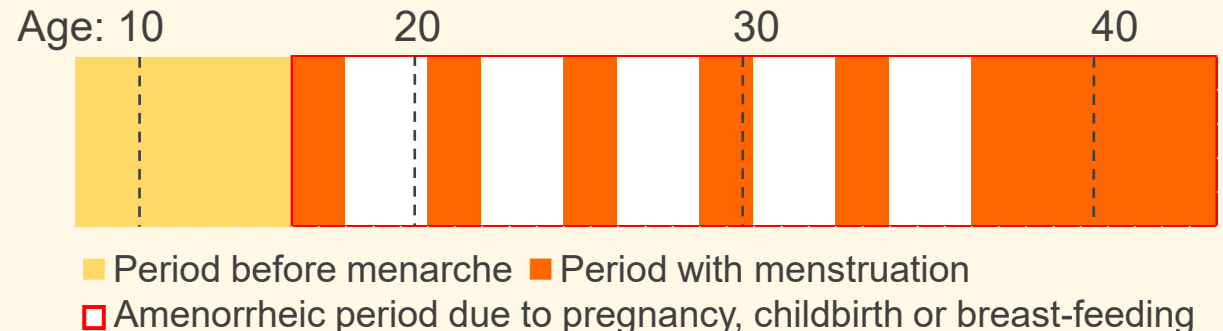


Number of MCs experienced by women in past generations

Number of lifetime MCs: **Approx. 50**

Number of lifetime childbirths: **Approx. 5**

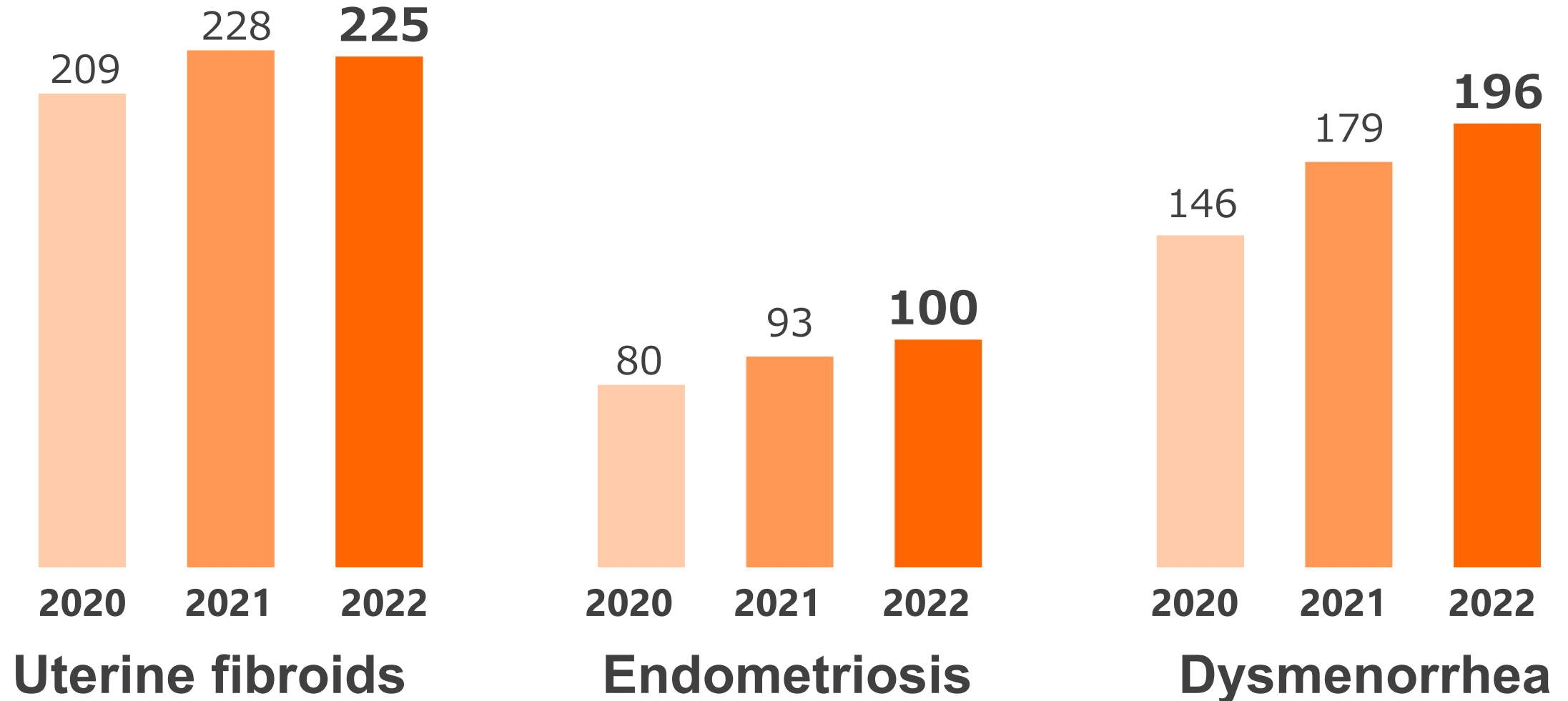
Menstrual periods of women in past generations



Number of Uterine Fibroids/Endometriosis/Dysmenorrhea Patients

(Extended estimates from electronic receipt data, 12 months from January of each year to December of the following year)

(Million of patients)



About Hataphar

Company name : Ha Tay Pharmaceutical Joint Stock Company

Founded : 1965

Head office: Hanoi, Vietnam

Number of employees : Approx. 1000

Listed stock exchanges : Hanoi Securities Trading Center (2008)

Net sales in FY2022: 1,837 billion VND (11,223 million yen)

Operating profit in FY2022: 114 billion VND (855 million yen)

Net profit in FY2022: 98 billion VND (599 million yen)

Business: Manufacturing, sales and importation of pharmaceuticals, nonprescription and nutraceutical products

- 3rd largest pharmaceutical company in Vietnam in terms of net sales in FY2022
- Branch offices and others in major cities, with distribution and sales covering nationwide in Vietnam



ASKA Pharmaceutical Holdings' Material Issues

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

Environmental

- Environmental protection and continuous reduction of environmental impact

Governance

- Corporate governance
- Secure compliance with laws and regulations, enforcement of compliance



Social

- **Contribution to women's health**
- **Contribution to animal health**
- Human resource development
- Employee engagement
- Creation of innovative products
- Expanding access to healthcare
- Stable supply of high-quality products
- Promotion of proper use of products

ASKA scrutinized 17 material issues and consolidated those into 11 issues

Inquiries

Corporate Planning Department

Tel : +81-3-5484-8366

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