

**FY2018**

**Overview of Consolidated Settlement**

**ASKA Pharmaceutical Co., Ltd.**

**Maruo, Senior Director**

# Consolidated statements of income

Millions of yen	FY2017	FY2018	Increase (decrease)	Rate of changes
Net sales	48,944	46,706	△2,238	△ 4.6%
Cost of sales	30,060	27,816	△2,243	△ 7.5%
Gross profit	18,884	18,890	5	0.0%
Selling, general and administrative expenses	16,060	17,107	1,047	6.5%
Operating income	2,824	1,782	△1,041	△ 36.9%
Ordinary income	3,073	1,980	△1,093	△ 35.6%
Profit attributable to owners of parent Net income	2,388	1,744	△ 644	△ 27.0%

# Net Sales by Industry Segment (Consolidated)

Millions of yen	FY2017	FY2018	Percentage of total	Increase (decrease)	Rate of changes
Ethical drugs	44,127	41,757	89.5%	△2,370	△ 5.4%
Drug for animal	4,572	4,669	9.9%	96	2.1%
Other	243	278	0.6%	35	14.4%
Total	48,944	46,706	100.0%	△2,238	△ 4.6%

# Sales of Main Products

Millions of yen

Area	Finished products	FY2017	FY2018		FY2019	
		Result	Result	YoY (%)	Plans	YoY (%)
Medical	※ 1,※2 Candesartans	13,226	11,924	90.2%	13,600	114.1%
	Thyradin	4,912	5,657	115.2%	6,982	123.4%
	Rifxima	1,062	2,478	233.3%	3,893	157.1%
	Lipidil	4,292	1,803	42.0%	1,208	67.0%
	※ 1 Amlodipine	1,616	1,390	86.0%	1,525	109.7%
	Mercazole	1,096	1,159	105.7%	1,338	115.5%
Obstetrics and gynecology	Norlevo	1,208	1,294	107.1%	664	51.3%
	Menoaid	736	882	119.9%	1,051	119.1%
	Ange	894	835	93.4%	1,000	119.8%
	※ 1 Frewell	-	668	-	2,010	300.9%
	Luteum	416	392	94.3%	483	123.0%
	Relumina	-	363	-	1,981	545.9%
Urology	※ 1,※3 Leuprorelin	4,164	4,167	100.1%	4,524	108.6%
	※ 1 Bicalutamide	1,576	1,221	77.5%	1,058	86.6%
	Prostal	710	410	57.8%	395	96.2%

※ 1 Generic Pharmaceutical

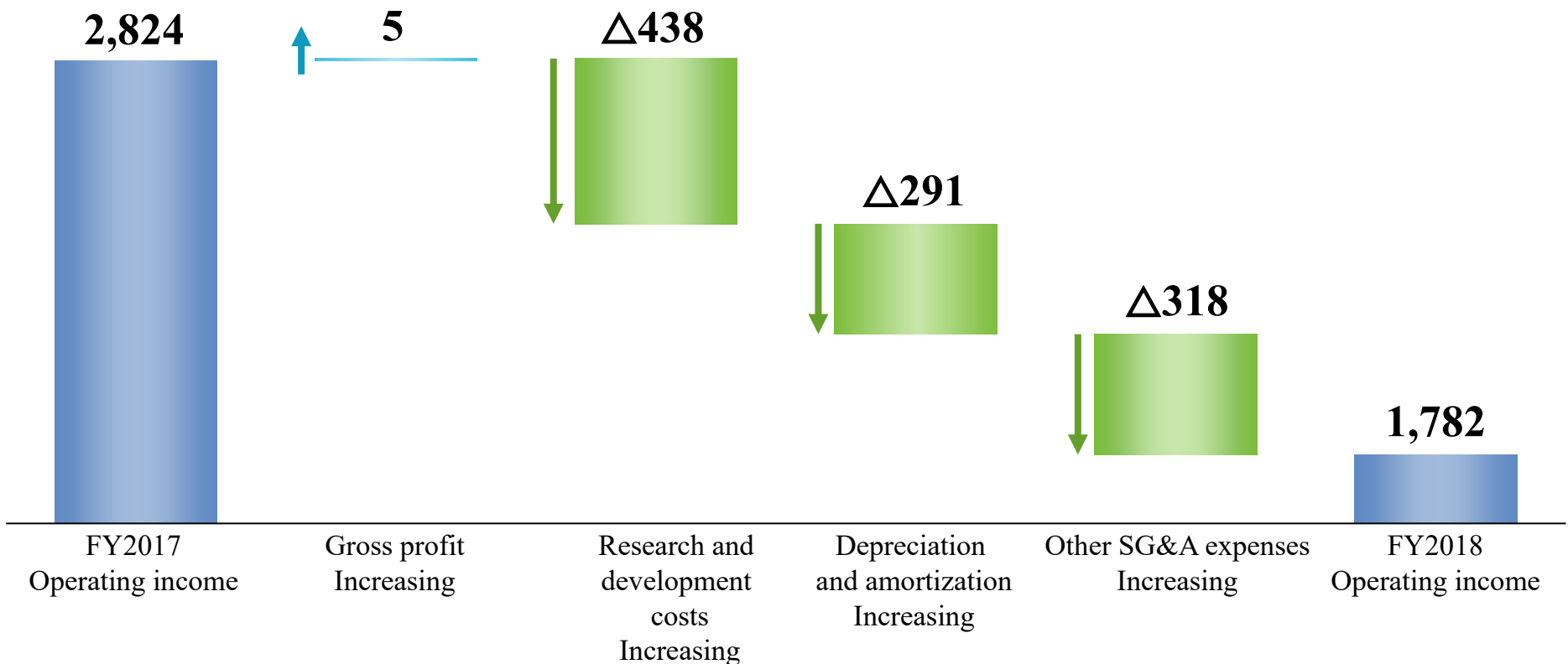
※ 2 Include combination drugs

※ 3 The 1.88mg formulation is for obstetrics and gynecology only, but it totals 3.75mg.

Adoption of "Accounting Standard for Revenue Recognition" from FY2019

# Operating Income Analysis (YoY)

Millions of yen



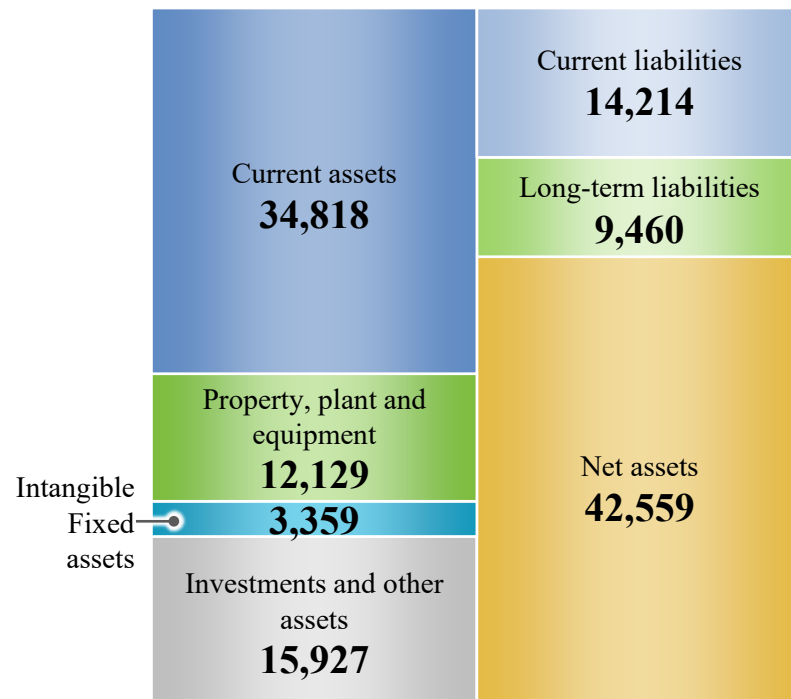
## Attribution

- Operating income decreased due to an increase in selling, general and administrative expenses, mainly in R&D expenses.

# Consolidated Balance Sheet

## End of fiscal 2017

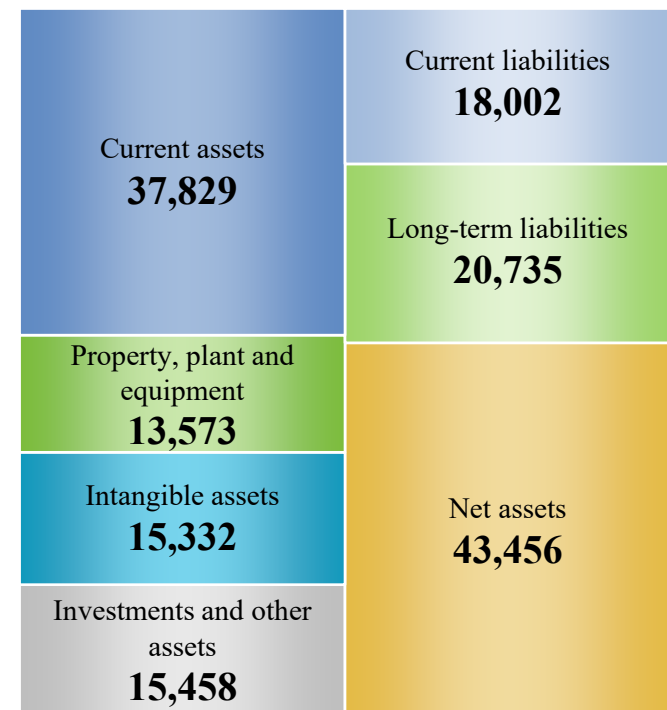
Millions of yen



Total assets 66,235 million yen

## End of fiscal 2018

Millions of yen



Total assets 82,194 million yen

	Total assets	Current assets	Property, plant and equipment	Intangible assets	Investments and other assets	Current liabilities	Long-term liabilities	Net assets
Increase (decrease)	15,959	3,010	1,444	11,972	Δ469	3,787	11,275	896

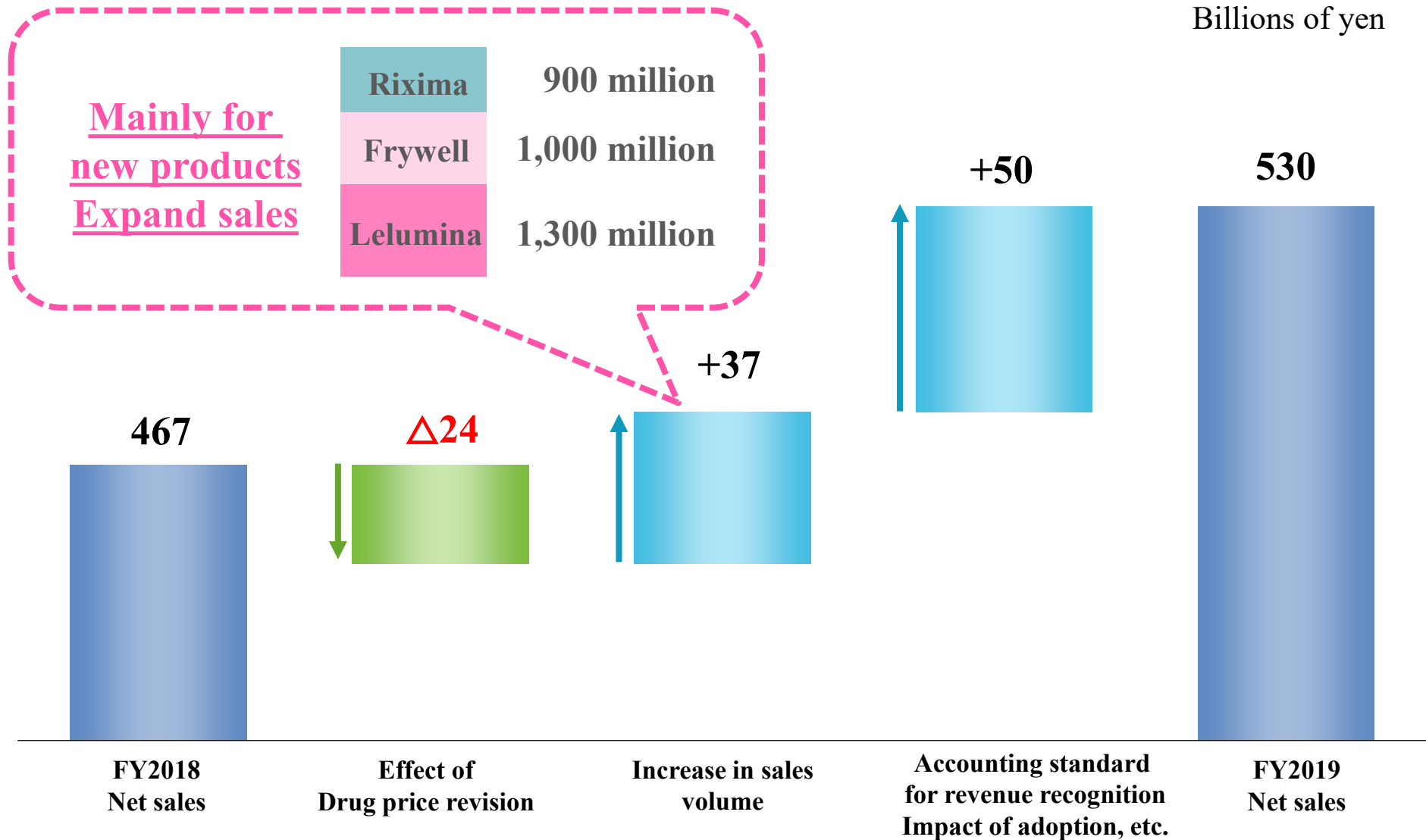
# FY2019 Forecast (Consolidated)

Millions of yen	FY2018 Result	FY2019 Forecast	From the previous year Increase (decrease)	From the previous year Rate of changes
Net sales	46,706	53,000	6,294	13.5
Operating income	1,782	2,000	218	12.2
Ordinary income	1,980	2,100	120	6.1
Profit attributable to owners of parent Net income	1,744	1,000	△744	△42.7

## Factor

- Net sales are expected to increase due to the impact of the adoption of the "Revenue Recognition Accounting Standard" and the increase in sales of new products in the field of obstetrics and gynecology, including RELUMINA, and of RIFXIMA.
- In terms of profits, operating income and ordinary income are expected to increase in line with the increase in net sales. On the other hand, net income attributable to owners of the parent is expected to decline due to an extraordinary loss associated with the relocation of the Research Institute.

# Factors behind the increase in sales in fiscal 2019





**FY2018 Summary**  
**FY2019 Initiatives**

**ASKA Pharmaceutical Co., Ltd.**  
**Yamaguchi, president of director**

# Today's content

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- **Summary of Fiscal 2018**
- **Efforts since FY2019**
  - **Rixima**
  - **Obstetrics and gynecology**
  - **Thyroid**
  - **Relocation to Shonan i-Park**
  - **Development pipeline**
  - **Outlook for the Medium-Term Management Plan**

# FY2018 Summary

## Major Achievements in FY2018 ①

- Maintain share and increase volume of candesartan products
- Maintain market share and increase volume of leuprorelin
- Ongoing activities to raise awareness of thyroid diseases
- **Steady market penetration of RIFXIMA**
- **Acquisition and launch of new products in the field of obstetrics and gynecology**



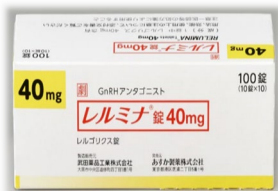
Launched on October 4, 2018 from Nobel Pharma Corporation  
Treatment for dysmenorrhea

**JEMINA® Combination Tablets**      Co-promotion



Launched on December 14, 2018  
Treatment for dysmenorrhea

**FREWELL® Combination Tablet LD/ULD "ASKA" authorized generics**



Launched on March 1, 2019  
GnRH antagonist

**RELUMINA® Tablet 40mg** Introduced from Takeda Pharmaceutical Co., Ltd.

- Development pipelines (AKP-009, Ulipristal, etc.)

# FY2018 Summary

## Major Achievements in FY2018 ②

### ■ Important investment



<Global Initiatives>

NeoASKA Pharma Private Limited



<Improvement of production system>

Fourth Pharmaceutical Building of  
Iwaki Plant (expansion of dedicated chilladen line)



<Strengthening of drug discovery research functions>

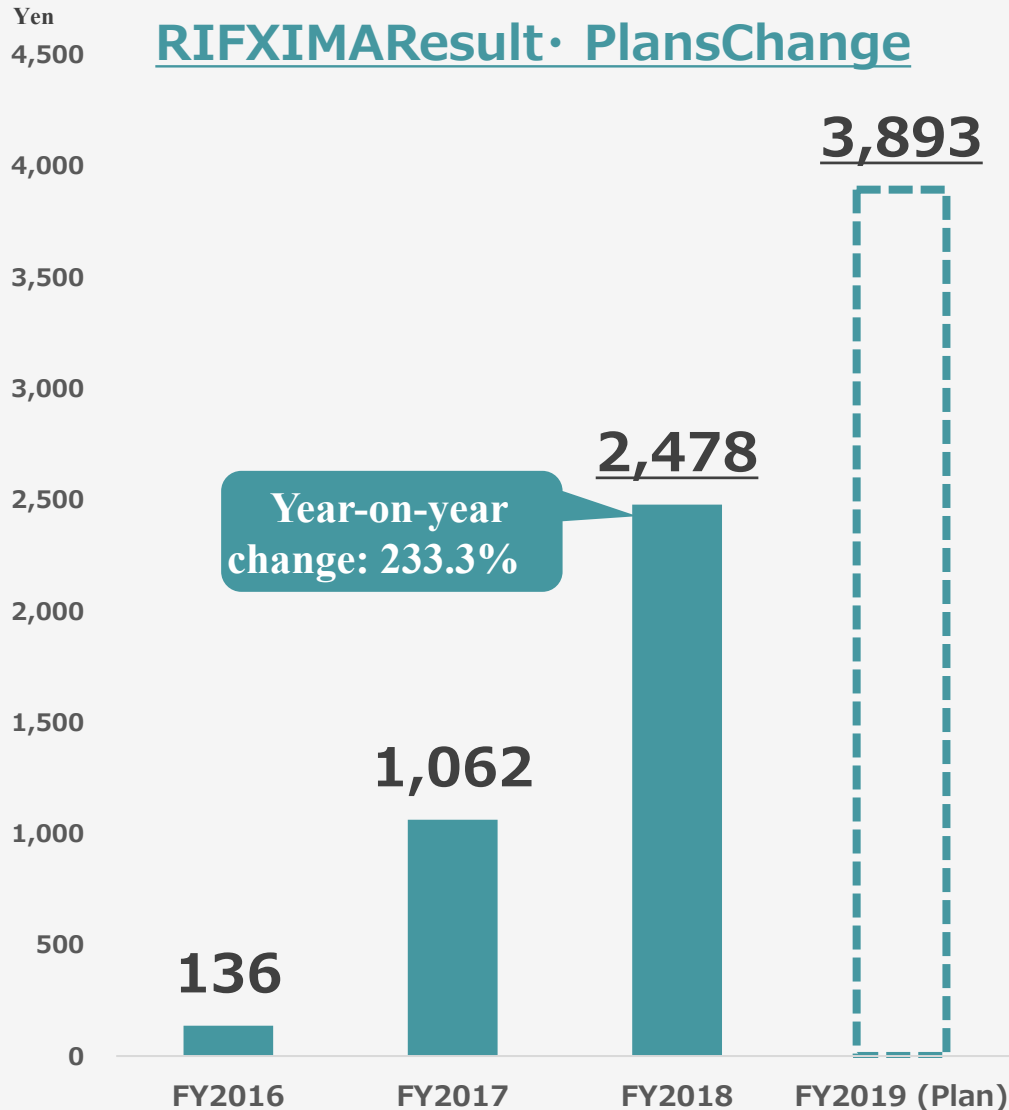
Concluded a tenant agreement  
with Shonan i-park Co., Ltd.

# RIFXIMA: Results

※ Our financial statements

※ Volumes

## RIFXIMA Result · Plans Change



"Revenue Recognition" from FY2019  
Adoption of accounting standards for

## Sales trends after the launch



# RIFXIMA: Toward Value Maximization

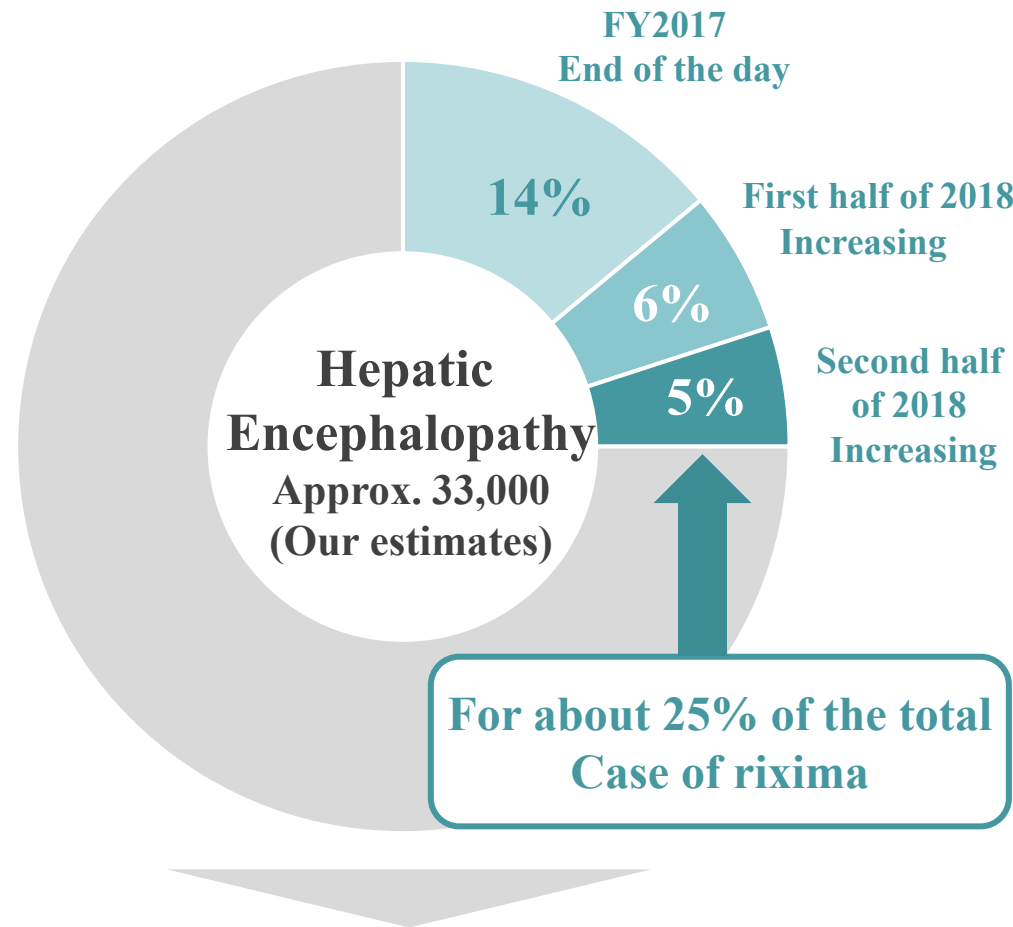
## To the Key Drug of hepatic encephalopathy

- 1 Switching from existing antibiotics**
  - Target of all surveys
  - Distribution management items

- 2 Combination with existing treatments**
  - Release of restrictions on the number of prescriptions
  - All cases deregistered

- 3 Positioning of Central Drugs**

- 4 Achieve further market penetration**



**For the treatment of HE**  
**Aim for "1st line"**

# Obstetrics and Gynecology: New Products

<FY2018>

Launch and promotion of 3 products

Under development

- Uripristal  
Uterine fibroid
- Relugolix  
Endometriosis

**RELUMINA<sup>®</sup> Tablets 40mg**  
※ Uterine leiomyoma

Authorized generics

**FREWELL<sup>®</sup> Combination Tablets LD/ULD "ASKA"**

**JEMINA<sup>®</sup> Combination Tablets**  
※ Copromotion

<FY2019>

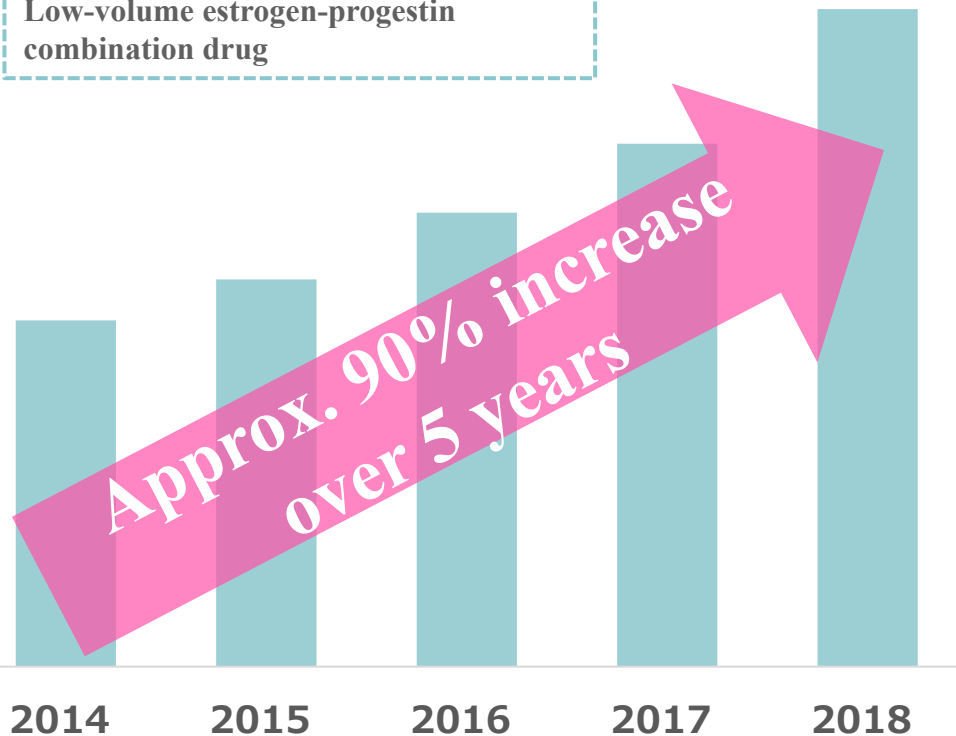
- **Fostering three products**
- **Progress of Products under Development**

# Ob/Gyne: JEMINA (LEP formulation)\* co-promotion

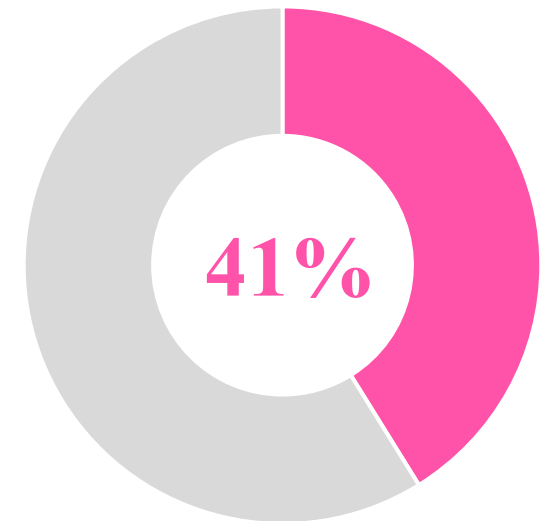
## Increasing LEP Market

※ Number of tablets 15

LEP Products ※ Defined in-house  
Low dose Estrogen Progestin  
 Low-volume estrogen-progestin  
 combination drug



Jeminer adoption rate at the target  
 (Launched in October 2018-April 2019)



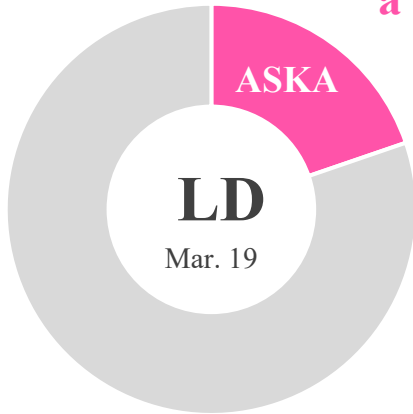
September 2019

Release of restrictions on the number of prescriptions



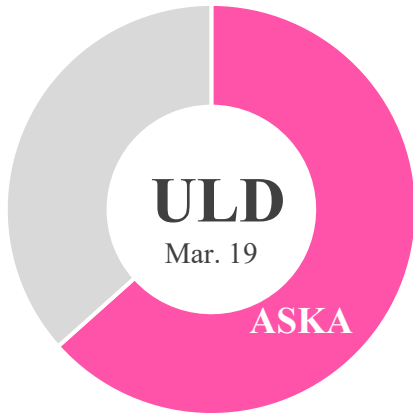
# Ob/Gyne: FREWELL(LEP formulation)\* Authorized generics

Share within GE as a total of LD and ULD



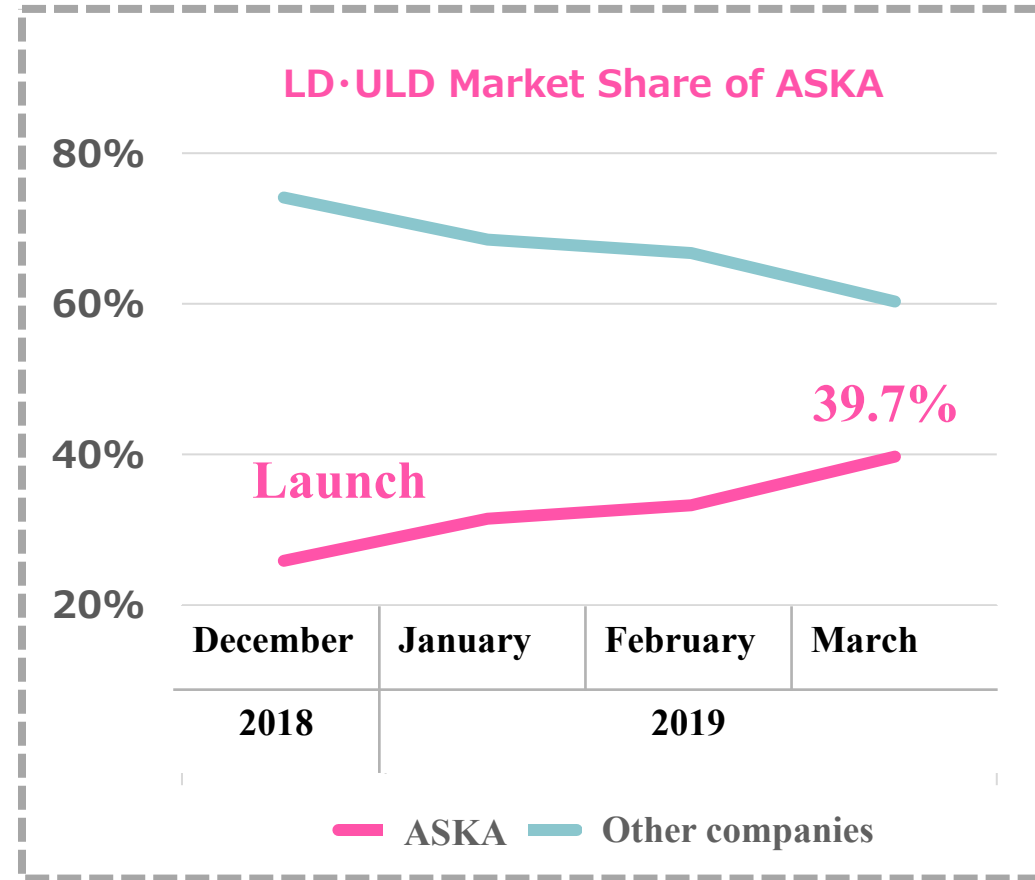
**19.7%**

※ Launch after selling by others



**63.4%**

※ Simultaneous launch by other companies

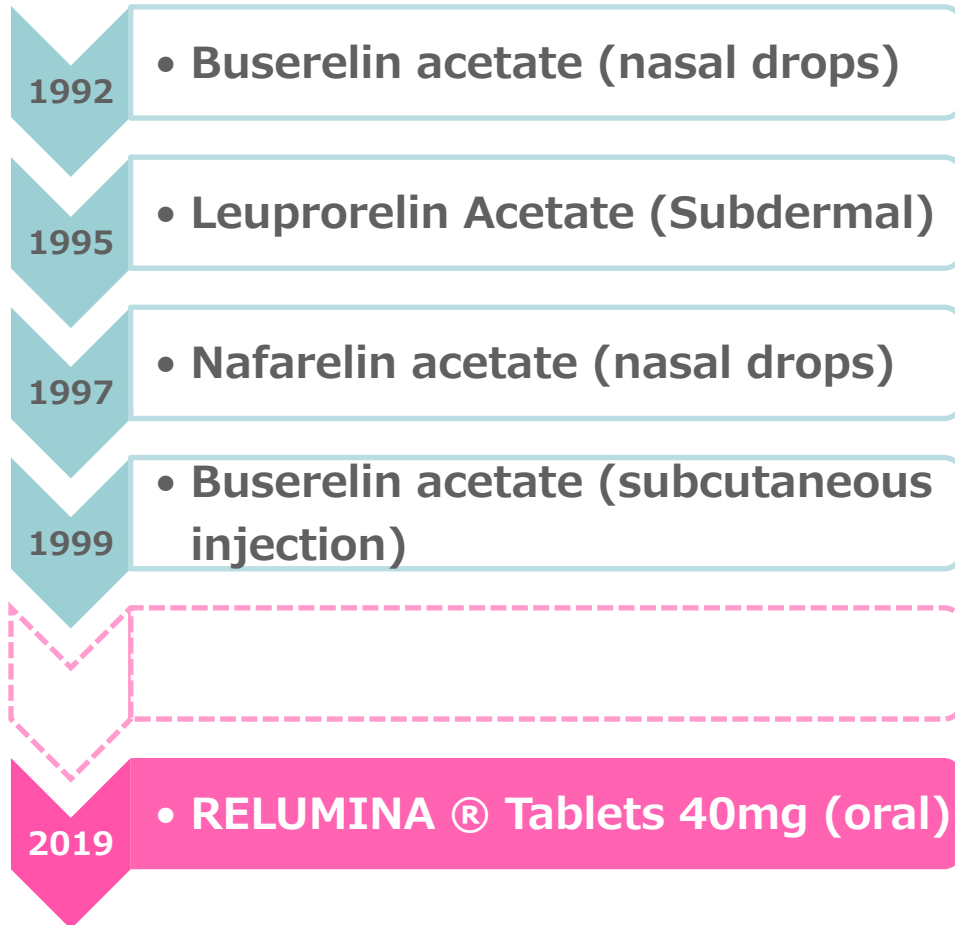


Share of LD/ULD in GE

**Aim for 60%**

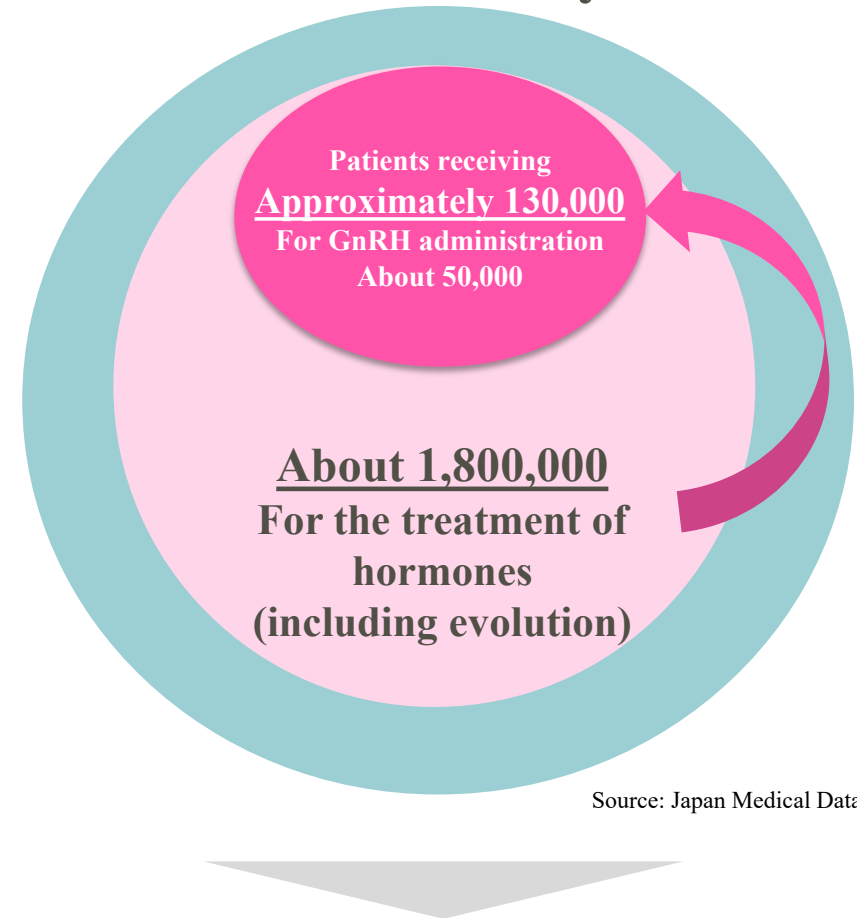
# Infiltration of the uterology treatment

Year of launch of the agent for the treatment of Uterine Myoma



Uterine Myoma Treatment  
For the first time in 20 years

## Patients who are diagnosed with Uterine Myoma



Source: Japan Medical Data Center

Provide new alternatives of  
Uterine Myoma treatment

# Ob/Gyn: RELUMINA ②

## Properties of Relumina

**GnRH antagonist formulation**  
**For the first once-daily oral administration in Japan**

**Decreased for the level of estradiol in the sera within one day of administration**

Studies that assess the effectiveness (amelioration of the passage of length of time) for patients with myeloma have verified non-inferiority to leuprorelin Acetate

Be based on uterine fibroids in Japanese clinical studies  
 Symptoms (too many months, feminine abdominum, low back pain, and anemia)  
 It has been confirmed that the improvement is effective.

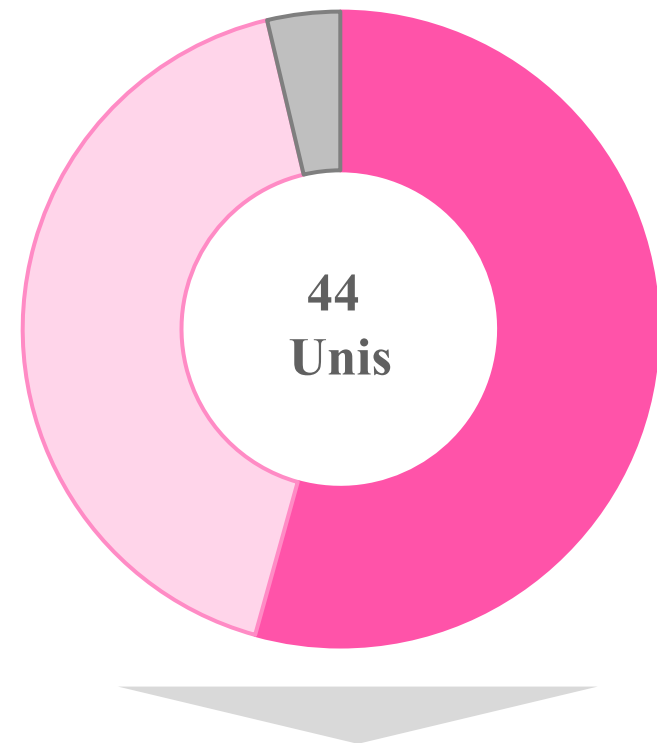
### Side Effect

193 out of 225 (85.8%) in domestic clinical trials up to approval. Adverse effects, including abnormal clinical laboratory values, are recognized, and major side effects are recognized. As follows: Hot and fraudulent uterological haemorrhage (42.2% each), overage of month (21.8%), This was due to headache (10.2%), hyperperspiration (8.9%) and sexual bleeding (6.7%). Significant adverse reactions included depression (<1%) and hepatic dysfunction (Frequency unknown) is reported.

※ For details, please refer to the attached document.

## Recruitment status of all 81 universities hospitals

- Adapted
- Expected to be adopted in the first half of 19
- Expected to be adopted from the second half of 19

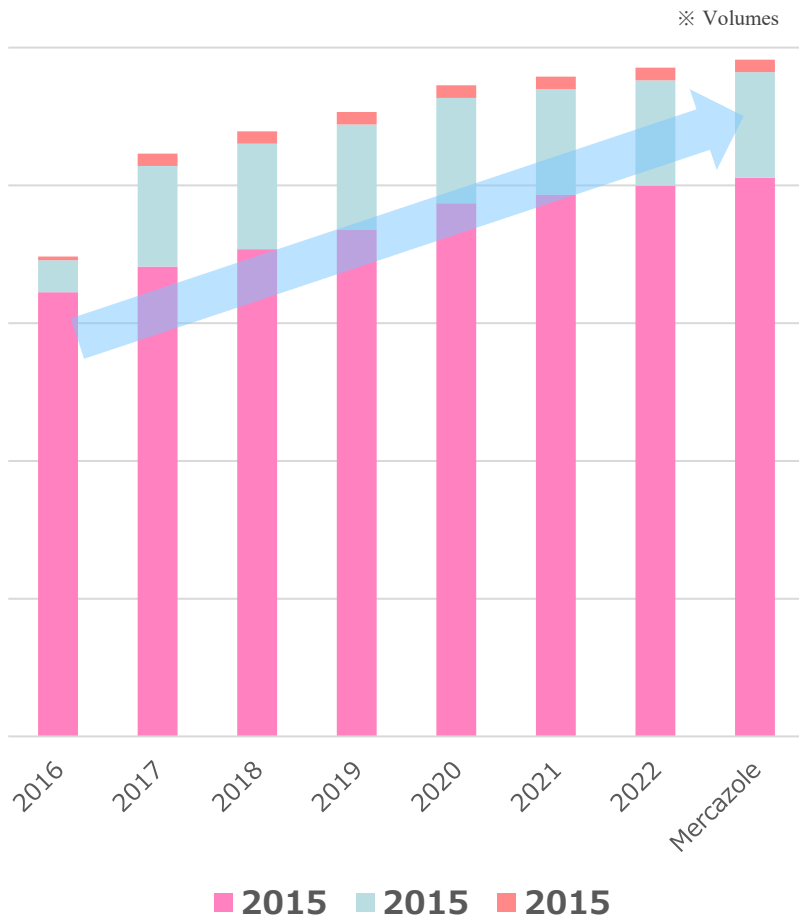


**Meet medical needs**

# Thyradin

~ Toward the 100th anniversary of the birth of Thyradin in 2022

## Sales trend of Thyradin



▶ Increasing the volume of sales

## Disease enlightenment



### May 25: World Thyrogenic Day

Symbol for raising awareness of thyroid diseases  
**“Butterfly ribbon”**

We have set as the educational period every May,  
**Employees wear these badges**

From the Japanese Thyroid Society

## Academic Society Activities, etc

- <4/26> 91st sponsored symposium held by the Japan Endo-economics Society
- <4/28> 91st Endocrine Society of Japan Hot Topics
- <5/25> Global Thyle Day Public lectures (Kobe on May 19, Kyoto on May 20, Osaka on May 27)
- <6/2> 85th Roundtable on Clinical Endocrine Tuberculosis
- <6/28> 30th Endocrine Surgery Society of Japan sponsored symposium
- <9/1> Daytime health fair
- <10/28> 51st Japan Thyroid Surgery Association Morning Seminar
- <11/23> 61st Japan Thyroid Society luncheon seminar
- <12/1> 86th Roundtable on Clinical Endocrine Measures
- <2/9> Thyroid Pathophysiology Study Group 35th Session Sales trends for thyroid products

▶ Continue activities to raise awareness of diseases and academic societies

# Relocation of Shonan Health Innovation Park

## Target

**Accelerating Open Innovation to Strengthen Drug Discovery Functions**

## Expected benefits


- **Efficiently Promote Advanced Drug Discovery Research by Utilizing the Latest Devices and Technologies**
- **Collaboration with tenant companies such as drug discovery support ventures and academia-originated bioventures**
- **Accumulated many researchers and organizations, and active exchanges with researchers from various industries, academia, and government**

## Timing of relocation

**Relocation completed by the first half of FY2020**

# Development Pipelines

## Status of R&D (as of May 2019)

 Changes from the previous assessment

Development Number (generic name)/Area/Indication	Ph I	Ph II	Ph III	Application	Approved
<b>AKP-015 (levothyroxine sodium)</b> Myxoedematous coma/severe hypothyroidism		(PhII and PhIII not required)		<b>Under application</b>	
<b>CDB-2914 (Ulipristal)</b> Uterine leiomyoma					
<b>TAK-385(relugolix)</b> Endometriosis			<b>Starting PhIII</b>		
<b>AKP-501 (folitropin gamma)</b> Infertility		<b>PhI termination</b>			
<b>L-105 (rifaxin)</b> Crohn's disease		<b>PhI termination</b>			
<b>L-105 (rifaxin)</b> Hepatic encephalopathy (Children)	Preparing				
<b>AKP-009</b> Benign Prostatic Hyperplasia		<b>PhI termination</b>			

# Medium-Term Management Plan

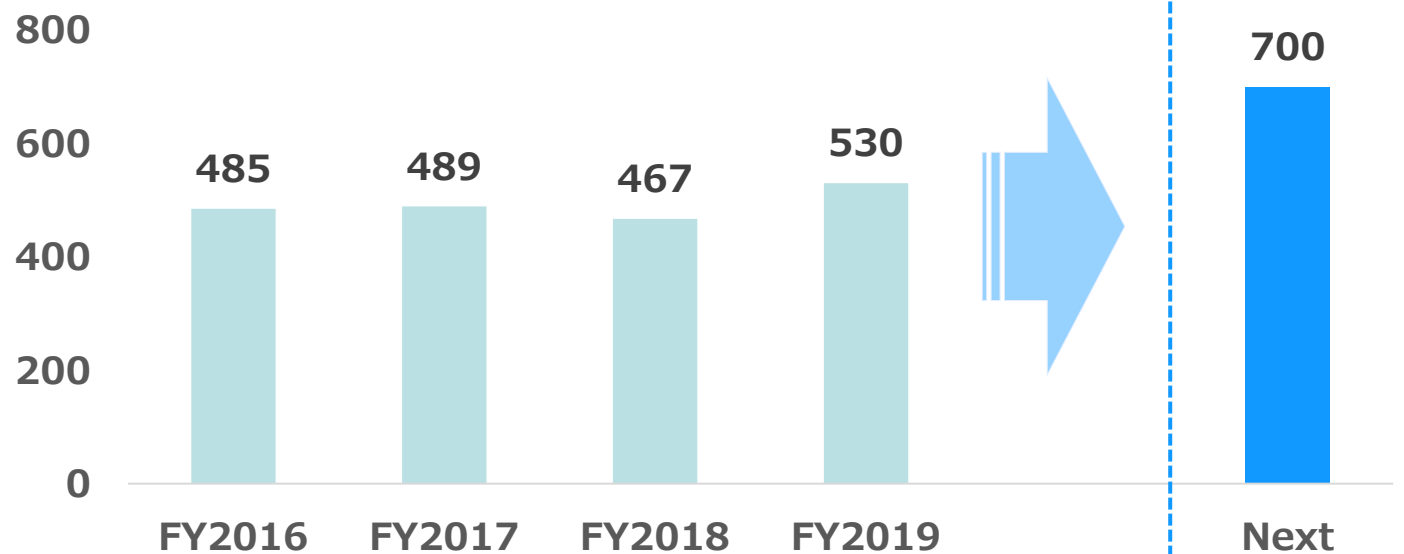
Consolidated	FY2016	FY2017	FY2018	FY2019	Next Management Plan
	Results	Results	Results	Plan	Estimated Targets
Net Sales	485	489	467	530	700
Operating income margin	3.7%	5.8%	3.8%	3.8%	10.0%
ROE	7.8%	5.8%	4.1%	2.3%	8.0%

## Medium-Term Management Plan

Consolidated	FY2020 Estimated Targets
Sales	70.0
Operating income margin	10.0%
ROE	8.0%

(¥100million)

## Net sales



# Aska Pharmaceutical Co., Ltd.

## Ethical drug business



ASKA Pharmaceutical Medical Co., Ltd.



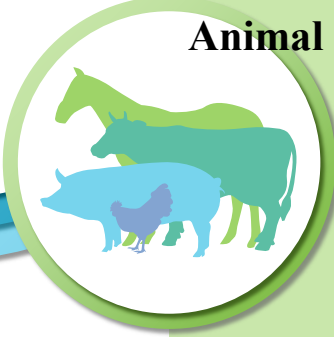
## Inspection and Healthcare Businesses



Aska Animal Health Co., Ltd.



## Animal Feed and Pharmaceutical Business





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.

# References: "Revenue Recognition Accounting Standard"

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## 1. Summary

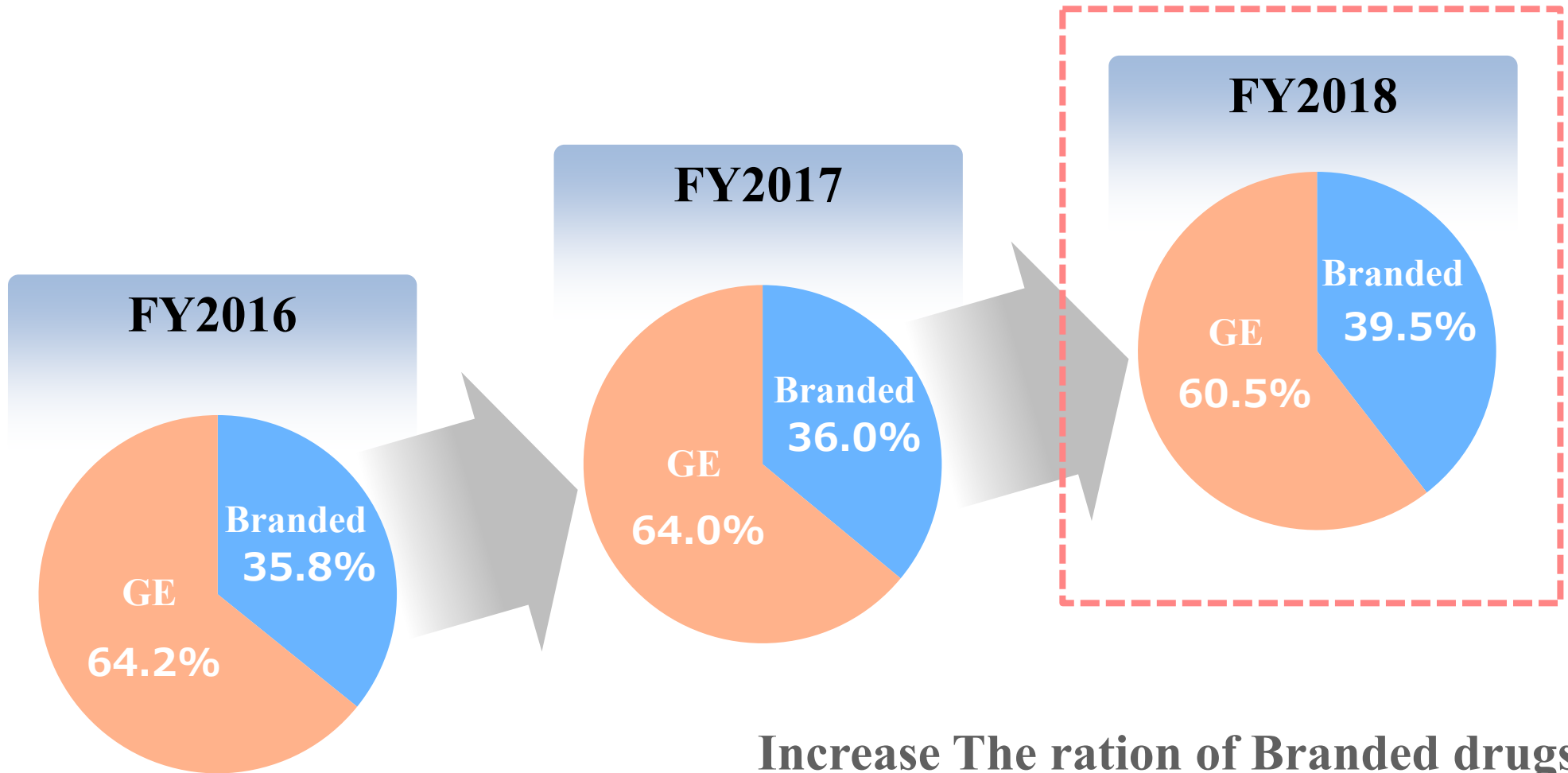
- On March 30, 2018, the Corporate Accounting Standards Committee released the "Accounting Standards for Revenue Recognition" ("This Standard").
- This system was enacted and will be enforced from FY2021 (early adoption from FY2018 onward). Previously, under Japanese accounting standards, there was no comprehensive accounting standard for revenue recognition. Instead, sales were recorded on the basis of "delivery of goods" and "receipt of cash equivalents." However, this standard has been issued and will be applied in order to conform with the International Financial Reporting Standards (IFRS).
  - Revenue is recognized when not only "ownership" and "possession" but also "significant risks" are transferred to the customer.
  - In agency transactions (brokerage, etc.), only commissions are net sales after offsetting net sales against purchases.
  - Rebates are deducted from sales rather than recorded as SG&A expenses.
- We are able to compare sales with those of other companies by changing the timing of recording sales. We also introduced ERP in fiscal 2018, and the environment for applying this standard is in place, so we have reached early adoption.

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## 2. Effect of this standard on us

- Previously, sales were recorded when products were shipped to Takeda Pharmaceutical.
- Under this standard, the "significant risks" are deemed to have been transferred when Takeda Pharmaceutical delivers the product to the dealer. Therefore, the timing of recording sales of Takeda Pharmaceutical after the adoption of this standard is the time when the product is handed over to the dealer.

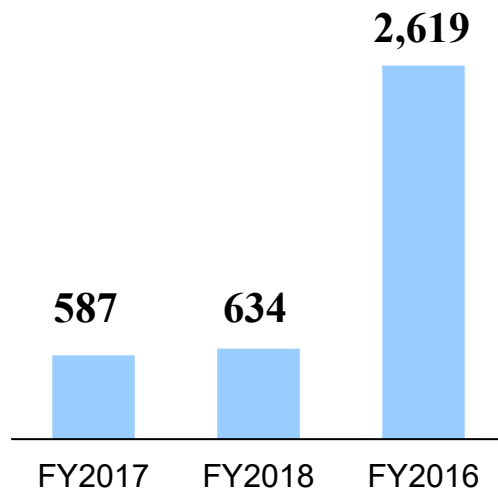
## References: Percentage distribution of ethical drugs



# Reference: Investment cost

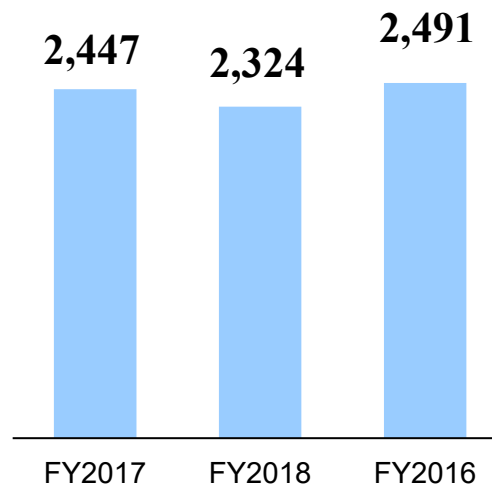
## Capital investment

Yen



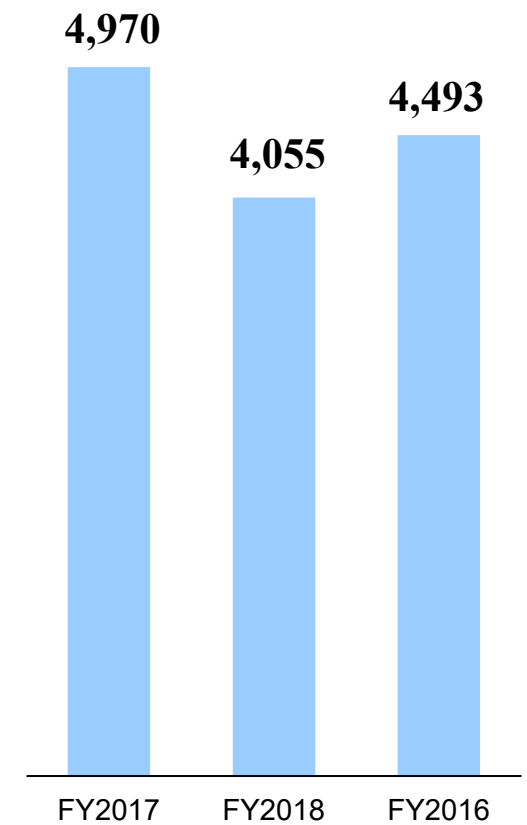
## Depreciation and amortization

Yen



## Research and Development costs

Yen



- The contents regarding future forecast in this material are known, un-known risks, uncertain due to information based on our assumption and forecasts by press release at the time that we presented.
- Actual results and development forecasts may differ materially from these forecasts due to various factors.
- This information includes information on pharmaceuticals (including those under development), but the content of this information is not intended for advertising or medical advice.

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