

Business Results for the First Half of the Fiscal Year Ending September 30, 2019

May 17, 2019

**Eiji Takemasa,
President and Chief Executive Officer**

**Fuji Pharma Co., Ltd.
(4554/TSE1)**

FujiPharma

- **Summary of 1H FY9/19 Consolidated Financial Results**
- **New Products/Drugs in the Pipeline**
- **Activities for the “FujiPharma 2030” Long-term Vision**
 - (1) Start selling Fuji Pharma brand drugs in Thailand**
 - (2) Alliance with Alvogen Group**

➤ **Summary of 1H FY9/19 Consolidated Financial Results**

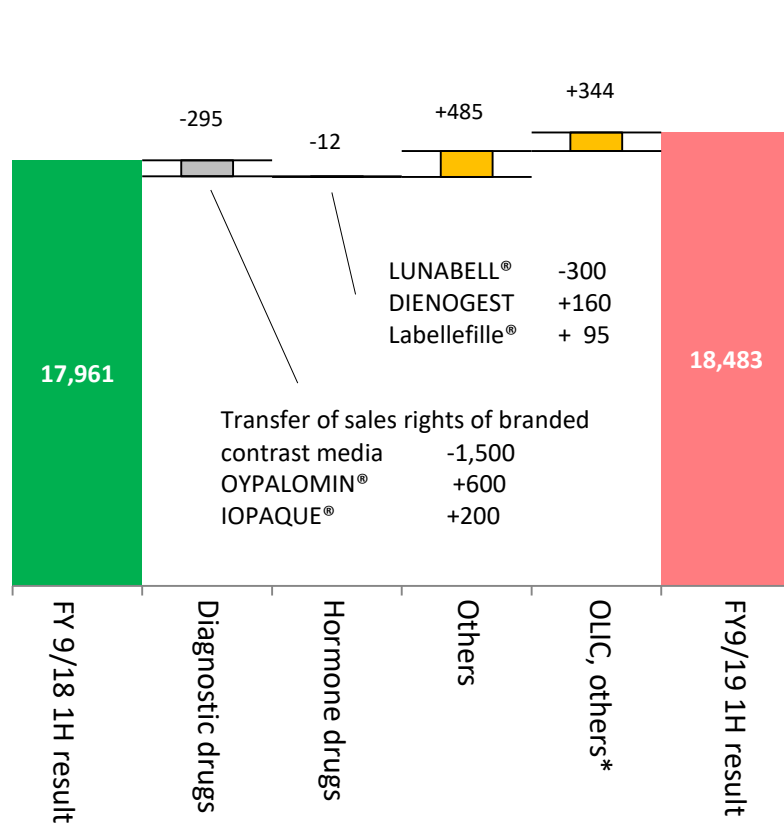
Summary of 1H FY9/19 Consolidated Financial Results

- Net sales increased by 2.9%, or ¥521 million YoY, due to the contribution from generic contrast media and new products
- Operating profit increased by 8.4%, or ¥192 million YoY, due to efficient use of R&D expenses
- Ordinary profit increased by 6.0%, or ¥141 million YoY, due to a foreign exchange loss caused by transactions with subsidiaries

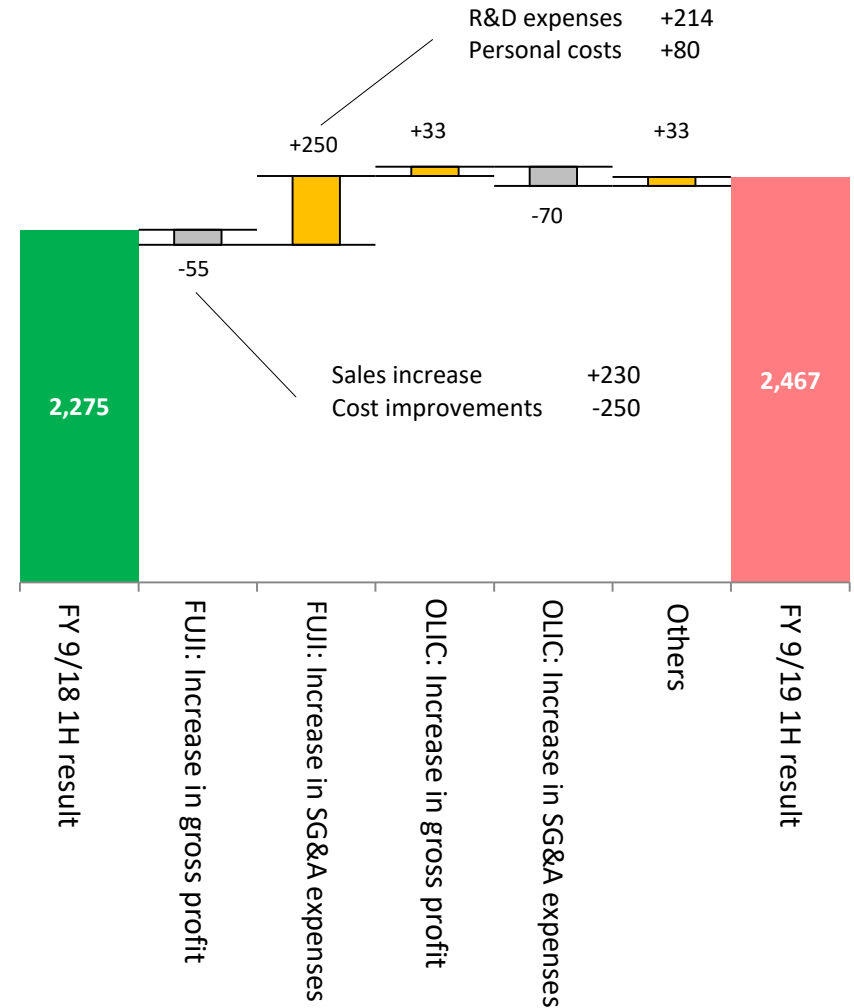
(¥million)	FY9/18	FY9/19	YoY Change		1H FY9/19	
	1H	1H	Amount	Ratio	Fcst	Vs. Fcst
Net Sales	17,961	18,483	521	2.9%	18,751	98.6%
Gross Profit	7,919	7,921	2	0.0%		
Gross Margin	44.1%	42.9%				
SG&A Expenses	5,644	5,454	-190	-3.4%		
SG&A Margin	31.4%	29.5%				
Operating Profit	2,275	2,467	192	8.4%	2,574	95.8%
Operating Margin	12.7%	13.3%				
Ordinary Profit	2,360	2,501	141	6.0%	2,611	95.8%
Ordinary Margin	13.1%	13.5%				
Profit Attributable to Owners of Parent	1,743	1,695	-48	-2.8%	1,886	89.9%
Profit Margin	9.7%	9.2%				
Capital Expenditure	557	326	-231	-41.5%		
Depreciation (including Leased Equipment)	1,003	972	-31	-3.1%		
R&D Expenses	913	699	-214	-23.4%		
R&D Expenses Ratio	5.1%	3.8%				

Summary of 1H FY9/19 Consolidated Financial Results

Net Sales (¥million)



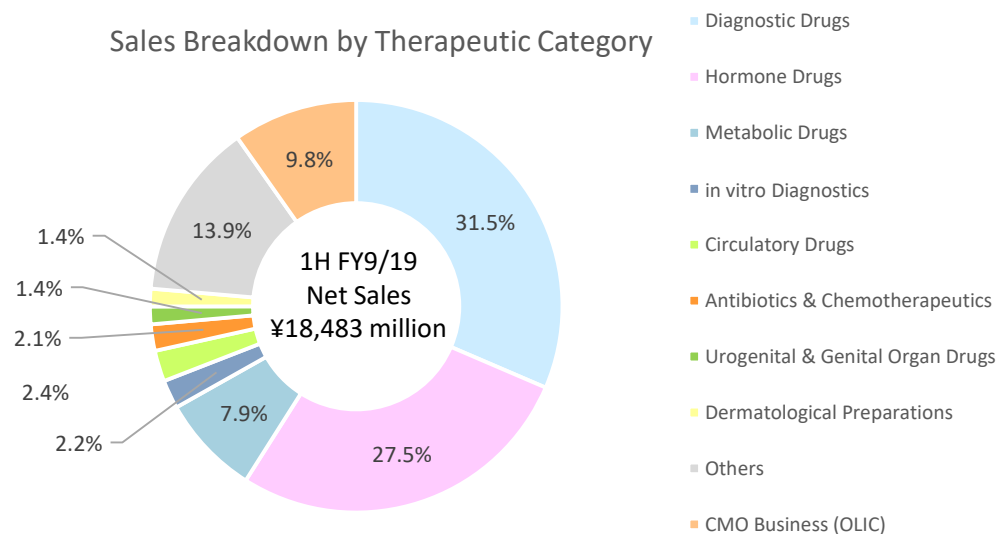
Operating Profit (¥million)



Sales by Therapeutic Category

(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Diagnostic Drugs	6,323	6,028	-295	-4.7%
Hormone Drugs	5,290	5,278	-12	-0.2%
Metabolic Drugs	1,442	1,505	63	4.4%
in vitro Diagnostics	581	431	-150	-25.8%
Circulatory Drugs	460	466	6	1.3%
Antibiotics & Chemotherapeutics	409	397	-12	-2.9%
Urogenital & Genital Organ Drugs	246	266	20	8.1%
Dermatological Preparations	198	265	67	33.8%
Others	1,716	2,656	940	54.8%
CMO Business (OLIC)	1,529	1,873	344	22.5%
Total	17,961	18,483	521	2.9%

*Total amounts are after consolidation adjustments.



Sales of Major Products

Product Name (¥million)	Therapeutic Category	FY9/18 1H	FY9/19 1H	YoY Change		FY9/19	
				Amount	Ratio	Full-year Fcst	vs Fcst (%)
OYPALOMIN® injection	Diagnostic drugs	2,947	3,580	633	21.5%	7,763	46.1%
IOPAQUE® injection	Diagnostic drugs	910	1,115	205	22.5%	2,476	45.0%
<u>LUNABELL® tablets (LD/ULD)</u>	<u>Hormone drugs</u>	<u>1,289</u>	<u>978</u>	<u>-311</u>	<u>-24.1%</u>	<u>1,975</u>	<u>49.5%</u>
<u>Filgrastim BS injection</u>	<u>Metabolic drugs</u>	<u>847</u>	<u>945</u>	<u>98</u>	<u>11.6%</u>	<u>1,752</u>	<u>53.9%</u>
<u>OPTIRAY® injection</u>	<u>Diagnostic drugs</u>	<u>1,054</u>	<u>731</u>	<u>-323</u>	<u>-30.6%</u>	<u>629</u>	<u>116.2%</u>
DIENOGEST tablets	Hormone drugs	373	532	159	42.6%	941	56.5%
DEXART® injection	Hormone drugs	431	435	4	0.9%	891	48.8%
HMG intramuscular injection	Hormone drugs	447	400	-47	-10.5%	916	43.7%
<u>UTROGESTAN® Vaginal Capsules</u>	<u>Hormone drugs</u>	<u>298</u>	<u>332</u>	<u>34</u>	<u>11.4%</u>	<u>869</u>	<u>38.2%</u>
FAVOIR® tablets	Hormone drugs	335	328	-7	-2.1%	600	54.7%
Labellefile® tablets	Hormone drugs	223	316	93	41.7%	649	48.7%
FOLYRMON®-P injection	Hormone drugs	304	316	12	3.9%	751	42.1%
LIMAPROST ALFADEX tablets	Metabolic drugs	316	300	-16	-5.1%	650	46.2%
ALPROSTADIL injection	Circulatory drugs	256	276	20	7.8%	526	52.5%
Total Top 14 Sales		10,028	10,585	557	5.6%	21,395	49.5%
Pct. of Total Sales		55.8%	57.3%				
New Products		2,477	1,358	-1,119	-45.2%		
Other Products		4,162	5,352	1,190	28.6%		
OLIC CMO Business (excluding transactions among group companies)		1,362	1,358	-4	-0.3%		
Total		17,961	18,483	521	2.9%	36,815	50.2%

Acute Medical Care

Women's Healthcare

* New Products: products launched in FY9/14 or afterward (excluding the top 14)

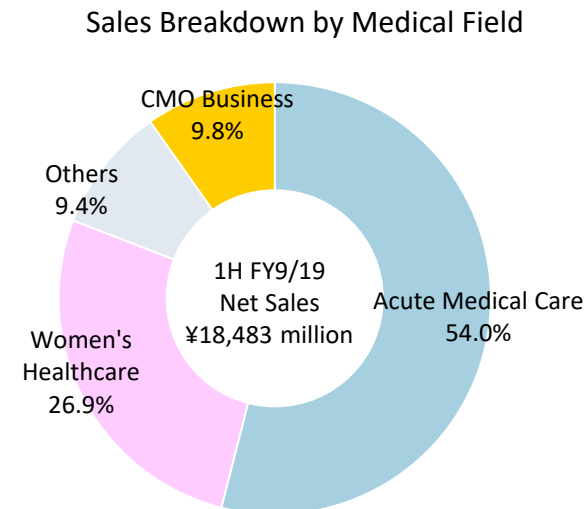
* Underlined products are the Fuji Pharma branded drugs, branded generic drugs (marketing approval received from original drug manufacturers) and biosimilars.

* Total amounts are after consolidation adjustments.

Sales by Medical Field and Drug Form Category

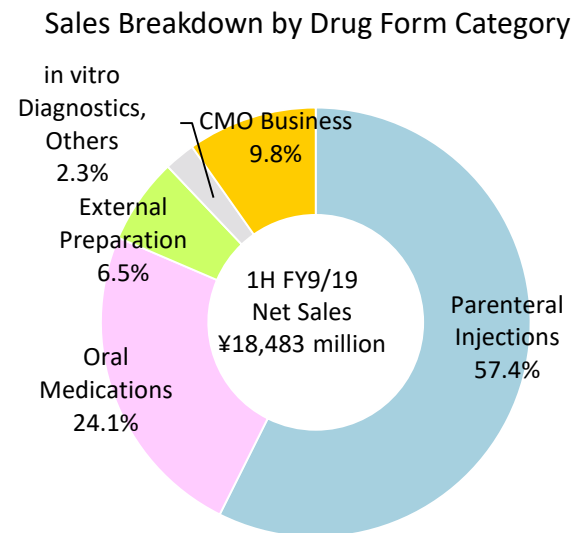
(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Acute Medical Care	9,980	10,347	367	3.7%
Women's Healthcare	5,222	5,154	-68	-1.3%
Others	1,464	1,795	331	22.6%
CMO Business (OLIC)	1,529	1,873	344	22.5%
Total	17,961	18,483	521	2.9%

*Total amounts are after consolidation adjustments.



(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Parenteral Injections	10,603	10,998	395	3.7%
Oral Medications	4,362	4,614	252	5.8%
External Preparation	1,104	1,238	134	12.1%
in vitro Diagnostics, Others	583	445	-138	-23.7%
CMO Business (OLIC)	1,529	1,873	344	22.5%
Total	17,961	18,483	521	2.9%

*Total amounts are after consolidation adjustments.

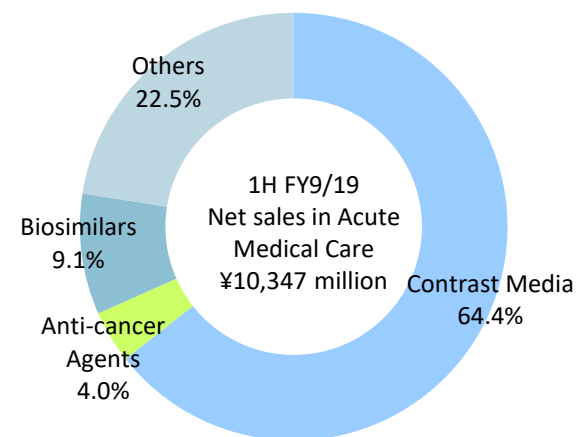


Sales in Acute Medical Care/Women's Healthcare

◆ Acute Medical Care

(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Contrast Media	6,194	6,661	467	7.5%
Anti-cancer Agents	462	410	-52	-11.3%
Biosimilars (BS)	847	945	98	11.6%
Others	2,476	2,329	-147	-5.9%
Total	9,980	10,347	367	3.7%

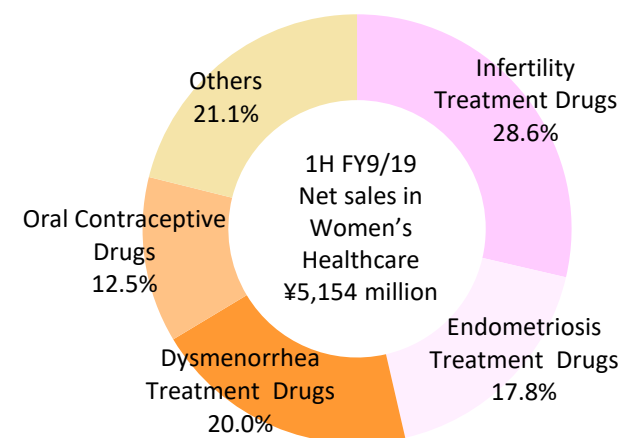
Sales Breakdown by Acute Medical Care



◆ Women's Healthcare

(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Infertility Treatment Drugs	1,468	1,475	7	0.5%
Endometriosis Treatment Drugs	741	915	174	23.5%
Dysmenorrhea Treatment Drugs	1,435	1,030	-405	-28.2%
Oral Contraceptive Drugs	557	644	87	15.6%
Others	1,019	1,088	69	6.8%
Total	5,222	5,154	-68	-1.3%

Sales Breakdown by Women's Healthcare



Summary of 1H FY9/19 Consolidated Balance Sheet

(¥million)	FY9/18	FY9/19	YoY Change	
	Sep. 30, 2018	Mar. 31, 2019	Amount	Ratio
Assets				
Current Assets	34,927	34,753	-174	-0.5%
Cash and Deposits	6,251	6,435	184	2.9%
Notes and Accounts Receivable-Trade	16,903	15,693	-1,210	-7.2%
Inventories	11,285	11,176	-109	-1.0%
Other	486	1,447	961	197.7%
Non-current Assets	18,189	24,259	6,070	33.4%
Property, Plant and Equipment	11,700	11,688	-12	-0.1%
Intangible Assets	2,220	3,409	1,189	53.6%
Investments and Other Assets	4,269	9,162	4,893	114.6%
Total Assets	53,117	59,013	5,896	11.1%
Liabilities				
Current Liabilities	11,546	12,383	837	7.2%
Notes and Accounts Payable-Trade	6,746	5,562	-1,184	-17.6%
Other	4,800	6,821	2,021	42.1%
Non-current Liabilities	6,220	9,875	3,655	58.8%
Total Liabilities	17,767	22,258	4,491	25.3%
Net Assets				
Shareholders' Equity	34,438	35,747	1,309	3.8%
Capital Stock	3,799	3,799	0	0.0%
Capital Surplus	5,023	5,023	0	0.0%
Retained Earnings	27,119	28,411	1,292	4.8%
Treasury Shares	-1,504	-1,486	18	-1.2%
Accumulated Other Comprehensive Income	909	1,004	95	10.5%
Total Net Assets	35,350	36,754	1,404	4.0%
Total Liabilities and Net Assets	53,117	59,013	5,896	11.1%

Acquisition of GABAPEN®
marketing authorization

Purchase of stock of Alvotech
Holdings

Bank loan to fund the Alvotech
HD investment

Summary of 1H FY9/19 Consolidated Statement of Cash Flows

(¥million)	FY9/18	FY9/19	YoY Change	
	1H	1H	Amount	Ratio
Cash Flows from Operating Activities	1,702	2,281	579	34.0%
(Major Breakdown)				
Profit Before Income Taxes	2,360	2,499	139	5.9%
Depreciation	961	930	-31	-3.2%
Amortization of Goodwill	138	139	1	0.7%
Decrease (Increase) in Notes and Accounts Receivable-Trade	601	1,207	606	100.8%
Decrease (Increase) in Inventories	-101	105	206	-204.0%
Increase (Decrease) in Notes and Accounts Payable-Trade	-450	-1,178	-728	161.8%
Income Taxes Paid	-911	-308	603	-66.2%
Cash Flows from Investing Activities	-233	-8,150	-7,917	3397.9%
(Major Breakdown)				
Purchase of Investment Securities	-	-5,548	-5,548	-
Purchase of Property, Plant and Equipment	-662	-783	-121	18.3%
Proceeds from Sales of Property, Plant and Equipment	1,272	1	-1,271	-99.9%
Purchase of Intangible Assets	-120	-1,499	-1,379	1149.2%
Cash Flows from Financing Activities	-1,322	6,068	7,390	-559.0%
(Major Breakdown)				
Proceeds from Long-term Loans Payable	-	7,000	7,000	-
Repayments of Long-term Loans Payable	-653	-210	443	-67.8%
Cash Dividends Paid	-374	-419	-45	12.0%
Repayments of Lease Obligations	-263	-302	-39	14.8%
Cash and Cash Equivalents at Beginning of Period	5,503	6,251	748	13.6%
Cash and Cash Equivalents at End of Period	5,624	6,435	811	14.4%
Free Cash Flows	1,469	-5,869	-7,338	-499.5%

Purchase of stock of
Alvotech Holdings

Acquisition of
GABAPEN® marketing
authorization

Bank loan to fund the
Alvotech HD investment

FY9/19 Consolidated Forecast

- Net sales: Forecast contributions from existing hormone drugs and new products but a 2.9% decrease in sales due to the transfer of sales rights of branded contrast media
- Operating profit: Expect higher R&D expenses but an increase in earnings resulting from a decline in the cost of sales and the efficient use of SG&A expenses

(¥million)	FY9/18	FY9/19 (Forecast)	YoY Change	
			Amount	Ratio
Net Sales	37,909	36,815	-1,094	-2.9%
Operating Profit	4,391	4,535	144	3.3%
Operating Margin	11.6%	12.3%	-	-
Ordinary Profit	4,472	4,506	34	0.8%
Ordinary Margin	11.8%	12.2%	-	-
Profit Attributable to Owners of Parent	3,372	3,396	24	0.7%
Profit Margin	8.9%	9.2%	-	-
Capital Expenditure	1,109	2,130	1,021	92.1%
Depreciation (Including Leased Equipment)	2,060	1,718	-342	-16.6%
R&D Expenses	1,760	2,439	679	38.6%
R&D Expenses Ratio	4.6%	6.6%	-	-

➤ **New Products/Drugs in the Pipeline**

New Products 2019

LEVONORGESTREL tablets 1.5mg 「F」

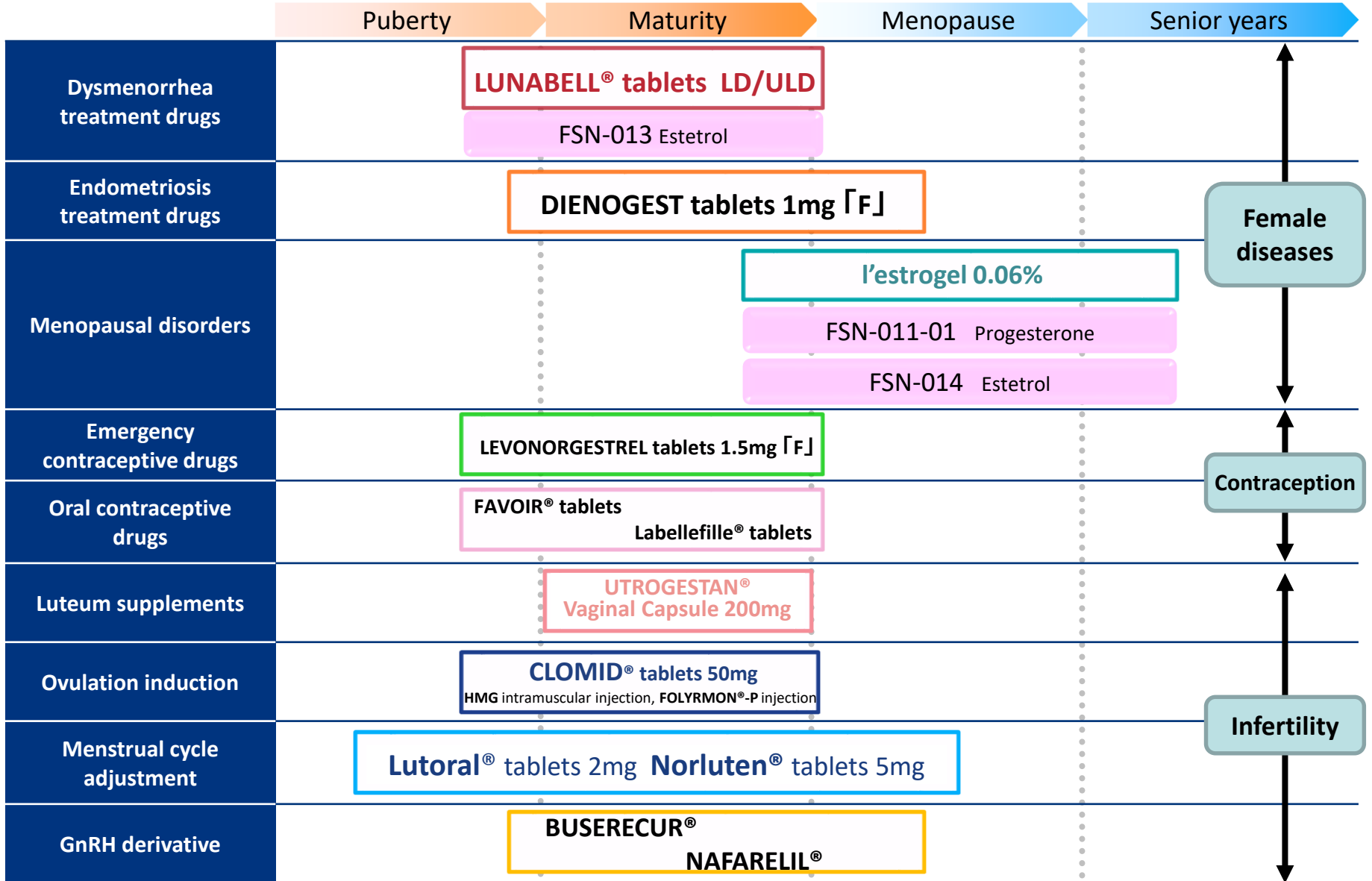
- ✓ Released on March 19, 2019
- ✓ Japan's first generic emergency contraceptive drug
 - **Reduces the cost of this drug for users**
- ✓ Used after unprotected intercourse to prevent an unwanted pregnancy
 - **A pregnancy prevention method with a lower physical impact**



GABAPEN® tablets 200mg, GABAPEN® tablets 300 mg, GABAPEN® tablets 400 mg, GABAPEN® syrup 5%

- ✓ In December 2018, an agreement was reached with Pfizer Japan Inc. for the transfer of the marketing authorization for this drug to Fuji Pharma
(Transfer of the manufacturing and sales authorization is expected to take place in 2019)
- ✓ Sales of this anti-epileptic drug started in Japan in September 2006
In July 2011, approval was received for the treatment of children above age three. A syrup version was introduced in Oct. 2011 for greater ease of administration to children and ease of controlling the dosage.
 - **This drug gives Fuji Pharma a base for the growth of activities in the field of rare diseases, primarily for children.**

Women's Healthcare Drug Portfolio Profile



➤ **Activities for the “FujiPharma 2030” Long-term Vision**

◆ Our Commitment

Vision

A specialty company that delivers new medical value by providing close support to each individual’s long life starting from the birth of life

- Towards 2030, when medical needs become diversified, we will pursue innovation and offer a wide range of solutions globally, primarily in the areas of Women’s Healthcare / Men’s Healthcare / Rare diseases.

Achievement goal

No. 1 in Japan / Asia in the area of Women’s Healthcare

- > As a specialty company, **we regard the area of Women’s Healthcare as one of our focuses**
- > **Full-scale entry into Asia** to create a foothold for global expansion
- > **Become No. 1** as Specialty

Branded drug sales ratio: 50%

- > **As a specialty company, increase the branded drug sales ratio to 50%**, including licensed products and biosimilars
- > Continuously focus on **generic drugs** also

Overseas sales ratio: 30%

- > **Increase the overseas sales ratio to 30%** as a result of global expansion
- > **Overseas expansion is critical** in the competitive environment of the domestic market

(1) Start selling Fuji Pharma brand drugs in Thailand

(1) Start selling Fuji Pharma brand drugs in Thailand - 1) Profile of OLIC

【Overseas base】 OLIC (Thailand) Limited

Established	1984 (Moved to current location in 1997)
Employees	771 (As of September 30, 2018)
Location	Ayutthaya, Thailand
Major shareholders	Fuji Pharma Co., Ltd.: 99.93%

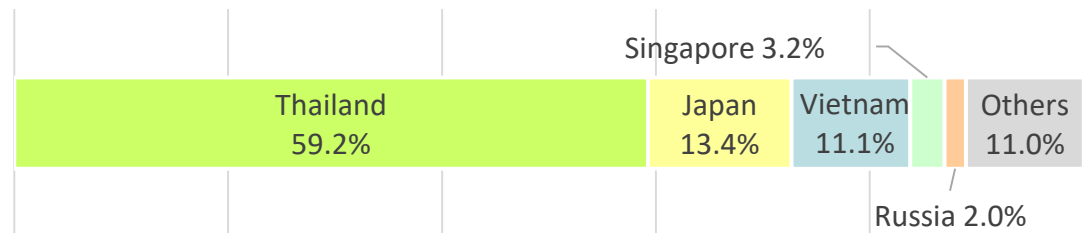


- The largest contract manufacturing company in Thailand
- Capable of supplying tablets, parenteral injections, liquid drugs, nasal spray drugs and many other types of drugs
- Supplies drugs to more than 35 companies, mainly large multinational corporations (primarily for use in SE Asia)
- Manufacturing capabilities that meet the strict production and quality oversight requirements and inspections of Thailand regulators, the Japanese Pharmaceuticals and Medical Devices Agency, the U.S. FDA and other regulatory authorities

“Using OLIC to supply Japanese-quality pharmaceuticals to emerging countries”



Destinations of OLIC Shipments in 2017



(1) Start selling Fuji Pharma brand drugs in Thailand - 2) Sales Activities

◆ Consistent production of generic drugs for Japan at OLIC

UTROGESTAN® (infertility/soft gel capsule, OYPALOMIN®, IOPAQUE® (contrast media/parenteral injections), etc.



◆ Using OLIC to supply Japanese-quality pharmaceuticals to SE Asian countries

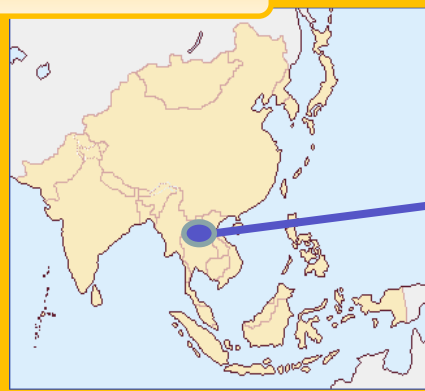
→ Started with sales of contrast media in Thailand; next step is pharmaceuticals for women

- Jun. 2018: Alliance with APO PLUS STATION(THAILAND)CO.,LTD. for sales activities in Thailand
- Oct. 2018: Established a sales business unit at OLIC
- Feb. 2019: Approval to manufacture IOPAQUE® contract media in Thailand
- Summer '19: Start sales of IOPAQUE® contract media in Thailand
- Later in '19: Approval to manufacture OYPALOMIN® contract media in Thailand and start of sales



Southeast Asia

- Increasing standard of living, population and female labor force participation
- Disease composition similar to that of industrialized countries
- High expectations for drugs made to Japanese quality standards



The Next Steps

Fuji Pharma will use OLIC for the production using Japanese quality standards of contract media and pharmaceuticals for women for sale in SE Asia



(2) Alliance with Alvogen Group

<Activities with the Alvogen Group>

1) Capital and business alliance with Alvotech hf

2) Capital and business alliance with Lotus Pharmaceutical

Profile of Alvotech Group

- Established in 2009
- Pharmaceutical group that develops, manufactures and sells generic, branded and biosimilar drugs globally
- Operates in 35 countries with a workforce of about 2,800
- Production and development bases in the U.S., Romania, South Korea and Taiwan

(2) Alliance with Alvogen Group - 1) Capital and Business Alliance with Alvotech hf

✓ November 2018

Partnership agreement with Alvotech hf including exclusive rights to commercialize in Japan biosimilars developed by Alvotech hf

✓ January 2019

US\$50 million equity investment in Alvotech Holdings, the parent company of Alvotech hf

- Purchased 281,400 shares (4.22% of all shares issued)
- One Fuji Pharma executive has become an Alvotech Holdings director

Profile of Alvotech hf

- Established in 2013
- Pharmaceutical manufacturer with R&D and production activities for biosimilars (antibody drugs)
- Based in Iceland, with drug development bases in Germany and Switzerland and a factory in Iceland
- Develops antibody drugs for cancer, eye diseases, autoimmune disorders and other diseases
- Key strength is integrated operations extending from active ingredients to finished products

【Commercialization scheme for Japan】



 **alvotech**

 **Fuji Pharma Co., Ltd.**

(2) Alliance with Alvogen Group - 1) Capital and Business Alliance with Alvotech hf

Alliance with an overseas company specializing in the development and manufacture of biosimilars



Aim to **make biosimilars a core business** in addition to women's healthcare and acute medical care

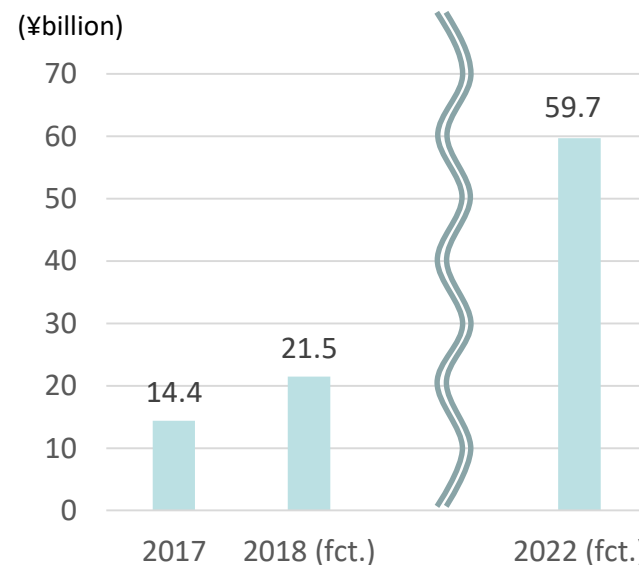
The use of biosimilars is increasing in Europe.

The biosimilar market in Japan is growing steadily. Sales totaled ¥14.4 billion in 2017 and are estimated to reach ¥21.5 billion in 2018.

Biopharmaceuticals are increasing consistently as a share of all drug sales. High drug prices is a major issue concerning healthcare expenditures.

Expect rapid growth in the use of biosimilars in Japan as one way to hold down the increase in healthcare expenditures.

[Biosimilar Sales in Japan]



Source: Fuji Pharma

(2) Alliance with Alvogen Group - 2) Capital and Business Alliance with Lotus

✓ April 2019

Mutual equity investments by Fuji Pharma and Lotus

- Fuji Pharma: Purchased 4,913,220 shares of Lotus stock (2.0% of all shares issued)
- Lotus: Purchased 1,219,300 shares of Fuji Pharma stock (3.91% of all shares issued)

Profile of Lotus

- Established in 1966
- Oversees Alvogen Group's operations in Asia; about 1,000 employees
- Based in Taiwan with development and manufacturing bases in Taiwan and South Korea
- 2018 sales of 6,429 million Taiwan dollars (about ¥23 billion at 1TWD=¥3.58)
- Avoiding generic market competition by concentrating on products that are difficult to develop and produce (molecularly targeted drugs, hormone drugs, etc.).

The Asian Operations of Lotus

Lotus Pharmaceutical Co.,Ltd. (Taiwan)

About 360 overseas salespeople

Subsidiaries: Alvogen Korea, Alvogen Taiwan, Alvogen India, etc.

Direct sales using local subsidiaries in Taiwan, South Korea, Thailand and Vietnam

Agent sales via local subsidiaries in Singapore, Malaysia, Myanmar, Philippines, Hong Kong and China

(2) Alliance with Alvogen Group - 2) Capital and Business Alliance with Lotus

Business alliance with an overseas company with Asia sales channels and specializing in developing generic anti-cancer drugs and other drugs



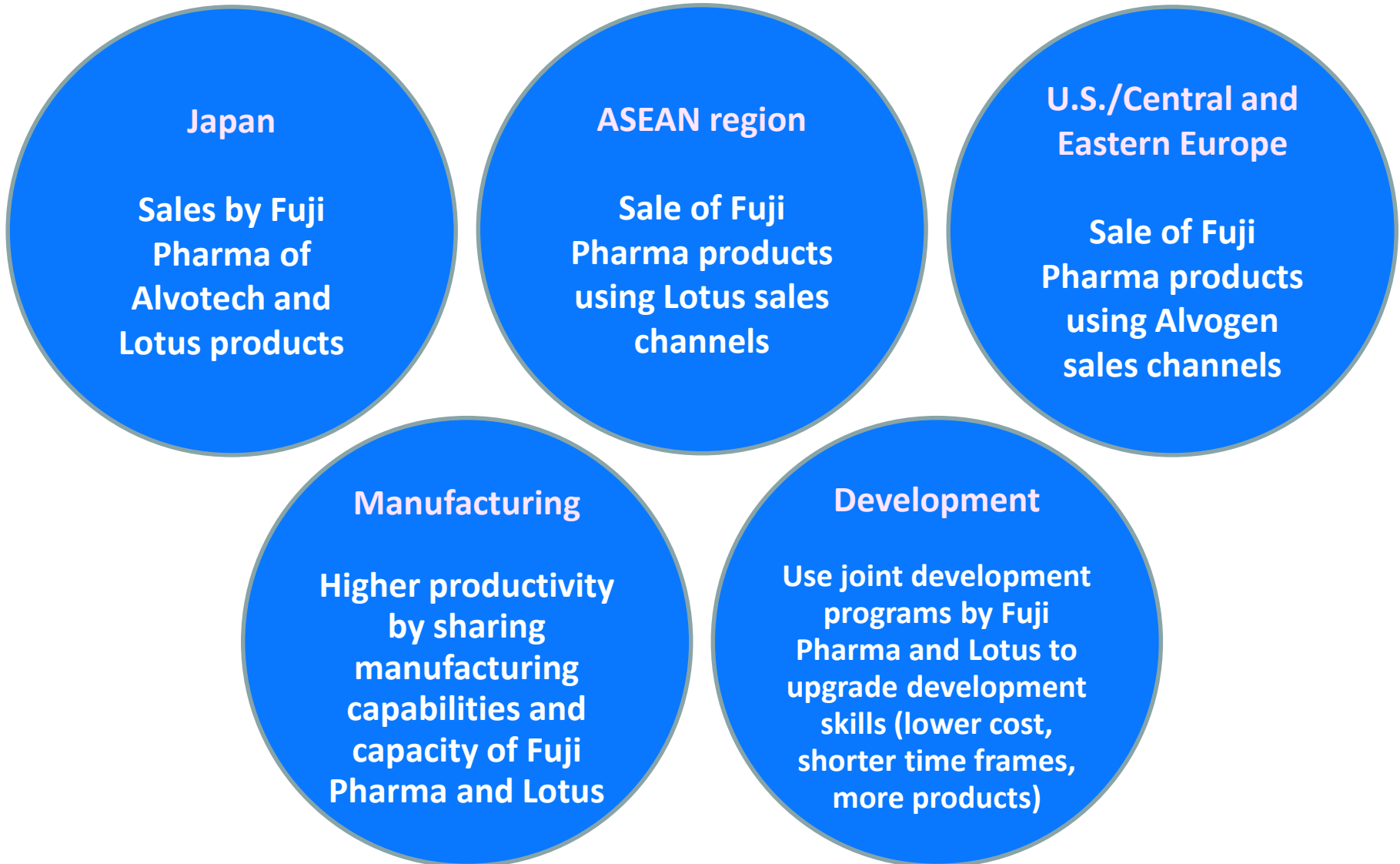
◆ Four components of the alliance

1. Use the Lotus pipeline for generic anti-cancer drugs and other drugs in Japan.
2. Use the ASEAN sales channels of Lotus to sell the women's healthcare drugs and other products of Fuji Pharma.
3. Improve productivity through the mutual use of the manufacturing capabilities of Fuji Pharma and Lotus.
4. Jointly develop value-added products that meet demands in each market in Japan and the ASEAN region.



[Faster growth on a global scale](#)

(2) Alliance with Alvogen Group - Overview of the Alvogen Group Business Alliance



Contact Information

The financial forecasts and other projections provided in this presentation are based on information available at the time of its compilation and it therefore contains an element of uncertainty and potential risks.

Actual results may differ significantly from these forecasts for a number of reasons.

It should also be noted that the views and/or facts presented here may be altered or deleted without prior notification.

Information in this presentation about pharmaceuticals (including items in the pipeline) is not provided for the purpose of marketing or advertising or of supplying medical advice.

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