# Business Results for the Fiscal Year Ended September 30, 2016

November 22, 2016

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President and Chief Executive Officer

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



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# Summary of FY9/16 Consolidated Financial Results

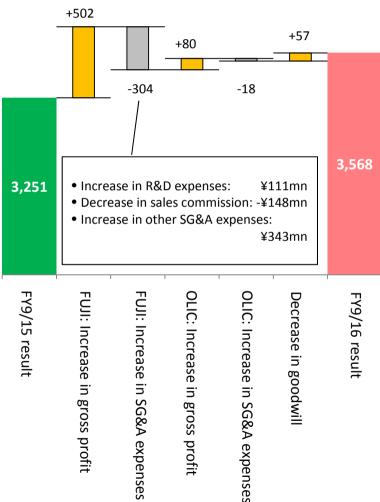
- Net sales increased by 8.0%, or ¥2,549 million YoY, due to the contribution from branded drugs
- The gross margin declined by 1.3 points mainly because of the change in product mix and a reduction in drug prices following the NHI drug price revision
- Operating income increased by 9.7%, or ¥317 million YoY, mainly due to higher earnings from subsidiaries

	FY9/15	FY9/16	YoY Ch	ange	FY9/16	vs Fcst
(¥million)	Full Year	Full Year	Amount	Ratio	Fcst	Change in Amount
Net Sales	31,680	34,229	2,549	8.0%	34,470	-241
Gross Profit	12,970	13,537	567	4.4%	-	-
Gross Margin	40.9%	39.6%			_	-
SG&A Expenses	9,718	9,969	251	2.6%	-	-
SG&A Margin	30.7%	29.1%			_	-
Operating Income	3,251	3,568	317	9.7%	3,480	88
Operating Income Margin	10.3%	10.4%			10.1%	
Ordinary Income	3,099	3,251	152	4.9%	3,430	-179
Ordinary Income Margin	9.8%	9.5%			10.0%	
Profit Attributable to Owners of Parent	2,092	2,118	26	1.2%	2,230	-112
Profit Margin	6.6%	6.2%			6.5%	
Return on Equity	7.3%	7.3%				
Net Income per Share (Yen)	137.55	141.64	4.09	3.0%		
Capital Expenditure	1,694	2,427	733	43.3%		
Depreciation	1,768	1,667	-101	-5.7%		
Leased Equipment	297	274	-23	-7.7%		
R&D Expenses	1,729	1,840	111	6.4%		
R&D Expenses Ratio	5.5%	5.4%				

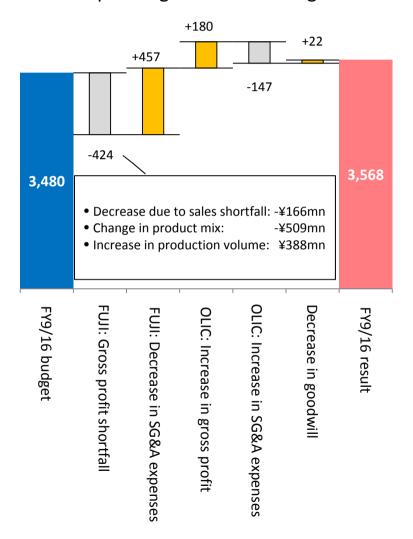


# Summary of FY9/16 Consolidated Financial Results

## YoY Changes in Operating Income



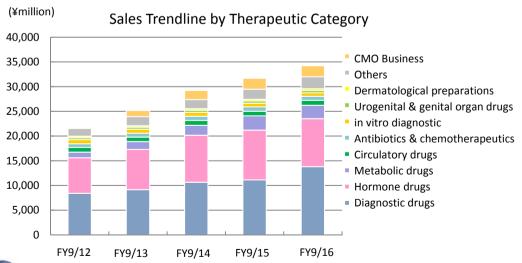
## Operating Income Vs. Budget

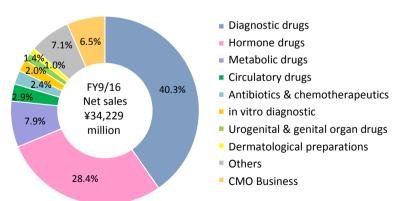




## Sales by Therapeutic Category

(¥million)	FY9/12	FY9/13	FY9/14	FY9/15	FY9/16	YoY Ch	ange
(+111111011)	113/12	113/13	113/14	113/13	115/10	Amount	Ratio
Diagnostic Drugs	8,419	9,158	10,656	11,123	13,808	2,685	24.1%
Hormone Drugs	7,189	8,134	9,511	10,071	9,709	-362	-3.6%
Metabolic Drugs	1,129	1,584	2,003	2,893	2,706	-187	-6.5%
Circulatory Drugs	962	920	985	937	1,008	71	7.6%
Antibiotics & Chemotherapeutics	726	793	845	874	812	-62	-7.1%
in vitro Diagnostics	856	802	799	742	695	-47	-6.3%
Urogenital & Genital Organ Drugs	396	406	437	464	486	22	4.7%
Dermatological Preparations	285	289	301	327	352	25	7.6%
Others	1,554	1,856	1,857	2,055	2,414	359	17.5%
CMO Business		1,226	1,818	2,190	2,236	46	2.1%
Total	21,520	25,174	29,215	31,680	34,229	2,549	8.0%





Sales Breakdown by Therapeutic Category



# **Sales of Major Products**

Product Name	Therapeutic	EVO/12	FV0/12	FV0/14	FV0 /1 F	FV0/16	YoY Ch	ange
(¥million)	Category	FY9/12	FY9/13	FY9/14	FY9/15	FY9/16	Amount	Ratio
OYPALOMIN® injection	Diagnostic drugs	6,233	6,727	6,465	6,500	7,029	529	8.1%
LUNABELL® tablets (LD/ULD)	Hormone drugs	<u>2,511</u>	<u>2,967</u>	<u>3,491</u>	<u>3,756</u>	<u>3,017</u>	<u>-739</u>	<u>-19.7%</u>
IOPAQUE® injection	Diagnostic drugs	1,648	1,876	1,754	1,968	2,133	165	8.4%
OPTIRAY® injection	Diagnostic drugs			<u>1,861</u>	<u>1,972</u>	<u>1,927</u>	<u>-45</u>	<u>-2.3%</u>
Filgrastim BS injection Syringe	Metabolic drugs		<u>243</u>	<u>539</u>	<u>1,344</u>	<u>1,481</u>	<u>137</u>	10.2%
MAGNESCOPE® intravenous injection	Diagnostic drugs				<u>57</u>	<u>1,310</u>	<u>1,253</u>	
HMG intramuscular injection	Hormone drugs	921	854	901	939	917	-22	-2.3%
DEXART® injection	Hormone drugs	641	682	680	724	813	89	12.3%
LIPIODOL® injection	Diagnostic drugs				<u>24</u>	<u>722</u>	<u>698</u>	
SOL-MELCORT for injection	Hormone drugs	633	649	607	627	598	-29	-4.6%
ALYPROST® injection	Circulatory drugs	634	586	609	550	593	43	7.8%
LIMAPROST ALFADEX tablets	Metabolic drugs	370	474	587	600	588	-12	-2.0%
FAVOIR® tablets	Hormone drugs	149	301	394	456	537	81	17.8%
FOLYRMON®-P injection	Hormone drugs	490	491	528	507	512	5	1.0%
BUSERECUR®	Hormone drugs	337	389	423	450	473	23	5.1%
Total Top 15 Sa	les	14,903	16,567	19,538	20,481	22,658	2,177	10.6%
Pct. of Total Sa	les	69.3%	65.8%	66.9%	64.6%	66.2%		
New Products				436	1,109	1,742	633	57.1%
Other Products		6,617	7,381	7,423	7,900	7,593	-307	-3.9%
CMO Business (OLIC)			1,226	1,818	2,190	2,236	46	2.1%
Total		21,520	25,174	29,215	31,680	34,229	2,549	8.0%

Acute Medical Care Medical Care for Women

<sup>\*</sup> Underlined products are the Fuji Pharma branded drugs, branded generic drugs (with receipt of marketing approval) and biosimilars.

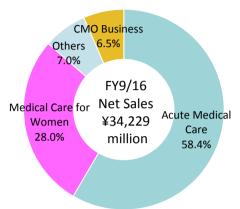


<sup>\*</sup> New Products: products launched in FY9/14 or afterward (excluding the top 15)

# Sales by Medical Field and Drug Form Category

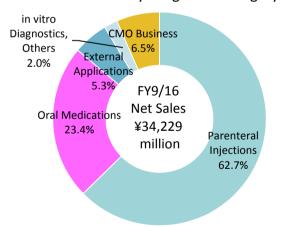
Breakdown by Medical Field (¥million)	FY9/12	Y9/13	FY9/14	FY9/15	FY9/16	YoY Ch	nange Ratio
Acute Medical Care	12,796	14,059	15,663	17,082	19,997	2,915	17.1%
Medical Care for Women	6,776	7,969	9,400	9,943	9,582	-361	-3.6%
Others	1,948	1,919	2,333	2,463	2,413	-50	-2.0%
CMO Business (OLIC)		1,226	1,818	2,190	2,236	46	2.1%
Total	21,520	25,174	29,215	31,680	34,229	2,549	8.0%

#### Sales Breakdown by Medical Field



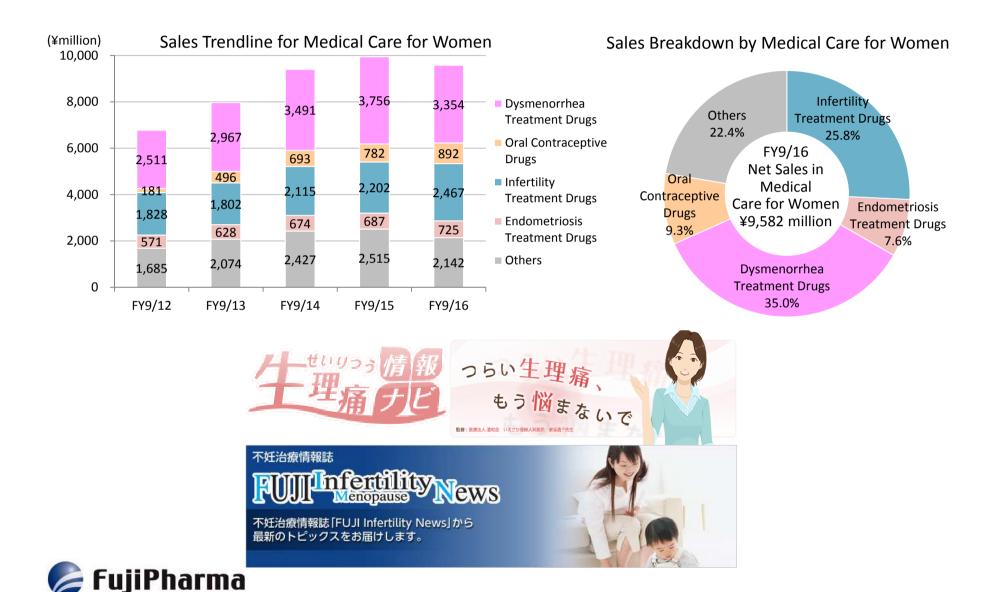
Breakdown by Drug Category (¥million)	FY9/12	FY9/13	FY9/14	FY9/15	FY9/16	YoY Ch	nange Ratio
Parenteral Injections	14,442	15,463	17,212	18,596	21,452	2,856	15.4%
Oral Medications	5,053	6,416	7,974	8,663	8,020	-643	-7.4%
<b>External Applications</b>	1,123	1,243	1,399	1,477	1,818	341	23.1%
in vitro Diagnostics, Others	902	825	811	752	701	-51	-6.8%
CMO Business (OLIC)		1,226	1,818	2,190	2,236	46	2.1%
Total	21,520	25,174	29,215	31,680	34,229	2,549	8.0%

#### Sales Breakdown by Drug Form Category

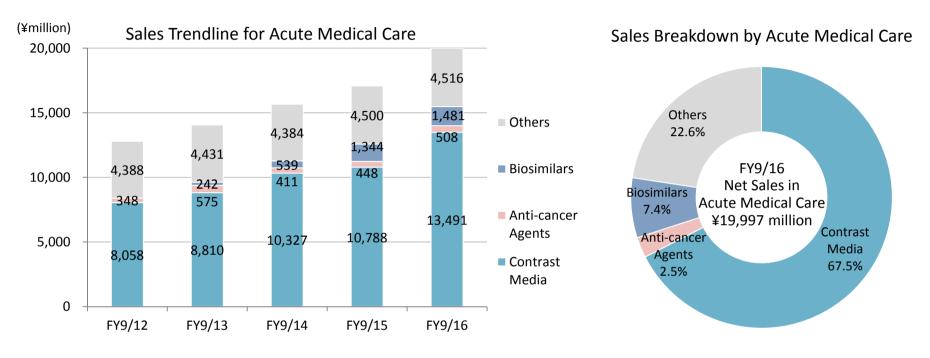




## Medical Care for Women: Sales Trendline



## Acute Medical Care: Sales Trendline

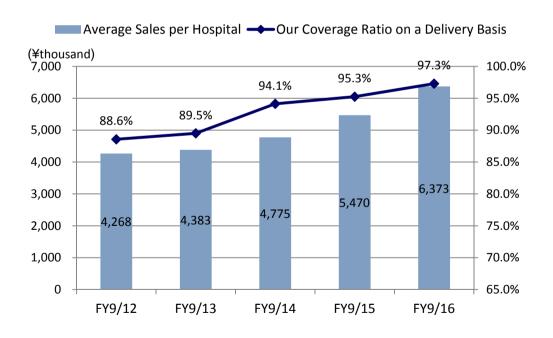






# Acute Medical Care: Sales Trendline for DPC-based Hospitals

	FY9/12	FY9/13	FY9/14	FY9/15	FY9/16	YoY Ch	ange
	F19/12	F19/13	F19/14	F19/13	F13/10	Amount	Ratio
No. of Hospitals Adopting DPC System	1,505	1,496	1,585	1,580	1,667	87	5.5%
No. of DPC Hospitals with Our Coverage	1,333	1,339	1,492	1,505	1,622	117	7.8%
Coverage Ratio	88.6%	89.5%	94.1%	95.3%	97.3%		
Average Sales per Hospital (¥thousand)	4,268	4,383	4,775	5,470	6,373	903	16.5%





# Summary of FY9/16 Consolidated Balance Sheet

(¥million)	FY9/15	FY9/16	YoY Cha	inge
(#IIIIIIOII)			Amount	Ratio
Assets				
Current Assets	30,714	32,309	1,595	5.2%
Cash and Deposits	5,158	6,815	1,657	32.1%
Notes and Accounts Receivable-Trade	12,337	13,072	735	6.0%
Inventories	11,396	11,569	173	1.5%
Other	1,822	852	-970	-53.2%
Non-current Assets	15,059	15,838	779	5.2%
Property, Plant and Equipment	10,618	11,016	398	3.7%
Intangible Assets	3,876	3,060	-816	-21.1%
Investments and Other Assets	564	1,762	1,198	212.4%
Total Assets	45,773	48,147	2,374	5.2%
Liabilities				
Current Liabilities	10,989	12,739	1,750	15.9%
Notes and Accounts Payable-Trade	6,102	6,291	189	3.1%
Other	4,886	6,448	1,562	32.0%
Non-current Liabilities	6,190	6,181	-9	-0.1%
Total Liabilities	17,180	18,921	1,741	10.1%
Net Assets				
Shareholders' Equity	27,988	29,278	1,290	4.6%
Capital Stock	3,799	3,799	0	0.0%
Capital Surplus	5,023	5,023	0	0.0%
Retained Earnings	20,669	21,944	1,275	6.2%
Treasury Shares	-1,504	-1,488	16	
Accumulated Other Comprehensive Income	604	-53	-657	-108.8%
Total Net Assets	28,593	29,226	633	2.2%
Total Liabilities and Net Assets	45,773	48,147	2,374	5.2%



# Summary of FY9/16 Consolidated Statement of Cash Flows

(Vacillian)	FY9/15	FY9/16	YoY Cha	inge
(¥million)			Amount	Ratio
Cash Flows from Operating Activities	589	4,509	3,920	665.5%
(Major Breakdown)				
Profit Before Income Taxes	3,105	3,148	43	1.4%
Depreciation	1,768	1,667	-101	-5.7%
Amortization of Goodwill	311	254	-57	-18.3%
Decrease (Increase) in Notes and Accounts Receivable-Trade	-722	-796	-74	10.2%
Decrease (Increase) in Inventories	-2,250	-240	2,010	-89.3%
Increase (Decrease) in Notes and Accounts Payable-Trade	-537	240	777	-144.7%
Income Taxes Paid	-1,010	-874	136	-13.5%
Cash Flows from Investing Activities	999	-3,319	-4,318	-432.2%
(Major Breakdown)				
Purchase of Property, Plant and Equipment	-1,512	-2,308	-796	52.6%
Proceeds from Sales of Property, Plant and Equipment	2,508	453	-2,055	-81.9%
Purchase of Intangible Assets	-31	-346	-315	1016.1%
Cash Flows from Financing Activities	-4,635	78	4,713	-101.7%
(Major Breakdown)				
Purchase of Treasury Shares	-1,504	-0		
Net Increase (Decrease) in Short-term Loans Payable	-1,189	-		
Proceeds from Long-term Loans Payable	-	2,000	2,000	
Repayments of Long-term Loans Payable	-921	-921	0	0.0%
Cash Dividends Paid	-675	-674	1	-0.1%
Cash and Cash Equivalents at Beginning of Period	8,680	5,664	-3,016	-34.7%
Cash and Cash Equivalents at End of Period	5,664	6,815	1,150	20.3%
Free Cash Flows	1,588	1,190		



# FY9/17 Consolidated Forecast

- Sales forecast to increase by ¥2,071 million (+6.0%), mainly due to the start of sales of VESANOID® capsule
  with marketing approval and higher sales of branded drugs
- Forecast 2.0 point improvements in the gross margin due to the contribution from cost reductions resulting from the lower drug ingredient prices and production increase of contrast agents
- Profit increase and operating income to increase with the ratio of 20.5%, by holding down other SG&A expenses while forecasting R&D expenses to increase by ¥590 million

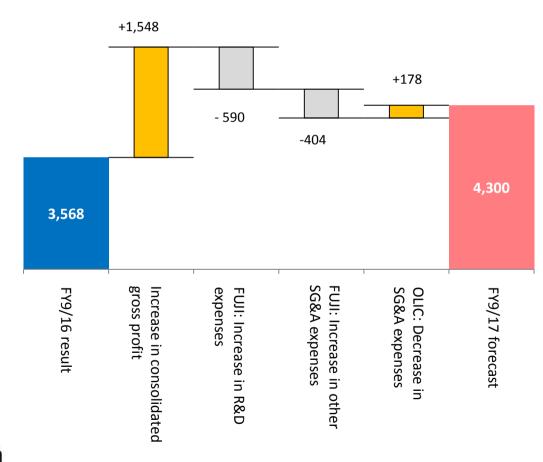
(Ymillian)	FY9/16	FY9/17	YoY Cha	ange
(¥million)	F19/10	(Forecast)	Amount	Ratio
Net Sales	34,229	36,300	2,071	6.0%
Operating Income	3,568	4,300	732	20.5%
Operating Income Margin	10.4%	11.8%	-	-
Ordinary Income	3,251	4,180	929	28.5%
Ordinary Income Margin	9.5%	11.5%	-	-
Profit Attributable to Owners of Parent	2,118	2,800	682	32.2%
Profit Margin	6.2%	7.7%	-	
Capital Expenditure	2,427	1,550	-877	-36.1%
Depreciation	1,667	1,850	183	11.0%
Leased Equipment	274	100	-174	-63.5%
R&D Expenses	1,840	2,430	590	32.1%
R&D Expenses Ratio	5.4%	6.7%	-	-



# FY9/17 Consolidated Forecast

YoY Changes in FY9/17 Operating Income Forecast

- Increase in gross profit due to expansion of acute medical care
- Increase in R&D expenses due to start of clinical trials
- Small increase in personnel costs and promotion expenses





# Sales Forecast by Therapeutic Category and Medical Field

(M. 1111 - )	E)/0/46	FY9/17	YoY Cl	nange
(¥million)	FY9/16	(Forecast)	Amount	Ratio
Diagnostic Drugs	13,808	14,430	622	4.5%
Hormone Drugs	9,709	10,350	641	6.6%
Metabolic Drugs	2,706	3,010	304	11.2%
Circulatory Drugs	1,008	1,030	22	2.2%
Antibiotics & Chemotherapeutics	812	820	8	1.0%
in vitro Diagnostics	695	740	45	6.5%
Urogenital & Genital Organ Drugs	486	460	-26	-5.3%
<b>Detmetological Preparations</b>	352	400	48	13.6%
Others	2,414	2,790	376	15.6%
CMO Business (OLIC)	2,236	2,270	34	1.5%
Total	34,229	36,300	2,071	6.0%

(Vas:II; a.r.)	FV0/46	FY9/17	YoY Change	
(¥million)	FY9/16	(Forecast)	Amount	Ratio
Acute Medical Care	19,997	21,500	1,503	7.5%
Medical Care for Women	9,582	10,160	578	6.0%
Others	2,413	2,370	-43	-1.8%
CMO Business (OLIC)	2,236	2,270	34	1.5%
Total	34,229	36,300	2,071	6.0%



# Sales Forecast for Major Products

Product Name		FY9/16	FY9/17	YoY Change	
(¥million)	Therapeutic Category		Forecast	Amount	Ratio
OYPALOMIN® injection	Diagnostic drugs	7,029	7,050	21	0.3%
LUNABELL® tablets (LD/ULD)	Hormone drugs	<u>3,017</u>	<u>2,850</u>	<u>-167</u>	<u>-5.5%</u>
IOPAQUE® injection	Diagnostic drugs	2,133	2,220	87	4.1%
OPTIRAY® injection	<u>Diagnostic drugs</u>	<u>1,927</u>	<u>2,130</u>	<u>203</u>	<u>10.5%</u>
Filgrastim BS injection	<u>Others</u>	<u>1,481</u>	<u>1,730</u>	<u>249</u>	<u>16.8%</u>
MAGNESCOPE® intravenous injection	Diagnostic drugs	<u>1,310</u>	<u>1,520</u>	<u>210</u>	<u>16.0%</u>
HMG intramuscular injection	Hormone drugs	917	930	13	1.4%
UTROGESTAN® Vaginal Capsules	Hormone drugs	<u>254</u>	<u>930</u>	<u>676</u>	266.1%
LIPIODOL® injection	<u>Diagnostic drugs</u>	<u>722</u>	<u>890</u>	<u>168</u>	23.3%
DEXART® injection	Hormone drugs	813	820	7	0.9%
ALYPROST® injection	Circulatory drugs	593	620	27	4.6%
LIMAPROST ALFADEX tablets	Others	588	610	22	3.7%
FAVOIR® tablets	Hormone drugs	537	600	63	11.7%
SOL-MELCORT for injection	Hormone drugs	598	580	-18	-3.0%
FOLYRMON®-P injection	Hormone drugs	512	520	8	1.6%
Total Top 15 Sales		22,440	24,000	1,560	7.0%
Pct. of Total Sales		65.6%	66.1%		
New Products*		1,487	2,150	663	44.6%
Other Products		8,065	7,880	-185	-2.3%
CMO Business (OLIC)		2,236	2,270	34	1.5%
Total		34,229	36,300	2,071	6.0%
Acute Medical Care	Medical Care for Women				

<sup>\*</sup>New products are products launched in FY9/14 or afterward (excluding the top 15)

<sup>\*</sup>Underlined products are the Fuji Pharma branded drugs, branded generic drugs (with receipt of marketing approval) and biosimilars.



## Medium-term Growth Strategy

#### ■ Medium to Long-term Growth Strategy that Supports our Medium-term Business Plan

Build a unique business model that produces synergies in strategic fields by combining brands, generic drugs and contract manufacturing

Fuji Pharma brands are branded drugs, branded generic drugs (with receipt of marketing approval) and biosimilars

#### ■ Goals of the Medium-term Business Plan



# Vigorously implement the brand strategy for the people, companies and products of the Fuji Pharma Group

Use the corporate culture of a strong affection for people and a leadership development plan, increase productivity and the return on capital, maximize customer value in targeted business domains.



#### Build a new stage and framework centered on branded drugs

Establish a business plan and strategy centered on branded drugs, upgrade and renew all corporate capabilities, rebuild the framework for business operations.



#### Grow on a global scale

Use OLIC to sell major products outside Japan, establish a strategy for alliances with overseas companies, aim to become the leading CMO in the Asia-Pacific region.



## Progress Report on Medium-term Business Plan (1)

Vigorously implement the brand strategy for the people, companies and products of the Fuji Pharma Group

Achieve a Transformation from a Generic to a Specialty Pharmaceutical Company

#### **Medical Care for Women**

Become Japan's leading company in this field with emphasis on hormone drugs

- Launch the first generic versions of drugs in large volumes
- Expand field of application involving new drugs that have been launched
- Activities for creating new drugs

#### **Acute Medical Care**

Contrast agents: Use generic/branded drug synergies to increase market share

Expand field of application involving new drugs that have been launched

Anti-cancer drugs: Establish a presence in the market in targeted cancer domains (blood and mammary gland)

• Consider starting the sale of DDS agents

#### **CMO**

Production of value-added pharmaceuticals at the No. 5 Pharmaceutical Plant of the Toyama plant

• Contract manufacturing of anti-cancer injection agents

OLIC: Conduct contract manufacturing at the current pharmaceutical plant and the new parenteral injection plant

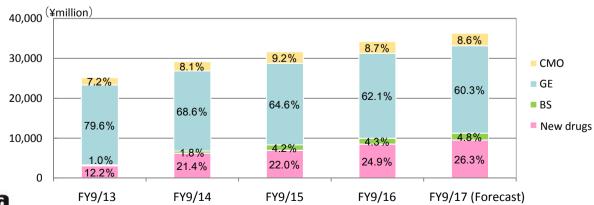


# Progress Report on Medium-term Business Plan (2)

## ♦ Build a new stage and framework centered on branded drugs

## **Shift to Branded Drugs**

June 2012:	l'estrogel 0.06%	Medical Care for Women	New drugs
May 2013:	Filgrastim BS injection Syringe [F]	Hematology	Biosimilars
May 2013:	LUNABELL® tablets ULD	Medical Care for Women	New drugs
December 2013:	OPTIRAY® injection	Contrast agents	New drugs
	CLOMID® tablets 50mg, Lutoral® tablets Norluten® tablets 5mg, Flagyl® vaginal tablets 250mg	Medical Care for Women	New drugs
October 2015:	MAGNESCOPE® intravenous injection, LIPIODOL® injection HEXABRIX® injection	Contrast agents	New drugs
February 2016:	Utrogestan Vaginal Capsules 200mg	Medical Care for Women	New drugs
November 2016:	VESANOID® capsule 10mg	Hematology	New drugs

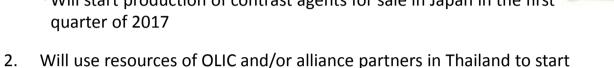




## Progress Report on Medium-term Business Plan (3)

### Grow on a global scale

- 1. Construction of a new parenteral injection plant and warehouse at subsidiary OLIC (Thailand)
  - · To be completed in January 2017
  - · Will start production of contrast agents for sale in Japan in the first quarter of 2017



- building an infrastructure for selling OLIC's own products in Thailand
  - · Drugs for external use: Regulatory approval for three drugs has been received; negotiations with a sales agent are under way
  - · Contrast agents: Plan to receive regulatory approval for two contrast agents in 2017
  - · Hormone drugs: Currently performing a market survey

#### New pharmaceutical plant

- Production plant: >3,700m
- Start of operations: First guarter of 2017
- Products: Liquid terminal sterilization (5mL 200mL vials)
- Complies with PIC/S GMP, PMDA, U.S. FDA, EMEA
- All processes use equipment with the latest technologies
- Automated and visual inspections
- Produces high-quality injectable agents
- 3,900m<sup>2</sup> warehouse (with temperature-controlled section)





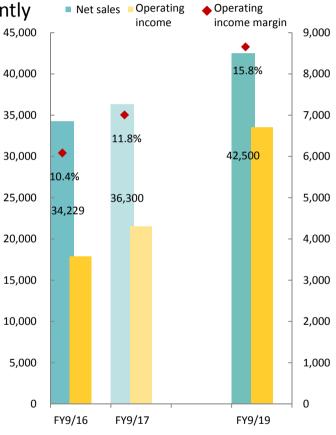




# Medium-term Numerical Targets

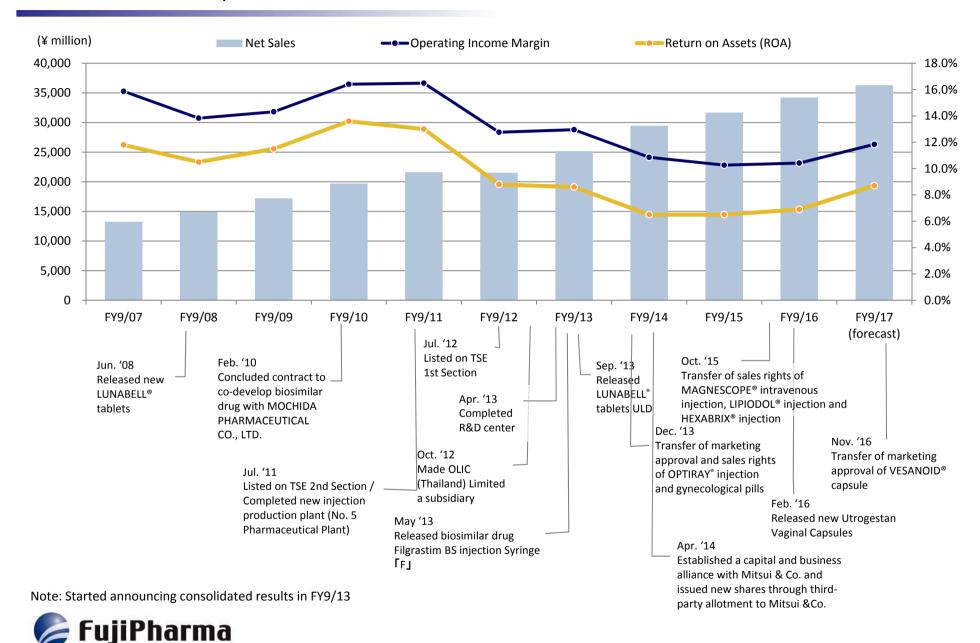
- Sustainable growth in sales, and recovery in profit margins
- Aggressive R&D investments to support long-term growth
- Constantly take actions aimed at using expenses more efficiently

(¥million)	FY9/16	FY9/17	FY9/19
Net Sales	34,229	36,300	42,500
Operating Income	3,568	4,300	6,700
Operating Income Margin	10.4%	11.8%	15.8%
Ordinary Income	3,251	4,180	6,650
Ordinary Income Margin	9.5%	11.5%	15.6%
Profit	2,118	2,800	4,350
Profit Margin	6.2%	7.7%	10.2%
R&D Expenses	1,840	2,430	2,800





## Business Outline / Business Performance Trendlines



#### **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.

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