

January 31, 2005

Fujisawa Announces Financial Results for the First Nine Months of FY 03/2005

Japan, January 31, 2005 – Fujisawa Pharmaceutical Co., Ltd. today announced its financial results for the first nine months of the fiscal year ending March 2005 (FY 03/2005).

Consolidated net sales for the period increased by 2.5 % to **323,059 million yen (US \$ 3,106 million)** over the year earlier. Operating income of **77,708 million yen (US \$ 747 million)**, recurring income of **79,146 million yen (US \$761 million)** and net income of **48,629 million yen (US \$468 million)** are more than annual forecast of the Company announced on November 4, 2004, respectively. The Company announced the revision of its annual forecast today separately. Comparison to previous period is not available for incomes as this is the first announcement of the income on a first nine months basis.

**Financial Highlights**

	First Nine Months				Full Year	
	FY03/2004 results(a)	FY03/2005 results(b)		Change (b/a)	FY03/2004 results	FY03/2005 forecast**
	Million Yen	Million Yen	Million US\$*	(%)	Million Yen	Million Yen
Sales	315,203	323,059	3,106	+2.5	395,401	409,000
Cost of sales	-	106,864	1,028	-	140,916	n/a
SG&A expenses	-	89,686	862	-	124,139	n/a
R&D expenses	-	48,800	469	-	73,642	72,000
Operating income	-	77,708	747	-	56,702	78,000
Recurring income	-	79,146	761	-	59,475	77,000
Net income	-	48,629	468	-	41,468	32,000
Earnings per share (yen)	-	146.19	1.41	-	125.63	n/a
Shareholders' equity	-	430,135	4,136	-	375,944	n/a
Total assets	-	550,055	5,289	-	499,693	n/a

\* : The U.S. dollar amounts in this announcement represent, for convenience only, translations of the financial results in Japanese yen at the rate of 104 yen per U.S. dollar.

\*\* : Revised.

This press release contains forward-looking statements about the future performance of Fujisawa. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. Consequently, undue reliance should not be placed on these statements. Fujisawa cautions the reader that a number of important factors could cause actual results to differ materially from those discussed in the forward-looking statements.

**[Summary of the First Nine Months of FY 03/2005]****Net Sales**

- Sales in Japan decreased by 3.8% to **170,540 million yen (US\$ 1,640 million)**. Domestic ethical pharmaceuticals stayed at almost the same level to the same period of the previous year, in spite of the overall 4.2% price cut on the National Health Insurance Drug Price, implemented in April 2004. Although the candidin antifungal agent “*Funguard Injection*”, antipsychotic agent “*Seroquel*”, the hypnotic “*Myslee*”, the vaccines, the immunosuppressant “*Prograf*” and antidepressant “*Luvox*” showed robust sales growth, the sales decrease of the oral cephalosporin antibiotic “*Cefzon*” and the antihypertensive “*Nivadil*” due to the competitive market environment in addition to the termination of “*Rescula Eye Drops*”, an anti-glaucoma and anti-ocular hypertension agent business resulted in the level-offs of the sales. The overall sales in Japan decreased due to withdrawal from chemicals business and the OTC business transferred to Zepharma Inc., a joint venture company between Yamanouchi Pharmaceutical Co., Ltd. and the Company, which started operation on October 1, 2004.
- North America recorded 9.5% increase with **96,811 million yen (US \$ 931 million)** despite appreciated yen against dollar and withdrawal from the chemicals business. Sales of Fujisawa Healthcare, Inc. increased by 17.3% on a local currency basis thanks to strong sales of “*Prograf*”, pharmacologic stress imaging agent “*Adenoscan*” and “*Protopic*” for the treatment of atopic dermatitis.
- Sales in Europe increased by 12.7% to **49,359 million yen (US \$ 475 million)** mainly because of the growth of both “*Prograf*” and “*Protopic*” at Fujisawa GmbH.
- Overseas sales during the period was **165,302 million yen (US\$ 1,589 million)**, which occupies 51.2% of net sales.

**Income****Operating income**

- Operating income was **77,708 million yen (US \$ 747 million)**.
- The ratio of cost of sales to total sales was 33.1 %.
- Operating income exceeded the annual forecast of 67 billion yen announced in November 2004 since sales in the third quarter tend to be inflated due to advanced shipment according to year-end holiday season. Slow progress of expenses during the third quarter also pushed up the operating income for the period.

**Recurring income**

- Recurring income was **79,146 million yen (US \$ 761 million)**.

**Net income**

- Net income was **48,629 million yen (US \$ 468 million)**.
- Extraordinary loss in relation to upcoming merger with Yamanouchi for the period was **2,751 million yen (US \$ 26 million)**.
- Income taxes were **27,755 million yen (US \$ 267 million)**.

**Sales of Top 15 Ethical Pharmaceutical Products**

(Unit: Billion Yen)

Product Name	Generic Name	First Nine Months		Full Year	Remarks
		FY03/2004	FY03/2005	Forecasts FY03/2005	
<b>1. Prograf</b>	tacrolimus	<b>83.8</b>	<b>96.1</b>	<b>117.8</b>	Immunosuppressant
<b>2. Adenoscan</b>	adenosine	<b>21.7</b>	<b>25.7</b>	<b>32.7</b>	Pharmacologic stress imaging agent
<b>3. Cefzon</b>	cefdinir	<b>22.4</b>	<b>18.3</b>	<b>25.1</b>	Oral cephalosporin
<b>4. Protopic</b>	tacrolimus	<b>13.1</b>	<b>16.4</b>	<b>21.1</b>	For atopic dermatitis
<b>5. Myslee</b>	zolpidem	<b>9.5</b>	<b>11.1</b>	<b>14.5</b>	Hypnotic
<b>6. Funguard</b>	micafungin	<b>8.7</b>	<b>10.6</b>	<b>13.1</b>	Candin antifungal agent
<b>7. Seroquel</b>	quetiapine	<b>8.2</b>	<b>10.1</b>	<b>12.8</b>	Antipsychotic
<b>8. Vaccines</b>		<b>7.5</b>	<b>9.0</b>	<b>8.1</b>	
<b>9. AmBisome</b>	liposomal amphotericin B	<b>7.4</b>	<b>7.1</b>	<b>7.7</b>	Antifungal
<b>10. Intal</b>	sodium cromoglycate	<b>6.6</b>	<b>6.9</b>	<b>9.9</b>	Anti-asthmatic and anti-allergic
<b>11. Luvox</b>	fluvoxamine maleate	<b>6.2</b>	<b>6.9</b>	<b>8.6</b>	Antidepressant
<b>12. Nivadil</b>	nilvadipine	<b>7.7</b>	<b>6.0</b>	<b>7.8</b>	Antihypertensive
<b>13. Cefamezin</b>	cefazolin	<b>6.5</b>	<b>5.8</b>	<b>7.1</b>	Injectable cephalosporin
<b>14. Dogmatyl</b>	sulpiride	<b>6.1</b>	<b>5.8</b>	<b>7.1</b>	Anti-ulcer and neuroleptic
<b>15. Targocid</b>	teicoplanin	<b>4.4</b>	<b>4.9</b>	<b>5.9</b>	Glycopeptide antibiotic
Average Yen / US \$		114.62	108.38	110	
Average Yen / Euro		132.69	135.07	130	

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## Products Under Clinical Development

### [Japan] NDA filed

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
tacrolimus	FK506	rheumatoid arthritis	immunosuppressant	capsule	New indication
tacrolimus	FK506	ulcerative colitis	immunosuppressant	capsule	New indication
miconazole	FK463	deep-seated fungal infection (for pediatric)	antifungal	intravenous	New indication

### [Japan] Phase 3

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
tacrolimus	FK506	lupus nephritis	immunosuppressant	capsule	New indication

### [Japan] Phase 2

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
	FK614	non-insulin dependent diabetes mellitus (NIDDM)	insulin sensitizer	tablet	
	FK352B	dialysis-related hypotension	adenosine A1 antagonist	intravenous	
quetiapine fumarate	FK949	behavior psychological symptoms of dementia	antipsychotic	tablet	Licensed from AstraZeneca New indication
strontium ranelate	FK481	osteoporosis	bone formation stimulating and antiresorptive agent	powder	Licensed from Servier
tacrolimus	FK506	suppression of organ rejection in organ transplant (new oral formulation)	immunosuppressant	capsule	New formulation

### [USA] NDA Filed

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
miconazole	FK463	deep-seated fungal infection	antifungal	intravenous	NDS Filed in Canada (02/6)
dapsone	(Aczone™)	acne	antibiotic and antiphlogistic agent	gel	Licensed from Atrix

**[USA] Phase 3**

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
tacrolimus	FK506	rheumatoid arthritis	immunosuppressant	capsule	New indication
tacrolimus	FK506	atopic dermatitis	immunosuppressant	cream	New indication & formulation
	RSD1235	atrial fibrillation and atrial flutter	antiarrhythmic agent	intravenous	Licensed from Cardiome
regadenoson	CVT-3146	pharmacologic stress agent in cardiac perfusion imaging studies	adenosine A <sub>2a</sub> agonist	intravenous	Licensed from CV Therapeutics
tacrolimus	FK506	psoriasis	immunosuppressant	gel/cream	New indication & formulation
tacrolimus	FK506	suppression of organ rejection in organ transplant (new oral formulation)	immunosuppressant	capsule	New formulation

**[USA] Phase 2**

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
	FK614	non-insulin dependent diabetes mellitus (NIDDM)	insulin sensitizer	tablet	
tacrolimus	FK506	dry eye	immunosuppressant	eye drops	Licensed to Sucampo New indication & formulation
	FK778	suppression of organ rejection in liver and kidney transplants	immunosuppressant	tablet	Licensed from Aventis
carperitide	(hANP)	acute heart failure	Alfa-human atrial natriuretic peptide	intravenous	Licensed from Daiichi Suntory Pharma
	FK962	Alzheimer's disease	antidementia	tablet	

**[Europe] In Preparation for MAA Filing**

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
micafungin	FK463	deep-seated fungal infection	antifungal	intravenous	

**[Europe] Phase 3**

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
tacrolimus	FK506	suppression of organ rejection in organ transplant (new oral formulation)	immunosuppressant	capsule	New formulation

**[Europe] Phase 2**

Generic Name	Code	Target Indication	Product Category	Formulation	Remarks
tacrolimus	FK506	rheumatoid arthritis	immunosuppressant	capsule	New indication
	FK778	suppression of organ rejection in liver and kidney transplants	immunosuppressant	tablet	Licensed from Aventis
tacrolimus	FK506	asthma	immunosuppressant	inhalation	New indication & formulation

**[Japan] In-licensed product with no clinical development by Fujisawa**

Generic Name	Target Indication	Stage	Remarks
fluvoxamine maleate	social anxiety disorder	filed	Licensed from Solvay Seiyaku K.K. New indication
telithromycin	skin and soft tissue infections & uterine infection	filed	Licensed from Aventis Pharma New indication
telithromycin	pediatric use	Phase 3	Licensed from Aventis Pharma New indication

Changes from the previous announcement (November 4, 2004)

- Fujisawa Pharmaceutical Co., Ltd. have reached an agreement with Senju Pharmaceutical Co., Ltd. in January 2005, whereby Senju and Fujisawa co-develop an eye drop formulation of tacrolimus in Japan and Fujisawa grants the exclusive manufacturing and marketing rights of the compound in Japan to Senju.
- Fujisawa plans SPC harmonization of Prograf across the European Union. All indications currently approved in the European Union, including the primary heart claim along with the available clinical data relating to this indication, will be reviewed by EMEA/CHMP.