

November 4, 2004

Fujisawa Announces Interim Financial Results for FY 03/2005 and Revises its Full Year Forecasts

Japan, November 4, 2004 - Fujisawa Pharmaceutical Co., Ltd. today announced its interim (April 1, 2004 to September 30, 2004) financial results and the revision of its full year forecasts for the fiscal year ending March 2005 (FY 03/2005).

In the interim financial results, consolidated net sales increased by 4.1 % to **204,500 million yen (US \$ 1,842 million)** over the year earlier period. Operating income of **43,206 million yen (US \$ 389 million)** and recurring income of **44,222 million yen (US \$ 398 million)** showed 46.6 % and 44.5 % growth over the year earlier period, respectively. Net income rose 55.8 % to **27,324 million yen (US \$ 246 million)**. Average currency exchange rates for the period were 110.30 yen for U.S. dollar and 133.62 yen for euro, which were 117.71 yen for U.S. dollar and 133.96 yen for euro for previous interim period, respectively.

Fujisawa also revised its full year forecasts for FY 03/2005. Net sales are forecasted to be **409,000 million yen (US \$ 3,685 million)**, up by 3,000 million yen from the previous forecasts. Operating income and recurring income also rose to **67,000 million yen (US \$ 604 million)** and **68,000 million yen (US \$ 613 million)**, respectively, while net income is forecasted to be **32,000 million yen (US \$ 288 million)**, down by 6,000 million yen from the previous forecasts. The increase in net sales is due to brisk sales in North America and other areas outside Japan. Cost-to-sales ratio, as well as selling, general and administrative expenses is expected to be lower than original forecasts while R&D expenses remain unchanged. The improved gross margin and lower expenses make operating income enlarge by 6,000 million yen than the previous forecasts. Recurring income is also become larger than the previous forecasts, thanks to the increase in operating income. Net income, however, is expected to be lower by 6,000 million yen than the previous forecasts because Extraordinary loss of 15,000 million yen is expected to incur in relation to the upcoming merger with Yamanouchi Pharmaceutical Co., Ltd. Additional appropriation could be carried out for this merger related expenses further from now on. In the revised forecast, Net sales, Operating income and recurring income are expected to renew the historical highs while net income is lower than the previous year.

Note:

The U.S. dollar amounts in this announcement represent, for convenience only, translations of Japanese yen at the rate of 111 yen per U.S. dollar.

Financial Highlights of the Interim Period

	FY03/2004	FY 03/2005		% (*1)
	Million Yen	Million Yen	Million US\$	
Net sales	196,472	204,500	1,842	+4.1
Operating income	29,480	43,206	389	+46.6
Recurring income	30,599	44,222	398	+44.5
Net income	17,536	27,324	246	+55.8
Shareholders equity	353,342	413,089	3,722	+16.9
Per share profit (yen)	53.19	82.54	\$0.74	+55.2
Total assets	508,354	525,853	4,737	+3.4
R&D expenses	33,676	32,766	295	-2.7

*1: Changes from previous year in %.

Revision of the Full Year Forecasts

	Revised Forecasts for FY03/2005 (October22)		Previous Forecasts (Apr.27)	Changes	Previous year results FY03/2004
	Million Yen	Million US \$	Million Yen	%	Million Yen
Net sales	4,090	3,685	4,060	+0.7	3,954
Operating income	670	604	610	+9.8	567
Recurring income	680	613	630	+7.9	594
Net income	320	288	380	-15.8	414

[Summary of the Interim Period for FY 03/2005]

Sales

- Sales in Japan decreased by 1.4 % with **106,263 million yen (US \$ 957 million)**. Although domestic ethical pharmaceuticals recorded sales growth absorbing the effect of price-cut on the drug price list of the National Health Insurance, the decrease because of the withdrawal from Chemicals business during previous period affected the sales. The increases in sales of ethical pharmaceuticals come from the candid antifungal agent “*Funguard Injection*”, the antipsychotic agent “*Seroquel*”, the hypnotic “*Myslee*”. Antidepressant “*Luvox*” and immunosuppressant “*Prograf*” also experienced favorable sales while the sales of such products as the cephalosporin antibiotic “*Cefzon*” and the antihypertensive “*Nivadil*” declined. Home care business and medical supplies and systems increased the sales but OTC drugs business decreased the sales due to harsh market environment in Japan.

- North America recorded 10.5 % growth with **62,318 million yen (US \$ 561 million)**. Sales of Fujisawa Healthcare, Inc. increased due to robust sales of “Prograf” and the pharmacologic stress imaging agent “Adenoscan”. “Protopic” for the treatment of atopic dermatitis also showed increases in sales over the year earlier period.
- Sales in Europe increased by 10.0 % to **31,657 million yen (US \$ 285 million)** over the year earlier period. Fujisawa GmbH increased its sales because of the growth of “Prograf”. The “Protopic” also contributed to the sales increase.
- In other regions, the sales increased by 20.9 % to **4,261 million yen (US \$ 38 million)**.

Income

Operating income

- Increased sales and improved gross margin due to favorable changes in product mix in the sales made the gross profit become larger by 12 billion yen compare to the year earlier period.
- Expenses, the sum of R&D expenses and selling, general and administrative expenses decreased by 1.7 billion yen than the year earlier period.
- Operating income increased by 46.6% to **43,206 million yen (US \$ 389 million)** thanks to the larger gross profit and lower expenses.
- All geographic segments, Japan, North America, Europe and Others enjoyed the growth in operating income .

Recurring income

Recurring income increased by 44.5 % to **44,222 million yen (US \$ 398 million)** thanks to the increase in operating income.

Net income

- Extraordinary loss, of about 1.7 billion yen incurred in relation to the upcoming merger with Yamanouchi Pharmaceutical Co., Ltd., in this interim period.
- Income taxes increased by 5.3 billion yen.
- As a result of the above, net income increased by 55.8 % to **27,324 million yen (US \$ 246 million)** from the previous interim period.

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.

Statement of Income

	Interim Period			Full Year Period	
	FY03/2004 (a)	FY03/2005 (b)		Changes (b-a)	FY03/2004
	Million Yen	Million Yen	Million US\$	Million Yen	Million Yen
Net sales	196,472	204,500	1,842	8,028	395,401
Cost of sales	71,369	67,325	607	-4,044	140,917
Gross profit	125,102	137,176	1,236	12,074	254,484
Selling, general and administrative expenses	61,945	61,204	551	-741	124,139
R&D expenses	33,676	32,766	295	-910	73,642
Operating income	29,480	43,206	389	13,726	56,702
Non-operating income	3,156	4,130	37	974	6,634
1. Interest income	(483)	(428)	4	(-55)	(923)
2. Dividend	(232)	(247)	2	(15)	(398)
3. Others	(2,440)	(3,454)	31	(1,014)	(5,313)
Non-operating expenses	2,037	3,114	28	1,077	3,862
1. Interest expense	(230)	(73)	1	(-157)	(403)
2. Others	(1,807)	(3,040)	27	(1,233)	(3,459)
Recurring income	30,599	44,222	398	13,623	59,475
Extraordinary gain	268	-	-	-268	16,008
Extraordinary loss	3,405	1,713	15	-1,692	6,344
1. Expenses related to the merger	-	(1,713)	(15)	(1,713)	-
2. Others	(3,405)	-	-	(-3,405)	(6,344)
Income before income taxes	27,462	42,508	383	15,046	69,138
Income taxes	9,898	15,168	137	5,270	27,796
Minority interest in consolidated subsidiaries	27	15	0	-12	-126
Net income	17,536	27,324	246	9,788	41,468

Sales of Top 15 Ethical Pharmaceutical Products

(unit: yen in billion)

Product Name	Generic Name	FY03/2004		FY03/2005		
		Interim	Full Year	Interim	Full Year	
		Actual	Actual	Actual	Forecast	
1. Prograf	tacrolimus	53.8	104.4	61.0	117.8	Immunosuppressant
2. Adenoscan	adenosine	13.8	28.3	17.3	32.7	Pharmacologic stress imaging agent
3. Cefzon	cefдинир	14.0	27.8	10.6	25.1	Oral cephalosporin
4. Protopic	tacrolimus	8.2	17.3	10.1	21.1	For atopic dermatitis
5. Myslee	zolpidem tartrate	5.8	12.2	7.1	14.5	Hypnotic
6. Funguard	micafungin	5.2	11.1	6.4	13.1	Antifungal
7. Seroquel	quetiapine fumarate	5.1	10.4	6.4	12.8	Atypical antipsychotic
8. AmBisome	liposomal amphotericin B	4.7	8.9	4.6	7.7	Antifungal
9. Luvox	fluvoxamine maleate	3.9	7.8	4.3	8.6	Antidepressant
10. Intal	sodium cromoglicate	3.9	9.2	4.2	9.9	Anti-asthmatic and anti-allergic
11. Nivadil	nilvadipine	5.0	9.6	4.1	7.8	Antihypertensive
12. Dogmatyl	sulpiride	3.8	7.4	3.8	7.1	Anti-ulcer and neuroleptic
13. Cefamezin	cefazolin	4.1	8.0	3.7	7.1	Injectable cephalosporin
14. Targocid	Teicoplanin	2.8	5.6	3.1	5.9	Glycopeptide antibiotic
15. Vaccines		2.2	7.5	3.0	8.1	
Average Yen / US \$		117.71	112.73	110.30	110.00	
Average Yen / euro		133.96	132.57	133.62	130.00	

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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
tacrolimus	FK506	vernal conjunctivitis	immunosuppressant	eye drops	New indication & formulation

[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 ₂ a 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	
tacrolimus	FK506	suppression of organ rejection in heart transplant	immunosuppressant	capsule	New indication

[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 (July 30, 2004)

- A sNDA of micafungin for pediatric use was filed in Japan in July 2004.
- In the USA, a NDA of Aczone™ (dapson topical gel) for the treatment of acne was submitted to the FDA in August 2004.
- Status of tacrolimus cream for psoriasis progressed to Phase 3 in the USA in September 2004.
- TRK-820 was deleted from the pipeline because the collaboration with Toray Industries, Inc. (originator) on this compound in Europe was terminated in October 2004.
- The European development status of micafungin was changed to “to be filed” because Fujisawa decided to submit additional data for approval in September 2004.
- Status of tacrolimus capsule for suppression of organ rejection in heart transplant progressed to preparation for MAA filing in Europe in July 2004.
- The European development of tacrolimus gel and cream for psoriasis was discontinued in September 2004 as a result of re-allotment of development resources in European operations.