



Financial Highlights

Years ended March 31, 2001 and 2000

	Millions of yen		Thousands of U.S. dollars*	
	2001	2000	2001	Change (%)
Net sales	¥297,517	¥289,142	\$ 2,399,330	102.9
Income before income taxes	36,190	36,554	291,855	99.0
Net income	20,529	22,907	165,556	89.6
Shareholders' equity	278,581	249,106	2,246,620	111.8
Amounts per share (in yen and dollars):				
Net income				
Basic	¥ 63.62	¥ 71.09	\$ 0.51	89.5
Diluted	61.76	68.85	0.50	89.7
Cash dividends	12.00	12.00	0.10	100.0
Total assets	¥462,325	¥421,689	\$3,728,427	109.6
Research and development expenses ...	52,016	45,565	419,484	114.2

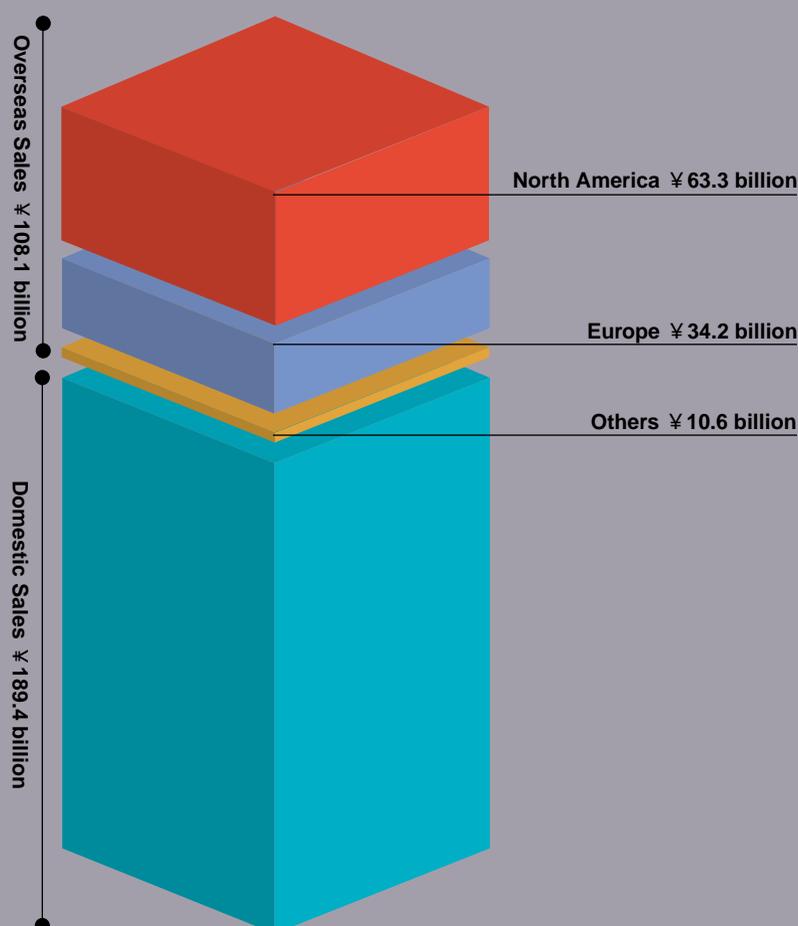
* The U.S. dollar amounts in this report represent, for convenience only, translations of Japanese yen at the rate of ¥124=US\$1.

Note:

For accounting changes and reclassifications, see Notes 1-(2), 1-(3), 1-(5), 1-(10), and 1-(12) of Notes to Consolidated Financial Statements.

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Statements made in this annual report with respect to Fujisawa's current plans, estimates, strategies and beliefs and other statements that are not historical facts are 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. Such factors include, but are not limited to: (i) changes in general economic conditions in, and the Pharmaceutical Affairs Law and other laws and regulations relating to, Fujisawa's markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Fujisawa to market existing and new products effectively, (v) Fujisawa's ability to continue to research and develop products accepted by customers in highly competitive markets and (vi) infringements of Fujisawa's intellectual property rights.

Corporate Mission

Fujisawa is a research-driven pharmaceutical company active in the world's major markets—Japan, North America, Europe and Asia—with sales outside Japan accounting for over one-third of net sales. True to its corporate mission “Fujisawa contributes to healthier, more prosperous lives around the world by exploring the frontiers of human health and disease,” Fujisawa is firmly committed to innovative research to satisfy unmet medical needs and contribute to the progress of medical care.

VISION 2005

Fujisawa operates its business under the VISION 2005 long-term management policy, which ensures its growth as a truly global enterprise toward the year 2005 and beyond. Sales of ¥400 billion, split evenly between Japan and overseas, net income of ¥40 billion and R.O.E. of 10% are set out as financial targets for 2005. In order to be a winner in the competitive world pharmaceutical market, the Company has set out four basic strategies.



Message from the President

Revolutionary progress in biomedical science, in particular genomics, in addition to rapid advances in information technology over the last few years, have been changing the paradigms of both R&D and business in the pharmaceutical industry. These changes present us with great challenges but also tremendous opportunities. There is no single prescription for success. Fujisawa has set out a growth strategy for becoming a global player under its VISION 2005 long-term management policy, and is steadily evolving in that direction.

On behalf of Fujisawa's 8,300 employees, it gives me great pleasure to report to you our annual accounts for the year ended March 31, 2001. The term under review was the second year of the VISION 2005 long-term management policy and also for me as President and Chief Executive Officer. The term was highlighted by a series of new product launches in Japan and global business expansion led by the immunosuppressant *Prograf*. Hereunder, I discuss our strategy and recent achievements.

Business Performance

Net sales of ¥297,517 million (US\$2,399 million) for the term under review set a new historical high for the second consecutive year with 2.9% growth over the previous term, mainly thanks to robust overseas operations. On the other hand, a high level of investment in research and development activities reduced operating income by 3.6% to ¥33,606 million (US\$271 million). Net income also decreased to ¥20,529 million (US\$166 million), down 10.4% year-on-year. The yen's appreciation on the foreign exchange market, in particular against the euro, negatively affected our performance. If we had translated the results of overseas operations at the previous term's rates, operating income would have stayed virtually flat.

Tacrolimus Business Development

Tacrolimus-related products, currently *Prograf* and *Protopic* for the treatment of atopic dermatitis, are a growth driver for Fujisawa and play a vital role in achieving the goals set out in the VISION 2005. *Prograf* is now commercially available in 47 countries, having been launched in nine more countries during the term under review. Consolidated sales of *Prograf* in the term rose to ¥50.6 billion (US\$408 million). Its market share in the major transplant markets—North America and Europe—has risen continuously with the inflow of various new data that clearly show the clinical advantages of *Prograf*-based immunosuppressive therapy. We believe *Prograf* is now being recognized as a global standard immunosuppressant, and we envisage consolidated sales of *Prograf* reaching ¥63.3 billion (US\$510 million).

Protopic, tacrolimus ointment for the treatment of atopic dermatitis, has almost completed clinical development and has moved to the stage of commercialization or New Drug Application (NDA) filing. Following its launch in Japan in November 1999, *Protopic* was approved in the USA in December 2000 and has been commercially available since early 2001. Though the US sales of *Protopic* are not included in the results for the term to March 2001, as the financial year of our US subsidiary ends in December, we expect a good contribution by *Protopic* to both revenue and profits in the term ending March 2002. Further, we received approval of

Protopic in Canada in June 2001. In Europe, we submitted to the European Medicines Evaluation Agency an application for marketing authorization of *Protopic* under the centralized procedure. We anticipate regulatory approval of *Protopic* in Europe in early 2002. NDAs for *Protopic* were also filed with the regulatory agencies of Switzerland and South Korea during the term under review and in Taiwan in June 2001. In fiscal 2001, *Protopic* sales were recorded only in Japan, at ¥1.3 billion (US\$10 million). Sales were rather slow to take off in Japan, but I anticipate that sales will climb as physicians, mainly dermatologists and pediatricians, become accustomed to the use of this product. Combined sales of *Prograf* and *Protopic* were ¥51.9 billion (US\$419 million) in fiscal 2001. The figure should surpass ¥70 billion in fiscal 2002.

Research and Development

Innovative research into unmet medical needs is the source of Fujisawa's competitive advantage. We invest heavily in research and development, which is always at the top of our priority list. Research and development expenses for fiscal 2001 increased by 14.2% to ¥52,016 million (US\$419 million) over fiscal 2000. The ratio to net sales reached 17.5%, the highest in Fujisawa's history. When we drew up the VISION 2005 in April 1999, we envisaged accumulated investment in research and development amounting to ¥350 billion (US\$2,823 million) for the seven years from fiscal 2000 to fiscal 2006. However, we have revised these figures to ¥400 billion (US\$3,226 million) taking into account the increase in global clinical development expenses of compounds in our pipeline.

In line with our motto—"Best in the class, first in the class"—Fujisawa currently focuses its research efforts on four therapeutic areas, immunology/inflammation, cerebral diseases, metabolic diseases and infectious diseases. It is my firm belief that creativity and networking are the keys to success in the area of pharmaceutical R&D. Therefore, Fujisawa is very keen on expanding its research network with outside institutions or emerging research ventures that possess novel technologies or ideas for drug discovery. Two recent joint efforts are expected to enhance Fujisawa's research activities. In June 2001, Fujisawa, with other Japanese companies, set up the Reverse Proteomics Research Institute to study co-action between proteins expressed from full-length cDNA clones and low molecule compounds. The Company is also a founding member of the Protein Structure Analysis Consortium, which was established by 22 Japanese pharmaceutical companies in June 2001. Further, Fujisawa Investments for Entrepreneurship L.P.—a fund for equity investments in start-up pharmaceutical research ventures with innovative research ideas or technologies—has made six investments since its inception of September 1999. Based on the satisfactory performance of this fund, we established Fujisawa Investments for Entrepreneurship II, L.P. with Orix Capital Corporation in April 2001 which Nissho Iwai Corporation also joined in May 2001.



As for compounds at clinical development stage (phase II and after), since our annual report 2000 was issued, there have been some changes in our pipeline due to the progress of clinical development, product launch and discontinuation. Among the compounds changed, the progress of micafungin, an injectable antifungal agent, is particularly notable. Micafungin shows excellent activity against both candida and aspergillus, major fungi involved in deep-seated fungal infections. An NDA for micafungin for the treatment of deep-seated fungal infections was filed with the Japanese authorities at the end of June 2001. Phase III by Fujisawa Healthcare, Inc. has almost been completed and the NDA is scheduled to be filed in 2002. An application for marketing authorization for micafungin in Europe is also scheduled to be filed in 2002.

Development of Japanese Ethical Pharmaceuticals Business

The ethical pharmaceuticals business on the Japanese market now accounts for about 48% of net sales, and thus the growth of this business is crucial in achieving the goals set out in the VISION 2005 in parallel with our global operations. Currently we hold a share of about 2.6% in the Japanese ethical pharmaceuticals market and our target is 3.0% in fiscal 2003.

Although the Japanese ethical drug market recorded growth of about 2.5% in fiscal 2001 with no price cuts implemented in April 2001 according to the press, we see only modest or flat growth over the next few years because of healthcare cost containment measures that are still mainly targeting drug expenses.

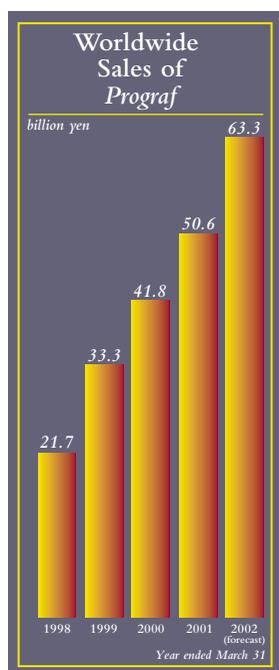
Amid the current environment, we are taking measures to secure growth through new product launchings and extensive marketing activities. We launched two new pharmaceuticals in fiscal 2000—*Protopic* and the antidepressant *Luvox*—and four in fiscal 2001—*Dovonex* for the treatment of psoriasis, *Colonel* for irritable bowel syndrome, the hypnotic *Myslee* and the antipsychotic *Seroquel*. These new products are expected to make a significant contribution to sales expansion in fiscal 2002.

Among several measures taken to strengthen our marketing activities during the term under review, we increased the number of medical representatives to about 1,100 from the previous level of about 1,000. We plan to further increase the number, with a target of 1,150 to 1,200 in fiscal 2003.

Global Business Development

While Fujisawa covers a wide range of therapeutic areas in Japan, the Company is promoting a niche strategy in its global business taking into account our product portfolio and management resources. “Global Niche Player” is the buzzword for the Company under the VISION 2005, and we have been successful in implementing this strategy. The ratio of overseas sales to net sales is targeted at 50% in fiscal 2006. The ratio was 36.3% in fiscal 2001, but we expect it to rise to 40% in fiscal 2002.

Fujisawa Healthcare, Inc., the biggest operations of Fujisawa outside Japan, is now on the way to becoming a US\$1 billion company. *Prograf* is the main contributor, but not the only one. Other products such as the pharmacologic stress agent *Adenoscan* and the antifungal



agent *AmBisome* have also boosted the sales of Fujisawa Healthcare. With these products and the launch of *Protopic*, the expansion of Fujisawa Healthcare is now accelerating.

In Europe, we are implementing a two-step business reorganization plan, which was announced in January 2001. Fujisawa GmbH is now the European headquarters, having such functions as legal affairs, R&D, central marketing, business development. Fujisawa Deutschland GmbH will be formed by the merger of the German operations of Fujisawa GmbH into Klinge Pharma GmbH at the beginning of 2002. Fujisawa Deutschland GmbH will have a sales force covering both hospitals and general practitioners. Our next target is business expansion in countries other than Germany where we have only *Prograf* operations, albeit efficient and profitable ones.

Development of Businesses other than Ethical Pharmaceuticals

In addition to the ethical pharmaceuticals business carried out both in Japan and overseas, we have several healthcare related businesses, i.e. OTC drugs, medical supplies and systems, chemicals, and the home care business. These businesses will be encouraged to grow in an interdisciplinary manner and contribute to the consolidated business performance.

Among these, the home care business, where home oxygen therapy (HOT) is the main service, is expected to expand in line with the general growth of medical care at home in the current Japanese healthcare scene. On the other hand, the chemicals business included some fragmented businesses. Considering the future prospects of the respective businesses, we have transferred the animal health business and decided to transfer the industrial cleansing and hygiene business, to an outside party, respectively. Further, we have formed a joint venture company in the concrete admixture business where we hold a minority interest.

While we are navigating a sea of uncertainty, I believe we are moving in the right direction toward the goal set in the VISION 2005, which has been set up to maximize the corporate value of Fujisawa. I would like to express my sincere appreciation for the generous and continued support for our business activities shown by all our shareholders.

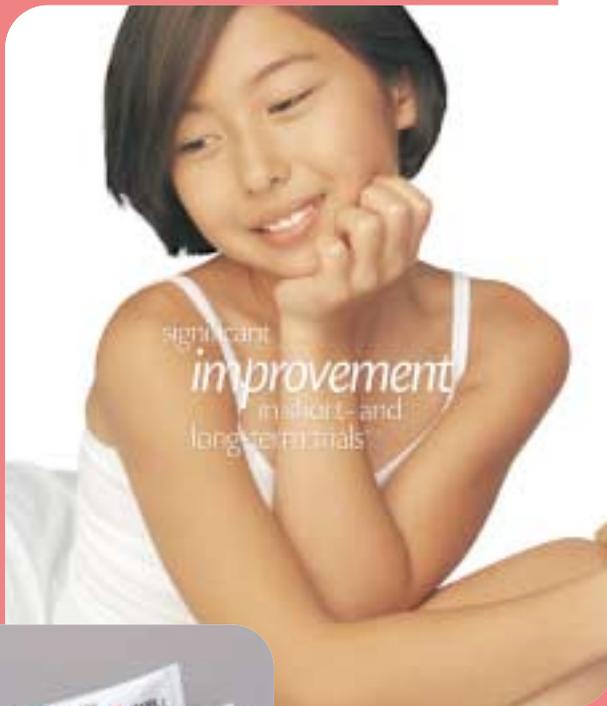


Hatsuo Aoki, Ph. D.

President and Chief Executive Officer



The immunosuppressant *Prograf* is leading Fujisawa's global business development. *Protopic*, for the treatment of atopic dermatitis, is the next global product for the Company following *Prograf*. *Protopic*, already launched in Japan and the US, is now on the way to making its debut in the world's major markets.



Worldwide Operations

Fujisawa's business is composed of pharmaceuticals and other healthcare-related businesses. Pharmaceuticals are further divided into ethical pharmaceuticals and OTC drugs. The ethical pharmaceuticals business is the core of Fujisawa's operations and is growing both through its own bases in Japan, North America, Europe and Asia and also in collaboration with partners. The OTC drug business, meanwhile, is carried out in Japan.

Healthcare-related businesses include medical supplies and systems, the home care business, and chemicals. While the former two solely target the Japanese market, the Company is active in the chemicals business in the world market, having its own base in the United States.

Sales by Business Segment

Pharmaceuticals

Total sales of pharmaceuticals in fiscal 2001 recorded 3.0% growth over fiscal 2000, at ¥263,020 million (US\$2,121 million). The ratio of net sales was flat at 88.4% compared with 88.3% the previous year.

■ Ethical Pharmaceuticals

Sales of ethical pharmaceuticals increased by 3.5% year-on-year to ¥248,325 million (US\$2,003 million). A breakdown of sales by therapeutic category is given on page 9.

■ OTC Drugs

Sales came to ¥14,695 million (US\$119 million), down 4.7% from the previous year due to stagnant OTC drug consumption in Japan and stiff competition. Increased sales of the athlete's foot treatment *Pyroace* were more than counteracted by a decrease in sales of *Eurax* brand dermatological drugs and others.

Other Businesses

■ Medical Supplies and Systems

While there were some ups and downs in sales of individual products, total sales came to ¥2,984 million (US\$24 million), almost the same level as in fiscal 2000.

■ Chemicals

Sales declined 1.7% to ¥22,084 million (US\$178 million). While sales of the food additive *Helshas* increased, those of major products such as the food acidulant *Fujiglucon*, the food antioxidant *Eribate* and the chelating agent and food additive *Sodium Gluconate* decreased.

■ Home Care Business

Sales jumped 29.7% to ¥5,652 million (US\$46 million) thanks to robust growth in the home oxygen therapy business, the main service line.

Sales By Business Segment

Years ended March 31	Millions of yen		
	2001	2000	Change (%)
■ Pharmaceuticals	¥263,020 (88.4%)	¥255,450 (88.3%)	103.0
Ethical pharmaceuticals	248,325 (83.5%)	240,028 (83.0%)	103.5
OTC drugs	14,695 (4.9%)	15,422 (5.3%)	95.3
■ Other Businesses	34,497 (11.6%)	33,692 (11.7%)	102.4
Medical supplies and systems	2,984 (1.0%)	2,944 (1.0%)	101.4
Chemicals	22,084 (7.4%)	22,469 (7.8%)	98.3
Home care business	5,652 (1.9%)	4,358 (1.5%)	129.7
Others	3,777 (1.3%)	3,920 (1.4%)	96.3
Total	¥297,517 (100.0%)	¥289,142 (100.0%)	102.9
Overseas sales (included in the above total)	¥108,080 (36.3%)	¥102,195 (35.3%)	105.8

Sales of Ethical Pharmaceuticals by Therapeutic Category

■ *Antibiotics and Biological Preparations*

Though this is the largest category in the ethical pharmaceuticals business with a share of 30.6%, sales of this category decreased by 2.8% to ¥75,921 million (US\$612 million). Its share of total ethical pharmaceuticals sales dropped 1.9 percentage points from 32.5% in the previous year.

While sales of *AmBisome* marketed by Fujisawa Healthcare soared 30.5%, overall sales in this category declined owing to a fall in sales of cephalosporin products. Sales of the oral cephalosporin antibiotic *Cefzon*, the leading product not only in this category but also in the domestic ethical pharmaceuticals business as a whole, dropped by 14.2%. A very mild outbreak of influenza in Japan in the winter of fiscal 2001 negatively affected sales of this product. *Cefspan*, another oral cephalosporin antibiotic, posted slightly weaker sales. The export of bulk chemicals of *Cefspan* is the major element in this business. Increases in export sales were counteracted by the sales decline on the Japanese market and flat sales in the German market together with the increased weakness of the euro against the yen. Sales of the injectable cephalosporin antibiotic *Cefamezin* also posted a decline due to stiff competition in the Japanese market.

■ *Metabolic Drugs*

Sales growth of 21.6% pushed up this category to second place in the rankings with sales of ¥51,354 million (US\$414 million). *Prograf* is the main product in this therapeutic category, being now commercially available in 47 countries worldwide. By region, more than half of *Prograf* sales come from the North America market with US\$263 million, followed by Europe and Japan. Though sales in Japan were relatively low compared with North America and Europe, they have been steadily increasing, and Japan now occupies the number two place after the US on an individual country basis. *Prograf* maintained first place among Fujisawa's top 10 ethical pharmaceuticals. Sales rose strongly by 21.1% to ¥50.6 billion (US\$408 million). As a leading immunosuppressant, it is expected to maintain its growth momentum.

■ *Cardiovascular and Respiratory Drugs*

This category fell to number three in the rankings due to the upsurge of metabolic drugs and a slight sales decrease. Sales inched down 1.2% to ¥41,854 million (US\$338 million). Double-digit growth in sales of *Adenoscan* by Fujisawa Healthcare was not able to fully offset decreased sales of the antihypertensive agent *Nivadil* and also of the respiratory products of Klinge Pharma GmbH.

■ *Nervous System and Sensory Organ*

Drugs

Total sales of this category came to ¥33,335 million (US\$269 million), virtually flat compared with fiscal 2000. *Luvox*, launched in Japan in May 1999, recorded its first full-year sales.

Myslee was also launched in Japan in December 2000. A decline in sales of the anti-glaucoma *Rescula* due to fierce competition held down sales growth in this category.

Top-Selling Ethical Pharmaceuticals

Product Name	Billions of yen			
	Years ended March 31	2001	2000	Change (%)
1) Prograf		50.6	41.8	121.1
2) Cefzon.....		29.1	33.9	85.8
3) Intal		16.0	15.7	101.9
4) Nivadil.....		14.2	15.4	92.2
5) Adenoscan		13.1	11.1	118.0
6) Cefamezin.....		11.8	13.0	90.8
7) Cefspan		9.7	10.0	97.0
8) Dogmatyl.....		8.6	8.4	102.4
9) Rescula.....		7.7	10.0	77.0
10) AmBisome.....		7.7	5.9	130.5

■ *Anti-Allergy Drugs*

Sales increased by 3.1% to ¥16,131 million (US\$130 million). The anti-allergic *Intal* is a main drug in this category.

■ *Digestive System Drugs*

The launch of *Colonel* in Japan in October 2000, as well as growth in sales of the prokinetic *Ganaton*, contributed to the 25.2% growth of this therapeutic category to ¥5,366 million (US\$43 million).

■ *Others*

Sales increased by 12.5% to ¥12,714 million (US\$103 million). Topical formulations such as *Protopic* and *Dovonex* are included in this category. Both *Protopic*, launched in Japan in November 1999, and *Dovonex*, launched in June 2000, contributed to the increase in sales.

OTC Drugs

Fujisawa's OTC drugs business covers a broad range of therapeutic categories from *Precol* brand cold remedy to *Newvita Gold* vitamin preparation, *Pyroace* brand remedy, *Fujipap* anti-inflammatory and analgesic plasters, and *Eva Youth* women's health products.

The Japanese OTC drug market, which has been flat for several years because of stagnant consumer spending, is not anticipated to regain its buoyancy for some years to come. In this climate, Fujisawa is very keen to introduce new products—including line extensions—in order to achieve growth in this business. In line with this strategy, in fiscal 2001 the Company launched: *Precol Time-Release Tablet*, *Precol Hot*, *Eurax Jun Milk Lotion* and *Eurax Jun Cream*, *Fujipap ID 1.0% Liquid*, *Children's Precol Hot*, *New Livahealth Gold*, a 500ml bottle version of the eyewash *FRESH EYE AG*, *Evayouth B26*, *Evayouth Acne* and *Evayouth C Chewable*.

Sales of Ethical Pharmaceuticals by Therapeutic Category

Years ended March 31	Millions of yen		Change (%)
	2001	2000	
Nervous system and sensory organ drugs	¥ 33,335 (13.4%)	¥ 33,234 (13.8%)	100.3
Cardiovascular and respiratory drugs	41,854 (16.9%)	42,380 (17.7%)	98.8
Digestive system drugs	5,366 (2.2%)	4,285 (1.8%)	125.2
Metabolic drugs	51,354 (20.7%)	42,231 (17.6%)	121.6
Anti-allergy drugs	16,131 (6.5%)	15,639 (6.5%)	103.1
Antibiotics and biological preparations	75,921 (30.6%)	78,117 (32.5%)	97.2
Others	12,714 (5.1%)	11,299 (4.7%)	112.5
Processing fees	7,816 (3.1%)	8,322 (3.5%)	93.9
Royalty income	3,834 (1.5%)	4,522 (1.9%)	84.8
Total	¥248,325 (100.0%)	¥240,028 (100.0%)	103.5



In spite of an overall 7% price cut on the National Health Insurance Drug Price List in April 2000, the Japanese pharmaceutical market as a whole showed positive growth of about 2.5% for fiscal 2001 according to the press, mainly thanks to the launch of new products with major sales potential. This reconfirms our belief that continuous introduction of innovative new products is the key to success in this market.

Two new products launched in fiscal 2000—*Luvox* (fluvoxamine maleate) and *Protopic Ointment*—made full-year contributions to the Company's business results for fiscal 2001. While the uptake of sales of *Protopic* was rather slow, partly due to the fact that Fujisawa has focused its promotional efforts on the appropriate use of this drug to dermatologists, *Luvox*, the first selective serotonin re-uptake inhibitor and the only drug having an indication for obsessive-compulsive disorder in Japan, achieved 50% growth over fiscal 2000.

During fiscal 2001, Fujisawa introduced five new products in the Japanese market. Of these, four were new chemical entities. In June 2000, *Dovonex Ointment* (calcipotriol), a vitamin D analogue, was launched. *Dovonex*, originally developed by Leo Pharmaceutical Products A/S of Denmark, has already captured the top share in the psoriasis market. *Colonel* (polycarbophil calcium) was launched in October. In December, the Company launched *Myslee* (zolpidem tartrate). *Myslee* is a short-acting hypnotic drug, originally discovered by Sanofi-Synthelabo of France and jointly developed by Fujisawa, Fujisawa Sanofi-Synthelabo Co., Ltd. and Sanofi-Synthelabo K.K. Zolpidem has long been on the world market under the names *Ambien* and *Stilnox* as the largest-selling hypnotic. *Seroquel* (quetiapine fumarate) was launched in February 2001. As indicated for the treatment of schizophrenia, *Seroquel* is effective against both the positive and negative symptoms of schizophrenia. Fujisawa obtained an exclusive marketing right to *Seroquel* in Japan from AstraZenaca, which was the original developer and sells this drug in the world market.

Further, though not a new chemical entity, Fujisawa launched a new *Cefamezin α Kit* (cefazolin sodium hydrate) in October 2000. While the original kit preparation was introduced in 1990, the new kit product has been developed to address increasing demands for easier preparation, disposal procedures and space saving. Further, in May 2001, Fujisawa launched the nonsteroidal anti-inflammatory drug *Rectos*. *Rectos* is a disposable pre-filled syringe of diclofenac sodium ointment for use as a suppository.



Dovonex



Colonel



Myslee



Seroquel



New micafungin synthesis facilities at the Toyama Plant

In addition to a series of new products, Fujisawa has also been reinforcing its domestic marketing activities. The number of its medical representatives (MRs) has been increased to about 1,100 from the previous level of about 1,000. Approximately 100 MRs moved to Fujisawa from Fujisawa Fisons Co., Ltd., a then joint venture between Fujisawa and Aventis, in early 2001. This move results from the December 2000 agreement between the two parties to restructure the joint venture as well as the business of *Intal* (sodium antichromoglycate). Under the agreement, the joint venture was dissolved, and Fujisawa has again taken over all *Intal* business, which had previously been transferred to the joint venture in a step-by-step manner. The Company further plans to increase the number of MRs to a total of between 1,150 and 1,200 in fiscal 2003. Fujisawa has also deployed about 100 MRs for exclusive detailing to dermatologists, pediatricians and ophthalmologists since April 2001. In addition, Fujisawa has increased the number of antipsychotics managers to capitalize on its good opportunities for strengthening its CNS (central nervous systems) franchise, which arises from the launch of new products such as *Luvox*, *Myslee* and *Seroquel*.

Turning to production, Fujisawa has made capital investments for tacrolimus-related products in the Toyama Plant of the Company and also for the antifungal micafungin in anticipation of its NDA filing and subsequent launch. New facilities for the formulation and packaging of *Protopic* were constructed at an investment of ¥3,860 million (US\$31 million) in February 2001. Commercial shipments for the Japanese market are planned to start in the spring of 2002. In June 2001, new manufacturing facilities for the bulk chemicals of tacrolimus were also completed at an investment of about ¥8,000 million (US\$65 million). Commercial production is planned to start sometime between late 2003 and the spring of 2004. Further, shipments for the Japanese market from the new facilities for the formulation and packaging of *Prograf* capsules—whose construction was completed in the Toyama Plant in November 1999—were started in November 2000.

The manufacturing process of micafungin is divided into fermentation, synthesis, and formulation and packaging. Starting in April 2000, Fujisawa invested a total amount of about ¥6,300 million (US\$51 million) in manufacturing facilities for micafungin at its three domestic plants. Fermentation equipment has been installed at the Nagoya Plant; new synthesis facilities at the Toyama Plant were completed in March 2001; and new formulation and packaging facilities at the Takaoka Plant were completed in June 2001. With the completion of the construction at Takaoka, all capital investments with regard to micafungin have been completed.



I have been working as a medical representative for Fujisawa for four years. Covering small hospitals, clinics and general practitioners in my area, I am busy providing the physicians with medical and scientific information. Recently, I have been focusing much of my efforts on detailing our CNS drugs like *Seroquel*, *Myslee* and *Luvox*. I often hear from a physician in detail that a patient taking *Seroquel* is showing improvement. I feel very motivated to know that a drug I promote is benefiting a patient.

**Naomi Nakahara
Medical Representative,
Higashi-Osaka Area,
Osaka Business Branch**



Located in Deerfield, Illinois, Fujisawa Healthcare, Inc. is the largest business base after Japan, and is rapidly expanding both its business and organization. It is also maturing both in terms of sales and profits, with sales exceeding US\$600 million in 2001. The development of Fujisawa Healthcare, Inc. as a successful business underscores the viability of the Company's strategy of aiming to be a "Global Niche Player."

Fujisawa Healthcare's growth strategy is to maintain and expand its leading position in the niche markets it enters, such as immunology, infectious diseases (systemic fungal infections) and cardiovascular diseases (pharmacologic stress imaging etc.). It is also newly developing its dermatology business with the recent introduction of *Protopic* to the US market. Further, Fujisawa Healthcare is actively pursuing in-licensing and product acquisition opportunities in order to secure future growth.

Currently, *Prograf* places first in the product list of Fujisawa Healthcare, followed by *Adenoscan* (adenosine injection), *AmBisome* (liposomal amphotericin B) and *Adenocard* (adenosine injection) for paroxysmal supraventricular tachycardia (PSVT). *Prograf* accounted for nearly half of Fujisawa Healthcare sales in fiscal 2001. Combined sales of these four major products account for over 90% of US sales. These key products show evidence of continued growth in fiscal 2002. *Prograf* is continuously gaining shares in the US transplant markets. Its market share to newly transplanted patients is now over 70% for liver transplants and is approaching 50% for kidney transplants. In particular, the growth in kidney transplants during the year 2000 was remarkable. In the USA, the use of pharmacologic stress imaging has been growing by over 15% annually. Within this growing market, *Adenoscan* has achieved a market share of over 45% and is now recognized as a main agent in this market. *AmBisome*'s share has



At the American Academy of Dermatology in Washington DC in February 2001



Discussion at Fujisawa Canada

been increasing since its launch in 1997, and it now accounts for almost 60% of sales in the market for amphotericin B related products.

Protopic made its debut in the US market in early 2001. Fujisawa Healthcare has created a dedicated dermatology sales force of 65 professional representatives deployed nationwide to promote *Protopic* as the “New World Power” in dermatology.

As the business performance of Fujisawa Healthcare has been improving, its clinical development activities are also growing stronger. Clinical development work on micafungin is on schedule with an NDA submission to the FDA planned in 2002. Phase III studies of *Prograf* for severe chronic rheumatoid arthritis continue to progress. Further, early-stage clinical studies are ongoing for DTI-0009 and CVT-3146. DTI-0009 is a selective adenosine A₁ agonist for the treatment of PSVT. Fujisawa Healthcare acquired exclusive North American rights to the injectable formulation of DTI-0009 from Discovery Therapeutics, Inc. in 1999. Fujisawa Healthcare and CV Therapeutics, Inc. have entered into a collaboration agreement to develop CVT-3146, a selective A_{2A} agonist, as a second-generation pharmacologic cardiac stress agent.

The Grand Island, New York plant of Fujisawa Healthcare is a manufacturing facility dedicated to the formulation and packaging of *Protopic*. As commercial shipment begins for the Japanese market at the new *Protopic* formulation and packaging facilities located in the Toyama Plant, the Grand Island facility will focus on providing *Protopic* to the North American and European markets.

In September 2000, Fujisawa Healthcare won a Gold Award in the patient education category of the seventh annual 2000 National Health Information Awards for the children’s guidebook “Me and My Marrow,” published by Fujisawa Healthcare in March 2000 to help guide children and their families through the bone marrow transplant process and treatment.

Fujisawa Canada, Inc., a subsidiary of Fujisawa Healthcare, Inc., is also steadily strengthening its presence with *Prograf*, *Adenocard* and *AmBisome* in the Canadian market. *AmBisome* was launched in Canada in February 2000. Fujisawa Canada filed an NDA for *Protopic* in June 2000 and received the approval in June 2001.

Apart from direct business through affiliated companies, cefdinir and cefixime are marketed in the US and cefixime is available in Canada, by major multinationals. Abbott Laboratories markets *Ominicef* (cefdinir) in the United States. Its US sales have been expanding since its launch on the American market in 1998, and 2000 sales were slightly below US\$50 million. *Ominicef* sales are expected to substantially increase in 2001. *Ominicef* has now climbed up to fourth place among all antibiotics for use by children. The 2001 edition of “Sanford Guide,” a widely used prescription manual, has included *Ominicef* in its recommendation list for the treatment of otitis media and paranasal sinusitis. Abbott has started co-promotion of *Ominicef* in the dermatological field with Medicis Pharmaceuticals, Inc. since June 2001. *Suprax* (cefixime) is available in the US through Wyeth Ayerst, a division of American Home Products and in Canada through Aventis Pharma.



We have seen our cardiology franchise grow significantly during the 10 years I have been with Fujisawa. Our strong relationships with world-renowned clinicians, combined with excellent Fujisawa teamwork, have helped ADENOCARD™ and ADENOSCAN™ become market leaders. This successful partnership will help us continue to identify and grow new markets in the future.

**Jerry Olszewski
Product Director,
Cardiovascular Products,
Fujisawa Healthcare, Inc.**



I am responsible for the sales force in the area of Dermatology and Primary Care (GP).

Assuring the marketing success of *Suprax* and *Protopic*, and supporting the idea, spirit and identity of the new company (Fujisawa Deutschland GmbH) and its expansion into the dermatological field fascinates me and provides me with motivation.

**Friedrich Erath
Head, Sales Force
Primary Care /
Dermatology
Klinge Pharma GmbH**



Fujisawa currently has three operational bases in Europe. Fujisawa GmbH and Klinge Pharma GmbH, both located in Munich, run pharmaceutical business in tandem, while Fujisawa Ireland Limited, located in Killorglin, mainly works as a manufacturing base for the formulation and packaging of *Prograf*.

Fujisawa GmbH is responsible for the tacrolimus business in Europe. It has marketing subsidiaries in the UK, France, Italy, Spain, Austria and Sweden. Sales of *Prograf*, now commercially available in 18 European countries, have been sharply increasing. It has been recognized as the cornerstone immunosuppressant for organ transplantation and has captured a majority market share in the transplantation field in most countries. On the product development side, an application for marketing authorization for *Protopic* under the centralized procedure has been pending with the European Medicines Evaluation Agency since its filing in August 2000. Fujisawa GmbH is now also conducting Phase III studies for micafungin.

Klinge Pharma GmbH conducts pharmaceutical business mainly in Germany, and has subsidiaries in Austria, Switzerland and Ireland. Klinge offers pharmaceutical products for the treatment of respiratory, anti-infectives, analgesics and oncological area. In the anti-asthma line, *Bronchoretard* (theophylline) is the best-selling product of Klinge. *Suprax* (cefixime) represents the anti-infective line.

In European operations, improvements in operational efficiency and profitability as well as the establishment of a strong presence in German-speaking countries had been at the top of Fujisawa's agenda. In order to achieve these strategic goals, Fujisawa announced a two-step reorganization plan of its European business in January 2001. Since January 2001, Fujisawa GmbH has become the parent company of Klinge Pharma GmbH and also the European headquarters of Fujisawa, having such functions as legal affairs, R&D central marketing and business development. At the beginning of 2002, Fujisawa Deutschland GmbH, headquartered in Munich, will be formed by the merger of Fujisawa GmbH's German operations into Klinge Pharma GmbH. With sales of 200 million euro and 750 employees, Fujisawa Deutschland GmbH will have a sales force covering both hospitals and general practitioners, and will handle a variety of products including *Prograf* and current Klinge lines. *Protopic* and micafungin will be new and important additions. Fujisawa expects that this reorganization will also lead to expanded opportunities for strategic partnerships such as in-licensing and product acquisition not only in Germany but throughout the rest of Europe as well.

Cefixime is available under various brand names in nearly 20 European countries. For instance, Klinge markets it as *Suprax* in Germany, as *Aerocef* in Austria, and *Cephoral* in



At a transplantation congress in Europe in August 2000

Switzerland while Aventis Pharma sells it as *Oroken* in France and as *Suprax* in the UK and Ireland. Cefixime has been taking more than a 20% share in the oral cephalosporins market on average in the five major European markets—Germany, France, Italy, Spain and the UK. The atypical antipsychotic zotepine, another Fujisawa compound, is commercially available in six European countries. *Zoleptil* in the Czech Republic and Slovakia, both by Avalanche, has had a good start after its launch in January 2001.



Cefixime joint licensee meeting in Hong Kong in 2000



Prograf Symposium in South Korea in April 2001



Asia Fujisawa Taiwan Co., Ltd. is Fujisawa's oldest and largest operational base in Asia. Fujisawa Taiwan has been a significant presence in the Taiwanese market for almost 40 years since its establishment in 1962. Today, Fujisawa Taiwan sells a variety of ethical pharmaceutical products from Fujisawa's in-house pipeline or from outside partners. Its product portfolio comprises *Prograf*, *Cefspan*, *Cefamezin* and the hypnotic *Stilnox* (zolpidem tartrate) from Sanofi-Synthelabo of France. *Lodopin* (zotepine), generated from Fujisawa's research pipeline, was launched in July 2000. *Rescula* from R-Tech Ueno Ltd. of Japan has been approved and is waiting for price approval. Its launch is planned in 2001. *Protopic* was filed in Taiwan at the end of June 2001 and in preparation for an NDA filing in China.

Fujisawa Taiwan is also responsible for the *Prograf* business in China through Fujisawa Hong Kong, Ltd., its wholly owned subsidiary. Fujisawa Hong Kong promotes *Prograf* in Hong Kong and China through its offices in Beijing, Shanghai and Guangzhou. Sales of *Prograf* in China are growing in line with the Company's expectations.

Fujisawa Korea Ltd. markets *Prograf* in the South Korean market. Fujisawa Korea made an NDA filing for *Protopic* at the end of March 2001.

In Pacific Rim countries other than Taiwan, China and South Korea, *Prograf* is marketed by the Johnson & Johnson Group. *Prograf* is now commercially available in Australia, New Zealand, Malaysia, Singapore, the Philippines, Thailand and Brunei.

Cefixime is available in major Asian countries. In South Korea, *Suprax* has been marketed by Dong A Pharmaceutical Co., Ltd. since 1989 and has been the top-brand oral cephalosporin for the past several years. The new indication of cefixime for the treatment of typhoid fever, a life-threatening infection in many developing countries, is now being approved in these Asian countries.

Another oral cephalosporin, cefdinir, is available in South Korea, Thailand, Indonesia and the Philippines. In South Korea, cefdinir has been available as *Ominicef* through JE IL Pharmaceutical Co., Ltd. for three years since its launch. *Ominicef* is now on the way to becoming the No.2 brand oral cephalosporins following *Suprax*.

It is a wonderful opportunity for me to work for Fujisawa. And fortunately, I have the good luck to work on the *Prograf* project. Since the advent of *Prograf*, I have been devoting my efforts to fostering the growth of this ground-breaking product, and sales are now rising sharply thanks to the work of Fujisawa's excellent local and global staff. By the middle of next year, we will have a second product, *Protopic*. Through these two tacrolimus "sisters," I am sure that Fujisawa Korea will dynamically expand its business activities.

Hyun-Sook Kim
Prograf Product Manager,
Fujisawa Korea Ltd.

Other Businesses

The Medical Supplies and Systems Business is operated solely in Japan and markets as its main products three reagent lines of Becton Dickinson and Company (BD) of the US, and those of BD PharMingen, BD Transduction and BD Biosciences, as well as gene diagnosis-related compounds manufactured by Vysis of the US. Since 1993, Fujisawa has been distributing flow cytometry reagents manufactured by PharMingen of the US, which was acquired by BD in 1997. In January 1999, Fujisawa started distribution of BD Biosciences' line, which had previously been marketed by BD's Japanese subsidiary. Flow cytometry reagents are widely used in fields ranging from basic research in immunology through disease diagnosis for cell analysis to immune reaction. In July 1999, Fujisawa started distribution of the BD Transduction line, a cell biology reagent line. Further, Genosensor System (Genomic Array System for Assessing Vysis Gene Copy Number) was launched in March 2001. Besides products for high-end research, products for general health screening, such as urine test sticks and stool occult blood tests, are also important areas for this segment.

The Home Care Business is also operated solely in Japan. The Japanese home care market is expected to grow in line with the expansion of medical care at home under the current climate of the Japanese healthcare scene. Since its entry into the Japanese home oxygen therapy (HOT) market in 1995, the Company's home care business has been growing. In addition to HOT as its main area of service, Fujisawa has also been expanding its service to include Home Infusion therapy (HIT), Continuous Positive Airway Pressure (CPAP) for Sleep Apnea Syndrome (SAS), and BiLevel for Non-invasive Intermittent Positive Pressure Ventilation (NIPPV).

In order to strengthen its product portfolio in the respiratory care device business and meet even broader customer needs, Fujisawa started the marketing in Japan of home-care medical devices provided by the US-based Respironics, Inc. in collaboration with the Tokyo-based Fuji RC, Ltd. in February 2001. Fuji RC, Ltd. is the largest marketer of home-care respiratory care devices in Japan and also the Japanese agency of Respironics, Inc., which holds the first place in the US respiratory device market. Fujisawa now jointly promotes with Fuji RC two home-care products of Respironics, the "BiPAP" series for non-invasive intermittent positive pressure ventilation, and the CPAP system to SAS.

The Chemicals Business features the full range of capabilities from product development and manufacturing to marketing both in Japan and overseas. Until recently, the chemicals business had been composed of various fragmented businesses. Considering the future perspectives of the respective businesses, the Company has transferred the animal health products business to an outside party and has a similar plan for the industrial cleaning and hygiene business, while its concrete admixture business has been transformed into a joint-venture company.

In March 2001, Fujisawa and DiverseyLever, the professional cleaning and hygiene business of Unilever, signed an agreement under which Fujisawa will transfer its industrial cleaning and hygiene business carried out by Daisan Kogyo Co., Ltd. (Daisan) to DiverseyLever

over three years. Daisan, with sales of about ¥7 billion, is one of the largest manufacturers of industrial cleaning and hygiene products for the brewing and beverage industry in Japan. Fujisawa currently owns 50.1% of Daisan's share capital. The rest of the shares have now been purchased by DiverseyLever. Fujisawa's shareholdings will be transferred to DiverseyLever in November 2003, until which time Fujisawa will remain the majority shareholder.

In April 2001, Fujisawa and NIPPON PAPER INDUSTRIES CO., LTD. merged their respective concrete admixture businesses to form a joint venture named SANFLO PARIC CO., LTD. Fujisawa's business in this area had been conducted by FPK Co., Ltd., a wholly owned subsidiary of Fujisawa. The combined technology base of the formerly independent businesses is expected to lead to improved profitability and further expansion of operations. Fujisawa now owns 34% equity of the new company.

In June 2001, Fujisawa transferred its animal health business—with annual sales of about two billion yen, primarily in the areas of livestock and aquaculture—to Schering-Plough K.K. (SPKK), a wholly owned subsidiary of Schering-Plough Corporation.

Fujisawa now focuses the resources of the chemicals business on industrial chemicals. The Company's industrial chemicals lineup includes the chelating agent and food additive *Sodium Gluconate*, the food antioxidant *Eribate* (sodium erythorbate), the food acidulant *Fujiglucon* (glucono delta lactone) and the calcium fortifier *Calcium Gluconate*. These products enjoy a leading position in their respective markets worldwide.

The chemicals business is engaged in mainly by the parent company and PMP Fermentation Products, Inc. headquartered in Itasca, Illinois. Fujisawa's Nagoya plant and PMP's plant in Peoria, Illinois serve as production bases for industrial chemicals and food additives.

In December 2000, PMP, the largest US manufacturer of *Sodium Gluconate*, celebrated the 15th anniversary of its establishment as a subsidiary of Fujisawa.



Dr. Aoki celebrates the 15th anniversary of the founding of PMP Fermentation Products, Inc.



Gluconic acid and its salts like Sodium Gluconate, and sodium erythorbate have long been used in food processing, bottle washing, metal surface treatment and so on. It is our task to make widely known the safe and useful properties of these “old but new” products, leading to their much wider use.

**Yoshio Iwai
Assistant Manager,
Sales & Marketing,
Chemicals**

As the primary weapon in gaining a competitive advantage in the pharmaceutical market, Fujisawa maintains a focus on innovative research. The Company invested ¥52,016 million—equivalent to 17.5 % of net sales—into research and development activities, and its research network is expanding both in Japan and overseas. Clinical development of Fujisawa compounds is also carried out in Japan, North America and Europe.



R&D Activities

Under the catchwords of “speed,” “focus” and “flexibility,” Fujisawa is vigorously conducting research and development activities, with research efforts currently focusing on immunology/inflammation, cerebral diseases, metabolic diseases and infectious diseases.

Reflecting Fujisawa’s deep commitment to innovative research, research and development expenses of the Company have been increasing in terms of both volume and ratio to net sales since the middle of the 1990s. Research and development expenses for fiscal 2001 were ¥52,016 million (US\$419 million), up 14.2% over fiscal 2000. The ratio to net sales climbed 1.7 percentage points to 17.5% from 15.8% in fiscal 2000. Both the volume and the ratio to net sales are historical highs.

Research Network

In addition to the 10 domestic laboratories where the Company’s research activities are mainly conducted, Fujisawa owns satellite research laboratories overseas, Fujisawa Research Institute of America (Research Division), and The Fujisawa Institute of Neuroscience in Edinburgh (FINE). The former is in collaboration with Northwestern University, while FINE has been operated as a collaborative research venture between Fujisawa and the University of Edinburgh in the area of the central nervous system since 1989. In May 2001, Fujisawa and the University agreed to extend this joint project for another five years to 2007.

■ *Genomic Research*

In addition to in-house activities, genomic research of the Company is enhanced through various joint projects. Since 1996, Fujisawa has been affiliated to the Helix Research Institute, a six-year joint venture project between the Japanese government and Japanese companies. In June 2001, Fujisawa, together with other Japanese companies, set up the Reverse Proteomics Research Institute to study co-action between proteins expressed from full-length cDNA clones gained through the activities of Helix and other institutions, and low molecule compounds. The Company is also a founding member of the Protein Structure Analysis Consortium, which was established by 22 Japanese pharmaceutical companies in June 2001.

■ *Venture Capital Funds*

Fujisawa Investments for Entrepreneurship, L.P. (FITE), a fund for equity investments in start-up pharmaceutical research ventures with innovative research ideas or technologies, has made six investments since its inception in September 1999. Based on this satisfactory performance, in April 2001 Fujisawa established Fujisawa Investments for Entrepreneurship II, L.P. with Orix Capital Corporation, a subsidiary of ORIX Corporation, headquartered in Tokyo. Future investments into research ventures by FITE will be jointly made with FITE II. In May 2001, Nissho Iwai Corporation joined FITE II. FITE I and FITE II made the first joint investment in July 2001.

■ *Immunology/Inflammation*

Collaboration with Protein Design Labs, Inc., which started in June 1999, is now in the second stage for the humanization of an antibody against a certain protein that plays an important role in immunological and inflammatory response.

Clinical development of malononitrilamide compounds is proceeding satisfactorily, and Fujisawa exercised an option to acquire the exclusive worldwide rights from Aventis in this area in June 2001.

■ *Cerebral Diseases*

In the field of neurodegenerative diseases, Fujisawa has been working with Arena Pharmaceuticals, Inc. for the discovery of new chemical entities to selected orphan

I have been working as the global project leader for the development of micafungin with working team members from Fujisawa subsidiaries. An NDA filing in Japan for micafungin was supported by clinical data from the US and EU. The mutual utilization of global clinical data highlights an advantage of Fujisawa's global organization. The micafungin project demonstrates the importance of global management for efficient clinical development. I am proud to be part of this project and to have the honor of working with so many talented colleagues.

Noriaki Inamura, Ph.D.
 FK463 Global Project
 Leader,
 Development



G protein-coupled receptors using Arena's proprietary technology.

Further, Fujisawa is proceeding with collaborative research with Quark Biotech, Inc. aiming at the discovery and analysis of stroke-related genes, and encouraging findings have been made.

Metabolic Diseases

Fujisawa licensed strontium ranelate, a new type of agent for the prevention and treatment of osteoporosis, from the Servier Research Group of France in Japan in May 2001. Fujisawa will start Phase I in Japan.

Tacrolimus Development

Clinical Development of *Protopic* has almost been completed, and the product is commercially available both in Japan and the US and has been approved in Canada. In Japan, an additional indication for pediatric use (from age 2 to 15) of *Protopic* will be filed in late 2001. In Europe, an application for marketing authorization of *Protopic* under the European centralized procedure has been pending since August 2000, and approval is anticipated in early 2002. An NDA for *Protopic* was also filed in Switzerland and South Korea during fiscal 2001 and in Taiwan in June 2001. Application will soon be made in China.

In the area of auto-immune diseases, Phase III studies for chronic rheumatoid arthritis are now underway both in Japan and the US, while it is in Phase II in Europe. Prograf has also been available for the treatment of myasthenia gravis since its approval in Japan in September 2000. Phase II studies are underway in Japan for such diseases as lupus nephritis, inflammatory bowel diseases, and vernal conjunctivitis as well as perennial allergic conjunctivitis by eye drop formulation.

Micafungin

Micafungin, (codename FK463) a next global product following *Prograf* and *Protopic*, is an injectable antifungal agent having a novel mode of action and belonging to a new class called "echinocandins." With a high safety profile, micafungin shows excellent activity against both candida and aspergillus, major fungi involved in deep-seated fungal infections. An NDA for micafungin for the treatment of deep-seated fungal infections was filed with the Ministry of Health, Labor and Welfare in Japan at the end of June 2001. Phase III by Fujisawa Healthcare, Inc. is almost complete, and the NDA is scheduled to be filed in 2002. Fujisawa also plans to file an application for marketing authorization for micafungin in Europe in 2002.



Other Products under Late-Stage Clinical Development

■ Cerebral Diseases

FK960 is an antimentia agent expected to have a different mode of action from anti-cholinesterase. FK960 is now in Phase II both in Japan and the US and promises to be effective in the improvement of memory, the impairment of which is a core symptom of Alzheimer's disease.

■ Metabolic Diseases

Zenarestat is an aldose reductase inhibitor for diabetic neuropathy. The data of Japanese Phase III are now under analysis. Phase III studies outside Japan by Pfizer Inc., holder of worldwide rights for zenarestat with the exception of Japan and certain other countries, have been suspended since October 2000 following interim safety analysis by Pfizer.

FK614, a benzimidazole derivative having a different molecular structure from glitazones, is an insulin sensitizer expected to have potent hypoglycemic effects. FK614 is now in Phase II for non-insulin dependent diabetic mellitus both in Japan and the US.

■ Other Diseases

Abciximab is a chimeric monoclonal antibody fragment targeted at GP IIb/IIIa receptors. Fujisawa has licensed abciximab, marketed in the US and other countries, from Centocor of the US. Abciximab is now in late Phase II for use in high-risk angioplasty in Japan.

FK317 is an anticancer antibiotic agent with potential effects on solid cancers such as lung cancer. FK317 is in Phase II in Japan and in Phase I in the US.

FK228 is a histone deacetylase inhibitor anticancer with potential effects on a wide range of cancers such as melanoma, lymphoma, prostate cancer and renal cancer. FK228 is in preparation for Phase II in the US.

Products under Clinical Development

	Product Name	Generic Name	Product Category	Phase I	Phase II	Phase III	Filed
Japan		miconazole (FK463)	antifungal (deep-seated fungal infections)				
		zenarestat (FK366)	aldose reductase inhibitor				
	Prograf	tacrolimus	immunosuppressant (chronic rheumatoid arthritis)				
	Protopic	tacrolimus (pediatric)	immunosuppressant (atopic dermatitis ointment for pediatric use)				
	ReoPro	abciximab	monoclonal antibody to GP IIb/IIIa receptors				
		FK960	antimentia				
		FK317	anticancer antibiotic				
		FK614	insulin sensitizer				
	Prograf	tacrolimus	immunosuppressant (lupus nephritis)				
		tacrolimus	immunosuppressant (vernal conjunctivitis and perennial allergic conjunctivitis (eye drops))				
	Prograf	tacrolimus	immunosuppressant (inflammatory bowel disease)				
North America		miconazole (FK463)	antifungal (deep-seated fungal infections)				
	Prograf	tacrolimus	immunosuppressant (chronic rheumatoid arthritis)				
		FK960	antimentia				
		FK614	insulin sensitizer				
		FK228*	anticancer				
	FK317	anticancer antibiotic					
Europe	Prograf	tacrolimus	immunosuppressant (heart transplant)				
	Protopic	tacrolimus (adult/pediatric)	immunosuppressant (atopic dermatitis ointment)				
		miconazole (FK463)	antifungal (deep-seated fungal infections)				
	Prograf	tacrolimus	immunosuppressant (chronic rheumatoid arthritis)				

* Products in preparation for Phase II

Environmental Protection

Environmental protection is a key management issue for Fujisawa in the 21st century, and the Company has long been implementing measures to improve the internal environment of its plants and protect the external environment. In September 1994, Fujisawa adopted its “Guiding Principles for Environmental Activities,” for application to the parent company. The Guiding Principles were revised and renamed the “Fujisawa Environmental Principles” in fiscal 2001 (See box at bottom). Under the Principles, which now apply equally to all companies in the Fujisawa group, the Fujisawa Environmental Guidelines have been elaborated as a practical guide for all group companies, helping them to reinforce their own environmental management and address environmental conservation issues. Further, during fiscal 2001, Fujisawa published the “GLOBE”, its first annual environmental report in Japanese to outside stakeholders. The report is available in print and on the Company’s website. Fujisawa plans to publish an English version in the future.

Based on the Fujisawa Environmental Guidelines, each group company is working to establish its own environmental management system in conformity with the ISO 14001 international environmental management system standard. Obtaining ISO 14001 certification is one of the group’s major concerns. The parent company obtained ISO 14001 certification for its plants in Nagoya, Toyama, Takaoka and Fuji, as well as for a plant belonging to a domestic subsidiary. The Irish plant of Klinge Pharma GmbH is now in the final stage of preparations to acquire ISO 14001 certification in 2001.

In fiscal 1996, Fujisawa introduced an in-house environmental audit system in order to annually monitor the effective and appropriate practice of environmental management, including the continued reduction of environmental burden resulting from business activities. In fiscal 2001, the auditors carried out on-site audits at thirteen facilities, including the research, development and manufacturing divisions of the parent company, all domestic subsidiaries, two US subsidiaries and Fujisawa Taiwan Co., Ltd. and found no major issues for concern with regard to environmental protection. However, the audits revealed some disparities between the levels at various group companies. As a result of these findings, Fujisawa plans to improve the level of environmental management at group companies.

In recognition of the fact that bringing a new drug to market—from early research to commercial production—is a very long process, Fujisawa has explicitly stated in the Guidelines that it makes assessments of environmental impacts for a pharmaceutical compound

Fujisawa Environmental Principles

Fujisawa recognizes effective management of the natural environment is one of our highest corporate priorities. We reaffirm that commitment and pledge our continual efforts to consider environmental impact in all business operations and improve the natural environment.

[Universality]

We, all of Fujisawa’s group companies, shall strive to ensure that worldwide business operations take consideration of regional environmental impact.

[Compliance]

We shall make efforts not only to comply with environmental laws and regulations, but also to establish effective environmental management activities by setting more stringent targets.

[Environmental Management]

We shall establish an environmental management system and promote organized continual environmental conservation activities.

[Product Development]

We shall investigate potential environmental impacts of products and business operations and strive to develop effective products and technologies to avoid negative environmental impacts.

[Environmental Performance]

We shall set numerical targets and challenges to achieve those continually to prevent global warming and to reduce wastes and emission of chemical substances.

[Pollution Control]

We shall promote pollution control and emergency preparedness vigorously from the viewpoint of environmental risk.

[Education & Motivation]

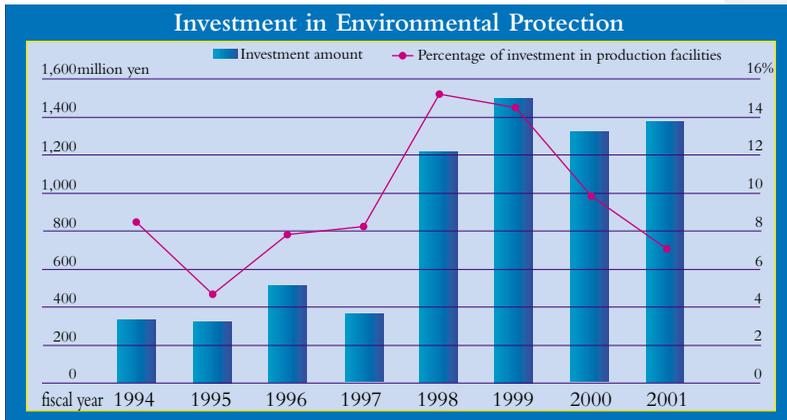
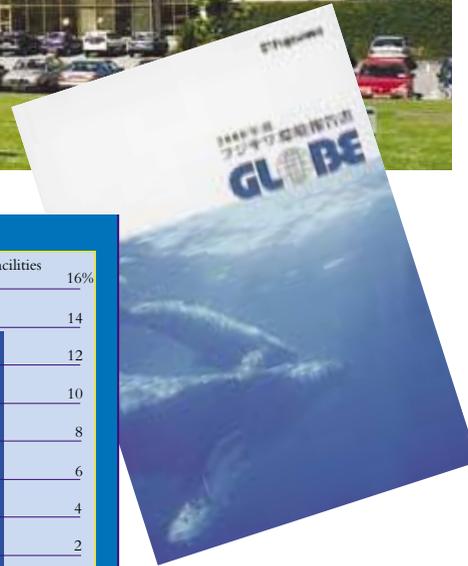
We shall notify all employees of Fujisawa Environmental Principles by continual education and motivation.

[Openness & Co-operation]

We shall foster co-operation and co-existence with the local community and present environmental information appropriately.



Fujisawa's Irish Plant (Killorglin)



at each stage. To this end, the parent company introduced an environmental assessment system in fiscal 1999 under which measures to minimize environmental burden in the production processes and construction of R&D and manufacturing facilities is mandatory. In fiscal 2001, environmental assessment was carried out for 11 compounds in the research pipeline and 4 new facilities, and all group companies are expected to adopt this system.

Prevention of environmental pollution and preparatory measures to deal with emergencies are crucial issues that receive close attention during environmental auditing. Fujisawa's plants maintain drain storage tanks and/or reservoir for emergencies. Measures have also been taken to enhance the training of staff in the handling of emergencies, as well as to set up a communication network for emergencies.

Fujisawa has set numerical targets for its main environmental conservation activities. Regarding waste control and chemical substance management, for example, the target for reduction of landfill waste in Japan in fiscal 2006 is under 20% of the landfill waste volume in fiscal 1991. Fujisawa has already reduced waste to 25% of fiscal 1991 level in fiscal 2001. In 2000, the plant in Ireland achieved the numerical target initially planned for 2002, and is now aiming at a much higher level. In Japan, Fujisawa set a numerical target for the reduction of dichloromethane emissions, and succeeded in lowering emissions to 46% of the volume in fiscal 1996.

The parent company, and group companies using organic solvents, are vigorously tackling the tasks of recycling such solvents as methanol and acetone. In Japan, Fujisawa has attained a recycling rate of 80%-90% in total for the four different organic solvents. PMP Fermentation Products, Inc. refines and re-uses more than 95% of methanol used, while the Irish plant recycles 84% in total of four different solvents, including toluene and ethanol.

Safe management of chemical substances has emerged as an important environmental issue on a world basis. The Company puts high priority on this issue and requests group companies to strictly manage chemical substances. All group companies engaged in manufacturing activities monitor their usage and emission of chemical substances and take measures to reduce both usage and emission.

Environmental protection and pollution prevention are core parts of Fujisawa Ireland's management system.

Through internal environmental training and promotion, a greater sense of environmental awareness is fostered among our employees. More recently our activities have extended to the local community, in particular the local schools.

We are committed to a policy of continuous improvement in environmental performance.

**Patricia Quane
General Manager
Manufacturing, Engineering,
Quality and Materials
Fujisawa Ireland Limited**

Board of Directors



Akira Fujiyama
Chairman of the Board



Michio Iida
*Vice Chairman and
Chief Financial Officer*



Hatsuo Aoki, Ph.D.
President and Chief Executive Officer



Koichi Sejima
*Corporate Executive Vice President and
Chief Administrative Officer*



Tomokichiro Fujisawa, Ph.D.
Chairman Emeritus



Akiro Kojima
*Member of the Board
(Chairman, Daicel Chemical Industries, Ltd.)*



Kanji Kobayashi
*Member of the Board
(Vice Chairman, Nippon Life Insurance Company)*

Members of Management Committee



(Front row, from left)

Hideo Tanaka
Corporate Senior Vice President, External Relations

Noboru Maeda
Corporate Executive Vice President and Chairman, Fujisawa Healthcare, Inc.

Takeshi Shimomura
Corporate Executive Vice President, Sales & Marketing

Shuji Inoue
Corporate Senior Vice President, European & Asian Operations

(Back row, from left)

Masanobu Kohsaka, Ph.D.
Corporate Senior Vice President, Science & Technology

Michio Iida
Vice Chairman and Chief Financial Officer

Hatsuo Aoki, Ph.D.
President and Chief Executive Officer

Koichi Sejima
*Corporate Executive Vice President and
Chief Administrative Officer*

Masafumi Nogimori
*Corporate Senior Vice President,
Global Corporate Strategic Planning*