

Bringing smiles to everyone



The origin of Kaken Pharmaceutical Co., Ltd. can be traced back to the Institute of Physical and Chemical Research (Riken), established in 1917. The Company started pharmaceutical business with full-scale development of penicillin and streptomycin based on Riken's own technologies in 1948, and since then broadened the scope of its business and drug development activities through merger and alliance. Kaken's prestige has soared accordingly.

While the Company has established strength in developing and selling pharmaceuticals for orthopedics, it is now expanding its involvement in other medical fields, such as hyperlipidemia and diabetes. The Company contributes to improving people's health by cultivating its own original technologies, engaging in joint development initiatives, introducing new technologies and acquiring marketing rights.

As a fruit of its technology and product introduction, the Company has been since June 2001 marketing Fiblast Spray consisting of Trafermin, a recombinant form of human basic fibroblast growth factor (bFGF) for the first time in the world, licensed from a US bio-pharmaceutical company, Scios, in the area of regenerative medicine (wound healing medicine).

#### **Corporate Philosophy**

By serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals, Kaken helps improve the quality of life for patients.

**Business Philosophy: Three Joys** 

# KAKEN conducts business by

## Creating joy for patients.

We strive to create and offer effective drugs that satisfy the needs of patients and medical professionals.

## Creating joy as a company.

We recognize our social responsibility as a pharmaceutical company with a high ethical standard and society's trust.

## Creating joy for

Our objective is to become a company with vitality and resence whose employees enjoy and take pride in their work.

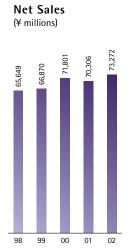
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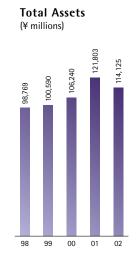
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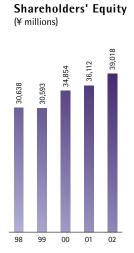
## ■ Consolidated Financial Highlights Kaken Pharmaceutical Co., Ltd. and Consolidated Subsidiaries.

	Million	Thousands of U.S. dollars (Note)	
	2002	2001	2002
For the years ended March 31,			
Net sales	¥ 73,272	¥ 70,306	\$550,917
Operating income	7,725	6,805	58,083
Net income	1,765	1,999	13,271
At March 31,			
Total shareholders' equity	39,018	36,112	293,368
Total assets	114,125	121,803	858,083
	Y	én	U.S. dollars (Note)
Per share data:			
Net income (Basic)	¥ 18.74	¥ 21.78	\$ 0.141
Cash dividends	7.50	7.50	0.056
ROE (%)	4.70	5.63	
Capital adequacy ratio (%)	34.19	29.65	

Note: U.S. dollar amounts are translated, for convenience only, at the rate of \$133 = \$1 effective on March 31, 2002.







#### ■ President's Message

#### **BUSINESS CLIMATE AND PERFORMANCE**

During Fiscal 2001, ended March 31, 2002, the Japanese pharmaceutical business faced severe challenges. Despite difficulties in the business environment, we generally succeeded in expanding our business by launching new products into the market. From a long-term perspective, however, we need to find appropriate solutions for further development by intensifying R&D activities to discover innovative new drugs, beef up business capabilities, and improve management efficiency.

There have been years of discussion regarding the amendment of the Japanese health care system to cap increases in medical expenses as the proportion of the elderly among the population increases. As the culmination of this debate, the government enforced a decision in April 2002 to cut National Health Insurance (NHI) price by an average of 6.3 percent industry-wide, reduce medical fees at medical institutions, and increase the patients' co-payment for health insurance.

We anticipate that these reforms will affect the pharmaceutical industry. They will shrink demand in the market, if only temporarily. Accordingly, our business environment has grown harsher against a backdrop of swelling development costs. In addition, successive mergers among big pharmaceutical companies have created mega-companies in the industry, and their Japanese corporations have bulldozed their way into the market through activities in product development and sales promotion with the help of their business networks worldwide and a unique project, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). These new trends have aggravated all-or-nothing competition industry-wide.

In this climate, we have spared no effort to expand the market share of our existing products, enhance our sales activities for new products, and conduct R&D activities and clinical trials.

As a result, consolidated net sales of the Company and its subsidiaries reached ¥73,272 million (US\$550.9 million) during this fiscal year, a year-on-year increase of 4.2 percent, and operating income totaled ¥7,725 million (US\$58.1 million), up

13.5 percent from the previous year. In contrast, however, net income fell 11.7 percent, to ¥1,765 million (US\$13.3 million) during the same period, which resulted mainly from year-end evaluation losses on investment securities due to the sluggish stock market.

During the year under review, we paid a dividend of ¥7.50 per share, the same amount we have paid for the past five years. Our fundamental policy is to provide stable dividends to all our shareholders whenever possible, regardless of our business performance. Additionally, in consideration of our future development, we are allocating funds to internal reserves to invest in R&D activities and shore up our financial foundation.

#### **R&D ACTIVITIES**

We are always looking at ways to enhance our future development to emphasize our brick-and-mortar presence in the community and in the industry. We pay particular attention to strengthening our development capabilities and improving our financial position to maximize our corporate value as a whole. We also are eager to rationalize the R&D process and make clinical trials more effective. To achieve this objective, we are concentrating our R&D resources on selected medical fields and jointly working with pharmaceutical companies and institutions worldwide to obtain the latest scientific information and technology.

Our corporate efforts also are devoted to reinforcing our business foundation. We are currently expanding our involvement in other medical sectors, such as hyperlipidemia and diabetes treatment, along with our existing field of orthopedics, in which we have established pharmaceutical development and sales as one of our strengths.

For instance, we have received the plaudits of the market for our intractable skin ulcer medication Fiblast Spray, a new drug in the field of regenerative medicine. In June 2001, we were the first to place a drug of this type on the market. Since then, the number of university hospitals and major hospitals using Fiblast Spray for medical treatment has been increasing, and its sales are rapidly growing.

In the future, we continue to exert our efforts to penetrate the pharmaceutical market with our products as a pioneer in regenerative medicine. Concurrently, our target is to harness the potential of basic Fibroblast Growth Factor (bFGF), for which we are conducting clinical trials for use in bone fractures and periodontitis.

We have completed clinical trials and requested the production approval for marketing our new drug Aldos for diabetic neuropathy treatment. Contrary to our expectations, however, we are still conducting additional clinical experiments, which will require a few more years. Thus, there will be a delay before we launch Aldos into the market.

To reinforce our new drug initiatives, we are focusing our R&D capabilities on treating allergic diseases and osteoporosis (bone disease).

As these examples clearly illustrate, we are aggressively making advances in new drug development.

#### **OUR OBJECTIVES**

Japanese business environment is supposed to be rife with difficulties. These will include a further decline in the number of children and the adoption of additional measures to curb medical expenditures. This trend will become more pronounced as big pharmaceutical companies expand the pharmaceutical market in Japan. Consequently, we anticipate that competition in the market will grow harsher.

Confronted with these new challenges, we intend to secure our unique position in the industry. To achieve this objective, we have made our priority enhancing corporate value rather than expanding our business activities. Consequently, we will add to our expertise in the fields in which we specialize, cultivate new fields as potential catalysts for revenue creation, strengthen and broaden our R&D pipeline, and expedite production activities to achieve our targets. We also will secure financial liquidity, solidify our corporate financial structure, and emphasize business ethics.



As our guidance for revenue in Fiscal 2002, ending March 31, 2003, we project an increase of two percent in consolidated sales and consolidated ordinary income. Among the components contributing to increased sales, we can count on Lipantil, Fiblast Spray, and Seprafilm. On the other hand, sales of such existing drugs as Artz and Procylin will decline, affected by decreases in drug prices and by industry-wide competition intensified. We also expect gains in net income, as we no longer need to report evaluation losses on investment securities as we did this year.

In the wake of the recent breakdown of business ethics world-wide, we are determined to engage in business activities based on strict ethical standards. For this purpose, we have established our corporate philosophy and business philosophy. Specifically, we have drawn up Kaken's Business Behavior Guidelines, implemented compliance programs, and published a guidebook for compliance with laws and regulations. Accordingly, each employee of our company recognizes our social responsibilities as a corporation in the pharmaceutical, agrochemical, and animal health product industry, while maintaining business activities pursuant to laws and regulations as well as corporate ethics.

We look forward to the continued support and cooperation of our stockholders.

June 27, 2002



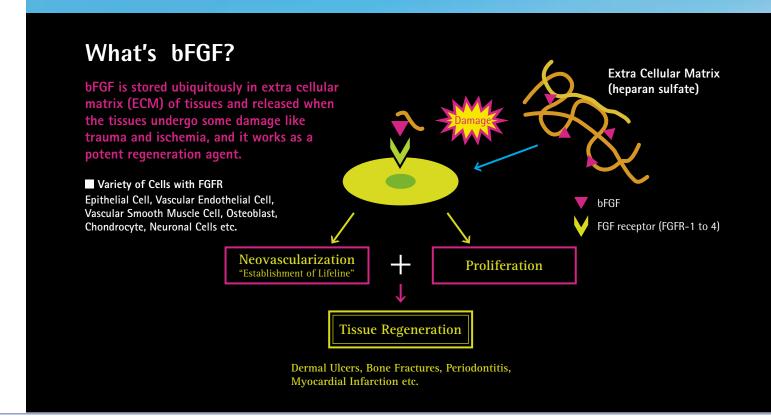
Shiro Inui President

# Fiblast Spray - a New Track in Regenerative Medicine

Kaken has actively been pursuing pharmaceutical development in tissue regeneration, pain treatment, endocrine diseases, metabolic disorders, systemic mycosis, arthritis, inflammation, and bone diseases. Fiblast Spray is a remarkable product from our R&D activities in regenerative medicine.

The worldwide attention on regenerative medicine testifies the latest development in the pharmaceutical industry. Regenerative medicine has enormous potential, and it is expected to become a huge market in the future. R&D activities in this new field have rapidly expanded and diversified with government support.

While research on regenerative medicine has been progressing by using cellular cultures, we have started to develop regenerative drugs using bFGF, a protein that stimulates the growth and differentiation of blood vessels, muscles, bones, and other tissue cells. Kaken was the first to commercialize a human bFGF as a regenerative medicine product. After conducting clinical studies in patients with intractable skin ulcers, we launched Fiblast Spray into the market in June 2001. Fiblast Spray contains Trafermin, a human recombinant form of bFGF, licensed from Scios Inc., in the U.S.





In 1988, we contracted a licensing agreement with Scios Inc. in the U.S. and introduced bFGF into our research programs. Since then, we have focused our research activities on the pharmaceutical applications of bFGF for intractable skin ulcers and conducted numerous clinical studies.

First introduced into the market as a bFGF application, Fiblast Spray is effective in treating bed sores and other various kinds of intractable skin ulcers, producing highly vascularized granulation tissues, and promoting the formation of new blood vessels. Quite easy to use, Fiblast Spray is a handy spray for daily application to the wound. When applied to the tissues damaged by burns or ulcers, it regenerates natural skin in two to three weeks.

Presently in Japan, some 200,000 to 300,000 patients are estimated to be suffering from intractable skin ulcers, for which applicable drugs have a Japanese market worth some \$14,000 to \$15,000 million. If the range of applications of these drugs should widen in the future, their market could yield \$20,000 million a year.

A type of protein called growth factor, bFGF is unique in stimulating the growth and differentiation of blood vessels, muscles, bones, nerve and other numerous tissue cells. It also effectively promotes the formation of new blood vessels. In addition, bFGF is essential for wound healing in the body.

The objectives of regenerative medicine are to eliminate the rejection caused by artificial skin or skin grafts and to improve

the poor prognosis that burn patients face. In this respect, bFGF can accelerate the formation of new blood vessels and their networks, through which they help supply oxygen and nutrients. They also help destroyed tissues recover by promoting cellular proliferation. Moreover, bFGF binds to the receptors on osteoblasts and nerve cells. This characteristic is expected to contribute to regenerating lost functions by stimulating the recovery of injured bones and nerves. We will conduct further R&D activities and clinical tests to exploit this characteristic.

From a broader perspective, bFGF has the distinct potential for treating various diseases, *i.e.*, skin ulcers, osteopathy, including intractable bone fractures and osteoporosis, periodontitis, such ischemic heart diseases as myocardial infarction, and nerve injuries. We are assiduously conducting basic research and clinical development into this wide range of applications. For instance, when applied to periodontitis, for which as much as 80 percent of people aged 40 and over are reportedly known to need medical treatment, bFGF stimulates periodontal tissues and improves periodontal health. Clinical experiments with animals have proved that bFGF successfully contributed to periodontal regeneration.

In light of these results, we will continue to carry out our R&D activities in regenerative medicine to discover wider applications for internal medicine and the circulatory system.

Kaken is now developing Trafermin (bFGF) in the both therapeutic areas of bone fractures (Phase-II) and periodontitis (Phase-II).



## Pharmaceuticals

#### YEARLY SUMMARY

Pressed hard by the sales promotion activities of our competitors in the industry, the sales of our major products Artz, Procylin, and Adofeed declined. On the other hand, we secured gains in sales from Fiblast Spray and Seprafilm. Fiblast Spray attracted clinicians' significant attention since these products were launched into the market in June 2001. As a result, non-consolidated sales of pharmaceuticals and other medical products increased 5.1 percent year on year to ¥64,050 million.

In the wake of April 2002's new regulations on drug prices, the prices of our products were reduced by nearly seven percent while drug prices were cut by an average of 6.3 percent industry-wide. Reflecting these new drug prices, our major products may lose their sales slightly. Nevertheless, we believe we can achieve sales gains by aggressively promoting Fiblast Spray, Lipantil, and other new products. We also have launched Pronase-MS, a mucus solubilizer to be used as pretreatment for conventional gastro-endoscopy in December 2001. The following is a summary of our main products.







**Artz (anti-osteoarthritic)** Artz is made of ultra-pure sodium hyaluronic acid extracted from rooster combs. Hyaluronic acid is a naturally occurring, biocompatible polymer found throughout the body, particularly in synovial fluid. A viscoelastic supplement, Artz replaces the diseased synovial fluid found in osteoarthritic knees and restores the physical properties and elastoviscosity of this diseased synovial fluid. It is injected directly into the knee joint by the physician.

**Procylin (Prostacyclin analog)** Procylin is an orally active and chemically stable prostacyclin analog (Beraprost) that directly acts on the PGI2 receptor to inhibit platelet aggregation. It is already in wide clinical use for treating chronic artery occlusive disease. In September 1999, Procylin was approved for the additional indication of pulmonary hypertension, which cannot be cured with most remedies currently in use.



**Adofeed (pain-relieving plaster)** Adofeed is a pain-relieving plaster containing Flurbiprofen as its active ingredient, which is absorbed through the skin. Applied to the affected area twice a day, Adofeed has proven effective in treating osteoarthritis, tennis elbow, muscle pain, and other inflammatory diseases.



Mentax (topical antifungal) Mentax is a topical antifungal with Butenafine as its main ingredient. An original Kaken product, Mentax is sold worldwide, including in the U.S. through Bertek/Mylan and in Canada through Schering-Plough. In December 2001, Mentax was approved as OTC Drug in the U.S., which is sold under the trade name of Lotrimin Ultra through Schering-Plough.





**Lipantil (anti-hyperlipidemic)** A fibrate type of lipid lowering agent, Lipantil containing Fenofibrate lowers both triglyceride and cholesterol. Originally developed by Fournier in France, Lipantil was sublicensed to Kaken in 1996 from a Japanese licensee, Grelan Pharm. Kaken launched Lipantil on the Japanese market in May 1999.

**Seprafilm (post-operative anti-adhesive)** Seprafilm is a sheet-type, bioabsorbable, anti-adhesive, biomaterial consisting of hyaluronic acid and CMC. This unique product, licensed from Genzyme Corp., was already in use in the gynecological field in Japan. In June 1999, it received additional approval for use in preventing post-operative abdominal adhesions.





**Fiblast Spray (wound healing agent)** Consisting of Trafermin, a human recombinant form of bFGF, this is a new type of drug for treating bed sores and other skin ulcers. Fiblast Spray strongly stimulates the growth of endothelial cells and fibroblasts. It also accelerates wound healing by producing highly vascularized granulation tissues. Introduced by Scios Inc., Fiblast Spray was first developed by Kaken, which commenced sales in June 2001.





**Ebrantil** ( $\alpha$  1-blocker) Ebrantil is a specific  $\alpha$ 1-adrenergic receptor antagonist (Urapidil) for neurogenic dysuria. Clinical studies have shown that twice-daily administration of Ebrantil capsules significantly improves difficulty in urination caused by central or peripheral neural disorders without causing significant hypertension. It was approved for this indication in November 1999. Ebrantil already has been in use for hypertension and dysuria caused by BPH (Benign Prostatic Hyperplasia).

**Cytotec (ulcer preventive)** An ulcer preventive whose active ingredient is Misoprostol, Cytotec is effective for NSAIDs - induced gastric ulcer. It was developed by Searle (now Pharmacia Corporation), and has been sold by Kaken since 1995.

**Norinyl T28 (Low-dose oral contraceptive)** Norinyl T28 is a Sunday-start-type, low-dose oral contraceptive pill containing a combination of two hormones: norethisterone and ethinylestradiol. Incidence of metrorrhagia, which is often observed by users of this type product, is low. Norinyl T28 was developed by Monsanto Company and Daiichi Pharmaceutical Co., Ltd. and received approval in June 1999. In September 1999, Kaken launched this product into the Japanese market. Kaken is currently marketing Norinyl T28 in collaboration with Morinaga Milk Industry Co., Ltd.

**Eyecare 0.1 (Eye drop for corneal disorders)** Hyaluronic acid, a naturally occurring, biocompatible polymer, was first discovered in the eye and has proved to promote to healing cornea epithelium wounds. It is also a major component of Kaken's Artz for the treatment of osteoarthritis. Eyecare 0.1 eye drop solution, containing ultrapure hyaluronic acid (0.1%), was approved in March 2000, for the treatment of corneal disorders, including dry eyes. It was launched into the Japanese market in July 2000 and co-marketed with Teika Pharmaceutical Co., Ltd. under the same brand name.

**Mirol (Anti-glaucoma)** Consisting of Levobunolol (0.5%), Mirol is a -blocker for treating glaucoma and ocular hypertension. Mirol is used once daily as eye drops without heavy viscosity. This product was launched in February 2001. Originally developed by Allergan Inc. in the U.S., Mirol was sublicensed to Kaken from a Japanese licensee, Kyorin Pharmaceutical Co., Ltd.





#### **R&D** Pipeline

*				
Products	Stage	Category	Indication	Note
CR-1505 (Loside)	NDA	CCK antagonist (iv)	Acute pancreatitis	Jointly developed with Mitsubishi Pharma Corp.
KP-102D (GHRP-2)	NDA	GH secretagogue	Diagnostic	Developed In-house
CR-1505 (Loside)	Pre-NDA	CCK antagonist (po)	Chronic pancreatitis	Jointly developed with Mitsubishi Pharma Corp.
SNK-860 (Aldos)	Phase III	ARI	Diabetic Neuropathy	Jointly developed by N. K Curex Co., Ltd.
				and Sanwa Kagaku Kenkyusho Co., Ltd.
TRK-100STP (Procylin)	Phase II	Orally active	ASO	New Indication:
		prostacyclin		Jointly developed with Toray Industries, Inc.
KCB-IB (Trafermin)	Phase II	bFGF	Bone fractures	New Indication
KCB-ID (Trafermin)	Phase II	bFGF	Periodontitis	New Indication
KP-102LN (GHRP-2)	Phase II	GH secretagogue	Short stature	Developed In-house
KP-107 (Arthrotec)	Phase I	Diclofenac+Misoprostol	RA/OA	Developed In-house
KN-48	Phase I	Lidocaine patch	Postherpetic neuralgia	Developed In-house
SPK-843	Phase I	Polyene antibiotic	Mycosis (systemic)	Developed In-house
KP-496	Pre-clinical	LT/TX dual inhibitor	Asthma	Developed In-house

## Agrochemicals and Animal Health Products

#### YEARLY SUMMARY

While overall agrochemical sales slumped, sales grew for Polyoxin, a fungicide for fruits and vegetables. Partly affected by the government's regulations for further rice acreage reduction, we struggled to promote the paddy herbicide Pentoxazon, which still posted a sales increase. Characteristic of fewer pollutants, Pentoxazon has fewer adverse affects on the water and the soil. For this reason, we received the Society Award of Pesticide Science Society of Japan in 2001.

In the animal health product sector, sales of our main products Eustin and Colistin decreased owing to price cutting in foreign markets.

#### **AGROCHEMICALS**

**Polyoxin (Fungicide)** Polyoxin is a fungicide produced by a certain type of bacterium isolated from the soil in the Aso region of Japan. It is particularly effective for treating damage caused by alternalia in apple, pear and other fruit trees, as well as flowering trees and tobacco plants. It is also effective against botrytis rot and powdery mildew. With low toxicity, it does not damage crops and is highly safe for use.

**Pentoxazon (Herbicide)** Pentoxazon is a new type of paddy herbicide. It is effective against first-year weeds and has long-lasting effects. It is highly safe for use in rice paddies and can be used before, during or after transplantation.



#### ANIMAL HEALTH PRODUCTS

**Salinomycin (Anti-coccidiosis in fowls)** Salinomycin was developed originally by Kaken. It is sold in Japan, Europe, North America, Asia and other regions. It is the most widely used agent in the world to prevent and treat coccidiosis, a contagious disease that begins when protozoans become parasitic in the intestinal tracts of fowls. When transmitted, coccidiosis causes stunted growth and even death. The disease can be known to cause major economic damage in modern, large-scale chicken farms.

**Colistin (Antibiotic)** Colistin is used to prevent diseases caused by Gram-negative bacteria, such as colon bacillus and salmonella. Colistin is highly safe and is one of the few drugs used against Gramnegative bacteria. It has found widespread use. It is sold in Japan, European and Asian countries.

#### ■ R&D, Production and Quality Control, and MR System

## Research and Development

#### **DISCOVERY RESEARCH**

Kaken is committed to returning smiles of happiness to the faces of many people. To achieve that objective, we have intensified our R&D activities in drug formation, pharmacokinetics, and metabolism. In so doing, we are striving to take the initiative in discovering and developing new drugs. We also are engaged in effective R&D activities to create our own drugs, for which we have developed strong and wide-ranging tie-ups with other academic institutions and pharmaceutical companies.

Drug Discovery Research Laboratories are located in Kyoto, the ancient capital of Japan. There, surrounded by historic and cultural remains, our dedicated researchers are constantly studying the latest scientific information and technologies.

Currently, our main therapeutic interests lie in inflammation and immunology, endocrine and metabolic diseases, and infections. While conducting research in these areas, we are diversifying our research activities into some twenty programs, such as growth factor stimulants. In addition, we are constantly improving the quality of our drugs by adding new applications and developing optimal dosage forms. Responding to recent fundamental changes in drug discovery processes throughout the pharmaceutical science and biotechnology sectors, our research laboratories employ new technologies to accelerate discoveries and optimization processes.

Computer-aided drug design (CADD) is an important part of the rational approach to drug discovery. Our medicinal chemists constantly explore chemical candidates synthesized in vari-





ous projects in order to design a superior peptidemimetic focusing library.

To establish a strong presence in cost-consuming genomic approach and other state-of-the-art technologies, we are actively involved in joint research programs with other laboratories and academic institutions. We contract license agreements with these organizations as necessary. We expect these collaborations to result in more effective R&D activities and obviate unforeseeable risks in R&D investment.

In this respect, Toray Industries Inc. and Kaken are jointly developing the prostacyclin analog Procylin. Further, The Institute of Physical and Chemical Research (RIKEN) and Kaken are jointly working to expedite research into the structure and function of proteins. Based on our blueprints for candidate drugs, we are analyzing the three-dimensional structure of proteins and the genomic DNA clone, and searching for new candidate compounds.

Besides, our laboratories are exploring a number of innovative technologies in collaboration with leading academic scientists and pharmaceutical companies. As a result, our expertise has expanded to the fields of asthma, endocrinology, systemic mycosis, cardiology, and oral care.

As these examples illustrate, our top-notch capability for R&D activities leads the industry. In 2001, Kaken's scientist was awarded the ASBMR Young Investigator Award from the American Society for Bone and Mineral Research (ASBMR) for our osteoporosis

Recently, we have succeeded in developing Fibrast Spray, a human recombinant form of bFGF, which is the first drug in the regenerative medicine field. Cognizant of the great potential of



## Research and Development

this drug, we are expanding our R&D activities in regenerative medicine, a promising field for the treatment of bone fractures and periodontitis while promoting the recovery of nerve cells and the growth and differentiation of blood vessels.

Our researchers are highly motivated and dedicated to excellence at every phase of drug discovery research. Moreover, we have a highly refined education program that is producing many talented young researchers.

#### **DEVELOPMENT RESEARCH**

Development Research Laboratories are located in Shizuoka Prefecture. We undertake a wide range of research activities in a stimulating environment. Our objective here is to develop candidate compounds discovered during drug discovery research into new drugs. Our drug development research activities encompass pharmacokinetics research, drug formulation, safety evaluation and quality assurance.

Our drug development research is highly acclaimed. In fact, we have received the Okochi Memorial Prize five times in the past. This is the most respected prize for companies and researchers who have contributed to innovative drug production.

For instance, the Pharmacokinetics Research Group utilizes the latest equipment and technologies to study the absorption, distribution, metabolism and excretion of drugs in order to determine their effectiveness and safety in the body. The Drug Formulation Group studies general pharmaceutical designs and formulations using drug delivery systems (DDSs) and targets technologies to

develop optimal dosage forms. The Safety Evaluation Group strictly evaluates the safety of candidate compounds. The Quality Assurance Control Group works to ensure that information generated in all Kaken laboratories is of the highest quality and reliability.

Our R&D activities are progressing in several kinds of medical fields. For instance, we are engaged in clinical trials for a new drug in an effort to develop KP-102, a growth hormone-releasing peptide (GHRP), for treating pituitary dwarfism. Clinical trials are also in progress for diagnosing hypothalamic pituitary functions.

Kaken signed a sales agreement for Aldos (anti-diabetic neuropathy) with N.K. Curex Co., Ltd., which was applied for approval to manufacture by N.K. Curex and Sanwa Kagaku Kenkyusho Co., Ltd. We also formed an agreement with IDD Inc. of the United States to undertake R&D activities aimed at developing treatments for diabetes.

During the year under review, our R&D expenses reached ¥5,252 million on a consolidated basis, an increase of 5.5 percent year on year.

#### AGROCHEMICAL DEVELOPMENT

In our effort to develop agrochemicals and animal health products, we continue to search for new compounds from synthetic and natural resources. A number of promising candidates are now under further investigation. We also continue to develop new herbicides to expand our presence in the industry.



## **Production and Quality Control**

Located on the east bank of the Ohi River, and near Mt. Fuji, our production facilities in Shizuoka Prefecture are among the first to have introduced factory automation systems. Today, the Shizuoka facilities are in compliance with the Good Manufacturing Practices (GMP) of Japan, which stipulate requirements for drug manufacturing and quality control.

In addition to these regulations, we have stricter in-house regulations for the facilities. In particular, the quality of export products is governed by the GMP regulations of the U.S., which were formulated by the U.S. Food and Drug Administration (FDA) under the authority of the Federal Food, Drug, and Cosmetic Act. Thus, we are enforcing thorough quality control regulations.

The Shizuoka facilities also are equipped with the latest technology for implementing environmental measures. The facilities have a recycling rate of more than 99.6 percent and have already acquired ISO14001 certification.

During the year under review, our capital expenditure totaled ¥1,581 million on a consolidated basis. This was mainly used for purchasing manufacturing equipment for pharmaceuticals in the Shizuoka facilities and the land allocated for the construction of the Sapporo Branch.







## Medical Representative System

Kaken's medical representatives (MRs) provide doctors with updated information on our products and respond promptly to requests from medical professionals. At the same time, they garner medical information related to the safety and effectiveness of our drugs and channel feedback from the customers to the relevant departments.

Our MRs also play an important role in our R&D and production activities through their communication with doctors and patients. As front-line staff, they obtain invaluable information from doctor's offices and other medical institutions.

Additionally, our MRs help us develop user-oriented package design and product descriptions by incorporating the suggestions of medical professionals.



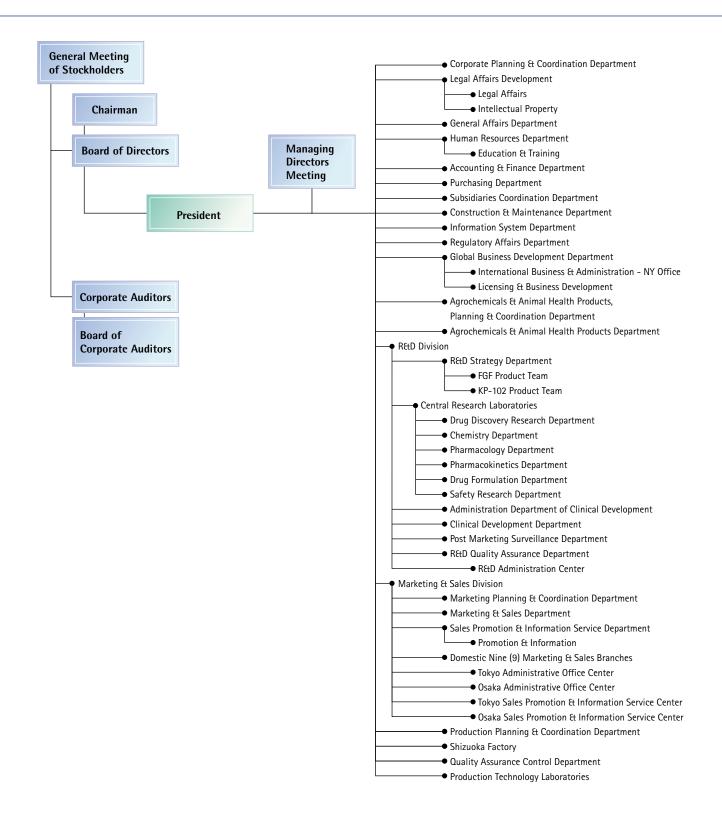


We introduced information technology (IT) into our customer service operations in March 2002 to enhance the quality of these operations, enabling us to promptly respond to inquiries from medical institutions. We intend to utilize IT to provide greater satisfaction to our customers. For this purpose, we will oversee the information management of the safety and effectiveness of our existing products as well as the drugs in clinical trials. We also will create a database for all information related to our business.

We presently employ around 650 MRs. In the future, we plan to hire more MRs to form a group of 700, which we will strategically assign to the expanding fields such as internal medicine. Adding staff will result in galvanizing our information and communication channels at medical institutions, which we expect to contribute to boosting our R&D capabilities and enlarging our market share.



#### Organizations



#### ■ Consolidated Financial Review

Kaken Pharmaceutical Co., Ltd. and Consolidated Subsidiaries.

Consolidated Five-Year Summary

	Millions of yen					Thousands of U.S. dollars (Note)
	2002	2001	2000	1999	1998	2002
For the years ended March 31,						
Net sales	¥ 73,272	¥ 70,306	¥ 71,801	¥ 66,870	¥65,649	\$550,917
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Net income	1,765	1,999	1,989	647	72	13,271
At March 31,						
Total shareholders' equity	39,018	36,112	34,854	30,593	30,638	293,368
Total assets	114,125	121,803	106,240	100,590	98,769	858,083
			Yen			U.S. dollars (Note)
Per share data:						
Net income (Basic)	¥ 18.74	¥ 21.78	¥ 21.68	¥7.06	¥0.79	\$ 0.141
Cash dividends (Non-Consolidated)	7.50	7.50	7.50	7.50	7.50	0.056
ROE (%) Capital adequacy ratio (%)	4.70 34.19	5.63 29.65	6.08 32.81	2.11 30.41	0.23 31.02	

Note: U.S. dollar amounts are translated, for convenience only, at the rate of ¥133 = \$1 effective on March 31, 2002.

#### **OVERVIEW**

During the year under review, we posted ¥73,272 million in consolidated net sales, about 95.9 percent of which resulted from pharmaceuticals, agrochemicals, and animal health products. Sales of these products amounted to ¥70,268 million. Other businesses, which account for the remaining 4.1 percent of sales, reached ¥3,004 million.

#### **BUSINESS PERFORMANCE**

#### **Pharmaceuticals**

Kaken's pharmaceutical business includes pharmaceuticals, medical devices, agrochemicals, and animal health products. The consolidated net sales of these products increased 4.5 percent from the previous year, to ¥70,268 million. Operating income rose 22.0 percent from the year before, to ¥6,502 million.

Sales of the viscoelastic supplement Artz declined slightly

year on year due to competing products. Sales of the prostacyclin analog Procylin and the flurbiprofen plaster Adofeed sank below the previous year's levels due to harsher competition with other drugs in the same categories.

In contrast, sales of the fenofibrate Lipantil steadily increased thanks to our aggressive sales activities. Sales of Cytotec, a misoprostol preventing NSAIDs-induced gastric ulcers, have contributed to pushing sales up since we acquired the exclusive marketing right in January 2002. In the past, both Pharmacia Corporation and Kaken marketed Cytotec in Japan. In addition, Fiblast Spray sales rapidly increased since we placed it on the market in June 2001. This increase in sales reflects medical professionals' acknowledgement of the advantages for the treatment of skin ulcers.

Sales of the hyaluronic acid film Seprafilm soared as medical professionals increased Seprafilm use since health insurance started to widely cover abdominal operations in February 2001.

While overall sales of agrochemicals slumped, sales of the fungicide Polyoxin rose against a backdrop of intensified sales activities. Despite the downward pressure exerted by the government's additional regulations to reduce rice acreage, sales of the paddy herbicide Pentoxazon grew in the severe business environment.

In the animal health products sector, sales of the salinomycin feed additive Eustin and the antibiotic Colistin dropped as we were faced with the industry-wide trend to slash product prices in world markets.

#### Other Businesses

Sales in this segment, which mainly stem from the land we own, declined 1.0 percent year on year to ¥3,004 million, and operating income fell 17.1 percent to ¥1,223 million during the same period.

#### **EARNINGS**

In the wake of our performance noted in the foregoing, we posted consolidated net sales of ¥73,272 million, up 4.2 percent from the year before. Operating income amounted to ¥7,725 million, up 13.5 percent during the same period. Net income, however, stumbled to ¥1,765 million, down 11.7 percent year on year. This decline was due to year-end evaluation losses on investment securities. EPS was ¥18.74 and ROE 4.70 percent.

#### **CASH FLOWS**

Cash and cash equivalents at the end of Fiscal 2001 totaled ¥16,410 million, a decline of ¥7,531 million year on year. This downturn resulted mostly from the redemption of convertible bonds. The following describes changes in funds during the year under review.

Cash flows from operating activities. Cash flows from operating activities tumbled to ¥3,142 million, a ¥2,976 million decline, or 48.6 percent lower than the previous year. This significant decline stemmed from the 7.7 percent year-on-year drop to ¥4,191 million in income before income taxes and minority interests, and the growth of income taxes paid from ¥2,363 million to ¥5,366 million.

Cash flows from investing activities. Owing to our investing activities, our cash and cash equivalents decreased ¥2,004 million, which decreased ¥2,521 million in Fiscal 2000. The primary factors behind this decline include the ¥995 million for new product equipment in the Shizuoka and other facilities, and ¥1,488 million for the purchase of sales rights.

Cash flows from financing activities. Cash flows from financing activities during the term totaled \$8,669 million, a \$17,679 million decline year on year, with \$6,256 million allocated for the redemption of convertible bonds and \$1,499 million for payment of long-term debt.

#### ■ Consolidated Financial Statements

Kaken Pharmaceutical Co., Ltd. and Consolidated Subsidiaries.

Consolidated Balance Sheets

As of March 31, 2002 and 2001	Millio	ns of yen	Thousands of U.S. dollars (Note 3)
ASSETS	2002	2001	2002
Current Assets:			
Cash on hand and at bank (Note 4)	¥ 14,439	¥ 19,884	\$108,564
Marketable securities (Notes 4 and 5)	2,191	4,285	16,474
Receivables:			
Notes and accounts receivable-trade	39,436	37,442	296,511
Accounts receivable-other	561	566	4,218
	39,997	38,008	300,729
Less: Allowance for doubtful accounts	(11)	(11)	(83)
	39,986	37,997	300,646
Inventories (Note 6)	9,796	8,522	73,654
Deferred tax assets (Note 13)	830	904	6,241
Other current assets	882	775	6,632
Total current assets	68,124	72,367	512,211
Machinery and equipment  Less: Accumulated depreciation  Land	17,136 52,190 (26,982) 25,208 3,844 29,052	18,139 53,003 (26,655) 26,348 3,583 29,931	128,842 392,406 (202,872) 189,534 28,902 218,436
Investments and Other Assets: Investment securities (Note 5)	3,869 773 4,318 6,027	6,561 773 3,415 4,775	29,090 5,812 32,466 45,316
Deferred charges	151	366	1,135
Other assets	1,811	3,615	13,617
	16,949	19,505	127,436
TOTAL ASSETS	¥114,125	¥121,803	\$858,083

The accompanying notes are an integral part of the Consolidated Financial Statements.

	Millior	Thousands of U.S. dollars (Note 3)	
LIABILITIES AND SHAREHOLDERS' EQUITY	2002	2001	2002
Current Liabilities:			
Short-term bank loans (Note 7)	¥ 6,204	¥ 6,409	\$ 46,647
Current portion of long-term debt (Note 7)	19,167	6,602	144,113
Payables:	•	,	,
Notes and accounts payable-trade	14,482	13,953	108,887
Notes and accounts payable-construction	643	526	4,835
Accounts payable-other	3,261	2,383	24,519
	18,386	16,862	138,241
Accrued expenses	557	463	4,188
Accrued bonuses	1,773	2,112	13,331
Accrued sales rebates	472	481	3,549
Accrued income taxes (Note 13)	1,506	3,402	11,323
Other current liabilities	560	622	4,210
Total current liabilities	48,625	36,953	365,602
Total current natifices	40,023		303,002
Non-Current Liabilities:			
	10 160	41 017	144 120
Long-term debt (Note 7)	19,169 6,162	41,817	144,128 46,331
Accrued pension and severance costs (Note 10)	500	5,780 511	•
		373	3,759
Deferred tax liabilities (Note 13)	319		2,398
Other long-term liabilities	331	256	
Total non-current liabilities	26,481	48,737	199,105
Minority interests in consolidated subsidiaries	1	1	8
Commitments and contingencies (Note 14)			
Shareholders' Equity:			
Common stock, 2001 — 50 yen par value, 2002 — no par value			
Authorized: 360,000,000 shares			
Issued: 91,799,041 shares as of March 31, 2001			
and 94,518,374 shares as of March 31, 2002	17,000	15,923	127,820
Additional paid-in capital	15,735	14,661	118,308
Retained earnings	6,557	5,537	49,301
returned currings	<del></del>	<del></del>	
Less:	39,292	36,121	295,429
Net unrealized loss on valuation of other securities,			
net of taxes (Note 2)	(258)		(1,940)
Treasury stock, at cost	(16)	— (9)	(1,340) $(121)$
			<del></del>
Total shareholders' equity	39,018	36,112	293,368
TOTAL LIABILITIES AND			
SHAREHOLDERS' EQUITY	¥114,125	¥121,803	\$858,083
01111012210 2Q0111		1121,003	<del>+030,003</del>

Consolidated Statements of Income

For the years ended March 31, 2002 and 2001	Millions of yen		Thousands of U.S. dollars (Note 3)
	2002	2001	2002
Net sales	¥73,272	¥70,306	\$550,917
Cost of sales	37,500	36,321	281,955
Gross profit	35,772	33,985	268,962
Selling, general and administrative expenses (Note 12)	28,047	27,180	210,879
Operating income	7,725	6,805	58,083
Other Income (Expenses):			
Interest and dividend income	102	157	767
Interest expense	(813)	(862)	(6,113)
Amortization of net obligation at transition	(525)	(525)	(3,947)
plant and equipment, net	279	(423)	2,098
Loss on sales of investment securities, net	(304)	_	(2,286)
Revaluation loss of investment securities	(1,882)	(340)	(14,150)
Equity in losses of affiliates	(0)	(0)	(0)
Revaluation loss of golf membership	(6)	(316)	(45)
Others, net	(385)	45	(2,895)
	(3,534)	(2,264)	(26,571)
Income before income taxes and minority interests	4,191	4,541	31,512
Income taxes (Note 13):			
Current	3,471	4,579	26,098
Deferred	_(1,045)	(2,037)	(7,857)
	2,426	2,542	18,241
Income before minority interests	1,765	1,999	13,271
Minority interests	0	0	0
Net income	¥ 1,765	¥ 1,999	\$ 13,271
	Y	en	U.S. dollars (Note 3)
Per share data:			_
Net income:			
Basic	¥ 18.74	¥ 21.78	\$ 0.141
Diluted	¥ 16.17	¥ 18.89	\$ 0.122
			· ·
Cash dividends	¥ 7.50	¥ 7.50	\$ 0.056

The accompanying notes are an integral part of the Consolidated Financial Statements.

Consolidated Statements of Shareholders' Equity

For the years ended March 31, 2002 and 2001				Millions	of yer	n			
	Number of common stock	Common stock	Additional paid-in capital	Retained earnings	loss	realized on other curities	ste	isury ock cost	Total shareholders' equity
Balance at March 31, 2000  Net income		¥ 15,923	¥ 14,661	¥ 4,272 1,999 (688) (46)	¥	_	¥	(2) (7)	¥ 34,854 1,999 (688 (46
Balance at March 31, 2001  Net income		¥ 15,923	¥ 14,661	¥ 5,537 1,765 (699) (46)	¥	_	¥	(9)	¥ 36,112 1,765 (699) (46) 2,151
valuation of other securities, net of taxes Treasury stock acquired, net						(258)	_	(7)	(258
Balance at March 31, 2002	94,518,374	¥ 17,000	¥ 15,735	¥ 6,557	¥	(258)	¥	<u>(16</u> )	¥ 39,018
			Thousands	of U.S. dollars	(Note	3)			
	Number of common stock	Common stock	Additional paid-in capital	Retained earnings	Uni	realized on other curities	ste	isury ock cost	Total shareholders' equity
Balance at March 31, 2001  Net income  Cash dividends  Directors' bonuses  Shares issued on conversion		\$119,722	\$110,233	\$41,632 13,271 (5,256) (346)	\$	_	\$	(68)	\$271,519 13,271 (5,256 (346)
of convertible bonds	, ,	8,098	8,075		(1	1,940)		(53)	16,173 (1,940 (53
Balance at March 31, 2002	94,518,374	\$127,820	\$118,308	\$49,301	\$(1	1,940)	\$(	<u>121</u> )	\$293,368

Consolidated Statements of Cash Flows
For the years ended March 31, 2002 and 2001

For the years ended March 31, 2002 and 2001	Million	Thousands of U.S. dollars (Note 3)		
	2002	2001	2002	
I. Cash flows from operating activities				
Income before income taxes and minority interests	¥ 4,191	¥ 4,541	\$ 31,512	
Adjustments for:	1 1,131	1 1/3 11	\$ 51,51 <b>2</b>	
Depreciation	2,073	2,100	15,586	
Amortization of long-term prepaid expenses	1,491	1,228	11,211	
Amortization of deferred charges	215	296	1,617	
Equity in losses of affiliates	0	0	0	
Revaluation loss of golf membership	6	316	45	
Accrual for pension and severance costs, less payments	382	556	2,872	
Interest and dividend income	(102)	(157)	(767)	
Interest expense	813	862	6,113	
Loss on sale of investment securities	304	-	2,286	
Revaluation loss of investment securities	1,882	340	14,150	
Loss on disposals of property, plant and equipment	77	468	579	
	(356)	(45)	(2,677)	
Gain on sale of property, plant and equipmentIncrease in notes and accounts receivable-trade				
	(2,052)	(3,818)	(15,429)	
Decrease in inventories	487	11	3,662	
Increase in notes and accounts payable-trade	371	2,367	2,789	
Paid bonuses to directors	(46)	(46)	(346)	
Other, net	(527)	(642)	(3,962)	
	9,209	8,377	69,241	
Interest and dividends received	107	151	804	
Interest paid	(808)	(854)	(6,075)	
Gain on settlement of legal proceeding		807	( , _ ,	
Income taxes paid	(5,366)	(2,363)	(40,346)	
•				
Net cash provided by operating activities	<u>3,142</u>	6,118	23,624	
II. Cash flows from investing activities				
Acquisition of investment securities	(10)	(846)	(75)	
Proceeds from sales of investment securities	`67	11	<b>5</b> 03 <sup>°</sup>	
Acquisition of property, plant and equipment	(995)	(1,366)	(7,481)	
Proceeds from sales of property, plant and equipment	362	136	2,722	
Payment of long-term prepaid expenses	(1,488)	(530)	(11,188)	
Other, net	60	74	451	
	(2.004)	(2.521)	(15,069)	
Net cash used in investing activities	(2,004)	_(2,521)	_(15,068)	
III. Cash flows from financing activities				
Proceeds from long-term debt	_	30	_	
Repayment of long-term debt	(1,499)	(35)	(11,270)	
Proceeds from issuance of convertible bonds		9,726	(	
Redemption of convertible bonds	(6,256)	·	(47,038)	
(Decrease) Increase in short-term bank loan	(206)	(16)	(1,549)	
Cash dividends paid	(699)	(688)	(5,256)	
Other, net	(9)	(7)	(68)	
,				
Net cash (used in) provided by financing activities	<u>(8,669</u> )	9,010	<u>(65,180</u> )	
Net (decrease) increase in cash and cash equivalents	(7,531)	12,607	(56,624)	
Cash and cash equivalents at beginning of year	23,941	11,334	180,007	
Cash and cash equivalents at end of year (Note 4)	¥16,410	¥23,941	\$123,383	
Non-cash transactions:				
Increase in common stock due to conversion				
of convertible bonds	¥ 1,077	¥ —	\$ 8,098	
Increase in additional paid-in capital due to conversion of	1 1,011	1 —	Ψ 0,000	
convertible bonds	1,074		8,075	
Decrease in convertible bonds due to conversion	¥ 2,151	¥ —	<u>\$ 16,173</u>	

#### Notes to the Consolidated Financial Statements

#### 1. Basis of Presenting Consolidated Financial Statements:

The accompanying consolidated financial statements of KAKEN PHARMACEUTICAL CO., LTD. (the "Company") and its consolidated subsidiaries (collectively the "Group") are basically an English version of those which were prepared from accounts and records maintained by the Group and in accordance with accounting principles and practices generally accepted in Japan, which are different in certain respects from the application and disclosure requirements of International Accounting Standards, and filed with the Director of Kanto Finance Bureau. The consolidated

statements of shareholders' equity have been prepared to provide additional information.

Certain items presented in the consolidated financial statements have been reclassified for the convenience of readers outside Japan.

The consolidated financial statements are not intended to present the consolidated financial position, results of operations and cash flows in accordance with accounting principles and practices generally accepted in countries and jurisdictions other than Japan.

#### 2. Summary of Significant Accounting Policies:

#### (a) Principles of Consolidation

The Company had five subsidiaries as of March 31, 2002. The consolidated financial statements include the accounts of the Company and all of its subsidiaries. The consolidated subsidiaries as of March 31, 2002 are as follows:

KAKEN REALTY & SERVICE CO., LTD.
KAKEN PHARMA CO., LTD.
KAKEN LOGISTICS CO., LTD.
EIKO FILTER CO., LTD.
FUIIKA CORPORATION

The Company had an affiliate as of March 31, 2002. Investment in  $N \cdot K$  Curex Co., Ltd. is accounted for by the equity method.

All significant intercompany transactions, account balances and unrealized profits among the Group have been eliminated in consolidation

The difference between the cost of an investment in a subsidiary and the amount of underlying equity in net assets of the subsidiary is allocated to identifiable assets based on fair value at the date of acquisition. The unassigned residual value of the excess of the cost over the underlying net equity is recognized as goodwill, and amortized over a period of five years on a straight-line basis.

#### (b) Cash and Cash Equivalents

Cash and cash equivalents in the consolidated statements of cash flows are composed of cash on hand, bank deposits which are able to be withdrawn within three months and short-term investments with original maturity of three months or less and are considered to have minimal risk from market fluctuations.

#### (c) Marketable and Investment Securities

Securities are classified as one of four categories; (1) Trading, (2) Held-to-maturity debt, (3) Securities of subsidiaries and affiliated, and (4) Other. Trading securities are recorded at market value with unrealized gains and losses recognized in the current years earnings.

Debt securities that are expected to be held-to-maturity are carried at amortized cost. Securities of subsidiaries and affiliates are carried at cost. Other securities are expected to be sold in the long term and those, whose fair values are readily determinable, are carried at fair value with unrealized gains or losses included as a separate component in shareholders' equity, net of taxes. Other securities without market quotations are stated at cost, determined by the moving average method.

Effective from the year ended March 31, 2002, other securities, which are expected to be sold in the long-term and those, whose fair values are readily determinable, are carried at fair value with unrealized gains or losses included as a separate component in shareholders' equity, net of taxes.

Previously, such securities were carried at cost under a transition treatment of the new accounting standard for financial instruments which was effective in the year ended March 31, 2001.

As a result of this adoption, investment securities decreased by ¥445 million, and the related deferred tax assets (non-current) increased by ¥187 million. Net unrealized loss on valuation of other securities are reported as a separate component of shareholders' equity, net of taxes.

#### (d) Inventories

Inventories are stated at cost, this being determined by the average method.

#### (e) Property, Plant and Equipment

Depreciation is computed on the declining-balance method at rates based on the estimated useful lives of assets, except for buildings, structures, machinery and equipment for the Komagome office that are computed on the straight-line method. Consolidated subsidiaries principally adopted the straight-line method.

Furthermore, depreciation of buildings, except for ancillary facilities to buildings, acquired after April 1,1998, is computed using the straight-line method.

The range of useful lives is from 3 years to 60 years for buildings and from 2 years to 17 years for equipment.

#### (f) Pension and Retirement Benefits

Employees who terminate employment are entitled, under most circumstances, to lump-sum payments or pension payments as described below, determined by reference to current basic rate of pay, length of service and conditions under which the termination occurs. The minimum payment is an amount based on voluntary retirement. In addition to the minimum payment based on voluntary retirement, employees receive additional benefits for retirement due to age limit, death or other defined reasons. The Company has a non-contributory defined benefit funded pension plan (entrusted) which covers 30% of the benefits payable under the existing retirement plan to employees.

The accrued pension and severance costs represents the amount actuarially calculated projected benefit obligations less (1) the fair value of the plan assets (2) unrecognized actuarial loss or gain and (3) the unrecognized transition amount arising from adopting the new standard. If the fair value of the plan assets exceeds the projected benefit obligations, prepaid pension and severance costs are recorded. The transition amount (unfunded and unrecognized benefit obligation) of ¥7,902 million at April 1, 2000 is amortized on a straight-line basis over 15 years (for subsidiaries mainly 10 years). Unrecognized actuarial loss or gain is amortized on a straight-line basis over 10 years from the next year in which they arise. For the Company, prepaid pension and severance costs were recognized for a portion of the plan covered by the non-contributory pension plan assets and the accrued pension and severance costs were recognized for a portion of the plan not covered by the plan assets.

Accrued retirement benefits to directors and statutory auditors is provided in an amount equivalent to the liability the relevant company would have been required to pay upon retirement at the balance sheet date, as prescribed by its internal rules.

#### (g) Income Taxes

Income taxes are determined using the asset and liability approach, where deferred tax assets and liabilities are recognized for temporary differences between the tax basis of assets and liabilities and their reported amount in the financial statements.

#### (h) Consumption Taxes

Consumption taxes have been excluded from amounts shown on the accompanying consolidated statements of income.

#### (i) Research and Development Expenses

Previously significant research and development expenses for new products and new technologies had been capitalized and amortized over five years on the straight-line basis.

However, on April 1, 1999, a new accounting standard for Research and Development expenses (the "R&D expenses") was adopted. Under the new standard, R&D expenses are charged to income as incurred, while the capitalized amounts at March 31, 1999 are amortized over the remaining period.

#### (j) Hedge Accounting

#### Derivative financial instruments

With regard to interest rate swap and foreign exchange forward contracts, the Company uses an accrual method based on the short-cut method assuming that there is no ineffectiveness in the hedging relationship between hedged items and hedging instruments. Fair value and unrealized gains/losses of derivative transactions are not required to be presented for the years ended March 31, 2002 and 2001, contractual values or notional amounts.

Derivative financial instruments have not been implemented by consolidated subsidiaries.

#### (k) Bond Issue Costs

Bond issue costs are capitalized and amortized over three years on the straight-line basis.

#### (1) Legal Reserves

#### Additional paid-in capital

Additional paid-in capital, recorded pursuant to the Japanese Commercial Code, primarily consists of proceeds on issuance of shares of common stock of the Company that were not recorded as "common stock". Additional paid-in capital may be transferred to other additional paid-in capital to the extent that the sum of additional paid-in capital and earned reserve (collectively, "legal reserves") does not fall below 25% of capital amount. However, additional paid-in capital may not transferred to retained earnings.

#### Earned reserve

The Japanese Commercial Code requires all companies to appropriate as an earned reserve an amount equivalent to at least 10% of cash payments for appropriation of retained earnings until the legal reserves equals 25% of stated capital. Earned reserve may be transferred to unappropriated retained earnings to the extent that the legal reserves do not fall below 25% of capital amount.

Legal reserves may be transferred to capital through suitable directors' actions or offset against deficit through suitable share-holders' actions.

#### (m) Net Income and Dividends per Share

Net income per share of common stock is based upon the weighted average number of shares of common stock outstanding during each financial year appropriately adjusted for subsequent free distribution of shares (stock splits), if applicable.

Cash dividends per share shown for each year in the accompanying consolidated statements of income represent dividends approved or declared as applicable to the respective years.

Fully-diluted net income per share is computed, based on the assumption that the convertible bonds were fully converted into common stock on the date of issue or at the beginning of the respective years subsequent to the issue, with appropriate adjustments of related interest expense (net of tax).

#### 3. United States Dollar Amounts:

The Group maintains its accounting records in yen. The dollar amounts included in the consolidated financial statements and notes thereto represent the arithmetical results of translating yen to dollars on the basis of \$133 = U.S.\$1. The inclusion of such

dollar amounts is solely for convenience and is not intended to imply that yen amounts have been or could be converted, realized or settled in dollars at \$133 = U.S.\$1 or any other rate.

#### 4. Cash and Cash Equivalents:

Cash on hand and at banks and marketable securities are reconciled to cash and cash equivalents of consolidated statements of cash flows as follows:

	Millions of yen		Thousands of U.S. dollars (Note 3)
	2002	2001	2002
Cash on hand and at banks	¥14,439	¥19,884	\$108,564
Marketable securities	2,191	4,285	16,474
	16,630	24,169	125,038
Time deposits which fall due in more than three months	(70)	(78)	(527)
Marketable securities due in more than three months	(150)	(150)	(1,128)
	(220)	(228)	(1,655)
Cash and cash equivalents	¥16,410	¥23,941	\$123,383

#### 5. Marketable Securities and Investment Securities:

#### For the year ended March 31, 2001

Securities classified as "Other securities" and those whose fair value are readily determinable are carried at cost as of March 31, 2001. Information for those securities is as follows:

	Millions of yen
Carrying amount in the balance sheet	¥6,337
Fair value	5,844
Unrecognized loss, net of tax	286
Deferred tax assets	207

#### For the year ended March 31, 2002

	Millions of yen				
	Cost	Market value	Unrealized gain (loss)		
Other securities:					
Market value available					
Equity securities	¥3,911	¥3,499	¥(412)		
Other securities	228	195	(33)		
	4,139	3,694	(445)		
Market value not available	2,989	2,989			
Total	¥7,128	¥6,683	¥(445)		
Held-to-maturity debt securities:  Market value not available	¥ 150	¥ 150	¥ —		

	Thousands of U.S.dollars (Note 3)		
	Cost	Market value	Unrealized gain (loss)
Other securities:			
Market value available			
Equity securities\$	29,406	\$26,308	\$(3,098)
Other securities	1,714	1,466	(248)
	31,120	27,774	(3,346)
Market value not available	22,474	22,474	` <u> </u>
Total <u>\$</u>	53,594	\$50,248	\$(3,346)
Held-to-maturity debt securities:			
Market value not available <u>\$</u>	1,128	\$ 1,128	<u>\$</u>

## Other securities sold during the fiscal years ended March 31, 2002 and 2001

	Millions of yen		Thousands of U.S.dollars (Note 3)
	2002	2001	2002
Proceeds from sales	¥ 67	¥—	\$ 504
Gross realized gains	_	_	_
Gross realized losses	304	_	2,286

#### Write down of investments in securities

During the year ended March 31, 2002, certain equity securities with market quotations were written down by ¥1,882 million. The Company writes down the book value of equity securities when the market value declines by more than 50%, or the market value declines approximately by more than 30% but less than 50% and the Company's management determines the decline to be other temporary.

#### 6. Inventories:

Inventories as of March 31, 2002 and 2001 are comprised of the following:

		s of yen	U.S. dollars (Note 3)	
March 31	2002	2001	2002	
Finished products	¥4,884	¥5,362	\$36,722	
Work in process	1,770	1,769	13,308	
Raw materials	2,464	805	18,526	
Supplies	481	439	3,617	
Raw materials in transit	<u>197</u>	147	1,481	
	¥9,796	¥8,522	<u>\$73,654</u>	

#### 7. Short-term Bank Loans and Long-term Debts:

Short-term bank loans outstanding as of March 31, 2002 and 2001 are represented by the notes issued by the Group to banks. Customarily, these notes are renewed at maturity subject to renegotiation of interest rates and other factors. The weighted-average

interest rates applicable to short-term bank loans as of March 31, 2002 and 2001 are 0.89% and 1.13%, respectively. Outstanding balance of short-term bank loans as of March 31, 2002 and 2001 were ¥6,204 million and ¥6,409 million, respectively.

Long-term debts as of March 31, 2002 and 2001 consisted of the following:

	Million	s of yen	Thousands of U.S. dollars (Note 3)
March 31	2002	2001	2002
Loans from banks and other financial institutions due 2002 to 2007	¥ 2,670	¥ 4,169	\$ 20,075
2.7% unsecured convertible bond due 2002 (a)	_	6,256	_
1.0% unsecured convertible bond due 2003 (b)	18,491	18,491	139,030
0.0% unsecured convertible bond due 2007 (c)	7,849	10,000	59,015
Other long-term debt with interest bearing due 2002 to 2033	9,326	9,503	70,121
	38,336	48,419	288,241
Less: current portion	(19,167)	(6,602)	_(144,113)
	¥ 19,169	¥41,817	<u>\$ 144,128</u>

- a) 2.7% Unsecured convertible bond Holders of this bond are entitled to convert these bonds into common stock (par value of ¥50) at a price of ¥1,357.10 during the period from April 1, 1993 to March 28, 2002.
- b) 1.0% Unsecured convertible bond Holders of this bond are entitled to convert these bonds into common stock (par value of ¥50) at a price of ¥1,610 during the period from April 1, 1994 to March 28, 2003.
- c) 0.0% Unsecured convertible bond Holders of this bond are entitled to convert these bonds into common stock (par value of ¥50) at a price of ¥791 during the period from August 9, 2000 to September 14, 2007.

Aggregate annual maturities of convertible bonds in the next five fiscal year are as follows:

	Millions of yen	Thousands of U.S. dollars (Note 3)
Within one year	¥18,491	\$139,030
Over one year less than two years	_	_
Over two years less than five years	_	_
More than five years and thereafter	7,849	59,015
	¥26,340	\$198,045

Aggregate annual maturities of long-term bank loans and other interest bearing debt are as follows:

_	Millions of yen			sands of ars (Note 3)
	Long-term bank loans	Other interest bearing debt	Long-term bank loans	Other interest bearing debt
Within one year	¥ 493	¥ 183	\$ 3,707	\$ 1,376
Over one year less than two years	1,488	188	11,188	1,414
Over two years less than three years	689	194	5,180	1,459
Over three years less than four years	0	200	0	1,504
Over four years less than five years	_	207	_	1,556
More than five years and thereafter	<u> </u>	8,354 ¥9,326	<u> </u>	62,812 \$70,121

As is customary in Japan, short-term and long-term bank loans are made under general agreements which provide that security and guarantees for future and present indebtedness will be given upon request of the bank, and that the bank shall have the right, as the obligations become due or in the event of their default, to offset cash deposits against such obligations due to the bank. The Group has not received any such requests to date.

At March 31, 2002 and 2001, assets pledged as collateral for certain short-term (\$1,410 million) and long-term debts (\$10,654 million), including current portion of long-term debts, were as follows:

	Million	Thousands of U.S.dollars (Note 3)	
March 31	2002	2001	2002
Assets pledged			
Buildings and structures	¥11,139	¥13,962	\$ 83,752
Machinery and equipment	2,117	2,326	15,917
Land	108	108	812
Investment securities	1,411	2,048	10,609
	¥14,775	¥18,444	\$111,090
Liabilities and secured			
Short-term bank loans	¥ 1,410	¥ 1,410	\$ 10,602
Long-term bank loans	1,328	2,816	9,985
Other interest bearing debt	9,326	9,503	70,120
	¥12,064	¥13,729	\$ 90,707

Under the terms of the agreement for the 2.7% convertible bonds due 2002, the cumulative amount of cash dividends may not exceed ¥400 million (\$3,008 thousand) plus the aggregate amount of ordinary income after income taxes (as defined in the agreement) of the Company beginning with the fiscal year ended March 31, 1993. Under the terms of the agreement for the 1.0% convertible bond due 2003, the cumulative dividends may not exceed ¥700 million (\$5,263 thousand) plus the aggregate amount of ordinary income after income taxes of the Company beginning with the fiscal year ended March 31, 1994.

#### 8. Accounting for Leases:

Leases that transfer substantially all the risks and rewards of ownership of the assets are accounted for as capital leases, however, leases that do not transfer ownership of the assets at the end of the lease term are accounted for as operating leases, in accordance with accounting principles and practices generally accepted in Japan.

Assumed data "as if capitalized" as to acquisition cost, accumulated depreciation, net book value and depreciation expense of the leased assets, which included the portion of interest thereon, were summarized as follows:

	Million	s of yen	Thousands of U.S.dollars (Note 3)
March 31	2002	2001	2002
Acquisition cost	¥15	¥15	\$113
Accumulated depreciation	6	4	45
Net book value	¥ 9	¥11	\$ 68
Depreciation	<u>¥ 2</u>	¥ 2	<u>\$ 15</u>

Depreciation is computed on the straight-line method over the lease term of the leased assets with no residual value.

Periodic lease expenses on finance lease contracts without ownership-transfer for the years ended March 31, 2002 and 2001 were summarized as follows:

	Millions of yen		Thousands of U.S.dollars (Note 3)
	2002	2001	2002
Periodic lease expense	¥2	¥2	<u>\$15</u>

The amount of outstanding future lease payments due at March 31, 2002 and 2001, which included the portion of interest thereon, was summarized as follows:

	Million	Thousands of U.S.dollars (Note 3)	
March 31	2002	2001	2002
Within one year	¥ 1	¥ 2	\$ 8
Over one year	9	_10	67
	¥10	¥12	<u>\$75</u>

#### 9. Derivative Financial Instruments:

Derivative financial instruments are utilized by the Company principally to reduce interest rate and foreign exchange rate risks. The Company has established a control environment which includes policies and procedures for risk assessments and for the approval, reporting and monitoring of transactions involving derivative financial instruments. The Company does not hold or issue derivative financial instruments for speculative purposes.

The Company is exposed to certain market risks arising from its forward exchange contracts and interest rate swap agreements. The Company is also exposed to the risk of credit loss in the event of non-performance by the counterparties to the currency and interest rate derivatives; however, the Company does not anticipate nonperformance by any of these counterparties all of whom are financial institutions with high bond ratings.

#### 10. Pension and Retirement Benefits:

The benefit obligation and plan assets, funded status and composition of amounts recorded in the consolidated balance sheet as of March 31, 2002 and 2001 is as follows:

	Millions	Millions of yen		
March 31	2002	2001	2002	
Projected benefit obligations	¥(22,561)	¥(21,441)	\$(169,632)	
Plan assets	8,048	7,980	60,511	
Funded status	(14,513)	(13,461)	(109,121)	
Unrecognized transition				
amount	6,844	7,372	51,459	
Unrecognized actuarial loss	1,763	467	13,256	
	(5,906)	(5,622)	(44,406)	
Amounts recognized in the				
balance sheet consists of —				
Prepaid pension cost	256	158	1,925	
Accrued pension and				
severance costs	¥ (6,162)	¥ (5,780)	<u>\$ (46,331)</u>	

The components of net pension and severance costs for the years ended March 31, 2002 and 2001 were as follows:

	Millions	Thousands of U.S.dollars (Note 3)	
	2002	2001	2002
Service cost	¥ 747	¥ 740	\$ 5,617
Interest cost	749	742	5,631
Expected return on plan assets	(199)	(203)	(1,496)
Amortization of transition amount	528	530	3,970
Actuarial loss	46		346
Net pension expense	¥1,871	¥1,809	\$14,068

Assumptions used in calculation of the above information as of March 31, 2002 were as follows:

Discount rate	2.8%
Expected rate of return on plan assets	1.5%
Method of attributing the projected	
benefits to periods of services	years of service

#### 11. Shareholders' Equity:

The following appropriations of the Company's retained earnings in respect of the year ended March 31, 2002 which were approved by the shareholders at the general meeting held on June 27, 2002, have not been incorporated in the accompanying consolidated financial statements.

	Millions of yen	Thousands of U.S.dollars (Note 3)
Retained earnings at the end of the year	¥6,032	\$45,354
Utilization of reserve		
Utilization of deferred gain on sales		
of property, plant and equipment	18	135
	6,050	45,489
Appropriations:		
Dividends (¥3.75 per share)	(354)	(2,662)
Bonuses to directors	(40)	(301)
[of which to statutory auditors]	[4]	[30]
Transfer to reserve:		
Deferred gain on sales of		
property, plant and equipment	(63)	(474)
Others reserves	(600)	(4,511)
Retained earnings carried forward to		
the following year	¥4,993	\$37,541

#### 12. Selling, General and Administrative Expenses:

Major elements of "Selling, general and administrative expenses" for two years in the period ended March 31, 2002 and 2001 are as follows:

	Millions of yen		Thousands of U.S. dollars (Note 3)	
	2002	2001	2002	
Salaries	¥6,926	¥6,934	\$52,075	
Bonuses	2,980	3,303	22,406	
Pension and severance costs	992	955	7,459	
Provision for retirement benefits to directors	75	79	564	
Research and development expenses	5,253	4,977	39,496	
Sales promotion	1,828	1,722	13,744	
Advertisement	651	571	4,895	
Rent and lease	1,731	1,734	13,015	
Travel	1,465	1,449	11,015	

#### 13. Income Taxes:

The Group is subject to several taxes based on income, which in the aggregate resulted in statutory tax rates of approximately 42.05% for the two years in the period ended March 31, 2002. Reconciliation of the differences between the statutory tax rate and the effective tax rate and the effective tax rate for the years ended March 31, 2002 and 2001 are as follows:

	2002	2001
Statutory tax rate	42.05%	42.05%
Increase (decrease) in taxes resulting from:		
Expenses not deductible for income tax		
purpose (ex. Entertainment expenses)	14.36	12.75
Income not included for income tax		
purpose (ex. Dividend income)	(0.30)	(0.28)
Inhabitant equalization taxes	1.86	1.78
Other	(0.09)	(0.33)
Effective tax rate	57.88%	55.97%

Significant components of deferred tax assets as of March 31, 2002 and 2001 are as follows:

		ns of yen	Thousands of U.S. dollars (Note 3)	
March 31	2002	2001	2002	
Deferred tax assets:				
Non-deductible portion of reserve for bonuses	¥ 475	¥ 475	\$ 3,571	
Provision for reserve for sales rebates	198	202	1,489	
Enterprise taxes payable	133	213	1,000	
Devaluation of financial instruments	1,069	285	8,038	
Amortization of R&D	56	98	421	
Amortization of long-term prepaid expenses	997	973	7,496	
Pension and severance costs	1,015	710	7,632	
Provision for retirement benefits to directors	210	215	1,579	
Non-deductible portion of allowance for bad debt	87	79	654	
Unrealized gain of property, plant and equipment	2,568	2,568	19,308	
Unrealized loss on other securities	187	_	1,406	
Other	62	28	466	
Total deferred tax assets	<del></del>	53,060		
Deferred tax liabilities:				
Deferred gain on sales of property, plant and equipment	(519)	(540)	(3,902)	
Other	0	0	0	
Total deferred tax liabilities	(519)	(540)	(3,902)	
Deferred tax assets, net	¥6,538	¥5,306	\$49,158	

#### 14. Commitments and Contingencies:

The Group had contingent liabilities arising from notes discounted at banks in the ordinary course of business in the amount of \$2,157 million as of March 31, 2002.

In addition, the Company was contingently liable for the guarantee of loans borrowed by N  $\cdot$  K Curex Co., Ltd., an affiliate, in the amount of \$2,800 million as of March 31, 2002.

#### 15. Segment Information:

Information about operations in industry segments of the Group for years ended March 31, 2002 and 2001 is as follows:

1 , 0	Millions of yen				
	2002				
	Pharmaceutical	Other*	Total	Eliminations or Corporate	Consolidated
I. Sales and Operating Income Sales to customers Inter-segment/transfer	¥70,268  70,268	¥ 3,004 <u>594</u> 3,598	¥73,272 594 73,866	¥ — (594) (594)	¥ 73,272 
Operating expenses  Operating income	63,766 ¥ 6,502	2,375 ¥ 1,223	66,141 ¥ 7,725	<u>(594)</u> ¥ <u>—</u>	65,547 ¥ 7,725
Capital Expenditures Assets Depreciation Capital Expenditures	¥ 2,913 ¥ 3,649	¥20,899 ¥ 866 ¥ 58	¥89,627 ¥ 3,779 ¥ 3,707	¥24,498 ¥ — ¥ —	¥114,125 ¥ 3,779 ¥ 3,707
			2001		
	Pharmaceutical	Other*	Total	Eliminations or Corporate	Consolidated
I. Sales and Operating Income Sales to customers Inter-segment/transfer	¥67,272 ——————————————————————————————————	¥ 3,034 892 3,926	¥70,306 892 71,198	¥ — (892) (892)	¥ 70,306 ——— 70,306
Operating expenses  Operating income	61,943 ¥ 5,329	2,450 ¥ 1,476	64,393 ¥ 6,805	(892) ¥ —	63,501 ¥ 6,805
Capital Expenditures Assets Depreciation Capital Expenditures	¥68,325 ¥ 2,697 ¥ 1,465	¥22,290 ¥ 927 ¥ 151	¥90,615 ¥ 3,624 ¥ 1,616	¥31,188 ¥ — ¥ —	¥121,803 ¥ 3,624 ¥ 1,616
	Thousands of U.S. dollars (Note 3)				
	2002				
	Pharmaceutical	Other*	Total	Eliminations or Corporate	Consolidated
I. Sales and Operating Income Sales to customers Inter-segment/transfer	\$528,331 — 528,331	\$ 22,586 4,466 27,052	\$550,917 <u>4,466</u> 555,383	\$ — (4,466) (4,466)	\$550,917 — 550,917
Operating expenses  Operating income	479,443	17,857 \$ 9,195	497,300 \$ 58,083	(4,466) \$ —	492,834 \$ 58,083
Capital Expenditures Assets Depreciation Capital Expenditures	\$516,752 \$ 21,902 \$ 27,436	\$157,135 \$ 6,512 \$ 436	\$673,887 \$ 28,414 \$ 27,872	\$184,196 <u>\$</u> — <u>\$</u> —	\$858,083 \$ 28,414 \$ 27,872

<sup>\*</sup>Other business fields consist of mainly real estate.

## Report of Independent Accountants

To the Board of Directors KAKEN PHARMACEUTICAL CO., LTD.

We have audited the accompanying consolidated balance sheets of KAKEN PHARMACEUTICAL CO., LTD. and its consolidated subsidiaries (collectively, the "Group") as of March 31, 2002 and 2001 and the related consolidated statements of income, shareholders' equity and cash flows for the years ended, all expressed in Japanese yen. Our audits were made in accordance with auditing standards, procedures and practices generally accepted and applied in Japan and, accordingly, included such tests of accounting records and such other auditing procedures as we considered necessary in the circumstances.

In our opinion, the accompanying consolidated financial statements referred to above present fairly the consolidated financial position of the Group as of March 31, 2002 and 2001 and the consolidated results of their operations and their cash flows for the years ended in conformity with accounting principles and practices generally accepted in Japan (See Note 1).

As described in Note 2 to the consolidated financial statements, the Group adopted new Japanese accounting standards for valuation of other securities in the year ended March 31, 2002.

The amounts expressed in U.S. dollars, which are provided solely for the convenience of the reader have been translated on the basis set forth in Note 3 to the accompanying consolidated financial statements.

ChuoAoyama Audit Corporation

Chus Aryania Audit Corporation

Hijiribashi Audit Corporation

Higiribashi Audit Corporation

Tokyo, Japan June 27, 2002

### Corporate Data (As of March 31, 2002)

REGISTERED HEAD OFFICE

28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan Tel: 81-3-5977-5002 Fax: 81-3-5977-5131

Founded

Incorporated
March 1948

Paid-in Capital

Common Stock

Issued: 94,518,374 shares (As of Sept. 30, 2002) Number of Shareholders: 23,470 Administration: 132 Sales & Marketing: 969 Production & Technology: 278 Research & Development: 276

Global Business Development 2-28-8, Hon-Komagome, Bunkyo-ku, Tokyo 113-8650, Japan

Director & General Manager Masao Ishida

Masao Ishida Tel: 81-3-5977-5046 Fax: 81-3-5977-5133

E-mail: masao-ishida@kaken.co.jj

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Fukuoka Branch

Plant

Shizuoka Factory

Research Laboratories

Shizuoka Research Laboratories Kyoto Research Laboratories Production Technology Laboratories

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## Board of Directors and Corporate Auditors

Chairman and Representative Director

Yoshiharu Wakiyama

President and Representative Director

Shiro Inui

Executive Managing Director

Susumu Yamazaki

(Agrochemicals and Animal Health Products)

Executive Managing Director

(Research and Development)

Executive Managing Director

Noriaki Ohsono (Accounting)

Executive Managing Director

Osamu Okamoto

(Regulatory and Licensing)

Executive Director
Nobuo Nunomura
(Production)

Executive Director
Tametsugu Watatani
(Marketing)

Executive Director Takeshi Hirahara

(Corporate Planning and Coordination)

Executive Director
Yoshinori Kambayashi
(Research and Development)

Executive Director Yutaka Handa (Personnel)

Executive Director Takeji Saito

(Marketing and Sales

Auditor
Ichiro Aota
(Standing)

Auditor Satoshi Shoj (Standing)

Auditor

Nobukazu Sakai

Auditor

Sumio Yoshizawa





#### Kaken Pharmaceutical Co., Ltd.

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