

(3) Results of Operations and Financial Position

1. Summary of Annual Results

1) Overview of Results

The slow-down in growth of the U.S. market, which accounts for almost 50 percent of the total ethical pharmaceutical market in the world, has continued due to the promotion of less expensive generic drug use and the increasing pressure for price reduction in branded products as a result of strong requests by the federal and state governments and Managed Care, together with the impact of prescription-to-OTC switch drugs. Especially in the peptic ulcer therapeutic area, one of Takeda's main franchises, the market for branded products has shown little growth due to the increasing penetration of generic drugs and RX-to-OTC switches. Medicare Part D (prescription drug benefits for outpatients under the federal insurance plan for the elderly), started in the U.S. in January 2006, is expected to bring quantitative expansion of the market in the short term. However, we cannot be very sure about the future as it is very likely that demand for price reduction will become stronger.

In Japan, upon the revision of NHI drug prices by the government for fiscal 2006, the additional price reduction for branded products, in case its generic versions are available, was implemented, in addition to the regular reduction of NHI drug prices. The use of generic drugs has also been promoted. In these situations, we expect that the growth rate of the market in Japan will remain low in fiscal 2006. Competition has also become keener for Takeda's two mainstay products for treatment of peptic ulcer and for diabetes respectively, because of launch of generic versions in July 2005.

Market growth is moderate in the European market due to similar factors including the reduction of drug prices, promotion of generic drug use and the continued expansion of parallel imports.

With the slowdown of the major markets in the world as explained above, corporate mergers by pharmaceutical companies are continuing, aiming to expand their scale to cover the increasing R&D costs. Accordingly, competition among companies is becoming fiercer.

Under these circumstances, consolidated results for the year ending March 31, 2006 were as follows:

(Billions of yen)		
		<u>Year-on-year change</u>
Net sales	¥1,212.2	¥89.2 (7.9%) increase
Operating income	¥402.8	¥17.5 (4.6%) increase
Ordinary income	¥485.4	¥43.2 (9.8%) increase
Net income	¥313.2	¥35.8 (12.9%) increase

[Consolidated net sales]

Consolidated net sales increased by ¥89.2 billion (7.9%) from the previous year to ¥1,212.2 billion.

- The increase in net sales was supported by the sales growth of in-house ethical drugs, which more than offset the decrease in sales resulting from the transfer of subsidiaries' and affiliated companies' stocks in the Life-Environment business in April 2005. Sales of ethical drugs increased from the previous year in all three markets of Japan, the U.S. and Europe.
- As for the movement in exchange rates, the yen was weaker against both the U.S. dollar and the euro, compared with the previous year. The net effect of these exchange rate fluctuations increased our consolidated net sales by 17.2 billion yen from the last year.
- The table below shows consolidated sales of international strategic products:

(Billions of yen)

Drug for prostate cancer and endometriosis treatment <i>Leuprorelin</i> (Domestic product name: <i>Leuplin</i>)	¥122.4	¥6.4 (5.5%) increase from the previous year
Drug for peptic ulcer treatment <i>Lansoprazole</i> (Domestic product name: <i>Takepron</i>)	¥159.9	¥0.1 billion (0.1%) decrease
Drug for hypertension treatment <i>Candesartan</i> (Domestic product name: <i>Blopress</i>)	¥191.3	¥38.9 (25.5%) increase
Drug for diabetic treatment <i>Pioglitazone</i> (Product name: <i>Actos</i>)	¥243.8	¥50.8 (26.3%) increase

[Gross profit]

Gross profit increased ¥86.3 billion (10.2%) from the previous year to ¥930.1 billion.

- The gross profit margin ratio improved 1.6 points to 76.7%, supported by an increase in sales of in-house ethical drugs that have high gross profit ratios, and the impact of the exclusion from the consolidated results of sales of Life-Environment Business products that have a lower gross profit ratio.

[Operating income]

Operating income increased ¥17.5 billion (4.6%) from the previous year to ¥402.8 billion.

- Operating income increased due to the increase in gross profit, which was partially offset by the increase in selling, general and administrative expenses by ¥68.8 billion from the previous year to ¥527.3 billion.
- R&D expenses included in these selling, general and administrative expenses increased by ¥28.2 billion to ¥169.6 billion, mainly due to increased cost resulting from the progress of development projects, promotion of in-licensing and alliance activities, and R&D expenditures in Takeda San Diego, Inc. (hereinafter "TSD"), a consolidated subsidiary acquired in March 2005.
- Selling, general and administrative expenses excluding R&D expenses also increased from the previous year due to the increased expenses incurred by Takeda Pharmaceuticals North America, Inc. (hereinafter "TPNA") for launching preparation of ROZEREM (a drug for treatment of insomnia), *ACTOplus Met* (a drug for Type II diabetes, a fixed combination of *Actos* and *metformin*) and *AMITIZA* (a drug for chronic idiopathic constipation).

[Ordinary income]

Ordinary income increased 43.2 billion (9.8%) from the previous year to ¥485.4 billion.

- In addition to the increase in the operating income, net non-operating income increased by ¥25.7 billion yen to ¥82.5 billion yen, which contributed to the increase in ordinary income.
- Equity in earnings of affiliated companies, which was reported in the non-operating income category, increased ¥8.8 billion (19.3%) to 54.2 billion, supported by the increase of profit in TAP Pharmaceutical Products Inc. (hereinafter “TAP”), a US affiliated company, which increased by ¥11.8 billion (29.4%) to ¥52.1 billion.
- Other net non-operating income increased ¥17.0 billion compared to the previous year, mainly due to the increase in interest income received by Takeda America Holdings, Inc. (hereinafter “TAH”), a U.S subsidiary of the Company.

[Consolidated net income]

Consolidated net income increased ¥35.8 billion (12.9%) from the previous year to ¥313.2 billion.

- In addition to the increase in the ordinary income, the extraordinary income recorded ¥32.6 billion (an increase by ¥33.6 billion from the previous year when the net of extraordinary income/expenses was negative) also contributed to the increase in the net income.
- Extraordinary income includes a gain from discontinuance of the handling of retirement annuities (employee pension fund) for the Company’s employees on behalf of the government, a gain from the transfer of stocks of subsidiaries and affiliated companies engaged in the Life Environment business, and a gain from the partial transfer of stocks of Wyeth K.K. and Takeda-Kirin Foods Corporation.
- Earnings per share increased ¥40.46 to ¥353.47.

2) Cash Flow

Cash flow for the current year resulted in a net surplus of ¥361.9 billion.

Cash flow increased by ¥197.4 billion from the previous year due to the increase in net income before tax adjustments, and a gain from the transfer of stocks of subsidiaries and affiliated companies engaged in the Life Environment business, and a gain from the partial transfer of stocks of Wyeth K.K. and Takeda-Kirin Foods Corporation. Investment in property, plant and equipment totaled ¥32.6 billion, including the construction of the new head office building of TPNA.

As a result, cash and cash equivalents (marketable securities and time deposits that mature or are redeemable within 3 months of the date of acquisition) as of March 31, 2006 totaled ¥1,626.2 billion.

Historical cash flow indicators are as shown below.

	Year ended 3/31/02	Year ended 3/31/03	Year ended 3/31/04	Year ended 3/31/05	Year ended 3/31/06
Shareholders’ equity ratio	72.3%	76.1%	76.3%	78.6%	77.2%
Shareholders’ equity ratio on market value basis	235.2%	190.4%	175.9%	177.7%	195.2%
Debt repayment term (years)	0.03	0.02	0.02	0.03	0.02
Interest coverage ratio	429.3	975.8	1,297.5	1,451.6	1,466.1

Notes:

Shareholders’ equity ratio: Shareholders’ equity/Total assets

Shareholders’ equity ratio on market value basis : Market capitalization/Total assets

Debt repayment term: Interest-bearing debt/Operating cash flow

Interest coverage ratio: Operating cash flow/interest expenses

* Each indicator is calculated based on consolidated financial results.

* Market capitalization is calculated by multiplying the closing price at the term-end by the number of outstanding shares at the term-end (excluding treasury stocks).

* Operating cash flow is net cash provided by operating activities reported on the consolidated statement of cash flow, less interest expense and income taxes paid. Interest-bearing debt includes all liabilities reported on the consolidated balance sheet on which interest is paid. For interest payments, the amount of interest payment reported on the consolidated statement of cash flow is used.

3) Dividend

Takeda plans to pay a year-end dividend of ¥53.00 per share. This, together with the interim dividend of ¥53.00 already paid, will achieve an annual dividend of ¥106.00 for the year ended March 31, 2006 (consolidated payout ratio of 30.0%), an increase by ¥18.00 yen from the previous year.

4) Results by Segment

(1) Business Segment

The following table shows sales and operating income of each business segment:

(Billions of yen)

Type of business	Net sales		Operating income	
	Amount	Year-on-year change	Amount	Year-on-year change
Pharmaceuticals Segment	¥1,074.5	¥104.0 increase	¥388.1	¥10.4 increase
Ethical Drugs	¥1,019.1	¥104.3 increase		
(Domestic)	(¥493.5)	(¥41.6 increase)		
(Overseas)	(¥525.6)	(¥62.7 increase)		
Consumer Healthcare	¥55.4	¥0.2 decrease		
Other Segment	¥137.7	¥14.8 decrease	¥14.7	¥7.1 increase
Total	¥1,212.2	¥89.2 increase	¥402.8	¥17.5 increase

(Note) From the current year, handling of the portion of costs and expenses not allocatable to specific business segments, which previously included in “Eliminations/Corporate” category, was changed. (For details, refer to 1. Business Segment Information (Note 3*)[10. Segment Information] in Page 30.

In response to this change, figures for the previous year are restated according to the new method.

Sales figures for each segment refer to sales to outside customers.

[Pharmaceuticals Segment]

Consolidated net sales by the Pharmaceuticals segment increased by ¥104.0 billion (10.7%) to ¥1,074.5 billion. Operating income increased by ¥10.4 billion (2.8%) to ¥388.1 billion.

- Sales by the Ethical Drugs business increased by ¥104.3 billion (11.4%) to ¥1,019.1 billion. Sales in the Japanese market increased by ¥41.6 billion (9.2%) to ¥493.5 billion, including the following major products:

(Billions of yen)

<i>Blopress</i>	¥123.4	¥19.9 (19.2%) increase
<i>Actos</i>	¥24.2	¥8.7(56.6%) increase
<i>Takepron</i>	¥55.0	¥7.6(16.0%) increase
<i>Leuplin</i>	¥63.2	¥3.5(5.9%) increase
<i>Basen</i> (Improving agent for postprandial hyperglycemia in diabetes mellitus)	¥63.6	¥2.1(3.4%) increase

- Sales of ethical drugs overseas increased by ¥62.7 billion (13.5%) to ¥525.6 billion, partly due to favorable impact by the weaker yen.

Although royalty income from TAP decreased, sales of *Actos* increased by US\$254 million to US\$1,783 million, supported by *ACTOplus Met*, launched in November 2005 by TPNA. Sales of ROZEREM, launched in September 2005, totaled US\$26 million. In April 2006, *AMITIZA* was launched.

In Europe, sales of *Actos* and *Leuprorelin* increased.

- Sales by the *Consumer Healthcare* business decreased by ¥0.2 billion (0.4%) to ¥55.4 billion. While sales of *Nicorette* increased due to the impact of the launch of *Nicorette Cool Mint* in December 2005 and sales of *Actage AN* tablets also increased, sales declines were recorded in the product categories of *Alinamin* tablets, *Alinamin* drinks, and *Hicee*.

[Other Segment]

Sales by Other segment decreased by ¥14.8 billion (9.7%) from the previous year to ¥137.7 billion. Operating income increased by ¥7.1 billion (93.7%) to ¥14.7 billion.

- The sharp decline in sales was due to exclusion from the consolidation of product sales by subsidiaries and affiliated companies engaged in the Life Environment business as a result of the transfer of their stocks in April 2005.

In April 2006, the beverage and food business of Takeda Food Products, Ltd., a Takeda subsidiary, was transferred to House Wellness Foods Corporation, Ltd., a joint venture between Takeda and House Foods Corp. As a result of this transfer, sales from the foods and beverage business of Takeda Food Products, Ltd. will be excluded from the consolidated financial report of the Company in fiscal 2006. (In connection with this transaction, it is expected that a gain from transfer of business about ¥19 billion will be recorded in fiscal 2006.)

(2) Geographical Segments

The following table shows sales and operating income of each geographical segment:

(Billions of yen)

Geographical segment	Net sales		Operating income	
	Amount	Year-on-year change	Amount	Year-on-year change
Japan	¥963.4	¥46.1 increase	¥517.3	¥55.8 increase
North America	¥216.3	¥44.8 increase	¥32.6	¥11.8 decrease
Europe	¥124.0	¥15.5 increase	¥24.6	¥6.9 increase
Asia	¥8.5	¥0.5 increase	¥1.6	¥0.2 increase
Elimination/Corporate	(¥100.0)	¥17.7 decrease	(¥173.3)	¥33.6 decrease
Total	¥1,212.2	¥89.2 increase	¥402.8	¥17.5 increase

(Note) From the current year, geographical segments, which were formerly classified as “Japan,” “North America” and “Europe and Asia,” are divided into the four regions of “Japan,” “North America,” “Europe” and “Asia.”

From the current year, handling of the portion of costs and expenses not allocatable to specific business segments, which was previously included in the “Eliminations/Corporate” category, was changed. (For details, refer to 2. Geographical Segment Information (Note 2*) of [10. Segment Information] in Page 31.)

In response to this change, figures in the previous year are restated according to the new method. In accordance with rules for consolidated financial statements, equity in earnings of affiliates is recorded as non-operating income.

5) Research & Development

Aiming at expanding our R&D pipelines that serve as resources for growth and launching new products in the market more quickly, Takeda intensively invests its business resources in the four core therapeutic areas of lifestyle-related disease; cancer and urological disease (including gynecology); central-nervous system diseases (including bone and joint diseases); and life-cycle management of gastroenterology diseases, through the three strategic pillars of in-house research and development, maximization of added value of products, and in-licensing and alliances activities. Major results of R&D activities during the current year are:

[In-house R&D]

- In July 2005, an approval for marketing was granted by the Food and Drug Administration (FDA) in the U.S. for ROZEREM, a drug for treatment of insomnia and the first in-house product of Takeda following on after Actos. It was launched by TPNA in September 2005.
- In July 2005, Takeda acquired from Pharmaceutical Product Development, Inc. (PPD), PPD’s 50% rights to develop and market the agents for diabetes *Dipeptidylpeptidase IV inhibitor (DPP IV)*, which had been invented by TSD and jointly developed with PPD.
- In July 2005, “Fast Track designation” was acquired from the U.S. FDA for TAK-242, a drug for severe sepsis. Now global Phase III trials are being conducted concurrently in Japan, the U.S. and Europe.
- In August 2005, TAP started the Phase III trials for TAK-390MR, a peptic ulcer treatment created by Takeda (the Phase I trials are being conducted in Japan).
- In September 2005, an approval for manufacturing was granted from the Ministry of Health, Labor and Welfare for *Pacif Capsule*, a drug for cancerous pain, and it was launched in April 2006.
- In January 2006, Takeda started the Phase III trials in the U.S. and Europe for SYR-322 (DPP IV inhibitor), a drug for diabetes treatment (the Phase I trials are being conducted in Japan).

- In February 2006, Takeda started the Phase II trials for patients with postherpetic neuralgia in the U.S. and Europe for TAK-583, a drug for neuropathic pain improving drug (the Phase I trials are being conducted in Japan).

[Maximization of Added Value of Products]

<Candesartan>

- In May 2005 in the U.S., approval for its combined use with an ACE inhibitor was granted by the FDA for chronic heart failure indication that had been already approved in the U.S.
- In October 2005, with regard to *Blopress tablets 2, 4 and 8mg* for hypertension treatment, Takeda received an approval for the indication for chronic heart failure from the Ministry of Health, Labor and Welfare, as the first angiotensin II receptor blocker for that indication in Japan.

<Pioglitazone>

- In June 2005, Takeda filed with the U.S. FDA a new drug application for marketing of a fixed combination product of *glimepiride*, which is *sulphonylurea* (SU), and *Actos*. A new drug application for this drug was also filed with the European Medicines Evaluation Agency in July 2005.
- In August 2005, an approval was granted by the U.S. FDA for marketing of *ACTOplus Met*, a fixed combination of *Actos* with *metformin*. Upon receipt of this approval, TPNA started marketing of this drug in November 2005.
- In September 2005, the results of PROactive Study (a randomized, double blind, placebo-controlled outcome study to determine the effect of ACTOS on mortality and morbidity associated with cardiovascular disease progression in high risk patients with type 2 diabetes) were announced. This is the first study in the world to show that a specific oral glucose lowering medication, *Actos*, can significantly improve cardiovascular outcomes by helping to delay or reduce heart attacks, strokes and death in high-risk patients.
- In March 2006, Takeda filed with the U.S. FDA a new drug application for marketing of *ACTOplus Met XR*, a fixed combination drug of *Actos* and *metformin extended release form*.

<Leuprorelin>

- In August 2005, regarding *Leuplin SR Injection Kit 11.25*, Takeda received an approval for an indication for premenopausal breast cancer from the Ministry of Health, Labor and Welfare. This approval also paved the way for its use as adjuvant postoperative therapy for premenopausal breast cancer.
- A new drug application for marketing a six-month depot formulation was filed in Germany (June 2005), Italy (October 2005) and France (November 2005), respectively.

<Ramelteon>

- In April 2004, aiming at an additional indication of Alzheimer's sleep/awakening disorder, Phase II trials were started in the U.S.

[In-licensing and Alliance Activities]

- In June 2005, Takeda reached an agreement with Paradigm Therapeutics of U.K. regarding joint research in the central nervous system therapeutic area, and commenced the joint research in July.
- In September 2005, Takeda and Merck KGaA of Germany reached an agreement on the joint development and sale in the U.S., Japan, Europe and some Asian countries, of Matuzumab, the humanized antibody against epidermal growth factor receptor, which is responsible for the production and progression of cancer.

- In November 2005, Takeda reached a license agreement with Pronova Biocare AS of Norway, with respect to *Omacor*, a drug for hypertriglyceridemia developed by Pronova. Under this agreement, Takeda acquired an exclusive license to develop and market the drug in Japan.
- In December 2005, Takeda acquired one of the candidates for new drug targets for Alzheimer's disease through joint research activities with Evotec Neurosciences GmbH, Germany.
- In January 2006, Takeda started the Phase II trials in Japan for ATL-962, a drug for obesity created by Alyzime Plc of U.K.
- In January 2006, Sucampo Pharmaceuticals, Inc. in the U.S. obtained from the FDA an approval for marketing *AMITIZA*, a drug for chronic idiopathic constipation, and TPNA, jointly with Sucampo, started marketing of *AMITIZA* in April 2006.
- In February 2006, Takeda concluded a license agreement with Affymax Inc. in the U.S., under which Takeda acquired an exclusive right to develop and market *HEMATIDE*, a drug for anemia in chronic kidney diseases and cancer, in Japan.
- In March 2006, Takeda concluded a license agreement with Lexicon Genetics Incorporated in the U.S., under which Takeda acquired an exclusive right to use LG474, a new drug target for cardiovascular diseases identified through a program developed by Lexicon.
- In March 2006, Takeda concluded a license agreement with BioNumerik Pharmaceuticals, Inc. (U.S.), ASKA Pharmaceutical Co., Ltd. (Japan) and KI Pharma (Japan) regarding *Tavocept*, a chemoprotective agent, under which Takeda acquired an exclusive right to market the agent in Japan.
- In March 2006, Takeda concluded an agreement with ARIUS Research Inc in Canada, regarding antibody drugs for cancer, under which Takeda acquired an exclusive access over three years to a certain number of functional mouse monoclonal antibodies showing anti-tumor activities.

2. Outlook for Fiscal 2006

The outlook for fiscal 2006 is:

		(Billions of yen)
		<u>Year-on-year change</u>
Net sales	¥1,230	¥17.8 (1.5%) increase
Ordinary income	¥486	¥0.6 (0.1%) increase
Net income	¥320	¥6.8 (2.2%) increase

[Consolidated net sales]

The consolidated net sales will increase compared with fiscal 2005. Although the transfer of the beverage and food business of Takeda Food Products, Ltd., a Takeda subsidiary, to House Wellness Foods Corporation, Ltd., a joint venture between Takeda and House Foods Corp. in April 2006, and the revision of NHI drug prices implemented in April 2006 in Japan will give negative impact on sales, Takeda expects that the growth of sales of *Actos*, *Blopres*, and *Embrel* (a drug for rheumatoid arthritis) in Japan, sales by TPNA of *Actos*, *ROZEREM*, and *AMITIZA* in the U.S., and sales of major products in Europe will more than offset such negative impacts.

[Ordinary income]

Ordinary income will slightly increase compared with fiscal 2005 supported by the increase in the gross profit due to the increase in ethical drug sales and the improvement in non-operating income including increase in interest income in TAH, which will be partially offset by the increase in R&D costs due to the progress of development activities and the increase of expenses related to new products at TPNA.

[Consolidated net income]

In addition to the increase in the ordinary income, Takeda expects to increase extraordinary income including a gain from the sale of the beverage and food business of a subsidiary. Moreover, the tax burden will decrease due to the increase in the tax credit for research and development expenses and other factors. Accordingly, Takeda expects an increase in the consolidated net income from fiscal 2005.

[Outlook assumptions]

The foreign exchange rates for these projections are assumed to be US\$1 = ¥110 and 1 euro = ¥130.

[Note concerning the projections above]

These projections related to operating results are based on information currently available to the management. Certain risks and uncertainties could cause actual results to differ from these projections.

(4) Risk Factors in Business

Takeda's business performance is exposed to various risks at present and in the future, and may experience unexpected fluctuations due to occurrence of those risks. Below is a discussion of assumed main risks Takeda might face in its business activities. Takeda intends to work to prevent any such occurrence, insofar as possible while fully identifying these potential risks — and will ensure a precise response in the event of their occurrence.

The future events contained in these items are envisioned as of the end of fiscal 2005.

1. Risk in R&D

While Takeda strives for efficient R&D activities aimed at launching new products in the trilateral markets of Japan, the United States and Europe as early as possible, ethical drugs are in nature only allowed placement on the market when they have been approved through rigorous investigations of efficacy and safety as stipulated by the competent authorities, whether they are in-house developed or licensed compounds.

If it turns out that the efficacy and safety of such compounds do not meet the required level for approval, or if reviewing authorities express concern regarding the nonconformity of such compounds, Takeda will have to give up R&D activities for such compounds at that point, or will conduct additional clinical or non-clinical testing. As a result, Takeda might be exposed to risk of uncollectibility of costs incurred, experience delay in launching new products, or be forced to revise its R&D strategy.

2. Risk in intellectual property rights

Takeda's products are protected by two or more patents covering substance, processes, formulations and uses for a certain period.

While Takeda strictly manages intellectual property rights, including patents, and always keeps careful watch for potential infringement by a third party, expected earnings may be lost if the intellectual property rights held by Takeda are infringed by a third party. Or, if Takeda's in-house product proved to have infringed a third party's intellectual property rights, Takeda might be asked for compensation.

3. Risk of sales decrease following patent expirations

While Takeda takes active measures to extend product life cycles, including the addition of new indications and formulations, generic drugs inevitably penetrate the market following patent expirations of most branded products. In addition, the increasing use of generic drugs and prescription-to-OTC switches also intensifies competition, both in domestic and overseas markets, especially in the U.S. market. Takeda's sales of ethical drugs may drop sharply, depending on such impact.