

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.

#### 4. Risk of side effects

Although ethical drugs are only allowed placement on the market after approval for production and marketing following rigorous investigation by the competent authorities around the world, accumulated data during the post-marketing period might expose side effects not confirmed at launch. If new side effects are identified, Takeda will be required to describe such side effects in a “precautions” section of the package insert or to restrict usage of such drugs, or will be forced to discontinue sale of or recall such products.

#### 5. Risk of price-reduction due to movements to constrain drug costs

In the U.S. market, which is the world’s largest, the use of lower priced generic drugs is promoted and the pressure for reduction of branded products prices is increasing as a result of the strong demand by the federal and state governments and Managed Care. In Japan, National Health Insurance (NHI) prices for drugs have been reduced every other year, and the use of generic drugs is also promoted. In the European market, drug prices have been reduced in similar situations, due to the efforts implemented in each country to control drug costs, and the expansion of parallel imports. Price reduction as a result of drug cost-restrictive efforts being made in each country can significantly influence the business performance and financial standing of the Takeda Group.

#### 6. Influence of exchange fluctuations

The Takeda Group’s overseas net sales in fiscal 2005 amounted to ¥537.1 billion, which accounted for 44.3% of total consolidated net sales. Among others, sales in North America were ¥335.9 billion, which accounted for 27.7% of total consolidated net sales. Moreover, with regard to TAP in the U.S., the “equity in earnings of affiliates” (non-operating income) was ¥52.1 billion. For this reason, Takeda Group’s business performance and financial standings are considerably affected by currency rates, especially fluctuations in the dollar-yen conversion rate.

#### 7. Risk of development of lawsuits

Civil litigations by patients and insurance companies etc. seeking damages (sometimes called ‘AWP Suit’), which involve numerous major U.S. pharmaceutical companies, are currently under disputation on an industry-wide scale. The complainants’ claim damages resulting from price discrepancies between the average wholesale prices (AWP) as publicized by independent industry compendia and the actual selling prices. As part of these civil litigations, actions have been brought against TAP and TPNA for damages in federal and state courts; Takeda has also faced part of such litigations. The progress of these lawsuits may affect Takeda’s business performance and financial standing.

If Takeda’s mainstay products, *Lansoprazole*, *Candesartan* and *Actos*, are involved in the above risk occurrence, Takeda’s business performance might be greatly affected. As for the AWP lawsuit filed regarding the sales of *Leuprorelin*, the case was substantially settled by the final approval of the class settlement by the court and other arrangements as detailed in the section of [5. Litigation] below.