

## [Qualitative Information and Financial Statements]

### 1. Results of Operations

#### (1) Analysis of Operation Results

##### 1) Introduction

Whole of the pharmaceutical industry has tendency to face a number of challenges, such as stagnation in creating breakthrough novel drugs due to the difficulties of translating new innovations to products in the marketplace, and increasingly strict criteria for the approval of new drugs in advanced countries. Drastic changes in the healthcare systems are underway in many countries, by which it is anticipated that the pharmaceutical industry will be considerably affected. First of all, in the U.S., a bill of healthcare reform which aims to increase the ratio of the insured population was passed. Under the bill, pharmaceutical companies are requested to bear the burden of some portion of funds in order to finance the expansion of available health insurance by increase of the number of policyholders. In Japan, the 2010 Revision of the National Health Insurance (NHI) Drug Price Scheme introduced experimentally an epoch-making system which allows pharmaceutical companies to collect R&D costs earlier by adding some amount of price to regular revised prices of new drugs meeting certain requirements through the patent protection period, such that the creation of new drugs will be encouraged and that it is to solve so-called drug lag issue of drugs unapproved in Japan which has been approved outside of Japan. On the other hand, in this system, prices of the off-patent brand drugs will drop significantly after the patent period expires due to promoting the uptake of generics in the market. In addition, in European countries, pharmaceutical industry has been continuously facing the difficult business environment such as reduction of drug prices by regulatory authorities and increase of parallel import/export from lower drug price countries to higher drug price countries as well as measure to encourage generics use.

On the other hand, the market of consumer healthcare products is tough due to drop in demands of First-class OTC Drugs, which are allowed to sell only through pharmacists after the amendment of Pharmaceutical Affairs Law in last year, and due to shrink of demand of general medicine for cold as a result of increase of examinations by doctors in medical institutions because of epidemic of the new type flu.

During the fiscal year 2009, Takeda (the "Company") realized a reorganization of its corporate structure by establishing the positions of Chief Scientific Officer (CSO), Executive Vice President (EVP) International Operations, and Chief Administrative Officer (CAO), which enables us to become a company with enhanced global operations. Takeda is able to make flexible, timely and right decisions by delegating the necessary authority from Takeda's President to the people filling these new key roles. Also, key management issues are discussed in the newly created Management and Operations Committee (MOC) (\*), and are being executed promptly by close collaboration among the company departments and subsidiaries based on the strategies and policies decided at the MOC and under the leadership of CSO, EVP International Operations and CAO.

With this corporate structure, Takeda has been working for achievement of our main strategies, which are mainly composed of "the enhancement of Takeda's global business infrastructure", "the enhancement of Takeda's R&D pipeline", and "the acquirement and development of global human resources".

(\*) The MOC is a reorganized committee of the former Executive Committee and Operations Committee where Takeda executives deliberate and decide important issues relating to strategy, management and business executions.

Firstly, with respect to leveraging "the enhancement of Takeda's global business infrastructure", Takeda has continuously expanded its sales presence focusing on developing countries and regions where high growth is anticipated in the pharmaceutical market. Through the efforts, we have established our oversea bases in twelve countries since last year, and as a result, our sales network has an access to markets of 26 countries including Japan in aggregate, which covers 84% of the global market. Also in December 2009, we have entered into an agreement with Pfizer, Inc. to co-promote "Actos" (generic name: pioglitazone), a drug for the treatment of type 2 diabetes, in order to increase its sales and our presence in China. We will work on establishment of geographically well-balanced sales network through maximizing our existing sales presence as well as continuous expansion of territory to the market where growth is anticipated.

With regard to new products, "Mepact" (generic name: mifamurtide), a drug for osteosarcoma (malignant bone cancer), became commercially available in Europe in February 2010. Also, we will make further effort for keeping and accelerating growth trend of "DEXILANT" (generic name: dexlansoprazole, formerly known as "KAPIDEX"), a drug for gastroesophageal reflux disease, and "ULORIC" (generic name: febuxostat), a drug for hyperuricemia for patients with chronic gout, both of which were introduced last year to the market in the U.S., the largest pharmaceutical market in the world. Additionally, in April 2010 we received an approval of production and marketing in Japan of 5 new drugs (Note) including "Nesina", for the treatment of type 2 diabetes. We will make efforts for early launch into market, and will adhere to the position as a leader of market in Japan through marketing of these new drugs.

(Note) Please see (\*1)-(\*5) for the detail of 5 products, "Unisia", "Nesina", "Metact", "Vectibix", and "Rozerem".

Next, with respect to "the enhancement of Takeda's R&D pipeline", which is the main source for our growth, Takeda has made several achievements. First, in the lifestyle-related diseases field which is one of our core therapeutic areas, we have entered into

a worldwide exclusive license, development and commercialization agreement with Amylin Pharmaceuticals, Inc. in the U.S. to co-develop and commercialize pharmaceutical products for the treatment of obesity and related indications, and Amylin and Takeda decided to advance toward Phase III development of “Pramlintide/Metreleptin” combination treatment for obesity. And, we received an approval of production and marketing for “Unisia”(\*1), a fixed-dose combination of “Candesartan” with “amlodipine besylate”, a calcium channel blocker, for treatment of hypertension, in Japan.

In the diabetes field, we have started the additional safety trial in October 2009, which was required by the U.S. Food and Drug Administration (FDA) for “SYR-322” (generic name: alogliptin), a drug for the treatment of type 2 diabetes. At this point, we anticipate the FDA evaluation to resume approximately two years from the studies’ beginning. In Japan, we received an approval of production and marketing for “SYR-322” as “Nesina”(\*2), and submitted an application for additional indications for combination therapy with sulfonylurea and combination therapy with biguanide. In addition, we received an approval of production and marketing for “Metact” (\*3), a fixed-dose combination of “Actos” with “metformin”, for treatment of type 2 diabetes in Japan.

In the oncology and urological diseases field, Takeda is making steady progress in strengthening the franchise in the oncology field with 100% subsidiary Millennium Pharmaceuticals Inc. (“Millennium”) in the U.S. being as our center of oncology, for establishing its position as the leading company in this field. In the U.S., we have initiated Phase II clinical trials of “TAK-700” for patients with advanced prostate cancer in 2009, and will advance this molecule into pivotal trials in fiscal 2010. To further strengthen the oncology pipeline, Millennium has entered into an agreement with Seattle Genetics, Inc. in the U.S. to partner in the global development of “SGN-35” and enable Takeda to commercialize in all territories other than the U.S. and Canada for the treatment of relapsed and refractory Hodgkin Lymphoma and anaplastic large cell lymphoma, and its Phase III development has started. In addition, several compounds have entered the development pipeline from discovery research during this fiscal year. Furthermore, we received an approval in Japan of production and marketing for “Vectibix”(\*4) (generic name: panitumumab), which we in-licensed from Amgen, Inc. located in the U.S., for treatment of advanced or recurrent colorectal cancer. Takeda will continue to make active efforts to develop new, high-quality drugs in the oncology field, which is our core therapeutic area next to the lifestyle-related diseases field.

And, “Hematide™” (generic name: peginesatide), which is in-licensed from Affymax, Inc in the U.S. is a drug for chronic kidney disease related anemia and chemotherapy-induced anemia, is currently in the final stage of phase III clinical trials in the U.S. and the Europe, and also entered into phase III clinical trials in Japan for the treatment of anemia in chronic renal failure. Furthermore, Takeda and AMAG, a U.S. based company, have entered into a license, development and commercialization agreement related to “Feraheme” (generic name: ferumoxytol) Injection for intravenous (IV) use in all therapeutic indications.

In the central nervous system field, we have decided to start additional clinical phase III studies on “Lu AA21004”, a drug for major depressive disorder and generalized anxiety disorder, which Takeda in-licensed from Lundbeck in Denmark, in patients with major depressive disorder. The pivotal programme is planned to commence in the first half of 2010. Also, we entered into an agreement with Janssen Pharmaceutical K.K. and Janssen Pharmaceutica N.V., a Belgium based company, regarding co-marketing in Japan of “R113675” (generic name: galantamine hydrobromide), which is a drug for Alzheimer’s Disease. And we received an approval of production and marketing for “Rozerem”(\*5) (generic name: ramelteon), for treatment of insomnia, in Japan.

(Please see page 9 to 12 for the detail of outcome of our R&D activities.)

Aiming to improve the success rates of R&D projects, we have changed radically our R&D focus from primarily “quantity and speed” to “quality”. In addition, under close communication between EVP International Operations and CSO, who are now based in Chicago, U.S., we have become able to prioritize not only development activities but also research activities through prompt and efficient exchange of information between the R&D functions and sales functions on a global basis, and such prioritization has enabled us to allocate resource efficiently. Because development of R&D pipeline which enables ethical drug sales of 2 trillion yen by 2015 is difficult to achieve at this time, we will make further effort to creation of innovative new drugs to satisfy unmet needs of patients in various fields such as the oncology field. At the same time, we will work actively for seeking the measures to apply emerging technologies such as nucleic-acid and regenerative drugs for practical use, in addition to antibody drugs which are being viewed as the next generation drugs due to less adverse effect than traditional small molecule drugs.

With respect to “the acquirement and development of global human resources”, we have gained brilliant people in the R&D and the sales functions through acquisitions such as Millennium and by making TAP Pharmaceutical Products Inc. (TAP) a wholly-owned subsidiary, and also actively hired talented persons with various backgrounds. Furthermore, we bring up leaders of global management through interchanges of personnel within Takeda Group and internal global leader development programme such as Takeda Leadership Institute, and make active efforts in order to deepen understanding about different culture and business environment and to build up human network of the group.

We made progress as a result that we had been promoting various efforts in “2006 – 2010 Mid-Range Plan” toward becoming a world-class pharmaceutical company. However we have prepared the “2010 – 2012 Mid-Range Plan” by moving up one year in order to respond flexibly to changes in the business environment surrounding the pharmaceutical industry and to ensure a sustained growth. In this new Mid-Range Plan, we will work to transform itself into a new Takeda by deciding on a new management policy referred to as the Vision, which focuses on Company activities on the themes of “Innovation”, “Growth” and “Culture”.

(Please see page 18 “3.(1) Basic Management Policy” for the detail of “2010-2012 Mid-Range Plan”)

Through these initiatives, we are working toward realization of Takeda’s management mission “We strive towards better health for patients worldwide through leading innovation in medicine”, which will ultimately lead the Company to both mid- and long-term growth and further returns to our stockholders.

## 2) Overview of Operating Results for Fiscal 2009

Consolidated results for the year ended March 31, 2010 were as follows:

|                  | <i>Billions of yen</i> | <i>Year-on-year change</i> |
|------------------|------------------------|----------------------------|
| Net Sales        | ¥1,466.0               | Decrease ¥ 72.4 ( 4.7%)    |
| Operating Income | ¥420.2                 | Increase ¥113.7 (37.1%)    |
| Ordinary Income  | ¥415.8                 | Increase ¥ 88.6 (27.1%)    |
| Net Income       | ¥297.7                 | Increase ¥ 63.4 (27.0%)    |

[Net Sales]

Consolidated net sales decreased by ¥72.4 billion (4.7%) from the previous year to ¥1,466.0 billion.

- Although there were positive factors such as sales increase of Velcade (a drug for multiple myeloma treatment) by Millennium in the U.S., contributions from new products; DEXILANT (formerly known as KAPIDEX) and ULORIC by Takeda Pharmaceuticals North America, Inc. (TPNA), and the sales-increase effect generated by one-month difference of attribution period of TAP and Millennium included in consolidated sales\*, total net sales were decreased due to the significant yen appreciation against the U.S. dollar and Euro (- ¥64.7 billion) and the patent expiration of Prevacid in the U.S. in November 2009.

\*In the previous year, sales of TAP and Millennium were recorded from May, whereas they are recorded from April in the current year.

- The table below shows consolidated sales of Takeda’s major international strategic products:

|   | <i>Billions of yen</i> |  |
|---|------------------------|--|
| Drug for Type 2 diabetes treatment<br>Pioglitazone (Japanese product name: Actos)   | ¥384.7                 | Decrease ¥2.3 billion (0.6%)<br>from the previous year   |
| Drug for peptic ulcer treatment<br>Lansoprazole (Japanese product name: Takepron)   | ¥218.1                 | Decrease ¥53.3 billion (19.6%)<br>from the previous year |
| Drug for hypertension treatment<br>Candesartan (Japanese product name: Blopress)  | ¥222.0                 | Decrease ¥8.4 billion (3.6%)<br>from the previous year   |
| Drug for treatment of prostate cancer,<br>breast cancer and endometriosis<br>Leuprorelin (Japanese product name: Leuplin) | ¥122.2                 | Decrease ¥4.0 billion (3.2%)<br>from the previous year   |

(Note) Excluding the negative impact of appreciation of the yen, net sales of Pioglitazone and Candesartan have increased.

[Operating Income]

Consolidated operating income increased by ¥113.7 billion (37.1%) from the previous year to ¥420.2 billion.

- While gross profit decreased by ¥67.9 billion (5.4%) to ¥1,180.9 billion, operating income was resulted in an increase due to the significant decrease of the selling and general administrative expense, mainly R&D expense, by ¥181.6 billion (19.3%).
- R&D expenses decreased by ¥156.7 billion (34.6%) from the previous year due to the one-off in-process R&D costs (US\$1,590 million) recorded as a result of the consolidation of TAP and Millennium as subsidiaries.
- Selling and general administrative expenses other than R&D expense decreased by ¥25.0 billion (5.1%) due to appreciation of the yen.

Billions of yen

| [Reference] Impact to the consolidated statements of income relating to business combinations of the previous year |             |                          |
|--|-------------|--------------------------|
| <Division and Consolidation of TAP>  | Fiscal 2008 | Fiscal 2009              |
| Amortization of intangible assets  | ¥25.8       | ¥21.2 [SG&A expense]     |
| In-process R&D   | ¥54.3       | - [R&D expense]          |
| Gain from transfer of the Lupron business  | ¥71.3       | - [Extraordinary income] |
| < Acquisition of Millennium>   | Fiscal 2008 | Fiscal 2009              |
| Amortization of intangible assets  | ¥42.7       | ¥44.0 [SG&A expense]     |
| Amortization of goodwill   | ¥13.9       | ¥14.0 [SG&A expense]     |
| In-process R&D   | ¥105.6      | - [R&D expense]          |

(Note) Descriptions in [ ] represent categories on the consolidated Statement of Income.

[Ordinary Income]

Consolidated ordinary income increased by ¥88.6 billion (27.1%) from the previous year to ¥415.8 billion.

- Non-operating income decreased by ¥25.1 billion due to a reduction in interest income resulting from lower interest rates, the decrease of equity in earnings of affiliates\*, and removal costs of fixed assets. However the ordinary income resulted in an increase since these were absorbed by the increase in operating income.

\*As for equity in earnings from TAP, one-month amounts were recorded until the end of April when TAP became the wholly-owned subsidiary in the previous year, whereas no amounts were recorded in the current year.

[Net Income]

Consolidated net income increased by ¥63.4 billion (27.0%) from the previous year to ¥297.7 billion.

- Although extraordinary income decreased by ¥71.3 billion because the gain (US\$709 million) from the transfer of the Lupron business was recorded in the previous year, this decrease was absorbed by the increase in ordinary income and reduced amount of tax. As a result, net income increased.
- Earnings per share increased by ¥87.37 (30.1%) to ¥377.19 compared to the previous year.
- Earnings per share excluding extraordinary income (loss) and other extraordinary factors arising from business acquisitions and similar events (see Note below), which the Company uses as one of its target management indices, decreased by ¥21.49 (4.6%) to ¥448.81.

(Note) "Earnings per share excluding extraordinary income (loss) and other extraordinary factors arising from business acquisitions and similar events" were calculated by deducting the following incomes, losses and charges from net income.

- (1) Extraordinary income/loss resulting from sales of non-pharmaceutical businesses and idle real estate, and
- (2) Amortization of goodwill and intangible fixed assets, and in-process R&D expenses arising in connection with business acquisitions and other similar events.

- Return on Equity (ROE) increased by 3.5 point from the previous year to 14.4%.

### 3) Results by Segment

#### 1) Business Segments

The following table shows sales and operating income of each business segment for the year ended March 31, 2010.

*Billions of yen*

| Type of business        | Net sales |                               | Operating income |                               |
|-------------------------|-----------|-------------------------------|------------------|-------------------------------|
|                         | Amount    | Change from the previous year | Amount           | Change from the previous year |
| Pharmaceuticals segment | ¥1,375.9  | Decrease ¥72.6                | ¥412.5           | Increase ¥115.6               |
| Ethical Drugs           | ¥1,317.7  | Decrease ¥66.4                |                  |                               |
| < Japan >               | <¥548.8>  | <Decrease ¥0.2>               |                  |                               |
| < Overseas >            | <¥768.9>  | <Decrease ¥66.3>              |                  |                               |
| Consumer healthcare     | ¥ 58.2    | Decrease ¥6.1                 |                  |                               |
| Other Segments          | ¥ 90.1    | Increase ¥0.2                 | ¥7.6             | Decrease ¥1.8                 |
| Total                   | ¥1,466.0  | Decrease ¥72.4                | ¥420.2           | Increase ¥113.7               |

(Note) Net sales for each segment refer to sales to other than consolidated Group companies.

#### [Pharmaceuticals Segment]

Consolidated net sales by the **Pharmaceuticals segment** decreased by ¥72.6 billion (5.0%) to ¥1,375.9 billion. However, operating income increased by ¥115.6 billion (38.9%) to ¥412.5 billion compared with the previous year, due to the decrease of selling, general and administrative expenses, which was recorded in the previous year as in-process R&D expenses in connection with the consolidation of TAP and Millennium as wholly-owned subsidiaries.

- Sales by the **Ethical Drugs** business decreased by ¥66.4 billion (4.8%) to ¥1,317.7 billion. Sales in **Japan** decreased by ¥0.2 billion to ¥548.8 billion. Although sales increase by growth of Takepron (a drug for peptic ulcer), Actos (a drug for type 2 diabetes treatment), and Enbrel (a drug for rheumatoid arthritis treatment) was recorded, it could not cover decrease in sales of Basen (Drug for treatment for postprandial hyperglycemia in diabetes mellitus) and so on.

The following table shows sales results of major products in Japan.

*Billions of yen*

|  |        |   |
|--|--------|---|
| Blopress (Drug for hypertension treatment)                                       | ¥136.2 | Decrease of ¥1.7 billion (1.2%) from the previous year  |
| Takepron (Drug for peptic ulcer treatment)                                       | ¥74.3  | Increase of ¥3.5 billion (5.0%) from the previous year  |
| Leuplin (Drug for treatment of prostate cancer, breast cancer and endometriosis) | ¥67.1  | Increase of ¥0.7 billion (1.1%) from the previous year  |
| Actos (Drug for type 2 diabetes treatment)                                       | ¥52.7  | Increase of ¥3.9 billion (7.9%) from the previous year  |
| Basen (Drug for treatment for postprandial hyperglycemia in diabetes mellitus)   | ¥43.0  | Decrease of ¥4.1 billion (8.6%) from the previous year  |
| Enbrel (Drug for rheumatoid arthritis treatment)                                 | ¥32.3  | Increase of ¥6.0 billion (22.7%) from the previous year |

Sales of **Ethical drugs in overseas markets** decreased by ¥66.3 billion (7.9%) to ¥768.9 billion compared to the previous year, due to the negative impact of the higher yen against the U.S. dollar and Euro.

In the U.S., despite sales increase by growth of Actos and Velcade, and due to contributions from new products such as DEXILANT and ULORIC, it was unable to absorb sales decrease by patent expiration of Prevacid. As a result, sales in local currency decreased. In Europe, net sales in local currency increased due to growth of Actos, but yen equivalent of the net sales decreased.

- Sales by the **Consumer Healthcare** business decreased by ¥6.1 billion (9.5 %) to ¥58.2 billion compared to the previous year. This is due to the decrease in sales of Benza (combination cold remedy), Nicorette (smoking cessation product) and other products as a result of increase of examinations by doctors in medical institutions because of epidemic of the new type flu and shrink of smoking cessation product market.

[Other Segments]

Sales by **Other Segments** increased by ¥0.2 billion (0.2%) to ¥90.1 billion, whereas operating income decreased by ¥1.8 billion (19.3%) to ¥7.6 billion compared to the previous year.

2) Geographical Segments

The following table shows sales and operating income of each geographical segment for the year ended March 31, 2010:

| Geographical segment  | Net sales |                               | Operating income |                               |
|-----------------------|-----------|-------------------------------|------------------|-------------------------------|
|                       | Amount    | Change from the previous year | Amount           | Change from the previous year |
| Japan                 | ¥794.6    | Decrease ¥32.0                | ¥513.1           | Decrease ¥7.3                 |
| North America         | ¥534.9    | Decrease ¥36.8                | ¥173.4           | Decrease ¥13.9                |
| Europe                | ¥126.4    | Decrease ¥4.6                 | ¥30.9            | Decrease ¥1.0                 |
| Asia                  | ¥10.0     | Increase ¥1.0                 | ¥0.5             | Decrease ¥0.9                 |
| Elimination/Corporate | —         | —                             | (¥297.7)         | Increase ¥136.8               |
| Total                 | ¥1,466.0  | Decrease ¥72.4                | ¥420.2           | Increase ¥113.7               |

(Note) Net Sales for each segment refer to sales to other than consolidated Group companies.  
Operating expenses included in the “Elimination/Corporate” classification include R&D expenses subject to central management of the Group.

#### 4) Research & Development

Takeda positioned “Lifestyle-related Diseases”, “Oncology and Urological Diseases”, “Central Nervous System Diseases” and “Gastroenterological Diseases” as core therapeutic areas while working to strengthen its pipeline and to launch new products to market. Takeda will concentrate investment of its management resources into newly designated core therapeutic areas of “Metabolic & CV” (obesity, diabetes, and atherosclerosis), “Oncology” and “Central Nervous System Diseases” (depression, schizophrenia, and Alzheimer's disease).

Major results of R&D activities during the reporting period are:

[In-house R&D]

- In April 2009, “Nature” published pre-clinical data on “MLN4924” —the first small molecule inhibitor of the NEDD8-Activating Enzyme (NAE), which modulates the level of proteins critical for the regulation of cancer cell growth and survival pathways, for treatment of advanced malignancies.

- In April 2009, Takeda decided to no longer pursue development of “TAK-379” for treatment of diabetes, because TAK-379’s profile does not meet the criteria to support continuation of further development activities.

- In June 2009, Takeda reviewed the development strategy for the Marketing Authorization Applications (MAAs) for its investigational compounds, “SYR-322” (a drug for type 2 diabetes) and “SYR-322/ACTOS”, in Europe, and accordingly, initiated an additional long-term clinical study for “SYR-322”. With the results of this additional study, Takeda expects that the MAA submissions will be made with a more robust data set necessary to ensure its approval. The target timing of the MAA submission is expected sometime in 2012.

- In June 2009, Takeda started Phase III clinical trials of “TAK-536” for treatment of hypertension in Japan.

- In June 2009, Takeda received a complete response letter from the FDA regarding the New Drug Application (NDA) for “SYR-322”. The FDA asked Takeda to conduct an additional trial. Based on the agreement with the FDA to the design of cardiovascular outcomes trial, Takeda started the relevant trial in October 2009. While this trial is dependent on the occurrence of CV events, at this point we anticipate that we will be able to submit interim results to the FDA approximately two years after the study begins that will meet the FDA Guidance criteria for drug approval.

- In June 2009, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an additional indication of “SYR-322” for combination therapy with thiazolidinediones, for treatment of type 2 diabetes.
- In June 2009, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an approval of production and marketing of a fixed-dose combination of “SYR-322” with “ACTOS”, for treatment of type 2 diabetes.
- In August 2009, Takeda started Phase II clinical trials of “TAK-700” for treatment of advanced prostate cancer in the U.S.
- In September 2009, Takeda received a complete response letter from the FDA regarding the NDA for the fixed-dose combination of “SYR-322” with “ACTOS”. The FDA informed Takeda that further review of this fixed-dose combination product would be conditional based upon additional data from the cardiovascular outcomes trial. Takeda anticipates that this trial will provide the FDA with the information needed to continue the NDA review also for this fixed-dose combination.
- In October 2009, Takeda started Phase II clinical trials of “TAK-438” for treatment of reflux esophagitis in Japan.
- In March 2010, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an additional indication of “SYR-322” for combination therapy with sulfonyleurea, for treatment of type 2 diabetes.
- In March 2010, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an additional indication of “SYR-322” for combination therapy with biguanides for treatment of type 2 diabetes.
- In April 2010, Takeda received an approval of production and marketing for “SYR-322”, for monotherapy and combination therapy with alfa-gulucosidase inhibitors for treatment of type 2 diabetes from the Japanese Ministry of Health, Labour and Welfare.
- In April 2010, Takeda received an approval of production and marketing for “TAK-375”, for treatment of insomnia from the Japanese Ministry of Health, Labour and Welfare.
- In April 2010, Takeda submitted the NDA to the FDA for marketing approval of TAK-491 for the treatment of hypertension.

[Maximization of Product Added Value]

<Voglibose (Japanese product name: Basen)>

- In October 2009, Takeda received approval from the Japanese Ministry of Health, Labour and Welfare for an additional indication of “Basen” for prevention of the onset of type 2 diabetes in patients with impaired glucose tolerance, thereby becoming the first product to receive such an indication in Japan. The results of the clinical trial supporting this indication were presented at the 51st Annual Meeting of the Japan Diabetes Society. Then in April 2009, “The Lancet” also published the Phase III clinical data of “Basen” for impaired glucose tolerance.

<Pioglitazone (Japanese product name: Actos)>

- In May 2009, Takeda received a marketing approval from the FDA for a fixed-dose combination of Actos with an extended-release metformin, “ACTOplus met XR”, for treatment of type 2 diabetes, and currently, Takeda is planning to launch it during the first half of fiscal 2010.
- In July 2009, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an approval of production and marketing for a fixed-dose combination of Actos with glimepiride, for treatment of type 2 diabetes.
- In January 2010, Takeda received approval of production and marketing for Actos orally disintegrating tablets, “Actos OD tablets 15 and 30”, for treatment of type 2 diabetes from the Japanese Ministry of Health, Labour and Welfare.
- Takeda withdrew a European Marketing Authorisation Application (MAA) for a prolonged-release formulation of its combination treatment for type 2 diabetes, “Competact”; a fixed-dose combination tablet of “Actos” with immediate release metformin hydrochloride and Takeda decided to discontinue its development, following discussions with The Committee for Medicinal Products for Human Use (CHMP) that they were unlikely to adopt a formal positive opinion as they required additional data to confirm the long-term efficacy of the prolonged release metformin component of the tablet.
- In April 2010, Takeda received an approval of production and marketing for a fixed-dose combination of “Actos” with “metformin”, for treatment of type 2 diabetes from the Japanese Ministry of Health, Labour and Welfare.

<Candesartan (Japanese product name: Blopress)>

- In June 2009, Takeda launched two new dose strengths of “Blopress Plus”, fixed-dose combination of candesartan and hydrochlorothiazide (diuretic) for treatment of hypertension, following marketing authorization in Germany. Takeda was granted marketing authorization in Austria, Portugal, Spain, Ireland, Italy and Switzerland.

- In April 2010, Takeda received an approval of production and marketing for a fixed-dose combination of “Candesartan” with “amlodipine besylate”, a calcium channel blocker, for treatment of hypertension from the Japanese Ministry of Health, Labour and Welfare.

<Lansoprazole (Japanese product name : Takepron)>

- In September 2009, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an approval of additional indications for Helicobacter pylori (“H. pylori”) eradication by concomitant therapy with proton pump inhibitor. This concomitant therapy consists of a proton pump inhibitor, amoxicillin hydrate, and either clarithromycin or metronidazole and is indicated for the eradication of H. pylori in gastric MALT lymphoma, the stomach after endoscopic resection of early stage gastric cancer, and idiopathic thrombocytopenic purpura.

- In November 2009, Takeda filed an application with the Japanese Ministry of Health, Labour and Welfare for an additional indication for “Takepron Capsules 15” and “Takepron OD Tablets 15” for the prevention of NSAIDs associated gastric ulcer/duodenal ulcer.

<Risedronate sodium hydrate (Japanese product name : Benet)>

- In March 2010, Takeda started Phase III clinical trials of the once-monthly formulation of “risedronate sodium hydrate” for the treatment of osteoporosis, which Takeda in-licensed from Ajinomoto Co., Inc. for the treatment of osteoporosis in Japan.

[In-licensing and Alliance Activities]

- In May 2009, Takeda entered into a license agreement with Novartis in Switzerland for vaccine for prevention of infection caused by Haemophilus Influenzae Type B.

- In June 2009, Phase II clinical trial of “CBP501”, which Takeda in-licensed from CanBas Co., Ltd., for the treatment of non-small cell lung cancer (NSCLC), was started in the U.S.

- In August 2009, the top line results from Phase III clinical trial of Panitumumab was announced. This trial was conducted by Amgen, Inc and Takeda Bio Development Center as a second-line treatment for patients with metastatic colorectal cancer. Panitumumab significantly improved progression-free survival when being used in combination with an irinotecan-based chemotherapy, compared to the said irinotecan-based chemotherapy alone, in patients with KRAS\* wild type metastatic colorectal cancer, and the results were reported to the Japanese Ministry of Health, Labour and Welfare.

\*KRAS plays an important role in cell growth regulation.

- In August 2009, Santhera of Switzerland started Phase III clinical trials of “Idebeneone”, for the treatment of Duchenne Muscular Dystrophy in Europe and North America, which is co-developed with Takeda.

- In October 2009, Takeda entered into a worldwide exclusive license, development and commercialization agreement with Amylin in the U.S. to co-develop and commercialize pharmaceutical products for the treatment of obesity and related indications and in February 2010, Takeda decided to start the Phase III clinical trials of “Pramlintide/Metreleptin” for the treatment of obesity.

- In December 2009, Takeda started Phase III clinical trials of “TAK-085”, which Takeda in-licensed from Pronova in Norway, for the treatment of hypertriglyceridemia in Japan.

- In December 2009, Millennium, Takeda’s wholly owned subsidiary, entered into an agreement with Seattle Genetics in the U.S. to globally develop and commercialize “SGN-35” excluding U.S. and Canada for the treatment of relapsed and refractory Hodgkin Lymphoma and systemic anaplastic large cell lymphoma. In April 2010, a phase III clinical trial of SGN-35 for post-transplant Hodgkin lymphoma patients was initiated in the U.S., Europe and Russia.

- In February 2010, Takeda started the Phase III clinical trials of “Hematide™/Peginesatide” for the treatment of anemia in chronic renal failure in Japan. “Hematide™/Peginesatide” which is in-licensed from Affymax, Inc in the U.S. is a drug for chronic kidney disease related anemia and chemotherapy-induced anemia.

- In March 2010, Takeda decided to initiate the additional Phase III pivotal clinical trials with “Lu AA21004”, which Takeda in-licensed from Lundbeck in Denmark for the treatment of major depressive disorder (MDD) and generalized anxiety disorder (GAD). The study results with the patients with MDD which Takeda received so far suggest that a higher dose may be more efficacious. The pivotal programme is planned to commence in the first half of 2010.

- In March 2010, Takeda decided to start Phase III clinical trials of “Lu AA24530” which Takeda in-licensed from Lundbeck in Denmark for the treatment of major depressive disorder (MDD) and generalized anxiety disorder(GAD). The pivotal programme is planned to commence by the end of 2010.

- In March 2010, Takeda signed an agreement with Janssen Pharmaceutical K.K. and Janssen Pharmaceutica N.V. regarding co-marketing in Japan of “galantamine hydrobromide”, which is a drug for Alzheimer's Disease. Following the development overseas of “galantamine hydrobromide” by Janssen Pharmaceutica N.V., for the treatment of Alzheimer's disease, Janssen Pharmaceutical K.K. developed it in Japan and submitted an application for production and marketing approval to the Ministry of Health, Labor and Welfare in February 2010. Once approved, Takeda and Janssen Pharmaceutical K.K. will co-market it under the same brand name.

- In March 2010, Takeda entered into an exclusive development and commercialization agreement related to “ferumoxytol” Injection for intravenous (IV) use in all therapeutic indications in 5 regions, including Europe, Canada, Turkey, the Commonwealth of Independent States and Asia Pacific countries, excluding Japan, China and Taiwan.

- In April 2010, Takeda received an approval of production and marketing for “Panitumumab”, which Takeda in-licensed from Amgen, Inc. for treatment of advanced or recurrent colorectal cancer.

[Improvement and Reinforcement of R&D Organization]

- In July 2009, Takeda held the commencement ceremony for construction of new research facilities, which is located on the border of the cities of Fujisawa and Kamakura in Kanagawa Prefecture, Japan. Takeda anticipates completion of the research facilities before the end of fiscal 2010. The new research facilities will serve as the center of Takeda's global research network, which will attract research institutions and researchers globally, while aiming to harmonize with local community there as a good corporate citizen.

## 5) Outlook for Fiscal 2010

The outlook for consolidated result for the full year of fiscal 2010 is follows:

*Billions of yen*

|                  |          | <u>Year-on-year change</u> |                |
|------------------|----------|----------------------------|----------------|
| Net Sales        | ¥1,400.0 | [Decrease                  | ¥66.0 ( 4.5%)] |
| Operating income | ¥330.0   | [Decrease                  | ¥90.2 (21.5%)] |
| Ordinary income  | ¥340.0   | [Decrease                  | ¥75.8 (18.2%)] |
| Net income       | ¥220.0   | [Decrease                  | ¥77.7 (26.1%)] |

[Net Sales]

Despite net sales in Japan are expected to increase from the previous year due to the contribution of new products including “Nesina”, a drug for treatment of type 2 diabetes with its approval of production and marketing in April 2010, consolidated net sales are expected to decrease from the previous year due to sales decrease by patent expiration of Prevacid in the U.S. and assumptions of foreign exchange rates, with a stronger Japanese yen from Fiscal 2009 to Fiscal 2010.

[Operating income and Ordinary income]

Both operating income and ordinary income will decrease from fiscal 2009 because gross profit will decrease due to the sales decrease, and R&D expenses will increase due to operation start of new research facilities.

[Net income]

Net income is expected to decrease from fiscal 2009 due to decrease of ordinary income.

[Assumptions used in preparing the Outlook]

The foreign exchange rates are assumed to be US\$1 = ¥90 and 1 Euro = ¥130.

[Forward looking statement]

Takeda and TPNA brought patent infringement lawsuits against companies that had submitted ANDAs for generic Actos and/or ACTOplus met. Although until the lawsuits that are currently pending and those that would be brought against companies who may submit ANDA, if any, are resolved or concluded, the date of entry of generic Actos is uncertain, while preparing the fiscal 2010 financial outlook, Takeda is operating on the assumption that the entry of generic versions of Actos will be August, 2012. The operating results of the Company are subject to various risks at present and in the future, such as changes of business environment and the impact from foreign exchange rate fluctuations. When we judge our operating results will be significantly impacted by events, which are not incorporated in this outlook, we will announce such facts promptly.

## (2) Analysis of Financial Position

### [Asset]

The total asset as of the end of Fiscal 2009 (March 31, 2010) is ¥2,823.3 billion, an increase of ¥63.1 billion compared to the previous year end due to increase in tangible fixed assets as a result of construction of new research facilities.

### [Liability]

The liability as of the end of Fiscal 2009 (March 31, 2010) is ¥658.5 billion, a decrease of ¥47.8 billion compared to the previous year end mainly due to the decrease of current liabilities.

### [Net Assets]

The net asset as of the end of Fiscal 2009 (March 31, 2010) is ¥2,164.7 billion, an increase of ¥110.9 billion compared to the end of the previous year end, because the increase of retained earnings derived from net income exceeded the decrease of retained earnings derived from dividend payment. The shareholders' equity ratio increased by 2.2 pt from the end of the previous year to 75.1%.

### [Cash Flows]

Cash flow for the current year resulted in a net inflow of ¥94.4 billion.

Net cash inflow increased by ¥949.6 billion, compared with the previous year, mainly because we did not have cash outflow in the current year such as ¥833.5 billion for the acquisition of Millennium and ¥280.3 billion for buyback of treasury stocks, which had occurred in the previous year.

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, 2010 was ¥852.5 billion.

## (3) Basic Policy for Profit Distribution and Dividends for Fiscal 2009 and 2010

### 1) Basic Policy for profit Distribution

Under "2010-2012 Mid-Range Plan", we will make strategic investments which are necessary for future growth in order to achieve sustainable growth and maximizing enterprise value of our group. With regard to profit distribution, it is our basic policy that dividend per share for Fiscal Years 2010, 2011 and 2012 be maintained at the same level as fiscal year 2009 to realize stable profit distributions.

### 2) Dividend for Fiscal 2009

Takeda plans to pay a year-end dividend of ¥90 per share. This, together with the dividend at the end of second quarter of ¥90 already paid, will achieve an annual dividend of ¥180 for the year ended March 31, 2010 (consolidated payout ratio on earnings before amortization of intangible assets associated with acquisition on Millennium is 42.0%), which is the same amount as the previous year.

### 3) Dividend for Fiscal 2010

For the next fiscal year, Takeda plans to pay an annual dividend of ¥180 per share, a same amount as fiscal year 2009.

## (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 such occurrence, insofar as possible while fully identifying these potential risks—and will ensure a precise response in the event of their occurrence.

In addition, the future events contained in these items are envisioned as of the end of fiscal 2009.

### 1) Risk in R&D

While Takeda strives for efficient R&D activities aimed at launching new products in each market of Japan, the United States, Europe and Asia as early as possible, marketing of ethical drugs is allowed only 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 effect

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 curtail drug costs

In the U.S. market, which is the world's largest, the use of low-value generic drugs is promoted and the pressure for reduction of brand drug prices is increasing as a result of the strong demand by the federal and state governments and the 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 measures implemented in each country to control drug costs, and the expansion of parallel imports. Price reduction as a result of drug cost-curtailling efforts being made by 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 2009 amounted to ¥777.0 billion, which accounted for 53.0% of total consolidated sales. Among others, sales in North America were ¥561.8 billion, which accounted for 38.3% of total consolidated sales. 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.