

1. Results of Operations

(1) Analysis of Consolidated Operating results

(i) Overview

The financial crisis in Europe may result in slower economic growth not only in developed countries but also in emerging markets and the world economy remains unpredictable. Meanwhile, in Japan, the Japanese yen's depreciation and higher stock prices have continued as a result of various factors, such as the setting of the inflation target by the Bank of Japan and the creation of a substantial supplementary budget after the governing party changed in December 2012. Consequently, the Japanese economy is seen to be on a recovery track.

In the global pharmaceutical market, negative factors including a string of patent expiry of major products, economic stagnation as well as increasingly severe policies for constraint of medical expenditures against the background of government financial reconstruction in many countries have impacted sales growth, mainly in developed countries. In the area of R&D, companies have been facing a number of challenges, such as relatively limited novel drug breakthroughs caused by difficulties in the translating of new innovations to products in the marketplace as well as increasingly stringent criteria for the approval of new drugs. Meanwhile, there are high expectations for new innovations with the potential for creating new drugs to meet currently unmet medical needs, in addition to the practical application of iPS cells technology.

Based on the "2012-2014 Mid-Range Plan," Takeda Pharmaceutical Company Limited ("Takeda") strived to achieve "Growth" through "Innovation" and "Culture" in order to realize the goal of "Transformation into a New Takeda."

In particular, in the area of R&D, Takeda made investments that are essential to sustainable growth in the future and continued efforts to improve R&D productivity. Efforts include obtaining approvals for late-stage pipeline products and creating new drugs by intensively allocating resources to core therapeutic areas based on clear priorities. The company is also working to elucidate pathologic mechanisms and develop evaluation methods in drug discovery utilizing novel technologies mainly through joint research by deepening its partnerships with bio-ventures and research institutions such as universities. In particular, the company steadily advanced development program for submissions and regulatory approvals. In the area of sales and marketing, the company strived to strengthen its global presence by providing products suitable to the respective market needs in developed and emerging markets. On the other hand, Takeda has clearly recognized that there are several challenges the company must overcome in facing the greater-than-expected penetration of generic products and intensifying competition among pharmaceutical companies.

<Initiatives in Developed Countries>

In Developed countries which represent the largest market sizes, Takeda is promoting a shift in product portfolio from existing to new ones.

In Japan, Takeda began marketing AZILVA (a drug for hypertension) in May 2012. In clinical trials comparing its effectiveness with BLOPRESS (angiotensin II receptor blocker), one of Takeda's core products and the most prescribed anti-hypertensive product in Japan, the superior effectiveness of AZILVA for lowering blood pressure was verified. It receives a high reputation from medical experts and is steadily penetrating into the market. In January 2013, Takeda also began marketing LOTRIGA (a drug for treatment of hyperlipidemia) in Japan. Since the launch, it has been steadily used by more medical institutions as a new treatment option for hyperlipidemia patients. In June 2012, Takeda strengthened its franchise in gout treatment in the U.S., through the acquisition of URL Pharma, Inc. with its leading product COLCRYS (a drug for treatment of acute gout). Here, Takeda is able to realize synergy with its existing product Uloric (a drug for hyperuricemia for adult patients with chronic gout). Regarding NESINA (generic name: alogliptin), OSENI (fixed-dose combination tablet of NESINA and ACTOS), and KAZANO (fixed-dose combination tablet of NESINA and metformin) which were approved by the U.S. Food and Drug Administration (FDA) for treatment of type 2 diabetes in January 2013, the company is now preparing their

launch in this summer. Meanwhile, as a result of new postmarketing reports regarding serious hypersensitivity reactions, in February 2013, the company voluntarily recalled OMONTYS (a drug for treatment of anemia due to chronic kidney disease), which was launched in April 2012 in the U.S. In Europe, Takeda began marketing ADCETRIS (a drug for treatment of lymphoma) which was granted orphan drug status from the Committee for Medicinal Products for Human Use (CHMP) and RIENSO (a drug for treatment of iron deficiency anaemia) in November 2012. In the clinical trials for adult patients with chronic kidney disease (CKD), Rienso significantly increased Hb levels as compared to oral iron across the spectrum of CKD.

<Initiatives in Emerging Markets>

Takeda has strengthened efforts in emerging markets which are expected to contribute approximately 70% of near term global pharmaceutical market growth.

In July 2012, Takeda acquired Multilab Indústria e Comércio de Produtos Farmacêuticos Ltda. (“Multilab”) and developed a sales structure to respond to diverse medical needs in Brazil. Multilab provides its own brand generic drugs (branded drugs that have lost exclusivity), OTC products including MULTIGRIP, the country’s best-selling OTC product for cold and flu treatment, and other drugs that have strong demand in Brazil. This acquisition positions Takeda as one of the top ten pharmaceutical companies in the country in terms of revenues and the business after the acquisition has proceeded according to our expectations.

In September 2012, Takeda completed construction of its pharmaceutical manufacturing facility in Yaroslavl which is one of the oldest cities in Russia and located north-east of Moscow. The company strives to have this facility fully operational in 2014 in order to contribute to the sustainable growth of Takeda’s business in the Russian market which is the company’s largest of the emerging markets in terms of revenues. In China, as the largest emerging market, Takeda continues aggressive investments to strengthen the business structure to achieve sustainable growth in this high growth market, including the opening of a development center in Shanghai to promote new drug development and increasing the number of sales representatives to expand sales.

<Initiatives of R&D>

In Japan, Takeda submitted a New Drug Application (NDA) to the Ministry of Health, Labour and Welfare (MHLW) for ADCETRIS in March 2013. In the U.S., the company submitted an NDA to the FDA for Lu AA21004 for the treatment of major depressive disorder (MDD) in adult patients in October 2012.

In Europe, Takeda submitted a Marketing Authorisation Application (MAA) for SYR-322 (generic name: alogliptin) for type 2 diabetes in April 2012, followed by a multiple number of MAAs for Lurasidone hydrochloride (an atypical antipsychotic medicine) in September 2012 and for MLN0002 (generic name: vedolizumab), a drug for the treatment of Ulcerative Colitis and Crohn’s disease, in March 2013 respectively.

Moreover, in October 2012, Takeda acquired Takeda Vaccines (Montana), Inc.* in the U.S. This acquisition provided the only norovirus vaccine under clinical development and several vaccine pipelines, and advanced Takeda’s presence in the global vaccine market. Then, the acquisition of Envoy Therapeutics, Inc. in the U.S. in November 2012 provides Takeda with innovative technology that enables the identification of novel targets expressed in disease-relevant cell populations and helps Takeda build on its heritage of innovative drug discovery. In addition, the company gains access to Envoy’s pre-clinical central nervous system (CNS) assets including programs for Parkinson’s disease and Cognitive Impairment Associated with Schizophrenia (CIAS).

* The company name of LigoCyte Pharmaceuticals, Inc. was changed to Takeda Vaccines (Montana), Inc. in March, 2013.

As described in the latter portion of this document (refer to [(iv) Activities and Results of Research & Development] on page 8), Takeda is strongly promoting various efforts including joint research and alliance activities with outside parties in order to raise R&D productivity.

The Takeda group is striving to transition the operating model to one that is more global, more efficient and better able to flexibly respond to changes in business environment both in Japan and globally. At the same time, Takeda is

working to enhance its cash-flow management structure. Moreover, under the newly adopted business policy named “Vision 2020” (refer to [3. Management Policy] on page 20) and in accordance with our business plans for fiscal 2013 and beyond, Takeda is making continuous efforts to achieve sustainable growth. Takeda will also strive to further develop the most globally competitive human resources and create the business environment in which diverse employees can fully deploy their capabilities in the whole organization.

Based on a corporate philosophy of “Takeda-ism” (Integrity: Fairness, Honesty and Perseverance), Takeda strives to ensure compliance with laws and regulations governing its operations, and conducts activities according to a corporate mission to “strive towards better health for people worldwide through leading innovation in medicine.”

(Note) Major products introduced in and after 2010 follow.

<Reference> Major new products launched in and after 2010

[Japan]

Launched in 2010

Nesina (a drug for type 2 diabetes, generic name: alogliptin benzoate)

Unisia (a drug for treatment of hypertension: a fixed dose combination of Blopress and a calcium channel blocker (amlodipine besilate))

Vectibix (a cancer drug, generic name: panitumumab)

Rozerem (an insomnia drug, generic name: ramelteon)

Metact (a drug for type 2 diabetes: a fixed dose combination of Actos and biguanide (metformin hydrochloride))

Actos OD (orally-disintegrating tablets) (a drug for type 2 diabetes)

Lampion pack (a drug for secondary eradication of *Helicobacter Pylori*: a single pack containing Takepron, amoxicillin hydrate and metronidazole)

Launched in 2011

Reminyl (a drug for Alzheimer's dementia, generic name: galantamine hydrobromide, licensed from Janssen and jointly marketed with the licensor)

Sonias (a drug for type 2 diabetes: a fixed dose combination of Actos and sulfonylurea (glimepiride))

Liovel (a drug for type 2 diabetes: a fixed dose combination of Actos and Nesina)

Launched in May 2012

Azilva (a drug for treatment of hypertension, generic name: azilsartan)

Launched in January 2013

Lotriga (a drug for treatment of hyperlipidemia, generic name: omega-3-acid ethyl esters 90)

[North America]

<U.S.A.>

Launched in 2010

Actoplus met XR (a drug for type 2 diabetes: a fixed dose combination of Actos and biguanide (metformin timed-release drug))

Launched in 2011

Edarbi (a drug for treatment of hypertension, generic name: azilsartan medoxomil)

Launched in February 2012

Edarbyclor (a drug for treatment of hypertension, a fixed dose combination of Edarbi and thiazide diuretic (chlorthalidone))

<Canada>

Launched in 2010

Dexilant (a drug for gastroesophageal reflux disease, generic name: dexlansoprazole)

Uloric (a drug for hyperuricemia for patients with chronic gout, generic name febuxostat)

Launched in 2011

Daxas (a drug for chronic obstructive pulmonary disease, generic name: roflumilast)

Launched in September 2012

Feraheme (a drug for treatment of iron deficiency anaemia, generic name: ferumoxytol)

[Europe]

Launched in 2010

Mepact (a drug for non-metastatic osteosarcoma, generic name: mifamurtide)

Launched in January 2012

Edarbi (a drug for treatment of hypertension, generic name: azilsartan medoxomil)

Launched in November 2012

Rienso (a drug for treatment of iron deficiency anaemia, generic name: ferumoxytol)

Adcetris (a drug for treatment of relapsed/refractory CD30 positive Hodgkin lymphoma and relapsed/refractory systemic anaplastic large cell lymphoma, generic name: brentuximab vedotin)

[Emerging markets]

<Brazil>

Launched in 2011

Daxas (a drug for chronic obstructive pulmonary disease, generic name: roflumilast)

<Russia>

Launched in March 2012

Daxas (a drug for chronic obstructive pulmonary disease, generic name: roflumilast)

<Mexico>

Launched in 2011

Dexilant (a drug for gastroesophageal reflux disease, generic name: dexlansoprazole)

Mepact (a drug for non-metastatic osteosarcoma, generic name: mifamurtide)

Launched in March 2012

Edarbi (a drug for treatment of hypertension, generic name: azilsartan medoxomil)

Launched in January 2013

Daxas (a drug for chronic obstructive pulmonary disease, generic name: roflumilast)

Launched in March 2013

Edarbyclor (a drug for treatment of hypertension, a fixed dose combination of Edarbi and thiazide diuretic (chlorthalidone))

(ii) Operating Results for Fiscal 2012

Consolidated results for the year ended March 31, 2013 were as follows:

	<u>Billions of yen</u>	<u>Year-on-year change</u>
Net Sales	¥1,557.3	Increase ¥ 48.3 (3.2%)
Operating Income	¥122.5	Decrease ¥142.5 (53.8%)
Ordinary Income	¥113.2	Decrease ¥157.2 (58.1%)
Net Income	¥131.2	Increase ¥ 7.1 (5.7%)

[Net Sales]

Consolidated net sales were ¥1,557.3 billion, an increase of ¥48.3billion (3.2%) compared to the previous year.

- In Japan, sales of NESINA (a drug for type 2 diabetes treatment) increased, and in the U.S, sales of VELCADE (a drug for multiple myeloma treatment), DEXILANT (a drug for gastroesophageal reflux disease) and ULORIC (a drug for hyperuricemia for patients with chronic gout) also increased.

In addition to the sales contribution of AZILVA (a drug for hypertension) newly launched in Japan in May 2012, sales increased mainly in Europe and emerging markets including Asia as a result of the expansion of sales channels due to the acquisition of Nycomed at the end of September 2011. Furthermore, due to the acquisition of URL Pharma, Inc. (“URL”) in June 2012, the sales of URL products in the U.S. also added to consolidated net sales. Such positive factors including the yen’s depreciation (positive impact: ¥8.4 billion)

absorbed negative factors such as the decrease in sales of Actos (a drug for type 2 diabetes treatment) and Candesartan (a drug for hypertension treatment) in the U.S., Europe and Japan.
In total, consolidated net sales increased.

Consolidated sales of Takeda's major ethical drugs:

Billions of yen

Drug for hypertension treatment Candesartan (Japan product name: Blopress)	¥169.6	Decrease of ¥46.7 billion (21.6%) from the previous year
Drug for type 2 diabetes treatment Pioglitazone (Japan product name: Actos)	¥122.9	Decrease of ¥173.3 billion (58.5%) from the previous year
Drug for treatment of prostate cancer, breast cancer and endometriosis Leuprorelin (Japan product name: Leuplin)	¥116.5	Decrease of ¥4.2 billion (3.5%) from the previous year
Drug for peptic ulcer treatment Lansoprazole (Japan product name: Takepron)	¥110.2	Decrease of ¥11.9 billion (9.7%) from the previous year
Drug for peptic ulcer treatment Pantoprazole	¥ 78.0	Increase of ¥39.3 billion (101.7%) from the previous year (note)
Drug for multiple myeloma treatment VELCADE (U.S. sales)	¥ 72.9	Increase of ¥14.8 billion (25.4%) from the previous year

(Note) As for Pantoprazole which was acquired with the Nycomed acquisition at the end of September 2011, the comparative sales amount before the acquisition (from April to September 2011) is not included.

[Operating Income]

Consolidated operating income was ¥122.5 billion, a decrease of ¥142.5 billion (53.8%) compared to the previous year.

- Although gross profit increased by ¥33.9 billion (3.2%) due to higher sales, selling, general and administrative expenses increased by ¥176.4 billion (21.8%) from the previous year. As a result, operating income decreased.
- R&D expenses were ¥324.3 billion, an increase of ¥42.4 billion (15.0%) compared to the previous year.
- Selling, general and administrative expenses, excluding R&D expenses, were ¥662.8 billion, an increase of ¥134.0 billion (25.3%) compared to the previous year, mainly due to increased amortization of goodwill and intangible assets related to the Nycomed business combination as well as the full year impact of operating expenses net of restructuring savings following the acquisition.

[Ordinary Income]

Consolidated ordinary income was ¥113.2 billion, a decrease of ¥157.2 billion (58.1%) compared to the previous year.

- Due to the decrease in operating income, ordinary income also decreased from the previous year.

[Net Income]

Consolidated net income was ¥131.2 billion, an increase of ¥7.1 billion (5.7%) compared to the previous year.

- The company recorded net extraordinary income of ¥16.5 billion (*1) and a refund for past paid taxes (*2), and these factors absorbed the decrease in ordinary income.
 - (*1) Gains on sales of investment securities [gain ¥53.1 billion], government subsidy for vaccine business [gain ¥22.8 billion], interest on the refund related to transfer price tax [gain ¥15.1 billion], gains on sales of fixed assets [gain ¥4.0 billion], impairment loss on fixed assets [loss ¥43.6 billion], restructuring costs in overseas subsidiaries [loss ¥25.2 billion] and loss on voluntary recall of product [loss ¥9.6 billion].
 - (*2) Past paid tax refund related to transfer price taxation [gain ¥57.4 billion] (refer to section [(2) Litigation and Other Legal Matters] on page 22.)
- Earnings per share ("EPS") was ¥166.25, an increase of ¥8.96 (5.7%) compared to the previous year.
- EPS excluding extraordinary income (loss) and other special factors arising from business acquisitions and similar events (*3) was ¥233.78, a decrease of ¥80.60 (25.6%) compared to the previous year.

(*3) EPS excluding extraordinary income (loss) and special factors is calculated by deducting any extraordinary income (loss), special factors such as amortization of goodwill and intangible assets, etc. related to business acquisitions and the tax refund related to transfer price taxation from net income.

- Return on Equity ("ROE") was 6.3%, an increase of 0.2 point compared to the previous year.

(iii) Results by Segment

The following table shows sales and operating income of each business segment for the year ended March 31, 2013.

Billions of yen

Type of Business	Net sales		Operating income	
	Amount	Change from the previous year	Amount	Change from the previous year
Ethical Drug	¥1,401.7	Increase ¥42.9	¥99.0	Decrease ¥144.7
(Japan)	<¥588.4>	< Decrease ¥ 3.8>		
(Overseas)	<¥813.3>	< Increase ¥46.8>		
Consumer Healthcare	¥ 66.9	Increase ¥5.2	¥13.2	Increase ¥1.3
Other	¥ 93.1	Increase ¥0.0	¥12.4	Increase ¥0.7
Total	¥1,557.3	Increase ¥48.3	¥122.5	Decrease ¥142.5

(Note) Net sales for each segment refer to sales to outside customers.

[Ethical Drug Business]

Net sales in the Ethical Drug Business were ¥1,401.7 billion, an increase of ¥42.9 billion (3.2%) compared to the previous year, while operating income decreased by ¥144.7 billion (59.4%) to ¥99.0 billion.

- Net sales in Japan were ¥588.4 billion, a decrease of ¥3.8 billion (0.6%), compared to the previous year. Despite higher sales of products launched in 2010 such as NESINA and Vectibix in addition to the contribution of AZILVA launched in May 2012, the drop in sales of Actos and Blopress mainly due to the drug price reduction could not fully absorbed.
- The following table shows sales results of major products in Japan:

Billions of yen

Blopress (Drug for hypertension treatment)	¥134.0	Decrease of ¥8.7 billion (6.1%) from the previous year
Takepron (Drug for peptic ulcer treatment)	¥69.1	Decrease of ¥7.4 billion (9.7%) from the previous year
Leuplin (Drug for treatment of prostate cancer, breast cancer and endometriosis)	¥66.0	Decrease of ¥1.8 billion (2.6%) from the previous year
Nesina (Drug for type 2 diabetes treatment)	¥37.8	Increase of ¥22.2 billion (143.4%) from the previous year
Actos (Drug for type 2 diabetes treatment)	¥19.1	Decrease of ¥12.7 billion (39.8%) from the previous year
Vectibix (Drug for cancer treatment)	¥18.8	Increase of ¥1.6 billion (9.5%) from the previous year

- Sales in overseas markets were ¥813.3 billion, an increase of ¥46.8 billion (6.1%) compared to the previous year, mainly due to sales increases in Europe and emerging markets including Asia, accompanied by the acquisition of Nycomed and the sales contribution of URL products in the U.S. These factors and positive effects of the yen's depreciation more than offset the decline in sales of Pioglitazone and Candesartan in the U.S. and Europe.

- The following table shows sales results of major products in overseas markets:

Billions of yen

Pioglitazone (Drug for type 2 diabetes treatment)	¥103.7	Decrease of ¥160.6 billion (60.8%) from the previous year
Pantoprazole (Drug for peptic ulcer treatment)	¥78.0	Increase of ¥39.3 billion (101.7%) from the previous year (note)
Velcade (Drug for multiple myeloma treatment)	¥72.9	Increase of ¥14.8 billion (25.4%) from the previous year
Leuprorelin (Drug for treatment of prostate cancer, breast cancer and endometriosis)	¥50.5	Decrease of ¥2.4 billion (4.6%) from the previous year
Lansoprazole (Drug for peptic ulcer treatment)	¥41.2	Decrease of ¥4.4 billion (9.8%) from the previous year
Candesartan (Drug for hypertension treatment)	¥35.6	Decrease of ¥38.0 billion (51.7%) from the previous year
Dexilant (Drug for gastroesophageal reflux disease)	¥32.7	Increase of ¥8.5 billion (35.3%) from the previous year

(Note) As for Pantoprazole which was acquired with the Nycomed acquisition at the end of September 2011, the comparative sales amount before the acquisition (from April to September 2011) is not included.

[Consumer Healthcare Business]

Net sales in the Consumer Healthcare Business were ¥66.9 billion, an increase of ¥5.2 billion (8.4%) compared to the previous year, mainly due to an increase in sales of Alinamin tablets and health tonics (vitamin-containing products) and Benza medicines (combination cold remedies). Operating income rose by ¥1.3 billion (11.4%) to ¥13.2 billion due to the increase in gross profit accompanied by sales growth.

[Other Business]

Sales in the Other Business were ¥93.1 billion, same as the previous year, and operating income increased by ¥0.7 billion (6.0%) to ¥12.4 billion mainly due to the decrease in selling, general and administrative expenses .

(iv) Activities and Results of Research & Development

Takeda determines R&D strategy based on the latest medical needs. Takeda's core therapeutic areas are Cardiovascular & Metabolic, Oncology, Central Nervous System, Immunology & Respiratory, General Medicine and Vaccine. By concentrating investment of management resources in these therapeutic areas, Takeda strives to achieve leading innovation in medicine. Major activities and results of R&D thus far during the reporting period are:

[In-house R&D activities]

- In April 2012, Takeda received a complete response letter from the U.S. Food and Drug Administration (FDA) regarding New Drug Applications (NDAs) for NESINA (generic name: alogliptin) and OSENI, a fixed-dose combination (FDC) of NESINA and pioglitazone, both for the treatment of type 2 diabetes. In July 2012, Takeda resubmitted NDAs to the FDA for NESINA and OSENI. In January 2013, Takeda received approvals from the FDA for NESINA and OSENI.
- In May 2012, Takeda received confirmation of the acceptance of the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for SYR-322 (generic name: alogliptin) for the treatment of type 2 diabetes.
- In May 2012, Takeda announced top-line results that met primary endpoints of improvement in clinical remission in induction and maintenance phase from the GEMINI II Phase III trial evaluating IBD (Inflammatory Bowel

Disease) drug MLN0002 (generic name: vedolizumab) in patients with moderately to severely active Crohn's disease who have failed at least one conventional therapy, including TNF α antagonists. In March 2013, Takeda submitted an MAA to the EMA for the treatment of moderately to severely active ulcerative colitis and Crohn's disease.

- In June 2012, Takeda presented Phase I and Phase I/II preliminary results from three studies evaluating the safety, tolerability and dosing of MLN9708 (generic name: ixazomib citrate) in patients with relapsed and/or refractory multiple myeloma (MM), at the annual meeting of the American Society of Clinical Oncology (ASCO). In June 2012, Takeda initiated an international Phase III clinical trial, TOURMALINE-MM1, evaluating MLN9708, the first oral proteasome inhibitor, in patients with relapsed and/or refractory multiple myeloma. In December 2012, Takeda presented data from a Phase I/II study of once a week investigational MLN9708 in combination with standard dose lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma (MM), and data from a Phase I study in patients with relapsed or refractory systemic light-chain (AL) amyloidosis at the 54th American Society of Hematology (ASH) Annual Meeting.
- In June 2012, Takeda presented the results from a Phase II trial of prostate cancer drug TAK-700 (generic name: orteronel) dosed without prednisone in patients with non-metastatic castration resistant prostate cancer (nmCRPC) and rising prostate-specific antigen (PSA) in a poster discussion session at the annual meeting of ASCO.
- In August 2012, Takeda submitted an application to the Japanese Ministry of Health, Labour and Welfare seeking an approval of Helicobacter pylori ("H. pylori") gastritis as an additional indication for H. pylori eradication by concomitant therapy with the proton pump inhibitor TAKEPRON (generic name: lansoprazole) in Japan. This concomitant therapy consists of TAKEPRON, amoxicillin hydrate and either clarithromycin or metronidazole. In February 2013, Takeda received an approval for this additional indication.
- In December 2012, Takeda presented results from two studies evaluating the safety and efficacy of VELCADE (generic name: bortezomib) based therapy at the 54th ASH Annual Meeting.

[Fixed Dose Combination activities]

- In June 2012, Takeda received confirmation of the acceptance of the submission of MAAs to the EMA for a FDC of SYR-322 and pioglitazone, and a FDC of SYR-322 and metformin, for the treatment of type 2 diabetes.
- In January 2013, Takeda received approval from the FDA for KAZANO, a FDC of NESINA and metformin.
- In March 2013, Takeda submitted an NDA for the FDC of TAKEPRON and low-dose aspirin to the Japanese Ministry of Health, Labour and Welfare.
- In April 2013, Takeda submitted an NDA for the FDC of AZILVA and Amlodipine Besylate to the Japanese Ministry of Health, Labour and Welfare.

[Alliance activities]

- In April 2012, Takeda received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the EMA for RIENSO (generic name: ferumoxytol), which Takeda in-licensed from AMAG Pharmaceuticals of the U.S., for the treatment of iron deficiency anaemia (IDA) in adult patients with chronic kidney disease (CKD). In June 2012, Takeda was granted marketing authorisation by the European Commission and in November 2012, Takeda launched RIENSO it in Europe.
- In June 2012, Takeda received a positive opinion from the CHMP of the EMA for REVESTIVE (generic name: teduglutide), which Takeda in-licensed from NPS Pharmaceuticals of the U.S., for the treatment of short bowel syndrome (SBS). In August 2012, Takeda was granted marketing authorisation by the European Commission for REVESTIVE. In March 2013, Takeda transferred back commercial rights of REVESTIVE and PREOTACT, a

treatment of post-menopausal osteoporosis (generic name: recombinant human parathyroid hormone 1-84), for territories outside of North America to NPS Pharmaceuticals.

- In June 2012, Takeda and Amgen of the U.S. entered into a new agreement which provides Takeda with the exclusive worldwide rights to independently develop, manufacture and commercialize motesanib diphosphate. In July 2012, Takeda initiated a Phase III clinical trial in Japan, Hong Kong, South Korea and Taiwan, evaluating motesanib diphosphate in combination with chemotherapy in patients with advanced non-squamous non-small cell lung cancer (NSCLC).
- In August 2012, Takeda decided to stop the Japanese portion of the global Phase III trial in metastatic adenocarcinoma of the pancreas for AMG479 (generic name: ganitumab), which Takeda in-licensed from Amgen of the U.S., following the decision of Amgen to halt the global trial.
- In September 2012, Takeda received an approval from the Japanese Ministry of Health, Labor and Welfare for LOTRIGA (generic name: omega-3-acid ethyl esters 90), which Takeda in-licensed from Pronova of Norway, for the treatment of hyperlipidemia. In January 2013, Takeda launched LOTRIGA.
- In October 2012, Takeda submitted an NDA to the U.S. FDA for multimodal antidepressant Lu AA21004 (generic name: vortioxetine), which Takeda in-licensed from Lundbeck of Denmark, for the treatment of major depressive disorder (MDD) in adult patients.
- In October 2012, Takeda received confirmation of the acceptance of the submission of an MAA to the EMA for atypical antipsychotic lurasidone hydrochloride, which Takeda in-licensed from Daiippon Sumitomo of Japan, for the treatment of schizophrenia.
- In October 2012, Takeda submitted an NDA to the Japanese Ministry of Health, Labour and Welfare for ATL-962 (generic name: cetilistat), which Takeda in-licensed from Norgine BV of the Netherlands, for the treatment of obesity.
- In October 2012, Takeda received a conditional marketing authorization from the European Commission for lymphoma drug ADCETRIS (generic name: brentuximab vedotin), which Takeda in-licensed from Seattle Genetics of the U.S., for the treatment of relapsed or refractory CD30 positive Hodgkin lymphoma (HL) following autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT or multi-agent chemotherapy is not a treatment option, and for the treatment of adult patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). In November 2012, Takeda launched ADCETRIS in Europe. ADCETRIS has been granted orphan drug status in both the EU and Korea.
In December 2012, Takeda presented the results from two arms of a Phase I clinical trial of ADCETRIS in combination with chemotherapy for the treatment of newly diagnosed mature T-cell lymphoma (MTCL) patients, including patients with sALCL and a Phase I clinical trial of ADCETRIS in combination with chemotherapy for the treatment of patients with newly diagnosed advanced stage HL at the 54th American Society of Hematology (ASH) Annual Meeting.
In March 2013, Takeda submitted an NDA for brentuximab vedotin to the Japanese Ministry of Health, Labour and Welfare for the treatment of relapsed or refractory CD30 positive HL and relapsed or refractory CD30 positive anaplastic large cell lymphoma.
- In December 2012, Takeda and Amylin Pharmaceuticals, Inc. of the U.S. mutually terminated their worldwide agreement, originally signed in October 2009, to co-develop and commercialize compounds for obesity.
- In December 2012, Takeda received an approval from the Ministry of Health, Labour and Welfare in Japan for a once-monthly formulation of BENET (generic name: risedronate sodium hydrate), which Takeda in-licensed from Ajinomoto Pharmaceuticals Co., Ltd. of Japan, for the treatment of osteoporosis. In February 2013, Takeda launched BENET in Japan.
- In January 2013, Takeda presented the data from the post-marketing survey of VECTIBIX (generic name: panitumumab) for the treatment of unresectable advanced or recurrent colorectal cancer at the American Society of Clinical Oncology, Gastrointestinal Cancers Symposium (ASCO GCS).

- In March 2013, Takeda submitted NDAs to the Japanese Ministry of Health, Labour and Welfare for cell culture-based pandemic influenza vaccines (H5N1 and prototype*) using technologies which Takeda in-licensed from Baxter International Inc. of the U.S.

* To facilitate registration of a vaccine in the event of a pandemic caused by an influenza strain other than H5N1.

[Joint Research]

- In August 2012, Takeda formed a research collaboration with the BC Cancer Agency of Canada to explore new drug targets based on gene analysis at Takeda's Shonan Research Center. The partnership will be the first project conducted as part of Takeda's new Shonan Incubation Laboratories. Through this program, distinguished researchers from external institutions will work side-by-side with Takeda researchers in the Shonan Research Center, bringing new insights to drug discovery through intensely collaborative research.

- In October 2012, Takeda and Advinus Therapeutics Ltd. ("Advinus"), a research-based pharmaceutical company in India, entered into an agreement to initiate a three-year discovery collaboration focused on novel targets for major therapeutic areas, including Inflammatory, CNS and Metabolic diseases.

- In February 2013, Takeda and Resolve Therapeutics, LLC, a research-based pharmaceutical company in the U.S., entered into a partnership to develop compounds for the treatment of lupus (also known as Systemic Lupus Erythematosus, or SLE) and other autoimmune diseases.

[Improvement and Reinforcement of R&D organization]

- In October 2012, Takeda acquired Takeda Vaccines (Montana), Inc.* in the U.S., and in May 2013, Takeda entered into a definitive agreement with Inviragen, Inc. in the U.S. to acquire it to advance the company's commitment to vaccines and global public health.

* The company name of LigoCyte Pharmaceuticals, Inc. was changed to Takeda Vaccines (Montana), Inc. in March, 2013.

- In November 2012, Takeda acquired Envoy Therapeutics Inc. ("Envoy") of the U.S. to advance innovative drug discovery.

(v) Outlook for Fiscal 2013

The outlook for consolidated result for the full year of fiscal 2013 is as follows:

Billions of yen

		<u>Year-on-year change</u>	
Net Sales	¥1,590.0	[Increase	¥32.7 (2.1%)]
Operating income	¥140.0	[Increase	¥17.5 (14.3%)]
Ordinary income	¥125.0	[Increase	¥11.8 (10.5%)]
Net income	¥95.0	[Decrease	¥36.2 (27.6%)]

[Net Sales]

Consolidated net sales are expected to increase from the previous year. Despite the drop in sales of Actos in the U.S. due to the entry of generic version, sales increase such as NESINA and AZILVA in Japan and DEXILANT and ULORIC in the U.S., and sales growth in emerging markets will absorb the sales decrease.

[Operating income and Ordinary income]

Both operating income and ordinary income will increase from the previous year, mainly due to the increase of gross profit by sales growth.

[Net income]

Although operating income will increase, positive effects including tax refunds relating to the correction for transfer pricing taxation in previous year are not in FY2013. As a result, net income is expected to decrease from the previous year.

[Assumptions used in preparing the Outlook]

The foreign exchange rates assumptions for fiscal 2013 are US\$1 = ¥90 and 1 Euro = ¥120.

[Forward looking statement]

Our operations are exposed to various risks at present and in the future, such as changes in the business environment and fluctuation of foreign exchange rates. All forecasts in this presentation are based on information currently available to the management, and various factors could cause actual results to differ. We will disclose necessary information in a timely manner when our management believes there will be significant impacts to our consolidated results due to changes in the business environment or other events.

(2) Analysis of Consolidated Financial Position

[Assets]

Total assets as of Fiscal 2012 end were ¥3,955.6 billion, an increase of ¥378.6 billion compared to the previous fiscal year end. Current assets increased by ¥176.1 billion and noncurrent assets increased by ¥202.5 billion mainly due to the increase of foreign assets resulting from yen's depreciation at the fiscal year end and an increase in intangible assets including goodwill accompanied by acquisitions.

[Liabilities]

Total liabilities as of Fiscal 2012 end were ¥1,732.2 billion, an increase of ¥227.1 billion compared to the previous fiscal year end. Despite the yen's depreciation, current liabilities decreased by ¥138.1 billion mainly due to the repayment of short term borrowing accompanied with the Nycomed acquisition for refinancing, while noncurrent liabilities increased by ¥365.2 billion mainly due to the issuance of \$3.0 billion in unsecured senior notes.

[Net Assets]

Total net assets as of Fiscal 2012 end were ¥2,223.4 billion, an increase of ¥151.5 billion compared to the previous fiscal year end, mainly due to an increase in foreign currency translation adjustment caused by the yen's depreciation. The shareholders' equity ratio decreased by 1.7 pt. to 54.6% from the previous fiscal year end.

[Cash Flows]

Cash flow for the current year resulted in a net inflow of ¥91.3 billion, while the previous year resulted in a net outflow of ¥418.5 billion mainly due to the payments for acquisition of Nycomed.

Net cash inflow by operating activities (¥307.7 billion) absorbed cash outflow by investing activities (¥111.4 billion) and cash outflow by financing activities (¥150.6 billion).

(3) Basic Policy for Profit Distribution and Dividends for Fiscal 2012 and 2013

(i) Basic Policy for Profit Distribution

In order to achieve sustainable growth and maximize the enterprise value of the Takeda group, we have established a mid-range growth strategy focused on the development of our global business operations in both emerging markets and developed countries, the realization of scientific innovation, and the transformation to a robust and efficient operating model suitable for a global pharmaceutical company. In addition, we are taking initiatives to further improve cash efficiency, and to maintain and enhance our strong and sound financial base which will support our growth strategy. With regard to profit distribution in accordance with steady implementation of these fundamental strategies, we will strive for a stable profit distribution with an emphasis on return to shareholders. The company hereby announces plans to maintain annual dividends of ¥180 per share for each of the fiscal years 2013 to 2015.

(ii) Dividend for Fiscal 2012

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, 2013, which is the same amount as the previous year.

(iii) Dividend for Fiscal 2013

For the next fiscal year, Takeda plans to pay an annual dividend of ¥180 per share, a same amount as fiscal year 2012.

(4) Risk Factors in Business

Takeda's business performance is subject to various present and future risks, and may experience unexpected fluctuations due to the occurrence of risk events. Below is a discussion of the main assumed risks that Takeda faces in its business activities. Takeda works to fully identify potential risks and takes all possible steps to prevent them from materializing. Moreover, Takeda will ensure a precise response if risk events occur.

The future events contained in these items are envisioned as of the end of fiscal 2012.

(i) 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, whether in-house developed or licensed compounds, is allowed only when they have been approved through rigorous investigations of efficacy and safety as stipulated by the competent authorities.

If the efficacy and safety of compounds Takeda is preparing to bring to market do not meet the required level for approval, or if the reviewing authorities express concern regarding the conformity of such compounds, Takeda will have to give up R&D activities for such compounds at that point, or conduct additional clinical or non-clinical testing. As a result, Takeda risks the inability to recoup the costs incurred, a delay in launching new products, or being obliged to revise its R&D strategy.

(ii) Risk in intellectual property rights

Each of Takeda's products is protected for a certain period by various patents covering substance, processes, formulations and uses.

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. Moreover, if Takeda's in-house product is proven to have infringed a third party's intellectual property rights, Takeda may be required to pay compensation.

(iii) 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 as a result of these trends.

(iv) Risk of side effect

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

(v) Risk of price-reduction due to movements to curtail drug costs

In the U.S. market, which is the world’s largest, authorities are promoting the use of low-price generic drugs, and pressure to reduce brand drug prices is increasing as a result of strong demand from the federal and state governments and Managed Care programs. In Japan, authorities have been reducing National Health Insurance (NHI) prices for drugs every other year and are also promoting the use of generic drugs. In the European market, drug prices have been reduced in a similar fashion, due to measures implemented in each country to control drug costs and the expansion of parallel imports. Price reduction as a result of efforts to curtail drug costs in each country can significantly influence the business performance and financial standing of the Takeda Group.

(vi) Influence of exchange fluctuations

The Takeda Group’s overseas net sales in fiscal 2012 amounted to ¥8,228 billion, which accounted for 52.8% of total consolidated sales. Sales in the Americas were ¥4,235 billion, which accounted for 27.2% of total consolidated sales. For this reason, the Takeda Group’s business performance and financial standing are considerably affected by fluctuations in foreign exchange rates, especially in the dollar-yen conversion rate.

(vii) Risk related to Corporate Acquisitions

As part of its global business development in order to realize sustainable growth, Takeda engages in corporate acquisitions. However, there is a possibility that the intended result or profit expected from an acquisition may not be realized, as business activities in countries around the world are confronted by many risks including, but not limited to, changes in law and regulations, political unrest, economic uncertainty and differences in business practices. In addition, there may be an impact on the financial results and financial condition of Takeda if write-downs etc. occur due to a decrease in the value of acquired assets resulting from investment activities such as corporate acquisitions.

(viii) Country risk in the countries and regions in operation

With developing its business globally, Takeda establishes its risk management structure to reduce the damage from and cope with the risks, including governmental, social and economic risks in the countries and regions in operation. However, Takeda may face unexpected situations. As a result, there may be an impact on the financial results and financial condition of Takeda.

(ix) Risk related to stable supply

In tandem with rapid international expansion of its sales network, Takeda is strengthening its global supply chain. However, in the event of technical or legal / regulatory problems in Takeda’s production or distribution facilities, or other disruption due to fires or other disasters, Takeda may have a suspension of or substantial delay in the supply of products. As a result, there may be an impact on the financial results and financial condition of Takeda.

(x) Risk related to litigation and other legal matters

Regarding to Takeda’s operational activities, in addition to the existing litigations, there is a possibility that a suit may be brought to court in terms of an adverse effect of pharmaceutical product, product liability, labor issues, fair trade, etc. As a result, there may be an impact on the financial results and financial condition of Takeda.