SUMMARY OF FINANCIAL STATEMENTS [Japan GAAP] (CONSOLIDATED) Financial Results for the First Quarter (April 1 to June 30, 2012) of the Fiscal Year Ending March 31, 2013

July 30, 2012

Takeda Pharmaceutical Company Limited

URL: http://www.takeda.co.jp

Stock exchange listings:

TSE Code: 4502

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Scheduled date of securities report submission: August 8, 2012

Scheduled date of dividend payment commencement:

Supplementary materials for the quarterly financial statements: Yes Presentation to explain for the quarterly financial statements: Yes

(Millions of yen, rounded to the nearest million)

Osaka, Tokyo, Nagoya, Fukuoka, Sapporo

1. Consolidated Financial Results (April 1 to June 30, 2012) for the Fiscal Year Ending March 31, 2013

(1) Consolidated Operating Results (year to date)

(Percentage figures represent changes over the same period of the previous year.)

	Net sale	S	Operating in	come	Ordinary in	come	Net incor	ne
	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)
First quarter ended June 30, 2012	398,292	11.5	62,566	(46.2)	66,233	(44.5)	87,563	15.8
First quarter ended June 30, 2011	357,219	0.7	116,210	8.3	119,236	14.8	75,584	17.9

(Note) Comprehensive income First quarter ended June 30, 2012 $\frac{1}{4}$ (40,247) million(-%) First quarter ended June 30, 2011 $\frac{1}{4}$ 51,322 million(-%)

	Earnings per share(¥)	Fully diluted earnings per share(¥)
First quarter ended June 30, 2012	110.92	110.90
First quarter ended June 30, 2011	95.75	95.74

(2) Consolidated Financial Position

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	Total assets	Net assets	Shareholders' equity	Shareholders' equity per
	(¥ million)	(¥ million)	ratio(%)	share(¥)
As of June 30, 2012	3,467,951	1,950,199	54.5	2,395.44
As of March 31, 2012	3,577,030	2,071,866	56.2	2,548.53

(Reference) Shareholders' equity As of June 30, 2012 ¥ 1,890,993 million As of March 31, 2012 ¥ 2,011,841 million

2. Dividends

		Annual dividend per share (¥)					
	1st quarter end	1st quarter end 2nd quarter end 3rd quarter end Year-end Total					
Fiscal 2011	_	90.0		90.0	180.0		
Fiscal 2012	_						
Fiscal 2012 (Projection)		90.0		90.0	180.0		

(Note) Modifications in the dividend projection from the latest announcement: None

3. Forecasts for Consolidated Operation Results for Fiscal 2012 (April 1, 2012 to March 31, 2013)

(Percentage figures represent changes over the same period of the previous year.)

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	Net sale	es	Operating is	ncome	Ordinary in	come	Net inco	me	Earnings per share
	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥)
First half year	780,000	11.0	100,000	(52.6)	95,000	(54.7)	105,000	(22.6)	133.01
Fiscal 2012	1,550,000	2.7	160,000	(39.6)	150,000	(44.5)	155,000	24.8	196.35

(Note) Modifications in forecasts of consolidated operating results from the latest announcement: None

4. Additional Information

- (1) Changes in significant subsidiaries during the period : No (changes in specified subsidiaries resulting in the change in consolidation scope)
- (2) Adoption of special accounting treatments for quarterly consolidated financial statements: Yes (Note) For details, refer to "2. Additional Information in Summary" in Page 10.

(3) Changes in accounting policies, changes in accounting estimates and restatements

1) Changes in accounting policies due to revisions of accounting standards etc
2) Changes in accounting policies other than 1)
3) Changes in accounting estimates
4) Restatements
(Note) For details, refer to "2. Additional Information in Summary" in Page 10.

(4) Number of shares outstanding (common stock)

1) Number of shares outstanding (including treasury stock) at term end:
June 30, 2012 789,666,095 shares
March 31, 2012 789,666,095 shares

2) Number of shares of treasury stock at term end:

June 30, 2012 253,017 shares March 31, 2012 252,486 shares

3) Average number of outstanding shares (during the first quarter ended June 30):

June 30, 2012 789,413,287 shares June 30, 2011 789,378,045 shares

* Implementation status about the quarterly review

• This summary of financial statements is exempt from quarterly review procedures required by Financial Instruments and Exchange Act. A part of quarterly review for securities report based on Financial Instruments and Exchange Act has not finished at the time of disclosure of this summary of financial statements. Securities report of the first quarter is scheduled to disclose on August 8, 2012 after completion of the quarterly review.

* Note to ensure appropriate use of forecasts, and other comments in particular

- 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 rate. All forecasts in this presentation are based on information currently available to the management. We will disclose necessary information in a timely manner when our management believes there will be significant impacts to our consolidated results due to the changes in the business environment or other events. For further details, please refer to "1. Qualitative Information for the first quarter of the Fiscal Year 2012 (3) Outlook for Fiscal 2012" on Page 9.
- Presentation materials for the earnings release conference call which is scheduled on July 30 and the audio
 of the conference including question-and-answer session will be promptly posted on the Company's
 website.

(Website of the Company)

http://www.takeda.com/investor-information/quarterly-results/index 869.html



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1.Qualitative Information for the first quarter of the Fiscal Year 2012

(1) Analysis of Consolidated Operation Results

(i) Introduction

The financial crisis in Europe still remains unpredictable and it has affected economic environment in the U.S. and other developed countries. Growth in emerging countries which are expected to be the driving force for global economic growth is also becoming slightly subdued. In addition, while there appears to be an economic recovery by demands for reconstruction from the damages of the Great East Japan Earthquake, the Japanese economy is obstructed by various factors such as its diminished international competitiveness, prolonging strong yen and rising energy costs, and therefore the recovery cannot be assured. The economic trend is increasingly uncertain on a global scale.

In the global pharmaceutical market, although insurance subscribers in the U.S. will be expected to increase in the medium- and long-term because the healthcare reform law was held to be constitutional by US supreme court, however the current growth has been slow due to a string of patent lapse for major products and the economic stagnation. In addition, the business environment for us has become more severe because of stringent standard for approval review and medical cost reduction initiatives implemented globally, such as NHI prices revision in this spring and continuous encouragement to use generic drugs in Japan. In spite of the severe environment, innovative new drugs that can satisfy unmet medical needs are strongly expected in developed countries, while there are strong needs for various drugs and medical care as people become increasingly health-conscious in emerging countries where relatively high economic growth is expected.

From fiscal 2010, we have been striving to achieve "Growth" through "Innovation" and "Culture" in order to realize the goal of "transformation into a New Takeda." In fiscal 2011, we acquired and consolidated Nycomed, a company having strong business foundations in Europe and emerging countries. The R&D pipeline in the late stage has also progressed. Based on these accomplishments, we have created and started the 2012-2014 Mid-Range Plan, to ensure a sustainable medium- and long-term growth starting from fiscal 2012.

According to this Mid-Range Plan, we will generate top-line synergy by launching Takeda's products in the countries where we acquired a strong base by the acquisition of Nycomed and strengthen Takeda's presence by providing products suitable to the market needs both of developed and emerging countries. We will also strive to obtain approvals for pipeline products in the late stage. We will continue investment which is necessary for future sustainable growth to improve the R&D productivity by creating new compounds by intensively allocating resources to our core therapeutic areas and maximizing the value of existing products through life cycle management.

<Initiatives in Developed Countries>

To strengthen our business foundation and the franchise for the gout treatment area in the U.S., we agreed on and completed the acquisition of "URL Pharma, Inc." in June 2012. As for new products, we began marketing of "OMONTYS" (a drug for treatment of anemia due to chronic kidney disease) in April 2012 in the U.S.. This is the first once-in-a-month erythropoiesis stimulating agent approved in the U.S. for adult patients on dialysis. In Japan, we began marketing of "AZILVA" (a drug for hypertension) in May 2012. In the clinical trials comparing its effectiveness with "Blopress" (angiotensin II receptor blocker), one of Takeda's core products and the most popular prescription drug in Japan, the effectiveness of "AZILVA" for lowering the blood pressure was verified.

<Initiatives in Emerging Countries>

In March 2012, we began marketing of "EDARBI" (a drug for hypertension) in Mexico. To respond to diverse medical needs in Brazil, we agreed on and completed the acquisition of "Multilab Indústria e Comércio de Produtos Farmacêuticos Ltda. ("Multilab")" that provides its own brand generic drugs, OTC drugs and other strongly-demanded drugs in Brazil.



<Initiatives of R&D >

In April 2012, we filed an application for marketing approve in Europe for "SYR-322" (generic name: alogliptin) for Type 2 diabetes. In June 2012, we obtained marketing approval for "Rienso" (a drug for treatment of iron deficiency anaemia) in Europe. Moreover, we obtained excellent results in the Phase III clinical trial of "MLN0002" (a drug for ulcerative colitis and Crohn's disease). The development of "MLN9708" (a drug for multiple myeloma) has progressed to the Phase III clinical trial.

With regard to "NESINA" (generic name: alogliptin) and fixed-dose combination of "NESINA" and "ACTOS" under investigation in the U.S. for type 2 diabetes, we received a Complete Response Letter from the Food and Drug Administration (FDA) in April 2012. Based on meeting with the FDA in late June, Takeda resubmitted New Drug Applications (NDAs) to the FDA for "NESINA" and fixed-dose combination of "NESINA" and "ACTOS" in July 2012.

<Enhancement of Corporate Governance>

In April 2012, to further strengthen its management strategy and business management, Takeda restructured the Corporate Strategy & Planning Department and the Finance & Accounting Department. These departments are now reformed into the "Corporate Strategy Department" and the "Corporate Finance & Controlling Department" that report directly to the President. Takeda will continue its efforts to develop and implement strategies for further growth and achieve globally consistent business management.

Over the long corporate history exceeding 230 years, Takeda has developed a corporate philosophy of "Takeda-ism = integrity, meaning fairness, honesty and perseverance". Based on this philosophy, we continue to fulfill our responsibilities as a global company to strive for environmental conservation and strict compliance with laws and regulations in its business operations, and we will work to realize Takeda's management mission: "strive towards better health for patients worldwide through leading innovation in medicine."

(Note) For your reference, major products introduced in and after 2010 are listed as follows;

< Reference > Major new products launched during 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 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 tablet of "Actos" and sulfonylurea (glimepiride))
- "Liovel" (a drug for type 2 diabetes: a fixed dose combination tablet of "Actos" and "Nesina")

Launched in May 2012

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



[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))

Launched in April 2012

"Omontys injection" (a drug for treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis, generic name: peginesatide)

<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)

[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)

Planned to be launched in series in and after October 2012

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

[Emerging countries]

<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)



(ii) Overview of Operating Results

Consolidated results (April 1 to June 30, 2012) were as follows:

	Billions of yen	Year-on-year change
Net Sales	¥398.3	Increase ¥ 41.1 (11.5 %)
Operating Income	¥ 62.6	Decrease ¥ 53.6 (46.2 %)
Ordinary Income	¥ 66.2	Decrease ¥ 53.0 (44.5 %)
Net Income	¥ 87.6	Increase ¥ 12.0 (15.8 %)

[Net Sales]

Consolidated net sales increased by ¥41.1 billion (11.5%) to ¥398.3 billion over the same period of the previous year.

In addition to domestic sales contribution from Nesina (a drug for type 2 diabetes treatment) and overseas sales growth of VELCADE (a drug for multiple myeloma treatment) by Millennium Pharmaceuticals Inc. (Takeda's wholly owned subsidiary in the U.S.), DEXILANT (a drug for gastroesophageal reflux disease) and ULORIC (a drug for hyperuricemia for patients with chronic gout) by Takeda Pharmaceuticals U.S.A., Inc., the sales of Nycomed acquired at the end of September 2011 were added to consolidated net sales. The sales increase absorbed the Yen's appreciation against the U.S. dollar and Euro (negative effects: ¥4.8 billion), and 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.

As a result, consolidated net sales increased.

- The table below shows consolidated sales of Takeda's major ethical drugs:

Billions of yen

Drug for type 2 diabetes treatment Pioglitazone (Japanese product name: Actos)	¥55.8	Decrease ¥37.3 billion (40.1%) over the same period of the previous year
Drug for hypertension treatment Candesartan (Japanese product name: Blopress)	¥47.5	Decrease ¥11.1 billion (19.0%) over the same period of the previous year
Drug for treatment of prostate cancer, breast cancer and endometriosis Leuprorelin (Japanese product name: Leuplin)	¥29.7	Decrease ¥0.4 billion (1.5%) over the same period of the previous year
Drug for peptic ulcer treatment Lansoprazole (Japanese product name: Takepron)	¥27.2	Decrease ¥4.9 billion (15.2%) over the same period of the previous year
Drug for peptic ulcer treatment Pantoprazole	¥20.2	Increase ¥20.2 billion (- %) over the same period of the previous year
Drug for multiple myeloma treatment VELCADE (Sales in the U.S.)	¥17.6	Increase ¥3.5 billion (24.7%) over the same period of the previous year

[Operating Income]

Consolidated operating income decreased by ¥53.6 billion (46.2%) to ¥62.6 billion over the same period of the previous year.

- Although gross profit increased by ¥16.7 billion (6.0%) due to sales increase, selling, general and administrative expenses further increased by ¥70.3 billion (43.4%) over the same period of the previous year. As a result, operating income decreased.



- R&D expenses increased by ¥21.2 billion (36.7%) to ¥78.9 billion over the same period of the previous year.
- Selling, general and administrative expenses, excluding R&D expenses, increased by ¥49.1 billion (47.1%) to ¥153.5 billion over the same period of the previous year, mainly due to increase in amortization of goodwill and intangible assets related to the business combination and the join of Nycomed's expenses.

[Ordinary Income]

Consolidated ordinary income decreased by ¥53.0 billion (44.5%) to ¥66.2 billion over the same period of the previous year.

- Although non-operating income and loss resulted favorably by 0.6 billion over the same period of the previous year, ordinary income decreased due to the decrease in operating income.

[Net Income]

Although ordinary income decreased, consolidated net income increased by ¥12.0 billion (15.8%) to ¥87.6 billion over the same period of the previous year, mainly due to accounting for the tax refund (including interest) for the past paid additional tax due based on correction for transfer pricing taxation.

- Earnings per share ("EPS") increased by ¥15.17 (15.8%) to ¥110.92 over the same period of the previous year.
- "EPS excluding extraordinary income (loss) and other special factors arising from business acquisitions and similar events (see Note below)", decreased by \(\frac{\pma}{32.72}\) (29.7%) to \(\frac{\pma}{77.34}\) over the same period of the previous year.
 - (Note) "EPS excluding extraordinary income (loss) and special factors" is calculated by deducting any extraordinary income (loss), and special factors such as amortization of goodwill and intangible assets, etc. related to business acquisitions, from net income.

(iii) Results by Segment (April 1 to June 30, 2012)

The following table shows sales and operating income of each business segment for the first quarter (April 1 to June 30, 2012).

Billions of yen

	N	let sales	Opera	ating income
Type of Business	Amount	Amount Change over the same period of the previous year		Change over the same period of the previous year
Ethical Drug	¥ 360.6	Increase ¥ 40.7	¥ 55.0	Decrease ¥53.9
(Japan)	<¥ 145.5>	<decrease 2.7="" ¥=""></decrease>		
(Overseas)	<¥ 215.0>	<increase 43.4="" ¥=""></increase>		
Consumer Healthcare	¥ 15.9	Increase ¥ 0.9	¥ 4.5	Increase ¥ 0.5
Other	¥ 23.0	Decrease ¥ 0.6	¥ 3.6	Decrease ¥ 0.2
Total	¥ 398.3	Increase ¥ 41.1	¥ 62.6	Decrease ¥53.6

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

[Ethical Drug Business]

Net sales <u>in the Ethical Drug Business</u> increased by ¥40.7 billion (12.7%) to ¥360.6 billion over the same period of the previous year, while operating income decreased by ¥53.9 billion (49.5%) to ¥55.0 billion.

- Net sales <u>in Japan</u> decreased by ¥2.7 billion (1.8%) to ¥145.5 billion. Despite a rise in sales of products launched in 2010 such as Nesina, it couldn't absorb the decrease in Actos and Blopress.



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

Billions of ven

Blopress (Drug for hypertension treatment)	¥33.8	Decrease of ¥2.2 billion (6.1%) over the same period of the previous year
Takepron (Drug for peptic ulcer treatment)	¥17.3	Decrease of ¥1.4 billion (7.3%) over the same period of the previous year
Leuplin (Drug for treatment of prostate cancer, breast cancer and endometriosis)	¥16.1	Decrease of ¥0.6 billion (3.5%) over the same period of the previous year
Nesina (Drug for type 2 diabetes treatment)	¥ 7.1	Increase of ¥5.2 billion (275.6%) over the same period of the previous year
Actos (Drug for type 2 diabetes treatment)	¥ 5.4	Decrease of ¥6.2 billion (53.6%) over the same period of the previous year
Vectibix (Drug for cancer treatment)	¥ 4.8	Increase of ¥0.8 billion (21.2%) over the same period of the previous year

- Sales <u>in the overseas markets</u> increased by ¥43.4 billion (25.3%) to ¥215.0 billion over the same period of the previous year mainly due to the join of Nycomed's sales which absorbed the decline in sales of Actos and Prevacid in the U.S. and Europe, including negative effects of the Yen's appreciation.

[Consumer Healthcare Business]

Net sales in the Consumer Healthcare Business increased by ¥0.9 billion (6.1%) to ¥15.9 billion over the same period of the previous year, mainly due to an increase in sales of Alinamin health tonics and tablets (vitamin-containing products) and Benza (combination cold remedy). Operating income rose by ¥0.5 billion (12.0%) to ¥4.5billion due to the increase in gross profit.

[Other Business]

Sales <u>in the Other Business</u> decreased by \$0.6 billion (2.4%) to \$23.0 billion over the same period of the previous year, and operating income decreased by \$0.2 billion (4.8%) to \$3.6 billion.

(iv) Activities and Results of "Research & Development"

Takeda always decides its R&D strategy in accordance with the latest medical needs. In the "2012-2014 Mid-Range Plan", Takeda's core therapeutic areas have been redefined as Cardiovascular & Metabolic, Oncology, Central Nervous System, Respiratory & Immunology, General Medicine (Gastrointestinal and Genitourinary), and Vaccine. By concentrating investment of its management resources into these therapeutic areas, Takeda will challenge innovation in medicine. Major activities and results of R&D thus far during the reporting period are:

[In-house R&D activities]

In April, Takeda received a complete response letter from the United States (U.S.) Food and Drug Administration (FDA) regarding New Drug Applications (NDAs) for SYR-322 (generic name: alogliptin) and fixed-dose combination (FDC) of SYR-322 and pioglitazone, both for the treatment of type 2 diabetes. In July, Takeda resubmitted NDAs to the FDA for SYR-322 and FDC of SYR-322 and pioglitazone.

- In May 2012, Takeda submitted 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 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 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), the first oral proteasome inhibitor being studied 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 in patients with relapsed and/or refractory multiple myeloma.
- In June 2012, Takeda presented the results from a Phase II study of TAK-700 (generic name: orteronel), a selective oral 17,20 lyase inhibitor, 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.

[Fixed Dose Combination activities]

- In June 2012, Takeda submitted MAAs to the EMA for a FDC of SYR-322 (generic name: alogliptin) and pioglitazone, and a FDC of SYR-322 and metformin.

[Alliance activities]

- In April, Takeda received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the EMA for Rienso (generic name: ferumoxytol), a new intravenous (IV) iron therapy with a proposed indication for the treatment of iron deficiency anaemia (IDA) in adult patients with chronic kidney disease (CKD), which Takeda in-licensed from AMAG Pharmaceuticals of the US. In June 2012, Takeda received MAA from the European Commission (EC) for Rienso.
- 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 US, as a once-daily treatment for adult patients with short bowel syndrome (SBS).
- In June 2012, Takeda and Amgen entered into a new agreement which provides Takeda with the exclusive worldwide rights to independently develop, manufacture and commercialize AMG706 (generic name: motesanib diphosphate). In July, Takeda initiated a phase III clinical trial in Japan, Hong Kong, South Korea and Taiwan, evaluating motesanib in combination with chemotherapy in patients with advanced non-squamous non-small cell lung cancer (NSCLC).
- In July 2012, Takeda received a positive opinion from the CHMP of the EMA for ADCETRIS (generic name: brentuximab vedotin), which Takeda in–licensed from Seatle Genetic, for the treatment of adult patients with 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).

(2) Analysis of Consolidated Financial Position

[Assets]

The amount of total assets as of June 30, 2012 is ¥3,468.0 billion, a decrease of ¥109.1 billion compared to the previous fiscal year end. Current assets decreased by ¥81.8 billion mainly due to a decrease in marketable securities, and noncurrent assets decreased by ¥27.3 billion mainly due to a decrease in intangible assets including goodwill.

[Liabilities]

The amount of total liabilities as of June 30, 2012 is \(\xi\$1,517.8\) billion, an increase of \(\xi\$12.6\) billion compared to the previous fiscal year end.



[Net Assets]

The amount of total net asset as of June 30, 2012 is \(\frac{\pmathbf{\frac{4}}}{1,950.2}\) billion, a decrease of \(\frac{\pmathbf{\frac{4}}}{121.7}\) billion compared to the previous fiscal year end, mainly due to a decrease in foreign currency translation adjustment caused by the Yen's appreciation. The shareholders' equity ratio decreased by 1.7 pt. to 54.5% from the previous fiscal year end.

(3) Outlook for Fiscal 2012

The forecast for consolidated results for the full year of fiscal 2012 has not been changed from the previous forecast (announced at the fiscal 2011 financial results announcement on May 11, 2012), considering the current results, the revised foreign exchange rates for the forecast and the effect on the business combination of "Multilab" acquired in July, 2012.

[Full-year consolidated forecasts (April 1, 2012 to March 31, 2013)]

Billions of yen

	Net Sales	Operating income	Ordinary income	Net income
First half of the fiscal 2012	¥780.0	¥100.0	¥95.0	¥105.0
Fiscal 2012	¥1,550.0	¥160.0	¥150.0	¥155.0

[Assumptions for the Forecast]

The average of foreign exchange rates for the full year of fiscal 2012 are assumed to be US\$1 = \$80 and Euro1 = \$100.

[Forward looking statements]

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 forecast, we will announce such facts promptly.

The effects of acquisition of "URL Pharma, Inc." and "Multilab" included in this revised forecast for FY2012 may be changed within one year from the acquisition date, according to the business combination accounting standards. The final amount will be settled through the audit by our independent auditor.



2. Additional Information in Summary

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in consolidation scope):

No applicable event occurred during the period.

(2) Adoption of special accounting treatments for quarterly consolidated financial statements

(i) Calculation of the tax expenses

The effective tax rate expected to be imposed on pretax net income (after tax effect accounting) applicable to the tax year in which this first quarter is included was estimated based on reasonable assumptions. Then, tax expenses for the first quarter were calculated by multiplying the pretax net income for the quarter by the estimated effective tax rate.

(3) Changes in accounting policies, changes in accounting estimates and restatements

- Changes in accounting policies which are difficult to distinguish from changes in accounting estimates
- (i) Effective from the first quarter of the current fiscal year, the Company and its domestic subsidiaries changed the depreciation method for the relevant tangible assets newly acquired from April 1, 2012 according to the amendment of Corporation Tax Act in Japan.
 - However this change had only minor impact on operating income, ordinary income and income before income taxes and minority interests in this first quarter.



3. Consolidated Financial Statements for the First Quarter (April 1 to June 30, 2012)

(1) Consolidated Balance Sheets

		Millions of ye
	As of March 31, 2012	As of June 30, 2012
ASSETS		
Current assets		
Cash and deposits	214,885	205,395
Notes and accounts receivable	344,679	337,127
Marketable securities	240,740	175,937
Merchandise and products	93,514	101,935
Work in process	52,594	53,892
Raw materials and supplies	48,906	47,692
Deferred tax assets	221,230	210,308
Other current assets	65,303	67,579
Allowance for doubtful receivables	(2,855)	(2,671)
Total current assets	1,278,996	1,197,194
Non-current assets		
Tangible assets	488,702	487,011
Intangible assets		
Goodwill	582,257	563,797
Patent rights	322,537	382,511
Sales rights	570,166	505,696
Other intangible assets	41,288	40,498
Total intangible assets	1,516,247	1,492,502
Investments and other assets		
Investment securities	186,697	179,987
Other assets	106,507	111,343
Allowance for doubtful receivables	(119)	(85)
Total investments and other assets	293,085	291,244
Total non-current assets	2,298,035	2,270,757
Total Assets	3,577,030	3,467,951



Millions of yen As of March 31, 2012 As of June 30, 2012 **LIABILITIES Current liabilities** 101,950 99,463 Notes and accounts payable Short-term loans 241,411 241,456 24,097 31,766 Income taxes payable Reserve for employees' bonuses 35,288 41,034 Other reserves 11,883 15,235 337,103 297,484 Other current liabilities Total current liabilities 751,731 726,437 Non-current liabilities Bond 190,000 190,000 111,393 111,349 Long-term loans Deferred tax liabilities 301,758 301,555 Reserve for employees' retirement benefits 49,978 54,430 Other reserves 10,941 10,017 Other non-current liabilities 84,911 128,417 Total non-current liabilities 753,433 791,316 1,505,165 Total liabilities 1,517,752 **NET ASSETS** Shareholders' equity Common stock 63,541 63,541 Capital surplus 49,638 41,245 2,254,075 Retained earnings 2,270,583 Treasury stock (808)(810)Total shareholders' equity 2,366,446 2,374,559 **Accumulated other comprehensive income** Unrealized gains on available-for-sale 87,046 83,493 securities Deferred gains/losses on derivatives under 2 224 hedge accounting Foreign currency translation adjustments (441,653)(567,284)Total accumulated other comprehensive (354,605)(483,567)income Stock acquisition rights 504 620 Minority interests in income 59,522 58,586 Total net assets 2,071,866 1,950,199 Total liabilities and net assets 3,577,030 3,467,951



(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Consolidated Statements of Income

		Millions of yen
	First quarter ended June 30, 2011	First quarter ended June 30, 2012
	(April 1 to June 30, 2011)	(April 1 to June 30, 2012)
Net sales	357,219	398,292
Cost of sales	78,900	103,313
Gross profit	278,320	294,978
Selling, general and administrative expenses		
R&D expenses	57,715	78,878
Other	104,394	153,534
Total selling, general and administrative expenses	162,109	232,412
Operating income	116,210	62,566
Non-operating income		
Interest income	477	343
Dividend income	1,717	1,782
Equity in earnings of affiliates	108	315
Gain on transfer of operation	2,793	3,695
Other non-operating income	2,696	2,062
Total non-operating income	7,792	8,198
Non-operating expenses		
Interest expenses	265	781
Donations and contributions	531	251
Loss from foreign exchange	1,944	1,638
Other non-operating expenses	2,026	1,861
Total non-operating expenses	4,766	4,531
Ordinary income	119,236	66,233
Extraordinary income		
Interest on tax refund	_	11,593
Total extraordinary income	_	11,593
Extraordinary loss		
Restructuring costs	_	2,096
Total extraordinary loss	_	2,096
Income before income taxes and minority interests	119,236	75,730
Income taxes	42,615	33,005
Refund for past paid taxes	-	(45,622)
Total income taxes	42,615	(12,618)
Income before minority interests	76,621	88,347
Minority interests	1,037	784
Net income	75,584	87,563
1,00 1110 01110		01,505



Consolidated Statements of Comprehensive Income

		Millions of yen
	First quarter ended	First quarter ended
	June 30, 2011	June 30, 2012
	(April 1 to June 30, 2011)	(April 1 to June 30, 2012)
Income before minority interests	76,621	88,347
Other comprehensive income		
Unrealized gains/losses on available-for-sale securities	2,277	(3,574)
Deferred gains/losses on derivatives under hedge accounting	4,266	222
Foreign currency translation adjustments	(31,799)	(125,235)
Share of other comprehensive income of affiliates accounted for using equity method	(44)	(6)
Total other comprehensive income	(25,299)	(128,594)
Comprehensive income	51,322	(40,247)
[Comprehensive income attributable to] Comprehensive income attributable to owners of the		
parent	50,386	(41,399)
Comprehensive income attributable to minority interests	935	1,152



(3) Note regarding assumption of a going concern

First quarter ended June 30, 2012 (April 1 to June 30, 2012) No events to be noted for this purpose

(4) Note regarding significant changes in the amount of shareholders' equity

First quarter ended June 30, 2012 (April 1 to June 30, 2012) No events to be noted for this purpose

(5) Segment Information

(i) Net sales and profit by business segment

First quarter ended June 30, 2011 (April 1 to June 30, 2011)

Millions of ven

	Bus	iness Segment	S			Amount reported
	Ethical Drug	Consumer Healthcare	Other	Total	Adjustments	on statement of income for Q1
Net sales						
Sales to outside customers	319,906	14,935	23,575	358,416	(1,196)	357,219
Intersegment sales and transfers	739	31	1,463	2,233	(2,233)	_
Total	320,644	14,966	25,038	360,649	(3,429)	357,219
Segment profit	108,893	4,021	3,829	116,743	(533)	116,210

First quarter ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

	Bus	iness Segment	S			Amount reported	
	Ethical Drug	Consumer Healthcare	Other	Total	Adjustments	on statement of income for Q1	
Net sales							
Sales to outside customers	360,559	15,850	23,015	399,425	(1,133)	398,292	
Intersegment sales and transfers	809	101	1,571	2,481	(2,481)		
Total	361,368	15,952	24,586	401,906	(3,614)	398,292	
Segment profit	54,977	4,505	3,646	63,128	(562)	62,566	

(Note)Segment profit equals operating income on each segment.

(ii) Information regarding regions

Net sales

First quarter ended June 30, 2011 (April 1 to June 30, 2011)

Millions of yen

	Americas			Eur	ope			<i>J J</i>
Japan		United States	Latin America	1341	Russia /CIS	Asia	Other	Total
183,190	120,899	117,069	1,303	43,919	20	6,943	2,269	357,219

First quarter ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

		Americas		Eur	ope			
Japan		United	Latin		Russia	Asia	Other	Total
_		States	America		/CIS			
180,894	119,373	101,024	13,824	77,072	15,106	14,869	6,084	398,292



(Note)

- 1. Effective from the first quarter of current fiscal year, the Company changed the classification of region for the purpose of providing more detailed sales information (previous "Asia and other regions" was divided into "Asia" and "Other"). For fair comparison over the same period last year, the amounts reported in the same period of last year are modified according to the new classification. In addition, the regional category of some countries in other than Americas was also changed as this reclassification.
- 2. "Other" region includes Middle East, Oceania and Africa.

(6) Sales Results (Sales to outside customers)

First quarter ended June 30, 2011 (April 1 to June 30, 2011)

Millions of yen

	Ethical Drug oan) (Overseas) Subtotal		Ethical Drug Consumer					Amount reported	
(Japan)			Healthcare	Other	Adjustments	on statement of income for Q1	[Royalties]		
148,244	171,662	319,906	14,935	23,575	(1,196)	357,219	[8,952]		

First quarter ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

	Ethical Drug		Common			Amount reported	
(Japan)	(Overseas)	Subtotal	Consumer healthcare	Other	Adjustments	on statement of income for Q1	[Royalties]
145,525	215,034	360,559	15,850	23,015	(1,133)	398,292	[8,507]

(7) Significant Subsequent Event

(i) Issuance of U.S. dollar unsecured senior notes

The Company issued U.S. dollar unsecured senior notes on July 17, 2012 based on the resolution of Board of Directors' meeting on June 22, 2012, as outlined below.

	U.S. dollar unsecured senior notes (due in 2015)	U.S. dollar unsecured senior notes (due in 2017)			
1. Issue Amount	US\$1.5 billion	US\$1.5 billion			
2. Issue Price	100% of the principal amount				
3. Coupon	1.031% per annum	1.625% per annum			
4. Maturity Date	March 17, 2015	March 17, 2017			
5. Method of redemption	Bullet redempt	ion at maturity			
6. Use of proceeds	To partially repay short-term interest-bearing debt which resulted from the acquisition of Nycomed A/S				
7. Important special provision	Negative pledge clause				



4.Supplemental Information

(1) Ethical Drugs Sales [Consolidated]

Billions of yen

	First quarter	First quarter		er the same previous year
	ended June 30, 2011	ended June 30, 2012	Amount	Increase (decrease) in percent
Domestic sales	148.6	146.1	(2.5)	(1.7%)
Overseas sales	161.9	205.6	43.7	27.0%
Americas	116.5	115.7	(0.8)	(0.7%)
United States	114.0	97.5	(16.5)	(14.5%)
Latin America	1.2	13.8	12.5	_
Europe	37.5	70.2	32.7	87.4%
Russia/CIS	0.0	15.1	15.1	_
Asia	5.8	13.8	8.1	139.9%
Other	2.2	5.9	3.7	169.0%
Royalty Income and Service Income	10.1	9.7	(0.5)	(4.8%)
Domestic	0.4	0.3	(0.1)	(33.0%)
Overseas	9.8	9.4	(0.4)	(3.7%)
Total sales	320.6	361.4	40.7	12.7%

(Note)

- 1. Sales amount includes intersegment sales.
- 2. Effective from the first quarter of current fiscal year, the Company changed the classification of region for the purpose of providing more detailed sales information (previous "Asia and other regions" was divided into "Asia" and "Other"). For fair comparison over the same period last year, the amounts reported in the same period of last year are modified according to the new classification. In addition, the regional category of some countries in other than Americas was also changed as this reclassification.
- 3. "Other" region includes Middle East, Oceania and Africa.

Ratio of Overseas sales	53.5%	59.5%
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Foreign exchange rates

First quarter ended June 30, 2011

US\$ average rate

81.7

Euro average rate

First quarter ended June 30, 2012

81.7

80.2

(1.6)

102.8



Daxas

(2) Ethical Drugs: Major products sales (Regional basis) [Consolidated]

Billions of yen Change over the same period of First quarter First quarter the previous year ended June ended June 30, Increase Amount (decrease) 30, 2011 2012 in percent Leuprorelin Worldwide sales 29.7 30.1 (0.4)(1.5%)Japan..... 16.7 16.1 (0.6)(3.5%)4.0 4.2 0.2 Americas 5.1% 7.9 7.5 Europe (0.5)(6.1%)Asia/Other..... 1.5 1.9 0.4 28.3% Lansoprazole Worldwide sales 32.1 27.2 (4.9)(15.2%)18.7 17.3 (1.4)Japan..... (7.3%)8.0 6.3 Americas (1.7)(21.6%)Europe 4.5 2.2 (2.3)(50.6%)Asia/Other..... 0.9 1.4 0.5 51.2% Candesartan (*) Worldwide sales 58.6 47.5 (11.1)(19.0%)Japan..... 36.0 33.8 (2.2)(6.1%)Americas/Europe/Asia/Other 22.6 13.7 (8.9)(39.4%)Pioglitazone Worldwide sales 93.1 55.8 (37.3)(40.1%)11.5 5.4 (6.2)Japan..... (53.6%)Americas 73.4 46.9 (26.5)(36.1%)Europe 6.8 2.3 (4.5)(66.1%)Asia/Other 1.3 1.2 (0.2)(12.0%)17.6 VELCADE (U.S.) 14.1 3.5 24.7% Amitiza (U.S.) 5.0 5.0 (0.0)(0.6%)4.8 7.0 2.2 DEXILANT (Americas) 45.2% 3.8 ULORIC (Americas) 3.0 0.8 28.0% 20.2 20.2 *Pantoprazole*

(Note) Worldwide sales of *Candesartan* are divided into only two areas (Japan and Americas/Europe/Asia/Other), because export sales of *Candesartan* to licensees are recorded under a single route.

0.7

0.7



(3) Ethical Drugs: Major products domestic sales [Unconsolidated]

Billions of yen

Product name	Launched	Category	First quarter ended	First quarter ended	Change over the same period of the previous year	
Product name	Month/Year	Category	June 30, 2011	June 30, 2012	Amount	Increase (decrease) in percent
Blopress	6/1999	Hypertension	36.0	33.8	(2.2)	(6.1%)
<ecard></ecard>	3/2009	Hypertension	3.3	3.2	(0.1)	(2.3%)
<unisia></unisia>	6/2010	Hypertension	3.7	5.3	1.6	42.9%
Takepron	12/1992	Peptic ulcers	18.7	17.3	(1.4)	(7.3%)
Leuplin	9/1992	Prostate cancer, breast cancer and endometriosis	16.7	16.1	(0.6)	(3.5%)
Enbrel	3/2005	Rheumatoid arthritis	10.3	10.8	0.4	4.4%
Nesina	6/2010	Diabetes	1.9	7.1	5.2	275.6%
<liovel></liovel>	9/2011	Diabetes	_	0.8	0.8	_
Actos	12/1999	Diabetes	11.5	5.4	(6.2)	(53.6%)
Basen	9/1994	Diabetes	7.0	5.2	(1.8)	(25.5%)
Vectibix	6/2010	Colorectal cancer	4.0	4.8	0.8	21.2%
Benet	5/2002	Osteoporosis	4.4	3.5	(0.9)	(21.5%)
Takeda freeze-dried live attenuated measles / rubella combined vaccine	1/2006	Vaccine for measles /rubella	3.1	2.6	(0.5)	(17.3%)
Azilva	5/2012	Hypertension	_	1.9	1.9	_
Seltouch	9/1993	Topical NSAID	2.1	1.8	(0.3)	(13.1%)
Reminyl	3/2011	Alzheimer-type dementia	0.3	1.8	1.4	454.0%
Rozerem	7/2010	Insomnia	0.4	1.0	0.7	170.6%

(4) Consumer Healthcare: Major products sales

Billions of yen

			Change over the same period of the previous year	
Product name	roduct name First quarter ende June 30, 2011		Amount	Increase (decrease) in percent
Alinamin health tonics	3.6	4.2	0.6	15.9%
Alinamin tablets	3.9	4.1	0.1	3.8%
Biofermin	1.8	2.1	0.3	16.4%
Benza (excluding drinks)	1.1	1.2	0.1	6.6%
Borraginol	1.0	1.0	0.0	2.5%



(5) Development activities

■ US/EU/Jpn

Development code/product name <generic name=""></generic>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
Feraheme® / Rienso® <ferumoxytol></ferumoxytol>	IV iron (injection)	Iron deficiency anaemia in adult patients with chronic kidney disease	EU	Approved (Jun 12)	In-license (AMAG)
		Diabetes mellitus	US	FDA Complete Response Letter (Apr 12)	
			EU	Filed (May 12)	
SYR-322 <alogliptin></alogliptin>	DPP-4 inhibitor (oral)	Diabetes mellitus (Fixed-dose combination with Actos)	US EU	FDA Complete Response Letter (Apr 12) Filed (Jun 12)	In-house
		Diabatas mallitus /Fixed dags			
		Diabetes mellitus (Fixed-dose combination with metformin)	US EU	Filed (Nov 11) Filed (Jun 12)	
TAK-390MR <dexlansoprazole></dexlansoprazole>	Proton pump inhibitor (oral)	Erosive esophagitis (healing and maintenance) and non-erosive gastro-esophageal reflux disease	EU Jpn	Filed (Mar 12) P-II	In-house
		Relapsed or refractory Hodgkin lymphoma	EU Jpn	Filed (May 11) P-I/II	
		Relapsed or refractory systemic	EU	Filed (May 11)	
SGN-35	CD30 monoclonal	anaplastic large cell lymphoma	Jpn	P-I/II	In-license
<pre><bre><bre><bre><bre>vedotin></bre></bre></bre></bre></pre>	antibody-drug conjugate (injection)	Relapsed cutaneous T-cell lymphoma	EU	P-III	(Seattle Genetics)
vedotiii>	(Injection)	Post-ASCT Hodgkin lymphoma	EU	P-III	Geneucs)
		Front line Hodgkin lymphoma	EU	P-I	
		Front line systemic anaplastic large cell lymphoma	EU	P-I	
OMONTYS® <peginesatide></peginesatide>	Synthetic, peptide-based erythropoiesis-stimulating agent (injection)	Anemia due to chronic kidney disease in adult patients on dialysis	EU	Filed (Feb 12)	In-license (Affymax)
TAK-085 <omega-3-acid ethyl<br="">esters 90></omega-3-acid>	EPA/DHA agent (oral)	Hyperlipidemia	Jpn	Filed (Sep 11)	In-license (Pronova)
Revestive [®] <teduglutide></teduglutide>	Glucagon-like peptide 2 analogue (injection)	Short bowel syndrome	EU	Filed (Mar 11)	In-license (NPS)
Contrave [®] <naltrexone bupropion="" sr=""></naltrexone>	Mu-opioid receptor antagonist and dopamine/norepinephrine re-uptake inhibitor (oral)	Obesity	US	FDA Complete Response Letter (Jan 11)	In-license (Orexigen)
TAI/ 075	GPR40 agonist		US	P-III	
TAK-875 <->	(Glucose-dependent insulin secretagogue) (oral)	Diabetes mellitus	EU Jpn	P-III P-III	In-house
TAV 700			US	P-III	
TAK-700	Non-steroidal androgen synthesis inhibitor (oral)	Prostate cancer	US EU	P-III	In-house
	Non-steroidal androgen	Prostate cancer	US		In-house
	Non-steroidal androgen	Prostate cancer Ulcerative colitis	US EU Jpn US	P-III P-III P-III	In-house
	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal		US EU Jpn US EU	P-III P-III P-III	
<orteronel></orteronel>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin	Ulcerative colitis	US EU Jpn US EU Jpn	P-III P-III P-III P-III P-I	In-house
<orteronel></orteronel>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal		US EU Jpn US EU	P-III P-III P-III	
<orteronel></orteronel>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell	US EU Jpn US EU Jpn US EU US EU	P-III P-III P-III P-III P-III P-III P-III P-III	
<pre><orteronel> MLN0002 <vedolizumab></vedolizumab></orteronel></pre>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin (injection)	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell lymphoma	US EU Jpn US EU Jpn US EU	P-III P-III P-III P-III P-III P-III P-III P-III P-III	
<orteronel></orteronel>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell	US EU Jpn US EU Jpn US EU US EU	P-III P-III P-III P-III P-III P-III P-III P-III	
<pre><orteronel> MLN0002 <vedolizumab> MLN8237</vedolizumab></orteronel></pre>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin (injection) Aurora A kinase inhibitor	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell lymphoma Aggressive NHL, Acute myelogenous leukemia (AML), High-risk myelodysplastic syndrome (MDS),	US EU Jpn US EU US EU US EU US EU US	P-III	In-house
<pre><nteronel> MLN0002 <vedolizumab> MLN8237 <alisertib></alisertib></vedolizumab></nteronel></pre>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin (injection) Aurora A kinase inhibitor (oral)	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell lymphoma Aggressive NHL, Acute myelogenous leukemia (AML), High-risk myelodysplastic syndrome (MDS), Ovarian cancer	US EU Jpn US EU	P-III	In-house
<pre><orteronel> MLN0002 <vedolizumab> MLN8237</vedolizumab></orteronel></pre>	Non-steroidal androgen synthesis inhibitor (oral) Humanized monoclonal antibody against α4β7 integrin (injection) Aurora A kinase inhibitor	Ulcerative colitis Crohn's disease Relapsed or refractory peripheral T-cell lymphoma Aggressive NHL, Acute myelogenous leukemia (AML), High-risk myelodysplastic syndrome (MDS), Ovarian cancer Progressive cancer	US EU Jpn US EU	P-III	In-house



Development code/product name <generic name=""></generic>	Drug Class (administration route)	Indications oute)			In-house/ In-license
			Jpn	P-III	
SYR-472	DPP-4 inhibitor	Diabetes mellitus	US	P-II	In-house
<trelagliptin></trelagliptin>	(oral)	2.020.000	EU	P-II	
TAK-491 <azilsartan medoxomil></azilsartan 	Angiotensin II receptor blocker (oral)	Hypertension (Fixed-dose combination with chlorthalidone)	EU	P-III	In-house
TAK-536 <azilsartan></azilsartan>	Angiotensin II receptor blocker (oral)	Hypertension (Fixed-dose combination with amlodipine besilate)	Jpn	P-III	In-house
TAK-438 <->	Potassium-competitive acid blocker (oral)	Acid-related diseases (GERD, Peptic ulcer, etc.)	Jpn	P-III	In-house
TAK-375SL <ramelteon></ramelteon>	MT ₁ /MT ₂ receptor agonist (sublingual)	Bipolar disorder	US	P-III	In-house
		Advanced non-squamous non-small	US	P-III	
AMG 706	VEGFR1-3, PDGFR, c-Kit	cell lung cancer	EU	P-III	In-license
<motesanib< td=""><td>inhibitor (oral)</td><td></td><td>Jpn</td><td>P-III</td><td>(Amgen)</td></motesanib<>	inhibitor (oral)		Jpn	P-III	(Amgen)
diphosphate>	,	Breast cancer	US	P-I/II	, ,
		Major depressive disorders	US	P-III	
Lu AA21004	Multimodal anti-depressants	major doprodorvo diodracio	Jpn	P-III	In-license
<vortioxetine></vortioxetine>	(oral)	Generalized anxiety disorders	US	P-III	(Lundbeck)
AMG 386	Anti-angiopoietin peptibody (injection)	Ovarian cancer	Jpn	P-III	In-license (Amgen)
AMG 479 <ganitumab></ganitumab>	Human monoclonal antibody against human type 1 insulin-like growth factor receptor (IGF-1R) (injection)	Metastatic pancreas cancer	Jpn	P-III	In-license (Amgen)
ATL-962 <cetilistat></cetilistat>	Lipase inhibitor (oral)	Obesity	Jpn	P-III	In-license (Norgine BV)*
	Mitochondria targeted			*2	
Sovrima [®] <idebenone></idebenone>	anti-oxidant (oral)	Friedreich's ataxia Duchenne muscular dystrophy	EU EU	P-III ^{*2} P-III	In-license (Santhera)
-	Atypical antipsychotic agent	Schizophrenia	EU	P-III	In-license
<pre><lurasidone< pre=""></lurasidone<></pre>	(oral)	Bipolar disorder	EU	P-III	(Dainippon
hydrochloride> TAK-816 <->	Hib vaccine (injection)	Prevention of infectious disease caused by Haemophilus influenza Type b (Hib)	Jpn	P-III	Sumitomo) In-license (Novartis)
TAK-428	Neurotrophic factor production accelerator (oral)	Diabetic neuropathy	US EU	P-II P-II	In-house
	, ,	E.A			
TAK-385 <->	LH-RH antagonist (oral)	Endometriosis, Uterine fibroids Prostate Cancer	Jpn -	P-II P-I	In-house
	CD20 monoclonal antibody		US	P-II	In-license
- <veltuzumab></veltuzumab>	(injection)	Rheumatoid arthritis	EU	P-II	In-license (Immunomedic
				1 11	`
TAK-361S <->	Quadruple vaccine (injection)	Prevention of infectious disease caused by Diphtheria, Pertussis, Tetanus, Polio	Jpn	P-II	In-license (Japan Polio
TAK-329 <->	Glucokinase activator (oral)	Diabetes mellitus	-	P-I	In-house
TAK-448 <->	Metastin analog (injection)	Prostate cancer	-	P-I	In-house
TAK-733	MEK inhibitor (oral)	Solid tumors	-	P-I	In-house

^{*1} Alizyme assigned ATL-962 (Cetilistat) business to Norgine BV on 15 October, 2009.

^{*2} Re-submission subject to data analysis.



Development code /product name <generic name=""></generic>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
TAK-960 <->	PLK1 inhibitor (oral)	Solid tumors	-	P-I	In-house
TAK-441 <->	Hedgehog signaling pathway Inhibitor (oral)	Solid tumors	-	P-I	In-house
TAK-272 <->	Direct renin inhibitor (oral)	Hypertension	-	P-I	In-house
TAK-259 <->	α1D-adrenoceptor antagonist (oral)	Overactive bladder	-	P-I	In-house
TAK-357 <->	Cognitive enhancer (oral)	Alzheimer's disease	-	P-I	In-house
TAK-063 <->	PDE10A Inhibitor (oral)	Schizophrenia	-	P-I	In-house
MLN4924 <->	NEDD 8 activating enzyme inhibitor (injection)	Advanced malignancies	-	P-I	In-house
MLN0128* ³ < - >	mTORC1/2 inhibitor (oral)	Solid tumors Multiple myeloma Waldenstrom's macroglobulinemia	-	P-l	In-house
MLN1117* ⁴ <->	Pl3Kα isoform inhibitor (oral)	Solid tumors	-	P-I	In-house
MLN0264 <->	Antibody-Drug Conjugate targeting GCC (injection)	Advanced gastrointestinal malignancies	-	P-I	In-house
MLN2480 <->	pan-Raf kinase inhibitor (oral)	Solid tumors	-	P-I	In-license (Sunesis)
MT203 <namilumab></namilumab>	GM-CSF monoclonal antibody (injection)	Rheumatoid arthritis	US EU	P-I P-I	In-licence (Micromet)*5
Lu AA24530 <->	Multimodal anti-depressants (oral)	Major depressive and generalized anxiety disorders	US Jpn	P-I * ⁶ P-I	In-license (Lundbeck)
AMG 403 <fulranumab></fulranumab>	Human monoclonal antibody against human Nerve Growth Factor (NGF) (injection)	Pain	Jpn	P-I	In-license (Amgen)
ITI-214 <->	PDE1 Inhibitor (oral)	Cognitive impairment associated with schizophrenia	-	P-I	In-license (Intra-Cellular)

^{*3} MLN0128 used to be INK128.

^{*4} MLN1117 used to be INK1117.

^{*5} On Mar 7th, 2012, Amgen completed a tender offer for the outstanding shares of Micromet, making Micromet its wholly owned subsidiary.

^{*6} To be prepared for P-III in the US.



Additional indications/formulations of compounds

Development code/product name <generic name=""> Brand name (country / region)</generic>	Drug Class	Indications or formulations	Stage	In-house/ In-license
NE-58095 <risedronate> Benet (Jpn)</risedronate>	Bone resorption inhibitor	Once-monthly formulation	Jpn Filed (Mar 12)	In-license (Ajinomoto)
AMITIZA® <lubiprostone></lubiprostone>	Chloride channel activator	Opioid-Induced Constipation (OIC)	US Filed (Jul 12)	In-license (Sucampo)
TAP-144-SR <leuprorelin acetate=""> Leuplin (Jpn) Lupron Depot (US) Enantone, etc. (EU)</leuprorelin>	LH-RH agonist	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn P-III	In-house
VELCADE® 	Proteasome inhibitor	Front line MCL Relapsed diffuse large B cell lymphoma	US P-III US P-II	In-house
Vectibix® <panitumumab></panitumumab>	Human monoclonal antibody (Mab) against the human EGFR	Squamous cell carcinoma of head and neck	Jpn P-III	In-license (Amgen)
AD4833/TOMM40	Insulin sensitizer/ Biomarker assay	Alzheimer's disease prevention	US P-I EU P-I	In-license (Zinfandel)

■ Recent progress in stage Progress in stage since release of FY2011 results (May 11, 2012)

Development code	Indications	Country/Region	Progress in stage
Feraheme [®] /Rienso [®]	Iron deficiency anaemia in adult patients with chronic kidney disease	EU	Approved (Jun 12)
SYR-322	Diabetes mellitus	EU	Filed (May 12)
SYR-322	Diabetes mellitus (Fixed-dose combination with Actos)	EU	Filed (Jun 12)
SYR-322	Diabetes mellitus (Fixed-dose combination with metformin)	EU	Filed (Jun 12)
lubiprostone	Opioid-Induced Constipation (OIC)	US	Filed (Jul 12)
MLN9708	Multiple myeloma	US, EU	P-III
TAK-375SL	Bipolar disorder	US	P-III
TAK-357	Alzheimer's disease	-	P-I
TAK-063	Schizophrenia	-	P-I
MLN0264	Advanced gastrointestinal malignancies	-	P-I
ITI-214	Cognitive Impairment Assocuated with Schizophrenia	-	P-I

■ Discontinued projects Discontinued since release of FY2011 results (May 11, 2012)

Development code	Indications (Stage)	Reason
TAK-701	Advanced malignancies (P-I)	The decision to discontinue development was made because it no longer fits in the product development portofolio of Takeda.
TAK-591	Hypertension (P-I)	As TAK-536 has been launched, there is no need to keep the backup compound.
MLN0518	Inhibitor of receptor kinases (FLT3, PDGFR, c-KIT) (US P-II)	Clinical data from both single agent and a combination study did not warrant further development in glioblastoma.



Filings and Approvals in Regions other than US/EU/Jpn

Region	Country	Development code / product name (stage)
	Brazil	SYR-322 (Filed Aug 11), TAK-491 (Filed Nov 11), TAK-491/chlorthalidone (Filed Jun 12)
Americas Ex. US	Colombia	DAXAS* ⁷ (Filed Aug 11)
	Venezuela	DAXAS (Filed Jan 10)
	Albania	DAXAS (Filed May 12)
E E EU	Kosovo	DAXAS (Approved May 12)
Europe Ex. EU	Montenegro	DAXAS (Filed Jun 11)
	Switzerland	Rienso (Filed Aug 10), lurasidone (Filed Mar 12)
D 1 - (O10	Armenia	DAXAS (Filed Jun 12)
Russia/CIS	Uzbekistan	DAXAS (Approved Jun 12)
	China	DAXAS (Filed Dec 11), SYR-322 (Filed Mar 12)
	Hong Kong	TAK-390MR (Filed Aug 11), TAK-491 (Filed Mar 12)
	Indonesia	SYR-322 (Filed Jan 11), TAK-491 (Filed Feb 12), DAXAS (Filed Sep 10)
	Philippines	TAK-491 (Filed Oct 11), TAK-390MR (Filed Nov 11), TCV-116*8/amlodipine besilate (Filed Jan 12)
	Singapore	DAXAS (Filed Aug 11)
Asia Ex. Jpn	S. Korea	TAK-390MR (Filed Sep 11), SYR-322 (Filed Mar 12)
	Taiwan	SYR-322 (Filed Mar 11), TAK-491 (Filed Aug 11), TAK-491/chlorthalidone (Filed May 12),
		DAXAS (Approved Jul 12), TAK-390MR (Filed Sep 11)
	Thailand	TAK-390MR (Filed Aug 11), TAK-491 (Filed Sep 11), TAK-491/chlorthalidone (Filed Jun 12),
		DAXAS (Filed Jan 11)
	Vietnam	DAXAS (Filed Dec 10)
	Botswana	DAXAS (Filed Dec 11)
	Egypt	DAXAS (Filed Jan 12)
	Isreal	DAXAS (Filed Aug 11)
	Mauritius	DAXAS (Filed Mar 11)
Others	Saudi Arabia	DAXAS (Filed May 12)
	South Africa	DAXAS (Filed Aug 09)
	Tanzania	DAXAS (Filed Sep 11)
	Uganda	DAXAS (Filed Apr 11)
	Zambia	DAXAS (Filed Feb 12)

^{*7} DAXAS® < roflumilast> PDE4 inhibitor (oral) for the treatment of Chronic Obstructive Pulmonary Disease

^{*8} TCV-116 <candesartan cilexetil> Angiotensin II receptor blocker (oral) for the treatment of Hypertension