Summary of Financial Statements for the Three Month Period Ended June 30, 2013 (Japan GAAP, Consolidated)

July 31, 2013

Takeda Pharmaceutical Company Limited

Stock exchange listings: Tokyo, Nagoya, Fukuoka, Sapporo

TSE Code: 4502
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Scheduled date of securities report submission: August 9, 2013
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)

1. Consolidated Financial Results for the Three Month Period Ended June 30, 2013 (April 1 to June 30, 2013)

(1) Consolidated Operating Results (year to date)

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

	Net sales		Operating income		Ordinary income		Net income	
	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)
Three month period ended June 30, 2013	410,302	3.0	47,705	(23.8)	52,490	(20.7)	29,076	(66.8)
Three month period ended June 30, 2012	398,292	11.5	62,566	(46.2)	66,233	(44.5)	87,563	15.8

(Note) Comprehensive income Three month period ended June 30, 2013 ¥ 124,628 million(－%)
Three month period ended June 30, 2012 ¥ (40,247) million(－%)

	Earnings per share (¥)	Fully diluted earnings per share (¥)
Three month period ended June 30, 2013	36.83	36.79
Three month period ended June 30, 2012	110.92	110.90

(2) Consolidated Financial Position

	Total assets (¥ million)	Net assets (¥ million)	Shareholders' equity ratio (%)	Shareholders' equity per share (¥)
As of June 30, 2013	3,933,711	2,276,514	56.2	2,800.62
As of March 31, 2013	3,955,599	2,223,359	54.6	2,734.79

(Reference) Shareholders' equity As of June 30, 2013 ¥ 2,210,978 million
As of March 31, 2013 ¥ 2,159,006 million

2. Dividends

	Annual dividend per share (¥)				
	1st quarter end	2nd quarter end	3rd quarter end	Year-end	Total
Fiscal 2012	—	90.0	—	90.0	180.0
Fiscal 2013	—				
Fiscal 2013 (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 2013 (April 1, 2013 to March 31, 2014)

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

	Net sales		Operating income		Ordinary income		Net income		Earnings per share
	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥ million)	change (%)	(¥)
First half year	830,000	5.5	80,000	(26.3)	75,000	(33.7)	55,000	(54.1)	69.67
Fiscal 2013	1,680,000	7.9	140,000	14.3	125,000	10.5	95,000	(27.6)	120.34

(Note) Modifications in forecasts of consolidated operating results from the latest announcement: Modified

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 11.

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

1) Changes in accounting policies due to revisions of accounting standards, etc.	: No
2) Changes in accounting policies other than 1)	: No
3) Changes in accounting estimates	: No
4) Restatements	: No

(4) Number of shares outstanding (common stock)

1) Number of shares outstanding (including treasury stock) at term end:	
June 30, 2013	789,666,095 shares
March 31, 2013	789,666,095 shares
2) Number of shares of treasury stock at term end:	
June 30, 2013	207,277 shares
March 31, 2013	205,831 shares
3) Average number of outstanding shares (for the three month period ended June 30):	
June 30, 2013	789,459,453 shares
June 30, 2012	789,413,287 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. The securities report for the three month period ended June 30, 2013 is scheduled to be disclosed on August 9, 2013 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 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.
- Regarding the assumptions made and the items to be considered in the financial forecasts, please refer to "1. Qualitative Information for the Three Month Period Ended June 30, 2013 (3) Outlook for Fiscal 2013" on Page 10.
- Takeda has decided to voluntarily adopt International Financial Reporting Standards (IFRS) from the year-end earnings announcement of Fiscal 2013. For details, and for estimated consolidated financial results for the three month period ended June 2013 calculated under IFRS reflecting the major differences between Japanese Generally Accepted Accounting Principles and IFRS accounting, please refer to pages 11 and 18 of the quarterly supplementary material, "Consolidated Financial Results for the Three Month Period Ended June 30, 2013."
- Presentation materials for the earnings release conference call which is scheduled on July 31 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/results/

Attachment Index

1.Qualitative Information for the Three Month Period Ended June, 2013

(1) Consolidated Operating Results

(i) Overview

While the U.S. economy continues to experience a mild recovery, Europe remains stagnant in the wake of the debt crisis and emerging markets are experiencing a slowing down of economic growth, resulting in a global economy that remains unpredictable. Meanwhile, in Japan the expectation of overcoming deflation and achieving economic recovery has increased with the support of the Japanese government’s fiscal policies and monetary easing by the Bank of Japan.

In the global pharmaceutical market, particularly in developed countries, sales growth has slowed due to factors including blockbuster products being replaced by generics after patent expiry, and increasingly severe policies to constrain healthcare expenditures arising from government financial reforms. In the area of Research & Development, companies have been facing challenges in innovative drug discovery and technological breakthroughs as well as increasingly stringent regulatory criteria for new drug approvals. However, there are high expectations for new products that address currently unmet medical needs, and the practical application of iPS cell technology.

In light of these circumstances, Takeda Pharmaceutical Company Limited ("Takeda", "the Company"), as a global company, has formulated “Vision 2020” to articulate our aspiration of where we want the company to be in the year 2020. The objective of Takeda's business is to "pursue innovative medicines as well as high-quality branded generics, life-saving vaccines, and OTC medicines - to help as many people as we can, as soon as we can."
To realize Vision 2020, Takeda has initiated a Mid-Range Growth Strategy starting from fiscal 2013 that will further deepen and expand previous strategies, centered around the core principles of "Globalization," "Diversity" and "Innovation." In particular, Takeda will focus on building a robust and efficient operating model suitable for a global pharmaceutical company, and on further enhancing cash management. This will allow us to continue to execute strategic investments to strengthen our overseas business infrastructure and reinforce the company’s R&D pipeline.

<Commercial Initiatives>
In developed countries, Takeda is promoting a shift in product portfolio towards new products, while in emerging markets, in addition to launching new in-house products, Takeda aims to acquire and promote diverse portfolios tailored to local needs in order to achieve sales growth that exceeds the market growth in each region.
In the U.S. in June 2013, Takeda began marketing three new products for the treatment of type 2 diabetes: NESINA (a dipeptidyl peptidase-4 inhibitor (DPP-4i)), KAZANO (fixed-doze combination of NESINA and metformin), and OSENI (fixed-doze combination of NESINA and the thiazolidinedione (TZD) ACTOS). OSENI is the first product in the U.S. to include both a DPP-4i and TZD in a single tablet.
In Europe, the sales of ADCETRIS for the treatment of lymphoma have expanded steadily. In addition, in June 2013, Takeda presented the interim data from the clinical trials evaluating ADCETRIS in pediatric patients diagnosed with CD30-positive relapsed or refractory Hodgkin lymphoma (HL) or relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). It showed a high effectiveness for reduction in tumor volume.
In Japan, Takeda is striving to maximize the sales of strategic products such as the NESINA family for the treatment of type 2 diabetes, AZILVA for the treatment of hypertension, and LOTRIGA for the treatment of hyperlipidemia. In particular, prescriptions for AZILVA are increasing after the restriction on long-term prescriptions was lifted in May 2013.

<R&D Initiatives>
Takeda is promoting innovation in R&D by proposing new healthcare solutions from prevention to care and cure. Currently, the rich late-stage pipeline includes assets such as TAK-875 (generic name: fasiglifam) for the treatment of type 2 diabetes, MLN0002 (generic name: vedolizumab) for the treatment of Crohn's disease and ulcerative colitis, TAK-700 (generic name: orteronel) for the treatment of prostate cancer, MLN9708 (generic name: ixazomib citrate) for the treatment of multiple myeloma and Lu AA21004 (generic name: vortioxetine) for the treatment of major depressive disorder (MDD). Takeda is focusing its efforts on swiftly obtaining new drug approvals for these late-stage pipeline assets. In addition, in June 2013, Takeda submitted a Biologics License Application to the U.S. Food and Drug Administration (FDA) for MLN0002.
Takeda has also taken several major steps forward towards its goal of establishing a world-class global vaccine business, with the October 2012 acquisition of Takeda Vaccines (Montana), Inc.* of the U.S. with its first-in-class norovirus vaccine candidate, and the May 2013 acquisition of Inviragen, Inc. ("Inviragen") of the U.S. with its pipeline assets including a vaccine for dengue fever. Both of these companies also provided Takeda with new expertise and technological capabilities in vaccine R&D.
Moving forward, Takeda will continue to promote various efforts to increase R&D productivity, including joint research and alliance activities with external parties.

*formerly LigoCyte Pharmaceuticals, Inc., the company name was changed in March 2013.

Based on the corporate philosophy of "Takeda-ism" (Integrity: Fairness, Honesty and Perseverance) developed over its long corporate history of more than 230 years, Takeda strives to ensure compliance with laws and regulations governing its operations, and conducts activities according to the corporate mission to "strive towards better health for people worldwide through leading innovation in medicine."

<Reference> Major 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 a 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 a sulfonylurea (glimepiride))
Liovel (a drug for type 2 diabetes: a fixed dose combination of Nesina and Actos)

Launched in 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 a biguanide (metformin extended- release))

Launched in 2011

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

Launched in 2012

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

Launched in June 2013

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

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

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

<Canada>

Launched in 2010

Dexilant (a drug for acid 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 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 2012

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

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 acid reflux disease, generic name: dexlansoprazole)

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

Launched in 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 a thiazide diuretic (chlorthalidone))

(ii) Operating Results

Consolidated results (April 1 to June 30, 2013):

Billions of yen

	Amount	*Change over the same period of the previous year*
Net Sales	¥410.3	Increase ¥ 12.0 (3.0%)
Operating Income	¥47.7	Decrease ¥ 14.9 (23.8%)
Ordinary Income	¥52.5	Decrease ¥ 13.7 (20.7%)
Net Income	¥29.1	Decrease ¥ 58.5 (66.8%)

[Net Sales]

Over the three month period ended June 30, 2013, consolidated net sales were ¥410.3 billion, an increase of ¥12.0 billion (3.0%) compared to the same period of the previous year.

- In Japan, the sales of AZILVA (a drug for hypertension) launched in 2012 increased. In the U.S, in addition to the sales contribution of COLCRYS (a drug for hyperuricemia and gout treatment) which was acquired with the URL acquisition in June 2012, the sales of VELCADE (a drug for multiple myeloma treatment) and DEXILANT (a drug for acid reflux disease treatment) increased. Furthermore, the sales of ADCETRIS (a drug for treatment of lymphoma) in Europe expanded steadily and sales in emerging markets including Asia also increased, in addition to the yen's depreciation (positive impact: ¥40.3 billion). On the other hand, the sales of ACTOS (a drug for type 2 diabetes treatment) in the U.S. drastically decreased due to the penetration of generic products after the patent expiry.
  In total, consolidated net sales increased by ¥12.0 billion.

- Consolidated sales of Takeda's major ethical drugs:

Billions of yen

Drug for hypertension treatment Candesartan (Japan product name: Blopress)	¥42.4	Decrease of ¥5.1 (10.8%) over the same period of the previous year
Drug for treatment of prostate cancer, breast cancer and endometriosis Leuprorelin (Japan product name: Leuplin)	¥32.6	Increase of ¥2.9 (9.7%) over the same period of the previous year
Drug for peptic ulcer treatment Lansoprazole (Japan product name: Takepron)	¥29.7	Increase of ¥2.4 (8.8%) over the same period of the previous year
Drug for multiple myeloma treatment Velcade (U.S. sales)	¥23.8	Increase of ¥6.1 (34.8%) over the same period of the previous year
Drug for peptic ulcer treatment Pantoprazole	¥22.9	Increase of ¥2.7 (13.6%) over the same period of the previous year
Drug for hyperuricemia and gout treatment Colcrys (U.S. sales)	¥13.7	Increase of ¥10.7 (359.6%) over the same period of the previous year (see Note below)
Drug for type 2 diabetes treatment Pioglitazone (Japan product name: Actos)	¥10.5	Decrease of ¥45.2 (81.1%) over the same period of the previous year

(Note) As for Colcrys which was acquired with the URL acquisition in June 2012, the comparative sales amount before the acquisition (from April to May 2012) is not included.

[Operating Income]

Consolidated operating income was ¥47.7 billion, a decrease of ¥14.9 billion (23.8%) compared to the same period of the previous year.

- Despite sales increase, gross profit remains within a small increase mainly due to the sales drop of high-yield product, ACTOS. In addition, selling, general and administrative expenses increased by ¥15.1 billion (6.5%) compared to the same period of the previous year mainly due to the yen's depreciation. As a result, operating income decreased.
- R&D expenses were ¥77.5 billion, a decrease of ¥1.3 billion (1.7%) compared to the same period of the previous year.
- Selling, general and administrative expenses, excluding R&D expenses increased by ¥16.4 billion (10.7%) to ¥170.0 billion over the same period of the previous year mainly due to the yen's depreciation, despite cost saving by the effect of restructuring in overseas subsidiaries.

[Ordinary Income]
Consolidated ordinary income was ¥52.5 billion, a decrease of ¥13.7 billion (20.7%) compared to the same period of the previous year mainly due to the decrease in operating income.

[Net Income]
Consolidated net income was ¥29.1billion, a decrease of ¥58.5billion (66.8%) compared to the same period of the previous year.

- In addition to the decrease in ordinary income, the tax refunds of ¥52.8 billion (including interest) relating to the correction for transfer pricing taxation were included in the same period of the previous year. As a result, consolidated net income decreased.
- Earnings per share ("EPS") was ¥36.83, a decrease of ¥74.09 (66.8%) compared to the same period of the previous year.
- EPS excluding extraordinary income (loss) and other special factors (see Note below) was ¥79.05, an increase of ¥1.71 (2.2%) compared to the same period of the previous year.
  (Note) EPS excluding extraordinary income (loss) and other special factors is calculated by deducting any extraordinary income (loss), special factors such as amortization of goodwill and intangible assets due to business acquisitions and the tax refund related to transfer price taxation from net income.

(iii) Results by Segment

Sales and operating income by business segment (April 1 to June, 2013):

Billions of yen

Type of Business	Net sales		Operating income	
	Amount	Change over the same period of the previous year	Amount	Change over the same period of the previous year
Ethical Drug	¥ 371.9	Increase ¥11.4	¥39.0	Decrease ¥16.0
(Japan)	<¥140.2>	< Decrease ¥ 5.3>		
(Overseas)	<¥231.7>	< Increase ¥16.7>		
Consumer Healthcare	¥ 16.6	Increase ¥ 0.7	¥ 5.4	Increase ¥ 0.9
Other	¥ 22.9	Decrease ¥ 0.1	¥ 3.8	Increase ¥ 0.1
Total	¥ 410.3	Increase ¥12.0	¥47.7	Decrease ¥14.9

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

[Ethical Drug Business]

Net sales in the Ethical Drug Business were ¥371.9 billion, an increase of ¥11.4 billion (3.2%) compared to the same period of the previous year, while operating income was ¥39.0 billion, a decrease of ¥16.0 billion (29.1%).

- Net sales in Japan were ¥140.2 billion, a decrease of ¥5.3 billion (3.7%) compared to the same period of the previous year. Higher sales of products launched in 2010 such as NESINA in addition to the sales contribution of AZILVA and LOTRIGA launched in 2012 could not fully absorb the drop in sales of ACTOS and BLOPRESS, and the distribution sales decline due to the expiration of distribution agreement for some products.

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

Billions of yen

Blopress (Drug for hypertension treatment)	¥32.9	Decrease of ¥0.9 (2.6%) over the same period of the previous year
Takepron (Drug for peptic ulcer treatment)	¥17.3	Decrease of ¥0.0 (0.2%) over the same period of the previous year
Leuplin (Drug for treatment of prostate cancer, breast cancer and endometriosis)	¥16.3	Increase of ¥0.2 (1.3%) over the same period of the previous year
Nesina (Drug for type 2 diabetes treatment)	¥7.3	Increase of ¥0.2 (3.3%) over the same period of the previous year
Vectibix (Drug for cancer treatment)	¥4.8	Increase of ¥0.0 (0.4%) over the same period of the previous year
Actos (Drug for type 2 diabetes treatment)	¥4.3	Decrease of ¥1.1 (20.3%) over the same period of the previous year
Azilva (Drug for hypertension treatment)	¥3.0	Increase of ¥1.1 (60.1%) over the same period of the previous year

- Sales in overseas markets were ¥231.7 billion, an increase of ¥16.7 billion (7.8%) compared to the same period of the previous year. In addition to the sales contribution of COLCRYS accompanied by the URL acquisition and the sales increases in emerging markets including Asia, the yen's depreciation more than offset the significant decline in sales of Pioglitazone and Candesartan due to the market entry of generic products in U.S. and Europe.

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

Billions of yen

Velcade (Drug for multiple myeloma treatment)	¥23.8	Increase of ¥6.1 (34.8%) over the same period of the previous year
Pantoprazole (Drug for peptic ulcer treatment)	¥22.9	Increase of ¥2.7 (13.6%) over the same period of the previous year
Leuprorelin (Drug for treatment of prostate cancer, breast cancer and endometriosis)	¥16.3	Increase of ¥2.7 (19.7%) over the same period of the previous year
Colcrys (Drug for hyperuricemia and gout treatment)	¥13.7	Increase of ¥10.7 (359.6%) over the same period of the previous year (see Note below)
Lansoprazole (Drug for peptic ulcer treatment)	¥12.4	Increase of ¥2.4 (24.5%) over the same period of the previous year
Dexilant (Drug for acid reflux disease treatment)	¥11.1	Increase of ¥4.1 (57.9%) over the same period of the previous year
Candesartan (Drug for hypertension treatment)	¥9.5	Decrease of ¥4.2 (31.0%) over the same period of the previous year
Pioglitazone (Drug for type 2 diabetes treatment)	¥6.3	Decrease of ¥44.1 (87.6%) over the same period of the previous year

(Note) As for Colcrys which was acquired with the URL acquisition in June 2012, the comparative sales amount before the acquisition (from April to May 2012) is not included.

[Consumer Healthcare Business]

Net sales in the Consumer Healthcare Business were ¥16.6 billion, an increase of ¥0.7 billion (4.4%) compared to the same period of the previous year, mainly due to the increase in sales of ALINAMIN tablets and health tonics (vitamin-containing products). Operating income increased by ¥0.9 billion (19.8%) to ¥5.4 billion mainly due to the increase in gross profit accompanied by sales growth and the decrease in expenses.

[Other Business]

Net sales in the Other Business were ¥22.9 billion, a decrease of ¥0.1 billion (0.6%) compared to the same period of the previous year, while operating income increased by ¥0.1 billion (3.7%) to ¥3.8 billion.

(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 2013, Takeda submitted a New Drug Application (NDA) for the fixed-dose combination (FDC) of AZILVA (generic name: azilsartan) and amlodipine besylate to the Japanese Ministry of Health, Labour and Welfare.

- In May 2013, Takeda presented results of a Phase III clinical trial evaluating the safety and efficacy of TAK-875 (generic name: fasiglifam) in Japanese patients with type 2 diabetes at the 56th Annual Meeting of the Japan Diabetes Society.

- In June 2013, Takeda presented results of a Phase I clinical trial evaluating single agent 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 2013, Takeda submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MLN0002 (generic name: vedolizumab), for the treatment of adults with moderately to severely active Crohn's disease (CD) and ulcerative colitis (UC).

- In July 2013, Takeda unblinded the ELM-PC 5 (Evaluation of the Lyase inhibitor orteronel in Metastatic Prostate Cancer 5) (C21005) Phase III study of TAK-700 (generic name: orteronel) in patients with metastatic, castration-resistant prostate cancer that had progressed during or following chemotherapy based on the recommendation of the independent data monitoring committee.

- In July 2013, Takeda received a positive opinion from the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA) for VIPIDIA (generic name: alogliptin), VIPDOMET, an FDC of VIPIDIA and metformin, and INCRESYNC, an FDC of VIPIDIA and pioglitazone, for the treatment of type 2 diabetes.

[Alliance activities]

- In May 2013, Takeda and H. Lundbeck A/S (Lundbeck) presented results of Phase III clinical trials evaluating Lu AA21004 (generic name: vortioxetine), which Takeda in-licensed from Lundbeck of Denmark, in adult patients with major depressive disorder (MDD), at the 166th American Psychiatric Association Annual Meeting (APA).

- In June 2013, Takeda presented interim data from a Phase I portion of Phase I/II clinical trials evaluating ADCETRIS (generic name: brentuximab vedotin), which Takeda in-licensed from Seattle Genetics, Inc. of the U.S., in pediatric patients diagnosed with CD30-positive relapsed or refractory Hodgkin lymphoma (HL) or relapsed or refractory systemic anaplastic large cell lymphoma (sALCL), at ASCO.

- In July 2013, Takeda withdrew the European Marketing Authorization Application (MAA) submitted in February 2012 for peginesatide, which Takeda in-licensed from Affymax, Inc. of the U.S., intended to be used for treatment of symptomatic anaemia associated with chronic kidney disease in adult patients undergoing dialysis.

- In July 2013, Takeda and Zinfandel Pharmaceuticals, Inc. of the U.S. presented new data on the performance characteristics of a genetics-based biomarker risk assignment algorithm including TOMM40 to identify the risk of developing mild cognitive impairment due to Alzheimer's disease, at the Alzheimer's Association International Conference (AAIC).

[Improvement and Reinforcement of R&D organization]
- In May 2013, Takeda acquired Inviragen, Inc. of the U.S. to advance the company’s commitment to vaccines and global health.

(2) Consolidated Financial Position

[Assets]
Total assets as of June 30, 2013 were ¥3,933.7 billion, a decrease of ¥21.9 billion compared to the previous fiscal year end. Noncurrent assets increased by ¥50.9 billion mainly due to the increase of foreign assets resulting from yen’s depreciation and an increase in intangible assets including goodwill accompanied by acquisitions, while current assets decreased by ¥72.8 billion mainly due to the decrease in marketable securities.

[Liabilities]
Total liabilities as of June 30, 2013 were ¥1,657.2 billion, a decrease of ¥75.0 billion compared to the previous fiscal year end mainly due to the decrease in current liabilities.

[Net Assets]
Total net assets as of June 30, 2013 were ¥2,276.5 billion, an increase of ¥53.2 billion compared to the previous fiscal year end, which despite dividend payments, was mainly due to the increase in foreign currency translation adjustment caused by the yen’s depreciation in addition to net income. The shareholders’ equity ratio increased by 1.6 pt. to 56.2% from the previous fiscal year end.

(3) Outlook for Fiscal 2013

The outlook for consolidated results for the first half year and the full year of fiscal 2013 has been revised from the previous forecast (announced at the fiscal 2012 financial results announcement on May 9, 2013) as follows, considering the current results, the revised foreign exchange rates for the forecast and the effect on the business combination of "Inviragen" acquired in May 2013.

[First half year consolidated forecasts (April 1 to September 30, 2013)]

	Net Sales (¥ billion)	Operating income (¥ billion)	Ordinary income (¥ billion)	Net income (¥ billion)	Earnings per share "EPS" (¥)
Previous forecast (A)	¥780.0	¥70.0	¥65.0	¥45.0	¥57.00
Revised forecast in this document (B)	¥830.0	¥80.0	¥75.0	¥55.0	¥69.67
Change (B-A)	Increase ¥50.0	Increase ¥10.0	Increase ¥10.0	Increase ¥10.0	
Change	Increase 6.4%	Increase 14.3%	Increase 15.4%	Increase 22.2%	

[Full-year consolidated forecasts (April 1, 2013 to March 31, 2014)]

	Net Sales (¥ billion)	Operating income (¥ billion)	Ordinary income (¥ billion)	Net income (¥ billion)	Earnings per share "EPS" (¥)
Previous forecast (A)	¥1,590.0	¥140.0	¥125.0	¥95.0	¥120.34
Revised forecast in this document (B)	¥1,680.0	¥140.0	¥125.0	¥95.0	¥120.34
Change (B-A)	Increase ¥90.0	—	—	—	
Change	Increase 5.7%	—	—	—	

[Assumptions for the Forecast]

The foreign exchange rates from the 2nd quarter are assumed to be US$1 = ¥100 and Euro1 = ¥130. The average of foreign exchange rates for the full year of fiscal 2013 are assumed to be US$1 = ¥100 and Euro1 = ¥129.

[Forward looking statements]

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. 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 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 reporting period is included was estimated based on reasonable assumptions. Then, tax expenses for the three month period ended June 30, 2013 were calculated by multiplying the pretax net income for the reporting period by the estimated effective tax rate.

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

No applicable event occurred during the period.

3. Consolidated Financial Statements for the Three Month Period Ended June 30, 2013

(1) Consolidated Balance Sheets

Millions of yen

	As of March 31, 2013	As of June 30, 2013
ASSETS		
Current assets		
Cash and deposits	289,613	266,883
Notes and accounts receivable	345,532	367,160
Marketable securities	258,092	117,999
Merchandise and products	108,328	111,543
Work in process	65,168	68,607
Raw materials and supplies	56,035	57,374
Deferred tax assets	240,149	236,584
Other current assets	95,330	159,648
Allowance for doubtful receivables	(3,166)	(3,510)
Total current assets	1,455,081	1,382,289
Noncurrent assets		
Tangible assets	511,101	509,870
Intangible assets		
Goodwill	675,353	704,030
Patent rights	363,057	365,045
Sales rights	582,869	606,851
Other intangible assets	68,456	83,391
Total intangible assets	1,689,735	1,759,318
Investments and other assets		
Investment securities	176,702	191,312
Other assets	123,047	91,038
Allowance for doubtful receivables	(67)	(115)
Total investments and other assets	299,682	282,235
Total noncurrent assets	2,500,518	2,551,422
Total Assets	3,955,599	3,933,711

Millions of yen

	As of March 31, 2013	As of June 30, 2013
LIABILITIES		
Current liabilities		
Notes and accounts payable	118,692	106,395
Short-term loans	1,795	1,525
Income taxes payable	113,430	25,643
Reserve for employees' bonuses	72,338	48,615
Other reserves	10,928	13,121
Other current liabilities	296,449	348,320
Total current liabilities	613,632	543,620
Noncurrent liabilities		
Bond	428,830	428,830
Long-term loans	111,329	111,293
Deferred tax liabilities	322,133	330,250
Reserve for employees' retirement benefits	60,153	63,721
Other reserves	19,842	20,670
Other noncurrent liabilities	176,320	158,814
Total noncurrent liabilities	1,118,608	1,113,578
Total liabilities	1,732,240	1,657,198
NET ASSETS		
Shareholders' equity		
Common stock	63,541	63,541
Capital surplus	39,381	38,739
Retained earnings	2,243,113	2,201,131
Treasury stock	(587)	(594)
Total shareholders' equity	2,345,449	2,302,817
Accumulated other comprehensive income		
Unrealized gains/losses on available-for-sale securities	77,960	87,075
Deferred gains/losses on derivatives under hedge accounting	—	(503)
Foreign currency translation adjustments	(264,403)	(178,411)
Total accumulated other comprehensive income	(186,443)	(91,839)
Stock acquisition rights	934	1,095
Minority interests	63,418	64,441
Total net assets	2,223,359	2,276,514
Total liabilities and net assets	3,955,599	3,933,711

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

Consolidated Statements of Income

Millions of yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013
Net sales	398,292	410,302
Cost of sales	103,313	115,091
Gross profit	294,978	295,211
Selling, general and administrative expenses		
R&D expenses	78,878	77,546
Other	153,534	169,960
Total selling, general and administrative expenses	232,412	247,506
Operating income	62,566	47,705
Non-operating income		
Interest income	343	225
Dividend income	1,782	1,765
Equity in earnings of affiliates	315	491
Gains on transfer of operation	3,695	3,958
Other non-operating income	2,062	6,123
Total non-operating income	8,198	12,561
Non-operating expenses		
Interest expenses	781	726
Donations and contributions	251	190
Loss from foreign exchange	1,638	747
Fair value adjustment of contingent consideration	557	2,557
Other non-operating expenses	1,305	3,556
Total non-operating expenses	4,531	7,776
Ordinary income	66,233	52,490
Extraordinary income		
Interest on tax refund	11,593	—
Total extraordinary income	11,593	—
Extraordinary loss		
Restructuring costs	2,096	2,303
Total extraordinary loss	2,096	2,303
Income before income taxes and minority interests	75,730	50,187
Income taxes	33,005	20,476
Refund for past paid taxes	(45,622)	—
Total income taxes	(12,618)	20,476
Income before minority interests	88,347	29,712
Minority interests	784	635
Net income	87,563	29,076

Consolidated Statements of Comprehensive Income

Millions of yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013
Income before minority interests	88,347	29,712
Other comprehensive income		
Unrealized gains/losses on available-for-sale securities	(3,574)	9,117
Deferred gains/losses on derivatives under hedge accounting	222	(503)
Foreign currency translation adjustments	(125,235)	86,190
Share of other comprehensive income of affiliates accounted for using equity method	(6)	112
Total other comprehensive income	(128,594)	94,916
Comprehensive income	(40,247)	124,628
[Comprehensive income attributable to]		
Comprehensive income attributable to owners of the parent	(41,399)	123,680
Comprehensive income attributable to minority interests	1,152	948

(3) Notes to Consolidated Financial Statements

(Note regarding going concern assumptions)

Three month period ended June 30, 2013 (April 1 to June 30, 2013)

No events to be noted for this purpose

(Note regarding significant changes in shareholders' equity)

Three month period ended June 30, 2013 (April 1 to June 30, 2013)

No events to be noted for this purpose

(Segment Information)

1. Net sales and profit by business segment

Three month period ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

	Business Segments			Total	Adjustments	Amount reported on statement of income
	Ethical Drug	Consumer Healthcare	Other			
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

Three month period ended June 30, 2013 (April 1 to June 30, 2013)

Millions of yen

	Business Segments			Total	Adjustments	Amount reported on statement of income
	Ethical Drug	Consumer Healthcare	Other			
Net sales						
Sales to outside customers	371,924	16,552	22,867	411,343	(1,041)	410,302
Intersegment sales and transfers	745	507	1,412	2,664	(2,664)	—
Total	372,669	17,059	24,279	414,007	(3,706)	410,302
Segment profit	38,981	5,398	3,781	48,161	(456)	47,705

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

2. Information regarding regions

Net sales

Three month period ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

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

Three month period ended June 30, 2013 (April 1 to June 30, 2013)

Millions of yen

Japan	Americas			Europe		Asia	Other	Total
		United States	Latin America		Russia /CIS			
176,100	110,686	85,917	18,853	96,763	21,132	19,734	7,019	410,302

(Note) "Other" region includes Middle East, Oceania and Africa.

(Sales Results (Sales to outside customers))

Three month period ended June 30, 2012 (April 1 to June 30, 2012)

Millions of yen

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

Three month period ended June 30, 2013 (April 1 to June 30, 2013)

Millions of yen

Ethical Drug			Consumer healthcare	Other	Adjustments	Amount reported on statement of income	[Royalties]
(Japan)	(Overseas)	Subtotal					
140,201	231,723	371,924	16,552	22,867	(1,041)	410,302	[18,916]

(Significant Subsequent Event)

The Company issued unsecured straight bonds and obtained long-term loans based on the resolution regarding the allowable range of borrowing funds and the interest rates at the Board of Directors' meeting on June 24, 2013, for the purpose of using the proceeds mainly to repay the existing bond and for general corporate purposes.
The terms and conditions for the issues of unsecured straight bonds were determined on July 10, 2013.
The details are as follows.

1. Domestic unsecured straight bonds

Series name	Fourteenth Series	Fifteenth Series
1. Issue amount	¥60.0 billion	¥60.0 billion
2. Issue price	100% of the principal amount	
3. Issue date	July 19, 2013	
4. Coupon rate (per annum)	0.5%	0.7%
5. Maturity date	July 19, 2019	July 17, 2020
6. Method of redemption	Bullet redemption at maturity	
7. Important special provision	Negative pledge clause	

2. Long-term loans

1. Financial Institution	Nippon Life Insurance Company	Syndicated loan (see Note below)	
2. Amount	¥10.0 billion	¥60.0 billion	¥60.0 billion
3. Effective date	July 4, 2013	July 25,2013	
4. Maturity Date	July 4, 2020	July 25, 2019	July 27, 2020
5. Collateral security	None		

(Note) This syndicated loan is provided by a group of lenders administrated by domestic banks such as Sumitomo Mitsui Banking Corporation.

4.Supplemental Information

(1) Ethical Drugs Sales [Consolidated]

Billions of yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent
Domestic sales	146.1	140.5	(5.6)	(3.9%)
Overseas sales	205.6	211.7	6.1	2.9%
Americas	115.7	103.4	(12.3)	(10.6%)
United States	97.5	79.0	(18.5)	(19.0%)
Latin America	13.8	18.7	4.9	35.7%
Europe	70.2	82.8	12.6	18.0%
Russia/CIS	15.1	21.1	6.0	39.9%
Asia	13.8	18.7	4.9	35.2%
Other	5.9	6.8	0.9	15.1%
Royalty Income and Service Income	9.7	20.5	10.9	112.7%
Domestic	0.3	0.5	0.2	93.9%
Overseas	9.4	20.0	10.6	113.2%
Total sales	361.4	372.7	11.3	3.1%

(Note) 1.Sales amount includes intersegment sales.
2. “Other” region includes Middle East, Oceania and Africa.

Ratio of Overseas sales	59.5%	62.2%

Foreign exchange rates

Yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Increase (decrease)
US$ average rate	80.2	98.1	17.9
Euro average rate	102.8	127.1	24.3

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

Billions of yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent
Candesartan	47.5	42.4	(5.1)	(10.8%)
Leuprorelin	29.7	32.6	2.9	9.7%
Lansoprazole	27.2	29.7	2.4	8.8%
Velcade	17.6	23.8	6.1	34.8%
Pantoprazole	20.2	22.9	2.7	13.6%
Colcrys	3.0	13.7	10.7	—
Dexilant	7.0	11.1	4.1	57.9%
Pioglitazone	55.8	10.5	(45.2)	(81.1%)
Actovegin	3.9	7.4	3.5	89.5%
Nesina	7.1	7.3	0.2	2.5%
Uloric	3.8	6.5	2.7	71.6%
Amitiza	5.0	6.1	1.1	21.5%
Calcium	3.7	4.4	0.8	20.5%
Tachosil	3.8	4.2	0.4	11.2%
Daxas	0.7	1.0	0.3	35.6%

(3) Ethical Drugs: Major products overseas sales (Regional basis)

Billions of yen

	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent
Candesartan ***(Note 2)***				
Americas/Europe/ Asia and other regions	13.7	9.5	(4.2)	(31.0%)
Leuprorelin				
Americas	4.2	5.4	1.1	26.6%
Europe	7.5	8.8	1.3	17.8%
Asia and other regions	1.9	2.2	0.2	12.1%
Lansoprazole				
Americas	6.3	7.5	1.2	19.8%
Europe	2.2	3.0	0.8	34.2%
Asia and other regions	1.4	1.9	0.4	30.1%
Pantoprazole				
Americas	7.7	8.0	0.3	4.2%
Europe	8.3	9.4	1.2	14.3%
Asia and other regions	4.2	5.5	1.2	29.5%
Pioglitazone				
Americas	46.9	3.0	(43.9)	(93.5%)
Europe	2.3	2.1	(0.2)	(6.8%)
Asia and other regions	1.2	1.1	(0.1)	(5.9%)

(Note)1. This chart shows the major overseas product sales classified as "Americas," "Europe," "Asia and other regions" and does not include sales in Japan.

2. The sales of *Candesartan* are shown in one area (Americas/Europe/Asia and other regions), because export sales of *Candesartan* to licensees are recorded under a single route.

(4) Ethical Drugs: Major products domestic sales

Billions of yen

Product name (generic name)	Launched Month/Year	Category	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Change over the same period of the previous year	
					Amount	Increase (decrease) in percent
Blopress (candesartan)	6/1999	Hypertension	33.8	32.9	(0.9)	(2.6%)
<*Ecard*>	3/2009	Hypertension	3.2	3.0	(0.2)	(6.5%)
<*Unisia*>	6/2010	Hypertension	5.3	6.2	1.0	18.1%
Takepron (lansoprazole)	12/1992	Peptic ulcers	17.3	17.3	(0.0)	(0.2%)
Leuplin (leuprorelin)	9/1992	Prostate cancer, breast cancer and endometriosis	16.1	16.3	0.2	1.3%
Enbrel	3/2005	Rheumatoid arthritis	10.8	11.0	0.2	1.9%
Nesina	6/2010	Diabetes	7.1	7.3	0.2	3.3%
<*Liovel*>	9/2011	Diabetes	0.8	1.6	0.9	111.6%
Vectibix	6/2010	Colorectal cancer	4.8	4.8	0.0	0.4%
Basen	9/1994	Diabetes	5.2	4.4	(0.9)	(16.7%)
Actos (pioglitazon)	12/1999	Diabetes	5.4	4.3	(1.1)	(20.3%)
Azilva	5/2012	Hypertension	1.9	3.0	1.1	60.1%
Benet	5/2002	Osteoporosis	3.5	2.9	(0.5)	(15.0%)
Reminyl	3/2011	Alzheimer-type dementia	1.8	2.8	1.0	57.7%
Rozerem	7/2010	Insomnia	1.0	1.4	0.3	31.6%
Lotriga	1/2013	Hyperlipidemia	–	0.7	0.7	–

(5) Consumer Healthcare: Major products sales

Billions of yen

Product name	Three month period ended June 30, 2012	Three month period ended June 30, 2013	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent
Alinamin tablets	4.1	4.6	0.6	13.7%
Alinamin health tonics	4.2	4.3	0.1	3.2%
Biofermin	2.1	2.0	(0.1)	(4.9%)
Benza	1.2	1.0	(0.2)	(14.7%)
Borraginol	1.0	1.0	(0.0)	(3.7%)

(6) Development activities

■ US/EU/Jpn

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
TAK-390MR <dexlansoprazole>	Proton pump inhibitor (oral)	Erosive esophagitis (healing and maintenance), Non-erosive gastro-esophageal reflux disease	EU Jpn	Filed (Mar 12) P-II	In-house
SYR-322 <alogliptin>	DPP-4 inhibitor (oral)	Diabetes mellitus	EU	Filed (May 12)	In-house
		Diabetes mellitus (Fixed-dose combination with metformin)	EU	Filed (Jun 12)	
		Diabetes mellitus (Fixed-dose combination with pioglitazone)	EU	Filed (Jun 12)	
MLN0002 <vedolizumab>	Humanized monoclonal antibody against α4β7 integrin (injection)	Ulcerative colitis	US EU Jpn	Filed (Jun 13) Filed (Mar 13) P-I	In-house
		Crohn's disease	US EU	Filed (Jun 13) Filed (Mar 13)	
<lurasidone hydrochloride>	Atypical antipsychotic agent (oral)	Schizophrenia	EU	Filed (Sep 12)	In-license (Dainippon Sumitomo)
		Bipolar disorder	EU	P-III	
Lu AA21004 <vortioxetine>	Multimodal anti-depressant (oral)	Major depressive disorder	US Jpn	Filed (Oct 12) P-III	In-license (Lundbeck)
		Generalized anxiety disorder	US	P-III	
ATL-962 <cetilistat>	Lipase inhibitor (oral)	Obesity	Jpn	Filed (Oct 12)	In-license (Norgine BV)*1
SGN-35 <brentuximab vedotin>	CD30 monoclonal antibody-drug conjugate (injection)	Relapsed or refractory Hodgkin lymphoma	Jpn	Filed (Mar 13)	In-license (Seattle Genetics)
		Relapsed or refractory systemic anaplastic large cell lymphoma	Jpn	Filed (Mar 13)	
		Relapsed cutaneous T-cell lymphoma	EU	P-III	
		Post-ASCT Hodgkin lymphoma	EU	P-III	
		Front line Hodgkin lymphoma	EU	P-III	
		Front line mature T-cell lymphoma	EU Jpn	P-III P-III	
BLB-750	Influenza vaccine (injection)	Prevention of pandemic influenza	Jpn	Filed (Mar 13)	In-license (Baxter)
Contrave® <naltrexone SR /bupropion SR>	Mu-opioid receptor antagonist and dopamine/norepinephrine re-uptake inhibitor (oral)	Obesity	US	FDA Complete Response Letter (Jan 11)*2	In-license (Orexigen)
TAK-875 <fasiglifam>	GPR40 agonist (oral)	Diabetes mellitus	US EU Jpn	P-III P-III P-III	In-house
TAK-700 <orteronel>	Non-steroidal androgen synthesis inhibitor (oral)	Prostate cancer	US EU Jpn	P-III P-III P-III	In-house
MLN9708 <ixazomib citrate>	Proteasome inhibitor (oral)	Multiple myeloma	US EU Jpn	P-III P-III P-I	In-house
		Relapsed or refractory primary (AL) amyloidosis	US EU	P-III P-III	
		Solid tumors	US	P-I	

*1 Alizyme assigned ATL-962 (cetilistat) business to Norgine BV on 15 October, 2009
*2 CV study currently ongoing to support re-submission

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
MLN8237 <alisertib>	Aurora A kinase inhibitor (oral)	Relapsed or refractory peripheral T-cell lymphoma	US EU	P-III P-III	In-house
		Diffuse large B-cell lymphoma, Non-small cell lung cancer, Small cell lung cancer, Gastroesophageal cancer, Head and neck cancer, Breast cancer, Ovarian cancer	US EU	P-II P-II	
		Non-Hodgkin lymphoma	Jpn	P-I	
		Solid tumors	Jpn	P-I	
SYR-472 <trelagliptin>	DPP-4 inhibitor (oral)	Diabetes mellitus	Jpn US EU	P-III P-II P-II	In-house
TAK-438 <vonoprazan>	Potassium-competitive acid blocker (oral)	Acid-related diseases (GERD, Peptic ulcer, etc.)	Jpn	P-III	In-house
<motesanib diphosphate>	VEGFR1-3, PDGFR, c-Kit inhibitor (oral)	Advanced non-squamous non-small cell lung cancer	Jpn	P-III	In-license (Amgen)
AMG 386 <trebananib>	Anti-angiopoietin peptibody (injection)	Ovarian cancer	Jpn	P-III	In-license (Amgen)
Sovrima® <idebenone>	Mitochondria targeted anti-oxidant (oral)	Friedreich's ataxia	EU	P-III	In-license (Santhera)
		Duchenne muscular dystrophy	EU	P-III	
TAK-816	Hib vaccine (injection)	Prevention of infectious disease caused by Haemophilus influenza Type b (Hib)	Jpn	P-III	In-license (Novartis)
<peginesatide>	Synthetic, peptide-based erythropoiesis-stimulating agent (injection)	Anaemia associated with chronic kidney disease in adult patients undergoing dialysis	EU	P-III*3	In-license (Affymax)
TAK-428 < - >	Neurotrophic factor production accelerator (oral)	Diabetic neuropathy	US EU	P-II P-II	In-house
DENVax	Dengue vaccine (injection)	Prevention of dengue fever	-	P-II	In-house
TAK-385 <relugolix>	LH-RH antagonist (oral)	Endometriosis, Uterine fibroids	Jpn	P-II	In-house
		Prostate Cancer	-	P-I	
<veltuzumab>	CD20 monoclonal antibody (injection)	Systemic lupus erythematosus	US EU	P-II P-II	In-license (Immunomedics)
TAK-361S	Quadruple vaccine (injection)	Prevention of infectious disease caused by Diphtheria, Pertussis, Tetanus, Polio	Jpn	P-II	In-license (Japan Polio)
Norovirus vaccine	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-I/II	In-house
TAK-329 < - >	Glucokinase activator (oral)	Diabetes mellitus	-	P-I	In-house
TAK-733 < - >	MEK inhibitor (oral)	Solid tumors	-	P-I	In-house
TAK-272 < - >	Direct renin inhibitor (oral)	Hypertension	-	P-I	In-house
TAK-063 < - >	PDE10A inhibitor (oral)	Schizophrenia	-	P-I	In-house
INV21	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I	In-house

*3 Resubmission subject to data analysis

Development code/ product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
MLN4924 < - >	NEDD 8 activating enzyme inhibitor (injection)	Advanced malignancies	-	P-I	In-house
MLN0128 < - >	mTORC1/2 inhibitor (oral)	Multiple myeloma, Waldenstrom's macroglobulinemia, Solid tumors	-	P-I	In-house
MLN1117 < - >	PI3Kα 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>	GM-CSF monoclonal antibody (injection)	Rheumatoid arthritis	EU	P-I	In-licence (Amgen)*4
Lu AA24530 < - >	Multimodal anti-depressant (oral)	Major depressive disorder, Generalized anxiety disorders	US Jpn	P-I P-I	In-license (Lundbeck)
AMG 403 <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)

*4 Deal made with Micromet; on Mar 7th, 2012, Micromet became a wholly owned subsidiary of Amgen

■ Additional indications/formulations of compounds

Development code/ product name <generic name> Brand name (country / region)	Drug Class	Indications or formulations	Stage	In-house/ In-license
AG-1749 <lansoprazole> Takepron® (Jpn) Prevacid® (US) Ogast®, etc. (EU)	Proton pump inhibitor	Fixed-dose combination with low-dose aspirin	Jpn Filed (Mar 13)	In-house
TAK-536 <azilsartan> Azilva® (Jpn)	Angiotensin II receptor blocker	Hypertension (Fixed-dose combination with amlodipine besilate)	Jpn Filed (Apr 13)	In-house
Rienso® <ferumoxytol>	IV iron	Iron deficiency anemia in all patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used	EU Filed (Jun 13)	In-license (AMAG)
TAP-144-SR <leuprorelin acetate> Leuplin® (Jpn) Lupron Depot® (US) Enantone®, etc. (EU)	LH-RH agonist	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn P-III	In-house
TAK-375SL <ramelteon> Rozerem® (US, Jpn)	MT1/MT2 receptor agonist	Bipolar (sublingual formulation)	US P-III	In-house
TAK-491 <azilsartan medoxomil> Edarbi® (US, EU)	Angiotensin II receptor blocker	Hypertension (Fixed-dose combination with chlorthalidone)	EU P-III	In-house
VELCADE® <bortezomib>	Proteasome inhibitor	Front line mantle cell lymphoma Relapsed diffuse large B-cell lymphoma	US P-III US P-II	In-house
AD4833/TOMM40	Insulin sensitizer/ Biomarker assay	Alzheimer's disease prevention	- P-I	In-license (Zinfandel)

■ Recent progress in stage **Progress in stage since release of FY2012 results (May 9, 2013)**

Development code/ product name	Indications	Country/Region	Progress in stage
MLN0002	Ulcerative colitis	US	Filed (Jun 13)
MLN0002	Crohn's disease	US	Filed (Jun 13)
Rienso®	Iron deficiency anemia in all patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used	EU	Filed (Jun 13)
SGN-35	Front line mature T-cell lymphoma	Jpn	P-III

■ Discontinued projects **Discontinued since release of FY2012 results (May 9, 2013)**

Development code	Indications (Stage)	Reason
AMG 479 <ganitumab>	Metastatic pancreas cancer (Jpn P-III)	Independent Data Monitoring Committee (DMC) reviewed the interim analysis and concluded that it is unlikely to meet the primary endpoint

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

Region	Country	Development code / product name (stage)
Americas Ex. US	Argentina	TAK-491 (Filed Oct 12)
	Brazil	TAK-491 (Filed Nov 11), SYR-322/metformin (Filed Jun 12), TAK-491/chlorthalidone (Filed Jun 12), SYR-322/pioglitazone (Filed Dec 12), SYR-322 (Filed Feb 13)*5
	Colombia	DAXAS*6 (Filed Aug 11), TAK-491 (Filed Aug 12), SYR-322 (Filed Sep 12), SYR-322/metformin (Filed Sep 12), SYR-322/pioglitazone (Filed Oct 12), TAK-491/chlorthalidone (Filed Dec 12), TAK-390MR (Filed Dec 12(30mg)/Mar 13(60mg))
	Venezuela	DAXAS (Filed Jan 10)
Europe Ex. EU	Albania	DAXAS (Approved Apr 13)
	Montenegro	DAXAS (Filed Jun 11)
	Switzerland	lurasidone hydrochloride (Filed Mar 12), SYR-322 (Filed Jul 12), SYR-322/metformin (Filed Jul 12), TAK-390MR (Filed Sep 12), TAK-491/chlorthalidone (Filed Jan 13)
Russia/CIS	Belarus	DAXAS (Filed Apr 13)
	Kazakhstan	TAK-491 (Filed Jan 13)
	Russia	TAK-491 (Filed Apr 13)
	Ukraine	TAK-491 (Filed Dec 12)
Asia Ex. Jpn	China	SYR-322 (Approved Jul 13), DAXAS (Filed Dec 11)
	Hong Kong	TAK-491/chlorthalidone (Filed Mar 13)
	Indonesia	SYR-322 (Filed Jan 11), TAK-491 (Filed Feb 12), TAK-491/chlorthalidone (Filed Jul 12), TCV-116*7/amlodipine besilate (Filed Oct 12), TAK-390MR (Filed Oct 12)
	Malaysia	TAK-390MR (Filed Sep 12), TAK-491 (Filed Jan 13), TAK-491/chlorthalidone (Filed Mar 13)
	Singapore	TAK-390MR (Filed Oct 12), TAK-491 (Filed Dec 12), TAK-491/chlorthalidone (Filed Mar 13)
	S. Korea	SYR-322 (Approved May 13), SGN-35 (Approved May 13)
	Taiwan	TAK-491 (Approved Jun 13), SYR-322 (Filed Mar 11), TAK-491/chlorthalidone (Filed May 12), TCV-116/amlodipine besilate (Filed Nov 12)
	Thailand	TAK-390MR (Approved Jun 13), TAK-491/chlorthalidone (Filed Jun 12), TCV-116/amlodipine besilate (Filed Aug 12), SYR-322/pioglitazone (Filed Mar 13)
	Vietnam	DAXAS (Approved Apr 13)
Others	Australia	SYR-322 (Filed Aug 12), SYR-322/metformin (Filed Nov 12)
	Botswana	DAXAS (Filed Dec 11)
	Egypt	DAXAS (Filed Jan 12)
	India	DAXAS (Filed Mar 13)
	Jordan	DAXAS (Filed Mar 13)
	Kenya	DAXAS (Filed Jul 12)
	Mauritius	DAXAS (Filed Mar 11)
	Saudi Arabia	DAXAS (Filed May 12)
	Tanzania	DAXAS (Filed Sep 11)
	Uganda	DAXAS (Filed Apr 11)
	UAE	TAK-390MR (Filed Jun 13)
	Zambia	DAXAS (Filed Feb 12)

*5 Originally filed in August 2011, we refiled in February 2013 due to delay of approval in the US

*6 **DAXAS® <roflumilast>** PDE4 inhibitor (oral) for the treatment of Chronic Obstructive Pulmonary Disease

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