

# Summary of Financial Statements for the Nine Month Period Ended December 31, 2014 (IFRS, Consolidated)

February 5, 2015

## Takeda Pharmaceutical Company Limited

Stock exchange listings: Tokyo, Nagoya, Fukuoka, Sapporo

TSE Code: 4502

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Scheduled date of dividend payment commencement: —

Supplementary materials for the financial statements: Yes

Presentation to explain for the financial statements: Yes

(Millions of yen, rounded to the nearest million)

## 1. Consolidated Financial Results for the Nine Month Period Ended December 31, 2014 (April 1 to December 31, 2014)

### (1) Consolidated Operating Results (year to date)

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

	Revenue		Operating profit		Profit before tax		Net profit for the period		Net profit attributable to owners of the Company	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
Nine month period ended December 31, 2014	1,339,985	4.1	199,052	12.6	187,566	(5.8)	82,345	(39.8)	79,745	(40.2)
Nine month period ended December 31, 2013	1,286,872	—	176,716	—	199,013	—	136,808	—	133,280	—

	Total comprehensive income for the period		Basic earnings per share	Diluted earnings per share
	(¥ million)	(%)	(¥)	(¥)
Nine month period ended December 31, 2014	188,600	(53.6)	101.39	101.16
Nine month period ended December 31, 2013	406,395	—	168.82	168.64

### (2) Consolidated Financial Position

	Total assets (¥ million)	Total equity (¥ million)	Equity attributable to owners of the Company (¥ million)	Ratio of equity attributable to owners of the Company to total assets (%)	Equity attributable to owners of the Company per share (¥)
As of December 31, 2014	4,653,372	2,572,867	2,503,479	53.8	3,186.11
As of March 31, 2014	4,569,144	2,540,635	2,470,739	54.1	3,129.63

## 2. Dividends

	Annual dividends per share (¥)				
	1st quarter end	2nd quarter end	3rd quarter end	Year-end	Total
Fiscal 2013	—	90.00	—	90.00	180.00
Fiscal 2014	—	90.00	—	—	—
Fiscal 2014 (Projection)	—	—	—	90.00	180.00

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

## 3. Forecasts for Consolidated Operation Results for Fiscal 2014 (April 1, 2014-March 31, 2015)

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

	Revenue		Operating profit		Profit before tax		Net profit attributable to owners of the Company		Basic earnings per share
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥)
Fiscal 2014	1,725,000	2.0	170,000	22.1	160,000	0.7	65,000	(39.1)	82.64

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

## Additional Information

- (1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in consolidation scope) : No
- (2) Changes in accounting policies and changes in accounting estimates
- 1) Changes in accounting policies required by IFRS : Yes
  - 2) Changes in accounting policies other than 1) : No
  - 3) Changes in accounting estimates : No
- (Note) For details, refer to "2. Additional Information in Summary" in Page 17.
- (3) Number of shares outstanding (common stock)
- 1) Number of shares outstanding (including treasury stock) at term end:
    - December 31, 2014 789,776,095 shares
    - March 31, 2014 789,680,595 shares
  - 2) Number of shares of treasury stock at term end:
    - December 31, 2014 4,029,201 shares
    - March 31, 2014 212,853 shares
  - 3) Average number of outstanding shares (for the nine month period ended December 31):
    - December 31, 2014 786,554,842 shares
    - December 31, 2013 789,463,563 shares

### \* Implementation status about the audit

- 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 completed at the time of disclosure of this summary of financial statements. The securities report for the Nine month period ended December, 2014 is scheduled to be disclosed on February 12, 2015 after completion of the quarterly review.

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

- Takeda has adopted International Financial Reporting Standards (IFRS) from the FY2013 ended March 31, 2014 and the disclosure information in this material is based on IFRS. According to this adoption, the previous year's information is also based on IFRS.
- 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 Nine Month Period Ended December 31, 2014 (3) Outlook for Fiscal 2014" on page 15.
- Supplementary materials for the financial statements (presentation materials for the earnings release conference which is scheduled on February 5, 2015) 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

<b>1. Qualitative Information for the Nine Month Period Ended December 31, 2014 .....</b>	<b>2</b>
(1) Consolidated Operating Results .....	2
(2) Consolidated Financial Position .....	14
(3) Outlook for Fiscal 2014 .....	15
(4) Litigation .....	15
<b>2. Additional Information in Summary .....</b>	<b>17</b>
(1) Changes in significant subsidiaries during the period .....	17
(2) Changes in accounting policies and changes in accounting estimates .....	17
<b>3. Condensed Interim Consolidated Financial Statements [IFRS] .....</b>	<b>18</b>
(1) Condensed Interim Consolidated Statement of Income.....	18
(2) Condensed Interim Consolidated Statement of Income and Other Comprehensive Income.....	19
(3) Condensed Interim Consolidated Statement of Financial Position .....	20
(4) Condensed Interim Consolidated Statement of Changes in Equity.....	22
(5) Notes to Condensed Interim Consolidated Financial Statements.....	24
(Going Concern Assumption) .....	24
(Significant Changes in Equity Attributable to Owners of the Company).....	24
(Segment Information) .....	24
(Breakdown of Revenues) .....	25
(Contingent Liabilities) .....	26
(Significant Subsequent Events) .....	26
<b>4. Supplemental Information .....</b>	<b>27</b>
(1) Ethical Drugs Revenues [Consolidated] .....	27
(2) Ethical Drugs: Global major products' sales [Consolidated] .....	28
(3) Ethical Drugs: Overseas major products' sales (Regional basis) .....	29
(4) Ethical Drugs: Japan major products' sales.....	30
(5) Consumer Healthcare: Major products' sales .....	30
(6) Development activities.....	31

## 1. Qualitative Information for the Nine Month Period Ended December 31, 2014

### (1) Consolidated Operating Results

#### (i) Overview

Takeda Pharmaceutical Company Limited ("Takeda", "the Company"), as a global pharmaceutical company, has formulated "Vision 2020" to articulate the aspiration of where the Company wants to be in the year 2020. This vision determines the Company's long-term objective to pursue innovative medicines as well as high-quality branded generics, life-saving vaccines, and OTC medicines - to help as many people as possible, as soon as possible.

In September of 2014, under the leadership of Chairman of the Board & Chief Executive Officer (CEO) and President & Chief Operating Officer (COO), Takeda announced a redesign of its global organizational structure to focus on and leverage its growth drivers and to operate more efficiently and competitively as a global company. Placing a patient and customer centric mindset as the top priority, Takeda aims to clearly define accountability and ownership, and simplify the organization. Through these changes, Takeda will realize its goal of becoming a more agile, best-in-class pharmaceutical company, able to capitalize on growth opportunities across the globe.

The organization reflects the company mid-term growth drivers which are new global innovative products, especially in the fields of Gastroenterology (GI) and Oncology, as well as Value Brands (branded generics and OTC products) in emerging markets.

Under the new organizational structure, the R&D organization will be realigned into four Therapeutic Area Units, namely Central Nervous System (CNS), Cardiovascular and Metabolic (CVM), Gastroenterology (GI), and Oncology. Additionally, all regional commercial divisions will be redefined into the five newly established Regional Business Units of Japan Pharma, Emerging Markets, United States, Europe-Canada, and Japan Consumer Healthcare, and two global Specialty Business Units will be newly established in Oncology and Vaccines (regarding the Specialty Business Unit for Oncology, Takeda is retiring the "Millennium: The Takeda Oncology Company" brand, and replacing it with "Takeda Oncology").

#### <Commercial Initiatives>

Details of major commercial initiatives during the reporting period, divided by therapeutic area, are as follows;

##### Central Nervous System (CNS)

- In Japan, Takeda is progressing with new partnering initiatives, and in October 2014 commenced co-promotion activities with Meiji Seika Pharma for the insomnia treatment ROZEREM.
- BRINTELLIX, a treatment for major depressive disorder in-licensed from Lundbeck, and atypical antipsychotic LATUDA in-licensed from Dainippon Sumitomo Pharma, were approved in fiscal 2013 in the U.S. and Europe, respectively, and Takeda is now focusing on achieving swift market penetration to quickly maximize the value of these new products.

##### Cardiovascular and Metabolic (CVM)

- In Japan, in June 2014, Takeda launched ZACRAS (a fixed-dose combination of anti-hypertensive treatment AZILVA and the calcium channel blocker amlodipine), a treatment for hypertension that is anticipated to provide a strong and sustained anti-hypertensive effect, improving control of blood pressure levels, and the aspirin/lansoprazole combination TAKELDA (a fixed-dose combination of gastric ulcer treatment TAKEPRON and the antiplatelet low-dose aspirin).
- In May 2014, Takeda received approval in Japan for changes in the indication of NESINA for type 2 diabetes, enabling concomitant therapy with all the oral anti-diabetic agents and insulin.
- In June 2014, Takeda entered into an agreement with Sanofi to build a collaborative system within Japan in the field of diabetes awareness and education.
- In the U.S., in October 2014, Takeda launched CONTRAVE, the product in-licensed from Orexigen, as a new treatment option to meet the needs of patients with obesity.

- In January 2015, Takeda and Prasco Laboratories of the U.S. entered into a distribution and supply agreement for the rights to distribute Colchicine Tablets, USP, the Authorized Generic version of gout treatment COLCRYS, and the product was launched in the U.S. under the Prasco label.

#### Gastroenterology (GI)

- In the U.S., in June 2014, Takeda launched ENTYVIO for the treatment of ulcerative colitis and Crohn's disease, and the Company has also commenced the marketing of ENTYVIO in Europe. ENTYVIO is a groundbreaking new product that offers a new treatment option to patients with inflammatory bowel disease who have failed to respond to treatment with existing products, and it is anticipated to be a blockbuster global product for Takeda.
- In October 2014, Takeda entered into a global license, development, commercialization and supply agreement for lubiprostone (U.S. product name: AMITIZA) with Sucampo Pharmaceuticals. Through this agreement, Takeda expanded its exclusive rights beyond the U.S. and Canada to all global markets, except Japan and China.

#### Oncology

- In Japan, in April 2014, Takeda launched ADCETRIS for the treatment of malignant lymphomas, a highly anticipated new treatment option for patients. The Company is steadily increasing the number of countries in which this treatment is now available, including in emerging markets.
- Multiple myeloma treatment VELCADE has grown to become Takeda's top selling product, and Takeda is pursuing further Life Cycle Management opportunities to expand its approved indications.

#### <R&D Initiatives>

Takeda is committed to addressing the unmet medical needs of people worldwide through increased R&D productivity and the discovery and delivery of innovative healthcare solutions.

- In the short term, Takeda is striving to ensure the steady approval of Phase III programs. In Gastroenterology, the approval of ENTYVIO in the U.S. and Europe within the same month for ulcerative colitis and Crohn's disease is an example of a significant success in this area. Also, in December 2014, Takeda achieved the important milestone of approval in Japan for TAKECAB, a potassium-competitive acid blocker that provides a strong and sustained acid secretion inhibitory effect with a novel mechanism of action for treating acid-related diseases.
- In the medium term, Takeda will progress the early-stage portfolio as quickly as possible, and also focus on in-licensing new assets and exploring additional indications for existing compounds. In Oncology, oral proteasome inhibitor MLN9708 (ixazomib) was designated Breakthrough Therapy status by the U.S. FDA for the treatment of relapsed or refractory systemic light-chain (AL) amyloidosis, supported by preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over available therapies. Also, Takeda is proceeding with several clinical trials evaluating additional indications of malignant lymphoma treatment ADCETRIS, such as for front line Hodgkin lymphoma and post-ASCT Hodgkin lymphoma.
- In the long term, Takeda will invest in cutting-edge science and technology to further invigorate drug discovery research, and strengthen alliances with research organizations and consortiums. Examples of long term initiatives include the Takeda's partnership with MacroGenics, a company with expertise in complex diseases such as auto-immune disorders, and the strategic investment Takeda has made in BioMotiv, which will leverage the strengths of both organizations to identify and develop pioneering medical innovations in the therapeutic areas of Immunology/Inflammatory and Cardiovascular and Metabolic diseases. Additionally, an alliance agreement with GE Healthcare in the area of liver disease will enable Takeda to utilize GE Healthcare's diagnostic technologies towards the development of innovative therapeutic drugs.

For further details of R&D activities including the progression of clinical trials, please refer to section (iv) "Activities and Results of Research & Development" on page 11.

Andrew "Andy" Plump, M.D., Ph.D., has joined Takeda as Chief Medical and Scientific Officer (CMSO) Designate, following the planned retirement in June 2015 of Tadataka "Tachi" Yamada, M.D., Takeda's current CMSO. Under the guidance of Andy, with his deep experience in drug discovery and development and high level of expertise spanning across a number of disease areas, Takeda will sustain and enhance its best-in-class R&D enterprise.

<Manufacturing Activities>

Takeda is further reinforcing its manufacturing network and global supply operations in order to consistently provide high quality products to patients and healthcare providers throughout the world. As one initiative of this, in November 2014, Takeda announced that it has decided to focus its Osaka Plant to become a specialty manufacturing site for LEUPLIN, one of Takeda's main products, for the treatment of prostate cancer and premenopausal breast cancer. The manufacturing of solid products will be transferred to plants at Hikari (Yamaguchi Prefecture, Japan) and Oranienburg (Brandenburg, Germany).

With the corporate philosophy of "Takeda-ism" (Integrity: Fairness, Honesty and Perseverance) developed over its long history of more than 230 years at the core of its operations, Takeda strives to strengthen corporate governance, further ensure compliance\* with laws and regulations governing its operations and conducts operations as a globally integrated company, according to the corporate mission to "strive towards better health for people worldwide through leading innovation in medicine."

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\*With regards to the issues surrounding the CASE-J study of anti-hypertensive treatment BLOPRESS, Takeda has fully cooperated with a third-party investigation. As a result of the investigation, it did not find any indications that Takeda was involved in "accessing the research data," "data falsification or fabrication," nor had "direct involvement in the statistical analysis work." However, it was confirmed that there were multiple incidences of involvement and encouragement by Takeda employees in the investigator-led clinical research study, raising suspicions about the fairness and independence of this study.

Based on the results of this investigation, Takeda has implemented internal disciplinary actions, and has strengthened its internal review system for promotional materials by adding new members to review materials from both a legal and medical perspective. Additionally, Takeda has strengthened its system for the screening and evaluation of donations. Takeda will continuously implement measures to prevent recurrences of this kind of event in the future, including ensuring transparency through clarifying the role of each department and strengthening each department's checking systems, as well as thoroughly ensuring that Takeda employees are completely uninvolved in investigator-led clinical research related to Takeda products.

The promotional activities by Takeda related to this case were deemed in violation of the Japan Pharmaceutical Manufacturers Association's (JPMA's) "Prescription Drugs Promotion Code". As a consequence, Takeda received notice of sanctions imposed by the JPMA that Takeda's activities as Vice President of the JPMA would be temporarily suspended for six months from April 2014, and an additional sanction has tentatively extended this suspension by a further six months.

**<Reference> Major products launched in and after 2010**

**[Japan]**

Launched in 2010	
<i>Nesina</i>	a drug for type 2 diabetes, generic name: alogliptin
<i>Unisia</i>	a drug for treatment of hypertension: a fixed dose combination of Blopress and a calcium channel blocker (amlodipine)
<i>Vectibix</i>	a cancer drug, generic name: panitumumab
<i>Rozerem</i>	an insomnia drug, generic name: ramelteon
<i>Metact</i>	a drug for type 2 diabetes: a fixed dose combination of Actos and a biguanide (metformin)
<i>Actos OD (orally-disintegrating tablets)</i>	a drug for type 2 diabetes
<i>Lampion pack</i>	a drug for secondary eradication of Helicobacter Pylori: a single pack containing Takepron, amoxicillin and metronidazole
Launched in 2011	
<i>Reminyl</i>	a drug for Alzheimer's dementia, generic name: galantamine, licensed from Janssen and jointly marketed with the licensor
<i>Sonias</i>	a drug for type 2 diabetes: a fixed dose combination of Actos and a sulfonylurea (glimepiride)
<i>Liovel</i>	a drug for type 2 diabetes: a fixed dose combination of Nesina and Actos
Launched in 2012	
<i>Azilva</i>	a drug for treatment of hypertension, generic name: azilsartan
Launched in 2013	
<i>Lotriga</i>	a drug for treatment of hyperlipidemia, generic name: omega-3-acid ethyl esters 90
Launched in April 2014	
<i>Adcetris</i>	a drug for treatment of malignant lymphoma, generic name: brentuximab vedotin
Launched in June 2014	
<i>Takelda</i>	a fixed dose combination of Takepron and low-dose aspirin
<i>Zacras</i>	a drug for treatment of hypertension: a fixed dose combination of Azilva and amlodipine

**[North America]**

**<U.S.A.>**

Launched in 2010	
<i>Actoplus met XR</i>	a drug for type 2 diabetes: a fixed dose combination of Actos and a biguanide (metformin extended- release)
Launched in 2013	
<i>Nesina</i>	a drug for type 2 diabetes, generic name: alogliptin
<i>Kazano</i>	a drug for type 2 diabetes: a fixed dose combination of Nesina and a biguanide (metformin)
<i>Oseni</i>	a drug for type 2 diabetes: a fixed dose combination of Nesina and Actos
Launched in January 2014	
<i>Brintellix</i>	a drug for treatment of major depressive disorder, generic name: vortioxetine
Launched in June 2014	
<i>Entyvio</i>	a drug for the treatment of ulcerative colitis and Crohn's disease, generic name: vedolizumab

Launched in October 2014	
<i>Contrave</i>	a drug for the treatment of obesity: a fixed dose combination of naltrexone and bupropion extended-release

<Canada>

Launched in 2010	
<i>Dexilant</i>	a drug for acid reflux disease, generic name: dexlansoprazole
<i>Uloric</i>	a drug for hyperuricemia for patients with chronic gout, generic name: febuxostat
Launched in 2011	
<i>Daxas</i>	a drug for chronic obstructive pulmonary disease, generic name: roflumilast

[Europe]

Launched in 2010	
<i>Mepact</i>	a drug for non-metastatic osteosarcoma, generic name: mifamurtide
Launched in 2012	
<i>Edarbi</i>	a drug for treatment of hypertension, generic name: azilsartan medoxomil
<i>Adcetris</i>	a drug for treatment of malignant lymphoma, generic name: brentuximab vedotin
Launched in 2013	
<i>Latuda</i>	an atypical antipsychotic, generic name: lurasidone hydrochloride
<i>Vipidia</i>	a drug for type 2 diabetes, generic name: alogliptin
<i>Vipdomet</i>	a drug for type 2 diabetes: a fixed dose combination of Vipidia and a biguanide (metformin)
<i>Incrasyn</i>	a drug for type 2 diabetes: a fixed dose combination of Vipidia and Actos
Launched in July 2014	
<i>Dexilant</i>	a drug for acid reflux disease, generic name: dexlansoprazole
<i>Entyvio</i>	a drug for the treatment of ulcerative colitis and Crohn's disease, generic name: vedolizumab

[Emerging markets]

<Brazil>

Launched in 2011	
<i>Daxas</i>	a drug for chronic obstructive pulmonary disease, generic name: roflumilast

<Russia>

Launched in 2012	
<i>Daxas</i>	a drug for chronic obstructive pulmonary disease, generic name: roflumilast
Launched in October 2014	
<i>Edarbi</i>	a drug for treatment of hypertension, generic name: azilsartan medoxomil

<Mexico>

Launched in 2011	
<i>Dexilant</i>	a drug for acid reflux disease, generic name: dexlansoprazole
<i>Mepact</i>	a drug for non-metastatic osteosarcoma, generic name: mifamurtide
Launched in 2012	
<i>Edarbi</i>	a drug for treatment of hypertension, generic name: azilsartan medoxomil
Launched in 2013	
<i>Daxas</i>	a drug for chronic obstructive pulmonary disease, generic name: roflumilast
<i>Edarbyclor</i>	a drug for treatment of hypertension, a fixed dose combination of Edarbi and thiazide diuretic (chlorthalidone)



Launched in January 2014	
<i>Adcetris</i>	a drug for treatment of malignant lymphoma, generic name: brentuximab vedotin
Launched in April 2014	
<i>Nesina</i>	a drug for type 2 diabetes, generic name: alogliptin
Launched in October 2014	
<i>Oseni</i>	a drug for type 2 diabetes: a fixed dose combination of Nesina and Actos

<China>

Launched in 2013	
<i>Nesina</i>	a drug for type 2 diabetes, generic name: alogliptin

**(ii) Operating Results**

Consolidated results (April 1 to December 31, 2014):

*Billions of yen*

	<u>Amount</u>	<u>Change over the same period of the previous year</u>	
Revenue	1,340.0	+ 53.1	+ 4.1%
Operating profit	199.1	+ 22.3	+12.6%
Net profit for the period (attributable to owners of the Company)	79.7	- 53.5	- 40.2%
Core Earnings (Note)	275.4	- 13.5	- 4.7%
Core EPS (yen) (Note)	213.57	- 32.22	- 13.1%

(Note) Core Earnings is calculated by deducting any temporary factors such as impacts from business combination accounting and amortization/impairment losses of intangible assets etc. from operating profit. Also, Core EPS is earnings per share based on Core Net Profit that is calculated by deducting any temporary factors that have the similar factors listed above and tax effects on them from Net profit for the period.

[Revenue]

Consolidated revenue was ¥1,340.0 billion, an increase of ¥53.1 billion (+4.1%) compared to the same period of the previous year.

- In Japan, the sales of AZILVA (a drug for hypertension) and LOTRIGA (a drug for hyperlipidemia) significantly increased. In the U.S., in addition to the increase in sales of VELCADE (a drug for multiple myeloma), the sales of BRINTELLIX (a drug for major depressive disorder) and ENTYVIO (a drug for ulcerative colitis and Crohn's disease) which were launched in 2014 had a smooth launch. Especially, the sales of ENTYVIO during seven month after launch amounted to ¥16.4 billion by addressing the unmet medical needs. Furthermore, the sales of ADCETRIS (a drug for lymphoma) continued to expand in Europe. Such positive factors and the yen's depreciation absorbed the decrease in sales mainly due to the penetration of generic products after the patent expiry of blockbuster products such as CANDESARTAN (a drug for hypertension) and LANSOPRAZOLE (a drug for peptic ulcer), and the National Health Insurance price reduction in Japan.

In total, consolidated revenue increased by ¥53.1 billion.

Underlying revenue growth (Note) increased by 2.4% compared to the same period of the previous year.

(Note) Underlying revenue growth: Constant currency and without divestments

- Consolidated revenue of Takeda's major ethical drugs:

*Billions of yen*

Indications / Product Name	Amount	Change over the same period of the previous year	
Multiple myeloma / Velcade	114.4	+ 13.0	+ 12.8%
Hypertension / Candesartan (Japan product name: Blopress)	101.8	- 22.3	- 18.0%
Prostate cancer, breast cancer and endometriosis / Leuprorelin (Japan product name: Leuplin)	94.6	- 3.5	- 3.6%
Peptic ulcer / Lansoprazole (Japan product name: Takepron)	78.1	- 13.1	- 14.3%
Peptic ulcer / Pantoprazole	77.6	- 0.1	- 0.2%
Hyperuricemia and gout / Colcrys	43.7	+ 5.6	+ 14.6%
Type 2 diabetes / Pioglitazone (Japan product name: Actos)	25.3	- 4.3	- 14.5%

(Note) Revenue amount includes royalty income and service income.

[Operating profit]

Consolidated operating profit was ¥199.1 billion, an increase of ¥22.3 billion (+12.6%) compared to the same period of the previous year.

- Gross profit increased by ¥36.3 billion (+4.0%) due to revenue increase. Selling, general and administrative expenses increased by ¥39.2 billion (+9.8%) mainly due to the launch of new products in the U.S., and amortization and impairment losses on intangible assets associated with products increased due to recognition of impairment loss for a product. On the other hand, other operating income significantly increased mainly due to reversal of a contingent consideration (Note) related to the product recognized impairment loss and the gains on sales of property, plant and equipment. As a result, operating profit increased.
- R&D expenses increased by ¥10.2 billion (+4.3%) to ¥249.2 billion compared to the same period of the previous year.
- On an underlying basis, which excluding FX impacts and others, selling, general and administrative expenses increased by 4.7% (general and administrative expenses, excluded selling expenses, decreased by 1.4%) and R&D expenses decreased by 1.5%, respectively.

(Note) A fair value liability of estimated additional consideration based on future specific events to transfer to former owners of an acquired company.

[Net profit for the period (attributable to owners of the Company)]

Consolidated net profit for the period was ¥79.7 billion, a decrease of ¥53.5 billion (-40.2%) compared to the same period of the previous year.

- Although operating profit increased, net financial income/expenses decreased mainly due to the decrease in gains on sales of financial assets compared to the same period of the previous year. In addition, tax expenses increased mainly due to a reassessment of the recoverability of a deferred tax asset for R&D tax credits as the result of Takeda adopting a tax method which allows for R&D expenditures to be expensed in the year incurred. As a result, consolidated net profit for the period decreased.
- Basic earnings per share was ¥101.39, a decrease of ¥67.44 (-39.9%) compared to the same period of the previous year.

[Core Earnings]

Core Earnings was ¥275.4 billion, a decrease of ¥13.5 billion (-4.7%) compared to the same period of the previous year.

- Core Net Profit (Note) was ¥168.0 billion, a decrease of ¥26.1 billion (-13.4%) compared to the same period of the previous year.

- Core EPS was ¥213.57, a decrease of ¥32.22 (-13.1%) compared to the same period of the previous year.

(Note) Core Net Profit is calculated by deducting any temporary factors such as impacts from business combination accounting and amortization/impairment losses of intangible assets etc. and tax effects on them from Net profit for the period.

**(iii) Results by Segment**

Revenue and operating profit by business segment (April 1 to December 31, 2014):

*Billions of yen*

Type of Business	Revenue		Operating profit	
	Amount	Change over the same period of the previous year	Amount	Change over the same period of the previous year
Ethical Drug	1,214.7	+51.3	151.1	+1.9
<Japan>	<437.1>	< -17.1>		
<Overseas>	<777.6>	< +68.4>		
Consumer Healthcare	58.2	+0.9	17.7	+1.2
Other	67.1	+0.9	30.2	+19.3
Total	1,340.0	+53.1	199.1	+22.3

[Ethical Drug Business]

Revenue in the Ethical Drug Business was ¥1,214.7 billion, an increase of ¥51.3 billion (+4.4%) compared to the same period of the previous year, and operating profit was ¥151.1 billion, an increase of ¥1.9 billion (+1.3%) compared to the same period of the previous year.

- Revenue in Japan was ¥437.1 billion, a decrease of ¥17.1 billion (-3.8%) compared to the same period of the previous year. Contribution from sales increase of products launched in and after 2010 such as AZILVA and NESINA could not fully absorb the decrease in sales mainly due to the National Health Insurance price reduction and the penetration of generic products.

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

*Billions of yen*

Product Name (Indications)	Amount	Change over the same period of the previous year	
Blopress (Hypertension)	78.8	- 21.2	- 21.2%
Leuplin (Prostate cancer, breast cancer and endometriosis)	44.7	- 6.5	- 12.7%
Takepron (Peptic ulcer)	41.2	- 12.8	- 23.7%
Azilva (Hypertension)	33.0	+ 17.1	+ 107.9%
Nesina (Type 2 diabetes)	29.7	+ 0.2	+ 0.7%
Vectibix (Cancer)	14.1	- 0.7	- 4.7%
Reminyl (Alzheimer's dementia)	10.4	+ 1.4	+ 14.9%
Lotriga (Hyperlipidemia)	9.1	+ 5.6	+ 160.3%
Actos (Type 2 diabetes)	8.6	- 3.9	- 31.5%

- Revenue in overseas markets was ¥777.6 billion, an increase of ¥68.4 billion (+9.6%) compared to the same period of the previous year. In addition to the sales increase of VELCADE and DEXILANT in the U.S., contribution from new products such as BRINTELLIX and ENTYVIO, and the yen's depreciation could fully absorb the decrease in sales due to the penetration of generic products.
- The following table shows revenue results of major products in overseas markets:

*Billions of yen*

Product Name (Indications)	Amount	Change over the same period of the previous year	
Velcade (Multiple myeloma)	109.0	+ 8.8	+ 8.8%
Pantoprazole (Peptic ulcer)	77.6	- 0.1	- 0.2%
Leuprorelin (Prostate cancer, breast cancer and endometriosis)	49.9	+ 3.0	+ 6.3%
Dexilant (Acid reflux disease)	45.2	+ 9.0	+ 24.7%
Colcrys (Hyperuricemia and gout)	43.7	+ 5.6	+ 14.6%
Lansoprazole (Peptic ulcer)	36.9	- 0.3	- 0.8%
Candesartan (Hypertension)	23.0	- 1.2	- 4.8%
Pioglitazone (Type 2 diabetes)	16.7	- 0.3	- 1.9%

(Note) Revenue amount includes royalty income and service income.

[Consumer Healthcare Business]

Revenue in the Consumer Healthcare Business was ¥58.2 billion, an increase of ¥0.9 billion (+1.6%) compared to the same period of the previous year, mainly due to the increase in sales of ALINAMIN tablets (vitamin-containing products). Operating profit increased by ¥1.2 billion (+7.0%) to ¥17.7 billion mainly due to the improvement in gross profit margin.

[Other Business]

Revenue in the Other Business was ¥67.1 billion, an increase of ¥0.9 billion (+1.4%) compared to the same period of the previous year. Operating profit increased by ¥19.3 billion (+175.6%) to ¥30.2 billion mainly due to the gains on sales of property, plant and equipment.

#### **(iv) Activities and Results of Research & Development**

By April 2015, Takeda will realign its research and development functions into the four Therapeutic Area Units (TAUs) of Central Nervous System, Cardiovascular/Metabolic, Gastroenterology, and Oncology to further promote therapeutic area strategy and asset strategies as well as to achieve a global leadership position in each area and to meet unmet medical needs of patients. In addition, Specialty Business Units will be established for Oncology and Vaccines, which will include operational and commercial functions. Regarding the Specialty Business Unit for Oncology, Takeda is retiring the "Millennium: The Takeda Oncology Company" brand, and replacing it with "Takeda Oncology".

Major events from R&D activities during the reporting period are as follows;

[In-house R&D activities]

- In May 2014, Takeda received approval from the U.S. Food and Drug Administration (FDA) for ENTYVIO (generic name: vedolizumab) for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). Also in May 2014, Takeda received approval from the European Commission (EC) for ENTYVIO.
- In May 2014, Takeda received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for an application for changes to the indication of type 2 diabetes treatment NESINA (generic name: alogliptin). The newly approved indication is "Type 2 Diabetes", which includes the previously unapproved indication of concomitant therapy with a rapid-acting insulin-secretion stimulating agent. The "Type 2 Diabetes" indication now allows concomitant therapy of NESINA with all the oral anti-diabetic agents and insulin.
- In May 2014, Takeda presented the results of five Phase III trials for TAKECAB (generic name: vonoprazan), for the treatment of acid-related diseases, at the poster session of Digestive Disease Week (DDW). In December 2014, Takeda received approval from the Japanese MHLW.
- In June 2014, Takeda decided to terminate the global development program for TAK-700 (generic name: orteronel) for prostate cancer. The decision followed the results of two Phase III clinical trials in which TAK-700 failed to meet the primary endpoint of improved overall survival, and also after consideration of the availability of other therapies in this indication.
- In August 2014, Takeda received approval from the FDA for an additional indication of VELCADE (generic name: bortezomib) for the retreatment of adult patients with multiple myeloma (MM) who had previously responded to VELCADE therapy and relapsed at least six months following completion of prior VELCADE treatment. In addition, in October 2014, Takeda received approval from the FDA for an additional indication of VELCADE for use in previously untreated patients with mantle cell lymphoma (MCL).

- In August 2014, Takeda submitted the data of the post-marketing commitment, a 10-year epidemiology study, to regulatory authorities including the FDA, the European Medicines Agency (EMA) and the Japanese MHLW / Pharmaceuticals and Medical Devices Agency (PMDA) for pioglitazone containing medicines, including ACTOS (generic name: pioglitazone). This study was conducted by the University of Pennsylvania and Division of Research at Kaiser Permanente Northern California (KPNC) and findings demonstrate that there is no statistically significant increased risk of bladder cancer among patients ever exposed to pioglitazone.
- In September 2014, Takeda submitted a New Drug Application (NDA) to the Japanese MHLW for LEUPLIN (generic name: leuprorelin) 6 month depot, a treatment for prostate cancer and premenopausal breast cancer.
- In September 2014, Takeda presented the results of a Phase III trial for SYR-472 (generic name: trelagliptin) for type 2 diabetes, at the 50<sup>th</sup> Annual Meeting of the European Association for the Study of Diabetes.
- In November 2014, Takeda was granted Breakthrough Therapy\* status from the FDA for MLN9708 (generic name: ixazomib) for the treatment of relapsed or refractory systemic light-chain (AL) amyloidosis. This is the first proteasome inhibitor and first investigational therapy for AL amyloidosis to receive Breakthrough Therapy designation. In December 2014, the data used to support this designation was presented at the 56<sup>th</sup> American Society of Hematology (ASH) annual meeting. At the same meeting, Takeda also presented results from a Phase II study evaluating the safety and efficacy of oral, single-agent MLN9708 as maintenance therapy in patients with multiple myeloma (MM) who had received MLN9708, lenalidomide and dexamethasone as induction therapy.

\* Breakthrough Therapy designation is intended to expedite the development and review of new medicines to treat serious or life-threatening conditions.

[Alliance activities]

- In April 2014, Takeda and Teva Pharmaceutical Industries Ltd. of Israel announced an agreement allowing Takeda to commercialize rasagiline (generic name), Teva's innovative treatment for Parkinson's disease, in Japan. Under the terms of the agreement, Takeda will develop rasagiline for the Japanese market and submit a NDA for registration of the product in Japan. In January 2015, Takeda announced the start of Phase II/III and Phase III clinical trials of rasagiline in Japan.
- In May 2014, Takeda and MacroGenics, Inc. of the U.S. concluded an option agreement for the development and commercialization of MGD010, a product candidate for the treatment of autoimmune diseases. In September 2014, the companies entered into a further agreement to develop and commercialize up to four additional product candidates.
- In June 2014, Takeda and H. Lundbeck A/S (Lundbeck) of Denmark announced results of a study of BRINTELLIX (generic name: vortioxetine), a treatment for major depressive disorder (MDD) which Takeda has in-licensed from Lundbeck, on sexual functioning in MDD patients experiencing treatment-emergent sexual dysfunction at the American Society of Clinical Psychopharmacology Annual Meeting. Also in June 2014, Takeda and Lundbeck announced data evaluating the effect of BRINTELLIX on aspects of cognitive function at the International College of Neuropsychopharmacology World Congress.
- In June 2014, Takeda and Affymax, Inc. of the U.S. decided that based on the findings of a detailed investigation into postmarketing reports of serious hypersensitivity reactions and discussion between the companies, the product collaboration and license agreement for chronic kidney disease related anemia treatment OMONTYS (generic name: peginesatide) would be terminated, and Takeda would work with the FDA to withdraw the OMONTYS NDA. The agreement was terminated in September 2014.

- In July 2014, Takeda and Zinfandel Pharmaceuticals of the U.S. presented several data including an update of the Phase III TOMMORROW study\* of AD-4833 (generic name: pioglitazone)/TOMM40 at the Alzheimer's Association International Conference.  
\*This clinical trial is investigating a biomarker risk assignment algorithm (including the TOMM40 genotype) to predict risk of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) within a five year period and to evaluate the efficacy of the investigational low dose AD-4833 in delaying the onset of MCI due to AD in cognitively normal individuals at high risk as determined by the risk assignment algorithm.
- In September 2014, Takeda obtained approval from the Japanese MHLW for Fomepizole Intravenous Infusion 1.5g "TAKEDA" (generic name: fomepizole), which Takeda in-licensed from Paladin Labs Inc. of Canada, for the treatment of ethylene glycol and methanol poisonings.
- In September 2014, Takeda and Seattle Genetics, Inc. of the U.S. announced results from the Phase III trial (AETHERA trial) for ADCETRIS (generic name: brentuximab vedotin), a treatment for malignant lymphoma which Takeda in-licensed from Seattle Genetics, as consolidation therapy immediately following an autologous stem cell transplantation in patients with Hodgkin lymphoma. In December 2014, Takeda and Seattle Genetics presented this data at the 56th ASH annual meeting. Four-year overall survival (OS) data from the ADCETRIS pivotal Phase II clinical trial in relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) was also presented at this meeting.
- In October 2014, Takeda and Intra-Cellular Therapies, Inc. of the U.S. announced an agreement to mutually terminate the license agreement covering Intra-Cellular Therapies' proprietary compound ITI-214 for the treatment of cognitive impairment associated with schizophrenia, and related PDE 1 inhibitors, and to return the rights for these compounds to Intra-Cellular Therapies.
- In November 2014, Takeda and Amgen of the U.S. announced top-line secondary endpoint results of overall survival (OS) from the Phase III TRINOVA-1 trial evaluating AMG386 (generic name: trebananib), which Takeda in-licensed from Amgen, plus paclitaxel, versus placebo plus paclitaxel in patients with recurrent ovarian cancer.
- In November 2014, Takeda and GE Healthcare of the U.K. announced an alliance agreement for research and development focusing on imaging modalities in the field of hepatic fibrosis, a key factor in the diagnosis and treatment of liver diseases. The collaborative effort aims to help develop therapeutic drugs as well as new diagnostic technologies for liver diseases.
- In December 2014, Takeda submitted an NDA to the Japanese MHLW for glatiramer acetate (generic name), which Takeda in-licensed from TEVA Pharmaceutical Industries Ltd. of Israel, for the relapse prevention of multiple sclerosis.
- In December 2014, Takeda and AMAG Pharmaceuticals of the U.S. announced an agreement to mutually terminate the development and commercialization agreement, for ferumoxytol (generic name), a treatment for iron deficiency anemia, in the European Union (EU) and other territories.
- In February 2015, Takeda announced the voluntary discontinuation of the development of TAK-361S, a four-component, combination Diphtheria-Tetanus-acellular Pertussis (DTaP) and Sabin inactivated poliovirus vaccine (sIPV).\*
- \* In 2008, Takeda entered into an agreement with Japan Poliomyelitis Research Institute (now The Research Foundation for Microbial Diseases of Osaka University) for sharing of seed viruses for the Sabin-inactivated poliovirus vaccine.

[Joint Research activities]

- In December 2014, Takeda and Monash University of Australia announced a strategic research alliance to develop new medicines to address significant unmet medical needs in gastroenterology.

[Improvement and Reinforcement of R&D organization]

- In April 2014, Takeda was selected as a recipient of a supplemental subsidy from the Japanese government to support investments associated with the development and production of pandemic influenza vaccines.
- In September 2014, Takeda made a strategic investment in BioMotiv of the U.S., and the companies decided to form a partnership that will leverage the strengths of both organizations to identify and develop pioneering medical innovations.

## **(2) Consolidated Financial Position**

[Assets]

Total assets as of December 31, 2014 were ¥4,653.4 billion, an increase of ¥84.2 billion compared to the previous fiscal year end mainly due to the increase in foreign assets and goodwill resulting from yen's depreciation.

[Liabilities]

Total liabilities as of December 31, 2014 were ¥2,080.5 billion, an increase of ¥52.0 billion compared to the previous fiscal year end mainly due to the increase in foreign liabilities resulting from yen's depreciation.

[Equity]

Total equity as of December 31, 2014 was ¥2,572.9 billion, an increase of ¥32.2 billion compared to the previous fiscal year end, which despite dividend payments, was mainly due to the increase in exchange differences on translation of foreign operations caused by the yen's depreciation as of December 31, 2014, in addition to net profit for the period.

The ratio of equity attributable to owners of the Company to total assets decreased by 0.3 pt. to 53.8% from the previous fiscal year end.



### (3) Outlook for Fiscal 2014

The outlook for consolidated results for the full year of fiscal 2014 has been revised from the previous forecast (announced at 2<sup>nd</sup> quarter of fiscal 2014 financial results announcement on October 30, 2014) as follows, considering the current results and foreign exchange rates.

[Full year consolidated forecasts for Fiscal 2014 (April 1, 2014 to March 31, 2015)]

*Billions of yen*

	Previous forecast (A)	Revised forecast (B)	Change (B-A)	Change
Revenue	1,725.0	1,725.0	—	—
R&D expenses	350.0	350.0	—	—
Operating profit	150.0	170.0	+20.0	+13.3%
Net profit for the year (attributable to owners of the Company)	85.0	65.0	-20.0	-23.5%
EPS	107.67 yen	82.64 yen		
Core Earnings (Note)	280.0	280.0	—	—
Core Net Profit (Note)	180.0	180.0	—	—
Core EPS (Note)	228.01 yen	228.01 yen		

(Note) Core Earnings is calculated by deducting any temporary factors such as impacts from business combination accounting and amortization/impairment losses of intangible assets etc. from operating profit. Also, Core EPS is earnings per share based on Core Net Profit that is calculated by deducting any temporary factors that have the similar factors listed above and tax effects on them from Net profit for the year/period.

[Assumptions used in preparing the Outlook]

The foreign exchange rates assumptions for fiscal 2014 are US\$1 = ¥109 and 1 Euro = ¥141

[Forward looking statement]

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

### (4) Litigation

#### (i) Product liability litigation regarding pioglitazone-containing products

The Company, Takeda Pharmaceuticals U.S.A., Inc. (“TPUSA”), and certain Company Affiliates located in the U.S. have been named as defendants in lawsuits pending in U.S. federal and state courts in which plaintiffs allege to have developed bladder cancer as a result of taking pioglitazone-containing products (some cases alleged other injuries). Eli Lilly & Co. (“Eli Lilly”) is a defendant in many of these lawsuits. Also, proposed personal injury class action lawsuits have been filed in Canada; a lawsuit seeking compensation for bladder cancer has been filed in France.

The Company is vigorously defending these lawsuits.

Of the eight lawsuits tried to-date in the U.S. or state courts, five cases have resulted in judgments in favor of Takeda. Plaintiffs in those cases are challenging the judgments in post-trial motions or appeals.

In 2014, the first trial was conducted in the federal multi district litigation (“MDL”)\*, in the case of Terrence Allen, et al. v. TPNA, et al. On April 7, 2014, the jury reached a verdict in favor of plaintiffs and awarded \$1,475 thousand in compensatory damages against Takeda defendants and Eli Lilly, allocating liability 75% to Takeda defendants and 25% to Eli Lilly. The jury also assessed \$6 billion in punitive damages against Takeda defendants and \$3 billion in punitive damages against Eli Lilly. In June, Takeda and Eli Lilly filed post-trial motions challenging the verdict. In August, the court denied the post-trial motion for judgment in favor of Takeda and Eli Lilly and in September, entered a judgment on the jury verdict mentioned above. The compensatory damages award was reduced from \$1,475 thousand to \$1,270 thousand under New York law as the result of this judgment. On October 27, the court ruled on the post-trial motion to reduce the punitive damage award, entering an amended judgment to reduce the punitive damage award against Takeda defendants to \$27.65 million and against Eli Lilly to \$9.22 million.

In October, the jury in a state court located in Philadelphia County, Pennsylvania, found in favor of the plaintiff and awarded \$2,050 thousand in compensatory damages. In November, the jury in a state court located in Berkeley County, West Virginia found in favor of Takeda on plaintiffs’ claims that Takeda failed to warn about the risks of bladder cancer or that pioglitazone containing product caused plaintiff’s bladder cancer. However, the jury found in favor of plaintiffs on their claim for spoliation of evidence and awarded \$155 thousand in compensatory damages.

Takeda intends to challenge these adverse outcomes through all available means, including post-trial motions and appeals.

Many additional state court trials are scheduled to take place going forward, and the Company is vigorously and appropriately defending them, as well.

\* An MDL consolidates similar cases filed in federal courts under one federal jurisdiction primarily for pre-trial and discovery purposes.

#### **(ii) Patent infringement litigation and administrative litigation regarding colchicine product**

On September 30, 2014, the U.S. Food and Drug Administration (“FDA”) granted approval to Hikma Pharmaceuticals PLC (“Hikma”) for colchicine capsules, to be marketed under the name Mitigare. In response Takeda filed a patent infringement lawsuit against Hikma and Hikma subsidiaries in the District Court for the District of Delaware asserting that their colchicine product infringes several Takeda patents applicable to Colcrys, the first single-ingredient oral colchicine product approved by the FDA. Takeda also filed a request for a temporary restraining order (“TRO”) and a preliminary injunction prohibiting the launch of Mitigare. On October 9, the court granted a TRO pending its decision on Takeda’s motion for a preliminary injunction. On November 4, the court denied Takeda’s motion for a preliminary injunction. The court further ruled, however, that the TRO would remain in place, provided Takeda filed an immediate, expedited appeal. In response, Takeda filed a notice of appeal in the Federal Circuit Court of Appeals. On January 9, 2015, the Federal Circuit Court of Appeals affirmed the denial of the preliminary injunction, allowing Hikma to launch its product. Takeda intends to proceed with its patent infringement claims against Hikma in the trial court, where Takeda will seek a permanent injunction and damages, including lost profits caused by the launch of Hikma’s product.

In parallel, shortly after filing the patent infringement lawsuit in October 2014, Takeda filed a lawsuit against the FDA in the District Court for the District of Columbia seeking an order rescinding or staying approval of Mitigare. The lawsuit claims that the FDA violated the Administrative Procedure Act in approving Hikma’s Mitigare. On January 9, 2015, the court denied Takeda’s claims. Takeda intends to appeal the court’s ruling.

## 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) Changes in accounting policies and changes in accounting estimates

The significant accounting policies adopted for the condensed interim consolidated financial statements are the same as those for the fiscal year ended March 31, 2014 with the exception of the items described below. The Companies calculated income taxes for the nine month period ended December 31, 2014, based on the estimated average annual effective tax rate.

(Changes in accounting policies)

The accounting standards applied by the Companies effective from the first quarter ended June 30, 2014 are as follows.

IFRS		Description of new standards, interpretations and amendments
IAS 32	Financial Instruments: Presentation	Presentation of offsetting financial assets and financial liabilities
IAS 39	Financial Instruments: Recognition and Measurement	Amendment to novation of derivatives and continuation of hedge accounting
IFRS 10	Consolidated Financial Statements	Amendment to definition of investment entity and accounting treatment for the investments
IFRS 12	Disclosure of Interests in Other Entities	New disclosure requirements related to the amendment to IFRS 10
IFRIC 21	Levies	Clarification of the accounting for levies

The above standards do not have a material impact on the condensed interim consolidated financial statements.

### 3. Condensed Interim Consolidated Financial Statements [IFRS]

#### (1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014
Revenue	1,286,872	1,339,985
Cost of sales	(369,589)	(386,407)
Gross profit	917,283	953,578
Selling, general and administrative expenses	(398,877)	(438,036)
Research and development expenses	(238,987)	(249,227)
Amortization and impairment losses on intangible assets associated with products	(88,496)	(126,478)
Other operating income	14,526	94,664
Other operating expenses	(28,733)	(35,449)
Operating profit	176,716	199,052
Finance income	40,113	14,912
Finance expenses	(18,574)	(27,719)
Share of profit of associates accounted for using the equity method	758	1,321
Profit before tax	199,013	187,566
Income tax expenses	(62,205)	(105,222)
Net profit for the period	136,808	82,345
Attributable to:		
Owners of the Company	133,280	79,745
Non-controlling interests	3,529	2,600
Net profit for the period	136,808	82,345
Earnings per share (yen)		
Basic earnings per share	168.82	101.39
Diluted earnings per share	168.64	101.16

**(2) Condensed Interim Consolidated Statement of Income and Other Comprehensive Income**

(Millions of yen)

	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014
Net profit for the period	136,808	82,345
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	1,528	(6,412)
	1,528	(6,412)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translating foreign operations	263,735	105,091
Net changes on revaluation of available-for-sale financial assets	4,091	8,436
Cash flow hedges	233	(860)
	268,059	112,667
Other comprehensive income, net of tax	269,587	106,255
Total comprehensive income for the period	406,395	188,600
Attributable to:		
Owners of the Company	400,539	182,994
Non-controlling interests	5,856	5,606
Total comprehensive income for the period	406,395	188,600

**(3) Condensed Interim Consolidated Statement of Financial Position**

(Millions of yen)

	As of March 31, 2014	As of December 31, 2014
<b>ASSETS</b>		
Non-current assets		
Property, plant and equipment	542,253	539,801
Goodwill	814,671	880,981
Intangible assets	1,135,597	1,058,229
Investment property	32,083	30,442
Investments accounted for using the equity method	10,001	11,103
Other financial assets	192,806	237,900
Other non-current assets	40,772	38,979
Deferred tax assets	208,424	152,145
Total non-current assets	2,976,607	2,949,581
Current assets		
Inventories	254,329	282,659
Trade and other receivables	430,620	489,021
Other financial assets	184,981	74,992
Income taxes recoverables	12,044	11,200
Other current assets	43,510	62,645
Cash and cash equivalents	666,048	781,507
Subtotal	1,591,531	1,702,024
Assets held for sale	1,005	1,766
Total current assets	1,592,536	1,703,791
Total assets	4,569,144	4,653,372

	As of March 31, 2014	As of December 31, 2014
<b><u>LIABILITIES AND EQUITY</u></b>		
<b><u>LIABILITIES</u></b>		
Non-current liabilities		
Bonds and loans	704,580	731,084
Other financial liabilities	110,129	76,537
Net defined benefit liabilities	76,497	90,208
Provisions	14,399	18,208
Other non-current liabilities	39,555	79,703
Deferred tax liabilities	280,595	246,845
Total non-current liabilities	1,225,755	1,242,585
Current liabilities		
Bonds and loans	155,404	181,791
Trade and other payables	184,900	168,488
Other financial liabilities	48,817	74,650
Income taxes payables	52,332	73,617
Provisions	125,349	130,463
Other current liabilities	235,953	208,911
Total current liabilities	802,754	837,920
Total liabilities	2,028,509	2,080,505
<b><u>EQUITY</u></b>		
Share capital	63,562	63,740
Share premium	39,866	56,681
Treasury shares	(621)	(18,185)
Retained earnings	1,901,307	1,824,972
Other components of equity	466,624	576,272
Equity attributable to owners of the Company	2,470,739	2,503,479
Non-controlling interests	69,896	69,387
Total equity	2,540,635	2,572,867
Total liabilities and equity	4,569,144	4,653,372

**(4) Condensed Interim Consolidated Statement of Changes in Equity**

Nine month period ended December 31, 2013 (From April 1 to December 31, 2013)

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Share premium	Treasury shares	Retained earnings	Other components of equity	
					Exchange differences on translating foreign operations	Net changes on revaluation of available-for-sale financial assets
As of April 1, 2013	63,541	40,257	(587)	1,927,795	177,083	64,598
Net profit for the period				133,280		
Other comprehensive income					261,474	4,024
Comprehensive income for the period	—	—	—	133,280	261,474	4,024
Issuances of new shares	21	21				
Acquisitions of treasury shares			(30)			
Disposals of treasury shares			2			
Dividends				(142,119)		
Changes in the ownership interest in subsidiaries						
Transfers from other comprehensive income to retained earnings				1,528		
Share-based payment transactions		422				
Put options written on non-controlling interests		(1,222)				
Total transactions with owners	21	(779)	(28)	(140,590)	—	—
As of December 31, 2013	63,562	39,478	(614)	1,920,484	438,557	68,623

	Equity attributable to owners of the Company				Non-controlling interests	Total equity
	Other components of equity			Total		
	Cash flow hedges	Remeasurements of defined benefit plans	Total			
As of April 1, 2013	1,416	—	243,097	2,274,103	64,183	2,338,286
Net profit for the period			—	133,280	3,529	136,808
Other comprehensive income	233	1,528	267,260	267,260	2,327	269,587
Comprehensive income for the period	233	1,528	267,260	400,539	5,856	406,395
Issuances of new shares			—	42		42
Acquisitions of treasury shares			—	(30)		(30)
Disposals of treasury shares			—	2		2
Dividends			—	(142,119)	(1,081)	(143,200)
Changes in the ownership interest in subsidiaries			—	—	2,354	2,354
Transfers from other comprehensive income to retained earnings		(1,528)	(1,528)	—		—
Share-based payment transactions			—	422		422
Put options written on non-controlling interests			—	(1,222)		(1,222)
Total transactions with the owners	—	(1,528)	(1,528)	(142,905)	1,272	(141,633)
As of December 31, 2013	1,648	—	508,828	2,531,738	71,311	2,603,049



Takeda Pharmaceutical Company Limited (4502)  
Summary of Financial Statements for the Nine Month  
Period Ended December 31, 2014 (Consolidated)

Nine month period ended December 31, 2014 (From April 1 to December 31, 2014)

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Share premium	Treasury shares	Retained earnings	Other components of equity	
					Exchange differences on translating foreign operations	Net changes on revaluation of available-for-sale financial assets
As of April 1, 2014	63,562	39,866	(621)	1,901,307	406,151	60,771
Net profit for the period				79,745		
Other comprehensive income					102,139	8,369
Comprehensive income for the period	—	—	—	79,745	102,139	8,369
Issuances of new shares	178	178				
Acquisitions of treasury shares			(17,569)			
Disposals of treasury shares		(0)	1			
Dividends				(141,781)		
Changes in the ownership interest in subsidiaries				(7,901)		
Transfers from other comprehensive income to retained earnings				(6,399)		
Share-based payment transactions		5,359	3			
Put options written on non-controlling interests		11,277				
Total transactions with the owners	178	16,814	(17,565)	(156,081)	—	—
As of December 31, 2014	63,740	56,681	(18,185)	1,824,972	508,290	69,141

	Equity attributable to owners of the Company				Non-controlling interests	Total equity
	Other components of equity			Total		
	Cash flow hedges	Remeasurements of defined benefit plans	Total			
As of April 1, 2014	(298)	—	466,624	2,470,739	69,896	2,540,635
Net profit for the period			—	79,745	2,600	82,345
Other comprehensive income	(860)	(6,399)	103,249	103,249	3,006	106,255
Comprehensive income for the period	(860)	(6,399)	103,249	182,994	5,606	188,600
Issuances of new shares			—	357		357
Acquisitions of treasury shares			—	(17,569)		(17,569)
Disposals of treasury shares			—	1		1
Dividends			—	(141,781)	(2,035)	(143,816)
Changes in the ownership interest in subsidiaries			—	(7,901)	(4,079)	(11,980)
Transfers from other comprehensive income to retained earnings			6,399	6,399	—	—
Share-based payment transactions			—	5,362		5,362
Put options written on non-controlling interests			—	11,277		11,277
Total transactions with the owners	—		6,399	6,399	(6,114)	(156,368)
As of December 31, 2014	(1,159)	—	576,272	2,503,479	69,387	2,572,867

**(5) Notes to Condensed Interim Consolidated Financial Statements**

(Going Concern Assumption)

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

No events to be noted for this purpose.

(Significant Changes in Equity Attributable to Owners of the Company)

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

No events to be noted for this purpose.

(Segment Information)

1. Revenues and operating profit by reportable segment and other information

Nine month period ended December 31, 2013 (April 1 to December 31, 2013)

(Millions of yen)

	Reportable Segments			Total	Condensed interim consolidated financial statements
	Ethical Drugs	Consumer Healthcare	Other		
Revenues	1,163,386	57,282	66,204	1,286,872	1,286,872
Operating profit	149,189	16,554	10,974	176,716	176,716
				Finance income	40,113
				Finance expenses	(18,574)
				Share of profit of associates accounted for using the equity method	758
				Profit before tax	199,013

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

(Millions of yen)

	Reportable Segments			Total	Condensed interim consolidated financial statements
	Ethical Drugs	Consumer Healthcare	Other		
Revenues	1,214,676	58,207	67,101	1,339,985	1,339,985
Operating profit	151,086	17,717	30,249	199,052	199,052
				Finance income	14,912
				Finance expenses	(27,719)
				Share of profit of associates accounted for using the equity method	1,321
				Profit before tax	187,566

## 2. Geographic Information

### Revenues

(Millions of yen)

	Japan	United States	Europe and Canada	Russia /CIS	Latin America	Asia	Others	Total
Nine month period ended December 31, 2013	570,011	263,518	242,285	66,944	59,211	62,819	22,084	1,286,872
Nine month period ended December 31, 2014	553,437	300,375	247,675	64,009	66,612	81,791	26,085	1,339,985

(Note)

1. Revenue is classified into countries or regions based on the customer location.
2. Effective from the nine month period ended December 31, 2014, the Company changed the regional classification to ensure consistency with its global organizational structure (previous "North America" was divided into "United States" and "Canada", and "Canada" and previous "Europe" were integrated into "Europe and Canada"). For fair comparison purpose, the amounts for the same period of the previous year were modified according to the new classification.
3. "Others" region includes Middle East, Oceania and Africa.

### (Breakdown of Revenues)

Nine month period ended December 31, 2013 (April 1 to December 31, 2013)

(Millions of yen)

Ethical Drugs			Consumer healthcare	Other	Condensed interim consolidated statement of income	[Royalties]
(Japan)	(Overseas)	Subtotal				
454,135	709,251	1,163,386	57,282	66,204	1,286,872	[64,462]

Nine month period ended December 31, 2014 (April 1 to December 31, 2014)

(Millions of yen)

Ethical Drugs			Consumer healthcare	Other	Condensed interim consolidated statement of income	[Royalties]
(Japan)	(Overseas)	Subtotal				
437,052	777,625	1,214,676	58,207	67,101	1,339,985	[45,152]

## (Contingent Liabilities)

### 1. Litigation

The Company, Takeda Pharmaceuticals U.S.A. Inc. ("TPUSA") and certain Company Affiliates located in the U.S. have been named as defendants in lawsuits pending in U.S. federal and state courts in which plaintiffs allege to have developed bladder cancer as a result of taking pioglitazone-containing products (some cases alleged other injuries). Eli Lilly & Co. ("Eli Lilly") is a defendant in many of these lawsuits. Also, proposed personal injury class action lawsuits have been filed in Canada, and a lawsuit seeking compensation for bladder cancer has been filed in France.

Of the eight lawsuits tried to-date in the U.S. or state courts, five cases have resulted in judgments in favor of Takeda. Takeda is challenging the three judgments entered against it in post-trial motions or appeals. Plaintiffs are challenging the judgments in favor of Takeda in post-trial motions or appeals. In the case of Terrence Allen, et al. v. Takeda Pharmaceuticals North America, Inc. (the existing "TPUSA"), et al, No. 6:12-cv-00064, the jury found in favor of the plaintiffs and awarded \$1,475 thousand in compensatory damages. The allocation of liability was 75% to Takeda defendants and 25% to Eli Lilly. The jury also awarded \$6 billion in punitive damages against Takeda defendants and \$3 billion in punitive damages against co-defendant, Eli Lilly. The trial began on February 3<sup>rd</sup>, 2014 in the United States District Court for the Western District Louisiana. In June, Takeda and Eli Lilly filed post-trial motions challenging the verdict. In August, the court denied the post-trial motion for judgment in favor of Takeda and Eli Lilly and in September, entered a judgment on the jury verdict mentioned above. The compensatory damages award was reduced from \$1,475 thousand to \$1,270 thousand under New York law as the result of this judgment. On October 27, the court ruled on the post-trial motion to reduce the punitive damage award, entering an amended judgment to reduce the punitive damage award against Takeda defendants to \$27.65 million and against Eli Lilly to \$9.22 million.

Takeda defendants believe a damage award as of any amount is not justified based on the evidence presented in this trial and intend to vigorously challenge this outcome through an appeal. While we are aware that this case is also subject to similar uncertainties inherent to lawsuits, we have not disclosed the range of potential loss arising from those uncertainties in accordance with paragraph 92 of IAS 37 ("Provisions, Contingent Liabilities and Contingent Assets".)

### (Significant Subsequent Events)

No applicable event occurred during the period.

**4. Supplemental Information**  
**(1) Ethical Drugs Revenues [Consolidated]**

*Billions of yen*

	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Change over the same period of the previous year		Three month period ended December 31, 2013	Three month period ended December 31, 2014	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<b>Domestic revenues</b>	452.6	430.6	(22.0)	(4.9%)	162.6	151.2	(11.4)	(7.0%)
<b>Overseas revenues</b>	640.2	724.0	83.7	13.1%	222.9	269.4	46.5	20.8%
United States	235.7	284.1	48.4	20.5%	80.5	109.4	28.9	35.9%
Europe and Canada	198.3	216.7	18.5	9.3%	67.6	77.5	10.0	14.8%
Russia/CIS	66.9	62.5	(4.4)	(6.6%)	25.7	24.9	(0.8)	(3.0%)
Latin America	58.8	63.4	4.6	7.9%	21.0	24.2	3.2	15.4%
Asia	59.4	74.8	15.4	26.0%	21.2	27.8	6.6	31.0%
Others	21.2	22.4	1.2	5.7%	7.0	5.6	(1.4)	(20.1%)
<b>Royalty Income and Service Income</b>	70.6	60.1	(10.4)	(14.8%)	29.1	24.0	(5.1)	(17.6%)
Domestic	1.5	6.5	4.9	319.2%	0.6	2.7	2.1	367.0%
Overseas	69.0	53.7	(15.3)	(22.2%)	28.6	21.3	(7.2)	(25.3%)
<b>Total revenues</b>	1,163.4	1,214.7	51.3	4.4%	414.7	444.5	29.9	7.2%

(Note)

- Effective from the nine month period ended December 31, 2014, the Company changed the regional classification to ensure consistency with its global organizational structure (previous "North America" was divided into "United States" and "Canada", and "Canada" and previous "Europe" were integrated into "Europe and Canada"). For fair comparison purpose, the amounts for the same period of the previous year were modified according to the new classification.
- "Others" region includes Middle East, Oceania and Africa.

<b>Ratio of Overseas sales</b>	61.0%	64.0%
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60.5%	65.4%
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**Foreign exchange rates (Reference)**

*yen*

	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Three month period ended December 31, 2013	Three month period ended December 31, 2014
US\$ average rate	98.7	105.7	99.7	112.1
Euro average rate	130.8	139.7	135.8	141.1

**(2) Ethical Drugs: Global major products' sales [Consolidated]**

*Billions of yen*

	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Change over the same period of the previous year		Three month period ended December 31, 2013	Three month period ended December 31, 2014	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Velcade</i>	101.3	114.4	13.0	12.8%	37.1	41.6	4.5	12.1%
<i>Candesartan</i>	124.2	101.8	(22.3)	(18.0%)	40.7	29.4	(11.3)	(27.8%)
<i>Leuprorelin</i>	98.1	94.6	(3.5)	(3.6%)	32.7	33.3	0.6	1.8%
<i>Lansoprazole</i>	91.2	78.1	(13.1)	(14.3%)	30.5	28.0	(2.5)	(8.2%)
<i>Pantoprazole</i>	77.7	77.6	(0.1)	(0.2%)	29.5	27.0	(2.5)	(8.4%)
<i>Dexilant</i>	36.2	45.2	9.0	24.7%	12.6	17.9	5.3	42.3%
<i>Colcrys</i>	38.1	43.7	5.6	14.6%	12.4	14.0	1.5	12.4%
<i>Nesina</i>	31.0	33.9	2.9	9.3%	12.6	12.0	(0.6)	(4.9%)
<i>Pioglitazone</i>	29.6	25.3	(4.3)	(14.5%)	9.5	7.0	(2.5)	(26.2%)
<i>Uloric</i>	19.4	23.8	4.4	22.4%	7.0	9.7	2.7	39.3%
<i>Amitiza</i>	18.5	22.9	4.4	23.7%	6.4	8.9	2.5	38.3%
<i>Adcetris</i>	9.5	17.4	8.0	84.4%	3.3	5.8	2.4	72.6%
<i>Actovegin</i>	20.6	16.7	(3.9)	(19.1%)	8.1	6.8	(1.3)	(15.9%)
<i>Calcium</i>	14.2	16.1	1.9	13.4%	5.2	6.2	1.0	18.8%
<i>Tachosil</i>	12.8	13.5	0.7	5.9%	4.7	5.1	0.3	7.3%

(Note) Sales amount includes royalty income and service income.

**(3) Ethical Drugs: Overseas major products' sales (Regional basis)**

	<i>Billions of yen</i>							
	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Change over the same period of the previous year		Three month period ended December 31, 2013	Three month period ended December 31, 2014	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<b><i>Candesartan (Note 2)</i></b>								
United States								
Europe and Canada	24.2	23.0	(1.2)	(4.8%)	6.4	6.8	0.4	6.8%
Emerging Markets .....								
<b><i>Leuprorelin</i></b>								
United States .....	12.4	11.9	(0.5)	(3.9%)	4.2	5.2	1.1	26.0%
Europe and Canada .....	25.9	27.5	1.6	6.3%	8.6	9.5	0.9	10.0%
Emerging Markets .....	8.6	10.4	1.8	21.1%	2.5	3.6	1.0	41.1%
<b><i>Lansoprazole</i></b>								
United States .....	21.0	20.6	(0.4)	(1.9%)	6.4	8.6	2.1	33.1%
Europe and Canada .....	9.6	8.9	(0.7)	(7.4%)	3.0	3.1	0.1	4.4%
Emerging Markets .....	6.7	7.5	0.8	12.2%	2.3	2.6	0.3	13.5%
<b><i>Pantoprazole</i></b>								
United States .....	12.4	7.4	(5.0)	(40.3%)	6.6	3.9	(2.6)	(40.1%)
Europe and Canada .....	36.4	37.8	1.4	3.7%	12.9	13.4	0.5	4.2%
Emerging Markets .....	28.9	32.4	3.5	12.1%	10.1	9.7	(0.4)	(3.8%)
<b><i>Pioglitazone</i></b>								
United States .....	6.0	5.3	(0.7)	(11.4%)	1.5	0.5	(1.0)	(66.1%)
Europe and Canada .....	6.0	5.5	(0.5)	(8.8%)	1.9	1.7	(0.3)	(13.9%)
Emerging Markets .....	5.0	5.9	0.9	17.6%	1.9	2.1	0.2	10.9%

- (Note)1. This chart shows the overseas revenues in major products classified as "United States," "Europe and Canada," "Emerging Markets (Latin America, Russia/CIS, Asia and Other regions)" and does not include revenues in Japan.
2. The revenues of *Candesartan* are shown in one area (United States, Europe, Emerging Markets), because export revenues of *Candesartan* to licensees are recorded under a single route.
3. Sales amount includes royalty income and service income.

#### (4) Ethical Drugs: Japan major products' sales

*Billions of yen*

Product name	Launched Month/Year	Category	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Change over the same period of the previous year		Three month period ended December 31, 2013	Three month period ended December 31, 2014	Change over the same period of the previous year	
					Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Blopress</i> (candesartan)	6/1999	Hypertension	100.0	78.8	(21.2)	(21.2%)	34.3	22.6	(11.8)	(34.3%)
<i>Leuplin</i> (leuprorelin)	9/1992	Prostate cancer, breast cancer and endometriosis	51.2	44.7	(6.5)	(12.7%)	17.5	15.0	(2.4)	(13.9%)
<i>Takepron</i> (lansoprazole)	12/1992	Peptic ulcers	54.0	41.2	(12.8)	(23.7%)	18.8	13.7	(5.1)	(27.0%)
<i>Azilva</i>	5/2012	Hypertension	15.9	33.0	17.1	107.9%	7.9	12.7	4.7	59.7%
<i>Enbrel</i>	3/2005	Rheumatoid arthritis	34.4	31.4	(3.0)	(8.6%)	11.9	11.1	(0.8)	(7.1%)
<i>Nesina</i>	6/2010	Diabetes	29.5	29.7	0.2	0.7%	11.6	10.1	(1.5)	(13.0%)
<i>Vectibix</i>	6/2010	Colorectal cancer	14.8	14.1	(0.7)	(4.7%)	5.2	4.9	(0.4)	(6.9%)
<i>Reminyl</i>	3/2011	Alzheimer-type dementia	9.1	10.4	1.4	14.9%	3.3	4.0	0.6	19.3%
<i>Lotriga</i>	1/2013	Hyperlipidemia	3.5	9.1	5.6	160.3%	1.7	4.1	2.4	139.1%
<i>Basen</i>	9/1994	Diabetes	12.9	8.9	(4.0)	(31.0%)	4.3	2.9	(1.4)	(33.1%)
<i>Actos</i> (pioglitazon)	12/1999	Diabetes	12.5	8.6	(3.9)	(31.5%)	4.2	2.8	(1.4)	(34.2%)
<i>Benet</i>	5/2002	Osteoporosis	9.1	8.0	(1.0)	(11.5%)	3.1	2.7	(0.3)	(11.2%)
<i>Rozerem</i>	7/2010	Insomnia	4.5	5.0	0.5	11.7%	1.6	1.8	0.2	10.8%

#### (5) Consumer Healthcare: Major products' sales

*Billions of yen*

Product name	Nine month period ended December 31, 2013	Nine month period ended December 31, 2014	Change over the same period of the previous year		Three month period ended December 31, 2013	Three month period ended December 31, 2014	Change over the same period of the previous year	
			Amount	Increase (decrease) in percent			Amount	Increase (decrease) in percent
<i>Alinamin tablets</i>	15.0	16.3	1.3	8.4%	5.7	6.4	0.7	13.0%
<i>Alinamin health tonics</i>	12.5	12.3	(0.2)	(1.7%)	4.2	3.9	(0.2)	(5.9%)
<i>Benza</i>	9.0	8.5	(0.5)	(5.8%)	3.0	2.5	(0.4)	(15.0%)
<i>Biofermin</i>	6.5	6.3	(0.1)	(2.2%)	2.3	2.2	(0.1)	(4.3%)
<i>Borraginol</i>	3.3	3.2	(0.1)	(4.1%)	1.3	1.3	(0.0)	(2.7%)



## (6) Development activities

Note: This table primarily shows the indications for which we will actively pursue approval. We are also conducting additional studies of certain assets to examine their potential for use in further indications.

### ■ US/EU/Jpn

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage	In-house/ In-license	
MLN0002 <vedolizumab>	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Ulcerative colitis	US EU Jpn	Approved (May 14) Approved (May 14) P-III	In-house
		Crohn's disease	US EU Jpn	Approved (May 14) Approved (May 14) P-III	
		Subcutaneous formulation	-	P-I	
TAK-438 <vonoprazan>	Potassium-competitive acid blocker (oral)	Acid-related diseases	Jpn	Approved (Dec 14)	In-house
Contrave® <naltrexone XR /bupropion XR>	Mu-opioid receptor antagonist and dopamine/norepinephrine re-uptake inhibitor (oral)	Obesity	US	Approved (Sep 14)	In-license (Orexigen)
<fomepizole>	Alcohol dehydrogenase inhibitor (injection)	Ethylene glycol and methanol poisonings	Jpn	Approved (Sep 14)	In-license (Paladin Labs)
SYR-472 <trelagliptin>	DPP-4 inhibitor (oral)	Type 2 diabetes	Jpn	Filed (Mar 14)	In-house
TAK-816	Hib vaccine (injection)	Prevention of infectious disease caused by Haemophilus influenzae type b (Hib)	Jpn	Filed (Sep 13)	In-license (Novartis)
<glatiramer acetate>	Immunomodulator (injection)	Relapse prevention of multiple sclerosis	Jpn	Filed (Dec 14)	In-license (Teva)
MLN9708 <ixazomib>	Proteasome inhibitor (oral)	Previously untreated multiple myeloma	US EU Jpn	P-III P-III P-III	In-house
		Relapsed or refractory multiple myeloma	US EU Jpn	P-III P-III P-III	
		Relapsed or refractory primary (AL) amyloidosis	US EU	P-III P-III	
		Maintenance therapy in patients with multiple myeloma following autologous stem cell transplant	US EU	P-III P-III	
		Solid tumors	US	P-I	
MLN8237 <alisertib>	Aurora A kinase inhibitor (oral)	Relapsed or refractory peripheral T-cell lymphoma	US EU	P-III P-III	In-house
		Small cell lung cancer, Ovarian cancer	US EU	P-II P-II	
		Non-Hodgkin lymphoma	Jpn	P-I	
		Solid tumors	Jpn	P-I	
Lu AA21004*1 <vortioxetine>	Multimodal anti-depressant (oral)	Major depressive disorder	Jpn	P-III	In-license (Lundbeck)
<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)
<rasagiline>	Monoamine oxidase B (MAO-B) inhibitor (oral)	Parkinson's disease	Jpn	P-III	In-license (Teva)

\*1 Additional indications being pursued in the US have been moved to the section "Additional indications/formulations of approved compounds"

Development code/product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
<b>MLN0264</b> < - >	Antibody-Drug Conjugate targeting GCC (injection)	Gastric cancer, Pancreatic cancer	US EU	P-II P-II	In-house
<b>TAK-385</b> <relugolix>	LH-RH antagonist (oral)	Prostate cancer Endometriosis Uterine fibroids	US EU Jpn Jpn	P-II P-II P-I P-II P-II	In-house
<b>MLN0128</b> < - >	mTORC1/2 inhibitor (oral)	Breast cancer Solid tumors	US EU -	P-II P-II P-I	In-house
<b>TAK-003</b> *2	Tetavalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-II	In-house
<b>TAK-214</b> *3	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II	In-house
<b>TAK-114</b> *4	Pro-inflammatory cytokine inhibitor (oral)	Ulcerative colitis	US EU Jpn	P-II P-II P-I	In-license (Natrogen)
<b>MT203</b> <namilumab>	GM-CSF monoclonal antibody (injection)	Psoriasis Rheumatoid arthritis	EU EU Jpn	P-II P-I P-I	In-licence (Amgen)
<b>TAK-272</b> < - >	Direct renin inhibitor (oral)	Early stage diabetic nephropathy Hypertension	Jpn -	P-II P-I	In-house
<b>TAK-850</b>	Influenza vaccine (injection)	Prevention of influenza disease caused by influenza virus subtype A and B contained in the vaccine	Jpn	P-I/II	In-license (Baxter)
<b>TAK-733</b> < - >	MEK inhibitor (oral)	Solid tumors	-	P-I	In-house
<b>TAK-063</b> < - >	PDE10A inhibitor (oral)	Schizophrenia	-	P-I	In-house
<b>TAK-137</b> < - >	AMPA receptor potentiator (oral)	Psychiatric disorders and neurological diseases	-	P-I	In-house
<b>TAK-659</b> < - >	SYK kinase inhibitor (oral)	Solid tumors, Hematologic malignancies	-	P-I	In-house
<b>TAK-233</b> < - >	(oral)	-	-	P-I	In-house
<b>TAK-935</b> < - >	CH24H inhibitor (oral)	Diseases related to glutamate excitotoxicity	-	P-I	In-house
<b>TAK-058</b> < - >	5-HT3 receptor antagonist (oral)	Schizophrenia, especially cognitive impairment associated with schizophrenia	-	P-I	In-house
<b>TAK-079</b> < - >	Cytolytic monoclonal antibody (injection)	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I	In-house
<b>INV21</b>	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I	In-house
<b>MLN3126</b> < - >	CCR9 antagonist (oral)	Sjogren's syndrome	-	P-I	In-house
<b>MLN4924</b> < - >	NEDD 8 activating enzyme inhibitor (injection)	Advanced malignancies, Acute myeloid leukemia	-	P-I	In-house
<b>MLN1117</b> < - >	PI3K $\alpha$ isoform inhibitor (oral)	Solid tumors	-	P-I	In-house

\*2 Formerly known as DENVax

\*3 Formerly known as Norovirus vaccine

\*4 Formerly known as Natura-alpha

Development code/ product name <generic name>	Drug Class (administration route)	Indications	Stage		In-house/ In-license
MLN7243 <->	UAE Inhibitor (injection)	Solid tumors	-	P-I	In-house
MLN2480 <->	pan-Raf kinase inhibitor (oral)	Solid tumors	-	P-I	In-license (Sunesis)
Lu AA24530 <->	Multimodal anti-depressant (oral)	Major depressive disorder, Generalized anxiety disorder	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)

## ■ Additional indications/formulations of approved compounds

Development code <generic name> Brand name (country / region)	Drug Class	Indications or formulations	Stage		In-house/ In-license
<bortezomib> Velcade® (US)	Proteasome inhibitor	Retreatment of multiple myeloma Front line mantle cell lymphoma	US US	Approved (Aug 14) Approved (Oct 14)	In-house
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	Filed (Sep 14)	In-house
TAK-375SL <ramelteon> Rozerem® (US, Jpn)	MT1/MT2 receptor agonist	Bipolar (sublingual formulation)	US	P-III	In-house
SYR-322 <alogliptin> Nesina® (US, Jpn) Vipidia® (EU)	DPP-4 inhibitor	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	P-III	In-house
AD-4833/TOMM40	Insulin sensitizer/ Biomarker assay	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US EU	P-III P-III	In-license (Zinfandel)
SGN-35 <brentuximab vedotin> Adcetris® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate	Relapsed cutaneous T-cell lymphoma Post-ASCT Hodgkin lymphoma Front line Hodgkin lymphoma Front line mature T-cell lymphoma	EU EU Jpn EU Jpn	P-III P-III P-III P-III P-III	In-license (Seattle Genetics)
Lu AA21004 <vortioxetine> Brintellix® (US)	Multimodal anti-depressant	Generalized anxiety disorder Attention Deficit Hyperactivity Disorder (ADHD) in adult patients	US US	P-III P-II	In-license (Lundbeck)
<lubiprostone> Amitiza® (US)	Chloride channel activator	New formulation Pediatric functional constipation	US US	P-III P-III	In-license (Sucampo)
<febuxostat XR> Uloric® (US)	Non-purine, selective xanthine oxidase inhibitor	Extended-release formulation	US	P-III	In-license (Teijin)
<lurasidone hydrochloride> Latuda® (EU)	Atypical antipsychotic agent	Bipolar disorder	EU	P-III	In-license (Sumitomo Dainippon Pharma)
TAK-390MROD <dexlansoprazole> Dexilant® (US)	Proton pump inhibitor	Orally disintegrating tablet	-	P-I	In-house

■ **Recent progress in stage** Progress in stage since release of FY2013 results (May 8<sup>th</sup>, 2014)

Development code <generic name>	Indications	Country/Region	Progress in stage
<b>MLN0002</b> <b>&lt;vedolizumab&gt;</b>	Ulcerative colitis	US	Approved (May 14)
<b>MLN0002</b> <b>&lt;vedolizumab&gt;</b>	Crohn's disease	US	Approved (May 14)
<b>MLN0002</b> <b>&lt;vedolizumab&gt;</b>	Ulcerative colitis	EU	Approved (May 14)
<b>MLN0002</b> <b>&lt;vedolizumab&gt;</b>	Crohn's disease	EU	Approved (May 14)
<b>&lt;bortezomib&gt;</b>	Retreatment of multiple myeloma	US	Approved (Aug 14)
<b>Contrave®</b> <b>&lt;naltrexone XR /</b> <b>bupropion XR&gt;</b>	Obesity	US	Approved (Sep 14)
<b>&lt;fomepizole&gt;</b>	Ethylene glycol and methanol poisonings	Jpn	Approved (Sep 14)
<b>&lt;bortezomib&gt;</b>	Front line mantle cell lymphoma	US	Approved (Oct 14)
<b>TAP-144-SR</b> <b>&lt;leuprorelin acetate&gt;</b>	Prostate cancer, Premenopausal breast cancer (6-month formulation)	Jpn	Filed (Sep 14)
<b>MLN9708</b> <b>&lt;ixazomib&gt;</b>	Maintenance therapy in patients with multiple myeloma following autologous stem cell transplant	US, EU	P-III
<b>SYR-322</b> <b>&lt;alogliptin&gt;</b>	Type 2 diabetes (fixed-dose combination with metformin)	Jpn	P-III
<b>MLN0264</b> <b>&lt;-&gt;</b>	Gastric cancer, Pancreatic cancer	US, EU	P-II
<b>TAK-385</b> <b>&lt;relugolix&gt;</b>	Prostate cancer	EU	P-II
<b>MLN0128</b> <b>&lt;-&gt;</b>	Breast cancer	EU	P-II
<b>MLN0002</b> <b>&lt;vedolizumab&gt;</b>	Subcutaneous formulation	-	P-I
<b>TAK-935</b> <b>&lt;-&gt;</b>	Diseases related to glutamate excitotoxicity	-	P-I
<b>TAK-058</b> <b>&lt;-&gt;</b>	Schizophrenia, especially cognitive impairment associated with schizophrenia	-	P-I
<b>MLN4924</b> <b>&lt;-&gt;</b>	Acute myeloid leukemia	-	P-I
<b>TAK-079</b> <b>&lt;-&gt;</b>	Rheumatoid arthritis, Systemic lupus erythematosus	-	P-I
<b>MLN3126</b> <b>&lt;-&gt;</b>	Sjogren's syndrome	-	P-I
<b>TAK-385</b> <b>&lt;relugolix&gt;</b>	Prostate cancer	Jpn	P-I
<b>TAK-438</b> <b>&lt;vonoprazan&gt;</b>	Acid-related diseases	Jpn	Approved (Dec 14)
<b>&lt;glatiramer acetate&gt;</b>	Relapse prevention of multiple sclerosis	Jpn	Filed (Dec 14)
<b>&lt;rasagiline&gt;</b>	Parkinson's disease	Jpn	P-III
<b>Lu AA21004</b> <b>&lt;vortioxetine&gt;</b>	Attention Deficit Hyperactivity Disorder (ADHD) in adult patients	US	P-II
<b>TAK-272</b>	Early stage diabetic nephropathy	Jpn	P-II
<b>MT203</b> <b>&lt;namilumab&gt;</b>	Rheumatoid arthritis	Jpn	P-I

Progress in stage since the announcement of FY2014 Q2 results (October 30<sup>th</sup>, 2014) are listed under the bold dividing line

■ **Revised collaboration agreement** Revised since release of FY2013 results (May 8<sup>th</sup>, 2014)

Development code/ product name <generic name>	Indications (Stage)	Reason
<b>Rienso<sup>®</sup> / Feraheme<sup>®</sup></b> <ferumoxytol>	Iron deficiency anemia from all causes in patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used (EU, Filed)	Following a strategic product portfolio review, ferumoxytol no longer fits within Takeda's current strategy. Takeda and AMAG announced in December 2014 that they have entered into an agreement to mutually terminate the March 2010 license, development and commercialization agreement, which granted Takeda exclusive rights to market ferumoxytol in Canada, the European Union and Switzerland, as well as certain other geographic territories.
<b>ITI-214</b> < - >	Cognitive impairment associated with schizophrenia (P-I)	Based on a prioritization of Takeda's portfolio, the companies agreed to return the program to Intra-Cellular Therapies so it could continue development.

Revised collaboration agreements since the announcement of FY2014 Q2 results (October 30<sup>th</sup>, 2014) are listed under the bold dividing line

■ **Discontinued projects** Discontinued since release of FY2013 results (May 8<sup>th</sup>, 2014)

Development code <generic name>	Indications (Stage)	Reason
<b>SYR-472</b> <trelagliptin>	Type 2 diabetes (US, EU P-II)	Discontinued in the US and EU after consideration of the development costs that would be necessary in order to obtain approval.
<b>TAK-700</b> <orterone1>	Prostate cancer (US, EU, Jpn P-III)	Takeda decided to end the development program for orterone1 (TAK-700) based on the results of two Phase 3 clinical trials. The studies found that while orterone1 plus prednisone could extend the time patients lived before their cancer progressed, it did not extend overall survival in these patients.
<b>&lt;peginesatide&gt;</b>	Anaemia associated with chronic kidney disease in adult patients undergoing dialysis (EU P-III)	In February 2013, all lots of peginesatide were voluntarily recalled in the US following postmarketing reports of serious hypersensitivity reactions. A detailed investigation of these reactions has confirmed that no quality or manufacturing issues were present but has not identified a specific root cause for the reactions. Based on these findings, further clinical development of peginesatide will not be pursued.
<b>TAK-361S</b>	Prevention of infectious disease caused by diphtheria, pertussis, tetanus, poliomyelitis (Jpn P-II)	Takeda decided to voluntarily discontinue the development of TAK-361S to shift development resources to allow Takeda to focus on vaccine programs that address significant unmet needs.

Discontinued projects since the announcement of FY2014 Q2 results (October 30<sup>th</sup>, 2014) are listed under the bold dividing line

■ **Filings and Approvals in Brazil, China & Russia**

Takeda is steadily progressing its pipeline assets through the filing and approval process on a global scale, including in emerging markets. This table shows filings and approvals in the key emerging markets of Brazil, China & Russia.

Country	Development code/generic name (stage)
<b>Brazil</b>	TAK-491* <sup>5</sup> /chlorthalidone (Approved Jul 14), SGN-35 (Approved Sep 14), mifamurtide* <sup>6</sup> (Approved Oct 14), SYR-322/metformin (Filed Jul 13), SYR-322/pioglitazone (Filed Dec 13), TAK-375* <sup>7</sup> (Filed Mar 14), MLN0002 (Filed Sep 14)
<b>China</b>	roflumilast* <sup>8</sup> (Filed Dec 11), SGN-35 (Filed May 13)
<b>Russia</b>	TAK-390MR* <sup>9</sup> (Approved May 14), SYR-322 (Approved Oct 14), SYR-322/metformin (Filed Mar 14), SGN-35 (Filed May 14), TAK-491/chlorthalidone (Filed May 14), lurasidone (Filed Dec 14)

\*5 **TAK-491 <azilsartan medoxomil>** Angiotensin II receptor blocker (oral) for the treatment of hypertension

\*6 **<mifamurtide>** Immunostimulant (injection) for the treatment of non-metastatic osteosarcoma

\*7 **TAK-375 <ramelteon>** MT1/MT2 receptor agonist (oral) for the treatment of insomnia

\*8 **<roflumilast>** PDE4 inhibitor (oral) for the treatment of Chronic Obstructive Pulmonary Disease

\*9 **TAK-390MR <dexlansoprazole>** Proton pump inhibitor (oral) for the treatment of erosive esophagitis and gastro-esophageal reflux disease