# Summary of Financial Statements for the Three Month Period Ended June 30, 2016 (IFRS, Consolidated)

July 29, 2016

Takeda Pharmaceutical Company Limited Stock exchange listings: Tokyo, Nagoya, Fukuoka, Sapporo

TSE Code: 4502 URL: <a href="http://www.takeda.co.jp">http://www.takeda.co.jp</a>

Representative: Christophe Weber, President & CEO

Contact: Noriko Higuchi Telephone: +81-3-3278-2306

Global Finance, IR Head

Scheduled date of securities report submission: August 10, 2016

Scheduled date of dividend payment commencement: — Supplementary materials for the financial statements: Yes Presentation to explain for the financial statements: Yes

(Million JPY, rounded to the nearest million)

# 1. Consolidated Financial Results for the Three Month Period Ended June 30, 2016 (April 1 to June 30, 2016)

(1) Consolidated Operating Results (year to date)

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

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	Revenue		Operating profit		Profit before tax		Net profit for the period	
	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)
Three month period ended June 30, 2016	434,005	(2.8)	152,933	208.6	149,677	207.2	100,343	294.6
Three month period ended June 30, 2015	446,295	8.5	49,559	(22.2)	48,721	(18.8)	25,429	(25.9)

	Net profit attributable to owners of the Company				Basic earnings per share	Diluted earnings per share
	(Million JPY)	(%)	(Million JPY)	(%)	(JPY)	(JPY)
Three month period ended June 30, 2016	99,527	304.9	(52,047)	_	127.30	126.75
Three month period ended June 30, 2015	24,583	(26.4)	120,383	_	31.32	31.12

#### (2) Consolidated Financial Position

(2) Consolidated Financial Fosition								
	Total assets (Million JPY)	Total equity (Million JPY)	Equity attributable to owners of the Company (Million JPY)	Ratio of equity attributable to owners of the Company to total assets (%)	Equity attributable to owners of the Company per share (JPY)			
As of June 30, 2016	3,817,012	1,869,283	1,808,683	47.4	2,315.77			
As of March 31, 2016	3,824,085	2,011,203	1,948,692	51.0	2,487.04			

#### 2. Dividends

		Annual dividends per share (JPY)							
	1st quarter end	2nd quarter end	3rd quarter end	Year-end	Total				
Fiscal 2015	_	90.00	_	90.00	180.00				
Fiscal 2016	_								
Fiscal 2016 (Projection)		90.00	_	90.00	180.00				

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

# 3. Forecasts for Consolidated Operation Results for Fiscal 2016 (April 1, 2016-March 31, 2017)

(Percentage figures represent changes from previous fiscal year)

	Revenue		Operating profit		Profit before tax		Net profit attributable to owners of the Company		Basic earnings per share
	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(Million JPY)	(%)	(JPY)
Fiscal 2016	1,720,000	(4.8)	135,000	3.2	132,500	9.9	88,000	9.8	112.31

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

#### **Additional Information**

(1) Changes in significant subsidiaries during the period : No (changes in specified subsidiaries resulting in the change in consolidation scope)

(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) : Yes

2) Changes in accounting policies other than 1)
 3) Changes in accounting estimates
 (Note) For details, refer to "2. Additional Information in Summary" in page 13.

(3) Number of shares outstanding (common stock)

1) Number of shares outstanding (including treasury stock) at term end:

June 30, 2016 790,342,895 shares March 31, 2016 790,284,095 shares

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

 June 30, 2016
 9,314,080 shares

 March 31, 2016
 6,745,181 shares

3) Average number of outstanding shares (for the Three month period ended June 30):

 June 30, 2016
 781,821,909 shares

 June 30, 2015
 785,026,072 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 Three month period ended June 30, 2016 is scheduled to be disclosed on August 10, 2016 after completion of the quarterly review.

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

- All forecasts in this document are based on information currently available to the management, and do
  not represent a promise or guarantee to achieve those forecasts. Various uncertain factors could cause
  actual results to differ, such as changes in the business environment and fluctuation of foreign exchange
  rates. If a significant event occurs that requires the forecasts to be revised, the Company will disclose it
  in a timely manner.
- For details of the financial forecast, and the management guidance indicators for actual business performance, please refer to "1. Qualitative Information for the Three Month Period Ended June 30, 2016 (3) Outlook for Fiscal 2016" on page 12.
- Supplementary materials for the financial statements (databook, presentation materials for the earnings release conference to be held on July 29, 2016) and the audio of the conference including question-andanswer session will be promptly posted on the Company's website.
   (Website of the Company)

http://www.takeda.com/investor-information/results/

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#### 1. Qualitative Information for the Three Month Period Ended June 30, 2016

### (1) Business Performance

# (i) Consolidated Financial Results (April 1 to June 30, 2016):

Billion JPY

	<u>Amount</u>	Change over the same period of the previous ye		
Revenue	434.0	-12.3	-2.8%	
R&D expense	76.5	-3.2	-4.1%	
Operating profit	152.9	+103.4	+208.6%	
Profit before tax	149.7	+101.0	+207.2%	
Net profit for the period (attributable to owners of the Company)	99.5	+74.9	+304.9%	
EPS(JPY)	127.30	+95.99	+306.5%	

#### [Revenue]

Consolidated revenue was 434.0 billion JPY, a decrease of 12.3 billion JPY (-2.8%) compared to the same period of the previous year.

Sales of Takeda's growth drivers (\*) steadily increased, such as ENTYVIO (for ulcerative colitis and Crohn's disease), which is marketed in numerous countries including in the U.S. and Europe, and NINLARO (for multiple myeloma), which was launched in the U.S. in December 2015. In Japan, in addition to strong sales of TAKECAB (for acid-related diseases) which is one of the growth drivers, AZILVA (for hypertension) and LOTRIGA (for hyperlipidemia) also experienced sales growth.

On the other hand, in addition to the negative impact of foreign exchange rates due to the appreciation of the yen (-26.9 billion JPY), there was also a loss of revenue resulting from the transfer of the fast declining long-listed products in Japan such as BLOPRESS (for hypertension) to Teva Takeda Yakuhin Ltd., an associate company accounted for using the equity method that was established in April 2016.

(\*) Takeda regards GI, Oncology, CNS and emerging markets as growth drivers and focuses on the growth of these fields.

Breakdown of Consolidated revenue (April 1 to June 30, 2016):

Billion JPY

1		1	1		Billion or 1
		Amount	Change over period of the pr		Underlying growth(Note)
Prescription Drug		394.0	-13.8	-3.4%	+9.7%
	U.S.	129.7	+6.6	+5.4%	+14.9%
	Japan	126.7	-8.4	-6.2%	+9.7%
	Europe and Canada	75.5	-1.3	-1.7%	+6.2%
	Emerging Markets	62.1	-10.6	-14.6%	+3.9%
Co	onsumer Healthcare and Other	40.0	+1.5	+3.8%	+4.1%
Consolidation total		434.0	-12.3	-2.8%	+9.1%

(Note) Underlying growth: It excludes the impact of foreign exchange and product divestments.

- In U.S. strong sales growth of ENTYVIO (for ulcerative colitis and Crohn's disease) and NINLARO (for multiple myeloma) and sales contribution of TRINTELLIX (\*) (for major depressive disorder) offset the impact of appreciation of the yen, resulting in revenue of 129.7 billion JPY, an increase of 6.6 billion JPY (+5.4%) compared to the same period of the previous year. On an underlying basis, U.S. revenue increased by +14.9%.
  - (\*) TRINTELLIX is the brand name used since June 2016 for the product previously marketed as BRINTELLIX. The formulations, indication and dosages of TRINTELLIX remain the same as that of BRINTELLIX.
- In Japan, TAKECAB (for acid-related diseases), which was launched in February 2015, has experienced significant sales expansion since March 2016 when the 2-week limit on the prescription period was lifted. In addition, AZILVA (for hypertension) and LOTRIGA (for hyperlipidemia) have also experienced sales growth. On the other hand, the transfer of the fast declining long-listed products in Japan to Teva Takeda Yakuhin Ltd. in April 2016, resulted in a loss of revenue from products such as BLOPRESS (for hypertension). Those revenue in the same period of the previous year was totaling 22.6 billion JPY. In total, Japan revenue was 126.7 billion JPY, a decrease of 8.4 billion JPY (-6.2%) compared to the same period of the previous year. On an underlying basis, excluding the impact of the transfer of long-listed products, Japan revenue increased by +9.7%.
- Europe and Canada sales were strongly impacted by the appreciation of the yen, resulting in revenue of 75.5 billion JPY, a decrease of 1.3 billion JPY (-1.7%) compared to the same period of the previous year. On a constant currency basis, ENTYVIO (for ulcerative colitis and Crohn's disease) and ADCETRIS (for malignant lymphoma) performed well. On an underlying basis, Europe and Canada revenue increased by +6.2%.
- In Emerging Markets, revenue was 62.1 billion JPY, a decrease of 10.6 billion JPY (-14.6%) compared to the same period of the previous year, mainly impacted by the appreciation of the yen. On a constant currency basis, sales grew steadily for ADCETRIS (for malignant lymphoma) and DEXILANT (for acidrelated diseases), and China and Russia both performed well. On an underlying basis, Emerging Markets revenue increased by +3.9%.

The consumer healthcare business and other businesses benefited from favorable sales of ALINAMIN tablets, resulting in revenue of 40.0 billion JPY, an increase of 1.5 billion JPY (+3.8%) compared to the same period of the previous year.

As a result of the factors listed above, underlying revenue of the prescription drug business grew by +9.7%, and total consolidated revenue grew by +9.1%.

Consolidated revenue of Takeda's major prescription drug (April 1 to June 30, 2016):

Billion JPY

Product name / Indications	Amount	_	er the same previous year	Underlying growth(Note1)
VELCADE / Multiple myeloma	35.5	-6.7	-15.9%	-8.7%
ENTYVIO / Ulcerative colitis and Crohn's disease	32.0	+15.9	+98.2%	+113.9%
LEUPRORELIN (Japan product name: LEUPLIN) / Prostate cancer, breast cancer and endometriosis	30.8	-0.1	-0.4%	+2.5%
PANTOPRAZOLE / Peptic ulcer	20.1	-4.2	-17.3%	-7.4%
AZILVA / Hypertension	17.7	+3.6	+25.6%	+25.6%
DEXILANT / Acid reflux disease	16.2	-2.7	-14.3%	-5.9%
LANSOPRAZOLE (Japan product name: TAKEPRON) / Peptic ulcer	13.4	-12.6	-48.4%	-14.8%
ALOGLIPTIN (Japan product name: NESINA) / Type 2 diabetes	13.3	+1.2	+9.5%	+11.6%
CANDESARTAN (Japan product name: BLOPRESS) / Hypertension	11.3	-11.4	-50.4%	-18.9%
ADCETRIS / Malignant Lymphoma	7.8	+1.0	+14.3%	+27.2%
LOTRIGA / Hyperlipidemia	6.8	+1.8	+36.8%	+36.8%
TRINTELLIX (Note 2) / Major depressive disorder	6.4	+1.4	+27.6%	+38.2%
TAKECAB / Acid-related diseases	6.4	+5.8	- %	- %
NINLARO / Relapsed or refractory multiple myeloma	6.0	+6.0	- %	- %

<sup>(</sup>Note1) Underlying growth: It excludes the impact of foreign exchange and product divestments.

<sup>(</sup>Note2) TRINTELLIX is the brand name used since June 2016 for the product previously marketed as BRINTELLIX. The formulations, indication and dosages of TRINTELLIX remain the same as that of BRINTELLIX.

<sup>(</sup>Note3) Revenue amount includes royalty income and service income.

Takeda Pharmaceutical Company Limited (4502) Summary of Financial Statements for the Three Month Period Ended June 30, 2016 (Consolidated)

# [Operating profit]

Consolidated operating profit was 152.9 billion JPY, an increase of 103.4 billion JPY (+208.6%) compared to the same period of the previous year.

- Gross profit decreased by 26.6 billion JPY (-8.2%) mainly due to the decrease in revenue caused by the negative impact of appreciation of the yen.
- Selling, general and administrative expenses decreased by 16.7 billion JPY (-10.4%) mainly due to the decrease in sales promotion expenses for new products in the U.S. and the impact of appreciation of the yen.
- R&D expenses decreased by 3.2 billion JPY (-4.1%).
- Amortization and impairment losses on intangible assets associated with products decreased by 5.3 billion JPY (-15.7%), mainly due to a decrease of amortization costs of intangible assets resulting from appreciation of the yen.
- Other operating income increased by 105.0 billion JPY, mainly due to the recognition of 102.9 billion JPY of
  profit related to the transfer of the fast declining long-listed products business in Japan to Teva Takeda
  Yakuhin Ltd. at the transfer date.
- Other operating expenses decreased by 0.3 billion JPY (-4.6%).

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

Consolidated net profit for the period was 99.5 billion JPY, an increase of 74.9 billion JPY (+304.9%) compared to the same period of the previous year, as a result of the increase in operating profit and a tax increase of 26.0 billion JPY (+111.8%).

- Basic earnings per share was 127.30JPY, an increase of 95.99 JPY (+306.5%) compared to the same period of the previous year.

Revenue and operating profit by business segment (April 1 to June 30, 2016):

Billion JPY

	Rev	enue	Operating profit		
Business segment	Amount	Change over the same period of the previous year	Amount	Change over the same period of the previous year	
Prescription Drug	394.0	-13.8	142.2	+107.3	
Consumer Healthcare	20.4	+1.0	7.4	-0.2	
Other	19.6	+0.5	3.3	-3.7	
Total	434.0	-12.3	152.9	+103.4	

#### [Prescription Drug]

Revenue in the <u>Prescription Drug Business</u> was 394.0 billion JPY, a decrease of 13.8 billion JPY (-3.4%) compared to the same period of the previous year, and operating profit was 142.2 billion JPY, an increase of 107.3 billion JPY compared to the same period of the previous year.

#### [Consumer Healthcare Business]

Revenue in the <u>Consumer Healthcare Business</u> was 20.4 billion JPY, an increase of 1.0 billion JPY (+4.9%) compared to the same period of the previous year, mainly due to the increase in sales of ALINAMIN tablets (vitamin-containing products). Operating profit was 7.4 billion JPY, a decrease of 0.2 billion JPY (-3.3%).

# [Other Business]

Revenue in Other Business was 19.6 billion JPY, an increase of 0.5 billion JPY (+2.7%) compared to the same period of the previous year. Operating profit was 3.3 billion JPY, a decrease of 3.7 billion JPY (-52.7%) compared to the same period of the previous year, mainly due to the decrease of royalty income related to the past transferred business.

# (ii) Underlying Growth (Note1) (April 1 to June 30, 2016):

	Change over the sam	ne period of the previous year
	<u>%</u>	Billion JPY
Underlying Revenue	+9.1	+35.4
Underlying Core Earnings (Note2)	+40.4	+20.7
Underlying Core EPS (JPY) (Note3)	+54.2	+22.28

- (Note1) "Underlying growth", comparing two periods of financial results under a common basis, shows the real performance of the business. Takeda adopts "Underlying Growth" of revenue, Core Earnings and Core EPS as its indicators for management guidance. It excludes the impact of foreign exchange and divestments.

  The impact of divestments in this period are the transfer of the fast declining long-listed products business to Teva Takeda Yakuhin Ltd., the divestment of the respiratory portfolio to AstraZeneca and the termination of exclusive distributorship agreement for CONTRAVE (for Obesity).
- (Note2) Core Earnings is calculated by taking gross profit and deducting selling, general and administrative expenses and R&D expenses. In addition, certain other items that are significant in value and non-recurring or non-core in nature will be adjusted. This includes, amongst other items, impact of natural disasters, purchase accounting effects, major litigation costs, integration costs and government actions.
- (Note3) Core EPS is calculated by taking Core Earnings and adjusting for items that are significant in value and non-recurring or non-core in nature within each account line below operating profit. This includes, amongst other items, fair value adjustments and the imputed financial charge related to contingent consideration. In addition to the tax effect related to these items, the tax effects related to the adjustments made in Core Earnings will also be adjusted for when calculating Core EPS.
- Underlying Revenue growth was +9.1 % compared to the same period of the previous year, mainly due to growth of innovative products such as ENTYVIO (for Ulcerative colitis and Crohn's disease), NINLARO (for Relapsed or refractory multiple myeloma) and TAKECAB (for Relapsed or refractory multiple myeloma).
- Underlying Core Earnings growth was +40.4 %, mainly due to Underlying Revenue growth and the decline in sales promotion expenses for new products mainly in the U.S. Underlying selling, general and administrative expenses decreased by 2.8%, and underlying R&D expenses increased by 1.7% compared to the same period of the previous year.
- Underlying Core EPS growth was +54.2% compared to the same period of the previous year primarily reflecting growth of Underlying Core Earnings.

### (iii) Activities and Results of Research & Development

Major R&D events and business development contracts, press released from April 2016 to date, are listed as follows (chronologically by therapeutic area):

### **Oncology**

#### [NINLARO]

- In April 2016, the results from the international, randomized, double-blind, placebo-controlled TOURMALINE-MM1 Phase III clinical study, evaluating once-weekly oral NINLARO (generic name: ixazomib) capsules plus lenalidomide and dexamethasone versus placebo plus lenalidomide-dexamethasone in patients with relapsed and/or refractory multiple myeloma, was published in the *New England Journal of Medicine (NEJM)*.
- In May 2016, the Committee for Medical Products for Human Use (CHMP) adopted a negative opinion, recommending against the authorization of NINLARO, an oral proteasome inhibitor for the treatment of patients with relapsed and/or refractory multiple myeloma. Takeda filed an appeal for this opinion and requested a re-examination by the CHMP.
- In July 2016, Takeda submitted a New Drug Application (NDA) to the Ministry of Health, Labour and welfare (MHLW) for the treatment of relapsed or refractory multiple myeloma.

### [ADCETRIS]

- In May 2016, the CHMP has adopted a positive opinion for the extension of the conditional approval of ADCETRIS (generic name: brentuximab vedotin), a treatment for malignant lymphoma which Takeda inlicensed from Seattle Genetics, Inc. of the U.S., and recommended its approval for the treatment of adult patients with CD30+ Hodgkin lymphoma at increased risk of relapse or progression following Autologous Stem Cell Transplant (ASCT). In July 2016, European Commission (EC) has extended the current conditional marketing authorization and approved the additional indication for ADCETRIS.
- In July 2016, the final data of the ADCETRIS monotherapy pivotal Phase 2 clinical trial in relapsed or refractory classical Hodgkin lymphoma were published in the journal *Blood*.

### [Partnership/Business Development]

- In June 2016, Takeda and M2Gen<sup>®</sup> of the U.S. established a new collaboration to generate broad genomic data from consenting cancer patients. M2Gen has partnered with the nation's leading cancer centers through the Oncology Research Information Exchange Network (ORIEN), a unique research partnership among North America's top cancer centers. Under the agreement, Takeda will help build the ORIEN Avatar<sup>TM</sup> Research Program based on the Total Cancer Care<sup>®</sup> Protocol, a prospective observational study enrolling patients with various cancers, and access information generated under this program.
- In June 2016, Takeda revised an existing collaboration agreement with Amgen Inc. of the U.S., under which Takeda had rights to develop and commercialize multiple molecules / products from Amgen's pipeline for the Japanese market. By the revisions, such rights for molecules / products including AMG403 (generic name: fulranumab) and AMG386 (generic name: trebananib) will be returned to Amgen, effective immediately. Takeda and Amgen will continue to collaborate on the development and commercialization of remaining molecules / products for the Japanese market, including Vectibix (generic name: panitumumab), a leading treatment for unresectable advanced or recurrent colorectal cancer.

#### Gastroenterology

#### [ENTYVIO]

- In May 2016, two data analyses for ENTYVIO (generic name: vedolizumab) for the treatment of ulcerative colitis and Crohn's disease: one evaluating the optimal position of vedolizumab in the ulcerative colitis (UC) treatment paradigm, and a second separate analysis assessing whether early vedolizumab trough levels were associated with subsequent drug efficacy, were orally presented during the 2016 Digestive Disease Week (DDW).

#### [Partnership/Business Development]

- In June 2016, Takeda and Theravance Biopharma, Inc. of Ireland entered into a global license, development and commercialization agreement for TD-8954, a selective 5-HT4 receptor agonist being investigated for potential use in the treatment of gastrointestinal motility disorders, including enteral feeding intolerance.
- In July 2016, Takeda and Altos Therapeutics LLC of the U.S. entered into a definitive agreement to further development of Altos's proprietary compound ATC-1906, an oral dopamine D2/D3 receptor antagonist that addresses the symptoms of nausea and vomiting in gastroparesis patients. Additionally, the agreement includes an exclusive option for Takeda to acquire Altos beginning on the date of the agreement and continuing for a period of time following the completion of ongoing Phase 1 studies of ATC-1906.
- In July 2016, Takeda and TiGenix NV of Belgium entered into an exclusive ex-U.S. license, development and commercialization agreement for Cx601, a suspension of allogeneic adipose-derived stem cells (eASC) injected intra-lesionally for the treatment of complex perianal fistulas in patients with Crohn's disease. In 2009 the EC granted Cx601 orphan designation for the treatment of complex perianal fistulas. In March 2016, TiGenix announced that it submitted the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Cx601.

#### <u>Vaccines</u>

[Norovirus Vaccine]

- In June 2016, Takeda dosed the first subject in a Phase 2b field efficacy trial of TAK-214, the only norovirus vaccine candidate in human clinical trials.

#### [Partnership/Business Development]

- In May 2016, Takeda entered into a partnership agreement with the Bill & Melinda Gates Foundation of the U.S., to support global polio eradication in developing countries. Under the terms of the agreement, the Gates Foundation will provide a 38 million USD grant to Takeda to leverage its innovative vaccine manufacturing platform to develop and license a safe and effective Sabin-strain inactivated poliovirus vaccine (sIPV), and make at least 50 million doses per year available at an affordable price for more than seventy developing countries receiving Gavi(\*) support.
  - (\*) Gavi (Global Alliance for Vaccine and Immunization) is a global vaccine alliance, bringing together public and private sectors with the shared goal of creating equal access to new and underused vaccines for children living in the world's poorest countries.

#### **Others**

[Alogliptin]

 In June 2016, a new post hoc analysis from the EXAMINE, a global cardiovascular safety outcomes trial of type 2 diabetes treatment NESINA (generic name: alogliptin), was presented at the American Diabetes Association's (ADA) 76th Scientific Sessions.

#### [Partnership/Business Development]

- In May 2016, Takeda, Astellas Pharma Inc. and Daiichi Sankyo Company, Limited announced that they have entered into a joint research agreement. It is an agreement to comprehensively acquire and analyze fundamental biomarker data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines. Based on this agreement, Astellas, Daiichi Sankyo, and Takeda will comprehensively acquire fundamental data from healthy adult volunteers that is required for clinical studies, and undertake joint analysis thereon. Samples will be acquired at a clinical research organization associated with Leiden University in the Netherlands.
- In May,2016, Takeda and The Global Alliance for TB Drug Development (TB Alliance) of the U.S. entered into an agreement that further explores hits generated from a high-throughput screening program conducted to find novel compounds to improve treatment of tuberculosis(\*). The joint research program is funded through the Global Health Innovative Technology Fund.
- (\*) In June 2013, TB Alliance and Takeda initiated a program to screen Takeda's library of 20,000 proprietary compounds to identify potential candidates that showed promise to be further developed into new tuberculosis treatments. The new collaboration advances the successful hits from the screening program.
- In June 2016, Takeda and Roivant Sciences Ltd. announced the formation of Myovant Sciences Ltd., a biopharmaceutical company focused on delivering innovative women's health and prostate cancer solutions. Takeda has granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to TAK-385 (generic name: relugolix), a clinical stage product candidate being studies for the treatment of for uterine fibroids, endometriosis and prostate cancer. Takeda has also granted Myovant an exclusive, worldwide license to RVT-602 (formerly TAK-448), a novel, oligopeptide kisspeptin receptor agonist as a product candidate for the treatment of infertility in females.
- In June 2016, Takeda and Ultragenyx Pharmaceutical Inc. of the U.S. entered into a strategic partnership to develop and commercialize therapies to treat rare genetic diseases.
- In June 2016, Takeda, Memorial Sloan Kettering Cancer Center, The Rockefeller University and Weill Cornell Medicine announced that they will expand the focus of the successful Tri-Institutional Therapeutics Discovery Institute, Inc. (Tri-I TDI), a partnership established in 2013 to expedite early-stage drug discovery of innovative new therapies. Under this expansion, Tri-I TDI will extend its current relationship with its industry partner, Takeda from the realm of small molecule discovery into the new research area of antibody drug discovery.

# (2) Consolidated Financial Position

#### [Assets]

Total assets as of June 30, 2016 were 3,817.0 billion JPY, a decrease of 7.1 billion JPY compared to the previous fiscal year end. Along with the increase in cash and cash equivalents resulting from the new loan in this period, investments accounted for using the equity method on Teva Tekeda Yakuhin Ltd., newly established in this period, increased. Meanwhile, goodwill and intangible assets decreased due to the impact of the appreciation of the yen.

#### [Liabilities]

Total liabilities as of June 30, 2016 were 1,947.7 billion JPY, an increase of 134.8 billion JPY compared to the previous fiscal year end, mainly due to the increase in new loans payable of 200.0 billion JPY.

#### [Equity]

Total equity as of June 30, 2016 was 1,869.3 billion JPY, a decrease of 141.9 billion JPY compared to the previous fiscal year end. While net profit for the period exceeded dividend payments mainly due to gain on the transfer of long-listed products business in Japan to Teva Takeda Yahuhin Ltd. resulting in the increase in retained earnings, exchange differences on translation of foreign operations significantly decreased due to the impact of appreciation of the yen.

The ratio of equity attributable to owners of the Company (\*) to total assets decreased by 3.6 pt. from the previous fiscal year end to 47.4%.

(\*) It's equivalent to shareholders' equity ratio by JGAAP.

### (3) Outlook for Fiscal 2016

The forecast for consolidated results for the full year of fiscal 2016 has not been changed from the previous forecast (announced at the fiscal 2015 financial results announcement on May 10, 2016). In the first quarter of fiscal 2016, each line of profit exceeded the forecast for the full year, as a result of the 102.9 billion JPY gain on the transfer of long-listed products in Japan to Teva Takeda Yakuhin Ltd., and some benefit from the phasing of expenses. However, the forecast for the rest of the fiscal year assumes the use of budgeted expenses, and significant one-time expenses of 25.0 billion JPY related to the R&D transformation and 30.0 billion JPY for potential impairments of products and pipeline assets. In addition, exchange rates remain volatile, and therefore Takeda has not changed its forecast for the full year of fiscal 2016, which is as follows:

Billion JPY

			Billion of 1
	<u>Amount</u>	Change over the p	orevious year
Revenue	1,720.0	- 87.4	- 4.8%
R&D expense	325.0	- 20.9	- 6.0%
Operating profit	135.0	+4.2	+3.2%
Profit before tax	132.5	+12.0	+9.9%
Net profit for the period (attributable to owners of the Company)	88.0	+7.8	+9.8%
EPS(JPY)	112.31	+10.05	+9.8%

# Management Guidance - Underlying growth (\*)

Underlying Revenue	Mid-single digit growth (%)			
Underlying Core Earnings	Low- to mid-teen growth (%)			
Underlying Core EPS	Low- to mid-teen growth (%)			

<sup>(\*)</sup> Please refer to the "(1) Business Performance (ii) Underlying Growth" on page 7.

#### [Assumptions used in preparing the Outlook]

The foreign exchange rates assumptions for fiscal 2016 are US\$1 = 110 JPY, 1 Euro = 125 JPY, 1 RUB = 1.6 JPY, 1 BRL = 31.2 JPY and 1 CNY = 17.4 JPY.

#### [Forward looking statement]

All forecasts in this document are based on information currently available to the management, and do not represent a promise or guarantee to achieve those forecasts. Various uncertain factors could cause actual results to differ, such as changes in the business environment and fluctuation of foreign exchange rates. If a significant event occurs that requires the forecasts to be revised, the Company will disclose it in a timely manner.

# 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, 2016 with the exception of the items described below.

# 1) Change in accounting policies required by IFRS

The accounting standard applied by the Companies effective from the Three month period ended June 30, 2016 is as follows.

	IFRS	Description of new standards, interpretations and amendments
IAS 16	Property, Plant and Equipment	Amendment to clarify the acceptable methods of depreciation
IAS 38	Intangible Assets	Amendment to clarify the acceptable methods of depreciation
IFRS 11	Joint Arrangements	Amendment to the accounting for acquisitions of an interest in a joint operation
IFRS 10	Consolidated Financial Statements	
IFRS 12	Disclosure of Interests in Other	Clarifying exceptions for applying consolidation
IAS 28	Entities	and the equity method for investment entities
	Investments in Associates and	
	Joint Ventures	

The above standard does not have a material impact on the condensed interim consolidated financial statements.

#### 2) Change in accounting policies other than 1)

In this fiscal year, the Company changed the accounting policy for government grants, which were previously presented in "Other operating income", to offset corresponding "Cost of sales", "Selling, general and administrative expenses" and "Research and development expenses" in accordance with the nature of each grant. This is to clarify the expenses substantially incurred by the Company and to provide more relevant information regarding classification of profit or loss.

As a result of this change applied retrospectively, "Cost of sales", "Selling, general and administrative expenses", "Research and development expenses" and "Other operating income" decreased by 6 million JPY, 1 million JPY, 767 million JPY and 774 million JPY, respectively, in the Condensed Interim Consolidated Statement of Operations for the three month period ended June 30, 2015. This change did not have an effect on the operating profit.

Takeda Pharmaceutical Company Limited (4502) Summary of Financial Statements for the Three Month Period Ended June 30, 2016 (Consolidated)

# (Changes in Presentation)

The Company previously presented amortization and impairment losses on intangible assets acquired through business combinations or in-licensing of products / pipelines in "Research and development expenses" or "Amortization and impairment losses on intangible assets associated with products" in accordance with their functionality. From this fiscal year, the Company changed this policy to present these expenses in "Amortization and impairment losses on intangible assets associated with products", as this would provide more relevant information considering the nature of such expenses.

As a result of this change applied retrospectively, "Amortization and impairment losses on intangible assets associated with products" increased by 429 million JPY while "Research and development expenses" decreased by 429 million JPY in the Condensed Interim Consolidated Statement of Operations for the three month period ended June 30, 2015.

This change did not have an effect on the operating profit.

# 3. Condensed Interim Consolidated Financial Statements [IFRS] (1) Condensed Interim Consolidated Statement of Operations

(Million JPY)

		(17111101101117)
	Three month period ended TI June 30, 2015	hree month period ended June 30, 2016
Revenue	446,295	434,005
Cost of sales	(121,115)	(135,395)
Gross profit	325,181	298,610
Selling, general and administrative expenses	(161,693)	(144,955)
Research and development expenses	(79,795)	(76,550)
Amortization and impairment losses on intangible assets associated with products	(33,809)	(28,515)
Other operating income	6,636	111,626
Other operating expenses	(6,961)	(7,283)
Operating profit	49,559	152,933
Finance income	4,153	2,475
Finance expenses	(5,799)	(5,372)
Share of profit (loss) of associates accounted for using the equity method	808	(359)
Profit before tax	48,721	149,677
Income tax expenses	(23,292)	(49,333)
Net profit for the period	25,429	100,343
Attributable to:		
Owners of the Company	24,583	99,527
Non-controlling interests	846	816
Net profit for the period	25,429	100,343
Earnings per share (JPY)		
Basic earnings per share	31.32	127.30
Diluted earnings per share	31.12	126.75

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

		(Million JPY)
	Three month period ended Th June 30, 2015	nree month period ended June 30, 2016
Net profit for the period	25,429	100,343
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurements of defined benefit plans	6,818	(1,818)
	6,818	(1,818)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	72,584	(147,208)
Net changes on revaluation of available-for-sale financial assets	15,336	(3,549)
Cash flow hedges	217	185
	88,136	(150,573)
Other comprehensive income for the period, net of tax	94,954	(152,391)
Total comprehensive income for the period	120,383	(52,047)
Attributable to:		
Owners of the Company	119,255	(50,707)
Non-controlling interests	1,127	(1,341)
Total comprehensive income for the period	120,383	(52,047)

# (3) Condensed Interim Consolidated Statement of Financial Position

		(Million JPY)
	As of March 31, 2016	As of June 30, 2016
<u>ASSETS</u>		
NON-CURRENT ASSETS		
Property, plant and equipment	551,916	529,339
Goodwill	779,316	706,672
Intangible assets	743,128	662,001
Investment property	26,626	26,660
Investments accounted for using	·	·
the equity method	10,016	121,222
Other financial assets	149,548	148,474
Other non-current assets	18,975	18,164
Deferred tax assets	170,773	130,952
Total non-current assets	2,450,298	2,343,484
OUDDENT AGOSTO		
CURRENT ASSETS	054.040	040.004
Inventories	254,010	242,201
Trade and other receivables	415,379	426,781
Other financial assets	108,600	151,101
Income taxes recoverable	15,192	13,637
Other current assets	64,145	56,928
Cash and cash equivalents	451,426	581,670
Subtotal	1,308,752	1,472,318
Assets held for sale	65,035 1,373,787	1,210 1,473,528
Total current assets	1,373,707	1,473,526
Total assets	3,824,085	3,817,012
		(Millian IDV)
		(Million JPY)
	As of March 31, 2016	As of June 30, 2016
LIABILITIES AND EQUITY		
<u>LIABILITIES</u>		
NON-CURRENT LIABILITIES		
Bonds and loans	539,760	739,779
Other financial liabilities	102,120	92,849
Net defined benefit liabilities	84,867	79,571
Provisions	34,421	31,898
Other non-current liabilities	71,032	68,780
Deferred tax liabilities	123,469	112,092
Total non-current liabilities	955,668	1,124,969
CURRENT LIABILITIES		
Bonds and loans	228,464	214,625
Trade and other payables	191,089	190,310
Other financial liabilities	37,168	36,867
Income taxes payable	43,133	62,043
Provisions	115,341	99,946
Other current liabilities	226,899	218,720
Subtotal	842,094	822,511
Liabilities held for sale	15,119	250
Total current liabilities	857,213	822,761
Total liabilities	1,812,882	1,947,729
	•	, ,
EQUITY		
Share capital	64,766	64,850
Share premium	68,829	61,386
Treasury shares	(35,974)	(47,059)
Retained earnings	1,523,127	1,549,977
Other components of equity	327,944	179,529
Equity attributable to owners of the Company	1,948,692	1,808,683
Non-controlling interests	62,511	60,600
Total equity	2,011,203	1,869,283
Total liabilities and equity	3,824,085	3,817,012

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

Three month period ended June 30, 2015 (From April 1 to June 30, 2015)

(Million JPY)

		Equity attributable to owners of the Company							
				Retained	Other components of equity				
	Share	Share	Treasury		Exchange	Net changes on			
	capital	premium	shares	earnings	differences on	revaluation of			
	Сарнаі	premium	Silales	earrings	translation of	available-for-sale			
					foreign operations	financial assets			
As of April 1, 2015	64,044	59,575	(18,203)	1,601,326	355,692	75,685			
Net profit for the period				24,583					
Other comprehensive income					72,204	15,433			
Comprehensive income for the period	_	_	-	24,583	72,204	15,433			
Issuances of new shares	168	168							
Acquisitions of treasury shares			(22,300)						
Disposals of treasury shares		0	1						
Dividends				(70,738)					
Changes in the ownership interest in subsidiaries									
Transfers from other components of equity				6,818					
Share-based payments		(2,717)	4,355						
Total transactions with owners	168	(2,549)	(17,944)	(63,920)		_			
As of June 30, 2015	64,212	57,025	(36,147)	1,561,990	427,896	91,119			

	Equity	Equity attributable to owners of the Company				
	Other	components of	equity		Non-controlling	Total
	Cash flow hedges	Remeasureme nts of defined benefit plans	Total	Total	interests	equity
As of April 1, 2015	(1,073)	-	430,305	2,137,047	69,129	2,206,176
Net profit for the period			-	24,583	846	25,429
Other comprehensive income	217	6,818	94,672	94,672	282	94,954
Comprehensive income for the period	217	6,818	94,672	119,255	1,127	120,383
Issuances of new shares			_	335		335
Acquisitions of treasury shares			_	(22,300)		(22,300)
Disposals of treasury shares			_	1		1
Dividends			_	(70,738)	(571)	(71,309)
Changes in the ownership interest in subsidiaries			_	_	(3,303)	(3,303)
Transfers from other components of equity		(6,818)	(6,818)	_		· –
Share-based payments				1,638		1,638
Total transactions with the owners	_	(6,818)	(6,818)	(91,064)	(3,874)	(94,937)
As of June 30, 2015	(856)	-	518,159	2,165,238	66,383	2,231,621

Three month period ended June 30, 2016 (From April 1 to June 30, 2016)

		Eqi	uity attributable	to owners of t	he Company	
					Other components of equity	
	Share	Share	Treasury	Retained	Exchange	Net changes on
	capital	premium	shares	earnings	differences on	revaluation of
	Capitai	premium	Silaies	earrings	translation of	available-for-sale
					foreign operations	financial assets
As of April 1, 2016	64,766	68,829	(35,974)	1,523,127	272,361	58,523
Net profit for the period				99,527		
Other comprehensive income					(145,062)	(3,539)
Comprehensive income for the period	_	_	l	99,527	(145,062)	(3,539)
Issuances of new shares	84	84				
Acquisitions of treasury shares			(20,994)			
Disposals of treasury shares		0	1			
Dividends				(70,859)		
Changes in the ownership interest in subsidiaries						
Transfers from other components of equity				(1,818)		
Share-based payments		(7,527)	9,908			
Total transactions with owners	84	(7,443)	(11,084)	(72,677)	_	_
As of June 30, 2016	64,850	61,386	(47,059)	1,549,977	127,299	54,985

	Equity	Equity attributable to owners of the Company				
	Other	components of	onents of equity		Non controlling	Total
	Cash flow hedges	Remeasureme nts of defined benefit plans	Total	Total	Non-controlling interests	equity
As of April 1, 2016	(2,940)	_	327,944	1,948,692	62,511	2,011,203
Net profit for the period			-	99,527	816	100,343
Other comprehensive income	185	(1,818)	(150,234)	(150,234)	(2,157)	(152,391)
Comprehensive income for the period	185	(1,818)	(150,234)	(50,707)	(1,341)	(52,047)
Issuances of new shares			-	168		168
Acquisitions of treasury shares			_	(20,994)		(20,994)
Disposals of treasury shares			_	1		1
Dividends			_	(70,859)	(571)	(71,430)
Changes in the ownership interest in subsidiaries			_	. –		
Transfers from other components of equity		1,818	1,818	_		_
Share-based payments			_	2,382		2,382
Total transactions with the owners	_	1,818	1,818	(89,302)	(571)	(89,873)
As of June 30, 2016	(2,755)	_	179,529	1,808,683	60,600	1,869,283

# (5) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern Assumption)

Three month period ended June 30, 2016 (April 1 to June 30, 2016)

No events to be noted for this purpose.

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

Three month period ended June 30, 2016 (April 1 to June 30, 2016)

No events to be noted for this purpose.

#### (Segment Information)

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

Three month period ended June 30, 2015 (April 1 to June 30, 2015)

(Million JPY)

	Re	Reportable Segments			Condensed interim		
	Ethical Drugs	Consumer Healthcare	Other	Total	consolidated financial statements		
Revenues	407,811	19,427	19,057	446,295	446,295		
Operating profit	34,858	7,639	7,062	49,559	49,559		
			Finance income	Finance income			
			Finance expense	(5,799)			
			Share of profit of accounted for usi the equity method	808			
			Profit before tax		48,721		

Three month period ended June 30, 2016 (April 1 to June 30, 2016)

(Million JPY)

	Re	Reportable Segments			
	Ethical Drugs	Consumer Healthcare	Other	Total	consolidated financial statements
Revenues	394,049	20,385	19,571	434,005	434,005
Operating profit	142,201	7,389	3,343	152,933	152,933
			Finance income	2,475	
			Finance expense	(5,372)	
			Share of profit (lo accounted for usi the equity method	(359)	
			Profit before tax		149,677

#### 2. Geographic Information

Revenues

							,		
	Japan	United States	Europe and Canada	Emerging Markets	Russia/ CIS	Latin America	Asia	Others	Total
Three month period ended June 30, 2015	170,917	123,902	77,474	74,002	15,764	18,445	30,877	8,917	446,295
Three month period ended June 30, 2016	163,775	130,500	76,459	63,271	12,804	14,964	27,506	7,997	434,005

<sup>(</sup>Note) 1. Revenues are attributable to countries or regions based on the customer location.

<sup>2. &</sup>quot;Others" region includes Middle East, Oceania and Africa.

#### (Investments Accounted for Using the Equity Method)

Significant company split and establishment of business venture

On April 1, 2016, Takeda split off its off-patented and data exclusivity expired products business ("long listed products business") via an absorption-type split and the business was transferred to Taisho Pharm. Ind., Ltd. ("Taisho"), a Japanese wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. headquartered in Israel ("Teva"). According to this business transfer, Taisho became a business venture of Takeda and Teva and the company name of Taisho changed to Teva Takeda Yakuhin Ltd. ("Teva Takeda Yakuhin"). This is a triangular absorption-type company split among Teva Pharma Japan Inc. ("Teva Pharma"), a Japanese wholly owned subsidiary of Teva, and Teva Takeda Yakuhin, as well as Takeda. In this absorption-type company split, Takeda is the splitting company and Teva Takeda Yakuhin is the succeeding company. Takeda's long listed products business was transferred to Teva Takeda Yakuhin, and Teva Takeda Yakuhin allocated shares of Teva Pharma, which is its parent company, to Takeda as consideration for the company split. Teva Takeda Yakuhin, which succeeded Takeda's long listed products business and also continues its generics business, and Teva Pharma, which continues its generics business, jointly engages in the new business.

Teva holds 51% of Teva Pharma's shares through Teva Holdings KK, which is also the Japanese subsidiary of Teva, and Takeda holds 49% of Teva Pharma's shares. As a result, Teva Takeda Yakuhin and Teva Pharma became Takeda's associates which are accounted for using the equity method. The company name of Teva Pharma will become Teva Takeda Pharma Ltd. after October, 2016.

- (1) Purpose of company split and the establishment of business venture Takeda's leading brand reputation and strong distribution presence in Japan combined with Teva's global expertise in supply chain, operational networks, commercial deployment, and R&D and scientific insight, brings forward a new, collaborative business model in line with government objectives that will ultimately serve millions of patients.
- (2) Outline of company split
  - 1) Name of succeeding company
  - 2) Content of business to be split off
  - 3) Business result
  - 4) Book value of assets and liabilities to be split off
  - 5) Effective date of the company split
  - 6) Transfer price
- (3) Outline of business venture
  - 1) Company name
  - 2) Location
  - 3) Representative
  - 4) Scope of business
  - 5) Capital
  - 6) Date of establishment
  - 7) Number of shares issued
  - 8) Major shareholders and ratio of shares held

Teva Takeda Yakuhin Ltd.

Off-patented and data exclusivity expired products of ethical drugs business

Revenue recognized in consolidated operating results of

FY2015: 81,679 million JPY Assets: 3,755 million JPY Liabilities: Not applicable

April 1, 2016

205,517 million JPY

Teva Takeda Yakuhin Ltd. Koka-City, Shiga Prefecture

Representative Director: Ichiro Kikushige

Development, manufacturing, sales and marketing of pharmaceutical products

3,170 million JPY April 1, 2016

12 shares

Teva Pharma Japan Inc. 100%

Name to be changed to Teva Takeda Pharma Ltd. in or

after October, 2016

#### (4) Outline of accounting treatment

Takeda's accounting treatment for the company split is conducted based on IAS28 "Investments in Associates and Joint Ventures. At the date of the company split, Takeda recognized 102,899 million JPY as Other operating income on the Consolidated Statement of Operations and 106,654 million JPY as "Investments accounted for using the equity method" including Goodwill on the Consolidated Statement of Financial Position.

#### (Significant Subsequent Events)

No events to be noted for this purpose.