

## Consolidated Financial Results for the Three Month Period Ended June 30, 2013

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Senior Vice President  
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July 31, 2013

Takeda Pharmaceutical Company Limited

## Consolidated Financial Results for the Three Month Period Ended June 30, 2013



	FY2012	FY2013	Year-on-year change		excl.
	Apr.-Jun. (billion yen)	Apr.-Jun. (billion yen)	(billion yen)	(%)	Fx effect (billion yen)
<b>Net Sales</b>	<b>398.3</b>	<b>410.3</b>	+ 12.0	<+ 3.0>	- 28.3
<b>Gross Profit</b>	<b>295.0</b>	<b>295.2</b>	+ 0.2	<+ 0.1>	- 32.6
<b>SG&amp;A Expenses</b>	<b>153.5</b>	<b>170.0</b>	+ 16.4	<+ 10.7>	- 8.8
excl. Special factors *1	121.0	132.8	+ 11.8	<+ 9.8>	- 9.1
<b>R&amp;D Expenses</b>	<b>78.9</b>	<b>77.5</b>	- 1.3	<- 1.7>	- 10.7
<b>Operating Income</b>	<b>62.6</b>	<b>47.7</b>	- 14.9	<- 23.8>	- 13.1
excl. Special factors *2	95.8	85.6	- 10.2	<- 10.6>	- 12.6
<b>Ordinary Income</b>	<b>66.2</b>	<b>52.5</b>	- 13.7	<- 20.7>	- 11.6
<b>Extraordinary Income/Loss</b>	<b>9.5</b>	<b>- 2.3</b>	- 11.8	-	- 11.8
<b>Net Income</b>	<b>87.6</b>	<b>29.1</b>	- 58.5	<- 66.8>	- 56.0
excl. Extraordinary Income/Loss & Special factors *3	61.1	62.4	+ 1.4	<+ 2.2>	- 0.9
<b>EBITDA (excl. Extraordinary Income/Loss)</b>	<b>114.4</b>	<b>109.0</b>	- 5.4	<- 4.7>	
<b>EPS</b>	<b>111 yen</b>	<b>37 yen</b>	- 74 yen	<- 66.8>	
excl. Extraordinary Income/Loss & Special factors *3	77 yen	79 yen	+ 2 yen	<+ 2.2>	
<b>Exchange Rate</b>	<b>USD</b>	<b>80 yen</b>	<b>98 yen</b>	<b>+ 18 yen</b>	
	<b>EUR</b>	<b>103 yen</b>	<b>127 yen</b>	<b>+ 24 yen</b>	

\*1: Special factors in SG&A Expenses : amortization of intangible assets and goodwill resulting from corporate acquisitions, etc.

\*2: Special factors in Operating Income : increase in COGS related to inventory step-up due to revaluation to fair value and amortization of intangible assets and goodwill resulting from corporate acquisitions, etc.

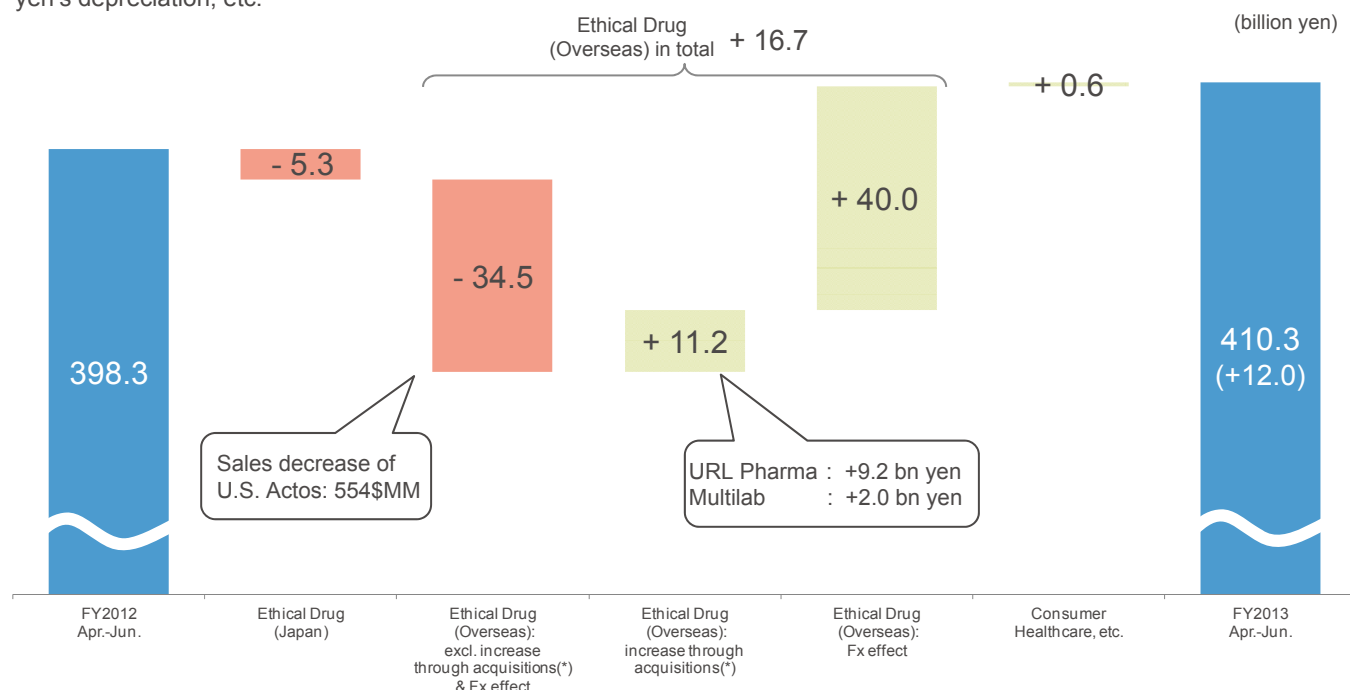
\*3: Special factors in Net Income and EPS : in addition to \*2, non-operating expenses resulting from corporate acquisitions and transfer price tax refund

# Breakdown of Change in Net Sales by Business Segment



Ethical Drug (Overseas) in total increased by 16.7 billion yen

Despite sales decrease of Actos in U.S., overseas sales increased due to acquisitions of URL Pharma and Multilab and the yen's depreciation, etc.



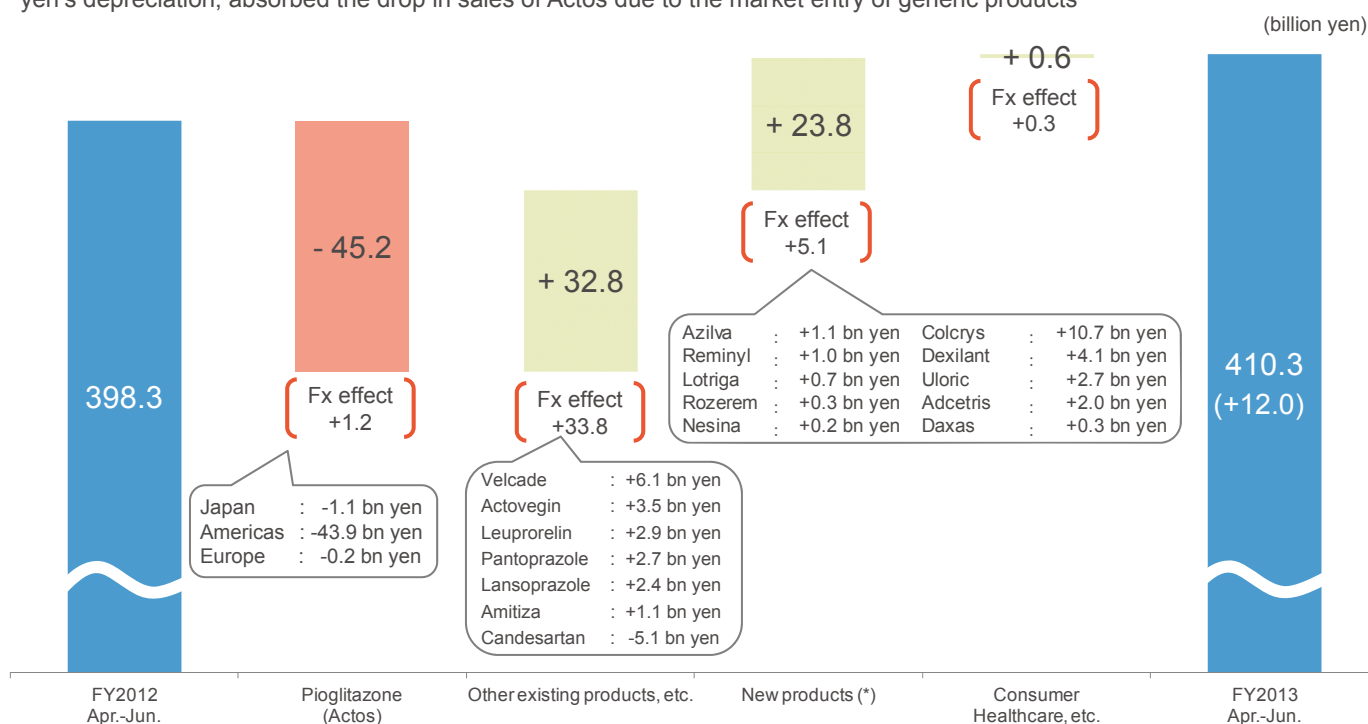
(\*): Increase in Net Sales related to acquisitions in and after FY2012, i.e. URL Pharma (June 2012) and Multilab (July 2012).

It consists of URL Pharma sales (Apr. and May 2013) and Multilab sales (Apr.- Jun. 2013). The sales are regarded as the increase through acquisition because the same periods in previous year were not consolidated.

# Breakdown of Change in Net Sales by Product



Sales contribution of new products such as Azilva, Dexilant and Colcrys aquired with the URL acquisition, in addition to the yen's depreciation, absorbed the drop in sales of Actos due to the market entry of generic products



(\*): New products represent products launched in and after 2009 (including the new products in acquired companies, but excluding fixed dose drugs with the existing drugs and formulation change drugs.)

# Net Sales by Region



Sales increased steadily in emerging markets

(billion yen)



		Year-on-year change < % >		excl. Fx effect	
Ethical Drugs	<b>Total</b>	+ 12.0	<+ 3.0%>	- 28.3	<- 7.1%>
	U.S. and Canada	- 13.8	<- 13.2%>	- 27.8	<- 26.5%>
	Europe(*)	+ 13.6	<+ 22.2%>	- 0.6	<- 1.0%>
	Emerging Markets	+ 16.9	<+ 34.6%>	+ 5.1	<+ 10.4%>
	Japan	- 5.3	<- 3.7%>		
	Consumer Healthcare, etc.	+ 0.6	<+ 1.7%>	+ 0.4	<+ 1.0%>

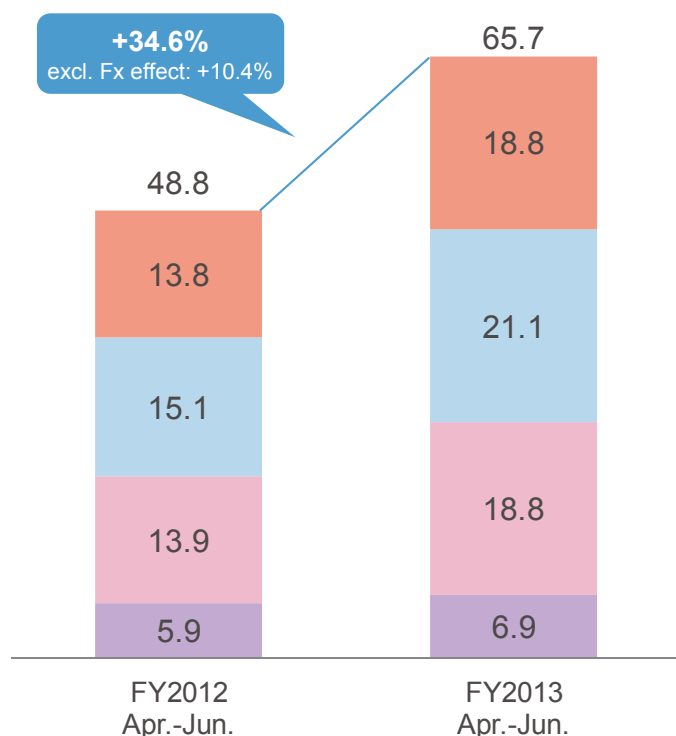
(\*): Excl. Russia/CIS

# Net Sales in Ethical Drugs Emerging Markets



Sales increased in each region

(billion yen)

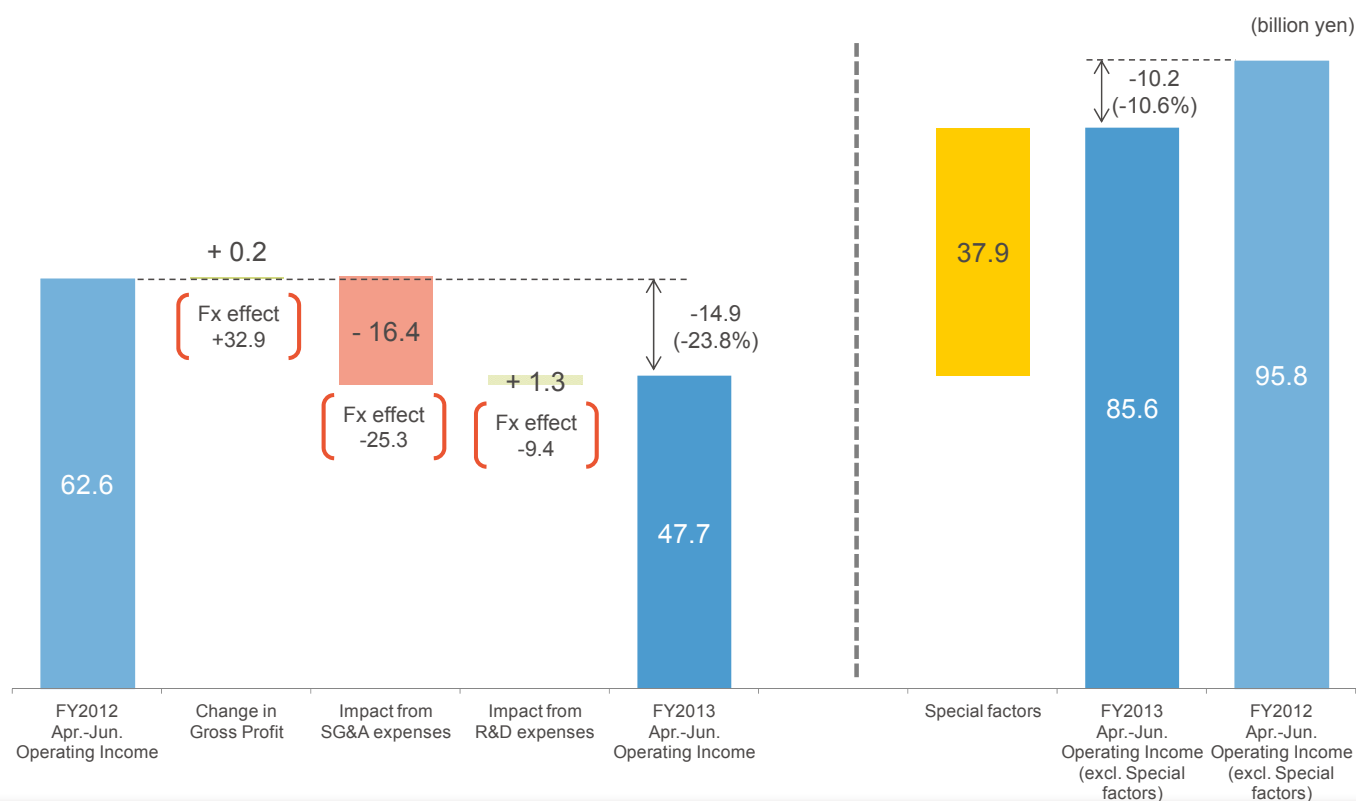


		Year-on-year change < % >		excl. Fx effect	
<b>Net Sales in Emerging Markets</b>		+ 16.9	<+ 34.6%>	+ 5.1	<+ 10.4%>
Latin America		+ 5.0	<+ 36.3%>	+ 2.1	<+ 15.0%>
Russia/CIS		+ 6.0	<+ 39.9%>	+ 2.0	<+ 13.2%>
Asia		+ 4.9	<+ 35.0%>	+ 1.3	<+ 9.6%>
Middle East, Oceania & Africa		+ 1.0	<+ 16.2%>	- 0.0	<- 0.6%>

# Breakdown of Change in Operating Income



SG&A expenses increased due to the yen's depreciation

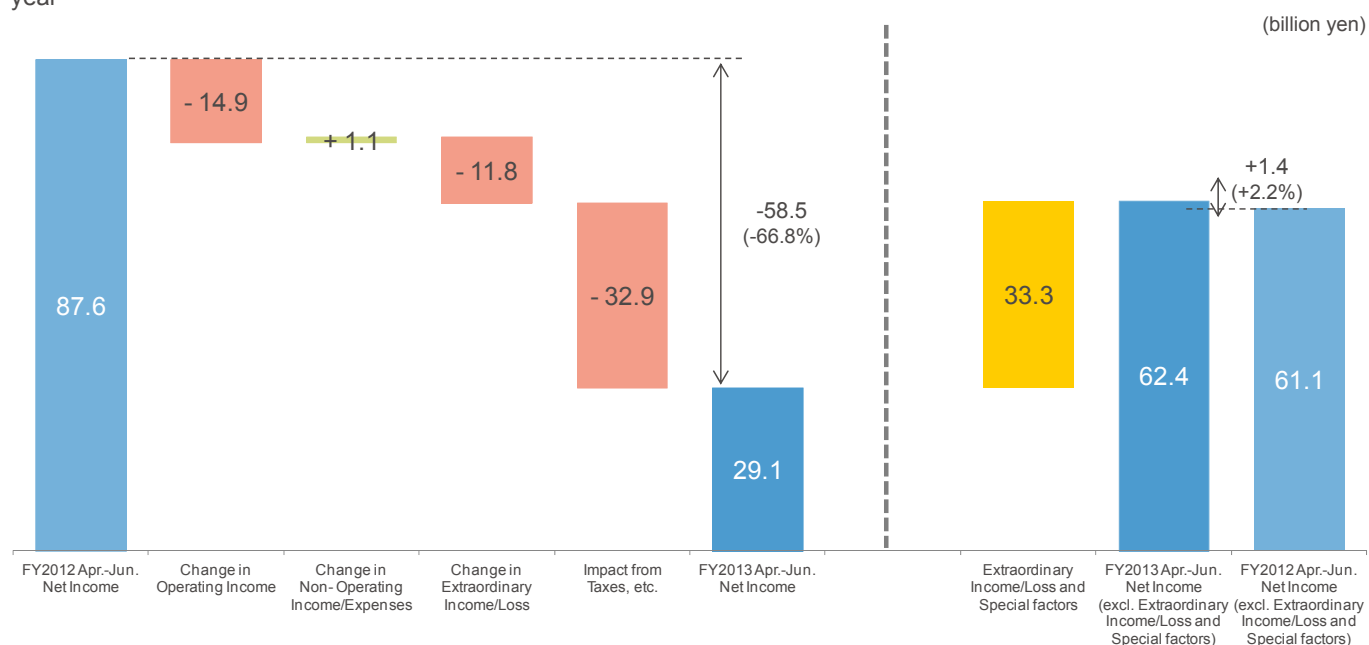


# Breakdown of Change in Net Income



Net income decreased significantly compared to the previous year

Tax refunds and interest on tax refund (net income impact 52.8 billion yen) were included in the same period of the previous year



- Changes in Extraordinary Income/Loss -11.8 billion yen :  
 FY2012: Net Extraordinary Income/Loss 9.5 billion yen (gain) (Mainly interest on tax refund related to Prevacid transactions)  
 FY2013: Net Extraordinary Income/Loss 2.3 billion yen (loss)
- Increase in Taxes, etc.(loss) +32.9 billion yen:  
 FY2012: Transfer price tax refund related to Prevacid transactions 45.6 billion yen (gain)

# Cash Flow Statement



		FY2012 Apr.-Jun. (billion yen)	FY2013 Apr.-Jun. (billion yen)	Ref: FY2012 Apr.-Mar. (billion yen)
<b>Net cash provided by (used in) operating activities</b>		<b>104.1</b>	<b>- 89.5</b>	<b>307.7</b>
Major items	Income before income taxes and minority interests	75.7	50.2	129.7
	Depreciation and amortization	39.0	42.7	166.7
	Amortization of goodwill	7.8	10.6	34.4
	Increase/decrease in working capital	- 11.6	- 35.5	12.3
	Income tax paid (incl. tax refund and interest on tax refund)	29.3	- 97.2	34.5
<b>Net cash provided by (used in) investing activities</b>		<b>- 99.0</b>	<b>- 16.7</b>	<b>- 111.4</b>
Major items	Payment for purchases of property, plant and equipment	- 28.2	- 10.8	- 78.2
	Payment for acquisition of subsidiaries' shares	- 60.9	- 3.4	- 86.3
<b>Net cash provided by (used in) financing activities</b>		<b>- 62.3</b>	<b>- 63.2</b>	<b>- 150.6</b>
Major items	Net increase (decrease) in short-term loans	0.1	0.1	- 242.9
	Proceeds from issuance of bonds	-	-	238.0
	Dividends paid	- 61.0	- 62.1	- 142.1
<b>Effect of exchange rate changes on cash and cash equivalents</b>		<b>- 17.3</b>	<b>8.6</b>	<b>45.6</b>
<b>Net increase (decrease) in cash and cash equivalents</b>		<b>- 74.4</b>	<b>- 160.8</b>	<b>91.3</b>
<b>Cash and cash equivalents, end of period</b>		<b>379.8</b>	<b>384.8</b>	<b>545.6</b>

note: Since the statutory disclosure of Cash Flow Statement is not required for the first quarter, the figures have not been audited.

## FY2013 Financial Forecast - Compared to original forecasts (1st Half/ Annual)



Net sales will be 1,680.0 billion yen, 90.0 billion yen increased versus the original forecast mainly due to the revised assumption of foreign exchange rates  
Operating income will be 140.0 billion yen, unchanged from the original forecast because costs are also expected to increase due to the revised foreign exchange rates

	FY13 Forecasts: Original		FY13 Forecasts: Updated		Comparison with Original Forecasts		
	1st half (billion yen)	Annual (billion yen)	1st half (billion yen)	Annual (billion yen)	1st half (billion yen)	Annual (billion yen)	
<b>Net sales</b>	780	1,590	830	1,680	+ 50	+ 90	
<b>R&amp;D expenses</b>	160	325	165	340	+ 5	+ 15	
<b>Operating income</b>	70	140	80	140	+ 10	—	
excl. Special factors *1	140	280	155	295	+ 15	+ 15	
<b>Ordinary income</b>	65	125	75	125	+ 10	—	
<b>Net income</b>	45	95	55	95	+ 10	—	
excl. Extraordinary income/loss & Special factors *2	90	185	100	195	+ 10	+ 10	
<b>EBITDA(excl. Extraordinary Income/Loss)</b>	170	340	190	355	+ 20	+ 15	
<b>EPS</b>	57 yen	120 yen	70 yen	120 yen	+ 13 yen	—	
excl. Extraordinary income/loss & Special factors *2	114 yen	234 yen	127 yen	247 yen	+ 13 yen	+ 13 yen	
<b>Exchange Rate</b>	<b>USD</b>	90 yen	90 yen	99 yen	100 yen	+ 9 yen	+ 10 yen
	<b>EUR</b>	120 yen	120 yen	129 yen	129 yen	+ 9 yen	+ 9 yen

\*1: Special factors in Operating Income : increase in COGS related to inventory step-up due to revaluation to fair value and amortization of intangible assets and goodwill resulting from corporate acquisitions, etc.

\*2: Special factors in Net Income and EPS : in addition to \*1, non-operating expenses resulting from corporate acquisitions and transfer price tax refund

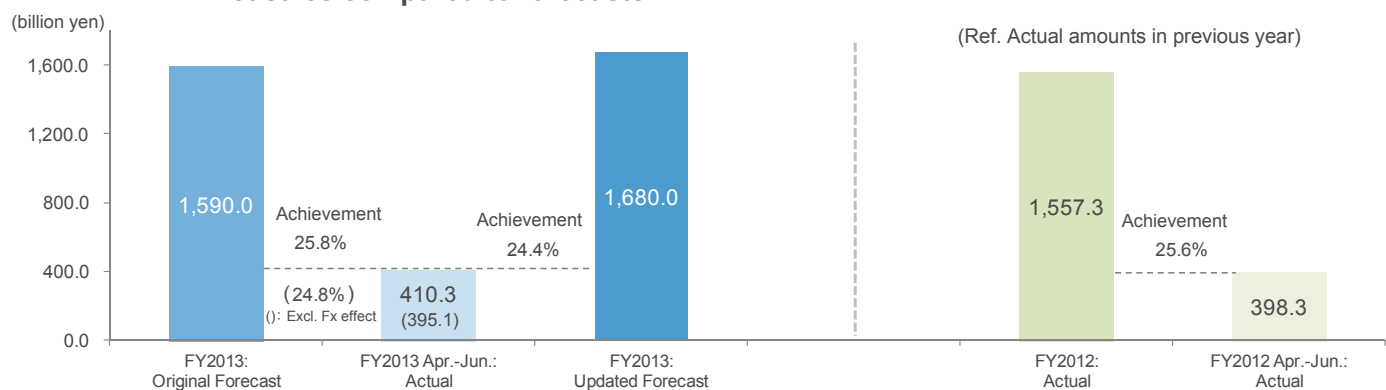
Reference: Impact of 1 yen change in the foreign exchange rate	FY2013 (billion yen)	
	USD	EUR
Net Sales	3.7	4.2
Operating Income	- 0.8	0.2
Net Income	- 0.5	0.0

# FY2013 Financial Forecast

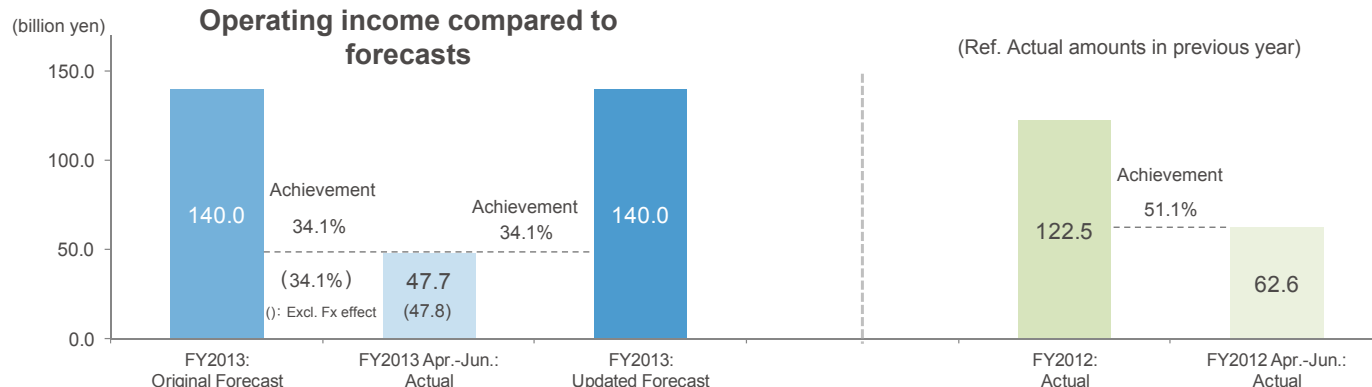
## - Actual amounts compared to forecasts



### Net sales compared to forecasts



### Operating income compared to forecasts



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Takeda Pharmaceutical Company Limited

# (Reference) Consolidated financial result in IFRS

## - Provisional figures



Due to impacts by non-amortized goodwill etc., FY13 1<sup>st</sup> Q Operating income in IFRS provisional figures is roughly 56.2 billion yen, which is 8.5 billion yen higher than that of current Japan GAAP (Refer to Appendix as for details)

(billion yen)

	FY2013 Apr.-Jun. Actual			FY2013 Apr.-Mar. Forecasts announced in May			FY2013 Apr.-Mar. Forecasts Updated		
	J-GAAP	IFRS provisional figures	Differences	J-GAAP	IFRS provisional figures	Differences	J-GAAP	IFRS provisional figures	Differences
<b>Net sales</b>	410.3	410.3	—	1,590.0	1,590.0	—	1,680.0	1,680.0	—
<b>R&amp;D expenses</b>	77.5	79.0	+1.5	325.0	335.0	+10.0	340.0	345.0	+5.0
<% of Net sales>	18.9%	19.3%	+0.4pt	20.4%	21.1%	+0.6pt	20.2%	20.5%	+0.3pt
<b>Operating Income</b>	47.7	56.2	+8.5	140.0	155.0	+15.0	140.0	160.0	+20.0
<% of Net sales>	11.6%	13.7%	+2.1pt	8.8%	9.7%	+0.9pt	8.3%	9.5%	+1.2pt
<b>Net Income</b>	29.1	36.4	+7.3	95.0	115.0	+20.0	95.0	120.0	+25.0
<% of Net sales>	7.1%	8.9%	+1.8pt	6.0%	7.2%	+1.3pt	5.7%	7.1%	+1.5pt
<b>EBITDA**</b>	109.0	103.6	-5.4	340.0	370.0	+30.0	355.0	380.0	+25.0
<b>Core Earnings*</b>	—	90.5	—	—	280.0	—	—	295.0	—
<% of Net sales>	—	22.1%	—	—	17.6%	—	—	17.6%	—

#### \* What is "Core Earnings"?

- It is a profit based on companies' regular business, which excludes temporary factors such as impacts from business combination accounting and from amortization/ impairment loss of intangible assets etc., from operating income under IFRS.
- It has been widely utilized and disclosed by companies mainly in the US and Europe as major index, which indicates corporate performance in regular business.

\*\* EBITDA in J-GAAP does not include extraordinary income/loss.

Please note it is possible that "Apr.- Jun. Actual under IFRS," which is provisionally created by adjusting major differences between J-GAAP and IFRS from "Actual under J-GAAP," would differ from those finally defined through audit in May 2014.

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Takeda Pharmaceutical Company Limited

# APPENDIX

## Changes of Net Sales in Ethical Drugs by Major Products

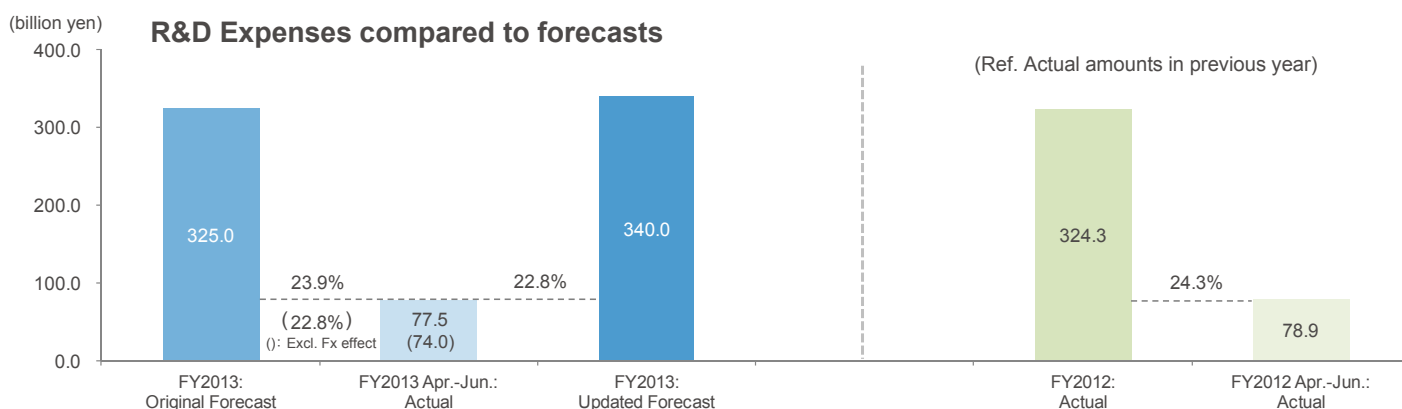
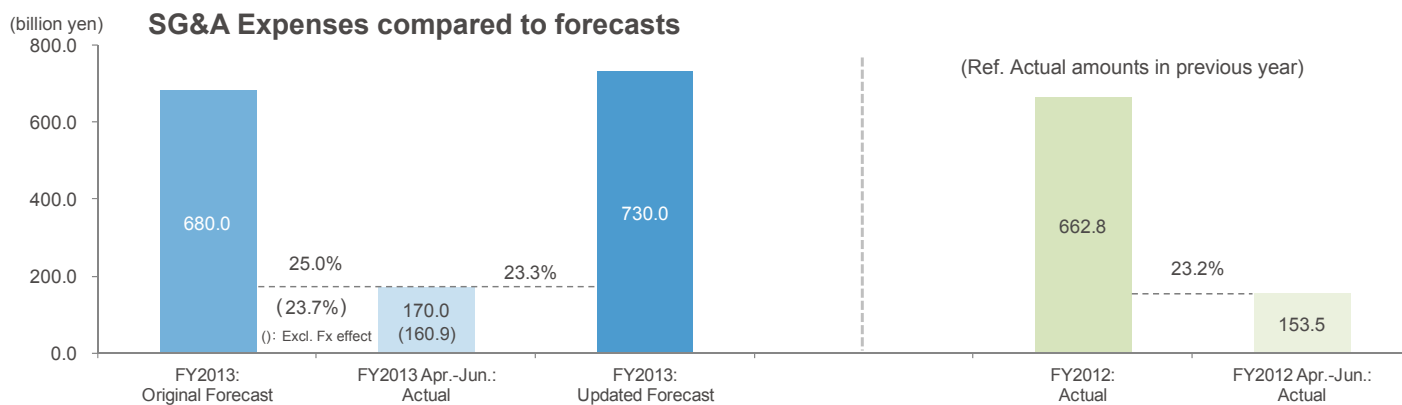
	Major Sales Region	FY2010 Actual (billion yen)	FY2011 Actual (billion yen)	FY2012 Actual (billion yen)	FY2012 Actual Apr.-Jun. (billion yen)	FY2013 Actual Apr.-Jun. (billion yen)	Year-on-year Change (billion yen)	<%>
Candesartan	Worldwide	218.0	216.3	169.6	47.5	42.4	- 5.1	<- 10.8>
Leuprorelin	Worldwide	116.4	120.7	116.5	29.7	32.6	+ 2.9	<+ 9.7>
Lansoprazole	Worldwide	133.6	122.1	110.2	27.2	29.7	+ 2.4	<+ 8.8>
Pioglitazone	Worldwide	387.9	296.2	122.9	55.8	10.5	- 45.2	<- 81.1>
Enbrel	Japan	38.4	41.4	43.2	10.8	11.0	+ 0.2	<+ 1.9>
Nesina	Japan	1.6	15.5	37.8	7.1	7.3	+ 0.2	<+ 2.5>
Vectibix	Japan	9.4	17.2	18.8	4.8	4.8	+ 0.0	<+ 0.4>
Velcade	U.S.	50.8	58.1	72.9	17.6	23.8	+ 6.1	<+ 34.8>
Colcrys (*1)	U.S.	12.6	36.8	40.7	9.9	13.7	+ 3.7	<+ 37.7>
Dexilant	U.S.	18.1	24.2	32.7	7.0	11.1	+ 4.1	<+ 57.9>
Uloric	U.S.	9.1	12.9	17.7	3.8	6.5	+ 2.7	<+ 71.6>
Amitiza	U.S.	18.6	18.7	22.3	5.0	6.1	+ 1.1	<+ 21.5>
Pantoprazole (*2)	Europe/ Emerging Markets	105.6	82.6	78.0	20.2	22.9	+ 2.7	<+ 13.6>
Actovegin (*2)	Europe/ Emerging Markets	16.9	18.6	19.6	3.9	7.4	+ 3.5	<+ 89.5>
Calcium (*2)	Europe/ Emerging Markets	14.9	15.7	15.4	3.7	4.4	+ 0.8	<+ 20.5>
Tachosil (*2)	Europe/ Emerging Markets	12.9	13.8	13.2	3.8	4.2	+ 0.4	<+ 11.2>
Daxas (*2)	Europe/ Emerging Markets	0.4	2.4	3.0	0.7	1.0	+ 0.3	<+ 35.6>
<b>Ref. Nycomed Products in Total (approx.) (*2) (Million EUR)</b>	Europe/ Emerging Markets	2,838	2,984	3,126	754	813	+ 59	<+ 7.8>
<b>Exchange Rate</b>	USD	86 yen	79 yen	82 yen	80 yen	98 yen	+ 18 yen	
	EUR	113 yen	109 yen	106 yen	103 yen	127 yen	+ 24 yen	
	Ref.:EUR (fiscal year ended Dec.)	116 yen	-	-	-	-	-	

\*1: Colcrys is a product of URL Pharma, Inc. acquired in June 2012. The sales until May 2012 represent the amount before acquisition. Each amount before acquisition is reclassified to Takeda fiscal year (Apr. to Mar.).

\*2: Those are products of Nycomed acquired at the end of Sep 2011. The sales until Sep 2011 represent the amount before acquisition. The sales in FY2010 show calendar year sales, but in FY2011, the sales are reclassified to Takeda fiscal year (Apr. to Mar.).

# FY2013 SG&A Expenses and R&D Expenses

- Actual amounts compared to forecasts



# Breakdown of Special factors and Extraordinary Income/Loss



(billion yen)  
(negative amount represents gain)

Breakdown of Special factors and Extraordinary Income/Loss	FY2012 Apr.-Jun.	FY2013 Apr.-Jun.
<COGS> Increase in COGS related to inventory step-up due to revaluation to fair value resulting from corporate acquisitions	0.6	0.7
<SG&A, R&D> Amortization of intangible assets	24.8	26.7
TAP integration	2.5	-
Millennium acquisition	9.5	11.6 Amortize until 2018
Nycomed acquisition	11.5	13.1 Amortize until 2026
URL Pharma acquisition	1.0	1.6 Amortize until 2029
<SG&A> Amortization of goodwill	7.8	10.6
Millennium acquisition	3.0	3.7 Amortize until 2028
Nycomed acquisition	4.4	5.5 Amortize until 2031
URL Pharma acquisition	0.2	0.7 Amortize until 2028
<SG&A> Others	-	-0.1
Impact of Special factors on Operating Income	33.2	37.9
<Non-Operating Expenses> Non-Operating Expenses resulting from corporate acquisitions	0.6	2.6
<Extraordinary Income/Loss>	-9.5	2.3
Interest on tax refund	-11.6	-
Restructuring costs	2.1	2.3
Impact of Special factors and Extraordinary Income/Loss on Income before Income Taxes and Minority Interests	24.3	42.8
Income Taxes and Deferred Income Taxes related to impact described above	-5.2	-9.4
Tax refund related to Prevacid transactions	-45.6	-
Impact of Special factors and Extraordinary Income/Loss on Net Income	-26.5	33.3

Nycomed: 18.6



# Breakdown of EBITDA



(billion yen)

Breakdown of EBITDA	FY2012 Apr.-Jun.	FY2013 Apr.-Jun.
<b>Ordinary Income</b>	<b>66.2</b>	<b>52.5</b>
+ Amortization of intangible assets resulting from corporate acquisitions	24.8	26.7
+ Amortization of goodwill resulting from corporate acquisitions	7.8	10.6
+ Depreciation and Amortization (other than those listed above)	14.2	16.0
+ Interest paid	0.8	0.7
+ Others	0.6	2.4
<b>EBITDA (excl. Extraordinary Income/Loss)</b>	<b>114.4</b>	<b>109.0</b>

# Consolidated Financial Position



	FY2012 End Actual (billion yen)	FY2013 Jun. Actual (billion yen)	Compared to FY2012 End (billion yen)
<b>Total Assets</b>	<b>3,955.6</b>	<b>3,933.7</b>	<b>-21.9</b>
<b>Liabilities</b>	<b>1,732.2</b>	<b>1,657.2</b>	<b>-75.0</b>
Loans and Bond	542.1	541.8	-0.3
<b>Net Assets</b>	<b>2,223.4</b>	<b>2,276.5</b>	<b>+53.2</b>
<b>Shareholders' Equity Ratio</b>	<b>54.6%</b>	<b>56.2%</b>	<b>+ 1.6Pt</b>

Fund procurement executed in July 2013 to repay the existing bond and for general corporate purposes

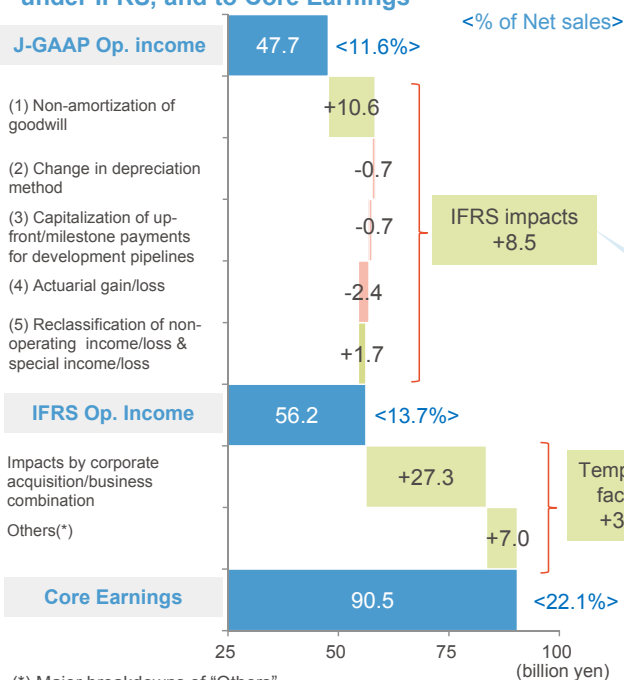
	Amount	Maturity Date
Domestic unsecured straight bonds	120.0 billion yen	2019 and 2020
Long-term loans	130.0 billion yen	2019 and 2020

# Consolidated Financial Results for the three Month Period Ended June 30, 2013 under IFRS provisional figures



- Adjustments from Operating Income under J-GAAP to Operating Income under IFRS, and to Core Earnings

## Adjustments to FY13 1<sup>st</sup> quarter Operating Income under IFRS, and to Core Earnings



## Major differences between J-GAAP and IFRS that make impacts to our income/loss

Items	J-GAAP	IFRS
(1) Goodwill amortization	➢ Amortized within 20 years	➢ Non-amortized, and impairment test required every fiscal year
(2) Depreciation method of property, plant and equipment	➢ Declining balance method except overseas subsidiaries ➢ Expensed "R&D equipment for specific purpose" at once when acquired	➢ Straight-line method ➢ Capitalized "R&D equipment for specific purpose" when acquired, and depreciated after operation
(3) Treatments of up-front/milestone payments for development pipelines	➢ Recognized R&D expenses when transactions occurred	➢ Capitalized when transactions occurred and amortized from the timing of launch through approval by authorities ➢ Impairment test required in case of development discontinuation or when future cash flow to be worsen, etc.
(4) Actuarial gain/loss	➢ Amortized in 5 years from the year when occurred (Amortized as gain in FY13)	➢ Recognized all amounts as Other Comprehensive Income at once when occurred, not amortized
(5) Reclassification of non-operating income/loss & special income/loss	➢ Recognized income/loss from other than regular business as non-operating income/loss, and for those recognized temporarily or unexpectedly as special income/loss	➢ Non-operating income/loss to be limited only to financial gain/loss (ex.) Interest paid/received, Gain on securities sales, Dividend income etc. ➢ Most of non-operating income/loss & extraordinary income/loss except financial gain/loss to be reclassified as operating income/loss (Recognized as income/loss above operating income/loss)

(\*) Major breakdowns of "Others"

... Amortization of intangible assets related to licensed-in compounds etc.

Please note it is possible that these actual figures under IFRS, which is provisionally created by adjusting major differences between J-GAAP and IFRS from those under J-GAAP, would differ from figures finally defined through audit in May 2014.

Better Health, Brighter Future



## First Quarter of Fiscal 2013 Updates Related to R&D Activities

Tsudoi Miyoshi  
Senior Vice President  
Head of Chief Medical & Scientific Officer Office

July 31, 2013

# R&D Pipeline Stage-ups (since May 9, 2013)



			P-1	P-2	P-3	Filing	Approval
NESINA® (alogliptin)	Type 2 diabetes	China					→
MLN0002 (vedolizumab)	Ulcerative colitis & Crohn's disease	US			→		
RIENSO® (ferumoxytol)	Iron deficiency anaemia in all patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used	EU			→		
MLN9708 (ixazomib)	Front line multiple myeloma	US/EU		→			
SGN-35 (brentuximab vedotin)	Front line mature T-cell lymphoma	JP	→				

## peginesatide MAA withdrawal in Europe:

In June 2013, Takeda announced that it has withdrawn the European Marketing Authorization Application (MAA) for peginesatide solution for injection, which was intended to be used for treatment of symptomatic anaemia associated with chronic kidney disease in adult patients undergoing dialysis.

# MLN0002 (vedolizumab) Biologics License Application filed in US



## Program Status

- A novel class of gut-selective monoclonal antibody targets  $\alpha 4\beta 7$  integrin on leukocytes involved in **ulcerative colitis** (UC) and **Crohn's disease** (CD)
- Filed in the EU (Mar 2013) and US (Jun 2013)
- MLN0002 has demonstrated efficacy in patients who are anti-TNF naïve and those with prior anti-TNF failure in both UC and CD
- No reported cases of progressive multifocal leukoencephalopathy (PML) in any of the GEMINI studies to date (~3000 patients, median exposure > 18 months)

## Key Phase 3 Clinical Trial Programs

<b>GEMINI I</b>	Met primary endpoints of response (induction) and remission (maintenance) in patients with moderate to severe UC
<b>GEMINI II</b>	Met primary endpoints of remission (both induction and maintenance) in patients with moderate to severe CD
<b>GEMINI LTS</b>	Open-label long-term safety study (currently ongoing)

## Ulcerative colitis

- Affects as many as 700,000 people in the US\*
- Impacts the large intestine, including colon and rectum

## Crohn's disease

- Affects as many as 700,000 people in the US\*
- Can impact any part of the gastrointestinal tract

\* Source: Crohn's & Colitis Foundation of America

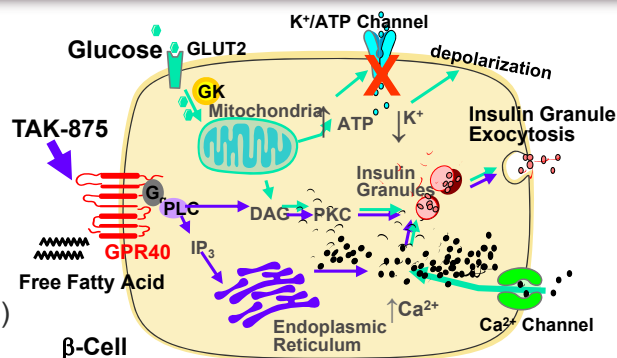
# TAK-875 (fasiglifam)

## Steady Progression of Phase 3 Trials



### Program Status

- First in class GPR40 agonist for **type 2 diabetes**
- Phase 3 program ongoing in US, EU and Japan
- Reduces glucose levels with low risk of hypoglycemia (2.0% versus glimepiride 19% in Phase 2 trial)
- Well tolerated, no dose adjustment in renal impairment
- Projected approval in FY2015 (Japan), FY2016 (US & EU)



### Key Phase 3 Trial Program for Robust NDA/MAA Submissions

Study	Design	Region	Patients
Study 301	Placebo-controlled	US/EU	421 patients
Study 302	Head to head comparison vs sitagliptin (on top of metformin for 104 weeks)	US/EU	1,080 patients
Study 303	Concomitant with sitagliptin	US/EU	390 patients
Study 304	Head to head comparison vs. glimepiride (on top of metformin)	US/EU	2,610 patients
Study 306	Cardiovascular outcomes study	US/EU	5,000 patients
Study 309	Concomitant with glimepiride	US/EU	260 patients
Study 310	Head to head comparison vs. sitagliptin (on top of metformin for 24 weeks)	US/EU	620 patients
Study CCT-003	Placebo-controlled (completed)	Japan	192 patients
Study OCT-003	Open-label monotherapy (completed)	Japan	334 patients
Study OCT-002	Open-label safety study	Japan	1,130 patients

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# TAK-875 (fasiglifam)

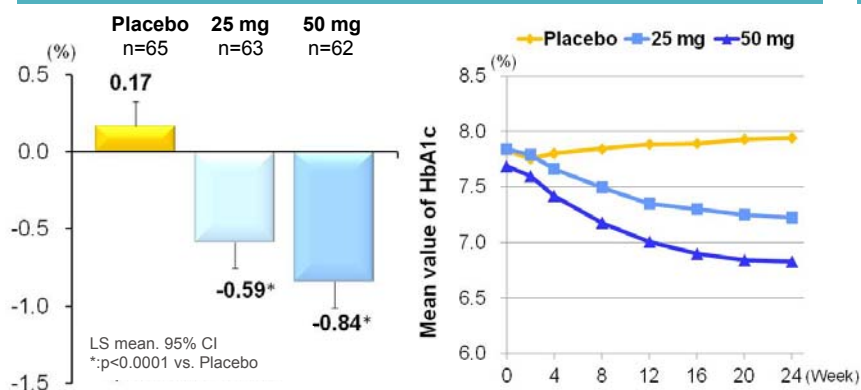
## Phase 3 data presented at Japan Diabetes Society Annual Meeting



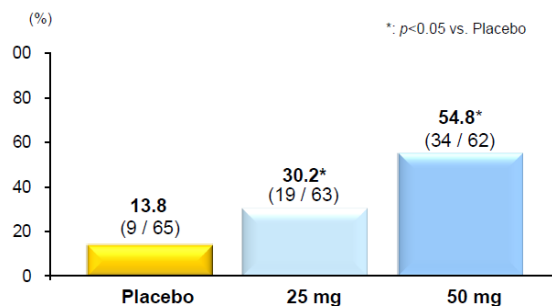
### Phase 3 (Study CCT-003) Results in Japanese Type 2 Diabetes Patients

- Statistically significant HbA1c reduction at 24 weeks compared to placebo
- Statistically significant percentage of patients whose HbA1c levels were reduced to the glycemic target (less than 6.9%) compared to placebo
- Both 25mg and 50 doses showed continued glucose lowering effects up to 24 weeks
- Incidence of hypoglycemia was similar to placebo for both TAK-875 25mg & 50mg, with no weight gain

#### Mean HbA1c Change from Baseline at Week 24



#### Percent of Subjects with HbA1c <6.9% at Week 24



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# Lu AA21004 (vortioxetine)

Phase 3 data presented at American Psychiatric Association

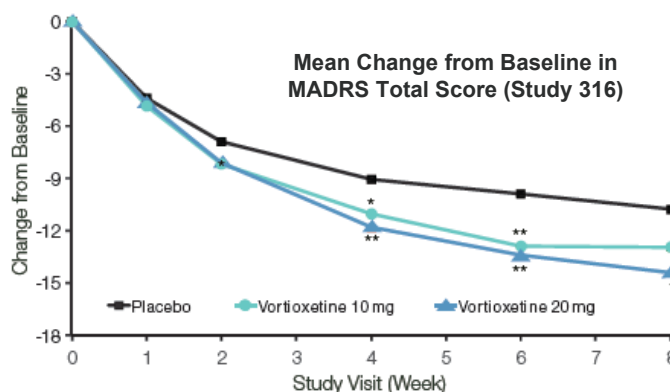


## Program Status

- Novel multimodal anti-depressant with potential for favorable short and long term safety and tolerability and improvement of cognitive dysfunction of depression
- Filed in the US (Oct 2012) for **major depressive disorder**, PDUFA date is October 2<sup>nd</sup>, 2013
- The data package that is currently under review by the FDA includes data from seven positive studies – six short-term studies and one long-term maintenance study
- Partnership with H. Lundbeck A/S of Denmark

## Phase 3 Data Presented at APA

- Data presented from four trials of vortioxetine in doses ranging from 10-20 mg per day
- Three of the four pivotal studies met the primary efficacy endpoint in the change from baseline of the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at week 8
- Two studies included duloxetine as an active reference arm that validated the studies and confirmed assay sensitivity



\*Nominal P<0.050, \*\*Nominal P<0.010, †P<0.01 statistically significantly different from placebo by the testing sequence

# Ensuring Steady Pipeline Approval



	FY13	FY14	FY15	FY16 - FY17
<b>JP</b>	azilsartan (TAK-536) CCB <sup>1</sup> lansoprazole (AG-1749) LDA <sup>2</sup> cetilistat (ATL-962) influenza vaccine (BLB-750) brentuximab vedotin (SGN-35)	trelagliptin (SYR-472) vonoprazan (TAK-438) vortioxetine (Lu AA21004)	fasiglifam (TAK-875) ixazomib (MLN9708) orteronel (TAK-700) leuprorelin 6M (TAP-144-SR) Hib vaccine (TAK-816)	relugolix (TAK-385) motesanib
<b>US</b>	vortioxetine (Lu AA21004)	vedolizumab (MLN0002) orteronel (TAK-700)	ixazomib (MLN9708) alisertib (MLN8237)	fasiglifam (TAK-875) ramelteon (TAK-375) SL
<b>EU</b>	alogliptin (SYR-322) alogliptin MET <sup>3</sup> alogliptin PIO <sup>4</sup> dextansoprazole (TAK-390MR) lurasidone	azilsartan medoxomil CLD <sup>5</sup> vedolizumab (MLN0002)	ixazomib (MLN9708) orteronel (TAK-700)	fasiglifam (TAK-875)
<b>EM NA<sup>6</sup></b>	In emerging markets and North Asia, compounds including alogliptin, azilsartan medoxomil, brentuximab vedotin, MEPACT, ramelteon, dextansoprazole, DAXAS will be launched consecutively.			

Please note that approval timing of several products, including certain in-licensed items, are not disclosed

<sup>1</sup> Calcium Channel Blocker (amlodipine), <sup>2</sup> Low Dose Aspirin, <sup>3</sup> Metformin, <sup>4</sup> Pioglitazone (ACTOS), <sup>5</sup> Chlorthalidone, <sup>6</sup> Emerging Markets + North Asia,

In-house

In-license

## Value

Takeda is a pharmaceutical company committed to the discovery and delivery of innovative solutions addressing unmet medical needs of patients through R&D investment

## Mission

- Meet the future promise of Takeda as a leader in the pharmaceutical industry by providing solutions to patients with unmet medical needs
- Transform the R&D organization to be an engine of growth that is an industry leader in R&D productivity

## Forward-Looking Statements

This presentation contains forward-looking statements regarding the Company's plans, outlook, strategies, and results for the future.

All forward-looking statements are based on judgments derived from the information available to the Company at this time. Forward looking statements can sometimes be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "potential," "target," "forecast," or "intend" or other similar words or expressions of the negative thereof.

Certain risks and uncertainties could cause the Company's actual results to differ materially from any forward looking statements contained in this presentation. These risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding the Company's business, including general economic conditions in the US and worldwide; (2) competitive pressures; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) decisions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates; and (8) integration activities with acquired companies.

We assume no obligation to update or revise any forward-looking statements or other information contained in this presentation, whether as a result of new information, future events, or otherwise.

