



Better Health, Brighter Future

FY2018 1st Quarter DATA BOOK

Takeda Pharmaceutical Company Limited (TSE code 4502)

Contact: Global Finance, IR

TEL: +81-3-3278-2306

<https://www.takeda.com/>

Quarterly Announcements / Presentations

<https://www.takeda.com/investors/reports/>

Contents

I. Financial Results

1. Revenue by Region

- ◆ Consolidated Revenue 1
- ◆ Consolidated Prescription Drugs Revenue 1
- ◆ Prescription Drugs: Global major products' sales 2

2. Exchange Rate 3

II. Pipeline

1. Development Activities 4-6

- Oncology
- Gastroenterology
- Neuroscience
- Vaccines

2. Recent progress in stage 7

3. Exploring Alternative Value Creation 7

4. Main Research & Development collaborations 8-10

- Oncology
- Gastroenterology
- Neuroscience
- Vaccines
- Other / Multiple Therapeutic Area
- Completed Partnerships
- Clinical study protocol summaries

Appendix

- ◆ Prescription Drugs: US major products' sales (in US\$) 11
- ◆ Prescription Drugs: Japan major products' sales 12
- ◆ Consumer Healthcare: Japan major products' sales 13

I. Financial Results

1. Revenue by Region

◆ Consolidated Revenue

(Billion JPY)

	FY15	FY16	FY17	FY17 Q1	FY18 Q1	YOY	
Total revenue	1,807.4	1,732.1	1,770.5	448.2	449.8	1.6	0.4%
Japan	688.1	655.3	580.3	160.3	144.3	-16.0	-10.0%
<% of revenue>	<38.1%>	<37.8%>	<32.8%>	<35.8%>	<32.1%>	<-3.7pt>	
United States	514.4	520.2	598.3	148.6	161.1	12.5	8.4%
<% of revenue>	<28.5%>	<30.0%>	<33.8%>	<33.1%>	<35.8%>	<2.7pt>	
Europe and Canada	309.3	279.7	313.7	73.6	79.1	5.5	7.5%
<% of revenue>	<17.1%>	<16.1%>	<17.7%>	<16.4%>	<17.6%>	<1.2pt>	
Emerging Markets	295.6	276.9	278.1	65.8	65.4	-0.4	-0.7%
<% of revenue>	<16.4%>	<16.0%>	<15.7%>	<14.7%>	<14.5%>	<-0.1pt>	
Russia/CIS	61.8	57.5	68.2	17.0	14.1	-2.9	-17.1%
<% of revenue>	<3.4%>	<3.3%>	<3.9%>	<3.8%>	<3.1%>	<-0.7pt>	
Latin America	68.4	72.5	75.7	17.0	18.5	1.6	9.2%
<% of revenue>	<3.8%>	<4.2%>	<4.3%>	<3.8%>	<4.1%>	<0.3pt>	
Asia	126.0	112.8	104.0	25.2	26.9	1.7	6.9%
<% of revenue>	<7.0%>	<6.5%>	<5.9%>	<5.6%>	<6.0%>	<0.4pt>	
Other	39.4	34.0	30.2	6.6	5.8	-0.8	-12.1%
<% of revenue>	<2.2%>	<2.0%>	<1.7%>	<1.5%>	<1.3%>	<-0.2pt>	
Royalty income and service income	56.5	60.1	76.7	30.3	13.0	-17.3	-57.1%

*1 Revenue amount is classified into countries or regions based on the customer location.

*2 Other region includes Middle East, Oceania and Africa.

◆ Consolidated Prescription Drugs Revenue

(Billion JPY)

	FY15	FY16	FY17	FY17 Q1	FY18 Q1	YOY		Underlying Growth
Total prescription drugs revenue	1,648.7	1,568.9	1,691.5	427.2	434.5	7.3	1.7%	8.2%
Japan	541.7	504.7	501.4	139.3	129.0	-10.3	-7.4%	6.6%
United States	511.0	516.7	598.3	148.6	161.1	12.5	8.4%	14.1%
Europe and Canada	305.6	276.0	313.7	73.6	79.1	5.5	7.5%	2.0%
Emerging Markets	290.4	271.5	278.1	65.8	65.4	-0.4	-0.7%	6.2%
Russia/CIS	61.8	57.5	68.2	17.0	14.1	-2.9	-17.1%	-10.7%
Russia	43.5	41.9	51.3	12.5	10.5	-2.0	-16.3%	-7.8%
Latin America	68.2	72.5	75.7	17.0	18.5	1.6	9.2%	25.5%
Brazil	38.1	39.0	46.2	10.0	11.8	1.8	18.5%	41.7%
Asia	121.2	107.8	104.0	25.2	26.9	1.7	6.9%	10.7%
China	66.0	57.6	49.6	12.3	14.0	1.7	13.4%	28.6%
Other	39.2	33.7	30.2	6.6	5.8	-0.8	-12.0%	-8.3%
Royalty income and service income	55.8	59.5	76.2	30.2	12.9	-17.3	-57.3%	5.6%
Japan	6.6	18.7	31.3	18.1	3.2	-14.9	-82.3%	-14.3%
Overseas	49.3	40.9	44.9	12.1	9.7	-2.4	-19.8%	14.0%
Ratio of overseas prescription drugs revenue	67.1%	67.8%	70.4%	67.4%	70.3%	2.9pt		

*1 Revenue amount is classified into countries or regions based on the customer location.

*2 Other region includes Middle East, Oceania and Africa.

◆ Prescription Drugs: Global major products' sales *1

(Billion JPY)

		FY15	FY16	FY17	FY17	FY18	YOY	FY18	FY18Q1
					Q1	Q1		Forecasts*3	Underlying Growth
Entyvio	U.S.	63.1	99.6	133.6	31.0	41.9	11.0	35.5%	39.3%
	EUCAN	21.9	39.5	60.2	13.5	17.2	3.7	27.5%	21.0%
	EM	1.3	4.0	7.5	1.4	2.2	0.7	50.4%	56.7%
	Total	86.2	143.2	201.4	45.9	61.3	15.4	33.6%	34.1%
Velcade	U.S.	131.6	112.9	113.7	30.7	26.2	-4.5	-14.7%	-12.1%
	Other than U.S.	30.4	24.7	23.6	5.5	5.2	-0.3	-6.1%	-3.4%
	Total	162.0	137.6	137.3	36.2	31.4	-4.8	-13.4%	-10.8%
Leuprorelin	Japan	53.8	48.6	47.6	11.0	10.5	-0.5	-4.7%	-4.7%
	U.S.	17.3	18.3	19.7	5.2	6.2	1.0	19.3%	19.9%
	EUCAN	35.3	31.1	34.5	8.1	8.4	0.4	4.7%	-1.1%
	EM	18.0	16.3	12.7	3.0	3.5	0.4	14.2%	10.6%
	Total	124.4	114.2	114.4	27.3	28.6	1.3	4.7%	2.7%
Azilva	Japan	59.0	66.9	73.0	16.8	19.4	2.6	15.5%	15.5%
	Total	59.0	66.9	73.0	16.8	19.4	2.6	15.5%	15.5%
Pantoprazole	U.S.	13.6	10.1	7.2	1.9	2.0	0.1	6.8%	9.3%
	EUCAN	43.4	30.5	30.6	7.9	7.2	-0.6	-8.0%	-13.6%
	EM	43.7	33.7	28.0	7.0	7.0	-0.0	-0.1%	0.8%
	Total	100.8	74.2	65.8	16.7	16.2	-0.5	-3.1%	-5.4%
Dexilant	U.S.	64.0	49.7	49.5	12.8	13.0	0.2	1.4%	4.2%
	EUCAN	5.4	5.7	6.4	1.4	1.7	0.3	18.7%	16.2%
	EM	5.7	7.3	9.9	2.1	2.7	0.6	30.4%	37.1%
	Total	75.1	62.6	65.7	16.3	17.4	1.1	6.6%	9.7%
Takecab	Japan	8.4	34.1	55.1	11.3	14.2	3.0	26.4%	26.4%
	Total	8.4	34.1	55.1	11.3	14.3	3.0	26.5%	26.5%
Nesina	Japan	36.9	32.9	30.1	7.3	7.8	0.5	6.8%	6.8%
	U.S.	5.3	5.2	6.0	1.2	1.2	-0.1	-6.9%	-3.9%
	EUCAN	3.5	6.1	9.0	2.0	2.6	0.6	28.7%	20.4%
	EM	3.3	4.9	8.6	1.4	2.6	1.2	84.3%	90.7%
	Total	48.9	49.1	53.7	11.9	14.1	2.2	18.2%	18.0%
Trintellix	U.S.	24.5	31.9	48.4	11.2	14.1	2.9	25.8%	29.4%
	Total	24.5	31.9	48.4	11.2	14.1	2.9	25.8%	29.4%
Uloric	U.S.	41.8	41.4	45.8	11.2	13.8	2.6	23.4%	27.1%
	EUCAN	0.7	0.7	0.8	0.2	0.2	0.0	4.2%	2.3%
	EM	-	0.1	0.3	0.1	0.1	0.0	17.1%	21.6%
	Total	42.5	42.2	46.8	11.4	14.1	2.6	23.1%	26.7%
Ninlaro	Japan	-	-	2.5	0.2	1.2	0.9	-	-
	U.S.	4.0	29.1	39.4	9.0	11.1	2.1	23.1%	26.8%
	EUCAN	-	0.2	4.0	0.6	1.6	0.9	147.5%	134.7%
	EM	0.0	0.1	0.6	0.1	0.1	0.0	39.7%	41.8%
	Total	4.1	29.4	46.4	10.0	14.0	4.0	39.6%	43.3%
Colcrys	U.S.	46.5	38.9	40.3	9.6	9.2	-0.4	-4.3%	-1.6%
	Total	46.5	38.9	40.3	9.6	9.2	-0.4	-4.3%	-1.6%
Adcetris	Japan	3.1	3.3	3.8	1.0	1.1	0.1	10.8%	10.8%
	Europe	17.4	17.5	20.1	4.7	5.5	0.8	17.7%	10.9%
	EM	7.2	9.3	14.3	3.6	4.3	0.7	20.0%	33.2%
	Total	27.6	30.1	38.5	9.3	11.0	1.7	17.8%	18.9%
Lansoprazole	Japan *2	41.3	8.1	4.7	1.5	0.9	-0.6	-42.2%	-9.1%
	U.S.	27.5	20.0	15.2	3.8	2.0	-1.7	-46.1%	-44.3%
	EUCAN	10.5	7.1	7.2	1.9	1.7	-0.2	-10.5%	-15.4%
	EM	10.2	9.2	9.7	2.5	2.4	-0.1	-4.5%	-5.8%
	Total	89.5	44.4	36.8	9.7	7.0	-2.7	-27.7%	-23.4%
Amitiza	U.S.	37.2	33.7	33.7	8.6	7.8	-0.8	-8.9%	-6.2%
	EUCAN	0.1	0.1	0.1	0.0	0.0	0.0	5.7%	3.1%
	EM	-	0.0	0.0	0.0	0.0	-0.0	-38.8%	-36.6%
	Total	37.3	33.8	33.8	8.6	7.9	-0.8	-8.9%	-6.2%
Iclusig	U.S.	-	2.7	20.4	4.7	6.3	1.6	34.2%	38.2%
	Other than U.S.	-	0.2	2.7	0.5	0.7	0.2	43.9%	48.0%
	Total	-	2.9	23.1	5.2	7.0	1.8	35.1%	39.1%
Alunbrig	U.S.	-	-	2.8	0.2	1.1	0.8	-	-
	Total	-	-	2.8	0.2	1.1	0.8	-	-

U.S.: United States, EUCAN: Europe and Canada, EM: Emerging Markets

*1 Sales amount includes royalty income and service income.

*2 Products were transferred to the Joint Venture with Teva in Japan (monotherapy in April 2016 and fixed dose combinations in May 2017).

Supply sales of these products to the JV is currently recognized.

*3 See page 3 for the profit forecast disclaimer.

➡ ± <10% ➡ +10%~20% ➡ +20%~30% ➡ +>30% ➡ -10%~20% ➡ -20%~30% ➡ ->30%

*4 Effective from FY2018, sales of certain products in Japan are now disclosed on a net basis, deducting items such as discounts and rebates, in alignment with the global managerial approach applied to individual product sales. The change in disclosure of individual product sales has been revised retrospectively, with prior year figures reclassified on a net basis to enable year-on-year comparisons. This reclassification has no impact on Takeda's financial statements and does not represent a correction of prior year figures.

2. Exchange Rate

Average Exchange Rate	(yen)			
	USD	EUR	RUB	BRL
FY15	121	132	1.9	34.1
FY16	109	120	1.7	32.9
FY17	111	129	1.9	34.5
FY17Q1 (April-June)	111	121	2.0	34.8
FY18Q1 (April-June)	108	130	1.8	31.0
FY18 Assumption	108	133	1.9	33.0

Impact of 1% depreciation of yen	(100 million yen)			
	USD	EUR	RUB	BRL
Revenue	+57.6	+20.5	+4.9	+4.2
Core Earnings	+12.9	-2.4	+2.6	+1.1
Operating Profit	+4.7	-7.5	+1.9	+0.9
Net Profit	+3.2	-5.3	+1.4	+0.6

This table shows annual impact of 1% depreciation of yen as the FY2018 forecast including FY2018 assumption of average exchange rate is unchanged.

[Profit Forecast for Takeda for the year ending March 31, 2019]

Takeda is currently in an offer period (as defined in the City Code on Takeovers and Mergers (the “Code”)) with respect to Shire plc. Pursuant to Rule 28 of the Code, statements made regarding Takeda’s guidance for FY2018 (including statements regarding forecasts for FY2018 revenue, Core Earnings, Operating profit, Profit before income taxes, Net profit attributable to owners of the Company, Basic earnings per share, R&D expenses, Amortisation and impairment and other income/expense, Underlying Revenue, Underlying Core Earnings and Underlying Core EPS) constitute a profit forecast for the year ending March 31, 2019 (the “Takeda Profit Forecast”). For additional information regarding the Takeda Profit Forecast and the required statement by its Directors that such profit forecast is valid and has been properly compiled on the basis of the assumptions stated and that the basis of accounting used is consistent with Takeda’s accounting policies, please see page 21 of Takeda’s Financial Results (Tanshin) for the Fiscal Year Ended March 31, 2018, dated May 14, 2018.

II. Pipeline

1. Development activities

- 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 and in additional formulations.
- The listings in this table are limited to the US, EU and Japan and China but we are also actively conducting development activities in other regions, including in Emerging Markets. This listing only shows regional activity for pivotal programs, or regional in-licensing deals.
- Stage-ups are recognized in the table upon achievement of First Subject In.
- 'Global' refers to US, EU, China and Japan

■ Oncology

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
<brigatinib> ALUNBRIG® (US)	ALK inhibitor (oral)	ALK-positive metastatic Non-Small Cell Lung Cancer in patients who have been previously treated with crizotinib	EU	Filed (Feb '17)
			CN	P-I
		Front line ALK-positive Non-Small Cell Lung Cancer	US	P-III
			EU	P-III
			CN	P-I
		Japanese patients with ALK-positive, Non-Small Cell Lung Cancer who have been previously treated with ALK inhibitors	Jpn	P-II(a)
SGN-35 <brentuximab vedotin> ADCETRIS® (EU, Jpn)	CD30 monoclonal antibody-drug conjugate (injection)	Front line Hodgkin Lymphoma	EU	Filed (Nov '17)
			Jpn	Filed (Jan '18)
		Front line Peripheral T-cell Lymphoma (PTCL)	EU	P-III
			Jpn	P-III
		Relapsed/refractory Hodgkin Lymphoma	CN	P-II
		Relapsed/refractory systemic Anaplastic large-cell lymphoma (sALCL)	CN	P-II
MLN9708 <ixazomib> NINLARO® (Global)	Proteasome inhibitor (oral)	Newly diagnosed Multiple Myeloma	US	P-III
			EU	P-III
			Jpn	P-III
			CN	P-I
		Maintenance therapy in patients with newly diagnosed Multiple Myeloma following autologous stem cell transplant	US	P-III
			EU	P-III
		Maintenance therapy in patients with newly diagnosed Multiple Myeloma not treated with stem cell transplant	Jpn	P-III
			CN	P-I
Relapsed/refractory primary amyloidosis	US	P-III		
	EU	P-III		
		CN	P-III	
Relapsed/refractory Multiple Myeloma (doublet regimen with dexamethasone)	US	P-III		
	EU	P-III		
		Jpn	P-III	
Relapsed/refractory Multiple Myeloma (triplet regimen with daratumumab and dexamethasone)	Global	P-II		
<ponatinib> ICLUSIG® (US)	BCR-ABL inhibitor (oral)	Philadelphia chromosome-positive Acute Lymphoblastic Leukemia	US	P-III
			EU	P-III
			Jpn	P-III
		Dose ranging study for second-line patients with chronic-phase Chronic Myeloid Leukemia	US	P-II(b)
TAK-924 <pevonedistat>	NEDD 8 activating enzyme inhibitor (injection)	High-Risk Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, Low-blast Acute Myelogenous Leukemia	US	P-III
			EU	P-III
TAK-385 <relugolix>	LH-RH antagonist (oral)	Prostate cancer	Jpn	P-III
			CN	P-I
TAK-228 <sapanisertib>	mTORC1/2 inhibitor (oral)	Endometrial cancer	US	P-II(b)
TAK-659 <->	SYK/FLT3 kinase inhibitor (oral)	Diffuse Large B-cell Lymphoma	-	P-II(a)
		Solid tumors, Hematologic malignancies	-	P-I
TAK-931 <->	CDC7 inhibitor (oral)	Metastatic Colorectal cancer, Squamous esophageal cancer, Squamous Non Small Cell Lung Cancer	-	P-II(a)
<cabozantinib>	Multi-targeted kinase inhibitor (oral)	Renal cell carcinoma	Jpn	P-II(a)
TAK-079 <->	Cytolytic monoclonal antibody (injection)	Relapsed/refractory Multiple Myeloma	-	P-I
		Systemic lupus erythematosus	-	P-I

TAK-164 <->	Anti-guanylyl cyclase C antibody drug conjugate (injection)	GI Malignancies	-	P-I
TAK-573 <->	CD38-targeted IgG4 genetically fused with an attenuated IFN α (injection)	Relapsed/refractory Multiple Myeloma	-	P-I
TAK-788 <->	EGFR/HER2 inhibitor (oral)	Non-Small Cell Lung Cancer	-	P-I
TAK-522 / XMT-1522*¹ <->	HER2 dolaflexin antibody-drug conjugate (injection)	HER2 positive solid tumors	-	P-I
<niraparib>	PARP1/2 inhibitor (oral)	Multiple cancer	Jpn	P-I

*1 Takeda and Mersana Therapeutics, Inc. will co-develop XMT-1522, and Mersana will lead execution of the Phase 1 trial.

Additions since 2017 Q4: TAK-164 - GI Malignancies

Removals since 2017 Q4: TAK-385 - Uterine fibroids Jpn, Endometriosis Jpn (out-licensed May 2018). Takeda retains the rights for development in prostate cancer in parts of Asia including Japan, and for women's health indications in China and parts of Asia excluding Japan.
Brigatinib – ROS1 positive Non-Small Lung Cancer (On hold in this indication. Evaluating plans for life cycle management)

■ Gastroenterology

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
MLN0002 <vedolizumab> ENTYVIO [®] (US, EU, Jpn)	Humanized monoclonal antibody against $\alpha 4\beta 7$ integrin (injection)	Crohn's disease	Jpn	Filed (Jul '18)
		Ulcerative colitis	CN	P-III
		Subcutaneous formulation (for Ulcerative colitis, Crohn's disease)	US	P-III
		Adalimumab head-to-head in patients with ulcerative colitis	EU	P-III
			Jpn	P-III
		Adalimumab head-to-head in patients with ulcerative colitis	Global	P-III
	Graft-versus-Host Disease steroid refractory	-	P-II(a)	
	Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	-	P-II(a)	
SPI-0211 <lubiprostone> AMITIZA [®] (US)	Chloride channel activator (oral)	New formulation (initially for Chronic Idiopathic Constipation and Opioid-Induced Constipation)	US	P-III
Cx601 <darvadstrocel> ALOFISEL [®] (EU)	A suspension of allogeneic expanded adipose-derived stem cells (injection)	Refractory complex perianal fistulas in patients with Crohn's disease	US	P-III
TAK-438 <vonoprazan> TAKECAB [®] (Jpn)	Potassium-competitive acid blocker (oral)	Non-Erosive Reflux Disease in patients with Gastro-esophageal Reflux Disease	Jpn	P-III
		Acid-related diseases	CN	P-III
		Gastro-esophageal Reflux Disease in patients who have a partial response following treatment with a proton pump inhibitor	EU	P-II(b)
TAK-954*² <->	5-HT ₄ receptor agonist (injection)	Enteral feeding intolerance	-	P-II(b)
TAK-906 <->	Dopamine D ₂ /D ₃ receptor antagonist (oral)	Gastroparesis	-	P-II(a)
TIMP-GLIA*³ <->	Tolerizing Immune Modifying nanoParticle (TIMP) (injection)	Celiac Disease	-	P-I
Kuma062*⁴ <->	Glutenase (oral)	Celiac Disease	-	P-I

*2 Partnership with Theravance Biopharma

*3 Partnership with Cour Pharmaceuticals; Cour lead Phase 1 development.

*4 Partnership with PVP Biologics; PVP lead Phase 1 development.

Additions since 2017 Q4: Cx601 - Complex perianal fistulas in patients with Crohn's disease U.S. (acquired TiGenix in June '18)
Kuma062 – Celiac Disease (P-I)

Removals since 2017 Q4: MLN0002 – Ulcerative colitis Jpn (approved Jul '18)

SPI-0211 - Pediatric functional constipation (indication was not obtained from US FDA)

■ Neuroscience

Development code <generic name> BRAND NAME	Drug Class (administration route)	Indications / additional formulations	Stage	
Lu AA21004 <vortioxetine> TRINTELLIX [®] (US)	Multimodal anti-depressant (oral)	Treatment Emergent Sexual Dysfunction	US	Filed (Dec'17)
		Major depressive disorder	Jpn	P-III
TAK-935* ⁵ < - >	CH24H inhibitor (oral)	Rare pediatric epilepsies	-	P-II(a)
TAK-831 < - >	D-amino acid oxidase (DAAO) inhibitor (oral)	Friedreich's ataxia	-	P-II(a)
		Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-II(a)
TAK-041 < - >	GPR139 agonist (oral)	Negative symptoms and/or cognitive impairment associated with schizophrenia	-	P-I
TAK-418 < - >	LSD1 inhibitor (oral)	Kabuki syndrome	-	P-I
TAK-653 < - >	AMPA receptor potentiator (oral)	Treatment resistant depression	-	P-I
TAK-925 < - >	Orexin 2R agonist (injection)	Narcolepsy	-	P-I
TAK-341 / MEDI-1341* ⁶	Alpha-synuclein antibody (injection)	Parkinson's Disease	-	P-I

*5 Co-development with Ovid Therapeutics

*6 Partnership with AstraZeneca; AstraZeneca lead Phase 1 development

■ Vaccines

Development code BRAND NAME	Type of vaccine (administration route)	Indications / additional formulations	Stage	
TAK-003	Tetravalent dengue vaccine (injection)	Prevention of dengue fever caused by dengue virus	-	P-III
TAK-214	Norovirus vaccine (injection)	Prevention of acute gastroenteritis (AGE) caused by norovirus	-	P-II(b)
TAK-195	Sabin inactivated polio vaccine (injection)	Prevention of poliomyelitis	-	P-I/II
TAK-021	EV71 vaccine (injection)	Prevention of hand, foot and mouth disease caused by enterovirus 71	-	P-I
TAK-426	Zika vaccine (injection)	Prevention of zika virus infection	-	P-I

2. Recent progress in stage [Progress in stage disclosed since release of FY2017 results (May 14th, 2018)]

Development code <generic name>	Indications / additional formulations	Country/Region	Progress in stage
MLN0002 <vedolizumab>	Ulcerative colitis	Jpn	Approved (Jul '18)
MLN0002 <vedolizumab>	Crohn's disease	Jpn	Filed (Jul '18)
MLN0002 <vedolizumab>	Graft-versus-Host Disease prophylaxis in patients undergoing allogeneic hematopoietic stem cell transplantation	-	P-II(a)
MLN9708 <ixazomib>	Relapsed/refractory Multiple Myeloma (triplet regimen with daratumumab and dexamethasone)	Global	P-II
Kuma062 <- >	Celiac Disease	-	P-I
TAK-164 <- >	GI Malignancies	-	P-I

3. Exploring Alternative Value Creation [Update disclosed since release of FY2017 results (May 14th, 2018)]

Development code <generic name>	Indications (Stage)	Reason
TAK-385 <relugolix>	Uterine fibroids (Japan Filed) Endometriosis (Japan P-II(b))	Out-licensed to ASKA Pharmaceutical Co., Ltd., which has a strong presence in the gynecology therapeutic area in Japan, to maximize product value and to deliver relugolix to as many patients as possible.

Externalized assets in which Takeda retains a financial interest

Partner	Nature of Partnership	
ASKA Pharmaceutical Co., Ltd	Takeda granted exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis for Japan to maximize the product value of relugolix (TAK-385).	
Biological E. Limited	Takeda agreed to transfer existing measles and acellular pertussis vaccine bulk production technology to develop low-cost combination vaccines for India, China and low- and middle-income countries.	
Cardurion Pharmaceuticals	Takeda provided a 12-person cardiovascular research team from its Shonan (Japan) site, including fully equipped laboratory space, development resources and licenses to a portfolio of preclinical-stage cardiovascular drug programs.	
Cerevance	Takeda provided a 25-person neuroscience research team from its Cambridge (UK) site, fully equipped laboratory space, and licenses to a portfolio of undisclosed preclinical and clinical stage drug programs.	
Izana Biosciences	Takeda granted Izana Biosciences an exclusive, worldwide license to develop, manufacture and commercialise namilumab in all indications. As part of the licence agreement, Takeda has taken a strategic equity stake in Izana.	
Myovant Sciences	Takeda granted Myovant an exclusive, worldwide license (excluding Japan and certain other Asian countries) to relugolix (TAK-385) and an exclusive, worldwide license to MVT-602 (TAK-448).	
Rhythm	Exclusive, worldwide rights from Takeda to develop and commercialize T-3525770 (now RM-853). RM-853 is a potent, orally available ghrelin o-acyltransferase (GOAT) inhibitor currently in preclinical development for Prader-Willi Syndrome	
Schoia Pharma	Takeda granted Schoia Pharma exclusive rights for the research, development, manufacture, marketing, etc. of eight of Takeda's R&D projects, including TAK-272, TAK-792 and TAK-094.	
Samsung Bioepis	Strategic collaboration agreement to jointly fund and co-develop multiple novel biologic therapies in unmet disease areas. The program's first therapeutic candidate is TAK-671, which is intended to treat severe acute pancreatitis	
Stargazer	Takeda outlicensed own asset to Stargazer Pharmaceuticals	
Entrepreneurial Venture Programs (EVPs)	Aikomi	Developing a new digital therapy for persons with dementia.
	ChromaJean	Established unique chromatography algorithm/software platform.
	Chordia Therapeutics	Takeda provided a 6-person oncology research team from its Shonan (Japan) site, fully equipped laboratory space, development resources and licenses to a portfolio of preclinical-stage oncology drug programs including CDC like kinase inhibitors.
	Fimecs	A drug discovery biotech creating a new class of drugs based on protein degradation
	GenAhead Bio	Through providing two technologies; nucleic acid delivery on specific cell types as well as efficient genome editing, fee for service and/or collaboration in cell/gene therapies are delivered.
	GEXVal	Drug discovery for orphan disease (eg. PAH etc.) using Takeda's late research & early clinical assets.
	Reborna Biosciences	Developing small molecules that modulate RNA degeneration associated with genetic disease.
	Seedsupply	Provides HTS FFS using novel binder selection technology and Takeda's compound library. Provides target identification FFS using novel binder selection technology and own protein library.
ARTham	Focus on clinical and preclinical development of high quality assets identified via drug repurposing approach	

4. Main Research & Development collaborations

Oncology

Partner	Country	Subject
Adimab	US	The discovery, development and commercialization of three mAbs and three CD3 Bi-Specific antibodies for oncology indications.
Centre d'Immunologie de Marseille-Luminy	France	The collaboration will bring together expertise and knowledge in innate biology with Takeda's BacTrap capabilities to identify novel targets and pathways in myeloid cells.
Crescendo Biologics	UK	The discovery, development and commercialization of Humabody [®] -based therapeutics for cancer indications
Exelixis, Inc.	US	Exclusive licensing agreement to commercialize and develop novel cancer therapy cabozantinib and all potential future cabozantinib indications in Japan, including advanced renal cell carcinoma and hepatocellular carcinoma
GammaDelta Therapeutics	UK	Novel T cell platform, based on the unique properties of gamma delta ($\gamma\delta$) T cells derived from human tissues, to discover and develop new immunotherapies in oncology
Haemalogix	Australia	A research collaboration and licensing agreement for the development of new therapeutics to novel antigens in multiple myeloma.
Heidelberg Pharma	Germany	ADC Research Collaboration on 2 Targets and Licensing Agreement (α -amanitin payload and proprietary linker)
ImmunoGen, Inc.	US	Antibody-Drug Conjugate technology
Maverick Therapeutics	US	T-cell engagement platform created specifically to improve the utility of T-cell redirection therapy for the treatment of cancer
Mersana Therapeutics	US	Antibody-Drug Conjugate technology
Molecular Templates	US	Application of engineered toxin bodies (ETB) technology platform to potential therapeutic targets
Nektar Therapeutics	US	Research collaboration to explore combination cancer therapy with five Takeda oncology compounds and Nektar's lead immuno-oncology candidate, the CD122-biased agonist NKTR-214
Noile-Immune Biotech	Japan	The development of next generation chimeric antigen receptor T cell therapy (CAR-T), developed by Professor Koji Tamada at Yamaguchi University
Seattle Genetics	US	Antibody-Drug Conjugate technology
Shattuck Labs	US	Explore and develop checkpoint fusion proteins utilizing Shattuck's unique Agonist Redirected Checkpoint (ARC) [™] platform which enables combination immunotherapy with a single product.
Tesaro	US	Exclusive licensing agreement to develop and commercialize novel cancer therapy niraparib for the treatment of all tumor types in Japan, and all tumor types excluding prostate cancer in South Korea, Taiwan, Russia and Australia
Teva	Israel	Worldwide License to TEV-48573 (CD38-Attenukine) and Research Collaboration (Attenukine platform)

Gastroenterology

Partner	Country	Subject
Arcturus	US	RNA- based therapeutics for the treatment of liver disorders
Beacon Discovery	US	G-protein coupled receptor drug development program for gastrointestinal disorders
BioSurfaces, Inc.	US	Research program designed to develop innovative medical devices to treat patients with GI diseases using BioSurfaces' proprietary nanomaterial technology
Cour Pharmaceutical Development Company	US	Immune modulating therapies for the potential treatment of celiac disease and other gastrointestinal diseases, utilizing Cour's Tolerizing Immune Modifying nanoParticle (TIMP) platform
Emulate Bio	US	Drug discovery in inflammatory bowel disease using organ-on-chip microengineered cell models
enGene	Canada	Novel therapies for specialty gastrointestinal (GI) diseases using enGene's "Gene Pill" gene delivery platform
Enterome	France	Microbiome targets thought to play crucial roles in gastrointestinal disorders, including inflammatory bowel diseases (e.g. ulcerative colitis) and motility disorders (e.g. irritable bowel syndrome)
Finch Therapeutics	US	Global agreement to develop FIN-524, a live biotherapeutic product composed of cultured bacterial strains linked to favorable clinical outcomes in studies of microbiota transplantations in inflammatory bowel disease
Hemoshear Therapeutics	US	Novel target and therapeutic development using Hemoshear's proprietary REVEAL-Tx drug discovery platform
Karolinska Institutet & Structural Genomics Consortium	Sweden	Proprietary collaboration to discover and validate new potential intervention points for the treatment of inflammatory bowel disease
NuBiyota	Canada	Development of Microbial Ecosystem Therapeutic products for gastroenterology indications
PvP Biologics	US	Global agreement to develop Kuma062, a novel enzyme designed to break down the immune-reactive parts of gluten in the stomach
Theravance Biopharma	US	Global agreement for TAK-954, a selective 5-HT4 receptor agonist for motility disorders

Neuroscience

Partner	Country	Subject
Affilogic	France	Affilogic's proprietary Nanofitins [®] platform in therapies targeting the central nervous system
AstraZeneca	UK	Joint development and commercialization of MEDI1341, an alpha-synuclein antibody currently in development as a potential treatment for Parkinson's disease
Cerevence	US, UK	Discovery and development of novel therapeutics for neurological and psychiatric disorders
Denali Therapeutics	US	A strategic option and collaboration agreement to develop and commercialize up to three specified therapeutic product candidates for neurodegenerative diseases, incorporating Denali's ATV platform for increased exposure of biotherapeutic products in the brain.
Lundbeck	Denmark	Collaboration to develop and commercialize vortioxetine
Mindstrong Health	US	Explore development of digital biomarkers for selected mental health conditions, in particular schizophrenia and treatment-resistant depression
Ovid Therapeutics	US	Development of TAK-935, an oral CH24H inhibitor for rare pediatric epilepsies. Takeda and Ovid Therapeutics will share in the development and commercialization costs of TAK-935 on a 50/50 basis and, if successful, share in the profits on a 50/50 basis.
Teva	Israel	Collaboration to develop and commercialize Rasagiline
Wave Life Sciences	US	Research, development and commercial collaboration and multi-program option agreement to develop antisense oligonucleotides for a range of neurological diseases

Vaccines

Partner	Country	Subject
U.S. Government - The Biomedical Advanced Research and Development Authority (BARDA)	US	Partnership to develop TAK-426, a Zika vaccine candidate, to support the Zika response in the US and affected regions around the world
Bill & Melinda Gates Foundation	US	Partnership to develop TAK-195, a Sabin-strain Inactivated Polio vaccine (sIPV) candidate, to support polio eradication in developing countries
Zydus Cadila	India	Partnership to develop TAK-507, a Chikungunya vaccine candidate, to tackle an emerging and neglected infectious disease in the world

Other / Multiple Therapeutic Area

Partner	Country	Subject
AMED	Japan	Development of a novel drug for hypertrophic cardiomyopathy using iPSC cells-derived cardiomyocytes with disease-causing mutations induced by gene-editing technology (CiCLE: Cyclic Innovation for Clinical Empowerment by AEMD)
Arix Bioscience	UK	Value creation through venture and biotech partnerships
Arcellx	US	Develops format for T cell-mediated anti-tumor therapy.
ArmaGen	US	ArmaGen's proprietary technology platform takes advantage of the body's natural system to non-invasively deliver therapeutics to the brain.
Atlas Ventures	US	Fund XI Limited Partner to drive venture investments
Astellas, Daiichi Sankyo	Japan	Fundamental biomarker data on healthy adult volunteers in order to optimize and accelerate the development of innovative medicines
BioMotiv	US	Therapeutic accelerator to identify and develop pioneering medical innovations specifically in the therapeutic areas of immunology & inflammation and cardio-metabolic diseases
BioMx	Israel	Discovered and validated proprietary bacterial targets, and develop rationally designed phage therapies that seek and destroy harmful bacteria in microbiome-related diseases such as inflammatory bowel disease (IBD) and cancer
Bridge Medicines	US	Building upon Tri-I TDI, Bridge Medicines will give financial, operational and managerial support to move projects seamlessly from a validating, proof-of-concept study to an in-human clinical trial
Center for iPSC Cell Research Application, Kyoto University	Japan	Clinical applications of iPSC cells in Takeda strategic areas including applications in neurosciences, oncology and GI as well as discovery efforts in additional areas of compelling iPSC translational science
Cortexyme	US	Cortexyme is developing therapeutics based on data supporting a new theory of the cause of Alzheimer's and other degenerative disorders.
Dementia Discovery Fund (DDF)	UK	New global investment fund to support discovery and development of novel dementia treatments
Emendo	Israel	Emendo is at the forefront of cutting-edge genetic medicine, developing genome editing technology that can repair and eliminate genetic mutations in living cells that cause serious diseases or disorders
Fujifilm	Japan	Collaboration to develop regenerative medicine therapies using cardiomyocytes derived from iPSC for the treatment of heart failure.
FutuRx	Israel	Israel seed stage venture fund/biotech accelerator to access innovation in Israel; de-risked through pre-formed syndication
Harrington Discovery Institute at University Hospitals in Cleveland, Ohio	US	Collaboration for the advancement of medicines for rare diseases
HITGen	China	HitGen will apply its advanced technology platform, based on DNA-encoded library design, synthesis and screening, to discover novel leads which will be licensed exclusively to Takeda
HiFiBio	US	Functional therapeutics high-throughput antibody discovery platform that enables identification of antibodies for rare events for discovery of therapeutic antibodies for GI & Oncology therapeutic areas.

Hoopkipa Biotech	Austria	Value creation through venture and biotech partnerships
Isogenica	UK	Access to a sdAb platform to generate a toolbox of VHH to various immune cells and targets for pathway validation and pipeline development across Oncology and GI portfolio
National Cancer Center of Japan	Japan	A partnership to develop basic research to clinical development by promoting exchanges among researchers, physicians, and others engaged in anti-cancer drug discovery and cancer biology research
Numerate	US	Joint-discovery programs aimed at identifying clinical candidates for use in Takeda's core therapeutic areas: oncology, gastroenterology, and central nervous system disorders, which is using its AI-driven platform, from hit finding and expansion through lead design/optimization and ADME toxicity modeling
OrphoMed	US	OrphoMed is a clinical-stage biotechnology company with a proprietary dimer therapeutics platform. The company is focused on developing best-in class treatments for patients with gastrointestinal disorders.
Obsidian Therapeutics	US	Obsidian is developing next-generation cell and gene therapies with pharmacologic operating systems
Presage	US	Presage uses CIVO [®] , a platform that enables assessment of multiple early stage agents simultaneously and directly in the context in which they were meant to be used—the human patient
Portal Instruments	US	The development and commercialization of Portal's needle-free drug delivery device for potential use with Takeda's investigational or approved biologic medicines.
Recursion Pharmaceuticals	US	Provide pre-clinical candidates for Takeda's TAK-celerator™ development pipeline
Ribon Therapeutics	US	Ribon Therapeutics is pioneering the discovery and development of monoPARP (mono ADP-ribose polymerase) inhibitors to block cancer cells' fundamental ability to survive under stress.
Schrödinger	US	Multi-target research collaboration combining Schrödinger's in silico platform-driven drug discovery capabilities with Takeda's deep therapeutic area knowledge and expertise in structural biology.
Seattle Collaboration	US	SPRInT (Seattle Partnership for Research on Innovative Therapies): accelerate the translation of Fred Hutchinson Cancer Research Center's and University of Washington's cutting-edge discoveries into treatments for human disease (focusing on Oncology, GI and Neuroscience)
Stanford University	US	Collaboration with Stanford University to form the Stanford Alliance for Innovative Medicines (Stanford AIM) to more effectively develop innovative treatments and therapies.
Stride Bio	US	StrideBio develops engineered viral vectors for gene therapy for the treatment of rare diseases. StrideBio's technology engine utilizes structure-inspired design to engineer AAV vectors which can escape pre-existing neutralizing antibodies (NAbs).
Trianni, Inc.	US	Trianni's transgenic mouse platform to identify fully human monoclonal antibodies against disease targets in all therapeutic areas
Tri-Institutional Therapeutics Discovery Institute (Tri-I TDI)	US	Collaboration of academic institutions and industry to more effectively develop innovative treatments and therapies
Ultragenyx	US	Collaboration to develop and commercialize therapies for rare genetic diseases
Univercells	Belgium	Univercells is a technology company delivering novel biomanufacturing platforms, aiming at making biologics available & affordable to all
VHsquared	UK	VHsquared is a clinical stage company developing transformational therapies – Vorabodies™ – for inflammatory bowel disease. (Note: A Vorabody is an oral domain antibody)

Note: List is not inclusive of all Takeda R&D collaborations

Completed Partnerships

Partner	Country	Subject
Gencia LLC	US	Mitochondrial Associated Glucocorticoid Receptors (MAGR) agonists for potential use primarily in hematological and inflammatory diseases
Prana Biotechnology Ltd.	Australia	Collaboration with Takeda to study ability of Prana's pbt434, to slow or prevent neurodegeneration of gastrointestinal system
TiGenix	Belgium	Ex-U.S. rights to Cx601 for complex perianal fistulas in Crohn's disease
Keio University, Niigata University, Kyoto University	Japan	The search for and functional analysis of disease-related RNA-binding proteins, that may lead to treatments in the areas such as neuroscience and oncology

■ Clinical study protocol summaries

Clinical study protocol summaries are disclosed on the English-language web-site (<https://takedaclinicaltrials.com/>) and clinical study protocol information in the Japanese-language is disclosed on the Japanese-language web-site (<https://www.takeda.com/jp/what-we-do/research-and-development/takeda-clinical-trial-transparency/>).

We anticipate that this disclosure will assure transparency of information on Takeda's clinical trials for the benefit of healthcare professionals, their patients and other stakeholders, which we believe will contribute to the appropriate use of Takeda's products worldwide.

Appendix

◆ Prescription Drugs: US major products' sales (in US\$) *¹ (Million US\$)

	FY15	FY16	FY17	FY17 Q1	FY18 Q1	YOY	
Entyvio	524	913	1,202	278	387	109	39.3%
Velcade	1,059	1,000	995	268	235	-32	-12.1%
Trintellix	203	294	435	101	130	30	29.4%
Uloric	347	380	411	101	128	27	27.1%
Dexilant	530	457	445	115	120	5	4.2%
Ninlaro	34	267	354	81	103	22	26.8%
Colcrys	386	358	362	87	85	-1	-1.6%
Amitiza	308	310	303	77	72	-5	-6.2%
Iclusig	-	22	171	40	55	15	37.8%
Prevacid (lansoprazole)	222	179	132	33	18	-15	-46.0%
Alunbrig	-	-	25	2	10	8	-

*1 Product sales (royalty income and service income are excluded).

◆ Prescription Drugs: Japan major products' sales

(Billion JPY)

	Launched	Therapeutic Class	FY15	FY16	FY17	FY17 Q1	FY18 Q1	YOY	
Azilva * ¹	(12. 5)	Hypertension	59.0	66.9	64.0	16.8	19.4	2.6	15.5%
Takecab * ¹	(15. 2)	Acid-related Diseases	8.4	34.1	48.5	11.3	14.2	3.0	26.4%
Leuplin (leuprorelin)	(92. 9)	Prostate cancer, breast cancer and endometriosis	53.8	48.6	41.2	11.0	10.5	-0.5	-4.7%
Enbrel	(05. 3)	Rheumatoid arthritis	40.8	40.4	37.1	9.9	9.9	-0.0	-0.0%
Lotriga	(13. 1)	Hyperlipidemia	22.3	27.5	28.5	7.2	8.1	0.9	13.2%
Nesina * ¹	(10. 6)	Diabetes	36.9	32.9	26.6	7.3	7.8	0.5	6.8%
Vectibix	(10. 6)	Colorectal cancer	18.4	18.8	18.9	5.0	5.4	0.4	8.0%
Reminyl	(11. 3)	Alzheimer-type dementia	16.0	17.4	16.1	4.3	4.5	0.2	4.7%
Rozerem	(10. 7)	Insomnia	7.4	8.1	8.0	2.1	2.5	0.4	19.4%
Benet	(02. 5)	Osteoporosis	9.7	8.3	6.8	1.9	1.7	-0.2	-10.2%
Adcetris	(14. 4)	Malignant Lymphoma	3.1	3.3	3.8	1.0	1.1	0.1	10.8%
Ninlaro	(17. 5)	Multiple Myeloma	-	-	2.5	0.2	1.2	0.9	-
Azilect	(18. 6)	Parkinson's disease	-	-	-	-	0.3	0.3	-

*1 The figures include the amounts of fixed dose combinations and blister packs.

*2 Effective from FY2018, sales of certain products in Japan are now disclosed on a net basis, deducting items such as discounts and rebates, in alignment with the global managerial approach applied to individual product sales. The change in disclosure of individual product sales has been revised retrospectively, with prior year figures reclassified on a net basis to enable year-on-year comparisons. This reclassification has no impact on Takeda's financial statements and does not represent a correction of prior year figures.

◆ Consumer Healthcare: Japan major products' sales

(Billion JPY)

	FY15	FY16	FY17	FY17 Q1	FY18 Q1	YOY	
Alinamin tablet	25.2	24.1	25.1	7.4	5.3	-2.1	-28.5%
Alinamin drink	14.9	16.1	14.7	3.9	3.6	-0.3	-6.8%
Benza	9.8	10.0	9.3	1.2	1.0	-0.2	-15.9%
Borraginol	4.5	4.5	4.5	1.1	0.9	-0.1	-12.8%
Mytear	4.2	3.9	4.0	0.8	0.8	0.0	0.8%
Midori-no-Shukan	1.1	2.7	3.4	0.9	0.7	-0.1	-13.2%

*1 This table shows sales amount of Takeda Consumer Healthcare Company Limited (TCHC) in Japan. TCHC succeeded the business of Takeda's Japan Consumer Healthcare Business Unit (JCHBU), and started its business on April 1, 2017 as the new company.

*2 Effective from FY2018, sales of certain products in Japan are now disclosed on a net basis, deducting items such as discounts and rebates, in alignment with the global managerial approach applied to individual product sales. The change in disclosure of individual product sales has been revised retrospectively, with prior year figures reclassified on a net basis to enable year-on-year comparisons. This reclassification has no impact on Takeda's financial statements and does not represent a correction of prior year figures.



Takeda Pharmaceutical Company Limited