July 29, 2016

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Financial Results of Astellas for the First Three Months of FY2016 (IFRS)

Japan, July 29, 2016 – Astellas Pharma Inc. (hereinafter referred to as "the Company") today announced the financial results for the first three months (April 1, 2016- June 30, 2016) of the fiscal year 2016 (FY2016) ending March 31, 2017.

Consolidated financial results for the first three months of FY2016 (April 1, 2016 – June 30, 2016) (core basis)

(Millions of yen)

	First three months of FY2015	**First three months of FY2016**	Change (%)
Sales	343,659	**337,752**	-5,907 (-1.7%)
Core operating profit	67,820	**93,951**	+26,131 (+38.5%)
Core profit for the period	45,031	**67,148**	+22,117 (+49.1%)
Basic core earnings per share (yen)	20.57	**31.60**	+11.03 (+53.6%)

Cautionary Notes
In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.
Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

1. Qualitative information on consolidated financial results for the first three months of FY 2016

(1) Information on business performance

<Consolidated financial results (core basis [(Note)])>

Consolidated financial results (core basis) in the first three months of FY2016 showed a decrease in sales and increases in core operating profit and core profit for the period as follows.

Consolidated financial results (core basis)

(Millions of yen)

	First three months of FY2015	**First three months of FY2016**	Change (%)
Sales	343,659	**337,752**	-5,907 (-1.7%)
Core operating profit	67,820	**93,951**	+26,131 (+38.5%)
Core profit for the period	45,031	**67,148**	+22,117 (+49.1%)
Basic core earnings per share (yen)	20.57	**31.60**	+11.03 (+53.6%)

Research and development (R&D) expenses

(Millions of yen)

	First three months of FY2015	**First three months of FY2016**	Change
R&D expenses	55,980	**51,022**	-4,958 (-8.9%)

(Note) The Company discloses financial results on a core basis as an indicator of its recurring profitability. Certain items reported in financial results on a full basis that are deemed to be non-recurring items by the Company are excluded as non-core items from these financial results on a core basis. These adjusted items include impairment losses, gain/loss on sales of property, plant and equipment, restructuring costs, loss on disaster, a large amount of losses on compensation or settlement of litigations and other legal disputes, and other items that are deemed to be excluded based on the Company's judgment. A reconciliation table between results on a full basis and results on a core basis is provided on page 22 of the "Supplement Documents for Results Q1/FY2016."

Impact of foreign exchange on financial results

The foreign exchange rates for the yen in the first three months of FY2016 are shown in the table below. The resulting impacts were a ¥25.6 billion decrease in sales and a ¥0.4 billion increase in core operating profit compared with if the exchange rates of the three months of FY2015 were applied.

Average rate	First three months of FY2015	**First three months of FY2016**	Change
US$/¥	121	**108**	¥13 (Strengthening of yen)
€/¥	134	**122**	¥12 (Strengthening of yen)

Change from beginning to end of period	As of June 30, 2015	**As of June 30, 2016**
US$/¥	¥2 (Weakening of yen)	**¥10 (Strengthening of yen)**
€/¥	¥7 (Weakening of yen)	**¥13 (Strengthening of yen)**

Sales

Consolidated sales in the first three months of FY2016 decreased by 1.7% compared to those in the corresponding period of the previous fiscal year ("year-on-year") to ¥337.8 billion.

- Consolidated sales decreased due to the negative impacts such as a NHI drug price revision in Japan enforced in April 2016 as well as the impact of foreign exchange.
- In terms of global products, sales of XTANDI for the treatment of prostate cancer and overactive bladder ("OAB") treatments Vesicare and Betanis / Myrbetriq / BETMIGA grew. Meanwhile, sales of Prograf, an immunosuppressant, decreased due to foreign exchange while sales of Prograf increased on a constant currency exchange rate basis.

Sales by region

*Sales by region calculated according to locations of sellers.

<Japan>

Sales in Japan decreased by 1.1% year-on-year to ¥124.2 billion. Sales in the Japanese market decreased by 6.1% year-on-year to ¥114.8 billion due to the negative impacts such as the NHI drug price revision.

- There was growth in sales of products including OAB treatments Vesicare and Betanis, the anti-inflammatory and anti-pain treatment Celecox, and Symbicort for the treatment of bronchial asthma.

- Sales of XTANDI decreased due to the NHI drug price revision.
- Sales of Vaccines declined mainly due to the continued impact of the restrain of shipment by manufacturer in FY2015, in addition, sales of products including Lipitor for the treatment of hypercholesterolemia and Gaster for the treatment of peptic ulcer and gastritis declined, mainly due to the impact of generics.

<The Americas>

Sales in the Americas decreased by 6.3% year-on-year to ¥107.6 billion. The sales on a U.S. dollar basis increased by 5.2% year-on-year to US$995 million.

- Sales of XTANDI grew and azole antifungal CRESEMBA contributed to sales.
- Sales of products including OAB treatments VESIcare and Myrbetriq, Prograf and the pharmacologic stress agent Lexiscan decreased due to the impact of foreign exchange. The sales of each product on a U.S. dollar basis increased.

<EMEA>

Sales in EMEA increased by 4.4% year-on-year to ¥85.3 billion. The sales on a euro basis increased by 14.8% year-on-year to €699 million.

- Sales of XTANDI grew.
- Sales of overall OAB treatments Vesicare and BETMIGA.
- Prograf declined mainly due to the impact of foreign exchange. The sales of Prograf on a local currency basis increased.

* EMEA: Europe, the Middle East and Africa.

<Asia and Oceania>

Sales in Asia and Oceania decreased by 3.8% year-on-year to ¥20.7 billion.

- XTANDI, overall OAB treatments Vesicare and BETMIGA, and Harnal for the treatment of functional symptoms of benign prostatic hyperplasia showed growth in sales.
- Sales of Prograf declined due to the impact of foreign exchange.

Core operating profit / Core profit for the period

- Gross profit increased by 5.0% year-on-year to ¥266.3 billion, because a decrease in cost of sales exceeded a decrease in sales. The cost-to-sales ratio fell 5.1 percentage points year-on-year to 21.2%, owing to changes in the product mix and the foreign exchange rate impact from the elimination of unrealized gains in intra-group transactions.
- Selling, general and administrative expenses decreased by 5.7% year-on-year to ¥111.9 billion partly due to the foreign exchange rate impact.
- Research and development (R&D) expenses decreased by 8.9% year-on-year to ¥51.0 billion partly due to the impact of foreign exchange, although steady progress of development was shown. The R&D cost-to-sales ratio was down 1.2 percentage points year-on-year to 15.1%.
- Amortization of intangible assets was ¥9.0 billion, down 17.5% year-on-year.

As a result of the above, core operating profit increased by 38.5% year-on-year to ¥94.0 billion. Meanwhile, core profit for the period increased by 49.1% year-on-year to ¥67.1 billion and basic core earnings per share increased by 53.6% year-on-year to ¥31.60.

Resulting from the transfer of the global dermatology business in April 2016, the sales and the expenses of the transferred products were not included in the first three month of FY2016. On the other hand, consideration of the business transfer was recognized as revenue over certain periods. As a result, there were certain positive impacts on sales and profit for the first three months of FY2016.

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first three months of FY2016 are shown in the table below. Sales decreased while operating profit, profit before tax and profit for the period increased.

The full basis financial results include “other expense” (including impairment losses, loss on sales of property, plant and equipment, restructuring costs), and gain on sales of available-for-sale financial assets (included in “finance income”) which are both excluded from the core basis financial results.
“Other expense” in the first three months of FY2016 was ¥1.3 billion (¥7.2 billion in the same period of the previous fiscal year). Gain on sales of available-for-sale financial assets in the first three months of FY2016 was ¥0.7 billion (¥5.5 billion in the same period of the previous fiscal year).

Consolidated financial results (full basis)

(Millions of yen)

	First three months of FY2015	**First three months of FY2016**	Change (%)
Sales	343,659	**337,752**	-5,907 (-1.7%)
Operating profit	61,911	**92,866**	+30,955 (+50.0%)
Profit before tax	67,664	**93,184**	+25,521 (+37.7%)
Profit for the period	44,622	**66,613**	+21,991 (+49.3%)
Basic earnings per share (yen)	20.38	**31.35**	+10.97 (+53.8%)
Comprehensive income	71,834	**-34,006**	-105,840 (-)

(2) Information on financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of June 30, 2016 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets saw a decrease of ¥105.7 billion compared to the end of the previous fiscal year to ¥1,693.6 billion.

<Non-current assets> ¥854.7 billion (a decrease of ¥47.1 billion)

- Other intangible assets decreased by ¥16.1 billion compared to the end of the previous fiscal year to ¥319.6 billion.

<Current assets> ¥838.9 billion (a decrease of ¥58.6 billion)

- Cash and cash equivalents decreased by ¥48.0 billion compared to the end of the previous fiscal year to ¥312.0 billion.

Equity

Total equity as of June 30, 2016 saw a decrease of ¥68.7 billion compared to the end of the previous fiscal year to ¥1,190.5 billion, making the ratio of owners' equity to gross assets 70.3%.

- While profit for the period stood at ¥66.6 billion, the Company paid ¥34.0 billion of dividends of surplus.
- In addition, the effect of foreign currency translation adjustments decreased equity by ¥95.1 billion.
- Cancellation of treasury shares totaling ¥110.2 billion (68 million shares) was carried out on June 20, 2016.

Liabilities

Total liabilities decreased by ¥37.0 billion compared to the end of the previous fiscal year to ¥503.1 billion.

<Non-current liabilities> ¥106.5 billion (a decrease of ¥20.2 billion)
<Current liabilities> ¥396.6 billion (a decrease of ¥16.8 billion)

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities decreased year-on-year by ¥11.5 billion to ¥18.2 billion.

- Income tax paid was ¥23.2 billion.

Cash flows from investing activities

Net cash flows used in investing activities was ¥6.6 billion, a decrease in outflow of ¥1.7 billion year-on-year.

- Purchases of property, plant and equipment used cash of ¥7.4 billion, a decrease in outflow of ¥1.8 billion year-on-year.

Cash flows from financing activities

Net cash flows used in financing activities was ¥35.2 billion, a decrease in outflow of ¥21.0 billion year-on-year.

- Dividends paid totaled ¥34.0 billion, a decrease in outflow of ¥1.1 billion.

Additionally, cash and cash equivalents decreased ¥24.4 billion due to effect of exchange rate changes. As a result, cash and cash equivalents totaled ¥312.0 billion as of June 30, 2016, a decrease of ¥48.0 billion compared to the end of the previous fiscal year.

(3) Information on consolidated business forecasts for FY2016 and other forward-looking statements

The Company's business forecasts for FY2016 are presented on a core basis and full basis.
The consolidated full-year business forecasts for FY2016 are shown below. The Company has chosen to leave its business forecasts unchanged from the consolidated full-year business forecasts announced in May 2016 because it does not expect large deviations from the forecasts.

Consolidated full-year business forecasts (core basis)

(Millions of yen)

	FY2015 Results	**FY2016 Forecasts**	Change (%)
Sales	1,372,706	**1,350,000**	-22,706 (-1.7%)
Core operating profit	267,456	**270,000**	2,544 (1.0%)
Core profit for the year	198,802	**199,000**	198 (0.1%)
Basic core earnings per share (yen)	92.12	**93.65**	1.53 (1.7%)

Consolidated full-year business forecasts (full basis)

(Millions of yen)

	FY2015 Results	**FY2016 Forecasts**	Change (%)
Sales	1,372,706	**1,350,000**	-22,706 (-1.7%)
Operating profit	248,986	**267,000**	18,014 (7.2%)
Profit before tax	261,770	**268,000**	6,230 (2.4%)
Profit for the year	193,687	**197,000**	3,313 (1.7%)
Basic earnings per share (yen)	89.75	**92.71**	2.96 (3.3%)

Expected foreign exchange rate for FY2016	**¥110/US$**	**¥125/€**
Foreign exchange rate for FY2015	¥120/US$	¥133/€

2. Matters Related to Summary Information (Notes)

(1) Changes in Accounting Policies and Accounting Estimates

The significant accounting policies adopted for the condensed interim consolidated financial statements of Astellas Pharma Inc. and its subsidiaries (collectively, the"Group") for the three months ended 30 June 2016 are the same as those applied for its consolidated financial statements for the fiscal year ended 31 March 2016.

The Group calculated income tax expense for the three months ended 30 June 2016 based on the estimated average annual effective tax rate.

3. Condensed Interim Consolidated Financial Statements
(1) Condensed Interim Consolidated Statement of Income

（Millions of yen）

	Three months ended 30 June 2015	Three months ended 30 June 2016
Sales	343,659	337,752
Cost of sales	(90,079)	(71,465)
Gross profit	253,581	266,287
Selling, general and administrative expenses	(118,662)	(111,885)
Research and development expenses	(55,980)	(51,022)
Amortisation of intangible assets	(10,882)	(8,982)
Share of losses of associates and joint ventures	(236)	(446)
Other income	1,262	230
Other expense	(7,171)	(1,315)
Operating profit	61,911	92,866
Finance income	6,029	1,218
Finance expense	(277)	(899)
Profit before tax	67,664	93,184
Income tax expense	(23,042)	(26,572)
Profit for the period	44,622	66,613
Profit attributable to:		
Owners of the parent	44,622	66,613
Earnings per share		
Basic（Yen）	20.38	31.35
Diluted（Yen）	20.35	31.31

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended 30 June 2015	Three months ended 30 June 2016
Profit for the period	44,622	66,613
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Remeasurements of defined benefit plans	1,254	(1,496)
Subtotal	1,254	(1,496)
Items that may be reclassified subsequently to profit or loss		
Foreign currency translation adjustments	28,762	(95,141)
Fair value movements on available-for-sale financial assets	(2,803)	(3,981)
Subtotal	25,959	(99,122)
Other comprehensive income, net of tax	27,213	(100,618)
Total comprehensive income	71,834	(34,006)
Total comprehensive income attributable to:		
Owners of the parent	71,834	(34,006)

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of 31 March 2016	As of 30 June 2016
Assets		
Non-current assets		
Property, plant and equipment	200,955	192,135
Goodwill	152,920	139,661
Other intangible assets	335,698	319,620
Trade and other receivables	24,103	26,599
Investments in associates and joint ventures	2,435	1,829
Deferred tax assets	81,497	79,980
Other financial assets	89,424	81,581
Other non-current assets	14,769	13,294
Total non-current assets	901,801	854,699
Current assets		
Inventories	161,691	158,219
Trade and other receivables	327,599	336,070
Income tax receivable	16,403	3,303
Other financial assets	14,394	12,726
Other current assets	17,221	16,624
Cash and cash equivalents	360,030	311,985
Sub total	897,337	838,927
Assets held for sale	200	—
Total current assets	897,537	838,927
Total assets	1,799,338	1,693,626

(Millions of yen)

	As of 31 March 2016	As of 30 June 2016
Equity and liabilities		
Equity		
Share capital	103,001	103,001
Capital surplus	176,903	176,913
Treasury shares	(157,111)	(47,405)
Retained earnings	973,054	893,849
Other components of equity	163,363	64,169
Total equity attributable to owners of the parent	1,259,209	1,190,527
Total equity	1,259,209	1,190,527
Liabilities		
Non-current liabilities		
Trade and other payables	1,599	1,158
Retirement benefit liabilities	39,797	39,295
Provisions	7,083	8,491
Other financial liabilities	722	828
Other non-current liabilities	77,569	56,758
Total non-current liabilities	126,769	106,531
Current liabilities		
Trade and other payables	181,559	158,790
Income tax payable	19,312	9,116
Provisions	89,858	81,074
Other financial liabilities	1,505	36,486
Other current liabilities	121,126	111,101
Total current liabilities	413,359	396,568
Total liabilities	540,129	503,099
Total equity and liabilities	1,799,338	1,693,626

(4) Condensed Interim Consolidated Statement of Changes in Equity

(Millions of yen)

	Equity attributable to owners of the parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Subscription rights to shares	Foreign currency translation adjustments
As of 1 April 2015	103,001	176,822	(86,997)	905,083	2,241	177,306
Comprehensive income						
Profit for the period	—	—	—	44,622	—	—
Other comprehensive income	—	—	—	—	—	28,762
Total comprehensive income	—	—	—	44,622	—	28,762
Transactions with owners of the parent						
Acquisition of treasury shares	—	—	(20,937)	—	—	—
Disposals of treasury shares	—	—	76	(37)	(39)	—
Cancellation of treasury shares	—	—	49,577	(49,577)	—	—
Dividends	—	—	—	(35,090)	—	—
Share-based payments	—	—	—	—	73	—
Transfers	—	—	—	1,254	—	—
Total transactions with owners of the parent	—	—	28,716	(83,450)	34	—
As of 30 June 2015	103,001	176,822	(58,281)	866,255	2,274	206,068

As of 1 April 2016	103,001	176,903	(157,111)	973,054	2,126	132,134
Comprehensive income						
Profit for the period	—	—	—	66,613	—	—
Other comprehensive income	—	—	—	—	—	(95,141)
Total comprehensive income	—	—	—	66,613	—	(95,141)
Transactions with owners of the parent						
Acquisition of treasury shares	—	—	(765)	—	—	—
Disposals of treasury shares	—	(78)	253	(103)	(71)	—
Cancellation of treasury shares	—	—	110,219	(110,219)	—	—
Dividends	—	—	—	(34,000)	—	—
Share-based payments	—	88	—	—	—	—
Transfers	—	—	—	(1,496)	—	—
Total transactions with owners of the parent	—	10	109,706	(145,817)	(71)	—
As of 30 June 2016	103,001	176,913	(47,405)	893,849	2,055	36,993

(Millions of yen)

	Equity attributable to owners of the parent				Total equity
	Other components of equity			Total	
	Fair value movements on available-for-sale financial assets	Remeasurements of defined benefit plans	Total		
As of 1 April 2015	40,461	—	220,007	1,317,916	1,317,916
Comprehensive income					
Profit for the period	—	—	—	44,622	44,622
Other comprehensive income	(2,803)	1,254	27,213	27,213	27,213
Total comprehensive income	(2,803)	1,254	27,213	71,834	71,834
Transactions with owners of the parent					
Acquisition of treasury shares	—	—	—	(20,937)	(20,937)
Disposals of treasury shares	—	—	(39)	0	0
Cancellation of treasury shares	—	—	—	—	—
Dividends	—	—	—	(35,090)	(35,090)
Share-based payments	—	—	73	73	73
Transfers	—	(1,254)	(1,254)	—	—
Total transactions with owners of the parent	—	(1,254)	(1,220)	(55,954)	(55,954)
As of 30 June 2015	37,658	—	246,000	1,333,796	1,333,796

As of 1 April 2016	29,103	—	163,363	1,259,209	1,259,209
Comprehensive income					
Profit for the period	—	—	—	66,613	66,613
Other comprehensive income	(3,981)	(1,496)	(100,618)	(100,618)	(100,618)
Total comprehensive income	(3,981)	(1,496)	(100,618)	(34,006)	(34,006)
Transactions with owners of the parent					
Acquisition of treasury shares	—	—	—	(765)	(765)
Disposals of treasury shares	—	—	(71)	0	0
Cancellation of treasury shares	—	—	—	—	—
Dividends	—	—	—	(34,000)	(34,000)
Share-based payments	—	—	—	88	88
Transfers	—	1,496	1,496	—	—
Total transactions with owners of the parent	—	1,496	1,425	(34,677)	(34,677)
As of 30 June 2016	25,122	—	64,169	1,190,527	1,190,527

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended 30 June 2015	Three months ended 30 June 2016
Cash flows from operating activities		
Profit before tax	67,664	93,184
Depreciation and amortisation	17,374	15,970
Impairment losses and reversal of impairment losses	6,357	—
Finance income and expense	(5,752)	(318)
(Increase) decrease in inventories	4,174	(10,947)
(Increase) decrease in trade and other receivables	(23,149)	(36,638)
Increase (decrease) in trade and other payables	(31,544)	(5,253)
Other	20,378	(14,678)
Cash generated from operations	55,501	41,320
Income tax paid	(25,859)	(23,170)
Net cash flows from operating activities	29,642	18,150
Cash flows from investing activities		
Purchases of property, plant and equipment	(9,236)	(7,420)
Proceeds from sales of property, plant and equipment	342	485
Purchase of intangible assets	(5,924)	(1,012)
Purchase of available-for-sale financial assets	(8)	(189)
Proceeds from sales of available-for-sale financial assets	7,922	993
Interest and dividends received	576	572
Other	(1,922)	(11)
Net cash flows used in investing activities	(8,250)	(6,583)
Cash flows from financing activities		
Acquisition of treasury shares	(20,937)	(765)
Dividends paid to owners of the parent	(35,090)	(34,000)
Other	(196)	(472)
Net cash flows used in financing activities	(56,223)	(35,237)
Effect of exchange rate changes on cash and cash equivalents	9,937	(24,375)
Net increase (decrease) in cash and cash equivalents	(24,893)	(48,044)
Cash and cash equivalents at the beginning of the year	396,430	360,030
Cash and cash equivalents at the end of the period	371,537	311,985

(6) Notes to condensed interim consolidated financial statements

Notes on going concern assumption

Not applicable.

Business Combination

For the three months ended 30 June 2016

On 10 February 2016, Ocata Therapeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.) became a consolidated subsidiary of Astellas Pharma Inc. through tender offer to purchase all issued and outstanding shares of common stock in cash.

During the three months ended 30 June 2016, further facts came to light and additional analysis was performed on the fair value measurement of the assets acquired and liabilities assumed at the acquisition date. As a result, the provisional fair value was adjusted as follows:

(Millions of yen)

	Provisional fair value	Fair value adjustments	Provisional fair value (as adjusted)
Property, plant and equipment	151	－	151
Other intangible assets	17,456	(3,736)	13,720
Deferred tax assets	3,167	1,327	4,494
Cash and cash equivalents	1,084	－	1,084
Other assets	41	－	41
Other liabilities	(2,494)	－	(2,494)
Fair value of assets acquired and liabilities assumed (net)	19,405	(2,409)	16,996
Goodwill	24,332	2,409	26,741
Total	43,737	－	43,737
Fair value of purchase consideration transferred	43,737	－	43,737

Due to the adjustments of the provisional fair value at the acquisition date, the Group retrospectively revised the corresponding balance in the condensed interim consolidated statement of financial position as of 31 March 2016. As a result, “Goodwill” and “Deferred tax assets” increased by 2,260 million yen and 1,245 million yen respectively, while “Other intangible assets” decreased by 3,504 million yen.

The initial accounting for the business combination is incomplete as of 30 June 2016 as the Group is still in the process of finalizing the fair value measurement.

Supplementary Documents [IFRS]

Financial results for the first three months of the fiscal year 2016 (FY2016)

Astellas Pharma Inc.

- Q1/FY2016 Financial Results
- Pipeline list

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Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

1. Consolidated Results (Full Basis)

Unit: B¥

	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 Change (%)
Sales	343.7	337.8	-5.9	-1.7%	1,350.0	-1.7%
Cost of sales	90.1	71.5	-18.6	-20.7%		
Ratio to Sales	26.2%	21.2%				
Gross profit	253.6	266.3	12.7	5.0%		
SG&A expenses	118.7	111.9	-6.8	-5.7%		
Ratio to Sales	34.5%	33.1%				
Advertising and Sales Promotion	41.6	35.8	-5.8	-13.9%		
Personnel expenses	45.1	43.5	-1.6	-3.5%		
Other	32.0	32.6	0.6	1.9%		
R&D expenses	56.0	51.0	-5.0	-8.9%	231.0	2.4%
Ratio to Sales	16.3%	15.1%			17.1%	
Amortisation of intangible assets	10.9	9.0	-1.9	-17.5%		
Share of losses of associates and joint ventures	-0.2	-0.4	-0.2	-		
Other income	1.3	0.2	-1.0	-81.8%		
Gain on sales of property, plant and equipment	0.1	0.0	-0.1	-89.6%		
Net foreign exchange gains	0.6	-	-0.6	-		
Other expense	7.2	1.3	-5.9	-81.7%		
Loss on sales and disposal of property, plant and equipment	0.1	0.1	0.0	39.8%		
Impairment losses	6.6	-	-6.6	-		
Net foreign exchange losses	-	0.4	0.4	-		
Operating profit	61.9	92.9	31.0	50.0%	267.0	7.2%
Ratio to Sales	18.0%	27.5%			19.8%	
Finance income	6.0	1.2	-4.8	-79.8%		
Gain on sales of available-for-sale financial assets	5.5	0.7	-4.8	-88.1%		
Finance expense	0.3	0.9	0.6	225.1%		
Impairment losses for available-for-sale financial assets	0.0	0.3	0.3	888.3%		
Profit before tax	67.7	93.2	25.5	37.7%	268.0	2.4%
Ratio to Sales	19.7%	27.6%			19.9%	
Income tax expense	23.0	26.6	3.5	15.3%		
Profit for the period	44.6	66.6	22.0	49.3%	197.0	1.7%
Ratio to Sales	13.0%	19.7%			14.6%	
Comprehensive income for the period	71.8	-34.0	-105.8	-		

2. Consolidated Results (Core Basis)

Unit: B¥

	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 Change (%)
Sales	343.7	337.8	-5.9	-1.7%	1,350.0	-1.7%
Cost of sales	90.1	71.5	-18.6	-20.7%		
Ratio to Sales	26.2%	21.2%				
Gross profit	253.6	266.3	12.7	5.0%		
SG&A expenses	118.7	111.9	-6.8	-5.7%		
Ratio to Sales	34.5%	33.1%				
Advertising and Sales Promotion	41.6	35.8	-5.8	-13.9%		
Personnel expenses	45.1	43.5	-1.6	-3.5%		
Other	32.0	32.6	0.6	1.9%		
R&D expenses	56.0	51.0	-5.0	-8.9%	231.0	2.4%
Ratio to Sales	16.3%	15.1%			17.1%	
Amortisation of intangible assets	10.9	9.0	-1.9	-17.5%		
Share of losses of associates and joint ventures	-0.2	-0.4	-0.2	-		
Operating profit	67.8	94.0	26.1	38.5%	270.0	1.0%
Ratio to Sales	19.7%	27.8%			20.0%	
Finance income	0.6	0.6	0.0	2.8%		
Finance expense	0.1	0.6	0.5	624.3%		
Profit before Tax	68.3	93.9	25.6	37.5%		
Ratio to Sales	19.9%	27.8%				
Income tax expense	23.3	26.8	3.5	15.1%		
Profit for the period	45.0	67.1	22.1	49.1%	199.0	0.1%
Ratio to Sales	13.1%	19.9%			14.7%	

3. Exchange Rate

Unit: yen

	FY15 APR. - JUN.Ave.	FY16 APR. - JUN.Ave.	FY15 End	FY16 Q1 End	Forecasts FY16 Full Year
USD/Yen	121	108	113	103	110
EUR/Yen	134	122	128	114	125

* Exchange rate fluctuations had negative impact by 25.6 billion yen on sales and positive impact by 0.4 billion yen on Core operating profit in Q1/FY2016

4. Reconciliation of Full Basis to Core Basis

Unit: B¥

	FY15 APR. - JUN.			FY16 APR. - JUN.		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	**343.7**	**-**	**343.7**	**337.8**	**-**	**337.8**
Cost of sales	90.1	-	90.1	71.5	-	71.5
Gross profit	**253.6**	**-**	**253.6**	**266.3**	**-**	**266.3**
SG&A expenses	118.7	-	118.7	111.9	-	111.9
R&D expenses	56.0	-	56.0	51.0	-	51.0
Amortisation of intangible assets	10.9	-	10.9	9.0	-	9.0
Share of losses of associates and joint ventures	-0.2	-	-0.2	-0.4	-	-0.4
Other income *1	1.3	-1.3	-	0.2	-0.2	-
Other expense *1	7.2	-7.2	-	1.3	-1.3	-
Operating profit	**61.9**	**5.9**	**67.8**	**92.9**	**1.1**	**94.0**
Finance income *2	6.0	-5.5	0.6	1.2	-0.7	0.6
Finance expense *2	0.3	-0.2	0.1	0.9	-0.3	0.6
Profit before tax	**67.7**	**0.6**	**68.3**	**93.2**	**0.7**	**93.9**
Income tax expense	23.0	0.2	23.3	26.6	0.2	26.8
Profit for the period	**44.6**	**0.4**	**45.0**	**66.6**	**0.5**	**67.1**

*1. “Other income” and “Other expense” are excluded from Core results.
“Other income” and “Other expense” include gain/loss on sale and disposal of property, plant and equipment, impairment losses, loss on the restructuring, litigation costs and foreign exchange gains/losses, etc.

*2. Gain/loss on sale of available-for-sale (“AFS”) and impairment losses of AFS included in “Finance income” and “Finance expense” are excluded from Core results as non-core items.

5. Sales by Region

Unit: B¥

		FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 (%)
Sales		343.7	337.8	-5.9	-1.7%	1,350.0	-1.7%
	Japan	125.6	124.2	-1.4	-1.1%	480.8	-3.3%
	Ratio to Sales	36.6%	36.8%			35.6%	
	Americas	114.8	107.6	-7.2	-6.3%	441.2	-3.1%
	Ratio to Sales	33.4%	31.8%			32.7%	
	EMEA	81.7	85.3	3.6	4.4%	339.6	3.1%
	Ratio to Sales	23.8%	25.3%			25.2%	
	Asia and Oceania	21.5	20.7	-0.8	-3.8%	88.3	-3.1%
	Ratio to Sales	6.3%	6.1%			6.5%	

- Calculated according to locations of sellers.
- EMEA: Europe, the Middle East and Africa

6. Depreciation/Amortisation

Unit: B¥

		FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 (%)
Depreciation (PP&E)							
	Consolidated	5.0	5.5	0.5	9.9%	22.0	5.0%
Amortisation (Intangible Assets) *							
	Consolidated	12.4	10.4	-1.9	-15.4%	43.5	-9.8%

* Amortisation (Intangible Assets): Including amortisation of software, etc.

7. Sales of major products

1) Sales of global products

Unit: B¥

	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 Change (%)
XTANDI	59.1	64.2	5.2	8.7%	295.9	17.4%
US	36.2	35.7	-0.5	-1.4%	163.7	10.3%
ex-US	22.8	28.5	5.7	24.8%	132.2	27.5%
Japan	6.8	6.1	-0.7	-10.7%	25.7	-2.0%
Americas (ex-US)	1.0	1.8	0.7	70.0%	6.1	36.3%
EMEA	14.6	20.0	5.4	37.0%	95.9	35.8%
Asia and Oceania	0.4	0.7	0.3	62.5%	4.5	88.2%
Eligard	4.4	4.4	-0.0	-0.1%	17.6	0.1%
EMEA	4.4	4.4	-0.0	-0.6%	17.3	-0.7%
Asia and Oceania	0.0	0.1	0.0	59.5%	0.3	67.7%
Vesicare	35.4	30.4	-5.0	-14.0%	119.1	-12.2%
Japan	6.8	7.0	0.1	1.7%	27.2	2.7%
Americas	17.1	13.6	-3.5	-20.5%	53.7	-15.7%
EMEA	10.2	8.7	-1.5	-14.8%	32.4	-18.7%
Asia and Oceania	1.2	1.2	-0.0	-3.3%	5.4	2.8%
Betanis/Myrbetriq/BETMIGA	18.1	23.6	5.5	30.1%	100.4	22.8%
Japan	4.9	6.4	1.6	32.5%	27.4	29.0%
Americas	9.8	12.9	3.1	31.4%	51.9	13.7%
EMEA	3.3	3.5	0.2	6.4%	18.3	36.4%
Asia and Oceania	0.1	0.7	0.6	606.9%	2.8	94.5%
Harnal/Omnic	14.2	12.1	-2.1	-14.6%	46.4	-13.1%
Sales by Astellas	13.3	11.5	-1.8	-13.3%	44.2	-12.3%
Japan	3.4	2.6	-0.9	-25.1%	9.4	-25.7%
EMEA	4.7	3.7	-1.1	-22.5%	13.7	-11.5%
Asia and Oceania	5.0	5.2	0.2	3.3%	20.5	-4.6%
Bulk and Royalties	0.9	0.6	-0.3	-34.4%	2.2	-26.8%
Prograf	50.4	49.4	-1.0	-1.9%	187.9	-7.7%
Sales by Astellas	49.9	48.7	-1.2	-2.4%	185.4	-7.6%
Japan (Including Graceptor)	12.7	12.9	0.2	1.4%	47.8	-3.9%
Americas	8.4	7.7	-0.7	-8.4%	26.9	-22.3%
EMEA	19.6	19.0	-0.6	-2.8%	73.6	-5.5%
Advagraf	7.5	7.9	0.4	5.1%		
Asia and Oceania	9.2	9.0	-0.1	-1.3%	37.1	-3.5%
Exports to third parties	0.5	0.8	0.2	45.6%	2.5	-13.1%
Funguard/MYCAMINE	10.3	10.0	-0.3	-2.5%	40.4	-3.0%
Japan	2.9	2.7	-0.2	-7.0%	11.5	-1.7%
Americas	3.3	3.1	-0.2	-4.9%	11.8	-9.8%
EMEA	2.8	2.8	-0.1	-2.8%	11.2	-0.4%
Asia and Oceania	1.3	1.5	0.2	14.9%	6.0	4.7%

- Sales of products in Japan are shown in a gross sales basis.
- EMEA: Europe, the Middle East and Africa

2) Sales of products in Japan

Unit: B¥

<Global products>	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 Change (%)
XTANDI	6.8	6.1	-0.7	-10.7%	25.7	-2.0%
Vesicare	6.8	7.0	0.1	1.7%	27.2	2.7%
Betanis	4.9	6.4	1.6	32.5%	27.4	29.0%
Harnal	3.4	2.6	-0.9	-25.1%	9.4	-25.7%
Prograf （Including Graceptor）	12.7	12.9	0.2	1.4%	47.8	-3.9%
Funguard	2.9	2.7	-0.2	-7.0%	11.5	-1.7%
<Local products in Japan>						
Micardis [Family]	24.8	24.7	-0.1	-0.4%	90.8	-6.5%
Micombi	2.7	2.5	-0.1	-4.8%		
Micamlo	6.5	6.8	0.3	5.2%		
Celecox	11.8	12.4	0.6	4.9%	50.4	8.2%
Symbicort	9.0	9.8	0.8	9.3%	41.1	9.9%
Bonoteo	3.7	3.6	-0.0	-0.8%	15.1	7.1%
Geninax	2.8	2.5	-0.3	-12.5%	10.2	-6.1%
Vaccines	6.6	3.8	-2.8	-42.4%	25.9	-37.1%
Argamate	1.5	1.5	-0.0	-0.4%	6.1	-1.4%
Kiklin	0.4	0.4	-0.0	-1.6%	2.0	28.7%
Gonax	0.9	1.1	0.1	14.7%	4.6	17.6%
Cimzia	1.6	1.9	0.3	20.8%	9.6	47.1%
Suglat	2.0	2.3	0.3	14.9%	12.5	71.1%
Lipitor	8.3	6.4	-1.9	-22.8%	22.4	-27.4%
Myslee	4.7	3.9	-0.7	-15.8%	14.6	-18.5%
Gaster	3.9	3.0	-1.0	-24.6%	10.5	-28.3%
Seroquel	3.0	2.2	-0.7	-25.3%	7.2	-31.3%
Total Rx Sales In Japanese market	122.2	114.8	-7.5	-6.1%	456.6	-5.5%

- Sales of products in Japan are shown in a gross sales basis.

3) Sales of products in Americas and EMEA

Unit: B¥

	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 Change (%)
Tarceva	13.1	9.4	-3.7	-28.4%		
(US)	9.7	6.8	-2.9	-30.2%		
(ex-US)	3.4	2.6	-0.8	-23.3%		
Scan* (Americas)	20.8	19.3	-1.5	-7.3%	70.1	-8.0%
AmBisome (Americas)	2.8	2.4	-0.4	-12.9%	9.8	-10.3%
CRESEMBA (Americas)	0.3	1.3	1.0	346.4%	5.0	91.5%
Qutenza (EMEA)	0.5	0.6	0.1	10.3%		
DIFICLIR (EMEA)	0.6	0.6	-0.0	-6.9%		

* Adenoscan + Lexiscan

- EMEA: Europe, the Middle East and Africa

4) Sales in Americas and EMEA (Local currency)

Unit: M$

Americas	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 (%)
Sales	946	995	49	5.2%	4,011	5.9%
XTANDI	307	347	40	12.9%	1,544	21.3%
US	298	330	32	10.7%	1,488	20.5%
Americas (ex-US)	9	16	8	90.8%	56	48.9%
Tarceva	108	87	-21	-19.6%		
US	80	63	-17	-21.6%		
ex-US	28	24	-4	-13.9%		
VESIcare	141	126	-15	-10.7%	488	-8.0%
Myrbetriq	81	119	38	47.5%	472	24.2%
Prograf	69	71	2	2.8%	245	-15.1%
Scan*	171	178	7	4.0%	637	0.4%
MYCAMINE	27	29	2	6.7%	107	-1.5%
AmBisome	23	23	-1	-2.2%	89	-2.1%
CRESEMBA	2	12	9	400.9%	45	109.1%

* Adenoscan + Lexiscan

Unit: M€

EMEA	FY15 APR. - JUN.	FY16 APR. - JUN.	Change	Change (%)	Forecasts FY16 Full Year	Change from FY15 (%)
Sales	609	699	90	14.8%	2,717	9.4%
XTANDI	109	164	55	50.6%	767	44.0%
Eligard	33	36	3	9.3%	138	5.4%
Vesicare	76	71	-5	-6.3%	259	-13.7%
BETMIGA	25	29	4	16.9%	146	44.7%
Omnic	42	35	-7	-16.9%	127	-8.8%
Sales by Astellas	35	30	-5	-14.8%	109	-6.1%
Bulk and Royalties	7	5	-2	-27.8%	18	-22.3%
Prograf	150	162	12	8.2%	609	-0.1%
Sales by Astellas	146	156	10	6.8%	589	0.2%
Advagraf	56	65	9	15.6%		
Exports to third parties	4	6	2	59.8%	20	-7.9%
MYCAMINE	21	23	1	6.9%	90	5.7%
Qutenza	4	5	1	21.3%		
DIFICLIR	5	5	0	2.4%		

- EMEA: Europe, the Middle East and Africa

8.Consolidated statements of financial position

Unit: B¥

			31-Mar-16	30-Jun-16	
			Amount	Amount	Change
Assets			**1,799.3**	**1,693.6**	**-105.7**
	Non-current assets		**901.8**	**854.7**	**-47.1**
		Property, plant and equipment	201.0	192.1	-8.8
		Goodwill	152.9	139.7	-13.3
		Other intangible assets	335.7	319.6	-16.1
		Trade and other receivables	24.1	26.6	2.5
		Investments in associates and joint ventures	2.4	1.8	-0.6
		Deferred tax assets	81.5	80.0	-1.5
		Other financial assets	89.4	81.6	-7.8
		Other non-current assets	14.8	13.3	-1.5
	Current assets		**897.5**	**838.9**	**-58.6**
		Inventories	161.7	158.2	-3.5
		Trade and other receivables	327.6	336.1	8.5
		Income tax receivable	16.4	3.3	-13.1
		Other financial assets	14.4	12.7	-1.7
		Other current assets	17.2	16.6	-0.6
		Cash and cash equivalents	360.0	312.0	-48.0
		Assets held for sale	0.2	-	-0.2

- Due to the adjustments of the provisional fair value for the acquisition of Ocata Therepeutics, Inc. (The company name was changed to Astellas Institute for Regenerative Medicine in May 2016.), consolidated statement of financial position as of 31 March, 2016 was retrospectively revised. For the details, refer to Financial Results P.18

Unit: B¥

	31-Mar-16	30-Jun-16	
	Amount	Amount	Change
Equity and Liabilities	**1,799.3**	**1,693.6**	**-105.7**
Equity	**1,259.2**	**1,190.5**	**-68.7**
Equity attributable to owners of the parent	**1,259.2**	**1,190.5**	**-68.7**
Share capital	103.0	103.0	-
Capital surplus	176.9	176.9	0.0
Treasury shares	-157.1	-47.4	109.7
Retained earnings	973.1	893.8	-79.2
Other components of equity	163.4	64.2	-99.2
Liabilities	**540.1**	**503.1**	**-37.0**
Non-current liabilities	**126.8**	**106.5**	**-20.2**
Trade and other payables	1.6	1.2	-0.4
Retirement benefit liabilities	39.8	39.3	-0.5
Provisions	7.1	8.5	1.4
Other financial liabilities	0.7	0.8	0.1
Other non-current liabilities	77.6	56.8	-20.8
Current liabilities	**413.4**	**396.6**	**-16.8**
Trade and other payables	181.6	158.8	-22.8
Income tax payable	19.3	9.1	-10.2
Provisions	89.9	81.1	-8.8
Other financial liabilities	1.5	36.5	35.0
Other current liabilities	121.1	111.1	-10.0

R&D Pipeline (As of July 2016)

Underlined items indicate for changes from the previous announcement on May 11, 2016.

1. Global Development

(1) Regulatory decision

*Compounds with "In-house" in this column include ones discovered by collaborative research. (The same applicable hereafter.)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor*	Remarks
YM905 solifenacin	Muscarine M_3 receptor antagonist	Overactive bladder in pediatric patients of 5-18 years	Europe	Oral	In-house	Received a notification for end of procedure for the type 2 variation. The indication was not approved but pediatric information was included in the label to enable patent extension of 6 months.

(2) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
MDV3100 enzalutamide*	Androgen receptor inhibitor	Metastatic castration-resistant prostate cancer (Tablet)	Europe Filed (Mar. 2016)	Oral	Medivation	New formulation

* Withdrew the US sNDA in Feb. 2016 for tablet.

(3) Phase-lll / Phase-ll (1/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
MDV3100 enzalutamide	Androgen receptor inhibitor	Non-metastatic castration-resistant prostate cancer	US/Europe/Asia Phase-III	Oral	Medivation	New indication
		Prostate cancer in patients with non-metastatic biochemical recurrence	US/Europe/Asia Phase-III			New indication
		Metastatic hormone-sensitive prostate cancer	US/Europe/Japan/Asia Phase-III			New indication
		Triple-negative breast cancer	US/Europe/Japan/Asia Phase-III			New indication
		Breast cancer (ER/PgR positive, HER2 positive)	US/Europe Phase-II			New indication
		Hepatocellular carcinoma	US/Europe/Asia Phase-II			New indication

(3) Phase-III / Phase-II (2/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP0113 (VCL-CB01)	DNA vaccine for cytomegalovirus	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe/Japan Phase-III	Injection	Vical	
		Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe Phase-II			
YM905 solifenacin	Muscarine M_3 receptor antagonist	Neurogenic detrusor overactivity in pediatric patients	US/Europe Phase-III	Oral	In-house	New indication (pediatric)
EB178 solifenacin/ mirabegron	Concomitant use of solifenacin and mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	US/Europe/Asia Phase-III	Oral	In-house	
fidaxomicin	Macrocyclic antibiotic	Infectious enteritis (bacterial target: *Clostridium difficile*)	Japan Phase-III	Oral	Merck	
		Clostridium difficile infection in pediatric patients	Europe Phase-III			New indication (pediatric)
ASP015K peficitinib	JAK inhibitor	Rheumatoid arthritis	Japan/Asia Phase-III US/Europe Phase-II	Oral	In-house	
ASP1517 (FG-4592) roxadustat	HIF stabilizer	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe Phase-III Japan Phase-III	Oral	FibroGen	

(3) Phase-III / Phase-II (3/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP2215 gilteritinib	FLT3/AXL inhibitor	Acute myeloid leukemia	US/Europe/Japan/Asia Phase-III	Oral	In-house	
		Non-small cell lung cancer	US/Japan/Asia Phase-I			
ASP8273	Mutant-selective irreversible EGFR inhibitor	Non-small cell lung cancer	US/Europe/Japan/Asia Phase-III	Oral	In-house	
YM178 mirabegron	Beta 3 receptor agonist	Neurogenic detrusor overactivity in pediatric patients	Europe Phase-III	Oral	In-house	New indication (pediatric)
YM311 (FG-2216)	HIF stabilizer	Renal anemia	Europe Phase-II Japan Phase-I	Oral	FibroGen	
ASKP1240 bleselumab	Anti-CD40 monoclonal antibody	Recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients*	US Phase-II	Injection	Kyowa Hakko Kirin	
ASP1707	GnRH antagonist	Endometriosis	Europe/Japan Phase-II	Oral	In-house	
		Rheumatoid arthritis	Japan Phase-II			
ASP8232	VAP-1 inhibitor	Diabetic nephropathy	Europe Phase-II	Oral	In-house	
		Diabetic macular edema	US Phase-II			

* It was in the Phase-II stage in the US and Phase-I stage in Japan for prevention of organ transplant rejection. We have decided to focus on recurrence of focal segmental glomerulosclerosis in de novo kidney transplant recipients in future development.

(3) Phase-III / Phase-II (4/4)

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP3662	11beta-HSD1 inhibitor	Painful diabetic peripheral neuropathy	US Phase-II	Oral	In-house	
		Alzheimer's disease	US Phase-I			
CK-2127107	Fast skeletal tropoinin activator	Spinal muscular atrophy	US Phase-II	Oral	Cytokinetics	
		Chronic obstructive pulmonary disease	US Phase-II			
ASP7962	TrkA inhibitior	Osteoarthritis	Europe Phase-II	Oral	In-house	
AGS-16C3F	ADC targeting ENPP3	Renal cell carcinoma	US/Europe Phase-II	Injection	In-house (ADC technology in-licensed from Seattle Genetics)	
RPE cell program	Cell therapy (Retinal pigment epithelium cell)	Dry age-related macular degeneration, Stargardt's macular degeneration	US Phase-II	Injection	In-house (Astellas Institute for Regenerative Medicine)	

2. Local Development: Japan

(1) Filed

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
ASP7374	Influenza vaccine	Prophylaxis of seasonal influenza	Japan Filed (May 2014)	Injection	UMN Pharma	
ASP1585 (AMG 223) bixalomer	Amine-functional polymer	Hyperphosphatemia in patients on dialysis with chronic kidney disease (granule formulation)	Japan Filed (Sept. 2015)	Oral	Amgen	New formulation
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Irritable bowel syndrome with constipation	Japan Filed (Feb. 2016)	Oral	Ironwood	

(2) Phase-III / Phase-II

Code No. Generic Name	Classification	Target Disease	Area / Phase	Dosage Form	Licensor	Remarks
FK949E quetiapine	Serotonin / dopamine antagonist	Depressive episode in bipolar disorders	Japan Phase-III	Oral	AstraZeneca	New indication New formulation
ASP3550 degarelix	GnRH antagonist	Prostate cancer (3-month formulation)	Japan Phase-III	Injection	Ferring	New formulation
AMG 785 romosozumab	Anti-Sclerostin monoclonal antibody	Osteoporosis	Japan Phase-III	Injection	Amgen (co-development with Amgen Astellas)	
ipragliflozin/ sitagliptin	Fixed dose combination of ipragliflozin and sitagliptin	Type 2 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with MSD and Kotobuki)	
ASP1941 ipragliflozin	SGLT2 inhibitor	Type 1 diabetes mellitus	Japan Phase-III	Oral	In-house (co-development with Kotobuki)	New indication
ASP0456 linaclotide	Guanylate cyclase-C receptor agonist	Chronic constipation	Japan Phase-III	Oral	Ironwood	New indication
ASP7373	Influenza vaccine	Prophylaxis of H5N1 influenza	Japan Phase-II	Injection	UMN Pharma	
AMG 103 blinatumomab	Anti-CD19 BiTE	Acute lymphoblastic leukemia	Japan Phase-II	Injection	Amgen (co-development with Amgen Astellas)	

3. Phase-I

Code No. Generic Name	Target Disease	Dosage Form	Licensor
ASG-22ME enfortumab vedotin	Solid tumors, Urothelial cancer	Injection	In-house (co-development with Seattle Genetics)
ASG-15ME	Urothelial cancer	Injection	In-house (co-development with Seattle Genetics)
ASP5878	Cancer	Oral	In-house
AGS67E	Lymphoid Malignancies	Injection	In-house (ADC technology in-licensed from Seattle Genetics)
ASP2205	Stress urinary incontinence	Oral	In-house
ASP5094	Rheumatoid arthritis	Injection	In-house
ASP4132	Cancer	Oral	In-house
ASP4345	Cognitive impairment associated with schizophrenia	Oral	In-house
ASP6282	Underactive bladder	Oral	In-house
ASP4070 (JRC2-LAMP-vax)	Pollinosis caused by Japanese red cedar	Injection	Immunomic Therapeutics
ASP0819	Fibromyalgia	Oral	In-house
ASP8062	Fibromyalgia	Oral	In-house
ASP7398	Nocturia	Oral	In-house
ASP6294	Bladder pain syndrome / Interstitial cystitis	Injection	In-house
ASP7266	Severe asthma	Injection	In-house
ASP0892	Peanut allergy	Injection	Immunomic Therapeutics
AGS62P1	Acute myeloid leukemia	Injection	In-house (ADC technology, EuCODE license from Ambrx)

4. Other items changed from the previous quarterly announcement on May 11, 2016

-Removed the description for new indication of Kiklin (bixalomer), which was approved in February 2016 in Japan.