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Financial Results of Astellas for the First Six Months of FY2015 (IFRS)

Japan, October 30, 2015 – Astellas Pharma Inc. (hereinafter referred to as "the Company") today announced the financial results for the first six months of the fiscal year 2015 (FY2015) ending March 31, 2016.

Consolidated financial results for the first six months of FY2015 (April 1, 2015 – September 30, 2015) (core basis)

(Millions of yen)

	First six months of FY2014	**First six months of FY2015**	Change (%)
Sales	594,453	**687,501**	+93,047 (+15.7%)
Core operating profit	119,175	**145,170**	+25,995 (+21.8%)
Core profit for the period	81,051	**103,938**	+22,887 (+28.2%)
Basic core earnings per share (yen)	36.61	**47.76**	+11.16 (+30.5%)

1. Qualitative information on consolidated financial results for the first six months of FY2015

(1) Information on business performance

1) Overview of the first six months of FY2015

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

Consolidated financial results (core basis) in the first six months of FY2015 showed increases in sales, core operating profit and core profit for the period, as follows.

Consolidated financial results (core basis)

(Millions of yen)

	First six months of FY2014	**First six months of FY2015**	Change (%)
Sales	594,453	**687,501**	+93,047 (+15.7%)
Core operating profit	119,175	**145,170**	+25,995 (+21.8%)
Core profit for the period	81,051	**103,938**	+22,887 (+28.2%)
Basic core earnings per share (yen)	36.61	**47.76**	+11.16 (+30.5%)

Research and development (R&D) expenses

(Millions of yen)

	First six months of FY2014	**First six months of FY2015**	Change
R&D expenses	97,027	**112,041**	+15,014

(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 3 of the "Supplement Documents for Results 2Q/FY2015."

<u>Impact of exchange rate on financial results</u>

The exchange rates for the yen in the first six months of FY2015 are shown in the table below. The resulting impacts were a ¥36.0 billion increase in sales and a ¥9.6 billion increase in core operating profit compared with if the exchange rates of the six months of FY2014 were applied.

Average rate	First six months of FY2014	**First six months of FY2015**	Change
US$/¥	103	**122**	¥19 (Weakening of yen)
€/¥	139	**135**	¥4 (Strengthening of yen)

Change from beginning to end of period	As of September 30, 2014	**As of September 30, 2015**
US$/¥	¥7 (Weakening of yen)	**¥0 (Strengthening of yen)**
€/¥	¥3 (Strengthening of yen)	**¥5 (Weakening of yen)**

<u>Sales</u>

Consolidated sales in the first six months of FY2015 increased by 15.7% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥687.5 billion.

- In addition to XTANDI for the treatment of prostate cancer, sales of overactive bladder (OAB) treatments Vesicare and Betanis / Myrbetriq / BETMIGA grew. Additionally, sales of products including Prograf, an immunosuppressant, increased.

Sales by region

*Sales by region are calculated according to the locations of the sellers.

<u><Japan></u>

Sales in Japan increased by 4.2% year-on-year to ¥247.1 billion. Sales in the Japanese market increased by 4.6% year-on-year to ¥240.0 billion.

- There was growth in sales of XTANDI and other products, including overall sales of OAB treatments Vesicare and Betanis, Prograf, the anti-inflammatory and anti-pain drug Celecox, Symbicort for the treatment of bronchial asthma and Micardis for the treatment of hypertension.
- On the other hand, 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 increased by 38.6% year-on-year to ¥232.9 billion. The sales on a U.S. dollar basis increased by 17.3% year-on-year to US$1,912 million.

- In addition to the sales of XTANDI, overall sales of OAB treatments VESIcare and Myrbetriq grew.
- Sales of products, including Prograf and the pharmacologic stress agent Lexiscan also increased.

<EMEA*>

Sales in EMEA increased by 3.7% year-on-year to ¥162.3 billion. The sales on a euro basis increased by 6.6% year-on-year to €1,201 million.

- In addition to XTANDI and overall OAB treatments Vesicare and BETMIGA, sales of Prograf and others grew.

* EMEA: Europe, Middle East and Africa.

<Asia and Oceania>

Sales in Asia and Oceania increased by 38.3% year-on-year to ¥45.2 billion.

- Products such as Prograf and Harnal for the treatment of functional symptoms of benign prostatic hyperplasia showed growth in sales, resulting in an increase in revenue.
- In addition, XTANDI contributed to increased sales.

Core operating profit / Core profit for the period

- The increase in sales and a decrease in the cost-to-sales ratio resulted in a gross profit of ¥519.1 billion, up 19.2% year-on-year. The cost-to-sales ratio decreased 2.3 percentage points year-on-year to 24.5%, owing to changes in the product mix and other factors.
- Selling, general and administrative expenses increased by 18.8% year-on-year to ¥239.7 billion, which in addition to increased expenditures for co-promotion of XTANDI in the US, was partly due to the foreign exchange rate impact.
- Research and development (R&D) expenses were ¥112.0 billion, up 15.5% year-on-year, which in addition to increased expenses related to progress of development projects, was partly due to the foreign exchange rate impact. The R&D cost-to-sales ratio remained largely unchanged year-on-year at 16.3%.
- Amortisation of intangible assets was ¥21.9 billion, up 22.1% year-on-year.

As a result of the above, core operating profit increased by 21.8% year-on-year to ¥145.2 billion. Meanwhile, core profit for the period increased by 28.2% year-on-year to ¥103.9 billion and basic core earnings per share increased by 30.5% year-on-year to ¥47.76.

<Consolidated financial results (full basis)>

Consolidated financial results on a full basis in the first six months of FY2015 are shown below. Sales, operating profit, profit before tax and profit for the period increased.

Items at a total of ¥13.4 billion, including impairment losses for property, plant and equipment and net foreign exchange losses, which are excluded from results on a core basis, were recorded in "other expense." In addition, gain on sales of available-for-sale financial assets at a total of ¥12.1 billion was recorded in "finance income." "Other expense" and gain on sales of available-for-sale financial assets in the same period of the previous fiscal year were ¥20.8 billion and ¥1.0 billion, respectively.

Consolidated financial results (full basis)

(Millions of yen)

	First six months of FY2014	**First six months of FY2015**	Change (%)
Sales	594,453	**687,501**	+93,047 (+15.7%)
Operating profit	103,187	**132,637**	+29,450 (+28.5%)
Profit before tax	102,671	**145,418**	+42,747 (+41.6%)
Profit for the period	69,984	**102,933**	+32,949 (+47.1%)
Basic earnings per share (yen)	31.61	**47.30**	+15.69 (+49.7%)
Comprehensive income	87,780	**104,868**	+17,088 (+19.5%)

2) Other

The Company has been pursuing initiatives geared towards achieving sustainable growth over the mid to long term, and in May 2015 accordingly released its three-year Strategic Plan 2015–2017 which sets forth three main strategies geared toward: "Maximizing the Product Value," "Creating Innovation" and "Pursuing Operational Excellence."

<Initiatives for Maximizing the Product Value>

We have been taking steps toward maximizing the Company's OAB franchise comprised of Vesicare and Betanis / Myrbetriq / BETMIGA, and also maximizing its oncology franchise centered on XTANDI. We also obtained approval for new products, including the aforementioned in various countries and launched sales of such products.

<Initiatives for Creating Innovation>

With respect to our strategy of creating innovation, the source of our sustainable growth, we have been further enhancing our capabilities to deliver innovative medicine while actively advancing into new opportunities. Accordingly, we have added Muscle Diseases and Ophthalmology as new therapeutic areas (TAs) for prioritized disease area for research to our existing TAs given focus thus far which include Urology, Oncology, Immunology, Nephrology and Neuroscience, and have otherwise been aiming to create new drugs by taking advantage of collaboration with external partners.

With respect to drug discovery research, we have been promoting open innovation in the drug discovery process by employing a network research system which involves appointing optimal personnel and researchers (Best Talent) from both inside and outside the Company to undertake dynamic research activities in the best possible environments (Best Place), and based on the world's most innovative science (Best Science). Moreover, we have been working to reduce research and development period and streamline expenses by adopting the FASTEN (FAST-Ex-NEW-standard) framework and thereby engaging in multi-track research and development processes.

With respect to clinical development, we have been further reinforcing our global development organization and system while accelerating the speed of product development by concentrating management resources on high-priority projects. The following are the main development advances made during the first six months of FY2015.

Global Development project

- With respect to Vesicare (generic name: solifenacin succinate, development code: YM905), the Company submitted an application for approval in Europe in September 2015 for the indication of overactive bladder in pediatric patients of 5-18 years.

Local Development projects by region

Japan

- With respect to Irribow (generic name: ramosetron hydrochloride, development code: YM060) for the treatment of diarrhea-predominant irritable bowel syndrome, the Company obtained approval in May 2015 for the additional indication of diarrhea-predominant irritable bowel syndrome in females.

- With respect to Cimzia (generic name: certolizumab pegol) for the treatment of adult patients with rheumatoid arthritis, the Company obtained approval in May 2015 for the additional indication of rheumatoid arthritis in patients without previous treatment with anti-rheumatic drugs.
- With respect to Kiklin (generic name: bixalomer, development code: ASP1585) for the treatment of hyperphosphatemia, the Company submitted an application for approval in September 2015 for granule formulation.

EMEA

- With respect to Qutenza (generic name: capsaicin) for the treatment of peripheral neuropathic pain, the Company obtained approval in August 2015 for the additional indication of peripheral neuropathic pain in diabetic patients.

The following are the alliances with outside organizations made during the first six months of FY2015.

Initiatives for alliances with outside organizations, etc. in R&D

- In April 2015, the Company announced the signing a memorandum of understanding with MSD K.K. for co-development and co-commercialization of combination product of selective DPP-4 inhibitor JANUVIA and selective SGLT2 inhibitor Suglat in Japan.
- In April 2015, the Company entered into an option agreement with The University of Texas MD Anderson Cancer Center (US) regarding research and development of a monoclonal antibody drug for patients with acute myeloid leukemia.
- In April 2015, the Company entered into an agreement with Potenza Therapeutics, Inc. (US) for exclusive research and development collaboration geared towards building a portfolio of immuno-oncology therapeutics.
- In May 2015, the Company entered into an agreement with Anokion SA (Switzerland) for research collaboration focused on discovery of therapeutic drugs for treating autoimmune disease based on technology for the induction of immune tolerance.
- In July 2015, the Company announced the initiation of collaborative research with the National Institute of Advanced Industrial Science and Technology (AIST), utilizing Astellas' own protein-ligand complex structural information and AIST's highly advanced IT drug-discovery technologies.
- In September 2015, the Company entered into a license and collaboration agreement with Chromocell Corporation (US) for the development and commercialization of new therapeutics to treat neuropathic pain and other pain conditions.

<Initiatives for Pursuing Operational Excellence>

We have been continuing to engage in initiatives in anticipation of changing environments from various perspectives with the aims of creating organizations and systems capable of resiliently

responding to changing environments and further improving quality and efficiency of operations.
The following are the main initiatives taken in the first six months of FY2015.

- In July 2015, the Company established the Real World Informatics and Analytics (RWI) function in the aim of making available the big data that was previously deployed in the respective functions or departments, and concentrating this capability as a single dedicated function, in order to maximize big data utilization in the Company.
- In August 2015, the Company reached agreement with Maruishi Pharmaceutical Co., Ltd. involving succession to Maruishi Pharmaceutical Co., Ltd. of the manufacturing and marketing approval for suxamethonium muscle relaxant which the Company manufactures and markets in Japan as of October 1, 2015.
- In August 2015, the Company announced that it will change to a new Sales (Medical Representative (MR)) structure in Japan as of October 1, 2015. This will allow MR to provide more accurate medical information based on the flow of patient treatment by each region and by each individual medical institution.

(2) Information on financial position

1) Assets, equity and liabilities

An overview of the consolidated statement of financial position as of September 30, 2015 and the main changes from the end of the previous fiscal year are shown below.

Assets

Total assets as of September 30, 2015 saw a decrease of ¥22.9 billion compared to the end of the previous fiscal year to ¥1,770.7 billion.

<Non-current assets> ¥817.1 billion (a decrease of ¥10.5 billion)

- Other intangible assets decreased by ¥10.2 billion compared to the end of the previous fiscal year to ¥285.7 billion.

<Current assets> ¥953.6 billion (a decrease of ¥12.4 billion)

- Cash and cash equivalents decreased by ¥8.3 billion compared to the end of the previous fiscal year to ¥388.1 billion.

Equity

Total equity as of September 30, 2015 saw an increase of ¥5.2 billion compared to the end of the previous fiscal year to ¥1,323.1 billion, making the ratio of owners' equity to gross assets 74.7%.

- While profit for the period stood at ¥102.9 billion, the Company paid ¥35.1 billion of dividends of surplus and acquired ¥64.7 billion of own shares.
- Cancellation of treasury shares totaling ¥49.6 billion (38 million shares) was carried out on May 29, 2015.
- In addition, the effect of foreign currency translation adjustments increased equity by ¥9.8 billion.

Liabilities

Total liabilities decreased by ¥28.1 billion compared to the end of the previous fiscal year to ¥447.6 billion.

<Non-current liabilities> ¥52.4 billion (a decrease of ¥2.4 billion)
<Current liabilities> ¥395.2 billion (a decrease of ¥25.7 billion)

2) Cash flow

Cash flows from operating activities

Net cash flows from operating activities decreased year-on-year by ¥4.9 billion to ¥95.0 billion.

- Income tax paid was ¥43.3 billion, an increase in outflow of ¥5.5 billion year-on-year.

Cash flows from investing activities

Net cash flows used in investing activities was ¥6.8 billion, a decrease in outflow of ¥9.7 billion year-on-year.

- Purchases of property, plant and equipment used cash of ¥14.6 billion and purchase of intangible assets used cash of ¥7.6 billion, while proceeds from sales of available-for-sale financial assets provided cash of ¥16.4 billion.

Cash flows from financing activities

Net cash flows used in financing activities was ¥100.2 billion, an increase in outflow of ¥38.7 billion year-on-year.

- Dividends paid totaled ¥35.1 billion, an increase in outflow of ¥3.9 billion year-on-year. Other outflow included cash of ¥64.7 billion used for the acquisition of own shares.

As a result of the above, cash and cash equivalents totaled ¥388.1 billion as of September 30, 2015, a decrease of ¥8.3 billion compared to the end of the previous fiscal year.

(3) Information on consolidated business forecasts for FY2015 and other forward-looking statements

Consolidated full-year business forecasts (core basis [(Note)])

(Millions of yen – fractions rounded)

	FY2014 Full-year results	**FY2015 Full-year forecasts**	Change (%)
Sales	1,247,259	**1,384,000**	+136,741 (+11.0%)
Core operating profit	216,500	**244,000**	+27,500 (+12.7%)
Core profit for the year	153,244	**175,000**	+21,756 (+14.2%)
Basic core earnings per share (yen)	69.37	**80.76**	+11.39 (+16.4%)

(Note) The definition of financial results on a core basis is described in page 2.

Expected exchange rate for

FY2015 ¥121/US$ ¥133/€

(Expected exchange rate for the last six months of FY2015: ¥120/US$, ¥130/€)

FY2014 (Result) ¥110/US$ ¥139/€

Consolidated full-year business forecasts on a core basis are shown in the table above.
The Company has upwardly revised its forecasts for consolidated sales, core operating profit and core profit for the year from the figures announced in May 2015 ("initial forecasts") based on the trend of financial results for the first six months of FY2015 and the trend of foreign exchange rates. Fluctuations in the foreign exchange rate are anticipated to cause a ¥19.9 billion increase in sales and a ¥3.9 billion increase in core operating profit compared to if the expected exchange rates of the initial forecast were applied.
The Company forecasts consolidated sales of ¥1,384.0 billion (upwardly revised by ¥22.0 billion from initial forecasts). Global sales of products including XTANDI, OAB treatments Vesicare and Betanis / Myrbetriq / BETMIGA are projected to exceed initial forecasts. Looking at sales by region, sales are projected to exceed initial forecasts in the Americas, EMEA, and Asia and Oceania. Sales in the Japanese market, however, are projected to be below initial forecasts.
In addition to the projection that sales will exceed initial forecasts, the cost-to-sales ratio is expected to be below initial estimation as a result of changes in product mix and other factors. Consequently, gross profit is projected to exceed initial estimation.
The Company forecasts R&D expenses of ¥238.0 billion (upwardly revised by ¥9.0 billion from initial forecasts). Selling, general and administrative expenses are projected to exceed initial estimation, mainly reflecting an expectation of increases in expenditures for co-promotion related to XTANDI in the US.

As a result of the above, the Company forecasts core operating profit of ¥244.0 billion (upwardly revised by ¥6.0 billion from initial forecasts) and core profit for the year of ¥175.0 billion (upwardly revised by ¥5.0 billion from initial forecasts).

Consolidated full-year business forecasts (full basis)

(Millions of yen – fractions rounded)

	FY2014 Full-year results	**FY2015 Full-year forecasts**	Change (%)
Sales	1,247,259	**1,384,000**	+136,741 (+11.0%)
Operating profit	185,663	**229,000**	+43,337 (+23.3%)
Profit before tax	189,683	**242,000**	+52,317 (+27.6%)
Profit for the year	135,856	**172,000**	+36,144 (+26.6%)
Basic earnings per share (yen)	61.50	**79.37**	+17.88 (+29.1%)

Consolidated full-year business forecasts on a full basis are shown in the table above.
The Company has revised its forecasts upwardly for consolidated sales, downwardly for operating profit and upwardly for profit before tax and profit for the year, from initial forecasts announced in May 2015.
The Company forecasts consolidated sales of ¥1,384.0 billion (upwardly revised by ¥22.0 billion from initial forecasts).
The Company forecasts operating profit of ¥229.0 billion (downwardly revised by ¥9.0 billion from initial forecasts), mainly because ¥16.0 billion is forecasted as “other expense” excluded from forecasts on a core basis,” such as impairment losses for property, plant and equipment and net foreign exchange losses.
Moreover, the Company forecasts profit for the year of ¥172.0 billion (upwardly revised by ¥2.0 billion from initial forecasts), which includes the forecast that “finance income,” such as a gain on sales of available-for-sale financial assets and “finance expense,” such as an impairment loss on available-for-sale financial assets will net a gain of ¥13.0 billion.