

Astellas Reports Financial Results for the First Nine Months of FY2017

- Sales (-0.6%) and core operating profit (-8.8%) decreased due to the impact of certain items such as the transfer of the global dermatology business in April 2016 and the transfer of long-listed products in Japan in April 2017. Excluding these items, as well as the impact of foreign exchange, sales decreased -1.3% and core operating profit -2.6%, respectively.
- Sales of key global products such as XTANDI® for the treatment of prostate cancer and Betanis® / Myrbetriq® / BETMIGA® for the treatment of overactive bladder (“OAB”) grew.
- Operating profit (-22.3%) and profit for the period (-20.2%) on a full basis decreased mainly due to the impact of one-time impairment losses and charges associated with the review of development project plans and the wind-down of research operations of subsidiary Agensys, Inc. being recorded during the first six months of FY2017.

Tokyo, January 31, 2018 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced the financial results for the first nine months of fiscal year 2017 ending March 31, 2018 (“FY2017”).

“Key global products including XTANDI® continued to demonstrate steady growth in the first nine months of FY2017. We achieved many milestones including the acquisition of Mitobridge, Inc. in January 2018 by exercising the option right to acquire Mitobridge. The transaction accelerates Astellas’ research and development in diseases associated with mitochondrial dysfunctions,” said Yoshihiko Hatanaka, president and CEO, Astellas. “We remain committed to creating innovative medical solutions and delivering value for patients and all stakeholders, as we continue to advance our strategic plan by maximizing the value of our products, creating innovation and pursuing operational excellence.”

Consolidated Financial Results (April 1, 2017 – December 31, 2017) (core basis)

(Millions of yen)

	First nine months of FY2016	First nine months of FY2017	Change (%)
Sales	1,005,587	999,443	Δ6,144 (Δ0.6%)
Core operating profit	241,837	220,459	Δ21,378 (Δ8.8%)
Core profit for the period	177,189	167,877	Δ9,312 (Δ5.3%)

Quarterly Revenue Highlights

Sales in the first nine months of FY2017 decreased 0.6% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥999.4 billion due to the impact of certain items such as the transfer of the global dermatology business in April 2016 and the transfer of long-listed products in Japan in April 2017.

- Oncology franchise

Sales of XTANDI® increased 16.2% year-on-year to ¥219.9 billion. Sales grew steadily in all regions including Japan, the Americas, EMEA¹ and the Asia and Oceania region.

- Urology OAB franchise

Sales of Betanis® / Myrbetriq® / BETMIGA® increased 30.0% year-on-year to ¥93.1 billion. Sales increased in all regions of the world. Sales of Vesicare®, however, decreased 12.1% year-on-year to ¥78.5 billion.

- Transplantation franchise

Sales of Prograf® increased 5.6% year-on-year to ¥150.2 billion, and continued to grow in Japan, EMEA and the Asia and Oceania regions.

- Other new and key products

In the Japanese market, continued growth was achieved for products such as Celecox® for the treatment of inflammation and pain, Symbicort® for the treatment of bronchial asthma, Suglat® for the treatment of type 2 diabetes, and Cimzia® for the treatment of adult patients with rheumatoid arthritis. Meanwhile, we are working to further penetrate the hypercholesterolemia market following our launch of Repatha®, which occurred in April 2016, and of LINZESS® for the treatment of irritable bowel syndrome with constipation, which launched in March 2017. In the Americas, sales of azole antifungal CRESEMBA® grew.

(Billions of yen)

	First nine months of FY2016	First nine months of FY2017	Change
Oncology franchise	232.3	260.8	+12.3%
XTANDI®	189.2	219.9	+16.2%
Urology OAB franchise	160.9	171.6	+6.6%
Vesicare®	89.3	78.5	Δ12.1%
Betanis® / Myrbetriq® / BETMIGA®	71.6	93.1	+30.0%
Transplantation franchise	142.2	150.2	+5.6%

Sales by Region²

Sales in Japan and EMEA decreased, while sales in the Americas and the Asia and Oceania region increased. As for the Japanese market, sales decreased 13.7% year on year to ¥309.0 billion largely due to the impact of transferring 16 long-listed products in April 2017, and the introduction of generics for Micardis[®] for the treatment of hypertension in June 2017. In EMEA, sales decreased due to the impact of transferring the dermatology business in April 2016, yet sales showed an increase when calculated excluding this impact.

FY2017 Guidance

The company's business forecasts for FY2017 remain unchanged from the consolidated full-year business forecasts announced in October 2017.

Strategic Quarterly Highlights

Astellas continues to create sustainable growth over the mid-to-long term through the pursuit of three main strategies: "Maximizing the Product Value," "Creating Innovation" and "Pursuing Operational Excellence." The company achieved multiple accomplishments against these strategies as outlined below:

Maximizing the Product Value

- Continued to maximize the growth of the Oncology franchise centered on XTANDI[®] and the Urology OAB franchise including Vesicare[®] and Betanis[®] / Myrbetriq[®] / BETMIGA[®] with new launches across various countries and a growth in franchise sales globally.
- Extended the agreement pertaining to the sale of Telmisartan (Micardis[®] family) in October 2017.
- Concluded a co-promotion agreement with MSD K.K. for a combination drug of the DPP-4 inhibitor sitagliptin phosphate hydrate and the SGLT2 inhibitor ipragliflozin L-Proline for the treatment of type-2 diabetes in Japan in November 2017.

Creating Innovation

- Launched "JOINUS," a new drug discovery program using a drug-repositioning compound library jointly conducted by Astellas, Mitsubishi Tanabe Pharma, and Daiichi Sankyo, in October 2017.
- Announced a collaboration utilizing Universal Donor Cell Technology to create a cell therapy product that can be administered to any recipient without the need for human leukocyte antigen matching.in October 2017.
- Announced – and completed – execution of Astellas' exclusive option right to acquire Mitobridge in December 2017 and January 2018, respectively.

The following lists the main development advances achieved during this quarter of FY2017:

- Announced that the first Phase 3 trial in Japan evaluating roxadustat for anemia in chronic kidney disease patients demonstrated positive efficacy results in October 2017.

- Submitted a new drug application for Gonax[®] 12-week extended-release formulation for treatment of prostate cancer in Japan in November 2017.

- (1) EMEA: Europe, the Middle East and Africa
- (2) Sales by Region: based on location of sellers

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at <https://www.astellas.com/en>.

Cautionary Notes

In this press release, 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 press release is not intended to constitute an advertisement or medical advice.

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