

Press Release

Astellas Reports First Quarter FY2017 Financial Results

- Sales (-4.5%), core operating profit (-30.7%) and core profit (-22.7%) for the period decreased due to the impacts such as the transfer of the global dermatology business in April 2016 and the transfer of long-listed products in Japan in April 2017.
- Sales of XTANDI® (enzalutamide) for the treatment of prostate cancer grew. Sales of overactive bladder (“OAB”) treatments Betanis® / Myrbetriq® / BETMIGA® (mirabegron) expanded, while total sales of OAB treatments including Vesicare® (solifenacin succinate) decreased.
- Astellas continues to create solid and resilient growth over the mid-to-long term.

Tokyo, July 28, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) today announced the financial results for the first quarter of fiscal year 2017 (“FY2017”), ending March 31, 2018.

“Financial results for the first quarter of FY2017 were in line with our expectations and the previously announced consolidated forecasts. Although some development programs were discontinued, the rest of our development activities are progressing steadily, and the acquisition of Ogeda expanded Astellas’ late-stage clinical pipeline including fezolinetant,” 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 through maximizing the product value, creating innovation and pursuing operational excellence.”

Consolidated Financial Results (April 1, 2017 – June 30, 2017) (core basis)

(Millions of yen)

	Q1 FY2016	Q1 FY2017	Changes (%)
Sales	337,752	322,571	-15,182 (-4.5%)
Core operating profit	93,951	65,124	-28,827 (-30.7%)
Core profit for the year	67,148	51,914	-15,233 (-22.7%)
Basic core earnings per share (yen)	31.60	25.14	-6.46 (-20.4%)

Quarterly Revenue Highlights

Sales in the first three months of FY2017 decreased by 4.5% compared to those in the corresponding period of the previous fiscal year (“year-on-year”) to ¥322.6 billion due to impacts 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 by 5.8% year-on-year to ¥67.9 billion. Sales in the United States (“U.S.”) decreased, but sales grew steadily in Japan, the Americas excluding the U.S., EMEA¹, Asia and Oceania regions.

- Urology OAB franchise

Sales of Betanis® / Myrbetriq® / BETMIGA® increased by 15.6% year-on-year to ¥27.2 billion. Sales increased in all regions: Japan, the Americas, EMEA, Asia and Oceania. Sales of Vesicare®, however, decreased by 19.2% year-on-year to ¥24.6 billion.

- Transplantation franchise

Sales of Prograf® (tacrolomis) remained largely unchanged year-on-year to ¥49.4 billion, and continued to grow in the EMEA, Asia and Oceania regions.

- Other new and key products

In the Japanese market, continued growth was achieved with products such as Celecox[®] (celecoxib) for the treatment of inflammation and pain, Symbicort[®] (budesonide and formoterol fumarate dihydrate) for the treatment of bronchial asthma, Suglat[®] (ipragliflozin) for the treatment of type 2 diabetes, and Cimzia[®] (certolizumab pegol) for the treatment of adult patients with rheumatoid arthritis. Accordingly total sales of these four products increased by 4.6% year-on-year to ¥27.7 billion. Meanwhile, we have been steadily working to penetrate the market with our launches of Repatha[®] (evolocumab) for the treatment of hypercholesterolemia in April 2016 and of LINZESS[®] (linaclotide) for the treatment of irritable bowel syndrome with constipation in March 2017. In the Americas, sales of azole antifungal CRESEMBA[®] (isavuconazonium sulfate) grew.

(Billions of yen)

	Q1 FY2016	Q1 FY2017	Change
Oncology franchise	79.1	81.8	+3.4%
XTANDI[®]	64.2	67.9	+5.8%
Urology OAB franchise	54.0	51.8	-4.0%
Vesicare[®]	30.4	24.6	-19.2%
Betanis[®] / Myrbetriq[®] / BETMIGA[®]	23.6	27.2	+15.6%
Transplantation franchise	49.4	49.4	+0.0%

Sales by Region²

Sales in Japan, the Americas and EMEA decreased, while sales in Asia and Oceania increased. As for the Japanese market, sales decreased by 7.5% year on year to ¥106.1 billion yen largely due to the impact of transferring 16 long-listed products in April 2017, and the introduction of generics for Micardis[®] (telmisartan) for the treatment of hypertension during the first quarter of FY2017. Meanwhile 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 April 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 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 growth in sales.

Creating Innovation

- Completed the acquisition of Ogeda SA in May 2017.
- Announced the inauguration of “Alliance Station” with the aim of realizing advanced medical treatments with Kyoto University in June 2017.

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

- Submitted an application for marketing approval of a combination drug of sitagliptin phosphate hydrate and ipragliflozin L-Proline for the treatment of type-2 diabetes in Japan in May 2017.
- Submitted a supplemental new drug application for mirabegron for the use in combination with solifenacin succinate for the treatment of OAB in the U.S. in June 2017.

NOTE: For further information on the results, please refer to the reference documents: Financial Results, Supplementary Documents, Overview of R&D Pipeline and Presentation Material for Information Meeting available on the Astellas website.

- (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 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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