

Mylan's capacity will rise to 50 bn doses in APAC during 2012

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Mylan was recently chosen as the leading supplier of antiretroviral (ARV) drugs to India's National AIDS Control Organization (NACO), a division of India's Ministry of Health and Family Welfare that is responsible for overseeing HIV/AIDS control programs in India.

Mylan set up its India operations in August this year with the launch of a comprehensive portfolio of 18 antiretroviral (ARV) products for the treatment of HIV/AIDS. In an informative interaction with BioSpectrum, Mr Rajiv Malik, president, Mylan, talks about the firm's expansion plans, their strategy for garnering market share in ARV drugs, their strategic partnership with Biocon and much more. Following is an excerpt.

Mylan has been chosen as an ARV supplier to NACO. How will this impact your operations?

Mylan's mission is to provide the world's seven billion population with access to high quality medicine and from this perspective we are extremely excited to partner with an organizations like NACO as one of their key suppliers of ARVs. As one of the world's leading generics and specialty pharmaceutical companies, Mylan has a powerful global manufacturing presence, with capacity for more than 45 billion doses across our various products.

Today, approximately one-third of people in the developing world being treated for HIV/AIDS, depend on a Mylan products and we recently launched commercial operations in India with a broad portfolio of ARVs. Our very strong ARV manufacturing and supply chain network is well prepared to meet the needs of the Indian market and the NACO agreement, and we look forward to differentiating Mylan in this space through our quality, innovation and service.

What is the growth that you are expecting for this fiscal year? How well placed are Mylan's India operations as compared to other countries?

Mylan has provided guidance of \$2.45-\$2.55 in adjusted diluted earnings per share (EPS) for 2012 as compared to \$2.04 for 2011) and a target of \$2.75 in adjusted diluted earnings per share for 2013. We have also indicated that we intend to triple the adjusted diluted EPS to \$6.00 by the end of 2018 and double the size of the company in terms of manufacturing capacity and product portfolio.

We identified India's commercial operations and ARV growth to be two important strategic drivers of this growth. At our investor day in February this year, we indicated that we expect revenues from ARV's to grow at a compound annual growth rate of approximately 13 percent from 2011-16 and aim to be a leading player in India.

What has been Mylan's strategy for its ARV range, considering that there are already established players (such as Cipla) in this segment?

In the next five years, our goal will be to build Mylan's brand equity in India and position ourselves as a high quality, innovative and cutting edge pharmaceutical company with global standards. In the long-term, we aim to be a top 10 company in India.

While we understand that we will be entering a highly competitive market, the key to differentiating ourselves from local players and other MNCs is by educating Indian physicians, pharmacists, customers and consumers about what the Mylan brand stands for: unmatched supply reliability, outstanding customer service, operational integrity and high quality products. Our sales force will be another key differentiator. We have hired what we believe is the best talent and have provided them with world class training to empower them to be Mylan's brand ambassadors in India

Moving ahead, what are your plans about releasing the rest of the products in the Mylans' ARV 43 ARV drug portfolio?

In the first phase we have made available a comprehensive range of 18 products from our HIV division portfolio available in the Indian market. We are looking at the market requirement and depending on its need we will continue to launch other products from our ARV portfolio.

Mylan expects to launch product portfolios in additional therapeutic categories, such as women's health care and oncology, in the future. We will provide more details on these plans and the number and types of products as we launch those therapeutic categories.

Can you describe development of innovations in these drugs such as heat stable ARV products, combo blister packs ?

Innovation is one of Mylan's core values and we are constantly looking at ways to innovate across our product portfolio, as we have done with ARVs, and we will seek to bring to the Indian market additional innovative, market-appropriate products in other therapeutic categories over time.

Mylan also has introduced a number of ARV innovations, for instance producing single blister "combo" packs, which provide a reduced pill burden and once-a-day dosage. Mylan also developed three FDA/WHO-approved heat-stable ARV products, which can be distributed and used in countries where refrigeration infrastructure is not widely available. In addition, Mylan has been a global leader in producing ARV formulations for pediatric use.

Are there any patient access programs currently in place for the ARV drugs?

For its ARV business, Mylan is targeting ARV specialists with its sales force and will have one of the largest field forces exclusively specializing in HIV/AIDS in India. Through specialists, we believe we will be able to reach the majority of our target patient population. Mylan will deploy a multi pronged distribution to ensure that medicines are accessible where they are needed, which will include through doctors, NGOs, pharmacists and bodies such as the National Aids Control Organization (NACO). Our objective is to reach these therapies wherever there are HIV patients and we are evaluating a

number of other programs to enhance access.

Can you elaborate on the efforts that Mylan has taken to expand its existing infrastructure in India?

Our commercial launch in India is one of Mylan's strategic growth drivers and we intend to invest in the business appropriately to support its success. Globally, Mylan is investing \$1.4 billion in CapEx and \$2 billion in R&D to support our growth. We expect to increase our manufacturing capacity in the Asia Pacific region from 17 billion doses today to 50 billion doses in 2012. Much of this expansion is expected to be in India.

What is the current status of the research collaboration with Biocon? By when do you see this partnership reaching fruition?

We are pleased with the progress of this collaboration. We have five products in development and will begin clinical development this year, and expect to launch our first products in 2014-15 for developing markets and 2015-16 for developed markets.

Can you elaborate about your arrangement with Gilead Life Sciences?

Mylan has licensed the rights to produce and market generic versions of Gilead HIV/AIDS therapies, consisting of single and fixed-dose combinations containing Emtricitabine. Emtricitabine is marketed by Gilead under the brand name Emtriva, and a fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate is available under the brand name Truvada. Emtricitabine also is an essential component of the "Quad," an investigational treatment which combines four Gilead medicines in a once-daily, single tablet regimen for the treatment of HIV.

Under previous licensing agreements with Gilead, Mylan Laboratories obtained licensing rights to Gilead products, which are currently in late-stage clinical development, including Elvitegravir, an investigational integrase inhibitor; Cobicistat, an investigational antiretroviral (ARV) boosting agent; and the "Quad." Additionally, Mylan Laboratories obtained non-exclusive rights to produce and market active pharmaceutical ingredients and finished products, including generic versions of Viread, (Tenofovir Disoproxil Fumarate or TDF), Truvada (Emtricitabine/Tenofovir Disoproxil Fumarate) and other TDF-based combinations in over 100 developing countries including India.

Lastly what are the challenges that you currently facing in the Indian market?

As with any market, healthcare policies, including pricing and reimbursement are keys in driving growth. Currently, discussions are taking place in India on increasing its expenditures on health, including providing universal health care, which depending on the exact scope of the changes and implementation, could contribute to accelerated growth.