

Panacea expands its footprint in the US

08 April 2013 | News | By BioSpectrum Bureau



Panacea Biotec, an Indian firm whose three cardinal business principles have been to focus on innovation, brand building and collaboration, has been extremely committed towards the US market and built an eclectic pipeline of high-barrier-to-entry technology-based generics as well as drug delivery-based NDAs. Panacea, like many other Indian firms is leveraging on [big pharma's change in strategy from 'profit alone' model to 'profit together' model](#)

Dr Rajesh Jain, joint managing director, Panacea Biotec, while speaking about the importance of the company's strong pipeline, said that, "In order to fully leverage the potential of such a strong pipeline, it is essential to partner for these products with organizations offering a strong synergy and develop a partnership model that is non-conventional and is win-win in the true sense for both organizations."

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In 2012, Panacea collaborated with two companies in the US, including Kreamers Urban and Osmotica Pharmaceutical. Dr Jain mentioned, "Both these partnerships while having distinct and individual flavors from a deal structuring standpoint

represent a very strong synergy and win-win business model."

Kremers Urban is a specialty generic business subsidiary of UCB, with an exclusive focus on pharmaceutical products that have a "high-barrier-to-entry." Panacea Biotec announced the strategic alliance with Kremers Urban in the month of November 2012 for 11 high barrier-to-entry generic products in the US market representing an opportunity of \$4 billion at the innovator sales level in US.

The first product in this portfolio to reach the market was Tacrolimus capsules, which was launched in the US in November 2012. Panacea Biotec was granted approval of the product from US FDA in September 2012. This would be followed by a series of high-barrier-to-entry generic product launches that are being developed by Panacea Biotec.

In this collaboration, Panacea Biotec would take the lead in R&D, registration and commercial supplies of products while Kremers Urban would be leading marketing, sales and distribution. The business collaboration is based on long-term profit sharing by both companies. So far, under the partnership, one product has been launched, one more ANDA has been filed and additional nine ANDAs will be filed in the next 12 months.

Osmotica Pharmaceuticals is a drug delivery specialized company and brings to the collaboration an immense expertise on the regulatory and commercialization aspects of complex drug delivery based generics. Panacea Biotec entered into a strategic alliance for the R&D and commercialization of drug delivery based, high barrier to entry generic and branded pharmaceutical products in the US and key strategic markets across the globe with Osmotica. The collaboration is designed to build upon each company's highly complementary strengths and quality assets.

Panacea Biotec would lead product identification, research, development and manufacturing while Osmotica would lead product registration, legal matters, marketing, sales and distribution.

The collaboration products are expected to be sold under an Osmotica and Panacea Biotec label. This collaboration is based on a 50:50 risk, investment and profit sharing by both companies and starts with a portfolio of 18 products across a broad range of therapeutic categories, with a provision to add new products by the Joint Steering Committee represented by both Osmotica and Panacea Biotec.

Dr Jain informs that Panacea Biotec has received a research fee from Osmotica on signing and milestone payments over the past months. Moving forward, Panacea Biotec will receive agreed amounts of milestone payments representative of 50 percent share of development costs from Osmotica on achievement of development milestones. For every new product added to the collaboration and for each new market thereof, Panacea Biotec shall receive a fixed license fee besides receiving the 50 percent development costs. Post-commercialization of the products in US and other markets as may be added from time to time, both Panacea Biotec and Osmotica shall share the profits equally.