

Zydus Cadila to bring 50 products in US market

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Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies.

Ahmedabad-based Cadila Healthcare, on the back of a 64 percent surge in its last financial year's business in the US, is going strong on boosting its pipeline for the world's largest single-country drug market.

Cadila Healthcare is one such company that can deliver on multiple fronts. Strong domestic presence, growing US pipeline especially in complex generics and biologics, which have high entry barriers and a robust position in high-growth therapeutic areas, including dermatology, pain management, respiratory and cardiology, are positives.

The management has guided for 50+ product launches in the US in FY19. Its US pipeline (cumulative) consists of 330 filed ANDAs, and 144 pending final approvals. The company's shift in focus towards building its specialty pipeline in the US in pain management, dermatology and oncology products should pay off well in one to two years.

Cadila Healthcare has at least ten para IV filings for the US. As such, the company aims to launch 50 products in the US during the current fiscal year.

Zydus aspires to be a research-based pharmaceutical company by 2020. When an abbreviated new drug application (ANDA) filed with the US Food and Drug Administration (USFDA) contains a paragraph IV certification, the product (when it gets the final approval from the FDA) can be eligible for 180 days of marketing exclusivity.

Under paragraph IV, a company can seek FDA approval to market a generic drug before the patent expires. This involves litigation with the patent holder.