

New EU approval for Bluefish – antidepressant on its way to market

The Swedish company Bluefish has had its second product approved in an EU market and plans to launch it in several European countries over the next few months. This is the antidepressant Mirtazapin Bluefish, an orodispersible variant of a drug in a category that registered sales of SEK 120 million in Sweden alone last year. At the same time, Bluefish is consolidating its position in anticipation of sharp market growth over the next few years.

“We have built up an effective structure for manufacturing and distribution which means that we are well placed to compete quickly now that more and more patents are expiring,” says President and CEO Karl Karlsson. “For example, during the year we will be able to launch the antimigraine drug sumatriptan, the patent for which recently expired.”

The global generics market is growing massively at present. More patents are expiring, there is heavy pressure on costs in the health service and distribution and logistic costs are being forced down. More and more countries are reforming the use of medicines and are increasingly moving towards the use of more generic products. After reliability of supply, price is the major factor in the market.

“Proven medicines at low cost provide quality of life for more patients. This is one of the forces driving the rapid growth in the sector. There is space for more market players, but for smaller players too it’s a case of being able to build up your company in a global world - every little step in the process has to be taken as cost-effectively as possible,” says Karlsson.

The company has two medicines that have been approved for sale – the diabetes treatment Metformin HCl Bluefish and the antidepressant Mirtazapin Bluefish. They have both been first approved by the Medicines Evaluation Board in the Netherlands, whose approval is then transferred to a number of other EU markets, normally within 120 days. Bluefish has a total of nine products that have either been approved or for which applications have been submitted. Bluefish anticipates substantially broadening its product portfolio within a few years.

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Bluefish Pharmaceuticals AB is a Swedish specialty pharma company that buys or licenses the rights to manufacture medicines, principally generic products. Low prices are maintained through efficient production and distribution. Bluefish has a wholly owned subsidiary in Chennai (India) focusing on product development and manufacturing. Bluefish is owned by, among others, the venture capital company Quesada, its founder Karl Karlsson and a number of private investors, who include Bo Rönnerberg and Lars-Göran Kjellin