Paxil CR may return

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Glaxo Sees Early Return of 2 Suspended Drugs
by Heather Timmons, New York Times, 29 April 2005

London, April 28 - GlaxoSmithKline's antidepressant Paxil CR and its diabetes drug Avandamet may be back on the market by midyear, months earlier than expected, the company said Thursday...

Glaxo, Europe's largest drug company, said it signed a consent decree with the United States Food and Drug Administration, which seized millions of tablets in March because of manufacturing defects. Glaxo said it had identified and addressed the cause of those defects, and agreed to put an independent observer at its factory in Cidra, P.R., where the drugs were made.

Glaxo, which is based in London, recalled some Paxil batches in February because the pills were splitting apart, and in March the F.D.A. shut the Cidra plant that makes both drugs...

On Thursday, Glaxo also reported better-than-expected first-quarter earnings... up 15.9 percent from a year ago...

Before Thursday's announcement, analysts were concerned that the company would not be able to reintroduce Paxil CR, a timed-release version of Paxil, until next year, which could have cost the company several hundred million dollars in sales...

The Paxil CR tablets that split open left consumers with half a tablet with no medication, and another half with no buffering product. Some Avandamet tablets had inconsistent doses of medicine... [full article (http://www.nytimes.com/2005/04/29/business/businessspecial3/29glaxo.html)]