

## Therapeutic focus - Tough market for new wave of epilepsy drugs



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For a therapeutic area that generated an impressive annual growth rate of 16% over the past ten years, the market for epilepsy drugs is set for a dramatic decline following the sudden expiry of key patents for four of the top five biggest-selling blockbuster products within the last nine months. Having peaked at \$12.8bn in 2008 sales of epileptic drugs are set to decline 5% annually to \$9.32bn by 2014 (see table below).

Nevertheless, a number of new epilepsy drugs are set to reach the market within the next couple of years and assuming they match current expectations could generate significant revenues for the likes of UCB and Johnson & Johnson. For UCB a successful launch of Vimpat in the US and positive phase III data for Rikelta are crucial events this year which will have a strong bearing on the group's market valuation.

### Market heads into reverse

Of the top five epilepsy drugs last year, only Pfizer's Lyrica is set to continue to dominate the market over the next few years, although it is important to note that a significant portion of forecast sales are also attributed to the drug's use for neuropathic pain, anxiety and fibromyalgia.

Anti-epileptic market: top 10 products in 2014						WW annual sales (\$m)		
Rank	Product	Company	Pharmacological Class	Market status	Patent Expiry	2008	2014	CAGR (08 - 14)
1	Lyrica	Pfizer	Alpha 2 delta ligand	Marketed	Dec 2018	2,573	4,671	10%
2	Vimpat	UCB	CRMP-2 modulator	Marketed	Mar 2017	3	725	150%
3	RWJ333369	Johnson & Johnson	Anti-convulsant	Filed	-	-	485	n/a
4	Rikelta	UCB	Pyrrolidone	Phase III	Dec 2021	-	438	n/a
5	Depakine	Sanofi-Aventis	GABA agonist	Marketed	Jan 2005	483	413	(3%)
6	Tegretol	Novartis	Iminostilbene	Marketed	Feb 2011	451	346	(4%)
7	Lamictal	GlaxoSmithKline	Sodium channel antagonist	Marketed	Jan 2009	1,714	322	(24%)
8	Neurontin	Pfizer	GABA agonist	Marketed	Jul 2000	387	181	(12%)
9	Depakote	Abbott Laboratories	GABA agonist	Marketed	Jul 2008	1,364	145	(31%)
10	Inovelon	Eisai	Anti-convulsant	Marketed	Nov 2015	12	137	51%
Other						5,802	1,455	(21%)
<b>Total anti-epileptic market</b>						<b>12,789</b>	<b>9,317</b>	<b>(5%)</b>

The following table highlights the products that will contribute the most to the overall decline in revenues for epilepsy drugs, as almost 90% of aggregate sales of \$8.1bn in 2008 are expected to be lost by 2014.

Anti-epileptic market: growth brakes (2008 - 2014)				WW annual sales (\$m)			Total change (\$m)
Rank	Product	Company	Patent expiry	2008	2014	CAGR (08 - 14)	
1	Topamax	Johnson & Johnson	Mar 2009	2,731	127	(40%)	(2,604)
2	Keppra	UCB	Nov 2008	1,855	79	(41%)	(1,776)
3	Lamictal	GlaxoSmithKline	Jan 2009	1,714	322	(24%)	(1,393)
4	Depakote	Abbott Laboratories	Jul 2008	1,364	145	(31%)	(1,219)
5	Neurontin	Pfizer	Jul 2000	387	181	(12%)	(206)
<b>Total</b>				<b>8,052</b>	<b>854</b>		<b>(7,198)</b>

#### New products attempt to offset decline

Behind Lyrica, the importance of successful launches and approvals of three new drugs is clear.

Vimpat, which suffered a significant setback when the FDA rejected its use for diabetic neuropathic pain in July 2008, finally gained approval for epilepsy in October ([UCB finally has something to celebrate](#), October 29, 2008). The setback in the pain setting has already significantly reduced the drug's commercial prospects. Archive consensus forecasts from EvaluatePharma reveal that since the FDA rejection estimates for sales by 2014 have been trimmed by over a quarter to currently sit at \$725m. Vimpat's imminent launch in the US and initial uptake rate will therefore be of great interest to investors and analysts alike.

The first set of phase III data for another of UCB's pipeline epilepsy drugs, Rikelta, due in the third quarter, will also provide a binary event for the company's share price. Currently estimated to be worth as much as \$930m, according to EvaluatePharma's NPV Analyzer, the drug is also the second most valuable product in the Belgian group's portfolio.

Meanwhile, J&J's RWJ333369 was filed with the FDA last October and therefore has an estimated PDUFA date in August. Valued at \$870m the drug is J&J's fourth most valuable pipeline candidate and also slated to be one of the biggest product launches this year ([Which of 2009's launches will be future blockbusters?](#), February 17, 2009).

The following table lists some other important late stage clinical candidates which could also help to offset the overall decline in the epilepsy market.

### Anti-epileptic market: R&D pipeline

Phase	Product	Generic Name	Company	Pharmacological Class	NDA Classification	First Introduction
<b>Filed</b>	RWJ333369	carisbamate	Johnson & Johnson	Anti-convulsant	New molecular entity	Dec 2011
	Lamictal XR	lamotrigine	GlaxoSmithKline	Sodium channel antagonist	NDA	Dec 2004
	Stedesa	eslicarbazepine	Sepracor	Iminostilbene	New molecular entity	Jun 2011
<b>Phase III</b>	Rikelta	brivaracetam	UCB	Pyrrolidone	New molecular entity	Jun 2011
	Retigabine	retigabine	GlaxoSmithKline + Valeant Pharmaceuticals + Meda	GABA agonist & potassium channel agonist	New molecular entity	Jun 2011
	DM-5689/DM-1796	gabapentin	Depomed + Solvay	GABA agonist	NDA	Jun 2011
	IV Carbamazepine	carbamazepine	Lundbeck	Iminostilbene	NDA	-
	Fosphenytoin	fosphenytoin	CyDex	Anti-convulsant	NDA	-
	Epliga	oxcarbazepine	Supernus Pharmaceuticals	Iminostilbene	NDA	-
<b>Phase II</b>	JZP-8	clonazepam	Jazz Pharmaceuticals	Benzodiazepine	NDA	Jun 2011
	Ganaxolone	ganaxolone	Marinus Pharmaceuticals	GABA A receptor modulator	New molecular entity	-
	SPN-538	topiramate	Supernus Pharmaceuticals	Sulphamate	NDA	-
	SRx-502	-	Spherics	CNS agent	New molecular entity	-
	DP-VPA	-	D-Pharm	Anti-convulsant	New molecular entity	-

### Upcoming events

As well as the potentially catalytic events already discussed, the summary below of EvaluatePharma's Calendar of Events highlights some further important milestones to take place in the epilepsy market this year.

A product largely under the radar and which could yet generate far larger revenues than currently forecast is GlaxoSmithKline's retigabine. Licensed from Valeant Pharmaceuticals last August for \$125m upfront and potentially a further \$545m in milestones, Glaxo clearly has high hopes for the drug, although the timing of regulatory filings in both the US and Europe appears to have slipped slightly, from the first quarter to sometime this year.

**EvaluatePharma's Calendar of Events: selected key events for anti-epileptic drugs**

Event Type	Product	Company	NPV (\$m)	NPV as % of Mkt Cap	Event	Event Status	Start Date	End Date
<b>US Product Launch</b>	Vimpat	UCB	705	13%	Expect US Launch of Vimpat (lacosamide) for Partial Onset Seizures in Adults with Epilepsy	In-Play (62%)	01 Jan 2009	30 Jun 2009
<b>US Product Approval (PDUFA)</b>	Lamictal XR	GlaxoSmithKline	131	0%	FDA Decision Date (PDUFA) on Lamictal XR for Epilepsy	Overdue by 104 days	09 Jan 2009	09 Jan 2009
	Sabril	Ovation Pharmaceuticals	0		FDA Decision Date (PDUFA) on Sabril for Infantile Spasms (IS) & Refractory Complex Partial Seizures (CPS)	Overdue by 23 days	08 Jan 2009	31 Mar 2009
	RWJ333369	Johnson & Johnson	870	1%	FDA Decision Date (PDUFA) on RWJ333369 for Epilepsy	Starts in 123 days	24 Aug 2009	24 Aug 2009
<b>US Product Filing</b>	Retigabine	GlaxoSmithKline	152	0%	Expect US Filing for Retigabine in Epilepsy	Overdue by 23 days	01 Jan 2009	31 Mar 2009
<b>EU Product Filing</b>	Retigabine	GlaxoSmithKline	152	0%	Expect EU Filing for Retigabine in Epilepsy	Overdue by 23 days	01 Jan 2009	31 Mar 2009
<b>Phase III Trial Results</b>	Rikelta	UCB	929	17%	Phase III Trial Results for Rikelta as Adjunctive Treatment in Partial-Onset Epilepsy	Starts in 69 days	01 Jul 2009	30 Sep 2009
<b>Phase II Trial Results</b>	JZP-8	Jazz Pharmaceuticals	49	257%	Phase II Trial Results for JZP-8 for Epilepsy	In-Play (62%)	01 Jan 2009	30 Jun 2009

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