

Liftoff for 2012's big drug hopes



[Joanne Fagg](#)

If there was a common thread to coverage of the pharma and biotech industries in 2012, it was one of renewed enthusiasm. The stock market performance is convincing, and a review of the year's expected launches provides additional evidence.

Nine of the 10 biggest small-molecule hopes for 2012 won approval, along with eight of 10 of the biggest projected biologicals, making last year the best since *EP Vantage* began tracking the fate of blockbuster prospects ([Which of 2012's launches will be future blockbusters?, January 17, 2012](#)). Some question marks hang over such products as Novo Nordisk's Tresiba, Biogen Idec's BG-12 and Amarin's Vascepa; however, for others like Gilead Sciences' Stribild and Astellas Pharma's Xtandi, the outlook keeps improving (see table).

The good

The quick rate of drug approvals last year has helped drive enthusiasm in the field, as the FDA returned to a pace not seen since the 1990s ([Friendly FDA ups number of NMEs, January 10, 2013](#)).

What might be even more impressive is how the consensus views have changed – five of the biotech products and six of the conventional pharma drugs have seen upgrades to their forecasts. In the aggregate, the 2016 forecasts for the top 10 biotech and small-molecule products have risen since January 2012 – another first for this analysis.

This should not be too surprising: Stribild and Xtandi have seen their 2016 forecasts treble in the past year, for example, and Onyx Pharmaceuticals' Kyprolis has more than doubled, according to *EvaluatePharma* data. Xtandi in particular has been the beneficiary of an unusually quick approval and optimism about its use in pre-chemotherapy prostate cancer patients ([Medivation gets surprise early approval for prostate cancer pill, September 3, 2012](#)).

Two products that failed to leave the launch pad, Sanofi's Lemtrada and Kynamro, have more than doubled, showing that a launch date miss does not necessarily result in disappointment – as long as you have a big pharma backer.

Progress of biggest products forecast to have launched in 2012

Biotechnology	Rank	Product	Pharmacology class	Company	Status 2012	Current status
	1	Ryzodeg/Tresiba	Insulin	Novo Nordisk	Filed	Approved
	2	Perjeta	Anti-HER2 (ErbB-2) MAb	Roche	Filed	Marketed
	3	Bexsero	Meningococcal B vaccine	Novartis	Filed	Approved
	4	Jetrea	Plasmin	ThromboGenics	Filed	Marketed
	5	Menhibrix (HibMenCY-TT)	Hib & meningococcal C & Y vaccine	GlaxoSmithKline	Filed	Approved
	6	Zaltrap	VEGFr kinase inhibitor	Sanofi	Filed	Marketed
	7	Gattex	GLP-2 agonist	NPS Pharmaceuticals	Filed	Approved

	8	Kynamro	Apolipoprotein B-100 antisense	Sanofi	Filed	Filed
	9	Prochymal	Mesenchymal stem cell	Osiris Therapeutics	Filed	Marketed
	10	Lemtrada	Anti-CD52 MAb	Sanofi	Phase III	Filed
<i>Total biotech products</i>						
Conventional	1	Vascepa	Omega-3 fatty acid	Amarin/undisclosed partner sales	Filed	Approved
	2	BG-12	Fumarate	Biogen Idec	Phase III	Filed
	3	Xeljanz	JAK-3 inhibitor	Pfizer	Filed	Marketed
	4	Qsymia	Adrenoreceptor agonist & anti-convulsant	VIVUS	Filed	Marketed
	5	Kalydeco	CFTR potentiator	Vertex Pharmaceuticals	Filed	Marketed
	6	Stribild	Nucleoside reverse transcriptase inhibitor, HIV integrase inhibitor & CYP3A inhibitor	Gilead Sciences	Filed	Marketed
	7	Linzess/Constella	Guanylate cyclase type-C receptor agonist	Ironwood Pharmaceuticals/Forest Laboratories/Almirall	Filed	Approved/M
	8	Xtandi	Androgen receptor antagonist	Astellas Pharma	Phase III	Marketed
	9	Forxiga	SGLT2 inhibitor	Bristol-Myers Squibb	Filed	Marketed
	10	Kyprolis	Proteasome inhibitor	Onyx Pharmaceuticals	Filed	Marketed
<i>Total conventional products</i>						

*change in forecast reflects Thrombogenics licensing ex-US rights to Novartis

Should it be launched, BG-12 is forecast as the biggest introduction of the year, at \$2.6bn in forecast 2016 sales – although it missed being a 2012 launch only by dint of a regulatory delay. It has wowed specialists as an oral MS drug effective at preventing relapses, and is thought to become a first-line therapy.

And despite its difficulties with the FDA, Tresiba remains the biotech product with the healthiest 2016 forecast – \$1.95bn, a number that has risen 35% in the past year. Approvals in Japan and Europe lend some confidence that the US regulator will nod Tresiba through, but cardiovascular concerns mean that this is not a sure thing ([Doubts linger after Novo Nordisk insulins scrape through US adcom, November 9, 2012](#)).

The bad

Approval in Europe has meant that Bristol-Myers Squibb and AstraZeneca's diabetes pill Forxiga can enter a major market. However, cancer worries have been its downfall in the US, and a competing product, Johnson & Johnson's canagliflozin, appears closer to the market – hence, the consensus has fallen 55% in the past year ([Adcom backing gives canagliflozin a chance at an open diabetes field, January 11, 2013](#)).

Two meningitis vaccines have seen forecasts fall, by 39% in the case of Novartis's Bexsero and 21% in the

case of GlaxoSmithKline's Menhibrix, and there are worries about their place in the vaccination schedules, as well as concerns that the relative rarity of meningitis could lead to lower than expected uptake.

Looking bad is the forecast for Thrombogenics' Jetrea. However, its 46% drop is reflective of the Belgian firm's decision to license European rights to the eye drug to Novartis. No consensus has been calculated – however, Deutsche Bank analysts forecast 2016 sales of \$272m, which when added to US sales of \$220m brings total sales to \$492m, higher than last year's forecast.

The ugly

If there is a counterweight to investor exuberance, it can be found in Vascepa and Qsymia, two drugs hyped as potential blockbusters.

It has been nearly six months since the FDA approved the former, Amarin's purified fish oil pill, for dyslipidaemia; a parade of patents have done little to stoke market confidence in the absence of new chemical entity (NCE) status. Amarin appears to have given up on partnership and today announced that it would launch solo next week; thus the title blockbuster-in-waiting might no longer apply as it did a year ago, as forecasts have slipped by 59%.

Hopes for Vivus's obesity pill Qsymia have fallen drastically with word that many patients were abandoning their prescriptions because of cash outlays, as well as a negative European opinion ([Arena says the magic combo word as reality hits Vivus](#), November 7, 2012). Like Vascepa, this has fallen from blockbuster forecasts to a more modest \$478m in 2016.

The biggest percentage drop in forecast sales belongs to Osiris Therapeutics' stem cell therapy Prochymal. Approval of the treatment for graft vs host disease in Canada and New Zealand has not built confidence in its overall promise; the 2016 forecast now sits at a modest \$25m, having fallen 83% in a year ([Osiris' battles will continue despite landmark approval for Prochymal](#), May 21, 2012).

All data sourced to EvaluatePharma.

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