

## Sarepta joins the big league as best-performing 2012 share



[Joanne Fagg](#)

When the insignificant biotech AVI Biopharma changed its name to Sarepta Therapeutics last July few saw the move as more than a desperate makeover in a crisis. But when this was followed by a positive phase IIb result with the Duchenne muscular dystrophy project eteplirsen, Sarepta was suddenly on all biotech watchers' lips.

With the year-end numbers in, Sarepta is confirmed as the best-performing pharma/biotech share of 2012. And who would have thought at the start of last year that India's Wockhardt would end up the highest small-cap riser, with an astonishing 468% share price surge? These and other small, micro and nano-cap successes are joined by the usual crop of failures for which the binary-outcome coin landed the wrong side up.

### **Not unequivocal**

Although Sarepta's success with eteplirsen was by no means unequivocal – and the study comprised only 12 patients – it was good enough for the company to finish 2012 up 473%, its market cap at one point even breaching the \$1bn barrier. Although there has been some retrenchment since the October highs, Sarepta clearly still has the confidence of most investors.

Among the micro-cap risers Sarepta easily beat the volatile Infinity Pharmaceuticals, which had started 2012 badly, halting a phase II trial of its pancreatic cancer project IPI-926. However, Infinity clawed back its share price with positive phase I results of its blood cancer project IPI-145, whose rights it regained from Mundipharma in July. The company still needs to secure a partner to fund late-stage development.

Wockhardt's breakout to claim the 2012 small-cap prize was driven by efforts to improve the company's balance sheet by divesting its nutritionals unit, and building sales of its all-important generic version of AstraZeneca's Toprol XL. More recent successes have included the launches of several other generic drugs.

## Small-cap (\$250m-2.5bn) pharma companies: top risers and fallers in 2012

		Share price (local currency)			Market capitalisation (\$m)		
Rank	Top 5 risers	31 Dec 11	31 Dec 12	Change	31 Dec 11	31 Dec 12	EP Vantage comment and analysis
1	Wockhardt	Rs276.95	Rs1,572.10	468%	614	3,242	<a href="#">Daily Market Movers (29 Aug 2012)</a>
2	Arena Pharmaceuticals	\$1.87	\$9.02	382%	273	1,960	<a href="#">Arena fends off the big question as lorcaserin delivers</a>
3	Pharmacyclics	\$14.82	\$57.78	290%	1,016	4,020	<a href="#">Asco EventAnalyzer - 2012's winners and losers</a>
4	AB Science	€6.08	€18.13	198%	255	745	<a href="#">AB Science's dog drug data raise more questions than answers</a>
5	Swedish Orphan Biovitrum	SKr16.10	SKr36.60	127%	603	1,462	<a href="#">Biogen and Swedish Orphan fixed for haemophilia success</a>
<b>Rank Top 5 fallers</b>							
1	Anthera Pharmaceuticals	\$6.14	\$0.62	(90%)	251	49	<a href="#">Anthera springs back to life but more surprises likely</a>
2	Chelsea Therapeutics	\$5.13	\$0.76	(85%)	317	51	<a href="#">Investors kick Chelsea after it trips on its Northera data again</a>
3	Clavis Pharma	NOK48.60	NOK7.80	(84%)	259	46	<a href="#">Leap failure sends Clavis and Clovis crashing back to earth</a>
4	Oncothyreon	\$7.58	\$1.92	(75%)	324	110	<a href="#">Stimuvax doomed in lung cancer</a>
5	Progenics Pharmaceuticals	\$8.54	\$2.98	(65%)	288	134	<a href="#">Progenics and Salix suffer as FDA blocks constipation drug</a>

While Pharmacyclics benefited from a \$150m deal with Johnson & Johnson for its the first-in-class kinase inhibitor ibrutinib, now hailed as a future blockbuster, Arena Pharmaceuticals continued to ride the sentiment wave that has recently buoyed all late-stage obesity treatment developers. Obviously, the M&A thesis continues to play heavily here – so far with little hard evidence to support it.

Still, despite securing approval Arena has yet to launch its drug Belviq in the US, and European approvability is a key unknown. Only once the drug hits pharmacy shelves will the mists begin to clear, and a fate like that of its competitor Vivus – for much of 2012 the standout obesity performer before a November crash – cannot be ruled out.

The year's other small-cap success stories included Swedish Orphan Biovitrum, on the back of good data for its Biogen Idec-partnered long-acting haemophilia treatment, rFIXFc, and AB Science, which said it scored a phase II hit in pancreatic cancer with masitinib.

Although AB's stock put on 198% during the year, plus another 17% just yesterday, the company has not even revealed what two subgroups had apparently performed so well in the data dredge of its failed masitinib study; extreme caution should be urged.

Still, there was no way of spinning the phase II failure, also in pancreatic cancer, of Clavis Pharma's CP-4126. Despite previous positive findings and a well-designed study protocol there was no rescuing the project, and its discontinuation wiped 84% off Clavis's valuation, securing its spot among the top three small-cap fallers of 2012.

It was "bettered" only by Anthera Pharmaceuticals, which suffered the twin failures of its lupus candidate blisibimod and the cardiovascular project varespladib, and Chelsea Therapeutics, which suffered multiple slip-ups with a phase III study of its hypotension project Northera.

## Micro-cap (\$100-250m) pharma companies: top risers and fallers in 2012

Rank	Top 5 risers	Share price (local currency)			Market capitalisation (\$m)		EP Vantage comment and analysis
		31 Dec 11	31 Dec 12	Change	31 Dec 11	31 Dec 12	
1	Sarepta Therapeutics	\$4.50	\$25.80	473%	101	755	<a href="#">Sarepta's step forwards in muscular dystrophy raises the bar for competitors</a>
2	Infinity Pharmaceuticals	\$8.84	\$35.00	296%	236	1,581	<a href="#">Daily Market Movers (10 Dec 2012)</a>
3	Medigen Biotechnology	NT\$40.40	NT\$155.00	284%	144	682	
4	Santarus	\$3.31	\$10.98	232%	201	694	<a href="#">Daily Market Movers (4 Sep 2012)</a>
5	Affymax	\$6.61	\$18.99	187%	236	706	<a href="#">Daily Market Movers (12 July 2012)</a>
Rank	Top 5 fallers						
1	Agennix	€2.87	€0.32	(89%)	151	21	<a href="#">Agennix facing tough questions about its future following talactoferrin failure</a>
2	Theratechnologies	C\$2.79	C\$0.32	(89%)	167	19	<a href="#">Daily Market Movers (22 June 2012)</a>
3	Cardiome Pharma	C\$2.68	C\$0.39	(86%)	161	24	<a href="#">Merck's call on vernakalant a blow to Cardiome</a>
4	BioInvent International	SKr16.40	SKr3.30	(80%)	163	37	<a href="#">BioInvent scores unpleasant biotech triple</a>
5	Columbia Laboratories	\$2.50	\$0.64	(75%)	218	56	<a href="#">Daily Market Movers (23 Jan 2012)</a>

Among the micro caps, Santarus and Affymax boasted triple-digit share price increases last year. Santarus celebrated when its acid reflux drug Zegerid fought off a generic challenge from Par Pharmaceutical until 2016, and shares also rose on hopes for its diarrhoea project Rifamycin SV MMX and ulcerative colitis drug Uceris, which has a US action date this month.

For Affymax last year was all about the Takeda-partnered anaemia drug Omontys, which Fresenius agreed in July to supply for use in dialysis patients with chronic kidney disease.

### Double and triple whammies

The biggest loser in this group, Agennix, has not been able to recover from clinical failures of its immunomodulator talactoferrin, which tripped up in sepsis on safety issues and then failed to show efficacy in NSCLC.

The Swedish company Bioinvent went one further, suffering a triple whammy of bad news; Roche's decision to pull out of a deal for the oncology project TB-403 was followed by TB-402 failing a phase II study in preventing venous thromboembolism in hip-replacement surgery, before its atherosclerosis treatment BI-204 failed to meet a phase II primary endpoint.

And partners let down two Canadian companies. Theratechnologies was hit when Ferrer Internacional withdrew the EU marketing authorisation for the lipodystrophy drug tesamorelin on long-term cardiovascular risks, while its neighbour Cardiome Pharma suffered the discontinuation by Merck & Co of an oral version of its atrial fibrillation treatment vernakalant.

## Nano-cap (<\$100m) pharma companies: top risers and fallers in 2012

Rank	Top 5 risers	Share price (local currency)			Market capitalisation (\$m)		EP Vantage comment and analysis
		31 Dec 11	31 Dec 12	Change	31 Dec 11	31 Dec 12	
1	BioDelivery Sciences International	\$0.81	\$4.31	435%	24	162	<a href="#">Daily Market Movers (6 Jan 2012)</a>
2	Celsion	\$1.70	\$8.19	382%	56	287	
3	Medgenics	\$1.70	\$7.44	338%	12	91	<a href="#">Weekly Market Movers (to 24 Aug 2012)</a>
4	ACADIA Pharmaceuticals	\$1.08	\$4.65	331%	57	263	<a href="#">Acadia scores big with pimavanserin data but new trial awaits</a>
5	Scancell	£0.12	£0.48	311%	16	151	<a href="#">Weekly Market Movers (to 17 Aug 2012)</a>
Rank	Top 5 fallers						
1	Lotus Pharmaceuticals	\$0.35	\$0.01	(97%)	10	0	
2	Bionovo	\$0.23	\$0.01	(96%)	13	1	
3	K-V Pharmaceutical Company	\$1.40	\$0.06	(96%)	84	3	<a href="#">K-V Pharmaceutical orders a beer in last-chance saloon</a>
4	D-Pharm	ILS11.39	ILS0.59	(95%)	50	7	<a href="#">Daily Market Movers (24 Jan 2012)</a>
5	Allon Therapeutics	C\$0.26	C\$0.02	(94%)	25	2	<a href="#">Allon pays the price for binary biotech strategy</a>

Leading the pack of the tiniest companies – those capitalised at under \$100m – in 2012 was BioDelivery Sciences International, which started off the year by licensing its chronic pain project BEMA buprenorphine to Endo.

Expectations for Celsion's liver cancer agent ThermoDox in combination with radiofrequency ablation continued to rise while Acadia Pharmaceuticals surged when its Parkinson's disease psychosis project pimavanserin scored a pivotal study success in November. The only UK company to make it into the top ranks, Scancell, was the fifth-highest riser among nano-cap stocks.

Meanwhile, the biggest failures among this group featured two filers for bankruptcy protection – Bionovo and K-V Pharmaceutical – as well as Israel's D-Pharm, slammed after halting phase III studies of the stroke agent DP-b99, and Allon Therapeutics, which rounded off 2012 suspending its lead project, davunetide.

While K-V might well come out of bankruptcy protection it is fair to assume that the woeful pricing strategy for its premature birth drug Makena and attempt to sue the US FDA have ensured that its best days are behind it. It is now among the ranks of the smallest companies, whose share prices swing wildly on the tiniest developments.

For investors with the right appetite for risk that is not necessarily a bad thing.

To contact the writers of this story email [Jacob Plieth](mailto:Jacob.Plieth) or [Joanne Fagg](mailto:Joanne.Fagg) in London at [news@epvantage.com](mailto:news@epvantage.com) or follow [@JacobEPVantage](https://twitter.com/JacobEPVantage) and [@JoEPVantage](https://twitter.com/JoEPVantage) on Twitter

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Evaluate HQ  
44-(0)20-7377-0800

Evaluate Americas  
[+1-617-573-9450](tel:+16175739450)

Evaluate APAC  
[+81-\(0\)80-1164-4754](tel:+8108011644754)

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