

Small caps produce clear winners and losers in 2011



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As always among the smaller companies of the drug development world, 2011 produced some clear winners and losers on the stock market, with clinical successes and failures largely responsible for some huge shifts in valuation over the year.

Among the best performing stocks, hopes for a paradigm shift in the treatment in hepatitis C drove demand for companies like Pharmasset and Inhibitex while Medivation and Curis scored goals with novel cancer drugs. Meanwhile clinical disappointments for companies including Sweden's Active Biotech and diabetes researcher Diamyd and gene specialist Amsterdam Molecular Therapeutics meant European companies were well represented in the fallers list (see tables).

Small caps

A company acquired for \$11bn can hardly be described a small cap but at the beginning of 2011 Pharmasset was still technically a member of this group. Now in the process of being acquired by Gilead, the company was on track to top the small cap table even before Gilead offered a huge 89% takeout premium, in what must have been a very competitive bidding process.

Prior to the bid emerging on November 21, Pharmasset stock had advanced 232% on the year and was one of its group's biggest gainers in 2010 ([Comeback stories drive small cap risers in 2010, January 7, 2011](#)).

Medivation was a late arrival to the top of the table; the stock was flat on the year until phase III data on prostate cancer drug MDV3100 in November smashed expectations. The androgen receptor antagonist generated a survival benefit equal or better than marketed products and late stage candidates; the drug is shaping up as a keen competitor in an increasingly competitive class.

Questcor's MS therapy Acthar has gone from strength to strength since it gained orphan status, facilitating significant drug price hikes. Sales in 2011 are expected to have reached \$191m.

Ariad has also put on a strong performance over the year. Strong data from Merck & Co-partnered drug ridaforolimus in January provided a boost and the sarcoma therapy should reach the market later this year.

Pharmacyclics meanwhile climbed steadily over the year on growing hopes for blood-cancer drug PCI-32765, a first-in-class Bruton's tyrosine kinase (Btk) inhibitor. In December those hopes were realised when Johnson & Johnson paid a huge \$150m for rights to the drug, the biggest upfront paid for a phase II asset last year.

Small cap (\$250m-\$2.5bn) pharma companies: top risers and fallers in FY 2011

Rank	Top 5 Risers	Share price (local currency)			Market capitalisation (\$m)		EP Vantage comment and analysis
		31-Dec-10	30-Dec-11	% change	YE 2010	YE 2011	
1	Pharmasset (\$)	23.60	133.43	466%	1,607	10,081	Gilead betting the Pharmasset on hepatitis C
2	Medivation (\$)	15.17	46.11	204%	524	1,610	Medivation roars back to life as prostate cancer drug delivers
3	Questcor Pharmaceuticals (\$)	14.73	41.58	182%	919	2,644	Daily Market Movers (26 Oct 2011)
4	Pharmacyclics (\$)	6.08	14.82	144%	1,016	1,016	J&J pays handsomely for first-in-class blood cancer drug
5	ARIAD Pharmaceuticals (\$)	5.10	12.25	140%	647	1,890	Ariad soars on sarcoma success
	Top 5 Fallers						
1	Diamyd Medical (SKr)	129.50	8.95	-93%	275	38	Market allergic to failure of Diamyd diabetes vaccine
2	Alimera Sciences (\$)	10.38	1.25	-88%	305	39	Alimera and pSivida strike out
3	Active Biotech (SKr)	169.00	22.10	-87%	1,629	229	Laquinimod falls behind MS pack
4	Bavarian Nordic (DKr)	245.00	38.40	-84%	564	183	Bavarian Nordic misses out on Provenge effect
5	Intercell (€)	11.60	1.90	-84%	746	127	Intercell resets strategy as staph vaccine fails

The list of small cap fallers meanwhile looks pretty much the same as at the nine-month stage. The only new arrival is Alimera, which in November received a second complete response letter from the FDA for the eye implant drug Iluvien, designed to treat diabetic macular edema.

With a request for two additional clinical trials to prove the product is safe and effective in DME, the setback is hugely embarrassing for the company, which only listed in the US in April 2010.

The fact that the remaining four worst performing small cap stocks are European underlines what a disappointing year it has been for the region's small drug developers, and their investors.

Active Biotech was hurt by disappointing results from Teva-partnered oral MS drug, laquinimod, compounded by a very strong performance from Biogen Idec's rival oral MS candidate, BG-12. Fellow Swede Diamyd was forced to scrap further development of its eponymous diabetes vaccine after a European trial failed to show significance and partner Johnson & Johnson handed back its rights to the product.

Meanwhile investor sentiment towards Bavarian nose-dived over the year after the German vaccine specialist failed to win support for its decision to push on with trials of prostate cancer vaccine Provenge alone, tapping investors for the cash instead of finding a partner.

Finally Intercell has been struggling to allay doubts its strategic direction after a string of clinical failures, most recently a Staphylococcus aureus infection treatment, V710, which was abandoned by partner Merck & Co in June.

Micro Caps

Inhibitex and Achillion have been beneficiaries of the hepatitis C boom, with encouraging if early clinical data and speculation that they could be the next takeover target making them a popular pick among investors.

Cancer specialist Curis has been boosted by hopes for vismodigib, a skin cancer agent partnered with Roche, and other promising pipeline projects.

Australia's Bionomics continues to find fans, particularly for its anxiety drug BNO210. And despite being in the notoriously risky area of cancer vaccines Vical has had a good year, with growing hopes for its malignant melanoma gene therapy Allovectin-7.

Micro cap (\$100m-\$250m) pharma companies: top risers and fallers in FY 2011							
Rank	Top 5 Risers	Share price (local currency)			Market capitalisation (\$m)		EP Vantage comment and analysis
		31-Dec-20	30-Dec-11	% change	YE 2010	YE 2011	
1	Inhibitex (\$)	2.60	10.94	321%	162	857	Inhibitex soars on interferon-free hopes
2	Curis (\$)	1.98	4.68	136%	135	358	Therapeutic focus - Hedgehog targets given boost with phase II skin cancer data
3	Vical (\$)	2.02	4.41	118%	145	317	Daily Market Movers (26 Apr 11)
4	Bionomics (AUS\$)	0.32	0.59	84%	110	207	Daily Market Movers (12 Apr 2011)
5	Achillion Pharmaceuticals (\$)	4.15	7.62	84%	242	531	Achillion riding hepatitis C wave as data approaches
Top 5 Fallers							
1	StemCells (\$)	10.80	0.82	-92%	137	18	
2	Emisphere Technologies (\$)	2.41	0.22	-91%	125	13	Emisphere on the brink
3	NeurogesX (\$)	6.36	0.82	-87%	114	24	Product sales in 2010: hits and misses
4	Somaxon Pharmaceuticals (\$)	3.15	0.45	-86%	142	22	Intermezzo approval not the end of Transcept thriller
5	Newron Pharmaceuticals (€)	12.69	2.20	-83%	122	17	Biotie calls off Newron merger over safinamide dispute

Despite embarking on and fully enrolling a first-ever phase I/II trial of a transplant of adult neural stem cells, StemCells suffered through a difficult year that featured a 10-for-1 reverse stock split, sacking 30% of its workforce and selling off corporate assets, and a disappointing share sale in December that managed to raise less than half of the hoped-for \$20m. The company ended the third quarter of 2011 with \$12.5m.

Emisphere Technologies ended its dismal year with the failure of its lead product SMC021 in phase III osteoporosis trials.

NeurogesX's post-shingles pain product Qutenza has failed to impress since launch while Somaxon has also struggled to find demand for its insomnia product Silenor; the US company effectively threw in the towel in December and said it had hired advisors to explore "strategic alternatives".

Finally Newron has floundered in the wake of the loss of Merck as a partner for Parkinson's drug safinamide, which prompted prospective merger partner Biotie to walk away, all the while cash at the Italian company has been dwindling.

Nano Caps

Top riser Cellceutix reported in March last year that in animal studies its anti-cancer drug Kevetrin demonstrated potent anti-tumour activity against a range of cancers including lung, breast, colon and leukaemia. In November the company applied to start trials in man in early 2012.

OHR pharmaceuticals Cachexia treatment is also in a positive position: OHR/AVR118 was shown to be safe and effective, with the first patients enrolled it is Phase 2b trial.

Oncothyreon has continued to rise ahead of phase III results on its Merck KGaA-partnered non-small cell lung cancer vaccine, Stimuvax. In 2011 the company also initiated the Phase II portion of its Phase I/II trials for the anti-cancer treatment PX-866.

Meanwhile Trius Therapeutics reported positive Phase III results of torezolid phosphate in acute bacterial skin and skin structure infections. The company also formed a strategic collaboration with Bayer to develop and commercialise torezolid phosphate in Asia-Pacific and emerging markets.

Nano cap (\$25m-\$100m) pharma companies: top risers and fallers in FY 2011							
Rank	Top 5 Risers	Share price (local currency)			Market capitalisation (\$m)		EP Vantage comment and analysis
		31-Dec-10	30-Dec-11	% change	YE 2010	FY 2011	
1	Cellceutix (\$)	0.14	0.70	400%	65	65	Weekly Market Movers (to 11 Mar 2011)
2	OHR Pharmaceutical (\$)	0.25	0.65	160%	26	26	Therapeutic focus - Cachexia pipeline gaining weight
3	Oncothyreon (\$)	3.26	7.58	133%	98	324	Event - Oncothyreon awaits pivotal cancer vaccine data
4	Trius Therapeutics (\$)	3.71	7.15	93%	88	204	
5	Cytomedix (\$)	0.59	1.13	92%	26	60	
	Top 5 Fallers						
1	mondoBIOTECH (SFr)	43.93	0.49	-99%	65	38	
2	Marina Biotech (\$)	1.55	0.12	-92%	43	11	Vantage Point - Clinical progress required to reignite RNAi field
3	Soligenix (\$)	0.19	0.03	-85%	41	6	Daily Market Movers (15 Sep 2011)
4	Cytos Biotechnology (SFr)	12.50	1.95	-84%	68	11	Pharmasset continues to lead small cap gainers so far in 2011
5	Amsterdam Molecular Therapeutics (€)	1.88	0.37	-81%	58	12	AMT's second rebuff for gene therapy could be a fatal blow

The fallers include Marina Biotech which specialises in RNAi, tarnished by lack of progress in the field. However their newly formed alliance with private microRNA company Mirna Therapeutics may improve their position in 2012.

Soligenix suffered when its lead pipeline hope, orBec for the treatment of acute gastrointestinal Graft-versus-Host disease, was halted in phase III trials by safety monitors. It was unlikely to achieve its primary objective after interim results were reviewed.

Cytos, the Swiss therapeutic vaccine company, also experienced pipeline setbacks and suspended all of its research except for studies of the asthma treatment, CYT003-QbG10. It also cut its workforce to 10 employees

from 82.

Finally, Amsterdam Molecular Therapeutics suffered a blow in October with the second and final EU rejection of its gene therapy Glybera. On the upside its gene therapy treatment for haemophilia B was granted orphan drug designation by the EU in November and most recently by the FDA, but with funds dwindling the future looks bleak.

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