



# Biotech Daily

Thursday December 16, 2010

*Daily news on ASX-listed biotechnology companies*

## The Year In Review

The year after the so-called global financial crisis has seen not a single biotech dead, buried or cremated.

**Rockeby** finally departed the ASX after a prolonged coma. New Zealand's **Genesis R&D** and **Norwood Abbey** linger in palliative care, while **Fermiscan**, **Select Vaccines**, **Safety Medical** and **OMI** are in intensive care. **Agenix** has been moved to the recovery ward, while **Prima Biomed** has been resuscitated by Martin Rogers and Lucy Turnbull and, pending test results, is considered 100 percent fit for duty.

There have been some great successes and a few almost crippling disasters, among the Biotech Daily Top 40, with Prof Silviu Itescu's **Mesoblast** merger with **Angioblast** and \$1.7 billion deal with **Cephalon** the highlight and the **Chemgenex** application to the US Food and Drug Administration, the lowlight.

Biotech Daily unreservedly withdraws its editorial concern on owner-drivers (BD: Sep 19, 2008), following Prof Itescu's unequivocal success in taking his own invention, first to an ASX listing and then winning the ultimate prize - a big pharma deal worth a huge amount of money and still leaving him very much in control.

**Acrux** has also performed remarkably this year with its **Eli Lilly** deal worth at least \$670 million for one application of its platform technology and also reaching the goal of a second FDA approval.

The **Phylogica** \$100 million deal with **Medimmune**, while executed in a less than orthodox fashion, is also a notable success. It also proves Biotech Daily's view on market capitalization: size isn't everything. Phylogica's market cap has fallen from \$25 million on November 30, 2009 to \$14 million on November 30, 2010.

In fact, 23 of the Biotech Daily Top 40 Index (BDI-40) companies have fallen in the 12 months to November 30, 2010, but the total value has increased by 12.4 percent, led by Acrux, **Heartware** and Mesoblast; with **Impedimed**, **Nanosonics**, **Psivida**, **QRX**, **Starpharma** and **Tissue Therapies** all performing exceptionally well.

**Biota** has tumbled from \$546 million to \$179 million, with **Cellestis** and **Sirtex** also falling significantly. All three have product in the market and revenue – go figure!

Following equivocal trial results at **Pharmaxis** and serious criticism of its application execution by **Chemgenex**, there have been many in the industry who privately voice concerns over the Byzantine world of the US FDA.

While Biotech Daily will always give a sympathetic hearing to a small Australian caught up with a less than transparent US bureaucracy, not all of them are Julian Assange fighting the State Department. US companies also complain about the FDA process and there are some that argue that the FDA makes the former Soviet bureaucracy look mean, fit and agile by comparison.

But to be fair, there are several, predominantly device or diagnostic, companies who have told Biotech Daily that they have had no problems at all in their FDA dealings.

Biotech Daily also supports the high bar the FDA places on obesity drug trials. Eat less, exercise more. It isn't too much to ask. And think of how much great scientific effort and research and development expenditure could be spent on serious drugs, rather than wasting time trying to find a remedy for fast food outlets and too many electronic games.

Which brings us to the year that saw **Chemgenex** devalued from \$5.50 a share to \$2.90 a share and not much enthusiasm that the board and management will extract even half of the latter figure from Cephalon.

Compare the Chemgenex deal with Cephalon's **Arana** and Mesoblast deals. Cephalon buys 10 percent of Chemgenex for 50 cents and a further 20 percent for 70 cents. Why would they offer \$2.90 for the rest? The investors who can give Cephalon a majority in Chemgenex, Alta Partners and GBS Venture Partners, bought shares at a range of prices, but probably average around 40 cents (like Biotech Daily's editor and analyst). What will they want from Cephalon for control of a company that could have been great?

It begs the question of how this happened and that takes us back to the FDA. Chemgenex failed to take bone marrow aspirations of at least two patients as per the FDA-approved trial protocol – and that's just one of many criticisms leveled at the company by either the FDA or the Oncologic Drugs Advisory Committee. It appears the process is back on track with a healthier attitude to the regulator, but a year has been lost in the process, along with a halving of market capitalization. So Cephalon picks up low-hanging fruit, instead of paying a significant premium to the market price, like it did with Arana and Mesoblast.

**Novogen** has had to admit its phase III trial results were less than glowing, but this has been the trigger for a reorganization, taking the anti-cancer compounds to US subsidiary **Marshall Edwards** and leaving Novogen to concentrate on over-the-counter consumer health products.

Finally in mergers and capital raisings, **Broadvector** couldn't raise its \$5 million minimum, **Bioniche** is hoping for up to \$30 million, while **Reva** has been oversubscribed to \$85 million. Clean story plus good board and management equals investor confidence.

On the political front, the **Federal Government** has failed to provide its R&D Tax Concession, leaving us dependent on **Commercialisation Australia** and innovation investment funds and in need of a real funding mechanism for phase II and III trials. **Victoria** has lost its champion of biotech, **John Brumby**, but there is hope that the new **Innovation Minister Louise Asher**, will pick up the baton and build on the Brumby infrastructure successes.

Biotech Daily's last formal edition for 2010 will be published tomorrow and we return on January 17, 2011. Any major breaking news over the summer holiday period will be reported as a news flash with details in the January 17 catch-up edition. There will be a 5.3 percent subscription price increase to a base rate of \$790 in the New Year.

We wish all our readers a very relaxing Summer holiday break, Merry Christmas, a sunny Summer Solstice and a brilliant biotech New Year in 2011.

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