Biotech Daily

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Daily news on ASX-listed biotechnology companies

Trials, Tribulations And Transparency

To fail one phase II trial is unfortunate, to fail two phase II trials (and change technologies while losing 40 staff) appears to be carelessness.

It has been a rough three weeks for Australian biotechnology, as Jessica Gardner put it in Melbourne's The Age, today: "biotech stocks are hitting the wall at the rate of one a week".

Thankfully biotechnology success is measured in decades, not weeks and there have been far more high-level successes than failures.

While some of the Biotech Daily Top-20 companies have stumbled, few have fallen and most have performed extremely well.

The BDI-20 companies that have had major technology failures – that is non-significant phase II or III trial results – or have discontinued programs include Metabolic, Avexa, Neuren, Novogen, Phosphagenics, Prima, Virax, Progen, Pharmaxis, CBio, QRX, Starpharma, Bionomics and now Prana.

Other companies have failed to commercialize products like Ventracor, Cathrx, Healthlinx, Impedimed, Phylogica and Resonance, with the last three still very much in the game.

In the case of the drug developers, Bionomics chief executive officer Dr Deborah Rathjen has created a broad portfolio, so that if BNC105 is ditched as the evidence indicates it should be, the company has a pipeline supporting its share price.

Neuren overcame the glypromate failure by having NNZ2566 in already-funded programs.

Pharmaxis, for all its non-significant results and regulator rebuffs, has both Aridol and Bronchitol on sale, while QRX continues to take the regulatory fight to the US FDA.

Phosphagenics originally claimed that its tocopheryl phosphate mixture or phosphorylated vitamin E crème technology was able to carry large molecules, like insulin, through the skin. Basic anatomy says the skin is a barrier to keep things that do not belong in, out.

The lure of replacing daily insulin injections for diabetes with a patch was a very lucrative proposition, except the company never demonstrated it could do it.

TPM-insulin was very quietly dropped, while a range of other, already transdermally available, drugs were highlighted, along with cosmetics that don't earn much money and the fat-busting AOD9604 that doesn't.

It is hard to understand how Phosphagenics will compete with the big guns in the already saturated transdermal opioid market. Insulin anyone?

Which brings us to transparency.

In February 2007, Metabolic's AOD9604 failed its 536-patient, phase II trial for obesity and in August the company shelved the development of its lead drug candidate ACV1 for neuropathic pain (BD: Feb 21, Aug 14, 2007).

Former chief executive officer Dr Roland Scollay made the announcements very clear and as he later said to Biotech Daily when asked about the failed trials: "Oh no, David. Our trials were very successful. They showed our drugs don't work."

Yesterday, Prana executive chairman Geoffrey Kempler won credit for at least making the bad news clear: "Prana's PBT2 did not meet its primary endpoint".

But Biotech Daily was concerned that the timing of Prana's trading halt and subsequent media release at 8.55pm and conference call at 11pm was directed at its new US investors and not its long-suffering Australian founders.

Last month, Bionomics came out of a trading halt, announcing a 9.30am conference call at 8.30am, and did not say clearly that BNC105 missed its primary endpoint for renal cell carcinoma, instead minimizing the negative and emphasizing the data-mining positive.

Even the acknowledgment of failing to meet its primary endpoint looked positive: "Primary endpoint showed a similar proportion of patients in both treatment arms free of progression at 6 months in the unselected patient population" with a slightly more informative paragraph on the second page of the five-page release.

Starpharma has been unable to commercialize Vivagel for projects including HIV in Africa, precautionary use against rape-related pregnancy and HIV in the highlands of New Guinea and has had a phase III trial for 'cure' of bacterial vaginosis and a phase II trial for prevention of bacterial vaginosis, that despite barracking from analysts on conference calls, did not meet their primary endpoints.

The drop-off of activity in data presented in the prevention trial underlined the failure to 'cure' in the first trial.

But an earlier and completely separate study by the Melbourne Sexual Health Centre, co-authored by Dr Jackie Fairley's brother Dr Christopher Fairley showed that the risk of bacterial vaginosis recurrence was "halved with use of oestrogen-containing contraceptives". The proposed phase III trial of Vivagel for bacterial vaginosis recurrence does not appear a wise investment of shareholders' funds.

Starpharma chief executive officer Dr Fairley has been effective in winning major company investigations of the dendrimer technology for agricultural and other potential uses, but so far none have resulted in a major deal. The Vivagel condom-coating deals are yet to generate significant revenues.

Biotech Daily was always of the view that the dendrimer drug delivery that Starpharma first intended to develop was its most exciting project and the company should put more focus on the dendrimer-docetaxel studies and less on changing its name.

It is hard to understand what really went wrong at Reva Medical. The board and management appear to be as 'switched-on' as any in the sector, but the great idea of a bioresorbable, x-ray-visible, drug-eluting stent seems to have been overtaken by faster competitors. Investors are clearly upset that the Rezolve and Rezolve 2 have been shelved and suddenly the Fantom is the main game. Something clearly went wrong and a decision was made to ditch the previous generation, but it certainly did not look like an elegant transition to a better model.

Biotechnology is a difficult industry for investment with long lead-times and huge risks. Biotech Daily is not surprised that some very promising technologies do not deliver as expected. That's why we have rigorous trials. But investors should have the right to expect the results of those trials to be announced clearly and concisely.

If a company was successful it would say in the headline and first sentence of its media release to the ASX that drug XYZ-123 was effective against its target. If the drug fails to meet its primary endpoint, that should be equally prominent, too.

David Langsam
Editor