



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Biotron

By TIM BOREHAM

ASX code: BIT

Share price: 16.5 cents

Shares on issue: 531,314,728*

Market cap: \$87.7 million

Chief executive officer: Dr Michelle Miller

Board: Michael Hoy (chairman), Dr Michelle Miller, Dr Susan Pond, Mr Rob Thomas, Prof Stephen Locarnini

Financials (year to June 30 2018): revenue nil, loss of \$1.59 million (previously \$3.09 million loss), cash of \$1.62 million (previously \$1.65 million)

Identifiable biggest holders: Armco Barriers Pty Ltd 2.79%, Dr Angela Fay Dulhunty 1.99%, Scott's AV Pty Ltd 1.76%

* Ahead of exercise of 78.4 million in-the-money options by the end of November

Move over Viralytics, the immune-oncology outfit acquired by Merck for \$502 million earlier this year at a 160 percent premium.

Absent of any further pre-Christmas revelations from revved-up biotechland, this year's Biotech Dazzler of the Year award goes to Biotron, which has migrated from the sub \$10 million market cap 'death zone' to a substantive entity with a near \$100 million valuation.

The astonishing appreciation came about all because of the 'c' word that should be sparingly used in drug development. We're not being rude, but 'c' refers to a potential cure for a common disease, in this case HIV.

The top line clinical results showed the company's BIT 225 compound zapped - rather than merely suppressed - the HIV virus.

Until then, Biotron's program has invoked yawns, on the presumption the existing anti-retroviral (ART) drugs did the trick for HIV.

True, the ARTs have been effective in reducing viral loads and keeping HIV/AIDS patients healthy and alive. But the sneaky virus lurks in cells and never goes away, which means the patients can never go off the drugs.

What's more, the persistence of the virus causes the immune system to age more rapidly and presents other problems such as AIDS-related dementia.

Astonishingly, only one human has been known to be cured of HIV. Dubbed the Berlin Patient, Timothy Ray Brown had leukaemia and underwent a bone marrow transplant and eight years later is drug-free and healthy.

While Biotron now has the share capital to raise decent licks of money without ridiculous dilution, the company plans to seek a deep-pocketed partner for further clinical development.

"We are heading to the US in early November to share data confidentially with potential partners," says Biotron chief executive Michelle Miller.

"Being the head of a \$100 million market cap company makes my life a lot easier when I go to talk to the guys in America than when we had a \$10 million market cap, even though the technology has always been the same."

About Biotron

Biotron spun out of the Australian National University in 2000 and listed in January 2001 after raising \$12 million.

With a PhD in virology, venture capitalist Dr Miller became involved in the company shortly thereafter.

"I saw lot of deals that didn't have clean intellectual property and the freedom to operate and were not in markets you could make a difference in," she says. "This company had a way of targeting viruses in a way other people weren't, and was scientifically strong."

Dr Miller says Biotron hasn't deviated from its focus on developing small molecule drugs to treat key viral infections, with the aim of partnering at clinical stage.

Since then, the company has plugged away at programs for HIV, Hepatitis C and Hepatitis B, while keeping a weather eye on other indications including Dengue fever, the Zika virus and Epstein-Barr virus (glandular fever).

Biotron's chairman since listing, Michael Hoy, is a former director of the Fairfax media group and a one-time restaurateur. Fellow director Rob Thomas is also on the Starpharma board.

This week, the company announced the appointment of Prof Steven Locarnini, director of the World Health Organisation's regional reference laboratory for hepatitis B and D.

What's all the fuss about?

On September 28, Biotron announced that a phase II trial involving 27 HIV-infected patients showed "statistically significant immunological benefits", which in layman's terms means "you bloody ripper".

Carried out in Thailand, the trial combined BIT225 with the current standard-of-care ART drugs.

The trial targeted macrophage reservoir cells, which house the residual virus even when tests show the ARTs have eliminated the nasties from the bloodstream.

"What we saw was an immune response generated by non-infectious virus coming out from macrophages," Dr Miller says. "We did not expect to see this."

The 12-week, placebo-controlled trial involved previously untreated subjects receiving a once-daily 200mg dose of BIT225 along with the ART drugs.

"We knew from laboratory-based studies that BIT225 targets and kills viruses that hide in long-lived reservoir cells," Dr Miller said. "The challenge was how to show this in humans. No one has done this before, and there were no guidelines to follow."

What happens now?

As per biotech etiquette, the trial data announced to the ASX was only a non-geeky top-line summary of the clinical results.

The full results are to be presented at a conference of learned peers, probably at the end of November.

Just as newspapers like their yarns to be exclusive, the conferences demand that the presentation material not be aired beforehand. And if you don't front these confabs, the clinical big wigs don't want to know you.

“There’s ongoing work,” Dr Miller says. “Clinical trials are a source of fun and games for a long time to come. Further clinical analysis won’t affect the outcome but they’ll add to the picture of what is happening.”

Management envisages a ‘treatment interruption’ study, by which patients are taken off the ART drugs and treated with either BIT225 or a placebo. That way, it becomes clearer how and why BIT225 is working.

A successful result raises the prospect of patients enjoying a “treatment holiday” from the ARTs. There’s also the prospect of mitigating AIDS-related dementia.

Another reason to get patients off the ARTs is that as they get older, they probably need drugs for other conditions and this can create complications.

Despite the market’s focus on the HIV program, Dr Miller says investors should not forget that Biotron has a program for hepatitis C, a sector that has seen renewed interest.

An earlier hepatitis C trial created a frisson of interest after reporting “significantly improved clinical outcomes”.

But until recently the hepatitis C message has been hard to sell because of the perception that drug giant Gilead cornered the market after acquiring Pharmasset - developer of the blockbuster drug Solvadi - in 2011.

But Dr Miler notes that 85 percent of people with hepatitis C in the US are not being treated with anything “and the number of people being cleared each year is being eclipsed by the number of new patients”.

Biotron is also pursuing partnerships in China, where there are a between 30 million and 40 million hepatitis C patients and a large incidence of co-infection with hepatitis B.

Finances and performance

In June, Biotron raised \$1.4 million in a rights issue at 1.5 cents apiece, just to keep the lights on.

Now, the company secretary is being besieged by shareholders asking how to convert their options, which with a 6.0 cents strike price and November expiry were assumed to be worthless a month ago.

These instruments will pull in \$4.7 million. Miller herself has converted a swag of her own options for an additional \$850,000. With a June 30 cash balance of \$1.5 million and a \$1 million Federal R&D Tax Incentive, Biotron has around \$7 million to play with.

In a cautious move, management has guaranteed the \$4.7 million will come through the door by entering an underwriting deal with Perth firm CPS Capital Group. “You never know what this market is going to do,” Dr Miller says.

Still, it looks like money for old rope for CPS, which takes a 5.0 percent clip for negligible risk.

If another party funds the \$5 million to \$6 million cost of a further HIV trial and the company does not launch one for another indication, Biotron will only burn about \$250,000 of cash per quarter.

Having traded as low as 1.6 cents this year, Biotron shares spiked briefly to 44.5 cents on October 16 before investors took some semblance of a reality check.

Dr Miller says Biotron has a history of raising only enough equity as required at the time. Still, it must be tempting to avail of the enhanced share collateral and raise a decent wad with minimal dilution.

Dr Boreham's diagnosis:

An obvious question is why any one of the half dozen or so HIV (or hepatitis C) drug companies would want to foster a 'cure' that kills their business.

Dr Miller notes that many of the ARTs are coming off-patent, so the big pharmas are scouring for other products. These drug companies could also preserve their margins by charging a small fortune for the new treatment.

Given the reduced incidence of hospitalization on the part of 'cured' patients, Biotron will have the blessing of the health insurers who ultimately foot the bill.

For commercial reasons, Biotron will focus on the US HIV market. But if Bill and Melinda Gates want to fund access for the millions of sufferers in developing countries, well and good ...

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. The fact he is still writing for this column reflects the sad reality that he does not own Biotron shares.