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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Acrux

By TIM BOREHAM

ASX Code: ACR

Market cap: $25.8 million

Share price: 15.5 cents

Shares on issue: 166,521,711

Chief executive officer: Michael Kotsanis

Board: Ross Dobinson (chairman and founder), Michael Kotsanis, Bruce Parncutt, Dr Tim Oldham, Dr Geoff Brooke, Dr Simon Green

Financials (year to June 30 2017): revenue $23.93 million (down 16 percent), * net loss $243,000 ($11.1 million profit previously), cash of $34 million (versus $29.3 million)

Identifiable holders: ** Hugh Elphinstone 3.06 percent, Asia Union 2.10 percent, Paul Cozzi 1.80 percent, Ian and Debra Lancini 1.23 percent, Michael and Rechaelle Sylvester 0.87 percent, Christopher Abbott 0.84 percent

***** Net loss includes a non-cash impairment of $10.68 million
****** Allan Gray, held 14 per cent but has since gone below the substantial threshold.

In a nasty case of corporate detumescence, shares in the developer of the roll-on testosterone product Axiron are trading at less than their cash backing after a series of setbacks.

While Acrux's woes in the US have been well-documented, it's an intriguing valuation given the company could receive a substantial damages pay-out should a US legal appeal prove successful (more on that later).

And while Axiron is effectively dead and buried in the US, the company hopes to pave an alternative revenue path by developing up to 12 topical and transdermal generic drugs.

Acrux shares tumbled 30 percent on September 6 when Acrux and distributor Eli Lilly "mutually agreed" to terminate their Axiron distribution agreement.

The divorce is effective immediately in the US and elsewhere 90 days thereafter.

For what they're worth now, the global rights revert to Acrux.

When the tie-up was unveiled in 2010 it was one of the biggest in Australian biotech history with a trumpeted value of $US335 million in upfront payments, approval payments and commercialization milestones.

Testosterone deficiency - or hypogonadism - is linked with a number of clinical problems, with an estimated 40 percent of blokes aged under 45 years being deficient in the hormone.

Founded in 1998 by Prof Barrie Finnin and Ross Dobinson as a Monash Uni spin-off, Acrux developed Axiron from its 'Patchless Patch' fast drying topical technology.

In 2011, Axiron was approved in US, which until recently has accounted for 95 percent of global testosterone sales.

The reason is not just because Yanks want to be more virile: because the drug cost much more in the US than elsewhere, drug companies have had more incentive to market the hormone harder.

According to reliable sources - Biotech Daily editor David Langsam actually - Eli Lilly has reaped revenue of more than $US800m from Axiron over the product's six-year life.

On Prof Langsam's back of the serviette sums, Acrux over this time has received $156 million in milestone payments and more than $145 million in royalty revenue.

A catalogue of woes

Axiron's woes began in 2014 when the Food and Drug Administration voiced its concerns about suspected linkages between testosterone treatment and heart attacks and strokes.

As a result the regulator requires a post-marketing clinical trial to address these risks.

In 2013 Acrux launched - and lost - a court action against four generic companies planning generic alternatives.

As a result, in July this year, Perrigo launched a generic version of Axiron and then Teva did the same in July.

Prasco then launched an authorised generic (licenced by Eli Lilly) in August.

The incursion of competitors saw a dramatic slide in Acrux's share of the topical testosterone market: from 14 percent at the start of the year to around 10 percent now.

Given the emergence of generic competition, Acrux and Eli Lilly decided the investment in the mandated clinical trials - and we're talking potentially hundreds and millions of dollars - was not worth it. And Axiron will be withdrawn from the US market.

The other headwind is that the FDA has limited testosterone prescriptions to "men with low testosterone levels caused by certain medical conditions and confirmed by lab tests".

Sounds reasonable to us.

The result of this dictate was that testosterone sales plunged by 50 percent overnight, which presumably means the hormone was widely being used by 'off label' by ageing Lotharios.

Generics: friend or foe?

While generics have been a curse for Acrux, they are also integral to the company's future.

Two years ago, the company realised it couldn't rely on Axiron and resolved to enter the generics game itself.

The company cites seven generics under development, increasing to 12 next year.

The company is keeping the nature of the indications close to its hairy chest, but the target market is worth more than $US1 billion in a topical US generic sector worth $US7 billion overall. The company hopes to initiate clinical trials next year.

Acrux's other path to redemption is using its compound ACR065 to treat onychomycosis. While this sounds like a nasty cancer, it's a fungal infection of the toenails and fingernails (and not very nice either presumably).

Lawyers: friends or foe?

In August last year, the US District Court ruled that the Axiron formulation was invalid, thus spurring the generic rivals to market.

Acrux and Eli Lilly have appealed the decision, with an appeal hearing scheduled for October 5.

The beauty for Acrux is that Eli Lilly has stumped up the costs for the legal groundwork, leaving a minimal cost for Acrux.

Given the valuation of Acrux shares ascribes no worth at all to the legal dispute, a successful appeal (and a chunky damages award) is all upside.

Dr Boreham's diagnosis:

Despite the travails, Acrux 2016-'17 year-end cash balance edged up 15 percent to $33.94 million.

The market cap of $26 million implies management could return all the funds to shareholders and have some lollies left over.

Acrux will continue to receive Axiron royalties while the Eli Lilly tie-up winds down; other than that, it's a case of back-to-the-future as a development company.

But Acrux boasts a hidden asset: it is a pooled development fund (PDF); one of the few ASX listed vehicles structured as such.

Introduced by Paul Keating, PDFs offer advantages including not being subject to capital gains tax and non-taxed dividends. The downside is that losses can't be claimed against capital gains.

With Mr Dividend likely to be absent for some time, Acrux cannot reap the advantage.

But because PDFs have been discontinued there's intrinsic value in the PDF structure.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His last testosterone fuelled romp was as a randy teenager.