



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Suda Pharmaceuticals

By TIM BOREHAM

ASX code: SUD

Market cap: \$14.2 million

Share price: 0.4 cents

Shares on issue: 3,556,371,635

Executive chairman: Paul Hopper

Board: Paul Hopper (chairman), Stephen Carter*, David Phillips, David Simmonds

* Mr Carter resigned as CEO, effective from September 23 and will also step down from the board. Mr Hopper has assumed the executive chairman role while a new CEO is found

Financials (year to June 30 2019): revenue \$1.2 million (up 186%), loss of \$7.8 million* (previously \$5.5 million deficit), cash of \$4.3 million (previously \$98,125)

* Includes \$6.27m impairment of the value of the Artimist malaria spray program

Identifiable major holders: Kamala Holdings 3.09%, Thomas McGellin/Tanya Karal 1.63%, Bamber Investments 1.56%, Scintilla Strategic Investments 1.41%, James Richardson 1.24%.

“History is bunk” declared industrialist Henry Ford, but unfortunately for the oro-mucosal delivery specialist distancing itself from its corporate past has not been a simple case of cranking up the Model T and hitting the road.

In another case of biotech's disappearing CEO syndrome, Suda this week announced that Stephen Carter had his last day in the big chair on September 23.

(Adalta's CEO Sam Cobb stepped down in August after 12 years at the helm).

Mr Hopper dubs the departure as "friendly", but gives some insight into the board's mindset.

"There's been a lot of different deals and [the company has] a lot of tentacles all over the place," he says.

"There's a little bit of fatigue with the shareholders about small deals with small upfronts so we would clearly like to chase some of the bigger transactions."

Suda's CEO for nine years, Mr Carter helped fix up a number of historical blotches, notably a damages claim stemming from a 2008 misfeat when the company was known as Eastland Medical.

In July last year, Suda agreed to settle the claim for EUR8 million (\$13 million), representing 10 cents in the dollar. In short, the matter related to non-existent patents promised to associate Berlin Pharma, which subsequently entered administration.

The settlement - and the urgent requirement for emergency capital raisings - has contributed to Suda shares trading at three tenths of a cent, which is normally quicksand territory for a small cap.

Yet the two raisings in July of this year and last year were well supported; oversubscribed in fact.

Suda was incorporated in 1999 and listed in 2001 as Eastland Medical, before changing its name to Suda in 2012.

In hindsight, the company should have wound up and started from scratch in which case it might have avoided the legacy woes.

Boardroom blitz

Ahead of Mr Carter's abrupt resignation, Suda's boardroom had been given the complete renovation makeover with the appointment of Mr Hopper and David Phillips as directors.

Mr Hopper needs no introduction as the former chair of Viralytics and he is also on the boards of the ASX listed Imugene and Prescient Therapeutics.

Mr Hopper has stepped up to be executive chairman until a new CEO is "identified", with his stipend increased to \$150,000 from \$80,000, previously.

Mr Hopper is also known for duchessing investors, so don't be surprised that the company has picked up its investor relations activity.

Mr Phillips is an ex-Glaxosmithkline bigwig, having spent seven years as a managing partner of its corporate venture arm.

Two other chaps, Andrew Curtis and David Simmonds, have also joined the board. Mr Curtis was a senior adviser to Johnson & Johnson, while Mr Simmonds was an audit partner with Ernst & Young for three decades.

Meanwhile, Mr Carter will provide consulting services to ensure a smooth handover.

Better delivery

Suda is all about reformulating common drugs into oral sprays in order to be more effective. After all, absorption through the mouth lining is a far more direct route to the bloodstream than the stomach.

The basis is Suda's so-called hydrotope technology, called Oromist.

Suda's thesis is that only about 10 to 30 percent of the active ingredients in a tablet get to the afflicted areas, which in your columnist's book amounts to a big fat fail.

Besides that, about half the populace has trouble swallowing a tablet (although rave party attendees seem to have no problem with ecstasy).

Suda has a portfolio of more than 300 patents, but it has honed its efforts on a handful of drugs likely to produce commercial returns.

One example is Duromist, the oro-mucosal version of Viagra.

Another is Zolpimist or zolpidem tartrate, the insomnia drug sold as Stilnox.

And no, don't take Duromist and Zolpimist at the same time.

Other applications in the works include cancer, migraine, childhood malaria, chemotherapy-induced nausea, epilepsy, autism and hypertension.

Suda plans to use the US fast-track approval pathway, which may allow the company to rely on the safety and efficacy data pertaining to the underlying drug.

Regulatory nerds will know this as the 505 (b) (2) provision.

Doing deals

Suda's revenue model is based on securing key distribution and development deals that deliver upfront payments, milestones and royalties.

Suda's most substantive opportunity to date lies with Zolpimist, which has been approved and sold in the US since 2008.

The trouble is, Suda does not hold the rights to that geography (or Canada).

But it does hold the rest of the world rights and has already farmed out the South American and Mexican coverage to Israel's generics giant Teva Pharmaceuticals.

Mitsubishi Tanebe Pharma Singapore has exclusive dibs over 10 Asian countries, while Eddingpharm takes care of China's sleepless masses.

Suda is working on a global licencing program for other countries and has lodged a new drug application with the US Food and Drug Administration.

Meanwhile Suda has a compact with Indian conglomerate Strides to develop a migraine treatment for the US market. This reformulation is based on sumatriptan, the generic name for Glaxosmithkline's blockbuster drug Imitrex.

This deal involves upfront and milestones of \$6 million, with Strides ponying up for \$4 million of development costs (including clinical trials).

Suda has also developed a "pleasant strawberry mint flavored" spray version of the benzodiazepine Midazolam, for epileptic seizures and anxiety.

TGA puts bite on malaria treatment

While Suda's key legal battle is over, it does have a wee problem with the Australian Therapeutic Goods Administration, which in May rejected marketing approval for its anti-malarial treatment Artimist. Suda has long-claimed the benefits of its transportable mouth spray over the need for intravenous quinine.

The TGA was concerned about the stability of the product in tropical climes, which Suda maintained was not justified by the evidence.

Suda has appealed, with a decision due by October 2 (yep, next week).

The malaria market is a philanthropic one, in that it's a huge killer in the third world (the mosquito-borne curse kills 10,000 children a week in the sub-Saharan).

But 'philanthropic' does not equate to unprofitable: pharmaceutical companies have been willing to spend up big on malaria drugs, either out of pure altruism or the knowledge that developing markets are tomorrow's broader drug buyers.

Novartis, the leading seller of malaria drugs, gives away 400 million doses at cost price each year.

Tackling the most difficult cancers

Suda owns the only patent for the use of anagrelide for treating cancer.

Anagrel-what?

Hitherto used for a rare blood disorder, anagrelide reduces blood platelet overproduction prevalent in many aggressive cancers such as ovarian cancer.

Mr Carter says past studies suggest that breast cancer and colorectal cancer patients with a low platelet count are 1.7 times more likely to survive, while for stomach cancer patients the chance of surviving for three years increases from 23 percent to 73 percent.

“Anagrelide has cardiac side effects, but if delivered via Suda’s (spray) then toxicity is potentially avoided,” he says.

Suda is in the throes of reformulating the drug into a spray before fronting the regulators.

Is ‘Dopamist’ the next big thing?

We would be dopes for not mentioning it, at least in passing.

Suda has compacts with both Zelda and Canberra’s Cann Pharmaceuticals to look at using Suda’s technology for mucosal delivery of cannabis therapies.

“There are a lot of variables,” Mr Carter says. “A deal’s not done until it’s done.”

Suda is licenced to acquire cannabis and cannabinoids for research purposes.

Finances and performance

A key rider to Suda’s full-year reported loss of \$7.8 million is that it includes a \$6.3 million write down on the value of the Artimist project.

Given the TGA’s rejection, management deems this as a prudent move but presumably this non-cash charge could be reversed if the company’s appeal succeeds (and management is mightily convinced it will).

Mr Hopper says there is no need for any further funds after the two rights issues that raised \$10.6 million, \$6.8 million of which funded the Berlin Pharma settlement.

The current cash balance of \$4.5 million should last the company for 12 to 15 months, all things being equal (which they never are).

The company also expects a \$1 million Federal R&D Tax Incentive.

Suda derived just over \$1.2 million in revenue, pertaining to the Strides, Mitsubishi Tanebe and Zelda deals.

“Based on current deals we should exceed that reasonably well,” Mr Carter says. “Each includes a component that pays for work done.”

Royalties are expected to flow within two years.

The company forecasts more than \$50 million of royalties from Zolpimist over the first 10 years of sales

The company expects \$6 million in upfront and milestone payments from Strides (sumatriptin) to develop product for the US market.

The Berlin Pharma settlement requires three further payments of EUR250,000 (\$404,000) in December this year and December next year and then EUR350,000 as a final expungement in December 2021.

Dr Boreham’s diagnosis:

Suda has more irons in the fire than a gold rush era blacksmith and shows far more promise than its penny-dreadful status - and \$14 million market capitalization - would suggest.

However, at this stage it’s hard to glean a holistic picture of likely long-term revenues and profits. And quite frankly, unexplained and abrupt CEO departures are highly unsettling.

Mr Hopper says the CEO search is “going at 100 miles an hour”. And don’t be surprised if he already has one lined-up.

The fund raisings - the first a one-for-one rights issue - means that Suda has 3.6 billion shares on issue.

“That’s why the share price is where it is,” Mr Carter says. “It’s not a lack of belief in the technology and the basic business model has not changed.”

When the final payments for the Berlin Pharma matter are made, history for Suda finally will be “bunk” and the company can motor down less hazardous roads.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He concurs with Henry that history is bunk, having fallen off one as a youngster