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

Share price: 4.4 cents

Shares on issue: 305,846,953

Market capitalization: $13.5 million

Chief executive officer: Dr Michael Baker

Board: Paul Hopper (chairman), Dr Baker, David Phillips, David Simmonds

Financials (Year to June 30 2020): revenue $532,690, loss of $9.94 million*****, cash of $4.9 million******

***** includes $5.93 million impairment of the Artimist program

****** Post $4.1 million capital raising

Major identifiable holders: Scintilla Strategic Investments 2.46%, Kamala Holdings 2.32%, Bamber Investments 1.52%, Sempai investments 1.2%.

To the witches in Macbeth, the "cauldron bubble" spelt double toil and trouble.

But for the oral spray drug delivery house Suda, being based in the coronavirus-free Perth bubble has been a much more pleasant experience than that prophesized by the three hags cackling around a boiling pot.

All of Suda's research and development activity takes place in the Western Australian capital, with limited disruption.

"We recognized quickly [Covid-19] could be a potential problem, not just for us but our partnerships and suppliers around the world," says Suda chief Michael Baker (who, by the way, is locked down in his native Melbourne).

"But we contacted them and they were okay to maintain an ongoing dialogue."

Such unfettered communication will be all the more important now, with Suda in late July winning Therapeutic Goods Administration (TGA) assent for its spray insomnia treatment, Zolpimist.

The agency is the first jurisdiction to approve Zolpimist outside North America.

A few weeks earlier, Suda announced a capital raising on the back of positive news about its cancer reformulation anagrelide.

The approval is the first for Suda for any of its programs, which are based on its hydrotope platform called Oromist.

Oromist 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.

"Zolpimist is clearly our most advanced program," Dr Baker says.

Hop(per) to it

When we last covered Suda a year ago (BD: Sep 27, 2019), the company was in a state of management flux, with the arrival of biotech sector demigod Paul Hopper as chairman and the departure of chief executive Stephen Carter.

Clearly a change agent, Mr Hopper opined the company had flitted across too many programs, with too little success in any.

"There's been a lot of different deals and [the company has] a lot of tentacles all over the place," Mr Hopper told your columnist at the time.

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

Mr Hopper's hand-picked chief executive, Dr Baker clocked-on in January this year. Dr Baker previously was an investment manager with boutique fund Bioscience Managers.

Dr Baker says he was "mindful" about Mr Hopper's concerns about the company lacking focus.

“It’s great to have a lot of products but I would prefer to do fewer things right and look to the programs where we are most likely to capture value in the longer term,” he says.

Suda, by the way was incorporated in 1999 and listed in 2001 as Eastland Medical, before changing its moniker to Suda in 2012.

Suda’s chief executive for nine years, Mr Carter helped fix a number of historical merde sandwiches, notably a damages claim stemming from a 2008 misfeat that culminated in a $13 million settlement against the company.

In (very) shorthand terms, the matter related to non-existent patents promised to associate Berlin Pharma, which subsequently entered administration.

You don’t want - or need – to know any more.

Zolpimist – more than a sleeper

The Therapeutic Goods Administration’s green light means that not only can Suda sell Zolpimist in Australia, but it can use the assent to leverage approvals elsewhere.

Zolpimist re-works zolpidem tartrate, which is widely prescribed in tablet form as Ambien (in the US) or Stilnox (Australia). In the US, Ambien accounts for around 30 million prescriptions annually.

The twist is that Suda doesn’t actually own the North American rights to Zolpimist; that honor goes to the Englewood, Colorado-based Aytu Bioscience.

Elsewhere, Suda has licensed Zolpimist to Teva in Mexico, Chile and Brazil; and to Mitsubishi Tanabe in South Korea, Singapore, Malaysia and the Philippines.

Zolpimist is already listed on the Australian Register of Therapeutic Goods, but Dr Baker admits that Suda does not have the core competencies to market and distribute a drug.

“A major focus for Suda is selecting the Australian partner to commercialize it,” he says. “That’s not something we are taking lightly. We want the right partner.”

Suda’s current partnerships cover 550 million sleepless people.

“Insomnia is a difficult market to quantify, but in the order of 10 to 30 percent of people will suffer from insomnia,” Dr Baker says. “It’s a pretty attractive market to have those partnerships in place.”

Clinical trials showed that Zolpimist sent 79 percent of participants to the land of nod within 15 minutes after a 10 milligram dose, compared with 26 percent for the tablet form.

That’s amazzzzzing!

Regulator swats malaria drug

Suda had less regulatory success with Artimist, the spray version of the malarial drug artemether.

That's because the Therapeutic Goods Administration swatted Artimist in May last year, with tolerability concerns overriding evidence the formulation was safe and efficient. Suda's subsequent protests fell on deaf ears.

Malaria kills 10,000 kids a week in the sub-Sahara, which shows that even Covid-19 isn't even trying when it comes to mortalities.

But the malaria market is philanthropic - it's the sort of thing Bill and Melinda do with their spare billions - while big pharma often has a less altruistic motive of providing such drugs to curry favor in developing countries.

Suda impaired the Artimist program by $6.27 million in the 2018-'19 year and then wiped off a further $5.33 million in the 2019-'20 year. This means the program is valued at nil, nada and zip - but it's still on the books.

"We could opportunistically partner it if someone showed interest," Dr Baker says. "But Suda won't be committing any more dollars to the program."

Cancer hope

Anagrelide has been approved by the US Food and Drug Administration and European Medicines Agency for essential thrombocythemia (high blood platelet levels).

Research suggests that patients with certain types of cancer have worse chances of survival with high platelet levels. The reason is that platelets help cells to grow and move around the body - including the tumorous ones.

"It's a nasty feedback loop because the platelets assist the cancer cells and the cancer cells signal to have more platelets provided," Dr Baker says.

But why bother converting into an oral spray? The answer is that if you take it as a tablet it's cardiotoxic, as it's metabolized by the liver.

"If we can create a spray that crosses the cheek, or the lining of the tongue without first-pass metabolism we can reduce the cardiotoxic effects," Dr Baker says.

So far, Suda has won patents in Europe, Japan and - this month - Australia.

In terms of clinical work, Suda engaged British contract research organization Covance to undertake a canine pharmacokinetic study.

As outlined this week, the final study showed the oral spray delivered a “statistically significant increase in bioavailability” compared with the commercial capsule Xagrid. The spray also did not result in increased heart rates.

Once a final formulation has been devised, the company intends to complete toxicology studies ahead of human clinical trials.

Taking pot luck with other programs

Meanwhile, Suda is in cahoots with Zelira Therapeutics and Cann Pharma in early-stage development of spray-version cannabinoid drugs.

The company has not specified the pot shots it’s taking, but it’s perhaps no coincidence that Zelira is developing what could be the world’s first approved cannabis-based insomnia treatment.

Cann Pharma’s work relates to drug-resistant epilepsy, melanomas and motion sickness - so take your pick.

With its migraine program, sumitriptan, Suda is partnered with the Indian-based pharma house Strides.

Sumatriptan is 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).

“When we finalize the formulation, we can move to pre-clinical work,’ Dr Baker says. “The nice thing is it’s a full development, licencing and supply agreement.”

Strides has the US franchise and has the first right of refusal for other territories.

Suda also retains a program called Duromist, which is a reformulation of the off-patent erectile dysfunction drug Viagra. Now, there’s a scenario where speed of efficacy is paramount.

Having said that, Suda has no plans to get the program up in the near future.

Finances and performance

The timing of Suda’s $4.1 million capital raising was intriguing, because the Australian news about Zolpimist’s approval was announced on the last day the offer was open.

The one-for-one rights issue raised $3.56 million, with a placement garnering $533,000 more.

Meanwhile, Suda generated just over half a million dollars of revenue in the year to June 30, 2020, but with no commercial sales. The income was from upfront fees from Mitsubishi Tanabe.

Suda's work is funded by its other partners, including Strides, Zelira, Ordesa (a paediatric program) and Sanofi-Aventis (undefined).

That leaves Suda's own commercial focus on signing a local distributor for Zolpimist.

"Until we have that partner locked away, I'm hesitant to give a time frame," Dr Baker says.

Last November, the company underwent a 25-to-one share consolidation.

Allowing for that, Suda shares in the last 12 months have vacillated between a high of 9.5 cents (late September 2019) and a low of 2.7 cents (late July this year). The shares peaked at $1.35 in January 2014.

Dr Boreham's diagnosis:

Arguably the investor excitement about Zolpimist relates to the drug being approved outside the US for the first time, rather than being green-lighted in Australia.

"Few [Australian] biotechs have an approved product," Dr Baker says. "It's an important milestone for Suda to show this is what we're capable of.

"Everyone knows Australia is a little market. For Suda it was off the back of a few bumps in the road - Artimist's TGA knock-back being a big one."

With a circa $14 million market cap Suda is being priced to fail.

Or perhaps the stock is a bargain in the context of frothy valuations elsewhere in the sector?

But in our view, Suda needs to maintain a laser-like focus on commercial and clinical progress, rather than just talk up prospects as it did in the past.

To reformulate the old saying: spray it, don't say it.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Let spray no-one notices.