Biotech Daily

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Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 1.51 percent on Friday September 25, 2020, with the ASX200 up 89.0 points to 5,964.9 points. Twenty of the Biotech Daily Top 40 stocks were up, 16 fell, three traded unchanged and one was untraded.

Osprey was the best, up 0.7 cents or 30.4 percent to three cents, with 19.2 million shares traded. Optiscan climbed 23.8 percent; Dimerix was up 13.95 percent; Antisense was up 9.5 percent; Amplia, LBT and Oncosil improved eight percent or more; Prescient rose 6.1 percent; Proteomics was up 4.1 percent; Nova and Volpara were up more than three percent; Clinuvel, Cyclopharm, Immutep and Imugene rose two percent or more; Kazia, Next Science, Opthea and Pharmaxis were up more than one percent; with CSL and Nanosonics up by less than one percent.

Actinogen led the falls, down 0.2 cents or 7.1 percent to 2.6 cents, with 7.9 million shares traded. Patrys lost 6.7 percent; Genetic Signatures and Telix fell more than four percent; Impedimed and Resonance were down more than three percent; Starpharma shed 2.1 percent; Compumedics, Orthocell, Paradigm and Polynovo were down more than one percent; with Avita, Cochlear, Cynata, Medical Developments, Mesoblast, Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: SUDA PHARMACEUTICALS

By TIM BOREHAM

ASX code: SUD

Share price: 4.4 cents; **Shares on issue:** 305,846,953; **Market cap:** $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 thrombocythaemia (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.

OPTHEA

Opthea says it has registered its proposed initial public offering of American depository shares to list on the Nasdaq.
Last month, Opthea said it had submitted a draft registration to the US Securities and Exchange Commission (SEC) (BD: Aug 24, 2020).
Today, the company said it had applied to list on the Nasdaq under the ticker code OPT and would continue to trade on the ASX but said the number of securities to be sold and the price had not been determined.
The SEC filing said the company proposed to raise up to $US150 million ($212.3 million) which Biotech Daily understands would more than cover the costs of at least one phase III trial of OPT302 for wet aged related macula oedema or diabetic macular oedema.
Opthea said Citigroup and SVB Leerink were acting as joint book-running managers for the offering with Oppenheimer & Co and Trust Securities acting as lead managers.
Opthea was up three cents or 1.1 percent to $2.87 with 413,667 shares traded.

STARPHARMA

Starpharma says the Australian Therapeutic Good Association has approved its over-the-counter Vivagel BV for the prevention of recurrent bacterial vaginosis.
Starpharma said one in three women contracted bacterial vaginosis, which was characterized by unpleasant vaginal odor and discharge caused by an overgrowth of pathogenic bacteria, with 40 to 50 percent of sufferers having a recurrence of bacterial vaginosis within three to six months
Starpharma chief executive officer Dr Jackie Fairley said it was “great to see the Australian approved indications for Vivagel BV now aligned with Europe and Asia”.
“We are also pleased that Australian women can use the product to prevent, as well as treat, this troublesome and highly recurrent condition,” Dr Fairley said.
Starpharma fell 3.5 cents or 2.1 percent to $1.605 with 700,759 shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says shareholders at its annual general meeting will vote to issue 3,000,000 options to director Dr Nicholas Hartnell exercisable as 15 cents each within four years.
The company said shareholders would vote to adopt the remuneration report, re-elect director Sean Mulhearn, ratify to the previous issue of shares, adopt the employee share option plan, and approve a 10 percent placement capacity.
The meeting will be held online on October 28, 2020 at 9:00 am (AEDT).
Allegra fell one cent or 5.9 percent to 16 cents.

COGSTATE

Cogstate says it proposes to issue chief executive officer Bradley O’Connor with 1,250,000 options and increase the director fee pool by 44.4 percent to $650,000.
Cogstate said the annual general meeting would vote to issue Mr O’Connor 1,250,000 options exercisable at 78.2 cents each, pending performance, expiring within five years.
The company said it proposed to increase the director fee pool from $450,000 to $650,000 a year and shareholders would vote to adopt the remuneration report and re-elect chair Martyn Myer and Richard van den Broek as directors.
The meeting will be held online on October 27, 2020 at 11am (AEDT).
Cogstate fell half a cent or 0.7 percent to 67.5 cents.

EXOPHARM

Exopharm says its annual general meeting will vote on the issue of 340,000 performance rights to managing-director Dr Ian Dixon and chair Jason Watson.
Exopharm said shareholders at its annual general meeting would vote to issue chief commercial officer Dr Chris Baldwin 75,000 shares based on the achievement of performance indicators.
The company said it proposed to issue 250,000 performance rights to Dr Dixon and 90,000 performance rights to Mr Watson on the achievement of performance hurdles.
Exopharm said Mr Dixon and Mr Watson's performance rights would vest in three equal tranches between on January 1, 2021, July 1, 2021 and January 1, 2022 when the company share price reached 50 cents, 60 cents and 75 cents respectively.
The company said shareholders would vote on the ratification of shares, the issue of 2,000,000 shares to Canary Capital, the approval of placement options, the issue of mandate options, the adoption of the performance rights plan.
The meeting will be held online on October 29, 2020 at 11am (AEDT).
Exopharm fell 1.5 cents or 4.8 percent to 29.5 cents.

IMMUTEP

Immutep said its annual general meeting would vote to issue 1,350,000 performance rights to director Grant Chamberlain in lieu of cash remuneration.
Immutep said the number of performance rights for Mr Chamberlain were based on three years of director fees of $90,000 a year and would vest in three equal tranches over three years, exercisable at no cost and expiring two years after the grant date.
The company said shareholders would vote to adopt the remuneration report, re-elect director Mr Chamberlain, approval a 10 percent placement capacity, ratify the issue of shares and approve potential termination benefits for executives.
The meeting will be held online on October 27, 2020 at 10:30am (AEDT).
Immutep was up half a cent or two percent to 25.5 cents with two million shares traded.

IMPEDIMED

Impedimed says its annual general meeting will vote to issue chief executive officer Richard Carreon 7,400,000 performance rights and 6,159,000 options.
Impedimed said Mr Carreon's proposed performance rights were valued at $511,000 or 6.9 cents vesting over three years, pending performance indicators including contracted revenue pipeline growth and total shareholder return.
The company said the Mr Carreon's options would vest in four equal annual tranches exercisable at the 5-day volume weighted average price to the grant date.
Impedimed said that under the executive share plan it proposed to issue up to 25,000,000 shares to Mr Carreon in lieu of 20 percent of his base salary.
The company said it proposed to issue 6,470,413 shares to directors in lieu of cash remuneration under the non-executive share plan, including 1,810,384 shares to chairman Scott Ward, 772,513 shares to Judith Downes, 1,299,036 shares to Don Williams, 1,062,848 shares to Amit Patel, 659,263 shares to Dr Robert Graham, 155,914 shares to David Anderson and 674,455 shares to former director Gary Goetze.
Impedimed said investors would vote to adopt the remuneration report, re-elect directors Ms Downes, Dr Graham and Mr Anderson, and approve a 10 percent placement capacity.
The meeting will be held online on October 28, 2020 at 9:00 am (AEDT).
Impedimed fell 0.2 cents or 3.2 percent to 6.1 cents with 7.4 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its annual general meeting will vote to increase the directors' fee pool by 100 percent from $400,000 to $800,000 a year.
Medical Developments said shareholders would vote to adopt the remuneration report and re-elect chairman David Williams and Christine Emmanuel as directors.
The meeting will be held online on October 28, 2020 at 10:30am (AEDT).
Medical Developments fell four cents or 0.8 percent to $5.07.

PROBIOTEC

Probiotec says shareholders at its annual general meeting will vote to issue 1,260,000 options to chief executive officer Wesley Stringer.
Probiotec said Mr Stringer's proposed options would vest two years after the grant date, exercisable at a 20 percent premium to the 10-day volume weighted average price to the grant date, expiring within one year of vesting.
The company said shareholders would vote to adopt the remuneration report and re-elect chairman Alexander Beard and director Jonathan Wenig.
The meeting will be held online on October 27, 2020 at 11am (AEDT).
Probiotec was up 4.5 cents or 2.6 percent to $1.78.

OPTISCAN IMAGING

Optiscan says it has received $701,242 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Optiscan said the rebate related to expenditure for the year to June 30, 2020.
Optiscan was up 2.5 cents or 23.8 percent to 13 cents with 14.1 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it will release 6,606,218 restricted shares from voluntary escrow on October 2, 2020, with 13,212,442 shares to remain in voluntary escrow.
Visioneering said the restricted shares were issued to employees in May in lieu of cash remuneration between April 6 and December 31, 2020.
According to Visioneering's most recent Appendix 2A, the company had 935,991,465 shares on issue, including the 19,818,660 voluntary escrow shares.
Visioneering was unchanged at 3.6 cents with 5.6 million shares traded.