Biotech Daily

Friday September 27, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.58 percent on Friday September 27, with the ASX200 up 38.5 points to 6,716.1 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and five were untraded.

Impedimed was the best, up two cents or 12.5 percent to 18 cents, with 506,778 shares traded. Pharmaxis climbed 10.8 percent; Compumedics was up 5.3 percent; Next Science improved 4.65 percent; Dimerix and Nanosonics were up more than three percent; Cochlear, Kazia, Medical Developments, Neuren, Orthocell, Prescient and Telix rose one percent or more; with CSL, Cyclopharm and Ellex up by less than one percent.

Imugene led the falls, down 0.2 cents or 8.7 percent to 2.1 cents, with 12.1 million shares traded. Antisense, Immutep and Resonance lost eight percent or more; Optiscan was down 6.25 percent; Avita, Opthea, Osprey and Patrys fell four percent or more; Proteomics was down three percent; Clinuvel, Mesoblast, Pro Medicus and Starpharma shed two percent or more; Polynovo and Volpara were down more than one percent; with Cynata, Paradigm and Resmed down by less than one percent.

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 Simmons 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-Sahara).

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

CELLMID

Cellmid says it has received $840,288 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cellmid said the rebate related to research and development expenditure for the year to June 30, 2019.
Cellmid was unchanged at 24 cents.

ONCOSIL MEDICAL

Oncosil says its annual general meeting will vote to issue up to 4,850,000 loan shares to chief executive officer Daniel Kenny, elect directors and to adopt the remuneration report.
Oncosil said the 4,850,000 loan shares to Mr Kenny would be at an issue price equal to the 30-day volume weighted average price at the close of trade the day prior to their date of issue.
The company said the shares would be vested in two tranches of 2,425,000 shares, with the first vested automatically if its total shareholder return had a compound annual growth rate (CAGR) of 15 percent and the second vested automatically if its total shareholder return had a CAGR of 25 percent.
Oncosil said Mr Kenny would hold 4.34 percent of the company following the share issue.
The company said it would vote to adopt the remuneration report and elect Dr Martin Cross and Michael Bassett as directors.
The meeting will be held at K & L Gates, Level 31, 1 O'Connell Street, Sydney, on October 29, 2019 at 11am (AEDT).
Oncosil was unchanged at 6.4 cents.

ACTINOGEN MEDICAL

Actinogen has requested a trading halt "pending an announcement regarding disclosure of clinical trial results".
Trading will resume on October 1, 2019 or on an earlier announcement.
Actinogen was untraded at 0.9 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt "pending an important announcement relating to pre-clinical study results in [its] opthalmology program" (sic).
Trading will resume on October 1, 2019 or on an earlier announcement.
Neuroscientific last traded at 24.5 cents.

ALCHEMIA

Alchemia says it has completed its one-for-20 share consolidation reducing its former 324,723,621 shares on issue to 16,234,845 shares, effective from today.
Earlier this month, Alchemia passed the 20-for-one reduction as part of a series of resolutions to become the Australian Primary Hemp (BD: Sep 16, 2019).
Alchemia was in a suspension and last traded at a consolidated price of 22 cents.

CRESO PHARMA

Creso says it has resubmitted an independent expert's report to the Australian Securities and Investments Commission for its proposed acquisition by Pharmacielo.
In June, Creso said the Vancouver, British Columbia-based Pharmacielo would acquire it for $122 million in a share and option scheme (BDL Jun 7, 2019).
Today, the company said it lodged a draft of scheme booklet for the proposed schemes of arrangement with Pharmacielo for a statutory review by the Australian Securities and Investments Commission on August 27, 2019.
Creso said the draft scheme booklet included a BDO Corporate Finance independent expert's report which said the scheme was not fair but was reasonable and the option scheme was both fair and reasonable, so both were in the best interests of shareholders.
Creso said it intended to seek orders convening meetings of its shareholders and listed option holders to consider and vote on schemes at a Supreme Court of Western Australia hearing on September 17, 2019.
The company said BDO withdrew its letter on September 16 after Pharrmacielo TSX Venture Exchange (TSXV) shares declined "below the valuation range outlined … to the point where BDO no longer considered the schemes to be in the best interests of Creso Pharma's security holders".
Last week, Creso requested a suspension following its trading halt pending an announcement on the proposed acquisition (BD: Sep 16, Sep 18, 2019).
Today, the company said that in correspondence with BDO, it provided information including Pharacielo's share price on the TSXV, which had "significantly increased".
The company said BDO since issued a new independent expert's report, which concluded that the schemes were in the best interests of its shareholders.
Creso said it updated its scheme booklet and had resubmitted it to the ASIC and would proceed to a first court hearing scheduled for October 2, 2019.
Creso was in a suspension and last traded at 38.25 cents.

AVITA MEDICAL

Morgan Stanley says it has become a substantial shareholder in Avita with the equivalent of 139,908,470 shares or 7.47 percent.
The New York-based Morgan Stanley said that it held 53,419 Amercian depository receipts (ADRs), equivalent to 1,068,380 Australian shares.
Morgan Stanley said that between June 3 and September 24, 2019, it borrowed, lent and bought shares and American depository receipts (ADRs), with the single largest purchase 609,441 shares for $267,384 or 43.9 cents a share on July 31, 2019.
Avita fell 2.5 cents or 4.3 percent to 55.5 cents with 18.8 million shares traded.

LIVING CELL TECHNOLOGIES

Dissident shareholders say they have become substantial shareholders in Living cell with 30,050,771 shares or 5.26 percent.
Earlier this month, Living Cell said it had received a call from unnamed members to replace directors' Dr Ken Taylor, Robert Willcocks and Laurie Hunter with Dr Andrew Kelly and Dr Roland Toder (BD: Sep 10, 2019).
Today, Pacific Channel Holdings, Richard Taylor and Brent Ogilvie, Masfen Securities, Terence Roland Harrison and T R Harrison Trustees said that on September 6, 2019 they combined their shareholdings for the board spill resolutions.
Living Cell was up 0.4 cents or 22.2 percent to 2.2 cents.

AUSCANN GROUP

Gemelli Nominees says it has ceased to be a substantial shareholder in Auscann.
In 2017, Gemelli said that it had become a substantial shareholder in Auscann with 13,226,331 shares or 6.11 percent of the company.
Today, in a substantial shareholder notice signed by Gemelli director and Zelda Therapeutics chairman Harry Karelis, Gemelli said that on February 4, 2019 it sold 1,350,113 shares for $707,999 or 52.4 cents a share.
Biotech Daily calculates that Gemelli holds 11,876,218 shares or 3.75 percent of Auscann.
Auscann was unchanged at 35.5 cents.

MEDIBIO

Medibio says it has eliminated 4,650,000 options exercisable at 30 cents each by April 1, 2017, which it had attempted to convert into partly-paid shares.
Medibio said that a review found that shares were not validly issued as conditions were not satisfied.
The company said option holders were offered partly paid shares equal to their holding of expiring options, subject to shareholder approval, obtained in September 2017 for partly paid shares at one cent a share and an unpaid amount of 29 cents a share.
Medibio said this did not satisfy the requirements of that condition of the offer and following a review and legal advice, it concluded that the shares were not issued validly.
The company said it requested agreements from the respective holders to rectify its register of members and holders of the overwhelming majority agreed in writing, with holders of a small majority of shares not responding.
Medibio said the 4,650,000 partly paid shares would be eliminated from its capital table and balance sheet as of June 30, 2019.
Medibio fell 0.1 cents or 7.7 percent to 1.2 cents with 1.4 million shares traded.

TRUSCREEN (FORMERLY POLARTECHNICS)

Truscreen says that chief executive officer Martin Dillon has resigned and will leave on completion of his notice period in late December 2019.
In March, Mr Dillon said the improved version of the Truscreen cervical cancer test could be used as a primary screening tool and in the decade since Polartechnics failed to commercialize the original diagnostic, the New Zealand-based company redeveloped it to be wireless, portable and connect to mobile telephones and computer systems, providing immediate, single-visit diagnosis (BD: Aug 14, 2008; Feb 11, 2010; Mar 19, 2019).
Today, Truscreen said Mr Dillon had been with the company since 2014 and was part of the team responsible for driving device development, overseeing distributors in China, Vietnam and Mexico and developing new markets in India, Zimbabwe and Russia.
The company said that Mr Dillon would continue as a consultant.
Truscreen said it would begin a recruitment process for a replacement chief executive.
On the NZX, Truscreen closed up 0.1 NZ cents or 0.95 percent to 10.6 NZ cents (9.9 Australian cents).