Biotech Daily

Friday December 8, 2017

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.28 percent on Friday December 8, 2017 with the ASX200 up 16.7 points to 5,994.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and five were untraded.

Factor Therapeutics was the best, up 0.3 cents or 6.4 percent to five cents with 403,939 shares traded.

ITL, Nanosonics and Orthocell rose more than two percent; Mesoblast, Optiscan, Resmed, Sirtex, Universal Biosensors and Volpara were up more than one percent; with Pro Medicus up 0.4 percent.

Dimerix led the falls, down 1.5 cents or 10.7 percent to 12.5 cents with 26,242 shares traded.

Actinogen lost 8.2 percent; LBT was down 6.25 percent; Benitec fell 4.9 percent; Telix and Viralytics were down more than three percent; Compumedics, Osprey and Polynovo shed more than two percent; Avita and Bionomics lost more than one percent; with Cochlear, Impedimed, Medical Developments and Starpharma down by less than one percent.

DR BOREHAM'S CRUCIBLE: LIVING CELL TECHNOLOGIES

By TIM BOREHAM

ASX code: LCT

Share price: 2.9 cents

Market cap: $16.6 million

Shares on issue: 571,440,981

Chief executive officer: Dr Ken Taylor

Board: Roy Austin (chair), Prof Robert Elliott, Laurie Hunter, Dr Bernard Tuch, Robert Willcocks

Financials (September quarter): revenue: nil *****, operating loss $1,385,000 (previously $680,000), cash $6,042,000 (down 20%), estimated December quarter cash burn $1,058,000

***** The company received grants of $270,027 during the quarter, compared with $190,731 previously.

At least the Auckland-based Living Cell can take solace that it's no Robinson Crusoe when it comes to failed clinical trials for treating the neurodegenerative condition Parkinson's disease, which affects seven to 10 million people globally.

The late boxer Muhammad Ali and the extant Michael J Fox are the foremost 'celebrity' sufferers, with the time-travelling actor actively crusading for a cure.

Despite this advocacy no new Parkinson's disease treatment has been approved in the US for at least two decades, with the standard-of-care drug levodapa now 50 years old.

The current treatments tackle only the symptoms, not the causes which centre on deprived levels of dopamine (a neurotransmitter that delivers messages to various parts of the brain).

Despite this limitation, Parkinson's disease drug sales globally topped $US2.4 billion in 2014.

Living Cell hasn't altogether raised the white flag on developing its NTCell treatment, but the standard will be hoisted up the mast if further analysis of the trial results fails to come up with anything different.

What happened?

On November 10, Living Cell shares plunged by 85 percent after the company reported "no statistical difference" between the efficacy of NTCell relative to the control group, in its 18-patient phase IIb trial.

The study was designed to confirm the most effective dose of NTCell, define any placebo component of the response and identify the initial target Parkinson's disease patient sub-group.

The study consisted of three groups of six patients, with two patients from each group having sham surgery with no NTCell implanted.

The active group received varying doses of NTCell implanted on each side of the brain.

While three of the four endpoints were met at the 26-week mark of the trial, they related to lack of adverse effects such as infection.

But measured on the globally-accepted unified Parkinson's disease rating scale (UPDRS), NTCell didn't work compared to patients who underwent 'sham' surgery.

"It is encouraging that some efficacy data is positive and that the treatment was well tolerated and safe," Dr Taylor said.

"More data analysis and input from our advisors is required but at this time we cannot proceed with a regulatory application."

He adds the company would not have carried out the trial any differently, such as choosing another endpoint.

"We did what we believed was the optimum study and we have to live with the outcome," Dr Taylor said.

Pigs might fly?

The NTCells are porcine encapsulated choroid plexus brain cells that provide neuroprotective factors and reduce toxins, derived from a herd of genetically isolated pigs from the even more isolated Auckland Island.

While not resiling from the fact the trial flopped, Living Cell has resolved to parse the data further, focusing on the patients that responded best.

Further 12 month results are due this month.

An earlier phase I/IIa trial resulted in the progression of Parkinson's disease being halted for all four patients.

What's next?

Living Cell had planned to seek rapid approval from New Zealand authorities, in view of a product launch in the first quarter of next year.

Suffice to say, the champagne order is on ice. The Living Cell board is meeting on December 20 and investors should expect a steer on what the company will do next.

Assuming the further trial results don't result in any joy, Living Cell's best hopes appear to hinge on developing the product platform for other neurodegenerative ailments, as well as retinal degeneration and chronic hearing loss.

Living Cell's earlier prezzos and the company's website also mentioned Alzheimer's disease - another disease that has defied a cure - as well as Huntington's disease and motor-neuron disease.

Earlier, Living Cell pursued a treatment for diabetes called Diabecell, also based on parts harvested from its special porkers.

The global rights to Diabecell are now housed in a US joint venture with Japan's Otsuka Pharma Factory. The venture, Diatranz Otsuka, has licenced Otsuka Pharma to use Diabecell in the US and Japanese markets.

Past Parkinson's flops

As Dr Taylor notes: "We are not the first company to get an encouraging first study placebo-controlled outcome and not meet the efficacy endpoint".

One problem is that because there are variants of the condition, large patient pools are needed for a decent trial.

Last year a Bristol based phase II GDNF trial (as in glial cell-derived neurotrophic factors) failed to reach primary endpoints in an advanced trial. Similarly, a smaller precursor trial had produced "astounding" results.

Last month, shares in Acorda Therapeutics tumbled after revelations its $US380 million a year Parkinson's disease drug Tozadenant could result in potentially fatal side effects including the loss of white blood cells.

Talk about the cure being worse than the disease.

Another Innate?

Living Cell's fall from grace mirrors that of fellow Kiwi based, ASX-listed biotech Innate Immunotherapeutics (ASX code IIL), which was backed by a bevy of White House heavies including Trump's Congress go-between Chris Collins.

The Republican money men will think twice about acting on tips shared at the country club: Innate in June reported its advanced clinical trial for multiple sclerosis (another difficult neurological condition) had failed.

Innate confessed that while it would do follow-up analysis the results were unlikely to be different.

Innate has shut its operations and with residual cash of $4,335,000 is looking to buy another technology (or perhaps get into medical cannabis, lithium or Pilbara gold).

Sorry day

The Living Cell trial results came ahead of the company's AGM, at which the apologetic board cancelled a proposed increase in the director remuneration pool, as well as a proposed issue of director options.

With Living Cell now valued at $17 million, compared with its cash backing of $6 million, investors expect the company to salvage at least some value from the clinical train wreck.

Diabecell, which is yet to be commercialized, may result in handy milestone payments of up to $15 million from Otsuka Pharma if development pans out successfully.

Dr Boreham's diagnosis:

We're told the Auckland Island swine make for especially flavorsome bacon. But whether Living Cell opts for charcuterie over alternative clinical work, the bald truth is that most shareholders were primarily interested in Living Cell's Parkinson's disease program, as they previously had been in the Diabecell cure for type 1 diabetes.

Founded in 1999 by University of Auckland paediatrics professor Robert Elliott and Kiwi company director David Collinson, Living Cell listed in August 2014 after raising $2 million at 20 cents a share.

The company has been around the block a few times and it's understandable the statute of limitations on investors' patience has expired.

If only they could borrow Michael J Fox's DeLorean and take a spin through time to unwind their investment.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His best White House tip was to put a lazy tenner on Trump at the last election.

VICTORIA GOVERNMENT

The Victoria Government says it has opened a trade office in Tel Aviv “to drive new investment and exchange opportunities between Victoria and Israel”.
A media release from the Victoria Premier Daniel Andrews said the announcement of the 22nd Victoria trade and investment office was made in Tel Aviv, where the State Government was conducting a trade mission.
The media release said the office was the only Australian state government trade and investment office in Israel and would see Victoria expand its representation in Israel, with Victoria’s Commissioner to Europe Ken Ryan increasing the time spent in the country.
The Government said that the office would be staffed by a team “charged with creating more opportunities for Victorian and Israeli businesses, individuals and communities … [and would] include a full-time biomedical director to increase the medical research and commercialization collaboration that is occurring between Victoria and Israel”.
Victoria said that the Israel-Australia Chamber of Commerce had been engaged to assist in driving trade and investment opportunities.
The Government said that as part of its increased presence in Israel, “a new dedicated Biomedical Innovation and Commercialisation Exchange program [would] be established to drive medical technology research, engagement and exchange”.
The State Government said that Israel had a reputation as a leader in commercialization and the biomedical director would focus on translating Victoria’s class medical research into commercial opportunities and would be complemented by a liaison officer based in the Melbourne Biomedical Precinct, who would connect Israeli organisations with Victoria’s world-leading biomedical sector.
Mr Andrews said that the Baker Institute would partner with Sheba Medical Centre for early studies on protecting the heart from arrhythmias, including development of new drugs to prevent and treat heart beat irregularities
Mr Andrews said that a collaboration between the Florey Institute of Neuroscience and the Hadassah Medical Centre would explore the link between iron levels and schizophrenia
“The new trade office will open doors for Israeli companies in Victoria creating local jobs here at home while at the same time promoting Victoria’s best and brightest on the world-stage,” Mr Andrews said.
“Tel Aviv is the biggest innovation hub outside of the United States and is the economic powerhouse of Israel,” Mr Andrews said.
“There is no better place for Victoria to do business,” Mr Andrews said.
“With the best clinicians, scientists, researchers and institutes and famous Parkville precinct, Melbourne is a world leader in medical research and this new partnership with Israel will only make us stronger,” Mr Andrews said.

INVITROCUE

Invitrocue says it has raised $1,491,835 through the issue of 18,647,936 shares at eight cents each, along with 4,661,981 warrants.
In an announcement entitled ‘Proposed issue of securities’ Invitrocue said the warrants were exercisable at eight cents each within five years of issue and the funds were for working capital.
In June and November the company issued a total of 22,718,583 shares at eight cents each, raising $1,817,487, along with the issue of 5,596,313 warrants also exercisable at eight cents each with five years of issue for development of its cancer patient-derived organoid, or Onco-PDO, business and for working capital (BD: Jul 3, Nov 10, 2017).
Invitrocue was untraded at 8.4 cents.

ORTHOCELL

Orthocell says a case study supports the use of its autologous tenocyte implantation (Ortho-ATI) for shoulder tendon pain.

Orthocell said the Brisbane study, entitled 'Autologous tenocyte implantation into shoulder tendon pathology in an elite swimmer' was published in the journal Physical Therapy in Sport and the article was available at: http://bit.ly/2BMivPS.

The study concluded that "An athlete who had previously undergone unsuccessful conservative management demonstrated significant improvement in function and in tendon morphology post intervention."

Orthocell said that Ortho-ATI "enabled [the] elite athlete to return to competitive swimming and resume normal daily activities".

The company said that the athlete had shoulder pain and had withdrawn from an international swimming competition in mid-August 2014 due to pain in the right shoulder, which required a reduction in swimming load and was unable to complete any speed work.

Orthocell said that to return to elite swimming, the patient underwent a range of conventional therapies including physiotherapy, injection therapy with local cortisone and platelet rich plasma, alternative therapies and de-loading of the tendon, without success.

The company said that as the symptoms were non-responsive to these interventions, the decision was made to trial Ortho-ATI.

Orthocell said that three independent radiologists, who had no prior knowledge of the case, were asked to report on pre and post intervention magnetic resonance imaging.

The company said that all three radiologists confirmed significant improvement in tendon morphology with two of the three assessors saying the tendon had completely healed following Ortho-ATI.

Orthocell said that following treatment with Ortho-ATI, the patient resumed modified training in the pool at 2.5 weeks and gradually progressed to full training over four weeks and was pain free at seven weeks post-intervention.

Orthocell managing-director Paul Anderson said the publication "further validates our exciting Ortho-ATI technology, as we continue to build strong clinical evidence and in-market validation of the safety and effectiveness of our technologies for the repair and regeneration of treatment resistance tendons".

Orthocell was up one cent or 2.7 percent to 38.5 cents.

MEDIBIO

Medibio says the White River Junction, Vermont-based US Veterans Affairs Medical Centre will join its depression diagnostic confirmatory study as a clinical research site.

Medibio said that the study began enrolling patients in August for its US Food and Drug Administration 510(k) de novo submission.

The company said the White River Junction team would be led by Dr Paul Holtzheimer, who was also a professor of psychiatry at the Lebanon, New Hampshire-based Dartmouth-Hitchcock Medical Centre.

Medibio said the confirmatory study followed the model of a previous exploratory study to validate the Medibio analysis approach in identifying depression.

Medibio chief executive officer Jack Cosentino said the involvement of the Veterans Affairs Medical Centre "marks an important milestone … [allowing] us to better understand indications such as [post-traumatic stress disorder] and generalized anxiety disorder in the next year in the interest of helping US veterans and those who suffer from these and other conditions".

Medibio was up two cents or 6.1 percent to 35 cents.

USCOM

Uscom executive chairman Prof Robert Phillips says he has increased his holding in the company from 21,352,794 shares (19.02%) to 22,852,794 shares (19.96%).
In his substantial shareholder notice Prof Phillips said that through Australian Cardiac Sonography Pty Ltd Phillips Superannuation account he acquired 1,500,000 employee share plan shares for no cost.
Uscom was untraded at 15 cents.

RHINOMED

W Whitney George says he has increased his holding in Rhinomed from 17,526,816 shares (18.72%) to 22,930,600 shares (19.59%).
The Carlsbad, California-based Mr George said he bought 5,271,281 shares for 15 cents a share on December 5, 2017.
Rhinomed was up half a cent or 3.3 percent to 15.5 cents.

ZELDA THERAPEUTICS

Zelda has requested a trading halt “pending an announcement regarding a material and significant partnership with a US-based research institution”.
Trading will resume on December 12, 2017 or on an earlier announcement.
Zelda last traded at 9.1 cents.

MESOBLAST

Mesoblast says it has won the first Frost and Sullivan ‘global technology leader in the cell therapy industry’ award.
Mesoblast chief executive Prof Silviu Itescu said he was “honored to be the first company named by Frost and Sullivan as the global technology leader in the cell therapy industry”.
“This award recognizes the efforts of the whole Mesoblast team and our investors whose support has been instrumental in the development of our innovative cell therapy product candidates,” Prof Itescu said.
Mesoblast was up 1.5 cents or 1.1 percent to $1.345 with 909,770 shares traded.