



Biotech Daily

Tuesday May 7, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: IMUGENE UP 6%; ACTINOGEN DOWN 69%**
- * **ACTINOGEN: 'XANAMEM FAILS ALZHEIMER'S ENDPOINTS'**
- * **THC SHARE PLAN RAISES \$3m**
- * **CSIRO, GENESISCARE \$5m FOR CANCER 'THERANOSTICS'**
- * **MEDADVISOR, ZUELLIG JV FOR ASIA SCRIPT REMINDERS**
- * **ZUCERO COMPLETES \$6m TBG (PROGEN) PG500 DEAL**
- * **ADMEDUS EXTENDS FUNDING SUSPENSION**
- * **ADHERIUM TELLS ASX: 'REVENUE COMING, POSSIBLE CAPITAL RAISING'**
- * **AUSTRALIAN ETHICAL DILUTED TO 11% OF PRESCIENT**
- * **LIVING CELL APPOINTS PROF CAROLYN SUE DIRECTOR**
- * **SHAREROOT APPOINTS DR JULIAN CHICK CHAIRMAN**

MARKET REPORT

The Australian stock market was up 0.19 percent on Tuesday May 7, 2019, with the ASX200 up 12.0 points to 6,295.7 points.

Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and three were untraded.

Imugene was the best, up 0.1 cents or 5.9 percent to 1.8 cents, with 2.9 million shares traded. Alterity (Prana), Antisense and Optiscan climbed more than four percent; Immutep was up 3.85 percent; Clinuvel and Ellex rose more than two percent; Medical Developments, Paradigm and Telix were up one percent or more; with Cynata and Volpara up by less than one percent.

Actinogen, led the falls on its Alzheimer's disease trial news (see below), down 3.3 cents or 68.75 percent to 1.5 cents with 322.7 million shares traded. Oncosil lost 15.1 percent; Kazia retreated 8.25 percent; Impedimed, Orthocell, Patrys and Prescient fell more than four percent; Opthea shed 2.2 percent; Compumedics, Dimerix, Genetic Signatures, Pharmaxis, Pro Medicus and Starpharma were down more than one percent; with CSL, Mesoblast, Nanosonics, Neuren, Polynovo and Resmed down by less than one percent.

ACTINOGEN MEDICAL

Actinogen fell as much as 70.8 percent on news that its 186-patient, phase II Xanadu trial of Xanamem for Alzheimer's disease "did not achieve statistical significance".

Actinogen said that despite missing primary and secondary efficacy endpoints the "results provide great encouragement to pursue higher dose and longer duration studies, consistent with ongoing Xanamem safety and target occupancy studies".

The company said that the randomized, placebo-controlled study at 25 sites in Australia, the US, and the UK investigated the effect of 12 weeks of daily oral dosing of Xanamem in patients with mild dementia due to Alzheimer's disease.

In 2014, Actinogen acquired the University of Edinburgh spin-out company Corticrine for its compound, UE2343, which had completed a phase I, single, ascending-dose study in healthy volunteers and was "well tolerated in humans with no serious adverse events" (BD: Aug 27, 2014).

The company said that UE2343, later renamed Xanamem, reduced cortisol production though inhibiting the 11beta-hydroxysteroid dehydrogenase type 1 (11b-HSD1), enzyme in the human brain (BD: Jun 30, 2018).

Today, Actinogen said that reducing the stress hormone cortisol could have an effect on the development of Alzheimer's disease.

The company said that the 10mg Xanamem dose did not demonstrate efficacy in improving cognition in Alzheimer's and the primary and secondary endpoint measures did not demonstrate statistical differences between Xanamem and placebo.

Actinogen did not specify the data differences between the Xanamem and placebo groups, or any other detailed results.

Actinogen chief executive officer Bill Ketelbey said the results were "encouraging" and that "while 10mg Xanamem was not shown to be a clinically effective dose in Alzheimer's disease, the safety and pharmacodynamic effects observed show potential that higher doses and a longer treatment duration of Xanamem may be efficacious".

In 2015, Actinogen said that a phase I dose-ranging trial showed that Xanamem was safe and well-tolerated from 10mg to 35mg (BD: May 12, 2015).

Today, the company said it would study the effects of 20mg and 30mg doses of Xanamem on cortisol production in the brain and expected initial results from the Xanahes higher dose safety studies by the end of June 2019 and it was confident in the relationship between raised cortisol and cognitive impairment.

"The inhibition of cortisol production in the brain with Xanamem represents a compelling approach to treating cognitive impairment in Alzheimer's and other neurological diseases, such as bipolar disorder and schizophrenia," Actinogen said.

In 2017, the company said it received US, UK and Australian approvals and treated the first patient in the trial (BD: Jan 22, Feb 10, Mar 8, May 16, 2017).

Actinogen fell as much as 70.8 percent to 1.4 cents before closing down 3.3 cents or 68.75 percent at 1.5 cents with 322.7 million shares traded.

THC GLOBAL GROUP

THC says its share purchase plan has raised \$2,983,500 at 50 cents a share, a 14.6 percent discount to the 5-day volume-weighted average price to April 4, 2019.

In April, THC did not disclose how much it hoped to raise in the offer nor the intended use of the funds, but said the offer was ahead of "the expected final licencing required to transition into full-scale medicinal cannabis production" (BD: Apr 8, 2019).

THC fell two cents or 4.65 percent to 41 cents with 1.8 million shares traded.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

CSIRO says it has a \$5.1 million research partnership with Sydney's Genesiscare to develop what it calls 'theranostics' or combined cancer diagnostics and therapies. CSIRO said the partnership would develop therapeutic and diagnostic agents for difficult-to-treat cancers, such as brain, pancreatic and ovarian cancers and metastatic cancers. CSIRO project lead Prof Stephen Rose said the collaboration would target "cancers that are currently the most untreatable, because that's where we think we can make a profound difference".

"We're exploring a very exciting approach called theranostic cancer treatment which is a type of precision medicine that finds and attacks individual cancer cells in a person's body, rather than attacking both cancerous and healthy cells," Prof Rose said.

Prof Rose told Biotech Daily that CSIRO and Genesiscare were providing matched funding for the project with laboratory and pre-clinical work to be conducted by the Organisation and first-in-human trials to be conducted by Genesiscare's private cancer trials network.

Prof Rose said that peptide developments would be undertaken at CSIRO's Melbourne laboratories with bio-informatics in Sydney and pre-clinical testing in Brisbane.

Prof Rose said that CSIRO would develop and test small molecule peptides to bind to cancer cells and carry a radio-nuclide payload for imaging and then substitute the imaging radio-nuclide for a treatment for the cancer.

He said that Genesiscare would be responsible for clinical trials.

"They have their own areas within private hospitals and they're interested in theranostics for patients with no options left," Prof Rose said.

CSIRO said that cancer was the leading cause of death in Australia "with almost 50,000 deaths from cancer estimated in 2019 including 3,051 deaths from pancreatic cancer, 1,549 deaths from brain cancer, and 1,046 deaths from ovarian cancer anticipated this year alone".

The Organisation said that access to this form of treatment had been limited globally and it hoped the investment might "help spark a new theranostics industry in Australia to improve patient outcomes".

MEDADVISOR

Medadvisor says it has a joint venture with the Hong Kong-based Zuellig Pharma to extend the company's medication management service in Asia.

Medadvisor said it had developed a mobile telephone application which provided patient medication reminders.

The company said the equal joint venture had established the Singapore-based ZP Medadvisor to operate the joint venture.

Medadvisor said that ZP Medadvisor had signed a software licence for its medication management product to be distributed in Asia.

The company said the joint venture companies would each contribute \$US750,000 (\$A1,065,993) to fund the initial working capital by February 2021.

The company said the joint venture would help up to 150,000,000 patients with their medication management and would focus initially on the Philippines and Malaysia.

Medadvisor said that Zuellig Pharma is one of Asia's largest healthcare services groups. Medadvisor was up 0.2 cents or 3.6 percent to 5.8 cents.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS) ZUCERO THERAPEUTICS

TBG says that Zucero has settled the \$5,999,000 deferred payment for the purchase of its PG500 assets, with \$1,999,000 in cash and \$4,000,000 in shares.

In 2016, TBG and the Brisbane-based Zucero announced the agreement with the payment to be finalized by August 2019 (BD: Aug 22, 2016).

Today, Zucero executive chairman Chris Burrell told Biotech Daily that his company was conducting an open-label, multi-centre, phase Ib study of the safety and tolerability of intra-venously infused pixatimod, or PG545, in combination with nivolumab, marketed as Opdivo, in patients with advanced solid tumors, with an expansion cohort in patients with metastatic pancreatic cancer.

Mr Burrell said that during the escalation phase of the study clinical benefit was observed in four of five metastatic colorectal cancer patients, including two patients demonstrating reductions of 86 percent and 48 percent in tumor burden.

TBG said that following the issue of 10,000,000 Zucero shares at 40 cents a share, it held 7.89 percent of Zucero.

Mr Burrell said that at the 40 cents valuation for the shares and with 126 million shares on issue, Zucero was valued at \$50.4 million.

Zucero's website said that TBG chairman Jitto Arulampalam was a director of the company.

TBG said that the terms of the settlement were "fair and in the best interests of the company and shareholders".

The company said that Zucero was working on the discovery and development of modified sugar compounds for the treatment of cancer and inflammatory conditions and its first clinical candidate, PG545, was originally designed to inhibit heparinase, a protein associated with cancer metastases, but more recently, it had been reported to be a potent immune-modulatory agent.

The company said that these properties differentiate PG545 from its competitors and offered a new approach to treat cancer.

TBG fell 0.3 cents or 7.7 percent to 3.6 cents.

Zucero is a public unlisted company.

ADMEDUS

Admedus has requested a further extension to its voluntary suspension to finalize its re-capitalization plan.

In April, Admedus requested a trading halt "pending an announcement regarding the previously announced Admedus immunotherapies sale transaction" and later requested a voluntary suspension, before responding to an ASX aware query and announcing the termination of the sale of Admedus Vaccines, formerly Coridon, and requesting an extension to the suspension of trading in its shares (BD: Apr 15, 23, 2019).

On April 23, Admedus said its sale of Admedus Vaccines, formerly Coridon, had been terminated, the ASX queried its announcements and it remained suspended for funding. Last year, Admedus said the Hong Kong-based Star Bright Holding intended to take 60 percent of Admedus Vaccines for \$18 million, with Admedus to retain 29.1 percent of the vaccines business and chief executive officer Wayne Paterson would be chairman of the venture for five years (BD: Apr 27, Jun 27, 2018; Apr 10, 2019).

Today, the company requested a further extension to the suspension which it expected to last until May 21, 2019 or the release of an earlier announcement.

Admedus last traded at six cents.

ADHERIUM

Adherium has told an ASX query that it “continues to assess its funding requirements ... objectives, including the expectation of revenue and potentially raising new capital”. Last week, Adherium said its cash burn for the three months to June 30, 2019 was expected to be \$2,579,000, with cash and cash equivalents at March 31 of \$1,951,000 and receipts from customers of \$405,000 (BD: May 1, 2019). Adherium fell 0.2 cents or 6.45 percent to 2.9 cents with 2.4 million shares traded.

PRESCIENT THERAPEUTICS

Australian Ethical Investment says its 44,141,543 share-holding in Prescient has been diluted from 15.24 percent to 11.20 percent in the recent capital raising. In March, Prescient said it expected to raise \$9.1 million in a placement and rights issue, which has been completed (BD: Mar 25, 2019). Prescient fell 0.2 cents or 4.4 percent to 4.3 cents with 1.0 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has appointed Prof Carolyn Sue as a non-executive director effective from May 16 with Laurie Hunter retiring at annual general meeting in November 2019. Living Cell said that Prof Sue had a background in neurological science and medicine in relation to chronic illnesses and was the Sydney-based Kolling Institute’s head of neuroscience research, director of neurogenetics and the National Centre for Adult Stem Cell Research and was a professor at the University of Sydney Medical School. Living Cell said Prof Sue held a Bachelor of Medicine and Bachelor of Surgery from Sydney’s University of New South Wales and a Doctor of Philosophy from the University of Sydney. Living Cell fell 0.3 cents or 6.25 percent to 4.5 cents.

SHAREROOT

Shareroot says it has appointed Dr Julian Chick as chairman of the health information technology company replacing Harvey Kaplan, effective from May 6, 2019. Shareroot said Dr Chick had more than 25 years of experience in the biotechnology and medical technology industry as well as five years in investment banking. The company said Dr Chick had led public and private companies, helped take a number of technologies from discovery to market and led multiple capital raisings. Shareroot said Dr Chick was a shareholder in, and advisor to, the company and helped develop the Media Consent Medical functionality and market entry plan, with Shareroot chief executive officer Michelle Gallaher. Shareroot said that Dr Chick would be paid \$40,000 a year and be granted 11,000,000 unlisted options, exercisable at half a cent per option within five years of issue. The company said that Dr Chick held a Bachelor of Science and a Doctor of Philosophy from La Trobe University. Shareroot was unchanged at 0.2 cents.