# Biotech Daily

Thursday December 10, 2015

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: ATCOR UP 17%, BIOTRON DOWN 10%**

*** CSL: 'FROM R&D TO 20% OF GLOBAL PROTEIN MARKET'**

*** WEHI TOXOPLASMA STUDIES 'COULD LEAD TO VACCINE, TREATMENTS'**

*** INVION PLAN, PLACEMENT RAISE FINAL TOTAL OF $2.1m**

*** VIRALYTICS $2.9m FEDERAL R&D TAX REFUND, FUND RAISING HALT**

*** SUDA EXPANDS AMHERST ZOLPIMIST, SUD-002 DEALS**

*** FIL TAKES 7% OF IMPEDIMED**

*** NOVOGEN APPOINTS DR JAMES GARNER CEO, STARTS ON $400k**

## MARKET REPORT

The Australian stock market fell 0.84 percent on Thursday December 10, 2015 with the ASX200 down 42.8 points to 5,037.7 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and two were untraded.

Atcor was the best, up three cents or 17.1 percent to 20.5 cents, with 665,657 shares traded.

Neuren was up 4.8 percent; Circadian climbed 3.3 percent; Optiscan, Prima, Pro Medicus and Reva rose two percent or more; with Acrux, CSL, Medical Developments and Sirtex up by less than one percent.

Biotron led the falls, down 0.6 cents or 10.3 percent to 5.2 cents with 150,000 shares traded.

Living Cell and Mesoblast lost more than eight percent; Antisense, Compumedics and Genetic Technologies fell more than seven percent; Impedimed shed 4.2 percent; Clinuvel and Psivida were down more than three percent; Bionomics, IDT and Tissue Therapies shed more than two percent; Benitec, Orthocell and Resmed lost more than one percent; with Admedus, Cochlear, Nanosonics and Starpharma down less than one percent.

CSL

CSL chief scientific officer and head of research and development Dr Andrew Cuthbertson says CSL is expanding and commercializing its research.

Dr Cuthbertson told the annual investors' research and development briefing that "previously we were talking about interesting science and prospective drugs and now we are talking about delivering high value products to commercial partners".

CSL's commercial operations head Bob Repella said the global plasma-proteins market was about $US25 billion and in the year to June 30, 2015, CSL had sales of $US5 billion.

Mr Repella said that CSL had $US2,326 million in sales in the immunoglobulin sector, worth $US8 billion in total; $US1,026 million sales in the $US10.5 billion haemophilia market, $US923 million in the $US2.9 billion specialty market and $US754 million in the $US3.3 billion albumin market.

Mr Repella said that provided room for growth, CSL was expanding to other countries including Russia, and in Asia "the demand for albumin … outstrips the available supply".

Dr Cuthbertson said that although the research and development budget fell from $US466 million in the year to June 30, 2014 to $US463 million in the year to June 30, 2015 much of the work had been performed in Australia and the falling Australian dollar meant that work was effectively cheaper.

Dr Cuthbertson said there were more than 1,000 scientists in research and development and more in the manufacturing facilities in the UK, US and Europe.

He said that along with expanding indications for existing drugs, as well as the geographical reach of the company, CSL needed to prime its pipeline with new compounds and maintain a focus on clinical work.

Dr Cuthbertson said that CSL's core focus was on protein therapies through the two platforms of plasma fractionation and recombinant biotechnology and among the priorities were the continued development of the reconstituted high-density lipoprotein CSL112 for heart attack, extending the half-life of recombinant factor VIII and influenza vaccines.

"We continue to look at our current assets and keep improving yield, geography and medical uses, and we also have responsibility for developing new and improved high-margin products," Dr Cuthbertson said.

Dr Cuthbertson said that progress to registration in the US and Europe had been made with the sub-cutaneous, recombinant factor VIII and the company was developing the sub-cutaneous, recombinant factor IX.

He said that the US Food and Drug Administration had approved the Broadmeadows plant in Melbourne for the manufacture of Privigen "and the first shipment left today".

CSL research senior vice-president Dr Andrew Nash told the investor conference that the hub of activities remained Bio-21 in Parkville and a major focus for the company remained haemophiliac disorders and finding new ways and molecules for bleeding disorders.

Dr Nash said that extending the half-life of factor VIII and factor XI meant patients could move to less frequent dosing, potentially one weekly or once fortnightly, and developing sub-cutaneous injection systems meant they could dose themselves at home rather than requiring intra-venous therapy in a clinic.

Dr Nash said that the Janssen collaboration on CSL362 for acute myeloid leukaemia aimed "to treat people in remission to remain in remission and keep them in remission indefinitely" and that 13 of 30 patients in the phase I trial remained in remission, with biomarkers and pharmaco-kinetics supporting the mechanism of action.

Dr Nash said the last phase I patient visit was in July 2015 and Janssen would be responsible for further oncological development of CSL362, treating the first phase II patient in August 2015 and would due begin a phase I lupus trial by the end of 2016.

CSL was up 17 cents or 0.2 percent to $99.20 with 1.3 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the Toxoplasma parasite hijacks host cells and stockpiles food to lie dormant, possibly changing its host's behaviour or personality.

The Institute said the findings could lead to a vaccine to protect pregnant women from Toxoplasma infection, which carried a serious risk of miscarriage or birth defects, as well as drugs to clear chronic infections in people with compromised immune systems.

The Institute said that Toxoplasma was a common parasite transmitted by cats and found in raw meat, with about 30 percent of the population infected.

WEHI said that the research projects were led by Dr Chris Tonkin, Dr Justin Boddey, Dr Alex Uboldi, James McCoy and Michael Coffey.

The studies are entitled 'Regulation of Starch Stores by a Ca2+-Dependent Protein Kinase Is Essential for Viable Cyst Development in Toxoplasma gondii' with an abstract at: http://www.cell.com/cell-host-microbe/abstract/S1931-3128(15)00458-8 and 'An aspartyl protease defines a novel pathway for export of Toxoplasma proteins into the host cell' published by the journal Elife with an abstract available at: http://elifesciences.org/content/early/2015/11/18/eLife.10809#sthash.BK3Bhd7a.dpuf

Dr Tonkin said Toxoplasma required a human host cell, such as a neuron or brain cell in which to live and the team discovered how the parasite hijacked the host cell to enable its own growth and survival, hibernating for decades by creating its own food reserve.

"Toxoplasma infection leads to massive changes in the host cell to prevent immune attack and enable it to acquire a steady nutrient supply," Dr Tonkin said.

"The parasite achieves this by sending proteins into the host cell that manipulate the host's own cellular pathways, enabling it to grow and reproduce," Dr Tonkin said.

Dr Boddey said some of the proteins might influence the behaviour of the host.

"There is a fascinating association between Toxoplasma infection and psychiatric diseases including schizophrenia and bipolar disorder," Dr Boddey said. "It is now possible to test whether proteins sent from the hibernating parasite into a host neuron disrupt normal brain function and contribute to development of these diseases."

WEHI said that once Toxoplasma parasites established infection, they could lie dormant for the rest of the person's life, but in people with suppressed immune systems the parasite could reactivate and cause neurological damage and even death.

Dr Tonkin said the teams had identified pathways that allowed the parasite to establish chronic infections, unveiling potential treatments to clear the dormant parasite.

"We discovered that, similar to animals preparing for hibernation, Toxoplasma parasites stockpile large amounts of starch when they become dormant," Dr Tonkin said. "By identifying and disabling the switch that drives starch storage, we found that we could kill the dormant parasites, preventing them from establishing a chronic infection."

Dr Tonkin said the finding could lead to a drug to clear chronic Toxoplasma infections, or even a vaccine to prevent infection in at-risk people, such as pregnant women.

"Cats are one of the primary transmitters of Toxoplasma parasites," Dr Tonkin said. "If the parasites are transmitted to pregnant women, for example through contact with kitty litter, there is a substantial risk of miscarriage or birth defects."

"We hope to use our discoveries to develop a vaccine that stops cats transmitting the parasite, to prevent these potentially catastrophic consequences," Dr Tonkin said.

Dr Boddey said it had long been a mystery how the Toxoplasma parasite transported proteins into the host and the study showed that the parasite included a signature on the exported proteins that earmarked them for transport into the host cell.

"Blocking transport makes the parasite much less dangerous in infection models, suggesting this may also be a new way of treating Toxoplasma infections," Dr Boddey said.

## INVION

Invion says that its placement and share purchase plan have raised a total of $2,128,493 at 0.73 cents a share.
Yesterday, Invion said it had definitive agreements to raise about $500,000 in the placement to sophisticated and professional investors who were existing shareholders and the share purchase plan raised about $1.3 million (BD: Nov 10, Dec 9, 2015).
Today Invion said that the share plan had final cleared subscriptions for $1,606,293 and the placement totalled $522,200 and the funds would be used for working capital.
In September, Invion said it had raised $1,001,000 in a placement at 1.4 cents a share to an unnamed US institutional investor (BD: Sep 1, 2015).
Invion fell 0.1 cents or 11.1 percent to 0.8 cents with 2.0 million shares traded.

## VIRALYTICS

Viralytics says it has received $2,928,530 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Viralytics said the rebate related to research and development expenditure in the year to June 30, 2015 and the funds would be used to develop its Cavatak clinical program.
Separately, Viralytics requested a trading halt “pending an announcement in relation to a potential capital raising”.
Trading will resume on December 14, 2015 or on an earlier announcement.
Viralytics last traded at 65 cents.

## SUDA

Suda says it has expanded its Amherst Pharmaceuticals Zolpimist and SUD-002 agreements to include South and Central America and South Africa.
Suda said that Zolpimist was a treatment for insomnia and SUD-002 was for nausea and vomiting and the agreement meant it had a global licence, excluding North America, to the US-registered oral spray of zolpidem tartrate for insomnia.
Suda said it would pay the New Jersey-based Amherst a six to 12 percent share of income from its commercialization of Zolpimist in the original territories and in the newly added countries, the companies would share the proceeds equally.
The company said that it had regained global rights to SUD-002, its oral spray of ondansetron for nausea and vomiting induced by chemotherapy, radiotherapy or surgery.
The company said that Amherst had previously licenced SUD-002 for the Americas and South Africa and the return of these rights stemmed from a restructure of Amherst’s activities and a revised strategy to focus on the launch of Zolpimist in the US market.
Suda said it intended to have a pre-new drug application meeting with the US Food and Drug Administration in 2016 to discuss a regulatory submission of SUD-002.
The company said that Canada had allowed a patent providing protection over the anti-emetic oral spray until 2026 and it had “approaches from several other US-based pharmaceutical companies that are interested in licencing SUD-002 for North America, subject to the outcome of the pre-NDA meeting”.
Suda executive chairman Stephen Carter said that “in relation to SUD-002, given Amherst’s limited capital resources, they were not in a position to undertake the regulatory steps required for a pre-NDA meeting with the FDA”.
“We aim to accelerate this process, the outcome of which will be an important catalyst for out-licensing SUD-002 in the US and elsewhere in the world,” Mr Carter said.
Suda was up 0.1 cents or 3.3 percent to 3.1 cents with 2.8 million shares traded.

## IMPEDIMED

The Singapore-based FIL Limited says it has increased its substantial shareholding in Impedimed from 18,112,316 shares (6.18%) to 21,137,709 shares (7.20%).
FIL, formerly Fidelity Investments Limited, said it bought and sold shares between August 5 and December 7, 2015, trading shares at prices between 91 cents and $1.21.
Impedimed fell 4.5 cents or 4.2 percent to $1.025.

## NOVOGEN

Novogen says it has appointed Dr James Garner as its chief executive officer effective from February 1, 2016 and starting on a base salary of $400,000 a year.
Novogen said that Dr Garner, 42, had “broad experience in drug development and commercialization” in the biotechnology and pharmaceutical sector with previous responsibilities leading non-clinical safety and efficacy, phase I to phase IV clinical trials, product registration, reimbursement, marketing and business development.
The company said that Dr Garner was currently Sanofi’s head of the unit development office based in Singapore and would relocate to Sydney in the New Year.
Novogen said that Dr Garner qualified in medicine at Imperial College, London and had worked for Bain & Company, Biogen, Progen, Quintiles and Takeda.
The company said that Dr Garner held a Bachelor of Sciences from University College London, a Bachelor of Medicine and Bachelor of Surgery from Imperial College London, as well as a Master of Arts and Master of Business Administration from the University of Queensland
Novogen said that Dr Garner would be paid a base salary of $400,000 a year, not including superannuation, with a performance bonus of up to 30 percent of the base salary at the board’s discretion and measured against key performance indicators, as well as receiving 7.5 million options under the executive share option plan, vesting in tranches over four years and exercisable at 45 percent to 90 percent premiums to the 30-day volume weighted average price to December 11, 2015.
Novogen was up half a cent or 4.35 percent to 12 cents.