



Biotech Daily

Thursday April 30, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ONCOSIL UP 14%, PHARMAXIS DOWN 6%**
- * **STARPHARMA: 'TRIAL PATIENTS TOLERATE HIGH DOSE DEP-DOCETAXEL'**
- * **POLYNOVO SELLS AOD9604 FOR \$1.5m TO DAVID KENLEY, LATERAL**
- * **'CNS DRUGS BACK IN FAVOR' BUCHAN BRAIN MEDICINE LUNCH TOLD**
- * **SYDNEY UNI, BALNAVES \$650k FOR 28 EARLY CAREER RESEARCHERS**
- * **UNIQUEST, ASTRAZENECA OPEN INNOVATION COLLABORATION**
- * **USCOM RECEIVES \$313k FEDERAL R&D TAX REFUND**
- * **ANALYTICA HAS LESS THAN TWO QUARTERS CASH**

MARKET REPORT

The Australian stock market fell 0.83 percent on Thursday April 30, 2015 with the S&P ASX 200 down 48.6 points to 5,790.0 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and four were untraded.

Oncosil was the best, up 1.3 cents or 14.1 percent to 10.5 cents with 5.0 million shares traded, followed by Starpharma up 13.7 percent to 58 cents with 2.1 million shares traded.

Patrys climbed 9.1 percent; Genetic Technologies was up 5.6 percent; Cellmid was up 4.2 percent; Clinuvel climbed 3.3 percent; Mesoblast and Viralytics rose more than two percent; with Cochlear and Resmed up by less than one percent.

Pharmaxis led the falls, down one cent or 6.1 percent to 15.5 cents with 1.3 million shares traded.

Biotron fell 4.2 percent; Admedus, Antisense, IDT, Prana and Sirtex lost more than three percent; Anteo, Atcor, Compumedics and Impedimed shed more than two percent; Acrux, Avita, Bionomics, Living Cell and Optiscan were down more than one percent; with Benitec, CSL, Medical Developments and Nanosonics down by less than one percent.

STARPHARMA HOLDINGS

Starpharma says the dendrimer-docetaxel dose in its phase I trial for solid tumors exceeds the most common 75mg/m² dose of docetaxel, with no dose limiting toxicities to date.

Starpharma said that about half the number of patients had been recruited to the trial of dendrimer-docetaxel, or DEP-docetaxel, for advanced solid cancers with several patients receiving up to six cycles of DEP-docetaxel.

The company said that DEP-docetaxel had been very well-tolerated, with no observations of neutropenia, or a low level of neutrophils in circulating white blood cells, to date.

Starpharma said that according to the available product information for Taxotere, the currently marketed docetaxel formulation, neutropenia occurred in virtually all patients given 60mg/m² to 100mg/m² of Taxotere, and the most severe grade 4 neutropenia occurred in 75 percent of patients given 60mg/m² of the product.

The company said that clinical data for DEP-docetaxel was in line with preclinical studies in animals that showed that DEP-docetaxel eliminated the neutropenia seen with equivalent doses of docetaxel alone whilst enhancing anticancer efficacy.

Starpharma said that there had been no reports of vomiting or hair loss related to the DEP-docetaxel treatment, events that occurred in a significant proportion of patients receiving Taxotere as monotherapy.

The company said that in contrast to Taxotere, which was formulated in polysorbate-80, a detergent that could cause significant hypersensitivity reactions, patients receiving DEP-docetaxel did not need to receive pre-treatment with corticosteroids because DEP-docetaxel was detergent free and patients receiving DEP-docetaxel did not require prophylactic treatment with anti-emetics to stop nausea and vomiting.

Starpharma said that available pharmacokinetic data showed, as previously reported, that DEP-docetaxel also had the benefits of longer half-life and reduced peak concentrations of docetaxel compared to when the drug was given in its native form.

Starpharma chief executive officer Dr Jackie Fairley said the company was "very pleased that the study is progressing so well".

"The fact that a number of patients have exhibited potential anti-cancer activity, across a range of tumor types, despite the absence of dose limiting toxicities and the maximum tolerated dose for DEP-docetaxel not yet being reached, is very encouraging," Dr Fairley said.

Starpharma said Taxotere was approved for breast, non-small cell lung, prostate, gastric and head-and-neck cancer and patients with a range of solid tumors were enrolled in the phase I trial, being conducted at Melbourne's Alfred Hospital, Melbourne's Austin Hospital, Sydney's Liverpool Hospital and the Royal Brisbane and Women's Hospital.

Starpharma was up seven cents or 13.7 percent to 58 cents with 2.1 million shares traded.

POLNOVO (FORMERLY CALZADA, FORMERLY METABOLIC PHARMACEUTICALS)

Polynovo says it has sold AOD9604 for \$1.5 million and sales royalties to Lateral Pharma Pty Ltd whose chief executive officer is former Calzada director David Kenley.

In 2010, Mr Kenley retired as a Calzada director to be the chief executive officer of subsidiary Metabolic Pharmaceuticals Pty Ltd, which held all of Calzada's remaining drug development assets, primarily focused on AOD9604. (BD: Feb 19, 2010).

The drug failed a large 2007 phase II trial for obesity and was at the centre of the Essendon Football Club drugs controversy (BD: Nov 21, 2014).

Today, Mr Kenley told Biotech Daily that Lateral would focus on the osteoarthritis application of AOD9604 and would begin animal trials this year.

Polynovo was up half a cent or 6.7 percent to eight cents.

BUCHAN CONSULTING, ACTINOGEN, BIONOMICS, INNATE IMMUNOTHERAPEUTICS

Speakers at a 'Brain Medicine' lunch in Melbourne say that neuroscience and central nervous system drugs are back in favor with investors and pharmaceutical companies.

The lunch, hosted by Buchan Consulting, and attended by about 60 biotechnology investors and analysts was told by Actinogen chief executive officer Dr Bill Ketelbey that Alzheimer's disease was the second leading cause of death in Australia.

Innate Immunotherapeutics chief executive officer Simon Wilkinson said that central nervous system drugs had seen some "spectacular failures" and until recently were out of favor.

But Mr Wilkinson told the meeting that in 2013 in the US, "15 percent of all pharmaceutical company transactions with small biotechnology companies were for central nervous system drugs, second only to oncology".

Mr Wilkinson said that venture capital and pharmaceutical companies were increasingly active as the importance of central nervous system diseases was increasingly recognized. Bionomics chief executive officer Dr Deborah Rathjen said that the US spent \$200 billion on Alzheimer's disease care.

Dr Rathjen said that there had been a resurgence of interest in the neuroscience space and her company had two major deals with Merck Inc, the more recent worth up to \$537 million for BNC375 for Alzheimer's and cognition and the earlier deal worth up to \$190 million for its neuropathic and chronic pain compound (BD: Jul 31, 2013; Jun 24, 2014).

Dr Rathjen said that separately the company was developing BNC210 for anxiety.

She said there was a "tremendous market opportunity" for BNC210 which could have application for Parkinson's disease, cognition, schizophrenia and attention deficit hyperactivity disorder (ADHD).

Dr Rathjen said that the Rockefeller family-related Third Rock Investment had been spinning out companies around neuroscience drug development.

Dr Rathjen said that while Glaxosmithkline and Astrazeneca had stepped away from neuroscience, others like Pfizer and Takeda had increased their investment.

Dr Ketelbey said that Actinogen had animal data indicating that the drug Xanamem should be successful in phase II human efficacy trials, expected to begin in 2016.

"It fixes Alzheimer's in rodents ... and even the amyloid is being cleared," Dr Ketelbey said.

UNIVERSITY OF SYDNEY MEDICAL SCHOOL, BALNAVES FOUNDATION

Sydney University Medical School and the Balnaves Foundation will provide \$650,000 in grants of up to \$25,000 each for 28 early career researchers.

The University said that the Early Career Researcher Kick Start Grants was a three-year initiative made possible through a commitment by the Balnaves Foundation, building on a seven-year investment program by the Medical School.

Sydney University Medical School dean Prof Bruce Robinson said that early career researchers were "the lifeblood of all successful medical research projects and face an increasing battle for grant funding due to their limited body of work, lack of experience and intense competition, but they face a classic dilemma, they need research expertise to receive grant funding, but they need grant funding to develop research expertise."

Balnaves Foundation founder Neil Balnaves said that "young people often have outside-of-the-box ideas and this type of research is often where breakthroughs occur".

"We want the novel ideas of these 28 young researchers to have the opportunity of coming to fruition and are excited to follow their progress over the next few years," Mr Balnaves said.

UNIQUEST

The University of Queensland's commercialization arm Uniquet says it will collaborative with Astrazeneca using 'open innovation' as a catalyst for drug discovery.

Uniquet said that University of Queensland researchers would have access to Astrazeneca compounds to investigate human mechanisms of disease and explore the development of novel target therapies for areas of high unmet medical need.

Uniquet said that the program would support its drive to expand the University's engagement with industry to help bring new medicines to patients and would provide Astrazeneca with the opportunity to collaborate with University researchers and their projects.

Uniquet chief executive officer Dr Dean Moss said that the initiative was "another important step towards the new era of medical discovery via open innovation and public-private collaboration".

The company said that each party brought complementary skills to foster medical innovation, with the University's thought-leadership and experience in accelerating the investigation of innovative therapeutic hypotheses and Astrazeneca's track record in global drug discovery and development.

Uniquet said that the collaboration would enable researchers to focus their proposals on Astrazeneca's core therapeutic areas including cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases.

The company said that successful research proposals resulting from the partnership would be jointly funded by Uniquet and Astrazeneca.

Astrazeneca's executive director, scientific partnering and alliances for Asia Pacific and emerging markets Dr Ajay Gautam said that "by giving leading academic research institutions such as the University of Queensland access to our compounds and expertise, we are opening doors to unexplored areas of pre-clinical and clinical research to help find the next generation of medical breakthroughs".

USCOM

Uscom says it has received \$313,050 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Uscom said the rebate related to research and development expenditure for the year to June 30, 2014.

Uscom was untraded at 21 cents.

ANALYTICA

Analytica says its net operating cash burn for the three months to March 31, 2015 was \$1,354,000 with cash at the end of the quarter of \$2,036,000.

Analytica said it had a further \$400,000 in loan facilities available.

Analytica chief executive officer Geoff Daly told Biotech Daily that "Analytica's board and management are closely monitoring expenditure and capital requirements and pursuing growth in revenue internationally".

Analytica was unchanged at two cents with 1.3 million shares traded.