



Biotech Daily

Monday September 19, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRANA UP 24%; ANTISENSE DOWN 11%**
- * **PHOSPHAGENICS, 3M OXYCODONE PATCH READY FOR PIVOTAL TRIALS**
- * **SUNSHINE HEART RAISES \$7.4m OF HOPED-FOR \$13.7m**
- * **STUDY BACKS PRANA'S PBT2 ACTION ON ALZHEIMER'S**
- * **VICTORIAN GOVERNMENT VOUCHER FOR LIQUITAB PILL CRUSHING**
- * **UNIVERSAL BIOSENSORS LICENCES SPEEDX'S MNAZYME**
- * **PATRYS ADDS BRISBANE HOSPITAL FOR PAT-SM6 MELANOMA TRIAL**
- * **DR GREG WINTER CHAIRS BIOSCEPTRE SCIENTIFIC ADVISORY BOARD**
- * **LIQUITAB APPOINTS BOB ATWILL CEO**

MARKET REPORT

The Australian stock market fell 1.64 percent on Monday September 19, 2011 with the S&P ASX200 down 67.9 points to 4,081.5 points.

Six of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and eight were untraded.

Prana was best, up four cents or 23.5 percent to 21 cents with 2.6 million shares traded.

Cochlear climbed 5.7 percent; Heartware, Phosphagenics and Phylogica were up three percent or more; with QRX and Psivida up more than one percent.

Antisense led the falls, down 0.1 cents or 11.1 percent to 0.8 cents with 491,944 shares traded.

Patrys lost 9.2 percent; Allied Health fell 7.1 percent; Bionomics was down 6.5 percent; Tissue Therapies was down 5.4 percent; Benitec, Reva and Sunshine Heart fell more than four percent; Mesoblast was down 3.1 percent; Anteo, CSL, Genetic Technologies, Prima and Starpharma shed more than two percent; with Acrux and Biota down more than one percent.

PHOSPHAGENICS

Phosphagenics says that completing the optimization of its tocopheryl phosphate mixture (or TPM) oxycodone patch paves the way for pivotal phase II/III trials.

Phosphagenics said the optimization was done in collaboration with 3M, which would produce the final patch with significantly improved oxycodone delivery and an extended wear profile for the pivotal oxycodone clinical trials (BD: May 23, 2011).

The company said it had previously shown that the prototype patches developed in-house were capable of delivering therapeutic amounts of oxycodone into the blood after daily application (BD: Oct 13, 2010).

Phosphagenics chief executive officer Dr Esra Ogru said that the performance of the finished patch was exceptional.

"We have developed a patch that delivers more oxycodone, at a faster rate, over a longer period of time," Dr Ogru said. "The commercial patch will not only provide flexibility for the treatment of a wider range of pain indications but will also be much smaller than our original prototype, an important element in patients' compliance."

Phosphagenics said its pivotal human trial program would begin in Australia in the next quarter and would be expanded next year into other countries including the US, with phase III expected to be completed by 2013.

The company said a steering committee had been appointed to design and oversee the trials and to ensure that the regulatory requirements needed to obtain US Food and Drug Administration approval were met.

Dr Ogru said that the successful completion of the human trials would "result in major commercial opportunities for the company and represents the culmination of many years of development".

Phosphagenics said a tocopheryl phosphate mixture-oxycodone patch would have advantages over other forms of pain medication, including the capability of diminishing breakthrough pain as well as avoiding gastro-intestinal tract inflammation and constipation, common consequences of administering oxycodone orally.

The company said that the patch should reduce the onset of drug tolerance in patients, which normally results in a need for these patients to increase their oxycodone intake over time to maintain therapeutic benefits of opioids.

Dr Ogru said the patches would reduce opioid abuse as it was more difficult to extract the drug from a patch than from most oral forms of oxycodone and applying multiple patches would not produce euphoria, the major reason for drug abuse.

Phosphagenics was up 0.5 cents or 3.5 percent to 15 cents with five million shares traded.

SUNSHINE HEART

Sunshine Heart says it has raised \$600,000 of the final \$6.9 million it had hoped to raise in a series of placements and a total of \$7.4 million of a hoped-for \$13.7 million.

In July, Sunshine Heart raised \$4.6 million in the US and said at that time that it hoped to raise a further \$9.1 million in Australia, the US and Canada (BD: Jul 25, 26, 2011).

Earlier this month, Sunshine Heart said it had raised \$2.2 million in Australia, leaving a further \$6.9 million (BD: Sep 5, 2011).

The company said the shares were placed at four cents each, with each new share having one attaching option to acquire 0.3 of a share exercisable at 5.6 cents within four years.

Sunshine Heart chief executive officer Dave Rosa said that one of the purposes of the capital raising "was to introduce the company to North American institutional investors and ... for the major pivotal trial coming up in 2012".

Sunshine Heart fell 0.2 cents or 4.35 percent to 4.4 cents.

PRANA BIOTECHNOLOGY

Prana says a new study explains how PBT2 is able to restore cognition in Alzheimer's disease sufferers through repair of affected Alzheimer's brains.

Prana said PBT2 liberated copper and zinc trapped in amyloid deposits and returned those essential metals to neurons, where they were needed for normal function.

Prana said the study, co-authored by its head of research Prof Robert Cherny, with the Victoria Mental Health Research Institute's Prof Colin Masters and Prof Ashley Bush, who consults to Prana, helped explain the rapid improvement in cognition previously reported in transgenic Alzheimer's mice and in patients in a phase IIa clinical trial with PBT2.

The article, published in the Journal of Neurochemistry is entitled 'The Alzheimer's therapeutic PBT2 promotes amyloid-B degradation and GSK3 phosphorylation via a metal chaperone activity'. An abstract is at: <http://www.ncbi.nlm.nih.gov/pubmed/21797865>.

Prof Cherny said PBT2 provides a combination of detoxification and neuronal restoration to bring about the cognitive improvement observed in patients and PBT prevented amyloid beta oligomer formation, delivering the neurologically active metals copper and zinc into neurons damaged in Alzheimer's disease. He said the data showed that delivery of those metals triggered intracellular molecular pathways which led to improved cognition and increased expression of neuronal markers.

"Our findings indicate that PBT2 causes phosphorylation of the key cellular kinase, GSK3 by inhibiting the activity of the phosphatase, calcineurin and refine our understanding of the mechanism of action of PBT2," Prof Cherny said. "Both GSK3 and calcineurin are viewed as important targets for [Alzheimer's disease] therapies."

The company said the activation of the pathway explained how PBT2 caused the large decrease in hyperphosphorylated tau, a brain protein associated with Alzheimer's disease.

Prana executive chairman Geoffrey Kempler said the data added significantly to the information published in the Public Library Of Science One in March (BD: Mar 21, 2011).

Prana was up four cents or 23.5 percent to 21 cents with 2.6 million shares traded.

VICTORIAN GOVERNMENT, SMALL TECHNOLOGIES CLUSTER, LIQUITAB

Liquitab says a Victorian Government voucher has funded development of its ultrasonic device to liquidize tablets for people who struggle to swallow tablets.

The Victorian Government's Small Technology Industry Uptake Program technical voucher funded assistance from engineering firm Grey Innovation and Monash University's Centre for Nanofabrication to improve the design of the product.

The Small Technology Industry Uptake Program manager Dr Buzz Palmer told Biotech Daily that the program was managed by the Small Technologies Centre and offered feasibility vouchers worth up to \$10,000 and technical vouchers worth up to \$50,000.

Details about the program are at: <http://stc-melbourne.com/index.php/stiup>.

A media release from the Small Technologies Cluster said the development reduced crushing time from six minutes to 70 seconds and ensured a more thorough crushing of the tablets and the alternative had been mortar and pestle.

The media release said that by altering the electronics of the Liquitab ultrasonic system and the position of the ultrasonics emitted, Grey and the Centre for Nanofabrication were able to greatly improve the efficiency of the energy transfer from the emitter into the pills.

Liquitab's founder Keith Dobson said that "Grey Innovation and the Victorian Government were the difference between Liquitab happening and not".

The media release said that as well as a homecare unit, Liquitab had a concept design for an institutional unit for nursing homes, hospitals and correctional facilities.

Liquitab is a public unlisted company based in Port Melbourne.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has signed a non-exclusive licence with the Sydney-based Speedx Pty Ltd, for access to its multi-component nucleic acid enzymes technology. Universal Biosensors said the Speedx multi-component nucleic acid enzymes (MNAzyme) technology was a sensitive and highly selective method for detecting sequences of DNA or RNA.

The company said the agreement allows it to use Speedx's technology in combination with its diagnostic biosensor to access the rapidly growing molecular diagnostics market. Universal Biosensors said the terms of the agreement were confidential.

The company said it would seek to develop a molecular diagnostic platform that could deliver rapid, low cost results at the point-of-care.

Universal Biosensors chief executive officer Paul Wright said the incorporation of Speedx's technology with his company's strip technology was "a very exciting prospect". "Having further validated the breadth of our technology with our recent deal with Siemens, we are now well placed to pursue further opportunities in this large emerging market," Mr Wright said.

"Performing molecular diagnostics at the point-of-care would have significant advantages for patients and UBI is looking forward to addressing this unmet need by developing low cost, rapid tests," Mr Wright said.

Universal Biosensors said the market for molecular diagnostics was valued at more than \$US3.5 billion worldwide and was expected to reach \$US6.2 billion by 2015 and it was broadly segmented into blood screening, infectious disease testing, genetic testing and oncology testing.

Universal Biosensors was unchanged at \$1.00.

PATRYS

Patrys says it has added Brisbane's Princess Alexandra Hospital as a second clinical centre, for its phase I trial of PAT-SM6 for the treatment of melanoma.

Patrys said the Royal Adelaide Hospital was recruiting the third group of three patients and no safety issues had been observed or reported for any patients treated with PAT-SM6.

Patrys chief executive officer Dr Marie Roskrow told Biotech Daily that the Princess Alexandra Hospital could help close the nine-patient trial if it located suitable melanoma patients or could be used to extend the trial.

The company said that a recent analysis of tumor samples from two patients treated with PAT-SM6 found that the antibody had penetrated into the tumor biopsies, even though the doses were substantially below the anticipated therapeutic levels (BD: Aug 22, 2011).

In a media release Dr Roskrow said that with the third cohort open for recruitment, "an additional centre involved in the study this should enable us to advance the study quickly". "As the trial progresses it is also important to have additional centres ready to assist in the next phase of testing for PAT-SM6," Dr Roskrow said.

Patrys said PAT-SM6 was a natural human antibody that had shown promise as a potential treatment for multiple types of cancer including melanoma.

The company said it was the first reported clinical product to target the GRP78 protein on the surface of cancer cells that plays a number of roles in cancer cell survival, growth and metastasis.

Patrys fell 0.6 cents or 9.2 percent to 5.9 cents.

BIOSCEPTRE INTERNATIONAL

Biosceptre says it has established a scientific advisory board and appointed Dr Greg Winter as chairman along with Prof Douglas Fearon and Prof Terence Rabbits.

Biosceptre said the three founding advisors had expertise in immunology and development of antibody therapeutics.

Dr Winter was formerly on the scientific advisory board of Peptech which became Arana later acquired by Cephalon.

Biosceptre said that Dr Winter was a member of the Medical Research Council's Laboratory of Molecular Biology in Cambridge, a Fellow of Trinity College Cambridge and was a founder and director of Cambridge Antibody Technology which was acquired by Astra Zeneca and a founder and director of Domantis acquired by Glaxosmithkline.

The company said that Prof Fearon was a professor of immunology at Cambridge University and senior group leader of the Cambridge Research Institute and formerly a professor of medicine at Harvard Medical School and Johns Hopkins Medical School, where he was director of the division of rheumatology.

Biosceptre said Prof Rabbits worked in the Cambridge Laboratory of Molecular Biology from 1973-2006 and was appointed the director of the Leeds Institute of Molecular Medicine from 2006 to 2010, chairman of the Cambridge Antibody Technology advisory board and of Quadrant Healthcare and a member the Domantis advisory board and is a member of the Oryzon Genomics and Dithera scientific advisory boards.

Biosceptre chief executive officer Dr Cliff Holloway said input from the eminent scientists would "be key to the direction of our internal R&D efforts as we advance our lead therapeutic towards clinical evaluation".

Biosceptre said its lead anti-cancer programs comprised antibody therapeutics directed towards a novel proprietary cancer target, non-functional P2X7 which was a major cellular receptor responsible for normal cell death or apoptosis.

The company said that a subtle change rendered P2X7 'non-functional' which in cancer prevents apoptosis and it had a range of antibody products in development capable of specifically detecting non-functional P2X7 and inducing cancer cell death without affecting normal healthy cells.

Biosceptre is a public unlisted company.

LIQUITAB SYSTEMS

Liquitab has appointed Bob Atwill as its chief executive officer.

Liquitab said Mr Atwill would review the company's strategic direction and assist with strategic planning, business development and commercialization of the company's technology for the treatment of dysphagia.

The company said Mr Atwill had been working with Biogrid as interim chief executive officer, with Mesoblast as a strategy and commercialization consultant and with business development consultancy Biocomm Squared.

Liquitab said that previously, Mr Atwill was the chief executive officer of Clinical Cell Culture, now Avita Medical and prior to that he was the sales and marketing director of orthopaedics company Corin Group Plc and European managing director at the US based long-term care provider Sun Healthcare Group.