Biotech Daily

Tuesday July 23, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 16%, CELLMID DOWN 9%**

*** PRANA COMPLETES PHASE II PBT2 HUNTINGTON'S TRIAL**

*** CALZADA SHARE PLAN RAISES $2.6m, TOTAL RAISED $3.85m**

*** NUSEP TO SELL 10% OF PRIME, SHARE PLAN FOR $1.9m**

*** PHARMAUST COMPLETES PITNEY, 3 CANCER PLATFORM ACQUISITION**

*** RESONANCE FERRISCAN TEST FOR PHASE II IRON OVERLOAD TRIAL**

*** ONCOSIL, ECKERT & ZIEGLER MANUFACTURING AGREEMENT**

*** NOVADEL APPROVES SALE TO SUDA**

*** CRAIG CHAPMAN, NAMPAC TAKE 18.5% OF AGENIX**

*** BRAIN FILES DEPRESSION TEST WITH FDA**

MARKET REPORT

The Australian stock market climbed 0.3 percent on Tuesday July 23, 2013 with the S&P ASX 200 up 15.2 points to 5,017.1 points.

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

Impedimed was the best, up two cents or 16 percent to 14.5 cents with 218,700 shares traded, followed by Neuren and Pharmaxis, both up 12.5 percent to nine cents and 12.5 cents, respectively, with 11.8 million and 2.2 million shares traded, respectively.

Alchemia and Compumedics climbed more than 10 percent; Reva was up 6.8 percent; Patrys and Phosphagenics rose more than four percent; Prima was up 3.6 percent; CSL, Osprey, Psivida, QRX, Sirtex and Universal Biosensors were up one percent or more; with Acrux and Mesoblast up by less than one percent.

Cellmid led the falls, down 0.3 cents or 9.4 percent to 2.9 cents with 2.4 million shares traded. Atcor lost 7.6 percent; Antisense fell 5.9 percent; Bionomics shed 2.7 percent; Anteo, Heartware, Living Cell, and Viralytics were down more than one percent; with Cochlear and Resmed down by less than one percent.

PRANA BIOTECHNOLOGY

Prana says it has completed its phase II clinical trial of PBT2 in patients with early to mid-stage Huntington disease and expects to announce the results in October 2013.

Prana nominated Huntington's disease as a second indication for PBT2, with Alzheimer's disease, in 2008 and began the trial last year (BD: Nov, 28, 2008; Apr 30, 2012)

Prana said the phase II trial, entitled the Reach2HD trial, was a randomized, double-blind, placebo-controlled trial testing the safety and efficacy of PBT2 for Huntington's disease.

The trial was conducted in collaboration with the Rochester, New York-based Huntington Study Group at 20 sites in the US and Australia.

Huntington Study Group director and principal investigator Dr Ray Dorsey said his group was "extremely pleased with the conduct of the trial, at all levels including recruitment and patient retention".

Prana said that the trial planned to recruit 100 patients in nine months, but 109 participants were enrolled in that period, of which 104 patients completed the trial.

The company said that a data safety monitoring board met on five occasions throughout the trial and on each occasion recommended that no changes or modifications to the study protocol be made, based on their review of the safety data.

Prana said that the primary outcome of the trial was safety and tolerability and included a number of secondary outcome measures from the cognitive, motor and behavioral domains affected in Huntington's disease.

The company said that a positive result for the trial would identify signals of therapeutic benefit in one or more of the domains measured, which would inform the design of the next clinical trial.

Prana chairman Geoffrey Kempler said "assuming we achieve the positive results we are hoping for in Reach2HD, we plan to meet with the US regulator, the Food and Drug Administration, and other regulatory agencies to discuss the next steps in the clinical development of PBT2 for the treatment of Huntington's disease".

"We plan to discuss the design of the next trial and agree on a set of clinical outcomes that, when achieved, will allow us to submit a new drug application for approval to start to market PBT2 for Huntington disease," Mr Kempler said.

Prana said that Huntington's disease was a complex and severely debilitating genetic, neurodegenerative disease, for which there was no cure.

The company said the disease often affected young adults and, while associated with severe physical movement symptoms and impacts the mind and emotions as well.

Prana said that Huntington's disease caused incapacitation and death about 15 to 25 years after onset and affects more than 30,000 people in the US and 70,000 worldwide.

Prana was unchanged at 27 cents.

CALZADA

Calzada says its share plan has raised $2.6 million through the issue of 40.2 million shares at 6.5 cents a share.

In June, Calzada said it had raised $1.25 million through an oversubscribed placement and hoped to raise a further $2 million from the share plan (BD: Jun 12, 2013).

Today, Calzada said it had raised a total of $3.85 million which would be used for US regulatory applications for its Novosorb polymer wound dressing; further research and development of the wound dressing and treatment including a trial in third degree burn patients; partnering Novosorb; licencing and pursuing 'generally recognized as safe' status for AOD9604 in the US as a supplement; and general working capital purposes.

Calzada was up 0.1 cents or 1.4 percent to 7.3 cents.

NUSEP

Nusep says it will sell up to 10 percent of its holding in the Singapore-based Prime Biologics in one percent blocks to external investors.

Last year Nusep said it would spin-out the Prime Biologics therapeutic plasma fractionation business, enabling it to focus on development of new Prime applications including in-vitro fertilization, recombinant proteins and renal dialysis, while generating the first of a series of high margin revenue streams (BD: Oct 10, 2012).

The company said last year that it had been difficult to finalize the external funding for Prime while it formed part of the Nusep group as Nusep had a market capitalization of less than $10 million relative to the $46 million valuation of Prime Biologics.

Nusep said last year that it held 90 percent of Prime Biologics and 10 percent was held by Luye Pharma Group and following an initial public offer Luye Pharma would hold 20 percent, an investor group would hold 10 percent, escrow Nusep shareholders would hold 50 percent, Nusep would hold 10 percent and the offer would raise 10 percent.

Today, Nusep said that the one percent shareholding blocks would be priced at $S665,000 ($A569,925) each, valuing Prime at $S66.5 million ($A57 million).

The company said the funding would be in addition, and complementary, to the funding from any cornerstone investor.

Nusep said that by placing up to 10 percent of Prime Biologics it had started the timeline to the clinical good manufacturing practice (cGMP) milestone, allowing it to bring in the additional funds at a later time and at a higher valuation than the current $57 million and enabling Nusep to maintain a higher ownership in Prime Biologics.

Nusep said it would be able to maintain about 70 percent of Prime Biologics while funding it through to its first commercial sale.

The company said that the process would enable it to demerge Prime Biologics to its shareholders at the time of its initial public offer and at a higher value than the current $57 million valuation.

Nusep said that the Prime Biologics funding would have two immediate impacts with Prime placing an order for $S1.1 million to supply the Prime Technology cGMP manufacturing unit and associated membranes and it would receive reimbursement for the Prime Biologics costs incurred since December 1, 2012.

Nusep said there were “a number of other organizations that [were] looking to setup Prime Biologics franchise facilities in other countries” which would be separately funded by the franchisee.

Nusep said it had taken the active decision to slow the progress of these franchise opportunities as the initial focus had to be on funding the Singapore facility and bring the initial Singaporean therapeutic plasma products to market.

The company said it had also been seeking funds for the development of the membrane manufacturing facility to make the Prime Biologics membranes and fund the next Prime Technology developments and it was in the process of applying for research grants to support both the Spermsep and Dengue applications of the Prime Technology.

Nusep said it would hold a share purchase plan at 4.5 cents a share to raise up to $1.8 million to develop Prime membrane manufacturing in its Homebush New South Wales facility, enabling it to manufacture the membranes that will be purchased by Prime Biologics and future franchise facilities.

The company said the record date was July 19, the offer would open on July 23 and close on August 19, 2103.

Nusep said that In order to repay investor support it intended to make a bonus share and option issue once the funding for the cGMP phase was resolved.

Nusep was unchanged at 4.5 cents.

PHARMAUST

Pharmaust says it has completed the acquisition of Pitney Pharmaceuticals and its three oncology platforms (BD: Apr 30, 2013).

In April, Pharmaust said that the acquisition would be up to 600 million shares and on completion of due diligence it would raise at least $3 million, as well as undertake a placement at one cent a share to raise $500,000 to fund costs associated with due diligence and working capital.

In May, Pharmaust raised the $500,000 (BD: May 14, 2013) and today said their would be a further capital raising of at least $2 million and a further share plan to raise $500,000.

Pharmaust said that the Sydney-based Peloton Capital was providing corporate advisory and capital raising services in support of the transaction.

Pharmaust said that the Sydney-based Pitney was developing three oncology platforms targeting liver, bowel, ovarian, lung and cervical cancer and one of the platforms was the subject of a research and option agreement for a veterinary product, while a second platform had completed two trials in humans and was ready for a phase II clinical trial.

The company said that Pitney had exclusive rights to three oncology platforms from Newsouth Innovations, the commercialization arm of the University of New South Wales.

Pharmaust said the first platform was Albendazole, an anthelminthic drug used in human and veterinary practice and shown to be a potent vascular endothelial growth factor (VEGF) inhibitor and evaluated at the St George Hospital for the treatment of ascites, a condition affecting about 10 percent of abdominal cancers.

The second platform entitled ‘Another Anthelminthic Drug’ was being investigated for its clinical scope and application in oncology and was the subject of a research and option agreement, while the third platform was the treatment of diseases involving mucin.

Pharmaust said that some abdominal cancers were characterized by the presence of large amounts of mucin, that reduced the efficacy of anti-cancer drugs and Pitney had the licence to a formulation that dissolved mucin in-situ and potentially allowed for more effective chemotherapy.

Pharmaust said that Dr Roger Aston would be appointed chairman with directors Prof David Morris, Sam Wright and Henry Gulev and Bryant Mclarty would stand down.

Pharmaust was unchanged at one cent with 1.2 million shares traded.

RESONANCE HEALTH

Resonance says an unnamed pharmaceutical company has contracted it to provide Ferriscan services to evaluate a phase II therapy for chronic transfusional iron overload.

Resonance said that the two-year contract would require it to work with about 25 magnetic resonance imaging facilities in a number of countries.

The company said that it would train the radiology facilities in the Ferriscan imaging requirements and would perform the patient scanning during the clinical trial.

Resonance said that the image data would be sent from the radiology facilities to Resonance’s certified facility in Perth where technicians would analyze the image data to quantify the liver iron concentration.

The company said there were a variety of diseases that could cause iron overload, with haemoglobinopathies such as thalassemia and sickle cell disease often requiring repeat blood transfusions, which resulted in the patient accumulating excess iron.

Resonance said that an iron chelating drug was required to remove the excess iron.

The company said that its Ferriscan was” internationally recognized as the gold standard non-invasive test for assessing liver iron concentration”.

Resonance was untraded at 1.4 cents.

ONCOSIL MEDICAL, (FORMERLY NEURODISCOVERY)

Oncosil says it has “a co-operation and costs-sharing agreement” with the Berlin-based nuclear medicine manufacturer Eckert & Ziegler.
Oncosil previously said it was developing Psivida’s Brachysil, a radioactive particle of silicon and phosphorus inserted directly into a tumor for pancreatic cancer and was preparing for a pivotal phase III trial (BD: Feb 7, 2013).
Today the company said that that Eckert & Ziegler manufactured devices, radio-chemicals and radiopharmaceutical precursors used for serious diseases and medical imaging.
The company said the agreement with Eckert & Ziegler was the first step towards a global strategic manufacturing alliance and the companies intended to enter into a formal process development and manufacturing agreement and were negotiating terms.
Oncosil said that it intended that its radiochemical device would be manufactured in Germany and it would use Eckert & Ziegler’s expertise in global shipping of radioactive packages.
The company said the agreement should provide significant commercial advantages, including capacity to meet long-term supply, access to Eckert & Ziegler’s radioactive manufacturing and storage facility, the ability to reduce the cost of goods as manufacturing increased for the pivotal registration study and the potential to provide research support for optimized second generation products.
Oncosil fell 0.3 cents or 3.6 percent to eight cents with 1.3 million shares traded.

SUDA

Suda says Novadel investors have approved the sale of their company and its oro-mucosal platform technology for $400,000 and 50,000,000 shares (BD: Apr 8, 2013).
Suda said that that all conditions relating to the acquisition had been met and it would finalize the acquisition within the next 10 days.
The company said that on settlement Novadel’s core technology Novamist, to be renamed Sudamist would be transferred to Suda.
Suda said in April that Novadel held a portfolio of granted and pending patents, covering the buccal and mucosal delivery of a range of drugs for the central nervous system, erectile dysfunction, pulmonary arterial hypotension, biologically active peptides hormones such as, insulin and cyclosporine.
The company said the patents covered antibiotics, anti-fungals, anti-virals, anti-asthmatics, barbiturates and opioids as well as, polar and non-polar sprays or capsules.
Suda said that the key product in development Duromist was a stable solution of lingual sildenafil, which was the active ingredient in Viagra that had shown preliminary bioequivalence to Viagra tablets in early clinical trials.
Suda was unchanged at 3.3 cents with 1.9 million shares traded.

AGENIX

Craig Graeme Chapman has increased his substantial shareholding in Agenix from 12,606,614 shares (14.35%) to 20,836,614 shares (18.53%).
The substantial shareholder notice said that the Kenmore, Queensland-based Mr Chapman held the shares as trustee for Nampac Discretionary Account and acquired the 8,230,000 shares for $174,350 or 2.1 cents a share and as part of the May capital raising which included a rights issue at three cents a share and a convertible notes issue (BD: Jan 21, Feb 22, May 17, 2013)
Agenix was untraded at 2.8 cents.

BRAIN RESOURCE

Brain Resource says it has completed its analyses of its Depression Treatment Test and has filed it with the US Food and Drug Administration.

Brain said that the Depression Treatment Test was based on a 30-minute battery of on-line tasks that measured memory, attention and the accuracy of identifying face emotions.

The company said that cognition test was fully automated and highly scalable and the company could generate a clinical report to the referring clinician within minutes of the patient undertaking the test.

Brain said the detailed results were confidential pending publication of a submitted article in a peer-reviewed journal, but said the test predicts treatment response in a subgroup of patients to the three most commonly prescribed antidepressants Escitalopram, Sertraline and Venlafaxine.

The company said that three patent applications had been filed covering these and related findings.

Brain said it expected feedback from the FDA within three months concerning the final step of the submission, to replicate the result in a new set of patients.

Brain was unchanged at 30 cents.