Biotech Daily

Friday March 8, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 18%, PHARMAXIS DOWN 3%**

*** PHARMAXIS COMPLETES BRONCHIECTASIS TRIAL, RESULTS BY JULY**

*** CIRCADIAN LICENCES VEGF TO SANTA CRUX FOR REAGENTS**

*** CSL CEO PAUL PERREAULT STARTS ON $1.7m A YEAR**

*** FEDERAL MINISTER GREG COMBET OPENS $25m PHEBRA FACILITY**

*** FDA APPROVES WIRELESS VERSION OF UNIVERSAL BIOSENSORS METER**

*** FDA REJECTS ISONEA SONOSENTRY, AIRSONEA ON-TRACK**

*** PRANA REPORTS PBT2-TAU MOUSE DATA**

*** SUDA APPOINTS KEN ROBSON DIRECTOR**

*** BIONICHE SPINS HUMAN HEALTH INTO BIONICHE THERAPEUTICS**

MARKET REPORT

The Australian stock market was up 0.28 percent on Friday March 8, 2013 with the S&P ASX 200 up 14.2 points to 5,123.4 points.

Eighteen of the Biotech Daily Top 40 stocks were up, five fell, 13 traded unchanged and four were untraded.

Patrys was the best, up 0.6 cents or 17.65 percent to four cents, with 1.0 million shares traded, followed by Cellmid up 13.6 percent to five cents, with 46.6 million shares traded.

Antisense climbed 9.1 percent; Psivida and QRX were up eight percent or more; Atcor, Neuren and Uscom were up five percent or more; Ellex, Optiscan and Viralytics climbed more than four percent; Circadian was up 3.85 percent; Sirtex and Universal Biosensors rose more than two percent; Anteo, Bionomics and GI Dynamics were up more than one percent; with Cochlear, CSL and Heartware up by less than one percent.

Pharmaxis led the falls, down 1.5 cents or 2.75 percent to 53 cents with 915,646 shares traded.

Clinuvel and Mesoblast fell more than two percent; with Acrux, Genetic Technologies and Resmed were down one percent or more.

PHARMAXIS

Pharmaxis says it has completed dosing and follow-up of the 485 patients in its 52 week, phase III trial of Bronchitol for bronchiectasis.

Pharmaxis said the last patient completed the final clinical visit in the double blind, controlled, randomized trial, which involved 83 hospitals in the US, Europe, South America and Australia, and began in October 2009.

The company said that the trial would examine the efficacy and safety of 52 weeks treatment with Bronchitol in subjects with non-cystic fibrosis bronchiectasis.

Pharmaxis chief executive officer Dr Alan Robertson said the trial was complex and "collected a vast amount of data over a long period and has already provided great insights into this under researched patient population".

"We are grateful to the volunteers in the trial and are hopeful that the data will allow us to make the benefits of Bronchitol available to a wider group of people," Dr Robertson said.

Pharmaxis said that the primary endpoint of the trial was to show a significant difference in the rates of graded pulmonary exacerbations in patients with bronchiectasis treated with Bronchitol compared to control, with secondary endpoints including quality of life, sputum weight and lung function as measured by spirometry.

Pharmaxis said that the headline results would be available by July 2013, following data review and statistical analysis.

The company said that about 600,000 people in the major pharmaceutical markets had bronchiectasis and no products were approved to assist with mucus clearance.

Pharmaxis said that exacerbation were serious life threatening complications for patients with bronchiectasis and often led to hospitalization as well as increased damage to the lungs and accelerated loss of lung function.

Pharmaxis said that a positive outcome from the trial might form the basis for an extension to the existing marketing approvals for Bronchitol in the European Union and Australia where patients seeking treatment were estimated at 210,000 and 18,000 respectively.

Pharmaxis fell 1.5 cents or 2.75 percent to 53 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that subsidiary Vegenics has licenced vascular endothelial growth factors to the Dallas, Texas-based Santa Cruz Biotechnology for use as research reagents.

Last month, Circadian said it intended to pursue the licencing of vascular endothelial growth factor (VEGF) for use as reagents (BD: Feb 27, 2013)

Today, Circadian said it had a "non-exclusive worldwide licence agreement with Santa Cruz … to market antibodies to Circadian's proprietary molecules VEGF-C, VEGF-D and VEGFR-3".

The company said it would receive an up-front payment and royalties on sales, but did not disclose the value of the licence.

Circadian chief executive officer Robert Klupacs said that Santa Cruz Biotechnology was "a world leader in the development of products for the biomedical research market, particularly research antibodies".

"They have identified the increasing importance of VEGF-C, VEGF-D and VEGFR-3 as key angiogenic proteins and the need to provide high quality reagents to measure and/or detect these proteins to the international research and drug discovery community," Mr Klupacs said.

"This partnership is also another example of the diverse range of commercial opportunities and value of our VEGF intellectual property," Mr Klupacs said.

Circadian was up one cent or 3.85 percent to 27 cents.

CSL

CSL says Paul Perreault will succeed Dr Brian McNamee as managing director and chief executive officer on July 1, 2013 on a base salary of $US1,700,000 ($A1,659,040).
CSL said that along with the $4,546 a day base salary, Mr Perreault would be entitled a maximum 'short term incentive' up to the same amount with two-thirds in cash and the balance "as phantom shares and settled in cash after three years".
The company said that Mr Perreault would also be entitled to a 'long term incentive' based on 60 percent of his base salary "in the form of hurdled performance rights" and a further 60 percent "in the form of phantom shares under the executive deferred incentive plan".
Should Mr Perreault meet his incentive milestones he would receive a maximum of $US5,440,000 ($A5,311,950) a year or $14,523 per day.
CSL was up 38 cents or 0.6 percent to $59.85 with 1.2 million shares traded.

PHEBRA (FORMERLY PHARMALAB)

The Minister for Industry and Innovation, Greg Combet has opened Phebra's $25 million pharmaceutical manufacturing facility in Lane Cove West in Sydney.
In a media release Mr Combet said the growth of the company was "another example of how innovation and strategic investment drives Australian manufacturing success".
Mr Combet said the company had grown steadily from its 1993 foundation as Pharmalab as a distributor of specialist pharmaceuticals by moving into research and development.
"Phebra manufactures critical medicines that would otherwise be unavailable in Australia," Mr Combet said.
"This latest investment includes new infrastructure that will increase their hourly production rate by up to five times," Mr Combet said.
Phebra chief executive officer Dr Mal Eutick told Biotech Daily that Phebra was a "supplier, developer and manufacturer of innovative critical medicine" and was strongly focused on development of both ideas and raw materials.
Dr Eutick said that Phebra was benefiting from the Federal Government's research and development tax incentive and expected to benefit from the proposed implementation of clinical trials reforms.
Mr Combet said that as a collaborator with hospitals in Sydney, Melbourne and Newcastle, Phebra would benefit from Federal Government support announced for clinical trials as part of the $1 billion 'Plan for Australian Jobs'.
"The Government is reforming the arrangements for clinical trials of new medicines and treatments in Australia to encourage innovation and investment in the pharmaceutical research industry," said Mr Combet.
"The Australian pharmaceutical industry is a major high tech industry," Mr Combet said.
"It employs more than 40,000 Australians, generates export earnings of around $4 billion a year and invests more than $1 billion a year in research and development," Mr Combet said.
"The Government's clinical trial reforms present a major opportunity for this industry to boost investment and high skilled jobs," he said.
"The reforms will improve efficiency, streamline administration and reduce costs to position Australia as a world leader in clinical research and the commercialization of new medical technologies," Mr Combet said.
Phebra is a private company.

UNIVERSAL BIOSENSORS

Johnson & Johnson's Lifescan says the US Food and Drug Administration has cleared the Universal Biosensors' Onetouch Verio Sync blood glucose monitoring system.
Lifescan said the Verio was the first meter to automatically send blood glucose results wirelessly via Bluetooth technology to an Iphone, Ipad or Ipod using the Onetouch Reveal mobile telephone application.
Universal Biosensors chief financial officer Salesh Balak told Biotech Daily that the technological adaptation approved by the FDA was undertaken by Lifescan, on the previously approved Universal Biosensors developed Onetouch Verio diagnostic.
Mr Balak said that Universal Biosensors would receive income from the wireless version which also used his company's test strips.
Universal Biosensors was up two cents or 2.5 percent to 82 cents.

ISONEA

Isonea says the US Food and Drug Administration has effectively rejected its application for Sonosentry as an over-the-counter wheeze monitor to replace the Wheezometer.
At the bottom of a media release entitled 'Isonea Unveils Regulatory Plans for Airsonea Wheeze Monitor', the company said that on March 6, 2013 it received a letter from the FDA saying the Sonosentry device was "not substantially equivalent" to its direct predecessor, the Wheezometer, and specified the additional data required to resolve the issues so that its review of a 510(k) application could be successfully completed.
Isonea said that the initial application for Sonosentry sought 510(k) clearance as an over-the-counter wheeze monitor to replace the Wheezometer device and was filed with the FDA in October 2012, based on the device's equivalence to the Wheezometer, but sought a label change from prescription to over-the-counter status.
Isonea said that in December 2012, it received a request from the FDA for additional information and submitted its response on January 11, 2013.
The company said it would re-submit a Sonosentry 510(k) application with the additional data requested by July 2013.
Isonea says that its Airsonea device was "still on track for launch in 2013, as previously advised" and the Airsonea application was not dependent on the Sonosentry outcome.
Isonea said that its Airsonea device was designed to detect and measure the presence and extent of wheezing, a principal sign of airway constriction that can indicate increasing risk of an asthma attack and combined its acoustic respiratory monitoring technology with universally available smart-phones.
Isonea said it would file an application for Airsonea with the Australian Therapeutic Goods Administration in April 2013 and expected the device to be marketed in Australia by October 2013.
The company said the US launch of Airsonea as an over-the-counter monitor would require review and clearance by the US Food and Drug Administration, which could be as short as 90 days or could take longer, depending on reviewer questions and/or requests for additional data.
Isonea said it expected to submit its 510(k) dossier to the FDA by October 2013.
The company said that the 510(k) review process for Sonosentry was "valuable … in identifying questions that can be anticipated from the Agency with regard to the Airsonea 510(k) submission".
Isonea said that the Sonosentry device was intended to provide access to wheeze monitoring technology for people who do not have smart-phones.
Isonea was unchanged at 7.5 cents.

PRANA BIOTECHNOLOGY

Prana says that new mouse data shows that PBT2 reduces brain cell damage caused by the accumulation of the tau protein and prevents subsequent cognitive impairment.

Prana said the data publication was at the request of the Australian Securities Exchange, following two earlier announcements this week (BD: Mar 4, 7, 2013).

Prana said the data was generated in a mouse model that over produced the tau protein giving rise to tangle-like inclusions similar to those which caused neuronal death in Alzheimer's disease.

The company said that while the anti-aggregation effects of PBT2 on amyloid beta had been documented, the results were generated in a model which was independent of the presence of amyloid beta, indicating that PBT2 had the ability to prevent neuronal damage via multiple metal mediated pathways, including amyloid beta and tau aggregation.

Prana said that data would be presented by Prana scientist Prof Paul Adlard tomorrow at a conference in Italy in a presentation entitled 'Metal Chaperones are novel therapeutic agents for tauopathy'.

Prana chief scientific advisor Prof Rudy Tanzi said the findings provided "further evidence that by targeting specific metal imbalances in the brain, PBT2 possesses the ability to ameliorate Alzheimer's pathology in relevant mouse models for both senile plaques and neurofibrillary tangles".

"This data, in combination with the previously reported phase IIa clinical trial results for PBT2 in Alzheimer's disease further support PBT2 as a potentially promising therapy for this devastating disease," Prof Tanzi said.

Prana's head of research Prof Robert Cherny said Prana had shown that PBT2 improved cognitive impairment, Abeta burden and tau hyperphosphorylation in the APP/PS1 transgenic mouse model of Alzheimer's disease which overexpressed Amyloid beta.

"Recent literature supports the notion that metals modulate the properties of tau and may affect the formation of neurofibrillary tangles which are a feature of several neurodegenerative diseases," Prof Cherny said. "In human beings, certain mutations in the gene encoding the tau protein lead to hereditary fronto-temporal dementia and Parkinsonism collectively known as tauopathies."

Prof Cherny said that Alzheimer's disease was an 'amyloid beta mediated tauopathy'.

Prana said that PBT2 was in a 12 month phase II Alzheimer's disease imaging clinical trial, expected to be completed at the end of the year.

Prana said that administration of PBT2 resulted in significant improvement in performance in the Y maze, a significant reduction in the number of neurofibrillary tangles and a significant increase in cortical and hippocampal neurons in the rTg4510 mouse model.

The company said that a significant increase in the levels of the PP2A protein, which was implicated in tau phosphorylation events, in PBT2 treated animals suggested that the drug might directly act upon biochemical pathways which led to neurofibrillary tangles formation as well as any potential interaction with tau itself.

Prana was unchanged at 23.5 cents.

SUDA (FORMERLY EASTLAND MEDICAL SERVICES)

Suda says it has appointed Ken Robson as a non-executive director.

The company said that Mr Robson was a corporate lawyer and adviser with experience in fundraising, market compliance and mergers and acquisitions.

Suda said that Mr Robson was a barrister and had experience as a company chairman and director in the US, Britain, Canada, Switzerland, New Zealand and Australia.

Suda was unchanged at 3.3 cents.

BIONICHE LIFE SCIENCES

Bioniche says it will reorganize its human health division into a wholly-owned private subsidiary to be called Bioniche Therapeutics Corp.

Bioniche said the subsidiary would function as a standalone unit and allow direct external investment to support research and development, commercialization and acquisition opportunities.

Primarily a veterinary company, Bioninche's phase III human health product Urocidin for bladder cancer was returned by Endo Pharmaceuticals (BD: Nov 6, 2012, Jan 20, 2013).

Bioniche chief executive officer Graeme McRae said that capital markets did not "recognize the full value of the company's underlying business units and technologies in their current configuration"

"With global rights to Urocidin negotiated back from Endo Pharmaceuticals, we believe that this is the right time to reconfigure the organizational structure to better highlight the inherent value in the human health business unit with this late-stage therapeutic asset," Mr McRae said.

The company said it would seek to source new investments in Bioniche Therapeutics to support commercialization of Urocidin as either private equity or licencing income through the out-licencing of Urocidin marketing rights.

Bioniche said a search was underway for a Bioniche Therapeutics chief executive officer.

Bioniche was up three cents or 15 percent to 23 cents.