Biotech Daily

Thursday August 28, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: OPTISCAN UP 14%, GENETIC TECHNO DOWN 7%**

*** VICTORIA TO ALLOW MEDICAL CANNABIS TRIALS**

*** FEDERAL GOVERNMENT, ARC OPEN MONASH BIO-NANO CENTRE**

*** JAPAN ALLOWS PHYLOGICA PEPTIDE PHYLOMER PATENT**

*** PHARMAXIS ANTI-INFLAMMATORY PXS4728A 'IN THE CLINIC IN 2015'**

*** PHARMAXIS REVENUE UP 56% TO $5m, LOSS UP 19% TO $52m**

*** ADMEDUS REVENUE UP 7% TO $8m, LOSS UP 239% TO $8m**

*** RESONANCE REVENUE UP 35% to $2m, LOSS DOWN 65% TO $72k**

*** PHARMAUST REVENUE UP 17% TO $2m, LOSS UP 156% TO $1.3m**

*** CRYOSITE REVENUE UP 4% TO $26m, PROFIT DOWN 18% TO $2m**

*** BLUECHIIP PLEADS SCHULTZ TO ASX 191% QUERY**

*** UNILIFE PLEADS SCHULTZ TO ASX 20% QUERY**

*** RHINOMED REQUESTS CAPITAL RAISING TRADING HALT**

*** LBT APPOINTS DANIEL HILL CFO**

MARKET REPORT

The Australian stock market fell 0.47 percent on Thursday August 28, 2014 with the S&P ASX 200 down 26.8 points to 5,624.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and five were untraded.

Optiscan was the best, up 0.5 cents or 14.3 percent to four cents with 332,787 shares traded. Antisense climbed 11.1 percent; Medical Developments was up 7.5 percent; GI Dynamics was up 6.7 percent; Mesoblast was up 5.5 percent; Oncosil climbed 4.35 percent; Living Cell was up 3.9 percent; Neuren and Universal Biosensors rose more than two percent; with Acrux, Alchemia and Atcor up more than one percent.

Genetic Technologies led the falls, down 0.2 cents or 6.9 percent to 2.7 cents with 124,167 shares traded. Compumedics fell 4.35 percent; Admedus, Anteo, Benitec and Pharmaxis were down more than three percent; Ellex, Phosphagenics, Prima and Starpharma shed two percent or more; with Impedimed, Osprey and Sirtex down more than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it will amend the law in order to facilitate clinical trials of medical cannabis.

A media release from Victoria's Minister for Health David Davis said that an expert advisory committee, composed of clinical and regulatory experts, would be appointed to work through the issues of obtaining approval to trial the use of cannabis compounds in treating or relieving symptoms for a range of illnesses and conditions.

The media release said that the Drugs, Poisons and Controlled Substances Act would be amended to make it easier to conduct clinical trials involving cannabis and similar highly regulated substances.

The Victoria Government said that the current law required medical practitioners to seek approval to treat every single patient who might be enrolled in such a trial.

The Government said that consideration might be given to amending the legislation to remove the prohibition on cultivation of narcotic plants for therapeutic purposes in the context of approved clinical trials, to ensure that the quality of the product being trialled was of an appropriate and assured standard.

Mr Davis said the State Government "supports access to pharmaceuticals that are safe and effective, and we commit to removing barriers around safe and effective medications".

On August 24, the Opposition Labor Party said that if elected in the November 2014 State election it would legalize medical cannabis.

The Government media release said that the Australian Therapeutic Goods Administration had approved the pharmaceutical-grade, oral spray, cannabis extract Sativex for treatment of symptoms of multiple sclerosis.

The media release said that Sativex would be investigated through a clinical trial in Victoria and other states for treatment of pain in patients with advanced cancer.

"The issues surrounding the use of cannabis compounds for treatment of medical conditions are extremely complex, requiring regulatory and legislative changes, but most importantly, sound medical advice," Mr Davis said.

"The Coalition Government will work with other authorities to facilitate and support clinical trials of some of these cannabis compounds, while ensuring that they are undertaken in a safe and ethical manner," Mr Davis said.

"The Coalition Government will support a major Victorian health service importing Sativex and prescribing it as clinically indicated," Mr Davis said. "The health service could also conduct clinical trials for its use to treat other conditions."

"The Coalition Government will also put the issue on the agenda for the Council of Australian Governments Health Council in October to ensure, where possible, that co-operative approaches to clinical trials are adopted," Mr Davis said.

Mr Davis said the Coalition Government would also enable further investigation of the medicinal use of pharmaceutical-grade product containing the cannabidiol compound.

"I will ask the advisory committee to consider the scientific evidence and ethics with a view to further research and trials in Victoria," Mr Davis said.

"If the advice supports this outcome, the Coalition Government will request the Commonwealth to reclassify that particular cannabis compound to allow those trials to take place more easily," Mr Davis said.

Mr Davis said the State Government would give in-principle support, subject to proper design, to local involvement in an international trial of Epidiolex.

The Government said that Epidiolex, which would be marketed for the treatment of certain chronic childhood epilepsy conditions, was not approved for marketing in any country, but trials were expected next year.

AUSTRALIAN RESEARCH COUNCIL, FEDERAL GOVERNMENT

The Australian Research Council says the Monash University ARC Centre of Excellence in Convergent Bio-Nano Science and Technology was officially opened today.

The Council said that chief executive officer Prof Aidan Byrne opened the Centre, located on the Parkville campus of the Monash Institute of Pharmaceutical Studies and said it would be the focus of bio-nano research activity in Australia.

“Nano-medicines are on the cusp of revolutionizing diagnosis and therapy in many diseases,” Prof Byrne said.

“The ARC Centre of Excellence in Convergent Bio-Nano Science and Technology comprises a multi-disciplinary team focused on understanding and controlling the interface of materials with biological systems,” Prof Byrne said.

“The expected outcomes through research at this Centre are better diagnostic and therapeutic tools that are designed via an enhanced understanding of the bio-nano interface,” Prof Byrne said.

“Researchers will design materials that in the future will transport and deliver vaccines, drugs and gene therapy agents, and will develop new innovations in diagnostic and therapeutic technologies,” Prof Byrne said.

The Council said that Prof Thomas Davis had been appointed as the inaugural Centre director and the Centre would receive $26 million in funding over seven years.

The ARC said that with 15 collaborating and partner organizations, the Centre brought together chemistry and chemical engineering, drug development and pharmaceutical science, cell biology, cellular and biomedical imaging, diagnostics, systems biology, and social theory.

PHYLOGICA

Phylogica says that Japan has allowed a patent application entitled ‘Methods of constructing and screening libraries of peptide structures’.

Phylogica said the core patent protected the Phylomer peptide class to November 2027 and was also granted in the US and Australia.

The company said that the patent covered generic methods of designing synthetic Phylomer peptide libraries based on the identification of parts of natural proteins, which were predicted to form structures independently when isolated from the parent protein from which they were derived and also contained methods for maximizing the diversity of the structures represented in synthetic libraries.

Phylogica said that the technology allowed it “to rationally choose from the most suitable structures found in nature, providing the ability to customize the properties of the peptides to suit particular screening applications”.

The company said, as an example, libraries could be designed to capture the most diverse set of different peptide shapes available with the greatest stability in the smallest set of Phylomers possible, providing potential for applications such as phenotypic screening of arrayed library libraries to discover new disease associated drug targets.

Phylogica company said that it had received notice that two patents had been granted in the US covering particular Phylomers relevant to inflammatory diseases, entitled ‘CD40-L inhibitory peptides’ covering a set of Phylomer peptides against a target relevant for the treatment of inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease and ‘Compositions and uses thereof for the treatment of acute respiratory distress syndrome (ARDS) and clinical disorders associated with therewith’, relating to Phylomers that blocked lung inflammation in an animal model of ARDS.

Phylogica was up 0.2 cents or 15.4 percent to 1.5 cents with 1.8 million shares traded.

PHARMAXIS

Pharmaxis says its semicarbazide-sensitive amine oxidase and vascular adhesion protein-1 inhibitor PXS4728A is ready for a phase I studies by April 2015.

Pharmaxis said that the SSAO/VAP-1 enzyme contributed to various forms of chronic inflammation in humans and was a marker for disease severity in conditions such as atherosclerosis, liver and kidney inflammation.

The company said that with preclinical development on PXS4728A completed it would focus on the clinical development on inflammatory diseases with high unmet clinical need including chronic obstructive pulmonary disease and non-alcoholic steatohepatitis.

Pharmaxis chief executive officer Gary Phillips said that the "extensive pre-clinical program performed on PXS4728A has confirmed that it has all characteristics of a successful once a day, oral drug".

"It has shown excellent efficacy in several in-vivo inflammation models including liver diseases such as [non-alcoholic steatohepatitis] and the findings will soon be presented at a scientific conference," Mr Phillips said. "In regulatory toxicity studies, PXS4728A has been well tolerated and shown a very good safety profile."

Pharmaxis said that non-alcoholic steatohepatitis incidence was growing, possibly driven by increased rates of obesity and diabetes.

Pharmaxis said that about 13 million people in the US and Europe might have non-alcoholic steatohepatitis and advanced fibrosis with the market estimated to be worth more than $35 billion.

The company said that although there were no existing approved drugs to treat non-alcoholic steatohepatitis, the disease was attracting considerable research interest with Genfit, Intercept and Gilead all due to report on proof-of-concept studies in coming months.

Mr Phillips said that as well as the anti-inflammatory SSAO/VAP-1 inhibitor program Pharmaxis had a small molecule anti-fibrotic lysyl oxidase inhibitor (LOXL2) program in pre-clinical development.

"As lysyl oxidase is the key enzyme in the fibrotic cascade this program has the potential to emerge as a competitor in the fibrosis treatment market, including [non-alcoholic steatohepatitis]," Mr Phillips said.

Pharmaxis said that it was "actively seeking development partners" for its SSAO/VAP-1 program and that discussions with a number of companies interested in taking this drug into the clinic in early 2015 were progressing well.

Pharmaxis fell 0.2 cents or 3.45 percent to 5.6 cents.

PHARMAXIS

Pharmaxis said that revenue from the sale of goods for the year to June 30, 2014 was up 55.6 percent to $5,036,000, with net loss after tax up 19.0 percent to $51,818,000.

Pharmaxis said that total revenue including grants, interest and Federal Research and Development Tax Incentive fell 9.7 percent to $19,486,000.

The company said that total sales of Bronchitol were up 90 percent from $1,728,000 in the 12 months to June 30, 2013 to $3,275,000 in the year to June 30, 2014.

Pharmaxis said that its net tangible asset backing per share fell 72.2 percent from 18 cents at June 30, 2013 to five cents at June 30, 2014, with diluted loss per share up 19.1 percent to 16.8 cents.

Pharmaxis said that it had cash and cash equivalents of $34,182,000 at June 30, 2014 compared to $63,943,000 at June 30, 2013.

ADMEDUS

Admedus says that revenue for the year to June 30, 2014, was up 7.1 percent to $7,940,622 with net loss after tax up 239.4 percent to $8,207,715.
Admedus said that the sales and marketing division was building its infusion systems portfolio and had expanded for the Cardiocel bovine cardiac repair tissue.
The company said that the overall loss reflected the cost of clinical study for the herpes simplex virus 2 program, costs within the Admedus bio-manufacturing facility, regulatory costs and research and development expenditure for Cardiocel, as well as the commercialization costs to set up sales channels.
Admedus said that at June 30, 2013, it held 50.3 percent of Coridon, now renamed Admedus Vaccines, increasing to 66.3 percent in July 2014.
Admedus said that its net tangible asset backing per share was up 316.0 percent to 2.08 cents, with basic loss per share up 165.4 percent to 0.552 cents.
Admedus said that it had cash and cash equivalents of $19,582,972 at June 30, 2014 compared to $2,445,423 at June 30, 2013.
Admedus fell half a cent or 3.1 percent to 15.5 cents with three million shares traded.

RESONANCE HEALTH

Resonance says revenue for the year to June 30, 2014, was up 35 percent to $2,309,036 reducing net loss after tax by 65 percent to $72,415.
Resonance said that a 50 percent increase in sales revenue was supported by a 32 percent increase in the volume of work with more than 50 new Ferriscan radiology services established during the 12 months to June 30, 2014.
The company said that basic loss per share fell 80 percent from 0.1 cents at June 30, 2013 to 0.02 cents at June 30, 2014 and net tangible assets per share improved 109.1 percent from 0.22 cents at June 30, 2013 to 0.46 cents at June 30, 2014.
Resonance said it had $2,097,607 in cash at June 30, 2014, compared to $1,092,943 at June 30, 2013.
Resonance was up 0.3 cents or 6.7 percent to 4.8 cents with 2.9 million shares traded.

PHARMAUST

Pharmaust said that revenue for the year to June 30, 2014 was up 17 percent to $2,007,000, with net loss after tax up 156 percent to $1,317,000.
Pharmaust said that the year to June 30, 2014 saw record revenues for its Epichem wholly-owned subsidiary up 12 percent to $1.89 million, from its manufacture and ssale of synthetic and medicinal chemistry.
The company said that its net tangible asset backing per share was up 260 percent from five cents at June 30, 2013 to 18 cents at June 30, 2014, with diluted loss per share up 11.1 percent to 0.1 cents.
Pharmaust said that it had cash and cash equivalents of $2,304,323 at June 30, 2014 compared to $362,874 at June 30, 2013.
Pharmaust was up 0.1 cents or 10 percent to 1.1 cents.

CRYOSITE

Cryosite says revenue for the 12 months to June 30, 2014 was up 7.5 percent to $9,421,000 with net profit after tax down 60.0 percent to $506,000.
Cryosite said that the reduction in profit was due to investing in sales and marketing, research and development to improve competitiveness in its existing cord blood storage and cryo-preservation operations and to develop additional revenue streams in new markets.
Cryosite said that an unfranked 1.0 cent dividend per share for shareholders on the record date of September 10, 2014 would be paid on September 24, 2014.
The company said that diluted earnings per share fell 59.6 percent to 1.07 cents at June 30, 2014, compared to the previous year's 2.64 cents and net tangible asset backing per share was down 6.7 percent from 13.4 cents to 12.5 cents.
Cryosite said that cash and cash equivalents at June 30, 2014 was $6,252,193 compared to the previous year's $5,777,097.
Cryosite was untraded at 40.5 cents.

BLUECHIIP

Bluechiip has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 190.5 percent from 7.4 cents on August 26 to 21.5 cents on August 27, 2014 and noted an increase in trading volume.
Bluechiip fell two cents or 12.5 percent to 14 cents with 23.6 million shares traded.

UNILIFE CORP

Unilife has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 40.0 percent from 42.5 cents on August 26 to 51 cents on August 27, 2014 and noted an increase in trading volume.
Unilife fell six cents or 11.9 percent to 44.5 cents with 1.3 million shares traded.

LBT INNOVATIONS

LBT says that Daniel Hill has been appointed as its chief financial officer, effective from August 25, 2014.
LBT said that Mr Hill had financial, accounting and business development experience and had worked as a director, chief financial officer or company secretary for a variety of companies in the construction, technology and financial services sectors.
The company said that Mr Hill was the chief financial officer of the $20 million venture capital fund Terra Rossa Capital and was the investment manager at the $34 million Paragon Private Equity Fund and was a director of AEM Cores and Cavitus Pty Ltd.
The company said that Mr Hill held a Master of Business Administration from the University of Adelaide and a Bachelor of Accountancy from the University of South Australia.
LBT said that Mr Hill would initially work part-time with company secretary Jamie Dreckow.
LBT was untraded at 12.5 cents.

RHINOMED

Rhinomed has requested a trading halt “pending an announcement in relation to a proposed capital raising”.

Trading will resume on September 1, 2014 or on an earlier announcement.

Rhinomed last traded at 4.2 cents.