Biotech Daily

Wednesday November 26, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: PHOSPHAGENICS UP 25%, PHARMAXIS DOWN 10%**

*** ANADIS BOVINE COLOSTRUM INFLUENZA THERAPY DATA**

*** ARANA STARTS PHASE II RHEUMATOID ARTHRITIS DOSING TRIAL**

*** UNILIFE APPOINTS THREE SENIOR EXECUTIVES**

*** VENTRACOR EXTENDS SHARE PLAN DATE**

*** NEURODISCOVERY DISSENT ON FOUNDER DIRECTOR DAVID MCAULIFFE**

*** SOLAGRAN SIGNS MID-EAST, ASIA DEALS**

*** STEM CELL EXTENDS TRADING HALT TO SUSPENSION**

*** UNIVERSAL BIOSENSORS RELEASES 27m ESCROW SHARES**

MARKET REPORT

The Australian stock market retreated 2.7 percent on Wednesday November 26, 2008 with the All Ordinaries down 95.8 points to 3,479.6 points.

Five of the Biotech Daily Top 40 stocks were up, 15 fell, nine traded unchanged and 11 were untraded.

Phosphagenics was best, up 1.5 cents or 25 percent to 7.5 cents with 10,000 shares traded, followed by Antisense up 0.4 cents or 13.33 percent to 3.4 cents. Peplin climbed 7.14 percent; Prana and Universal Biosensors rose more than three percent; with Cochlear up 0.38 percent.

Pharmaxis led the falls, down 12 cents or 9.84 percent to $1.10 with 145,120 shares traded, followed by Neuren down 9.09 percent, with Clinuvel and Labtech both down 8.33 percent to 22 cents and 11 cents, respectively.

Chemgenex lost 7.22 percent; Heartware, Mesoblast and Polartechnics were down more than five percent; Avexa and Optiscan fell more than four percent; Resmed was down 3.58 percent; Acrux, Bionomics and Novogen shed two percent or more; with Cellestis, CSL and Progen down by less than one percent.

ANADIS

Anadis says mice treated with a compound derived from colostrum from vaccinated cows markedly reduced levels of influenza virus in their respiratory tracts.

Anadis said a team from the University of Melbourne's Department of Microbiology & Immunology, led by Prof Lorena Brown, would present the trial data at the Australasian Society of Immunology conference in Canberra, December 7-11, 2008.

Previously, Anadis reported the study was designed to test influenza prevention and treatment and demonstrated the ability of the antibody spray to "switch-off" virus replication in the respiratory tract lining (see Biotech Daily; August 20, 2008).

The study entitled 'Anti-Influenza IgG And F(ab')2 Produced From Hyper-Immune Bovine Colostrum For The Prophylaxis And Treatment Of Influenza Infection' investigated immunoglobulin G antibody (IgG) and antibody fragment F(ab')2 purified from the hyper-immune colostrum of cows vaccinated with influenza A/Puerto Rico/8/34 (PR8) vaccine and was shown to have "very high haemagglutination-inhibitory and virus-neutralizing titres", Anadis said.

The company said the IgG preparation was tested for its therapeutic potential in BALB/c mouse models of upper and total respiratory tract infection by influenza.

A single 50µg dose of anti-PR8 IgG administered to the nose one day after the establishment of an upper respiratory tract infection "markedly reduced the levels of virus in the nasal turbinates" Anadis said.

At the peak of viral replication (day three, post-infection), anti-PR8 IgG-treated mice had 100-fold lower viral titres compared to an untreated group.

With a larger dose of 200µg, complete clearance of virus from the nose could be seen in 30 percent of treated animals.

Anti-PR8 IgG was also effective in reducing viral loads in the lungs when given one day after a total respiratory tract infection, Anadis said.

Anadis said complete pulmonary protection was observed in 60 percent of mice given a single dose of 500µg IgG and doubling the dose gave complete clearance in all animals.

The study said that in an experiment involving challenge with a lethal dose of PR8 virus, mice treated with non-immune colostrum-derived IgG or F(ab')2 were culled by day seven after showing rapid weight loss and severe clinical signs.

Mice given a single dose of anti-PR8 IgG or F(ab')2 showed no weight loss and the virus infection remained subclinical.

Anadis said the observations suggested "that a novel and commercially-scalable technique for preparing antibody from hyper-immune bovine colostrum is capable of providing preparations with significant protective activity post-exposure".

Anadis said that the study concluded that, as the current influenza vaccine was not administered to the entire population and was less than 100 percent efficacious in the vaccinated target groups; therapeutic antibodies topically applied to the mucosal surface could provide a significant additional tool to control influenza within the community.

Anadis's head of business development Dr Oren Fuerst said the results highlighted the commercial potential of the company's 'Flubody' intellectual property.

"For the first time, there are commercially available antibodies against flu that could be manufactured in large scale and at low cost," Dr Fuerst said.

"The current global market for prevention and treatment of flu and cold is around $US10 billion and together with commercial partners, we plan to become a significant player in this market," Dr Fuerst said.

"Given the excellent safety profile of the colostrum-based platform, we plan to initiate efficacy clinical trials within less than a year," Dr Fuerst said.

Anadis was unchanged at 5.1 cents.

ARANA THERAPEUTICS

Arana says it has submitted regulatory and ethics approvals to the Sri Lankan Drug Regulatory Authority for a pilot study of ART621 in rheumatoid arthritis.

Arana said the trial, designated ART621/223, would compare four different dose regimens of ART621 “to quickly obtain initial safety and efficacy data in this patient population”.

Arana vice-president clinical research Dr Alan Scott told Biotech Daily that the trial would investigate a range of doses as a well as the frequency of dosing.

Interim data from this study will be used to optimize the dosing regimen for the international multi-centre phase II dose ranging rheumatoid arthritis study, designated ART621/221.

Arana said the factorial-design, randomized, double-blind, placebo-controlled, ART621/223 study would investigate the safety, efficacy, immunogenicity and pharmacokinetics of different dose regimens of ART621 following multiple dose administration in subjects diagnosed with rheumatoid arthritis (RA) concomitantly taking methotrexate.

The company said the primary endpoint was safety with secondary endpoints including efficacy measures.

Arana said the study would be conducted at a single centre in Sri Lanka and would aim to enroll 20 patients.

Arana’s acting chief executive officer Dr Steffen Nock said the Sri Lankan study “offers the unique ability to rapidly obtain clinical data for the RA indication and also gives us the ability to potentially fine-tune the larger RA study while maintaining our momentum”.

“The two RA studies combine to give us a cost effective and risk managed approach to identifying the optimal dose regimen for ART621 in RA,” Dr Nock said.

Arana was unchanged at 79.5 cents.

UNILIFE MEDICAL SOLUTIONS

Unilife has made three key executive appointments.

Bernhard Optiz has been appointed senior vice-president of operations.

Mr Optiz holds a Masters of Science in mechanical and process engineering and speaks English, German, Italian and French.

Unilife said Mr Optiz had a 28 year career, has a background in the use of high speed robotic equipment and will co-ordinate the production and commercial supply of the Unilife Prefilled Syringe and other key company products.

Mark Iampietro has been appointed to the position of vice-president of quality and regulatory affairs.

The company said that with more than 30 years of quality experience across global pharmaceutical, biologics, and medical device markets.

Dr Graham Purches has been appointed to the position of operations director to coordinate the industrialization of the Unilife Prefilled Syringe.

Dr Purches worked for Resmed for eight years, where he was quality engineer, project manager and supplier alliance manager. He has a PhD in organometallic chemistry.

Unilife chief executive officer Alan Shortall said the appointments reflected the company’s “strong commercial position and the excitement which the industrialization program for the Unilife Prefilled Syringe is generating worldwide”.

Mr Optiz, Mr Iampierto and Dr Purches will join other senior executive personnel, including Mr Shortall, who are relocating to Unilife’s manufacturing facility in Pennsylvania.

Unilife climbed 1.5 cents or 6.52 percent to 24.5 cents.

VENTRACOR

Ventracor has extended of its share purchase plan closing date to December 9, 2008.
The company said the plan was scheduled to close on December 2, 2008.
Ventracor chairman John Ward said the company wanted to give shareholders "adequate time to consider the [share plan] following an inadvertent delay in mailing full information".
He said the additional time also allowed shareholders to have their questions addressed at the annual general meeting on November 28, 2008.
Ventracor also said a new hospital had undertaken its first implant in the US bridge-to-transplant clinical trial, bringing the number of hospitals in the US that have implanted at least one Ventrassist left ventricular assist device to 23 and the number of hospitals ready to implant to 27.
The company said that there were 53 hospitals trained and ready to implant, of which 40 had undertaken an implant of at least one Ventrassist cardiac pump.
Ventracor was unchanged at eight cents.

NEURODISCOVERY

Neurodiscovery founder and director David McAuliffe faced opposition in his reelection to the board at the company's annual general meeting.
A total of 5,752,490 proxy votes opposed Mr McAuliffe's re-election, with 10,400,586 proxy votes in favor. The election of director Dr Chris Moyses and the adoption of the remuneration report were carried overwhelmingly.
Neurodiscovery was untraded at five cents.

SOLAGRAN

Solagran says it signed distribution agreements for its Bioeffectives in the Middle East and Asia.
The company said one agreement was with Dubai-based Pulsemed for Bioeffective A 320 and covers the United Arab Emirates and five other countries.
Solagran said the agreement was finalized by director Charles Pellegrino.
The company said the Middle Eastern launch would be in the United Arab Emirates following completion of regulatory formalities, expected to take six to nine months.
Solagran said that once approved, an initial order valued at $US75,000 would be placed.
The agreement requires that orders must meet or exceed $US250,000 in the first 12 months after launch of the product.
The second agreement is with Pathfinder, a member of the Singapore-based Mercatus Group and includes Bioeffective A 320 and the Bioeffective B sauna therapy range together with planned topical and systemic line extensions.
The agreement covers six countries and sets out minimum orders of $100,000 per country in the first year for Bioeffective A 320 only.
Solagran fell two cents or 10 percent to 18 cents.

STEM CELL SCIENCES

Stem Cell Sciences has requested a suspension to follow on from the trading halt requested on November 25, 2008 relating to on "a review of the company's financial position and strategic options".
Stem Cell last traded at 15 cents

UNIVERSAL BIOSENSORS

Universal Biosensors says 27,189,052 shares held in mandatory escrow from its 2006 initial public offering will be released on December 13, 2008.

A further 960,560 unlisted options will also be released at the same time.

With the release of the escrowed shares the company's total share issue will be 156,976,937 shares.

Universal Biosensors closed up two cents or 3.51 percent to 59 cents.