Biotech Daily

Monday November 23, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PROGEN UP 11%; PHYLOGICA DOWN 8%**

*** TISSUE THERAPIES' FREMANTLE TRIAL REDUCES VENOUS ULCERS 75%**

*** FLUOROTECHNICS APPOINTS PROTEA FOR NORTH AMERICA SALES**

*** FDA COMMITTEE BACKS PHARMAXIS' ARIDOL APPLICATION**

*** MATER HOSPITAL APPROVES HEALTHLINX OVPLEX STUDY**

*** NYCOMED TO DISTRIBUTE IMMURON'S TRAVELAN**

*** PSIVIDA OPPOSED BY 19% ON AUTOMATIC STOCK INCREASES**

*** METABOLIC'S DAVID KENLEY OPPOSED BY 24%; CALZADA APPROVED**

*** PROBIOMICS REQUESTS DISTRIBUTION TRADING HALT**

*** VIRALYTICS APPOINTS PROF HARDEV PANDHA TO SCIENTIFIC BOARD**

*** ACUVAX APPOINTS DR ALEX BIRRELL DIRECTOR**

*** PRIMA APPOINTS DR NEIL FRAZER CHIEF MEDICAL OFFICER**

MARKET REPORT

The Australian stock market climbed 0.7 percent on Monday November 23, 2009 with the S&P ASX 200 up 31.2 points to 4,717.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, three traded unchanged and four were untraded.

Progen was best, climbing 5.5 cents or 11.0 percent to 55.5 cents with 3,000 shares, followed by Psivida up 7.5 percent to $4.30 with 6,272 shares traded. Compumedics and Viralytics climbed five percent or more; Chemgenex and Sirtex were up more than four percent; Novogen and Tissue Therapies were up more than three percent; Avexa, Benitec, Cytopia, Prana and Starpharma rose more than two percent; with Acrux, Biota, Circadian and Clinuvel up more than one percent.

Phylogica fell one cent or 8.3 percent to 11 cents with 142,217 shares traded, followed by Alchemia down 7.4 percent to 68.5 cents and LBT (formerly Labtech) down 7.1 percent to 13 cents. Sunshine Heart and Tyrian fell five percent or more; Cellestis fell 4.1 percent; Impedimed, Nanosonics and Phosphagenics shed more than two percent; with Antisense, Bionomics, Living Cell and Resmed down more than one percent.

TISSUE THERAPIES

Tissue Therapies' 11-patient Fremantle venous ulcer Vitrogro wound treatment trial has reduced the median area of damaged tissue by an average of 75.5 percent.

Tissue Therapies said the "excellent results are even better than the interim results for the first eight venous ulcer patients" announced in January (BD: Jan 19, 2009).

The company said the final report on the 11 patients treated with Vitrogro twice per week for two weeks showed that the median area of venous ulcers treated was reduced from 9.85 to 2.41 square centimetres in 24 days (75.5%).

Tissue Therapies said the ulcer healing "was highly statistically significant" ($p < 0.005$) and Vitrogro was safe and well tolerated.

The company said the results were "particularly impressive given that these patients had been receiving state of the art compression therapy for up to nine years before joining the Vitrogro study.

The patients were five females and six males who had ulcers up to 19.8 square centimetres at the time of starting Vitrogro treatment.

Tissue Therapies chief executive officer Dr Steven Mercer said he was "delighted to be repeating myself and saying that we once again have an excellent set of results demonstrating the predictable and powerful ability of Vitrogro to heal difficult to treat chronic skin ulcers".

Last week Tissue Therapies released "outstanding" results from its 10-patient Toronto trial (BD: Nov 18, 2009).

The company said the combined results of the Canadian and Australian trials gave it "a strong position to pursue negotiations with a short-list of international commercialization partners" which were expected to be concluded by the end of September 2010.

Dr Mercer told Biotech Daily that his company was preparing for a safety and efficacy trial of 40 patients, primarily aimed at European regulatory approval.

Dr Mercer said the trial was expected to involve two centres and be competed by the end of 2010 with results early in 2011.

Tissue Therapies was up half a cent or 3.03 percent to 17 cents.

FLUOROTECHNICS

Fluorotechnics has appointed Protea Biosciences as a non-exclusive sales, marketing and distribution partner for the North American market.

Fluorotechnics said its wholly-owned subsidiary the Gelcompany had agreed that Protea would be able to promote and distribute the high performance electrophoresis systems including horizontal electrophoresis towers and pre-cast gels, fluorescence-based consumables and other electrophoresis products.

Fluorotechnics chief executive officer James Walker said the West Virginia-based Protea was "a leading developer of new tools that address the critical needs of researchers for better and more reproducible protein data".

Mr Walker said Protea had an established sales team across America and he was "confident that our products will capture a larger share of this market through this partnership".

Protea's director of sales and marketing Dr Reid Asbury said his company would be able to better serve its proteomics customers by offering a full range of gel formats and sizes, stains and accessories.

"We will be capable of addressing the entire market from sample preparation to mass spectrometry," Dr Asbury said.

Fluorotechnics was unchanged at 33 cents.

PHARMAXIS

Pharmaxis says a US Food and Drug Administration advisory committee has recommended the approval of Aridol as a test for asthma.

Pharmaxis said the FDA's Pulmonary-Allergy Drugs Advisory Committee voted by an overwhelming majority in support of Aridol or the mannitol bronchial challenge test for use as a bronchial test to assess bronchial hyper-responsiveness to aid in diagnosing patients who have symptoms of asthma or symptoms that are suggestive of asthma.

Pharmaxis' chief executive officer Dr Alan Robertson said the company was "pleased that the committee has recognized the effectiveness and safety profile of Aridol".

The company said the decision was made following a meeting on November 20, 2009 (Washington time).

Dr Robertson said the discussion was "an important step in expanding the role of pulmonary function tests for patients suspected of having asthma and we look forward to working with the FDA to further address the points raised by the panel".

Pharmaxis said the committee voted on the question: "Do the data provide substantial and convincing evidence to support the use of the mannitol bronchial challenge test to assess bronchial hyper-responsiveness to aid in diagnosing patients who have symptoms of asthma or symptoms that are suggestive of asthma?"

For patients 18 years of age and older, the vote was 12 for, three against and one abstention; for patients aged 12 to 17 years, the vote was 14 in favor and two against; and for patients aged six to 11 years, the vote was 11 in favor and five against.

Pharmaxis said Aridol was approved in major European countries, Korea and Australia.

The company said Aridol was "an indirect lung function challenge test that relies on the presence of active airway inflammation to register a response".

Pharmaxis said that the committee reviewed efficacy and safety data from two phase III trials that were conducted in more than 1000 people.

The company said the FDA "often seeks the advice of its advisory committees when evaluating potential new products but is not required to follow its recommendation".

If approved, the FDA would determine final prescribing information.

Pharmaxis said it filed an NDA for Aridol in March 2009 and the FDA was scheduled to advise the result of its review by December 27, 2009.

Pharmaxis was up one cent or 0.4 percent to $2.36.

HEALTHLINX

Healthlinx says Queensland's Mater Hospital has approved participation in the Healthlinx clinical study of its ovarian cancer diagnostic Ovplex.

Healthlinx said the study had been designed to establish the diagnostic efficiency of Ovplex in symptomatic women and compare its performance to CA125 as a diagnostic.

Healthlinx said the clinical work at the Mater Hospital would involve 200 blood samples and would be led by gynaecological oncologist Prof Lewis Perrin and pathologists Prof Jane Armes and Prof Deon Venter.

Healthlinx managing director Nick Gatsios said ethics submissions were being approved "on a timely basis and are well within our project timelines".

Healthlinx said the trial would use a number of sites in Australia, Asia and the UK with up to 1150 patient samples and determine sensitivity and specificity for Ovplex when compared to CA125 alone and screen the samples using the company's original five biomarker panel as well as two novel biomarkers HTX005 and HTX010.

The trial is expected to begin early next year with first results due by the end of May 2010.

Healthlinx was up 0.4 cents or 4.7 percent to 8.9 cents.

IMMURON

Immuron has a “heads of agreement” with Nycomed Australia to distribute its over-the-counter diarrhoea product Travelan in Australia and New Zealand.
Immuron said Nycomed would consider introducing Travelan to other countries in which it operates and that arrangement would be subject to separate agreements.
Immuron said the Swiss-based Nycomed was the world’s 15th largest over-the-counter product company.
Immuron fell 0.4 cents or 5.1 percent to 7.5 cents with 1.1 million shares traded.

PSIVIDA

More than 19.2 percent of Psivida shareholder votes opposed a plan to ‘evergreen’ the company’s incentive plan, along with similar opposition to directors’ options.
While a resolution to increase the number of shares in the 2008 incentive plan was passed by 5,990,069 votes to 629,152 votes, a proposal that “provides for automatic annual increases in the number of shares authorized for issuance” was more narrowly won with 5,163,855 votes (80.8%) in favor and 1,227,850 cotes (19.2%) against.
By comparison, directors David Mazzo, Dr Paul Ashton, Paul Hopper, Michael Rogers and Peter Savas were all elected with more than 10 million votes in favor and none against.
The approval of options for non-executive directors was opposed by about one million votes with more than 5.5 million votes in support.
A resolution to provide shares to chief executive officer Dr Ashton was passed by 6.3 million votes in favor and 343,565 votes against, but a resolution to provide options to Dr Ashton saw opposition from 952,158 votes and support from 5.6 million votes.
Psivida was up 30 cents or 7.5 percent to $4.30.

METABOLIC PHARMACEUTICALS

A significant minority of Metabolic shareholders have opposed the election of David Kenley as a director.
A total of 84,496,981 proxy votes (75.9%) supported Mr Kenley, but 26,850,304 votes (24.1%) opposed him. The company’s name change to Calzada Ltd was supported by more than 95 percent of votes and other resolutions were passed by wider margins.
Metabolic was up 0.2 cents or 6.7 percent to 3.2 cents.

PROBIOMICS

Probiomics has requested a trading halt pending an announcement regarding a “global distribution agreement with a major European company”.
Trading will resume on November 25, 2009 or on an earlier announcement.
Probiomics last traded at 1.6 cents.

VIRALYTICS

Viralytics has appointed British oncologist Prof Hardev Pandha to its clinical and scientific advisory board.
Viralytics said Prof Pandha was the head of oncology at the University of Surrey and was an internationally recognized researcher and opinion-leader in the field of viro-therapy, who had published extensively on preclinical and clinical activity of oncolytic viruses.
Viralytics climbed 0.2 cents or five percent to 4.2 cents with 4.8 million shares traded.

ACUVAX

Acuvax has appointed Dr Alex Birrell as a non-executive director.
Acuvax said that Dr Birrell brought 15 years' experience in senior technology and financial services sector roles to the position.
Acuvax chairman Patrick Elliott said Dr Birrell's biotechnology experience would assist in accelerating the vaccine development programs, using recombinant protein technology.
The company said Dr Birrell began her career as a veterinarian and completed a PhD in diabetes at Sydney University.
Acuvax said Dr Birrell managed a research unit focusing on renal medicine, cardiovascular disease and hypertension at Sydney's Royal Prince Alfred Hospital.
Dr Birrell was operations vice-president at Hunter Immunology.
Acuvax said Dr Birrell's experience included submitting a new drug application to the US Food and Drug Administration, strategy, capital raising, branding, shareholder communication and business development.
Acuvax fell 0.1 cents or 5.3 percent to 1.8 cents.

PRIMA BIOMED

Prima has appointed Dr Neil Frazer as chief medical officer to oversee its clinical trials of its CVac ovarian cancer vaccine treatment.
Prima said Dr Frazer would be based in the United States, where he would oversee the CVac phase IIb pivotal clinical trial as well as the phase III Europe trial die to begin next year.
Prima said Dr Frazer had "more than 23 years experience in the pharmaceutical industry" and had expertise in managing the clinical development process of new drug applications.
The company said Dr Frazer had been involved in successful applications for 10 new chemical entities in multiple therapeutic areas and more than 20 applications for line extensions of pharmaceutical drug applications.
Prima said he has a high level of expertise in the US Food and Drug Administration's investigational new drug planning, submission and reviewing process.
The company said Dr Frazer would direct clinical development of its cancer vaccine drug candidates and help facilitate their approval with relevant international government agencies.
Dr Frazer has a Bachelor of Medicine and Bachelor of Surgery from the University of Edinburgh and is a Fellow of the Royal College of Anaesthetists and a Fellow of Pharmaceutical Medicine of the Royal College of Physicians.
Prima was up half a cent or 3.2 percent to 16 cents with 1.8 million shares traded.