Biotech Daily

Tuesday November 11, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: BIONOMICS UP 12%, PRANA DOWN 11%**

*** CANADA APPROVES TISSUE THERAPIES TRIAL, WA PATIENTS IMPROVE**

*** AUSBIOTECH: 'LITTLE EVIDENCE OF GOVERNMENT SUPPORT'**

*** PROGEN COUP GROUP CITES DEMANDS; TRADING HALT**

*** CHINA DELAYS, SLOW DOWN FORCE HELICON RESTRUCTURE**

*** MESOBLAST'S 13th HEART PATIENT TREATED LIVE BY SATELLITE**

MARKET REPORT

The Australian stock market fell 3.4 percent on Tuesday November 11, 2008 with the All Ordinaries down 138.2 points to 3,921.8 points.

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

Bionomics was best, up three cents or 12.0 percent to 28 cents with 4,500 shares traded, followed by Starpharma up one cent or 3.85 percent to 27 cents, Benitec and Ventracor up more than two percent, Phosphagenics up 1.18 percent, with Resmed and Sirtex up by less than one percent.

Prana led the falls, down 4.5 cents or 10.98 percent to 36.5 cents with 110,000 shares traded, followed by Antisense down 8.16 percent to 45 cents.

Acrux, Living Cell, Mesoblast and Optiscan lost more than seven percent; Avexa fell 6.67 percent; Alchemia fell five percent; CSL and Novogen were down more than three percent; Cochlear, Impedimed and Pharmaxis shed more than two percent; with Arana and Peplin down more than one percent.

TISSUE THERAPIES

Tissue Therapies has received approval from Health Canada for a trial of its Vitrogro wound care product for the treatment of diabetic, venous and pressure ulcers.

At the same time the company says that non-healing venous ulcers in the third and fourth patients of eight in its Western Australia trial had shown significant improvement.

The Canadian approval was expected in December 2007 but was delayed several times.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that the final approval mechanism began late last week, with all participants including ethics committees and the clinical trials team signing-off over the weekend and yesterday.

Dr Mercer said the 30 patient trial would begin in Toronto on Monday November 17, 2008.

In separate announcements, Tissue Therapies said the third patient in its Australian trial had a 46 percent reduction in wound area after 24 days of treatment, with Vitrogro applied twice weekly for the first two weeks of the trial.

As with the first two patients, the third patient had a noticeable improvement in tissue health at the edge of the ulcer, the company said.

The third patient was a 78-year-old female who had the venous ulcer for two years and had undergone unsuccessful compression therapy for more than one year.

Prior to the study the patient had varicose veins surgically removed from the leg with the treated ulcer. This may have assisted in the reduction in wound area.

The fourth patient was a 68-year-old female who had suffered from her venous ulcer for six months and had undergone unsuccessful compression therapy for seven weeks prior to taking part in the clinical trial of Vitrogro.

Tissue Therapies said there was a rapid reduction in wound area during Vitrogro treatment but “some increase in ulcer size after the Vitrogro therapy was stopped”.

This may have been due to excessive wound fluid water-logging the skin adjacent to the ulcer, Tissue Therapies said.

This patient had an unusually slow heart rate for a short period during the week after Vitrogro treatment had stopped.

There were no adverse medical consequences from this and there is no identifiable link between the treatment and the episode of slow heart rate, the company said.

Dr Mercer said results from the trial at the Vascular Research Laboratory in Fremantle had been “exceptional”.

“Trial results of Vitrogro on patients suffering from debilitating venous ulcers have so far been very positive, demonstrating its rapid wound healing properties and as yet there have been no indication of adverse reactions from its application,” Dr Mercer said.

“The expected positive results from the human trials in Australia and Canada, combined with our product classification, are likely to lead to the commercialization of Vitrogro within two years for widespread use on chronic ulcers - a market estimated to be worth $US4 billion annually worldwide,” Dr Mercer said.

Tissue Therapies chief scientific officer Prof Zee Upton said receiving human trial data that reflected the success achieved in the laboratory was encouraging.

“It is a wonderful feeling to see the practical application of so much scientific effort pay off with patients being treated with Vitrogro,” Prof Upton said.

“This is the stuff biological scientists dream of, particularly when we are working towards the ability to accelerate chronic wound healing and relieve a huge number of people of the pain, disability, social isolation and often literally threats to life and limbs these chronic wounds cause,” Prof Upton said.

Results are expected to be released during the Canadian trial, starting in late 2008, with final results available during the first half of 2009.

Tissue Therapies was unchanged at 10 cents.

AUSBIOTECH

Ausbiotech's chief executive officer Dr Anna Lavelle has accused the Federal Government of failing to support biotechnology despite a proclaimed focus on innovation.

In an opinion piece for Australian R&D Review (http://www.ardr.com.au) Dr Lavelle said the Rudd Government had "a choice about supporting the future or the past".

"Australia's vibrant and innovative biotechnology industry represents the future but is in real danger of falling behind due to the absence of substantial support for early stage innovation," Dr Lavelle said.

"A serious Government investment in research and development in the pharmaceutical sector must include support for biotechnology to maintain the advances we have made over recent decades.

She said the development of Australian biotechnology needed to be nurtured.

"Regretfully, to date we see little evidence of such support for the biotechnology industry from the Rudd Government," Dr Lavelle said.

She said the decision to end the commercial ready grant scheme, which provided dollar-for-dollar funding with private enterprise to help small companies "increased overnight the hurdles for hundreds of small and highly innovative Australian companies working at the cutting edge of science and knowledge".

"As a consequence, since commercial ready was axed the number of clinical trials has been in decline and biotechnology companies developing important new drug compounds are struggling in the face of the global credit crunch," Dr Lavelle said.

She said the Cutler Review of the National Innovation System and the Pharmaceuticals Industry Strategy Group both recognized this and called for a fund to support biopharmaceuticals and medical device companies undertaking clinical trials.

She said the Pharmaceuticals Industry Strategy Group draft direction paper was "a good summary of the challenges the pharmaceuticals industries are currently facing, but its recommendations do not go far enough".

"While acknowledging the need for a whole of sector approach, the paper lacks any sense of urgency towards biotechnology, which plays such a vital role for the future of every pharmaceutical company," Dr Lavelle said.

She said grants of $3 million to $5 million, with private investment, were urgently needed to optimize the creation of long-term economic value for our biotechnology and pharmaceutical industries and private funding must be rewarded with long-term co-funding from Government.

She said the Cutler Review's proposed competitive grants program to help 200 firms with $150 million a year with the grant repaid on commercialization "falls short of what is required and we do not support the imposition of repayment requirements".

Dr Lavelle said an average grant of $750,000 would help proof-of-concept stage companies but would provide "little or no support for companies as they mature".

"The program is underfunded and needs to be at least $250 million a year," she said.

She said Ausbiotech supported the Cutler Review recommendation of moving to a system of refundable tax credits "now, not as a recovery strategy when the sector is in decline".

"Australia's biotechnology sector needs refundable tax credits now. Not when there are few companies left to use it," Dr Lavelle said.

She said tax offsets should be replaced with a refundable tax credit system.

Dr Lavelle said a streamlined targeted grant system needed to be implemented immediately and targeted to companies undertaking clinical trials of drug and medical device candidates.

PROGEN

Progen has requested a trading halt pending an announcement “of the key recommendations from the … Beerworth and Partners strategic review”.
Late today, Biotech Daily was given the main demands of the shareholders group requisitioning a meeting to replace Progen’s board of directors.
Yesterday a group of shareholders narrowly failed to requisition a meeting to replace the Progen board (see Biotech Daily; November 10, 2008).
One of the proposed replacement directors, Bob Moses, told Biotech Daily that the group had a proposal for the realization of value from Progen’s remaining assets and what it intended to do with the company’s $66 million cash position. He would not elaborate.
Sources close to the shareholders group that attempted the meeting requisition, and continues in those efforts, told Biotech Daily today that they wanted “a complete restructure” of the company including a new business plan, a new image and ”a complete rebirthing of the company”.
The sources said the long-standing shareholders “have the view the board needs a shake up” and won’t change without a change of personnel.
Among the proposals is a return of capital to shareholders.
The other proposals relate to “releasing value” from the Progen pipeline, beginning with PI-88, which was in a phase III liver cancer trial when the project was terminated.
The sources said they had “in principle agreement for a collaboration and licencing agreement in the form of a term sheet”.
The shareholders group was described by the sources as wanting to release value from Progen’s earlier stage pipeline of molecules for cancer and inflammatory illnesses as well as “releasing value” from other Progen projects.
The sources said they wanted to provide “third party access and rights to Progen or the subsequent entity of polysaccharides that are close relatives of PI-88 that are more potent and less toxic ... to enhance the carbohydrate platform”.
Progen’s review was announced on July 23, 2008 when the company discontinued its phase III liver cancer trial with Beerworth and Partners named as conducting the review on August 22, 2008.
Trading will resume on November 13, 2008 or on an earlier announcement.
Progen last traded at 60.5 cents.

HELICON

Helicon says “ongoing delays” by China’s State Food and Drug Administration and an expected slow down in economic activity have forced a restructure.
The company said the restructuring and cost reduction programs should result in a reduction of operational costs by 40 to 50 percent from December 2008.
The cost management program that will follow will ensure the company has two years of funding, Helicon said.
“The company remains confident that its business model is viable and continues to actively pursue its strategy to gain regulatory approval for its existing range whilst also negotiating with various groups to add to its portfolio,” Helicon said.
Helicon is attempting to take advanced biopharmaceutical products that are not available in North Asian Markets or where there are market needs that are not being adequately addressed. The company said it would investigate other opportunities and directions.
Helicon chief executive officer Peter Abrahamson said the company recognized the short term hurdles and was “taking the longer term view in this restructure”.
Helicon climbed 0.6 cents or 42.86 percent to two cents, with 40,000 shares traded.

MESOBLAST

Mesoblast says the 13th patient in Angioblast's phase II clinical trial for congestive heart failure has been implanted with adult stem cells.

Mesoblast said the operation was performed by cardiologists from the Texas Heart Institute and broadcast during a satellite symposium entitled 'Future Direction of Stem Cells in Cardiovascular Disease' at the American Heart Association's annual conference, in New Orleans.

Mesoblast said its US sister company's multi-centre trial was testing the safety and effectiveness of Revascor a proprietary allogeneic or off-the-shelf stem cell product being developed for patients with congestive heart failure.

Mesoblast said Revascor was delivered to damaged areas of the heart by "a minimally invasive cardiac catheterization procedure performed under local anaesthesia while the patient is awake".

Patients undergoing the procedure are released from the hospital within 24 hours.

The company said the placebo-controlled trial would randomize up to 60 patients suffering from congestive heart failure at sites in the US.

The first cohort of patients in the trial is expected to be completed by the end of December.

Mesoblast said about six million Americans had congestive heart failure, a progressive form of cardiovascular disease that inhibited the heart from pumping blood throughout the body, with 550,000 new cases diagnosed each year.

The company said the "extensive morbidity and mortality" associated with the disease made it a principal health and economic burden in the Western world.

Existing therapies do not result in repair or regeneration of heart muscle.

Mesoblast fell 8.5 cents or 7.83 percent to $1.00.