Biotech Daily

Thursday September 10, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHYLOGICA UP 18%; GENETIC TECHNO DOWN 10%**

*** PHOSPHAGENICS' DICLOFENAC REACHES THE PARTS VOLTAREN CAN'T**

*** MESOBLAST STEM CELLS REPAIR DEGENERATED DISCS IN SHEEP**

*** BIONOMICS MEETING TO APPROVE $15m CAPITAL RAISING**

*** FEDERAL PARLIAMENT PASSES R&D TAX CREDITS BILL**

*** PFIZER, MERCK, GSK AT BIO-MELBOURNE SEPTEMBER PHARMA SHOW**

*** IM MEDICAL REAPPOINTS ROMAN NAJDECKI; AGM MOTIONS PASSED**

*** SOLAGRAN PLEADS SCHULTZ TO ASX 46% PRICE JUMP QUERY**

MARKET REPORT

The Australian stock market climbed 1.07 percent on Thursday September 10, 2009 with the S&P ASX 200 up 48.6 points to 4570.8 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and three were untraded. All three Big Caps were up.

Phylogica was best, climbing 1.5 cents or 17.9 percent to 9.9 cents with 1.4 million shares traded, followed by Viralytics up 0.3 cents or 12 percent to 2.8 cents.

Chemgenex and Universal Biosensors climbed more than nine percent; Optiscan was up 7.1 percent; Psivida and Tyrian were up more than five percent; Avexa, Mesoblast, Sunshine Heart and Tissue Therapies were up more than four percent; Cytopia, Living Cell and Progen were up more than three percent; Acrux, Cathrx and Pharmaxis rose more than two percent; with Circadian, Cochlear, Peplin and Sirtex up more than one percent.

Genetic Technologies led the falls, down half a cent or 9.1 percent to five cents with 1.7 million shares traded, followed by Bionomics down two cents or 7.4 percent to 25 cents.

Prana fell 6.4 percent; Antisense lost 5.7 percent; Clinuvel was down 3.2 percent; Benitec and Starpharma shed more than two percent; with Alchemia and Novogen down more than one percent.

PHOSPHAGENICS

Phosphagenics says a phase Ib trial of the inflammatory pain drug diclofenac shows that its tocopheryl phosphate mixture increased deep absorption by 380 percent.

Phosphagenics said that staff from Monash Medical Centre under the supervision of Dr Alex Veldman completed the 12-patient trial at the company's facilities earlier this year, finalizing the results last week.

The company said in February that an earlier trial showed an average plasma concentration of diclofenac in subjects administered the Phosphagenics formulation was seven times greater than those subjects given Voltaren (BD: Feb 24, 2009).

The company's research and development vice-president Dr Paul Gavin told Biotech Daily that in this second trial of a different formulation of the tocopheryl phosphate mixture or TPM containing the diclofenac – the active ingredient in Voltaren – was absorbed into the skin at a 400 percent greater rate than Voltaren gel.

He said equivalent plasma levels were not measured in the second trial which was primarily focused on dermal absorption.

Dr Gavin said that TPM-diclofenac deep skin penetration was 380 percent greater than Voltaren with time to onset and magnitude significantly greater than the commonly available topical gel for inflammatory pain.

In a media release to the ASX yesterday, Phosphagenics said diclofenac was "one of the leading products" among non-steroidal anti-inflammatory drugs (NSAIDs) with global sales of $US1 billion a year.

The company said diclofenac was used to reduce inflammation and pain associated with inflammation of tendons or joints (tendonitis or arthritis) and acute injuries, such as sport injuries.

Phosphagenics said diclofenac absorption was assessed by tape stripping, a standard, noninvasive procedure used to measure the amount of a diclofenac or other drugs found in the various layers of the stratum corneum, the outer layer of the skin.

The company said that 30 minutes after application, TPM-diclofenac delivered on average over 400 percent more diclofenac into the stratum corneum, than Voltaren ($p < 0.001$)

Phosphagenics' TPM/diclofenac also significantly augmented the depth of penetration, with 380 percent ($p < 0.001$) more diclofenac found in the deepest layers of the skin sampled.

The company said the TPM-diclofenac formulation had a quicker onset and greater magnitude of diclofenac delivery than Voltaren, with increased delivery maintained for at least six hours, the duration of the trial.

The open label, single centre trial studied 12 healthy adult volunteers enrolled in the bioavailability trial of dermal delivery.

Dr Gavin said the results obtained from the phase I programs "provided the conclusive evidence needed for the company to progress diclofenac into a phase II or III clinical trial or a phase II/III pivotal trial".

"We are in the process of designing the parameters of the study and preparing the paperwork required to initiate an efficacy trial by April 2010," Dr Gavin said.

"The human study will assess the efficacy of TPM-diclofenac for the reduction of pain in selected relevant indications such as arthritis or sports injuries," Dr Gavin said.

"We are also in the process of preparing an investigational new drug package for filing with the US Food and Drug Administration," he said.

He said Phosphagenics intended to submit the application by April 2010.

"We have had significant commercial enquires for this product and believe that these results will further these discussions," Dr Gavin said.

Phosphagenics was unchanged at 11.5 cents.

MESOBLAST

Mesoblast says a trial of its adult stem cells in sheep has shown a “dramatic reversal of the degenerative process” in a model of inter-vertebral disc disease.

The company said that in the placebo-controlled, randomized trial of 36 sheep a single injection of allogeneic or off-the -shelf adult stem cells into severely damaged inter-vertebral discs resulted in “dramatic reversal of the degenerative process, regrowth of disc cartilage and sustained normalization of disc pathology, anatomy and function”.

Mesoblast said the inter-vertebral discs were “indistinguishable from healthy non-degenerated discs in their histopathology, cartilage content, height, and structure” six months after treatment.

The company said that in contrast, severely degenerated discs which served as controls and were either not injected or injected with hyaluronic acid, continued to demonstrate significantly reduced disc height ($p < 0.01$), disordered disc structure ($p < 0.01$), disrupted histopathology ($p < 0.01$), and reduced cartilage content ($p < 0.05$) compared with healthy non-degenerated discs over six months of follow-up.

The company said the results of disc x-rays, magnetic resonance imaging and histopathology were reviewed by three blinded independent experts.

Mesoblast executive director Prof Silviu Itescu said the results indicated the company was “successful in developing a unique biologic disc repair product”.

“Mesoblast's cells may provide a novel therapeutic approach to reverse disc degeneration and address the number one cause of chronic low back pain,” Prof Itescu said.

The company said chronic low back pain due to degenerative disc disease affected about four million people in the US alone.

Mesoblast said short-term benefits might be obtained by bed rest, analgesics, physiotherapy and steroids, but many patients progress to unremitting, severe and debilitating pain due to ongoing progression of disc degeneration.

For these patients, the only option is major back surgery involving artificial disc replacement or spinal fusion, the company said.

Prof Itescu told Biotech Daily that “compared to major surgery, a simple injection to reverse the degenerative process, would be a major breakthrough” into an unmet market segment that is conservatively estimated at more than $US2 billion per year.

“We intend to proceed rapidly with a clinical program aimed at commercial registration of our biologic disc repair product,” Prof Itescu.

“We have sufficient funds in place to complete a phase II trial and this will progress in parallel with our other ongoing clinical programs, he said.

Mesoblast was up 4.5 cents or 4.29 percent to $1.095

BIONOMICS

Bionomics will hold an extraordinary general meeting on October 9, 2009 to approve two recent placements and a share plan (BD: Sep 3 and 8, 2009).

Bionomics said there would be three resolutions at the meeting which will be held 31 Dalgleish St, Thebarton, South Australia on October 9, 2009 at 10 am (ACST).

Bionomics fell two cents or 7.4 percent to 25 cents.

FEDERAL GOVERNMENT

The Federal Parliament has passed the Tax Laws Amendment Bill 2009 replacing research and development tax concessions with tax credits from July 1, 2010.

In a media release Treasurer Wayne Swan and Innovation Minister Senator Kim Carr said the Government had taken “a significant first step towards the biggest reform to business innovation support for more than a decade” by passing of the Tax Laws Amendment Bill (2009 Measures no 4).

The Government said that part of the Bill lifted the research and development expenditure cap for the tax offset from $1 million to $2 million for the 2009-10 financial year.

“This interim measure is the first step in a series of significant reforms for all companies, big and small, to the way Government supports R&D investment in Australia,” Senator Carr said.

“In the coming months the details of the new R&D Tax Credit will be refined in close consultation with stakeholders,” Senator Carr said. “The Government will be seeking feedback to help develop the scheme.”

“Once implemented, the new R&D Tax Credit will provide more effective and predictable support for Australian companies conducting R&D in Australia,” he said.

“In the meantime, the Government is addressing a long standing concern about the R&D expenditure threshold for the offset and I encourage all eligible firms to take advantage of this change,” Senator Carr said.

Further information on the R&D Tax Offset, the new R&D Tax Credit and the consultation process is available at www.ausindustry.gov.au.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network's annual Pharma Partnering Workshop, hosted by law firm Clayton Utz, will be held on September 24, 2009.

The industry organization said the Pharma Partnering Workshop was “the most popular event in the calendar attracting biotech CEOs, heads of research organizations and the wider pharmaceutical industry”.

The Network said the workshop was ”a highly valuable opportunity to understand the current focus of some of the world’s largest pharmaceutical companies and to renew or make contact with the key individuals responsible for licensing activity”.

The Network said that Pfizer, Merck Sharp and Dohme and Glaxosmithkline would present their perspectives on the changing landscape and their companies’ roles within it.

The presenters include Pfizer Australia’s head of strategic alliances for Australia, New Zealand and Singapore Dr Daniel Grant, Merck Sharp and Dohme Australia’s director of licencing and external research Dr Phil Kearney and Glaxosmithkline Australia’s head of research and development alliances for Australia and New Zealand Dr Ashley Bates.

The Bio-Melbourne Network said that following the individual presentations, a selection of representatives would sit on a panel addressing questions.

This will be followed by a panel that will address questions and comment on some of the major licencing deals that were announced in the past year.

For more information go to http://www.biomelbourne.org/events/view/38 or contact Anita Petris on +613 9667 8182 or mobile +613 (0) 417 559 123.

IM MEDICAL

IM Medical has reappointed Roman Najdecki chief executive officer and chief financial officer for another two years.

The company said Mr Najdecki, who was appointed acting chief executive officer last year (BD Jun 20, 2008), would be on a base salary of $180,000 plus superannuation, terminable by IM Medical on three months notice and by Mr Najdecki on one month notice.

IM Medical said all proposals to the annual general meeting were passed easily, but more than 7.5 million votes of the total 110 million votes opposed the issue of shares and options to Global Ventures and a a refreshing capacity to issue securities.

IM Medical was unchanged at 0.4 cents.

SOLAGRAN

Solagran has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 13 cents on September 8, 2009 to 19 cents, a 46.15 percent increase, on September 9 and noted an increase in trading volume.

In its response, Solagran said "no" or "not applicable" to most of the ASX questions, adding that it was "currently unable to provide any guidance on its result for the half year ending December 31, 2009" and that it was "in compliance with the listing rules, in particular, listing rule 3.1".

Solagran was unchanged at 16 cents.