Biotech Daily

Wednesday March 3, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 14%; AVEXA DOWN 9%**

*** CELLMID JUMPS 39% ON PHARMAHUNGARY CARDIAC COLLABORATION**

*** NHMRC $824k GRANT FOR UNI OF WA FOR NEUREN'S MOTIVA**

*** US USE-OF-PRODUCT PATENT FOR MESOBLAST**

*** PHYLOGICA EUROPEAN PATENT PROTECTS ALL PHYLOMER LIBRARIES**

*** SIENNA SNARES ROSS DOBINSON**

*** VICTORIA WOMEN'S GONG FOR NOBEL'S PROF ELIZABETH BLACKBURN**

*** STIRLING BUYS $20m FACTORY FOR $4m**

MARKET REPORT

The Australian stock market climbed 0.72 percent on Wednesday March 3, 2010 with the S&P ASX 200 up 33.8 points to 4735.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Impedimed was best, up nine cents or 14.1 percent to 73 cents with 48,934 shares traded followed by Viralytics up 0.5 cents or 10 percent to 5.5 cents with 783,999 shares traded.

Novogen climbed 8.9 percent; Cellmid and Phylogica were up more than six percent; LBT was up 5.9 percent; Mesoblast was up 4.9 percent; Bionomics was up 3.3 percent; Antisense and Optiscan rose more than two percent; with Nanosonics and Resmed up more than one percent.

Avexa led the falls, down one cent or 9.1 percent to 11 cents with 8.9 million shares traded, followed by Universal Biosensors down 5.6 percent to $1.70 with 27,641 shares traded.

Tissue Therapies fell 4.55 percent; Cathrx lost 3.7 percent; Sunshine Heart shed 2.7 percent; with Alchemia, Cellestis, Clinuvel, Psivida and Starpharma down more than one percent.

CELLMID

Cellmid leapt 38.7 percent to 4.3 cents on news it will collaborate with Pharmahungary on the use of its midkine assets for acute myocardial infarction.

Cellmid said Pharmahungary would provide its facilities and cardiac drug development expertise for Cellmid's acute myocardial infarction product development program, including in-vivo studies, analytical and scientific services, for a minority interest in the project.

The company said the pre-clinical studies would be undertaken as part of Cellmid's preparation for human clinical trials.

Pharmahungary will initially perform safety and tolerability studies, pharmacokinetic, dose-response and efficacy trials in small as well as in large animals.

Pharmahungary will make available to Cellmid its proprietary exclusion criteria studies, which are expected to increase clinical trial success.

Cellmid will pay Pharmahungary milestone payments on completion of the series of studies included in the research, development and collaboration agreements.

Subject to successful preclinical validation of midkine as an effective treatment for heart attack Cellmid and Pharmahungary are expected to further collaborate to achieve early proof-of-concept in phase Ib/IIa clinical trials on similar terms.

Cellmid chief executive officer Maria Halasz told Biotech Daily that administration of the midkine compound within 90 minutes in large animals including pigs showed a benefit for up to 24 hours.

Ms Halasz said that for a period of time after the acute myocardial infarction, cells continued to be damaged.

"The data indicates that if administered within 24 hours there is a benefit," Ms Halasz said.

Ms Halasz said the compound was delivered directly to the site of the infarction and was co-administered with the current protocol drugs for AMI.

Ms Halsz said there were multiple uses for the midkine compounds which her company acquired from Japan's Cell Signals Inc in 2008 for "about $3 million" (BD: Apr 17; Jul 3, 2008).

In a media release Ms Halasz said her company was "delighted to have access to Pharmahungary's expertise in developing treatments for cardiovascular diseases".

"In addition to the financial benefits we expect that their strong track record in cardiac drug development will enhance the likelihood of clinical trial success," Ms Halasz said.

Pharmahungary chief executive officer Prof Peter Ferdinandy said there was "an urgent need to tackle the problem of high mortality of heart attack patients with safe and effective therapies".

"We are excited to be involved with the midkine program having reviewed its safety and efficacy results to date," Prof Ferdinandy said.

Cellmid said Myocardial infarction was the leading cause of death in developed countries and in Australia about 28,000 people die from it every year accounting for 22 percent of all deaths. In the US about 250,000 people die from AMI each year.

The company said its midkine was a "validated cell protecting agent … expected to directly reduce cell death from myocardial injury and therefore improve immediate and long terms survival of heart attack patients".

In animal studies midkine showed significant reduction in mortality rates, from 33 percent to 10 percent, with long-term cardiac outputs and survival also improved significantly.

Cellmid said Pharmahungary was "a globally recognized expert in the development of treatments for cardiac pathologies", whose scientists were widely published with more than 100 peer-reviewed journal articles and more than 2000 citations.

Cellmid closed up 0.2 cents or 6.45 percent at 3.3 cents with 116.5 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says an $824,000 National Health and Medical Research Council grant to the University of Western Australia will fund a phase II trial of Motiva in post-stroke apathy.

Neuren said the grant would cover virtually all costs associated with the study other than the drug which it would provide from existing stock.

The head of the Neuropsychiatry Unit at Fremantle Hospital and the trial's principal investigator is Prof Sergio Starkstein an expert on apathy and depression in patients with stroke and other neurological diseases.

Neuren said enrolment was expected to begin this month.

Neuren said its right to develop Motiva or nefiracetam was acquired with Hamilton Pharmaceuticals in 2007.

The company said a previous phase II study of Motiva in post-stroke patients with depression showed a statistically significant benefit for patients with apathy.

Neuren said apathy was a potentially debilitating syndrome that occurs frequently among patients who have had a stroke as well as patients with depression, Parkinson's disease, traumatic brain injury, schizophrenia and many other neurological and psychiatric conditions.

The company said apathy often had deleterious effects on patients' functional capacity and ability to perform normal activities of daily living.

There are no drugs approved for this indication and none, including antidepressant medications, have been shown to be effective in treating apathy.

Prof Starkstein said that post-stroke apathy was "a major concern for patients, families and health care providers".

"Apathy after stroke is associated with longer hospital stays, impaired rehabilitation and worse functional outcomes," Prof Starkstein said.

"Post-stroke patients with apathy engage poorly in rehabilitation programs which hampers their physical and social recovery," Prof Starkstein said.

"Results from the previously completed trial in this population are encouraging and we are hopeful that the drug's benefits will be confirmed in this new study," Prof Starkstein said.

Neuren said that if the results were positive it would pursue pivotal trials under the open US investigational new drug application it had in place.

The company said it was also evaluating opportunities to conduct trials of Motiva to treat apathy in other conditions such as Parkinson's disease in which apathy is prevalent.

Neuren said the grant was awarded to Prof Starkstein, Prof David Bruce, Prof Osvaldo Almeida, Prof Robert Robinson and Prof Wendy Davis for 'A randomized, double-blind, placebo-controlled study of nefiracetam in patients with post-stroke apathy'.

The trial of 122 patients will be conducted at the Fremantle and Royal Perth Hospitals.

Patients will receive 900mg/day of Motiva or placebo for 12 weeks and the effect of the drug on apathy and functional capacity will be assessed after 12 and 36 weeks.

Neuren said that in the previous trial, 70 of 137 patients (51.1%) with post-stroke depression met published criteria for apathy.

Patients were randomly assigned to 600mg/day or 900mg/day of Motiva or placebo.

Among patients treated for at least four weeks, those who received the 900mg/day dose showed a significantly greater change in apathy scale scores than those receiving 600 mg/day of Motiva or placebo.

A paper, entitled 'Double blind treatment of apathy in patients with post-stroke depression using nefiracetam' was published in the Journal of Neuropsychiatry and Clinical Neurosciences in 2009.

An abstract is at: http://neuro.psychiatryonline.org/cgi/content/abstract/21/2/144.

Neuren was up 0.1 cents or 2.7 percent to 3.8 cents.

MESOBLAST

Mesoblast says the US Patent and Trademark Office has granted a key protecting its bone tissue-generating products through to at least the year 2019.

Mesoblast said that in conjunction with its existing 2006 composition-of-matter and 2008 manufacturing patents, the new patent ensures that only Mesoblast could commercialize bone tissue-generating products in the US using its mesenchymal precursor cells or adult stem cells.

Mesoblast executive director Prof Silviu Itescu told Biotech Daily the new patent covered the use of the products for bone tissue-generation.

Mesoblast said the potential applications for bone tissue generation had continued to broaden and included products for repair and healing of long bone fractures, spinal bony fusion of the cervical and lumbar inter-vertebral spaces, treatment of bone defects and treatment and prevention of osteoporosis-related fractures such as fractures of the hip and vertebral bodies.

The company said its spinal bony fusion product Neofuse was in phase II trials in the US and had "the potential to become a major revenue driver" as more than 500,000 lumbar and cervical spinal fusion procedures were performed each year in the US.

Mesoblast said that its fracture repair product targeted the non-union fracture market, which composed five percent to 10 percent of all long bone fractures

The company said an Australian pilot clinical trial had shown the fracture repair product to be "highly effective".

Mesoblast said it had applied for Australian regulatory approval of the product and expected that a positive outcome would facilitate its US registration strategy for a bone repair product.

Mesoblast was up nine cents or 4.9 percent to $1.94.

PHYLOGICA

Phylogica says the European Patent Office has allowed a patent entitled establishing ownership of Phylomer libraries.

The patent is entitled 'Isolating biological modulators from biodiverse gene fragment libraries' and Phylogica's chief scientific officer Dr Paul Watt told Biotech Daily that the patent "covers not just making phylomer libraries, which has already been granted, but covers the composition of matter on phylomers per se".

"Anyone who comes up with a phylomer library infringes our patent in Europe".

Phylogica said the patent was expected to be granted "in the near future".

The company said the broadest granted independent claim covered the use of any combination of compact, sequenced, genomes from both eukaryotes, like fungi, protozoa and higher organisms such us the Japanese puffer fish, or prokaryotes including bacteria or archaea, regardless of their origin.

Phylogica said there was no restriction to the size of genomic fragments required to construct Phylomer libraries.

The company said Phylomer peptides belonged to the fastest growing class of drugs, biologics, which include peptides, antibodies and other proteins.

The company said Phylomer libraries had impressive hit rates with an increased quality as well as quantity of primary hits over random peptide libraries.

Phylogica said this was likely because Phylomer libraries "constituted the most structurally diverse libraries available for the discovery of biologics, with billions of distinct peptides derived from thousands of distinct structural families".

Phylogica was up 0.5 cents or 6.1 percent to 8.7 cents.

SIENNA DIAGNOSTICS

Sienna says it has appointed Ross Dobinson as a director "in preparation for the company's major commercialization activities in 2010-'11.

The Melbourne-based, public unlisted, cancer diagnostic company said Mr Dobinson was a former stockbroker, merchant banker and corporate advisor, the founder, former chief executive officer and chairman of Acrux and a director of Starpharma.

Sienna said that through his advisory firm TSL Group, he has supported the development of a number of early stage technology and life science companies.

Sienna said it was the only cancer diagnostic company with rights to the cancer biomarker, telomerase, the focus of Nobel Prize winner Prof Elizabeth Blackburn.

Sienna managing director Dr Kerry Hegarty said Mr Dobinson would join her and the three other directors, Dr Geoff Cumming, Dr Donald Robertson and David Neate on the board.

Dr Hegarty said that over the next 18 months Sienna would advance its telomerase test technology, commercializing bladder and prostate cancer tests and establishing international partners and licences for the suite of related oncology products.

VICTORIA GOVERNMENT

The Victorian Government says it will add Nobel Prize winner Prof Elizabeth Blackburn to the Victorian Honour Roll of Women.

In a media release, Victoria's Premier John Brumby said Professor Blackburn was awarded the 2009 Nobel Prize for Physiology or Medicine along with colleagues Jack Szostak and Carol Geider.

"Prof Blackburn epitomizes the type of commitment, dedication and outstanding achievement the Victorian Honour Roll of Women recognizes," Mr Brumby said.

"The Victorian Honour Roll was launched in 2001 and aims to recognize and celebrate the achievements of women from all walks of life," Mr Brumby said. "Prof Blackburn is an exemplary addition to the roll."

STIRLING PRODUCTS

Stirling says it has acquired a $20 million "near new state-of-the-art pharmaceutical manufacturing facility" for $C3.6 million ($A3.85 million) in Cape Breton, Canada.

Stirling said the sale price was "due to the collapse of a significant Canadian pharmaceutical group and its institutional lender".

The company it would takes possession of the fully operational factory this week "to exploit a number of third party contract generics manufacturing opportunities, funded research opportunities and pharmaceutical product production".

The company said the good manufacturing practice factory had the capacity to manufacture and package more than 550 million tablets, 5 million bottles and blend up to 1.5 million kg of product a year along with a granulating and grinding capacity.

Payments include $A250,000 paid at settlement with monthly payments of $C25,000 for 30 months from August 26, 2010 and a final payment of $C2,600,000 with no interest.

In its half yearly report, Stirling said it had $134,040 in cash at December 31, 2009 with a six month cash burn of $755,006. The company said it raised $1.4 million through a share plan on Feb 26, 2010 at 1.2 cents a share.

Stirling was unchanged at 1.3 cents with 73.7 million shares traded.